Susanne Skjervold Smeby
Supervisor Gudmund Marhaug

Documentation and disclosure of adverse events that lead to patient injury
To what extent are patient injuries reported and documented in medical records by healthcare professionals?

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PREFACE

This student thesis is written in the form of an article, and we plan for it to be published in an international medical journal on quality and safety in healthcare. The student thesis will be handed in before submission to a medical journal for review, and it may be subject to changes before that time. In addition, the results in the article will be presented for the executive board of St. Olav’s Hospital HF.
ABSTRACT

Objective: To describe patient injury claims that have been granted compensation by the Norwegian System of Patient Compensation (NPE), a national insurance system for patient injuries. To assess how often patient injuries are documented in medical records and reported in an electronic incident reporting system. To assess the prevalence of disclosure of adverse events to patients, and whether patients have been informed about their legal rights to claim compensation.

Methods: The study from Trondheim University Hospital consisted of 167 patient cases that received financial compensation for patient injury between 2010 and 2012. The claims were categorised by medical specialty, type of injury and consequence for the patient. They were compared with incident reports, and the patients’ medical records were reviewed to study whether the adverse event and patient disclosure were documented.

Results: 20.4% of all patient injuries and 26.3% of patient injuries with serious consequences (death or a disability equal to or greater than 15%) had been reported. The event was documented in the patient’s medical records in 90.7% of cases, but only described as an adverse event causing patient injury in 3.4%. Documentation about patient disclosure lacked in 32.1% of cases. Documentation that the patient had been informed of his or her legal right to claim compensation lacked in 78.4% of cases. The most common type of adverse events were diagnostic and surgical errors.

Conclusion: Underreporting and nondisclosure of adverse events remain a problem, despite a mandatory reporting system. Helping physicians recognise adverse events, reporting them and the importance of discussing them with patients should be a priority for hospitals and medical schools.
INTRODUCTION

Adverse events occur too frequently in healthcare. 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]. More than half of the patients experienced no or minor disability, but 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 harm is a persistent problem, and may be hard to influence [5].

In order to learn from adverse events, they must be documented and reviewed to find their cause. Many countries, such as England, Wales, Denmark, Sweden and Australia, have adopted national reporting systems for adverse events [6]. In 2012, the national reporting central for adverse events in the specialist health services in Norway was moved from the Norwegian Board of Health Supervision to the Norwegian Knowledge Centre for the Health Services. The purpose was to create a system for learning and improvement which is not connected to sanctions. Since this new system was implemented, there has been a five-fold increase in the number of reports, and near misses (errors that have the potential to cause adverse events but fail to do so) have been reported more frequently [7].

By the Specialised Health Services Act §3-3, health trusts, hospitals and businesses that provide specialised healthcare 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 [8]. This is a non-punitive learning system, and reporting is done through the hospital’s internal electronic reporting system. By the same act, serious adverse events must also be reported to the Norwegian Board of Health Supervision. By the Patient’s Rights Act §3-2, 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) [9].

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 healthcare [10]. During our study period (2010-2012),
approximately 9200 claims connected to public healthcare in Norway were made to the NPE and financial compensation was given in 33.0% of claims. To be entitled to compensation, the injury must be a result of failure in the examination, 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 healthcare provided. However, this is rare and only accounts for 2% of the cases where the patient receives compensation [11]. 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 [12].

Underreporting of adverse events by health professionals is well documented [3, 13-15]. Most studies compare incident reporting with adverse events found by retrospective patient record review. Christiaans-Dingelhoff and co-workers found that only two percent of adverse events found by patient record review had been reported by healthcare professionals in an incident reporting system [3]. Similarly, Sari and co-workers found that five percent of adverse events identified by patient record review were reported [13]. Fewer studies compare incident reporting with patient’s report of adverse events. A Swedish study on malpractice claims from patients found that only 20% of severe adverse events had been reported [14].

The aim of our study is to describe the hospital’s documentation of adverse events that cause patient injury: To what extent are the adverse events reported in the electronic incident reporting system and documented in the patient’s medical records? Furthermore, we wanted to investigate to what extent the patient had been informed of the event and his or her right to apply for compensation through the NPE.

**METHODS**

*Study setting*

The study took place at Trondheim University Hospital/St. Olav’s Hospital Trust in Sør-Trøndelag County in Norway. The health trust consists of three somatic hospitals (747 beds in total), two psychiatric hospitals (246 beds in total) and four combined in-patient/out-patient psychiatric units. The health trust treated 59 000 inpatients, 577 000 outpatients and
performed 29 000 operations in 2013. An electronic incident reporting system, Extend Quality
System (EQS), was implemented at the hospital trust the 1st of March 2009.

Data sources

The sample consisted of patients treated at Trondheim University Hospital who received
compensation by the NPE for preventable patient injury from 2010 through 2012, where the
date of injury was after the 1st of March 2009. The data from the NPE include the following
details: location of injury (hospital), date of injury and an NPE ID-number. The health trust’s
administrative IT system was able to link the NPE ID-number with the patient’s name and
national identification number. Thus, we could access additional data sources:

1. **Expert medical reports.** The expert medical reports used by the NPE are written by
physicians who are independent, impartial, specialised in the given medical field and
are appointed by the NPE. The reports were used to identify medical specialty, type of
patient injury and consequence of the injury (disability/death).

2. **Incident reporting system.** The electronic incident reporting system (EQS) was used to
note whether the patient injury had been reported by health professionals.

3. **Electronic medical records.** The patient’s medical record was reviewed from date of
injury to present day and used to answer four questions: Firstly, is the event
documented in the patient’s medical records? Secondly, if the event is documented, is
it described as a patient injury/adverse event or is it described as a complication or
attributed to the nature of the disease? Thirdly, is patient disclosure of the event
documented? Regarding the information given, patients were categorised into three
groups: informed (disclosure explicitly stated in the medical records), not informed
(disclosure not explicitly stated in the medical records) and patient-identified (the
patient identified the event). When it comes to disclosure, we chose to look at
disclosure of the event, not necessarily disclosure of the event as an adverse event or
patient injury. Lastly, has the patient been informed of his or her right to apply for
patient injury compensation through the NPE?
Data collection

In total 181 patients were awarded compensation from 2010 through 2012. Of these, 13 patients were excluded because their date of injury was prior to 1\textsuperscript{st} of March 2009 and thus prior to the implementation of the electronic incident reporting system.

Based on information in the expert medical reports, the adverse events were classified into medical specialty and type of injury (listed in tables 2-5). In addition, the consequence of the adverse event was classified using the Index for Categorizing Medication Errors developed in the United States by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) as shown in Table 1 [16]. 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 harm. Within Category G (error that may have contributed to or resulted in permanent patient harm), we decided to distinguish between patients with disability below and above 15%. 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 equal to or greater than 15%.

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Circumstances or events that have the capacity to cause error</td>
</tr>
<tr>
<td>B</td>
<td>An error occurred but the error did not reach the patient</td>
</tr>
<tr>
<td>C</td>
<td>An error occurred that reached the patient but did not cause patient harm</td>
</tr>
<tr>
<td>D</td>
<td>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</td>
</tr>
<tr>
<td>E</td>
<td>An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention</td>
</tr>
<tr>
<td>F</td>
<td>An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalisation</td>
</tr>
<tr>
<td>G</td>
<td>An error occurred that may have contributed to or resulted in permanent patient harm</td>
</tr>
<tr>
<td>H</td>
<td>An error occurred that required intervention to necessary to sustain life</td>
</tr>
<tr>
<td>I</td>
<td>An error occurred that may have contributed to or resulted in the patient’s death</td>
</tr>
</tbody>
</table>

Table 1. Index for Categorizing Medication Error developed by NCC MERP [16].
**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.

**RESULTS**

**Study sample**

The study sample consisted of 167 patients treated at Trondheim University Hospital/St. Olav’s Hospital Trust, who received financial compensation in the 2010-2012 period. The mean patient age at 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 2 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%). Together, these accounted for almost 65% of all injuries granted compensation. However, this does not reflect the true differences between medical specialties, since adjustment for patient load and number of operations could not be performed. This is because the hospital’s administrative data only reflect administrative units, not medical specialties.

In altogether 40 cases (24.1%), the error resulted in temporary harm. Of these, two cases required intervention but did not lead to prolonged hospitalisation (Category E), 32 cases required prolonged hospitalisation (Category F) and six cases required intervention to sustain life (Category H). In 111 cases (67.9%), the harm was permanent (Category G). Of these, 68 patients had a disability equal to or greater than 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 Table 2 and 3 is 166.

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Patient injuries n (%)</th>
<th>Temporary harm n</th>
<th>Disabilities &lt; 15% n</th>
<th>Disabilities ≥ 15% n</th>
<th>Deaths n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthopaedics</td>
<td>79 (47.6%)</td>
<td>17</td>
<td>30</td>
<td>30</td>
<td>2</td>
</tr>
<tr>
<td>Obstetrics and gynaecology</td>
<td>14 (8.4%)</td>
<td>6</td>
<td>0</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Gastrointestinal surgery</td>
<td>13 (7.8%)</td>
<td>5</td>
<td>3</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>10 (6.0%)</td>
<td>2</td>
<td>2</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Anaesthesiology and intensive care</td>
<td>7 (4.2%)</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Oncology</td>
<td>6 (3.6%)</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Neurology</td>
<td>5 (3.0%)</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>32 (19.2%)</td>
<td>5</td>
<td>4</td>
<td>17</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>166</td>
<td>40 (24.1%)</td>
<td>43 (25.9%)</td>
<td>68 (41.0%)</td>
<td>15 (9.0%)</td>
</tr>
</tbody>
</table>

**Type of injury**

Table 3 presents the distribution of 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, 21 concerned joint infections or prosthetic joint infections. In 38 cases (22.8%), delayed diagnosis was the cause of injury, where 33 cases concerned the delayed primary diagnosis and five cases concerned delayed diagnosis of postoperative complications.
Incident reporting

Information about incident reporting in the EQS and documentation in medical records were unavailable in five cases because the patient was transferred to another hospital trust before the injury was diagnosed. Of the remaining 162 patients injuries, 33 (20.4%) had been reported. Of the 80 patients who suffered serious consequences of the injury (death or a disability equal to or greater than 15%), 21 (26.3%) had been reported.

Table 4 presents frequency of incident reporting by medical specialty based on the NPE injuries. Most specialties had reported around 30% of their patient injuries. Obstetrics and gynaecology and anaesthesiology and intensive care had reported approximately 60% of their patient injuries, in contrast to orthopaedics, where only 1.3% of patient injuries were found reported.
Table 5 presents distribution of injury type and incident reporting. Most types of injury had been reported in around 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.

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Patient injuries n</th>
<th>Incident report n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthopaedics</td>
<td>77</td>
<td>1 (1.3%)</td>
</tr>
<tr>
<td>Obstetrics and gynaecology</td>
<td>14</td>
<td>8 (57.1%)</td>
</tr>
<tr>
<td>Gastroenterologic surgery</td>
<td>13</td>
<td>4 (30.8%)</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>10</td>
<td>4 (40.0%)</td>
</tr>
<tr>
<td>Anaesthesiology and intensive care</td>
<td>6</td>
<td>4 (66.7%)</td>
</tr>
<tr>
<td>Oncology</td>
<td>6</td>
<td>2 (33.3%)</td>
</tr>
<tr>
<td>Neurology</td>
<td>5</td>
<td>1 (20.0%)</td>
</tr>
<tr>
<td>Other</td>
<td>31</td>
<td>9 (29.0%)</td>
</tr>
<tr>
<td>Sum</td>
<td>162</td>
<td>33 (20.4%)</td>
</tr>
</tbody>
</table>
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, while the rest were described as a complication or were attributed to the nature of the disease. Of the 15 cases where the event was not documented, nine concerned delayed diagnosis.

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.

Table 5. Number of incident reports by type of injury.

<table>
<thead>
<tr>
<th>Type of injury</th>
<th>Patient injuries n</th>
<th>Incident report n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delayed diagnosis</td>
<td>37</td>
<td>10 (27.0%)</td>
</tr>
<tr>
<td>Postoperative infection</td>
<td>29</td>
<td>1 (3.4%)</td>
</tr>
<tr>
<td>Other surgical injury</td>
<td>27</td>
<td>3 (11.1%)</td>
</tr>
<tr>
<td>Drug related injury</td>
<td>14</td>
<td>6 (42.9%)</td>
</tr>
<tr>
<td>Perioperative organ injury</td>
<td>13</td>
<td>3 (23.1%)</td>
</tr>
<tr>
<td>Perioperative nerve injury</td>
<td>9</td>
<td>2 (22.2%)</td>
</tr>
<tr>
<td>Obstetric injury</td>
<td>4</td>
<td>3 (75.0%)</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Bleeding</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Patient misidentification</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Falls</td>
<td>1</td>
<td>1 (100.0%)</td>
</tr>
<tr>
<td>Other</td>
<td>25</td>
<td>4 (16.0%)</td>
</tr>
<tr>
<td>Sum</td>
<td>162</td>
<td>33 (20.4%)</td>
</tr>
</tbody>
</table>

Documentation in medical records and disclosure to patients

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, while the rest were described as a complication or were attributed to the nature of the disease. Of the 15 cases where the event was not documented, nine concerned delayed diagnosis.

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 the most times (60%), while orthopaedic surgeons and oncologists the least (below 20%).

**DISCUSSION**

This study shows that one out of five patient injuries that qualified for financial compensation was reported by health personnel in the incident reporting system. Of those who suffered serious consequences of the injury (death or disability equal to or greater than 15%), one out of four were reported. These numbers are comparable with a similar study done in Sweden, which found that one out of five severe, patient-reported injuries were reported by health personnel [14]. Orthopaedics had the most patient injuries in our data, and by far the fewest number of incident reports, with only one report per 77 injuries.

In our dataset, the most common type of adverse events were diagnostic and surgical errors, both largely a result of medical care given by physicians. Underreporting of adverse events by physicians is well documented, and contributes to several weaknesses concerning incident reporting systems [17-20]. As Christiaans-Dingelhoff and co-workers point out, incident reports are largely made by nurses and therefore probably mainly concern nursing care, while adverse events that lead to patient injury often concerns care given by physicians [3]. In addition to an overall underreporting of patient injury, participation bias can lead to incorrect prioritisation of patient safety work because the frequency of reports from nurses give an impression that some errors are more of a problem than others [20].

The difference in reporting rates between nurses and physicians may come as a result of different views of what constitutes an adverse event or patient injury [18]. As argued by Öhrn and co-workers and Christiaans-Dingelhoff and co-workers, it is likely that physicians often perceive injuries as complications, rather than adverse events, and that they are therefore to be expected [3, 14]. A study on factors influencing incident reporting in surgical care found that surgical complications were not generally perceived to be reportable incidents [21]. In this study, through review of the patients’ medical records, we found that the error was described as a patient injury in only five of 147 cases (3.4%), while the rest were described as a
complication or were attributed to the nature of the disease. In addition, postoperative infections, which are commonly viewed as complications, were severely underreported with only one report among the 29 postoperative infections (3.4%).

Other barriers to incident reporting include lack of knowledge of what to report, lack of feedback, time constraint and the presence of ‘blame culture’ [17, 22, 23]. Waring argues in his article that cultural barriers to incident reporting go beyond the problems of ‘blame culture’ and consist of other deep-seated cultural attributes [23]. These include a perceived inevitability of error, and anxiety about a growing bureaucracy for monitoring and evaluating performance, that takes physicians away from ‘real’ medical work. Thus, as Waring concludes, when working with improving incident reporting one should not only focus on removing blame, but recognise the complex professional culture in medicine that inhibits reporting.

This study showed that patient disclosure lacked in more than 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 [24-26]. For example, 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 [25]. Physicians may have informed their patients without documenting the conversation, but the low rate of documentation indicates that physicians 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 [27-29].

Complete disclosure is important for patient centred care, supports patient autonomy and informed decision making. In addition, and which is especially relevant to this study, disclosure is important for patients who may be entitled to economic compensation because without information, they may not know that a medical error caused the injury [28]. A literature review on communicating with patients about medical errors showed that patients and families are strongly in favour of disclosure about errors that have affected them [30]. Furthermore, a study found that that 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 [31]. It is therefore interesting that physicians list the fear of potential consequences as a barrier to disclosure. In addition to talking to patients about errors, physicians should also discuss them with colleagues. This is not only important to understanding what went wrong and therefore essential in quality improvement, but may lighten the impact that patient injury has on physicians’ professional and private lives [32].

The strength of this study is that identification and degree of harm has been verified by an independent party. However, the numbers of harms identified this way only reflect the number of claims, not the real number of adverse events or patient injuries in the period. Our data has 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 adverse events were most common is consistent with data found by medical record reviews [4, 5]. A weakness of the 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. As mentioned under results, another limitation is that the distribution of medical specialties does not reflect the true differences between them, because the numbers could not be adjusted for patient load and number of operations performed.

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, with only one in four patient injuries reported. In addition, documentation of patient disclosure is far from complete. Helping physicians recognise adverse events, reporting them and the importance of discussing them with patients should be a priority for hospitals and medical schools.
REFERENCES


3. Christiaans-Dingelhoff, I., et al., To what extent are adverse events found in patient records reported by patients and healthcare professionals via complaints, claims and incident reports? BMC Health Serv Res, 2011. 11: p. 49.


