International Journal of Medicine and Medical Sciences ISSN: 2167-0404 Vol. 2 (10), pp.197-203, October, 2012.
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Full Length Research Paper

An analysis of closed claims related to death in the Danish health care system

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Received 22 July, 2012; Accepted 16 October, 2012

Studies based on closed claims are important in our efforts to improve patient safety. The circumstances of the worst possible outcome of medical treatment: patient deaths from a complication to treatment were investigated. This retrospective study investigated closed claims concerned with medical-related deaths registered by the Danish Patient Insurance Association (DPIA). The present study used data from all reported complications from medical treatment in the primary health care and hospitals setting in Denmark. The results revealed from 1996 to 2008, 45,953 claims were made to the DPIA covering all medical specialties. Of these, 836 patients died as a result of treatment or lack of treatment. The total cost of the 836 claims was 40.0 million € corresponding to an average compensation of 59,300 € per approved case (range: 1,500 -1,200,000 €). The majority of deaths involved generally healthy patients. Almost every clinical speciality reported deaths as a result of an adverse event. Surgery accounted for the largest group of deaths, with 279 deaths occurring as a direct result of surgical treatment and 145 deaths caused by surgical treatment that came too late or no surgical treatment at all despite valid indications. Fifty-four patients died as a result of substandard treatment in primary care, and 782 patients died as a result of treatment at a hospital. Of the 836 submitted claims, 435 deaths were considered by the DPIA or the courts of law as a result of substandard care and considered preventable. This study thus gives an overview of the claims concerning deaths in the Danish healthcare system.

Key words: Closed claims, patient death, injury, malpractice, no-blame no-fault system and patient safety.

INTRODUCTION

Studies based on closed claims are important in our efforts to improve patient safety. In this study, the worst possible outcome of medical treatment is described: death as a complication. The aims of this study are to give an overview of preventable and accidental deaths in the Danish healthcare system and that the presentation of these deaths may facilitate the development of prevention measures in the future.

In Denmark, patients may file a claim if their medical treatment results in an injury or an unexpected side effect. Upon injury, the injured patient, the patient's relatives, or the hospital can make a claim for financial compensation. The independent Danish Patient Insurance Association (DPIA) will consider these claims. The DPIA operates on a no-blame no-fault basis and does not take any legal action beyond assessing damages. As a result, patients may file a claim with the DPIA free of charge with the sole purpose of seeking financial compensation. Thus, the injured patient is spared the expense of legal fees and the trouble of going to court.

In general, financial compensation may be granted under any one of the following conditions given by the DPIA: (1) an experienced specialist would have acted differently, whereby the injury would have been avoided, (2) defects in or failure of the technical equipment were of major concern with respect to the incident, (3) the injury could have been avoided by using alternative treatments, techniques or methods if these were considered to be equally safe and potentially offer the same benefits, and finally, (4) the injury was rare, serious, and more extensive than the patient should be expected to endure.

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Compensation is calculated based on the extent of pain and suffering, reduced income, reduced ability to work, and medical expenses, as well as whether the consequences of the injury could be expected to be permanent. Compensation is rendered if the calculated amount exceeds 1,500 €. The government pays the compensations. After the decision has been reached, the patient may file an appeal to the Patient Damage Appeal Board and further through the courts of law. From 1996 to 2008, the DPIA received 45,953 claims; 39% of these were approved.

Until 2004 only injuries in public hospitals were covered, but after 2004 the coverage was extended to the total health care system.

MATERIALS AND METHODS

In this study all patients registered as dead in the DPIA database were included. Patients who died of natural causes with no relation to the claim (after reading the files) were excluded. Claims from the January 1- 1995 to December 31- 2008 were evaluated.

For each claim, the DPIA creates a patient folder where the documents of the case are kept; this information is then entered into a database where all submitted claims are registered according to the diagnosis, treatment and type of injury. Upon receiving a claim, the DPIA collects all medical records pertaining to the case. A lawyer evaluates the claim in collaboration with a medical specialist as to whether standard practice (that is, compliance with general recommendations and guidelines) was followed.

Information drawn from the internal data system of the DPIA and information from a detailed scrutiny of all patient folders were reviewed. A retrospective design was used that followed closed claims concerning all cases in which the patient was registered as dead due to the treatment. These closed claims were collected and analysed, and the decisions given by the DPIA, the appeal board or the courts of law in case of appeal were registered and used. Thus, all cases were originally judged by the team of external consulting medical specialists (usually professors). The cause of death was evaluated by these external medical specialists in the decisions.

Claims granted after criterion 1 by the DPIA were considered as possibly preventable and claims granted after criterion 4 by the DPIA were considered as accidental. Thus, there was no independent preventability decision made by the authors and only the decisions from DPIA were used.

From the patient folders, we evaluated the patients' health based on the ASA physical status classification system 1 with the purpose to assess the proportion of healthy persons (ASA 1 and 2) against persons with severe diseases (ASA 3 and 4) (Saklad, 1941).

The files and decisions of deaths resulting from treatment or no treatment after reading files were thoroughly read and evaluated by three medical specialists (in the fields of Surgery, Anaesthesiology, and Gynaecology and Obstetrics) in line with the classification system. With regard to preventability the decisions from DPIA were used.

The patient folders and the evaluation of each patient from the DPIA´s team of external consulting medical specialists were used to categorize the patients in the following two classification systems defined by the authors.

Classification system 1

The patients were divided into four groups, and each group was further divided into subgroups.

Death as a result solely of treatment

i) As a direct result of a surgical treatment or treatment given at a surgical department.
ii) As a direct result of anaesthesia procedures or treatment given in an intensive care unit.
iii) As a direct result of medical treatment.
iv) Other.

Death as a result of treatment in combination with coexisting diseases

i) As a result of surgical treatment or treatment given at a surgical department.
ii) As a direct result of anaesthesia procedures or treatment given in an intensive care unit.
iii) As a direct result of medical treatment.
iv) Other.

Death as a result of treating too late or not at all

i) Surgical treatment in time could have saved the patient.
ii) Intensive care in time could have saved the patient.
iii) Medical treatment in time could have saved the patient.

Other

i) Death as a result of delay in the diagnosis.
ii) Patient condition so poor that death was inevitable.
iii) Cancer diagnosis was delayed and prognosis worsened.

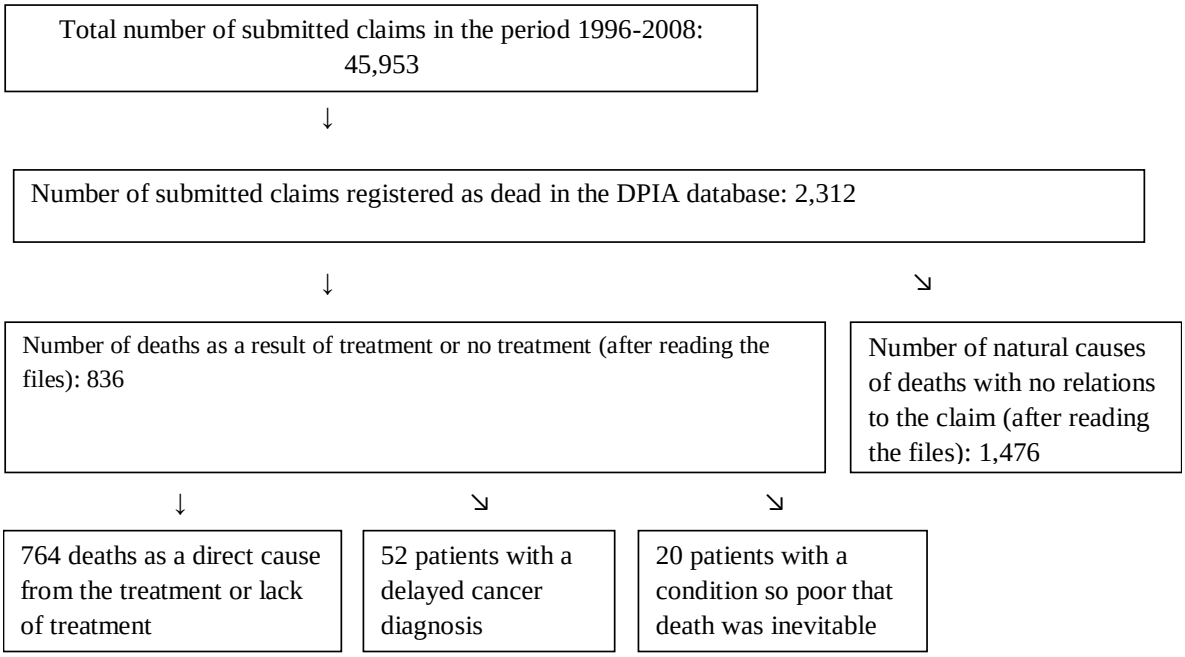

Figure 1. Flow diagram.

Classification system 2

All deaths were divided according to the main cause (causes) into the following categories:

i) Perforation of an internal organ.
ii) The severity of the disease or condition misjudged.
iii) Infection acquired from the hospital.
iv) Rupture of an anastomosis or other surgical reconstruction.
v) Failure or faulty use of a medical device.
vi) Medication error.
vii) Treatment/diagnosis too late, wrong diagnosis/treatment or no diagnosis/treatment at all.
viii) Side effect of medication.
ix) Failure to follow standard procedure (surgical or other).
x) Substandard care of the patient.
xi) Side effect to a procedure.
xii) Thrombosis or embolism after treatment.
xiii) Haemorrhage due to a procedure.
xiv) Injury due to a fall at the hospital
xv) Other.

When overlap arose the most suitable category that concerns the cause of death were used.

RESULTS

The total number of claims during this period was 45,953. A total of 2,312 submitted claims generated between January 1, 1996 and December 31, 2008 in which the patient was registered as dead were found. These 2,312 claims were analysed and it was concluded that in 836 cases, the patient died as a result of treatment or lack of treatment (1.8 %). The condition of 20 patients was so poor that death was inevitable, and 52 patients had a delayed cancer diagnosis whereby the prognosis worsened. Figure 1 shows a flow diagram of the process from 45,953 to 836 claims. The DPIA received 45,953 claims from 1996 to 2008. In 2,312 of the claims the patient had died before or during the evaluation of the claim. Evaluation time was about 1 - 2 years. By reading these 2,312 claims it could be concluded that in 836 cases the patient died as a result of treatment or no treatment. The rest 1,476 died of reasons with no relation to the claim.

The mean age of the patients was 52.9 years (range: 0 - 89 years). Median age was 58 years and standard deviation 22.0 years. Seventy-five deaths involved children less than 16 years of age. The gender of the patients: 402 were females and 436 males. Table 1 shows the distribution of deaths among the four main groups and four subgroups. Table 2 shows the distribution of deaths according to the type of incident which caused the death.

The deaths were registered based on the ASA physical status classification system (Saklad, 1941). Using this system, 291 patients were ASA 1; 143 patients were ASA 2; 353 patients were ASA 3; and 49 patients were ASA 4. Of the 836 submitted claims, 435 were approved as meeting criterion 1; that is, the medical expert judged that an experienced specialist would have acted differently, so

Table 1. Categories and the number of deaths.

1A- Death a direct result of surgical treatment	279	33
1B- Death a result of an anaesthetic procedure	39	5
1C- Death a result of medical treatment	63	8
1D- Other	4	0.5
2A- Death a result of surgical treatment in combination with coexisting diseases	51	6
2B- Death a result of an anaesthetic procedure in combination with coexisting diseases	10	1
2C- Death a result of medical treatment in combination with coexisting diseases	24	3
2D- Other where coexisting diseases played a role in the death	4	0.5
3A- Surgical treatment in time could possibly have saved the patient	145	17
3B- Intensive care in time could possibly have saved the patient	17	2
3C- Medical treatment in time could possibly have saved the patient	110	13
3D- Other treatment in time could possibly have saved the patient	18	2
4A- The patients died as a result of the treatment, but the conditions were so poor that death was inevitable	20	2
4B- Cancer diagnosis delayed and prognosis worsened	52	7
Total	836	100

Table 2. Type of complication, number of deaths and number of deaths with ASA 1 or 2 score.

Delayed diagnosis/treatment, wrong diagnosis/treatment or no diagnosis/treatment	244	29	144
Perforation of an internal organ	107	13	71
Standard procedure (surgical or other) not followed	83	10	51
Side effect of a procedure	68	8	28
Infection acquired at the hospital	63	7.5	32
Side effect of medication	56	6.5	18
Medication error	49	6	11
Haemorrhage due to a procedure	36	4.5	14
Severity of the disease/condition misjudged	30	3.5	22
Substandard care of the patient	25	3	10
Thrombosis or embolism after treatment	25	3	14
Rupture of an anastomosis or other reconstruction	22	2.5	13
Fall at the hospital	14	1.5	0
Failure or wrong use of a medical device	11	1.5	4
Other	3	0.5	2
Total	836	100	434

that the injury could have been avoided. Another 231 submitted claims were approved as meeting criterion 4. Finally, two cases were approved as meeting criterion 2, and six cases were approved for criterion 3.

One hundred and twenty-seven claims were rejected, and 43 claims were still under consideration. The total cost of the claims was 40.0 million €, corresponding to an average compensation of 59,300 € per approved case (range: 1,500 -1,200,000 €).

Table 3 shows the distribution of deaths according to the specialities involved and the total number of claims in specialities. Table 4 shows selected examples of deaths according to the type of incident which caused the death.

DISCUSSION

Our closed claims analysis shows that 764 patients died as a direct result of treatment or lack of treatment in the Danish healthcare system in the period from January 1- 1996 to December 31- 2008, and 72 patients who received a diagnosis of cancer too late or were in poor condition died as well.

Other studies have shown that only 1.5 to 3% of patients experiencing potentially negligent care actually file a malpractice claim, and the real number of deaths, therefore, remains uncertain but may in fact be many times higher (Ross, 2003; Cook et al., 2009).

Table 3. Percentage of deaths of total claims in specialty, the total number of claims in speciality and the number of dead ASA 1 or 2 patients in each specialty.

General surgery (including surgical gastroenterology)	191	5783	3.3	125
Internal medicine (including geriatrics, hepatology and endocrinology)	95	1640	5.8	32
Obstetrics	68	1340	5.1	65
Orthopaedic surgery	60	18057	0.3	31
General medicine	54	2150	2.5	37
Cardiology	47	686	6.9	11
Anaesthesiology	47	2104	2.2	20
Thoracic surgery	45	819	5.5	10
Gynaecology	29	1813	1.6	24
Radiology	25	784	3.2	10
Neurosurgery	24	1793	1.3	12
Oncology	16	671	2.4	3
Otorhinolaryngology	16	1172	1.4	7
Urology	15	847	1.8	8
Vascular surgery	12	521	2.3	4
Gastroenterology (med)	11	187	5.9	4
Paediatrics	11	274	4.0	5
Neurology	10	595	1.7	2
Rheumatology	10	649	1.5	1
Haematology	7	124	5.6	0
Psychiatry	7	538	1.3	6
Infectious diseases	6	65	9.2	4
Pathology	6	109	5.5	6
Pulmonology	6	131	4.6	2
Nephrology	6	153	3.9	1
Others	12	2948	0.4	4
Total	836	45953	1.8	434

Studies of deaths in healthcare settings have several problems concerning data interpretation. Two reviewers might have completely different opinion regarding preventability of a death (Hayward and Hofer, 2001). The decisions from the DPIA or, if appealed, the decision from appeal board or the courts of law were used to determine the preventability. Furthermore, many studies have not considered the underlying prognosis and health of the patients who died. In our study the patients were classified according to the ASA physical status classification system; the main part of the deaths was healthy people with ASA physical status 1 or 2. This might reflect in the assumption that when healthy people dies in the Danish healthcare system there will be a higher tendency to seek for economical compensation in comparison to when people with many co-morbidities dies.

It is noteworthy that wrong diagnosis, delayed diagnosis, or the absences of diagnosis were the primary reasons for the largest group of the deaths, followed by perforation of an internal organ. Surgery accounts for the majority of the deaths, with 279 deaths occurring as a direct result of a surgical procedure and 145 deaths caused by delayed surgical treatment or no surgical treatment at all despite indications to the contrary.

A large study of surgical closed malpractice claims revealed that many of these cases involve multiple layers of failure and the causes are a mixture of systems as well as individual errors (Rogers et al., 2006).

Almost every clinical speciality reported deaths as a result of an adverse event. Some specialities, e.g., orthopaedics and psychiatry, have many claims but only a small percentage of deaths. In comparison other specialities like cardiology and internal medicine, have fewer claims but a higher percentage of claims with fatal outcomes. The majority of deaths involved, as mentioned, generally healthy patients (ASA 1 and 2).

The prevention of deaths caused by problems with correct and timely diagnosis is often a matter of maximum care and excellent training of physicians. On the other hand, the prevention of thrombosis and embolism is very often possible by simple means. Perforation of an internal organ is often not preventable, but the care for patients at risk for perforation should make early diagnosis and treatment of the complication possible, so that death in many cases can be avoided.

Table 4. Examples.

Delayed diagnosis/treatment, wrong diagnosis/treatment or no diagnosis/treatment	A previously healthy 41-year old woman had at home during the evening suddenly developed a severe headache followed by unconsciousness with seizures. She came to herself in the ambulance, and shortly after she told about the sudden headache in the emergency room. After a brief examination she was discharged even though she had differently sized pupils. She was found dead in her bed the next morning. Autopsy showed a subarachnoid haemorrhage.
Perforation of an internal organ	A previously healthy 28-year old woman had a laparoscopic salpinx operation due to a cystic process. After 6 days a reoperation was performed where a large lesion in the colon was found and repaired. A week later the condition was critical with organ failures and septic shock and she died 7 days later.
Standard procedure (surgical or other) not followed	A 17-year old girl with chronic lung disease of unknown origin. A pleural drain was removed and x- rays the next day showed total re-collapse of the left lung. Without insertion of a new pleural drain a bronchoscopy was performed under general anaesthesia. During this procedure the girl developed cardiac arrest and died.
Side effect of a procedure	A 30-year old woman had an acute caesarean because of a short transient drop in the heart rate of the foetus. The head was difficult to deliver and it was necessary to push from the vagina. The baby was delivered but died shortly after. pH from the umbilical cord was 7.30. Autopsy revealed several fractures of the skull and underlying bleeding in the brain. It was stated that these injuries occurred as a result of the handling during the caesarean.
Infection acquired at the hospital	A 75-year old man had a spinal analgesia for transurethral resection of the prostate. Day 5 and 14 postoperatively development of neurologic symptoms and sepsis, respectively. MRI revealed cervical and thoracic abscesses. Died of sepsis at day 24 postoperatively.
Side effect of medication	A previous healthy 69-year old woman was scheduled for an operation for descensus uteri. Propofol 150 mg was given, and immediately after a severe anaphylactic reaction was observed. Intubation was not possible due to oedema. After several attempt acute tracheotomy succeeded but the patient went into cardiac arrest and resuscitation was unsuccessful.
Medication error	A 66-year old man was admitted to a hospital because of atrial fibrillation. An intravenous access was established and a drip with saline was intended but was confused with lidocaine. Lidocaine was given in a toxic dose. The patient went into cardiac arrest and resuscitation was unsuccessful.
Bleeding due to a procedure	A previous healthy 39-year old woman had a laparoscopic cholecystectomy. After the operation she was observed at the recovery room. After 20 min she went into cardiac arrest but was resuscitated. A myocardial infarction or embolism to the lungs was mistaken and the patient was transferred to another hospital. At arrival she went into cardiac arrest and resuscitation was unsuccessful. Autopsy showed lesion of an artery from the gallbladder and cause of death was haemorrhage.
Severity of the disease/condition misjudged	A 10-month old girl with a history of diarrhea, fever and vomiting for 3 days was seen by her general practitioner. The doctor did not admit the baby to a hospital and the next day the baby died of dehydration caused by virus gastroenteritis.
Substandard care of the patient	A 71-year old woman with depression was admitted to a psychiatric department after she tried to commit suicide by stuffing her upper airway with food. She was assessed to be suicidal. The next day she was unobserved during breakfast and she committed suicide by obstructing her airways with food.

Table 4. Contd.

Thrombosis or embolism after treatment	An 86-year old woman was admitted to a hospital because of a hip fracture. She waited 2 days for surgery because other operations had higher priority. After the operation she went into cardiac arrest and resuscitation was unsuccessful. Autopsy showed pulmonary embolism.
Rupture of an anastomosis or other reconstruction.	A previous healthy 58-year old man known with recurrent diverticulitis and therefore an elective sigmoidectomy was performed. 4 days after the operation he developed septic shock and a reoperation was performed, where an anastomosis leak was observed with severe faecal contamination. The patient died the next day.
Fall at the hospital	An 85-year old man was admitted to a hospital because of left side weakness. A CT scan showed a minor cerebral infarction. Suddenly the patient felt down from the scanning couch. The patient was severely injured with several rib fractures and a jaw fracture. The next day the patient died due to these injuries.
Failure or wrong use of a medical device	An 83-year old man had general anesthesia for tamponade of urine bladder After surgery while still orally intubated, the patient was transported to the ICU. In the ICU, he was connected to a misassembled CPAP system without expiratory valve. The patient developed severe bilateral pneumothorax with thoracic subcutaneous emphysema. Shortly thereafter, cardiac arrest developed, and resuscitation was unsuccessful.

Our material of deaths by perforation after coloscopy shows this very clearly.

The analysis of claims has developed into a useful tool of national quality management programs in medicine. A major advantage of the closed claims methodology is that though it rarely occurs, significant injuries can be identified. Such injuries are difficult to study with conventional large, retrospective studies, and they are difficult to screen in prospective clinical trials.

One of the first studies from Harvard of adverse events in hospitals concluded that they occurred in 3.7% of randomly selected records, and 13.7% of these led to deaths corresponding to 0.51% (Brenan et al., 1991). In a Swedish study, 23,364 claims from 1997 - 2004 were analysed, and among these claimants, 2.4% were deaths (Pukk-Härenstam et al., 2009). In our study, 4.6% of the 45,953 claims were registered as deaths, but after reviewing the records, it was concluded that only 836 deaths resulted from treatment. This corresponds to 1.7% deaths among the total number of claims.

In comparison, a study from Belgium analysed surgical errors from malpractice claims and found 26 surgical deaths over a ten-year period between 1996 and 2006 (Somville et al., 2010). This number is about ten times lower than that of our data, but it is believed that this is caused by the different insurance claims systems mentioned below.

A study from New Zealand found 2.8 deaths attributable to adverse events per 1000 admissions and it was estimated that 1.3 deaths per 1000 admissions were preventable (Briant et al., 2006).

The existing differences in medical and legal practices as well as difference in the method cause that a comparison of our findings with the results from other countries should be viewed with in respect to these differences. The nature of the data makes it difficult for calculation and advanced comparison of risk. In this study closed claims were used whereas many of the referred studies have used randomly selected medical journals.

It is important to emphasize that in Denmark and the other Nordic countries, the system is a no-fault no-blame system. This is in contrast to other countries where the payment is dependent on the proof of a negligent act or omission on the part of the physician. Rather, payment is made for any injury arising from a medical action, and the patients do not need to prove negligence and causation via litigation. This system results in an appreciable increase in the number of approved claims in comparison with a fault-based liability system.

To our knowledge, a descriptive study of this magnitude of potentially preventable deaths

collected from all medical specialities has not been published previously. It was not possible to find a suitable classification system for the deaths and therefore the authors defined the classification system 1 and 2. Denmark has 5 million citizens, and during the period 1996 to 2008, it was found that 782 patients died as a result of treatment at the hospital, and 54 patients died as a result of treatment in primary care. Although this seems to be a high number, it must be compared with the total number of hospital admissions in the same period, which were 14,821,227. Even when taken into account that perhaps only 5 – 10% of patient injuries are reported to the DPIA, the risk of dying as a consequence of treatment is very small.

Closed claims are a recognised source of information about the prevention of patient injuries. Since 2000, there have been 188 papers and 38 books about this subject cited in the US National Library of Medicine. Anaesthesia has been a preferred target for closed-claims studies, as the documentation about the occurrence is often complete, and the incidents, though rare, are often catastrophic (Hove et al., 2007).

CONCLUSIONS, LIMITATIONS AND STRENGTH

This study gives a description of the total collection of claims where the patient was registered as having died due to treatment in the Danish Healthcare system. In almost every clinical speciality some patients were registered as having died as a result of an adverse event. The majority of deaths were caused by a direct result of surgical treatment or a delay in surgical The risk of dying from treatment complications, according to this study, is about 53 per million hospital admissions. This is a minimal estimate, as many of the injuries are not reported. The number is low compared with deaths from motor accidents or violent crimes. Investigation of preventable fatal injuries in the health sector should lead to a desirable reduction in fatal and non-fatal injuries as well.

This study has some limitations. It represents a selected material of deaths reported to the DPIA. Many deaths in the primary care and at hospitals are not reported to the DPIA. Furthermore each death claim is evaluated by a medical specialist as to whether standard practice (that is, compliance with general recommendations and guidelines) was followed. It is a well-known problem that reviewers have different views regarding preventability (Hayward and Hofer, 2001).

The strength of this study is its magnitude. This study gives information about 836 deaths in the Danish healthcare system where the patient died as a result of treatment or lack of treatment. A similar study could not be found.

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