

Article

Documentation and disclosure of adverse events that led to compensated patient injury in a Norwegian university hospital

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Abstract

Objective: Primarily, to describe to what extent patient injury, compensated by a national system of patient compensation, was reported in the mandatory incident-reporting system and documented in the patient's medical records. Secondly, to investigate whether there is documentation of patient disclosure of the injury and documentation that the patient was informed of his or her right to apply for economic compensation.

Design: A retrospective study of administrative data and patient records.

Setting: Trondheim University Hospital, Norway.

Participants: Patients receiving financial compensation for patient injuries that occurred between the 1 March 2009 and the 31 December 2012.

Intervention: None.

Main Outcome Measures: Documentation of injury, type of injury and consequence for the patient. Patient disclosure in medical records. Prevalence of incident reports.

Results: 20.4% of all compensated patient injuries and 26.3% of serious compensated patient injuries, defined as death or a disability of >15%, had been reported. The injury was documented in the patient's medical records in 90.7% of cases, but as an adverse event causing patient injury in only 3.4%. Documentation about patient disclosure was missing in 32.1% of cases, and giving information of his or her legal right to claim compensation was documented in 21.6% of cases.

Conclusion: Underreporting and nondisclosure of patient injuries remain a problem, despite a mandatory reporting system. Helping physicians and surgeons recognize adverse events, reporting them and discussing them with patients should be a priority for hospitals and medical schools.

Key words: safety management, patient injury, incident reporting systems, patient disclosure

Introduction

Adverse events occur too frequently in health care. A systematic review on in-hospital adverse events from 2008 found an overall incidence of 9.2%, with 43.5% of events being classified as preventable [1]. Although more than half of the patients experienced no or minor disability, 7.4% of events contributed to death. Surgery and medication-related events were most common. Recent studies have shown similar results [2–4]. A longitudinal retrospective patient record review study that compared rates of adverse events in 2004 and 2008 found an increase in adverse events, which suggests that patient injury is a persistent problem and may be hard to influence [5].

Since the introduction of the Norwegian Specialised Health Services Act in 1999, health trusts, hospitals and businesses that provide specialized health care are obliged to report all medical errors that resulted in, or could potentially have resulted in, patient injury to the Norwegian Knowledge Centre for the Health Services [6]. This is a non-punitive learning system, and reporting is done through the hospital's internal electronic reporting system. According to the same law, serious adverse events must also be reported to the Norwegian Board of Health Supervision. The Patient's Rights Act, implemented in 1999, states that all health personnel are obliged to inform the patient of any adverse event or serious complication and must be made aware of their right to apply for compensation for patient injury through the Norwegian System of Patient Compensation (NPE) [7]. The NPE is a government agency under the Norwegian Ministry of Health and Care Services that handles compensation claims from patients who have sustained injury in the Norwegian health services, both public and private health care [8]. To be entitled to compensation, the injury must be a result of failure in the diagnosis, treatment or follow-up provided. Compensation can also be awarded if the injury is particularly severe or unexpected, even without a failure in the health care provided. However, this only accounts for 2% of the cases where the patient receives compensation [9]. The intention is for the compensation to cover increased costs or loss of earnings as a result of the injury but can also be awarded to compensate for reduced quality of life [10].

Underreporting of adverse events by health professionals is well documented [3, 11–13]. Christiaans-Dingelhoff and co-workers found that only 2% of adverse events found by patient record review had been reported by health care professionals in an incident reporting system [3]. Similarly, Sari and co-workers found that 5% of adverse events identified by patient record review were reported [11]. A Swedish study on malpractice claims from patients found that only 20% of severe adverse events had been reported [12].

The purpose of a mandatory electronic incident reporting system is to provide information for learning and quality and safety improvement. This requires a high compliance with the system among healthcare professionals. The aim of our study was to describe a hospital's documentation of adverse events that cause patient injury:

- To what extent were compensated patient injuries reported in the electronic incident reporting system and documented in the patient's medical records?
- Is there documentation of patient disclosure of the adverse event?
- Is there documentation that the patient was informed of his or her right to apply for economic compensation?

The terms error, harm and adverse event are in this study defined according to the National Quality Forum (Table 1), and the term patient injury is used equivalently to patient harm [14].

Table 1 Terms and definitions [14]

Term	Definition
Error	The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim (commission). The definition also includes failure of an unplanned action that should have been completed (omission).
Harm	Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury.
Adverse event	An event that results in unintended injury to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.

Table 2 Index for Categorizing Medication Error developed by NCC MERP [15]

Category	Description
A	Circumstances or events that have the capacity to cause error
B	An error occurred but the error did not reach the patient
C	An error occurred that reached the patient but did not cause patient harm
D	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or intervention to preclude harm
E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
G	An error occurred that may have contributed to or resulted in permanent patient harm
H	An error occurred that required intervention to necessary to sustain life
I	An error occurred that may have contributed to or resulted in the patient's death

Methods

Study setting

The study took place at Trondheim University Hospital/St. Olav's Hospital Trust in Sør-Trøndelag County in Norway. The trust provides tertiary care for 670 000 people; it is the primary hospital for 290 000 and treated 207 071 inpatients, corresponding to 970 753 inpatient days, in the study period from 1 March 2009 to 31 December 2012. The trust performs ~30 000 operations yearly. An electronic incident reporting system replaced the paper version on 1 March 2009.

Study sample

During the study period, 523 claims connected to health care given at Trondheim University Hospital were made to the NPE. Fifty claims were rejected by the NPE without evaluation for formal reasons. In 298 cases, compensation was declined and in 175 cases (33%), compensation was granted. Eight hospital patient files were insufficient for analysis. The study sample thus consisted of 167 patients who were awarded economic compensation from the NPE because of injury while receiving health care (Fig. 1).

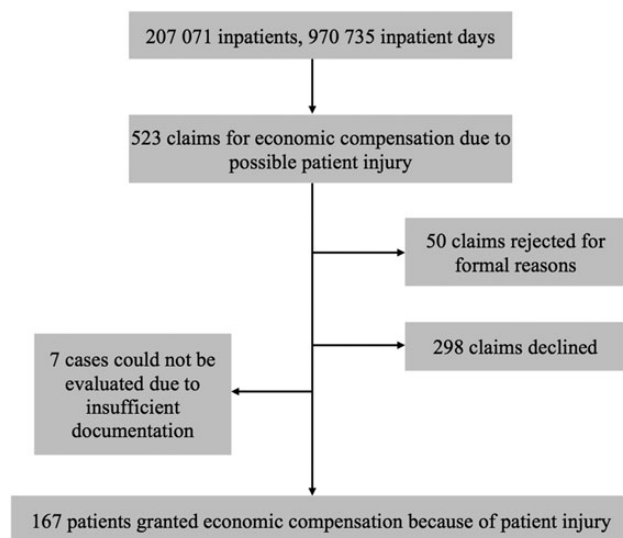


Figure 1 Claims for economic compensation from the Norwegian System of Patient Compensation for possible patient injury at Trondheim University Hospital, Norway, between 1 March 2009 and 31 December 2012.

Data sources

The data from the NPE made it possible to access additional data sources:

1. *Expert medical reports* written by physicians or surgeons who are independent, impartial, specialized in the given medical field and appointed by the NPE. The reports were used to identify medical specialty, type of patient injury and consequence of the injury.
2. *Mandatory electronic incident reporting system* was used to note whether health professionals had reported the patient injury.
3. *Electronic medical records* were reviewed from date of injury to present day and used to answer four questions:
 - (a) Is the patient injury documented in the patient's medical records?
 - (b) If the injury is documented, is it described as an adverse event or is it described as a foreseeable complication or attributed to the nature of the disease?
 - (c) Is patient disclosure of the injury documented? Patients were categorized into three groups: informed, not informed and patients with self-identified injury.
 - (d) Is there documentation that the patient has been informed of his or her right to apply for patient injury compensation?
4. *The hospital's administrative system* provided information on the number of inpatients, inpatient days and performed operations during the study period.

Data collection

Based on information in the expert medical reports, the 167 patient injuries were classified into medical specialty and type of injury (listed in Tables 3–6). In addition, the consequence of the adverse event was classified using the Index for Categorizing Medication Errors developed in the USA by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) as shown in Table 2 [15]. Even if this classification system is designed primarily for medication errors, it was found useful in this study. The index classifies the error into nine categories (A–I) according to severity of the

outcome. Categories E, F, G, H and I of the index describe errors that resulted in patient injury. Within Category G (error that may have contributed to or resulted in permanent patient injury), we decided to distinguish between patients with disability below and above 15%. Degree of disability was assessed by the independent medical experts based on detailed recommendations given by the Norwegian National Insurance Act of 1997 [16]. This cut-off was chosen because an injury, which leads to at least 15% disability, is the NPE's definition of significant injury and is required in order to be granted compensation for reduced quality of life. We have therefore decided to define serious consequences of the event as death or a disability $\geq 15\%$.

Ethics and approvals

Before its start, this study was approved as a quality improvement project by the Regional Committee for Medical and Health Research Ethics (2014/339/REK Midt) and approved by the health trust's CEO, the privacy ombudsman and the safety representatives for the staff.

Data analysis

SPSS21 was used for data analysis. Missing values did not exclude the patient from the study, only from those analyses for which the patient had missing data. The patients were grouped according to demographics, medical specialty, type of injury, consequence of injury and documentation of the event and disclosure in the medical records. Descriptive statistics were used to present the data.

Results

Patients

The study sample consisted of 167 patients treated at Trondheim University Hospital with a date of injury between 1 March 2009 and 31 December 2012. Fifty-three patients were awarded compensation after injury in 2009, 46 in 2010, 51 in 2011 and 17 in 2012. The mean patient age at the time of injury was 52.5 years (range, 0–86 years), with seven patients below 20 years of age; 93 (55.7%) were female and 74 (44.3%) were male. Table 3 presents the distribution of medical specialties and degree of injury. The largest groups by medical specialty were orthopaedics (47.6%), obstetrics and gynaecology (8.4%) and gastrointestinal surgery (7.8%), which accounted for almost 65% of all injuries granted compensation.

In 40 cases (24.1%), the error resulted in temporary injury. Of these, 2 cases required intervention but did not lead to prolonged hospitalization (Category E), 32 cases required prolonged hospitalization (Category F) and 6 cases required intervention to sustain life (Category H). In 111 cases (67.9%), the injury was permanent (Category G). Of these, 68 patients had a disability of $\geq 15\%$. The error contributed to or resulted in death (Category I) in 15 patients (9.0%). Information on disability was unavailable in one case, and the patient is therefore excluded from results relating to degree of disability, so that the total number of patients in Tables 3 and 4 is 166.

Type of injury

Table 4 presents the distribution of the type of injury and degree of injury. Surgical adverse events were most common, accounting for 47.3% of the total. These were subdivided into postoperative infections (30 cases [18.0%]), perioperative organ injury (13 cases [7.8%]), surgical nerve injury (nine cases [5.4%]) and other surgical injury (27 cases [16.2%]). Of the 30 cases of postoperative infections,

Table 3 Frequency of patient injury, distribution of medical specialties and degree of injury

Specialty	Patient injuries <i>n</i> (%)	Temporary harm <i>n</i>	Disabilities <15% <i>n</i>	Disabilities ≥15% <i>n</i>	Deaths <i>n</i>	Operations in study period <i>n</i>	Injuries per 1000 operations
Orthopaedics	79 (47.6%)	17	30	30	2	33 146	2.38
Obstetrics and gynaecology	14 (8.4%)	6	0	5	3	11 451	1.22
Gastrointestinal surgery	13 (7.8%)	5	3	4	1	28 588	0.45
Neurosurgery	10 (6.0%)	2	2	6	0	5417	1.84
Anaesthesiology and intensive care	7 (4.2%)	3	2	1	1	n.a.	n.a.
Oncology	6 (3.6%)	1	1	2	2	n.a.	n.a.
Neurology	5 (3.0%)	1	1	3	0	n.a.	n.a.
Other	32 (19.2%)	5	4	17	6	n.a.	n.a.
Sum	166	40 (24.1%)	43 (25.9%)	68 (41.0%)	15 (9.0%)	n.a.	n.a.

Table 4 Frequency of type of injury, distribution of type of injury and degree of injury

Type of injury	Patient injuries <i>n</i> (%)	Temporary harm <i>n</i>	Disabilities <15% <i>n</i>	Disabilities ≥15% <i>n</i>	Deaths <i>n</i>
Delayed diagnosis	38 (22.8%)	9	11	13	5
Postoperative infection	29 (17.5%)	6	5	16	2
Other surgical injury	27 (16.3%)	8	10	9	0
Drug related injury	15 (9.0%)	3	8	2	
Perioperative organ injury	13 (7.8%)	2	4	1	
Perioperative nerve injury	9 (5.4%)	1	4	4	0
Obstetric injury	4 (2.4%)	0	0	1	3
Other	31 (18.7%)	8	8	13	2
Sum	166	40 (24.1%)	43 (25.9%)	68 (41.0%)	15 (9.0%)

Table 5 Number of incident reports by medical specialty

Specialty	Patient injuries <i>n</i>	Incident reports <i>n</i>
Orthopaedics	77	1 (1.3%)
Obstetrics and gynaecology	14	8 (57.1%)
Gastroenterological surgery	13	4 (30.8%)
Neurosurgery	10	4 (40.0%)
Anaesthesiology and intensive care	6	4 (66.7%)
Oncology	6	2 (33.3%)
Neurology	5	1 (20.0%)
Other	31	9 (29.0%)
Sum	162	33 (20.4%)

Table 6 Number of incident reports by type of injury

Type of injury	Patient injuries <i>n</i>	Incident reports <i>n</i>
Delayed diagnosis	37	10 (27.0%)
Postoperative infection	29	1 (3.4%)
Other surgical injury	27	3 (11.1%)
Drug related injury	14	6 (42.9%)
Perioperative organ injury	13	3 (23.1%)
Perioperative nerve injury	9	2 (22.2%)
Obstetric injury	4	3 (75.0%)
Other	29	5 (17.2%)
Sum	162	33 (20.4%)

21 concerned joint infections or prosthetic joint infections. In 38 cases (22.8%), delayed diagnosis was the cause of injury, where 33 cases concerned delayed primary diagnosis and five cases concerned delayed diagnosis of postoperative complications.

Incident reporting

Information about incident reporting and documentation in medical records were unavailable in five cases because the patient was transferred to another hospital trust before the injury was diagnosed, so that the total number of patients in Tables 5 and 6 is 162. Of these, 33 (20.4%) had been reported, 8 in 2009, 7 in 2010, 9 in 2011 and 9 in 2012. Of the 80 patients who suffered serious consequences of the injury (death or a disability of ≥15%), 21 (26.3%) had been reported.

Table 5 presents frequency of incident reporting by medical specialty based on the NPE injuries. Most specialties had reported ~30% of their patient injuries. Obstetrics and gynaecology and anaesthesiology and intensive care had reported ~60% of their patient injuries, in contrast to orthopaedics, where only 1.3% of patient injuries were found reported.

Table 6 presents distribution of injury type and incident reporting. Most types of injury had been reported in ~25% of cases. Of injury types with more than one case, obstetric injuries had been reported most often with three of four cases reported. In contrast, only one of the 29 cases (3.4%) of postoperative infection and none of the cases of thrombosis, bleeding or patient misidentification were found reported.

Documentation in medical records

In the 162 cases where we had access to the patient's medical records, the event had been described in 147 cases (90.7%). Of these, five (3.4%) were described as patient harm, whereas the rest were described as a foreseeable complication to the procedure or treatment or were attributed to the nature of the disease. Of the 15 cases where the event was not documented, 9 concerned delayed diagnosis.

Disclosure to patients

Patient disclosure of the event was documented in the patient's medical records in 89 cases (54.9%). In another 21 cases (13.0%), the injury was patient-identified, and we would therefore not expect patient disclosure to be documented. In the remaining 52 cases (32.1%), there was no documentation of patient disclosure. Of the most common medical specialties, neurosurgery (100%) and oncology (83.3%) had most commonly informed their patients about the injury.

In 35 cases (21.6%), it was documented that the patient had been informed of his or her right to apply for compensation through the NPE. Neurosurgeons had informed their patients about the NPE on more occasions (60%), whereas orthopaedic surgeons and oncologists the least (below 20%).

Discussion

This study shows that one in five patient injuries that qualified for financial compensation was also reported by health personnel in the incident reporting system. Of those who suffered serious consequences of the injury (death or disability $\geq 15\%$), one out of four was reported. The most common types of injury were due to surgical and diagnostic errors. Orthopaedics had the most patient injuries, particularly when comparing the number of procedures performed with other surgical specialties. They had by far the fewest number of incident reports, with only one report per 77 injuries.

With only one in five compensated injuries reported, underreporting remains a problem. These numbers are comparable with a similar study done in Sweden, which found that one in five severe, patient-reported injuries were reported by health personnel [12]. A report from the Czech Republic documented the discrepancies between the presence of adverse event reporting systems and the actual use of these systems [17]. The most common types of adverse events in the present study were diagnostic and surgical errors, both largely a result of medical care given by physicians and surgeons. Underreporting of adverse events by physicians and surgeons, compared with nurses, is well documented and contributes to several weaknesses concerning incident reporting systems [18–21]. As Christiaans-Dingelhoff and co-workers pointed out, incident reports are largely made by nurses and therefore probably mainly concern nursing care, whereas adverse events that lead to patient injury often concern care given by physicians and surgeons [3]. Such participation bias can lead to incorrect prioritization of patient safety work because the frequency of reports from nurses gives an impression that some errors are more of a problem than others [21]. As argued by Öhrn and co-workers and Christiaans-Dingelhoff and co-workers, it is likely that physicians and surgeons often perceive injuries as foreseeable complications, rather than adverse events, and that they are therefore to be expected [3, 12]. A study on factors influencing incident reporting in surgical care found that surgical complications were not generally perceived to be reportable incidents [22]. In this study, through review of the patients' medical records, we found that the error was described as a patient injury in only 5 of 147 cases (3.4%), whereas the rest were

described as a foreseeable complication or were attributed to the nature of the disease. Postoperative infections were severely underreported with only one report among the 29 postoperative infections (3.4%).

Patient safety culture varies between countries and hospitals; first of all in dimensions of non-punitive response to error, feedback and communication about error, communication openness, learning from adverse events and management support [23]. The same elements could probably also influence to which degree adverse event reporting systems are used.

Barriers to incident reporting include lack of knowledge of what to report, lack of feedback, time constraint and the presence of a 'blame culture' [18, 24, 25]. Waring argues that cultural barriers to incident reporting go beyond the problems of a 'blame culture' and consist of other deep-seated cultural attributes [25]. These include a perceived inevitability of error and anxiety about a growing bureaucracy for monitoring and evaluating performance. When working with improving safety, one should not only focus on removing blame but recognize the complex professional culture in medicine that inhibits reporting [25].

Our study showed that patient disclosure lacked in >30% of cases, and information about the patient's right to apply for compensation lacked in almost 80% of cases. Other studies also suggest that patient disclosure is rare [26–28]. In a study of patients who had an iatrogenic event as the cause of intensive care unit admission, Lehmann and co-workers found that patient disclosure about the reason for admission was documented in only 5% of cases [27]. Physicians and surgeons may have informed their patients without documenting the conversation, but the low rate of documentation indicates that physicians and surgeons either have problems identifying adverse events or choose not to disclose errors to patients. There are several reasons for nondisclosure, including uncertainty about how to talk about errors, thinking the patient would not want to know, fear of upsetting the patient and fear of potential consequences, such as being reported by the patient or a lawsuit [29–31].

Complete disclosure is important for patient centred care, supports patient autonomy and informed decision-making. Patients who experience adverse events rate their quality of care at levels similar to patients who do not experience adverse events, if the hospital disclosed the event [32]. Disclosure is important for patients who may be entitled to economic compensation because without information, they may not know that an error caused the injury [30]. Patients and families are strongly in favour of disclosure about errors that have affected them [33]. Openness around errors may reduce the risk of punitive actions with patients being less likely to report the physician or file a lawsuit when informed of the error [34]. It is therefore interesting that physicians and surgeons list the fear of potential consequences as a barrier to disclosure. In addition to talking to patients about errors, physicians and surgeons should also discuss them with colleagues. This is not only important to understand what went wrong and therefore essential in improving safety but may lighten the impact that patient injury has on physicians' professional and private lives [35].

The strength of this study is that an independent party has identified and verified the degree of injury. However, the numbers of injuries identified this way only reflect the number of claims, not the real number of adverse events or patient injuries in the period, which is a limitation. Our data have a higher proportion of severe injuries (permanent injury and death) compared with those found by retrospective review of medical records [4, 5]. For example, Baines and co-workers found that 13.4% of adverse events led to permanent disability or death, compared with 75.9% of our cases [5]. However, our finding that surgical injuries were most common is consistent with data

found by medical record reviews [4, 5]. A weakness of our study could be that the patient records do not necessarily reflect the real communication between the hospital and the patient when it comes to disclosure. However, only what is documented can be used as measurements in future quality improvement.

Conclusion

Although Norway has a mandatory reporting system, which most importantly is a system for learning and improvement unconnected to sanctions, underreporting remains a problem. Only one in four patient-identified injuries qualifying for economic compensation was reported. In addition, documentation of patient disclosure is far from complete. Helping physicians and surgeons recognize adverse events and injuries, reporting them and the importance of discussing them with patients should be a priority for hospitals and medical schools.

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