UiT
THE ARCTIC
UNIVERSITY
OF NORWAY

Department of Clinical Medicine, Faculty of Health Sciences

Claims for compensation after alleged birth injury in Norway

A study of obstetric claims to the Norwegian System of Compensation to Patients from 1994-2008

Stine Andreasen

A dissertation for the degree of Philosophiae Doctor – XX-2015

UNIVERSITY OF TROMSØ

Cover: The draft ”Insektsfoster”, reprinted with kind permission from my colleague Kristin Skogøy

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Scientific environment

- Women's Health and Perinatology Research Group,
  Department of Clinical Medicine, Faculty of Health Sciences, University of Tromsø, Tromsø, Norway

- The Norwegian System of Compensation to Patients, NPE
  Oslo, Norway

- The Norwegian Medical Association
  Norway

- Department of Obstetrics and Gynecology
  Nordlandssykehuset, Bodø, Norway

Acknowledgements

First of all, I would like to express my deepest gratitude to my principal supervisor Professor Pål Øian who believed in me when I first asked him if this was something I could manage, for allowing me to ask and fail, for always being extremely patient with me, supporting me and supervising me through this project. I want to thank you for many scientific discussions, constructive feedback and for guiding me through some interesting scientific challenges. I would also like to thank my co-supervisor Dr. Bjørn Backe for your helpful attitude and valuable feed-back. I've been very fortunate being allowed to profit from your grand clinical and scientific experience.

I would also like to show my appreciation to my co-authors and collaborators in the projects: Professor Stian Lydersen for all your statistic knowledge, cooperation and explanation in our work with Paper III. Thank you for getting us through, I would not have made it without you. To Dr Kjell Øvrebø for sharing your clinical and scientific knowledge, and constructive comments to both statistical and linguistic presentation in Paper III.

This project could not be performed without all the help from the employees in NPE. I am very grateful to the Director of NPE, Rolf Gunnar Jørstad, for all your valuable information about how the NPE is organized, the history of the patient insurance system, comments to our papers, positive feedback and always quick responses. To Mads Morten Nøjd for organizing the economy and meetings, laws and rules. And last but not least to Mette Willumstad Thomsen for supporting me with all the patient documents, statistics from NPE including patient claims and payouts, always with a smile and happy to help.

I am also very grateful to all my colleagues in my department in Nordlandssykehuset Bodø for giving me this chance, supporting me and giving me the flexibility to perform this project. I would like to express my appreciation for all the support from my friends and family during my PhD period, especially my sister Lise for all it-support and giving useful linguistic input

and support. To my father, Arne, for teaching me that everything is possible, always encouraging me to reach my goals and always being there as a fantastic support for me and my family. To my dear husband, Kåre, thank you for giving me time and encouraging me to continue my work although life is busy. To my lovely children, Jakob, Ulrik, Kaja and Hanna, I am so proud of you. Every day with you is a day full of joy and happiness.

Bodø, June 2015

Stine Andreasen

Sammendrag på norsk (summary in Norwegian)

Fødselsskader er sjeldne i Norge i dag, men for de pasientene og familiene som rammes er det svært alvorlig. Konsekvensene ved å få et barn med handicap etter fødselsskade kan være store, og erstatningsutbetalingene fra Norsk pasientskadeerstatning (NPE) gjenspeiler dette. Erstatningsutbetalingen dekker noe av de økonomiske kostnadene pasientene er påført, men verken de fysiske skader eller sosiale konsekvenser. I NPE ligger mye informasjon om erstatningssaker. Ingen har tidligere studert dette materialet.

Ved gjennomgang av de 278 fødselsskadesakene som fikk medhold i perioden 1. januar 1994til 13. november 2008 fant vi at vanligste skade hos mor var alvorlige rifter, skade på blære og tarm, stor blødning og infeksjon etter fødsel. Oksygenmangel under fødsel og sekvele etter fastsittende skuldre var vanligste skade på barn. Vi fant at svikt i fødselshjelpen vanligvis skyldtes manglende kunnskap hos fødselshjelperen eller manglende kirurgiske ferdigheter (27 %). Av de 314 pasientene som søkte erstatning grunnet oksygenmangel under fødselen fant vi at mangelfull fosterovervåkning var vanligste årsak (50 %), enten grunnet feiltolkning av den elektroniske fosterovervåkingen eller manglende bruk av slik overvåking der det burde vært benyttet. Ifølge de medisinske sakkyndige var hovedansvarlig helsepersonell i disse sakene fødselslegen i 49 % og jordmor i 46 % av tilfellene. Menneskelig svikt ser ut til å være en viktig årsak til feilbehandling i alle typer fødselsskadesaker.

I vurderingen av samsvar i de medisinske vurderinger av hvorvidt det forelå feilbehandling var det kun moderat samsvar. Det var noe bedre samsvar i evalueringen av om feilbehandling var årsak til skade, men vi fant overraskende lav enighet i saker som omhandlet oksygenmangel under fødsel og sfinkterskade hos mor.

Gjennomgang av fødselsskadesaker er en viktig del av arbeidet med å redusere antall fødselsskader forårsaket av sviktende helsehjelp. Evaluering av de medisinske eksperters vurderinger vil kunne medføre bedret samsvar i denne type saker.

Summary

Birth injuries to mother or child are infrequent in Norway, but very serious to all patients and their families. The consequences of an asphyxiated child might be severe, and the payouts from the Norwegian System of Compensation to Patients (NPE) are huge. These payouts may compensate some of the economical expenses, but neither the physical sequela nor the social consequences. Despite this fact, the information concerning these cases has not previously been described.

Evaluating the 278 obstetric claims receiving compensation between January 1st 1994 and November 13th 2008, we found that sphincter injury, injury of intestines or urinary tract, hemorrhage and infection were the most common injuries of the mother. Asphyxia and sequela after shoulder dystocia were the most common injuries of the child. The most frequent reasons for inadequate care in all cases receiving compensation were failures in obstetrical and surgical skills (27%). Among the 314 patients claiming compensation due to alleged asphyxia to the child, we found inadequate fetal monitoring to be the most important factor leading to compensation (50%), including omission of monitoring despite indication or neglecting signs of fetal distress. According to the medical experts, the health personnel involved in the substandard treatment were an obstetrician in 49% and a midwife in 46% of the cases. Human error seems to be an important factor of inadequate obstetric care.

When we assessed the consistency of medical experts' evaluations of negligence in care, we found only moderate agreement. In the question concerning causality between the given care and the injury we found fair agreement, but there was an astonishingly low concordance between the experts in the evaluation of asphyxia and sphincter tear.

Describing cases of inadequate care is important when trying to decrease the frequency of obstetric injuries caused by inadequate care. Studying the experts' evaluations may increase the consistency in the judgment of these claims.

Abbreviations

CI	Confidence interval
CP	Cerebral palsy
CTG	Cardiotocography
ECG	Electrocardiogram
FIGO	The International Federation of Obstetrics and Gynecology
GBS	Group B Streptococcus
ICD	International Classification of Diseases
LMWH	Low molecular weight heparin
MMR	Maternal mortality ratio
MRI	Magnetic Resonance Imaging
NGF	The Norwegian Society of Gynecology and Obstetrics
NHSLA	National Health Service Litigation Awards
NPE	The Norwegian System of Compensation to Patients
OASIS	Obstetric anal sphincter injuries
PMR	Perinatal mortality rate
PPH	Postpartum hemorrhage
PSN	Patient Injury Compensation Board
STAN	ST segment analysis
WHO	World Health Organization

List of publications

The thesis is based upon three publications, referenced in the text by their respective roman numerals:

I. **Andreasen, S**, Backe, B., Jørstad, RG. and Øian, P. A nationwide descriptive study of obstetric claims for compensation in Norway. Acta Obstet Gynecol Scand 2012; 91: 1191–1195.

II. **Andreasen S***,* Backe B*,* Øian P*.* Claims for compensation after alleged birth asphyxia: a nationwide study covering 15 years*.* Acta Obstet Gynecol Scand 2014; 93:152-158.

III. **Andreasen S***,* Backe B, Lydersen S, Øvrebø K, Øian P*.* The consistency of experts' evaluation of obstetric claims for compensation. BJOG 2014; Epub ahead of print 26 August 2014.

"*Errare humanum est, perseverare autem diabolicum, et tertia non datur"*

(To err is human, to persist is of the Devil, and the third possibility is not given)

Lucius Annaeus Seneca, c. 4 BC–AD 65

1 Introduction

This thesis describes the obstetric claims for compensation in Norway in the period from 1994–2008. The quality in obstetric healthcare in Norway is high, and injury to mother and child is infrequent. Still such injury occurs, sometimes due to inadequate care. To put these adverse events in perspective, a historical description of fetal and maternal outcome is reviewed, followed by an introduction to the Norwegian System of Compensation to Patients (NPE), other reporting systems of patient injuries in Norway and compensation systems in the other Nordic countries, the UK and US. Further, methods for fetal monitoring in labor are described, as well as important maternal and child complications during delivery.

1.1 Historical, national and international perspectives

Pregnancy and labor have throughout history been a great risk to both mother and child. In 1900 the maternal mortality ratio (MMR; the number of maternal deaths during a time period per 100 000 live births) was 300/100 000 live births in Norway (1). The most common cause of maternal death was puerperal infection. From 1900 till 1960 the MMR decreased dramatically, reaching 30/100 000 live births. The main causes of death changed from infections to preeclampsia/eclampsia and hemorrhage. The reduced maternal mortality was probably mainly due to improved nutrition and hygiene. The direct MMR decreased further in the latter part of the 20th century to 5.5/100 000 live births (2). Today the direct MMR in Norway is 4.7/100 000 and the indirect MMR is 4.0/100 000 live births (3). The most common causes of maternal mortality in Norway today are hypertensive disorders in pregnancy and thromboembolism, half of which are deemed avoidable (3).

Maternal mortality is infrequent in Norway and other high-income countries, but still a severe problem in low- and middle-income countries. The worldwide MMR was 293/100 000 in 2013, representing a 22% reduction since 1990 (4). The MMR for developed and

developing countries was approximately 12 and 233 per 100 000 live births, respectively. The leading direct causes of maternal death in developing countries are hemorrhage (27%), hypertensive disorders (14%) and infection (11%).

Perinatal death is defined as stillbirths and deaths of the child in the first week of life. In 1900 the perinatal mortality rate (PMR; number of stillbirths or death of the child in the first week of life; the perinatal period commences at 22 completed weeks (154 days) of gestation and ends seven completed days after birth, divided by the number of live births during the same year, expressed per 1000 live births) in Norway was around 50/1000 live births (5), decreasing to 23/1000 live births in 1967 and 4.9/1000 live births in 2013 (6). Infection, an important cause of neonatal death in the first part of the last century, has decreased dramatically, and the total incidence of, for example, Group B Streptococcus (GBS) infections in newborns is around 1/1000 today (7;8). Case mortality rates for early onset GBS infection range from 2–3% for term infants to 20% for preterm infants. The main reasons for reduced PMR are probably improved nutrition and hygiene. It is probably also affected by antenatal and intrapartum care. In the beginning of the last century, there were only three delivery departments in Norway, and most women delivered at home. In 1950, 75% were in-hospital deliveries, and the number has increased to 97% today (5;6). The enhancement in patient selection according to risk and improved obstetric care is probably contributory to the positive development in fetal and maternal morbidity and mortality in Norway and other high-income countries over the last 50 years (9).

In 2000, perinatal deaths was the most common of all child deaths worldwide (10), and 99% of these four million deaths occurred in developing countries. The PMR was > 60/1000 live births in these countries, compared with < 10/1000 live births in high-income countries (11). The main causes of perinatal death in these countries are preterm birth, birth defects, infection and perinatal asphyxia (12).

In Norway, perinatal or maternal death is rare, but adverse events, causing injury to mother or child, are more common. Cerebral palsy (CP) following neonatal asphyxia often results in a severe physical, and sometimes also mental, disability. The consequences for affected families are huge, including for instance 24-hour care requirements, residential adjustments

and economic expense. Some of the financial costs will be compensated by social health services and the NPE, but the burden of a child with a disability can never be totally compensated for by financial resources. Similarly, a maternal injury, such as a sequela after obstetric anal sphincter injuries, can cause lifetime, everyday physical and psychological problems including fecal incontinence with social and economic consequences, including the lack of ability to work. Financial compensation can improve the economical, but not the social problems.

The Norwegian Society of Gynecology and Obstetrics (NGF) and the Norwegian Medical Association (DNL) have prioritized the improvement of quality in healthcare, including the establishment of guidelines and improved education. The first obstetric guidelines were published in 1995, and since then three revisions have been made. The national recommendations are the basis of most local guidelines, and are also important documents for medical experts evaluating adequacy in care.

In 2005 the NGF initiated a review of cases of birth injury reported to the NPE, with the long-term aim of reducing adverse events in obstetrics. According to their mandate the NPE should utilize information from compensation claims for quality improvement purposes. Thus, the NPE welcomed this opportunity to establish collaboration. A descriptive study was initiated, the protocol was developed in cooperation with members from the NGF and the NPE. Both organizations gave financial support.

1.2 The Norwegian System of Compensation to Patients

Until the Norwegian System of Compensation to Patients (NPE) was established in 1988, Norway had a traditional compensation legislation based on negligence. Through civil litigation, a person could receive compensation for injury if it was proven that health personnel acted negligently to cause their injury. This system was criticized because few patients managed to receive compensation, the rules for compensation were unclear, the courts of law were reluctant to impose liability on health personnel, and the risk of costs for the plaintiffs if they were denied compensation was too large (13). Successful compensation cases were rare when the patient had the burden of proof. The NPE was established with the

aim of preventing and compensating for injury to patients, to improve patients' legal protection (13;14).

The NPE is organized as a public body under the Ministry of Health and Care Services. All patient injuries, in the public or private sector, are now considered under the same compensation rules. The NPE is funded by the four regional health authorities in Norway. The distribution between authorities is determined based on each regional health authority's share of compensation payments over the last five years. Additionally, each hospital pays a certain amount for each case where they have been found liable (15).

Who is eligible for compensation from NPE?

The NPE is a no-fault system. To be eligible for compensation in Norway a patient's injury must have occurred due to or assumed to be a result of an error or omission in diagnosis or treatment, and the patient must also have sustained a financial loss. The main evaluations to be made by the medical experts are whether there has been a failure in healthcare provision (inadequate care), and if there is a causal connection between that failure and the patient's injury. These two criteria: liability due to failure in connection with healthcare provision and causal connection between injury and received healthcare must be fulfilled in order for the patient to be granted compensation.

When deciding whether an error or omission has taken place, the notion of reasonable expectation is employed. Hence, even though something irregular has occurred, the emphasis is not on whether someone is to blame for what happened. This implies that the patient can receive full compensation without anyone being found guilty of negligence. Negligence in care is legally defined as the failure of a physician or other healthcare provider to provide ordinary, reasonable or expected care, with the prudence or skill that would customarily be exercised by other reputable physicians treating similar patients, and which may result in foreseeable harm or injury. Negligence may be an act of omission either unintentional or intentional, characterized by inattention or thoughtlessness (16).

As a rule, compensation is granted if the injury is caused by a hospital associated infection even if care has been adequate, except where the infection is assumed to have been caused

by the patient's condition or illness. In special cases it is possible to award compensation even where the treatment is found to be professionally and medically sound, but where the injury has exceeded the level of risk which is deemed inevitable for the patient to accept from a legal point of view.

Case assessment

After receiving a compensation claim in the form of an injury report from the patient, the NPE obtains a statement from the care provider and a copy of the medical record. In most obstetric cases, the NPE requests an expert statement from one or more independent specialists in the relevant medical specialties. The claim officers consider the medical and legal circumstances to determine whether compensation should be granted. They will also assess the amount of compensation. The NPE's decisions may be appealed to the Patient Injury Compensation Board (PSN), and if rejected by the Board, claimants can choose to pursue the process through a court of law (15;17).

Before the establishment of the NPE in 1988, claims were handled by the hospitals' insurance companies. If the insurance companies denied responsibility, litigation was the only means for injured patients to claim compensation. The total number of cases in obstetrics brought before the court was less than ten, probably because the plaintiffs must carry the expenses if compensation was denied and because of the burden of establishing proof. Since 1988 around 60 obstetric cases have been brought before a court of law after being denied compensation by the NPE and PSN. In 25 of these cases the court decision was in the defendant's favor (J Storvik, NPE, October 6th 2014, personal communication).

1.3 Other reporting systems of adverse events in healthcare in Norway

This thesis is based on data from the NPE. There are parallel reporting systems in Norway, handling adverse events, but with other aims. This chapter will give a short introduction to the existing reporting systems in the study period.

The Norwegian Board of Health Supervision

In the study period, serious incidents of suspected inadequate healthcare were reported to the Norwegian Board of Health Supervision (Helsetilsynet). The intention was to collect

reports of incidents in specialist healthcare that led to or could have led to serious injury or the death of patients (18). The incidents are reported either by the patient/parents or by the healthcare provider, who is obliged by law to report patient injuries to the health authorities. The Norwegian Board of Health Supervision was responsible for the reporting system for adverse events in specialized health services until 2012. In 2012 the task of collecting reports was transferred to the Norwegian Knowledge Center for the Health Services (NOKC) (Kunnskapssenteret).

In the case of unexpected death or severe patient injury, an immediate report to the Norwegian Board of Health Supervision is required (19). These reports may result in prompt investigation in the hospital department to assess whether there has been negligence in care and also misconduct according to the Specialized Health Services Act. This is called incident-related supervision. If deficiencies are identified, the Norwegian Board of Health Supervision can give a formal response to the organization in the form of instructions to correct the situation, or a formal response to authorized healthcare personnel.

The Norwegian Board of Health Supervision receives approximately 30 obstetric claims every year (20;21). Inadequate care during pregnancy and labor is probably more frequent, since most adverse events do not cause injury to the patient (22).

Perinatal Audit Committees

A perinatal audit is the systematic, critical analysis of the quality of perinatal care, including procedures used for diagnosis and treatment, the use of resources and the resultant outcome and quality of life for women and their babies (23). The first Perinatal Audit Committee in Norway was established in 1984, following a perinatal audit in 1980 where 24% of 270 perinatal deaths in five counties of Norway were considered potentially avoidable (24). This audit was initiated when it was realized that Norway had the highest PMR among the Scandinavian countries, and led to national recommendations to establish county perinatal committees mandated to audit perinatal death on a continuous basis. The aim was to identify suboptimal practice with a view to improving perinatal outcomes and prevent potentially avoidable deaths.

The first perinatal audit in Norway in 1980 exposed the need for perinatal audits, but also the need for national guidelines, resulting in the first national obstetric guidelines published by the NGF in 1995 (24).

1.4 International reporting and compensation systems

Compensation systems such as the Norwegian no-fault system are rare in an international setting. Systems for reporting and compensation of adverse events are sometimes governmental, sometimes handled by the healthcare providers themselves and sometimes by insurance companies. This section will give a short introduction to reporting- and compensation systems in the other Nordic countries, the UK and the US.

The Nordic countries have a system similar to the Norwegian no-fault system, with minor diversities in the rules for compensation (25). These systems have made it easier for patients to claim compensation (26).

The UK has a well-developed system for reporting and investigating maternal deaths, and the "Saving Mother's Lives" report has been created every third year since 1952, including audits of maternal misses and near-misses (27). The UK also has an incident reporting system for all areas of the National Health Service (NHS), the NHS Commissioning Board Special Health Authority. This body receives confidential reports of patient safety incidents from healthcare staff across the UK. Clinicians and safety experts analyze these reports to identify common risks to patients and opportunities to improve patient safety.

In the UK the claimant needs to establish that there has been a breach of duty and an injury as a result of the breach. Claims are mainly handled by the National Health Service Litigation Authority (NHSLA) but also by a court of law. All delivery units in the UK are members of the NHSLA, and the total payout in obstetrical claims in 2012 was almost €600 million (28). Comparatively, the highest yearly payout in Norway is around 200 million NOK (€25 million) (2005), which is moderate compared to the British payouts, although the number of births is ten times higher than in Norway.

The US's healthcare system differs from Norway's, with a higher degree of private service- and insurance systems. The US health system has been a pioneer in quality assurance work, including that of the Joint Commission on Accreditation of Hospitals, evaluating healthcare organizations and inspiring them to excel in providing safe and effective care of the highest quality (29). In the US compensation claims are handled by no-fault compensation systems in some states (30), insurance companies or the court of law. The court system has been heavily criticized, one argument being that the experts' statements are not based on accepted practice and medical evidence (31). In many states in the US, obstetric litigation has become a serious threat to specialists in hospital practice, leading to defensive obstetric medicine with increased rates of cesarean delivery (32).

1.5 Monitoring and complications during labor

Obstetric care includes attendance during labor, assessment of fetal well-being, adequate clinical examination during and after labor, correct treatment when complications erupt and sufficient information for patients and relatives. To understand the assessment and judgment in obstetric claims for compensation to the NPE, knowledge concerning fetal monitoring and possible fetal- and maternal complications during delivery is necessary. This is described in this section.

1.5.1 Fetal monitoring during labor

Cardiotocography

Cardiotocography (CTG) was introduced in the sixties and is widely used for fetal monitoring during labor all over the world. Compromised fetuses have a higher incidence of bradycardia, decreased variability and non-reactivity, but although the sensitivity is high, the specificity is very low. The high rate of false positive CTG-traces have caused an increase in the rate of vaginal operative deliveries and emergency cesarean deliveries, clarifying the need for a supplementary test (33;34). Changes in CTG correlate to some extent with umbilical cord base deficit (BD) and its use may cause fewer neonatal seizures (34). However, the use of CTG seems not to affect perinatal mortality or pediatric neurologic morbidity (35).

The guidelines developed by the NGF are implemented in Norwegian hospitals (36), and CTG is classified according to the International Federation of Obstetrics and Gynecology (FIGO)-guidelines (Table 1). The recommendation for low risk women is not CTG, but traditional intermittent auscultation with a Pinard stethoscope or Doppler device every 15–30 minutes in the first stage of labor, and every fifth minute in the second stage of labor. High risk women should be examined by CTG intermittently or continuously. If the CTG is intermediary or pathological, it is recommended that major delivery departments apply a supplementary test (36).

Table 1. Classification of cardiotocographic patterns according to FIGO-guidelines

Cardiotocographic classification	**Baseline heart frequency**	**Variability reactivity**	**Decelerations**
Normal	110–150 beats/min	5–25 beats/min Accelerations	Early decelerations Uncomplicated variable decelerations with a duration of < 60 sec and a beat loss of < 60 beats/min
Intermediary*	100–110 beats/min 150–170 beats/min Short bradycardia episode	> 25 beats/min without accelerations < 5 beats/min for > 40 min	Uncomplicated variable decelerations with a duration of < 60 sec and a beat loss of > 60 beats/min
Pathological	150–170 beats/min and reduced variability >170 beats/min	< 5 beats/min for > 60 min Sinusoidal pattern	Repeated late decelerations Complicated variable decelerations with a duration of > 60 sec
Preterminal	Total lack of variability and reactivity with or without decelerations or bradycardia		
* Combination of several intermediary observations will result in an abnormal CTG.			

ST segment analysis

Because of the low specificity of the CTG, a supplement to this screening-test is required (37). The development of the fetal electrocardiogram (ECG) has led to ST segment analysis (STAN™), providing an electronic analysis of the fetal ECG. The ST waveform reflects the energy balance in the fetal myocardium (38). During hypoxia with anaerobic metabolism in the myocardium, there is an increase in the T-wave amplitude, and the STAN monitor will then display an "ST Event" alert. Action is then recommended according to clinical guidelines.

The use of fetal ECG in combination with CTG reduces the need for fetal blood sampling and the frequency of operative delivery, but a reduced risk of newborn morbidity has not been clearly demonstrated (39-46). The STAN is, however, not simple and interpretations are not straightforward (37). Some of the problems of STAN in clinical use are signal quality, lack of confidence following episodes where STAN's recording function was disconnected, misclassification of CTG, misclassification in cases of chorioamnionitis and the narrow time space from an ST event to the need for delivery (20 minutes) (37).

Fetal scalp blood sampling

Fetal blood sampling during labor, introduced in 1962, has been used as a supplementary test to CTG since the 1970s and is in daily use in many delivery departments today (36). The method is based on the pH value measured in the fetal scalp blood. The required volume for measurement in an acid-base machine is usually 15–50 μL. A pH value > 7.25 is regarded as normal, demonstrating fetal well-being and normal oxygenation. Values between 7.25 and 7.20 are regarded as sub-normal and require extra vigilance and repeat sampling within 20–30 min. Values of pH < 7.20 (or < 7.15 in the second stage of labor) are early warnings of fetal hypoxia requiring intervention such as intrauterine resuscitation or operative delivery (47). Lactate measurements require less blood and are technically easier to perform. Cutoff values depend on the method: commonly, values < 4.2 are regarded as normal, 4.2 to 4.8 are intermediate and should lead to repeated tests and > 4.8 should lead to intervention and delivery. Fetal blood sampling can provide additional information on fetal well-being, and may reduce the risk of operative vaginal deliveries and neonatal asphyxia (47).

1.5.2 Fetal and maternal complications during delivery

The most common complications in obstetric claims for compensation in NPE are described in this section, including incidence, risk factors, treatment and possible consequences. These complications may be caused by inadequate monitoring during labor, delayed or inadequate delivery or the patient may develop a sequela due to inadequate treatment of an obstetric injury. Some complications cause injury to the mother and some affect the child, while uterine rupture, placental abruption and infections are complications involving both mother and child. Neonatal asphyxia is the most common complication in NPE, and the evaluation of asphyxia, including the Apgar score, neonatal encephalopathy, Magnetic Resonance Imaging (MRI) findings and its correlation to CP is therefore described. Complications involving both mother and child are described first, followed by fetal complications and then maternal complications.

Uterine rupture

The incidence of uterine rupture varies from 0.03–1.0% for patients with a scarred uterus, depending on obstetric care, local health service and population studied (48;49). In an unscarred uterus, the risk of uterine rupture is extremely low, and estimated to occur in only 1/5700 to 1/20 000 pregnancies (50;51). The risk of uterine rupture after cesarean delivery is significantly increased in trial of labor (0.5%), compared with 0.03% in elective cesarean delivery (52). The risk is small in spontaneous labor without augmentation (0.15%), and considerably higher when there is augmentation with oxytocin (1.91%). Induction of labor with prostaglandin or oxytocin also increases the risk of rupture (0.55–0.88%) (53). Other risk factors include multiparity, obstructed labor and maternal age > 40 years (48;54).

The condition might cause injury, or even be life-threatening, to both mother and child, requiring immediate laparotomy with repair or hysterectomy. The risk of trial of vaginal birth after cesarean delivery is discussed (52;55;56). There is an increased risk of severe postpartum hemorrhage and adverse perinatal outcome in vaginal births after cesarean deliveries, but the maternal mortality rate, although low, is significantly increased for repeated elective cesarean delivery (52). The outcome of pregnancies following uterine rupture seems to be good providing delivery is by elective cesarean delivery (48;54;55).

Placental abruption

Placental abruption is the premature separation of the placenta from the uterine wall. The incidence is around 0.5%. Risk factors include smoking, hypertensive diseases, twin-pregnancies, previous cesarean delivery, abdominal trauma and cocaine use. The primary symptoms are vaginal bleeding and abdominal pain. Delivery should be performed immediately if the fetus is alive and at imminent risk of death. Maternal complications include severe hemorrhage, disseminated intravascular coagulation and renal failure, and the mother needs transfusion of crystalloids and blood to maintain circulating volume (55;56). The fetal outcome is severe, causing either death of the fetus or CP due to asphyxia in one third of the cases (57).

Infections

Sepsis is the most common cause of direct maternal death, and the incidence has increased from 0.85 deaths per 100 000 maternities in 2003–2005 to 1.13 deaths in 2006–2008 (27). Severe maternal sepsis can develop both before and after delivery. Sepsis before delivery might be due to premature rupture of membranes, but is also seen after miscarriages and other conditions. Half of these severe cases are, however, in women with intact membranes. Sepsis is often associated with preterm delivery and a high PMR (58). Severe sepsis after delivery is seen both after vaginal and cesarean deliveries. The most common microbes are Group A β-hemolytic streptococcus and E-coli (27;58).

Wound infection is reported in 2–16% of cesarean deliveries, depending on whether infection after hospital stay is included or not (59;60). The incidence in Norway is 8%, increasing with age older than 29 years and contaminated wounds (61). However, only 14–60% of infections are diagnosed during the hospital stay (61;62). According to Norwegian guidelines, prophylactic antibiotic is recommended in all acute cesarean deliveries in Norway (36).

Shoulder dystocia and brachial plexus injuries

Shoulder dystocia is a feared complication in vaginal deliveries, because it might be unpredictable and unpreventable. During the fetal head's cardinal movements of descent, flexion, and internal rotation within the bony pelvis, the shoulders descend to reach the

pelvic inlet. During the head's delivery, the shoulders rotate within the bony pelvis to arrive in its transverse diameter. If this rotation fails, the persistent anteroposterior orientation leads to obstruction of the anterior shoulder behind the symphysis pubis.

Shoulder dystocia is a clinical diagnosis. It should be suspected when the fetal head retracts into the perineum (turtle sign) after expulsion, due to reverse traction from the shoulders being impacted at the pelvic inlet. The diagnosis is made when the fetal head is delivered, but the shoulders do not deliver spontaneously or with gentle downward traction of the head. Another definition is a head-to-body interval of more than 60 seconds, or the need to use additional maneuvers apart from traction on the fetal head to deliver the shoulders. The incidence is around 0.5–2.5%, depending on the diagnostic criteria used and study population (63-65). There are many risk factors associated with shoulder dystocia, including maternal obesity and diabetes, primiparity, prolonged labor, post-term pregnancies and induction of labor, but the most important risk factors are high birth weight and operative vaginal delivery (64;66).

When shoulder dystocia is diagnosed, it is important to immediately apply the correct techniques to deliver the shoulders. If the fetus is not delivered by gentle lateral traction of the head, initiating McRobert's maneuvers (hip flexion) to straighten the lumbosacral angle is recommended. This will solve the problem in around 25%, with a low risk of injury to the child (67). McRobert's maneuvers can be combined with suprapubic pressure behind the fetal scapula. The next step is either rotation of the fetal shoulders to the transverse diameter or delivery of the posterior arm. Rotation is recommended because it is associated with fewer fetal injuries (67). Performing an episiotomy has been recommended, but an improved outcome is not proven (63).

There is an increased risk of shoulder dystocia in women with a prior shoulder dystocia, with a recurrence risk of 7.3% (68). Important risk factors in women with a prior delivery complicated by shoulder dystocia are birth weight greater than 5000 g, gestational diabetes and being overweight (69). These risk factors may help to identify patients at risk, but nonetheless 96% of shoulder dystocia in the second delivery arise in women without a previous history of shoulder dystocia (68).

Shoulder dystocia might cause asphyxia and even the death of the child. Brachial plexus injury and clavicular- or humeral fracture might be complications of the management of shoulder dystocia. Fractures are the most common complication, diagnosed in 15%. Brachial plexus injury is diagnosed in 5–15% of shoulder dystocia, depending on the management, but around 90% resolve themselves after 3–6 months without long-term disabilities (55;70).

It is the excessive lateral flexion of the fetal head, thereby overstretching the brachial plexus, which has been cited as the explanation for brachial plexus injury. This injury might, however, evolve without such traction, resulting in the "propulsionist" theory. When the anterior shoulder is arrested behind the symphysis pubis, the natural forces of uterine contractions might be sufficient to continue to propel the fetal body down the birth canal, resulting in damaging stress in the brachial plexus (71).

Neonatal asphyxia

Neonatal asphyxia might be defined as hypoxia (decrease in oxygenation of fetal tissue) with metabolic acidosis (72), or according to the World Health Organization (WHO) as the failure to establish breathing at birth (73). The ICD-10 classification defines severe asphyxia as heart rate < 100 beats/min at birth, no fetal respiration, pale color, no muscle tone and 1-minute Apgar 0–3 (74). Another definition is a deprivation of oxygen to a newborn infant that lasts long enough during the birth process to cause physical harm, usually to the brain (75;76). Historically, it was defined by a low Apgar score at 1 and 5 minutes, but a low Apgar score may have many other causes (77). Physiologically, asphyxia refers to the respiratory process leading to retention of CO_2, reduction in oxygenation and eventually metabolic acidosis. Hypoxia can be acute which is the case in cord prolapse, or chronic as in placental insufficiency. The fetus responds to hypoxia through increased oxygen extraction, increased heart rate and brain sparing. Sustained hypoxia leads to anaerobic metabolism with increased lactate production and metabolic acidosis.

The diagnosis of fetal asphyxia at delivery requires a blood gas and acid-base assessment (78). Umbilical cord sampling is easy and inexpensive, and pH and BD values are important to document intrapartum asphyxia. Samples should be extracted from both artery and vein immediately after delivery. The BD is calculated on the basis of the pH and the pCO_2 (79). An

exact cutoff for significant acidemia is discussed, but although not defined, a threshold of umbilical cord pH < 7.05 and BD > 12 mmol/L is associated with intrapartum asphyxia. The incidence of acidemia for term infants is around 4/1000 (80). For children with umbilical arterial pH < 7.0 there is a 6% mortality rate, while 18% has neonatal neurologic morbidity (80). There also seems to be a correlation between pH < 7.0 with BD > 12 mmol/L and CP, but this is difficult to measure due to the low frequency of CP (81). The metabolic component of fetal acidemia is the most important variable for predicting neonatal morbidity (82). Fetal stress estimated by fetal heart rate pattern may increase BD with as much as 1 mmol/L per two or three minutes, with terminal bradycardia being the most prominent CTG trace (83). Respiratory acidosis without BD is not seen to give long-term complications to the child (84;85).

Apgar score

The Apgar score was devised by Dr. Virginia Apgar in 1952 as a rapid way to assess the newborn. The system evaluates the newborn's need for resuscitation according to respiration, heart rate and skin color, neurological status by response to stimuli and muscle tone. Each element is given 0, 1 or 2 points and the sum is the Apgar score (ranging from 0 to 10).

The Apgar scoring system has a low specificity for intrapartum asphyxia, because many other factors such as prematurity, resuscitation and medication affect the values (86). An Apgar score at 5 minutes < 7 indicates need for further assessment and may indicate complications, especially < 4 (87). An Apgar score at 5 minutes < 7 is included in MacLennan's criteria of asphyxia, but few of these children develop a neurologic sequela (56). The current incidence of Apgar score at 5 minutes < 7 in Norway is 1.7/1000, and has remained unchanged for the last 15 years (5). More than half of the children diagnosed with CP have a normal Apgar score at delivery (77).

Neonatal encephalopathy

Neonatal encephalopathy is a clinical syndrome manifesting as respiratory difficulties, depression of tone and reflexes, a severely reduced level of consciousness (obtundation) and seizures. These symptoms develop in the early neonatal period. According to Sarnat and

Sarnat (88) neonatal encephalopathy is classified as stage I, II and III depending on the degree of symptoms, electroencephalogram (EEG) result and the duration of symptoms (Table 2). When neonatal encephalopathy is caused by hypoxic-ischemic brain injury it is appropriate to use the term hypoxic-ischemic encephalopathy (HIE).

The etiology of neonatal encephalopathy is varied: metabolic disorders, infection, hypoxic-ischemic brain injury and chromosomal abnormalities. The neurologic syndrome might be similar, independent of the etiology, and only a minor part of these cases develop CP (88-91).

Table 2. Classification of neonatal encephalopathy, according to Sarnat and Sarnat

Stage 1	▪ Duration < 24 hours with hyperalertness ▪ Uninhibited Moro and stretch reflexes ▪ Sympathetic effects ▪ Normal electroencephalogram.
Stage 2	▪ Obtundation ▪ Hypotonia ▪ Decreased spontaneous movements with or without seizures.
Stage 3	▪ Stupor ▪ Flaccidity ▪ Seizures ▪ Suppressed brain stem and autonomic functions ▪ The EEG may be isopotential or have infrequent periodic discharges.

Clinical signs suggestive of an early antenatal onset of acute brain injury include intrauterine growth restriction, small head size and contractures. As many as 70% of neonatal encephalopathy cases are associated with events arising before onset of labor (92). Intrapartum risk factors for neonatal encephalopathy include persistent occipito-posterior position, shoulder dystocia, emergency cesarean delivery, operative vaginal delivery, acute intrapartum events and chorioamnionitis. Emergency cesarean delivery and operative vaginal delivery are mostly due to signs of fetal hypoxia. Acute intrapartum events or sentinel events such as uterine rupture and placental abruption have a significantly increased risk of neonatal encephalopathy, but such events are only seen in 8% of infants diagnosed with neonatal encephalopathy (90).

MRI findings

Over the last 15 years MRI has been performed frequently as an investigation of the etiology of CP and in order to estimate prognosis. The dominating neuroimaging findings in neonatal encephalopathy are white matter and cortical/subcortical lesions. Periventricular leucomalacia is associated with chronic or subacute hypoxia, while lesions of the basal ganglia and thalamus occur after acute profound hypoxia (Figure 1) (93-96).

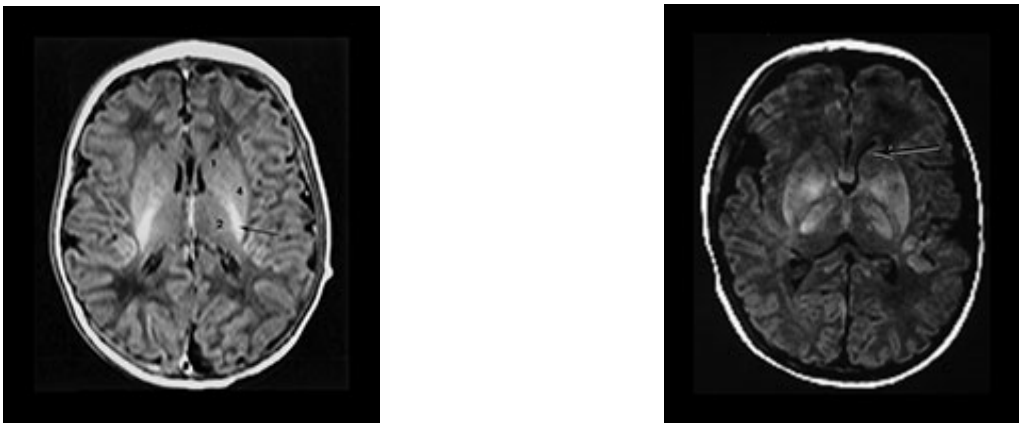


Figure 1. Normal and abnormal MRI signal intensity within the basal ganglia and thalami after hypoxic-ischemic brain injury

From *"MRI of perinatal brain injury, Pediatr Radiol 2010;40:819-33"*, with kind permission from Springer Science + Business Media.

If the results of the MRI obtained after the first 24 hours of life are interpreted by a trained neuroradiologist and no areas of injury are noted, it is unlikely that peripartum or intrapartum hypoxic-ischemic brain injury was a significant factor in the neonatal encephalopathy. Despite the advances in neuroimaging, the ability to precisely time the occurrence of an hypoxic-ischemic event is still limited (97).

Cerebral palsy

In 1862 the orthopedic surgeon William J Little (1810–1864) claimed CP to be a result of birth asphyxia, after studying the relationship between patients with spastic rigidity of the limbs and their birth histories (98). The obstetricians disagreed, arguing that most children born after prolonged labor and signs of asphyxia at delivery had no sequela, but the neurologists agreed with Little and named cerebral diplegia "Little's Disease". Sir William

Osler was the first to define the terminology of CP, but thought it was a disease of the spine (99). Sigmund Freud also studied the abnormal development of the brain after difficult labors, but the first definition of birth asphyxia and the relationship with CP came 130 years after Little's statement, published by The American Congress of Obstetricians and Gynecologists (ACOG) and American Academy of Pediatrics (AAP) in 1992 (7).

To determine whether birth asphyxia can be considered causative of CP, the International Cerebral Palsy Task Force developed MacLennan's criteria. The essential criteria are evidence of metabolic acidosis in the umbilical cord- or very early neonatal blood sample (pH < 7.0 and BD > 12 mmol/L), early onset of moderate or severe neonatal encephalopathy and CP of the spastic quadriplegic or dyskinetic type. Unspecific criteria helping to time the hypoxic event to the intrapartum period, but by themselves unspecific, include a sentinel hypoxic event followed by a sudden, rapid and persisting change in fetal heart rate (FHR), an Apgar score at 5 min < 7, signs of multisystem involvement and early imaging evidence of acute cerebral abnormality (100).

Cerebral palsy might develop as a sequela following shoulder dystocia, uterine rupture, placental abruption and other causes of intrapartum asphyxia. Other important causes of CP than birth asphyxia include metabolic disorders, prematurity, infection and chromosomal or congenital anomalies. It has been claimed that only around 8% of CPs are caused by peripartum asphyxia, but according to recent MRI studies the correct figure is about one out of three cases (90;101-103). The studies assessing reasons for CP are difficult to compare due to different criteria for acute intrapartum asphyxia and different study groups. In contrast to the moderate correlation between CP and neonatal encephalopathy or intrapartum asphyxia, the correlation with MRI findings is quite specific for the diagnosis (96;101).

Postpartum hemorrhage

Postpartum hemorrhage (PPH) is a feared complication, and in the developing world one of the most common reasons for maternal death. Postpartum hemorrhage is defined as either primary or secondary; primary PPH occurs in the first 24 hours after delivery and secondary PPH occurs 24 hours to 12 weeks after delivery. There are several definitions and

classifications of PPH. It might be diagnosed clinically as excessive bleeding resulting in signs of hypovolemia. Heavy vaginal bleeding is most common, but there might be internal bleeding after cesarean delivery or cervical laceration. Other definitions for PPH are estimated blood loss ≥500 mL after vaginal birth or ≥1000 mL after cesarean delivery or a 10% decline in postpartum hemoglobin concentration from antepartum levels (55).

The incidence of PPH (> 500 mL) is around 5% , 1–2% for severe PPH with blood loss more than 2000 mL (104;105). Uterine atony is the cause of PPH in 80–85% and might be caused by overdistension of the uterus due to twins, macrosomia or polyhydramnion, prolonged or induced labor, infection, inversion of the uterus, retained placenta or placenta fragments, or abnormal invasive placenta. Other causes are genital tract injury or coagulation disorders (105).

Active management of the third stage of labor has been shown to reduce blood loss (106;107). This includes administration of uterotonic agents after delivery of the child, uterine massage and active delivery of the placenta, of which uterotonic agents are the most important (108). Hypovolemia should be treated and blood loss replaced. Operative intervention might be necessary, including uterine balloon tamponade, B-Lynch sutures, iliac artery ligation or uterine devascularization, arterial embolization and – ultimately – hysterectomy (109). No method has proven better for the management of severe postpartum hemorrhage (109). Severe PPH may lead to maternal death, renal failure or Sheehan's syndrome due to infarction of the pituitary gland (85).

Injury to intestines or the urinary tract

The incidence of injury to the urinary tract after cesarean delivery is 0.3%, and bowel injury is even less frequent (110). There is an increased risk of injury in repeat cesarean deliveries (0.14 vs. 0.56), cesarean delivery with fully dilated cervix, cesarean delivery without an adequate urinary catheter, adhesions and uterine rupture (60;110).

Thromboembolism in pregnancy and the puerperium

The incidence of thromboembolism in pregnancy and postpartum is 1/1000 deliveries (111), and it is the second most common cause of maternal mortality in Norway (3). The relatively

high risk is caused by the hypercoagulable state of pregnancy. Antenatal risk factors include thrombophilia, obesity, heart disease, assisted reproduction, hyperemesis, gestational diabetes, age older than 35 years, multiple pregnancy and primiparity (111-113). Postnatal risk factors include surgery, preeclampsia, hospitalization, fluid and electrolyte imbalance, postpartum infection and transfusion (112;113). Multiple risk factors increase the total risk (113). There is insufficient evidence from randomized controlled trials to guide clinical decision-making, and the present guidelines are consensus derived (114;115). According to national guidelines prophylaxis should be considered for all acute cesarean deliveries, all elective sections with one or more additional risk factor, including body mass index (BMI) > 30kg/m^2 and women with two or three risk factors depending on severity (36). Low molecular weight heparin (LMWH) is recommended as a prophylaxis.

Obstetric anal sphincter injuries (OASIS)

Obstetric anal sphincter injuries are birth injuries caused by perineal lacerations. Perineal lacerations are classified according to ICD-10 into grades I–IV. Grades I and II do not involve the anal sphincter. Grade III involves the external sphincter and is subdivided into three subtypes: IIIA: partial tear of the external anal sphincter involving less than 50% thickness, IIIB: greater than 50% tear of the external anal sphincter and IIIC: internal sphincter is torn, in addition to rupture of the external anal sphincter. Grade IV involves the anal sphincter and the anal epithelium. Grade III and IV are characterized as OASIS. Established risk factors include primiparity, birth weight > 4000 g, instrumental vaginal deliveries, and previous OASIS. Others are maternal age 30 years or older, episiotomy, diabetes, induction of labor by prostaglandin, head circumference 35 cm or more, and African or Asian country of birth (116;117). Some of these factors are correlated to each other, such as birth weight > 4000 g, head circumference > 35 cm, diabetes, induction of labor and instrumental vaginal delivery. An episiotomy seems to be protective in instrumental vaginal deliveries (117).

The incidence of OASIS after vaginal delivery varies considerably, ranging from 0.1% to 17% (117;118). Even among the Nordic countries there has been a significant difference in the frequency of OASIS, with the lowest rates reported in Finland (0.6%), compared to the other Nordic countries (3.6–4.2%) (119). One of the main reasons might be the routines with manual assistance, and instructions to the mother during the last part of the second stage of

delivery. Another cause may be the episiotomy rate, which is significantly higher in Finland compared with the other Nordic countries (119). Different routines for diagnosing and registration might also account for the wide differences in reported incidence across different studies.

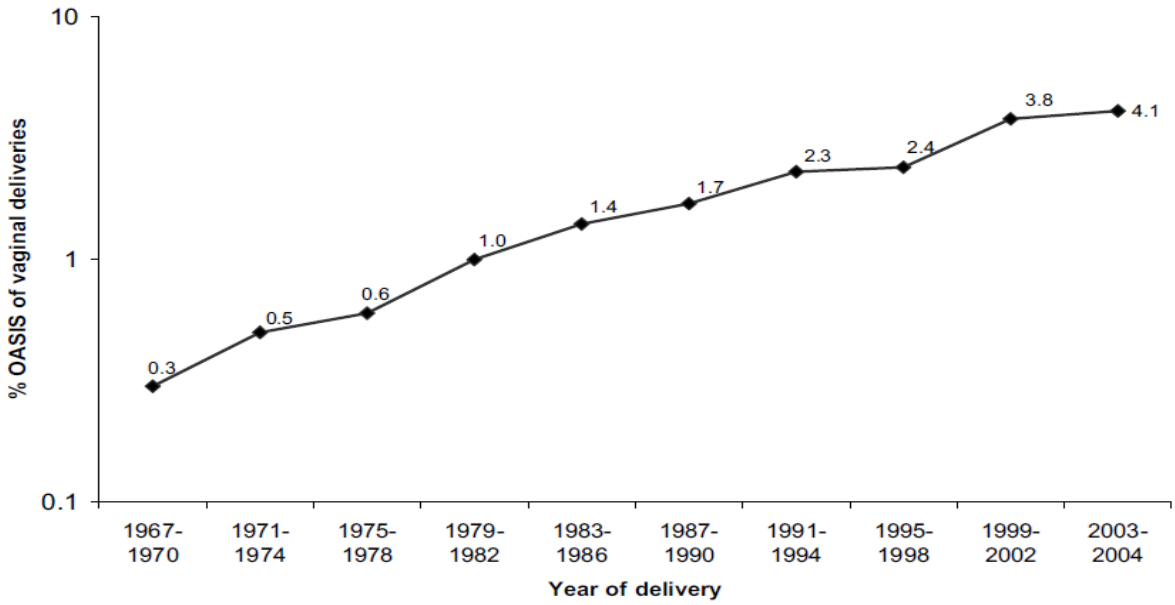


Figure 2. The occurrence of OASIS in vaginal deliveries by year of delivery 1967–2004, Norway.

From *Trends in risk factors for obstetric anal sphincter injuries in Norway, Obstet Gynecol. 2010 ;116:25-34*, with kind permission from Elham Baghestan

It is essential that OASIS is detected early to reduce the risk of complications. After delivery the mother should be examined for OASIS by rectal examination (120;121). If a sphincter rupture is diagnosed, the injury should be repaired according to guidelines (120). If diagnosis of an OASIS is delayed, or is inadequately repaired, the woman may have suffered a birth injury.

After primary repair of OASIS, 20–50% of the patients have symptoms of anal incontinence after two years, but the number decreases with time (122-124). The risk of anal incontinence is higher in grade IV injuries and when an anal sphincter muscle defect is diagnosed by ultrasound at follow-up (125).

2 Aims of the thesis

The main aims of this thesis were to:

- describe claims for compensation in obstetrics reported to NPE from 1994–2008, focusing mainly on those receiving compensation
- describe claims after neurological sequela or death following alleged birth asphyxia
- analyze the consistency of experts' evaluations of different types of birth injury, concerning inadequate care, and causality between injury and the healthcare provided.

Specifically, we intended to:

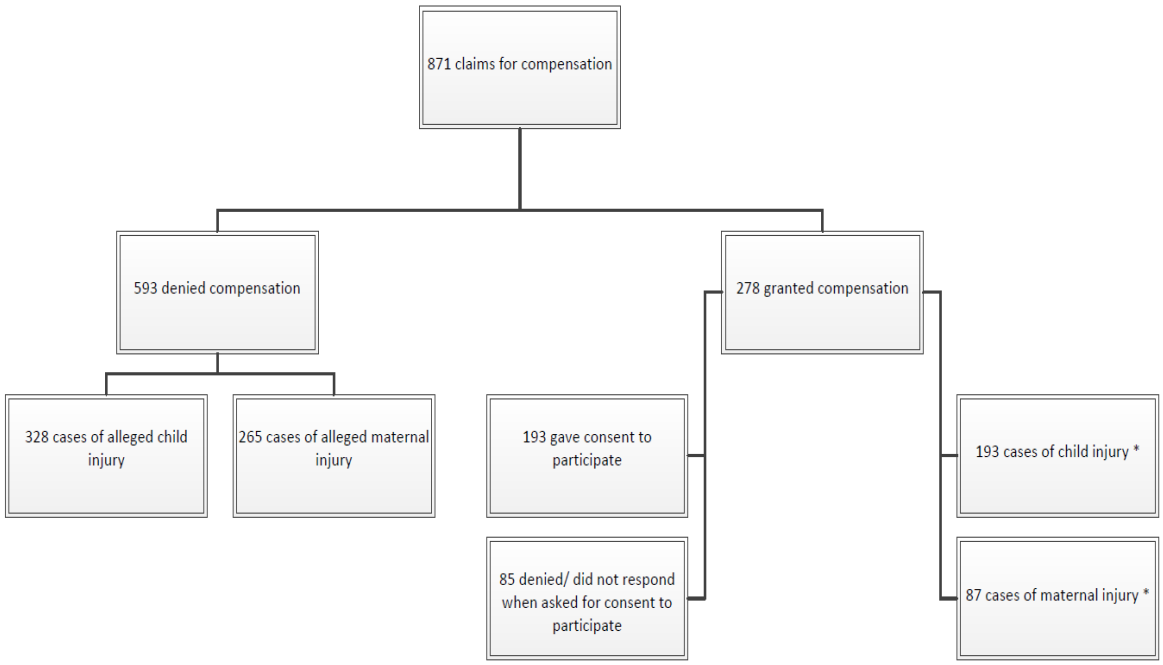
- explore which type of obstetric cases were involved
- explore reasons for inadequate care
- suggest measures for quality improvement in clinical practice.

3 Materials and methods

3.1 Study design and populations

Paper I is a descriptive cohort study of all closed obstetric claims for compensation in the study period between January 1st 1994 and November 13th 2008. The material comprises 871 obstetric claims made to the NPE, of which 278 claims resulted in compensation (Figure 3). Of the 278 claims granted compensation, 193 were cases of child injury, 87 were cases of maternal injury, and two cases involving injury to both mother and child. When asked to participate, 193 gave consent and 85 declined or did not answer. Cases denied compensation were reviewed according to type of injury and reason for denial.

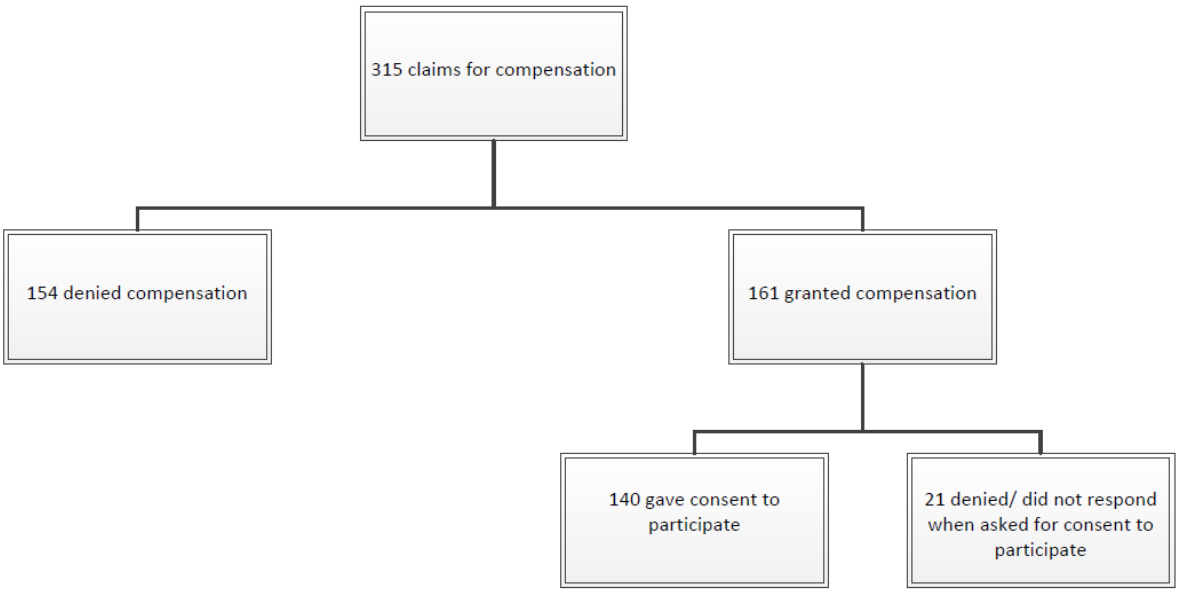
Figure 3. Flowchart of study population in *Paper I*, showing compensated and denied claims for compensation, consent to participate and cases of maternal- and child injury



* Two cases with injury both to mother and child

Paper II is a descriptive cohort study including all claims for compensation after alleged birth asphyxia. All 315 cases received by NPE between January 1st 1994 and November 13th 2008 and closed before the start of the study were included, of which 161 were granted and 154 denied compensation (Figure 4). Of those granted compensation, 140 parents gave consent to participate and 21 declined or did not answer.

Figure 4. Flowchart of study population in *Paper II*, showing compensated and denied claims for compensation after alleged birth asphyxia, and consent to participate



Paper III is a case-based survey of different experts' opinions in typical cases of birth injury. A total of 14 of the 15 medical experts that were most frequently used by the NPE during the last five years returned a questionnaire where 12 typical cases were outlined.

3.2 Methods

In *Paper I* and *II* we reviewed the statements of the experts and the conclusion made by the NPE, as well as the judicial documents when available. In cases where consent was given we reviewed copies of the medical records of the mother and infant including the antenatal record, the partogram, statements made by health workers involved and histology and autopsy reports.

All information was entered into a registration form designed for these studies (Appendix I). This registration form was designed before study commencement. The registration form was scanned by The Arctic University of Norway, Faculty of Health Science, Clinical Research Department.

Because the risk of complications during labor is increased in the presence of antenatal risk factors, we categorized the pregnancies as low or high risk at admission (91). The low risk group comprised singleton pregnancies with:

- cephalic presentation
- no chronic disease
- uncomplicated pregnancy
- spontaneous onset of labor
- gestational week 37+0 to 42+2.

All others were classified as high risk. The categorization remained unchanged although risk factors occurred during labor.

For the compensated claims we recorded:

- metabolic acidosis (pH < 7.0 and BD > 12 mmol/L)
- early, moderate or severe encephalopathy
- CP of the spastic quadriplegic or dyskinetic type
- signs of an intrapartum event as a sentinel hypoxic event or a sudden, rapid and persisting change of FHR
- Apgar score ≤ 6 at 5 minutes
- signs of multiorgan involvement
- early imaging evidence of acute cerebral abnormality
- neurological and mental disorders of the child
- assessment of the fetal electronic monitoring
- judgment of the actual mode of delivery
- decision-to-delivery interval.

In cases denied compensation and cases where consent was declined, the available information was limited to the experts' reports, including risk factors, Apgar score, sequela, etc. which proved insufficient for further description.

The cause of inadequate care was categorized into eight groups and are here exemplified:

- “failure in obstetrical or surgical treatment”: Anal sphincter tear not diagnosed at delivery, postoperative complications ignored or insufficient obstetric skills including trial of operative vaginal delivery where cesarean delivery should have been performed, inadequate treatment of shoulder dystocia
- “inadequate fetal monitoring”: CTG/STAN registration not performed despite indication, or misinterpretation of the fetal monitoring
- “errors in drug administration”: Inappropriate use of oxytocin, deficient antibiotic or LMWH treatment
- “more competent health personnel not being called when needed”: Midwife not calling a senior midwife or the doctor, resident not calling specialist and obstetrician not seeking help from other colleagues when needed
- “non-compliance with written guidelines”: Fetal monitoring not performed although recommended in national or local guidelines, deficient medical treatment (antibiotics/ LMWH/uterotonic agents) according to guidelines
- “time conflict in the delivery room”: Contemporary events in the department requiring the same health personnel
- “lack of written guidelines”: local procedures did not exist
- “poor organization of the department”: lack of material or human resources.

In *Paper II* the category “Failure in obstetrical or surgical treatment” was renamed “Lack of clinical knowledge and skills”, while there was no surgical treatment (repair of OASIS/surgical bleeding/intestinal or urinary tract damage) in the cases concerning asphyxia. “More competent health personnel not being called when needed” was renamed “Failure in obtaining senior medical help” following referee advice. The categorization of inadequate care in *Paper I* and *II* was agreed by consensus among the authors (SA/PØ).

The following principles for ranking of the causes were followed: In *Paper I,* the three most obvious causes of inadequate care were given by order of priority if multiple causes were present. In *Paper II* the causes of inadequate care were classified as either the main factor or a contributing factor if more than one cause was observed. If health personnel had neglected signs of fetal distress we always categorized “inadequate fetal monitoring” as the

main factor and “lack of clinical knowledge and skills” as a contributing factor. If the fetus was not monitored according to guidelines “inadequate fetal monitoring” was the main factor and “non-compliance with written guidelines” was categorized as a contributing factor. Cases with injuries following shoulder dystocia were categorized as “lack of clinical knowledge and skills”, but as “non-compliance with written guidelines” if the woman should have delivered by cesarean delivery due to known risk factors such as diabetes, previous obstetric history or macrosomia (36). Cases with a sequela after OASIS were categorized as “failure in obstetrical or surgical treatment” when inadequately diagnosed or repaired, with “more competent health personnel not being called when needed” as a contributing factor if the resident did not call for help. Uterine ruptures were categorized as “error in drug administration” if the woman was hyperstimulated, and as “failure in obstetrical or surgical treatment” if the rupture was not diagnosed despite signs and symptoms, or inadequately treated.

In *Paper I* injury to the infant was classified as:

- asphyxia
- infection
- fracture of skull or long bones
- shoulder dystocia
- brachial plexus injury
- intracerebral hemorrhage.

Whether the injury was related to events during pregnancy, intrapartum or postpartum was recorded. If the child was diagnosed with CP, the MacLennan criteria for a causal relationship to intrapartum events were used (100).

Injury to the mother was classified as:

- severe hemorrhage
- anal sphincter tear
- intestinal or urinary tract damage
- infection
- thromboembolism

- uterine rupture.

For each condition the extent of damage and sequela was recorded. Cause of death was recorded from the autopsy report, when possible.

In *Paper III,* we mailed an inquiry to the 15 medical experts most frequently used by the NPE during the last five years. Non-responders were followed-up once. No incentives were offered for participation, and all answers were anonymous. A 24-page questionnaire was presented to the medical experts, comprising 12 clinical scenarios with birth injuries to mother or child (*Paper III*; Appendix 1). There were three cases (cases 1, 9 and 12) with OASIS, two cases (cases 4 and 10) with peripartum hysterectomy, five cases (cases 3, 5, 6, 8 and 11) with birth asphyxia and two cases (cases 2 and 7) with shoulder dystocia. All scenarios were based on real compensation claims to the NPE, modified for confidentiality reasons.

A set of seven questions was asked in each case. These questions were formulated in the same way as the questions posed by the NPE to medical experts (*Paper III*; Table 1). We asked whether antenatal care and care during delivery had been in accordance with guidelines and recommendations, whether a different mode of delivery should have been performed, and in relevant cases whether the delivery was delayed. We also asked if there was a causal relationship between the healthcare provided and the injury, and if the patient had sustained a permanent injury because of inadequate healthcare.

3.3 Statistics

Papers I and *II* are descriptive studies. In *Papers I* and *II* analyses were performed in SPSS 18.0; the test of relative proportions and the Chi-square test were applied. Data are presented as mean, numbers or proportions (%).

In *Paper III* the degree of agreement was quantified in terms of absolute agreement, according to Fleiss' kappa and Gwet's AC1. Absolute agreement is the probability that two experts rate the same case in the same category. However, even if the experts categorized cases "without looking at the case", there would be some agreement due to chance. The Fleiss kappa and the Gwet AC1 inter-rater agreement quantify the agreement which exceeds

that due to chance, such that a value of 0 would indicate agreement no better than chance, and a value of 1 would indicate perfect agreement. Fleiss' kappa (126) for more than two experts is similar to Cohen's kappa for two experts (127). However, Fleiss' kappa, as well as Cohen's kappa, has the paradox of giving smaller values when there is high agreement in one category. Gwet's AC1 (128), on the other hand, does not have this paradox property.

The following categorization of chance-corrected agreement was used (129): A value < 0.2 is considered poor agreement, 0.21–0.4 fair, 0.41–0.6 moderate, 0.61–0.8 strong, and > 0.80 near complete agreement.

In addition to quantifying inter-rater agreement, we analyzed whether some experts tended to answer yes more often than other experts using a logistic model with questions and experts as crossed random factors (130).

Inter-rater agreement measures were calculated using the software AgreeStat 2013.1. This software uses methods described by Gwet (127). The logistic regression analysis was done in Stata 12. Ninety-five percent confidence intervals (CI) are reported where relevant.

3.4 Ethical considerations

According to the current practice of the Norwegian Ethical Committees we needed consent from all patients or relatives to have access to the medical records. *Paper I* includes patients receiving compensation, and all these patients or relatives were contacted and asked for consent. For the 85 not responding or declining to participate, we had access to the expert statements and the case summaries (Figure 3). These reports were provided by the NPE officers who removed all information from which the patient could be identified. Information from cases denied compensation was provided by NPE. These patients were not contacted for informed consent, since some of those patients and relatives had been working to receive compensation for years without success and might have a difficult relationship with NPE officers.

In *Paper II* all cases involving children aged less than sixteen years were included, and application for consent sent to the parents. We contacted the relatives (*n*=161) to obtain

consent to have access to the records in cases awarded compensation. For those not responding or declining to participate (*n*=21), and in those cases denied compensation (*n*=154), we had access to anonymous versions of the experts' reports (Figure 4).

The 12 scenarios in *Paper III* were all based on real compensation claims to the NPE. However, the scenarios could in theory be recognizable to the patients, relatives and involved health personnel. Because our study would not have any consequences for the real cases and involved patients, The Regional Committee for Medical and Health and Research Ethics gave exemption from this secrecy.

3.5 Approval

Papers I, II and *III* were approved by The Data Inspectorate at the University Hospital of North Norway (2009/1375). For *Paper III* the Regional Committee for Medical and Health and Research Ethics gave exemption from this secrecy (REK Nord 2010/3341-4).

4 Main results

Paper I

In *Paper I* we found that out of 871 claims after alleged birth injury, 278 (31.9%) resulted in compensation. In 13% of the cases the experts found healthcare adequate, but despite this the patients received compensation due to infection or according to the reasonability rule. Failure in obstetric or surgical treatment was the main reason for compensation in 27.0% and a contributing factor in 34.5%, seen for example as a failure in recognizing postoperative complications, trial of operative delivery where cesarean delivery should have been performed, or undiagnosed OASIS. Inadequate fetal monitoring was the main reason in 11.9%, including both lack of monitoring despite indication and failure in recognizing fetal compromise. Errors in drug administration, most frequently of uterotonic agents, antibiotics and LMWH, was the main reason in 4.3%, more competent health personnel not being called when needed, including midwife, resident and obstetrician, was registered in 7.6% and non-compliance with written guidelines in 14.4%. We defined these causes as mainly human errors and, according to this definition, human error was evident in 92% of the cases of inadequate care.

The system errors were poor organization of the department (the main reason in 2.5%), lack of written guidelines (0.4%) and time conflicts in the delivery unit (0.7%). System error was the main reason in only 8% of compensated claims where inadequate care was identified.

An obstetrician was the main responsible health profession in 51.2% of cases, and a midwife in 37.1%. In the remaining cases a resident, an anesthesiologist or a pediatrician was involved. In 9.8% of the cases a midwife and an obstetrician were equally involved in the inadequate care.

Injury to mother and child and amount of compensation given were described (*Paper I*, Table 1). The most common reasons for rejecting claims were the lack of a causal relationship between the care provided and the injury (66%), and care found to be adequate (28%). In 6%, compensation was not granted because there was no financial loss.

Paper II

Among the 315 claims for injury caused by birth asphyxia, compensation was awarded in 161 (51%) cases. In 13 cases the healthcare was found to be adequate by the experts, but the patients received compensation after appeal or in the court of law. Human error was the main responsible factor for fetal asphyxia in 89% of cases, while system error was only present in 3%. Inadequate fetal monitoring was the most important main factor leading to compensation (50%). Lack of clinical knowledge and skills was the main factor in 14% of cases, and a common contributing factor of inadequate care (47%), both in cases of misinterpretation of fetal monitoring and in obstetric emergencies such as shoulder dystocia, uterine rupture or placental abruption. Non-compliance with written guidelines, such as cases involving induction and stimulation of labor without indication, or CTG not performed according to guidelines, was the main factor of inadequate care in 11% of the cases. Failure in obtaining senior medical help was the main factor in 10% of cases, causing delayed diagnosis and treatment. Error in drug administration was the main factor in 4% of the cases, usually due to failure in oxytocin administration.

When we compared cases rewarded versus those denied compensation we found a significantly lower Apgar score at 5 minutes in cases rewarded compensation ($p < 0.0001$). Among cases rewarded compensation, asphyxia according to MacLennan´s three main criteria (100) was registered in 21% of surviving children and 56% of children with a fatal outcome. In 37% of surviving children and 44% with a fatal outcome, umbilical cord pH was not recorded, but the five additional criteria (100) were fulfilled. In 26/153 cases receiving compensation the Apgar score was > 6 at 5 minutes, and compensation was rewarded in 42% of surviving children with either a normal Apgar score or normal pH/BD. Cerebral palsy of the spastic quadriplegic or dyskinetic type was recorded in 75% of compensated cases, and only in 12% of denied cases, whereas unspecified CP syndrome was more frequent, with 19% in denied, compared with 2% in compensated cases.

According to the medical experts the health personnel involved in inadequate treatment was an obstetrician in 49%, a midwife in 46%, a resident in 9% and a pediatrician or anesthesiologist in 4% of cases. In some cases two or more categories of health personnel were involved, resulting in a sum > 100%.

Based on the findings in *Papers I* and *II*, measures to improve quality in clinical practice are suggested and discussed in 5.4.

Paper III

In the study of experts' agreement in claims for compensation, the main questions were whether care was inadequate (negligence) and if there was a causal relationship between the injury and the healthcare (causality). We found only moderate agreement in the evaluation of negligence in care. In the question concerning causality between the care given and the injury we found fair agreement, but there was an astonishing low concordance between experts in the evaluation of cases with asphyxia (*n*=5) (kappa 0.05) and sphincter tear (*n*=3) (kappa 0.09). However, the overall kappa value was strongly affected by good concordance in evaluation of hysterectomy (*n*=2) (kappa 0.39) and shoulder dystocia (*n*=2) (kappa 1.0).

A logistic model with the outcome that the experts stated negligence and causality, showed that the probability of answering "yes" varied considerably between the cases, but did not vary between the experts. But some cases (such as case numbers 9 and 12) appeared "difficult" to judge, resulting in discrepancies between expert judgments for these cases. It was not that some experts tended to answer "yes" more frequently than other experts.

5 Discussion

5.1 Discussion of main findings

In *Papers I* and *II* we categorized inadequate care in eight groups to identify the most important reasons for inadequate care, and distinguish between human and system error. Human errors were responsible for almost all compensated cases, with error in fetal monitoring and lack of clinical knowledge and skills (failure in obstetric or surgical treatment) as the most common reasons. Lack of clinical knowledge and skills included inadequately performed operative delivery, inadequate management of shoulder dystocia and incorrect assessment of labor progress. Error in fetal monitoring is also recorded as the most common cause of inadequate care in other studies (131-135), and seems to be one of the most difficult aspects of current obstetric practice. Inadequate fetal monitoring was registered in 71% of cases receiving compensation for birth asphyxia. The CTG classification in single cases will often be discussed because assessment is demanding, and even intra-observer consistency is low (136;137). Regular training in CTG interpretation may, however, lead to better inter-observer agreement, and improved quality of care (138). The use of STAN might reduce the need for operative delivery, but has not shown reduced perinatal morbidity or mortality (39-46). Nevertheless, despite the inherent complexity of CTG evaluation, many of the CTG recordings in our dataset were pathological to an extent that makes it difficult to understand why involved health workers did not act on them. Further research is recommended.

The analysis of claims for compensation after birth asphyxia in Sweden identified substandard fetal monitoring and delayed delivery as the most common types of inadequate care (139). In Denmark and Finland, too, failure in fetal monitoring, causing delayed diagnosis of asphyxia, was found to be the most common reason for error in obstetric care (26;133). Berglund et al. identified labor dystocia as the most frequent situation associated with inadequate care causing asphyxia, but also previous cesarean delivery, gestational or pregestational diabetes in pregnancy, small- and large-for-gestational-age infants, post-term pregnancies, twins, and breech deliveries were risk factors for inadequate care (140).

We found errors in oxytocin medication in 20% of the cases, which is less than in other studies (22;132;139;141) and might reflect our method as we rely on the experts' evaluation. For example, if the expert did not mention hyperstimulation as a problem, hyperstimulation was not registered by us. They might have focused on the inadequate fetal monitoring or inadequate operative delivery, instead of the possible cause, including fetal hyperstimulation. Errors in oxytocin administration causing patient harm and risk of litigation has led to the implementation of oxytocin checklists during labor. These checklists include assessment of the fetus, contractions and risk factors at certain intervals during labor (142-144). Such checklists seem to result in reduced oxytocin administration, may decrease the cesarean delivery rate, improve fetal outcome, and reduce litigation claims.

Umbilical cord pH and BD were registered in only 45% of cases. Low attendance to cord pH measurements are also seen in other studies (139;145). This may partly be explained by our cases going back to 1994 when umbilical cord pH was infrequently performed in Norway. In the 1998 Norwegian guidelines there were no recommendations of umbilical cord pH sampling (146). In the guidelines from 2008, sampling was recommended following acute cesarean delivery, operative vaginal delivery, in labor with fetal scalp blood sampling or CTG/STAN, and if the fetal condition was affected at delivery (36). Current practice in Norway varies; from cord sampling in all deliveries in half of all major departments, to less than one third of deliveries in smaller departments (147). Hopefully, blood sampling will be more frequent in future for the status of the newborn to be assessed in an objective manner.

The Apgar score was > 6 at 5 minutes in 26/153 cases receiving compensation due to birth asphyxia. These cases would be easier to evaluate in the presence of an umbilical cord pH, but in the absence of cord pH, experts should use the other MacLennan criteria (100). Some patients received compensation for neurologic injuries caused by asphyxia, despite a normal Apgar score at 5 minute and unknown cord pH. It is well known that patient outcome influences how we see the process, and in trying to explain failure investigators seek failure (148). These results may also be explained by an outcome bias; severe negative outcomes tend to result in more negative judgments of the given treatment than less serious outcomes (149). This may explain why there was a higher compensation rate after the death of a child.

There might also be some hindsight bias, meaning that elements or factors that were not seen or understood at the time when the injury occurred seem obvious in retrospect (148). Hindsight bias has been shown to be a disadvantage of nearly all methods of measuring error and adverse events within the healthcare system (150). If the critical data were known at the occurrence of the adverse event, it is tempting to judge the advent as an error, but the problem is often identifying the relevant observations among all the irrelevant data. This is a lot easier in hindsight when the outcome is known and all relevant data are present (151). A behavior that can seem irrational in hindsight was not necessarily erroneous at the time of the incident (152).

We attempted to create an overview of the inadequate obstetric care in our material, with an approach that could be reproduced in future studies. Categorizing causes of inadequate healthcare is difficult. We categorized inadequate treatment in eight groups, according to failure in diagnosis and treatment. Our categorization was based on well-known problems in obstetrics (i.e., fetal monitoring) and comparable studies (134;153). To provide consistency, the categorization was agreed by consensus between the two authors, who also decided the principles that should be followed and the ranking of causes.

Classification into categories represents a simplification, but provides a basis for increased understanding and development of strategies to reduce the frequencies of these incidents. A confidential enquiry into cases of neonatal encephalopathy categorized inadequate care as the failure to recognize, failure to act or failure to communicate during labor, or the failure to act appropriately after labor (134). Subgroups were failure in fetal monitoring, failure to recognize poor progress in labor, hyperstimulation, delay in communication and delayed information to more senior staff. They found that more than 90% involved care provided by health professional. Other studies have categorized errors as “knowledge-based errors”, “rule-based errors”, “skill-based errors” and “technical errors”, with similar results as our study (153). In half of all the incidents in anesthesia, some knowledge-based factors were involved. Rule-based errors, including the failure to apply to guidelines, contributed to between one quarter and one third of all accidents. Skill-based errors, slips and lapses, contributed to one quarter of all incidents, and only one out of eight incidents was due to

technical errors. The authors conclude that there were elements of human error in more than 80% of incidents and accidents.

The legitimacy of the NPE compensation system depends on its reproducibility, which is whether comparable patient scenarios are handled similarly. *Paper III* shows that there is only a moderate level of overall consistency among experts' evaluations of negligence and causality in common obstetric claims for compensation. The agreement was higher in cases with well-known diagnostic criteria and established guidelines, such as in the two cases of shoulder dystocia.

The cases in this study represented typical and frequent obstetric complications to mother or child and might have a constructed clarity not always seen in regular clinical cases. The agreement in real case scenarios might therefore be even poorer than our results. However, we might have chosen too many difficult cases. The intention was to select cases with an average level of difficulty. Some of these claims were awarded and some were denied compensation. The original outcomes of the claims were unknown to the experts. The categorization of treatment as correct or incorrect is sometimes difficult. However, some results surprised us: In cases of asphyxia the evaluation of a causal relationship did not follow the well-known criteria (100). Whether MacLennan's criteria are unknown to the experts or they deliberately disregard these accepted guidelines is unknown to us. According to NPE guidelines, even when care is considered to be inadequate, compensation should not be granted if there is no causal relationship between given care and the patient's injury. National and international guidelines, use of diagnostic criteria like MacLennan's (100), and establishment of clinical standards may improve the consistency of expert's work.

Medical experts engaged by the NPE today must complete an introductory course into judicial laws and the compensation system. When cases are handled by only one expert, the safety barriers in compensated claims are the NPE officers judging the case, the involved hospital department whose opinion is always collected, and the patient. In denied claims the judgment may be overruled by the PSN or the court of law.

All patients who may have sustained an injury due to received healthcare should be urged to file a claim to the NPE for economic compensation. In the first five years of the study period the mean number of obstetric claims for compensation was 85, of which 24 were granted compensation. In the period from 1999–2003 the number was 97, of which 27 were granted compensation, and in the last period the mean number of claims was 105, of which 40 were granted compensation. Using Poisson regression we found that the expected number of claims per year was approximately constant, but there was a yearly increase of 4.1% in number of claims receiving compensation after injury of the child (CI 1.5% to 6.8%, $p = .002$). In maternal claims, on the other hand, there was a yearly increase of 4.0% in the total number of claims (CI 2.0% to 6.1%, $p < .001$), and a yearly increase of 4.3% in the number of claims receiving compensation, so the proportion of claims granted compensation is approximately constant. The total payout from the NPE in obstetric claims is increasing propotional to the number of rewarded claims. The payout increased from a mean of 45 million NOK in 1994–1998 to 89 million NOK in 1999–2003, and 104 million NOK in 2004–2008. Claims are registered at the time of the submitted claim. The evaluation of the claims are often protracted, similarly, the determination of compensation amount. Therefore the numbers of claims and total payouts are likely to increase in the final years of the period.

The intention of the no-fault NPE system is to compensate for injuries caused by inadequate care. An ongoing discussion is whether the system leads to discrimination of patients with injuries that are not caused by inadequate care. For example, all patients with CP might benefit from economic compensation because of their health-related expenses, but only those very few caused by birth asphyxia following inadequate healthcare will receive compensation. The same applies to patients with permanent brachial plexus injuries, some will be compensated and others not depending on whether care is found to be adequate or not. It has been asked whether this compensation system is “fair” to patients, distinguishing between the “lucky unlucky” and the “plainly unlucky” (154).

5.2 How to assess healthcare?

Surveillance, assessment and understanding of adverse events in healthcare are demanding due to the complexity of the patient situation and the settings in which healthcare is provided. The Donabedian model, among others, provides a conceptual framework for

surveillance and evaluation of health services and care (155). According to Donabedian, assessment of quality of care relates to structure, process and outcome. Structure represents the system factors or setting in which healthcare is provided. Structure involves the resources available for care, including the economy, physical facilities, as well as the resources and limitations of patients and healthcare providers.

The process of care is the interaction where actual care is provided to the individual patient. In our material, examples of identified failure in process were: inadequate diagnosing and suturing of OASIS, failure in the process of operative vaginal delivery and failure of recognizing fetal compromise.

Health outcome represents the objectively observed results and events or even the patients subjectively experienced results of the care. The outcome is the ultimate validation of studied structures and processes in medical care (155). Outcomes of healthcare may be difficult to quantify and some outcomes manifest or are identified late (minimal brain dysfunction, learning disability, CP of the child) (156). Selection of outcomes for analyses of structure and process is demanding, and late manifests of healthcare malpractice need replacing with measurable outcomes. Fetal and maternal complications such as plexus brachialis injuries due to shoulder dystocia, brain damage due to neonatal asphyxia and anal incontinence due to OASIS were deemed important and relevant outcomes in our studies.

In analyses of outcome, the incidences may be due to one or several factors in structure or process or even due to factors within both areas. A healthy mother and child of pregnancy (outcome) in women admitted with placental abruption (structure) cannot be guaranteed despite optimal treatment (process). Any identified lack of clinical knowledge or skills among health personnel might be due to a structural problem, and education and training of doctors and midwives need to be evaluated in order to improve the healthcare. Moreover, in evaluation of obstetric claims for compensation, identification of structural problems is just as important as identification of inadequacy in the process of patient care.

5.3 Is it possible to distinguish between human error and system failure?

Distinguishing between human or system errors might be difficult, but probably useful in the understanding of why errors occur. In categorizing these events, we must be aware of the different concepts. An error may be defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve the aim (157). An adverse event is an injury caused by error in the medical management, rather than the underlying condition of the patient. Negligent adverse events represent preventable adverse events that satisfy legal criteria used in determining negligence (158).

A personal error indicates that the health personnel involved are responsible for the failure, either due to forgetfulness, inattention or sometimes even a lack of clinical knowledge and skills, sometimes referred to as slips and lapses (153). Human errors in our material could be a midwife not recognizing an abnormal CTG pattern despite proper education, or an obstetrician increasing the infusion of oxytocin when the uterus is hyperstimulated with a previous scar. The system approach indicates that the failure is caused by a system that lacks the necessary safety barriers and safeguards to limit the incidence of dangerous situations (157;159). In the system approach the failure is seen as the consequence rather than the cause. A system failure would be an untrained midwife being left to take care of a high risk woman with an abnormal CTG, without anyone to ask for help. It could also be the obstetrician ordering increased infusion of oxytocin without access to the woman's previous history of cesarean delivery and poor communication with the attending midwife.

The Swiss Cheese model developed by James Reason is a popular illustration of how system failures develop (157). An organization's defenses against failure are modeled as a series of barriers, in this model represented by slices of cheese (Figure 5). The holes in the slices represent weaknesses in each of the individual parts of the system. According to the Swiss Cheese model, the operator's part is usually that of adding the final step to a cascade of accidents, making the accident look like a man-made disaster (151). The model has, however, been criticized because sometimes personal failures may be the dominant factor: people just slip up (160). This may be the case in our studies where we sometimes were unable to find the system factors, finding only human error. We need to be aware of the

problem with human inattention and forgetfulness, as when neglecting a pathological CTG pattern despite obvious abnormality.

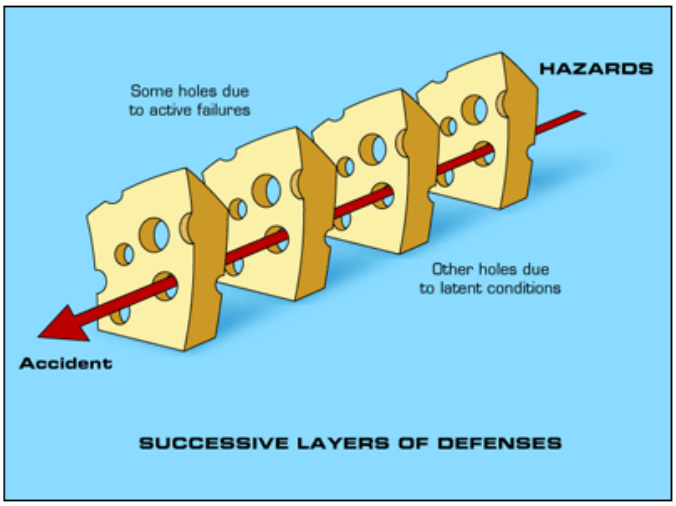


Figure 5. Illustration of the Swiss Cheese model.

From *Human error: models and management by J Reason (2000),* with kind permission from BMJ.

The risk of omission in treatment increases when clinical problems arise (152), and inadequate care is more common in cases of poor outcome (22). This could explain why the obstetricians make wrong decisions when the CTG is abnormal, the woman is tired, the contractions are poor or the baby's head is still too high for vaginal delivery. It may be influenced by simultaneous situations, such as a postpartum bleeding in the delivery room next door. In our study a midwife was involved in almost half of the claims. In the Nordic countries, normal vaginal deliveries are conducted by midwives. The obstetricians on call are not continuously present in the ward, but are summoned by the midwife when the situation changes from normal to abnormal. In these cases the problems should not have escalated before the doctor was called. There might, however, be some unrecognized organizational problems we were unable to uncover in our material, such as time pressures, poor supervision, and/or frequency and quality of training and education.

When evaluating adverse events it is important to remember where and when they occurred. It is tempting to judge according to our own facilities. Difficult medical situations

will be handled differently in small departments with limited resources, if time pressures occur or in understaffed units. Competitive events are the norm in many obstetric departments, and may increase the risk of slips, failures in communication and adverse events. We were not able to expose many situations like this in the data we investigated, but that does not necessarily mean they did not occur. The information provided by the NPE includes patient information and treatment given, but may not include potentially contributing factors such as management problems, communication problems, prolonged work hours or equipment problems. This may account for our tendency to interpret adverse events as mainly due to human error. Further studies should be performed, preferentially from a human factors approach (151), before firm conclusions are drawn.

When discussing human and system errors and how to build a system to reduce the uncertainty of the human factor, the health system is often compared to the field of aviation, which has had great success in decreasing the frequency of adverse events (158). Health systems can learn a lot from aviation, but not everything is comparable. When entering a plane we do not question who is piloting the aircraft, but when having surgery or obstetric care we like to know our surgeon and his reputation. Still the comparison between the pilots' work, repeating the same procedures every flight, every day, and the obstetricians' work including consultations and different surgical and obstetrical procedures, is unjust to the doctor. Although all pilots are adequate in normal flights, everyone would like the best pilot when an accident happens and personal qualifications counts. This is a question of education, personal skills and experience, and the system will never replace that kind of knowledge.

5.4 How to reduce inadequate healthcare?

Well-functioning reporting systems are necessary to improve future adverse events. Apart from an accessible no-blame system, there should also be a safety culture encouraging the reporting of these events (151). Deciding when to report, however, is not always clear. An adverse event may be interpreted as incompetence, system or technical failure or just bad luck, and should be evaluated according to expected skills, workload, patient morbidity, well-known complications and outcome.

The UK's confidential enquiries are useful in the assessment of inadequate care, and should be combined with feedback of evaluations of case-management to individual clinicians and clinical teams (27;134). Confidential enquiries are shown to improve obstetric practice (27;161). Perinatal audits look into cases of inadequate care. In internal audits, the caregivers involved in the cases are often part of the audit group. This might influence the assessment. Reporting adverse events in a national system displays the amount of adverse events and types of injuries, and also makes it possible to decrease the patient's risk of harm through the removal of irresponsible health personnel, or forcing the departments to conduct necessary improvements to increase healthcare quality (18). The fear of accusation from health authorities and colleagues must not interfere with the duty to report. It is important that the persons looking into the adverse events and audits should not be the same as those hiring, firing and blaming (151).

Guidelines are probably important to increase patient safety (162;163). Well-known and up-dated written procedures available to all employees, including temporary staff, will probably reduce inadequate care. Evaluating medical research and creating medical guidelines takes a lot of effort, but many international and national guidelines already exist, which could be adapted to local conditions. Guidelines concerning fetal monitoring must be embedded into clinical practice, and all staff using CTG or STAN must be able to interpret the recordings and act upon pathology. Error concerning fetal monitoring is a major problem in obstetric departments, causing asphyxiated children and sometimes death (83-85). We found inadequate fetal monitoring to be the most important single reason for birth injury. Training and testing of CTG interpretation should be mandatory, and midwives and obstetricians should undertake an annual assessment of a number of CTG interpretations to improve quality (164). This training could increase CTG knowledge and interpretive skills, lead to higher inter-observer agreement, better management of intrapartum CTG and improved quality of care (165). According to the individual approach all health personnel are responsible for being professionally qualified, including theoretical and practical training. According to the systemic approach, all departments must ensure that staff is trained in fetal monitoring.

The realization that most adverse events are the result of a breakdown in communication between people has led to the development of checklists (151). The introduction of surgical checklists was a success, reducing adverse events by as much as 50% (144;166). The introduction of a checklist in labor is a possibility to assure control and cooperation at every step of the labor process (167). A major cause of failure in our cases was neglecting to act when the woman changed from low to high risk during labor. Performing regular standard checks during the labor process would probably have identified some of these risk factors and alerted involved health workers. Such checklists have improved patient outcomes (162).

Simulating obstetrical scenarios has become a common method of training to improve both technical and communication skills in infrequent obstetric events. Simulation training in obstetric emergencies has proven beneficial effects on cooperation and communication in the team, and might have positive effects on clinical efficiency, adverse events and maternal and fetal outcomes (162;163;168-172). The evaluation of simulation training shows better self-reported qualifications, but evaluation in clinical practice is difficult (173;174). Practical training in obstetric emergencies such as shoulder dystocia and postpartum hemorrhage also reduces negative outcomes, and would probably be beneficial in reducing compensation claims (175). Simulation training can also demonstrate individual and team weaknesses that need to be addressed (176). Recommendations for simulation training in obstetric procedures including shoulder dystocia, eclampsia and PPH have been developed (177-179). Simulation training should involve midwives, obstetricians and other relevant health personnel, because efficient interaction is important in any difficult medical situation.

Independent of whether errors are caused by human or system failure, the most effective way to improve quality of care is probably by a system approach. The occurrences of OASIS in the Scandinavian countries is a good example: The prevalence of OASIS increased over several decades in all the Scandinavian countries, probably due to a change in routines during labor with less emphasis on protection of the perineum in the final part of the second stage of labor (Figure 2) (119). This led to a national action plan to reduce the rate of OASIS in Norway (180). The program included manual assistance during the final part of labor, slowing the delivery of the fetal head, instructing the mother not to push and supporting the perineum (181;182). These actions significantly decreased the national incidence of OASIS in

Norway from 4% in 2004 to 2% in 2012. In this way a problem apparently caused by human error was improved by a systems approach.

In the US litigation after obstetric negligence is a huge problem, causing defensive obstetric practice (183) and obstetricians leaving the specialty due to fear of litigation (184). In an attempt to improve quality, collaborative quality improvement programs have been implemented in many hospitals in the US. The aim has been to reduce negligence in care and litigation costs, and the programs have been facilitated by the liability insurers. The general principles include: implementation of evidence-based protocols and procedures, standardized educational interventions, mandatory electronic fetal monitoring training and enhanced in-house physician coverage (185;186). Implementation of such programs shows a significant reduction in adverse patient outcomes, a 42% decline in litigation claims and 20% reduction in litigation payouts (185;186).

6 Strengths and weaknesses

Paper I

Paper I is a descriptive study with a firm study protocol. The study data are complete national data of all compensation claims. In a prospective design, the data quality and the amount of collected information could have been improved. We would have preferred to be able to describe the involved health personnel in more detail including information on the clinical experience of the midwife and doctor, and whether it was a temporary or permanent employee. The size of the maternity ward also appears to be relevant, including in-house physician coverage: if there was none, only a resident or also obstetricians? A Danish report on this topic, concluded that large labor units (3000-3999 deliveries/year) have lower approval rates in claims for compensation, compared with very large (≥4000 deliveries/year) or small units (<1000 deliveries/year) (21;25). Most claims were approved with reference to the specialist rule, assuming that if an experienced specialist had conducted the treatment differently the injury could have been avoided. This was especially frequent in small units.

Type of injury in the compensated and denied group is described in our material. Reason for denied compensation was given, but we were not able to find adequate demographic or medical data for further description of denied cases due to restricted access to the medical records. In a descriptive study of adverse outcomes a suitable control group is difficult to find, and we do not believe that either claims denied compensation or a group of normal deliveries would improve the interpretation of our results.

Accessing NPE data is complicated since it requires consent from all patients. Applying for and receiving consent is especially difficult in claims where compensation has been denied, as these patients tend to be less interested in research into their cases. The national health authorities should consider the possibility of receiving passive consent from all patients claiming compensation, making their data more accessible for researchers. It is debatable whether patients should be able to refuse to share knowledge that others could benefit from.

A weakness in our categorization of inadequate care is that these groups are not totally inclusive and mutually exclusive, like for example the Robson system (187). If a strict and consequent ranking of causes is not performed different causes could be chosen as the main factor.

There is also a possibility that both the limited number of cases and the documentation received by NPE makes it difficult to uncover system errors. The NPE assesses whether there is inadequate care thereby causing patient injury, they do not assess if this is caused by human or system factors. Thus, some of the medical records that the medical experts must rely upon may be of poor quality, making their assessment difficult.

Paper II

Paper II comprises a complete, national set of data, obtained by reviewing all medical records in cases where compensation was given due to birth asphyxia. The cases cover a long period, but all cases were assessed according to the national guidelines in use at the time of birth. The limitation of the study is the restricted data from denied cases, but important information is provided by the experts' assessments (139). As was the case for *Paper I*, all assessments were performed by the medical experts, in contrast to other studies, where the assessment of adequate or inadequate care was performed by the authors (139). We might have come to different conclusions regarding reasons for inadequate care if the authors had performed the evaluation. Please see *Paper I* for information on prospective design, access to data and reasons for inadequate care.

Paper III

To our knowledge, a similar study to *Paper III* has not been performed previously. The weakness of our study is primarily the limited number of cases and experts included. The study includes only two to four cases in each clinical scenario, and may not be transferable to the overall judgment done by the NPE. Therefore caution should be exercised when drawing conclusions. However, the study shows that expert judgment in patient injury claims can be studied from a scientific perspective, and the experts participating in the study actually handle a substantial proportion of the obstetric claims in Norway. Any reduction in

the number of experts from the 14 in this study is likely to increase the risk of chance in case judgments and reduce the precision and validity of the expert judgment.

In hindsight it would have been interesting to ask the experts to evaluate the same cases after a period, to evaluate the intra-rater agreement. Unfortunately this was impossible due to the anonymity of the experts.

With regard to different inter-rater agreement measures, their strengths and weaknesses and confidence interval, please see, *Paper III; Strengths and weaknesses*.

In *Paper III* the expression "negligence in care" was chosen after recommendation from our referees. This is not in complete agreement with the Norwegian no-blame system , because negligence is not required. Medical errors of less serious type may well lead to compensation.

7 Conclusions and implications

This study was designed to explore claims for compensation following birth injury in the Norwegian System of Compensation to Patients, and has identified what types of injury to mother and child are most likely to occur, which categories of health personnel were involved and to some extent why errors occur. The study has also investigated the consistency in experts' evaluations of claims for compensation in obstetrics.

In *Paper I* we found that the most frequent birth injury to the child in cases receiving compensation was neonatal asphyxia (161/193) and injuries following shoulder dystocia (12/193). The most frequent injury to the mother was OASIS (26/87) and infection (20/87). Human error seems to be the main reason for inadequate care in birth injuries to mother and child, often caused by a failure in surgical or obstetric care (27%) or inadequate fetal monitoring (12%). An obstetrician was involved in 51% of the cases and a midwife in 37%.

In Paper II we analyzed claims for compensation following neonatal asphyxia including claims denied compensation. We recorded failure in fetal monitoring (49%) as the predominant cause of neonatal asphyxia, followed by lack of clinical knowledge and skills among health personnel (14%). According to our definition of human error, this was the main reason for inadequate care. Midwives (46%) were involved in inadequate care almost as often as obstetricians (49%).

In *Paper III* we studied agreement in evaluation of claims for compensation and found that the overall measure of consistency can be described as moderate concerning inadequate care (Fleiss' kappa=0.53/AC1=0.54), and causality between the injury and the care provided (Fleiss' kappa=0.41/AC1=0.54). However, experts' opinions showed considerable variation.

Data on birth injury cases reported to NPE and other bodies may help us understand the different factors involved in adverse events, why they evolve and how to reduce recurrence rates. Many questions concerning errors in healthcare remain unsolved, and further research on this topic is needed.

8 Future perspective

The NPE and other similar systems contain a wealth of information on inadequate healthcare. This information can and should be utilized to increase patient safety and quality in obstetrics.

Future projects would be improved if informed consent to use these data for quality and control purposes was unnecessary. We contacted all involved patients and relatives to collect approved consent. This is time consuming and due to non-consenting patients, led to incomplete data. One of NPE's objectives is to use their data to increase patient security and reduce adverse outcomes. The suggestion is that national health authorities consider the possibility of all claimants approving that their data may be used for research when filing a claim, which is now the standard in Denmark.

It would be fortunate for future studies if prospective data collection was conducted to obtain standardized and equal information in all cases, especially concerning involved health personnel, information in the medical records and information received by the patient from health personnel.

There are numerous relevant research questions that might improve our knowledge concerning adverse events during labor. The effect of guidelines and procedures, education and simulation training should be studied further. The optimal working hours for obstetricians, residents and midwives are unknown; shorter shifts and many handovers may increase the risk of communication failures or the overworked doctor might be a higher risk (151). The optimal number of doctors and midwives, the size of the delivery department and the importance of proper patient selection according to risk still needs researching.

To improve quality of care, every part of the system must be included: midwives, doctors, management and politicians. Both time and economical investments are needed, but the considerable economic, social and physiological expense of these injured mothers and children, justifies major investments.

In Paper III we found considerable variations in experts' evaluations of injury and inadequate care. Both the NPE system and the medical experts need to be aware of this modest agreement, and particularly in well-known difficult cases more than one medical expert or rather a group of experts should perform the evaluation. Further research should be recommended to investigate if our results from obstetrics are transferable to other medical fields, and how to increase the consistency in medical experts' evaluations of claims for compensation.

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Appendices

Copy of registration form

Approval from the Regional Committee for Medical and Health and Research Ethics

Trial invitation

Informed consent form

Paper I-III

"Gjennomgang av klagesaker meldt til Norsk Pasientskadeerstatning innenfor fagfeltet fødselshjelp og gynekologi"

Registreringsskjema

(All informasjon hentes fra journal/saksmappe hos NPE)

Innhold:

Del 1: Om klagens årsak
Del 2: Om kvinnen
Del 3: Om svangerskapet
Del 4: Fødsel
Del 5: Om barnet
Del 6-11: Skade hos mor
- **Del 6:** Generelt skade mor
- **Del 7:** Blødning
- **Del 8:** Sfinkterskade
- **Del 9:** Skade på tarm/urinv
- **Del 10:** Infeksjoner
- **Del 11:** Tromboembolier

Del 12-13: Skade hos barn
- **Del 12:** Generelt skade barn
- **Del 13:** Skulderdystoci

Del 14: Om vedtak

0.0 Registreringsnummer

				-						(saksnr i NPE)

1.0 Om klagens årsak / (antatt) skade på mor eller barn?

1.1 Hva er årsak til klagen?
(Hva anfører pasienten/"klager" som årsak til å henvendelsen/klagen til NPE?)
(kan være flere kryss)

Skade:

- ☐ på barn
- ☐ på mor

Dødsfall:

- ☐ av barn
- ☐ av mor

Hva er klagende parts påstand om årsak til antatte skade?

1.2 Fremsetter klager påstand om at den pågående forløsning burde vært avsluttet tidligere?

- ☐ Ja (beskriv)
- ☐ Nei/Ingen opplysninger

Beskriv:_____

1.3 Fremsetter klager en påstand om at det burde vært forsøkt en annen forløsningsmetode?
(kan være flere kryss)

- ☐ Burde vært forløst ved sectio
- ☐ Burde vært forløst ved vakuum/tang
- ☐ Annet, beskriv
- ☐ Nei/Ingen opplysninger

Beskriv:_____

1.4 Fremsetter klager en påstand om at det på forløsningstidspunktet forelå manglende kompetanse fra fødselshjelper (jordmor/lege)?

- ☐ Ja
- ☐ Nei/Ingen opplysninger

2.0 Om kvinnen

2.1 Kvinnens alder da aktuelle fødsel fant sted

☐☐ år

2.2 Kvinnens bostedsfylke

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

2.3 Paritet

☐ para 0

☐ para 1+

2.4 Hvis tidligere graviditeter, hva var forløsningsmåte ved tidligere fødsler (def. svangerskapsvarighet > 23 u)?

Tidligere vaginal uten instr.....	☐ Ja	☐ Nei
Tidligere tang eller vakuum.....	☐ Ja	☐ Nei
Tidligere elektivt keisersnitt.....	☐ Ja	☐ Nei
Tidligere akutt keisersnitt.....	☐ Ja	☐ Nei
Tidligere setefødsel.....	☐ Ja	☐ Nei

2.5 Hva er kvinnens utdanningsnivå?

☐ Grunnskole

☐ Videregående skole

☐ Høyskole/universitet = 3 år

☐ Høyskole/universitet > 3 år

2.6 Hva var kvinnens yrkesstatus forut for det aktuelle svangerskapet?

☐ Yrkesaktiv

☐ Sykemeldt

☐ Hjemmeværende

☐ Uføretrygdet

☐ Arbeidsledig

☐ Annet

Evt beskriv:_____

3.0 Om svangerskapet

3.1 Hadde kvinnen kroniske sykdommer av betydning for aktuelle svangerskap?
(ingen, ett eller flere kryss)

- ☐ Hypertensjon
- ☐ Kronisk nyresykdom
- ☐ Diabetes mellitus
- ☐ Epilepsi
- ☐ Trombofili (Eks: antitrombin mangel, protein C/S-mangel, antifosfolipidsyndrom lupus antikoag., antikardiolipin)
- ☐ Blødningstendens
- ☐ SLE
- ☐ Annen reumatisk sykdom
- ☐ Thyroidea-lidelser
- ☐ Psyk sykd
- ☐ Annet
  Beskriv:_____

3.2 Komplikasjoner påvist i aktuelle svangerskapet?
(ingen, ett eller flere kryss)

- ☐ Svangerskapsdiabetes
- ☐ Preeklampsi (BT=140/90, =+ proteinuri)
- ☐ Eklampsi (def: kramper under svsk/fødsel, tom 10 d etter fødsel)
- ☐ Placenta previa
- ☐ Erkjent vekstretardasjon (NB! Erkjent under svangerskapet)
- ☐ Immunisering (Rh, plater)
- ☐ Tvillinger/flerlinger
- ☐ Seteleie
- ☐ Annet
  Beskriv:_____

3.3 Var kvinnen antatt normalfødende ved fødselsstart?
(normalfødende = 4 kryss)

- ☐ Et foster i hodeleie
- ☐ Svangerskapsvarighet (36-42 uker)
- ☐ Spontan fødselsstart
- ☐ Ikke kroniske sykdommer el komplikasjoner i graviditeten (jfr over)

3.4 Kvinnen høyde (cm): ☐☐☐

Kvinnens pregravide vekt/evt første ktr (kg): ☐☐☐

BMI: ☐☐

4.0 Om fødsel

4.1 Hvor fødte kvinnen?

| | | | | | | | | | | | | | | (navn på fødeenhet)

☐ Fødestue
☐ Fødeavd
☐ Kvinneklinikk
☐ Hjemme
☐ Transport

4.2 Ble kvinnen overflyttet (til et høyere nivå) før/under/etter fødsel?

☐ Ja ☐ Nei

4.3 Svangerskapsvarighet ved fødsel? (ultralydtermin brukes)

| | | (antall uker) | | (antall dager)

4.4 Forløsningsmetode (i aktuelle svangerskap som klagesaken gjelder)?
(kan være flere kryss)

☐ Vaginalt uten instrumentell hjelp
☐ Vaginal med tang eller vakuum
☐ Sete forløsning
☐ Tvillingfødsel
☐ Keisersnitt, katastrofesnitt
☐ Keisersnitt, akutt
☐ Keisersnitt, elektivt
Beskriv evt. _____

4.5 Ble fødselen indusert? (F.eks. Cytotec, Prostingel, Pitocindrypp)?

☐ Ja
☐ Nei
☐ Ikke aktuelt/Ikke bedømbart
Angi medikament:_____

4.6 Ble kvinnen stimulert med oxytocin under fødselen?

☐ Ja
☐ Nei
☐ Ikke aktuelt/Ikke bedømbart

4.7 Var det i følge sakkyndige relevant/adekvat bruk av oxytocin?

☐ Ja
☐ Nei
☐ Ikke kommentert/Ikke bedømbart

4.8 Mormunnens åpning ved start på stimuleringen?

☐☐ cm

4.9 Forelå tegn til hyperstimulering/overstimulering (>5 rier per 10 min)

☐ Ja
☐ Nei
☐ Rier ikke registrert

4.10 Hvis ja i 4.9, var hyperstimulering erkjent av fødselshjelper?

☐ Ja
☐ Nei
☐ Ikke aktuelt/Ikke bedømbart

4.11 Var oxytocin gitt i.m. eller s.c. FØR barnet ble født?

☐ Ja
☐ Nei
☐ Ikke bedømbart

4.12 CTG-registrering (extern CTG) ved innkomst?

☐ Ja
☐ Nei
☐ Opplysninger mangler

4.13 Hvordan ble innkomst CTG *initialt/opprinnelig* tolket?

- ☐ Normal
- ☐ Avvikende
- ☐ Patologisk
- ☐ Ikke tatt
- ☐ Ikke tolket/ikke journalført
- ☐ Ikke tolkbar/teknisk dårlig

4.14 CTG registrering under fødselen?

- ☐ Ja
- ☐ Nei
- ☐ Opplysninger mangler

4.15 Hvordan ble CTG under fødsel initialt/opprinnelig tolket?

- ☐ Normal
- ☐ Avvikende
- ☐ Patologisk
- ☐ Ikke tolket/ikke journalført
- ☐ Ikke tolkbar/teknisk dårlig

4.16 STAN-registrering under fødselen?

- ☐ Ja
- ☐ Nei
- ☐ Opplysninger mangler
- ☐ STAN logg normal
- ☐ STAN logg patologisk
- ☐ STAN logg ikke tolket/ikke journalført

4.17 (kan være flere kryss)

- ☐ Epidural under fødselen
- ☐ Spinal
- ☐ Generell anestesi

5.0 Om barnet

5.1 Barnets fødselsvekt?

☐☐☐☐ (gram) | Ev Tv II: ☐☐☐☐ (gram)

5.2 Apgar score?

☐☐ etter 1 min
☐☐ etter 5 min
☐☐ etter 10 min

Ev Tv II:
☐☐ etter 1 min
☐☐ etter 5 min
☐☐ etter 10 min

5.3 Forelå utviklingsavvik (misdannelse) *neonatalt*?
(For eksempel Fallot's, gastrochise, omphalocele etc)

☐ Ja (beskriv)
☐ Nei
☐ Opplysninger mangler
Beskriv:_____

5.4 Navlestrengsarterie analyse etter fødselen?
(kan være flere kryss)

pH: ☐,☐☐
BD: ☐☐

☐ Nei, eller opplysninger mangler
☐ Ev annen prøve, beskriv:_____

5.5 Ble føtal blodprøve (FBS) tatt under fødselen?

☐ Nei
☐ Ja (Beskriv resultater der det foreligger)

pH: ☐,☐☐
BD: ☐☐

6.0 FYLLES UT VED SKADE HOS MOR (Ved skade hos barn, se del 12.0)

6.1 Antas skaden å være relatert til forhold:
(kan være flere kryss)

- ☐ i graviditet
- ☐ under fødsel
- ☐ etter fødsel
- ☐ ikke diskutert

6.2 Angi hovedtype skade hos mor?
(kan være flere kryss)

- ☐ blødning, se seksjon 7.0
- ☐ sfinkterskade, se seksjon 8.0
- ☐ skade på tarm/urinveier, se seksjon 9.0
- ☐ infeksjon, se seksjon 10.0
- ☐ tromboemboli, se seksjon 11.0
- ☐ annet. Beskriv:_____

6.3 Ved dødsfall, angi tilgrunnliggende dødsårsak? ☐
(Eks blødning, tromboemboli, infeksjon, komplikasjon til anestesi, eklampsi/preeklampsi, hjerneblødning osv)

_____

Detaljer i forhold til de aktuelle skadetypene:

7.0 Blødning (mor)

7.1 Ved blødning, angi årsak til og/eller type blødning?
(kan være flere kryss)

- ☐ Årsak/type ikke oppgitt/ikke bedømbart
- ☐ Atoni
- ☐ Kirurgisk blødning
- ☐ Annet

Ved kirurgisk blødning, konkretisere hvis mulig:
(kan være flere kryss)

- ☐ Rift, epsiotomi, sfinkter/cervix
- ☐ Rift uterus (ruptur, skade ved k.s.)
- ☐ Reoperasjon etter k.s.

Beskriv (organskade etc):_____

_____

7.2 Blødningens størrelse? ☐☐☐☐ ml estimert blødning

7.3 Transfusjon? antall enheter blod gitt: ☐☐

7.4 Ble adekvat behandling gitt, ref sakkyndiges uttalelser/faglige vurderinger?

☐ Ja ☐ Nei

7.5 Hvis "nei; adekvat behandling ikke gitt", opplyses det om årsak?

Beskriv:_____

_____

7.6 Medførte blødningen sequele?
(kan være flere kryss)

- ☐ Ja, for barnet
- ☐ Ja, for mor
- ☐ Nei/Ingen opplysninger

Beskriv:_____

_____

8.0 Sfinkter ruptur

8.1 Type ruptur? ☐ Grad III ☐ Grad IV Angi (a-c): ☐ a ☐ b ☐ c

8.2 Ble skaden (sfinkterruptur) oppdaget primært? ☐ Ja ☐ Nei

8.3 Ble skaden (sfinkterruptur) behandlet primært? ☐ Ja ☐ Nei

8.4 Ble adekvat behandling gitt, ref sakkyndiges uttalelser/faglige vurderinger? ☐ Ja ☐ Nei

8.5 Hvis "nei; adekvat behandling ikke gitt", opplyses det om årsak?

Beskriv:_____

_____

8.6 Ble tarm utlagt? ☐ Ja ☐ Nei

8.7 Hvis sfinkterskaden ikke ble oppdaget primært, når ble den oppdaget?

☐☐☐ antall dager etter fødsel

8.8 Ble kvinnen re-operert? ☐ Ja ☐ Nei

Beskriv ev. forløp:_____

_____

8.9 Burde annen forløsningsmetode vært valgt; ref sakkyndiges vurderinger? ☐ Ja ☐ Nei

Beskriv ev hvilken:_____

_____

8.10 Ved sfinkterskade, angi eventuelle sequele:
(kan være flere kryss)

☐ Ingen sequele
☐ Fekal inkontinens, ”soiling”
☐ Inkontinent for luft
☐ Sequele ikke angitt/ikke omtalt/ikke bedømbart
☐ Annet (Ev angi St. Marks score hvis opplyst)

Beskriv:_____

_____

9.0 Skade på tarm/urinveier:

9.1 Spesifiser lokalisasjon av skade på tarm/urinveier?
(kan være flere kryss)

☐ Tarm
☐ Ureter
☐ Blære
☐ Annet Beskriv:_____

9.2 Ved skade på tarm/urinveier; ble skaden oppdaget primært? ☐ Ja ☐ Nei

9.3 Ved skade på tarm/urinveier; ble skaden behandlet primært? ☐ Ja ☐ Nei

9.4 Ved skade på tarm/urinveier oppdaget senere, når?

			antall dager etter fødsel

9.5 Ble tarm utlagt? ☐ Ja ☐ Nei

9.6 Ble kvinnen re-operert? ☐ Ja ☐ Nei

Beskriv ev. operasjon/forløp:

_____

_____

10.0 Infeksjon

10.1 Ved infeksjon, angi utbredelse og omfang:
(kan være flere kryss)

☐ Lokal ☐ Sepsis
☐ Beskriv:

_____

_____

10.2 Tilkom sequele etter infeksjonen? ☐ Ja
☐ Nei
☐ Ikke bedømbart

Beskriv:

_____

_____

11.0 Tromboemboli

11.1 Ved tromboembolisk event, spesifiser:
(kan være flere kryss)

- ☐ DVT
- ☐ Lunge emboli
- ☐ Annen lokalisasjon

11.2 Ved tromboemboli, ble tromboseprofylakse gitt etter prosedyre?

- ☐ Ja
- ☐ Nei
- ☐ Usikkert

11.3 Ved tromboemboli, var diagnostikk adekvat?

- ☐ Ja
- ☐ Nei
- ☐ Usikkert

11.4 Ved tromboemboli, var behandling adekvat?

- ☐ Ja
- ☐ Nei
- ☐ Usikkert

11.5 Ved tromboemboli, foreligger noe sequele?

- ☐ Ja
- ☐ Nei
- ☐ Ikke bedømbart

Beskriv:_____

_____

11.6 Ved tromboemboli, er utredning for trombofili foretatt?

- ☐ Ja
- ☐ Nei
- ☐ Ikke bedømbart

Beskriv: (Feks type hvis trombofili er oppdaget)

_____

_____

12.0 Skade/dødsfall hos barn. (Ved skade hos mor, se foregående pkt 6-11)

12.1 Beskriv type skade/sequele hos barn:
(kan være flere kryss)

☐ Motorisk forstyrrelse
Beskriv:_____

_____

☐ Mental retardasjon
Beskriv:_____

_____

☐ (Alv) infeksjon
Beskriv:_____

_____

☐ Skallefraktur

☐ Rørknokkel fraktur

☐ Plexus skade

☐ Skulderdystoci, se seksjon 13.0 for angivelse av ytterligere detaljer

☐ Intrakraniell blødning

☐ Annet

☐ Beskriv: _____

12.2 Antas skaden å være relatert til forhold:
(kan være flere kryss)

☐ i graviditet

☐ under fødsel

☐ etter fødsel

☐ ikke bedømbar/klassifiserbar

12.3 Antar sakkyndige at behandlingen av pasienten var adekvat (*i.e* "lege artis")?

☐ Ja ☐ Nei

12.4 Ved dødsfall, angi tilgrunnliggende dødsårsak? ☐
(Eks blødning, tromboemboli, abr. placentae, infeksjon, komplikasjon til anestesi, eklampsi/preeklampsi, hjerneblødning osv)

_____

12.5 Er oksygenmangel/asfyksi; bekreftet ved:
(kan være flere kryss)
(Tilstedeværelse av de tre øverste faktorer taler for at skaden er sannsynlig påført under fødselen)

- ☐ Metabolsk acidose (navlearterie pH<7.00, BD>12.00 mmol/L)
- ☐ Tidlig alvorlig eller moderat neonatal encephalopati (HiE grad II og III) hos barn = 34 uker
- ☐ CP; type spastisk kvadriplegi eller dyskinetisk type
- ☐ Andre forhold som sakkyndige vurderer til å tale i retning av skade påført under fødsel

Sakkyndiges diskusjon/kommentarer rundt bruk eller tolking av CTG med referanse til skaden:

12.6 I følge sakkyndige; Burde CTG vært tatt i svangerskapet?

- ☐ Ja
- ☐ Nei
- ☐ Ikke kommentert/ikke bedømbart

12.7 Ble CTG/*STAN* feiltolket (*jfr vurderinger i ettertid*?)

- ☐ Ja
- ☐ Nei
- ☐ Ikke tolkbar/teknisk dårlig
- ☐ Beskriv evt _____

12.8 Ble CTG ev tolket av barnelege?

- ☐ Ja
- ☐ Nei
- ☐ Ikke kommentert/ikke bedømbart

13.0 Skulderdystoci

13.1 Forelå noen av de følgende faktorer hos kvinnen?
(sett ett el flere kryss)

	Ja	Nei	Ukjent/oppl. mangler
Estimert vekt barn > 4500 g.....	☐	☐	☐
Estimert vekt barn > 5000 g.....	☐	☐	☐
Mor diabetes/svangerskapsdiab.....	☐	☐	☐
Mor førstegangsfødende.....	☐	☐	☐

13.2 Når skulderdystoci var erkjent, ble:

	Ja	Nei	Ukjent/oppl. mangler
Fundustrykk foretatt.....	☐	☐	☐
Pitocin gitt eller doser økt.....	☐	☐	☐

(ovennevnte skal ikke utføres ved skulderdystoci)

13.3 Ble korrekte prosedyrer ved skulderdystoci fulgt?

	Forsøk	Ikke forsøkt	Oppl. mangler
McRoberts manøvre.....	☐	☐	☐
Rubin/Wood (Rotasj av skuldre)...	☐	☐	☐
Annet.....	☐	☐	☐

(Eks trykk over symfyse, nedhenting av arm etc)

☐ Ev beskriv: _____

13.4 Mener sakkyndige at mor burde vært forløst med sectio?

☐ Ja

☐ Nei

☐ Ikke kommentert/ikke bedømbart

☐ Beskriv: _____

_____

14.0 Om vedtak i NPE/Nemnda og saksbehandlingstid

14.1 Karakter på vedtak etter behandling hos NPE?

☐ Medhold ☐ Avslag

14.2 Angi kort begrunnelse fra NPE ☐

_____

_____

_____

_____

14.3 Ble endelig avgjørelse i saken fattet ved anke?

☐ Nei, saken ikke anket
☐ Ja, anket til Pasientskadenemnda

14.4 Karakter på vedtak etter behandling i Pasientskadenemda?

☐ Medhold ☐ Avslag

14.5 Angi kort begrunnelse fra Pasientskadenemda? ☐

_____

_____

_____

_____

14.6 Er saken behandlet i rettsvesenet?

☐ Nei
☐ Ja, anket til rettsvesenet

Evt vedtak i rettsvesenet: ☐

Beskriv:_____

14.7 Tid fra klage mottatt hos NPE til vedtak fattet i NPE?

☐☐ (hele måneder)

14.8 Evt tid fra vedtak i NPE til vedtak i Pasientskadenemda

☐☐ (hele måneder)

14.9 Ved medhold; størrelse på erstatningsbeløp?

☐☐☐☐☐☐☐☐ NOK

14.10 Antall sakkyndige involvert av NPE i avgjørelsen?

☐ en (1) sakkyndig
☐ to (2) eller flere sakkyndige

14.11 Ved flere sakkyndige: Var det diskrepans mellom dem?
(NB! Kan være uenighet mellom sakkyndige av samme fagbakgrunn eller mellom sakkyndige i ulike spesialiteter)

☐ Ja ☐ Nei

Beskriv: (Uenighet om CTG, forløsningstidspunkt etc) ☐

_____

_____

14.12 De sakkyndiges fagbakgrunn?

	Spes i gyn/obst	**Spes i pediatri**	**Spes i fys. med. og rehab**	**Spes i kirurgi**	**Spes i nevrologi**	**Annet**
Nr 1.....	☐	☐	☐	☐	☐	☐
Nr 2.....	☐	☐	☐	☐	☐	☐
Nr 3.....	☐	☐	☐	☐	☐	☐
Nr 4.....	☐	☐	☐	☐	☐	☐

Vurderinger foretatt av sakkyndige/NPE ila saksbehandlingen:

14.13 Ut i fra sakkyndiges vurderinger; Er (antatt) skade/svikt forårsaket av:
(Angi ett kryss, antatt hovedgrunn)

- ☐ Svikt i utredning/overvåking/behandling (ikke adekvat)
- ☐ Feil i utredning/overvåking/behandling (uaktsom, grov uaktsom)

14.14 I hvilken gruppe kan antatt skade/svikt klassifiseres?
(Angi ett kryss, antatt hovedgrunn)

- ☐ Svikt i bruk av teknologi (eks ikke brukt CTG/STAN der indik forelå)
- ☐ Feiltolket CTG/STAN
- ☐ Svikt i bruk av medikamenter; eks feildosering, unødig bruk (feks oxytocin) manglende bruk (feks tromboseprofylakse, inf.profylakse)
- ☐ Etablerte rutiner (prosedyrer) ikke fulgt/ikke kjent
- ☐ Manglende rutiner eller prosedyrer ikke laget
- ☐ Manglende opplæring/kompetanse hos behandlende helsepersonell
- ☐ Manglende tilkalling av kompetent personale i vanskelige situasjoner/ dårlig kommunikasjon mellom helsepersonell
- ☐ Mangler ved organisering av virksomhet, (eks for lite personale, manglende opplæring)
- ☐ Samtidighetskonflikt
- ☐ Annet
- ☐ Ev beskriv: _____

14.15 Ved svikt i uttredning/overvåking/behandling, antar man at svikt lå hos:
(Ett el flere kryss)

- ☐ Obstetriker, spesialist
- ☐ Lege under spes. i gyn/obst
- ☐ Jordmor
- ☐ Pediater
- ☐ Annet personell
- ☐ Ev beskriv: _____

14.16 Sakkyndiges vurdering ifht forløsning?

Fødselshjelper burde grepet inn tidligere:

☐ Ja ☐ Nei ☐ Usikker ☐ Ingen oppl.

Hvis ja, når? | | | | | (antall minutter)

Annen type forløsning burde vært foretatt/forsøkt:

☐ Ja ☐ Nei ☐ Usikker ☐ Ingen oppl.

Hvis ja, angi alt forløsningsmetode som burde vært forsøkt.

Beskriv:_____

_____

Fritekst:

Sakens hovedtrekk (kasus, hovedproblem, tvil/uenighet mellom sakkyndige, konklusjon, hva kan læres/forbedres i slike tilfelle):

_____

_____

_____

_____

_____

_____

_____

_____

Fra: Regional komite for medisinsk og helsefaglig forskningsetikk REK nord

Til:
Stine Andreasen
stan@nlsh.no arvid.paulsen@uit.no

Dokumentreferanse: 2010/3341-4
Dokumentdato: 28.01.2011

SAKKYNDIGVURDERING I NPE - INFORMASJON OM VEDTAK

Komiteen behandlet søknaden i møte 12.1.2011. I referatet heter det:

Prosjektleders prosjektomtale:
Norsk Pasientskadeerstaning ble opprettet i 1988 for å gi pasienter mulighet til å søke om erstatning dersom de mente å ha blitt påført skade av helsevesenet. Systemet bygger på at man ikke trenger å påvise skyld blant helsepersonell, kun påvist skade av pasient. Fra oppstart av NPE har det innkommet rundt 1000 skader innen fødselshjelp, både på mor og barn. Vurdering av medisinsk sakkyndige legges til grunn for hvorvidt den gitte behandling var adekvat eller ikke. Vedtak fattes av jurister i NPE. Ved gjennomgang av alle medholdssakene finner vi at det foreligger uenighet mellom de innvolverte sakkyndige, samt at det tilsynelatende er ulikt utfall i nærmest identiske klagesaker. Med bakgrunn i dette ønsker vi å utføre en studie der vi undersøker om sakkyndige har en enhetlig vurdering av fødselssaker, forelagt identiske opplysninger. Måler med studien er å verifisere om systemet er velfungerende, og evt kunne bedre dagens praksis med fokus på kvaliteten i sakkyndigvurderingen.

Komiteens merknader:

Endring prosjektleder og medarbeider
Pål Øian er oppgitt som prosjektleder i prosjektet. Stine Andreasen skal være prosjektmedarbeider 1.

Prosjektet faller utenfor helseforskningsloven, men må vurderes mht dispensasjon fra taushetsplikt
De prosjekt som skal fremlegges for komiteen er prosjekt som dreier seg om "medisinsk og helsefaglig forskning på mennesker, humant biologisk materiale eller helseopplysninger", jf. helseforskningsloven § 2. "Medisinsk og helsefaglig forskning" er i § 4 a) definert som "virksomhet som utføres med vitenskapelig metodikk for å skaffe til veie ny kunnskap om helse og sykdom". Det er altså formålet med studien som avgjør om et prosjekt skal anses som fremleggelsespliktig for REK eller ikke. Komiteen vurderer at dette prosjektet ikke vil gi ny kunnskap om sykdom eller helse, men skal undersøke om sakkyndige har en enhetlig vurdering av fødselsskader, forelagt identiske opplysninger. Målet er å verifisere om systemet er velfungerende, og evt. kunne bedre dagens praksis med fokus på kvaliteten i sakkyndigvurderingen. Prosjektet faller således ikke inn under helseforskningsloven, men det søkes også om dispensasjon fra taushetsplikt for at prosjektleder Pål Øian og prosjektmedarbeider Stine Andreassen skal kunne gjennomgå saksmappen i 10-12 og hente ut data fra allerede identifiserte saker som ikke har fått medhold i NPE. Dataene skal avidentifiseres når de hentes ut og skal i tillegg endres og modifiseres. På telefon opplyser prosjektmedarbeider også at de sakkyndige vurderingene ikke skal kunne legges til grunn for reelle saker, men at det er de sakkyndiges vurderinger som skal vurderes opp mot hverandre.

Etter forskrift av 2. juli 2009 er REK gitt myndighet til å gi slik dispensasjon i denne type saker etter helsepersonelloven § 29 første ledd og forvaltningsloven § 13 første ledd.

Hovedregelen er at det skal foreligge samtykke ved forskning på denne type opplysninger, men komiteen kan altså gi dispensasjon. Dette kan bare skje dersom forskningen er av vesentlig interesse for samfunnet og hensynet til deltakernes velferd og integritet er ivaretatt. Det kan settes vilkår for

bruken, jf. helseforskningslovens § 28. Prosjektleder er ansatt som stipendiat i NPE. Det er bare hun og veileder som skal ha tilgang til personidentifiserbart materiale. Materialet skal hentes ut uten personidentifiserbare kjennetegn. Søker opplyser at de saker man ønsker å bruke er identifiserte, slik at det ikke er nødvendig å gjennomgå saksdokumenter til flere enn 10-12 stykker. Materialet som helhet består av nesten 600 saker fordelt på årene 1994-2008.

Komiteen vurderer prosjektet som av vesentlig interesse for samfunnet. Det er viktig at både de enkeltpersoner det gjelder og samfunnet som helhet kan ha tillitt til at de sakkyndige uttalelsene som legges til grunn i disse sakene er av høy kvalitet. Spørsmålet om hvorvidt det foreligger et erstatningsbetingende forhold eller ikke har meget stor betydning for velferden til de som rammes. Det er kun to personer som skal ha tilgang til materialet. Det skal hentes ut avidentifisert og i tillegg modifiseres før det sendes ut til sakkyndige.

De sakkyndige skal heller ikke oppgi sitt navn eller andre personentydige kjennetegn på sine vurderinger. Det skal således heller ikke kunne stilles spørsmål ved om den enkelte sakkyndiges standpunkt vil kunne få betydning ved senere oppnevninger som sakkyndig for NPE.

På denne bakgrunn finner komiteen å kunne gi dispensasjon.

Vedtaket ble fattet mot stemmen til den juridisk fagkyndige.

Vedtak:
Etter søknaden fremstår prosjektet ikke som et medisinsk og helsefaglig forskningsprosjekt som faller innenfor helseforskningsloven. Prosjektet er ikke fremleggingspliktig, jf. helseforskningslovens § 10, jf. forskningsetikkloven § 4, 2. ledd.

Med hjemmel i forskrift av 02.07.09 nr. 989, der REK er delegert myndighet til å gi dispensasjon fra taushetsplikt etter helsepersonelloven § 29 første ledd og forvaltningsloven § 13 første ledd gis det dispensasjon fra taushetsplikt for innhenting av data hos NPE på en slik måte og omfang som det fremgår av søknaden. Dispensasjonen gjelder for prosjektleder Pål Øyan og prosjektmedarbeider Stine Andreassen.

Vennlig hilsen

May Britt Rossvoll
sekretariatsleder

Monika Rydland Gaare
førstekonsulent

REGIONAL KOMITÉ FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK, NORD-NORGE
REK NORD
Besøksadresse: TANN-bygget, Universitetet i Tromsø, N-9037 Tromsø
telefon sentralbord 77 64 40 00 telefon ekspedisjon 77620758 e-post:
post@helseforskning.etikkom.no

Vår referanse: 2008/03339-12 Vår dato: 24.04.2009
Deres referanse: Deres dato:

Flere mottakere iflg liste

Saksbehandler: Mads Morten Nøjd

Forespørsel om bruk av data i studien:

"Erstatningssaker i fødselshjelp og gynekologi: Hva kan vi lære i et kvalitets og skadeforebyggende perspektiv?"

Norsk gynekologisk forening (NGF) og Norsk pasientskadeerstatning (NPE) ønsker å foreta en systematisk gjennomgang av erstatningssaker meldt til NPE, innen fagfeltet fødselshjelp og gynekologi. **Formålet er å identifisere og belyse områder hvor det er rom for forebygging, forbedring og kvalitetssikring, i håp om at dette på sikt kan bidra til å unngå tilsvarende skader i framtiden.**

I den anledning sender vi ut denne forespørselen til personer som har meldt en erstatningssak til NPE innen det aktuelle fagområdet. I de tilfellene der saken gjelder skade på barnet, rettes forespørselen til barnets foresatte. Vi ber om forståelse for at det i denne sammenheng også er nødvendig for oss å rette en slik forespørsel til foresatte i saker der barnet har blitt alvorlig skadet eller skaden har hatt dødelig utfall.

Som du er kjent med, har NPE med samtykke innhentet journal og annen relevant informasjon som grunnlag for behandlingen av erstatningssaken. Vi ber med dette om din tillatelse til at opplysninger vedrørende ditt barns erstatningssak som allerede finnes i vårt arkiv, kan gjennomgås i studien.

I arbeidet med studien vil alle opplysninger som registreres om ditt barn og ditt barns sak være uten navn, fødselsnummer eller andre direkte identifiserende opplysninger. Etter at prosjektet er avsluttet, senest 31.12.2012, vil alle registrerte opplysninger bli anonymisert. Resultatene av undersøkelsen vil bli publisert som gruppedata, uten at den enkelte kan gjenkjennes.

Du vil ikke bli kontaktet eller belastet med spørsmål om ytterligere opplysninger utover den informasjon som allerede finnes i forbindelse med behandlingen av erstatningssaken hos NPE. Deltakelse i studien er frivillig, og vil ikke ha noen konsekvens for eventuell videre kontakt med NPE. Du kan når som helst under studien, og uten å oppgi grunn, trekke tilbake ditt samtykke. Barn som har fylt 16 år kan også selv trekke tilbake samtykket. Opplysningene registrert i prosjektet vil bli slettet dersom samtykket trekkes tilbake.

Studien er finansiert av Den norske legeforenings kvalitetssikringsfond og NPE og vil bli gjennomført med en professor i fødselshjelp og kvinnesykdommer som hovedansvarlig. Prosjektet er tilrådd av Personvernombudet, som innebærer at opplysninger behandles i henhold til Datatilsynets retningslinjer og personopplysningsloven.

Dersom du samtykker i bruk av opplysninger som beskrevet ovenfor, ber vi deg undertegne samtykkeerklæringen på vedlagte skjema og returnere skjemaet i vedlagte svarkonvolutt innen 08.05.2009.

Ved spørsmål er du velkommen til å kontakte en av undertegnede.

Det er av stor verdi for oss om du gir samtykke til å delta i studien. På forhånd tusen takk for hjelpen!

Med vennlig hilsen
Norsk pasientskadeerstatning

Mads Morten Nøjd
Avdelingsdirektør (medisinsk fagsjef) NPE
Mads.Morten.Nojd@npe.no
Telefon 22 99 44 48

Mette Willumstad Thomsen
Seniorrådgiver NPE
Mette.Willumstad.Thomsen@npe.no
Telefon 22 99 45 13

Samtykke til bruk av data i studien:

"Erstatningssaker i fødselshjelp og gynekologi: Hva kan vi lære i et kvalitets og skadeforebyggende perspektiv?"

Jeg samtykker til deltagelse i studien slik den er beskrevet i følgebrevet fra Norsk pasientskadeerstatning (24.04.2009), og bekrefter at opplysninger fra mitt barns saksmappe kan inkluderes i studien.

Sted:_____ Dato:_____

Foresattes navn: _____
(BLOKK BOKSTAVER)

Eventuelt barnets navn: _____
(BLOKK BOKSTAVER)

Foresattes signatur: _____

Vår referanse: 2008/03339-6 Vår dato: 17.04.2009

(Flere mottakere (SKADE MOR) iflg. liste)

Forespørsel om bruk av data i studien:

"Erstatningssaker i fødselshjelp og gynekologi: Hva kan vi lære i et kvalitets- og skadeforebyggende perspektiv?"

Norsk gynekologisk forening (NGF) og Norsk pasientskadeerstatning (NPE) ønsker å foreta en systematisk gjennomgang av erstatningssaker meldt til NPE, innen fagfeltet fødselshjelp og gynekologi. **Formålet er å identifisere og belyse områder hvor det er rom for forebygging, forbedring og kvalitetssikring, i håp om at dette på sikt kan bidra til å unngå tilsvarende skader i framtiden.**

I den anledning sender vi ut denne forespørselen til personer som har meldt en erstatningssak til NPE innen det aktuelle fagområdet.

Som du er kjent med, har NPE med ditt samtykke innhentet journal og annen relevant informasjon som grunnlag for behandlingen av din erstatningssak. Vi ber med dette om din tillatelse til at opplysninger vedrørende din erstatningssak som allerede finnes i vårt arkiv, kan gjennomgås i studien.

I arbeidet med studien vil alle opplysninger som registreres om deg og din sak være uten navn, fødselsnummer eller andre direkte identifiserende opplysninger. Etter at prosjektet er avsluttet, senest 31. desember 2012, vil alle registrerte opplysninger bli anonymisert. Resultatene av undersøkelsen vil bli publisert som gruppedata, uten at den enkelte kan gjenkjennes.

Du vil ikke bli kontaktet eller belastet med spørsmål om ytterligere opplysninger utover den informasjon som allerede finnes i forbindelse med behandlingen av din erstatningssak hos NPE. Deltakelse i studien er frivillig, og vil ikke ha noen konsekvens for din eventuelle videre kontakt med NPE. Du kan når som helst under studien, og uten å oppgi grunn, trekke tilbake ditt samtykke. Opplysningene om deg vil da bli slettet fra prosjektet.

Studien er finansiert av Den norske legeforenings kvalitetssikringsfond og NPE og vil bli gjennomført med en professor i fødselshjelp og kvinnesykdommer som hovedansvarlig. Prosjektet er tilrådd av Personvernombudet, som innebærer at opplysninger behandles i henhold til Datatilsynets retningslinjer og personopplysningsloven.

Dersom du samtykker i bruk av opplysninger som beskrevet ovenfor, ber vi deg undertegne samtykkeerklæringen på vedlagte skjema og returnere skjemaet i vedlagte svarkonvolutt innen 30. april 2008.

Ved spørsmål er du velkommen til å kontakte en av undertegnede.

Det er av stor verdi for oss om du gir samtykke til å delta i studien. På forhånd tusen takk for hjelpen!

Med vennlig hilsen
Norsk pasientskadeerstatning

Mads Morten Nøjd
Avdelingsdirektør (medisinsk fagsjef) NPE
Mads.Morten.Nojd@npe.no
Telefon 22 99 44 48

Mette Willumstad Thomsen
Seniorrådgiver NPE
Mette.Willumstad.Thomsen@npe.no
Telefon 22 99 45 13

Samtykke til bruk av data i studien:

"Erstatningssaker i fødselshjelp og gynekologi: Hva kan vi lære i et kvalitets- og skadeforebyggende perspektiv?"

Jeg samtykker til deltagelse i studien slik den er beskrevet i følgebrevet fra Norsk pasientskadeerstatning 17. april 2009, og bekrefter at opplysninger fra min saksmappe kan inkluderes i studien.

Sted:_____ Dato:_____

Navn: _____
(BLOKK BOKSTAVER)

Signatur: _____