# Complaints to the Norwegian System of Patient Injury Compensation 2001 – 14 following nerve blockade

**BACKGROUND** There has been a steady increase in cases reported to the Norwegian System of Patient Injury Compensation (NPE). We wished to look into what might characterise those cases of central and peripheral nerve blockade for anaesthesia that led to compensation claims.

**MATERIAL AND METHOD** Cases with codes for central and peripheral blockade within the field of anaesthesiology were retrieved from the NPE database for the period 2001 – 14. The cases were evaluated on the basis of variables including sex, age, type of anaesthesia, diagnosis, type of injury, site of injury, damages received, and written descriptions of treatment and injury. The expert reports were anonymised and reviewed in detail.

**RESULTS** A total of 339 patient compensation claims relating to nerve blockade were identified, of which 149 concerned spinal anaesthesia, 142 epidural anaesthesia, 21 combined spinal and epidural anaesthesia and 27 peripheral nerve blockade. The group consisted of 236 women and 103 men, and the average age was 46 years. The 339 cases comprised 0.8 % of all cases reported to the NPE in this period. A total of 107 claims resulted in compensation. Eighty-two million Norwegian kroner were paid out in total.

**INTERPRETATION** Peripheral and central nerve blockade accounts for only a small proportion of cases handled by the NPE. Only one in three applicants had their claim upheld, but when claims were upheld, the injuries were often severe and led to substantial pay-outs.

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## MAIN POINTS

**Regional anaesthesia accounted for only a small proportion of the cases handled by the Norwegian System of Patient Injury Compensation**

**Many patients reported problems and symptoms that were unrelated to the blockade procedure itself**

**Only a third of patients had their claims upheld**

The Norwegian System of Patient Injury Compensation (NPE) is a government agency under the Ministry of Health and Care Services. It was established in 1988 as an interim provision, and became part of Norwegian law when the Act on Patient Injury Compensation came into force in 2003.

The agency examines compensation claims from patients who believe they have sustained an injury with subsequent financial losses following incorrect treatment in the health service. With the aid of appropriate experts, the NPE decides whether to accept or reject the claim for compensation and, for claims that are upheld, also determines the size of the compensation pay-out. The agency's work is free of charge.

The principal aim of establishing the NPE was to strengthen patients' legal protections with respect to financial losses. It was also hoped to reduce the need for civil lawsuits against individual doctors and institutions. When the Act on Patient Injury Compensation was passed in 2001 (1), all public health services were included under the arrangement. In 2009, private service providers, including private hospitals and doctors with contracts with the public health service, also became part of the scheme.

For compensation to be awarded by the NPE, four criteria must be fulfilled (2, 3) (Box 1). Thus, even if a patient has his/her claim upheld, the sum awarded may still be zero if the individual has not suffered financial losses – the injury must have led to a loss of at least NOK 10 000 (NOK 5 000 for losses reported before 1 January 2016) or permanent medical disability of at least 15 %.

In addition, the Act on Patient Injury Compensation also includes a key exception clause, called «The reasonability rule», which may apply in cases where there is no error or omission of treatment, or objective liability. This exception allows for compensation to be awarded when the injury to the patient is particularly severe or particularly unforeseeable, and cannot be considered the outcome of an acceptable risk to the patient (1, 2).

We wished to examine those cases processed in the period 2001 – 14 within the field of anaesthesiology. In particular, we were interested in cases where the use of nerve blocks resulted in a claim being filed to the NPE – how these claims were assessed, the consequences of the injuries for the patients and whether any areas for improvement can be identified.

The period 2001 – 14 was chosen because the Act on Patient Injury Compensation was passed in 2001 and the recording of statistics by the NPE improved from this point forwards, including with the transition from ICD-9 to ICD-10.

BOX 1

**All four criteria must be fulfilled for compensation to be awarded**

The injury to the patient must be attributable to the treatment received (the balance of probability must be that there is a causal relation between the treatment and the injury)

As a general rule, there must have been an error or omission of treatment (treatment was not in accordance with good clinical practice, i.e. substandard care)

The injury must have led to financial losses of at least NOK 10 000 (NOK 5 000 for injuries reported before 1 January 2016) or a permanent medical disability of at least 15 %

The injury must not have occurred too long ago

## Material and method

The NPE has permission to store data on the basis of the consent granted by patients when seeking compensation and in accordance with the Archives Act (4). The lead author was granted access to anonymised data from the patient database.

From the database, information was retrieved on cases in the field of anaesthesiology (i.e. incidents in which anaesthetists were involved) with a decision date in the period 1 January 2001 to 31 December 2014, and with a code for central and peripheral blockade (spinal anaesthesia, epidural anaesthesia, combined spinal and epidural anaesthesia, sacral anaesthesia, nerve blocks), along with a number of other variables such as sex, age, type of anaesthesia, diagnosis, type of injury, site of injury, damages awarded and written descriptions of the treatment and injury. Further systematisation of cases was performed on the basis of information in the case summaries.

All expert reports concerning these cases were anonymised. This was achieved by means of an employee of the NPE Unit for Patient Security and Statistics physically removing sensitive personal information such as names and national identity numbers from the reports, and then copying them again. The reports were then reviewed in detail. Information was additionally obtained on whether each claim processed in the period was upheld or rejected, and on any damages awarded.

## Results

There were 940 cases within the field of anaesthesiology, 2.1 % of all cases handled by the NPE during this period. Of these, 256 (27 %) were accepted and 684 (73 %) were rejected.

A total of 339 patient injury cases related to nerve blockade were identified (0.8 % of all cases in the period): 149 spinal anaesthesia, 142 epidural anaesthesia, 21 combined spinal and epidural anaesthesia, as well as 27 peripheral nerve blocks. The complainants comprised 236 women and 103 men. The average age was 47 years (SD 17.9, range 12–92 years). The number of cases varied from year to year, but there was no particular increase in cases related to nerve blockade (Fig. 1). Orthopaedic surgery had the largest number of cases, followed by obstetrics (Table 1).

One hundred applicants (29 %) had their initial compensation claim upheld, but this number increased further after seven decisions were reversed following appeal and reconsideration. In the same period, a total of 44 701 decisions were made by the NPE, with 35 % of claims upheld. There was some variation in the proportion of claims accepted over the period in question. There is a tendency towards an increased proportion of rejections (especially from 2005), but the numbers are small.

The compensation claims concerned the following types of injuries: 93 peripheral nerve injuries, 67 central nerve injuries, 66 cases of back pain, 23 headache-related cases, eight injuries resulting in incontinence, and 82 «other». Several of the cases involved complaints regarding multiple symptoms, which may reflect complex injuries or injuries that are not fully characterised.

Of the 239 initial rejections, 60 % were on the grounds of «lack of causal relation» (between treatment and injury), and 39 % on the grounds of «no error or omission of treatment». Of the 100 upheld claims, 50 % reflected «substandard care», and 16 % an infection. «Infections» included local infections as well as meningitis, sepsis and epidural abscesses. Twenty-seven per cent of patients had their claim upheld as a result of the «reasonability rule». The distribution of accepted and rejected claims is shown stratified by case type in Table 1.

Four of the cases handled by the NPE regarding nerve blockade concerned patients who were deceased. Three of these patients had died from causes related to the blockade, and the compensation claims were upheld. One patient had died of another cause, and this claim was not upheld.

Nine patients had developed epidural haematoma or epidural abscesses following epidural or spinal anaesthesia. All nine had their cases upheld, eight because of an error or omission of treatment (delayed diagnosis) and one on the basis of the reasonability rule.

A total of NOK 82 million was awarded in compensation, which was approximately 1 % of the total amount paid out by the NPE during this period. Patients received an average of NOK 822 974 when a claim related to a nerve blockade was upheld, whereas the average for all cases handled by the NPE

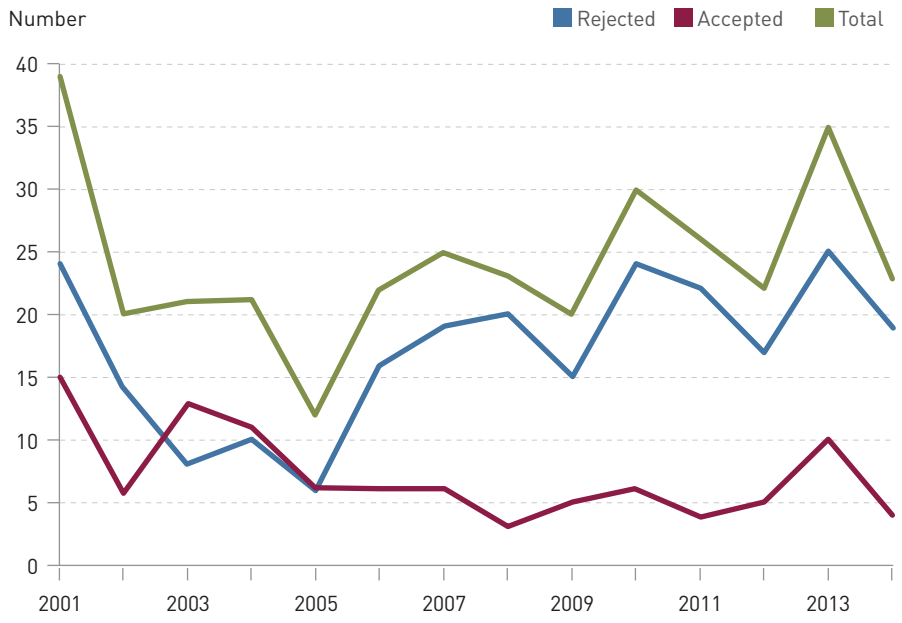


**Figure 1** *Number of claims for compensation submitted to the NPE between 2001 and 2014 inclusive regarding central and peripheral nerve blockade performed by anaesthetists, stratified by whether the claims were accepted or rejected*

was NOK 582 000. The size of the pay-outs ranged from NOK 0 to NOK 10 000 000. The median pay-out was NOK 347 500, which suggests that many pay-outs were relatively small. Forty per cent of patients who had their claims upheld received NOK 500 000 or more. The largest pay-outs were made for claims related to nerve blockade within orthopaedics (Fig. 2).

The expert reports from the first part of the period were less precise and in depth than those from later stages – this made it more difficult to identify the assessments that each patient had undergone in connection with their injury. On the basis of the available documents, we found that 83 patients underwent neurological evaluation and 39 underwent neurophysiological assessment.

## Discussion

A total of 339 patient injury claims relating to nerve blockade were identified, which comprised 0.8 % of all cases reported to the NPE during this period. In 32 % of cases, the patient had his/her claim upheld. These patients received compensation pay-outs totalling NOK 82 million, or approximately 1 % of the total pay-outs by the NPE. «Lack of causal relation» was the most common justification for rejection of a claim, whereas «substandard care» was the most common reason for a claim being upheld.

There has been a steady increase in the number of cases. This growth in caseload may be attributable to several factors, two of the most important being increasing awareness of the scheme and expansion of the scheme over the years. Parts of the primary health service and psychiatry were included in the scheme in 1992, with the remainder following after the Act on Patient Injury Compensation came into force in 2003. Private health care provision became part of the scheme in 2009 (1).

Cases related to anaesthesia account for a small proportion of those processed. Within the field of anaesthesia, cases related to dental injuries are the most common (5), but a third of cases involve central and peripheral nerve blockade. It has been reported that central and peripheral nerve blockade can cause serious and permanent injuries (6–8), and it is therefore important that these are examined.

The NPE summaries of closed cases consisted of short written accounts of varying quality, and therefore provided limited information. The expert reports also varied markedly, but do appear to have improved steadily over the course of the period examined. This meant that the classification of cases was to some degree a matter of judgement. We have not examined systematically either the expert statements or the casework procedures. Full disclosure of all cases would require the consent of each of the 339 applicants, which we did not seek.

Gaps in parts of the standardised information constitute the greatest weakness of our study. However, the study's strength is that it provides a complete picture of the anaesthesia-related cases handled by the NPE over a long period of time. Obtaining an overview of patient injuries related to central and peripheral nerve blockade can be challenging, as such patients are often primarily under the care of other medical disciplines besides anaesthesiology. It is also important for this reason to systematically analyse cases reported to the NPE within this field.

Unfortunately we have no information about the total number of nerve blocks performed in Norway. There are said to be 1.4 million neuraxial blocks (epidural and spinal anaesthesia) per year in Finland (9), and 1.96 million per year in Sweden (10). Taking the average of these two countries and adjusting for population size would mean that in Norway 1.19 million neuraxial blocks are performed each year, which corresponds to 16.6 million blocks in the 14-year period in which 339 cases were reported to the NPE.

**Table 1** Number of cases submitted to the NPE between 2001 and 2014 inclusive regarding central and peripheral nerve blockade performed by anaesthetists, stratified by medical discipline

| | Decision in claims | | | |
|---|---|---|---|---|
| Discipline | Rejected | Accepted | Total | Accepted (%) |
| Orthopaedic surgery | 85 | 43 | 128 | 33 |
| Obstetrics | 77 | 17 | 94 | 18 |
| Urology | 27 | 7 | 34 | 21 |
| Gastrointestinal surgery | 17 | 11 | 28 | 39 |
| Gynaecological surgery | 16 | 6 | 22 | 27 |
| Vascular surgery | 8 | 7 | 15 | 47 |
| General surgery | 5 | 6 | 11 | 55 |
| Other | 4 | 3 | 7 | 43 |
| **Total** | **239** | **100** | **339** | **29** |

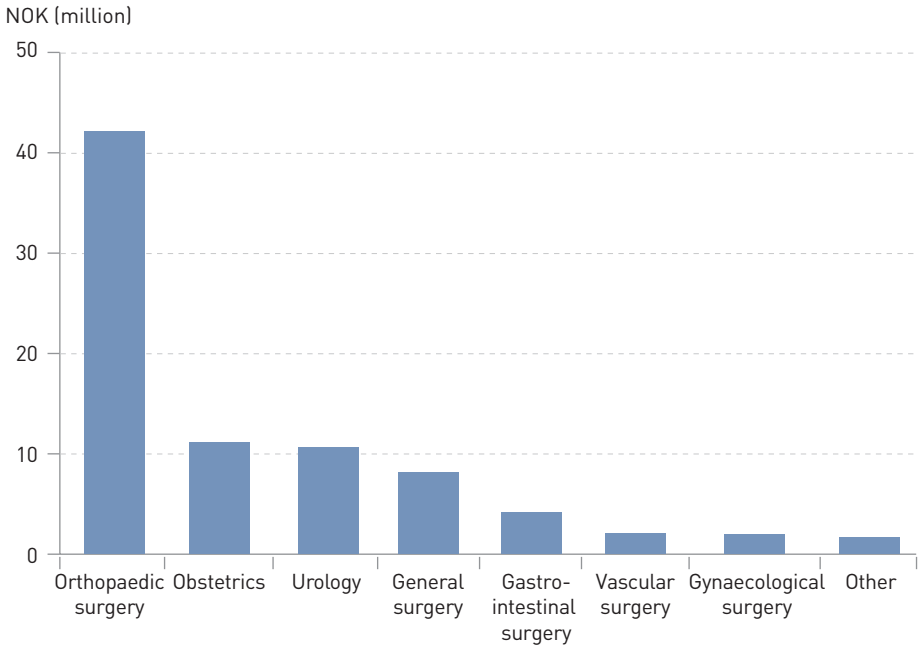


**Figure 2** *Total pay-outs in cases submitted to the NPE between 2001 and 2014 inclusive regarding central and peripheral nerve blockade performed by anaesthetists, stratified by medical discipline*

On the basis of these data it is not possible to draw any conclusions regarding the incidence of injuries associated with peripheral and central nerve blockade, as there is no systematic recording of injuries and complications resulting from the use of nerve blockade in anaesthesia. Sigurd Fasting has discussed the risks associated with anaesthesia in an article in this journal (11), citing unpublished data on nerve injuries resulting from regional anaesthesia, but in general little is known about this type of injury in Norway.

In the international literature, the incidence of serious neurological injuries resulting from use of central nerve blocks varies, but is in the region of 1:10 000–20 000 (12–14). The incidence in association with peripheral blocks is uncertain, but is said to be around 3–4 per 10 000 blocks (13).

A total of 339 patient injury cases over 14 years, a period in which there are likely to have been close to 16 million blocks, is not a huge number. Of these, 107 claims were accepted, while 232 were rejected (after appeal and reconsideration). But when cases were accepted, the injuries were often very severe and resulted in large pay-outs.

The reasonability rule can be used even if there is no error or omission in health care provision, or objective liability, and was used by 27 % of patients who had their initial claim upheld. The size of the awards varied. There was not always a correlation between the extent of the injury and the size of the pay-out – as it is the patient's financial losses that must be covered.

The filing of claims to the NPE is dependent on patients being aware of the possibility to apply for compensation and choosing to avail themselves of this right. Healthcare professionals have an obligation to inform patients about the possibility of seeking compensation if they have suffered an injury or serious complication in association with medical treatment (1). Little is known about whether doctors fail to disclose this information and, if so, why this might be.

The expert evaluation must provide information that will enable the case officer to decide whether or not the criteria for obtaining compensation have been fulfilled. Since there was deemed to be no causal link in 60 % of the claims that were rejected, and no error or omission of treatment in 39 %, this may suggest that many of the patients reported problems and symptoms that were unrelated to our procedures and/or that the nerve blockade was performed in accordance with good clinical practice. However, we appreciate that it may be difficult for patients to grasp an association (or lack of association) between their symptoms and the procedures that were performed in hospital.

The proportion of patients that appeal the decision is between 40 % and 50 %. It costs the patient nothing to appeal and it is not surprising that many take the opportunity to do so. According to the homepage of the Norwegian administrative appeals body for health services (15), approximately 13 % of disputed decisions are reversed. The percentage of reversals is lower for patient injuries related to nerve blockade (personal communication).

Several arenas have been established for the reporting of patient injuries – for the purposes of learning from adverse incidents (local systems for non-compliance reporting, various public reporting systems) (16, 17). But in most of these, it is the medical profession that does the reporting, whereas it is patients and their next of kin who report cases to the NPE. This means that the analysis of cases here is an important supplement to the analysis of cases reported to other systems.

Upon review of the 339 cases, we are left with the impression that documentation of the procedure is often incomplete and assessment of the injury inadequate. This means that it can be difficult to judge how a case was handled.

Where severe acute injury is suspected after neuraxial block (e.g. epidural haematoma), there are good guidelines available which should be followed (18). Good anaesthesia record-keeping is highly important. The records should describe the technique used, the number of injections, the drug and its concentration, problems and any complications. A postoperative follow-up is necessary for every patient who receives a nerve block, with systematic recording of efficacy and any adverse effects (12, 19).

When complications in the form of nerve injury are suspected after a central or peripheral block, the patient should be referred to a neurologist for assessment. This applies to patients with signs of paresis and/or paraesthesia, difficulties with walking and symptoms related to bladder/bowel control.

The neurologist will evaluate the indication for spinal MRI and/or neurophysiological assessment with EMG/neurography (occasionally supplemented with a Thermotest), dependent on whether there are signs of central and/or peripheral deficits in the clinical neurological examination. Signs of peripheral deficits in an extremity constitute an indication for EMG/neurography. A negative EMG/neurography result cannot rule out damage to the nerve root; the clinical neurological examination will be most important in this regard, in combination with spinal MRI.

The Thermotest is a semi-objective assessment and must always be interpreted in combination with a clinical neurological examination. The indication for a Thermotest should be evaluated by a neurologist. The test is offered only by some of the larger hospitals in Norway. None of the neurophysiological assessments alone will allow any definite conclusions to be drawn regarding the mechanism of injury; they only allow a nerve injury to be demonstrated in some cases.

## Conclusion

Complications in association with peripheral and central nerve blockade constitute a small proportion of the cases handled by the NPE. Of 339 cases, only 107 complainants had their claims upheld, but where claims were upheld, the injuries were often severe and led to large pay-outs.

That such a small proportion of claims was upheld may imply that patients report problems and symptoms that are unrelated to the treatment procedure, or that the nerve blockade was performed in accordance with good clinical practice. On the basis of these data, it is not possible to draw conclusions about the incidence of injuries associated with the use of peripheral and central nerve blockade in Norway.

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