

# Pathology-related cases in the Norwegian System of Patient Injury Compensation in the period 2010–2015

**BACKGROUND** The Norwegian System of Patient Injury Compensation (NPE) processes compensation claims from patients who complain about malpractice in the health services. A wrong diagnosis in pathology may cause serious injury to the patient, but the incidence of compensation claims is unknown, because pathology is not specified as a separate category in NPE's statistics. Knowledge about errors is required to assess quality-enhancing measures. We have therefore searched through the NPE records to identify cases whose background stems from errors committed in pathology departments and laboratories.

**MATERIAL AND METHOD** We have searched through the NPE records for cases related to pathology for the years 2010–2015.

**RESULTS** During this period the NPE processed a total of 26 600 cases, of which 93 were related to pathology. The compensation claim was upheld in 66 cases, resulting in total compensation payments amounting to NOK 63 million. False-negative results in the form of undetected diagnoses were the most frequent grounds for compensation claims (63 cases), with an undetected malignant melanoma ( $n = 23$ ) or atypia in cell samples from the cervix uteri ( $n = 16$ ) as the major groups. Sixteen cases involved non-diagnostic issues such as mix-up of samples ( $n = 8$ ), contamination of samples ( $n = 4$ ) or delayed responses ( $n = 4$ ).

**INTERPRETATION** The number of compensation claims caused by errors in pathology diagnostics is low in relative terms. The errors may, however, be of a serious nature, especially if malignant conditions are overlooked or samples mixed up.

The Norwegian System of Patient Injury Compensation (NPE) is a government agency subordinate to the Ministry of Health and Care Services. The agency processes claims for compensation submitted by patients who believe that they have sustained an injury as a result of an error in diagnosis or treatment in the health services. Initially the possibility for compensation applied only to the public health services, but has also been extended to private health services since 2009.

The NPE receives an increasing number of inquiries. From 2010 to 2015, the number of submitted cases increased by 30 per cent. Pathology is not specified in NPE's statistics, and the number of cases related to this specialty is therefore unknown.

Because pathology is largely based on individual recognition of patterns, it is also especially prone to erroneous diagnoses. Pathology departments and laboratories are also particular in the sense that manual routines remain widely used, not least in registration of patient data, labelling of samples and handling of the material through a number of different procedures. There is thus reason to expect compensation claims related to erroneous diagnoses and errors at the pre- and post-diagnostic level. Knowledge about such errors is valuable for efforts to enhance quality.

Reporting of adverse events in the specialist health services should be undertaken in accordance with routines defined by legislation and regulations (1). We may assume, however, that reporting practices vary (2). In case of serious adverse events, the patient must be informed about the opportunity to seek compensation (3). Complaints may therefore provide an indication of the type of error that has given rise to serious consequences. We have searched through the NPE's records to identify the types of cases that have their origin in errors committed in pathology diagnostics.

## Material and method

The study is based on a search through claims for compensation in the NPE's records for the period 1 January 2010–5 October 2015. The review included cases that had been decided in favour of the claimant as well as against. The NPE does not register cases related to pathology in a separate category. A hospital or medical centre is normally registered as tortfeasor, not the lower levels such as a department or laboratory. A search was therefore made using the NPE's internal codes for diagnostic procedures/examinations and subsequently through a review of brief summaries describing the injury that had occurred in

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## MAIN MESSAGE

During the period 2010–2015, a total of 93 pathology-related cases were reported to the Norwegian System of Patient Injury Compensation

The compensation claim was upheld in 66 cases, resulting in total compensation payments amounting to NOK 63 million

Most cases involved false-negative cancer diagnoses, the most frequent of which were malignant melanomas

each case. The searches were undertaken by NPE staff members and the summaries were reviewed by a pathologist.

In the summaries, the data had been de-identified with regard to the patient, the place and the pathologist who made the diagnosis. A few cases were registered with rulings in favour as well as against claimants who had submitted complaints against different parties. Cases with double registrations were counted as favourable to the claimant. The searches did not permit a clear distinction between public and private tortfeasors. Because of the de-identified processing, details of the cytological or histological diagnostics could not be investigated *ex post*.

## Results

Over the period 2010–2015, the NPE processed a total of 26 600 cases. A total of 33 per cent of cases ended in a ruling in favour of the claimant. Altogether 93 cases involved pathology-related diagnostics, of which 71 per cent (66 cases) were determined in favour of the claimant. Cases associated with pathology accounted for a total of three per cent of all registered cases that were determined in favour of the claimant because of diagnostic errors (66 out of 2 100).

The majority of the pathology-related cases involved erroneous diagnoses (Table 1, Box 1). The most frequent error was under-diagnosis, with a false-negative diagnosis of atypia and malignancy in melanomas as the largest group. In nine of the 66 cases that

were determined in favour of the claimant, the patient was registered as deceased. Six of these had a false-negative diagnosis of malignant melanoma, and in one case the stage of that disease had been erroneously identified.

False-negative cervical cytology diagnoses were also a common reason for compensation. Of the 13 misjudgements of cytology samples in the cases that were determined in favour of the claimant, altogether 12 had been performed with the old smear method and one with modern fluid-based techniques. It is unknown how many of these were performed as part of regular screening and thus collected from women who had no symptoms. None of the women with a false-negative cytology were registered as deceased as a result of undetected disease, but two of the women whose complaint was sustained had developed cancer, involving comprehensive subsequent interventions and poorer prognoses because of a delayed diagnosis of malignancy.

False-positive diagnoses were a less frequent cause of claims for compensation. The cases determined in favour of the claimant involved unnecessary treatment, such as chemotherapy, radiotherapy or surgery, partly with serious sequelae. One false-positive diagnosis of melanoma was due to a lack of confirmation of the diagnosis by two pathologists.

Other cases involved pre- or post-diagnostic issues, such as mix-up of samples, contamination of one sample by another,

## BOX 1

### Erroneous diagnoses

**False-negative diagnosis:** The sample has been erroneously diagnosed as benign (in case of suspected cancer) or normal despite being pathological, for example if having early-stage cancer or cancer.

**False-positive diagnosis:** The sample has been erroneously diagnosed as malignant or with another pathology despite being benign or normal.

mix-up of patient identities when taking dictation, or delayed communication of diagnoses. In all cases that involved contamination or mix-up, a ruling was made in favour of the claimant. None of these cases recorded as fatal outcomes, but seven out of eight cases resulted in unnecessary or the wrong type of cancer surgery.

To date, the cases that have been determined in favour of the claimant have entailed payments of NOK 63 million, with compensation sums ranging from NOK 8 000 to NOK 6 million. In a couple of cases the decision on a final compensation amount is still pending.

## Discussion

In the years 2010–2015, nearly six million diagnoses were made in the 17 public and two private pathology institutions in Nor-

**Table 1** Types of errors in pathology diagnostics in claims for compensation in the Norwegian System for Patient Injury Compensation in the period 2010–2015. Abbreviations: FNAC: Fine needle aspiration cytology; hist.: histological examination; cyt.: cytological examination

Type of error	Claim upheld		Claim rejected	
	Number	Specification	Number	Specification
False-negative diagnosis	43	Melanoma: 17 Cervix: 14 (13 cyt., 1 hist.) Breast: 3 (1 FNAC, 2 hist.) Other: 9 (gallbladder, prostate, sarcoma, thyroid (FNAC), ventricle)	20	Melanoma: 6 Cervix: 2 (cyt.) Lymphoma: 3 Other: 9 (sarcoma, breast (FNAC), thyroid, parathyroid, lung, skin, prostate, colon)
False-positive diagnosis	6	Breast: 3 (1 FNAC, 2 hist.) Cervix: 1 (hist.) Melanoma: 1	2	Ovary, cervix (cyt.)
Miscellaneous diagnostics	3	Wrong type of cancer: 2; wrong stage of melanoma	3	Wrong type of cancer
Delayed response	2	9 weeks, 12 months	2	2 weeks, 9 months
Contamination	4	Pipette material: 1; needle biopsy: 2; FNAC: 1	0	–
Mix-up	8	Course of events unestablished: 6; sample in the wrong cassette, answer dictated on the wrong request form	0	–
<b>Total</b>	<b>66</b>		<b>27</b>	

way (4). In light of this figure, the number of compensation claims is relatively low. Injury compensation from the NPE is a voluntary option, and applications are submitted by individual patients or their guardians. The number of cases in the NPE records therefore reveals nothing about the actual number of injuries caused by errors made in pathology departments or laboratories. Because the NPE does not register pathology-related cases as a separate category, we cannot exclude the possibility that some cases have been omitted from our searches.

The observation that false-negative diagnoses were the most frequent cause of claims for compensation is natural, for two reasons. First, inadequate or no treatment of cancer is potentially fatal, and as a rule more serious than overtreatment. Second, there is no system in place to capture false-negative diagnoses.

False-positive diagnoses are prevented by having two or more pathologists confirm a diagnosis of malignancy. Benign lesions, on the other hand, which predominate in daily diagnostics, are not controlled in a similarly systematic way. Diagnostics of large amounts of material expected to be benign may also increase the risk of errors if the diagnostics assume the character of routine screening (5).

Diagnostics of pigmented skin lesions are among the pathologists' most common tasks. Most of these lesions are benign moles or keratoses and easily diagnosed. However, the group of moles is also where pathologists face some of their most difficult diagnostic considerations when distinguishing between benign, irregular or atypical, and malignant, and where a misjudgement at worst may lead to a fatal outcome. Underdiagnosis of malignant melanomas is also reported as the most frequent cause of compensation claims internationally (6, 7).

The cause of false-negative or false-positive diagnoses is difficult to identify. Diagnosis of pathological changes largely depends on human factors, and even specialists with long-standing experience may commit errors of judgement. Some years ago in Sweden, underdiagnosis of malignant melanomas was revealed in a large group of patients (8, 9). The diagnoses were made by pathologists who had many years of experience (10).

There are no good studies of whether large workloads over time give rise to a higher number of errors in pathology diagnostics. Renshaw and Gould undertook studies of diagnostic safety with the aid of a blinded review of recently diagnosed biopsies and concluded that the workload had no significance for the number of errors (11).

However, this study was undertaken

among a small number of doctors over a limited period of time, and the participants were aware of the fact that a study was in progress. The doctors included in the study had previously had a limited workload, varying between 23 to 32 cases/diagnoses per day. Measuring workload in terms of diagnoses is also questionable as long as the type of diagnostics remains unspecified. The workload per case depends on the type of sample, the number of sections and further analyses, and will thus vary significantly, within as well as between different departments and laboratories.

The reasons why the diagnoses were overlooked in the Norwegian cases could not be identified by this study. Most likely, however, a double review of all samples by two pathologists, as practised when a malignant diagnosis is expected, might have prevented some of these errors.

A study of 359 pathology laboratories in the USA showed that departments that have systems for repeated review of a defined proportion of the cases prior to communication of a final result yielded a significantly lower proportion of revised diagnoses (12). However, no information is provided regarding the types of cases that were selected for review. Repeated review of all samples would require considerable resources and is regarded as unrealistic at a time when the shortage of pathologists has given rise to long waiting periods (5, 13).

Screeners are specially trained bioengineers who are schooled in assessing normal cell samples and in recognising samples with aberrant changes. False-negative cervical cytology diagnoses may have arisen due to erroneous assessments made by this group of professionals, although methodological problems may also have been a significant factor (14, 15).

The classical smear test is fraught with artefacts resulting from air drying, for example, which complicates the assessment. Mass screening of cervical cytology is therefore currently undertaken with the aid of fluid-based techniques, which eliminate sample collection errors such as poor smear technique, contamination by blood and air drying of the material. Although fluid-based testing is a relatively new technique, there is reason to assume that the improved morphology that can be achieved with this technique will considerably reduce the number of false-negative diagnoses in the future (16).

The number of pre-diagnostic and post-diagnostic errors accounted for 17 per cent of compensation claims. In the majority of the cases of mix-up (six of eight), the cause was registered as uncertain. Mix-ups can occur at many levels and involve patient

identities or requisitioners upon registration, sample containers upon reception, blocks or sections upon processing or diagnoses upon dictation of results.

Outdated ICT solutions and insufficient use of automated solutions are particular to pathology. The chain of safe patient identification is broken when samples arrive in the department. Today, only three of 17 public departments in Norway have systems for electronic requisitioning and possibilities for scanning patient IDs from test phials into their computer systems, but none of them use electronic requisitioning for all samples (according to a survey of public Norwegian pathology departments in March 2016 undertaken by G.C. Alfsen, unpublished data). Most departments transfer data on patients and requisitioners manually to their own computer systems. Hand-written clinical information is scanned from paper request forms, which are manually labelled along with the sample containers using stickers with bar codes internal to the department.

The handling of the material is also largely undertaken manually. Small tissue samples such as from curettage or pipelle, endoscopic biopsies or needle biopsies are moved manually several times – from the containers to transport cassettes and subsequently to casting moulds. Each handling procedure involves a risk of loss of tissue, contamination of one sample by another and mix-up. Many types of small tissue samples can be put directly into the cassette by the clinician when collecting the sample, but this requires electronic requisitioning and/or pre-marked cassettes and is used only in a single department in Norway for a limited proportion of samples. Automatic casting machines reduce the amount of manual handling of small samples, but have so far been procured by only a couple of departments and are used only for a selected proportion of the smallest samples.

Systematic reviews have detected contamination from various sources in the laboratories in 0.6 per cent of all sections (17, 18). We know from our own experience that contamination or mix-up of samples regularly cause near-misses which are prevented through control routines internal to the departments. There are no reliable figures for such near-misses.

The risk of erroneous diagnoses caused by mix-up of IDs or contamination has spurred the development of a system for routine comparison of the DNA of the patient with that of sample material in paraffin blocks (19). Mix-up of IDs may equally well occur when the sample is collected, i.e. before the sample arrives in the department. The US study described only prostate cancer diagno-

ses and detected no differences in risk of ID mix-up between the doctor who collected the sample (urologist) and the pathology department, with a total risk of mix-up in 0.26 per cent of the cancer samples. Contamination of the test blocks was detected in 0.67 per cent of the cases and was mainly caused by handling in the pathology departments. On the basis of this study, the number of false-positive prostate cancer diagnoses was estimated at approximately 4 500 per year and the annual costs were estimated at USD 880 million (20).

The incidence of overlooked diagnoses has not been systematically investigated in the same way, and thus the costs of the consequences ensuing from a delayed cancer diagnosis have not been estimated. Although there are only few compensation claims resulting from mix-up or contamination in our study, there is little reason to believe that the real incidence of such errors is lower in Norway than in other countries. It is therefore likely that an upgrade of ICT systems and introduction of electronic requisitioning and ID tracing of samples throughout the process would entail a considerable improvement in patient safety. Upgrading of the equipment base with a focus on preventing contamination is another measure that might reduce the number of pre- and post-diagnostic errors (21).

## Conclusion

Although the number of compensation claims because of errors committed in pathology departments and laboratories is relatively low, the errors often entail serious consequences for the individual patient and high costs to society. The number of cases in our study does not permit any conclusions regarding the real incidence of errors.

Errors that cause diagnoses to be overlooked could most likely be better prevented by the introduction of repeated review of selected groups of diagnoses. Errors caused by pre- or post-diagnostic issues and pertaining to the organisation of the receipt of samples and response routines or technical matters can be reduced with the aid of existing and commercially available solutions, but this would require financial investments.

Placing more emphasis on quality assurance of the diagnostics in Norwegian pathology departments could be an appropriate measure to enhance patient safety.

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