Approved claims for compensation from gynecological patients in Norway

-what characterizes the cases?

a 14-year nationwide study

Merethe Ravlo MD1,2, Marit Lieng MD, PhD3,4, Ida Rashida Khan Bukholm MD, PhD5,6, Mette Haase Moen MD, PhD1, Eszter Vanky MD, PhD1,2

1Department of Clinical and Molecular Medicine, Norwegian University of Science and Technology, Trondheim, Norway, 2Department of Obstetrics and Gynecology, St. Olav’s Hospital, University Hospital of Trondheim, Norway, 3Department of Gynecology, Oslo University Hospital, Oslo, Norway, 4Institute of Clinical Medicine, University of Oslo, Oslo, Norway, 5Norwegian System of Patient Injury Compensation, 6 Department of Surgery, Akershus University Hospital, Lørenskog, Norway.

## Corresponding author:

Merethe Ravlo,

Dept. of Obstetrics and Gynecology

St. Olav’s Hospital, University Hospital of Trondheim

Postboks 3250 Sluppen, 7006 Trondheim

Telephone: +47 48 07 45 31

E- mail: merethe.ravlo@ntnu.no

## Conflicts of interest

MHM and ML both work part-time at NPE as medical experts. IRKB is medical adviser in NPE.

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Abstract

**Introduction** The Norwegian System of Patient Injury Compensation (NPE) evaluates all patient reported claims in Norway. Our aim was to study the cases from gynecological patients approved by NPE, in order to identify the main reasons for the injuries, the consequences of the treatment failure for the women, and the time course when the treatment failure occurred.

**Material and methods** A retrospective, descriptive study of approved gynecological compensation claims during a 14-year period, based on patient files from NPE.

**Results** In all, 1454 women claimed compensation for injury related to gynecological treatment in Norway from 2000 to 2013. Compensation was approved for 438 (30.1%) women. Eleven women declined participation in the study and 16 cases were excluded, leaving 411 cases for further analyses. Consent to participation was given by 211 (51.3%) women, who gave full access to all NPE-files. Anonymized resumes and expert statements were used for the 138 (33.6%) women who did not respond, and the 62 (15.1%) women who were deceased.

Guidelines or good clinical practice were not followed in 40.5% of the cases. The most common reasons for injury were surgical complications (67.6%), delayed (22.4%) and incorrect (17.0%) diagnoses, and failure of communication (11.7%). The main consequences of injuries were need of extensive treatment (64.2%), permanent injury (55.2%) and impaired physical ability (41.9%). Worsening of cancer prognosis occurred in 58 women (14.1%), and death due to treatment failure in 29 (7.1%) women. Most failures occurred during the treatment period (75.2%).

**Conclusions** We found that the main reason for injuries in gynecological patients, was non-adherence to guidelines or good clinical practice. Surgery-related injuries were most common. Increased focus on adherence to guidelines and surgical skills might improve patient safety for gynecological patients in Norway.

**Key Words:** NPE, failure,compensation, gynecology, substandard health care, guidelines.

**Abbreviations:**

NPE: Norwegian System of Patient Injury Compensation (Norsk pasientskadeerstatning).

**Key Message:** Our study indicates that adherence to guidelines and surgical skills are important factors in preventing treatment failures.

## Introduction

The number of complaints after medical treatment in Norway has been continuously rising since The Norwegian System of Patient Injury Compensation (NPE) was founded in 1988.1,2 In 2016, almost 14% of patients in Norwegian hospitals experienced some kind of patient injury.3 Previous studies reported 2-16% preventable adverse events of hospitalised patients.4,5 Identifying and learning from errors might increase patient safety.6,7 An important foundation for patient safety improvement work is the analysis and learning from patient-reported failure.

NPE evaluates all claims for patient compensation in Norway. While previous studies reviewing claims for compensation to the NPE have been published,8-12 no investigation of treatment failure connected to gynecological conditions, has been carried out.

Our primary objective was to identify the reasons for NPE-compensated injuries related to gynecological treatment. Secondary objectives were to evaluate the consequences of the treatment failure for the women, and when in the course of treatment the failure occurred.

## Material and methods

The study is a retrospective, descriptive study of gynecological patients who received compensation from NPE during a 14-year period, from 2000-2013.

When receiving a complaint, NPE obtains all relevant available information, as well as a medical expert statement reviewing the case.2 The medical expert statement is vital part of the investigation. Lawyers at NPE then evaluate the medical expert statements and the legal aspects of the case, and approve or deny compensation. Resumés of closed cases are shared with the defendant care institution. In order to qualify for compensation, three conditions have to be met13: the injury must most likely be caused by a treatment failure, the patient must have sustained a financial loss, and requirement for compensation must be submitted within three years after awareness of the harm. There are two main exceptions from the basic rules (“exception rules”) where compensation can be granted without failure: injury after hospital-acquired infections, or severe and unexpected injury. In approved cases, compensation is given according to the “blame-free” principle system,14 similar to the compensation system in other Nordic countries.15

Cases were retrieved from the NPE database by diagnosis codes including all gynecological diagnoses (ICD10: C51-C58, D06-D07, D25-D28, N70-N99). All claims for compensation reported by gynecological patients between January 2000 and December 2013 were identified (figure 1). Earlier claims were not included because of changes in the NPE registration system. Moreover, old cases might not elucidate the medical challenges of today, and thus be less relevant. Cases from 2000-2008 were available as paper files, and cases from 2009-2013 as electronic files.

Only approved claims were studied. All living women who had their case approved, were asked by letter for consent to include their case in the study. Non-responders received a reminder after eight weeks. Complete NPE- files were assessed for those who consented. The files normally included the injury report composed by the applicant, a report from the treatment center(s), the expert statement(s), medical journal(s), and a summary, including the conclusion, made by the NPE-lawyer. For non-responders and for deceased, we used the anonymized expert statement(s) and the summary. These statements and summaries were detailed and structured, and together they contained nearly as much information as the complete files.Analyzes were done to find if the groups of women who consented and non-responders, were comparable. The groups were combined in the results.We did not ask relatives of the deceased for consent, as we did not know if relatives were informed about the medical condition and her claim for compensation.

Paper files, which are stored in NPE locations, were collected by the NPE-staff. Electronic files were available through an NPE computer. The first author (MR) was given access to the files, performed a review of all available documents, and registered the relevant data in a database. The review was structured by the study case reform form, which was designed during planning of the study. To ensure the quality and objectivity of this review, 10% of the cases, randomly selected, were anonymously reviewed by a co-author (MHM)*.*

Conclusions made by medical experts and NPE lawyers were unconditionally accepted and not evaluated by the authors.

Guidelines were crucial for medical experts to evaluate if medical malpractice had occurred. The National Norwegian Gynecological Guidelines, published by the Norwegian Association of Gynecology and Obstetrics were normally used. These guidelines are now available online, and are continually updated.16 All cases were judged according to guidelines available at the time of injury. In some cases, relevant guidelines did not exist. The medical experts then evaluated whether the treatment was performed according to “good clinical practice”.

To evaluate the reasons for approved claims, we categorized them as: surgical injuries, medication failures, failure of medical equipment, misinterpretation of diagnostic tests, or “other failures” including administrative and communication failures and failures related to concurrent conflicts of interest, and lack of documentation. We did not differentiate between surgery for benign and malign conditions. In our setting, dividing these groups of patients was not expedient.

Medical experts and NPE-lawyers did not specify, during the proceedings, whether the injury was caused by an individual or a system level failure. As far as we know, no generally accepted definition of individual and system level failures exists. Wu et al defined system errors as latent errors, where the system “sets up” individuals to make mistakes, and individual errors as deficiency in the physicians’ knowledge or attentiveness. 17

The outcome “consequences of failure” was categorized as: death, permanent injury, worsening of prognosis, impaired physical ability, extensive treatment, pain, psychological strain and financial loss. The categories were selected for this study by the authors. The first author categorized the consequences of failure, especially focusing on the expert statements. Often, more than one consequence was present.

To evaluate *when*during the treatment process the failure or omission occurred, we defined three time periods: “Pre-treatment” period included the time before any treatment had started; “treatment period” was throughout the entire medical treatment; “after treatment” was after discharge or after outpatient treatment.

*Data recording and analysis*

Data collection was performed using a web-based case report form, developed by the authors, and technically developed by Unit of Applied Clinical Research, Institute of Cancer Research and Molecular Medicine, Norwegian University of Science and Technology, Trondheim, Norway. The data were recorded and analysed using IBM SPSS Statistics for Mac, Version 24. (IBM Corp, Armonk, NY, USA). To test differences in the group who consented vs non-responders, we performed a chi-squared test. A probability value of p<0.05 was considered statistically significant.  
*Ethical approval*

The Regional Committee for Medical and Health Research Ethics stated that this study did not need an approval (2014.04.14, 2014/355/REK nord). Norwegian Social Science Data Services approved the project (2015.02.17, 40522/3/KS). NPE’s own in-house ethical committee also approved the study.

## Results

In total, 1454 gynecological patients reported claims for compensation to NPE from January 2000 to December 2013.

Compensation was approved in 438 cases (30.1%). Out of these, 11 (2.5%) declined study participation and 16 (3.7%) cases were excluded, leaving 411 cases for analyses. The exclusions were due to double reporting or because they were not strictly gynecological cases. Consent to participation was given by 211 (51.3%); 138 (33.6%) did not respond, and 62 (15.1%) women were deceased (figure 1). Baseline data of the included women are shown in table 1. Women who consented to inclusion, had higher mean age 45.4 (±13.1) vs 41.9 years (±12.8) (p=0.002), and a higher education level (≥13 years) (49% vs 11%, p<0.01) compared to non-responders.

The treatment was not in accordance with national guidelines or good clinical practice in 40.5% (table 2). In 14.6%, a medical indication for treatment was not present. This included cases of unnecessary surgery or medication therapy and/or excessive cancer treatment.

Table 3 shows the main reasons for injury. Surgical failure was the most common reason for approved complaints (67.6%), followed by delayed diagnoses (22.4%), incorrect diagnoses (17.0%) and failure of communication (11.7%). Communication failures most often occurred in relation to surgical procedures (lack of information regarding indication, procedure, treatment alternatives and/or risk of complications). The most frequent reasons for medication failures (9.3%) were incorrect hormone therapy and antibiotic treatment, or inadequate anticoagulant prescription.

Suboptimal examinations, such as not performing PAP-smear tests, gynecological examinations, transvaginal ultrasounds, CT-scans or biochemical analyses when appropriate, accounted for delayed diagnosis in 42 out of 92 cases (45.7%). Almost half of the incorrect diagnoses were related to cancer, and were followed by surgical procedures due to wrong diagnoses. Only one misdiagnosis was infection. Concurrency conflicts and failure of technical equipment were reported in 2.2% of the cases. Approval based on exception rules represented 20.0% of the cases.

The most prevalent failure among cancers was seen in cervical cancer (52%), followed by ovarian cancer (26%), endometrial cancer (17%), vulva cancer (3.6%) and other cancer types (2.7%). Also, 6.3% women were mistakenly treated for gynecological cancer without having cancer.

Except for delayed diagnosis, where non-responders were over-represented (25% vs 18%, p=0.004), no differences between the two groups, according to main reasons for injuries, were observed.

The main consequences of failures (table 4) were: need of extensive or prolonged treatment (64.2%), including re-operations, prolonged stay in intensive care unit and prolonged or more aggressive medication, permanent injury (55.2%); and impaired physical ability (41.9%). In total, 29 died due to a failure. Twenty-five out of 29 deaths (86.2%) occurred in women with a malignant diagnosis.

The majority of failures (75.2%) occurred during the treatment period (table 2). More than one failure or omission was found in 14.9% of the cases, for example both during treatment and follow-up. Failure was related to emergency care in 13.4%.

Compensation was denied for 1016 women (69.9%). The reasons for denial were that: no medical failure had occurred (45.9%); there was no correlation between patient complaint and treatment performed (38.3%); the diagnostics were due to good clinical practice (10.1%); the infections were due to patients’ underlying disease (2.0%); failure was not due to medical negligence (0.9%); and, that no economic loss from medical failure had occurred (2.3%).

## Discussion

Our main findings are that guidelines and good clinical practice were often not followed in approved NPE-cases in gynecology, and injury during surgery was the major cause of harm.

Guidelines are regarded as standards in medical treatment and are expected to assist clinical decision-making. Guidelines are not always absolute, and do not exist for all medical conditions. Deviation from guidelines may be accepted if the reason is medically rational and well documented. The statement that “guidelines were not followed” is part of the medical experts’ evaluation. It was not possible to extract information of what kind of guidelines were not followed. Concurrency conflicts and failures related to emergency situations were rare and cannot explain deviation from guidelines. Norwegian guidelines in gynecology have been available during the entire study period. All residents complete mandatory courses, supervision is compulsory, and continuous education is covered. Why, then, do physicians in Norway not adhere to guidelines? It has been reported that professionals adhere to new guidelines in only half of the cases one year after implementation.18 Physicians also seem to trust their own experience and “unwritten rules” more than written guidelines.19 According to NEHI, an effective way to promote adherence to guidelines is to encourage physicians to compare data.20 Registries for different types of treatments and complications have become more common in Norway and might raise awareness of medical failures. The health authorities encourage compliance to the quality registries, and from 2019, the funding of surgery to the health institutions is dependent on registry coverage. It is expected that this initiative will contribute to increased quality registry coverage, and contribute to increased patient safety. Guidelines are continuously updated. Information about new or revised guidelines, and implementation of them in medical practice throughout the country, is a challenge. Physicians have a responsibility to be up-dated. A system where changes in guidelines are shared, eg via e-mail, might be possible. NEHI has stated that physicians in the US believe guidelines will have strong influence on decision-making in the years to come.20 We have no information on whether Norwegian physicians are of the same opinion.

We did not perform analyses on variations between different healthcare settings. Private and public hospitals, and local and university hospitals in Norway, often treat different patients with different complexity. Comparing the rate and type of failures would consequently be difficult due to risk of selection-bias.

Delayed or incorrect diagnoses were the main reasons for failure during the pre-treatment period. To avoid these failures, some authors suggest guidelines and check-lists for common symptoms.21,22 Time limits for managing suspected gynecological cancer has lately been introduced by the Norwegian health authorities. This might decrease pre-treatment failures caused by delayed diagnoses. Systems for decision support are not widely available for gynecological conditions in Norway. Implementation of such systems might contribute to improved safety. Surgery-related failures dominated in the treatment period; this was in accordance with previous reports.15,23 During follow-up, complications not discovered after surgery and failure to follow-up pathologic PAP-smears were most common. Surgical complications are expected and accepted, and are not automatically compensated. Surgery often causes immediate and serious harm and might be easier to detect than other medical failures.A surgical procedure can have been performed in accordance with guidelines, without achieving an optimal outcome.To qualify for compensation, the injury must have been caused by a treatment failure.Surgical injuries resulted in approval mainly because the injury was not discovered within reasonable time postoperatively - even if the procedure itself might have been acceptable despite the harm.

We did not discriminate between benign and malignant surgery. Advanced surgery is more exposed to complications. But, as complications are not necessarily medical failures, advanced surgery is not more exposed to failures than routine surgery. Medical experts consider risk for complications when evaluating a complaint. For instance, ovarian cancer can be among the most radical procedures in gynecological cancer treatment. Still, no cases after surgical complications due to ovarian cancer were included among the approved cases.

We did not compare different types of surgical procedures, as this type of comparison demands larger, and preferably prospective, studies or prospective quality registries.

Surgery was the treatment most often performed without a proper medical indication. In case of unnecessary surgery, the surgery itself was the failure, even if the procedure was correctly performed. This underlines the importance of following guidelines also on indication for surgery. An example is performing oophorectomy due to a simple ovarian cyst in a premenopausal woman, when guidelines recommend an expectant attitude.

Focusing on both indication for surgery and surgical training might reduce surgical failures. In Norway, there is an ongoing revision about education of surgical specialties. The health authorities advocate a more efficient model for specialization, and suggest minimizing the number of surgical procedures necessary to become a specialist. It is not known what influence this will have on surgical skills. Previous studies indicate more complications when the surgeons are inexperienced.24 Experienced surgeons often perform more complicated procedures. Thus, comparisons based on level of provider experienceis difficult. Doctors experience is not documented in the medical papers from hospital, and was therefore not possible to analyze in this study.

It is difficult to distinguish between individual and system level failures in medical care.25 Individual failures might be influenced by system deficiencies such as long working hours, inadequate supervision and training, or stress due to working conditions. In order to recognize system failures, we need knowledge about the organization. It is widely accepted that a system approach to improve quality is more efficient than an individual approach.6 The Norwegian Board of Health Supervision underlines the importance of considering system failure when investigating medical errors.7 Our intention when planning the study, was to address the medical failures as systematic or individual, but available data was not sufficient to do this.

The main consequence of gynecological treatment failure was need of extensive treatment. This may cause longer hospitalization, worsening of prognosis, pain, insecurity, prolonged sick-leave and economic burdens. The implications not only affect the patient involved, but also have a negative economic impact for the society and may delay treatment of others.

This is the first study describing patient reported harms after gynecological treatment in Norway. The material is unique on a national level and comprises complete, nation-based data on patient complaints covering 14 years. No other registries include all types of complications from all health institutions in Norway. It is easy to forward a complaint to the NPE and the registrations here are more comprehensive than local hospitals’ registries.26

We consider it a strength of the study that 97.5% of available cases were included. However, only 51% of the included women consented to participate, and gave access to all files. Some information might have been lost where only anonymized medical expert statements and resumés of the cases were available.

We have no information about patients *not* claiming for compensation after failure. Bismark et al. found that only 1 out of 25 patients filed a complaint after a serious and preventable failure.27 We can only assume this is also the case in Norway. It is a risk that NPE-cases do not represent all medical failures. The external validity of the study population is consequently a limitation. However, the NPE registry is the most comprehensive of patient injuries available in Norway.

The NPE criteria for approval might fail to identify cases of blameworthy practices. Patients may experience harm without having an economic loss. The “exception rules” compensate for some of these occurrences, as they together represent one-fifth of all approved cases.

We have not evaluated denied cases. In almost all these cases, no medical failure had occurred, according to medical experts. We considered that studying complaints where no medical failure had occurred, was outside the scope of our work.

In conclusion, the present study indicates that in approved claims for compensation related to gynecology, guidelines were often not followed. Most failures occurred in connection with surgery. Focusing on adherence to guidelines and surgical skills for gynecologists may bring down the number of failures and increase patient safety.

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**Legends to figures:**

Figure 1. Study flow chart.

**Legends to tables:**

Table 1 Age and education of women granted compensation from NPE, and health care level of defendant institution.

Table 2 Adherence to guidelines or good clinical practiceand failure according to management timeline

Table 3 Main reasons for injury

Table 4 Main consequence of failure for women granted compensation