Relation between size of delivery unit and neonatal death in low risk deliveries: population based study

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Abstract

Aim—To examine risk of neonatal death after low risk pregnancies in relation to size of delivery units.

Methods—A population based study of live born singleton infants in Norway with birthweights of at least 2500 g was carried out. Antenatal risk factors were adjusted for.

Results—From 1972 to 1995, 1.25 million births fulfilled the criteria. The neonatal death rate was lowest for maternity units with 2001–3000 annual births and steadily increased with decreasing size of the maternity unit to around twice that for units with less than 100 births a year (odds ratio 2.1; 95 % confidence interval 1.6 to 2.8). Institutions with more than 3000 deliveries a year also had a higher rate (odds ratio 1.7; 95% CI 1.4 to 2.0), but analyses suggest that this rate is overestimated.

Conclusion—Around 2000 to 3000 annual births are needed to reduce the risk of neonatal deaths after low risk deliveries.

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There is no consensus on the optimal conditions for delivery after a normal pregnancy. On the one hand, well equipped hospitals are thought to be the safest place for all deliveries, as no antenatal screening procedure can guarantee an uncomplicated delivery.[1–4] On the other hand, a delivery with no known risk factors may actually be put at risk by the increased medical attention of technologically advanced maternity units, and low risk deliveries may benefit from the minimal intervention approach in small maternity units.[5–9]

Since 1967 every birth in Norway has been registered in The Medical Birth Registry of Norway. This was specifically designed to evaluate maternal health, pregnancy complications, quality of delivery, place of birth, and health of the neonate. This dataset may be particularly relevant for studying the performance of different places of delivery for the following reasons: the Registry covers the entire birth population of one country for nearly three decades; it contains information on numerous factors related to adverse outcome and to place of birth; and the collection and content of data have remained the same during the study period. Furthermore, the national health care plan has consistently provided antenatal, intrapartum, and postnatal care free of charge. Deliveries have been performed at the local maternity unit unless identification of risk factors has suggested that a larger hospital might better be able to deal with any adverse outcome. In all types of institutions certified nurse–midwives have performed deliveries after low risk pregnancies.

Referral of women with known risk factors to larger maternity units makes it difficult to compare directly the crude mortalities among institutions. There are, however, ways of addressing this. First, all pregnancies with risk factors potentially detectable before birth can be excluded. Outcomes for the remaining pregnancies in the different types of institutions should then indicate how successful they were in avoiding and handling unexpected hazards during delivery. Although the smallest institutions should ideally handle only low risk women, most of the criteria for selecting such groups will exclude a significant number of women actually delivering at these institutions. A second strategy is therefore to compare the outcomes of all deliveries among institutions after adjustments for the proportion of women with various antenatal risk factors. This study aimed to use the data from the Medical Birth Registry of Norway to study neonatal mortality in relation to the size and expertise of the delivery unit using both of these strategies.

Methods

The Medical Birth Registry of Norway contains information on 1.7 million births between 1967 and 1995 with a gestational age of 16 completed weeks or more. Complete ascertainment of all births in the country is ensured through record linkage with the central population registry run by Statistics Norway. The distribution of reported risk factors was different for the first five years, 1967–71, compared with later years, due to inconsistent reporting when the programme was first being introduced. This period was therefore excluded, leaving 1.35 million births in the period 1972–95. Of this group, 1 260 777 were singleton live born infants with birthweights of at least 2500 g, and 1 254 284 of these were registered as having been born in an institution.

For every woman we identified all conditions recorded in the registry that could have affected outcome and were potentially detectable before birth (table 1). Pregnancies without these factors were considered low risk. If the birthweight data were missing, only infants

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Table 1 Risk factors (%) registered in Medical Birth Registry of Norway 1972–95 among deliveries of singleton live born infants with birthweights ⩾2500 g

Congenital malformations*	2.2
Breech presentation	2.7
Transverse position	0.1
Placenta previa	0.2
Maternal age less than 18 years or more than 40 years	2.1
Maternal disease before pregnancy†	14.8
Maternal disease during pregnancy‡	18.2
Four previous births or more	2.0
Gestational age of more than 42 weeks	13.1
Hydramnios or oligohydramnios	1.0
Premature rupture of membranes	0.4
Low risk deliveries§	56.4
Total number of infants	1 260 777

The percentages total more than 100% as some deliveries have more than one risk factor.
*All congenital anomalies except congenital dysplasia of the hips.
†All reported maternal diseases before the start of pregnancy, except congenital dysplasia of the hips, allergic diseases, and urinary tract infections.
‡All reported maternal diseases with origin during the pregnancy potentially detectable before delivery, also including Rhesus immunisation.
§Women aged 18 to 40 years, with no more than three previous births and no reported diseases before or during a singleton pregnancy, giving births within 42 weeks gestational age to an infant without any congenital anomalies and with a birthweight of 2500 g or more. There were no breech or transverse position, no prolonged ruptures of the membranes, and no hydramnios or oligohydramnios.

Figure 1   Association between level and size of delivery units.

with a gestational age of at least 37 weeks were included.

The neonatal mortality (the number of deaths within 28 days of a live birth divided by the number of live births) was selected as the primary outcome parameter. The Medical Birth Registry is regularly linked to the central population registry which holds independently collected information on all deaths in Norway, to ensure complete ascertainment of deaths. The stillbirth rate (the number of stillborn infants divided by the number of total births) was also calculated, to see how the inclusion of stillbirths would affect the main results, and also to permit comparisons with previous studies that have included stillbirths.

In Norway the level of medical care and size of maternity units are closely linked (fig 1). Even within the group of county hospitals obstetric, anaesthetic, and paediatric services, as well as equipment, are closely related to the size of the maternity unit. Outcome was therefore analysed according to the number of deliveries in the same year in the unit where the birth took place. The maternity units were grouped into sizes of no more than 100 births a year, 101–500, 501–1000, 1001–2000, 2001–3000, and more than 3000 births a year. No institution had more than 5180 births in any year. If a mother was transferred from one institution to another during birth, the birth was registered at the institution where the infant actually was delivered, or excluded if the infant was born during transport. All home births were excluded.

In order to make the mothers who delivered at large and small centres comparable, the following two methods were used: we excluded all mothers having at least one of the conditions listed in table 1, leaving only the low risk mothers with no reported risk factors. For this subgroup, the relative risks of neonatal mortality between delivery units of different sizes
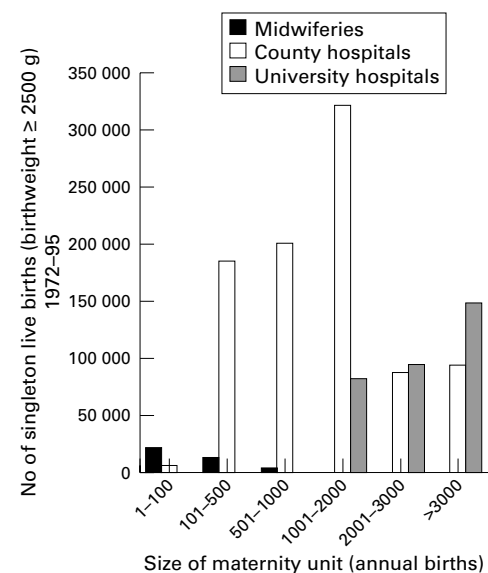
were calculated by odds ratio in logistic regression models. Second, the same analyses were also performed after inclusion of all births, but with adjustments for the effects on the neonatal mortality for each condition listed in table 1. This was done by including the conditions in the logistic regression model one at a time. After each step, continuing adjustment was done only for conditions shown to have significant effects on the neonatal mortality in the model. The sample size was thereby expanded from 700 000 to 1.25 million births. Year of birth was used as a continuous variable, the other factors as categorical variables. The analyses were first restricted to birthweights of 2500 g or more but subsequently also expanded to 1500 g or more. Inclusion of even lower birthweights was avoided as the number of infants with very low birthweight was negligible in the smallest institutions, but contributed greatly to neonatal mortality in the largest ones.

As the neonatal mortality and stillbirth rates, as well as the proportion of deliveries occurring at institutions of different sizes, changed over time, adjustments were made for year of birth. To examine possible bias due to the large time span, all analyses were repeated separately for the cohorts 1972–77, 1978–83, 1984–89 and 1990–95.

Both of the two strategies assumed that the maternity units adhered to the same criteria for reporting risk factors. To compare such practices, we used multivariate logistic models, with our definition of being at risk as the dependent variable. This was first done for all women delivering live born infants with birthweights of at least 2500 g, and then for the women whose infants had died. BMDP Statistical Software was used for the statistical analyses.[10]

Results

During the period 1972 to 1995, total neonatal mortality decreased from 7.7 to 3.5 per thousand live births and the stillbirth rate from

Table 2   Relative risk* of neonatal death after a low risk delivery† in maternity units of different size

Size of maternity unit‡ (No of births per year)	Low risk deliveries† (n)	Relative risk*	95% confidence interval
≤100	18 053	1.8	1.1–3.1
101–500	119 497	1.6	1.1–2.2
501–1000	117 175	1.3	0.9–1.8
1001–2000	217 524	1.5	1.1–2.1
2001–3000	98 136	1.0	ref.
>3000	136 099	1.5	1.1–2.2

*Relative risks were approximated by odds ratios in logistic regression models adjusted for year of birth.
†Low risk delivery is defined as in table 1.
‡There was an overall significant difference in mortality between maternity units with a p value of 0.043.

Table 3   Relative risk* of neonatal death among singleton infants with birthweights of at least 2500 g in maternity units of different size

Size of maternity unit† (No of births per year)	Deliveries (n)	Relative risk*	95% confidence interval
≤100	26 486	2.1	1.6–2.8
101–500	197 478	1.7	1.4–2.0
501–1000	203 735	1.5	1.3–1.8
1001–2000	403 506	1.5	1.3–1.8
2001–3000	181 959	1.0	ref.
>3000	241 120	1.7	1.4–2.0

*Relative risks were approximated by odds ratios in logistic regression models adjusted for year of birth, congenital anomalies, maternal disease during pregnancy, breech presentation, multiparas, hydramnios or oligohydramnios, premature rupture of the membranes and placenta previa.
†There was an overall significant difference in mortality between maternity units with a p value of less than 0.0001.

7.8 to 3.6 per thousand births, with a birthweight of at least 1000 g. The neonatal mortality and stillbirth rates for infants born after low risk pregnancies decreased from 1.0 to 0.5, and from 2.4 to 1.4, respectively.

The maternity units with 2001 to 3000 annual births had the lowest neonatal mortality rate both when the low risk group was evaluated separately (table 2), and when the different risk factors were adjusted for in the whole cohort (table 3). Infants born at institutions with no more than 100 annual births had the highest risk for neonatal death. The risk declined with increasing size of the maternity unit until 2001 to 3000 annual births, and then increased for the largest institutions. The ranking between the units of different sizes was consistent for both methods of analyses, and was also consistent during the intermediate

Table 4   Relative risk* of stillbirths and combined stillbirths and neonatal deaths among singleton infants with birthweights of at least 2500 g in maternity units of different size

Size of maternity unit (No of births per year)	Deliveries (n)	Stillbirths† Relative risk* (95 % CI)	Combined stillbirths and neonatal deaths‡ Relative risk* (95 % CI)
≤100	26 538	0.7 (0.6–1.0)	1.2 (1.0–1.4)
101–500	198 030	1.0 (0.9–1.2)	1.3 (1.1–1.4)
501–1000	204 261	1.0 (0.9–1.1)	1.2 (1.1–1.3)
1001–2000	404 635	1.0 (0.9–1.1)	1.2 (1.1–1.3)
2001–3000	182 437	1.0 (ref.)	1.0 (ref.)
>3000	241 698	1.1 (0.9–1.2)	1.3 (1.1–1.4)

*Relative risks were approximated by odds ratios in logistic regression models adjusted for year of birth, congenital anomalies, maternal disease during pregnancy, breech presentation, multiparas, hydramnios or oligohydramnios, premature rupture of the membranes and placenta previa.
†There was not an overall significant difference in mortality between maternity units with a p value of 0.17.
‡There was an overall significant difference in mortality between maternity units with a p value of less than 0.0001.

steps when the different risk factors were adjusted for in the logistic regression model. This was also true when birthweights of 1500 to 2499 g were included in the analyses.

Separate analyses for the smaller cohorts 1972–77, 1978–83, 1984–89 and 1990–95 had less statistical power, but the results were similar to those of the whole cohort. The proportion of unmarried mothers did not differ between institutions.

The relative risk of stillbirth was lower for institutions with less than 100 deliveries a year, but did not vary between larger institutions (table 4). The relative risk for combined stillbirths and neonatal deaths was lowest for institutions with 2001–3000 annual deliveries, but did not vary between the other institutions.

The proportion of pregnancies classified as at risk increased with increasing size of the maternity units up to 3000 annual births, but subsequently decreased significantly for institutions with more than 3000 deliveries. The same pattern with respect to risk factors was also demonstrated for the small group of women whose newborns died.

Discussion

The neonatal mortality rate for infants delivered after low risk pregnancies is extremely low irrespective of birth place compared with the total neonatal mortality (0.5 *vs* 3.5 per 1000 live births for infants born 1990–95). This underscores the need for large numbers in studies of low risk pregnancies. The reliability of a study also depends on how completely a large number of different biological risk factors are accounted for in the analyses.

Given the current low perinatal mortality, the stillbirth rate seems inappropriate as a measure of quality of delivery for the following reasons. First, most stillbirths occur before admission to the delivery unit,[11] and do not reflect the unit's ability to avoid and handle complications during birth. Second, in Norway stillbirths before labour will be referred away from the smallest institutions for evaluation and induction. The present data underscore this policy as the smallest institutions had the lowest stillbirth rate. Given the low number of neonatal deaths, inclusion of stillbirths in the analyses would obscure differences in the outcomes of live born infants (table 4).

The exclusion of stillbirths might, however, still bias the comparison in favour of the smaller units, as fetal distress in a large unit will tend to result in emergency delivery and subsequent death for some of these infants, while the results might be stillbirth in small units. A higher incidence of intrapartum fetal death among low risk women with decreasing levels of available perinatal technology has been reported before.[11–13]

Our study may also be biased in favour of smaller units because in our Registry, the birthplace is registered as the place where the baby was finally delivered. A neonatal death after emergency transfer from a small maternity unit will therefore be registered at the largest hospital if the woman arrived at this

hospital before delivery, or during transport if the neonatal death occurred before arrival.

The largest hospitals are located in the largest cities. A difference in risk of neonatal death between rural and urban areas due to social conditions might therefore bias the study. Information on marital status was the only parameter related to social conditions in the dataset. In Norway unmarried mothers are younger, less well educated, have lower socioeconomic status and have lower incomes than married women.[14] The proportion of single mothers did not differ with size of institution, suggesting that differences in social conditions may not explain differences in outcome.

In this study we assumed that the reporting of risk factors to the Registry was similar from all types of institutions. We therefore expected larger and more sophisticated units to report a higher proportion of risk pregnancies. That the rate of pregnancies and neonatal deaths with recorded risk factors increased with the size of institution up to a size of 3000 births a year, was consistent with this assumption. However, the lower rate of recorded risk factors at the largest and most technologically advanced delivery units indicates that these units were less conscientious in reporting risk factors. The women with the most severe problems within the respective risk factors were also probably transferred to the largest institutions, making adjustments for these factors more difficult. The findings of higher neonatal mortality in the units with more than 3000 deliveries compared with the second largest institutions, may thus at least partly be a result of bias due to less complete registration of risk factors.

Although the increased neonatal mortality for institutions with more than 3000 annual births may be biased because of under reporting of risk factors, it is also conceivable that no further benefit is accomplished by increasing the size of the maternity unit beyond 3000 deliveries. Institutions with 2001–3000 annual births may be large enough to maintain a high level of expertise, and immediate access to rapid intervention and highly trained personnel such as anaesthesiologists and neonatologists. The largest units may be more difficult to organise and more focused on pregnancies and deliveries at very high risk. It should be noted that while the other categories consisted of fairly large numbers of hospitals, only six were represented in the category with more than 3000 annual births, and most of these have extensive teaching responsibilities.

A high throughput of patients and therefore increased physician and staff experience, improves the outcome for infants in need of neonatal intensive care and for many surgical procedures.[15–17] Furthermore, studies have suggested that infants weighing less than 2500 g at birth have enhanced chances of survival in large obstetric units[18–23] and in teaching hospitals.[12] Several of these studies have, however, failed to show a benefit and some have even suggested an adverse effect on delivering infants with weighing over 2500 g at birth in large institutions.[12 18 19 21 23] In our population the risk of neonatal death increased as the number of deliveries in an institution decreased below 2000 a year. In institutions with less than 100 annual births the risk was doubled. The true difference may even be greater as the possible biases most probably favoured the results from the smallest institutions.

Given the limitations of this study, it is reasonable to conclude that the experience, expertise, and equipment of larger institutions can also reduce the risk of neonatal death to a minimum for low risk deliveries.

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Commentary

It is generally agreed that centralisation of obstetric services is essential to improve perinatal outcomes in high risk pregnancies. But does this apply to low risk pregnancies? The Norwegian study examines the relation between size of maternity unit and neonatal mortality. It concludes that hospitals delivering fewer than 100 babies a year show a twofold increase in risk of death in a low risk pregnancy.

Can these findings be extrapolated to the UK? Here, debate on the safety and place of delivery has centred on planned home births. In 1967 around one in five babies were delivered at home in England and Wales. This has declined to less than 1% in the 1980s and is now around 2%. Similar declines have been seen in numbers delivering in isolated general practitioner units (less than 2%). The statistical pitfalls discussed by the Norwegian authors have featured in this debate: differences in case mix; imprecise assessment of rare outcomes; and how to deal with transfer of cases.

It is now no longer possible to undertake a randomised controlled trial in the UK, and the biases inherent in retrospective data analysis preclude a conclusive answer to these questions. The problem continues to be tantalisingly elusive.

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