

Fatal outcome after unintended events following medical intervention: a forensic pathological case survey

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Background: There is an increasing focus on unintended events, sometimes fatal, following medical intervention. According to Danish law, unintended events following medical intervention and treatment must be reported to the DPSD (Danish Patient Safety Database).

Aim: To estimate and describe the fatal cases of unintended events, as autopsied at the Forensic Institute of Copenhagen during 1 year.

Methods: All case reports available were reviewed, and cases where the death could be a consequence of unintentional medical intervention, or lack of such, were selected. The autopsy findings, including the results of additional analyses were analyzed. To evaluate whether an unintentional event had preceded death, special attention was given to the sequence of events from 30 days before the death of the patient. Four groups of health personnel were defined in order to analyze the cases, as well as four types of unintended incidents: negligence; misjudgment of clinical symptoms; mistakes during invasive procedures or medical treatment, including medication errors; mistakes in care.

Results: We found 98 fatal cases possibly following unintentional incidents in relation to medical intervention out of 720 autopsies. In these cases, hospital doctors were responsible for 60% of the total number of unintended events and for 84% of the fatalities related to mistakes happening during invasive procedures or medical treatment. Private practitioners and on-call doctors were represented in approximately equal numbers. The on-call doctors account for 30% and private practitioners for 10% of misjudgment of clinical symptoms. Infection was the most common cause of death followed by cardiovascular disease.

Conclusion: We tried to formulate a brief checklist which could raise awareness for whether a fatality may be due to an unintended incident during a medical intervention. We propose the use of this checklist when issuing the death certificate, thus ensuring the correct reporting and further handling of the death.

Keywords: Denmark, fatality, hospital deaths, doctors, malpractice

Introduction

There is an ongoing public debate about the occurrence of unintended events following medical intervention, many of which prove to be fatal.¹ When death occurs unintentionally in relation to medical treatment or diagnostic procedures, or there may be suspicion hereof, the police must be informed according to Danish law.² Notification of the police in these cases must be carried out by the doctor pronouncing the death. The police must then decide whether further investigation is necessary, including requesting a medico-legal autopsy. A medico-legal autopsy is always preceded by a medico-legal inquest (including an external examination of the body), performed in

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Denmark as a collaboration between a forensic pathologist or a health medical officer and the police.

In Denmark, medico-legal autopsies are performed by the three departments of forensic medicine at the University of Copenhagen, Aarhus University and Odense University, while medico-legal examinations may be held at all Danish hospitals. The total population in Denmark in 2009 was 5,551,000. There were 54,872 deaths. Approximately 3,600 medico-legal inquests resulting in approximately 1,236 medico-legal autopsies were performed, corresponding to 2.25% of all deaths.³

The aim of this study was to evaluate how many deaths possibly following unintentional incidents in relation to medical treatment, examination or diagnostic procedures, were autopsied at our department, and tabulating the nature of the unintentional incidents, the responsible health personnel and the cause of death. We hoped that an outcome also could be that health care workers were made aware of the correct procedures for handling deaths, including attention to the possibility of unintentional death as a result of a medical intervention or malpractice.

Material and methods

This study was carried out as a prospective, consecutive study of autopsies performed in the Department of Forensic Medicine, at the University of Copenhagen. During 2009, the total number of deaths in the catchment area (eastern Denmark, comprising Copenhagen) was 25,251.³ A total of 720 medico-legal autopsies (2.1%) were performed as a result of 1,969 medico-legal inquests (equaling 36.6%).

The case reports available prior to autopsy ($n=720$) were reviewed. We selected all cases where the deceased had been in contact with a health caregiver 30 days or less prior to their death ($n=274$). This time interval of 30 days was chosen because we considered it more reliable to connect a possible unintended event with death over a shorter time. These cases were again reviewed, focusing on the sequence of events leading up to the death, existence of chronic diseases, alcohol and/or drug abuse, and data from hospitals and general practitioners or the individual persons involved. We then selected the fatalities where case reports indicated that the death could possibly be a consequence of unintentional medical intervention or lack of such intervention ($n=108$). The autopsy findings were analyzed, including results of additional analyses such as toxicology, histopathology, neuropathology, bacteriology and virology. We also registered sex, age and the stated cause of death. In a few cases ($n=10$) it was clear that there had been no unintentional consequences of medical intervention.

In total 98 cases were identified where an unintentional consequence of medical intervention (treatment, examination, diagnostic procedures or lack of such) was a possible cause of death. The age of the deceased ranged from newborn to 94 years, with an average age of 55.3 years. Fifty four cases were males (55%) and 44 cases were females (45%).

To evaluate whether an unintentional event had preceded death, we focused on the sequence of events leading up until the death. Information about calls to medical emergency services, general practitioners or a specialist, nurses or other health caregivers was registered. The response from these people were evaluated as to whether the health caregiver had obtained sufficient information, made relevant observations and examinations, and ordered/carried out examinations according to generally accepted procedures for handling the particular case; respected accepted indications and contraindications for the medical treatment; and also if invasive procedures were performed safely and competently according to accepted guidelines. If a more observational strategy without any intervention had been chosen, then we also sought to evaluate whether this was acceptable given the knowledge at hand. For these cases, based on our interpretation of the detailed events leading up to the death, an opinion on the possible health care worker responsible for the misadventure was given. In cases where several health care workers were involved, the one with the highest competence was registered as the responsible person. We also took into consideration that a death might have occurred outside the hospital where an unintentional event had happened (after discharge from a hospital). Only one such unintentional event was registered.

We defined four groups of health personnel: hospital doctors, private practitioners, emergency doctors and others, the latter group including midwives, nurses and psychiatric carers. Somatic diseases with a duration counted in years were registered as chronic. Mental illness was included if it was mentioned in the report either as a diagnosis or information about treatment with antipsychotic or antidepressant medicine. If both somatic and mental diseases were mentioned, the case was registered as mental. Alcohol and/or drug abuse was registered if it was mentioned in the documentation.

The cause of death was registered in the autopsy report. In a few cases ($n=7$) the cause of death was not determined with certainty. Four of these were aged 70–90 years with a history of ischemic heart disease. Of these four cases, the autopsy showed severe pathologic heart changes along with bleeding (two cases) and ileus (one case). Two cases were infants who had shown signs of infection which could not

be confirmed by autopsy, and another case was an infant who died during labor where the heart rate had been low for an uncertain period. None of the cases had been classed as “cause of death unknown.” In all seven cases we concluded that pathological findings could have influenced the fatal outcome.

Based on the above, as well as previous studies,^{4,5} four types of unintended incidents were defined: negligence; misjudgment of clinical symptoms; mistakes happening during invasive procedures or medical treatment, including medication errors; and mistake in care. Negligence was defined as insufficient examination and failure to obtain a proper anamnesis according to accepted guidelines in the particular case. For example, prescribing medicine for presumed diagnoses over the telephone, no ECG although the patient presented cardiac complains, or no CT scan after cranial trauma. Misjudgment of clinical symptoms was defined as incidents where symptoms were properly diagnosed and treated, but autopsy findings indicated that the diagnosis was wrong. For example, an aortic aneurysm misdiagnosed as lower back pain and myocardial infarction as a peptic ulcer. Included in this definition were also cases diagnosed correctly, but where the severity had been underrated. Mistakes during invasive procedures or medical treatment included complications at or after surgery and invasive procedures and medication errors. For example, a feeding tube in the trachea, pneumothorax following vascular cannulation, and a wrong drug/dose/application. A mistake in care was defined as inadequate observation. For example, leaving an intoxicated mentally or physically disabled person alone.

Results

We identified 98 autopsy cases where unintentional consequences of medical intervention (such as treatment, examination, diagnostic procedures or lack of such) was a possible cause of death. This corresponds to 13.6% of all the autopsy cases at our institute during 2009. Of these cases, doctors

in hospital were by far the largest group in terms of health personnel involved, as they were responsible for 59/98 (60%) of the total number of unintended events and for almost all, 21/25 (84%), of the fatalities related to mistakes happening during invasive procedures or medical treatment (Table 1). Private practitioners and on-call doctors were represented in approximately equal numbers. The on-call doctors made the most misjudgments of clinical symptoms, 10/30 (30%), versus private practitioners, 3/30 (10%). Permission to work as an on-call doctor requires the status as private practitioner, and it is interesting that the pattern of unintended events they are involved in differs between the two categories. For private practitioners negligence predominates, 10/34 (29.4%), versus 6/34 (17.6%) for on-call doctors. Thus, our results may show that doctors in these groups act differently according to their function at the time of the particular case. Other caregivers account for 7/98 (7.1%) of the unintended events and their major involvement is inadequate observation, for which they are responsible for 4/9 (44.4%) for these cases. The case with a nonspecified health care worker concerned the misplacement of a tracheal tube where it was not registered whether it was a nurse or a doctor who was responsible for the treatment.

Overall, infection was the most common cause of death (25/98, 25.5% of all cases). Second were cardiovascular diseases (15/98, 15.3%). Doctors in hospitals were responsible for the vast majority of these complications (infections: 17/25, 68.0%; cardiovascular: 8/15, 53.3%) (Table 2). The cause of death could not be determined with certainty in 7/98 cases (7.1%).

Cause of death in relation to unintended incidents is shown in Table 3. Fatal complications after invasive procedures or after medical treatment was most often due to infection (9/25, 36%). Fatal complications after misjudgment of clinical symptoms was also often infections (8/30, 26.7%). A quite large proportion of fatalities due to coronary disease and central nervous system lesions (both 8/34 (23.5%)

Table 1 Frequencies of health care practitioners in cases of possible unintentional consequences of medical interventions

	Negligence N (%)	Misjudgment of clinical symptoms N (%)	Mistakes during invasive procedures or medical treatment N (%)	Inadequate observation N (%)	Total N (%)
Doctors in hospital	17 (50.0)	16 (53.3)	21 (84.0)	5 (55.6)	59 (60.2)
Private practitioners	10 (29.4)	3 (10.0)	2 (8.0)	0 (0.0)	15 (15.3)
On-call doctors	6 (17.7)	10 (33.3)	0 (0.0)	0 (0.0)	16 (16.3)
Other health caregivers	1 (2.9)	1 (3.3)	1 (4.0)	4 (44.4)	7 (7.1)
Not specified	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	1 (1.0)
Total	34 (100.0)	30 (100.0)	25 (100.0)	9 (100.0)	98 (100.0)

Table 2 Causes of death as determined at autopsy, by health care practitioner group

	Infection N (%)	Cardiovascular diseases N (%)	Hemorrhage N (%)	CNS lesions N (%)	Pulmonary embolism N (%)	Poisoning N (%)	Aortic aneurysm N (%)	Others N (%)	Not specified N (%)	Total N (%)
Doctors in hospital	17 (68.0)	8 (53.3)	6 (60.0)	9 (75.0)	3 (42.9)	3 (37.5)	4 (80.0)	6 (66.7)	3 (42.8)	59 (60.2)
Private practitioners	2 (8.0)	3 (20.3)	3 (30.0)	0 (0.0)	4 (57.1)	1 (12.5)	0 (0.0)	1 (11.1)	1 (14.0)	15 (15.3)
On-call doctors	4 (16.0)	4 (26.7)	1 (10.0)	2 (16.7)	0 (0.0)	2 (25.0)	1 (20.0)	1 (11.1)	1 (14.3)	16 (16.3)
Other health caregivers	1 (4.0)	0 (0.0)	0 (0.0)	1 (8.3)	0 (0.0)	2 (25.0)	0 (0.0)	1 (11.1)	2 (28.6)	7 (7.1)
Not specified	1 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
Total	25 (100.0)	15 (100.0)	10 (100.0)	12 (100.0)	7 (100.0)	8 (100.0)	5 (100.0)	9 (100.0)	7 (100.0)	98 (100.0)

Note: "Others" means not one of the preceding causes, but had been specified.

Abbreviation: CNS, central nervous system.

Table 3 Causes of death as a result of possible unintentional consequences of medical interventions

	Infection N (%)	Cardiovascular diseases N (%)	Hemorrhage N (%)	CNS lesions N (%)	Pulmonary embolism N (%)	Poisoning N (%)	Aortic aneurysm N (%)	Others N (%)	Not specified N (%)	Total N (%)
Negligence	7 (28.0)	8 (53.3)	1 (10.0)	8 (66.7)	5 (71.4)	1 (12.5)	0 (0.0)	2 (22.2)	2 (28.6)	34 (34.7)
Misjudgment of clinical symptoms	8 (32.0)	3 (20.0)	3 (30.0)	1 (8.3)	2 (28.6)	5 (62.5)	5 (100.0)	0 (0.0)	3 (42.8)	30 (30.6)
Mistakes during invasive procedures or medical treatment	9 (36.0)	4 (26.7)	5 (50.0)	3 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (33.3)	1 (14.3)	25 (25.5)
Inadequate observation	1 (4.0)	0 (0.0)	1 (10.0)	0 (0.0)	0 (0.0)	2 (25.0)	0 (0.0)	4 (44.4)	1 (14.3)	9 (9.2)
Total	25 (100.0)	15 (100.0)	10 (100.0)	12 (100.0)	7 (100.0)	8 (100.0)	5 (100.0)	9 (100.0)	7 (100.0)	98 (100.0)

Note: "Others" means not one of the preceding causes, but had been specified.

Abbreviation: CNS, central nervous system.

happen due to negligence). Aortic aneurysm is the cause of death in 5/98 (5.1%) of fatalities and is only found as a result of misjudgment of clinical symptoms. The possibility of pulmonary embolism seems to be neglected with 5/7 deaths accounting for this unintended event.

Discussion

Madea and Preuss⁵ found an average of 4.4% fatalities resulting from unintended events from 17 forensic institutes, but the frequencies varied widely between the institutes, from 1.9% to 20%. Their cases were selected from autopsies carried out due to suspicion of medical malpractice. Sporaland and Morild⁶ found 0.9% and Nunno⁷ found 4.1%, using a selective procedure as we have done. Our estimated result of 13.6% is higher than these previous reports. The reason for our high number could be that prospective evaluation of the case reports prior to autopsy reveals more details and is more reliable. Hospital journals may be returned when the autopsy is completed and will not be present for retrospective analyses, and the information is thus based on case summaries and may have been subjected to varying degrees of interpretation.⁸

There are no unique and exclusive definitions for the types of mistakes. We would encourage future studies to use the definitions that we have set up. Furthermore, as most medical examinations, interventions and care are performed by health personnel as teamwork and within the scope of procedures and guidelines, it may not make sense to point out one single responsible person. Yet we think that identifying the responsible health care person may help to suggest where in the health system, and during which procedures, patients may be especially at risk. As such, while our study comprises a small number of cases, and only one observer (BS) read the autopsy results, we do think that our results may be of significance.

Doctors in hospitals were responsible for 60% of our cases. This confirms the findings of other authors.⁴⁻⁶ No complete data is available on how many patients are treated by private practitioners, on-call doctors or other health care workers, but we know that there are approximately 20 million interactions every year with private practitioners in our catchment area. According to the Danish General Practitioners Association, general practitioners treat around 90% of all contacts to the health system. According to Danish Society for Patients Safety, approximately 100,000 unintended events are reported yearly from the overall health care system. Only 1,350 of these reports (1.4%) are from primary care. This could indicate that quite a large number of doctors

working outside hospitals underreport fatal outcomes of unintentional events, something also hinted at by doctors in the media.⁹ We made the interesting observation that doctors with the same degree of specialization act differently according to their function as either general practitioners or on-call doctors at the time of the particular case (Table 1).

We found that negligence and misjudgment of clinical symptoms were the types of possible unintentional events that most often led to death, showing an overall agreement with previous studies.^{4-6,8,10} Still, literature about causes of death in relation to health personnel and unintended events is lacking. We found that infection was the most common cause of death happening after invasive procedures and medical treatment, and that hospital doctors are the responsible health care worker in this instance. This seems to be a logical connection, since most invasive procedures are undertaken in hospitals. But 90% of all contacts to the health system are dealt with by the general practitioners, who also have the role of being an on-call doctor. Schiøler et al⁸ found that 52% of unintended events disclosed during hospitalization, actually happened before the hospitalization. In our catchment area in 2009 there were more than 600,000 hospitalizations and 20.5 million contacts to general and private practitioners³. It is mainly the most seriously ill and weak patients who are hospitalized, and in this group the outcome of comparable unintended events is more likely death than among outpatients. This may explain the fact that hospital doctors are involved in such a great proportion of fatal cases. In hospitals the examination and treatment of patients is performed by teams and patient records are open to all health care workers. Many health care workers are aware of unintended events and the reporting of these is considered an important step in improving patient safety.¹¹

It has been stated that the number of deaths following unintended events is generally underestimated.⁴ While our data cannot directly ascertain whether under-reporting takes place, we can make several suggestions as to why this could be the case in Denmark: reporting requires time and paper-/computer-work and hospitals are busy workplaces. Doctors may choose to postpone that work – and the reporting may then be forgotten. In some fatalities the unintended event is not recent and may not have caught the attention of the health care worker. In addition, it could have been carelessness in the diagnostic procedure from the general practitioner or other health personnel around the patient, which will not be apparent to the hospital workers. In our opinion, it is the sequence of events and the health care persons involved that may hinder the proper recording of data. Hospitals increasingly focus on

patient safety and hopefully this will also result in a better reporting of unintended events.

Conversely, there has never been a tradition for reporting malpractice among general practitioners and there has not been mandatory reporting of unintentional events in Denmark by general practitioners since September 2010. The death certificate is issued by the doctor (or his/her deputy) who was last to treat the deceased, and it is furthermore presumed that the doctor had treated the deceased as a patient in the practice. The medical records are restricted to the general practitioner and no other doctors are able to access them. The consequence of this is that some doctors issuing the death certificate may actually not know the deceased; the history of the deceased; health before death; possible illness and treatment; and hence will not have the prerequisites for suspecting an unintended event. Even if the doctor was very familiar with the medical history of the deceased, the general practitioner must evaluate their own treatment, or lack of treatment, and determine whether they can issue the death certificate or if they should call the police because the death might be due to medical intervention or malpractice. If the relatives of the deceased patient do not complain, no one will follow-up on the procedure. In the UK an extreme case occurred, when a general practitioner was murdering patients, and this was only noted when undertakers began noticing and questioning the unusual number of deaths in his catchment area.¹²

In order to increase patient safety, it is important to know which health care person makes which mistakes and what the causes of death may be. Therefore a proper record is necessary. In order to increase the awareness of possible unintended events we suggest having two simple checklist items when writing the death certificate:

1. Up until 30 days before death, did the deceased have:
 - newly prescribed medication?
 - unexpected symptoms in chronic disease?
 - contact with a private practitioner, on-call doctors or other health care workers?
2. Given the above, has all relevant medical information been obtained?

General suggestions aside, we can point to some problematic issues, based on our forensic pathology work. One issue is the variation in the number of autopsies resulting from medico-legal external examination in the different regions of Denmark.¹³ The reasons for this have not been investigated. Conflicting interests may occur because the police are carrying the economic burden concerning the autopsy. In fact, new accounting and autopsy cost procedures resulted in a decrease in autopsy rates in Norway in 1990.¹⁴

In hospitals the process of declaring a person dead needs a higher priority than currently. It is a great advantage if the doctor has a broad, clinical experience. Pronouncing death is usually performed by inexperienced doctors during short breaks between busy calls. The doctors may never have seen the patient, may be distracted by the other procedures occurring around the death, and if not fully informed by nurses or other health care persons that an unintended event may be suspected, cannot by themselves investigate all the necessary information concerning the case. Clinical experience is mandatory in figuring out an illness course and spotting possible unintended events. If the doctor first becomes aware of (missing) medical data when performing the medico-legal examination with the police, then the doctor should then strongly emphasize the need for missing medical data to be obtained, which is a task for the police.

Conclusion

Although our work is limited in number of cases, and is the result of only one observer studying the autopsy reports, we find comparable trends to other studies of deaths following medical intervention, health care workers involved and types of unintended events. We would emphasize that investigations are needed to clear up the role of health care workers in the primary health care system, because their roles contribute to a significant number of cases. The registration of the frequency of death following medical intervention must be made more uniform, and it may be that many cases are not reported. Registration should be optimized, for example by using checklists, so that the number and nature of unintended events can be ruled out. The essential medical person in this setting is the doctor who first declares a person dead. We therefore recommend that the process of declaring death has a higher priority than it has today, both inside and outside hospitals, and that the process involves experienced and trained doctors. In the future we aim to perform a prospective registration of possible deaths following medical intervention.

Disclosure

The authors have no conflicts of interest in this work.

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