UK Neonatal Staffing Study

A national project funded by the NHS Executive Mother and Child Health Programme and endorsed by the British Association of Perinatal Medicine, the Neonatal Nurses Association (UK) and Scottish Neonatal Nurses Group

Final Report

A prospective evaluation of risk-adjusted outcomes of neonatal intensive care in relation to volume, staffing and workload in UK neonatal intensive care units.

NHS Executive
Mother and Child Health Initiative
Project reference **MCH06-07 (1996-2000)**

Submitted November 2000

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Acknowledgements

This study was funded by the NHS R&D Executive, Mother and Child Health Programme (grant number MCH:6-7), and the work was endorsed by the British Association of Perinatal Medicine, the Neonatal Nurses Association (UK) and Scottish Neonatal Nurses Group. We thank all UK neonatal units and staff for their help in phase I, but particularly those who took part in the prospective Phase II. We thank link research nurses, nurse managers and clinicians who collected the prospective data on our behalf. We are also grateful for the work of our research midwives and our secretarial and data management team in the Tayside Institute of Child Health, University of Dundee: Fiona Anderson, Carol Barnett, Fiona Bowie, Sylvia Newton, Margaret Fraser, Jane Culross and Ruth Miller, and staff at ScHARR in Sheffield for their support, especially Karen Collins with her work on the staff well being study. We thank Drs Alan Gibson, Sandy Calvert, John Davies, Joanne Meran, David Milligan. Harry Baumer, and Neil Marlow for their work on the consensus panel for diagnostic severity categories.

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Contents

I Summary

Objectives:

To assess whether risk-adjusted mortality and morbidity outcomes of UK neonatal intensive care are related to

- differences in primary organisational characteristics of volume, medical & nurse staffing levels, and workload
- adherence to national standards of service provision
- measures of staff well being

and to estimate the economic costs to purchasers of different models of neonatal intensive care provision.

Design, setting, and patients:

Phase 1: A UK-wide census of neonatal care units in 1997 allowed identification of neonatal intensive care units (NICUS) and stratification by primary organisational characteristics. *Phase 2:* A prospective, risk-adjusted study of a cohort of 14611 infants consecutively admitted (March 1998 till April 1999) to a random sample of 54 UK neonatal intensive care units. The NICUs were stratified into 12 types by high, medium or low volumes of patients, higher versus lower provision of nursing staff and higher versus lower neonatal consultant provision, with parallel evaluation of staff well being and collection of data to measure the economic costs to the purchaser. Occupancy and workload measures were also prospectively recorded twice daily at participating NICUs. Primary comparisons were between types of hospitals and workload measures not individual units.

Main outcome measures:

Outcomes of neonatal care should only include events influenced by care after birth. Thus by adjusting for initial differences in risk at or soon after birth using gestation, birthweight, initial severity of illness, including severity categorisation of diagnoses, physiological and other prognostic variables, the following outcomes were assessed in relation to the primary organisational characteristics

- death before hospital discharge or planned deaths at home (excluding lethal malformations)
- major brain damage on cerebral ultrasound (excluding damage of probable onset before birth)
- bacteraemia or septicaemia of probable nosocomial origin more than 48 hours after birth (excluding vertical transmission)

Secondary analyses also assessed these 3 risk-adjusted outcomes in relation to training, selected BAPM recommended standards (including surfactant guideline quality), resources and costs, overcrowding and staff well being.

Results

Phase 1 RESULTS

A 1997 census of unit activity and staffing uniquely achieved responses from 246 (100%) UK neonatal units. There was substantial variation between units with 186 (76%) who reported delivering sustained neonatal intensive care. These 186 units were identified as neonatal intensive care units (NICUs) and stratified into 12 types by the three primary organisational characteristics in a 3x2x2 factorial matrix:

1. **patient volume** (by annual number of VLBWT infants (High ≥58, Medium 35-57, Low ≤ 34))
2. **neonatal consultant availability** (by number consultants with >50% clinical sessions in neonatal care (higher ≥2, and lower <2))
3. **nurse provision** (using calculated nurse cot ratios of recommended vs actual nurse establishment (higher≥0.84, lower <0.84)).

The primary organisational characteristics were categorised using UK norm-referenced cut-off points, derived from the census distributions rather than arbitrary judgement. We chose to define high volume

NICUs and high nurse and neonatal consultant provision in terms of the upper third and upper halves of the distributions of admissions of very low birth weight infants and of nurse and consultant provision respectively. Fifty-four NICUs were randomly selected from the stratified matrix.

Phase 2 CLINICAL RESULTS

Of 14611 infants consecutively admitted to 54 NICUs, information was available for 14343 infants (98.2%). Of those, 13515 were eligible admissions, with abstracted data for 13401 (99%). There were 393 hospital deaths (2.9%), of which 322 (2.5%) were attributable to the participating hospitals of care (71 non-attributable deaths included lethal congenital conditions or complex cardiac and organ transplant surgery). Crude mortality rates were significantly higher in high volume NICUs than in low volume NICUs (OR 0.58 (0.38-0.87). Following risk-adjustment, the observed mortality and morbidity outcomes by patient volume, and by clinical and nurse staffing levels were not significantly different to that expected given the illness severity of their populations (e.g. OR for adjusted mortality and major cerebral abnormality in high volume vs low volume, 0.99 (0.69-1.43)). The results remained consistent when risk-adjustment variables modelled were those collected at time of birth, or used additional subsequent physiological data from the first 12 hours of life, and in analysis by hospital of birth.

However considering workload, risk-adjusted mortality did increase with increased occupancy of cots in all NICU types, and risk-adjusted nosocomial bacteraemia decreased in NICUs with lower consultant availability. Furthermore tests for association between pre-specified secondary organisational characteristics, (e.g. NICU overcrowding, clinical leadership, training, audit, and quality of guidelines and protocols, some of which were BAPM (1996) recommendations) showed no independent, significant relation to risk-adjusted outcome measures. The only exception was that risk-adjusted nosocomial bacteraemia was lower in units with an infection control nurse (OR 0.53 (0.35-0.79)).

In low volume units, a greater proportion of sicker infants are transferred out on the day of delivery than in medium and high volume units.

Phase 2 STAFF WELLBEING RESULTS

Anonymous questionnaires sent to staff in phase 2 NICUs included a validated tool to measure well being and mental health (MHI-5), demographic questions and an opportunity to respond with unstructured comments. A response rate of 83% was achieved. Of all 2261 respondents, 52.8% were recorded as nurses, 21% as doctors and 7.8% midwives. Three-quarters of respondents had been working in neonatal care for more than 1 year and one quarter for more than 10 years.

Analysis of variance of well-being scores showed no significant difference in scores among the 12 cell types (0.592). The mean score for the sample was 22.9, SD 3.9 which indicated good mental health. Two point three percent (2.3%) of the whole group scored below 13, which indicated potential mental health problems, and 60.9% of the respondents scored above 23 indicating positive mental health.

The opportunity to make unstructured comments was taken up by 40% of the participants and this group included at least 30% from each of the cell types. These responses indicated that although participants felt positively about their specialism, many had conflicting concerns about the pressures that working in the NHS placed upon their lives. These included pressures connected with obtaining qualifications while carrying out professional duties, dealing with managers and colleagues, staffing levels, home/work overlap, being valued at work, stressful situations with infant care and parents, emotional aspects of their lives at work, and NHS changes. Not all comments within these areas were negative.

A sub-sample of 45 staff participants was interviewed in depth. These included the lead consultant or clinical director and the clinical nurse manager from one unit in each cell type, randomly selected, and up to three other staff randomly selected from staff lists. The interviewer was “blinded” to the cell type at the time of the interviews. Analysis of the interviews produced a similar picture to the unstructured comments but produced detailed evidence and subjective explanations for the impact of working on a unit on well being.

Phase 2 COSTS OF NEONATAL INTENSIVE CARE IN THE UNITED KINGDOM

Questionnaires* were sent to all 54 units in phase 2 of the study to gain estimates of resource use. These questionnaires requested information on equipment, staffing, and other recurrent costs such as drugs, laboratory costs, and overhead costs. In addition, units were asked how many days of intensive, high dependency and special care they provided per year.

Forty-seven (87%) of the 54 units returned some data; 38 units provided detailed medical staffing (70%); 41 provided detailed nurse staffing (76%); 35 units provided details of other staff costs (65%); 35 units provided recurrent cost information (65%); and 33 units provided equipment costs. Twenty-eight units provided a complete description of all their costs and their activity levels (52%). All unit types were represented within these 28 units, 11 out of the 12 cells had two or more units with complete data. NICU type six had complete data from one unit only.

Significant variation in the cost of care was observed both within and between cells. However, the distribution across NICU types was sensible: larger NICUs and those with higher staffing ratios cost more than smaller NICUs and units with lower staffing ratios. The total annual cost ranged from £300,000 to £3,100,000. The average cost per day of care provided ranged from £178 to £592.

Regression analysis identified three parameters as robust predictors of the total cost of a neonatal intensive care unit (adjusted $R^2 = 0.77$): the proportion of care provided which is intensive care, the initial disease severity of the patients treated, and the total activity levels of the unit in relation to proportion of intensive care provision.

**(developed by the UK MRC Economics of Surfactant Study Team)*

Conclusions

These results indicate that infants in the UK have an equal chance of survival irrespective of the type of unit in which they were born. The finding that low volume units transfer out sicker infants than medium and high volume units suggests that hierarchical networks of care are already operating in accordance with earlier CSAG recommendations: where infants are transferred to other larger or even tertiary units according to their illness severity. High volume NICUs treat sicker infants, have higher occupancy and are busier than medium-sized and small NICUs. Nevertheless high volume NICUs perform as well as medium and small NICUs. At times of higher occupancy and decreased nurse to cot ratio, the performance of NICUs deteriorates. Higher occupancy is likely to occur more often in busier, high volume NICUs. Individual variables of recommended best practice from expert-defined standards and quality of surfactant guidelines did not appear to have a measurable impact on performance.

There are large variations in the costs of care both within unit types and across unit types. These large variations are not random and are related to the variations in (a) how sick the infants are which units treat, (b) the absolute and (c) relative levels of intensive care activity. Larger units are more efficient at providing intensive care than smaller units, and units treating sicker infants make more efficient use of resources than units treating less sick infants. However, true efficiency of units is not a simple function of activity but depends upon the characteristics of the infants treated and the maintained effectiveness of the care provided.

Relevance to NHS: Implications for the NHS – for health improvements/service practice

There is evidence that different types of units in the UK already treat very different groups of infants in terms of illness severity. The overall clinical delivery of neonatal care already operates networks that allow all infants to have an equal chance of an optimal outcome regardless of where they are born. Improvements to the service may be brought about by reducing the occasions when units approach close their maximum occupancy and where there are insufficient nurses for each infant. A policy enhancing the ratio and availability of specialist nurses would require rigorous evaluation to examine whether it brought about cost effective improvements in both mortality and morbidity.

II Introduction and background

The effect on outcomes of neonatal intensive care volume, staffing levels and workload is unknown, so although clinical and nursing skills are believed to be best developed and supported in higher volume units, performance may also deteriorate due to staff shortages or at high workload. We have investigated the relation between the directly alterable organisational characteristics of volume, staffing levels and workload and risk-adjusted outcomes in this prospective UK-representative study.

Centralisation of specialist neonatal intensive care services in the UK has been supported in the belief that it would improve effectiveness and efficiency. The proportion of hospital births in the UK resulting in very sick or premature infants who require *intensive* care is around 0.05 to 0.1%, although definition of intensive care varies and data is not routinely collected.[1, 2] In this type of low-volume, high cost specialty the aim is to provide specialist care of demonstrable highest quality, as efficiently as possible, and maintain access. The Short Report (1980)[3] recommended a tiered neonatal care system at a time of rapid technological advances in obstetrics and neonatal intensive care (NIC). Policy documents[4,5] in the last decade continue to support the tiered neonatal intensive care network and the concept that higher patient volume and accrued clinical and nursing expertise would optimise outcomes. It is clear that what constitutes intensive care changes with evolving technology, but in general maternity units have associated neonatal care provision that could be classified thus:[4]

1. Non-intensive care- Special care baby units (SCBUs)
2. Limited intensive care – some NIC but transfer complex problems
3. All intensive care for inborn babies but accept no transfers in (non-trading NICUs)
4. All NIC for both inborn and accept transfers in (both in utero and postnatal).

In 1996/97 NICUs throughout the UK demonstrated wide variation in annual levels of neonatal intensive care activity, staffing levels and skillmix.[6] Recent British Association of Perinatal Medicine (BAPM) recommendations[2] stated that NICUs: should be appraised against national criteria, develop clinical guidelines, have specified staffing and equipment levels, and be designated as neonatal intensive care units only if they attained a minimum number of 500 intensive care days per annum. This latter recommendation implied further centralisation of neonatal intensive care services. The Standards document however also noted that more empirical evidence was needed to support these recommendations.

The evidence to date in the UK of the relation between NICU performance and volume of neonatal intensive care activity is contradictory and raises the question of change through time. For example, reports comparing tertiary (and higher volume) and non-tertiary centres in both Scotland[7] and Trent[8] in the years 1987 to 1990 suggested improved risk-adjusted mortality in tertiary centres. However, two more recently reported regional UK studies [9-10] detected no significant differences in risk-adjusted outcome by unit size.

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III Study Design

In phase 1, census information was self-reported by UK NICUs. That information allowed stratification in a 3 x 2 x 2 factorial matrix of 12 groups by high, medium or low volumes of patients, higher versus lower provision of nursing staff and higher versus lower neonatal consultant provision, as shown in Table III-1.

Table III-1: Planned factorial matrix: stratification by 3 primary organisational characteristics

NICU type	Patient volume	High (> median) provision of neonatal consultants	High (>median) nurse cot ratio	NICUs per cell
groups				
1	high	+	+	3
2	high	+	-	3
3	high	-	+	3
4	high	-	-	3
5	medium	+	+	4
6	medium	+	-	4
7	medium	-	+	4
8	medium	-	-	4
9	low	+	+	5
10	low	+	-	5
11	low	-	+	5
12	low	-	-	5
Total				48

Phase 2 was a prospective, risk-adjusted study of clinical outcomes in relation to primary and secondary organisational characteristics and workload in a randomly selected and representative, stratified sample of UK neonatal intensive care units. Phase 2 planned to observe a cohort of at least 6400 infants consecutively admitted to participating NICUs. In addition concurrent evaluations of staff well being and the economic costs of neonatal intensive care to purchaser were also undertaken in phase 2.

In analysis comparisons are between groups of hospitals, not individual units. This design provides estimates of risk-adjusted outcomes within a shorter time span and with narrower confidence intervals than possible for individual units, where hospital mortality and severe morbidity outcomes are relatively rare events and subject to random effect.[1,2]

Main outcome measures

True outcomes of neonatal care should only include events influenced by care after birth.[3] Thus by adjusting for initial differences in risk at or soon after birth using gestation, birthweight, initial severity of illness, and other prognostic variables, this study will assess the following primary outcomes

- death before hospital discharge or planned deaths at home (excluding lethal malformations, metabolic conditions, and resuscitated stillbirths)
- major brain damage[4,5] on cerebral ultrasound (excluding damage of probable onset before birth)
- bacteraemia or septicaemia of probable nosocomial origin more than 48 hours after birth (excluding cases of probable vertical transmission[6])

Risk-adjustment and illness severity measures

Comparing outcomes between groups of neonatal units is misleading without adjustment for differences in risk or "case mix" in the babies they treat. Units which treat sicker babies may have higher crude mortality rates despite giving excellent care. Crude comparisons of outcomes may thus reflect confounding variations in health and prior risk rather than differences in quality of care. Optimal risk adjustment modelling will use data for all observed infants consecutively admitted to participating NICUs in phase 2. The adjustment will be empirically developed from the UK Neonatal Staffing Study's dataset using similar methods to those used in developing the risk-adjustment score for only premature infants, CRIB (Clinical Risk Index for Babies).[7]

The UK Neonatal Staffing Study design was a refinement of the method used in a national study of paediatric intensive care by Pollack et al in the USA,[8] with comparisons between groups of about 12 to 24 units rather than individual units. This was to ensure faster recruitment, greater power in comparisons of subgroups, and the ability to generalise the findings nationally.

Research aims and objectives

The pre-specified detailed hypotheses developed in the study protocol are noted at the start of each of the results chapters on primary and secondary clinical, economic and staff-well being results.

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IV Phase 1

A national census to obtain a randomly selected, stratified sample of UK NICUs

Background

On behalf of the BAPM, Milligan[1] surveyed neonatal intensive care provision in the UK for 1992-93 with an 84% response rate. He reported increased number of intensive care level 1 cots and increased intensive care activity compared with 1989. However, contrary to contemporary policy initiatives, most of the neonatal intensive care activity was delivered in small or medium sized units.

Methods

Two hundred and fifty hospitals with maternity units with associated neonatal units were identified and verified from available datasets of NNA, BAPM and RCOG in January 1997. The census aimed to identify those units providing neonatal intensive care as opposed to special care only. It aimed to describe current volume of neonatal intensive care activity and staffing provision in all UK neonatal intensive care units so allowing classification by the three primary organisational factors:-

- Volume (levels = high, medium or low)
- Nursing provision (levels = high versus low)
- Neonatal consultant staff (levels = high versus low)

A census form was mailed (with two postal reminders and one telephone reminder) to all 250 units in the UK in early 1997. (Appendix 1) The short questionnaire sought information about annual patient volume, activity levels and throughput, and nurse and medical establishment staffing levels. The nurse in charge of each unit was asked to complete the single-page questionnaire and return it after checking that the consultant in charge of the unit agreed with her replies.

Results

Of 250 UK hospitals surveyed in 1997, three had closed and two had merged. All remaining 246 units returned questionnaires using their most recent and available annual data (98% for 1996, 2% for 1995). One hundred and eighty-six units (76%) were categorised as neonatal intensive care units (NICUs) because they reported providing sustained neonatal intensive care as well as special care. The remaining 60 (24%) were special care baby units which provided only temporary intensive care before transfer to a NICU.

Neonatal intensive care activity measures

The reported cot establishment and descriptions of unit activity for 186 NICUs are summarised in Table IV-1. Definitions used to measure ventilation activity varied between units; both for the total number of infants ventilated or given CPAP and for the total counts of ventilated days. The minority of units counted ventilation activity only as that delivered by endotracheal tube, whereas the majority included other respiratory support delivered by nasal prongs or face mask in their counts. Thus the most complete, comparable and robust proxy measure available of neonatal intensive care activity was total annual admissions of very low birthweight (VLBW) babies. With the development and adoption of the BAPM Neonatal Dataset - for annual reporting of data for neonatal intensive care units,[3] there may be more reliable data routinely available for future comparisons of unit based intensive care activity.

Table IV-1 Reported cot establishment and activity levels in UK neonatal intensive care units

Establishment and activity variables (Reported per annum)	median (interquartile range)	minimum -maximum range	n NICUs total 186 (% item response)
Total number of admissions	318 (262-405)	48-1020	186 (100%)
Total number of cots in NICU	18 (14-22)	4-55	186 (100%)
Total number of IC level 1 cots	4 (2-6)	0*-16	186 (100%)
Total number of infants ventilated or given CPAP			
Counts only infants supported by endotracheal tube	52 (32-83)	10-269	33 (18%)
Counts infants supported by endotracheal tube, face mask or nasal prongs	66 (40-113)	12-310	141 (76%)
			Total 174 (94 %)
Total number of ventilator days			
Counts only for support by endotracheal tube	281 (139-817)	19-2688	34 (18%)
Counts for support by endotracheal tube, face mask and nasal prongs	451 (205-968)	13-3324	116 (62%)
			Total 150 (80%)
Total number of VLBWT(<1500g) infants admitted	40 (28-68)	2-227	182 (95%)

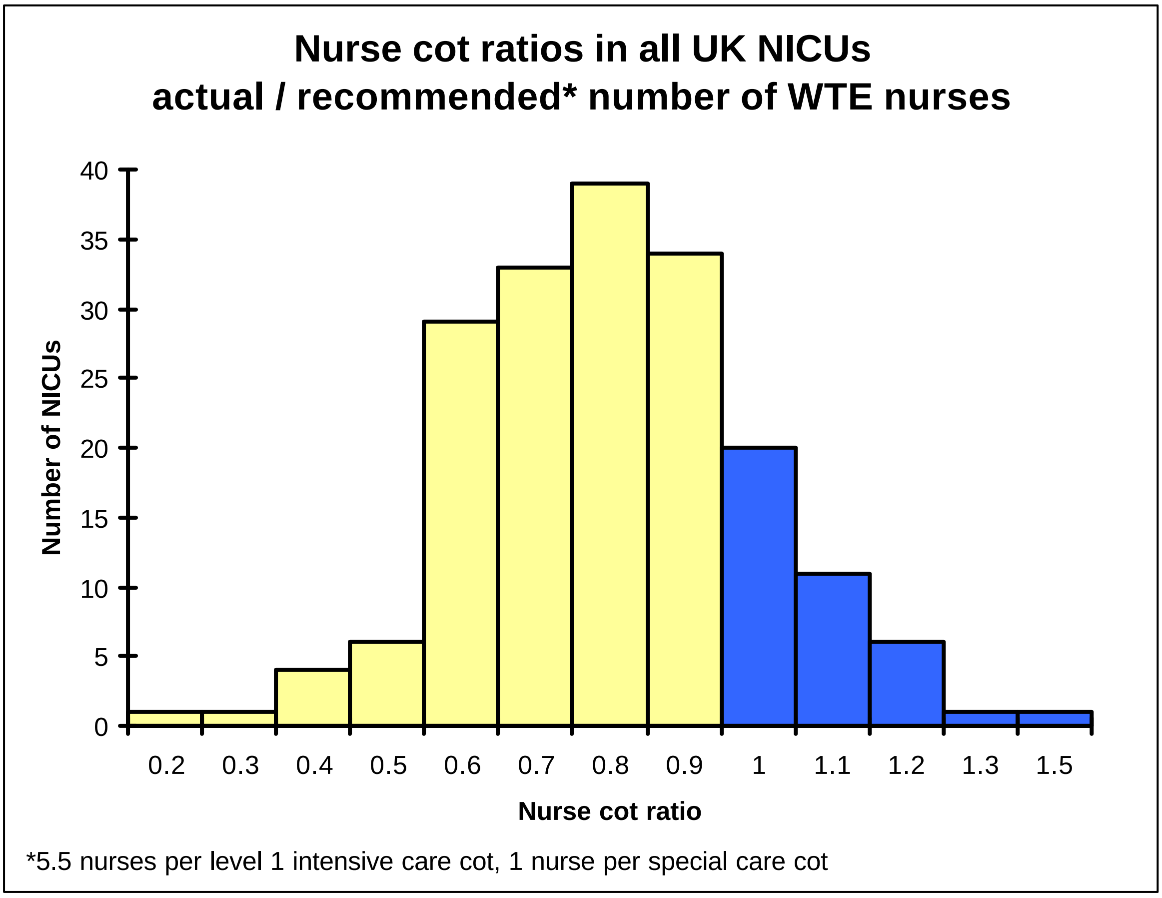
*4 NICUs reported and verified that they did deliver sustained intensive care support despite having no designated IC level 1 cots.

Staffing

Forty-six NICUs (25%) lacked the recommended minimum of one consultant[1] with prime responsibility to neonatal medicine (measured as >50% of clinical sessions dedicated to neonatal care). Reported numbers of business rounds per week ranged from 1 to 18, (median 6, IQR 4 to 7). In some NICUs consultants did no formal business rounds but individual consultants supervised their own patients according to need. Such variation made business rounds an unreliable measure of consultant availability.

The trained and qualified nurse staffing establishment proposals of 1992 [4] were 5.5 whole time equivalent (WTE) nurses per level 1 intensive care cot, 3.5 per level 2 intensive care cot and 1 per special care cot. We used more conservative assumptions (Figure 1, footnote) for two reasons. Firstly this census did not distinguish between level 2 intensive care cots and special care cots and secondly it did not distinguish between trained nurses, those with additional qualifications in neonatal specialty, nursery nurses and auxiliaries. A ratio of 1.0 indicates reported nursing establishment provision equivalent to the calculated requirement: 79% (147/186) of NICUs had ratios <1.0, range 0.3-1.5 (median 0.84, IQR 0.73 - 0.98, Figure 1).

Figure IV-1 Frequency distribution of Nurse cot ratios at 186 NICUs (1996/7)



The nurse cot ratio is given by the formula WTE / (5.5 x ICL1 + 1 x SC), where WTE=whole time equivalent nurses actually employed, ICL1=level 1 intensive care cots and SC=level 2 intensive care (ICL2) cots and special care cots. This calculation was derived from the British Association of Perinatal Medicine (1992) recommendation of 5.5 WTE per ICL1 cot, 3.5 per ICL2 cot and 1 per special care cot. However it provides a more conservative estimate of the recommended full number of nurses required as it equates ICL2 cots and special care cots, and equates trained, qualified and untrained nurses including auxiliary and nursery nurses.

The census results show continuing and substantial variation in NICU activity and staffing levels in the UK.[1] Despite conservative assumptions in our calculation, divergence between actual and calculated nurse requirement was notable. Similar wide variation has been described by Redshaw and colleagues.[5] The reasons for the variation in levels of NICU activity probably include different admission criteria and inherent differences in case-mix. The reasons for divergence in staffing provision could include varying definitions of cot types and categories of care,[6] resource constraints, problems in recruitment or retention of staff, or doubts about the validity of the staffing guidelines.[4]

Table IV-2: census variables and distribution cut-offs for stratification

Organisational Characteristic	Census variable	Stratification levels (centile distribution cut-off points)		
Volume	Annual number of VLBWT infants	Low ≤34 (33%)	Medium 35-57 (29%)	High ≥58 (38%)
Consultant availability	Number of consultants with>50% sessions in neonatal care	Lower <2 (52%)	-	Higher ≥ 2 (48%)
Nurse provision	Nurse Cot Ratio (see figure 1)	Lower ≤0.837 (44%)	-	Higher >0.837 (56%)

Table IV-3 186 UK NICUs stratified by volume, consultant availability, and nurse staffing

Census variable	Volume (annual n VLBWT infants (<1500g)	Availability of neonatal consultants (consultant with>50% sessions in neonatal care)	Nurse provision (nurse cot ratio see figure 1)	Number of NICUs stratified to cell type	Number of NICUs randomly selected per cell
Group	**High ³ 58** **Medium 35-57** **Low £ 34**	**Higher ³ 2** **Lower < 2**	**Higher ³ 0.84** **Lower < 0.84**		
1	high	✓	✓	16	3
2	high	✓	✗	29	3
3	high	✗	✓	6	3
4	high	✗	✗	12	3
5	medium	✓	✓	12	4
6	medium	✓	✗	12	4
7	medium	✗	✓	11	4
8	medium	✗	✗	19	4
9	low	✓	✓	14	5
10	low	✓	✗	7	5
11	low	✗	✓	14	8
12	low	✗	✗	34	8
Total				186	54

✓ higher ✗ lower

Cut-off points for stratification of each of the 3 primary organisational characteristics were set within the distributions as shown in Table IV-2. The NICUs were stratified into 12 groups according to the 3 x 2 x 2 factorial matrix shown in Table IV-3.

NICUs randomly selected were invited to participate in phase 2. The number of NICUs randomly selected per cell was increased with decreasing volume to ensure sufficient numbers of infants were observed in low volume/low throughput NICUs within the observation period. NICUs were invited to participate in phase 2, provided they anticipated no significant changes in their primary organisational characteristics over the observation period. If participation was not feasible for any NICU, or its categorisation was found to be invalid, it was replaced at random by another from that group. A total of fifty-four NICUs joined the second prospective phase.

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V Phase 2

The aim of the prospective phase 2 of the study was to collect clinical information about illness-severity risk (Appendix 2, *Admission form*) and outcomes (Appendix 3, *Outcomes form*) for consecutive babies admitted to participating NICUs. Daily workload information about patient number and dependency, staffing and skillmix (Appendix 4, *Workload log*) was collected during the whole of the observation period at each NICU using simple, uniform definitions. Information about the organisation of each unit, total unit costs (Appendix 5, *Economics questionnaire*) and staff stress and well being (Appendix 6, *Staff well-being questionnaire*) were also collected. The duration of the observation periods at each of the 54 NICUs are also summarised in Appendix 7.

(i) - Clinical evaluation

The clinical evaluation results are reported in two sections
1. Primary clinical hypotheses
2. Secondary clinical hypotheses

1. Primary Hypotheses

Primary hypotheses: **That three risk-adjusted adverse outcomes:**

(i) ***death before hospital discharge*** or discharged home to die (excluding lethal malformations)

(ii) ***death or major cerebral abnormality*** (excluding that of probable antenatal origin)

(iii) ***probable nosocomial bacteraemia*** (defined as first positive bacterial isolate from blood >48 hours after birth, and excluding cases of probable, vertical transmission)

are independently related to the following primary organisational characteristics:

- total annual volume of VLBW patients
- level of provision of nurses
- provision of neonatal consultants
- average number of infants receiving high dependency care per nurse per shift
- average number of infants receiving high dependency care per trained nurse per shift
- degree of exposure of each infant to increased total unit occupancy
- degree of exposure of each infant to increased total unit nursing dependency

Methods
The principal outcomes in this study were hospital mortality, mortality or major cerebral abnormality of probable postnatal origin, and probable nosocomial bacteraemia.

Stratification and random selection of NICUs
The census data collected in 1997 identified 186 UK hospitals with NICUs[1] . This allowed stratification into 12 unit types using a 3 (high, medium and low volume) by 2 (high and low consultant availability) by 2 (high and low nursing provision) factorial design. The resulting primary organisational characteristics, the

variable definitions and cut-off levels were shown in Table IV-3. Fifty four NICUs were then randomly selected from each type and invited to participate in this prospective phase.

Eligibility and attribution of outcomes for infants

Admission, discharge and blood gas data were abstracted from clinical records for eligible infants consecutively admitted to the 54 participating units. All infants admitted during the units' observation period aged less than 1 month old corrected for gestation were included. Attributable hospital deaths excluded lethal congenital abnormalities or metabolic disorders, deaths after complex cardiac surgery or organ transplant, or resuscitated stillbirths. Summary post-mortem information clinically verified non-attributable deaths. For transferred infants, deaths were attributed to the hospital of care when hospital of birth transferred ≤24 hours after birth. Transfers >24 hours were not attributable to the receiving hospital in analysis by hospital of care. In addition to risk-adjusted outcomes further analysis by hospital of birth was undertaken to check for postnatal selection bias[2] due to any systematic effect of clinical viability judgements and transfer decisions.

Adjustment for illness severity

The use of CRIB (Clinical Risk Index for Babies),[3] developed only for very low birthweight or extremely premature infants, or other existing risk-adjustment tools such as SNAP, [4] which requires collection of many data for each infant were not considered appropriate for this study. It was considered appropriate to empirically use information collected on each infant in the current study to adjust for differences in casemix between unit types.

Information was available to estimate initial illness severity at birth and in the first twelve hours. Multiple logistic regression models of the three principal outcomes were developed to adjust for risk before the study hypotheses were examined. Models were derived following standard methods[3,5,6] and provided the optimal means of taking into account the initial disease severity in this cohort of infants.

Variables available for the birth models were: birthweight, gestation, mode of delivery, whether the mother had antenatal steroids and gender. The centile of birthweight for gestational age in completed weeks was also obtained. Further variables available for the 12 hour models were: infant temperature, surfactant therapy, oxygen therapy (Fio2 records), and blood gas measures in the first 12 hours after admission (base excess, pH, SaO2, PaCO2, PaO2), and HCO3. Diagnostic severity categories were established and independently validated by an expert panel consensus[7] of eight neonatal specialists. Variable selection used the Akaike information criteria.[8] Once the birth model was identified, variables available up to 12 hours from birth were allowed to enter the model.

Analysis was based on multiple logistic regression, with each of the three primary outcomes as the dependent variable. Controversy still exists over the best time period from birth or admission to collect data for use in risk adjustment methods. In this study both birth and 12-hour models were developed. Model calibration was examined using the Hosmer-Lemeshow Goodness of fit statistic, and for discriminatory power using ROC curve areas.[9,10]

The unit characteristics of volume, consultant availability and nursing provision were related to each principal outcome, by adding the appropriate term to the models. Generalised estimating equations were used to correct the standard errors of the hospital-level variables for the effect of within-hospital correlation.[11]

Workload

Our study aimed to examine workload using a cross-sectional and longitudinal approach. The cross-sectional approach aimed to examine whether overall average unit workload during the study period was related to the primary outcomes. The longitudinal approach aimed to examine whether variations in workload and infants' exposure to variations within each unit during the study period were related to the primary outcomes.

Data Collection

Following study-nurse training, twice-daily simple and reliable measures of patient occupancy and dependency, and nurse staffing levels and skillmix[12,13] were collected throughout observation periods at each NICU. In each unit at midnight and midday throughout the observation period, measures of occupancy and dependency and clinical nurse staffing levels and skillmix were collected and used to calculate workload.

Measures of workload

Percent Maximum Occupancy:

We wanted to examine what effect the units being empty or full had on the principal outcomes. To do this we needed to derive a measure of unit fullness. This was done by first finding the maximum number of infants on each unit during the study period. For each time period in each unit, the number of infants on the unit was divided by this study period maximum number. Multiplying the resultant figure by 100 gave a value referred to as the percent maximum occupancy. Values of the percent maximum occupancy nearing 0 would indicate time periods when the unit was nearly empty, and values of the percent maximum occupancy nearing 100 would indicate time periods when the unit was nearly full.

Nurse-infant ratio:

Nursing ratio for each time period was calculated by dividing the observed number of nurses on duty by the number recommended (for the observed infant dependency) by the BAPM.[14]

Cross-sectional approach – Unit-based measures

Initially a cross-sectional analysis was performed to examine whether overall average workload values for each unit had any effect on the principal outcomes. For each workload measure, all infants in the same unit were assigned the same value, and this value was the unit average value over the study period. These workload measures were added in turn to the birth model for each primary outcome using generalised estimating equations.

Longitudinal approach – Infant-based measures

We also performed a longitudinal analysis to examine whether differences in workload within each unit had any effect on outcomes for individual infants exposed to the different levels of workload. Each infant in each unit was assigned the percent maximum occupancy and nurse-infant ratio values for the time period immediately prior to their admission. This value was not the same for all infants admitted to the same unit. The values assigned reflected how busy the unit was when the infant was admitted. We also derived a further nurse to infant ratio measure, which shall be referred to as the percent ranked nurse-infant ratio.

Percent Ranked Nurse Infant Ratio:

We wanted to examine what happened when a unit approached its own highest and lowest levels of nurse to infant ratio. To do this the nursing ratios in each unit were ranked, and transformed into percentiles. Thus a value of 50 (50^{th} percentile) would refer to the median nurse to infant ratio for that unit. Values approaching 0 would indicate times when the nurse to infant ratio was at its lowest for that unit, and values approaching 100 would indicate time periods when the nurse to infant ratio was at its highest for that unit. These percent ranked nurse infant ratio values enabled an analysis of whether within unit differences in nurse ratio were related to the primary outcomes.

Similar to the cross-sectional approach, these workload measures were added in turn to the birth model for each primary outcome using generalised estimating equations.

Results

Observed infants

Table 1 gives the number of NICUs recruited into each cell and the number of infants observed. Of 14611 infants consecutively admitted to 54 NICUs, information was available for 14343 infants (98.2%). Of those, 13515 were eligible admissions, with complete data for 13334 (98.6%). There were 393 hospital deaths (2.9%), of which 328 (2.5%) were attributable to the participating hospitals of care (non-attributable deaths also included lethal congenital conditions or complex cardiac and organ transplant surgery). The overall mean birthweight was 2581g ranging from 2266g in cell 1 to 2782g in cell 9. Median gestation ranged from 34 weeks in cell 1 to 37 weeks in cell 9.

Table V-1
Summary of Infants recruited by Unit Type

Unit Type	Patient Volume	High Consultant Availability	High Nurse Provision	Birthweight (g) Mean	SD	Gestation (weeks) Mean	SD	Units	Infants
1	High	✓	✓	2266	986	34	5	3	922
2	High	✓	×	2460	965	35	4	3	891
3	High	×	✓	2370	1010	35	4	3	691
4	High	×	×	2587	949	36	4	3	1133
5	Medium	✓	✓	2634	953	36	4	4	1277
6	Medium	✓	×	2619	898	36	4	4	1089
7	Medium	×	✓	2570	923	36	4	4	1104
8	Medium	×	×	2482	927	35	4	4	757
9	Low	✓	✓	2782	889	37	4	5	1061
10	Low	✓	×	2649	956	36	4	5	1081
11	Low	×	✓	2611	861	36	3	8	1717
12	Low	×	×	2693	867	36	3	8	1611
Unit Volume									
	High	58+		2434	981	35	4	15	3637
	Medium	35-57		2586	928	36	4	16	4227
	Low	<35		2676	889	36	4	26	5470
Consultant availability									
	High	2+		2581	953	36	4	24	6321
	Low	<2		2582	914	36	4	30	7013
Nursing provision									
	High	0.84+		2564	939	36	4	27	6772
	Low	<0.84		2599	925	36	4	27	6562
Total				2581	933	36	4	54	13334

Table V-2 shows each of primary outcomes by unit type. Overall 328 (2.5%) died before hospital discharge. This varied from 1.4% in unit type 12 to 4.7% in unit type 1. A further 232 (1.7%) infants developed Cerebral abnormality, varying from 8 (0.7%) in unit type 6 to 32 (2.8%) in unit type 4. Overall nosocomial bacteraemia was detected in 380 (2.8%) infants, varying from 25 (1.5%) in unit type 12 to 46 (4.9%) in unit type 1. The proportion of all outcomes appeared higher in the high compared to medium or low volume organisational characteristic.

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Table V-2
Primary outcomes by Unit Type

Unit Type	Patient Volume	High Consultant Availability	High Nurse Provision	Mortality		Cerebebral Abnormailty		Nosocomial Bacteraemia			
				N	%	N	%	N	%	Units	Infants
1	High	✓	✓	43	4.7%	21	2.3%	46	4.9%	3	922
2	High	✓	×	28	3.1%	12	1.3%	30	3.3%	3	891
3	High	×	✓	28	4.1%	14	2.0%	25	3.5%	3	691
4	High	×	×	34	3.0%	32	2.8%	21	1.8%	3	1133
5	Medium	✓	✓	31	2.4%	35	2.7%	62	4.8%	4	1277
6	Medium	✓	×	30	2.8%	8	0.7%	24	2.2%	4	1089
7	Medium	×	✓	19	1.7%	21	1.9%	23	2.1%	4	1104
8	Medium	×	×	26	3.4%	13	1.7%	31	4.0%	4	757
9	Low	✓	✓	16	1.5%	14	1.3%	29	2.7%	5	1061
10	Low	✓	×	24	2.2%	24	2.2%	35	3.2%	5	1081
11	Low	×	✓	26	1.5%	22	1.3%	29	1.7%	8	1717
12	Low	×	×	23	1.4%	16	1.0%	25	1.5%	8	1611
Unit Volume											
	High	58+		133	3.7%	79	2.2%	122	3.4%	15	3637
	Medium	35-57		106	2.5%	77	1.8%	140	3.3%	16	4227
	Low	<35		89	1.6%	76	1.4%	118	2.2%	26	5470
Consultant availability											
	High	2+		172	2.7%	114	1.8%	226	3.6%	24	6321
	Low	<2		156	2.2%	118	1.7%	154	2.2%	30	7013
Nursing provision											
	High	0.84+		163	2.4%	127	1.9%	214	3.2%	27	6772
	Low	<0.84		165	2.5%	105	1.6%	166	2.5%	27	6562
Total				328	2.5%	232	1.7%	380	2.8%	54	13334

Unadjusted analysis

Figures V-1 to V-3 illustrate the observed values of the three primary outcomes. These figures suggest that there is higher mortality, mortality or cerebral abnormality and nosocomial bacteraemia in high volume units than in medium and low volume units. Figure V-3 suggests that units with high consultant availability had a higher rate (3.6%) of nosocomial bacteraemia than units with low consultant availability (2.2%). Table V-3 gives unadjusted odds ratios for the unit characteristic comparisons. The odds ratios are derived using generalised estimating equations to take account of the cluster effect of within-hospital correlation. The unadjusted odds of mortality (odds ratio 0.58, 95% CI 0.38, 0.87) and mortality or cerebral abnormality (odds ratio 0.48, 95% CI 0.35, 0.65) were significantly lower for infants admitted to low compared with high volume units, otherwise there were no significant differences.

The unadjusted odds of infants developing nosocomial bacteraemia were lower in low compared with high volume units (odds ratio 0.53, 95% CI 0.33, 0.86), and in units with low compared to high consultant availability (odds ratio 0.57, 95% CI 0.40, 0.83).

Figure V-1:
Observed mortality by each of the three primary organisational characteristics

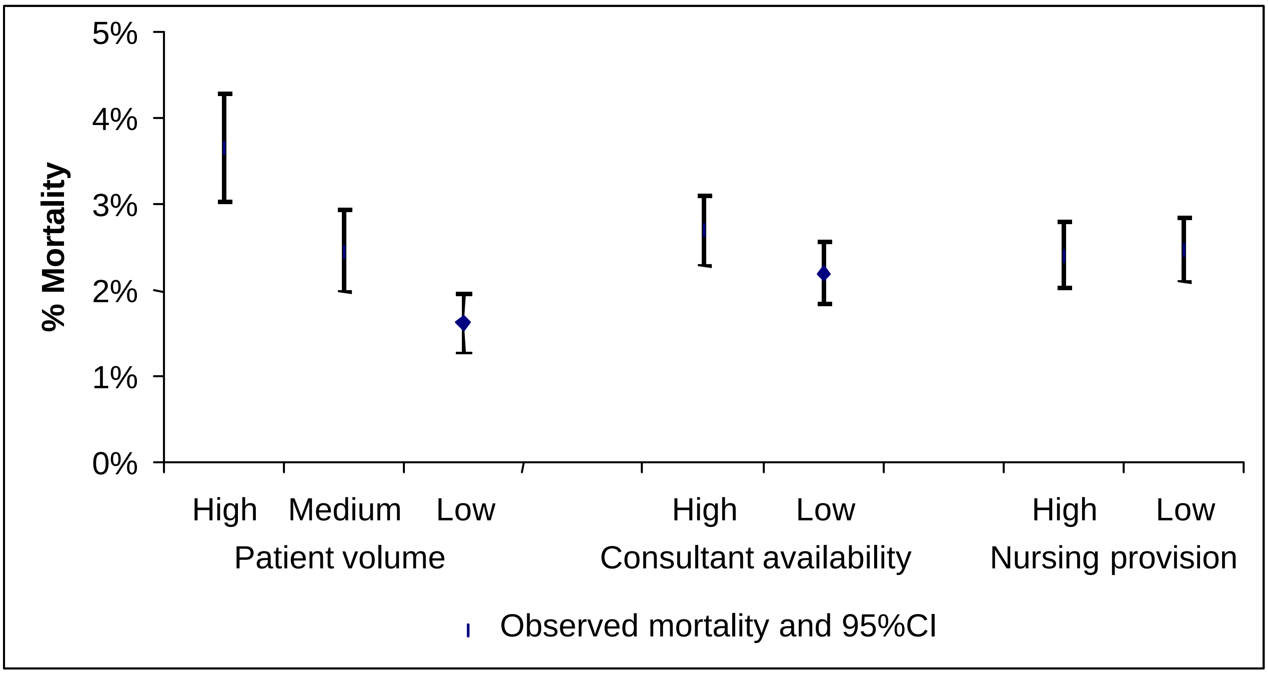


Figure shows observed mortality (%) together with bars representing the associated 95% confidence interval. This confidence interval does not take account of the clustered nature of the data and is for descriptive purposes only

Figure V-2:
Observed mortality or brain damage by each of the three primary organisational characteristics

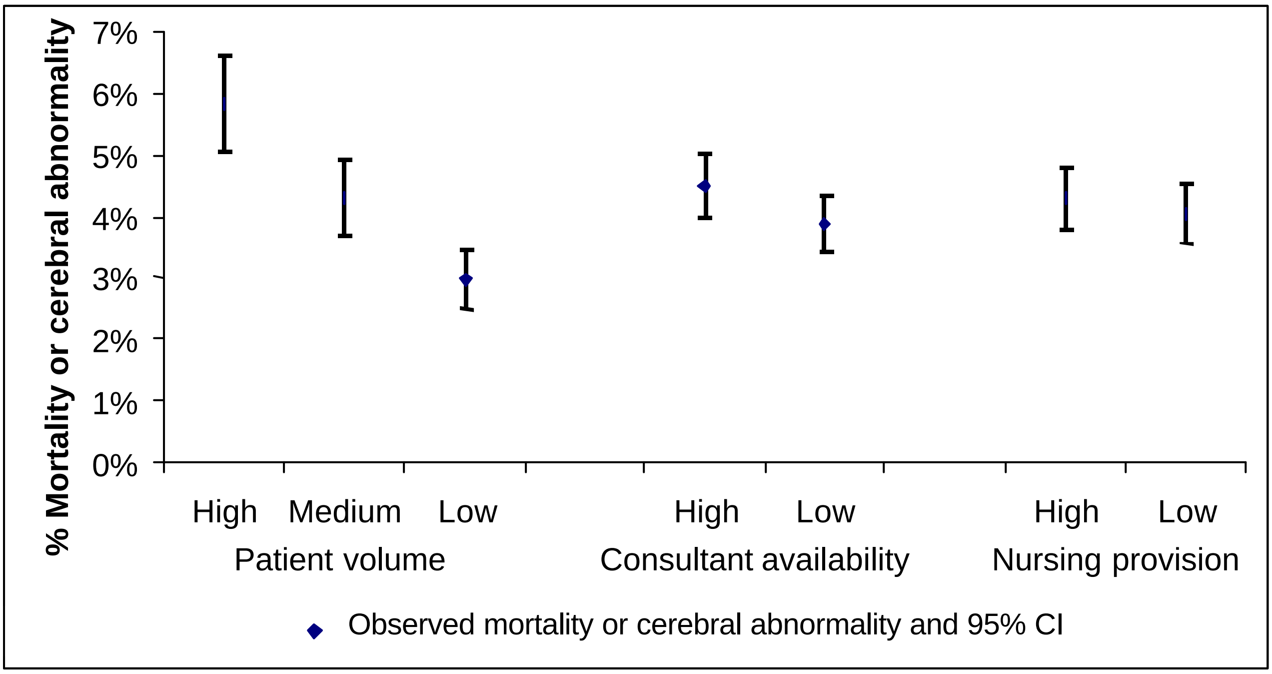


Figure shows observed mortality or cerebral abnormality (%) together with bars representing the associated 95% confidence interval. This confidence interval does not take account of the clustered nature of the data and is for descriptive purposes only

Figure V-3:
Observed Nosocomial Bacteraemia by each of the three primary organisational characteristics

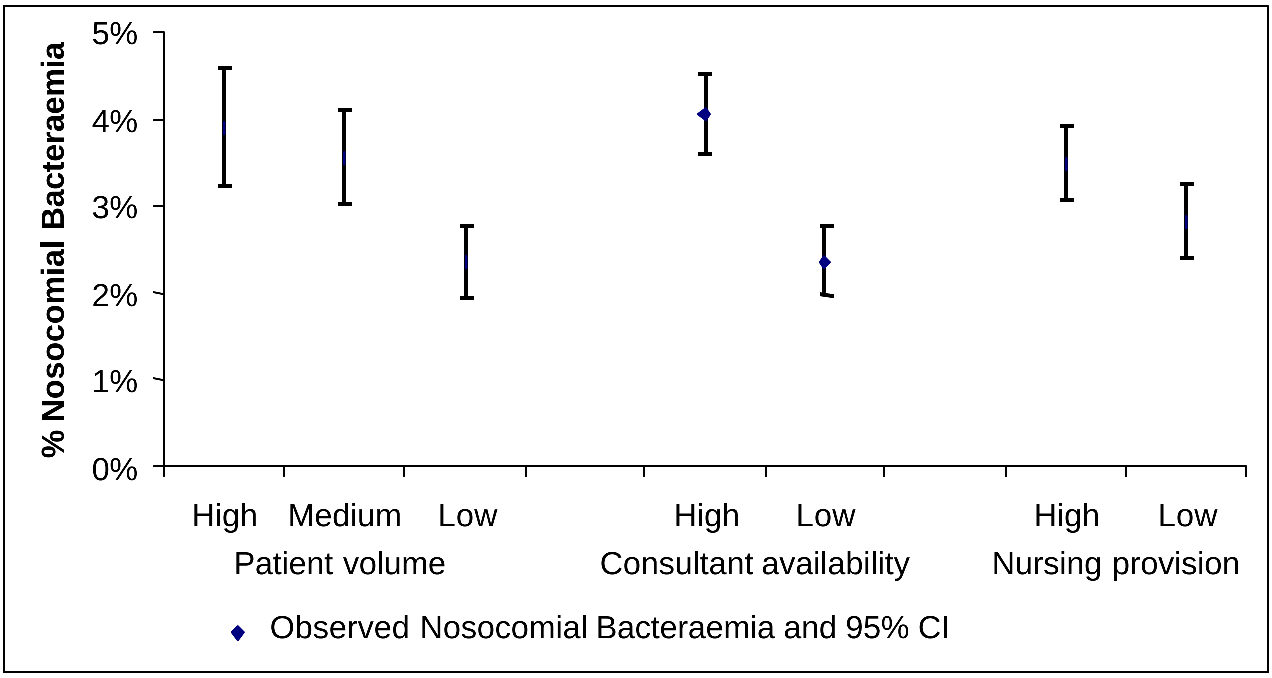


Figure shows Nosocomial Bacteraemia (%) together with bars representing the associated 95% confidence interval. This confidence interval does not take account of the clustered nature of the data and is for descriptive purposes only

Table V-3
Odds Ratios for the three primary clinical outcomes by each unit characteristic

	Generalised Estimating Equations	
	Crude Model	
Death before hospital discharge		
Patient Volume		
High		
Medium	0.86	(0.51, 1.45)
Low	0.58	(0.38, 0.87)
Consultant availability		
High		
Low	0.97	(0.64, 1.47)
Nursing provision		
High		
Low	1.35	(0.90, 2.04)
Death or brain damage before hospital discharge		
Patient Volume		
High		
Medium	0.73	(0.50, 1.05)
Low	0.48	(0.35, 0.65)
Consultant availability		
High		
Low	0.82	(0.59, 1.13)
Nursing provision		
High		
Low	0.95	(0.68, 1.32)
Nosocomial bacteraemia before hospital discharge		
Patient Volume		
High		
Medium	0.85	(0.55, 1.32)
Low	0.53	(0.33, 0.86)
Consultant availability		
High		
Low	0.57	(0.40, 0.83)
Nursing provision		
High		
Low	0.83	(0.56, 1.24)

Table shows the odds together with a 95% confidence interval of each primary outcome relative to the high level of each organisational characteristics. The odds ratios and 95% confidence intervals are derived using generalised estimating equations that adjust for the clustered nature of the data. An odds ratio > 1 indicates increased odds relative to the high level.

Risk Adjustment

For mortality, and mortality or cerebral abnormality the birth model contained the infant's gestation, size for gestation, sex, mode of delivery, diagnosis category, and maternal treatment with antenatal steroids. For nosocomial bacteraemia, the model also included whether the infant had a positive blood culture (indicating probable vertical transmission) in the first 48 hours after birth. For the 12 hour models admission temperature, the most extreme $PaCO_2$, mean appropriate FiO_2, and minimum base excess were also included. Tables V-4 and V-5 show the logistic regression models for the mortality birth and 12 hour models respectively.

The models displayed good discriminatory power. The areas (standard error) under the ROC curve were 0.86 (0.01), 0.82 (0.01), 0.81 (0.01) for the birth mortality, mortality or cerebral abnormality, and nosocomial bacteraemia models respectively, and 0.93 (0.01), 0.88 (0.01), 0.83 (0.01) for the respective 12 hour models. For each primary outcome the 12-hour models gave significantly ($p<0.001$) better discriminatory power than the birth models. Calibration for the birth mortality model was adequate, but there was some evidence of lack of calibration for the birth mortality or cerebral abnormality and nosocomial bacteraemia models. The Hosmer-Lemeshow goodness of fit statistics were $\chi^2 = 5.57$, 8df, p=0.695, $\chi^2 = 17.7$, 8df, p = 0.023 and $\chi^2 = 17.6$, 8df, p = 0.027 for the mortality, mortality or cerebral abnormality and nosocomial bacteraemia models respectively. For the 12 hour models calibration was adequate, the Hosmer-Lemeshow goodness of fit statistics were $\chi^2 = 5.84$, 8df, p=0.665; $\chi^2 = 12.3$, 8df, p = 0.136; and $\chi^2 = 7.4$, 8df, p = 0.491 for the mortality, mortality or cerebral abnormality or nosocomial bacteraemia outcomes respectively.

It is the authors intention to explore the potential of these risk adjustment models to form the basis of a new scoring system for all infants admitted to a neonatal intensive care unit. This new scoring system may then supersede the CRIB Score.

Table V-4
Summary of logistic regression model using variables obtained around birth: Birth model

Variable	Log Odds	S.E.	Wald	df	Sig	Odds	95% CI
Constant	18.74	0.77	585.8	1	<0.001		
Gestation (weeks)	-0.75	0.03	734.8	1	<0.001	0.47	(0.45, 0.50)
Female	-0.28	0.14	4.2	1	0.040	0.76	(0.58, 0.99)
Diagnosis category	2.45	0.58	17.6	1	<0.001	11.64	(3.70, 36.61)
Mode of delivery			10.2	3	0.017		
SVD	0					1	
for, vent	0.68	0.28	6.0	1	0.015	1.97	(1.14, 3.40)
Breech	0.56	0.27	4.47	1	0.037	1.75	(1.04, 2.97)
Caesarian	0.33	0.15	4.7	1	0.030	1.39	(1.03, 1.88)
Full course of maternal steroids	0.70	0.16	19.5	1	<0.001	2.01	(1.47, 2.73)
Percentile of birthweight for gestation	-0.009	0.002	12.6	1	<0.001	0.99	(0.99, 1.00)

Number of infants with complete data for this model = 13,233

Table V-5
Summary of logistic regression model using variables up to 12 hours from birth: 12hr model

Variable	Log Odds	S.E.	Wald	df	Sig	Odds	95% CI
Constant	12.49	1.12	125.22	1	<0.001		
Gestation (weeks)	-0.56	0.04	257.91	1	<0.001	0.57	(0.53, 0.61)
Female	-0.36	0.15	5.42	1	0.020	1.43	(0.52, 0.94)
Diagnosis category	1.37	0.80	2.95	1	0.086	0.25	(0.82, 18.80)
Full course of maternal steroids	0.45	0.18	6.59	1	0.010	0.64	(1.11, 2.21)
Percentile of birthweight for gestation	-0.01	0.00	9.91	1	0.002	1.01	(0.99, 1.00)
Difference from 36.8^{o} for admission temperature	0.33	0.08	18.68	1	<0.001	0.72	(1.20, 1.62)
$PaCO_2$ values recorded in 1st 12hrs	-0.07	1.00	0.00	1	0.948	1.07	(0.13, 6.70)
Biggest difference in $PaCO_2$ from 52mmHg in 1st 12hrs	0.02	0.01	11.34	1	0.001	0.98	(1.01, 1.03)
FiO_2 values recorded in 1st 12hrs	-0.28	0.39	0.52	1	0.470	1.33	(0.35, 1.63)
Mean appropriate FiO_2 in 1st 12hrs	2.88	0.37	61.16	1	<0.001	0.06	(8.64, 36.53)
Base Excess values recorded in 1st 12hrs	-1.48	0.93	2.50	1	0.114	4.38	(0.04, 1.42)
Min. Base Excess in 1st 12hrs	-0.12	0.02	61.14	1	<0.001	1.13	(0.86, 0.91)

Number of infants with complete data for this model = 13,095

Unit characteristics

Figures V-4 to V-6 illustrate observed and expected outcomes of the three primary outcomes. Expected percentage mortality in high volume units is higher than medium and low volume units, indicating that high volume units treat sicker infants than medium and low volume units. Table 2 gives the adjusted odds ratios by unit types. These odds ratios are provided using generalised estimating equations to correct the standard errors of the hospital-level variables for the cluster effect of within-hospital correlation. Using the birth or the 12-hour model, there were no differences in the odds of all primary outcomes between each of the unit characteristics (volume, consultant availability and nursing provision), with the exception of nosocomial bacteraemia and consultant availability. The adjusted odds of infants developing nosocomial bacteraemia were significantly lower in units with low consultant availability compared to units with high consultant availability (birth model odds ratio 0.65, 95% CI 0.43, 0.98).

Figure V-4:
Observed and expected mortality by each of the three primary organisational characteristics

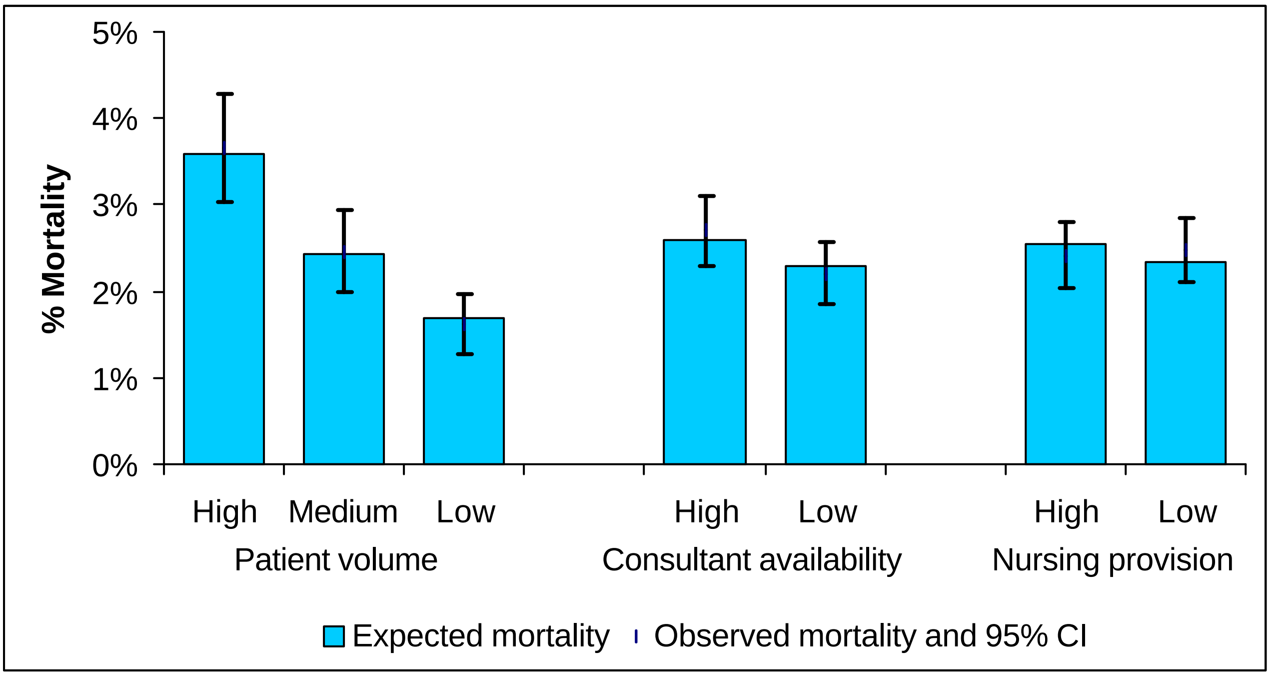


Figure shows observed mortality (%) together with bars representing the associated 95% confidence interval, and a solid block representing the expected mortality derived from applying the Birth model displayed in Table V-3. The confidence interval does not take account of the clustered nature of the data and is for descriptive purposes only

Figure V-5:
Observed and expected mortality or cerebral abnormality by each of the three primary organisational characteristics

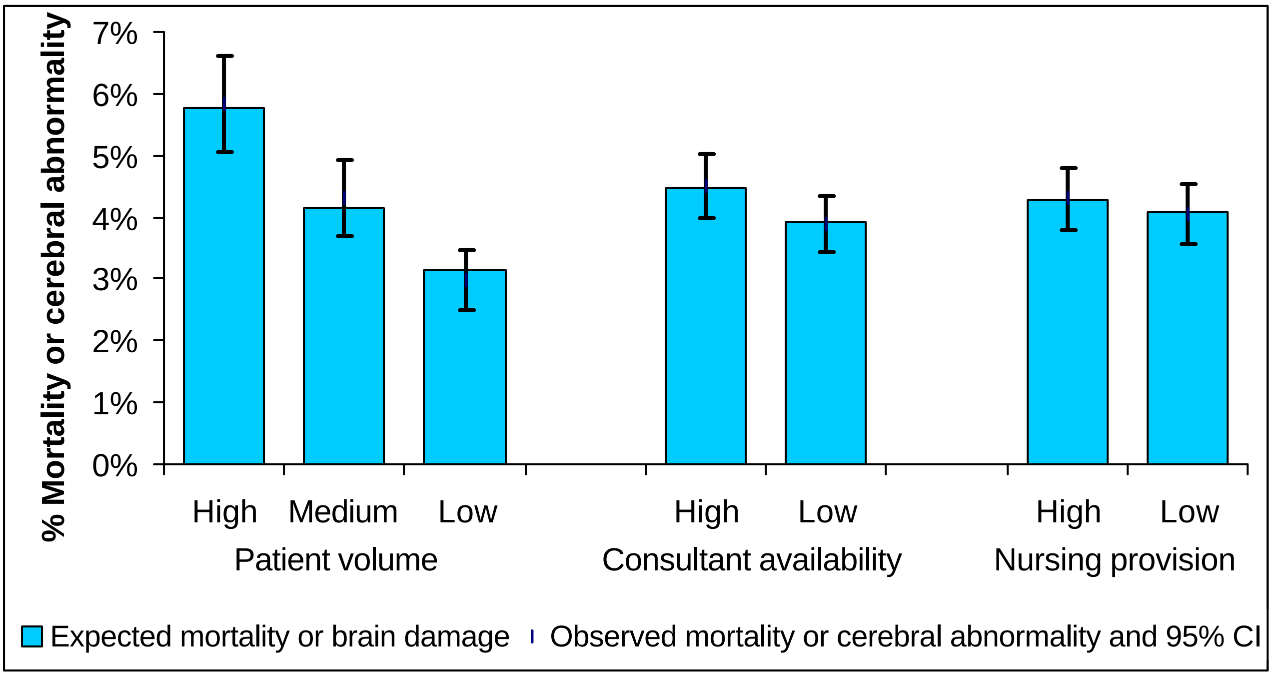


Figure shows observed mortality or cerebral abnormality (%) together with bars representing the associated 95% confidence interval, and a solid block representing the expected mortality derived from applying the Birth model displayed in Table V-3 calibrated for mortality or cerebral abnormality. The confidence interval does not take account of the clustered nature of the data and is for descriptive purposes only

Figure V-6:
Observed and expected nosocomial bacteraemia by each of the three primary organisational characteristics

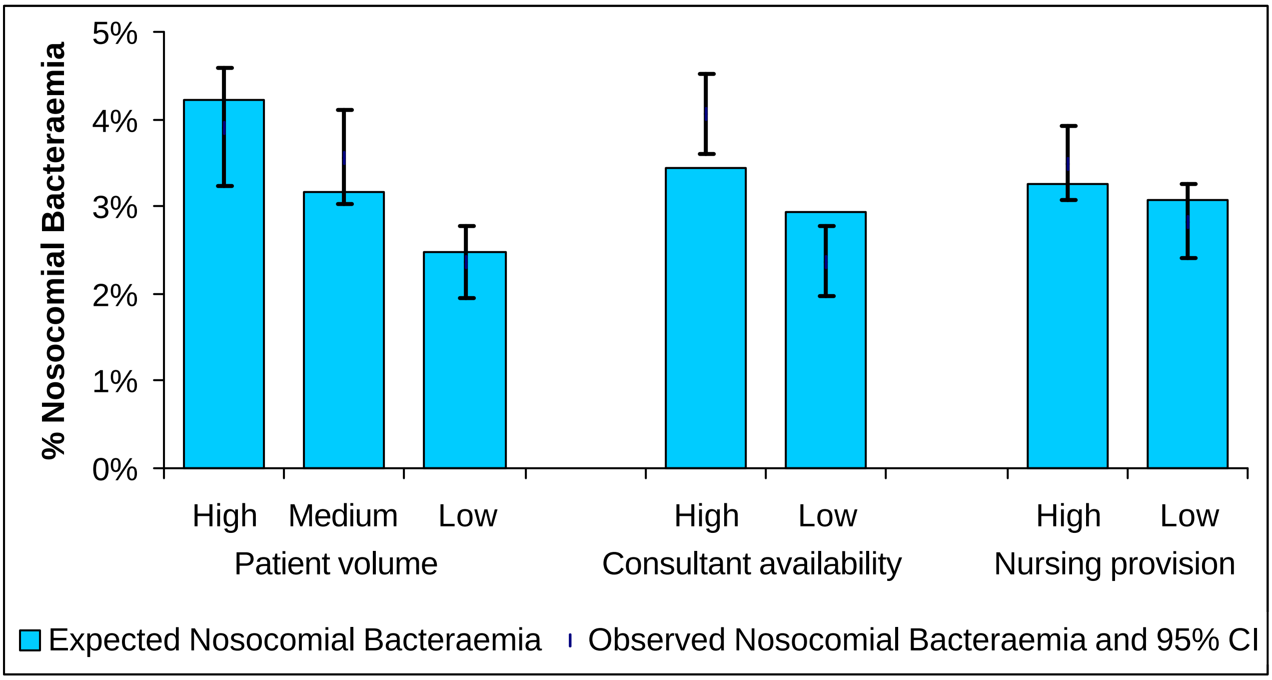


Figure shows observed nosocomial bacteraemia (%) together with bars representing the associated 95% confidence interval, and a solid block representing the expected mortality derived from applying the Birth model displayed in Table V-3 calibrated for nosocomial bacteraemia. The confidence interval does not take account of the clustered nature of the data and is for descriptive purposes only

Table V-6
Odds Ratios for the three primary clinical outcomes by each unit characteristic

	Generalised Estimating Equations Models					
	Crude Model		Birth Model		12hr Model	
Death before hospital discharge						
Patient Volume						
High						
Medium	0.86	(0.51, 1.45)	1.12	(0.76, 1.64)	1.10	(0.75, 1.62)
Low	0.58	(0.38, 0.87)	0.97	(0.70, 1.34)	0.86	(0.60, 1.23)
Consultant availability						
High						
Low	0.97	(0.64, 1.47)	0.92	(0.69, 1.22)	0.94	(0.71, 1.25)
Nursing provision						
High						
Low	1.35	(0.90, 2.04)	1.10	(0.82, 1.48)	1.14	(0.85, 1.53)
Death or brain damage before hospital discharge						
Patient Volume						
High						
Medium	0.73	(0.50, 1.05)	1.10	(0.71, 1.71)	1.19	(0.77, 1.83)
Low	0.48	(0.35, 0.65)	0.99	(0.69, 1.43)	0.92	(0.65, 1.30)
Consultant availability						
High						
Low	0.82	(0.59, 1.13)	0.96	(0.69, 1.33)	1.01	(0.73, 1.38)
Nursing provision						
High						
Low	0.95	(0.68, 1.32)	0.97	(0.70, 1.35)	0.99	(0.71, 1.37)
Nosocomial bacteraemia before hospital discharge						
Patient Volume						
High						
Medium	0.85	(0.55, 1.32)	1.38	(0.85, 2.22)	1.39	(0.87, 2.21)
Low	0.53	(0.33, 0.86)	1.23	(0.70, 2.15)	1.22	(0.70, 2.12)
Consultant availability						
High						
Low	0.57	(0.40, 0.83)	0.65	(0.43, 0.98)	0.65	(0.44, 0.96)
Nursing provision						
High						
Low	0.83	(0.56, 1.24)	0.86	(0.56, 1.32)	0.80	(0.53, 1.20)

Table shows the odds together with a 95% confidence interval of each primary outcome relative to the high level of each organisational characteristics. The odds ratios and 95% confidence intervals are derived using generalised estimating equations that adjust for the clustered nature of the data. An odds ratio > 1 indicates increased odds relative to the high level.

Workload

Cross-sectional, unit based approach

Table V-7 summarises the average workload values over the study period by unit characteristic. High volume units (median 0.70) tended to be operating closer to maximum occupancy than medium (median 0.61) and low (median 0.57) volume units. There were no apparent differences in occupancy between high and low consultant availability and high and low nursing provision.

For nurse to infant ratio, a value of 1 or more indicated that the number of nurses to infants had reached the recommended BAPM levels.[14] Overall the nurse to infant ratio was less than that recommended the BAPM. The standard was not reached on 57% of time periods. From Table V-8 there is some evidence of improved nurse to infant ratio with high unit volume compared to medium and low unit volume. However the percentage of time periods the BAPM standards were **not met** for high, medium and low volume units were 58%, 56% and 58%.

Similarly there appeared to be higher nurse to infant ratios for units with high compared to low consultant availability. For units with high consultant availability the BAPM nurse to infant ratios were **not met** on 56% of time periods, and for low consultant availability on 59% of time periods. The study design ensured that the nurse to infant ratio was higher for units with high compared to low nursing provision. For units with high nursing provision the BAPM recommendations were still **not met** on 52% of time periods, and **not met** on 63% of time periods for units with low nursing provision.

Table V-7

Average workload by unit type over the study period – Cross-sectional approach

	Percent maximum occupancy			Nurse to Infant Ratio		
Unit type	Median	Percentile 25th	Percentile 75th	Median	Percentile 25th	Percentile 75th
1	0.74	0.64	0.82	1.00	0.84	1.17
2	0.72	0.59	0.81	0.92	0.80	1.08
3	0.71	0.60	0.81	0.92	0.73	1.08
4	0.61	0.50	0.71	0.90	0.74	1.11
5	0.67	0.53	0.80	1.00	0.86	1.14
6	0.60	0.50	0.73	0.89	0.73	1.07
7	0.59	0.45	0.71	1.00	0.75	1.23
8	0.62	0.52	0.74	0.86	0.71	1.04
9	0.54	0.42	0.68	0.89	0.67	1.14
10	0.52	0.43	0.68	0.94	0.80	1.14
11	0.55	0.42	0.68	1.00	0.80	1.20
12	0.62	0.48	0.71	0.84	0.71	1.00
Patient Volume						
High	0.70	0.58	0.80	0.93	0.77	1.11
Medium	0.61	0.48	0.74	0.92	0.76	1.11
Low	0.57	0.44	0.69	0.89	0.73	1.11
Consultant availability						
High	0.61	0.48	0.75	0.93	0.77	1.13
Low	0.60	0.47	0.73	0.91	0.74	1.11
Nursing Provision						
High	0.62	0.47	0.75	0.95	0.80	1.14
Low	0.60	0.48	0.73	0.89	0.73	1.07
Total	0.61	0.48	0.74	0.92	0.75	1.11

In order to relate these cross-sectional values to the principal outcomes, each infant in each unit was assigned the same unit workload value. For example, in a unit whose average percent maximum occupancy was 0.65, and average nurse to infant ratio was 0.85, every infant in that unit was assigned a percent maximum occupancy value of 0.65 and a nurse to infant ratio of 0.85. In another unit, whose average percent maximum occupancy was 0.72, and average nurse to infant ratio was 0.88, every infant in that unit was assigned a percent maximum occupancy value of 0.72 and a nurse to infant ratio of 0.88.

These cross-sectional workload unit values were then added in turn to the birth and 12 hour models for the primary outcomes. Table V-8 shows the relationship between these cross-sectional workload measures and the primary outcomes. There were no significant relationships between any of the cross-sectional unit workload measures and the primary outcomes.

Table V-8
Relationship between the cross-sectional measures of workload and the primary outcomes.

		Percent Maximum Occupancy		Nurse to Infant Ratio	
	Model	Odds Ratio	95% CI	Odds Ratio	95% CI
Mortality	*Birth*	1.00	(0.85, 1.19)	1.02	(0.92, 1.12)
	12 hour	1.04	(0.85, 1.26)	1.07	(0.96, 1.20)
Mortality or Brain Damage	*Birth*	1.06	(0.89, 1.25)	1.01	(0.91, 1.12)
	12 hour	1.02	(0.86, 1.22)	1.04	(0.93, 1.16)
Nosocomial Bacteraemia	*Birth*	0.88	(0.68, 1.15)	0.95	(0.81, 1.10)
	12 hour	0.77	(0.59, 1.02)	0.91	(0.80, 1.04)

Table represents the change in odds of each primary outcome for per 10% increase in percent maximum occupancy, and per 0.1 increase in nurse to infant ratio. All adjusted for illness severity using the Birth and 12 hour models.

Longitudinal, infant based approach

The longitudinal approach aimed to examine whether differences in workload within each unit had any effect on the primary outcomes. In this case each infant in each unit was assigned the workload measures outline previously relating to the time period immediately prior to their admission. Now each infant in the same unit did not have the same workload values assigned to them.

Table V-9 summarises the percent maximum occupancy and nurse to infant ratio for each infant at their time of admission. Similar to the cross-sectional approach, high volume units appeared to be more occupied, than medium and low volume units. Also higher volume units had higher nurse to infant ratios than medium and low volume units, and units with high nursing provision had higher nurse to infant ratios than units with low nursing provision. Otherwise, there were no major differences between the unit types.

Percent Ranked Nurse Infant Ratio

For nurse to infant ratio an additional variable was calculated. This value indicated when the nurse to infant ratio was high or low for each unit. For example if the maximum nurse to infant ratio in a particular unit was 0.87, and an infant was admitted when the nurse to infant ratio was 0.87, then that infant would have a percentile ranked nurse infant ratio value of 100. If the median nurse to infant ratio in the same unit was 0.80, and an infant was admitted when the nurse to infant ratio was 0.80, then that infant would have a percentile ranked nurse to infant ratio of 50. This value aimed to examine whether there was some effect of "within unit perceived busy-ness" in relation to the primary outcomes. Table V-9 does not summarise the percent ranked nurse infant ratios because, by definition the median 25th and 75th percentile values for each unit are all 50, 25 and 75 respectively.

Table V-9
Average workload on day of admission for each infant by unit type over the study period – Longitudinal approach

Unit Type	% max occ Median	% max occ Percentile 25th	% max occ Percentile 75th	Nurse infant ratio Median	Nurse infant ratio Percentile 25th	Nurse infant ratio Percentile 75th
1	0.76	0.65	0.83	1.04	0.87	1.26
2	0.73	0.60	0.82	0.93	0.80	1.08
3	0.73	0.63	0.81	0.95	0.73	1.14
4	0.61	0.50	0.74	1.00	0.85	1.20
5	0.70	0.60	0.81	1.00	0.89	1.14
6	0.60	0.50	0.73	0.93	0.80	1.14
7	0.59	0.45	0.71	1.00	0.84	1.23
8	0.65	0.52	0.76	0.86	0.70	1.05
9	0.58	0.46	0.69	1.00	0.75	1.33
10	0.56	0.44	0.68	0.92	0.80	1.14
11	0.58	0.46	0.70	1.00	0.80	1.23
12	0.64	0.52	0.75	0.89	0.75	1.05
Patient Volume						
High	0.70	0.58	0.81	0.97	0.83	1.18
Medium	0.65	0.52	0.76	0.96	0.80	1.14
Low	0.60	0.47	0.71	0.94	0.80	1.14
Consultant availability						
High	0.65	0.53	0.78	0.96	0.80	1.18
Low	0.63	0.50	0.75	0.95	0.80	1.14
Nursing Provision						
High	0.65	0.52	0.77	1.00	0.83	1.20
Low	0.63	0.50	0.75	0.92	0.78	1.11
Total	0.64	0.50	0.76	0.96	0.80	1.17

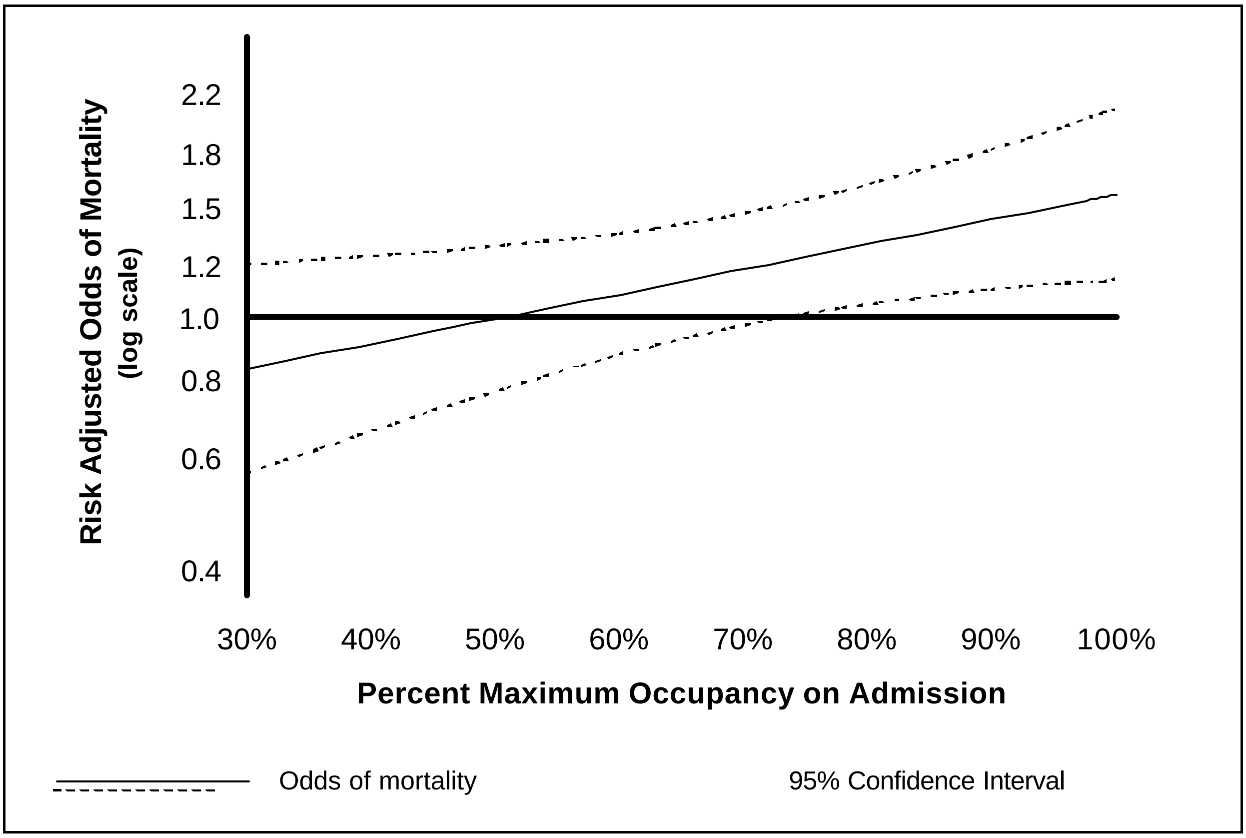
Table V-10 overleaf summarises the results of using within unit workload values as additional terms in the birth and 12 hour models. As percent maximum occupancy increased, the odds of mortality increased. This is illustrated in Figure V-7. There was no relationship between absolute nurse infant ratio and mortality, but the within unit ranked nurse infant ratio indicated that the odds of mortality increased as the number of infants per nurse increased. No significant relationships were found between the workload measures and the other primary outcomes.

Table V-10
Relationship between the longitudinal measures of workload and the primary outcomes.

	Model	Percent Maximum Occupancy		Nurse to Infant Ratio		Percent Ranked Nurse Infant Ratio	
		Odds Ratio	95% CI	Odds Ratio	95% CI	Odds Ratio	95% CI
Mortality	*Birth*	1.09	(1.01, 1.18)	0.98	(0.94, 1.02)	0.95	(0.90, 1.00)
	12 hour	1.11	(1.02, 1.20)	1.01	(0.96,1.06)	0.97	(0.92, 1.03)
Mortality or	*Birth*	1.03	(0.97, 1.11)	0.99	(0.95, 1.04)	0.98	(0.94, 1.03)
Brain Damage	*12 hour*	1.04	(0.97, 1.11)	1.01	(0.97, 1.06)	1.00	(0.95, 1.05)
Nosocomial	*Birth*	0.99	(0.94, 1.05)	0.99	(0.96, 1.02)	0.99	(0.95, 1.03)
Bacteraemia	*12 hour*	1.00	(0.95, 1.06)	1.00	(0.97, 1.03)	1.00	(0.96, 1.04)

Table represents the change in odds of each primary outcome for per 10% increase in percent maximum occupancy, per 0.1 increase in nurse to infant ratio and per 10% increase in percent ranked nurse infant ratio. All adjusted for illness severity using the Birth and 12 hour models.

Figure V-7:
Percent maximum occupancy by odds of mortality using the birth model



The continuous regression line represents the adjusted odds of mortality calculated from the birth & percent maximum occupancy model scaled relative to 50% occupancy. The 95% confidence interval illustrates the prediction error for individual values of percent maximum occupancy. The adjusted odds of mortality and 95% confidence interval associated with each 10% increase in percent maximum occupancy on admission is 1.09 (1.01 – 1.18) (See Table V-10). Infants admitted when the NICU was at 50% occupancy had about 55% lower odds of dying than infants admitted at maximum occupancy. Infants admitted at maximum occupancy (100%) had about 80% greater odds of dying than infants admitted at lowest occupancy.

Analysis by unit of birth

Transfers out of NICUs numbered 1592, of which 244 (15%) were within 24 hours of birth. Of those infants with a probability of mortality above 0.5, 1.3% (1/79), 4.2% (2/48), and 25.6% (11/43) were transferred out in the first 24 hours from high, medium and low volume units respectively (Table V-11). Infants transferred out in this immediate postnatal period from low volume units were more likely to be sicker than those from medium and high volume units. Including infants who were transferred out of the unit within 24 hours of birth in an analysis by hospital of birth did not significantly change the primary results. The odds ratios of all the organisational characteristics in relation to the primary outcomes is shown in Table V-12.

Table V-11
Number of infants transferred out of the unit less than 1 day after admission by probability of mortality

	Prob. Mortality <0.5		Prob. Mortality >0.5	
	Transferred Out		Transferred Out	
Patient Volume	Proportion	%	Proportion	%
High	48/3534	1.4%	1/79	1.3%
Medium	62/4186	1.5%	2/48	4.2%
Low	120/5514	2.2%	11/43	25.6%

Table shows the proportion and percentage of infants transferred out of the unit less than one day after admission by probability of mortality calculated using the Birth model.

Table V-12
Relationship between the within unit measures of workload and the primary outcomes.

	Generalised Estimating Equations Models					
	Crude Model		Birth Model		12hr Model	
Death before hospital discharge						
Patient Volume						
High						
Medium	0.92	(0.54, 1.56)	1.09	(0.75, 1.58)	1.07	(0.72, 1.60)
Low	0.66	(0.44, 1.01)	0.95	(0.68, 1.35)	0.88	(0.60, 1.30)
Consultant availability						
High						
Low	0.96	(0.64, 1.44)	0.88	(0.66, 1.18)	0.92	(0.67, 1.26)
Nursing provision						
High						
Low	1.51	(1.01, 2.24)	1.21	(0.90, 1.63)	1.32	(0.97, 1.81)
Death or brain damage before hospital discharge						
Patient Volume						
High						
Medium	0.80	(0.55, 1.17)	1.21	(0.77, 1.90)	1.20	(0.78, 1.86)
Low	0.53	(0.39, 0.73)	1.01	(0.67, 1.51)	0.83	(0.56, 1.22)
Consultant availability						
High						
Low	0.81	(0.59, 1.12)	0.92	(0.65, 1.29)	0.95	(0.67, 1.35)
Nursing provision						
High						
Low			1.04	(0.74, 1.47)	1.12	(0.79, 1.58)
Death or Nosocomial bacteraemia before hospital discharge						
Patient Volume						
High						
Medium	0.93	(0.62, 1.39)	1.40	(0.95, 2.05)	1.25	(0.84, 1.85)
Low	0.61	(0.43, 0.87)	1.05	(0.71, 1.54)	0.78	(0.52, 1.15)
Consultant availability						
High						
Low	0.81	(0.58, 1.12)	0.74	(0.54, 1.02)	0.71	(0.51, 0.99)
Nursing provision						
High						
Low	1.21	(0.87, 1.68)	0.98	(0.70, 1.37)	0.99	(0.71, 1.39)
Nosocomial bacteraemia before hospital discharge						
Patient Volume						
High						
Medium	0.89	(0.57, 1.38)	1.31	(0.80, 2.12)	1.01	(0.62, 1.65)
Low	0.54	(0.34, 0.86)	1.06	(0.61, 1.85)	0.64	(0.37, 1.09)
Consultant availability						
High						
Low	0.59	(0.41, 0.87)	0.64	(0.43, 0.97)	0.54	(0.36, 0.79)
Nursing provision						
High						
Low	0.85	(0.57, 1.26)	0.84	(0.54, 1.29)	0.78	(0.52, 1.19)

Table shows the odds together with a 95% confidence interval of each primary outcome relative to the high level of each organisational characteristics. The odds ratios and 95% confidence intervals are derived using generalised estimating equations that adjust for the clustered nature of the data. An odds ratio > 1 indicates increased odds relative to the high level.

Discussion

Our study showed that high volume NICUs in the UK cared for sicker infants, were busier and had higher crude mortality and morbidity than medium and low volume units. Adjusting for initial clinical risk and illness severity, the performance of high volume NICUs was comparable to that of medium and low volume NICUs. Low volume NICUs transferred out more infants in the first 24 hours, and these were relatively sick and destined for secondary or tertiary NICUs. A tiered network of care was operating, and there was no evidence of greater risk-adjusted mortality in any type of NICU. However, mortality increased with increasing workload in all types of NICU.

The finding that nosocomial bacteraemia was increased in NICUs with high consultant provision cannot be ignored and this finding is discussed more fully on page 46.

Reports of the relation between NICU patient volume and performance not consistent in the direction and size of effect in the literature. Improved hospital survival was reported for a UK region in 1990 for infants ≤28 weeks gestation cared for in NICUs with more than 500 ventilator days per annum.[15] That this finding was not sustained in the same region for 1994-96[16] may be due a number of factors: to major developments in perinatal care such as use of surfactant and maternal steroids or to increased investment in equipment and specialist staff in neonatal care in district general hospitals.[16] The later study also more fully adjusted for clinical risk.[16] Good adjustment for casemix, clinical risk and illness severity has been suggested to remove the apparent relationship between increased volume and improved outcome.[17] This has been borne out in some clinical settings but not in others.[18]

The risk adjustment models used in our study are empirically developed from the whole dataset. The use of CRIB[3] was inappropriate because it was developed specifically for very low birth weight or premature infants. Although SNAP is applicable to infants of all birthweights, it requires considerably more data [4] which would have been difficult to collect for our sample size.

Earlier neonatal studies, from the US[19] and a comparative Australia versus Scotland study, [20] did use risk adjustment and did appear to show improved outcomes for high volume NICUs. However, potentially significant methodological problems with these studies include possible bias due low follow-up data in the 4 biggest hospitals in the US study,[19] lack of comparability of the definitions of high volume,[21] the self-selected sampling of NICUs in the international comparison[20] and whether or not the clustered nature of the data are accounted for in analysis.[20, 22] Finally, international comparisons from different health care systems which use risk-adjustment tools developed in only one country are difficult to interpret, particularly if they include characteristics other than physiological variables.

Unaccounted differences in countries' healthcare systems, for example the market health care economy of the US, may also affect the volume/outcome relationship. Our prospective design was similar to a national study of paediatric intensive care provision in randomly selected stratified paediatric intensive care units (PICUs) which also showed no relation between patient volume and risk-adjusted outcomes. [23, 24] But again, conversely, other published studies of PICUs have shown an inverse relation between volume and risk-adjusted outcome.[25-27] Some of the methodological issues associated with previous studies might be addressed by more reliable, routine, population-based data and comparisons of neonatal mortality between countries where neonatal care is based on collaborative referral networks, as in the UK and Australia, rather than use of a competitive market comparator such as the US.[20, 27, 28]

UK and Australian collaborative neonatal networks appear to operate on different scales. In 1996, infants were treated in 186 NICUs in the UK[1] which has approximately 720,000 births per annum[29] whereas infants were treated in 23 NICUs in Australia, which has about 250,000 births per annum.[30] The number of annual deliveries per NICU was therefore approximately 4000 in the UK and 10 000 in Australia, with average admissions of very low birth weight infants per NICU of around 40 in the UK[1] compared with 90 in Australia.[30] In Australia a greater proportion of consultants who supervise NICUs are full time neonatal intensivists,[31, 32] and neonatal specialist training for nurses is longer, typically requiring a year compared with six months in the United Kingdom. Official recommendations for nurse-infant staffing ratios also differ: the British Association of Perinatal Medicine recommends up to two ventilated infants per nurse each shift[14] whereas the Australian Health Ministers' Advisory Council stipulates only one ventilated infant per nurse.[33] In population-based comparisons of data from 1993-1996, neonatal mortality rates for very low birth weight or very preterm infants were 20-30 % higher in Scotland or England and Wales than in Australia.[20,28,34] It should be noted that Australia's lower neonatal mortality rates are also consistent with better mortality rates at all ages compared with the UK,[35] and caution has been urged in attributing observed international differences, both in perinatal mortality[36, 37] and adult mortality,[35, 38] to particular organisational service characteristics. Nevertheless Australia's lower rates may not entirely reflect differences in genetic, social or environmental factors. They may be consistent, at least in part, with these differences in scale and staffing in the organisation of perinatal (i.e. obstetric and neonatal) care.[20] It may be that Australia's lower rates illustrate a potential benefit of centralising the treatment of only the sickest patients in fewer centres.[39-41] Provided there are no major constraints in the UK, such as inadequate availability or mobility of nursing staff or prohibitively high costs of re-configuration, further centralisation of the sickest infants in fewer centres may also facilitate clinical specialty development, and training and attaining higher nurse-infant ratios.

Geographical variation was reported recently in the UK, where some tertiary centres were forced to transfer out infants, in-utero and postnatally, due to lack of neonatal beds.[42] The majority of reported transfers-out were in-utero.[42] Our postnatal transfer data indicated, that for very sick infants (defined as those with a probability of mortality >0.5), early postnatal transfers out of tertiary units were rare (1.3%, 1/79).

However, our finding of increased risk of mortality in relation to high levels of occupancy and low nurse-infant ratios is cause for concern. These findings could not be explained by selection bias, as infants admitted at high occupancy experienced higher mortality rates after adjustment for their initial risk. This study cannot determine the optimum nurse-infant ratio, but it should be highlighted that when NICUs are busiest and nurse-infant ratio drops, the risk of mortality increases. This result is consistent with previous reports of increased adverse outcomes in relation to high workload in intensive and emergency care.[43-46] It should be noted that NICUs in this study experienced a rate of maximum occupancy which was greater than the number in its official cot establishment. These findings have implications for staffing policy in all types of NICU in the UK, particularly high volume NICUs, which had the highest rates of occupancy (Table V-7). It may be appropriate to consider staffing levels in neonatal intensive care which more closely resemble those in paediatric and adult intensive care.

Conclusions and implications for UK service provision

Our study demonstrated that different types of NICUs in the UK already treat infants with very different levels of clinical risk and illness severity. UK NICUs already appear to operate to some extent within collaborative perinatal networks, as suggested by CSAG in 1993, and so give infants an equal chance of survival regardless of where they are born. These outcome results of the study remained consistent and robust, by modelling risk at birth or at 12 hours old, and analysing by hospital of care or hospital of birth.

Efficiency may be improved if the best-resourced NICUs care for the sickest infants, with less sick infants efficiently and appropriately cared for in less well-resourced, but equally effective NICUs.
However parents must be aware of consequent trade-offs between access and more efficient care associated with such configurations.

Crucially, our results suggest that improvements to the service may be achieved by reducing the number of occasions when units reach maximum occupancy, workload is high and where there are insufficient nurses for each infant. Any policy enhancing the nurse-infant ratio, for example to more closely resemble those in paediatric or adult intensive care, should be accompanied by careful evaluation of whether it brought about cost-effective improvements in mortality and longer-term morbidity.

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V: 2. Secondary clinical hypotheses

The secondary clinical hypotheses examined the relation between risk adjusted outcomes and a number of pre-defined organisational, training, staffing and clinical practice characteristics in 54 NICUs in phase 2. These characteristics were considered to be indicators of quality of care.
The secondary variables to be tested included

- levels of specialist clinical and nursing staff provision
- hospital status, training and risk periods when new junior doctors took up post
- some specified standards or recommendations in the BAPM standards document of 1996.[1]

Methods
Methods used to adjust mortality and morbidity outcomes for risk and casemix remain the same as those described in the previous chapter V(i) for primary clinical analyses (page 17). Further data used in the secondary analyses included birth/admission times and dates to test for temporal or seasonal variation in outcomes.
Descriptive data for the 54 NICUs included unit profile data collected at site visit in 1998 (WTM, JT). Each phase 2 NICU also returned a detailed anonymous staff profile in 1998. The staff profiles listed each post within their nursing and medical establishment; the highest specialist qualifications of post-holders, grades, specialist roles and responsibilities. Whether each post was currently filled or where staff were on long-term sick leave were also recorded.

The secondary clinical hypotheses are listed below.

Secondary clinical hypotheses:

That the three risk-adjusted adverse outcomes are independently related to-

1. number of consultant led business rounds per week
2. whether one consultant is designated for the direction and management of the Unit, monitoring clinical policies, practice and standards, with the majority of his or her clinical sessions committed to neonatal care*
3. admission during the first 3 months after the most junior medical staff started work
4. whether a doctor with at least 6 months training in neonatal intensive care is continuously resident in the same building as the NICU*
5. whether a doctor with at least 2 years' full time equivalent training in neonatal intensive care is continuously resident in the same building as the NICU*
6. proportion of whole time equivalent neonatal nurse practitioners employed
7. delivery and admission outside normal working hours
8. quality of written protocol for administration of surfactant† (see chapter V (iii), page 45)
9. implementation of regular audit*
10. implementation of systematic training programme for junior medical staff*
11. hospital teaching status

That risk-adjusted rates of probable nosocomial bacteraemia are independently related to

12. average floor space per intensive care cot[2]

13. average number of sinks for handwashing per intensive care cot[2]

14. appointment of an infection control nurse or link nurse for the unit

15. quality of protocols for hand washing and infection control

* *in accordance with recommendations from the BAPM document on Standards for Hospitals Providing Neonatal Intensive Care* [1]

† *adapted from a recommendation from the BAPM document that there should be agreed, written protocols for nursing and medical staff which contain details of practical procedures*

Results

Unit profile questionnaires and detailed staffing establishments were returned from all 54 units. Descriptive results are summarised in tables and appendices below for each variable. Their relation to risk-adjusted outcomes are shown overleaf in Table V-2 (1).

1. Number of consultant led business rounds per week

The number of consultant business rounds per week in the 54 NICUs ranged from 3 to 15. On average there were 6 or 7 consultant business rounds per week. There was no association between the number of business rounds per week by higher or lower consultant provision. Those NICUs with higher consultant provision (n 24) had a mean of 7.21 (sd 3) consultant business rounds vs 6.7 (sd 3) for those NICUs with lower consultant provision (n 30). Similarly there was no relation between NICU volume and number of consultant rounds.

*2. Whether one consultant is designated for the direction and management of the Unit, monitoring clinical policies, practice and standards, with the majority of his or her clinical sessions committed to neonatal care** [1]

The majority of NICUs did have a consultant designated for the direction and management of the unit in accordance with the standards recommended by BAPM (1996). [1] More of the high volume NICUs (83%) had a dedicated consultant compared with medium (56%) or low volume (57%) NICUs. (Table V-2 (2)). There was no significant relation between NICUs having a designated consultant and risk-adjusted mortality or risk-adjusted mortality and brain damage. However, there was a significant relation between having a designated consultant and increased nosomial bacteraemia (Table V-2 (1) (odds ratio 1.56, 1.03 to 2.36)).

Table V-2 (2)
Designated consultant by cell type and patient volume

Cell Type	No Designated consultant	Yes Designated consultant	Volume	n NICUs
1	0	3		3
2	0	3	high	3
3	1	2	(83%)	3
4	1	2		3
5	2	2	medium	4
6	1	3	(56%)	4
7	2	2		4
8	2	2		4
9	3	2	low	5
10	0	5	(57%)	5
11	3	5		8
12	5	3		8
Total	20 (37%)	34 (63%)	(63%)	54 (100%)

Table V-2 (1) Secondary Clinical Hypotheses: the relation between process and organisational characteristics and risk-adjusted outcomes

	Death		Death or Brain Damage		Death or Nosocomial Bacteraemia		Nosocomial Bacteraemia	
Number of consultant led business rounds per week	1.00	(0.95, 1.07)	1.00	(0.94, 1.05)	1.01	(0.96, 1.06)	0.99	(0.93, 1.06)
Unit has a designated consultant	0.88	(0.65, 1.19)	0.86	(0.63, 1.16)	1.14	(0.81, 1.60)	1.56	(1.03, 2.36)
Doctor with at least 6 months training								
Always								
>50%	1.30	(0.92, 1.83)	1.43	(1.07, 1.92)	0.78	(0.51, 1.21)		
<50%	0.92	(0.66, 1.30)	0.78	(0.48, 1.27)	0.70	(0.48, 1.03)		
Never	5.52	(4.44, 6.88)	2.15	(1.75, 2.65)	1.59	(1.33, 1.89)		
Doctor with at least 2 years training								
Always								
>50%	0.76	(0.44, 1.32)	1.02	(0.63, 1.65)	0.92	(0.57, 1.48)		
<50%	0.76	(0.46, 1.25)	0.81	(0.50, 1.33)	0.78	(0.47, 1.29)		
Never	0.78	(0.44, 1.37)	0.97	(0.60, 1.57)	0.82	(0.50, 1.34)		
Missing	1.68	(1.10, 2.56)	1.83	(1.28, 2.62)	0.60	(0.42, 0.86)		
Proportion of wte neonatal nurse practioners	76.11	(0.04, >99)	150	(1.54, >99)	1.10	(0.00, >99)	0.60	(0.00, >99)
Unit has an Audit Nurse	1.16	(0.86, 1.56)	1.14	(0.81, 1.61)	1.17	(0.82, 1.66)	1.10	(0.70, 1.75)
Unit has an Audit Clinician	1.15	(0.86, 1.53)	0.93	(0.64, 1.35)	0.91	(0.59, 1.41)	0.76	(0.41, 1.40)
Unit has Self Reported Training Status	0.95	(0.66, 1.36)	0.88	(0.62, 1.25)	1.02	(0.71, 1.47)	1.14	(0.73, 1.78)
University Teaching								
Training (not Univ.)	0.90	(0.60, 1.35)	1.32	(0.89, 1.97)	0.79	(0.53, 1.16)	0.93	(0.54, 1.61)
No teaching, No medical training	0.82	(0.58, 1.17)	1.17	(0.79, 1.73)	0.79	(0.54, 1.17)	0.81	(0.49, 1.35)
Area (m2) per level 1 cot					0.99	(0.99, 1.00)	0.99	(0.98, 1.00)
Average n sinks per L1 cot					0.63	(0.41, 0.97)	0.52	(0.26, 1.02)
Unit has an infection control nurse					0.56	(0.40, 0.79)	0.53	(0.35, 0.79)
Quality score for hand washing signs					1.05	(0.99, 1.10)	1.03	(0.96, 1.11)

3. *Admission during the first 3 months after the most junior medical staff started work*

We compared the outcomes for babies born from 1 August through October 1999, with those born at all other dates. Although there are a number of start dates throughout the year for trainee doctors within NICU, the intake in August coincides for all trainees: general practitioners, paediatricians and neonatal specialists. This period was identified as a potentially risky period, possibly more likely to be associated with inexperience and medical accidents. All phase 2 NICUs were collecting prospective data throughout this 3-month period. (Appendix 7). In that 3 months 27% of the observed infant sample were admitted. There were no differences between the risk-adjusted outcomes for infants admitted in this time period compared with those admitted on all other dates. (eg. odds ratio risk-adjusted mortality 1.1.6 (0.88-1.36)).

4. *Whether a doctor with at least 6 months training in neonatal intensive care is continuously resident in the same building as the NICU**

The majority of units did have a doctor with at least 6 months specialist training continuously in the NICU building. (Table V 2:(3)) However there were no differences in any of the risk-adjusted outcomes between those units with and without a doctor with 6 months experience continuously in residence.

Table V-2 (3) Doctor with 6 months specialist training continuously in the NICU building by cell type and patient volume

Cell Type	Always	>50% time	<50% time	Never	n NICUs
1	3	0	0	0	3
2	2	0	1	0	3
3	2	0	1	0	3
4	2	1	0	0	3
5	3	1	0	0	4
6	3	0	1	0	4
7	4	0	0	0	4
8	3	1	0	0	4
9	2	2	1	0	4
10	4	1	0	0	5
11	7	0	1	0	8
12	4	2	1	0	8
Total	39	8	6	0	53
	(72%)	(15%)	(12%)	(0%)	(98%)*

1 non-response

5. *Whether a doctor with at least 2 years' full time equivalent training in neonatal intensive care is continuously resident in the same building as the NICU**

Only 20% of units had a doctor with at least 2 years specialist training continuously in the NICU building. (Table V-2 (4)) There were no differences in any of the risk-adjusted outcomes between those units with and without a doctor with 2 years training continuously in residence.

Table V-2 (4) Doctor with 2 years specialist training continuously in the NICU building by cell type and patient volume

Cell Type	Always	>50% time	<50% time	Never	n NICUs
1	1	1	0	0	3
2	1	0	0	0	3
3	1	0	1	1	3
4	0	2	0	0	3
5	1	0	2	2	4
6	2	0	0	0	4
7	0	0	1	1	4
8	0	0	1	1	4
9	1	0	2	2	4
10	1	3	0	0	5
11	1	1	5	5	8
12	2	1	3	3	8
Total	11 (20%)	8 (15%)	19 (35%)	15 (28%)	53 (98%)

6. *Proportion of whole time equivalent neonatal nurse practitioners employed*

From the detailed unit profiles, fourteen of the 54 NICUs reported at least one neonatal nurse practitioner. There were 20 posts in total. They were twice as likely in high volume and low consultant availability NICUs. Most were employed full time. They represented a very small proportion of WTE nursing establishments (0.01 to 0.11). Twelve had A19 qualifications, 4 had "other neonatal practitioner courses", and the remainder did not have recorded qualification levels. There were no measurable relation between the proportion of neonatal nurse practitioner employed and risk-adjusted outcomes (Table V 2 (1)).

7. *Delivery and admission outside normal working hours*

Comparisons of risk-adjusted outcome for diurnal variation found no significant difference for those born or admitted within normal working hours (48% of observed infants, 8 am to 5 pm) compared with those 52% born or admitted at all other times of day (eg. odds ratio 1.18 (0.90-1.55).

8. *Quality of written protocol for administration of surfactant (see section V (iii) pages 45-53)*

9. *Implementation of regular audit**

The great majority of NICUs (83%) had a member of staff responsible for clinical audit. Those without such an identified member of staff were more likely to be low volume NICUs. (Table V-2 (5)). There were no association between having identified staff for clinical audit and risk adjusted measures of mortality or morbidity (Table V-2 (1)). Similar results were obtained in analysis of risk adjusted outcomes in comparisons of units with and without an audit neonatal nurse.

Table V-2 (5) Identified member of staff responsible for clinical audit by cell type and patient volume

Cell Type	Yes Identified clinical audit	No Identified clinical audit	Volume % with clinical audit	n NICUs
1	3	0	High	3
2	3	0	92%	3
3	3	0		3
4	2	1		3
5	4	0	Medium	4
6	3	1	88%	4
7	4	0		4
8	3	1		4
9	3	2	Low	5
10	3	2	77%	5
11	6	2		8
12	8	0		8
Total	45 (83%)	9 (17%)	(83%)	54 (100%)

10. Implementation of systematic training programme for junior medical staff and 11 Hospital teaching status*

Evaluation of training programmes and training status of NICUs was complex. It became clear that many units would use their unit protocols and guidelines as texts, but these were held at or near the nursing station. Trainees would rarely be provided with personal copies or specifically prepared clinical training texts. Similarly, only the broad content of topics included in training were available for most NICUs and these were reported as being often supplemented. Few records or copies of supplementary material covered were available. Quality of post-graduate specialist training programmes needs closer systematic examination than was possible in this study.

Units had overlapping responsibilities for training SpR Paedatricians and General Practitioners as well as those SpR's intending to become neonatal intensive care specialists. NICUs were divided into University Teaching Hospitals, those who claimed training status with placements of trainees, and those with no training. Most NICUs with no training were medium or small volume NICUs (Table V-2 (6)).

Table V-2 (6) Training status of NICUs by cell type

Cell Type	University Teaching Hospital	Training	No Training	n NICUs
1	2	1	0	3
2	2	1	0	3
3	1	2	0	3
4	1	2	0	3
5	0	1	3	4
6	0	1	3	4
7	0	1	3	4
8	0	1	3	4
9	0	3	2	5
10	0	4	1	5
11	0	6	2	8
12	0	2	6	8
Total	6 (11%)	25 (46%)	23 (42%)	54 (100%)

There were no significant relationships between these training status categories and risk-adjusted outcomes. (Table V 2 (1))

Probable Nosocomial Bacteraemia
There were 402 (3%) infants observed who, following negative results of blood cultures at birth to 48 hours, had positive blood cultures after 48 hours. These were taken as probable cases of nosocomial bacteraemia. These cases were evenly distributed throughout the NICU types (33% in high volume NICUs, 36% in medium volume NICUs and 32% in low volume NICUs).

11. Average floor space per intensive care cot
The variation in floor area for each level 1 cot is summarised in table V-2 (7). Variation was wide but the area per level 1 cot tended to be greater in small volume NICUs. There was no relation between increasing floor area per level 1 cot and risk-adjusted nosocomial bacteraemia. (Table V 2 (1)).

Table V-2 (7) Floor area (m^2) per contracted level 1 cot

Cell Type	5-8 m^2	8-13 m^2	14-hi m^2	Mean (sd) area m^2	n NICUs
1	2	1	0	High	3
2	1	1	0	10.5 (5.5)	2
3	1	0	2		3
4	2	1	0		3
5	2	2	0	Medium	4
6	0	3	0	10.9 (3.7)	3
7	0	1	2		3
8	1	2	1		4
9	1	4	5	Low	5
10	1	2	1	14.6 (8.8)	4
11	2	1	4		7
12	4	1	2		7
Total					48 (88%)

12. Average no. of sinks for handwashing per level 1 intensive care cot (8)

The total number of hand basins within the level 1 care area was divided by the number of level 1 cots in that area for each NICU. The mean (sd) number of sinks for handwashing per NICU type are described in Table V-2 (8). The average was two level 1 cots to one handbasin. There was no significant relation between increasing numbers of sinks for handwashing and risk-adjusted nosocomial bacteraemia. (Table V2 (1))

Table V-2 (8) Average number of handwashing sinks per level 1 cot by cell type

Cell Type	Mean number of sinks per level 1 cot	sd	n NICUs
1	0.22	0.11	3
2	0.41	0.14	3
3	0.78	0.40	3
4	0.23	0.10	3
5	0.32	0.13	4
6	0.38	0.19	4
7	0.60	0.28	4
8	0.46	0.22	4
9	0.65	0.33	5
10	0.44	0.18	5
11	0.80	0.51	8
12	0.43	0.25	8
Total	0.51	0.32	54 (100%)

13. Appointment of an infection control nurse or link nurse for the unit

The majority of all types of NICU had an appointed infection control nurse or link nurse. (Table V-2(9)) There was a significant relation between having an infection control nurse and reduced incidence of risk-adjusted nosocomial bacteraemia, odds ratio 0.53, (0.35 to 0.79), Table V2 (1).

Table V-2 (9) Appointed infection control nurse or link nurse by cell type and patient volume

Cell Type	Yes Infection control Nurse	No Infection control Nurse	By Volume	n NICUs
1	2	1		3
2	2	1		3
3	3	0	(83%)	3
4	3	0		3
5	3	1		4
6	3	1	(75%)	4
7	3	1		4
8	3	1		4
9	3	2		5
10	5	0	(77%)	5
11	5	3		8
12	7	1		8
Total	42 (78%)	12 (22%)	(78%)	54 (100%)

14. *Quality of protocols for hand washing and infection control*

A proxy for quality of protocols for handwashing and infection control was taken as the number of handwashing signs, and their specific content . These data were collected at site visit. The content of each notice was scored for a) instructions on how to wash hands effectively and b) when it was necessary to wash hands. (The reliability of this measure is questionable because two NICUs stated that they had a specific policy to minimise all wallsigns and regularly used staff training for handwashing protocols) There was no relation between increasing quality score for hand washing signs and risk-adjusted nosocomial bacteraemia. (Table V-2 (1)).

Conclusions

The descriptive results for the variables in the secondary hypotheses indicate variation in staff skills, clinical expert availability, training settings and definition of neonatal nurse practitioner. There were very few neonatal nurse practitioners in post in this sample at the time of the study.
The results demonstrate wide variation in space, layout and facilities, eg. handwashing sink availability.

There were two statistically significant independent associations between individual secondary characteristics of NICUs and risk-adjusted outcomes, namely

- that those units with infection control nurses or link infection control nurses had significantly reduced risk-adjusted nosocomial bacteraemia.
- And that those NICUs with a designated consultant for the clinical management of units had significantly higher risk-adjusted nosocomial bacteraemia.

The latter finding is consistent with the earlier finding that higher consultant availability was associated with increased risk-adjusted nosocomial bacteraemia (p23).

Although it was associated with a wide confidence interval, the finding that nosocomial bacteraemia was increased in NICUs with high consultant provision cannot be ignored. Whilst this result may reflect an increased rate of contaminated blood cultures in those NICUs, the literature suggests that some invasive procedures,[3] overcrowding and understaffing in periods of increased workload,[4] poorer compliance with handwashing by clinicians compared with nursing staff,[5] and poorer compliance within intensive care settings[5] may provide some possible explanations to these findings.

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V (iii)– Secondary Clinical Hypothesis (continued)
Quality of surfactant guidelines in UK neonatal units and their relation to the three risk-adjusted adverse outcomes

Background

Clinical management guidelines are recommended within neonatal intensive care. The degree to which local neonatal guidelines are evidence-based has not previously been investigated. Within neonatal care, arguably the most important therapeutic advance in recent years has been the introduction of surfactant replacement therapy. The many clinical trials involving surfactant have demonstrated their benefit in terms of reduction in mortality and pneumothorax, and in need for respiratory support and intensive care. Soll has published a number of systematic reviews in the Cochrane database on the use of surfactant replacement therapy[1-4] In view of its expense, surfactant should be used to the maximum benefit within locally agreed guidelines taking account of the available evidence of benefit and cost.

The UK neonatal staffing study provided an opportunity to appraise the quality of surfactant therapy guidelines in a representative sample of neonatal intensive care units; to establish whether their content varied between different types of unit; and to look for associations with risk adjusted processes and outcomes of care.

Methods

The following features of surfactant replacement therapy, based on systematic reviews of the evidence published before 1998, were used as standards for guidelines:

1. *Prophylaxis is recommended in infants of less than between 30 and 32 weeks gestation.* A number of studies[1-4] have demonstrated benefit from prophylactic therapy when compared to rescue treatment. In the Cochrane review of prophylactic vs therapeutic administration of surfactant treatment[1-2] the meta-analysis supported a significant reduction in pneumothorax, PIE, mortality and death or chronic lung disease associated with prophylactic use in intubated infants less than 30-32 weeks. All studies used mammalian-derived surfactant. In more mature infants the frequency of RDS declines, and more infants receive surfactant unnecessarily with a policy of prophylactic intubation at delivery. The most appropriate upper gestation for prophylaxis is unknown, but was stated in the Cochrane review to lie somewhere between 30 and 32 weeks. One review in 1998[1] concluded that a policy of elective intubation and surfactant administration in infants up to 30 weeks gestation was justified.

   That a lower limit for prophylaxis should be less than 26 weeks gestation or less than 750 grams birthweight. Most studies have excluded infants less than 26 weeks gestation or less than 750 grams birthweight. There were 5 non-controlled studies [1-5] and a further 5 randomised controlled trials[1-5] of surfactant therapy in the smallest and most immature infants published before 1998. Although the non-controlled studies suggest benefit in these infants, this is less clearly the case in the randomised trials. A policy excluding surfactant use in infants below 26 weeks gestation or less than 750 grams birthweight was therefore considered consistent with the evidence available. The data sheet for ALEC stated a lower limit of 25 weeks, and that for curosurf a lower limit of 700 grams estimated birthweight.

2. *Prophylactic therapy should be administered as soon as possible after delivery*. The optimal timing of the first dose had not been established. There are theoretical grounds for favouring early administration, including the observation of damage to the bronchiolar epithelium 5 minutes after birth[1] in ventilated premature rabbits and a suggestion that surfactant suspension distributes more uniformly when administered to a fluid filled lung.[1] However, one study[1] had suggested that prophylactic administration following initial stabilisation might be more appropriate. The OSIRIS collaborative

group[1] found a significant reduction in risk of death, pneumothorax and death or bronchopulmonary dysplasia when synthetic surfactant was given 1 hour earler (2 vs 3 hours after delivery) in babies intubated at less than 2 hours after delivery. Therefore, guidelines that recommended early administration, either in the delivery room or after initial stabilisation in the neonatal unit were considered to be consistent with this standard.

3. *Natural (animal derived) surfactant is preferable to synthetic surfactant for rescue therapy.* A systematic review by Soll[3] of seven studies compared the effect of synthetic and natural surfactant in premature infants with established RDS. The meta-analysis supports a significant reduction in risk of pneumothorax and a trend towards a reduced mortality, with greater early improvement in ventilatory support infants receiving natural surfactant.

4. *At least 2 doses of surfactant therapy should be used in infants remaining intubated for respiratory support.* For exosurf, the OSIRIS study[2-3] established that there was no benefit from a 3rd or 4th dose. Two studies [1-2] comparing single doses of natural surfactant with multiple doses were reviewed in the Cochrane database.[4] These showed a significant reduction in pneumothorax and a trend towards reduced mortality with a policy of multiple doses in infants with ongoing respiratory insufficiency.

In addition, 4 further non-evidence based standards for surfactant guidelines were included:

1. *Practical instructions should be included on the preparation, storage and stability of the surfactant in use, that were consistent with the manufacturer's recommendations.*
2. *The guideline should be easy to follow, with no inappropriate exceptions, and without regimes differing between consultants.*
3. *There should be documentation that the guidelines had been reviewed since August 1996.* Two publications at that time had provided new information on the relative benefits of animal derived surfactant in rescue therapy. [1-2]
4. *Standards for audit should be included within the guideline.*

The written surfactant treatment guidelines were requested from the 54 participating neonatal units in the UK neonatal staffing study. These were anonymised, and their contents analysed against the standards by two independent investigators who were blind to the units' identities. Inter-observer concordance was 87%. All differences between the two investigators were then reviewed and reconciled.

The frequency of existence of a surfactant guideline and the number of desirable features present were compared between types of unit. The UK neonatal staffing study had selected units of differing workload (high, medium and low), level of nursing staffing (above and below the median), and level of consultant support (above and below the median).

Associations between the guideline characteristics and outcome were investigated in inborn infants below 32 weeks gestation. Gestation, size for gestation, sex, mode of delivery, use of antenatal steroids, the presence of a congenital malformation, each guideline feature and the existence of any guideline were used in two logistic regression models, with hospital mortality and abnormal cranial ultrasound scan as the dependent variables.
The use of surfactant was investigated in inborn infants between 26 and 30 completed weeks gestation. The timing of the first dose and frequency of use were compared in a risk adjusted model including type of unit, gestation, cot occupancy on the day of birth, each guideline feature and the existence of any guideline.

Results
Forty one of the 54 units (76%) could produce a written guideline on the use of surfactant therapy. The total number of features is shown by unit in figure V-3 (1), and the number of evidence-based features in

the different units' guidelines are shown in figure V-3 (2). In 22 (54%) of units with written guidelines less than 2 of the evidence-based standards were present.

Figure V-3 (1): Number of NICU's by total number of appropriate features in guideline

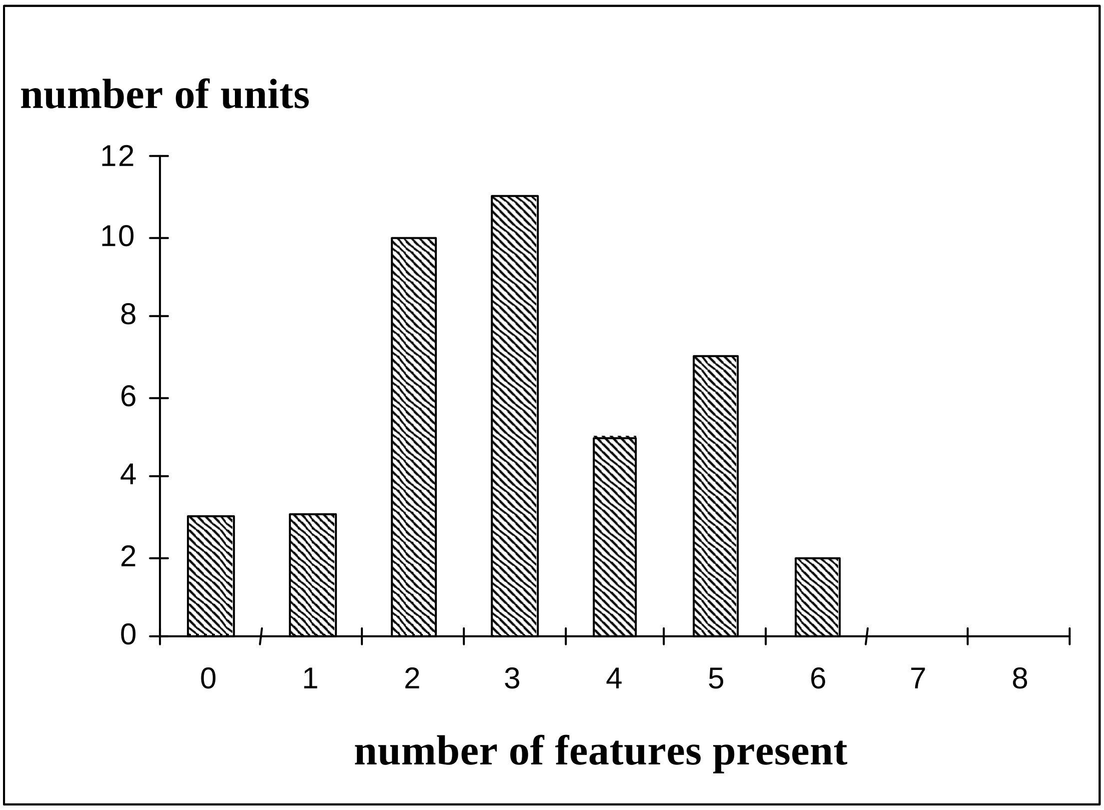
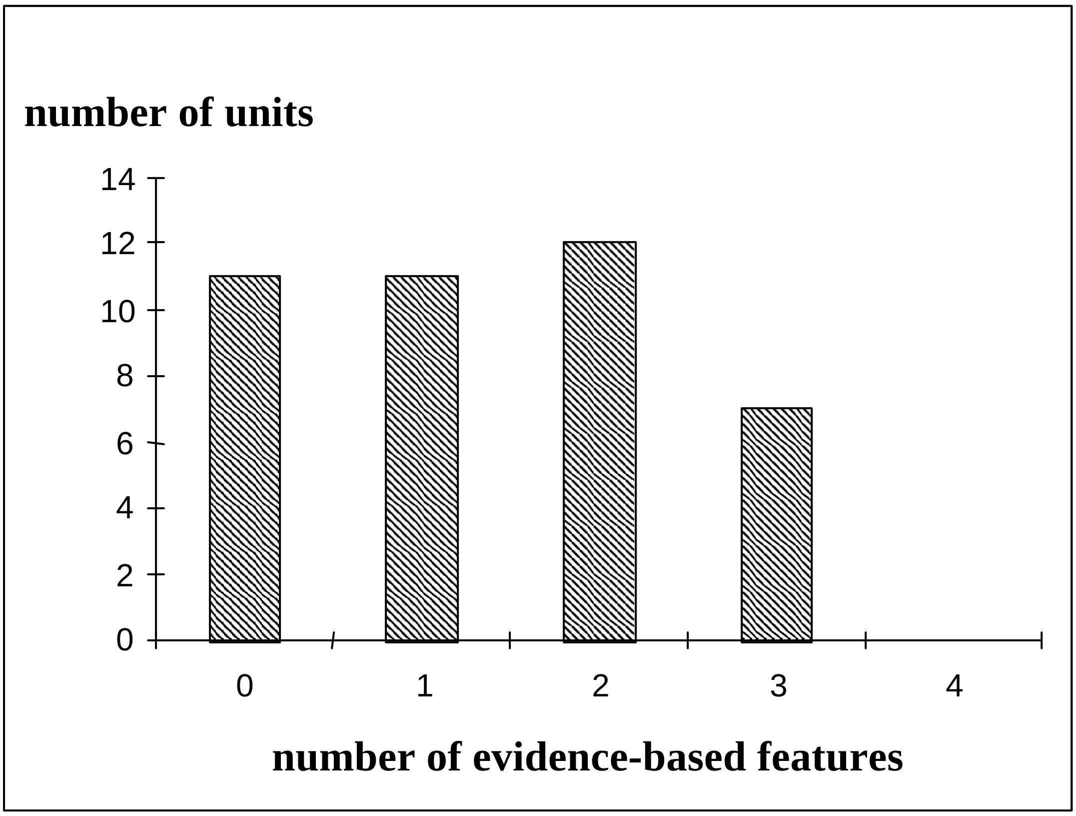


Figure V-3 (2): Number of NICU's by total number of evidence-based features in guideline



The number of units having each of the four evidence-based features and the four non-evidence based features is shown in Table V-3 (1). Nineteen of the 41 units with written guidelines made no recommendation for prophylaxis. Six gave an upper limit for prophylaxis at 28 weeks, one at 27 weeks and one at 1500grams birthweight. One unit recommended prophylaxis only in infants requiring intubation for resuscitation at birth. Seventeen of the 22 units recommending prophylactic surfactant stated that it should be given as soon as possible after delivery; the other 5 units' guidelines made no reference to timing. Seventeen units recommended animal derived surfactant use for rescue therapy; 15 units specified ALEC, in 7 for less ill infants; 4 specified exosurf, in 1 for less ill infants; 5 did not state which surfactant preparation to use.

Table V-3 (1): Guideline characteristics by unit

➢ Prophylaxis recommended consistent with 1997 Cochrane review	13
➢ Prophylaxis recommended as soon as possible after birth	17
➢ Animal derived surfactant recommended for rescue therapy	17
➢ At least 2 doses recommended in infants remaining intubated	32
➢ Practical instructions given on preparation, storage and stability	9
➢ Guideline straightforward to follow, no inappropriate exceptions	19
➢ Documented updated since Aug 1996?	14
➢ Audit standards identified	2

The guideline was considered straightforward to follow in 19 units. Terms such as 'prophylaxis' were used inconsistently, with some guidelines using the term to indicate the need for rescue administration as soon as possible after intubation for established RDS. In others, 'rescue' meant administration of extra doses or a different preparation to infants deteriorating after initial surfactant treatment. Only one unit had a guideline recommending treatments that differed between consultants. Some guidelines were very long, making it difficult to ascertain the specific guidance: one guideline discussed surfactant use in detail, but gave no indication at all of how it was to be used on the unit. Guidelines commonly had multiple criteria based on sex, gestation, arterial/alveolar ratios or inspired oxygen concentrations and whether the mother had received antenatal steroids. Fourteen units' guidelines had evidence of review since August 1996.

There was no significant association between the existence of guidelines or their characteristics and the type of neonatal unit. In inborn infants between 26 and 30 weeks gestation there was no significant association between risk adjusted mortality or intracranial morbidity and the existence of guidelines and their characteristics in a risk adjusted model.

In inborn infants between 26 and 30 weeks gestation, lower gestation infants were more likely to receive surfactant therapy and to receive it sooner after delivery as shown in figures V-3 (3)and (4).

Figure V-3 (3): Percentage infants observed (26 –30 weeks gestation) given surfactant

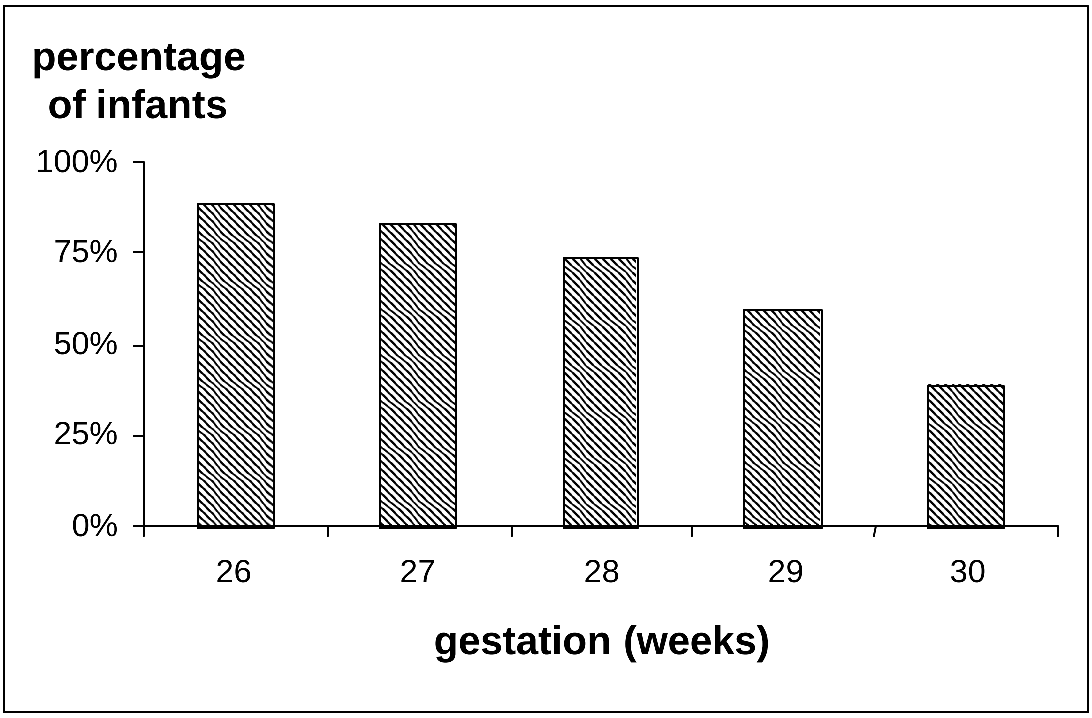
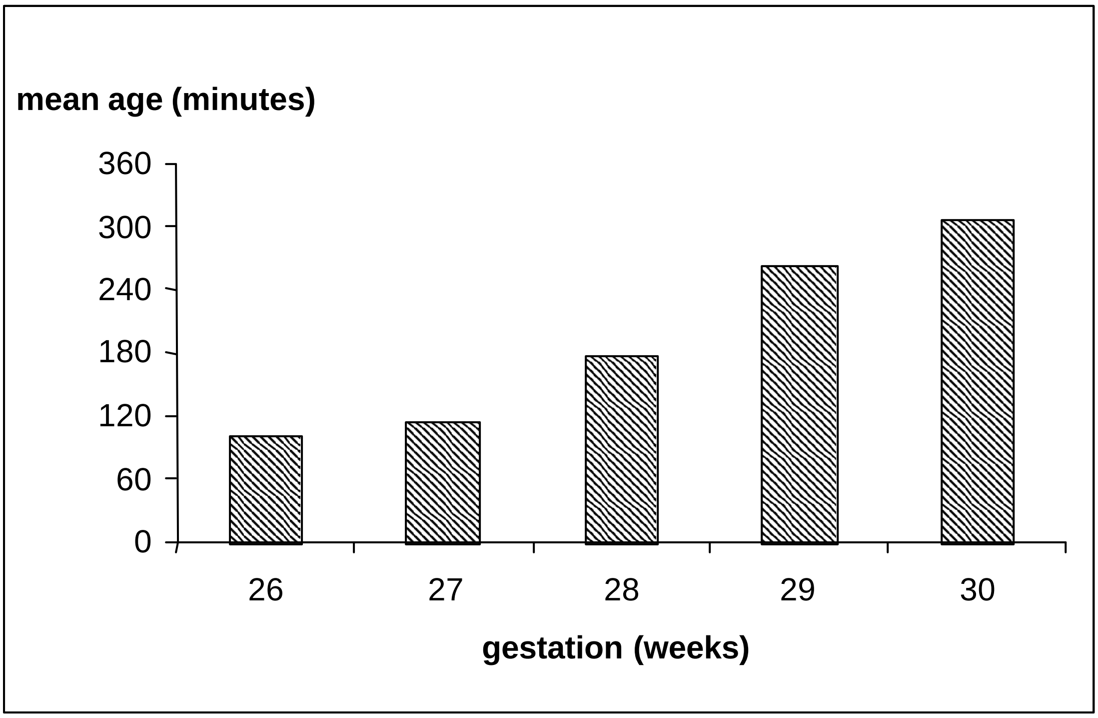


Figure V-3 (4): Number of infants observed (26 to 30 weeks gestation) by age at first surfactant dose



In a risk adjusted model, surfactant therapy was more likely to be administered within the first hour after delivery to inborn infants in units

- where the guideline stated that prophylaxis should be given as soon as possible after birth;
- where nurse provision was above the median;
- and in units with medium volume of activity when compared to those with a high activity volume (Table V-3 (2)).

Table V-3 (2): Characteristics of units associated with surfactant administration within 1 hour of birth (odds ratios (95% CI)

	Odds ratio (95% confidence limits)
Prophylaxis recommended as soon as possible after birth in local guideline (versus local guideline without this recommendation)	0.57 (0.33, 0.98)
Prophylaxis recommended as soon as possible after birth in local guideline (versus no local written guideline)	0.37 (0.15, 0.91)
Nurse provision above the median (versus below median)	0.52 (0.29, 0.92)
High volume units (versus medium volume)	4.13 (1.95, 8.77)*

*Indicates more likely to receive surfactant within 1 hour of birth in medium sized units

Discussion

This study demonstrates that in 1998, in a representative cross-section of UK neonatal units, three-quarters had clinical guidelines on the use of surfactant treatment. However, the quality of guidelines was variable, with none of the units with written guidelines having all of the evidence-based standards, and 1 in 4 of those with written guidelines having none.

The standards used to assess the quality of guidelines reflect the evidence that was available at the time of the study. Surfactant guidelines were chosen as this therapy had been investigated extensively in a large number of multicentre randomised controlled trials, and a well-conducted systematic review of aspects of surfactant therapy was available. Surfactant therapy guidance has changed little since 1998, apart from one synthetic surfactant (ALEC) being withdrawn, following publication of a study demonstrating higher hospital mortality compared with an animal derived surfactant.[1]

The non-evidence based standards could be criticised as lacking any evidence of patient benefit. Practical instructions may have been more appropriately kept separately. Having different guidelines for each consultant suggests that they are unwilling to compromise strongly held views, and is likely to be confusing for medical and nursing staff. However, this has not been shown to result in less satisfactory outcomes for patients. Whether a guideline is straightforward is a largely subjective matter. However, the relatively high inter-observer variation on a number of the objective features of guidelines in this study attests to the difficulty in interpreting the contents of many guidelines.

Regular review of written clinical guidelines is important. The review date is justified by the fact that two large randomised controlled trials comparing animal and synthetic surfactant use were published in August 1996. Whether or not these resulted in a change in the written guideline, a local review of surfactant therapy, especially in units using synthetic surfactant might have been expected. It is possible that even where this was not documented in the guideline, a local review may have occurred.

The inclusion of audit standards allows assessment of adherence to the most important aspects of management. These standards could be agreed at the time of undertaking audit, on the assumption that all clinicians have agreed the contents of the guideline. In addition, it could be argued that the lack of evidence base in many guidelines undermines effective audit as much as the lack of explicit audit standards.

It is possible that the units that were unable to produce written guidelines did actually have them. However, it could be argued that if the staff were either unaware of or unable to locate the unit's guidelines, they were unlikely to be used in practice.

The lack of statistically significant association between the existence and quality of clinical guidelines and unit characteristics was surprising for those units with greater consultant availability. These might be expected to have guidelines of a high quality. The number of participating units in each cell was small, but overall comparisons by higher vs lower consultant availability were 24 vs 27 units. It is possible that significant associations might have been found if a much larger number of units had been studied. It could also be argued that with larger numbers of available consultants it is more difficult to obtain consensus, and that this might have resulted in a lack of written guidelines.

Infants in units with a guideline encouraging early prophylactic surfactant use were more likely to receive it within one hour after delivery. They were also more likely to receive it within 2 hours after delivery when compared to infants in units without guidelines. This is likely to reflect a greater proportion of infants in whom surfactant was administered prophylactically, rather than an earlier recognition of infants requiring rescue therapy. The use of a risk adjusted model and exclusion of outborn infants suggests that the observed differences demonstrate real differences in practice rather than differences in patient characteristics. This association does not necessarily indicate that the writing of guidelines with a recommendation for prophylaxis itself leads to earlier administration. It is equally plausible to hypothesise that consultants who consider early surfactant prophylaxis important are more likely to write this in local guidelines and separately influence local practice.

There was no significant association between the availability of guidelines and risk adjusted mortality or morbidity. Large observed differences in mortality between units with and without guidelines after adjustment for risk were not statistically significant, suggesting that the study had insufficient power to detect clinically important differences.

The importance for medical and nursing staff in having good quality evidence-based guidelines was not investigated in this study. However, they can be expected to facilitate staff education by demonstrating a commitment to evidence-based practice, as well as reinforcing learning.

This is the first published account of surfactant use in a representative sample of all UK units. The study confirms that its use is widespread, but that not all infants receive it, even among the more immature infants. Just over half of all infants at 29 weeks gestation received surfactant at a mean of more than 4 hours after delivery, suggesting that it is common practice at this gestation to administer surfactant as rescue therapy to infants with established RDS. The reason for the earlier administration in medium sized units is unclear. The adjustment for gestation and restricting the analysis to inborn infants suggests that it is not the results of differences in casemix, nor due to delays in infants being transferred in.

Conclusions

Most neonatal units had written guidelines for surfactant administration, but their content varied widely, and some were not consistent with existing evidence. There was no detectable association of quality of surfactant guidelines with any unit characteristic. Infants in those units with a written policy to use surfactant prophylactically were more likely to administer it early after delivery. Infants in medium sized units and those with greater nursing availability were more likely to receive surfactant within 1 hour of birth. Although the study does not provide evidence of patient benefit from the availability of evidence-based guidelines, their importance for staff in training suggests that the overall standard of written guidelines in neonatal units could be improved.

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V (iv)– Economic evaluation

Economic Analysis alongside the UK Neonatal Staffing Study

Objectives

The constant pressure on health care budgets means that efficiency in the production of health care services is a priority for decision makers at all levels. The type of efficiency which concerns most decision makers is technical efficiency and this requires that the resources consumed to produce a given level of health care activity is minimised. Examining the nature of relationship between inputs and outputs in a specific area of health care provision may identify opportunities for improving its technical efficiency. There have been a series of papers looking at the technical efficiency of neonatal intensive care in the United Kingdom. All of these agree that economies of scale in the provision of neonatal intensive care exist. However there is much debate about how large these economies of scale are and how they should be attained. [1-8]

The UK Neonatal Staffing Study (UKNSS) provided an opportunity to construct and examine the cost structure of neonatal intensive care provision, and to relate these costs to outcomes in the largest representative sample of units in the UK to date. [9]

The original objectives of the economic component of the UK Neonatal Staffing Study (UKNSS) were to construct:

1. **a comprehensive description of the costs of NIC in the UK**
2. **a model for predicting the cost of neonatal intensive care**
3. **a description of the expected cost to purchasers of 'up-grading' an existing NICU to any other Unit Type associated with lower risk adjusted mortality**
4. **an estimate of the expected cost per one percent reduction in risk adjusted mortality associated with a change in the directly alterable variables which are the focus of the clinical study [9]**

Given the clinical component of the UKNSS found no difference in risk adjusted mortality associated with the directly alterable organisational variables studied, objectives three and four are redundant. Therefore, in this chapter we report a comprehensive description of the costs of NIC in the UK and present a model for predicting the cost of neonatal intensive care in the UK.

Methods

The perspective adopted by the analysis was that of the UK National Health Service (NHS) and more specifically that of the neonatal intensive care budget. Therefore only the direct costs incurred by the NHS within neonatal intensive care units were included in the following analyses.[10-12]

Data Collection

The fifty four units recruited to the second phase of the study were invited to provide unit level annual resource use and unit cost data for the financial year 1997/98 in the following resource categories:

Medical Staffing
Nurse Staffing
Technical, Administrative and Non-clinical Management Staffing
Equipment
Services and Overheads
Consumables and Transport

Units were also asked to provide summary activity data for the same period. In addition activity data was collected prospectively as part of the clinical study. The costs data collection instrument was an updated version of the questionnaire developed by the Medical Research Council Economics of Surfactant Study Team. (See Appendix 5). The completed questionnaires were signed off by the Medical, Nursing and Business Managers of each unit.[13]

Where resources were described but no cost given, the mean cost of that resource for all the units that did provide a cost was assumed (excluding outliers). Where the cost given was an outlier in the distribution across all units, the mean cost of distribution was assumed. Where the cost data was for a different year, the NHS pay and prices index was used to adjust costs to 1997/98. [13]

Capital equipment was assumed to have a five year life with no residual value and the annual equivalent cost was calculated assuming a 6% discount rate.

The costs were grouped in to Medical Staff, Nurse Staffing, Equipment and Consumables. Consumables included services, transport and overheads. Bar charts showing the distribution of each category of cost, and total cost across the twelve unit types were produced. (see appendices 8 to 11)

Cost Analysis Modelling

Linear regression analysis was used to examine the factors that determined the total annual unit cost. The potential determinants of the total cost considered were drawn for the literature.[1-8] In addition, the casemix of the units was provided by the clinical study. The candidate variables are listed in Table V-4 (1). Untransformed and natural log specifications of each model were estimated.

Table V-4 (1): Candidate variables used in cost analysis

➢ Total Days of care provided per annum
➢ Intensive Care days as a proportion of total days
➢ Average Occupancy per annum
➢ Cell type of unit
➢ Proportion of infants with ≥ 95% chance of survival on admission
➢ Proportion of infants with ≥80% and < 95% chance of survival on admission
➢ Proportion of infants with ≥50% and < 80% chance of survival on admission
➢ Proportion of infants with < 50% chance of survival on admission
➢ Interaction term of between total days and intensive care days as a proportion of total days.

Initially all candidate variables were entered in to the regression procedure. An interative estimation process was then undertaken whereby the variable with the least significant co-efficient was removed at each iteration. The iterations were continued until the explanatory power of the model was significantly reduced or its diagnostic performance was impaired by the removal of the least significant variable. Proportions were not logged.

For each model the following diagnostic statistics were calculated:

Adjusted R-squared
T-test of co-efficients
F-test
Durbin Watson
Whites test for Heteroskedasticity
Ramsey RESET test for mispecification

Analyses were carried out using the E-Views3 software (QMS 1998).

Results

Response and completion rates

Out of 54 units recruited to the second phase of the study, 47 supplied some resource use and cost data, giving an 87% response rate. Thirty eight units (70%) provided medical staffing costs, 41 units provided nurse staffing costs (76%), 35 units provided the other staff costs (65%), 35 units provided costs of consumables and services (65%), 33 units provided equipment costs (61%) and 31 units provided activity data (57%).

In the 31 units that provided complete cost data, all units types were represented. Two unit types had data from one unit only, two unit types had data from two units, and eight unit types had data from three units. Thus the sample used in the regression analysis presented here can be viewed as being broadly representative of the range of neonatal intensive care units in the United Kingdom.

Cost of Neonatal Intensive Care

The total annual cost of neonatal intensive care in this sample (n=31) was £41.2 million, suggesting that the total cost for all UK NIC provision was in the region of £330 million. The average cost per day for all units was £307, with a range of £178 to £592. Staff costs accounted for between 51% to 77% of total costs, with a mean of 63.4%.

The number of days of care provided ranged from 855 to 9020 days per year. Intensive care accounted for between 4% and 35% of all days provided. The average proportion for all units[14] was 6%. Figures V-4 (1A to 1D) (see Appendices 8-11) show the distribution of cost across unit type for each category of cost. Table V-4 (2) gives the difference in average total cost by unit type.

Table V-4 (2): Cost differences by Unit Type

Unit Type	1	2	3	4	5	6	7	8	9	10	11	Average Total Cost
1												£2,351,622
2	£556,627											£1,794,995
3	£824,275	£267,648										£1,527,347
4	£538,467	-£18,160	-£285,808									£1,813,155
5	£441,850	-£114,777	-£382,425	-£96,617								£1,909,772
6	£1,144,861	£588,233	£320,585	£606,393	£703,010							£1,206,762
7	£1,421,752	£865,125	£597,477	£883,285	£979,902	£276,892						£929,870
8	£1,383,238	£826,610	£558,963	£844,770	£941,388	£238,377	-£38,515					£968,385
9	£1,061,635	£505,008	£237,360	£523,168	£619,785	-£83,226	-£360,117	-£321,603				£1,289,987
10	£1,061,635	£505,008	£237,360	£523,168	£619,785	-£83,226	-£360,117	-£321,603	£0			£1,289,987
11	£1,532,466	£975,839	£708,191	£993,999	£1,090,616	£387,606	£110,714	£149,229	£470,831	£470,831		£819,156
12	£1,353,501	£796,874	£529,226	£815,034	£911,651	£208,640	-£68,251	-£29,737	£291,866	£291,866	-£178,965	£998,121

Cost Analysis

The preferred model describes total cost as a function of total activity and the casemix of the infants treated within a unit. The co-efficient on the total activity is not significantly different from 1, suggesting that there are constant returns to scale, if case mix is not taken in to account. The co-efficients on the casemix variables are all negative indicating that there are cost savings available through increasing the activity levels. The greatest cost savings from activity are available from increasing activity in the very sickest group of infants, those with a less than 50% chance of survival. Treating infants whose initial probability of survival lies between 50 and 80% has the second largest potential for cost saving. Infants whose initial probability of survival is greater than 95% provide the smallest potential for cost savings. By implication, managing infants whose initial probability of survival lies between 80 and 95%, the reference group, operates under constant returns to scale.

Table V-4 (3) gives the detailed description of the preferred model and the results of the diagnostic tests. The model has good explanatory power, superior to previous UK work in this area.(3,4,8) In addition, the model performs well with regard to the diagnostic tests. The co-efficients on each independent variable are either significant or close to significant at the p<0.1 level.

Table V-4 (3): Determinants of Total Cost in UK Neonatal Intensive Care

Dependent Variable: Natural Log of Total Cost (LNTC)
Method: Least Squares
Sample(adjusted): 1 30
Included observations: 28
Excluded observations: 2 after adjusting endpoints

Variable	Coefficient	Std. Error	t-Statistic	Prob.
Constant	11.02225	2.957389	3.727021	0.0011
Natural log of total days	1.105767	0.141275	7.827060	0.0000
Proportion of Infants with greater than 95% probability of survival at admission	-0.063265	0.032472	-1.948292	0.0637
Proportion of Infants with between 50 and 80% probability of survival at admission	-0.125149	0.081485	-1.535851	0.1382
Proportion of Infants with less than 50% probability of survival at admission	-0.131498	0.082794	-1.588245	0.1259
Adjusted R-squared	0.703429	F-statistic		17.01014
Durbin-Watson	1.614422	Prob(F-statistic)		0.000001
	0.244304			
White Heteroskedasticity Test:				
F-statistic	0.298261	Probability		0.957619
Obs*R-squared	3.124016	Probability		0.926335
Ramsey RESET Test:				
F-statistic	0.276447	Probability		0.604300
Log likelihood ratio	0.349649	Probability		0.554312

Discussion

It is clear that the cost structure of neonatal intensive care units varies a great deal. Although smaller units generally have lower costs than larger units, this is not always the case. In addition, there are examples of apparently similar units having very different costs. It is also clear that the provision of neonatal intensive care consumes a significant amount of NHS funds. With such large sums of money being expended, it is important to ensure that the money is well spent. The strong explanatory power of the estimated cost function suggests that the large variation in total cost is not random but rather relates to the differences in the casemix of the infants treated by each unit. Given the equality of risk adjusted outcomes between unit types, our analysis suggests that resources are being used appropriately.

Whilst our analysis suggests that there are economies of scale operating in neonatal intensive care, the extent of the economies of scale is dependent upon the casemix of the infant treated.

Our analysis represents a development from previous work in this area in three regards:

1. We have been able to explicitly incorporate casemix in to our analysis, rather than use proxies such as the proportion of intensive care days;
2. The data is drawn from a relatively large sample which can be said to be representative of UK neonatal intensive care units generally; and
3. *All* the resources used by these intensive care units have been identified, quantified and valued.

This said, the work by O'Neill and colleagues on the ECSURF study group does draw data from a larger sample (49 compared to 31). However, they were not able to obtain reliable estimates of equipment and building/overhead costs and thus the costs were not included in the dataset used for their analyses.

It should also be acknowledged that whilst the sample is representative in terms of volume, nurse to cot ratio and consultant availability; it is not necessarily representative in other terms such a geographical distribution. It may be that a proportion of the unexplained variation in the cost of neonatal intensive care may be attributable to geographical variation in the cost of resources. It is also a relatively small sample (15% of all UK NICUs) and co-efficients on some of the variables are not significant. However, model specifications that excluded these variables had poorer explanatory power and did not perform as well on the other diagnostic tests.

In the context of the debate around the proposed advantages of centralising neonatal intensive care provision, our analysis suggests that crude centralisation i.e. where large units care for large numbers of infants across the casemix spectrum, would be unlikely to produce significant economies of scale. The greatest savings available appear to be from centralising the management of the sickest infants (those with less than 50% probability of survival at admission), rather than centralising the provision of all neonatal intensive care. Efficiency in provision appears to lie in the tiered network of NICUs, with units in different tiers focusing on managing more or less sick infants. Further work is required to explore the complex interaction between casemix, volume and costs in neonatal intensive care provision.

Conclusion

We were unable to estimate the cost effectiveness of the primary organisational variables of high volume, high nursing and high consultant provision, as they were not associated with differences in outcome. We have therefore described the costs of neonatal intensive care in UK and developed a predictive model. Neonatal intensive care provision consumes a significant proportion of NHS resources. The cost function analysis indicates that the determinants of efficiency in neonatal intensive care provision are complex. Simplistic assumptions that bigger units will be more efficient are not supported by our results. The total cost of provision varies enormously between units, and the majority of this variation can be explained in terms of activity levels and the case mix of the infants treated. Volume and casemix interact to determine the degree of economies of scale. The current networked structure of UK neonatal intensive care provision, where the treatment of the sickest infant is largely centralised at a regional level, is likely to take advantage of the economies of scale that are available.

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V(v) Psychological evaluation of staff well being

This chapter describes the methodology, results and implications of the psychological evaluation of staff working in neonatal intensive care units which participated in phase 2 of the study. This is done in two parts. Firstly, it outlines the staff well-being (as measured by the MHI-5) survey of the participating units. Secondly, it outlines the findings from the in-depth interviews with a sample of staff from randomly selected units (one from each of the 12 NICU types).

The data from the survey of staff well-being indicate there is no difference between the MHI-5 scores across all types of unit and that all units have a high well-being score. The staff appear to value and enjoy their work overall. However, the unstructured comments on the questionnaire identify several day-to-day concerns about staffing, management structures, quality of communication and professional relationships, that impact negatively upon perceptions of job-related well-being.
The in-depth interviews indicate, similarly, that although the senior and long-term staff in particular, value their place of work and the specialist focus on neonatal intensive care, the pressures of increased workloads, poor promotion prospects and pay for many nurses, and poor communication are taking their toll.

Background

> *The kind of nursing and medical work carried out in neonatal units has changed dramatically over recent decades. A high degree of technical skill is required, in conjunction with skill and sensitivity in interpersonal behaviour and caretaking[1].*
>
> *… with increasing capability new burdens are created and new dilemmas present. Questions now are less about whether we can save these babies …. but about whether we should.[2]*

Neonatal intensive care presents dilemmas for all clinical staff and managers. It is a rapidly changing area of work. Nurses and doctors in NICUs have to be skilled equally in interpersonal communications and technical expertise. They work with babies who cannot tell of their distress and thus they rely on clinical and technological indicators. They have close contact with grief-stricken and highly anxious parents who spend time on the ward. They have to deal with technological developments, rapidly changing management structures and political climates, increasing professional scrutiny, financial constraints and bureaucratic demands. They are also faced with ethical dilemmas about the care and viability of their patients. Although the day-to-day roles are different for doctors and nurses on the whole, this array of tasks and the necessary skills for completing them overlap. The NICU is the kind of organisation that can only be effective with teamwork.

Working in the National Health Service is potentially a highly stressful experience[3] for both clinical and management staff. Nurses have a 40% higher risk of being screened as a psychiatric "case" than their comparison group in the general population, doctors, 30% higher and managers 50% higher. This demonstrates a shift from data gathered in the previous decade, when health service managers' stress levels were lower than those reported by managers and white collar and professional workers in industry[4].

There is little doubt that direct work with patients is stressful for nurses[5,6,7]and doctors in neonatal care[8]. Increased technical capability, increases in direct management responsibilities for clinical staff, with few resources to supplement these extra requirements, all take their toll - physically and emotionally.

The reasons for the high stress levels however, appear to be complex. One study indicated that although reported stress for doctors and nurses is at similar high levels, the reasons vary. Nurses were seen to be experiencing job-related stress while doctors appeared to have difficulties balancing private life demands with those from work[9] Even these differences were mediated by the grade of staff in both professional groups. There is further contrasting evidence about the causes of stress for clinical staff which have been variously hypothesised as low levels of satisfaction and burnout [10] and high satisfaction and stimulation which results in disappointment for staff unable to fulfil all the demands of their chosen careers[11]

These studies are mostly of a small scale and have not focused specifically upon the workload and differential organisational characteristics nor involve in-depth interviews as the background for examining stress and well-being.

Hypotheses

The stated hypothesis relevant to the psychological evaluation was:

> That staff well-being and stress as measured by the Mental Health Index (MHI-5) component of the SF36 Health Status Questionnaire is independent of type of NICU.

In order to address the hypothesis effectively, three psychology research questions[1] were developed:

1. Are there any differences in the MHI-5 scores between the cells representing different types of NICU?

2. Are there any relevant psychological factors in the additional information of the survey questionnaire to explain staff-well being or stress?

3. Is there added value in conducting in-depth interviews with staff to assess levels and explanations of stress and well-being in a representative sample of NICUs?

Methods

1. The well-being postal survey

All staff units on all participating units were sent an anonymous questionnaire six weeks after the clinical data collection began. The questionnaire included demographic questions, the MHI-5[12]scale and items to control for concurrent staff stress due to recent personal life events. Opportunity for unstructured comments was also provided[13] The questionnaire contained a box at the end covering around a third of a page. The question was *"In the space below, please add anything else you want to say about how you have felt generally in the last month"*.

This enabled a free choice as to whether to comment as well as providing scope to comment widely.

The questionnaire was sent out a second time, following it being highlighted in a dedicated article in the UKNNSS newsletter. As the survey was anonymous[2] respondents were requested not to complete the survey if they had done so previously[3].

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[1] The psychological evaluation was designed to identify the context in which the prospective study was conducted and complement the main findings.

[2] It had been decided that for such a close-knit group of professionals, anonymity in this case should take priority over being able to identify non-responders.

[3] Prior to final release of the data, the survey responses were checked by probability matching on responses, the demographic variables and comparing scripts in Dundee, to assess as far as possible whether any were from someone who had previously completed a questionnaire. Eleven were eliminated from the statistical analysis on this basis.

Data analysis

The quantitative data was entered and double-checked under the supervision of the project manager in Dundee. SPSS (version 9) was used to analyse this data and the qualitative data was analysed through identifying themes. [14]

Themes were identified from statements, which had been grouped by the data entry staff under one of each of the twelve cells. Beyond that nothing was known about the respondent other than information revealed in the statements. Thus the analysis focused on the issues raised rather than any differences between individuals and groups of individuals.

Two investigators (the main researcher and a colleague, otherwise not involved in the UKNSS study) each had a copy of the data. This was read and re-read independently, to identify issues that seemed important to the respondents, and that were also important to the investigators in that they directly addressed the key questions raised for discussion. These were then given a jointly agreed label (e.g. home/work overlap). This process is called indexing.

Results

The overall response rate was 83% from 2261 returned valid postal questionnaires. Those returned comprised 21% from doctors, 52.8% from nurses and 7.8% from midwives. The remainder did not declare their professional group.

MHI-5 scores

Research question 1: Are there any differences in the MHI-5 scores between the cells representing type of NICU?

a) For all respondents who returned the questionnaire throughout the 12 types of NICU the mean score was 22.9 (standard deviation 3.9, range 8 to 30). This was from a possible range of 5 to 30 with a high score being equivalent to positive mental health. A score of 13 or below was taken as the cut-off point to indicate psychiatric "caseness" or poor mental health.

Only 2.3% of the sample scored 13 or below[4] while 60.9% scored above 23 indicating a good sense of well-being. Of those scoring below 13, 6% were doctors, 55% nurses, 6% midwives and 26% did not declare their profession.

b) A one-way ANOVA was carried out to look for differences between the mean scores for each cell in order to fulfil the aims of the hypothesis stated above. There were no significant differences (0.592) between the MHI-5 scores across the units (see table 1)

c) A comparison was carried out similarly between professional groups. No significant differences were found (0.253).

d) A comparison of MHI-5 scores was carried out across respondents grouped according to the length of time an individual had worked in neonatal specialty. No significant differences were found (0.490).

Qualitative data from the postal questionnaire

Research question 2: Are there any relevant psychological factors in the additional information of the survey questionnaire to explain staff-well being or stress?

The data in Table V-5(1) is from the unstructured comments on the survey questionnaire[5]. Out of the 2,271 questionnaires returned overall, 901 (40%) included entries in the space provided for unstructured comment.

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[4] This contrasts sharply with Borrill et al 1998 where 26.8% of the staff were identified as potential psychiatric cases.

[5] The analysis of the unstructured comments was based upon the uncorrected data set as the comments were entered and sent to Sheffield for analysis before the test for duplication was carried out.

There was some variation in the extent to which this type of response was made across the cells (the range was 31 to 49%).

Table V-5 (1) Proportion of respondents who wrote unstructured comments in the postal questionnaire within each NICU type 1 to 12

celltype	Commented (n respondents)	%	celltype	Commented (n respondents)	%
1	75 (172)	44%	7	64 (159)	40%
2	55 (156)	35%	8	70 (183)	38%
3	62 (142)	44%	9	62 (174)	37%
4	58 (188)	31%	10	78 (196)	40%
5	99 (234)	43%	11	92 (265)	35%
6	79 (161)	49%	12	107 (242)	44%

Eight themes were identified from these statements following the method outlined above. These themes were:

1. *Qualifications and professional duties*
2. *Managers and colleagues*
3. *Staffing levels*
4. *Home/work overlap*
5. *Being valued at work, burnout and low morale*
6. *Stressful situations*
7. *Emotions*
8. *NHS changes.*

They are not mutually exclusive and have not been placed in any order in relation to frequency. Here the intention is to seek through examination of this data, a sense of the causes of well-being and stress of NICU staff.

In contrast to the overall positive well-being, as measured by the MHI-5, the statements provided better information about causes of stress than well-being. In what follows some examples chosen to represent each of the themes are provided. The type of unit is identified after each statement. The aim here is to give a sense of the way that similar statements cross the unit types.

Theme 1: qualifications and professional duties.

This represented a concern with training, levels of competence and team work/skill mix and the amount of work required on a daily basis on the units.

"Tired from on-calls, travelling plus training " (cell 7).

"Generally busy completing my MA, working full-time and with a family" (cell 8).

"At present I am on a course which is pretty stressful" (cell 11).

"During the past month I have been studying and writing a final dissertation for an honours degree. The ward has been quiet and I could have been spared time off. I feel bitter" (cell 7).

Theme 2: managers and colleagues

This is related to theme 1, but focuses more directly upon the attributions for stress.

"Confidentiality is not maintained" (cell 1).

"The bad times on the unit could have improved through greater management support and commitment" (cell 3).

"Unsupported professionally" (cell 10).

"Unsupported by other members of staff – medical and nursing. The nurses have been 'testing out' the new medical staff and this has been demoralising and stressful"(cell 9).

"Stressful, as having problems with manager " (cell12).

"I have frequently felt put upon and used " (cell 6).

Theme 3: staffing levels

Staffing levels were consistently discussed and identified as stressors in their own right although they clearly impact upon others identified in other themes.

"In the past month I have been looking for another job. That has a lot to do with the rota system and the number of nights we have to do" (cell 1).

"Generally feel frustrated with the number of babies on the unit and the workload. Rarely have time to give babies care in in-depth, thorough manner " (cell 5).

"Frustrated due to staffing levels. Have to rush from baby to baby. Would like to give more time to the parents" (cell 6).

"Frustrated because of lack of resources" (cell 9).

"Happy with the work" (cell 11).

"I have been able to get on with work projects which normally require me to stay late on duty. This has meant a sense of relief and achievement" (cell 6).

Theme 4: Home/work overlap

It is not surprising that staff working shifts and long hours and who have responsibility for life and death as with NICU staff, that time and emotions will overflow into the home environment. Clearly there will be domestic concerns that overlap in the other direction as well particularly with a mainly female workforce likely to have child-care responsibilities.

"Have felt there is not enough time to achieve all I want to achieve. I am trying to juggle preparing for my wedding, work and supporting the family of a sick friend!" (cell 1).

"Tired! Two young children at home. Stressed! Central heating just installed. No money" (cell 2).

"Recently I completed a short training course. This created havoc at home" (cell 6).

"Quite depressed but not due to work. I find being at work helped and people who care around me to talk to" (cell 7).

"Tired, but due to on-calls and being pregnant" (cell 9).

"I have had a baby. My high spirits and happiness are due to this … and of course maternity leave" (cell 6).

Theme 5: Being valued at work, burnout and low morale

An inevitable consequence of an organisation under pressure is that staff needs are neglected and people begin to feel undervalued and even "burnt out" as evidenced in some of the comments.

"Exhausted, past caring and I wish I could resign" (cell 5).

"Very tired and depressed … generally undervalued" (cell 5).

"Generally put upon and my position abused" (cell 6).

"Undervalued and demoralised" (cell 6).

Theme 6: Stressful situations

It is clear that the work on NICUs is high pressure and physically and emotionally demanding and there were many opportunities for specific situations that precipitated stress. These mainly concerned specific babies, parents or unit policies/actions.

"Completely cheesed off being so short of staff – and doctors still accepting babies that we are unable to cope with" (cell 1).

"Very concerned over a 2-3 day period over a very sick baby" (cell6).

"There is a long-term ventilated baby who is causing concern" (cell 3).

"stressed due to a very difficult and aggressive parent who was unpredictable" (cell 4).

"I feel the unit is dangerously uncovered and I am responsible" (cell1).

"This is a new area of work for me … I've had a lot of new skills to learn" (cell 12.)

"A lot of discrimination between junior staff from consultant … The nursing staff fake serious ailments in babies to make life difficult for some doctors" (cell 6).

Theme 7: Emotions

Some reports of stress appeared to be rooted in the way individuals responded to events and circumstances and how they felt about them. These appeared as comments about general anxieties and worry and reports of low self-confidence.

"I have been particularly worried about ….. as part of the extended role. I was worried that training had not been adequate" (cell 9).

"I sometimes lack confidence and need supporting" (cell 12).

"Worried about impending closure. Will I get another job?" (cell 3).

"At times I have felt out of my depth. There is a distinct lack of on-service training" (cell 3).

Theme 8: NHS changes

This theme was very prominent. Change is stressful in any organisation but it seemed that staff sensed that change was for the worse rather than having the potential to lead to exciting opportunities. Threatened or certain unit closure, lack of career opportunities, poor resources and poor communication of information, were cited as problematic.

"*Profoundly frustrated at the lack of strategic vision amongst neighbouring trust colleagues" (cell 1).*

"No excitement in the job, no managerial opportunities, low staff morale" (cell 7).

"Much interest in local media about a threatened closure" (cell 12).

"No opportunity for self-development or promotion here" (cell 8).

Conclusions

Staff on the 54 participating NICUs had high scores on the MHI-5 indicating good mental health and well-being. There were no significant differences in the scores across the 12 cell types, across professional groups or in relation to the length of time in specialty.

Over half the respondents had no extra comments to make about their well-being.

However 40% did take the opportunity to make specific comments about their day to day sense of well-being and it was clear that a proportion felt dissatisfied with the conditions of their work at the time of the survey. The reasons for this varied across 8 themes identified from analysis of the statements. Interpersonal and organisational support and frustrations related to carrying out professional roles were important factors in whether a sense of well-being could be maintained.

The striking contrast between the MHI-5 scores and the unstructured comments could be explained firstly in that the MHI-5 refers to a) individual mental health and b) over a period of one month. Many of the comments are connected with stresses that may not have a profound emotional impact on an otherwise well-supported self-confident individual. Thus many of the respondents would be coping well emotionally, but unhappy with events and actions that irritate but do not impact upon their fundamental sense of well-being.

Secondly, more than half of the sample did not return negative statements thus upholding the MHI-5 result.

Thirdly, despite assurances of confidentiality and anonymity, some may have been inhibited and not prepared to complete the MHI-5 with full openness.

The in-depth interviews

Research question 3: Is there added value in conducting in-depth interviews with staff to assess levels and explanations of stress and well-being in a representative sample of NICUs?

Methods

2. The in-depth interviews

Face-to-face interviews allow for greater exploration of issues connected with workplace stress and although the interviews were conducted prior to the researcher having any information about the survey results, similar ground was covered by design.

Sampling

A sub-sample of 12 of the 54 participating NICUs was selected to participate in this part of the study. The 12 units, one from each of the NICU types, were randomly selected in Dundee from where staff lists were sent to Sheffield University. From there, invitations, including the interview schedule and consent form were sent out to prospective respondents.

Respondents within the cells were selected as follows:

The clinical director (or lead consultant) and nurse manager in each unit were invited to participate and up to two other randomly selected members of the nursing staff were selected from each of the cells. Further junior medical staff were systematically invited for interview from cells 1,3,5,7,9 and 11. These 6 cells represented work environments for junior doctors of high/medium/low patient volume cells and higher/lower provision of neonatal consultant availability.

Fifty-four respondents were thus invited for interview. Four refused, 5 failed to keep the appointment. All lead consultants/clinical directors and nurse managers agreed and were duly interviewed. 16 other nurses, 5 other doctors were interviewed altogether (see table 2).

As stated above the respondents included 12 lead consultants or medical directors and 12 nurse managers. All the nurse managers were women as were five of the lead consultant/medical directors.

Of the other doctors interviewed 3 were women and two men. All the 16 other nurses were female. Thus 9 men and 36 women comprised the sample.

Procedure

The basis for these tape-recorded interviews was a semi-structured interview guide[6] used in previous studies where rich, discursive data was required[i]. The interview guide in this case was developed to correspond with the aims of the psychological evaluation and developed further following four pilot interviews.

The interviews were conducted “blind”[7] in relation to

a) the cell to which their unit is allocated and

b) the results of the data from the MHI-5.

The aims of these interviews were to explore:

1. respondents’ perceptions of their unit in general.
2. respondents’ views of the determinants of stress and well-being in the context of the neonatal unit and their unit in particular.
3. respondents’ own experiences of their roles and perceptions of their own competencies and those of their colleagues.

At the interview, the rationale for the interview was re-iterated and the respondent was shown the topic plan again and asked if it was acceptable. The tape recorder was then switched on and the interviewer began by asking generally about the first topic. The interviewer's task was to keep to the specified parameters and follow up relevant areas via prompts such as: "could you say more about....," "how did that make you feel?" "why...." and similar open-ended questions. When the researcher judged that discussion of a particular topic had been completed she asked: "is there anything else you consider to be important about 'X'" and then: "now could we move on to talk about 'Y'?"

Data analysis

All interviews were transcribed verbatim. Two researchers examined the transcriptions independently, in order to answer the questions posed.

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[6] See appendix 1

[7] Neither the interviewer nor the respondent were aware of the cell to which their unit was allocated.

Data of this kind potentially provides a wealth of information about perceptions and experiences of organisational characteristics. For this report though the focus remained tightly drawn towards providing insight into the context of the main study and assessing whether these interviews have added value to the findings from the questionnaire results.

Results[8]

These are presented in the context of the three questions posed immediately above. None of these areas is mutually exclusive and extracts are only selected examples.

a) Respondents' perceptions of their unit in general.

On the whole respondents were positive about the units in which they worked. Many of the lead consultants and nurses at all levels, had worked there for a number of years and were therefore committed to their unit. However it was clear that each person had a different perspective on what was good or bad about their specific unit in general, and their post in particular. For example:

> *I think it (the unit) is well run. You all know how each other tick. Who's got various kills, those that don't work, those that do. .. We have very controlled check-ins and we are all given a job to do and it's our responsibility to do that job before we leave the unit (E Grade nurse).*

The older/longer established senior respondents tended to describe their NICU in terms of their own particular influence. For example:

> *I know what my areas of responsibility are, and I know that S (manager of paediatric services) trusts me. She believes that what I do will be right and that I accept guidance (nurse manager).*

> *I get on very well with the nursing staff. I think generally our nurses are pretty happy. … I've always been trained to include them very much in management decisions (lead consultant).*

Few however felt that they worked in a perfect world and there were many problems facing them in their working lives.

> *I've been disappointed with Unit X at times – but that's not peculiar to Unit X. It's more disappointment with the health service – the deficiencies within it. I've become cynical about the whole thing (doctor).*

Nursing staff in particular, seemed above all else to focus upon patient care when talking about their units.

> *I love the fact that we get really sick babies in and you just think they are going to die and then they just get better – sometimes it's sad but the majority of them I think – it is wonderful most of the time (E grade nurse).*

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[8] No cell type will be identified in this section as only one set of interviews was carried out for each cell. There is therefore a high possibility that respondents could be identified.

Although this type of appraisal was offered by a small number of lead consultants too:

> *I think we can make a lot of difference. You can get right in at the beginning of somebody's life and make a huge difference to the whole of that life. I think you can pick up on a sick baby that is not going to survive and manage that properly and that makes a good difference. I just enjoy working with babies and I like being useful and that makes a good difference to parents. I just enjoy working with them and I like babies. It is rewarding (lead consultant).*

Many respondents evaluated their units in the context of their Trust or even the NHS and these comments frequently equally related to the content of the section below.

b) Respondents' views of the determinants of stress and well-being in the context of the neonatal unit and their unit in particular.

Few focused on clinical work per se as a source of stress, although many reported that poor equipment and reduced staff numbers prevented them using their clinical skills to best advantage.
The implications of budget constraints and quality of management decisions were considered by all to be an important aspect of their daily working lives.
For middle and senior grade nurses, main concerns were short staffing and lack of promotion prospects.

> *When people leave they are not replaced. It's money at the end of the day – why people leave. That's what it boils down to. I can only think because they go for a better position or are stressed out by the job (E grade nurse).*
>
> *There's definitely a promotion problem from my point of view. I'm quite well trained and I had to wait 2 years before they upgraded me from D to E (E Grade nurse).*
>
> *I won't swear! It makes me pretty fed up really because I come to work and I take charge of the unit so I'm doing the same job as someone who's getting paid a much higher salary (staff nurse).*

For the junior doctors the stress also came through having too much and too many different things to cope with, although this may not be specific to NICU work in their case.

> *There are times when you are really stressed out - you just feel like you can't cope because you have so many things coming at once. And you have to tell yourself well you have 2 hands you have someone else you can call - and that's the best you can do - there are times when you need to be in 3-4 places at once - but you can't (SHO).*

Some doctor-nurse inter-professional problems emerged during the interviews. These frequently referred to perceptions of unfair resource allocations and salary differences. There were also concerns expressed about clinical mistakes and differences between the way the two groups were treated. These distinctions were seen as potential stressors by some respondents:

> *. because again, you know, with the drugs. If they write it up – right - they'll probably get told off, but the nurse will probably get struck off. You know, and that never happens - very rarely to doctors, it seems. Maybe some of that's wrong, but its just what I've gathered over the last three years (D grade nurse).*

The quality of communication was the most important factor for almost all the respondents. This applied at the unit level within and between professional groups, and the unit/trust level where communication between trust managers and unit clinical managers and NICUs and other specialist units was frequently flawed.

I think this is the classic organisational problem. People get promoted to the limits of their ability. I'm afraid within the NHS as regards ability – we don't pay enough – we don't attract the right people. The net results – and it's partly because of funding – there isn't a 'can do' attitude (lead consultant).

There were specific causes of stress that impacted on more than one NICU. For example:

… with this unit we are under threat of closure….. regional re-organisation [is being discussed] and that's been going on for just over two years now. And that has been extremely stressful because it impacts upon morale, impacts on recruitment and there has been a loss of staff with fear of closure (sister).

Most importantly I think is to know, to get some stabilisation on the unit. We really need to know what funding we've got and how many IC cots we can have (F Grade).

Problems were identified in relationships particularly with obstetric units. Poor relationships brought about by communication difficulties between NICU staff and obstetricians and midwives were cited by almost everyone as a major cause of stress.

… midwives are sometimes a bit difficult but then they are in a difficult position – we have had problems when we have said 'no we can't take a baby' (nurse manager).

I think we need more communication between the two (NICU and midwifery) (E Grade nurse).

The liaison in the sense of 'do we talk to them about it' is 'yes', so at one level the liaison is there. Does the message get through? Well, based on the output the answer is 'no'. And that does annoy me because I - it means that we are not running a professional unit (lead consultant).

The staff had various ways of trying to make sense of why this barrier appeared so difficult to overcome.

… the obstetricians just don't get on with each other … and it doesn't help if they are fighting each other …. I can go to the obstetricians and say 'let's discuss the management'. They agree but they don't really .. they're fighting each other (lead clinician).

There were several anecdotal examples of poor communication that results in stress.

One of the things that annoys people most … is if we had a new piece of equipment and it just appears, and we're expected to use it (nurse practitioner).

Some doctors are really bad at communicating with parents basically (sister).

Some causes of stress were specific interpersonal problems, although in a close-knit team, this kind of issue resonated beyond the people immediately involved. Many of the "problem" staff had been there for a long time and had refused training. Sometimes new appointments were mistakes though:

We interviewed her and she seemed a very positive person and that she'd contribute to the team in developing standards and that, but in fact it's the opposite, she's very negative and it's very, very hard work with her all the time (nurse manager).

Home and work overlap caused difficulties for many. Nurses on shift work, particularly if they were juggling child care and other domestic responsibilities had some problems with their roles that caused stress particularly when they believed that some of their colleagues were taking too much time off sick and causing rota changes. It also caused stress for those trying to compile the off-duty time-tables.

School holidays are a main concern - you have to spread them out evenly. Off duty causes a lot of problems I think that is par for the course everywhere (senior sister).

I also try to keep my family from the pressures of the job that is actually my biggest stress. We are reasonably protected in that we have a rota - but you feel responsibility even if you are going off at 5pm - you go home whatever you feel some responsibility for that baby even though you are involved with what happens that night you feel it (lead consultant).

I think with my divorce as well and things that happened about that. I've had a lot of problems (E grade nurse).

c) *Respondents' own experiences of their roles and perceptions*

Many respondents discussed the fact that they were under much pressure at work and this was stressful.

This nurse manager for instance seemed to sum up the role, typical for many respondents in this position:

I act as the ward manager i.e. I do the managerial side of things make sure the unit runs smoothly make sure that the staffing is adequate and that the skill mix is adequate. I interview, I recruit. I am paid as a 8-4 Monday to Friday post but I actually do quite a bit of clinical input. I call myself the mopper-upper because I just mop up the sickness as and when. So if I am short of senior people which I have been over the last 6 months I act as that senior person (nurse manager)

Mostly there were strong similarities in experiences regardless of grade or professional group – organisational changes, poor consultation, poor staff relationships, workload, bad feeling over limitations in resources available for training and jobs under threat because of mergers or specific changes in the management structure for that Trust.

On the whole the more established respondents saw their role as being to ensure good quality care for the babies and that this needed to be done through team work. Therefore efforts went towards improving and maintaining good communications. There were a variety of perspective and strategies about how this was accomplished:

My desk has always got little messages on it. So that's what they do if they can't see me. They'll pop a little message on my desk and I will always get it (nurse manager).

We had an away-day recently for the G grade sisters because I felt that things had gone a bit disjointed. They weren't working particularly well together (nurse manager).

We tried monthly meetings, but they were a disaster because of the staffing you know. They were too frequent. I see the sisters, the sisters that are working each day – I talk to them daily (nurse manager).

It's critical to involve the junior doctors. The ward manager and I take issues related to interpersonal communications very seriously. So if there are anxieties from either my consultant colleagues about nursing staff or from the nursing colleagues about nursing staff or from the nursing colleagues about medical staff the ward manager and I will discuss it and would take these issues very seriously (lead consultant).

Some found that their perception of their role contrasted with colleagues' perceptions. This sometimes caused friction:

> *I've been criticised in the past by consultant colleagues for becoming too involved in nursing issues (medical director).*

This was particularly difficult for nurse practitioners if they experienced their colleagues or the trust managers as having a poor grasp of the implications of their particular role.

> *It's been difficult at times, because it's a new post, it was the first post, so there were a lot of problems, particularly in the first 12 months both with the doctors and nurses and getting established, and with everyone here knowing me, having been here for such a long time, coming back in a different role, that was quite difficult. Most people were very supportive, some of the nurses obviously felt very threatened, particularly a couple of the sisters who had been senior to me, when I came back I was trying to feel my feet and change things, and it was a bit difficult, but on the whole it's worked very well (nurse practitioner).*

There were "outliers" in the sample of respondents interviewed whose views and experiences did not seem to fit into the general patterns that emerged. For example there were those few who were not working in the area that they wanted. This senior house officer for example:

> *I just wanted a neonatal job … but it's to get a registrar's job. It's helpful experience and you know just to do something different. But I don't get enthused about it (SHO).*
>
> *In the end the experience of a particular role and the impact of that organisationally-related stress, relates to the subjective experience of each individual and their personal circumstances.*
>
> *At the end of the day it sounds very cliché - it's the job satisfaction. Really it is completely different to anything I have ever experienced and one of the biggest bonuses beside the actual work is the team that I work with. I have never experienced such a family atmosphere and we are so supportive of each other and that to me is just as important as the actual physical work I have done (senior sister).*

However, not everyone feels that level of support and as one respondent told me:

> *I sometimes feel I am waiting under a guillotine (lead consultant).*

Conclusions

The in-depth interviews confirm the findings from the survey, in that most feel very positive about the specialty and the prospects of their unit. Most find personal and organisational strategies to overcome interpersonal levels of conflict and tension.

However, the day to day experience of high pressure work, scarce resources and threats of closure or organisational disruption and change are hard to live with for everyone and they exacerbate any existing interpersonal tensions.

The added value of the in-depth interviews is in little doubt. They enabled a more thoughtful approach to explaining/qualifying some of the good and bad aspects of working in NICUs (the specific and the general). The interviews also enabled respondents to speculate about changes that might improve or reduce well-being in ways that provided detailed insight into some of the communication and management issues that impact upon well-being.

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VI Conclusions, and relevance for neonatal intensive care service provision

Effectiveness of care

- The results indicate that infants in the UK have an equal chance of survival irrespective of the type of unit in which they were born. There is no independent relation in this UK-representative study of the risk-adjusted outcomes of mortality and mortality or cerebral damage to unit characteristics of patient volume and staffing levels.
- High volume NICUs treat sicker infants, have higher occupancy and are busier than medium-sized and small NICUs. Nevertheless high volume NICUs perform as well as medium and small NICUs.
- Overall in the census nurse staffing levels were markedly lower than recommended, but there was no simple relation between risk-adjusted mortality and cerebral abnormality and nurse-infant ratios in cross sectional unit level analyses.
- However, when infants are admitted at times when NICUs are approaching within unit maximum occupancy with decreased nurse to infant ratio, risk-adjusted mortality increases.
- Nosocomial bacteraemia is more likely in units with higher consultant availability and in NICUs with no infection control nurse
- Individual elements of recommended best practice from expert-defined standards did not appear to have a measurable independent impact on performance.
- Quality of surfactant guidelines showed no association with patient volume or consultant availability. Timely and appropriately early surfactant administration was more likely in medium-sized units than high volume units.
- The overall performance results support other observations of improved performance in terms of falling neonatal hospital mortality in UK NICUs.

Costs and Efficiency

- Large variation in total cost is not random but rather related to the differences in the casemix of the infants treated
- Given the equality of risk adjusted outcomes between unit types, our analysis suggests that resources are being used appropriately.
- Simple economies of scale are not operating neonatal intensive care, as the extent of the economies of scale is dependent upon the casemix of the infant treated.
- The greatest savings available appear to be from centralising the management of the sickest infants (those with a less than 50% probability of survival at admission), rather than centralising the provision of all neonatal intensive care.
- Efficiency in provision appears to lie in endorsing the hierarchical network of neonatal intensive care units, with units in different tiers focusing on managing appropriately more or less sick infants.

Acceptability and staff wellbeing

- Staff on the 54 participating NICUs had high scores on the MHI-5 indicating good mental health and well-being. There were no significant differences in the scores between NICU types, professional groups or in relation to the length of time in specialty.
- However 40% did volunteer comments about their sense of well-being and their workplace. Commitment to specialty was clear, but a considerable proportion felt dissatisfied with the conditions of their work. The reasons included issues of organisation and management , training and workload and home/work conflicting demands.
- The in-depth interviews confirm the findings from the open –ended comments in the survey.

Main Recommendations

- Maintain hierarchical network of units delivering neonatal intensive care.
- Improve efficiency by caring for the sickest infants in the high volume NICUs, but only if resources and nurse staffing levels are improved to avoid simply exacerbating the excess risk-adjusted mortality associated with highest levels of occupancy.

Neonatal Intensive Care provision

Decisions about neonatal intensive care service configuration may not be prescribed in one simple model. Plans will take account of the demographic and geographical distribution of populations, as well as consideration of current plant, resources, availability of skilled manpower and cost of change. Improving nursing and specialist nursing provision is a priority, but factors beyond those examined in this study will be considered. For example, there is evidence of falling birth rates throughout the UK. Finally, Field (1999)[1] and CSAG (1993, [2]1995[3]) highlight the dilemma of differing perspectives in neonatal intensive care organisation and provision. Whereas clinical specialists may continue to recommend centralisation, seeking goals in excellence in specialty research and professional training; wider issues about maternity service configurations and maintaining access will also shape health care provider decisions.

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VII – Appendices

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Appendix 1 : PHASE 1 CENSUS FORM

Name of Nurse in Charge	Hospital

1. Please specify the time period used if other than the calendar year of 1996.

2. Total number of deliveries in your hospital ?

3. Does your unit provide only temporary support before safe transport for full intensive care elsewhere?

   Yes or No?

4. Total number of admissions to your NICU and/or SCBU?

5. Total number of admissions to your NICU and/or SCBU <1500g?

6. Total number of infants ventilated or given CPAP?

   Tick the box (Ö) if your total is only for those managed with an endotracheal tube

7. Total number of ventilator days?

   Tick the box (Ö) if your total is only for those managed with an endotracheal tube

8. Total number of cots?

9. Total number of maximum intensive care cots (level 1)?

10. Total number of consultants who contribute to the emergency on-call rota for neonatal care?

11. Total number of consultants with 50% or more of their clinical sessions dedicated to neonatal care?

12. Total number of fixed consultant-led business rounds per week?

13. Total number of whole-time equivalent (wte) nurses on neonatal unit staff?

14. Total number of whole-time equivalent (wte) nurses with a nationally-recognised qualification in neonatal intensive care?

15. Does your unit provide a neonatal tertiary cardiac or surgical service?

    Yes or No?

16. Do you expect significant changes to these same questions in 1997?

    Yes or No? (if Yes go to Q17)

17. Please describe any planned significant changes for 1997/98 here:

(please continue on the back page if necessary)

Appendix 2 : UK Neonatal Staffing Study - Admission form

CONFIDENTIAL **Study serial number** *(please leave blank)* ☐☐☐☐☐☐

Hospital name for your NICU/SCBU... (✓ tick one)

Source of admission
- inborn, booked this hospital ☐
- inborn, booked another hospital ☐
- outborn, another hospital-transported by their staff ☐
- outborn, another hospital-transported by your staff ☐

If another hospital, give name and town of hospital ....

Mother's name ☐ *surname* ☐ *forename* **Her DOB** ☐☐ *day* ☐☐ *month* ☐☐ *year*

Mother's postcode ☐ *Mother's postcode at time of delivery* **Her NHS No** ☐ *Mother's NHS number*

Baby's name ☐ *Baby's surname (if different from mother's)* ☐ *Baby's forename* **Baby's DOB** ☐☐ *day* ☐☐ *month* ☐☐ *year*

Baby's Hospital ID No ☐

Was this a multiple birth? (✓ *tick one*) ☐ *yes* ☐ *no*

If yes, write this baby's birth number ☐
eg baby 1, 2 or 3 if triplets

Mode of delivery for this baby ✓ *tick one*
- SVD ☐
- Forceps/ventouse ☐
- Breech vaginal ☐
- Caesarean section ☐

Gestation at delivery ☐☐
obstetric working estimate in completed weeks

Sex of the baby (✓ *tick one*) ☐ *male* ☐ *female*

Please photocopy your blood gas charts, including times when blood was taken, from birth (or admission for transferrred babies) till 12 hours after admission.

I have attached photocopied blood gas charts (✓ *tick one*) ☐ *yes* ☐ *no*

Temperature of baby at admission ☐☐ ° *C*
(✓ *tick one*) ☐ *Rectal* ☐ *Skin*

Time of birth ☐☐ ☐☐ *24 hour clock*

Date of admission to NICU/SCBU ☐☐ *day* ☐☐ *month* ☐☐ *year*

Time of admission to NICU/SCBU ☐☐ ☐☐ *24 hour clock*

Birthweight ☐☐☐☐ *g*

Apgar score at 5 minutes ☐☐

Was blood lactate measured in the first 6 hours after admission? (✓ *tick one*) ☐ *yes* ☐ *no*

If yes give first blood lactate ☐☐ . ☐☐ *mmol*$^{-l}$

Was surfactant therapy given at any time before/after admission? (✓ *tick one*) ☐ *yes* ☐ *no*

If yes, give age in hours& minutes when surfactant was started ☐☐ *hours* ☐☐ *mins*

Appendix 3 - UK Neonatal Staffing Study - Outcomes Form

CONFIDENTIAL **Study serial number** ***(please** leave blank)* ☐☐☐☐☐☐

Hospital name ....

(✓ tick one)

Was this baby was born before arrival at any hospital? *yes* ☐ *no* ☐

Mother's name ☐ *surname* ☐ *forename* **Her DOB** ☐☐ ☐☐ ☐☐ *day month year*

Baby's name ☐ *Baby's surname* ☐ *Baby's forename* **Baby's DOB** ☐☐ ☐☐ ☐☐ *day month year*

Baby's hospital ID number ☐ *Baby's hospital ID* **Baby's NHS No** ☐ *Baby's NHS No(if available)*

DID THE BABY HAVE ....

Complete the answers by ticking✓ 'yes' or 'no' or filling in numbers as appropriate.

1. Supplementary oxygen any time after admission? ☐ *yes* *no* ☐

2. Respiratory support by IPPV or CPAP by ET tube or nasal prongs or face mask any time after admission? ☐ *yes* *no* ☐

***If 'yes'** give **total days of IPPV and/or CPAP** by ET tube or nasal prongs or face mask (count any part day as whole day)* ➔ *days* ☐☐☐

3. Nitric Oxide at any time after admission? ☐ *yes* *no* ☐

***If 'yes'** give age in completed hours when started* ➔ *at hours old* ☐☐

4. High frequency oscillatory ventilation after admission? ☐ *yes* *no* ☐

***If 'yes'** give age in completed hours when started* ➔ *at hours old* ☐☐

6. Cerebral ultrasound scan(s) <u>during first 10 days</u> after birth ? ☐ *yes* *no* ☐

***If 'yes'**, did any scan show*

any intraparenchymal densities? ☐ *yes* *no* ☐

ventriculomegaly (ventricular index either side >4mm above 97th centile? (see table 1 overleaf) ☐ *yes* *no* ☐

any parenchymal cyst(s) (porencephalic cysts or cystic leukomalacia)? ☐ *yes* *no* ☐

7. Cerebral ultrasound scan(s) <u>after the first 10 days</u>? ☐ *yes* *no* ☐

***If 'yes'**, did any scan show*

any intraparenchymal densities? ☐ *yes* *no* ☐

ventriculomegaly (ventricular index either side >4mm above 97th centile? (see table 1 overleaf) ☐ *yes* *no* ☐

any parenchymal cyst(s) (porencephalic cysts or cystic leukomalacia)? ☐ *yes* *no* ☐

Outcomes Form *continued (A3 format)*

DID THE BABY HAVE ....

Complete the answers by ticking✔ 'yes' or 'no' or filling in answers as appropriate

8. Blood cultures in the first 48 hours from birth? *yes* ☐ *no* ☐

If 'yes', *write all organisms isolated (include contaminants)*➔ ……………………………………………………..

……………………………………………………..

9. Blood cultures after the first 48 hours from birth? *yes* ☐ *no* ☐

If 'yes', *write all organisms isolated (include contaminants)*➔ ……………………………………………………..

……………………………………………………..

10. Date of discharge from your hospital? ☐☐ ☐☐ ☐☐

day month year

11. What was the discharge outcome for the baby from your hospital? ✔*tick one(a-d)*

a) Discharged home alive? ☐
b) Discharged home for terminal care? ☐
c) Not known? ☐
d) Transferred to another hospital? ☐

If "transferred to another hospital" *give name and town of hospital*➔ ……………………………………………………

12. Did this baby die? (✔*tick one*) *yes* ☐ *no* ☐

If 'yes',*give date,* ➔ ☐☐ ☐☐ ☐☐

day month year (DOD)

13. Did the baby get ECMO? *(Extra Corporeal Membrane Oxygenation)* ☐ *yes* *no* ☐

14. Did the baby have respiratory distress syndrome? *(Confirmed by chest x-ray)* ☐ *yes* *no* ☐

15. Did the baby have early neonatal encephalopathy consistent with hypoxic ischaemic encephalopathy in the first 24 hours after birth? ☐ *yes* *no* ☐

If 'yes', *tick highest grade in the first 24 hours after birth (see table 2 overleaf)*➔ ☐ *grade 1* ☐ *grade 2* ☐ *grade 3*

16. Did the baby have any other diagnoses ? ☐ *yes* *no* ☐

If 'yes', *list all other diagnoses in capitals here (continue overleaf)*

………………………………………………………………………… ………………………………………………….

………………………………………………………………………… ………………………………………………….

17. Did the baby have surgery accompanied by a general anaesthetic? *yes* ☐ *no* ☐

If 'yes', *list each procedure in capitals here (continue overleaf)* ……………………………………………………………

…………………………………………………………………………….. ……………………………………………….

Appendix 4 UK Neonatal Staffing Study

A prospective, national study of workload, nursing and medical staffing provision and outcome, conducted for the NHS Executive, British Association of Perinatal Medicine, Neonatal Nurses Association (UK) and Scottish Neonatal Nurses Group.

NURSING WORKLOAD LOG

- **Please put this sheet on a clipboard by the nursing station**
- **Please complete every column of this log at noon and midnight without fail**

			Staff providing nursing care in the unit* *at noon and midnight* *** include your staff currently outside the unit on a transfer**			**Babies in the unit* *at noon and midnight*** *** include babies currently outside the unit being transferred by your staff**		
Day	**Date**	**Time**	**Total nursing staff, including auxiliaries /health care assistants & nursery nurses** *exclude any student nurse, student midwife, receptionist, clerk or housekeeper*	**Number of nurses with neonatal qualification** *eg. ENB 402, 405, 904 or A19: Scottish Neonatal Nursing Certificates or PSII module in neonatal critical care*	**Number of auxiliaries/ health care assistants or nursery nurses**	**Count of total number of babies in the unit**	**A** **Count of babies who have endo-tracheal tube *or* IPPV or CPAP by nasal prongs or facemask**	**B** ***Excluding all babies in column A….*** **Count of babies in >40% oxygen** ***or* having no food by mouth** ***or* current weight <1000g** ***or* with stoma,** *(tracheostomy, ileostomy, colostomy, chest abdomen, or urethral drains)*
Mon		12 noon						
		12 midnight						
Tues		12 noon						
		12 midnight						
Wed		12 noon						
		12 midnight						
Thurs		12 noon						
		12 midnight						
Fri		12 noon						
		12 midnight						
Sat		12 noon						
		12 midnight						
Sun		12 noon						
		12 midnight						

Appendix 5

UK Neonatal Staffing Study

Costs of Neonatal Intensive Care

Costs of Neonatal Intensive Care

This questionnaire asks for a description of the resources used in the provision of neonatal intensive care by the unit in the financial year1997 -98. To ensure confidentiality, a separate questionnaire has been sent to the unit Business Manager asking for the employment costs of all staff employed on the unit. This questionnaire is concerned with all non-staff costs Please return in the SAE provided.

Hospital Name	

Name(s) of member of staff completing this form

Name	Position	Date

Sign Off

	Name	Signature
Senior Clinician		
Unit Nurse Manager		
Unit Business Manager		

CONFIDENTIAL

UK Neonatal Staffing Study

Costs of Neonatal Intensive Care

This questionnaire asks for a description of the resources used in the provision of neonatal intensive care by the unit in the financial year1997 -98. To ensure confidentiality, a separate questionnaire has been sent to the unit Business Manager asking for the employment costs of all staff employed on the unit. This questionnaire is concerned with all non-staff costs Please return in the SAE provided.

Hospital Name	

Name(s) of member of staff completing this form

Name	Position	Date

Sign Off

	Name	Signature
Senior Clinician		
Unit Nurse Manager		
Unit Business Manager		

THE COSTS OF NEONATAL INTENSIVE CARE
STRICTLY CONFIDENTIAL

No data will be published which will allow individual Hospitals to be identified.

Notes

- Each section should be completed by relevant staff and returned directly to the Study Co-ordinator using the pre-addressed envelope* .

- The majority of this questionnaire should be completed by either the Unit Business Manager or the Nursing and/or Medical Management within the unit. We have suggested at the start of each section who is most likely to be able to complete the subsequent sections. We hope this will help to minimise the effort involved in completing this questionnaire.

- Where financial information is required, please give costs for the year 1 April 1997 - 31 March 1998. Please consult us if this is not possible.

- Non-financial data quoted should also be for 1 April 1997 - 31 March 1998, if this is possible, or for the calendar year 1997.

- If, for any reason, the year 1997/98 is significantly atypical, please explain why but do not modify the numbers. If in doubt, consult us*.

- Wherever possible, please try to use actual expenditure. However, in some places suggestions have been included in brackets showing the basis on which you may wish to make your estimates, e.g. maintenance costs may be based on % volume of the Unit against total hospital volume. If other methods are used, please give details.

- 'The Unit' is used to describe the facility within which neonatal intensive care, high dependency care, and special care are provided.

- The front page includes a box for the business manager, unit nurse manager and senior clinician to sign, saying that they have seen and agree with the answers provided.

- Further guidance for the completion of the questionnaire is enclosed.

---

* Contact Chris McCabe, Lecturer in Health Economics, University of Sheffield, ScHARR, Regent Court, 30 Regent Street, Sheffield, S1 4DA. Tel: 0114 2220728 Fax: 0114 2724095
E-mail: c.mccabe@sheffield.ac.uk

PLEASE PRINT YOUR ANSWERS CLEARLY

Section A

TO BE COMPLETED BY UNIT MANAGEMENT

Please give the name and telephone number of the person responsible for this part of the questionnaire:

Name: Tel:

GENERAL

1. Name and address of hospital
(Please include Postcode)

____

____

____

2. Total number of cots in the Neonatal Unit ________

3. Total number of available cots in the Unit ________

4. Total occupancy (in bed days) in 1997/98 (or 1997) ________

5. Where cot availability is less than the total, please give reasons for this:-

Questions 6-8 refer to those cots in the Unit which are designated for intensive and high dependency care. Give answers for the financial year 1997/1998 if possible.

6. Total number of intensive/high dependency care cots ________

7. Total number of available intensive/high dependency cots ________

8. Total occupancy (in bed days) of intensive/high dependency care cots ________

9. Total number of intensive, high dependency and nursery care days in 1997/98

IC ___________

HD ___________

NC ___________

10. Is the Unit a purpose built building? YES/NO

11. Approximately how long is it since the building was constructed or had a major refurbishment?

______ YEARS

12. a. Was the accommodation designed for a limited period of life? YES/NO

b. If YES, what was its design life? ______ YEARS

c. Is any major structural work planned for the Unit? YES/NO

If yes, please give details:

____

____

____

____

SUPPORT SERVICES AND WORKS

The following sections should be completed by or checked with the Unit Business/Finance Manager

Please give as accurately as possible:

13. the floor area of the Unit ________ m^2

14. the heated volume of the Unit ________ m^3

15. the cost of heat, light and power (including hot water) in 1997-98 if necessary apportion on the basis of the volume of the Unit as % of total hospital volume). If you prefer, give the total cost of heat, light and power (HLP)

Electricity	£	p.a.
Coal/Oil/Gas	£	p.a.
OR TOTAL HLP	£	p.a.

16. the 1997-98 building maintenance costs for the Unit (if necessary apportion on the basis of the volume of the Unit as % of total hospital volume)

£ pa

17. the Local Authority rates for 1997-98 and other utility charges (if necessary apportion on the basis of the volume of the Unit as % of total hospital volume)

General rates	£	pa
Water/Sewerage rates	£	pa

18. The 1997-98 support services costs for the Unit

Portering (if necessary, use bed occupancy to apportion)	£	pa
Cleaning (if necessary, use area cleaned to apportion)	£	pa
Laundry (if necessary, use number of pieces to apportion)	£	pa
Hospital administration (if necessary, use bed occupancy to apportion)	£	pa
Postage and/or telephone (if separate from administration)	£	pa
Medical records (if necessary, use bed occupancy to apportion)	£	pa
Transport (excluding ambulance service)	£	pa

19. If ambulance transport for the Unit is paid for by the hospital, please give the cost for 1997-98: £ pa

If not, please give an estimate of the number of babies **arriving** at the Unit by ambulance in 1997-98; ________

DIRECT PATIENT SUPPORT

20. Please give 1997-98 costs of the Unit for

Drugs and parental nutrition etc.	£	pa
Milk, special feeds and catering	£	pa
Medical gases (apportion where necessary)	£	pa
Imaging (actual or apportioned). Please include both charges for hospitals x-rays etc., and non staff running costs for Unit based equipment (excl. depreciation):	£	pa
Physiotherapy	£	pa

Either:	Total pathology (both in and outside the Unit)	£	pa
or:	Microbiology	£	pa
	Biochemistry	£	pa
	Haematology	£	pa
	Histopathology (including post mortem data)	£	pa
	Blood products and cross matching (If not covered above)	£	pa
	Other pathology (including cytogenetics)	£	pa

Please give 1997-98 supplies costs for the Unit

(actual or estimated)

Medical and Surgical supplies	£	pa
Dressings	£	pa
Disposable linen	£	pa
Linen	£	pa
Patients' clothing	£	pa
Staff uniforms	£	pa
Provisions	£	pa
CSSD/TSSU	£	pa
Other	£	pa

OTHER MEDICAL AND SURGICAL SERVICES NOT COVERED IN THE BUDGET

22. Please give, for 1997-98, a brief description of other medical and surgical services supplied to the Unit, but not charged to the Unit:

Please also give (or estimate*) the number of consultant sessions provided in or for the Unit in the following specialities, and where appropriate, the number of operations carried out:

	Consultant Sessions	Operations
Paediatric surgery		
Ophthalmology		
Cardiology		
Cardiac surgery		
ENT (including audiology)		
Neurosurgery		
Plastic surgery		
Orthopaedic surgery		

If the figure is an estimate please put (E) in brackets after the figure.

EQUIPMENT

Please list on the attached schedule all pieces of equipment available and used in 1997-98 in the Unit and give an estimate of actual replacement cost. The list should include any office equipment (e.g. computers, photocopiers, faxes etc.) located within the Unit. Please indicate items bought with charity, etc. monies.

Where the age of certain items varies, although the equipment is essentially unchanged, please quote the most recent purchase cost or, if possible, the replacement cost.

Where a maintenance contract is in force, please indicate this.

Please also indicate the running cost of items not covered elsewhere.

Finally, please indicate items which would ideally be replaced over the next 12 months.

The description of the items of equipment must be agreed between the Unit Nurse Manager and the most senior clinician working on the Unit. The financial data (cost, lease etc…) should be agreed by the Unit Business Manager.

	Item	Cost per Item**	Total Quantity	No. due for replacement (over the next 12 months)	Leased* **	Funded by Charity*
1	Cots and bassinet				Yes/No	Yes/No
2	Overhead heaters/radiant warmers. (excl resuscitaires)				Yes/No	Yes/No
3	Resuscitaires				Yes/No	Yes/No
4	Incubators				Yes/No	Yes/No
5	Transport incubators without ventilators				Yes/No	Yes/No
6	Transport incubators with ventilators				Yes/No	Yes/No
7	Ventilators				Yes/No	Yes/No
8	Humidifiers (free standing)				Yes/No	Yes/No
9	Cardio-respiratory monitors				Yes/No	Yes/No
10	Apnoea monitors				Yes/No	Yes/No
11	Intra-arterial O_2/blood pressure monitors				Yes/No	Yes/No
12	O_2 saturation monitors/pulse oximeters				Yes/No	Yes/No
13	Oxygen monitors/analyzers (e.g. Hudson)				Yes/No	Yes/No
14	Transcutaneous gas monitors				Yes/No	Yes/No
15	Non invasive blood pressure monitoring equipment (e.g. Dinamap)				Yes/No	Yes/No
16	(Separate) temperature monitors				Yes/No	Yes/No
17	Peristaltic/cassette infusion pumps				Yes/No	Yes/No
18	Syringe pumps				Yes/No	Yes/No
19	(Separate) phototherapy units				Yes/No	Yes/No
20	ECG machines				Yes/No	Yes/No
21	Defibrillators				Yes/No	Yes/No
22	Fibreoptic light sources				Yes/No	Yes/No
23	Blood gas analyzers (located in Unit)				Yes/No	Yes/No
24	Other side ward analyzers				Yes/No	Yes/No
25	Ultrasound (located in Unit)				Yes/No	Yes/No
26	Head boxes				Yes/No	Yes/No
27	Air/O_2 blenders				Yes/No	Yes/No
28	Flow meters				Yes/No	Yes/No
29	Breast pumps				Yes/No	Yes/No
30	Electronic scales				Yes/No	Yes/No
31	Portable suction pumps				Yes/No	Yes/No

Other (e.g. physiotherapy and medical physics equipment please specify)

	Item	Cost per Item**	Total Quantity	No. due for replacement (over the next 12 months)	Leased* **	Funded by Charity*
32					Yes/No	Yes/No
33					Yes/No	Yes/No
34					Yes/No	Yes/No
35					Yes/No	Yes/No
36					Yes/No	Yes/No
37					Yes/No	Yes/No
38					Yes/No	Yes/No
39					Yes/No	Yes/No
40					Yes/No	Yes/No

PLEASE DO NOT PUT THE SAME PIECE OF EQUIPMENT UNDER MORE THAN ONE CATEGORY

* Delete as appropriate

** If cost per item is not easily available please give the name of the equipment and the supplier on the form at the end of this questionnaire.

*** If the equipment is leased please give the annual cost and term of contract on the form at the end of this questionnaire.

COMMENTS

This section may be completed by all individuals involved in completing this questionnaire

The project will provide each participating hospital with data on the costs of the Unit, and comparative (anonymised) data to show the Unit in the context of other hospitals. If there is any other information which would be useful in calculating costs please provide it below.

We would also value any observations about the adequacy of existing facilities, equipment and staffing levels.

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE. WE KNOW IT IS TIME CONSUMING. PLEASE RETURN IT TO MR C MCCABE, ScHARR, UNIVERSITY OF SHEFFIELD, S1 4DA, BY 30 OCTOBER 1998.

ADDITIONAL INFORMATION ON UNIT EQUIPMENT

	Item	Name of Equipment	Supplier	Annual Cost of Lease	Duration of Contract***	Annual cost of maintenance contract
1	Cots and bassinet					
2	Overhead heaters/radiant warmers. (excl resuscitaires)					
3	Resuscitaires					
4	Incubators					
5	Transport incubators without ventilators					
6	Transport incubators with ventilators					
7	Ventilators					
8	Humidifiers (free standing)					
9	Cardio-respiratory monitors					
10	Apnoea monitors					
11	Intra-arterial O_2/blood pressure monitors					
12	O_2 saturation monitors/pulse oximeters					
13	Oxygen monitors/analyzers (e.g. Hudson)					
14	Transcutaneous gas monitors					
15	Non invasive blood pressure monitoring equipment (e.g. Dinamap)					
16	(Separate) temperature monitors					
17	Peristaltic/cassette infusion pumps					
18	Syringe pumps					
19	(Separate) phototherapy units					
20	ECG machines					
21	Defibrillators					

	Item	Name of Equipment	Supplier	Annual Cost of Lease	Duration of Contract***	Annual cost of maintenance contract
22	Fibreoptic light sources					
23	Blood gas analyzers (located in Unit)					
24	Other side ward analyzers					
25	Ultrasound (located in Unit)					
26	Head boxes					
27	Air/O_2 blenders					
28	Flow meters					
29	Breast pumps					
30	Electronic scales					
31	Portable suction pumps Other (e.g. physiotherapy and medical physics equipment - please specify)					
32						
33						
34						
35						
36						
37						
38						
39						
40						

Staff well-being questionnaire

This questionnaire is designed to take about 5 minutes to complete

What we'd like you to do

- Answer all the questions
- Give your first natural answer: be accurate and honest!
- Base your answers on how you have felt during the past month
- Then, return your form in the pre-addressed FREEPOST envelope to the study centre
- Thank you for your help

NICU TYPE 1 to 12 [ ]

Your answers will be held in confidence

First we would like some brief information about you.

1. **What is the title of your current post?** [ ]

In each of the following questions please tick <u>one answer</u> which applies to you

Tick one ✔

2. **What is your age?**
   - Below 25 [ ]
   - 25-34 [ ]
   - 35-44 [ ]
   - 45-54 [ ]

3. **Are you**:
   - Female [ ]
   - Male [ ]

4. **How long have you worked in your current Neonatal Intensive Care Unit?**
   - under 1 year [ ]
   - 1-5 years [ ]
   - 6-10 years [ ]
   - more than 10 years [ ]

5. **How long have you been in your <u>current post</u>?**
   - under 1 year [ ]
   - 1-5 years [ ]
   - 6-10 years [ ]
   - more than 10 years [ ]

6. **How long have you worked in Neonatal Intensive Care (or Special care) altogether?**
   - under 1 year [ ]
   - 1-5 years [ ]
   - 6-10 years [ ]
   - more than 10 years [ ]

7. **Tick any of the following neonatal nurse qualifications you have.**

   (*You can tick more than one✔*)

   - ENB 402 [ ]
   - ENB 405 [ ]
   - ENB 904 [ ]
   - None [ ]
   - Other [ ]
   - ENB A19 [ ]
   - Scottish Neonatal Nursing Certificate [ ]
   - Scottish Neonatal Nursing PSII module [ ]
   - *Clinicians tick here/not applicable* [ ]

8. **Do you have a friend at work you feel you can talk to about personal problems?**
   - yes [ ]
   - no [ ]

9. **Do you have a friend or relation at home you feel you can talk to about personal problems?**
   - yes [ ]
   - no [ ]

The following questions are about how you have been feeling during the past month.

For each question please circle the number of the answer that comes closest to the way you have been feeling during the past month.

How much of the time during the past month:

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Have you felt downhearted and low?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6

In the space below, please add anything else you want to say about how you have felt generally in the last month.

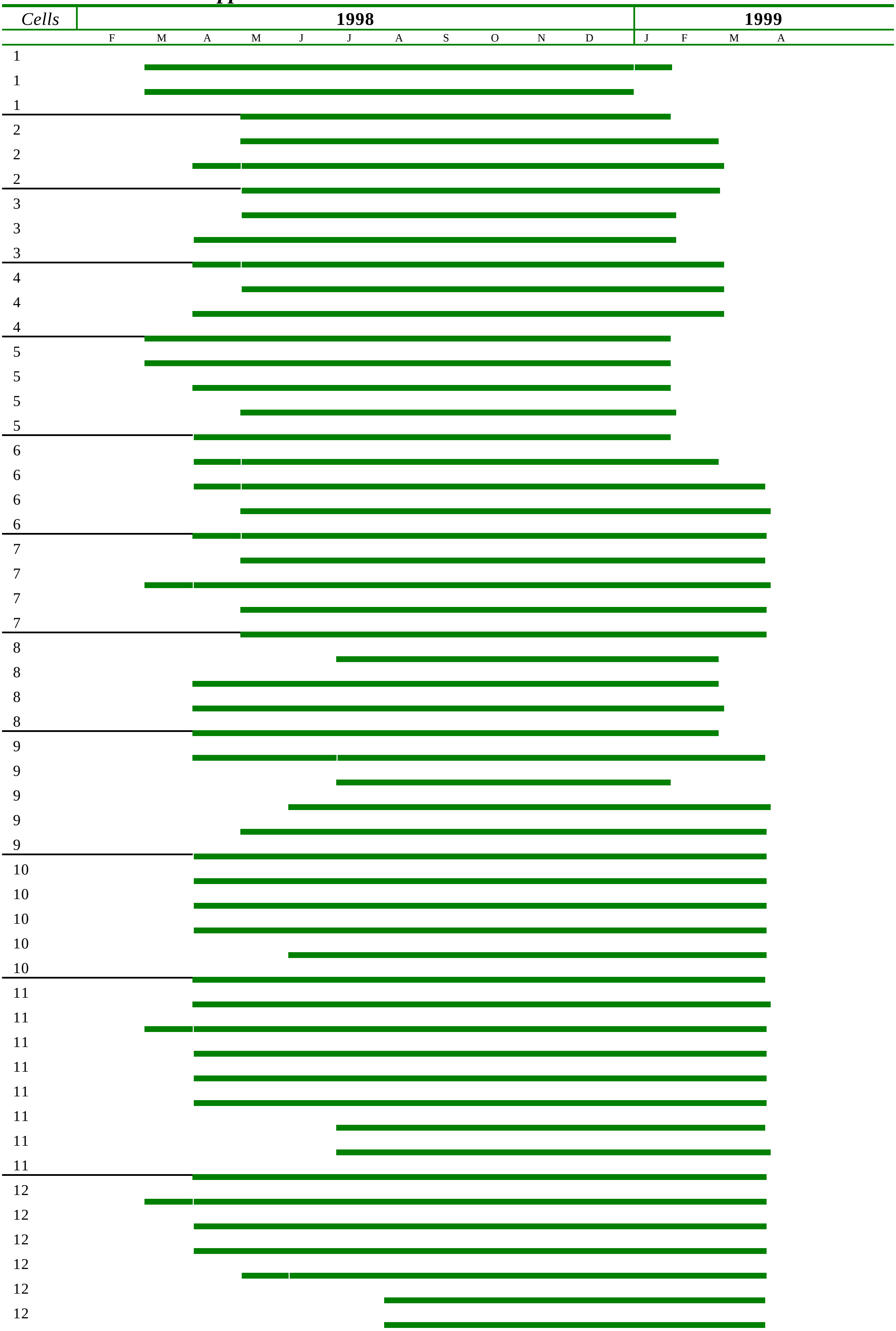
One more page - please turn over ➔

The following are major life events which people often find unsettling. This information will allow us to separate levels of stress experienced within and outside work. Replies will be strictly confidential and reported only as aggregate results for staff groups.
Have any of the following events happened to you <u>during the past month</u>?
Please tick as many as apply to you ✔

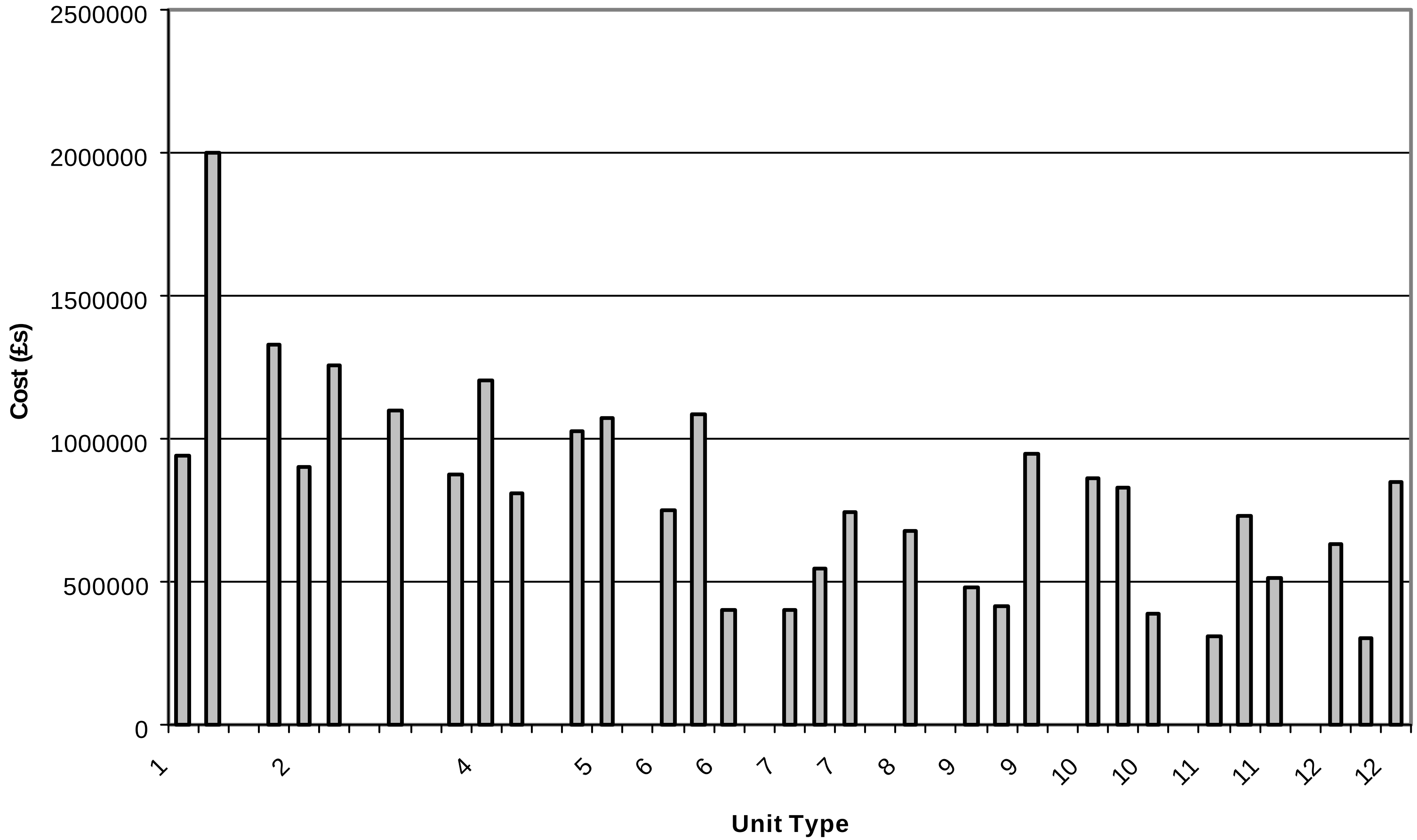
- ☐ You have married
- ☐ You have divorced
- ☐ You have changed jobs
- ☐ You have started a new significant emotional relationship
- ☐ You have experienced a break-up of a significant emotional relationship
- ☐ You have had a serious argument with a close friend
- ☐ You have made an important new friendship
- ☐ You have moved house
- ☐ You have been pregnant
- ☐ You have had difficulties with the process of selling or buying a house
- ☐ You have made a major financial gain through inheritance, winning a prize etc.
- ☐ Your partner has died
- ☐ A close friend or relative has died
- ☐ You, your partner or child has experienced serious illness
- ☐ You, your partner or child has experienced serious injury
- ☐ You, your partner or child has experienced a motor vehicle accident
- ☐ You have had a domestic burglary
- ☐ You have been a victim of any other crime
- ☐ You have had a baby
- ☐ You have had a religious experience of some kind
- ☐ You have had experience of legal proceedings (other than house purchase or divorce)
- ☐ You have taken an examination
- ☐ You have had the feeling that you were going through a personal crisis of some kind

If none of the above applies to you, tick here ✔ ☐

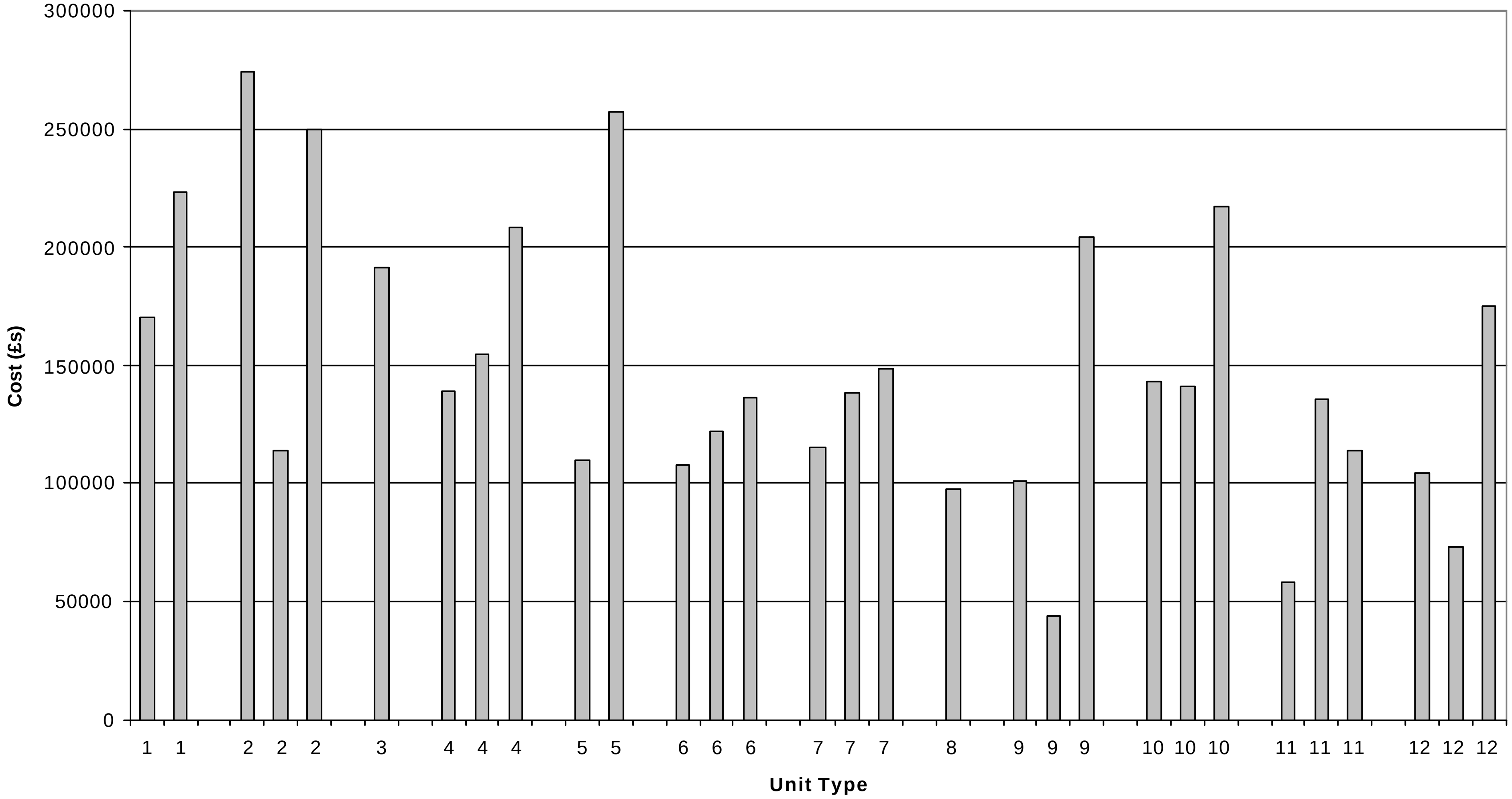
Appendix 7: Phase 2 Observation Periods at 54 NICUs



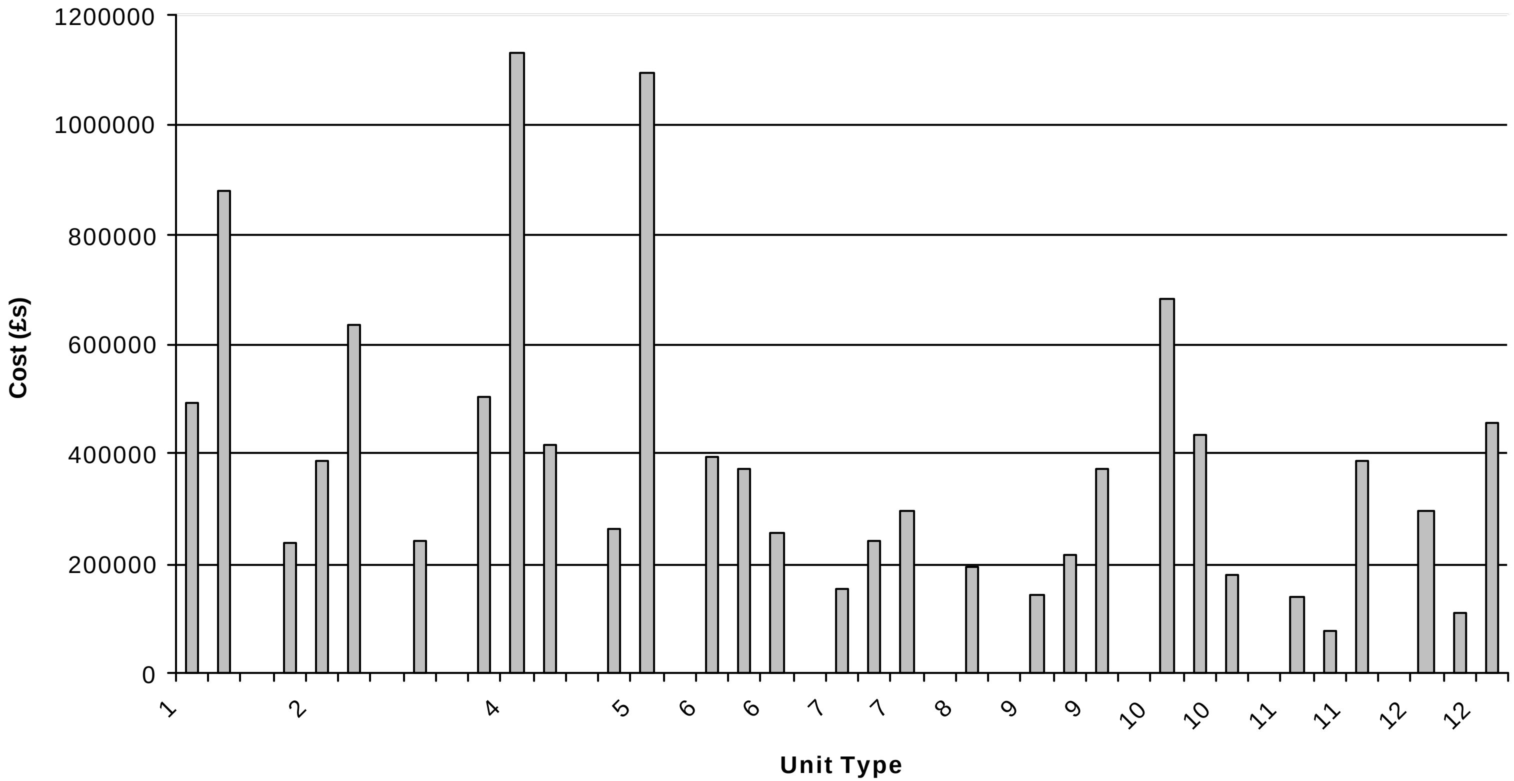
Appendix 8 : Figure 1A- Staffing Costs by Unit Type



Appendix 9: Figure 1B- Cost of Equipment by Unit Type



Appendix 10 Figure 1C- Consumables Cost by Unit Type



Appendix 11 Figure 1D- Total Cost of NICU