FACULTY OF HEALTH SCIENCE, AARHUS UNIVERSITY

Treatment Injuries in Danish Public Hospitals 2006-2012

Research Year Report

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Preface

This research year report is based on a study conducted during my research year at the Department of Clinical Epidemiology, Aarhus University Hospital, Denmark, from February 1st 2014 to January 31st 2015. During this year, I was introduced to the science of epidemiology and biostatistics – and a whole lot more.

I am deeply thankful to the Department of Clinical Epidemiology for giving me the opportunity to carry out the study and to let me be a part of Flying Spaces and DCE environment. But also to be a part of an environment with boarders much further from home, an international world of research.

I thank my supervisors for reading, commenting and editing my work, allowing me to prospectively learn and revise my work. Both the level of supervision and my understanding of clinical research seem to have improved over time – all to aim for in a research year, I think. Thank you for the supervision!

A special thanks to the Flying Folks. The innermost circle of research year conduction at DCE. Always there to share advice, simple and advanced, to remember the coffee breaks and lunch, to share new and old ideas, to interactively improve motivation, and making a happy, comfortable atmosphere at work and beyond.

Jens Tilma

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Abbreviations

PCA	Patient Compensation Association
GP	General Practitioner
DNRP	Danish National Registry of Patients
NAPRC	National Agency for Patients' Rights and Complaints
CRS	Civil Registration System
AE	Adverse Event
ICD-10	International Classification of Diseases, 10th revision
CCI	Charlson Comorbidity Index
CI	Confidence intervals
OR	Odds Ratio
US	United States (of America)
NZ	New Zealand

Contents

Abstract

Treatment injuries are responsible for considerable mortality, morbidity, and financial costs. Claims of treatment injuries have increased substantially in Denmark in the last decade. Data from closed compensation claims may be useful in identifying pitfalls in patient safety and in designing interventions to reduce injuries. For these reasons, we aimed to determine the incidence rate of approved treatment injuries in Danish public hospitals from 2006 through 2012 and to identify independent predictors of severe treatment injuries amongst patient and system characteristics.

The method was a nationwide observational study on data from all approved compensation claims to the Danish Patient Compensation Association from public hospitals. Information on comorbidity and health care activity and was obtained from the Danish National Registry of Patients and Statistics Denmark. Incidence rates were determined as treatment injuries per year by population and by public hospital contacts, respectively. By using a multivariable logistic regression model, we calculated mutually adjusted odds ratios to assess the association between potential predictors and severe treatment injuries (permanent disability ≥ 50% or death) among all approved closed claims.

We identified 10,959 approved treatment injury claims in 2006-2012. The total payout was 360 million USD. Mean incidence rates were 27.85 injuries per 100,000 inhabitants per year and 0.21 injuries per 1000 public hospital contacts per year with a stable rate 2006-2009 and then a decrease 2010-2012. Severe and preventable treatment injury comprised 11.0% [95%CI 10.4;11.6] and 41.0% [95%CI 40.1;42.0] of all cases, respectively. Predictors of severe treatment injury included age, gender, comorbidity (Charlson Comorbidity Index), medical specialty, and region. Being male was associated with an adjusted OR of severe injury of 1.31 [95%CI 1.13;1.52] compared to females. Age was almost linearly associated with the risk of severe injury, the exception being neonates, which had an increased the risk by an OR of 9.20 [95%CI 6.31;13.42] when compared to the reference age group of >0 to 40 years of age. A higher level of comorbidity was also associated with a higher risk of severe injury: adjusted ORs were 1.68 [95%CI 1.45;1.94] and 2.33 [95%CI 1.87;2.89] for mild and severe comorbidity, respectively.

Conclusively, the incidence rate of approved closed claims at Danish public hospitals are not increasing. A high proportion of the injuries are preventable and both patient- and system related factors might predict severe treatment injuries.

Dansk resumé

Behandlingsskader er ansvarlige for betydelig menneskelige og finansielle omkostninger. Antallet af kompensationskrav pga behandlingsskader er steget betydeligt i Danmark i det seneste årti. Data fra færdigbehandlede kompensationskrav kan være nyttige for at identificere faldgruber i patientsikkerhed og til at målrette metoder til at reducere skaderne. Med denne baggrund har vi forsøgt at bestemme incidensraten af godkendte behandlingsskader på danske offentlige sygehuse fra 2006 til 2012 og at identificere uafhængige prædiktorer for alvorlige behandlingsskader blandt patient- og systemfaktorer.
Metoden var et landsdækkende observationsstudie på data fra alle godkendte erstatningskrav til Patienterstatningen omhandlende offentlige sygehuse. Oplysninger om komorbiditet og aktivitet på hospitalerne og blev indhentet fra Landspatientregisteret og Dansk Statistik.
Incidensrater blev bestemt som antal behandlingsskader om året ift hhv befolkningen og offentlige sygehuskontakter. Vha multivariabel logistisk regressionsmodel, beregnede vi indbyrdes justerede odds ratioer for at vurdere sammenhængen mellem potentielle prædiktorer og svær behandlingsskade (permanent invaliditet ≥ 50% eller død) blandt alle godkendte erstatningskrav.
Vi identificerede 10.959 godkendte erstatningskrav i 2006-2012. Den samlede udbetaling var 360 millioner USD. De gennemsnitlige incidensrater var 27,85 skader per 100.000 indbyggere om året, og 0,21 skader pr 1000 offentligt hospitalskontakter om året. Svære og forebyggelige behandlingsskader udgjorde hhv 11,0% [95% CI 10,4; 11,6], og 41,0% [95% CI 40,1; 42,0] af alle tilfælde. Prædiktorer for alvorlig behandlingsskade omfattede alder, køn, komorbiditet (Charlson komorbiditetsindeks), medicinsk speciale og region. At være mand gav en OR på 1,31 [95% CI 1.13, 1.52] i forhold til kvinder. Alder var næsten lineært forbundet med risiko, med undtagelse af nyfødte, som have en mere end 9 gange højere risiko end referencegruppen på >0 til 40 år (OR var 9,20 [95% CI 6,31; 13,42]). De resterende aldersgrupper bestod af 10 års aldersintervaller op til >80 år, og gav en OR 1,62-4,75. Komorbiditet var forbundet med større risiko for alvorlig skade: OR var hhv 1,68 [95% CI 1,45; 1,94] og 2,33 [95% CI 1,87; 2,89] for mild og svær komorbiditet.
Sammenfattende var incidensraten af godkendt erstatningskrav på danske offentlige sygehuse ikke stigende. En stor del af skaderne kan forebygges, og både patient- og systemfaktorer kan forudsige alvorlige behandlingsskader.

Extract

Introduction

The simplest definition of patient safety is prevention of errors and adverse events when patients are treated or otherwise in contact with the health care system [1]. Historically, patient safety has not had a prominent position within health care, and there has not been a well-established tradition for working systematically to improve patient safety. However, the clinical, administrative, and political interest and awareness of patient safety has grown rapidly in recent years [2]. Consequently, collection of data on adverse events in patient safety is now a part of routine clinical work and analysis of such data are crucial for meeting the goal of building a stronger safety culture with focus on prevention of errors and injuries. Internationally, a number of studies, particularly from the U.S., have examined malpractice within surgery, emergency medicine, medical gastroenterology and pediatrics based on closed claims data regarding treatment injuries [3-6]. These studies have provided insights into high-risk patient groups and specialties; however, they do not represent an entire population, nor do they represent a health care system with universal coverage.

In Denmark, the Danish Patient Compensation Association (PCA) has collected detailed data on treatment injuries in health care through all claims for compensation since 1992. The PCA database is therefore a potential valuable information source when aiming to identify critical areas of patient safety in health care, which is a prerequisite for developing and implementing effective interventions to improve patient safety. We therefore conducted a nationwide study based on PCA data to examine time trends in the incidence of approved treatment injuries at Danish public hospitals. Furthermore, we aimed to characterize the injuries and to identify predictors of severe injuries.

Methods

Setting

The Danish Health care system offers free and equal access to hospital admissions, outpatient treatment, and general practitioners (GPs). Funding is approximately 85% publicly through taxes and approximately 15% privately, accounting mainly for out of pocket expenditure of

pharmaceuticals and dentistry. In case of illness, the citizen contacts the GP who may refer the patient to a specialist or the hospital if needed. Patients are treated on the least specialized level to ensure an effective, quick, and relevant care [7].

Compensation claims of treatment and medical injuries are given to the PCA, who administers the Danish Act on the Right to Complain and Receive Compensation within the Health Service and the Danish Liability for Damages Act, which are both no-fault systems of compensation. All patients injured by treatment, examinations, or by medication in the public or private healthcare system in all of Denmark are covered by the Danish Act on the Right to Complain and Receive Compensation within the Health Service regardless of private insurance. The PCA administration, casework and compensations are publicly funded; hence, the patient/claimant has no expenses regarding insurance, claim making, lawyers, or litigation in the PCA, and neither does the physician. It is possible to appeal the decision of the PCA to the National Agency for Patients' Rights and Complaints and secondly to the Court of Law.

The PCA database holds information on all claims received by the PCA. Upon receiving a claim, the PCA collects all the medical records pertaining to the case, as well as information on and declaration from the place where the injury occurred. A lawyer evaluates the claim in collaboration with a medical specialist to determine whether standard practice (i.e. compliance with general recommendations and guidelines) was followed. The decision is registered, as is the amount of compensation if such is assigned.

Design

We performed a nationwide cross-sectional study based on treatment injuries occurring from 2006 through 2012. Our data were updated until 2014 July 10th.

Claims data

We included closed claims on all types of treatment injuries occurring in public hospitals in the period 2006-2012, which resulted in compensation to the patient. PCA Data are somewhat dynamic, as new information may be received eg in case of appeals.

In general, financial compensation may be granted under any one of the following categories:

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, 4. the injury is rare, serious, and more extensive than the patient should be expected to endure, 5. accidents, and 6. donors and experiments.

We categorized the injuries into potentially preventable (category 1) and random/inevitable injuries (categories 2, 3, 4, and 5), respectively. Furthermore, the claims were categorized according to severity of patient outcome (severe injury meaning ≥ 50% permanent injury or death). Compensation is based on the extent of personal injury and medical expenses, loss of earnings and earning capacity, pain and suffering, and the expectations on whether the injury is permanent [8].

Potential predictors

From the PCA database, we obtained data on the following potential predictors of severe injury (death or ≥ 50% disability): age, gender, year of injury, place of treatment (region in Denmark), and medical specialty (surgery, orthopedic surgery, anesthesia/acute, and internal medicine/others).

From the Danish National Registry of Patients we obtained data on the hospitalization history of all patients included in the study. We then computed the Charlson Comorbidity Index of each patient based on previously recorded ICD-10 (International Classification of Diseases, version 10) diagnoses in order to characterize the comorbidity of the patients at the time of health care contact leading to treatment injury [9].

Statistical analysis

We first computed the yearly incidence rates of treatment injuries at Danish public hospitals as reflected by approved compensation claims from injuries occurring from 2006 through 2012. As the denominator, we used both the entire Danish population and the total number of hospital

admissions, respectively, which were obtained from Statistics Denmark and Statens Serum Institut [10].

We then examined the association between potential predictors and severe injury among all patients with approved closed claims using multivariable logistic regression. We corrected for clustering of patients within hospitals (recorded in the claims database) using robust estimates of the variance derived from the Huber/White/sandwich estimator of variance.

Analyses were performed using Stata, version 13.

Results

We identified 10,959 approved treatment injury claims in Danish public hospitals between 2006 and 2012. These originated from a total number of claims of 31.212, which was equal to a mean approval rate of 35.1% [95% CI 34.6;35.6]. No systematic development in the approval rate was observed during the study period. The total payout was 2,301,851,712 DKR (≈360 million USD). Mean age was 50.8 years [95%CI 50.5;51.2] and males comprised 43.6% [95%CI 42.7;44.6].

The mean incidence rate was 27.9 [95%CI 23.5;32.2] injuries (approved compensation claims for treatment injuries) per 100,000 inhabitants per year and 0.21 [95%CI 0.17;0.25] injuries per 1000 public hospital contacts per year. Incidence rates per year are shown in figures 1 and 2, respectively. Together, these figures show a stable incidence rate 2006-2009, and then a decline from 2010-2012. In our study the mean delay from injury until registration was 367 days [95%CI 360;375], whereas the processing time of the claims averaged 264 days [95%CI 261;267] from registration to decision and additional time went into compensation size calculations and appeals (mean 234 days [CI95% 229;239]). The combined mean time from injuries occurring in 2006-2012 until final conclusion was 866 days [95%CI 856;875].

Preventable cases comprised 41.0% [95%CI 40.1;42.0] of all cases and ranged from 38.8% in 2006 to 42.8% in 2010 with no clear trend over time. Severe treatment injury occurred in 11.0% [95%CI 10.4;11.6] of all approved claims ranging from 9.8% in 2011 to 14.0% in 2012, also with no clear trend over time. Among the examined potential predictors, the most meaningful in predicting severe treatment injury in patients experiencing a treatment injury were: Males had an adjusted

OR of 1.31 [95%CI 1.13;1.52] compared to females for a severe injury. Age was associated with risk in an almost linear way, except for being a neonate/infant, which increased the risk by an OR of 9.20 [95%CI 6.31;13.42] related to the reference age group >0 to 40 years of age. The remaining age groups consisted of 10 year intervals up to >80 years and gave an OR from 1.62 to 4.75. Comorbidity was associated with severe injury among approved treatment injuries in a linear way. A higher Charlson Comorbidity Index score was also associated with a higher risk of severe injury: ORs were 1.68 [95%CI 1.45;1.94] and 2.33 [95%CI 1.87;2.89] for mild and severe comorbidity, respectively. However, the outcome is rare, hence, the absolute risk might not be substantial despite a high OR. Mutually adjusted odds ratio estimates for all included predictors are shown in Table 1.

Discussion

Results summary

- Treatment injury incidence rates as reflected by approved compensation claims did not increase in Danish public hospitals 2006-2012.
- Preventable and severe treatment injuries comprised 41% and 11% of cases, respectively.
- Gender, age, and comorbidity significantly predicted severe treatment injuries.

Underreporting?

Underreporting in general and especially a low propensity to file claims has been reported among different groups, e.g. age, severity, and social status, in both the negligence and the no-fault compensation systems[11,12].

An explanation of these apparent uneven propensities is not obvious. Regarding the elderly, problems might arise from the lack of computer handling abilities, which demands assistance from others to be able to file a claim. Since mainly reduced working ability are compensated, only patients in or before the workforce age have the ability to achieve these earnings-related payments, removing an incentive for the retired to seek compensation.

The most ill patients are most vulnerable to injuries and disabilities, but also probably have the

shortest expected survival time, either due to high age or accelerated by their poor health, and they might not find the remainder of their lives worth spending on seeking compensation, that they might not themselves see paid.

As mentioned earlier, the health care and social security system in Denmark is mainly publicly funded and offered free of charge to those in need, hence, no extra expenses is associated to a patient experiencing a treatment injury, but a potentially reduced income if working.

Lodging a claim to the PCA is easily done requiring only a minimum of computer handling or assistance. There are no legal or economic demands or barriers, and thus follows the principal of free and equal access in the Danish Health Care system.

Even though all eligible treatment injuries might not result in a claim and potentially compensation, those that do, represent the patients' point of view of important issues regarding patient safety, because all claims are lodged by the patient or by relatives on behalf of the patient. This focuses our study on the patients' experiences of unexpected and unacceptable outcomes or side effects from treatment in the health care system.

How is underreporting developing? A hint is the fact that incidence rates of approved claims by year of injury appear stable, while number of claims per year increased. This leads to the assumption, that more claims are lodged and dismissed. Nevertheless, the approval rate was stable. Hence, the increase in claims does not reflect more dismissed claims, but suggests a catch-up in claims for older injuries, meaning a decrease in delay of claims. However, this is only suggestions and needs to be evaluated further in an updated dataset, where an indicator of claims catch-up could be a trend towards shorter claims delay.

Targeting – eligibility of claimants

As an indicator of targeting, we look at the approval rate of claims, which was 35% (ranging from 29% in 2012 to 38% in 2008, no clear tendency). This is lower than the acceptance rate of 43% in New Zealand in 1992-2000 [13] and 64% in NZ primary care July 2005 – June 2009 [14].

The explanation for the lower targeting level in Denmark is uncertain. However, more information to the patients appear warranted to improve the effectiveness of the Patient Compensation

Association in providing eligible patients compensation and minimizing ineligible claims.

The potential pool of claims and injuries because of substandard care seems to be similar across tort systems (e.g. U.S.) and systems with no-fault jurisdiction (e.g. Denmark/Scandinavia and New Zealand) [15,16].

Strengths

The data collection was nationwide. Data represents all compensation claims for treatment injuries from all authorized health care personnel in Denmark. All claims filed to the PCA are stored in the database for documentation and potential preventive initiatives.

Limitations

The study was conducted only on data from closed claims. No specific data on adverse events and the amount of potential compensable treatment injuries were available; hence, we are unable to determine the earlier discussed underreporting.

Some claims may be filed with a delay from the actual injury as shown in the results section. Therefore, some treatment injuries occurring in the study period might still be unreported or pending and unavailable for evaluation at the data output date 2014 July 10th. This might explain at least part of the apparent decrease in incidence rates seen in 2010-2012. A further update of the dataset, considering the claim delay, could reveal a more accurate development of treatment injury incidence rates during the latest years of the study period.

The data presented does not tell us the cause of treatment injuries in general. It gives us the possibility to identify predictors of severe injuries among all treatment injuries. To understand the causes of treatment injuries, further evaluation of medical records pertaining treatment injuries and those records without is needed.

Take Home Messages:

- Incidence rates of treatment injuries are not increasing. Evaluation of compensation claims is a way to monitor the development.
- Preventable treatment injuries comprises a high and stable proportion of injuries despite many years of focus on patient safety.
- Predictors of severe injury include gender, age, and comorbidity. These might be considered measures of patient fragility.
- The next step is to examine the causes of severe injuries and treatment injuries in general.

Acknowledgements

We would like to thank Lone Mortensen from the Danish Patient Compensation Association for her effort in obtaining the dataset used in this research.

Supplementary information

In order to give the best and most relevant information on the main data source of my project, the supplementary information is a systematic description of the Danish Patient Compensation Association. It describes the background of the PCA and arguments why and how the database is a useful data source much relevant to my main project. This supplementary section also reflects both what a fair part of my research time went into and the tools of my field of research – Clinical Epidemiology.

Introduction

The majority of the population in developed countries has at least one contact with the health care system each year. In the US 82.1 % of adults and 92.8 % of children were in contact with the health care system in 2012.[17] In Denmark 95% of all residents are in contact with the healthcare system corresponding in 2012 to 1.1 million admissions to hospitals, 11.5 million outpatient visits at hospitals, 11.5 million visits at private practicing specialists, and 40.5 million general practitioner visits.[18] The high activity will inevitably lead to healthcare related patient injuries as the results of either adverse events (AEs) or errors. The reported incidence of AEs varies between countries and health care systems (i.e. from 2.9% of all admissions in Utah and Colorado, US to 16.6% in New South Wales and South Australia). [19,20]

Globally, the awareness and focus on patient safety have increased over the last decades. [2] Several procedures and initiatives (eg safety checklists before surgical procedures[21] and programs for prevention of central line-associated blood stream infections)[22] have been launched and implemented in order to improve patient safety and quality of care.

Still, data on the effectiveness of interventions aimed at reducing the risk of AEs and errors remain sparse. A potential source of new insights into patient safety is the growing amounts of data on health care related injuries, which are collected as part of patient insurance and compensation administration.[23]

Denmark has a long tradition of collecting information on health care for the entire population in publicly governed registries. It is possible to link the registries at individual-level by the civil registration system (CRS) number – a personal identifier given to every citizen at birth or immigration. [24-27]

With this paper, we aim to present the Danish Patient Compensation Association (PCA) Database and outline the research potential in the database. The PCA is the organization responsible for managing the claims and compensation of injured patients in Denmark.

The Danish health care system

The health care system in Denmark guarantees free access to hospital admissions, outpatient treatment, and visits at general practitioners. It is publicly funded in the vast majority of its function as only approximately 15% of the costs are paid by own expense, mainly out of pocket expenditure on pharmaceuticals and dentistry. If a citizen contracts an illness, he/she will usually be seen by a general practitioner, who is a part of the primary health care. From there it is possible to be referred to a specialist or the hospital. A patient is intended to be treated on the least specialized level to maintain an effective and relevant treatment without too much or too expensive actions in order to give all patients the best treatment. [7]

The Danish Patient Compensation Association

The PCA was founded in 1992 in order to improve the patients' access to compensation following the passing of the Patient Insurance Act. According to the act, patients are to be compensated if they unexpectedly suffer injury while being treated anywhere in the entire Danish health care system. The PCA functions as a no-fault system of claims and the claimants are not charged any expenses for the casework.

Before 1992, compensation for an injury could only be obtained through the courts based on legal proof of an error by a health care professional. In practice, this meant that only a minority of patients with injuries received compensation. Following the passing of the Patient Insurance Act, legal proofs of errors are no longer required, but it has to be highly likely that the injury is related to the patient's treatment or examination. The PCA as an institution discloses and decides the outcome of the case, thereby assuring legal compensation in accordance with the Patient Insurance Act. In 1996, it was accompanied by the Act on Compensation for Medicine-Related Injuries. Since then, the area covered by the law has been expanded to include almost all areas and functions of the public and private health service. Both laws are now collected in the Danish Act on the Right to Complain and Receive Compensation within the Health Service and claims are ruled according to this. The covered health care areas are listed in Table 1.

All patients who suffer injury in the public and private health care system can file a claim as long as the health care person is authorized. The PCA is predominately tax funded through two sources: The Danish Regions, who finance the compensation for the public treatment injuries, and the Ministry of Health and Prevention, who finance the compensation for the medicine-related injuries. Private health care providers besides funded from public health care must take out a health care provider insurance on their own;

however, this does not affect the process of filing a claim from a patient perspective. The tortfeasors accounts for the administration fee.

In 2012 a total of 9,628 claims were made to the PCA. Of these, 33.1 % were accepted and granted a total of 143,949,117 USD [28]. Figure 1 shows the annual number of acknowledged and dismissed claims from 1996 through 2013.

Danish Patient Compensation Association Database

The PCA Database consists of claims from all of Denmark. Digital data collection has been made since the start of PCA in 1992. Until 2006, there were no systematic digital data on medical records, diagnostic imaging, specialist doctor's assessment, legal justification for decision, and additional material for case disclosure; however, data were stored in an analogue form and are accessible upon payment of transport expenses. Table 2 shows the data recorded in the PCA database, which includes information on the patient, the alleged injury, and information used to resolve the ruling.

When a claim is filed, a new folder is made for each case coded with a unique case number in addition to the CRS-number. Information is obtained from the patient's claim, medical records, a report from the place of treatment, remarks from the patient to the report, and possibly additional information from other places of treatment and specialist assessments. An overview of the distribution of reasons for acknowledging claims among the approved treatment injury claims in 2012 is presented in Figure 2. The most common cause was suboptimal diagnosis and treatment. The approved treatment injury claims constituted 33.1% of all closed claims in 2012 (2,783 out of 8,408).

A caseworker and usually an in-house specialist doctor will decide whether an injury has occurred and if so, whether it is entitled to compensation. The average processing time of a claim is 6-8 months regarding compensability. To determine the size of compensation, additional information is often requested, eg receipts for drugs, transportation expenses, a doctor statement(s) regarding degree of injury and loss of earning capacity. This process might take up to a year, though most of the compensation is paid immediately after compensability decision. Figure 3 describes the casework of a claim.

Data Linkage Possibilities

Linking data from the PCA Database with other population-based health care registers is a relatively simple yet powerful way of increasing the depths of the claims data. Data in the PCA database always include a

patient's CRS-number. Since this number is included in all public registries and databases in Denmark, it is feasible to link the data from the PCA database to a wide range of other data sources. Numerous registries are kept in Denmark spanning from birth to death of every Danish citizen and through record linkage it is therefore possible to obtain more detailed data on patients characteristics (including data on clinical, demographic, geographic, and socioeconomic variables) and to perform long-term follow-up (eg on mortality, readmissions or return to work) on the patients registered in the PCA database.[24] The DNRP is an example of a registry that will often be relevant to consider in relation to record linkage with the PCA database as it holds detailed data on all admissions to Danish hospitals since 1977 and since 1995 also on visits to outpatient clinics and emergency room visits.[29]

The PCA database covers treatment injuries through compensation claims. Another agency, The National Agency for Patients' Rights and Complaints, receives all complaints regarding the health care system, the appeals from the PCA, and also manages the reports of AEs for registration and learning. This registry, however, does not contain CRS-numbers and record linkage with other data sources or individual identification is therefore not possible.

Strengths and Limitations

The PCA database holds detailed data, which, except for trivial cases, are evaluated by specialist doctors on the different medical areas. However, only patients who actually file a claim are registered in the PCA database and therefore estimates based on PCA will underestimate the true incidence of injuries occurring in the Danish health care system. This problem is also known from other health care systems, eg, in New York State only 1.53% (95% CI 0,00;3.24%) of AEs caused by medical negligence resulted in a claim. [30] Likewise, a study from New Zealand found that only 0.4% of AEs and 4% of the preventable AEs resulted in a complaint. [11] Patients with permanent and fatal injuries were more likely to file a complaint than patients with temporary injuries (odds ratios 11.4, 95% CI 5.9;22.1 and 17.9, 95% CI 9.3;34.2, respectively). [11] Another study from New Zealand reported that only 2.9% of patients eligible for compensation actually filed a claim to the no-fault system of treatment injury compensation. [12]

Although injuries and AEs in the Danish health system are to be reported to the Danish Patient Safety Database (DPSD) under the National Agency for Patients' Rights and Complaints (NAPRC) this is not always the case. A, survey of the DPSD reporting system in 2006 suggested a maximum reporting of 85% of the AEs. In 2010 the proportion of reported AEs was estimated to be as low as 15%[28,31] despite increasing report counts of 12,370 in 2006 to 155,791 in 2012.[32] The real number of AEs and treatment injuries in the

Danish health care system therefore remains unknown. A contributing factor to the rise of AE reports and compensation claims is an increasing public knowledge of the existence of the compensation system and increased willingness to report injuries and seek compensation. The true incidence of AEs and injuries may therefore not be increasing, or at least not as much as the increasing number of reports suggests.[33] Still the fact that a substantial proportion of the complaints that are being filed concerns severe and potentially preventable injuries indicates that the DPAC database gives a potentially valuable insight on serious threats to patient safety. [11] Therefore, PCA data may potentially guide injury preventive efforts to improve health care quality.

Examples of studies using PCA data

Data from the PCA database have been used in a number of studies within recent years. In a study based on all closed claims concerning medical-related deaths in the Danish primary health care and hospital setting from 1996-2008, Hove et al identified 836 deaths caused by treatment or lack of treatment in the period of 1996-2008 with a total cost of compensations at 55 million USD. According to the PCA 435 (52%) of the deaths were preventable. [34]

Another study examined patient safety at labor wards according to ward size (number of deliveries per year). The study was based on PCA data on approved claims of obstetric injuries linked with data from the National Birth Registry. The approval rate of claims was lowest in large labor units (34.2%), and higher in very large (38.6%) and intermediate (41.7%), but highest in small labor units (50.0%). The study concluded that the results might reflect that large labor units are living up to the principle of best practice to a greater degree. [35]

Accessing PCA data

Data files are stored by the PCA (http://www.patienterstatningen.dk). From the database, the data is accessed by the lawyers and doctors of the PCA to rule in the claims, and the data are coded and published in annual reports by the PCA and in medical journals by researchers. Authorized health care researchers can be granted access to the database by contacting the medical coordinator at PCA, Kim Lyngby Mikkelsen (kim.lyngby.mikkelsen@patienterstatningen.dk).

The use of any personal data including health data is protected by The Danish Act on Processing of Personal Data and a specific permission from the Data Protection Agency is required (www.datatilsynet.dk)

Conclusion

The PCA database holds valuable information on treatment injuries in the Danish health care system. The approved closed claims are indicative of partly or totally preventable injuries and are therefore of great interest in designing efficient preventive initiatives and a health care system with better patient safety.

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Extract tables and figures

Figure 1 – Incidence rates by population

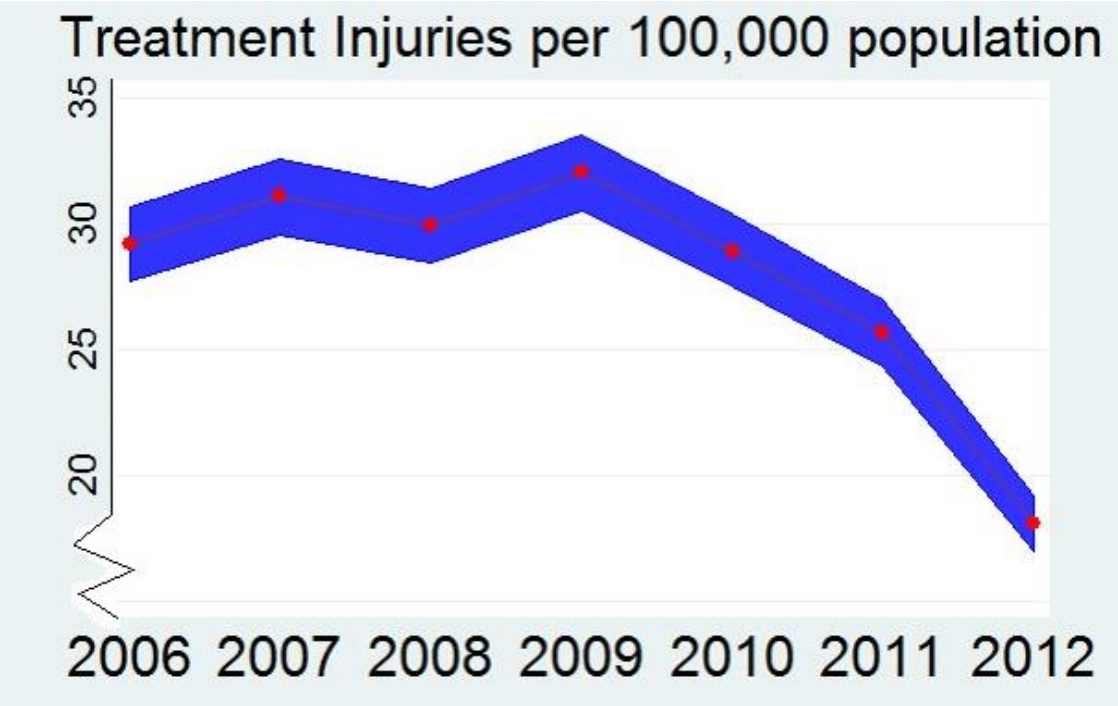


Figure 2 – Incidence rates by public hospital contacts

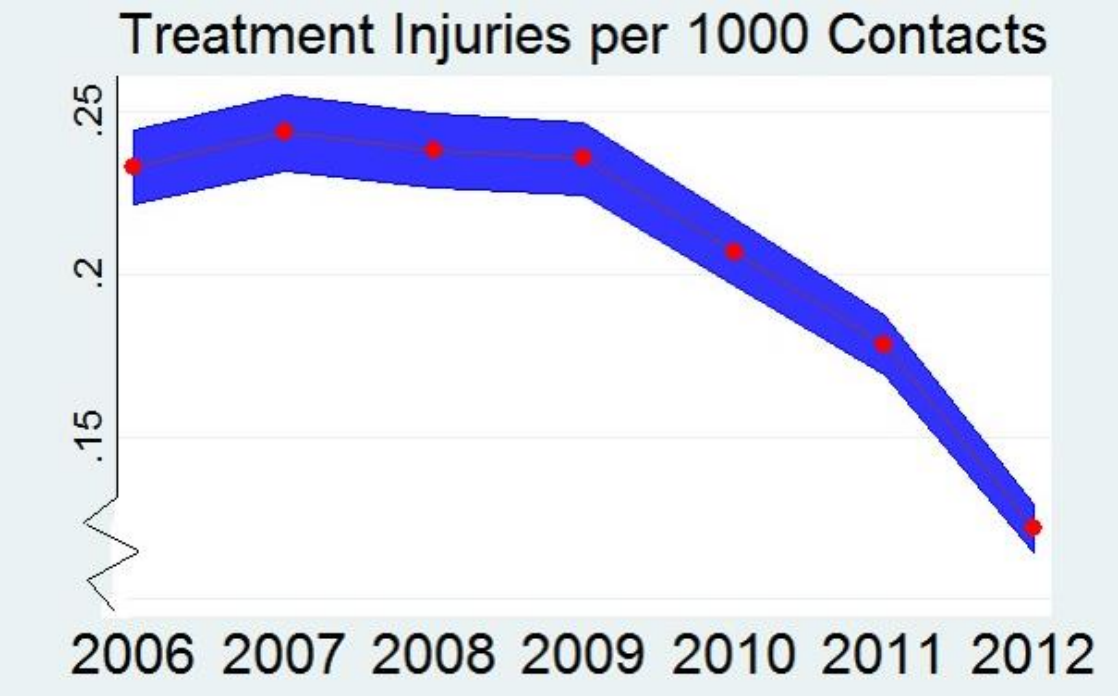
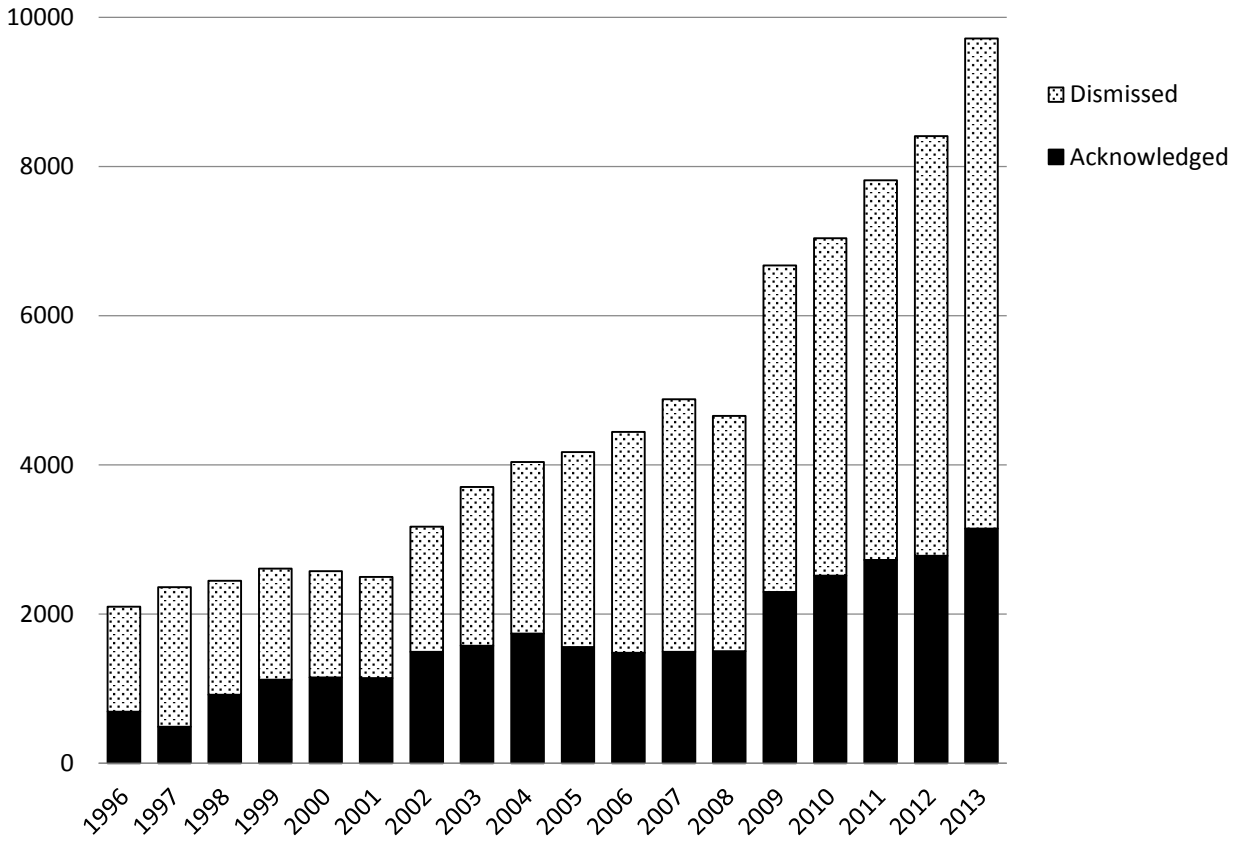


Table 1 – Mutually adjusted odds ratios from multivariable logistic regression model

	Odds ratio	95% confidence interval lower - higher	Reference group
Male	1.31	1.13 - 1.52	Female
0 years	9.20	6.31 - 13.42	>0 – 40 years
40-50 years	1.33	0.95 - 1.85	
50-60 years	1.62	1.17 - 2.24	
60-70 years	2.19	1.62 - 2.96	
70-80 years	3.66	2.77 - 4.85	
>80 years	4.75	3.10 - 7.28	
2007	1.01	0.78 - 1.30	2006
2008	1.13	0.84 - 1.52	
2009	1.25	1.01 - 1.56	
2010	0.89	0.67 - 1.17	
2011	0.90	0.70 - 1.15	
2012	1.11	0.81 - 1.54	
Central Jutland	1.13	0.91 - 1.41	Northern Jutland
Southern Denmark	1.21	0.98 - 1.48	
Capitol	1.33	1.03 - 1.73	
Zealand	1.23	0.94 - 1.61	
Orthopedic surgery	0.18	0.15 - 0.22	Non-orthopedic surgery
Anaestesia & acute	0.92	0.72 - 1.17	
Internal medicine +	1.07	0.83 - 1.39	
Mild comorbidity	1.68	1.45 - 1.94	No comorbidity
Severe comorbidity	2.33	1.87 - 2.89	

Supplementary tables and figures

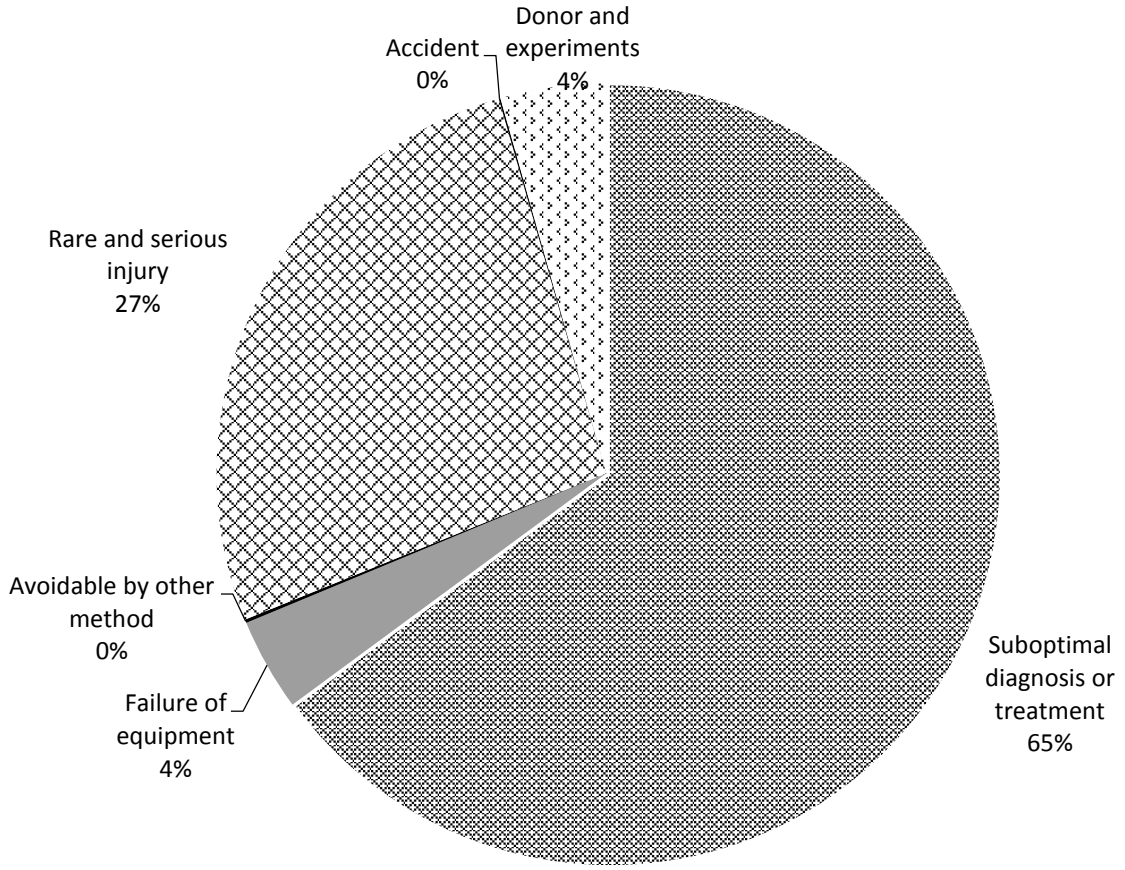
Figure 1 – The number of claims closed by the Danish Patient Compensation Association per year in 1996-2013 shown as acknowledged and dismissed.



1996: From this year data are available on both claims, closed claims, acknowledged, and dismissed.
2013: Latest available data – possibly dynamic numbers because of pending processes and appeals.

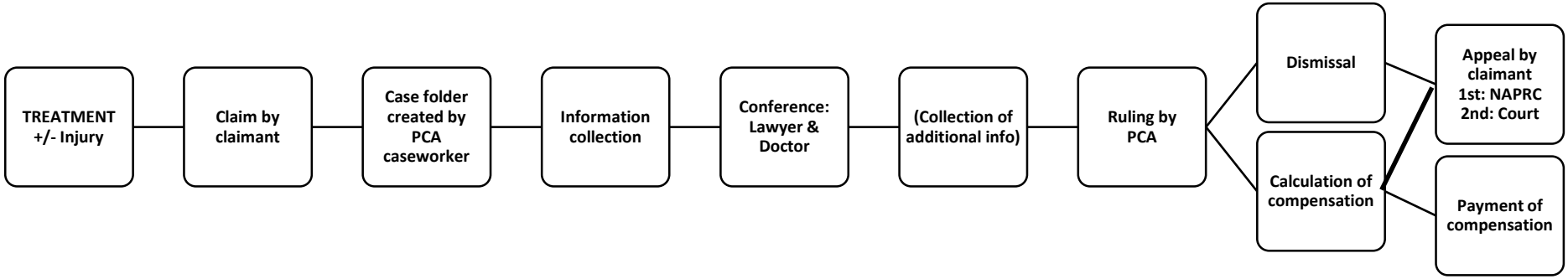
Pending claims not included, only claims closed in the given years.

Figure 2: The distribution of the reasons for acknowledging claims filed to the Danish Patient Compensation Association in 2012.



(Injuries due to suboptimal diagnosis or treatment are considered somewhat preventable)

Figure 3: Flowchart of casework



PCA: Danish Patient Compensation Association

NAPRC: National Agency for Patients' Rights and Complaint

Table 1 – The health care areas covered by the Danish Patient Compensation Association

Public and private hospitals
Treatment in the ambulance or at the location of the injury
Injuries on donors or test subjects/patients (if they are part of a medical test where a hospital, a governmentally funded educational unit or a general practitioner is in direct charge)
General practitioners and doctors from the emergency service
Private practicing specialists
General practicing dentists (claims should be directed to The Collective Insurance under The Dental Association in Denmark), dental therapist and clinical dental therapists
General practicing chiropractors, occupational therapists, physiotherapists and podiatrists
General practicing psychologists
General practicing nurses, midwives, clinical dietitians, medical laboratory technicians, surgical appliance makers, radiographers, opticians/contact lens opticians and social and health care workers
Authorized healthcare workers within the public health care services and the regional dental care and so on
The National board of Health in the event that patients that are being treated for life threatening cancer and heart diseases are exposed to mistakes in connection to The National Board of Health's' case handling
Preventative health care systems for children and teenagers, the home nursing care system, dental care, dental care for children and teenagers, rehabilitation offers and treatment for alcohol and drug abuse

Table 2 – The collected data available in the Danish Patient Compensation Association database

Patient	*Setting*	*Administration*
CRS-number	Institution causing the injury	Archive nr.
Age	Region code	Case nr.
Gender	Hospital code	Decision of the claim by the PCA
Basic diagnoses	Setting (admission, outpatient, acute, etc.)	Decision of 1st appeal (to the National Agency for Patients' Rights and Complaints)
Basic treatments	Category of personnel (consultant, other)	Decision of 2nd appeal (to the Court of Law)
Complications due to treatment	Specialty	Lex Maria (typical degree of injury in case of current complication)
Treatment of complication		Status of claim (closed, pending, other)
Date of complication		Date of registry
Death		Date of decision
Death caused by treatment		Judgment in court (if appealed)
Date of injury		Compensation in total DKR
Degree of injury		
Loss of earning capacity (percent and DKR)		
Additional days of pain and suffering		

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