


Neonatal deaths and injuries

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Summary

Background. It is rare for babies to die or be injured during birth in Norway. We aimed to investigate whether maternity care was inadequate in cases reported to the Norwegian Board of Health Supervision and to single out areas in maternity care where there is potential for improvement.

Material and method. The material consists of cases reported to the Norwegian Board of Health Supervision in the three-year period 2006–2008 in which babies died or were severely injured during delivery. We recorded data on: maternity unit, fetal monitoring, delivery method, personnel involved and type of inadequacy in maternity care.

Results. The material consists of 81 cases. Babies died during or after delivery in 58 cases and were severely injured in 23 cases. The health enterprises reported 42 of these events to the Board of Health Supervision; the remainder were reported by the patient ombudsman or the parents. There was inadequate fetal monitoring in 55 (68 %) of the births and delayed delivery in 56 (69 %). A gynaecological specialist was not called for 36 (44 %) of the births. The number of cases of injuries in relation to the number of deliveries reported to the Board of Health Supervision was significantly higher for small maternity units (< 1 000 births per year) than for larger units.

Interpretation. Doctors and midwives need a more thorough knowledge of fetal monitoring. Maternity units must develop sound procedures for singling out high-risk births, using fetal monitoring, calling for a doctor and reporting to the Board of Health Supervision. Exercises in dealing with acute situations should be held.

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Perinatal mortality (cases of babies who die after the twenty second week of gestation or during the first week of life) has been falling steadily in Norway. In 2010 it was 4.9 %. Half of the deaths take place during pregnancy (1) and in the remaining cases the baby dies either during birth or in the course of the first week of life.

Few babies die during labour and delivery (intrapartum deaths). A survey from Denmark and Sweden has revealed an incidence of intrapartum fetal death in non-malformed fetuses of 2–4 per 10 000 births (2). If the frequency is the same in Norway, that would be equivalent to about 12–24 intrapartum deaths per year. The cause of the baby's death in more than 90 % of these cases is severe lack of oxygen (3). A shortage of oxygen that develops over time (often hours) is the most common cause of a baby dying during or immediately after birth. Better monitoring and treatment could probably lead to better results.

In Norway, 98 % of all births take place in a maternity unit. Maternity units with > 1 000 births per year account for 79.4 % of the country's births (4). The Directorate of Public Health has drawn up new quality requirements for maternity units in Norway, and stresses the importance of high professional expertise, interdisciplinary cooperation, instruction, sound procedures for handling acute situations and clear guidelines as to who is responsible during a birth (5).

Fetal monitoring is a central topic in those births where a baby dies or is seriously injured. Today cardiotocography (CTG) is the most widely used method of monitoring high-risk births. Pinard stethoscopes, or alternatively Doppler ultrasound, can be used for monitoring healthy pregnant women with a normal labour and delivery. ST analysis of fetal ECG (STAN) and lactate/pH analysis of the baby's blood are more sophisticated methods of fetal monitoring which are recommended in high-risk births (6).

The Norwegian Board of Health Super-

vision receives about 100 cases annually in the specialty field of obstetrics and gynaecology. A third of the incidents are injuries in connection with births. The cases are first treated by the Board of Health Supervision at county level. The most serious cases (about a third of them) are forwarded to the central Norwegian Board of Health Supervision. In the period 2003–06, the Board of Health Supervision analysed 47 cases of a serious nature associated with pregnancies and births. Common features proved to be weaknesses in communication and collaboration, unclear responsibilities, inadequate competencies and weaknesses in the organisation of the activity (7).

The purpose of our study was to gather information on births where the baby dies or is seriously injured during or immediately after birth, and where the case was reported to the Board of Health Supervision at county level during the three-year period 2006–2008. The study was carried out as part of the Board of Health Supervision's regular supervisory work. We wanted to analyse the material with a view to identifying areas with a particular risk of error, and where there is a basis for work to improve quality.

Material and method

Cases that are treated by the Board of Health Supervision are based primarily on the regional health authorities' reporting pursuant to the statutory duty of notification of serious harm to patients (Act relating to the Specialist Health Service, section 3.3). The presentation of the case and conclusion of the Board of Health Supervision are shown in the closing letter. The document is not exempt from public disclosure apart from information that is confidential (8).

Main points

- There is often fetal monitoring error when a baby dies or is injured during birth
- Complicated labours and deliveries are not always handled by adequately qualified personnel
- Delayed delivery is a major cause
- The health enterprises do not observe their duty to report serious injuries during deliveries to the Norwegian Board of Health Supervision

Table 1 Number of babies who died or were seriously injured

Perinatal deaths	
Acute asphyxia	6
Prolonged or unspecified asphyxia	42
Fetomaternal haemorrhage	1
Prematurity	3
Disseminated intravascular coagulation (DIC)	1
Head injuries	5
Perinatal injury	
Plexus injury	2
Cerebral palsy	21

Table 2 Birth injuries reported to the Board of Health Supervision in 2006–2008 in relation to the size of the maternity units (77 % of births in Norway)

Maternity unit	< 1 000 births	≥ 1 000 births
Number of births in the hospitals in question	11 502	127 291
Birth injuries	21	60

The Boards of Health Supervision in each county were contacted with a request to send the closing letter in the cases that dealt with babies who died or were seriously injured during birth. Each case was reviewed and information about the pregnancy, labour and delivery and the child's condition after birth was recorded in a form made for this study. We classified the maternity units as small (< 1 000 births per year) and large (≥ 1 000 births per year) to see whether there was a difference in the number of injuries. We chose to set the dividing line at 1 000 births per years because our neighbours Sweden and Finland have recommended that maternity units should not have < 1 000 births per year. The closing letter provides a summary of the course of events, but does not contain detailed information about the labour and delivery. The letter indicates who was involved in the labour and delivery and where error occurred at both systemic and individual level.

According to the applicable rules concerning governance of public administrative bodies, the Board of Health Supervision is required to evaluate its own activities (9). The study was set up accordingly, and this article shows the findings of such a statutory evaluation.

Relative risk with 95 % confidence intervals has been calculated with the aid of a chi square test in SPSS Version 18.0.

Results

In the course of the study period, the county Boards of Health Supervision received 256

cases in the area of obstetrics and gynaecology. There were 101 cases related to births. In four cases it was not possible to obtain the closing letter, and in 16 cases it was a matter of minor injury to the child or birthing mother or an injury occurring during gestation. The material concerns 81 perinatal injuries reported by maternity units that account for 77 % of the births in Norway.

The health enterprises reported 42 incidents in accordance with the statutory duty to report pursuant to section 3.3 of the Act relating to the Specialist Health Service. The remaining cases were reported by the patient ombudsman or the mother/parents. The 81 cases consisted of 24 (30 %) babies who died during birth, 34 (42 %) who died shortly after birth and 23 (28 %) who incurred a serious injury. The reasons for the deaths or serious injuries are given in table 1. Of the 24 babies who died during birth, 17 were subjected to prolonged asphyxia.

Six babies suffered acute asphyxia as a result of difficult shoulder delivery, placental abruption or uterus rupture. There were five cases of intrauterine fetal deaths where the baby probably died during early labour, but where this was discovered when the mother entered hospital.

A total of 74 babies (91 %) suffered harm as a result of a serious shortage of oxygen or head injuries during birth.

58 (72 %) of patients had known risk factors before the labour began such as diabetes, preeclampsia, previous complicated labours, substantial overweight or weak life signs registered shortly before the birth.

Risk factors were added during labour in 54 (67 %) of cases. The risk factors were mainly changes in CTG/STAN in 31 patients (38 %), slow progress in 21 (26 %), discoloured amniotic fluid in ten and haemorrhaging during labour in seven. There were 58 primipara and 33 multipara.

55 (67 %) were surgical deliveries. Of these, 27 (33 %) were caesarean sections, 26 (32 %) vacuum-assisted deliveries and six (7 %) forceps deliveries. There were ten difficult shoulder deliveries.

Delayed delivery had a decisive effect in 56 (69 %) of the births. This took the form of delayed diagnosis of serious complications, delayed use of necessary monitoring and/or delay in the surgical delivery. At small maternity units (< 1 000 births per year) there was delayed delivery in 16 of the 21 cases (76 %) (table 2). In total there were 21 births with seriously incorrect interpretation of CTG/STAN over a period of several hours. In 13 cases the start-up of CTG monitoring was delayed. In nine cases the start of a caesarean section was considerably delayed after the decision to perform it had been taken. In five births there was a prolonged and difficult vacuum-assisted or forceps delivery (extraction time > 20 minutes). In three vaginal twin births delivery of the second twin was too slow.

The size of the maternity unit

Table 2 shows birth-related injuries distributed according to whether the maternity unit has ≥ or < 1 000 births per year. Serious incidents were reported by 26 of Norway's 53 maternity units. During the three-year period in question, these accounted for 77 % of the births in the country. There are significantly more cases of deaths or serious injuries in babies who are born at departments with < 1000 births per year than at larger departments (incidence 21/11502 = 1.8 per 1 000, 95 % confidence interval (CI) 1.5–2.04 versus incidence 60/127291 = 0.51 per 1 000, 95 % CI 0.46–0.54, RR 3.9, 95 % CI 2.4–6.4, $p < 0.001$).

Fetal monitoring

Fetal monitoring was unsatisfactory in a total of 55 births (68 %) (6). Inadequate monitoring was revealed in connection with 37 of 55 births. Most of them were due to failure to use cardiotocography, ST analysis of fetal ECG or scalp pH/lactate. Serious misinterpretation of cardiotocograms was the cause in 25 of the 55 births. The ST analysis was misinterpreted in six births.

Error on the part of medical personnel

Doctor and midwife often have shared responsibility for the assessments and decisions taken during the course of labour and delivery. Gynaecologists were present at 31 (38 %) of the births, but at 36 (44 %) of the births they were either not called for or were called for too late. A qualified doctor should have been called for in the majority of these cases. There is no information as to whether a specialist was present at 14 of the incidents. We found that there was an error in the medical assessment made by the doctor in 42 (52 %) of the cases. More than half of these consisted of misinterpretation of the fetal monitoring. In 29 cases (36 %) the incorrect assessment was determinative for the outcome.

There was error in the midwife's assessment in 36 of the births (44 %). The error consisted mainly of failure to monitor with cardiotocography or misinterpretation, but also failure to comply with departmental procedures. In 33 (41 %) of cases, the midwife's incorrect assessment was the main cause of the tragic outcome. Nine of these incidents occurred in maternity units with < 1 000 births per year.

Communication failure, mainly between midwife and doctor, was an essential factor in at least 19 (23 %) of the births.

Failure to comply with the department's internal routines (system failure) was reported in connection with 20 births (25 %). There were often inadequate procedures for monitoring during labour and delivery and handling of acute incidents. There was inadequate training of locums, inadequate equipment and a lack of guidelines for calling for doctors. Maternity units with

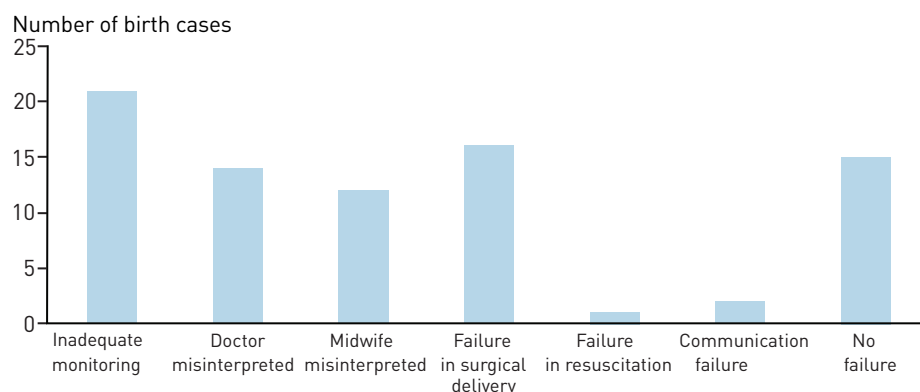


Figure 1 Main reasons for the adverse outcomes of 81 birth cases reported to the Board of Health Supervision in 2006–2008 which lead to the death of or serious injury to the baby

< 1 000 births received six such critical remarks.

Figure 1 provides an overview of what we regard as the main cause of error in each birth. In 15 births there was no error, because the serious outcome was due to preterm birth, unexpectedly sick child or acute obstetric emergency such as umbilical cord prolapse, placental abruption or shoulder dystocia. 52 (64 %) of births were suboptimally handled.

The Board of Health Supervision's decision

The county Boards of Health Supervision reached a conclusion of neglect of duty (breach of the health legislation) in 42 cases (62 %). Advice and guidance was given in 14 cases, and no significantly critical remarks in 27 cases (33 %). In the period 2006–08, 25 cases were forwarded to the Norwegian Board of Health Supervision because the neglect of duty was such that an administrative reaction (loss of or restricted authorisation, warning) could be called for. Thirteen warnings were issued, nine to doctors and four to midwives. In one case both midwife and doctor received warnings. In two cases an appeal was sent to the Norwegian Appeal Board for Health Personnel, but this did not lead to a change in the decision.

Discussion

Our study shows that in cases reported to the Board of Health Supervision where the child died during birth or incurred a serious injury, there were often risk factors present before birthing began. The principle causes of injury to babies were often wrong choices made during the course of labour and delivery, errors in interpretation and in the use of fetal monitoring, failure to call in qualified personnel and delay in the delivery. Significantly more cases were reported for maternity units with < 1 000 births per year than for bigger departments.

The material is based on perinatal injuries that were reported to the county Board of Health Supervision. This means that the material is selective and does not provide a full overview of the number of babies who

died or were seriously injured in Norway. The information was obtained from the closing letter in the supervisory board case and not directly from the patient records, which is a weakness. The figures must therefore be interpreted with caution. The material is also a case series, and relations are not necessary causal. Section 3.3 of the Act relating to the Specialist Health Service states that health institutions must make a written report to the county Board of Health Supervision as soon as possible in the event of serious injury to a patient as a result of the health service or incidents that could have led to a serious injury. In this material, the health enterprises reported a good half of the injuries. There may be different reporting cultures in different departments. The procedure for the type of injury that must be reported may be unclear or unknown in the department. The Board of Health Supervision knows from system audits carried out at eight small maternity units in the period 2009–10 that the reporting system for noncompliance or injuries is not well known or used in departments with < 1 000 births per year (10). This means that the number of injuries may be under-reported. It must also be borne in mind that small maternity units have already negatively selected and rejected some high-risk patients, so that the birthing population is different at small maternity units from that at large ones. Bearing this in mind, one would perhaps expect fewer serious incidents at the smaller maternity units.

The Norwegian Board of Health Supervision confirmed breach of the health legislation in 42 cases. These are first and foremost breaches of the requirement for prudence in section 4 of the Health Personnel Act, which states that health personnel shall conduct their work in accordance with the requirements to professional responsibility and diligent care that can be expected on the basis of their qualifications, the nature of their work and the situation in general. Warnings were issued in 12 of the cases in this material, but no cases ended with loss of authorisation.

The health enterprise may receive criticism for system error for breach of the requirement of prudence in section 2-2 of the Specialist Health Service Act if the management does not ensure that the healthcare personnel are able to perform their work properly. The system was criticised in 20 cases (25 %). The proportion that received criticism for system error in this material is somewhat lower than that found by the Board of Health Supervision in its analysis of cases subject to supervisory reaction following serious adverse events in the period 2003–2006 (7). The explanation may be that the Board of Health Supervision only deals with those cases where there has been gross error in the medical assessment or where there has been serious failure in the management and organisation system.

Our material shows that serious adverse events during births most frequently occur in pregnant women with known risk factors. This stresses the importance of recording risk factors before and during labour, so that the necessary precautions can be taken. It is important that women in labour are admitted to the right level with the necessary expertise. Our review indicates that risk factors are often not recognised or not adequately assessed in connection with admission to the maternity unit or during the course of labour. A number of high-risk births where a doctor should be involved take place without a doctor being called in. Specialists were called for in less than half of the births where there were serious risk factors.

It is primipara who are at the greatest risk during childbirth. There was a relatively high proportion of multipara in our material (41 %). A third of these had serious complications during previous births. Several of them were delivered by caesarean section. It is important to consider previous labours when the birth in question is to be monitored.

We found that fetal monitoring was deficient or that there was some misinterpretation in 68 % of the births. This finding is in agreement with other surveys (3). Delayed delivery is a substantial problem in over two thirds of the births. Cardiotocography that was started too late or misinterpreted often resulted in delayed summoning of a doctor. This underscores the importance of sound procedures in the department with regard to who is to receive cardiotocographic monitoring, but also the necessity of skilled interpretation. The department management is responsible for ensuring that the personnel regularly receive training in fetal monitoring, and they must ensure that both doctors and midwives are kept up to date. They must also ensure that the department has clear guidelines for who is to be called as needed, and when (5).

Delayed delivery in connection with surgical intervention was registered in connection with 18 births. Unclear reporting routines or service functions (operations, anaes-

thetia) without an on-call system may contribute to delayed delivery. The new quality requirements for maternity units stress that it must be possible to perform emergency caesarean sections within fifteen minutes.

Midwife and doctor must work well together in a maternity unit. We found that communication problems were a causal factor underlying the adverse outcome in 23 % of cases. Poor cooperation routines or little practice in acute situations may be the cause. We found that the midwife alone was responsible for the tragic outcome in 41 % of the births. In the light of our findings it appears reasonable to advise that the midwife and doctor environments in question should strive for more standardised and unambiguous communication and cooperation procedures.

A review of serious adverse events during labour and delivery reveals a high potential for learning. A Swedish-Danish survey from 1991 revealed suboptimal handling in 60 % of births with a fatal outcome (11). Half of these were due to misinterpretation of cardiotocograms, a fourth to poor departmental organisation. Misinterpretation of symptoms or complicated surgical deliveries were also often contributory factors. Berglund et al. in Sweden have reviewed labour and delivery cases where the child was awarded an Apgar score of < 7 after five

minutes and found that 62 % of the births were suboptimally handled (12). About half of these were due to misinterpretation of long-term cardiotocographic changes. In our material, 52 births (64 %) were suboptimally handled.

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References

1. Divisjon for epidemiologi, Folkehelseinstituttet, Oslo. www.fhi.no [20.10.2011].
2. Westergaard HB, Langhoff-Roos J, Larsen S et al. Intrapartum death of nonmalformed fetuses in

Denmark and Sweden 1991. *Acta Obstet Gynecol Scand* 1997; 76: 959–63.

3. Confidential inquiry into stillbirths and deaths in infancy. 4th Annual Report. London: Maternal and Child Health Research Consortium, 1995.
4. Medisinsk fødselsregister. <http://mfr-nesstar.uib.no/mfr/> [12.9.2011].
5. Et trygt fødetilbud – kvalitetskrav til fødeinstitusjoner. Oslo: Helsedirektoratet, 2010. www.helsedirektoratet.no [12.9.2011].
6. Veileder i fødselshjelp. Oslo: Norsk gynekologisk forening, Den norske legeforening, 2008. www.legeforeningen.no/id/131068.0 [12.9.2011].
7. Johansen BK, Braut B, Schou P. Uheldige hendelser på fødeavdelinger. *Tidsskr Nor Lægeforen* 2007; 127: 2670–2.
8. Lov 19. mai 2006 nr 16 om rett til innsyn i dokument i offentlig verksemd, kap. 2. www.lovdato.no/all/hl-20060519-016.html#2 [9.11.2011].
9. Virksomhetens interne styring, kapittel 2. Reglement for økonomistyring i staten. Bestemmelser om økonomistyring i staten. Fastsett 12. desember 2003 med endringer, senest 14. november 2006. Oslo: Finansdepartementet, 2006.
10. Helsetilsynet. Tilsynsrapporter. www.helsetilsynet.no [14.9.2011].
11. Langhoff-Roos J, Borch-Christensen H, Larsen S et al. Potentially avoidable perinatal deaths in Denmark and Sweden 1991. *Acta Obstet Gynecol Scand* 1996; 75: 820–5.
12. Berglund S, Pettersson H, Nnattinge S et al. How often is a low Apgar score the result of substandard care during labour? *BJOG* 2010; 117: 968–78.

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