Adverse events among hospitalised patients

Results and methodological aspects of a record review study

Marieke Zegers
The study presented in this thesis was conducted within NIVEL, the Netherlands Institute for Health Services Research (www.nivel.nl), the EMGO Institute for Health and Care Research (www.emgo.nl) and the Department of Public and Occupational Health of the VU University Medical Centre in Amsterdam, the Netherlands. NIVEL and the EMGO Institute for Health and Care Research participate in the Netherlands School of Primary Care Research (CaRe) which was re-acknowledged in 2005 by the Royal Netherlands Academy of Arts and Sciences (KNAW). The study was initiated by the Dutch Society of Medical Specialists (Orde van Medisch Specialists) with financial support from the Ministry of Health, Welfare and Sport. Financial support for the printing of the thesis has been kindly provided by NIVEL and the EMGO Institute for Health and Care Research.

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Adverse events among hospitalised patients

Results and methodological aspects of a record review study

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Adverse events among hospitalised patients
Chapter 1

General introduction and research questions
There were no known previous empirical data about patient harm as a result of hospital care in Dutch hospitals. The study described in this thesis addresses the incidence, nature, severity and preventability of adverse events among hospitalised patients in the Netherlands. Both results and methodological aspects of the retrospective patient record review study are reported. This introductory Chapter outlines the background of patient safety research and the increased attention for patient safety both in the Netherlands and internationally. In addition, the objectives and research questions of the Dutch Adverse Event Study are described.

Introduction

Today’s healthcare context is highly complex. Over the past decades the number and complexity of diagnostic tools and therapeutic interventions has increased markedly. The number of drugs in use has risen and the patient population has aged [1; 2]. Care is often delivered in a pressurised and fast-moving environment, involving a vast array of technology and many individual decisions and judgements by healthcare professionals [1]. More diseases can be treated successfully. Vulnerable patients, such as elderly patients with complex co-morbidity, can be operated upon more often. New and more complicated techniques for diagnostic and therapeutic interventions, plus the treatment of patients with higher risks, entail, in addition, an increased risk of complications and iatrogenic illness [2]. The potential for harm is further increased by the number of healthcare professionals involved in the care of patients, the size of healthcare institutions - with the consequent need for increased communication - and the complexity of systems employed [3]. Errors in the process of care, for example during a clinical procedure or as a result of a clinical decision, can result in unintended patient harm and can lead to temporary or permanent disability or death [1]. Unsafe medical care is a major source of morbidity and mortality throughout the world. The problem of adverse events in health care is not new. Studies as early as the 1950s and 1960s reported on adverse events, but they have been largely neglected [1]. Steel et al. (1981) gave a warning to the medical community in 1981 when they articulated the serious risks associated with hospitalisation [2; 4]. Subsequent studies showed that millions of people suffer disabling injuries or death attributable to medical care [5]. Patient safety has become a major concern throughout the world.
Background

Patient safety: a critical component of quality of care
A widely used definition for quality of care from Lohr (1990) is: “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge”. Good quality means providing patients with appropriate healthcare services in a technically competent manner, with good communication, shared decision-making, and cultural sensitivity [6]. In the literature, the quality of care is expressed in a variety of components such as timeliness, efficacy, efficiency, appropriateness, legitimacy, equity, safety, and the degree to which it is acceptable, optimal, accessible, and patient-oriented [7; 8]. The World Health Organization (WHO) defines patient safety as “the freedom for a patient from unnecessary harm or potential harm caused by adverse events made in any health care setting” [9; 10]. The Institute of Medicine (IOM) identified ‘safety’ as a dimension of quality. They divided quality of health care in three domains. The first domain of quality is safety, which refers to “freedom from accidental injury”. The second domain is evidence-based care, referring to the provision of healthcare services in a manner that is consistent with current medical knowledge and best practices. The third domain is patient-oriented care, which exemplifies the ability to meet customer-specific values and expectations, permitting the greatest responsiveness to individual values and preferences and maximum personalisation or customisation of care [11]. Safe care is not just a critical component of the quality of care, but in fact the minimum prerequisite for the quality of care. Only after safety is guaranteed, implying that care is delivered without unintended injury, can other aspects of quality of the care become relevant. Primum non nocere – First, do no harm - Safety first.

Increased international attention for patient safety
Studies of patient harm have been carried out for many years. Many examples could be given of isolated studies into errors and iatrogenic effects. But it was not until the 1970s that any attempt was made to provide an overview of the scale of adverse events. The rising rate of litigation in the 1970s and 1980s was an important stimulus in raising awareness of the problem of patient safety in the US [1]. Since the publication of “To err is human” by the IOM in 2000 [11], interest in research into patient safety has increased tremendously [12; 13]. The report showed that, based on the results of two large studies in New York,
and Utah and Colorado [14-16], at least 44,000 to 98,000 Americans die each year as a result of medical errors [11]. This means that, even using the lower estimate, death due to medical errors exceeds the number of deaths attributable to the 8th-leading cause of death. In the US, more people die in a given year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS.

The large study on the occurrence of adverse events in New York was carried out in 51 hospitals in 1984 and was based on an analysis of information in patient records. This so-called Harvard Medical Practice Study (HMPS) established the standard by which adverse events are measured in healthcare organisations and laid the groundwork for policy discussions on patient safety and patient safety research in several countries [17]. After the HMPS, studies on the occurrence of adverse events applying the same method were carried out in several countries [18-25]. These studies showed that the incidence rate of adverse events among hospitalised patients varied from 2.9% (US) to 16.6% (Australia). Of these adverse events, 4.4% (Spain) to 20.8% (Canada) contributed to death. A quarter (France) to half (Australia) of all adverse events was judged to be preventable.

Record reviews have had a major effect on the policies of national governments and patient safety initiatives by healthcare providers [26]. Patient safety has become an international priority with major research programmes being carried out in several countries [27]. Governments have responded to concerns over safety with initiatives such as the formation of the National Patient Safety Agency (NPSA) for England and Wales [12] and the National Patient Safety Foundation (NPSF) in the US. Also non-governmental organisations were initiated, such as the Australian Patient Safety Foundation (APSF) and the Canadian Patient Safety Institute [28]. The role of these institutes is to improve the safety of patients by initiating and supporting innovative projects for enhancing patient safety and promoting research into patient safety [29]. To improve patient safety worldwide, the WHO launched the World Alliance for Patient Safety in 2004 [1]. The WHO is committed to making patient safety a high priority for countries’ policies [30].

The development of patient safety in Dutch hospitals
Patient safety has become an important issue in Dutch health care, partly because of the publication of “To Err is Human” in 2000 and subsequent reports, suggesting that in the Netherlands thousands of patients die each year due to medical errors in hospitals [31]. In November 2003, the “Better Faster”
programme was introduced by the Dutch Ministry of Health to, among other things, stimulate patient safety by implementing best practices in a selected group of hospitals. One of the missions of the programme was to realise a substantial performance improvement in 20% of Dutch hospitals in the area of patient safety [32]. As part of the Better Faster programme, the Minister of Health asked for advice from the chief executive of Royal Dutch Shell about risk management in Dutch hospitals. Among other things, he advised implementing a certified safety management system in all Dutch hospitals in 2008. This safety management system must consist of a prospective risk-analysis, a system for (safe) incident reporting, incident analysis and a management system to plan and monitor interventions to enhance patient safety [33].

The Minister of Health also asked the Advisory Council on Health Research (Raad voor Gezondheidsonderzoek) for advice about the need for research on patient safety in Dutch hospitals. In 2005, the Advisory Council reported that in the past 25 years several hospitals have carried out research projects in the area of patient safety, and in recent years the number of improvement projects has grown rapidly. However, they concluded that research on patient safety in the Netherlands was fragmented and suffers from a lack of continuity and coherence [31].

In 2006, the results of the HARM-study (Hospital Admissions Related to Medication) were published. This study was a prospective, nested case-control study on the frequency of medication-related hospital admissions based on a study in 21 Dutch hospitals. The study showed that the frequency of medication-related hospital admissions was found to be 2.4% of all admissions and 5.6% of emergency admissions. Of these admissions, 46% were judged to be preventable. Applying this figure to the Netherlands would suggest that 19,000 of the 41,000 medication-related hospital admissions per annum were preventable [34].

However epidemiological data about the occurrence, nature and preventability of adverse events caused by hospital care in the Netherlands were missing.

Enhancing patient safety starts with knowledge to raise awareness

The WHO Working group on Patient Safety describes a process for patient safety research to identify solutions to enhance patient safety and reduce harm to patients (Figure 1.1). The process is divided into a number of stages which describe the actions required, and may also be used to assess the stage of development of a country or institution in the area of patient safety. These stages are all necessary and may proceed concurrently [30; 35].
The process involves an ongoing cycle of research to [30; 35]:

- **Measure the nature and scale of harm to patients in order to raise awareness:** drawing attention to harm caused by healthcare systems provides a receptive context for further studies and action on patient safety and should serve to make all stakeholders, including policy-makers and healthcare workers, realise that reported situations are not isolated, but are probably more general and widespread. Planning and prioritising effective safety interventions and setting research priorities requires a thorough understanding of the nature and scale of the problem. Countries should assess the burden of patient harm in order to guide policy. At clinical level, understanding the specific problems particular to each specialty is necessary for effective interventions.

- **Understand underlying causes of adverse events that lead to patient harm:** causes of adverse events may vary widely according to the country, the healthcare system, and the treatment or procedure in question. Because of the complex nature of health care, there is no single reason why things go
wrong. Research is needed to identify major modifiable factors in the causal pathway.

- Identify methods of prevention: methods of prevention will depend on the nature of the problem identified and the healthcare system in which the problem occurs. Research is needed to determine which prevention interventions are effective in making care safer and reducing patient harm. Healthcare systems could use strategies from high-risk industries, where safety is critical, in order to model safety enhancement, with a consequent emphasis on technological solutions and standardisation of complex processes.

- Develop and run safety programmes: health care systems should develop effective, ongoing safety programmes that aim both to monitor and to react to safety issues and proactively assess potential risks and hazards. Evidence-based practices from the preceding stage could serve as input for the fulfilment of safety programmes.

- Evaluate the impact of interventions and safety programmes: even when prevention interventions proved to be effective in research settings, it is important to assess and evaluate the impact, acceptability and affordability of the implemented interventions in real-life settings.

Patient safety research provides evidence and tools for taking action to make patient care safer. The different stages need different types of research to improve patient safety. The most common methods for raising awareness (stage 1) are government reports, patient safety literature, adverse events review studies, media attention, and litigation and complaints [30].

The study described in this thesis addresses the need for epidemiological data on the occurrence and nature of adverse events in Dutch hospitals, which is the first stage of the patient safety research process.

**Conceptual framework for patient safety research**

Improving the safety of health care has become the focus of scientific, management and policy effort. In order to establish whether or not a change in policy or management practice is effective, it is necessary to develop metrics of safety [36]. Patient safety research is a new field of study. Uniform definitions and concepts for patient safety research are needed in order to facilitate international comparisons; including comparing the Dutch research results with those from other countries [37].

As patient safety is a critical component of the quality of health care, Donabedian’s widely used quality of care framework is often applied to classify
patient safety research and measures [5; 38; 39]. The framework comprises three dimensions: structure, process and outcomes (Figure 1.2). Behind the framework lies the generic idea of a service (frontline healthcare) embedded in a system [39].

Figure 1.2 Structure, process and outcome model for patient safety research based on Donabedian and Reason [39; 40]

Structure is the system in which health care is delivered and consists of external factors that cannot be completely determined by managers within a healthcare organisation. Depending on the national context, these may include national directives, licensing procedures and the provision of resources, such as buildings, equipment and budget. The endogenous processes are divided into two types: management or organisational processes, for example human resource policy, training of new staff, and management of the supply chain, and clinical or ‘front-end’ processes, for example adoption of particular safety evidence-based practices and the quality of clinician-patient communication. This distinction accords with Reason’s distinction between latent conditions at the organisational level and active failures at the sharp end of the healthcare process, which involve direct human interactions [39; 40]. Most adverse events, seemingly caused by human action or a failure to act at first sight, are often partly caused by a care process that has not been properly organised. This is called the system approach to patient safety, which emphasises that most adverse outcomes are system-related and generally not solely attributable to an individual’s negligence or misconduct [11; 37-39]. The combination of active failures interacting with latent conditions results in adverse outcomes [27].
According to the framework, patient safety interventions can be divided into generic interventions, which are focused on management processes, and specific interventions, which are designed to impact on a clinical domain [39].

The last element of the framework is patient outcomes. Health care-associated infections and adverse drug events can be categorised as outcomes of unsafe care. The study in this thesis addresses the incidence and nature of harm to patients in Dutch hospitals. Counts and incidence estimates of patient harm are straightforward outcome measures for patient safety and address the last element of the framework (Figure 1.2) [38]. Measuring adverse patient outcomes will provide information which can be used to prioritise general and specific interventions to improve the management and clinical process in order to reduce the incidence of adverse outcomes.

Before measuring the incidence and nature of patient harm as a result of unsafe health care in Dutch hospitals, a Dutch framework with definitions of patient safety was developed. It was based on definitions and frameworks from previous patient safety studies [41]. An adverse event is defined as an unintended injury that results in temporary or permanent disability, death or prolonged hospital stay, and is caused by healthcare management rather than by the patient’s underlying disease process [42]. A preventable adverse event is an adverse event resulting from an error in healthcare management due to failure to follow accepted practice at an individual or system level. Accepted practice was taken to be 'the current level of expected performance for the average practitioner or system that manages the condition in question' [42]. Preventable adverse events are due to errors, caused by insufficient action according to professional standards and healthcare system failures. These adverse events are therefore of special interest as patient safety can be improved by the implementation of prevention strategies.

A detailed overview of the definitions and outcome measures of this study is described in Chapter 2.

Measures to assess adverse events

There are several methodologies available for studying adverse events in hospitals. They all have their strengths and limitations in terms of the effort required to achieve the desired outcome measures and the bias of under- or over-reporting (Table 1.1). The main problem of methods such as reporting systems, analysis of claims and complaints, and observation is that single events - numerators - are assessed that are not linked to denominators,
thereby restricting the ability to estimate incidence rates [43]. In addition, the capacity for reporting, analysing and learning from incidents is seriously hampered by a lack of methodological uniformity in identification and measurement, concerns over breaches in confidentiality of data, and the fear of professional liability [1; 5]. Michel et al. (2004) have compared three methods for the assessment of adverse events: retrospective record review in which the data are collected after discharge, prospective record review, in which the data are collected during hospital stay, and cross sectional record review, where data are gathered in one day. This study concluded that the retrospective method is more appropriate for estimating rates of adverse events; the prospective method should be preferred for describing causes and consequences of adverse events [21]. Sari et al. (2007) have compared routine incidence reporting with the record review method and found that the routine reporting system considerably under-reports the scale and severity of adverse events [44].

The most powerful epidemiological evidence of adverse events comes from retrospective review of patient records [1]. The results provide urgently needed insight into the current state of patient safety and areas for improvement of patient safety [30]. The methodology of patient record review has considerable strengths. It was already mentioned that record review provides a more complete indication of adverse events compared to reporting systems [45]. The review forms provide a standardised, structured, implicit method of recording. The epidemiological data obtained are potentially useful for comparative studies, although any comparison needs to take variations in methodology into account, particularly in relation to the used definitions and inclusion criteria. The record review method depends, however, on the accuracy, completeness and legibility of patient records. Moreover, previous record review studies reported low to moderate inter-rater reliability [14; 16; 18; 24; 46]. Finally, record review can be time-consuming and expensive. Despite these limitations, record review has yielded important epidemiological data that have had a major effect on government policies and action by healthcare providers [45]. Patient record review studies currently offer the best method available to assess the incidence and nature of adverse events. It is by far the most widely applied and thoroughly studied method for the measurement of adverse events, and therefore, safety in hospitals [46].
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<th>Methods</th>
<th>Strengths</th>
<th>Limitations</th>
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<td>Retrospective record review by external</td>
<td>- Effective and appropriate method to assess the nature and incidence of</td>
<td>- Information bias in case of incomplete or inadequate patient records</td>
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<td>reviewers</td>
<td>adverse events</td>
<td>- Hindsight bias</td>
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<td></td>
<td>- Almost no workload for staff</td>
<td>- No involvement of staff, lower face validity of results</td>
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<td>- No inconvenience for departments or interruptions of the healthcare</td>
<td>- Less appropriate for assessment of causal factors and preventability</td>
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<td>process</td>
<td>- High costs and time-consuming</td>
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<td>- Data collection is easily planned</td>
<td>- Poor to moderate reliability</td>
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<td>- Standardised method of recording</td>
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<td>- Commonly used</td>
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<td>- Much experience from previous studies</td>
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<td>Prospective record review combined with</td>
<td>- Effective and appropriate method to assess the nature, incidence,</td>
<td>- Workload for healthcare workers and external researchers</td>
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<td>interviews with healthcare workers</td>
<td>causes and preventability of adverse events</td>
<td>- Time-consuming to generate national adverse event incidence rates</td>
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<td>- High face validity</td>
<td>- Very expensive</td>
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<td>- Involvement of healthcare workers by interviewing them</td>
<td>- Observer bias</td>
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<td>increases the awareness of patient safety and the development of a</td>
<td>- Involvement of healthcare workers could lead to information bias</td>
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<td>- More sensitive</td>
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<td>Cross sectional: data gathered in one day</td>
<td>- Rapid, easy and systematic data collection</td>
<td>- Lack of follow up: lower effectiveness, lower validity (false positives</td>
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<td>by record review</td>
<td>- Less expensive</td>
<td>and false negatives), and underestimation of severe outcomes</td>
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<td>combined with interviews with healthcare</td>
<td>- Involvement of healthcare workers by interviewing them</td>
<td>- Workload for staff</td>
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<td>Litigation (liability claims) and complaints</td>
<td>- Data are available</td>
<td>- Reporting bias: underreporting of the scale of adverse events and minor</td>
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<td>- Epidemiological denominator to calculate incidence rate is hard to</td>
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### Methods

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| Voluntary (anonymous) incident reporting by healthcare providers and administrative personnel | - Involvement of healthcare workers raising the awareness about patient safety and the development of a patient safety culture            | - Workload for healthcare providers: registration and analysis by healthcare workers is time-consuming  
- Reporting bias: underreporting of scale of adverse events, severe outcomes, and some classes of adverse events depending on the willingness to report by the healthcare workers (fear, culture of blame, bad processes or tools, time constraints or delay of analysis and feedback)  
- Epidemiological denominator to calculate incidence rate is hard to determine  
- Low reliability  
- Hindsight bias |
| Direct observation                                                                         | - More insight into causes and preventability of adverse events  
- No bias associated with retrospective record review                                       | - High costs and time-consuming  
- Resource-intensive: observation of thousands of patients for determination of adverse event incidence rate  
- Possible to be overwhelmed with information  
- Potential Hawthorne effect  
- Epidemiological denominator to calculate incidence rate is hard to determine |
| Analysis of routinely collected or existing administrative hospital data (morbidity and mortality data) | - Data are readily available  
- Inexpensive  
- Computer readable  
- Covers large populations                                                                 | - Registration bias: data are collected for other purposes (coding irregularities) and could therefore be incomplete or inaccurate  
- Low reliability of routinely collected information  
- Low sensitivity, fair specificity  
- Limited clinical details |
Dutch Adverse Event Study

A lack of empirical data about adverse events in Dutch hospitals

Measurement of the incidence and nature of adverse events is the first step in identifying and prioritising solutions aimed at enhancing patient safety and reducing harm to patients. Gathering information about the status of patient safety will increase the awareness of improving patient safety. Up to now, systematic research to estimate national empirical data about the incidence, nature, severity and preventability of adverse events in Dutch hospitals was lacking. Extrapolation of the results of international studies into the Dutch situation was hampered, because definitions and methodology used vary between the studies. In addition, the percentage of adverse events has not always been calculated in the same way and the type of reviewer varies [49; 50].

Analysis of complaints, complications and incidents recorded in Dutch hospitals and taken from data on claims and disciplinary proceedings, has shown that adverse events occur in Dutch hospitals. However, such data are inappropriate for estimating the incidence of adverse events, because the epidemiological denominator is missing. Also, the current registrations of incidents and complications in hospitals are based on voluntary reports and thus the completeness of the registration depends on the willingness to report. It is believed that many incidents and complications are not recognised or they are not reported because of the culture. Therefore, the real number of incidents and complications will undoubtedly be higher than the registered number. Standardisation of the registration systems is also lacking. It is unknown which incidents are reported and which are not in the current registration systems.

Because of the lack of national epidemiological data, a sense of urgency to reduce, systematically, the incidence of adverse events was lacking. Information about the scale and nature of adverse events is necessary in order to raise awareness and attention for harm caused by unsafe health care. Healthcare workers, hospital managers and policy makers should realise that unintended injuries are not isolated cases. Insight into the occurrence of adverse events can be used for planning and prioritising safety interventions and research efforts in order to enhance patient safety in Dutch hospitals.

The Dutch Society of Medical Specialists (de Orde van Medisch Specialisten) initiated an extensive patient safety research programme in 2004, because healthcare professionals felt a strong need to gain insight into the extent to which patients suffer harm within Dutch hospitals. The first objective of this...
research programme was to get more insight into the occurrence, severity, nature and preventability of adverse events. Further objectives for the research programme were: to gain more insight into the causes of adverse events and near misses; to explore the safety culture in Dutch hospitals; to make an inventory of international best practices; and to implement and evaluate safety improvement initiatives [37].

The study described in this thesis focuses on the first objective of the research programme and is called the Dutch Adverse Event Study.

Objectives and research questions of the study

The Dutch Adverse Event Study was carried out in 2005 and 2006 in order to address the need for empirical information. The primary objective of the study was to measure the incidence, nature, preventability and severity of adverse events among hospitalised patients in the Netherlands. Moreover, the specialty and clinical process involved were studied. Furthermore, the variation in adverse event rates between hospitals and hospital departments was analysed. Previous studies showed that more than half of all adverse events were related to surgical care. Therefore, the surgical adverse events were analysed separately in this study.

The following research questions were formulated:

1. ‘What is the incidence of adverse events among Dutch hospital patients and what are the nature, severity and preventability of these adverse events?’ (Chapter 3)

2. ‘To what extent do rates of (preventable) adverse events vary between hospitals and hospital departments?’ (Chapter 4)

3. ‘What are the causes, occurrence and nature of surgical adverse events and potential strategies to prevent them?’ (Chapter 5)

Previous estimates of the incidence rates of adverse events taken from large international studies were based on a retrospective review of patient records. Therefore, the record review method was used to assess the incidence of adverse events among hospitalised patients in the Netherlands. Beside the occurrence and nature of adverse events among hospitalised patients, we also
wanted to examine two methodological aspects of the record review method in more detail: the inter-rater agreement between physician reviewers for the assessment of adverse events and the association between the adequacy of patient records and the occurrence of adverse events. Several previous studies investigated the validity and reliability of the record review method. These studies showed that the method was valid to assess adverse events, but showed poor to moderate inter-rater reliability [36; 51-53]. Therefore, a reliability study was conducted within the Dutch Adverse Event Study to evaluate the inter-rater agreement between physicians. To improve the inter-rater agreement for the assessment of adverse events, all records were independently reviewed by two physicians instead of one, and in case of disagreement, the two physicians discussed and reconsidered their review in order to obtain consensus. There is a risk of information bias in methods for identifying adverse events that relies exclusively on data from patient records. Incomplete, illegible, or untraceable information may make it more difficult to assess adverse events. In this study, the adequacy of the documented information in the patient records was measured and the association between the adequacy of the patient record and the occurrence of adverse events was analysed.

To examine the two methodological aspects, we formulated two extra research questions:

4 ‘Does the inter-rater agreement of retrospective assessments of adverse events improve with two physician reviewers per patient record?’ (Chapter 6)

5 ‘Is the adequacy of patient records an indicator of the quality of care or a source of bias in retrospective patient safety studies?’ (Chapter 7)

Relevance of the study
The Dutch Adverse Event Study is the first study that assessed the incidence of adverse events in Dutch hospitals on a national level. Epidemiological data about the scale and nature of adverse events makes all stakeholders - healthcare workers, hospital managers and policy makers- realise that adverse events are not isolated and unusual, but are probably more common and widespread. Measurement of adverse events in hospitals quantifies the
problem of patient harm as a result of health care and will create a sense of urgency towards making health care safer. It will also contribute to a more open culture in dealing with, and reporting of, safety problems. Insight into the occurrence and nature of adverse events and their context can be used to prioritise prevention strategies and research efforts aimed at improving health care. In addition, a national patient safety programme can be designed and safety-related performance indicators and guidelines can be formulated. Finally, the data from the Dutch Adverse Event Study can also be used for the development of a valid and reliable national registration system to monitor adverse events in hospitals.

**Outline of this thesis**

A description of the design of the retrospective patient record review study on the occurrence of adverse events in Dutch hospitals is given in Chapter 2. Attention is paid to the objective and relevance of this study and the strengths and limitations of the study design are discussed. Furthermore, alterations made in the research protocol compared to previous international studies are described.

The results of the retrospective record review study are described in Chapter 3, 4 and 5. The incidence, type, severity, and preventability of adverse events and potentially preventable deaths among hospitalised patients in Dutch hospitals are analysed in Chapter 3. The adverse events are classified by clinical process, admission department and age categories. Moreover, the adverse event incidence rate in Dutch hospitals is compared to the incidence rates of previous international adverse event patient record review studies. The variation in adverse event rates between hospitals and hospital departments is described in Chapter 4. In Chapter 5 the occurrence, nature, severity, adverse outcomes and prevention of surgical adverse events are analysed more thoroughly. The surgical adverse events are classified by specialty, diagnosis, and clinical process. The adverse outcomes of surgical adverse events are classified by clinical pathology. The causes of, and prevention strategies for, surgical adverse events are described.

Methodological aspects of the study are outlined in Chapter 6 and 7. The results of the reliability study carried out within the Dutch Adverse Event Study are presented in Chapter 6. The association between the adequacy of the patient records and the assessment of adverse events is studied in Chapter 7. Finally, the major findings and methodological considerations of this thesis are summarised and considered in the general discussion (Chapter 8). In addition,
the societal impact of the findings is described and recommendations for practice, policy and scientific research are proposed based on the findings of this thesis.
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Adverse events among hospitalised patients
Chapter 2

Design of a retrospective patient record study on the occurrence of adverse events among patients in Dutch hospitals

This article was published as:
Abstract

Background
Various international studies have shown that a substantial number of patients suffer from injuries or even die as a result of care delivered in hospitals. The occurrence of injuries among patients caused by health care management in Dutch hospitals has never been studied systematically. Therefore, an epidemiological study was initiated to determine the incidence, type and impact of adverse events among discharged and deceased patients in Dutch hospitals.

Methods/Design
Three stage retrospective patient record review study in 21 hospitals of 8,400 patient records of discharged or deceased patients in 2004. The records were reviewed by trained nurses and physicians between August 2005 and October 2006. In addition to the determination of presence, the degree of preventability, and causes of adverse events, also location, timing, classification, and most responsible specialty of the adverse events were measured. Moreover, patient and admission characteristics and the quality of the patient records were recorded.

Discussion
In this paper we report on the design of the retrospective patient record study on the occurrence of adverse events in Dutch hospitals. Attention is paid to the strengths and limitations of the study design. Furthermore, alterations made in the original research protocol in comparison with former international studies are described in detail.
Background

Various studies have shown that a substantial number of patients suffer from injuries or even die as a result of care delivered in hospitals [1-11]. The studies revealed that 2.9% to 16.6% of patients in acute care hospitals experienced one or more adverse events and that in 5% to 13% of the adverse events patients died. Approximately 50% of the adverse events were considered as preventable. An adverse event is defined as an unintended injury that results in disability at the time of discharge, death, or prolonged hospital stay and is caused by health care management rather than by the patient’s underlying disease process [1; 3; 9; 11]. The large variation in the incidence of adverse events among the studies in different countries may either be explained by true differences in patient safety of the different health care systems, or by methodological differences between the studies. Therefore, extrapolation of results from other countries will not give a valid estimate of patient safety in health care in e.g. Dutch hospitals.

The occurrence of injuries among patients caused by health care management in Dutch hospitals has never been studied systematically. Analysis of complaints, complications, medical errors and incidents recorded in Dutch hospitals and taken from data on claims and disciplinary proceedings, has shown - not surprisingly - that adverse events are occurring in Dutch hospitals [12-14]. However, such data are inappropriate to estimate the incidence of adverse events, because completeness of the registrations depends on the willingness to report in the hospitals and a standardisation of the registration systems is lacking. Therefore, in 2005, as first part of the Dutch Patient Safety Research Program, a study was initiated to determine the incidence, nature, type, impact and costs of adverse events among hospitalised patients in the Netherlands. Insight in preventable adverse events can offer a starting point for specific interventions to improve patient safety in hospitals.

The method used in this study was based on a protocol originally developed by the Harvard Medical Practice Study, which has studied the incidence of adverse events in New York state hospitals in 1984, based on analysis of information in patient records [2]. This protocol, with modifications, was used in subsequent studies in Australia, the United Kingdom, New Zealand, the United States (in Colorado and Utah), Denmark, France and Canada [1-3; 6; 8-11; 15]. The protocol and instruments used in this Dutch study are based on the most recent retrospective study of adverse events in hospitals, which was carried out in Canada. A pilot study showed that the method and instruments, with some
modifications, were valid and appropriate for the study of adverse events in Dutch hospitals [16]. However, our pilot study showed moderate to poor inter-rater reliability in the determination of adverse events and their preventability. Also in the previous studies inter-rater reliability appeared to be a major problem [1-3; 9; 11; 17-19]. Therefore, standing on the shoulders of our predecessors and keeping the method and instruments maximally comparable, we have tried to improve the reliability of the adverse events determination. The retrospective patient record study is the first epidemiological study on the occurrence of adverse events in Dutch hospitals. The objectives of this study are to:

1. determine the incidence, nature, type, impact, and costs of adverse events among hospitalised discharged and deceased patients;
2. examine the causes and preventability of these adverse events;
3. compare the rate of adverse events and preventable deaths between hospital types and between main specialties; and
4. compare the Dutch incidence of adverse events in acute care hospitals with international rates.

In this paper we report on the design of the retrospective patient record study on the occurrence of adverse events in Dutch hospitals. Attention is paid to the strengths and limitations of the study design. Furthermore, alterations made in the original research protocol in comparison with former international studies are described in detail. The results will be published in a separate article.

**Methods/Design**

**Design and setting**
The study is a retrospective patient record study carried out in Dutch hospitals. Patient records of randomly selected admissions of patients discharged in 2004 and admissions of patients who died in the hospital in 2004 were reviewed in a three stage review process by nurses and physicians between August 2005 and October 2006.

**Definitions**
The definitions used in this study were adopted from previous adverse event studies to enable a comparison of the results of this study with previous international studies. [1; 3; 9; 11]. The definitions are mentioned in Box 2.1.
Box 2.2 gives examples of cases with and without adverse events and preventability.

**Box 2.1  Definitions**

<table>
<thead>
<tr>
<th><strong>Definition</strong></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse event</strong></td>
<td>An unintended injury that results in temporary or permanent disability, death or prolonged hospital stay and that is caused by health care management rather than by the patient’s underlying disease process.</td>
</tr>
<tr>
<td><strong>Unintended Injury</strong></td>
<td>Refers to any disadvantage for the patient that leads to prolonged or strengthened treatment, temporary or permanent (physical or mental) impairment or death.</td>
</tr>
<tr>
<td><strong>Disability</strong></td>
<td>Refers to temporary or permanent impairment of physical or mental function attributable to the adverse event (including prolonged or strengthened treatment, prolonged hospital stay, readmission, subsequent hospitalisation, extra outpatient department consultations or death).</td>
</tr>
<tr>
<td><strong>Causation</strong></td>
<td>Refers to injury caused by health care management including acts of omission (inactions) i.e. failure to diagnose or treat, and acts of commission (affirmative actions) i.e. incorrect diagnosis or treatment, or poor performance.</td>
</tr>
<tr>
<td><strong>Health Care management</strong></td>
<td>Includes the actions of individual hospital staff as well as the broader systems and care processes. Health care management is any care related activity that involves the delivery of care or monitoring of health which is provided by individuals or a team of professionals.</td>
</tr>
</tbody>
</table>
| **Preventable adverse event** | Is an adverse event resulting from an error in management due to failure to follow accepted practice at an individual or system level. Accepted practice was taken to be ‘the current level of expected performance for the average practitioner or system that manages the condition in question’.

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**Box 2.2  Examples of cases with and without adverse events and preventability**

<table>
<thead>
<tr>
<th><strong>Adverse event (outcome of disease) [26]</strong></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No Adverse event</strong></td>
<td>An 80-year-old man presented with a myocardial infarction with three hours of chest pain. He was treated promptly with streptokinase, heparin and aspirin. On day 3 he had further chest pain, with new ECG changes, and he died 12 hours later of cardiogenic shock.</td>
</tr>
</tbody>
</table>
| **Adverse event (no preventability) [11]** | A 50-year old woman underwent coronary angiography for unstable angina. During the angiogram she sustained an anaphylactic reaction to the contrast, with cardiac arrest. She was able to be resuscitated promptly, without permanent sequelae, and hospitalisation was prolonged by 10 days. Evidence for prior contrast reactions was sought and not found.

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- box 2.2 continues -
- box 2.2 continued -

**Adverse event (no preventability) [1]**
Abdominal pain and fever following elective surgical procedure. Patient readmitted for antibiotic treatment.

**Adverse events (low preventability) [26]**
Young right handed man sustained a fracture of the radius within the wrist joint. It required operative reduction, K‐wire fraction and bone grafting. At the 10‐day check the position had shifted and re‐operation was required. The end result was very good.

**Adverse event (high preventability) [11]**
A 67‐year old woman underwent a laparoscopic cholecystectomy, which proceeded to an open operation. Endoscopic retrograde cholangiopancreatography was undertaken eight days after the operation to remove a gallstone in the common bile duct; cannulation was not possible and the procedure was aborted. Ten days after the operation the patient collapsed and died suddenly. Autopsy findings showed extensive deep venous thrombosis and saddle pulmonary embolus. There was no documented evidence of thromboembolic prophylaxis in the medical record.

**Adverse event (high preventability) [1]**
Admission because of severe anaemia. The anaemia had been documented in previous admission but not investigated fully, which resulted in delayed diagnosis of colorectal carcinoma.

**Power calculation**
The selection of hospital admissions was stratified for admissions of patients discharged alive and admissions of patients who died in the hospital. In patients who died during admission, the incidence of preventable adverse events associated with the death of the patient was assessed. Moreover, the incidence of adverse events was expected to be higher in this group, which made the study more efficient.

The power calculation of this study was based on the results of the Canadian adverse event study [1]. Assuming an incidence of adverse events during hospital admission of 8%, a sample of 4,200 hospital admissions of discharged patients and a sample of 4,200 admissions of deceased patients were necessary to detect an one‐side difference of 1% with the reference value with a power of 0.80 and an alpha from 0.05. Because of difference in patient mix and delivery of care, we expected a difference in incidence between hospitals. Therefore, the incidence per hospital type was measured. To measure the difference in incidence between hospital types a selection of 800 hospital admissions per hospital type were necessary to detect a difference from 2% to 3% by an incidence between 3% and 7%.
Hospital selection
To determine a national wide adverse events incidence rate a random sample of 21 hospitals, which is 20% of the hospitals in the Netherlands, was selected following stratification by hospital type and geographical area taking the density of population per region into account. The selected hospitals were: 4 university hospitals (out of 8), 6 tertiary medical teaching hospitals (out of 19) and 11 general hospitals (out of 74). The participating hospitals were randomly selected from all acute care hospitals in the Netherlands. Inclusion criteria for the hospitals were: a minimum of 200 beds, an emergency department and an intensive care department. Specialty and psychiatric hospitals were not included. If a selected hospital had more than one location, all locations of the hospital were taken into account for patient record selection.

Admission selection and record collection
A sample of 8,400 admissions was selected: 4,200 admissions of hospitalised patients and 4,200 admissions of patients who died during the admission in 2004. Admissions with a diagnosis most related to obstetrics or psychiatry and admissions of children younger than 1 year old were excluded. The method and instruments were considered inappropriate for these medical specialties. Of each hospital a random sample of 200 admissions of patients discharged alive (admissions less than 1 day were excluded) and 200 admissions of deceased patients were selected with the hospital information system (inpatient database). For both patient groups 50 extra admissions were selected which could be used in case of missing patient files. One admission, the index admission, per patient was included. In order to assess the representativeness of the selected admissions per hospital, the distribution of gender, age, admission duration, most responsible specialty and diagnosis of the admissions were compared with the pattern for all admissions in the hospital in 2004.

Of the selected index admissions the medical and nursing records, and if available the outpatient records, were collected. Admissions without nursing or medical records were excluded in this study and reasons why records were missing were recorded. The composition of the records was not uniform in all participating hospitals. Some hospitals had all (medical, nursing and outpatient) records in one document archived in a central medical archive. Other hospitals had separate records archived on various departments. Outpatient records that were archived on multiple locations were not involved for logistic considerations. In two hospitals the records were scanned and displayed on a computer screen.
Reviewer recruitment and training
The patient records were reviewed by a team of 66 nurses and 55 physicians. The team of recruited physicians consisted of 25 general internists, 20 general surgeons, 5 neurologists and 5 paediatricians. Most were recently retired. Recruitment of the physicians started through personal contacts of the project leader and was extended with contacts with the scientific association of internal medicine, surgery, neurology and paediatrics. The selection criteria for physicians were:
- at least ten years post graduate general clinical experience;
- good reputation among colleagues;
- no longer than five years retired;
- experience or affinity with analysis of incidents, complaints and errors;
- availability for at least one but preferably two days per week.

The nurses were recruited via the website of the association for nurses and websites of hospitals. The selection criteria for the nurses were:
- minimum five years clinical experience;
- experience or affinity with analysis of incidents, complaints and errors;
- availability for at least one, but preferably two days per week.

An additional expert panel of 18 physicians from other (sub)specialties was recruited to serve as experts for advices about accepted clinical practice. These specialists were authorities within their specialization and were recruited by the scientific associations of medical specialists. The panel consisted of specialists from all involved medical disciplines in the study. During the review process the physicians could get advice about accepted clinical practice from these authorities.

The nurses and physicians followed a one-day training in small groups (max 12 participants) led by one member of the research team and one experienced nurse or physician, respectively. During the training, the study protocol, definitions and review forms were explained and examples of (preventable) adverse events were discussed. The reviewers practiced with cases and the review forms and they were provided with a review manual. At the end of the training the nurses underwent a reliability test. After one month of reviewing, the reviewers had a half-day training session to discuss their problems concerning the review process and definitions and to update the reviewers with the latest insights about the review process. These training sessions were frequently repeated during data collection. The discussed problems were collected in a regularly updated Frequently Asked Questions (FAQ) document which was regularly handed out to all reviewers.
The reviewers were compensated for their review activities at an hourly rate and for expenses.

**Review process**

At each hospital, the patient records were reviewed in a three stage review process (Figure 2.1). In the first stage, nurses reviewed the complete nursing record from the selected index admission for the presence of one or more of 18 screening criteria known to be sensitive to the occurrence of an adverse event (Box 2.3). If one or more screening criteria were found in the nursing record, the case was forwarded to the second stage of the review procedure. In case no screening criteria were found in the nursing record, the nurse also studied the medical record. The screening criteria in the records were marked with self-stick notes.

The records with one or more screening criteria were reviewed by two physicians of the same specialty (general internists, general surgeons, neurologists or paediatricians) in the second stage of the review process. They reviewed the records independently and they determined whether an adverse event had occurred and whether the adverse event had been preventable with an extended second stage review form. If the physician determined an adverse event, the review was continued with questions about the nature and impact of the adverse event; location and involved specialty; classification, preventability and causes of the adverse event.

If there was disagreement about the presence of an adverse event and/or preventability score between the two independent physicians, they started a consensus procedure (stage 3). In this consensus procedure the physicians considered and discussed both reviews and reconsidered their reviews in order to come to consensus. When there was still no agreement, a third trained reviewer gave a final judgement based on his own judgement and information of the other two reviewers.

During the second and third stage of the review process the physicians could ask advice from the 18 specialists in the expert panel about accepted clinical practice outside their professional competence, in order to improve their own judgement of the presence of adverse events and their preventability.
Figure 2.1  Diagram of the review process

Adverse events among hospitalised patients
Box 2.3 Description screening criteria for potential adverse events [1]

<table>
<thead>
<tr>
<th>Screening criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Unplanned admission before index admission (admission reasons are related to</td>
</tr>
<tr>
<td>the index admission)</td>
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<tr>
<td>2. Unplanned readmission after discharge from index admission</td>
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<tr>
<td>3. Hospital-incurred patient injury (Permanent or temporary injury obtained (acquired)</td>
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<tr>
<td>during index admission)</td>
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<td>4. Adverse drug reaction</td>
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<tr>
<td>5. Unplanned transfer from general care to (an) intensive care (unit)</td>
</tr>
<tr>
<td>6. Unplanned transfer to another acute care hospital (after unexpected deterioration of</td>
</tr>
<tr>
<td>the patient)</td>
</tr>
<tr>
<td>7. Unplanned return to the operating room</td>
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<tr>
<td>8. Unplanned removal, injury or repair of organ during surgery</td>
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<tr>
<td>9. Hospital-acquired infection or sepsis</td>
</tr>
<tr>
<td>10. Other patient complication</td>
</tr>
<tr>
<td>11. Development of neurological deficit not present on admission</td>
</tr>
<tr>
<td>12. Unexpected death</td>
</tr>
<tr>
<td>13. Cardiac or respiratory arrest</td>
</tr>
<tr>
<td>14. Injury related to abortion or delivery</td>
</tr>
<tr>
<td>15. Inappropriate discharge to home</td>
</tr>
<tr>
<td>16. Dissatisfaction with care documented in the medical record</td>
</tr>
<tr>
<td>17. Documentation or correspondence indicating litigation</td>
</tr>
<tr>
<td>18. Any other undesirable outcome not covered above</td>
</tr>
</tbody>
</table>

Electronic review forms
The stage 1 and stage 2 review forms were paper based instruments converted into electronic templates in a highly secured web-based program called ProMlse [20]. In the hospitals, the reviewers filled out the electronic review forms using a computer connected to internet. Beforehand, general characteristics of all selected index admissions and patients were entered in the database. With a protected internet connection, the sampled data from the record review entered into ProMlse were immediately transferred and stored in a central database. No additional software was required. This way, no patient data on paper or portable electronic devices were left in the hospitals. In addition, working with electronic forms improved the efficiency of the data collection process and facilitated quality checks during data collection. The reviewers were trained to use this web-based program and received a manual
for working with ProMIse. A helpdesk for technical problems was continuously available. The review forms on paper (in Dutch) can be obtained from the author.

**Premises in participating hospitals**

Some preparations were necessary before starting the study in the hospital. Authorisation of the governing board and the medical staff was a first condition. Further, selection of a random sample of patient admissions in 2004 from the hospital information system had to be performed by a hospital employee in cooperation with a member of the research team. After the sample had proven to be representative of all hospital admissions, employees of the archive departments started searching for the records. In some hospitals, laboratory and radiology results were stored separately in an electronic database to which access had to be arranged. During the review period a minimum of two computers with internet connection were needed in a separate room in the hospital that could be locked. A member of the research team managed the review process and arranged the records in the hospitals.

**Reliability study**

To assess the variation of the review process between reviewers, a random sample of 5% of the records were independently reviewed by two nurses in the first stage. In the second stage 120 records were independently reviewed by a second pair of physicians.

**Confidentiality (Privacy)**

In this study anonymity of hospitals, health care providers and patients was of utmost importance. Several measures were taken to ensure confidentiality of the collected information. Reviewers and researchers (study staff) signed a confidentiality agreement to maintain the secrecy of the information. The reviewers never reviewed in hospitals where they have ever been employed in the medical or nursing staff and the reviewers would never contact individual patients or physicians. During the data collection, the records were never left unattended and they were stored in a locked room.

Each admission received an unique study number so that patients’ identity would not be revealed. Patient identifiers were kept in a dataset separately from the primary database. During the review process in hospital, the data were directly entered into a protected electronic database ProMIse. The reviewers had a personal password for the electronic database. The web-based
database complied with the safety and privacy requirements. Patients’ names were not included in the database and after completion of the data collection and analysis, medical record identifiers were destroyed. The identities of patients or physicians would not be revealed in research reports. If a reviewer had any concerns during the review process about unrecognized potential deliberate harmful acts, illegal acts, or repetitive negligent behaviour, these concerns could be discussed with the ethics committee set up for this study.

**Ethical approval**
The project and methods had been granted ethical approval by VU University Medical Centre in Amsterdam. The participating hospitals had formally consented to participate.

**Data Analysis**

**Outcome measurements**
The determination of adverse events was based on three criteria (Box 2.4). To determine whether the injury was caused by health care a 6-point scale was used. Causation scores of 4-6 were classified as adverse events. From each adverse event found in this study the degree of preventability on a 6-point scale was measured and location, involved speciality, involved healthcare providers, classification and causes were registered. Furthermore, patient demographics such as age, sex, and social economic status (obtained by postal code) and admission characteristics like length of stay, admission status (elective, urgent, transfer or readmission), admission and discharge diagnosis, admission speciality, discharge status (dead, alive and discharge to home, home with outpatient care etc), and procedures were collected. Most of the patient and admission characteristics were provided by the participating hospitals from their hospital information system (inpatient database). In addition, for the patients who died during the index admission, the expected life time of the patient, should the adverse event not have occurred, was estimated by medical reviewers. The adequacy and completeness of the documentation of each studied record were judged by the reviewers.
Determination of the presence of an adverse event was based on three criteria:

1. an unintended (physical and/or mental) injury which
2. results in temporary or permanent disability, death or prolongation of hospital stay, and is
3. caused by health care management rather than the patient’s disease

To determine whether the injury was caused by health care management or the disease process a 6-point scale was used:

1. (Virtually) no evidence for management causation
2. Slight to modest evidence of management causation
3. Management causation not likely (less than 50/50, but ‘close call’)
4. Management causation more likely (more than 50/50, but ‘close call’)
5. Moderate to strong evidence of management causation
6. (Virtually) certain evidence of management causation

The degree of preventability of the adverse events was measured on a 6-point scale, grouped into three categories:

No preventability
1. (Virtually) no evidence for preventability

Low preventability
2. Slight to modest evidence of preventability
3. Preventability not quite likely (less than 50/50, but ‘close call’)

High preventability
4. Preventability more than likely (more than 50/50, but ‘close call’)
5. Strong evidence of preventability
6. (Virtually) certain evidence of preventability

Timing of the adverse events in relation to index hospital admission.

The index hospital admission was the admission sampled. Adverse events were recorded if they occurred during the index admission and were detected during or after the index admission over the following 12-month period. Or adverse events that were related to hospital admissions within the 12-month preceding the index admission but were not detected until the index admission (Figure 2.2).

Figure 2.2  Timing of adverse event (occurrence and detection of AE)

<table>
<thead>
<tr>
<th>Before index admission</th>
<th>During index admission</th>
<th>After index admission</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

0 = Occurrence AE, X = detection AE
Statistical analysis

During the data collection data checks (identify out-of-range answers, inconsistent responses and missing data) were performed on a regular basis. Data extracted from ProMise were analysed using SPSS 14.0 for Windows. The national weighted average incidence of adverse events in Dutch hospitals in categories of preventability was calculated, corrected for oversampling of university hospitals and of patients who died during hospital admission. Differences in adverse event rates between hospital types, discharge diagnoses and most responsible specialties were calculated using multilevel analysis when appropriate, in order to disentangle variation at the patient and the hospital level. Potentially confounding determinants, such as age, sex, co-morbidity, life-expectance and quality of the patient record, were identified and differences in adverse event rates between groups were adjusted for potentially confounding determinants using multilevel multivariate analysis. All incidence rates were calculated with 95% confidence intervals. For the subgroup of patients who died during admission, all analyses were replicated. Direct medical costs associated with adverse events were measured as excess length of stay and charges for excess procedures during admission. For each admission in which the patient was discharged alive, the expected length of stay in hospital based on diagnosis, age and sex was estimated based on national data and excess length of stay was computed as the difference between actual length of stay and expected length of stay. Dutch guideline prices were used to value excess length of stay and procedures [21]. If not available, cost-prices or tariffs were used. Costs associated with adverse events were estimated using a linear regression model, adjusting for confounding factors such as age, sex and co-morbidity when appropriate. The inter-rater reliability of the review process by nurses and specialists was expressed as a kappa statistic with 95% confidence intervals and as percentage of records for which there was agreement. In the first stage the agreement between nurses was measured for finding screening criteria in the patient records. The kappa statistics in the second stage was measured for the determination of the degree of the injury, to what degree the injury was caused by health care management and to what degree the adverse event was preventable.
Discussion

Strengths and limitations of this study

To address the need for empirical information regarding the epidemiology of poor quality and iatrogenic injury, the first large population-based retrospective medical record study was developed in New York in 1984 (Harvard Medical Practice Study, HMPS) [2]. The HMPS established a standard method by which adverse events are measured and it formed the basis of political discussions on patient safety in several countries [22]. This method was proven valid to identify adverse events and estimate their incidence in hospitals nation wide [17]. The HMPS method has been used nation wide in Australia, the UK, New Zealand, and Canada and has become the benchmark method for research on adverse events in hospitals and for assessing the status of patient safety in hospitals around the world [22]. Based on the results of the large studies of patient records, areas with problematic patient safety can be identified and specific patient safety actions can be implemented. In short, the strengths of this method are: effective for estimating adverse event incidence; almost no workload for hospital staff; no inconvenience for departments or interruptions of the health care process, and the data collection is easy to plan [6]. By using a highly similar protocol and instruments in our study it is possible to compare our results with those from previous (European) studies. With more than 8000 patient records, the Dutch study on the occurrence of adverse events in hospitals is the largest retrospective patient record study in Europe. Although the results of these studies showed that the instruments are sensitive for identifying adverse events [17], some aspects can lead to an under- or overestimation of the adverse event incident rate. The record review method for identifying adverse events relies exclusively on data from hospital records. Only events documented in hospital records are included in the analysis and available information of events in the records can be insufficient for the adverse event determination [11; 23]. Without complete follow-up information on the patient, absolutely accurate estimates of disability are not possible [2]. This may underestimate the rate of adverse events in hospitals. In our study, the nurses and physicians assessed the completeness and adequacy of the records; also the relation between the quality of the information in the records and adverse events rate will be analysed. Insufficient records were excluded from the study.

Another potential source of error is missing records. In the HMPS the rate of adverse events in the missing records was measured by means of a follow-up
study. The rates of adverse events and negligence in the follow up study were lower overall than in the initial survey [2]. In our study, hospital records without nursing or medical record were excluded and reasons why records were missing were recorded. A follow-up study to assess the adverse event rate in the missing records was not possible because of practical reasons. Adverse events revealed after discharge are captured if they result in readmission to the hospital. If the patient is not readmitted, the adverse event is not discovered unless it is recorded in the hospital’s outpatient record. It is not possible to estimate the number of adverse events that will be missed, but most adverse events that cause major disability or have a substantial financial impact probably require hospitalisation [2]. Moreover, at some participating hospitals in our study, it was not feasible to collect outpatient records as they are stored in many different archives. The lack of the outpatient records in some hospitals will lead to an underestimation of the adverse events incidence or of the effect. Previous studies showed that adverse events can be identified accurately from information in hospital records, however, such records may not provide evidence or insight into the specific cause of an adverse event. The record review method is not the most suitable instrument to get insight into the specific cause of an adverse event [23].

Validity
The internal and external validity of the record review study depends on the representativeness of the selected admissions. A non-representative sample can lead to under- or overestimation. To ensure that all admissions from 2004 were involved in the selection procedure, the random samples of admissions in the participating hospitals were taken from the hospital information system rather than from records available in the archive department. For each hospital representativeness of the sample is verified by comparing general characteristics of selected admissions with those of all admissions of the participating hospitals. If the selection of admissions was not representative, a new random sample was selected. Before we extrapolated the results of our study to all Dutch hospitals the characteristics of the total sample of 8,400 admissions were compared with those of all admissions of all hospitals in the Netherlands.
Reliability

Unlike injuries in the workplace or motor-vehicle accidents, which usually occur in healthy people, medical injuries in the hospital generally occur in those who are already ill. Therefore, it is sometimes difficult to distinguish disabling injuries caused by medical interventions from those attributable to the illness for which the patient is being treated. It can also be difficult to distinguish between injuries resulting from errors and those that could not reasonably have been prevented [24]. Thus, even with the carefully structured review process, there may still be substantial variation in the judgements of physician reviewers. Reliability estimates on the assessment of adverse events were only moderate in previous studies; those relating to the degree of impairment attributable to the adverse event were even lower [22].

In our study, several efforts were made to reduce the inter reviewer variation of the review process. Like the Canadian protocol, experienced nurses and physicians were recruited. They received a standardized training and a manual in which the research protocol, instruments and definitions were defined. During the study, reviewer performance was monitored and they received personal feedback. The use of electronic review forms and data from hospital information systems also enhanced the efficiency of the study and the reliability of the measurements. The electronic review form ensured complete data entry and computerized hospital data of the patients were transported into the electric forms in advance. This improved the completeness and quality of the data collection.

On top of the efforts from the Canadian protocol several activities were undertaken in our study to enhance the accuracy of the reviews. During the research process the reviewers could discuss their problems concerning the review process, cases and definitions in regularly organised discussion meetings. The questions and discussed problems were noted in a regularly updated frequently asked questions list. The precision of the reviews also depends on the efficiency of the design. For that purpose, in our study the reviewers had to focus on their own expertise: nurses concentrated on the nursing records; physicians examined mainly the medical records and the self-stick notes of the nurses in the nursing records. Moreover, four different specialties were involved for the medical review instead of two: general internists, general surgeons, neurologists and paediatricians. Records with, for example, neurological screening criteria were reviewed in the second stage by two neurologists. And for questions about accepted clinical practice the physicians could consult an expert panel of medical specialists. In the second
stage all records were reviewed by two physicians instead of one. The consensus procedure and involvement of a third reviewer (in case of disagreement after the consensus procedure) should lead to a more reliable measurement.

**Modifications of protocol and instruments**

The protocol and instruments used in this record review study were adapted from the Canadian record review study [1]. As a result of the Dutch pilot study, some modifications were made in the protocol and the instruments for the Dutch Adverse Event Study [16].

**Selection of hospital admissions**

The Dutch study included patients older than one year and oversampled deceased patients. In the Canadian study only patients over 18 years old were included and there was no oversampling for deceased patients. For this reason paediatricians were involved in the medical review of the record review process. The oversampling of deceased patients enables us to determine the incidence of preventable deaths more precisely. Moreover, the incidence of adverse events is expected to be higher in this group, which makes the study more efficient.

**Review instrument**

In the review form for the second stage we have changed some components and added some questions. The classification categories of the types of adverse events were changed and the questions for the medication related adverse events were made more specific. To get more insight into the causes of the measured adverse events the questions about the contributing factors were extended and structured according to the PRIMSA classification of causes of incidents [25]. In the section ‘quality of the record’ questions about autopsy were added. Brennan (1991) wrote that the judgements of physicians that an adverse event has led to death also require a note of caution. Many patients who died after an adverse event had very serious underlying diseases, and several surely had shortened life expectancies independent of their iatrogenic injury [2]. In our study, the number of days of life lost as a result of the adverse event in the case of a terminally ill person was estimated to study the relation between the occurrence of adverse events and life expectancy. To improve the efficiency and quality of the data collection, control and analysis, the collected
patient information was transported to a central database with a web-based program. The changes in the protocol and the instrument are focussed on the improvement of the quality, efficiency and reliability of the adverse events determination and their preventability. In spite of these changes, comparison of the results of this study with the results of previous studies is still possible.
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Adverse events among hospitalised patients
Chapter 3

Adverse events and potentially preventable deaths in Dutch hospitals

Results of a retrospective patient record review study

This article was accepted as:
Abstract

Objective
In this study the incidence, type, nature, preventability and impact of adverse events (AEs) among hospitalised patients and potentially preventable deaths in Dutch hospitals were determined.

Methods
Using a three-stage retrospective record review process, trained nurses and physicians reviewed 7,926 admissions: 3,983 admissions of deceased hospital patients and 3,943 admissions of discharged patients in 2004, in a random sample of 21 hospitals in the Netherlands (4 university, 6 tertiary teaching and 11 general hospitals). A large sample of deceased patients was included to determine the occurrence of potentially preventable deaths in hospitals more precisely.

Results
In 5.7% (95% confidence interval [CI] 5.1-6.4) of all admissions one or more AEs were found and in 2.3% (95% CI 1.9-2.7) a preventable AE was found. Of all AEs, 12.8% resulted in permanent disability or contributed to death. The proportion of AEs and their impact increased with age. More than 50% of the AEs were related to surgical procedures.
Among deceased hospital patients, 10.7% (95% CI 9.8-11.7) suffered from an AE. Preventable AEs that contributed to death occurred in 4.1% (95% CI 3.5-4.8) of all hospital deaths. By extrapolation to a national level, between 1482 to 2032 potentially preventable deaths occurred in Dutch hospitals in 2004.

Conclusion
The incidence of AEs, preventable AEs, and potentially preventable deaths in the Netherlands is substantial and needs to be reduced. Patient safety efforts should focus on surgical procedures and elderly patients.
Introduction

Previous retrospective record review studies in several countries have shown that 2.9% to 16.6% of patients in acute care hospitals experience one or more adverse events (AEs) and in 4.5% to 20.8% of the AEs the patient dies [1-13]. Approximately 50% of the AEs were judged to be preventable. An AE is defined as an unintended injury that results in temporary or permanent disability, death or prolonged hospital stay, and is caused by health care management rather than by the patient's underlying disease process [2; 5; 8; 13]. Variation in the incidence of AEs will be partly determined by policies and characteristics at hospital level (within country variation, between hospitals), partly by policies at national level (between country variation) and partly by differences in methodology of the studies [14; 15]. The occurrence of AEs in Dutch hospitals has never been studied systematically. Insight in preventable AEs can increase the sense of urgency and offer a starting point for specific interventions to improve patient safety, whereas insight in unpreventable AEs may help to prioritise research areas. Therefore a retrospective patient record review study was conducted to determine the incidence, type, nature, impact and preventability of AEs among hospitalised patients in the Netherlands. This study is the largest population-based study on the occurrence of AEs carried out in Europe. It reflects the increasing attention paid to patient safety across Europe. The protocol and instruments were based on the Canadian Adverse Events Study [2].

Methods

Study design and setting
The design and methods of this study are described in Chapter 2 [16]. We have performed a retrospective patient record review study in a random, stratified sample of 21 of the 101 Dutch hospitals: 4 university, 6 tertiary teaching and 11 general hospitals. To measure the difference in incidence between hospital types, the sample of hospitals was stratified for hospital type. Proper representation of urban and rural setting in the sample was verified. Eligible hospitals had at least 200 beds, an emergency department and an intensive care unit. A large subsample of deceased hospital patients was included to determine the occurrence of potentially preventable deaths in hospitals more precisely than in previous studies.
The power calculation of this study was based on the results of the Canadian Adverse Events Study [2]. Assuming an incidence of AEs of 8%, a sample of 4,200 hospital admissions of discharged patients and a sample of 4,200 admissions of deceased patients were necessary ($\beta = 0.20$, $\alpha = 0.05$) to estimate a 95% confidence interval of 0.5% to both sides. To measure the difference in incidence between hospital types a selection of 800 hospital admissions per hospital type were necessary to detect a difference from 2% to 3% with an incidence between 3% and 7%. From each hospital, we randomly selected 200 admissions (>24 hours stay) of discharged patients and 200 (or less if the total of patients who died in 2004 was lower) admissions of deceased hospital patients in 2004, excluding admissions of psychiatry, obstetrics and children <1 year old [16].

**Review of patient records**

The nursing, medical and, if available, outpatient record of the sampled admissions were reviewed by 66 trained nurses and 55 trained physicians in a three stage review process between August 2005 and October 2006. In the first stage, a nurse screened the records by using 18 screening criteria indicating potential AEs (Appendix 3.A). In the second stage, two physicians independently reviewed the records with one or more positive screening criteria. Based on a standardised procedure they determined presence, nature, impact, clinical process, and degree of preventability of AEs. Also the life expectancy in case the AE had not occurred was estimated for deceased patients with AEs (Box 3.1). If there was disagreement about the presence and/or preventability of an AE between the two physician reviews, they started a consensus procedure (stage 3). If they could not reach consensus, a third trained physician reviewer gave the final judgement [16].

**Box 3.1  Definitions and outcome measures [16]**

<table>
<thead>
<tr>
<th>Adverse event determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>The determination of an AE was based on the presence of three criteria:</td>
</tr>
<tr>
<td>1. an unintended (physical and/or mental) injury, which</td>
</tr>
<tr>
<td>2. resulted in temporary or permanent disability, death or prolongation of hospital stay, and was</td>
</tr>
<tr>
<td>3. caused by health care management rather than the patient’s disease.</td>
</tr>
</tbody>
</table>

To determine whether the injury was caused by health care management or the disease process (criterion 3) a 6-point scale was used:  
1. (Virtually) no evidence for management causation
2. Slight to modest evidence of management causation
3. Management causation not likely (less than 50/50, but ‘close call’)
4. Management causation more likely (more than 50/50, but ‘close call’)
5. Moderate to strong evidence of management causation
6. (Virtually) certain evidence of management causation

Causation scores of 4 to 6 were classified as AEs.

**Timing AE**
The index hospital admission was the admission sampled. AEs were included if they occurred during the index admission and were detected during or within 12 months after the index admission. AEs were also included if they were related to hospital admissions in the same hospital in the 12 months preceding the index admission, but were not detected until the index admission.

**Preventability**
The degree of preventability of the AEs was measured on a 6-point scale, grouped into three categories:
- **No preventability**
  1. (Virtually) no evidence for preventability
- **Low preventability**
  2. Slight to modest evidence of preventability
  3. Preventability not quite likely (less than 50/50, but ‘close call’)
- **High preventability**
  4. Preventability more than likely (more than 50/50, but ‘close call’)
  5. Strong evidence of preventability
  6. (Virtually) certain evidence of preventability

AEs with a preventability score of 4 to 6 were defined as preventable AEs.

**Potentially preventable hospital deaths**
Potentially preventable hospital deaths were defined as highly preventable AEs which contributed to death during hospital admission. The adjective “potentially” is used because of the multifactorial nature of hospital deaths and the retrospective assessment of causality.

**Life expectancy**
The physician reviewers estimated the life expectancy of the deceased patients for the situation that the hospital admission would have evolved without an adverse event, taking into account the health status of the patient as described in the patient records and using their professional judgement.
Reliability study
To assess the reliability of the first stage of the record review process, a random sample of 415 records was independently reviewed by a second nurse. To assess the reliability of the final judgement (including consensus procedure and a third review if applicable) of the physician review, a random sample of 119 records was reviewed by a second pair of physicians [16].

Statistical analysis
The national weighted incidence of AEs and preventable AEs in Dutch hospitals with 95% confidence intervals (CIs) were calculated, corrected for the overrepresentation of patients admitted to a university hospital and for the overrepresentation of patients who died in hospital, using ‘complex samples’ option in SPSS 14.0. The sample weight was the inverse of the probability of being included in the sample owing to the sample design. It was calculated as N/n, where N = the number of elements in the population and n = the number of elements in the sample (Appendix 3.B). After weighting for the sampling frame, the total study sample (discharged and deceased patients) and the sub sample of deceased patients were representative for the Dutch population of hospitalised patients and for the Dutch population of deceased hospital patients, respectively (Appendix 3.C). Characteristics of AEs, such as disability and classification, and patient and admission characteristics were also assessed using weights to adjust for the sampling frame. The analysis for the subsample of deceased patients was only weighted for the overrepresentation of patients admitted to a university hospital.

The inter-rater agreement of the review process between nurses for finding screening criteria and for the determination of AEs and their preventability between two pairs of physicians was expressed as a kappa statistic with 95% CIs and as percentage of records for which there was agreement.

Results

Incidence of adverse events among hospitalised patients
Of the 8,415 sampled records, 8,032 were eligible for a first stage review (screening success rate was 95%) (Figure 3.1). In 54% of these records one or more screening criteria were identified (Appendix 3.A). In the second stage, physicians identified 744 AEs in 663 hospital admissions.
Figure 3.1 Flow chart of the review process

Admission selection
Randomly selected admissions of discharged and deceased patients (n=8415)

Records unavailable* (n=270)
Records inadequate** (n=113)

Stage 1
Reviewed records completed by nurses (n=8032)

Excluded records in stage 1** (n=66)
Negative for screening criteria (n=3609)

Stage 2
Positive for screening criteria (n=4357)

Excluded records in stage 2** (n=40)

Records with AE (n=663)
- Direct consensus AE 53%
- AE after consensus procedure 42%
- AE after third review 5%

Records without AE (n=3654)
- Direct consensus no AE 95%
- No AE after consensus procedure 4%
- No AE after third review 1%

Records with non preventable AE (n=276)
Records with low preventable AE (n=104)
Records with high preventable AE (n=283)

* Nursing and/or medical record of the index admission was missing; or the patient was hospitalised during the study. In one hospital, only records of hospital deaths were included for hospital-related logistical reasons.

** Patient was hospitalised during study; incomplete patient record; the sampled admission did not comply with the selection criteria; admission was sampled twice; the admission was too short (patient came with cardiac arrest on ‘ER’ or outpatient reanimation).
In 70 hospital admissions (10.6% of 663), two or more AEs were found. In total 504 AEs were found in 447 deceased and 240 AEs in 216 discharged patients. After weighing for the sampling frame, the national incidence of AEs among hospitalised patients was 5.7% (95% CI 5.1-6.4) and incidence of preventable AEs was 2.3% (95% CI 1.9-2.7) (Table 3.1).

Table 3.1  Weighted incidence of AEs in patients admitted to Dutch hospitals in 2004 by hospital type, both for the total sample (discharged patients and deceased patients) and for the subgroup of deceased patients

<table>
<thead>
<tr>
<th>Hospital type</th>
<th>Total sample* (n=7926)</th>
<th>Deceased patients** (n=3983)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>University</td>
<td>Tertiary teaching</td>
</tr>
<tr>
<td>No. of records reviewed</td>
<td>1378</td>
<td>2342</td>
</tr>
<tr>
<td>No. of records with AE</td>
<td>171</td>
<td>187</td>
</tr>
<tr>
<td>Weighted AE incidence, % (and 95% CI)</td>
<td>7.6</td>
<td>6.7</td>
</tr>
<tr>
<td>(5.9-9.8)</td>
<td>(5.5-8.1)</td>
<td>(4.1-5.7)</td>
</tr>
<tr>
<td>No. of records with preventable AE</td>
<td>37</td>
<td>90</td>
</tr>
<tr>
<td>Weighted preventable AE incidence, % (and 95% CI)</td>
<td>1.6</td>
<td>2.8</td>
</tr>
<tr>
<td>(0.9-2.9)</td>
<td>(2.1-3.8)</td>
<td>(1.7-2.8)</td>
</tr>
<tr>
<td>No. of records with preventable AE that contributed to the death of the patient</td>
<td>19</td>
<td>48</td>
</tr>
<tr>
<td>Weighted incidence of preventable AEs that contributed to the death of the patient, % (and 95% CI)</td>
<td>2.4</td>
<td>4.2</td>
</tr>
<tr>
<td>(1.6-3.8)</td>
<td>(3.1-5.5)</td>
<td>(3.6-5.4)</td>
</tr>
</tbody>
</table>

CI = confidence interval
* incidence rates and 95% CIs were weighted for oversampling of deceased patients and of patients admitted to a university hospital
** incidence rates and 95% CIs were weighted for oversampling of deceased patients admitted to a university hospital
The incidence rates of AEs were significantly higher in university hospitals than in general hospitals. Although not statistically significant, the incidence of preventable AEs was lower in university hospitals compared to the other types of hospitals. Of all AEs (n=744), 39.6% were considered preventable. More than half of all AEs (56.8%) resulted in no or minimal physical impairment or disability. However, 5.0% resulted in permanent disability and 7.8% contributed to death. The incidence of AEs was higher in surgical departments compared to non-surgical departments (Table 3.2).

Table 3.2  AEs by admission department: number of reviewed admissions, weighted AE incidence per department and % of AEs that were preventable

<table>
<thead>
<tr>
<th>Admission department</th>
<th>No of reviewed admissions (N=7,926)</th>
<th>Incidence of AEs (%) *</th>
<th>% of AEs that were preventable*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgical</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>116</td>
<td>9.5</td>
<td>15.4</td>
</tr>
<tr>
<td>Urology</td>
<td>221</td>
<td>7.8</td>
<td>32.0</td>
</tr>
<tr>
<td>Surgery</td>
<td>1,443</td>
<td>7.7</td>
<td>40.1</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>51</td>
<td>5.8</td>
<td>40.0</td>
</tr>
<tr>
<td>Ear, nose and throat</td>
<td>198</td>
<td>5.2</td>
<td>22.2</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>496</td>
<td>5.1</td>
<td>52.4</td>
</tr>
<tr>
<td>Gynaecology</td>
<td>135</td>
<td>4.7</td>
<td>50.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2,660</td>
<td>6.8 (95% CI 5.7-7.8)</td>
<td>39.5</td>
</tr>
<tr>
<td><strong>Non-surgical</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intensive care</td>
<td>373</td>
<td>9.4</td>
<td>50.0</td>
</tr>
<tr>
<td>Internal medicine</td>
<td>1,950</td>
<td>5.4</td>
<td>25.7</td>
</tr>
<tr>
<td>Cardiology</td>
<td>1,165</td>
<td>4.9</td>
<td>32.7</td>
</tr>
<tr>
<td>Lung diseases</td>
<td>787</td>
<td>5.4</td>
<td>71.0</td>
</tr>
<tr>
<td>Neurology</td>
<td>767</td>
<td>3.6</td>
<td>61.9</td>
</tr>
<tr>
<td>Paediatrics</td>
<td>142</td>
<td>1.6</td>
<td>50.0</td>
</tr>
<tr>
<td>Other medical</td>
<td>82</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5,266</td>
<td>4.8 (95% CI 4.1-5.7)</td>
<td>40.3</td>
</tr>
</tbody>
</table>

NA=not applicable

* percentages were weighted for oversampling of deceased patients and of patients admitted to a university hospital.
A quarter of all AEs occurred within 12 months before and was detected in the index admission in the same hospital. The majority of AEs (63%) occurred and was detected during the index admission, whereas 12% occurred during the index admission and was detected within 12 months after the index admission. More than half (54%) of all AEs were related to surgical procedures. Almost all AEs related to the diagnostic process were highly preventable and 23% contributed to death (Table 3.3). The proportion of AEs, preventable AEs and degree of disability increased with age (Table 3.4).

Table 3.3 AEs by clinical process and proportions judged preventable, leading to permanent disability (excluding death) and contributed to death

<table>
<thead>
<tr>
<th>Classification</th>
<th>No. AEs</th>
<th>Distribution AEs (Column %*)</th>
<th>Preventable (Row %*)</th>
<th>Permanent disability (Row %*)</th>
<th>Deaths (Row %*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>297</td>
<td>54.2</td>
<td>34.4</td>
<td>4.0</td>
<td>5.1</td>
</tr>
<tr>
<td>(events related to an operation or occurring within 30 days after an operation)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug/Fluid</td>
<td>157</td>
<td>15.3</td>
<td>31.2</td>
<td>2.6</td>
<td>10.5</td>
</tr>
<tr>
<td>(e.g. side effects, allergic reactions, anaphalaxis)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical procedure</td>
<td>135</td>
<td>17.0</td>
<td>27.9</td>
<td>9.3</td>
<td>7.0</td>
</tr>
<tr>
<td>(e.g. central catheters, endoscopies, pacemakers, intervention radiology)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostic</td>
<td>80</td>
<td>6.3</td>
<td>84.4</td>
<td>12.9</td>
<td>22.6</td>
</tr>
<tr>
<td>(e.g. missed, delayed or inappropriate diagnostic process)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other clinical management</td>
<td>56</td>
<td>3.7</td>
<td>78.9</td>
<td>0</td>
<td>15.8</td>
</tr>
<tr>
<td>(including nursing and paramedic care)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discharge</td>
<td>4</td>
<td>1.4</td>
<td>100.0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>(e.g. inappropriate discharge)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (e.g. fall)</td>
<td>15</td>
<td>2.1</td>
<td>81.8</td>
<td>0</td>
<td>9.1</td>
</tr>
<tr>
<td>Total</td>
<td>744</td>
<td>100.0</td>
<td>39.6</td>
<td>5.0</td>
<td>7.8</td>
</tr>
</tbody>
</table>

* Percentages were weighted for oversampling of deceased patients and of patients admitted to a university hospital.
Table 3.4  AEs by age: number of reviewed admissions, number of admissions with an AE and proportions judged preventable, contributed to permanent disability (excluding death) and death

<table>
<thead>
<tr>
<th>Age</th>
<th>No. reviewed admissions</th>
<th>No. admissions with AE(s)</th>
<th>Percentage AEs*</th>
<th>Preventable (Row %*)</th>
<th>Permanent disability (Row %*)</th>
<th>Deaths (Row %*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-18</td>
<td>330</td>
<td>7</td>
<td>1.7</td>
<td>20.0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>19-40</td>
<td>660</td>
<td>38</td>
<td>5.0</td>
<td>40.0</td>
<td>7.4</td>
<td>1.9</td>
</tr>
<tr>
<td>41-65</td>
<td>2,332</td>
<td>180</td>
<td>5.5</td>
<td>37.5</td>
<td>2.4</td>
<td>4.3</td>
</tr>
<tr>
<td>66-79</td>
<td>2,582</td>
<td>250</td>
<td>6.1</td>
<td>39.9</td>
<td>4.3</td>
<td>12.3</td>
</tr>
<tr>
<td>80+</td>
<td>2,013</td>
<td>188</td>
<td>8.2</td>
<td>46.2</td>
<td>9.8</td>
<td>15.2</td>
</tr>
<tr>
<td>Total</td>
<td>7,917</td>
<td>663</td>
<td>5.7</td>
<td>39.9</td>
<td>5.0</td>
<td>8.6</td>
</tr>
</tbody>
</table>

* percentages were weighted for oversampling of deceased patients and of patients admitted to a university hospital

** date of birth was missing for nine patients

Incidence of adverse events among deceased patients

The incidence of AEs and preventable AEs in the subsample of deceased patients was 10.7% (95% CI 9.8 - 11.7) and 5.2% (95% CI 4.5 - 5.9) respectively (Table 3.1). The incidence of preventable AEs contributing to death among deceased patients was 4.1% (95% CI 3.5 - 4.8). In 2004, 42,329 patients died in Dutch hospitals, amounting to 1,735 (95% CI 1,482 - 2,032) potentially preventable hospital deaths.

Compared to the total hospital population, AEs among deceased patients were more often preventable (47.7% versus 39.6%) and were more often related to the diagnostic process (14.8% versus 6.3%).

Almost half (49.1%) of the deceased patients with a potentially preventable AE that contributed to death had an estimated potential life expectancy of more than 1 year in case the potentially preventable AE would not have occurred. In 11% of the cases the life expectancy could not be determined (Table 3.5).

Agreement between reviewers

The reliability of the assessment of screening criteria by nurses was good, kappa 0.62 (95% CI 0.54-0.69), 82% agreement. The reliability of the determination of AEs was only fair, kappa 0.25 (95% CI 0.05-0.45), 76% agreement, and moderate for the determination of preventability of AEs, kappa 0.40 (95% CI 0.07-0.73) and 70% agreement.
Table 3.5  Estimated life expectancy of deceased patients with AEs, preventable AEs and potentially preventable AEs that were associated with death

<table>
<thead>
<tr>
<th>Life expectancy</th>
<th>Distribution AEs (Column %*)</th>
<th>Preventable AEs (Column %*)</th>
<th>Potentially preventable deaths (Column %*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some days</td>
<td>2.3</td>
<td>1.5</td>
<td>0.6</td>
</tr>
<tr>
<td>Some weeks</td>
<td>9.2</td>
<td>6.3</td>
<td>4.9</td>
</tr>
<tr>
<td>Some months</td>
<td>14.3</td>
<td>11.2</td>
<td>9.2</td>
</tr>
<tr>
<td>6 to 12 months</td>
<td>23.5</td>
<td>24.9</td>
<td>26.4</td>
</tr>
<tr>
<td>1-5 years</td>
<td>24.4</td>
<td>28.3</td>
<td>31.3</td>
</tr>
<tr>
<td>5 to 10 years</td>
<td>10.6</td>
<td>10.7</td>
<td>12.3</td>
</tr>
<tr>
<td>10 to 20 years</td>
<td>2.6</td>
<td>1.5</td>
<td>1.8</td>
</tr>
<tr>
<td>More than 20 years</td>
<td>1.6</td>
<td>3.4</td>
<td>3.7</td>
</tr>
<tr>
<td>Unable to determine</td>
<td>10.8</td>
<td>11.2</td>
<td>8.6</td>
</tr>
<tr>
<td>Missing, NA</td>
<td>0.7</td>
<td>1.0</td>
<td>1.2</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

NA = Not applicable

* percentages were weighted for oversampling of deceased patients admitted to a university hospital

Discussion

In 5.7% of all Dutch hospital admissions one or more AEs occurred of which 39.6% were preventable. Of all AEs, 12.6% resulted in permanent disability or contributed to death. More than half of the AEs were related to surgical procedures; the proportion of (preventable) AEs and their impact increased with age. Among deceased patients, 10.7% suffered from an AE, and in 4.1% a preventable AE contributed to death, amounting to 1,735 potentially preventable hospital deaths in the Netherlands in 2004.

In university hospitals more AEs but less preventable AEs occurred than in tertiary teaching and general hospitals. Tertiary teaching hospitals in the Netherlands provide highly specialised care and train physicians in collaboration with university hospitals. The level of care given lies in between that of a university hospital and that of general hospital. Generally, university hospitals and to some extent tertiary teaching hospitals treat more complex patients with more complex care [17]. This may explain the higher incidence rate of AEs with lower preventability in university hospitals. The higher proportion of AEs among elderly patients may be explained primarily by the clinical complexity of their care rather than age based discrimination [18].
The incidence of AEs in the Netherlands is substantial, although at the lower end of the range of results from previous retrospective patient record studies; only in the US lower incidence rates were reported (Table 3.6). However, these studies assessed negligence rather than preventability, which may have led to a more defensive assessment. The conservative level for causation (24) may have resulted in lower incidence estimates than in studies using level 2 as a threshold [4; 5; 13; 14]. On the other hand, we only included patient records of which both the nursing and the medical record were present. This may have led to higher estimates, because in almost 90% of our patient records with screening criteria indicating potential AEs, valuable information was detected in the nursing record. A further explanation of the lower incidence of AEs (and the rate of potentially preventable deaths) in our study could be that the review process with two independent physician reviewers per record has led to a stricter assessment.

Our study has several limitations. The potentially preventable deaths and life expectancy of deceased patients in case the AE would not have occurred were retrospectively determined, based on information in hospital records. It is difficult to estimate the probability of death given that the error was not made [6]. The reviewers were able to estimate the life expectancy in 81% of the cases, but the results must be treated with caution. In addition, moderate reliability of the review process is a well known problem of record review studies to identify AEs and their preventability, in which kappa values ranged from 0.2 to 0.6 [1; 5; 8; 13; 20; 21]. We aimed to improve the reliability of the review process by: intensifying the training of reviewers, including paediatricians and neurologists as reviewers in addition to general internists and surgeons, using two physicians instead of a single physician reviewer, continuous availability of expert consultation of 18 medical specialties, frequently updating and communicating a frequently asked questions list for reviewers and by using electronic review forms [16]. However, the kappa value between two pairs of physicians in this study was not better than in other studies. The high number of reviewers and the high proportion of often complex cases of hospital deaths may have led to lower reliability. Another general weakness of all retrospective studies is hindsight bias [22]. Knowing the outcome and its severity may influence judgement of causation and preventability. This could lead to an overestimation of preventable AEs that contributed to the patient’s death judged by the reviewers.
Table 3.6  Retrospective record review studies on the occurrence of (preventable) AEs of hospitalised patients between 1984 and 2005

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>% of admissions with ≥ 1 AE (95%CI) *</th>
<th>% of AEs that were preventable **</th>
<th>% of AEs that were associated with death</th>
<th>% of admissions associated with potentially preventable death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present study</td>
<td>21 Dutch hospitals, 7926 hospital admissions (2004)</td>
<td>5.7 (5.1-6.4)</td>
<td>39.6</td>
<td>7.6</td>
<td>0.12</td>
</tr>
<tr>
<td>Aranaz-Andres et al. [19]</td>
<td>24 Spanish hospitals, 5624 hospital admissions (2005)</td>
<td>8.4 (7.7-9.1)</td>
<td>42.6</td>
<td>4.4</td>
<td>0.19 ‡‡</td>
</tr>
<tr>
<td>Michel et al. [8]</td>
<td>7 hospitals in France, 778 hospital admissions (2002)</td>
<td>14.5</td>
<td>27.6</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Schioler et al. [10]</td>
<td>17 hospitals in Denmark, 1097 hospital admissions (2001)</td>
<td>9.0</td>
<td>40.4</td>
<td>4.9</td>
<td>0.178 ‡</td>
</tr>
<tr>
<td>Baker et al. [2]</td>
<td>20 Canadian hospitals, 3745 hospital admissions (2000)</td>
<td>7.5 (5.7-9.3)</td>
<td>36.9</td>
<td>20.8</td>
<td>0.66 †</td>
</tr>
<tr>
<td>Vincent et al. [12]</td>
<td>2 hospitals in London, England, 1014 hospital admissions (1998)</td>
<td>10.8</td>
<td>48</td>
<td>8</td>
<td>0.41 ‡</td>
</tr>
<tr>
<td>Davis et al. [4; 5]</td>
<td>13 hospitals in New Zealand, 6579 hospital admissions (1998)</td>
<td>12.9</td>
<td>37.1</td>
<td>4.5</td>
<td>0.28 ‡‡</td>
</tr>
<tr>
<td>Thomas et al. [11]</td>
<td>28 hospitals in Utah and Colorado, 14700 hospital admissions (1992)</td>
<td>2.9 (± 0.25D)</td>
<td>50</td>
<td>6.6</td>
<td>0.13 ‡‡</td>
</tr>
<tr>
<td>Wilson et al. [13]</td>
<td>28 hospitals in New South Wales and South Australia, 14179 hospital admissions (1992)</td>
<td>16.6 (15.2-17.9)</td>
<td>51.2</td>
<td>4.9</td>
<td>0.55 ‡‡</td>
</tr>
<tr>
<td>Brennan et al. [1]</td>
<td>51 hospitals in New York, 30195 hospital admissions (1984)</td>
<td>3.7 (3.2-4.2)</td>
<td>27.6***</td>
<td>13.6</td>
<td>0.26 ‡‡</td>
</tr>
<tr>
<td>Leape et al. [3]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
NR = not reported
* most of the studies used causation score ≥4, except the studies of Davis and Wilson. They used causation score ≥2. Not all studies reported on the 95% CI
** all studies reported on high preventable AEs (preventability score ≥4)
*** measured negligence instead of preventability
\( s \) reported [2]
† NR. Estimated by calculation: proportion AE \( * \) proportion of preventable AEs \( * \) proportion that contributed to death
‡‡ NR. Estimated by calculation: proportion AEs; \( * \) proportion preventable AE that contributed to death
Although judgement of presence of AEs is difficult, retrospective patient record studies currently offer the best method available to assess incidence of AEs [23]. The results provide urgently needed insight in the current state of patient safety and possibilities for improvement of patient safety and are therefore generally highly appreciated.

Before 2004, there was no widespread public attention for patient safety in the Netherlands. The results of this study form the basis of a patient safety action campaign for hospitals named ‘Prevent harm, work safely’ which will run from 2008 to 2012 [24].

Sufficiently powered studies, or analyses of pooled data from comparable international studies, are needed to get more insight in the incidence of (preventable) AEs for specific specialties or patient groups in order to develop more effective interventions to improve patient safety. An approach which combines record review with prospective methods, in which clinical staff is interviewed about the origin of the AE, will give a more complete picture of (preventable) AEs and organisational and human causal factors [8; 25]. To prevent highly preventable AEs, such as AEs related to the diagnostic process, interventions to optimise health care procedures and multidisciplinary management are of special interest. AEs currently defined as unpreventable require research to develop new techniques to make them preventable in the future.
References


**Appendix 3.A  Screening criteria indicating potential AEs**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
<th>Deceased patients (%)**</th>
<th>Discharged patients (%)**</th>
<th>Total sample (%)***</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Unplanned admission before index admission (admission reasons are related to the index admission)</td>
<td>24</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>2</td>
<td>Unplanned readmission after discharge from index admission</td>
<td>0</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>3</td>
<td>Hospital-incurred patient injury (Permanent or temporary injury obtained (acquired) during index admission)</td>
<td>16</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>4</td>
<td>Adverse drug reaction</td>
<td>7</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>Unplanned transfer from general care to (an) intensive care (unit)</td>
<td>13</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>Unplanned transfer to another acute care hospital (after unexpected deterioration of the patient)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>7</td>
<td>Unplanned return to the operating room</td>
<td>7</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>Unplanned removal, injury or repair of organ during surgery</td>
<td>4</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>9</td>
<td>Hospital-acquired infection or sepsis</td>
<td>21</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>10</td>
<td>Other patient complication</td>
<td>16</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>11</td>
<td>Development of neurological deficit not present on admission</td>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>12</td>
<td>Unexpected death</td>
<td>47</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>13</td>
<td>Cardiac or respiratory arrest</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>14</td>
<td>Injury related to abortion or delivery</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>15</td>
<td>Inappropriate discharge to home</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>16</td>
<td>Dissatisfaction with care documented in the medical record</td>
<td>6</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>17</td>
<td>Documentation or correspondence indicating litigation</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>18</td>
<td>Any other undesirable outcome not covered above</td>
<td>13</td>
<td>8</td>
<td>9</td>
</tr>
</tbody>
</table>

Percentage of records with screening criteria: 70 39 54

* more than one criterion could be identified for one hospital admission
** weighted for oversampling of patients admitted to a university hospital
*** weighted for oversampling of deceased patients and patients admitted to a university hospital

*Chapter 3* 71
Appendix 3.B  Weighting proportions

The calculation of the weighting proportions accounts for the sampling strategy. The sampling weight was the inverse of the probability of being included in the sample owing to the sampling design. It accounts for the proportion of hospital admissions in the 3 hospital types and the proportion of discharged and deceased patients in the Dutch population of hospital admissions compared to the proportion in this study.

Table 3.B.1  Proportions of hospital admissions for discharged status and hospital type

<table>
<thead>
<tr>
<th>Discharge status:</th>
<th>Proportion in Dutch population (%)</th>
<th>Proportion in this study (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deceased</td>
<td>3</td>
<td>50</td>
</tr>
<tr>
<td>Discharged</td>
<td>97</td>
<td>50</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital type:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>University</td>
<td>13</td>
<td>17</td>
</tr>
<tr>
<td>Tertiary teaching</td>
<td>28</td>
<td>30</td>
</tr>
<tr>
<td>General</td>
<td>58</td>
<td>53</td>
</tr>
</tbody>
</table>

Table 3.B.2  Weighting proportions for the different sampling strata

<table>
<thead>
<tr>
<th>Strata</th>
<th>Weighting factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deceased patients admitted to a university hospital</td>
<td>0.038</td>
</tr>
<tr>
<td>Deceased patients admitted to a tertiary teaching hospital</td>
<td>0.063</td>
</tr>
<tr>
<td>Deceased patients admitted to a general hospital</td>
<td>0.072</td>
</tr>
<tr>
<td>Discharged patients admitted to a university hospital</td>
<td>0.771</td>
</tr>
<tr>
<td>Discharged patients admitted to a tertiary teaching hospital</td>
<td>0.962</td>
</tr>
<tr>
<td>Discharged patients admitted to a general hospital</td>
<td>1.097</td>
</tr>
</tbody>
</table>
Appendix 3.C  Representativeness of the study sample

Table 3.C.1  Comparison of study patients and patients admitted to all Dutch acute care hospitals in 2004

<table>
<thead>
<tr>
<th>Patient data</th>
<th>Dutch population*</th>
<th>Total sample (weighted)**</th>
<th>Dutch population deceased patients***</th>
<th>Sample deceased patients (weighted)****</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of inpatient admissions</td>
<td>1,343,234</td>
<td>7,926 (0.6%)</td>
<td>42,329 (3.2%)</td>
<td>3,983 (9.4%)</td>
</tr>
<tr>
<td>(% of all patients/of all deceased patients in Dutch hospitals in 2004)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of admissions in university hospitals</td>
<td>179,998 (13.4)</td>
<td>1,378 (17.4)</td>
<td>4,972 (11.7)</td>
<td>780 (19.6)</td>
</tr>
<tr>
<td>(% of total population/sample)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age in years (SD)</td>
<td>55.9 (21.7)</td>
<td>57.5 (21.5)</td>
<td>73.4 (13.9)</td>
<td>73.9 (13.4)</td>
</tr>
<tr>
<td>Males (%)</td>
<td>49.7</td>
<td>49.1</td>
<td>53.4</td>
<td>53.8</td>
</tr>
<tr>
<td>Admission duration in days</td>
<td>7.3 (10.4 / 4.0)</td>
<td>8.5 (10.5 / 5.0)</td>
<td>12.1 (15.8 / 7.0)</td>
<td>12.3 (15.6 / 7.0)</td>
</tr>
<tr>
<td>(Mean (SD/median))</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urgent admissions (%)</td>
<td>46.6</td>
<td>53.7</td>
<td>81.0</td>
<td>87.9</td>
</tr>
<tr>
<td>Hospital admission department</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Surgery (%)</td>
<td>24.4</td>
<td>24.0</td>
<td>13.5</td>
<td>11.7</td>
</tr>
<tr>
<td>- Cardiology (%)</td>
<td>16.1</td>
<td>12.9</td>
<td>16.9</td>
<td>13.3</td>
</tr>
<tr>
<td>- Internal medicine (%)</td>
<td>16.1</td>
<td>15.8</td>
<td>33.4</td>
<td>31.1</td>
</tr>
<tr>
<td>- Orthopaedics (%)</td>
<td>8.7</td>
<td>10.4</td>
<td>1.6</td>
<td>1.8</td>
</tr>
<tr>
<td>- Neurology (%)</td>
<td>6.3</td>
<td>7.4</td>
<td>13.0</td>
<td>12.3</td>
</tr>
<tr>
<td>- Lung diseases (%)</td>
<td>6.5</td>
<td>7.2</td>
<td>13.6</td>
<td>13.5</td>
</tr>
<tr>
<td>- Ear, nose and throat (%)</td>
<td>4.5</td>
<td>4.3</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>- Urology (%)</td>
<td>5.0</td>
<td>4.2</td>
<td>1.4</td>
<td>1.3</td>
</tr>
<tr>
<td>- Other (%)</td>
<td>18.8</td>
<td>14.5</td>
<td>11.1</td>
<td>14.7</td>
</tr>
</tbody>
</table>

* all admissions in non-speciality and non-psychiatric acute care hospitals in the Netherlands in 2004 (Source: Prismant); hospitals with less than 200 beds and psychiatric and obstetric patients and patients <1 year were excluded. Admissions less than one day were excluded in the discharged patient group

** psychiatric and obstetric patients and patients <1 year were excluded. Day admissions were only excluded in the discharged patients. Figures were weighted for oversampling of deceased patients and patients admitted to a university hospital

*** all deceased patients in non-speciality and non-psychiatric acute care hospitals in the Netherlands in 2004 (Source: Prismant); hospitals with less than 200 beds and psychiatric and obstetric patients, patients <1 year and day admissions were excluded

**** psychiatric and obstetric patients and patients <1 year were excluded. Figures were weighted for oversampling of deceased patients admitted to a university hospital
Adverse events among hospitalised patients
Chapter 4

Variation in the rates of adverse events between hospitals and hospital departments

This article was submitted as:
Abstract

Background
The objective of this study was to analyse the variation in the rates of adverse events, whether or not preventable, between hospitals and hospital departments in order to investigate the room for improvement in reducing adverse events at both levels. In addition, to explore the extent to which patient, admission and hospital characteristics explain differences in adverse event rates.

Methods
Data were used from the record review study on the occurrence of adverse events among hospitalised patients in the Netherlands. Multilevel logistic regression analysis was used to analyse the variation in adverse events. On the first level, 7,752 patient admissions were nested within 303 hospital departments, which were the second level. These were, in turn, nested in 21 hospitals, the third level. The analysis was adjusted for patient, department and hospital characteristics.

Results
Adverse event rates varied significantly between hospitals and hospital departments. Preventable adverse event rates only varied significantly between hospital departments. Preventable adverse events clustered more in hospital departments than in hospitals (ICC 9.0% versus 4.3%). The type of hospital explained 31% of the inter-hospital variance in adverse events. Patient mix and type of admission department explained 24% of the inter-hospital department variance in preventable adverse events.

Conclusions
Patient safety differs between hospitals and even more between hospital departments. This implies that patients are better off in some hospitals than in others in terms of their risk of an adverse event. In addition, interventions to improve patient safety should focus on unsafe hospital departments and not only on unsafe hospitals.
Introduction

Patient record review studies have shown that a substantial number of patients in acute care hospitals experience adverse events and that part of the adverse events contributed to the patients’ death. Approximately half of the adverse events were judged to be preventable [1-10]. Based on these findings, patient safety programmes have been initiated to reduce the amount of adverse events. To enhance patient safety, the focus is mainly on preventable adverse events. Organisational factors form the centre of interest for the development of improvement strategies. A hierarchy of factors may influence clinical outcomes from the institutional context, via organisational and management factors, work environment, team factors, and individual factors of healthcare employees, to patient characteristics [11; 12]. The organisation of health care impacts is arranged at several levels. At the hospital level, for example, quality assurance is organised and financial decisions are made. At the hospital department level, staffing and incident reporting are organised. Lastly, at the level of the patient, individual patient care is arranged.

The variation of adverse events between the different levels of organisation has not been studied yet. Very little is known about the importance of different organisational levels for patient safety in hospitals. This hampers insight into the level at which interventions should focus: hospital-wide interventions or a decentralised approach. Interventions at the hospital department level can be tailored to the specific needs of a department. By contrast interventions at the hospital level may not be sufficient or effective at the level of the hospital department. Studying the variation in patient safety outcomes at different organisational levels in hospitals offers insight into this problem.

The composition of patients differs between hospitals and hospital departments. For example, complex patients are referred to university hospitals and patients admitted to surgical departments are at higher risk of an adverse event [13]. To attribute the variation in adverse event rates to hospitals and hospital departments, sufficient correction for patient mix and structural factors, such as hospital type and type of department, is required. The remaining variance after correction gives an indication of the room for improvement.

Between August 2005 and October 2006, a population-based retrospective record review study was carried out to assess the national incidence of adverse events in Dutch hospitals. The study showed that in 5.7% (95% CI 5.1-6.4) admissions, one or more adverse events were found. In addition, in 2.3% (95%
CI 1.9-2.7) of the admissions one or more preventable adverse events were assessed [13]. We used multilevel analysis to examine the variation in adverse event rates and preventable adverse event rates between hospitals and hospital departments in order to investigate the room for improvement at both levels. We also examined the effect of patient mix and department and hospital type on the variation in (preventable) adverse event rates. The research questions of this study are:

1. To what extent do (preventable) adverse event rates vary between hospitals and between hospital departments?
2. To what extent is the variation in adverse events between hospitals and between hospital departments a result of differences in the composition of the patient population, type of department and hospital type?

Methods

Study design and setting
A retrospective patient record review study was performed in a stratified random sample of 21 Dutch hospitals: 4 university, 6 tertiary teaching and 11 general, hospitals, in which admissions of university hospitals were oversampled to facilitate the comparison between hospital types. To increase the efficiency in identifying adverse events, admissions of deceased patients were oversampled [14].

From each hospital we used data covering 2004 and we selected at random 200 admissions (>24 hours stay) of discharged patients and 200 admissions of hospital patients who died. Of the initial 8415 sampled admissions, 383 records were unavailable or were inadequate. In addition, 106 records were excluded during the review process [13]. Forty-four (0.5%) hospital admissions could not be matched to the national hospital administration database. Since the admission department is only a proxy of the department responsible for patient care during the admission, all adverse events that were attributable to a hospital department other than the admission department were excluded from the analysis (n=130). In total, 3,898 admissions of discharged and 3854 admissions of deceased patients from 303 hospital departments were included in this study.
Structured review of patient records

The patient records of the sampled admissions were reviewed by a team of 66 trained nurses and 55 trained physicians between August 2005 and October 2006 using a structured record review process. In the first stage, a nurse screened the patient records by using 18 screening criteria indicating potential adverse events [14]. In addition patient and admission characteristics were recorded, such as age, sex, urgency of admission and admission department. In the second stage of the review process, two physicians independently reviewed the patient records positive for one or more screening criteria. They assessed the presence, preventability and responsible specialty of the adverse events. An adverse event was defined as an unintended injury among hospitalised patients that results in disability, death or prolonged hospital stay, and was caused by healthcare management. Preventable was defined as care that fell below the current level of expected performance for practitioners or systems. The review process is described elsewhere in more detail [13; 14].

Additional data were obtained from the national hospital administration database, notably the Charlson index for co-morbidity and diagnosis coded according to the International Statistical Classification of Diseases, 9\textsuperscript{th} revision (ICD-9). The Charlson index is a weighted estimate for co-morbidity and takes into account both the number and seriousness of co-morbid diseases [15]. The ICD-9 diagnoses were classified according to the Clinical Classifications Software (CCS) into homogeneous diagnostic groups [16]. The Major CCS diagnostic classification was used instead of ICD-9 diagnoses, because they showed a stronger association with adverse events than the ICD-9 main categories.

Statistical analysis

Descriptive statistics were calculated for the characteristics of the study population using weights for the oversampling of deceased patients and patients admitted to university hospitals in SPSS 14.0 [13]. The data in this study were hierarchical. Level one the patient admissions are nested within hospital departments, the second level. These were, in turn, nested within hospitals, the third level. Thus, the observations were not independent, which violates a major assumption of traditional regression analysis. Multilevel models are used to analyse hierarchically structured data [17; 18]. We used multilevel logistic regression (MLwiN version 2.02) to analyse the variance in adverse events, whether or not preventable. The dichotomous
outcome variables were adverse events and preventable adverse events, coded as ‘present’ or ‘not present’.

To ensure that the differences in adverse event rates found in the multilevel analysis were attributable to differences between hospitals and hospital departments and not to differences in composition of patient groups, we corrected for differences in patient characteristics. We presume that patient characteristics do not completely account for compositional differences. It is also necessary to correct for context factors, notably the type of admission department and type of hospital, because patients admitted to a surgical department or university hospitals have an increased risk of adverse events [13].

Model 1 was an empty model, in which the inter-hospital and inter-hospital department variation in adverse events were analysed without considering covariates. In model 2, the patient characteristics age, sex, urgency of admission, diagnostic groups and co-morbidity were added. Next, the type of department whether surgical or non-surgical was added (model 3). Finally the type of hospital notably university, tertiary teaching or general hospital was added (model 4). Using this strategy, we were able to separate variation between hospitals and that between hospital departments and to analyse, at each level, how much variability can be explained by patient mix, department type and hospital type.

All variables included in the models were centered to reference values for all Dutch hospital admissions and the variances of the models were tested for statistical significance using a one-sided Wald-test. Intra class correlations (ICCs) were calculated. The ICC is defined as the higher level variance as a percentage of the total variance. A high ICC at the hospital level means that there is more homogeneity (low variation) within hospitals (meaning patients are treated alike in a hospital), but high variation between hospitals [17; 18]. Within logistic models, the variance at the lowest level, in this study the patient, is approximated by \( \pi^2/3 \) to calculate the total variance [18]. In addition, median odds ratios (MORs) were calculated to quantify the differences in adverse event rates between hospitals and hospital departments (MOR for hospital variation = \( \exp \left( \sqrt{2 \times \text{hospital-level variance}} \right) \times 0.6745 \)). MOR=1 is found when there is no variation between hospitals or hospital departments. Meaning that it does not make a difference whether a patient is treated in one hospital or another as far as their risk of an adverse event is concerned. A larger MOR means that patients are better off in some hospitals than in others in terms of their risk of an adverse event [17; 19]. Finally, model
was used to assess the association between the covariates and the occurrence of adverse events by calculating ORs with 95% confidence intervals (CIs).

Results

Study sample
In this study, 7,752 admissions from 303 hospital departments in 21 hospitals were analysed. The patient, admission and hospital characteristics of both the study sample and the Dutch population of hospital patients are shown in Table 4.1.

Variation in adverse event rates
Multilevel logistic regression models for adverse events and preventable adverse events are shown in Table 4.2. In all models for adverse events, the intercept variation for the hospital level and the hospital department level was statistically significant, implying a significant variation in adverse events between hospitals and between hospital departments. Compared to model 1, the intercept-only model, the patient mix and department type did not reduce the variance in adverse events between hospitals. The variance in adverse events at the hospital level only reduced after adjustment for hospital type (31%). The variance in adverse events at the hospital department level reduced by 24% after adjustment for patient characteristics and 41% after adjustment for patient characteristics and admission to a surgical department. Additional correction for hospital type did not reduce the variance in adverse events between hospital departments.

After correcting for all covariates, the clustering of adverse events in hospital departments was almost two times higher than in hospitals, ICC 6.3% versus ICC 3.7%. This means that there is more variation in adverse events between hospital departments than between hospitals, implying that hospitals with a low adverse event rate may have departments with a high adverse event rate. The adverse event rate varied from 3.7% to 13.9% between hospitals and from 3.0% to 16.8% between hospital departments, which could not be explained by the covariates used. The MOR for adverse events was 1.43 for hospitals and 1.58 for hospital departments.
Table 4.1  Characteristics of both the study sample and the Dutch population of hospital admissions

<table>
<thead>
<tr>
<th></th>
<th>Study sample</th>
<th>Dutch population of hospital admissions**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of hospitals</td>
<td>21</td>
<td>101</td>
</tr>
<tr>
<td>Number of patient admissions</td>
<td>7,752</td>
<td>1,343,234</td>
</tr>
<tr>
<td>Number of patients admitted to a university hospital (% of total admissions)</td>
<td>1,341 (17.3)</td>
<td>781,611 (13.4)</td>
</tr>
<tr>
<td>Number of patients who died during admission (% of total admissions)</td>
<td>3,854 (49.7)</td>
<td>42,329 (3.2)</td>
</tr>
<tr>
<td>Mean age in years (SD)</td>
<td>57.4 (21.6)*</td>
<td>55.9 (21.7)</td>
</tr>
<tr>
<td>Sex (% male)</td>
<td>49.0*</td>
<td>49.7</td>
</tr>
<tr>
<td>Urgent admissions (%)</td>
<td>53.7*</td>
<td>46.6</td>
</tr>
<tr>
<td>Admission department (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Surgery</td>
<td>24.1*</td>
<td>23.8</td>
</tr>
<tr>
<td>- Cardiology</td>
<td>12.9*</td>
<td>16.1</td>
</tr>
<tr>
<td>- Internal medicine</td>
<td>15.7*</td>
<td>16.2</td>
</tr>
<tr>
<td>- Orthopaedics</td>
<td>10.6*</td>
<td>8.7</td>
</tr>
<tr>
<td>- Neurology</td>
<td>7.4*</td>
<td>6.3</td>
</tr>
<tr>
<td>- Pulmonary disease</td>
<td>7.2*</td>
<td>6.4</td>
</tr>
<tr>
<td>- Ear, nose and throat</td>
<td>4.3*</td>
<td>4.5</td>
</tr>
<tr>
<td>- Urology</td>
<td>4.2*</td>
<td>5.0</td>
</tr>
<tr>
<td>- Other</td>
<td>13.6*</td>
<td>13.0</td>
</tr>
<tr>
<td>Mean Charlson index for co-morbidity (% with a score ≥1)</td>
<td>0.10 (7.9)*</td>
<td></td>
</tr>
<tr>
<td>Major CCS (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Rest group</td>
<td>56.6*</td>
<td></td>
</tr>
<tr>
<td>- Septicaemia</td>
<td>7.4*</td>
<td></td>
</tr>
<tr>
<td>- Coma, shock</td>
<td>1.8*</td>
<td></td>
</tr>
<tr>
<td>- Diseases of the heart (AMI, VF, valve)</td>
<td>12.3*</td>
<td></td>
</tr>
<tr>
<td>- Acute cerebrovascular disease</td>
<td>2.4*</td>
<td></td>
</tr>
<tr>
<td>- Diseases of arteries, arterioles, and capillaries</td>
<td>2.4*</td>
<td></td>
</tr>
<tr>
<td>- Pneumonia</td>
<td>6.3*</td>
<td></td>
</tr>
<tr>
<td>- Diseases of the digestive system</td>
<td>5.7*</td>
<td></td>
</tr>
<tr>
<td>- Renal failure, urogenital infection</td>
<td>1.2*</td>
<td></td>
</tr>
<tr>
<td>- Fracture of neck of femur</td>
<td>1.7*</td>
<td></td>
</tr>
<tr>
<td>- Complication of surgical or medical procedures</td>
<td>2.2*</td>
<td></td>
</tr>
</tbody>
</table>

* weighted for the oversampling of deceased patients and of patients admitted to a university hospital

** source: national hospital administration database (www.prismant.nl)
### Table 4.2 Variance components of the multilevel logistic regression models for (preventable) adverse event rates

<table>
<thead>
<tr>
<th>Model 1 (intercept-only)</th>
<th>Adverse events</th>
<th>Preventable adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variance at hospital level (standard error)</td>
<td>0.20 (0.09)</td>
<td>0.17 (0.11)</td>
</tr>
<tr>
<td>Variance at hospital department level (standard error)</td>
<td>0.38 (0.10)</td>
<td>0.45 (0.16)</td>
</tr>
<tr>
<td>ICC hospital level</td>
<td>5.1%</td>
<td>4.4%</td>
</tr>
<tr>
<td>ICC hospital department level</td>
<td>9.8%</td>
<td>11.6%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model 2 (age, sex, urgency, diagnosis, co-morbidity)</th>
<th>Adverse events</th>
<th>Preventable adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variance at hospital level (standard error)</td>
<td>0.21 (0.09)</td>
<td>0.16 (0.11)</td>
</tr>
<tr>
<td>Variance at hospital department level (standard error)</td>
<td>0.29 (0.09)</td>
<td>0.43 (0.16)</td>
</tr>
<tr>
<td>Variance drop at hospital level versus Model 1</td>
<td>-9%</td>
<td>5%</td>
</tr>
<tr>
<td>Variance drop at hospital department level versus Model 1</td>
<td>24%</td>
<td>5%</td>
</tr>
<tr>
<td>ICC hospital level</td>
<td>5.6%</td>
<td>4.2%</td>
</tr>
<tr>
<td>ICC hospital department level</td>
<td>7.6%</td>
<td>11.1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model 3 (age, sex, urgency, diagnosis, co-morbidity, surgical admission)</th>
<th>Adverse events</th>
<th>Preventable adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variance at hospital level (standard error)</td>
<td>0.22 (0.10)</td>
<td>0.17 (0.10)</td>
</tr>
<tr>
<td>Variance at hospital department level (standard error)</td>
<td>0.22 (0.08)</td>
<td>0.34 (0.14)</td>
</tr>
<tr>
<td>Variance drop at hospital level versus Model 1</td>
<td>-14%</td>
<td>4%</td>
</tr>
<tr>
<td>Variance drop at hospital department level versus Model 1</td>
<td>41%</td>
<td>24%</td>
</tr>
<tr>
<td>ICC hospital level</td>
<td>6.0%</td>
<td>4.4%</td>
</tr>
<tr>
<td>ICC hospital department level</td>
<td>6.0%</td>
<td>9.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model 4 (age, sex, urgency, diagnosis, co-morbidity, surgical admission, hospital type)</th>
<th>Adverse events</th>
<th>Preventable adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variance at hospital level (standard error)</td>
<td>0.14 (0.07)</td>
<td>0.16 (0.10)</td>
</tr>
<tr>
<td>Variance at hospital department level (standard error)</td>
<td>0.23 (0.08)</td>
<td>0.34 (0.14)</td>
</tr>
<tr>
<td>Variance drop at hospital level versus Model 1</td>
<td>31%</td>
<td>6%</td>
</tr>
<tr>
<td>Variance drop at hospital department level versus Model 1</td>
<td>39%</td>
<td>25%</td>
</tr>
<tr>
<td>ICC hospital level</td>
<td>3.7%</td>
<td>4.3%</td>
</tr>
<tr>
<td>ICC hospital department level</td>
<td>6.3%</td>
<td>9.0%</td>
</tr>
<tr>
<td>Inter-hospital variation (95% CI)</td>
<td>3.7-13.9%</td>
<td>1.4-6.5%</td>
</tr>
<tr>
<td>Inter-hospital variation (95% CI)</td>
<td>3.0-16.8%</td>
<td>1.0-9.0%</td>
</tr>
</tbody>
</table>

Values are bold if the differences between hospitals and hospital departments are significant (p<0.05)

**Variation in preventable adverse events**

In all models for preventable adverse events, the intercept variation for hospital level was not significant, but the intercept variation for the hospital department level was statistically significant, implying significant variation of
preventable adverse event rates between hospital departments. The variance at both the hospital and hospital department levels reduced by 5% after adjustment for patient characteristics. But the variance just at the hospital department alone reduced by 24% after adjustment for patient characteristics and admission to a surgical department. Additional adjustment for hospital type did not affect the variance at either levels.

After correcting for all the covariates, the preventable adverse event rates varied between hospitals and hospital departments by between 1.4%-6.5% and 1.0%-9.0% respectively. The clustering of preventable adverse events in hospital departments was more than twice that found in hospitals (ICC 9.0% versus 4.3%), indicating that preventable adverse events varied more between hospital departments than between hospitals. The MOR for preventable adverse events was 1.46 for hospitals and 1.74 for hospital departments.

Table 4.3 Determinants of (preventable) adverse events analysed with multilevel logistic regression analysis adjusted for patient, admission and hospital characteristics

<table>
<thead>
<tr>
<th>Patient, admission and hospital characteristics (fixed effects of model 4)</th>
<th>Adverse events (n=532) OR (95%CI)*</th>
<th>Preventable adverse events (n=229) OR (95%CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>1.02 (1.01-1.02)</td>
<td>1.02 (1.02-1.03)</td>
</tr>
<tr>
<td>Sex (reference: male)</td>
<td>0.94 (0.78-1.13)</td>
<td>0.96 (0.73-1.26)</td>
</tr>
<tr>
<td>Urgency (reference: elective)</td>
<td>0.71 (0.57-0.89)</td>
<td>0.66 (0.47-0.92)</td>
</tr>
<tr>
<td>Surgical admission (reference: medical admission)</td>
<td>1.81 (1.35-2.43)</td>
<td>1.66 (1.09-2.53)</td>
</tr>
<tr>
<td>Major CCS - Rest group</td>
<td>0.84 (0.60-1.20)</td>
<td>1.15 (0.68-1.93)</td>
</tr>
<tr>
<td>- Septicaemia</td>
<td>1.19 (0.82-1.73)</td>
<td>1.06 (0.59-1.92)</td>
</tr>
<tr>
<td>- Coma, shock</td>
<td>1.23 (0.65-2.35)</td>
<td>1.92 (0.83-4.44)</td>
</tr>
<tr>
<td>- Acute cerebrovascular disease</td>
<td>0.50 (0.26-0.96)</td>
<td>0.35 (0.12-1.07)</td>
</tr>
<tr>
<td>- Diseases of arteries, arterioles, and capillaries</td>
<td>1.33 (0.81-2.19)</td>
<td>1.73 (0.84-3.56)</td>
</tr>
<tr>
<td>- Pneumonia</td>
<td>1.13 (0.73-1.75)</td>
<td>2.10 (1.18-3.75)</td>
</tr>
<tr>
<td>- Diseases of the digestive system</td>
<td>1.18 (0.74-1.90)</td>
<td>1.27 (0.62-2.59)</td>
</tr>
<tr>
<td>- Renal failure, urogenital infection</td>
<td>1.29 (0.65-2.57)</td>
<td>2.68 (1.16-6.19)</td>
</tr>
<tr>
<td>- Fracture of neck of femur</td>
<td>0.94 (0.48-1.86)</td>
<td>1.20 (0.48-3.06)</td>
</tr>
<tr>
<td>- Complication of surgical or medical procedures</td>
<td>2.98 (1.70-5.21)</td>
<td>3.10 (1.37-7.03)</td>
</tr>
<tr>
<td>Charlson (co-morbidity scale)</td>
<td>1.27 (1.12-1.43)</td>
<td>1.40 (1.20-1.61)</td>
</tr>
<tr>
<td>Tertiary teaching hospital</td>
<td>0.53 (0.30-0.94)</td>
<td>1.12 (0.53-2.34)</td>
</tr>
<tr>
<td>General hospital</td>
<td>0.48 (0.28-0.80)</td>
<td>1.05 (0.53-2.06)</td>
</tr>
</tbody>
</table>

* bold OR’s are statistically significant (p<0.05)
Determinants of (preventable) adverse events

Table 4.3 shows which patient groups have an increased risk of adverse events. Patients with a surgical admission, more co-morbidity, older age, elective admission, admission to a university hospital, and complication of surgical or medical procedure had a higher risk of adverse events during a hospital admission. Determinants for preventable adverse events were a surgical admission, more co-morbidity, older age, elective admission, and diagnosis of pneumonia, renal failure/urogenital infection or complication of a surgical or medical procedure.

Discussion

There is a growing interest in variation in the quality of health care and an increasing involvement by consumers in healthcare decision making which has resulted in increased hospital quality measurement [20]. A few previous studies have measured the association between hospital characteristics and adverse event rates [21; 22]. However, the variation in adverse events between levels of organisation and the room for improvement in patient safety at different organisational levels, after correction for several covariates, has not been reported before. The hierarchical structure of the data is mostly ignored in studies on adverse events and quality of care [23]. This is the first study that analysed the variation of (preventable) adverse events between hospitals and hospital departments in more detail. Moreover, we explored to what extent the variation in adverse events is a result of differences in the composition of the patient population, type of department and hospital type. After adjustment for patient, department and hospital characteristics, adverse event rates varied significantly between hospitals and between hospital departments, meaning that patient safety differs between hospitals and hospital departments. The preventable adverse event rates varied only significantly between hospital departments and the clustering of preventable adverse events in hospital departments was more than twice that found in hospitals, implying that there is more room for improvement in patient safety at the hospital department level than at the hospital level. The MOR gives an indication of the risk of a (preventable) adverse event due to differences between hospitals or between hospital departments. In this study, the MOR for preventable adverse events ranged from 1.46 to 1.74, meaning that the
differences between hospitals and hospital departments form a higher risk of preventable adverse events than co-morbidity (OR=1.40).

The determinants of (preventable) adverse events gave an insight into patient groups with a higher risk of (preventable) adverse events. Older age, more co-morbidity, elective admission, admission to a surgical department, admission to a university hospital, and complications were associated with a higher risk of adverse events. Determinants for preventable adverse events were a surgical admission, more co-morbidity, older age, elective admission, and diagnosis of pneumonia, renal failure/urogenital infection or complication of a surgical or medical procedure.

In this study, the inter-hospital variance in adverse events was mainly explained by hospital type. Patient mix and department type did not reduce the inter-hospital variance in adverse events, contrary to the general perception that differences in adverse event rates between hospitals are strongly related to differences in patient mix. The fact that inter-hospital variance actually increased after including patient mix and department type indicates that these variables masked some of the inter-hospital variance. The inter-hospital department variance in both adverse events and preventable adverse events was mainly explained by differences in the patient mix and department type.

Beyond the limitations related to record review [13; 14; 24], our study has some limitations. The main aim of the patient record review study was to measure the national incidence of adverse events in Dutch hospitals. We did not measure specific organisational factors at the hospital and hospital department level that could explain the remaining variance in adverse events. The exploratory factors on the hospital and hospital department level in this study were restricted to the type of admission department (surgical and non-surgical) and hospital type (university, tertiary teaching and general). In addition, it is difficult to ensure an optimal correction for patient mix.

The findings of our study have implications for strategies to improve patient safety in hospitals. This study shows that adverse events varied between hospitals and even more between hospital departments. Preventable adverse events varied only significantly between hospital departments, indicating that there is more room for improvement in patient safety at the hospital department level than at the hospital level. The implementation of prevention strategies and safety programmes should focus on the department level and not only on the hospital level. Directing all interventions at the hospital level, a
centralised approach, may not to be the best approach for improving patient safety. Efforts aimed at making improvements at the department level – decentralised- seem more worthwhile. Until now, efforts to measure, report and monitor the performance of health care and the effects of safety programmes are mainly done at the hospital level [25; 26]. However, hospital managers and policy makers should also be aware of unsafe hospital departments and not only of unsafe hospitals. Hospitals with a low adverse event rate may have departments with high adverse event rates. Measurement at the department level is more appropriate to formulate specific interventions tailored to the problems of departments. Hospital managers should identify high risk departments and safety programmes should focus on patient groups or clinical areas with a higher risk of preventable adverse events, such as elderly patients and surgical admissions.

Organisational factors, such as safety culture, level of experience and skills of medical personnel, total staffing, and availability and quality of facilities, may explain the remaining variance at hospital and hospital department level and should be explored in future studies. These factors should be the focus of prevention activities aiming at reducing the variance in adverse event rates. Future studies on the variation of adverse events could be extended to include a ‘physician level’ or ‘unit level’. Physicians or units, such as operation teams, are nested within departments and have their own culture and organisation of healthcare delivery. The variation associated with this unmeasured level was scattered over the department and patient levels in this study. An extra level in future studies should, however, be accompanied by the inclusion of more cases.

The study looked at the variance in adverse events between all the hospital departments (n=303) included in our research. It would be interesting to explore the variance in adverse events between specific specialties, such as cardio-thoracic surgery and intensive care units, in future studies. The number of cases in this study was too small to analyse the differences in adverse events between specific specialties.
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Adverse events among hospitalised patients


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Chapter 5

Surgical adverse events: occurrence, nature and potential prevention strategies

This article was submitted as:
Surgical adverse events: occurrence, nature and potential prevention strategies.
Abstract

Background
In this study, the occurrence, nature, preventability, causes and potential prevention strategies of surgical adverse events (AEs) among patients in Dutch hospitals were explored.

Methods
Retrospective structured record review of 7,926 admissions in 2004 in 21 Dutch hospitals by trained nurse and physician reviewers. They registered the presence and preventability of AEs attributable to surgical specialties and classified these by clinical procedure, pathological category, causes and potential prevention strategies.

Results
Of all identified AEs, 65% was attributable to surgical specialties, of which 5% resulted in permanent disability and 6% contributed to death. Forty-one percent was considered to be preventable. The majority of the surgical AEs (83%) were related to surgical procedures, of which 39% resulted in infection, 23% in bleeding, and 22% in injury by mechanical/physical-chemical cause. Causal factors of surgical AEs were predominantly human factors (65%). Frequently recommended potential prevention strategies were quality assurance (73%), training (59%), and evaluation (51%).

Conclusions
Two-third of all AEs in Dutch hospitals were attributable to surgical specialties. Potential strategies to minimise the occurrence of surgical AEs should focus on learning from safety incidents, training, and better control of existing protocols and guidelines.

Adverse events among hospitalised patients
Introduction

Several international patient record review studies assessed the occurrence of adverse events (AEs) and showed that the incidence of AEs varied from 3% (Utah and Colorado) to 17% (Australia) among hospitalised patients [1-10]. An AE is defined as an unintended injury among hospitalised patients caused by health care management and resulted in disability, death or prolonged hospital stay [1-3; 8; 11]. Most of the AEs resulted in minor or temporary disability, but a proportion of the AEs, 4% in Spain to 21% in Canada, contributed to patients’ death [1-10; 12]. In these studies, approximately 50% of the AEs were judged to be preventable and the majority of the AEs were attributable to surgical specialties [1; 2; 4; 8; 10; 13; 14].

Surgical care is an essential component of health care. Over the past decades the number and complexity of diagnostic efforts and therapeutic interventions has increased markedly, the number of drugs in use has risen yearly, and the patient population has aged. In recent years, more diseases can be treated successfully; vulnerable patients, such as old patients with complex comorbidity, can be operated more often. However, innovative and more complicated techniques for diagnostic and therapeutic interventions and treatment of patients with a higher risk also brings along an increased risk for AEs [15; 16].

To reduce the burden of morbidity and mortality as a result of health care, it is necessary to get insight into AEs caused by health care management instead of events that may be a result of the underlying disease of patients (complications). Insight in the nature and causes of AEs, and especially preventable AEs, gives clues for improvement of the health care process and system. Preventable AEs are the result of health care below the professional standards and by healthcare system failures [1; 4; 10; 11]. Most AEs, although seemingly caused by human actions or inactions, are however partly caused by a care process that has not been properly organised [17]. An AE arises often due to several causal factors, like technical, organisational, human, and patient related factors.

A large patient record review study on the occurrence of AEs was performed to assess the national incidence of AEs among hospitalised patients in the Netherlands [11]. The study showed that the AE incidence rate was 5.7% (95% CI 5.1-6.4) of which 39.6% was judged to be preventable [18]. In this paper, the AEs attributable to surgical specialties are explored in more detail.
Insight in the nature, causal factors and preventability of surgical AEs provides information to prioritise prevention strategies. The research questions are:

1. What are the occurrence, nature, and preventability of surgical AEs among hospitalised patients?
2. What are the causes and potential prevention strategies of surgical AEs?

There are two previous population-based record review studies on the occurrence of AEs among hospitalised patients that report on surgical AEs in more detail. These studies were carried out more than ten years ago in Australia and the US (Utah and Colorado) [13; 14]. Our study is the first population-based record review study on the occurrence of AEs in hospitals in an European country that reported on surgical AEs in more detail and provides more recent data about patient harm as a result of surgical AEs.

Methods

Study design and setting
To measure the occurrence of AEs in Dutch hospitals, trained nurses and physicians performed a retrospective patient record review study between August 2005 and October 2006. They reviewed 7,926 hospital admissions that were selected in a random sample of 21 hospitals: 4 university, 6 tertiary teaching and 11 general hospitals [11; 18]. In total, 3,983 admissions of deceased hospital patients and 3,943 admissions of discharged patients (>24 hours stay), excluding admissions of psychiatry, obstetrics and children < 1 year old were reviewed. Admissions of deceased patients and patients admitted to university hospitals were oversampled. We have described the design and methods of this study in more detail elsewhere [11].

Structured review of patient records
The nursing, medical and, if available, outpatient record of 7,926 sampled hospital admissions were reviewed by 66 trained nurses and 55 trained physicians in a three stage review process. In the first stage, a nurse screened the records by using 18 explicit screening criteria indicating potential AEs (Appendix 5.A). In the second stage of the review process, two physicians independently reviewed records screened positive. Records with screening criteria related to surgical issues were reviewed by two surgeons. They determined presence, nature, impact, and degree of preventability of AEs with an implicit structured electronic review form. If there was disagreement about
the presence and/or preventability of an AE between the two independent physician reviews, they started a consensus procedure to obtain consensus (stage 3). If they could not reach consensus, a third trained physician reviewer gave a final judgement [11].

**Outcome measures**
The presence of an AE and degree of preventability were measured on a six-point scale (Appendix 5.A). We used a score of at least four (more than 50% likely that health care management caused the AE) to indicate the presence of AEs. Also a score of at least four (more than 50% likely that the AE was preventable) was used to indicate a preventable AE [18].

Per AE, the physician reviewers registered the specialty that was responsible for the AE related care. *Surgical AEs* were defined as AEs attributable to surgical specialties. In addition, the physician reviewers classified the AE by clinical process: diagnostic procedure, drug related, surgical procedure, other procedure, other clinical management or discharge related. The AEs that were a result of surgical procedures were classified by pathological category (more options per AE), such as bleeding, infection, shock, thrombosis, necrosis, fistula forming, and abnormal wound healing. The classification by pathology category was according to the nationwide reporting system of adverse outcomes developed by the Association of Surgeons in The Netherlands [19; 20]. Moreover, causal factors that contributed to the occurrence of AEs were documented (more options per AE) [21]. The categories were: human (e.g. inadequate application of existing knowledge), organisational (e.g. inadequate transfer of knowledge/communication), technical (e.g. material defects) or patient related factors (e.g. co-morbidity, age, and compliance). Finally, for all preventable AEs, potential prevention strategies were recorded (more options per preventable AE). The review form distinguished ten prevention strategies: quality assurance/peer review, training, evaluation, procedures, motivation, information and communication, technology/equipment, personnel, upscaling, and financial investment. The physician reviewers selected the causal factors and potential prevention strategies based on information in the patient record and their perception of the situation [21].

**Statistical analysis**
The proportion of surgical AEs was calculated, weighted for the oversampling of patients admitted to a university hospital and for the oversampling of patients who died in hospital. After weighting for the sampling frame, the study
sample was representative for the Dutch population of hospitalised patients [18]. Characteristics of the surgical AEs, such as preventability, disability, classification by responsible specialty, clinical process, pathological category, causes and prevention strategies were also assessed using weights to adjust for the sampling frame. Data were analysed using SPSS 14.0 for Windows.

Results

Occurrence, preventability and nature of surgical adverse events
After weighting for the sampling frame, 64.5% of all identified AEs in the Dutch Adverse Event Study were attributable to surgical specialties of which 40.5% were judged to be preventable. Half of all surgical AEs (49.9%) resulted in no or minimal physical impairment or disability at discharge. However, 4.6% resulted in permanent disability and 5.8% contributed to death. Box 5.1 presents examples of surgical AEs identified in this study.

Box 5.1 Case descriptions of surgical adverse events

<table>
<thead>
<tr>
<th>Non preventable surgical adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumonia after thoracotomy, resulting in artificial ventilation and antibiotics.</td>
</tr>
<tr>
<td>Adverse drug (propofol and sufentanil) reaction (bronchospasm and exanthenm), resulting in extra treatment with medication.</td>
</tr>
<tr>
<td>Incisional hernia after laparotomy resulting in readmission and re-operation.</td>
</tr>
<tr>
<td>Infection tissue expander head, resulting in a readmission, operative removal and a reconstructive procedure.</td>
</tr>
<tr>
<td>Wound leakage and sepsis after colorectal anastomosis, resulting in a re-operation, IC (artificial ventilation), prolonged admission duration and repeated outpatient clinical visits.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preventable surgical adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong-site surgery with kidney transplantectomy, resulting in an extra incision of the skin.</td>
</tr>
<tr>
<td>Urosepsis after operation femur fracture caused by non-indicated CAD.</td>
</tr>
<tr>
<td>Technical inadequate hip prosthesis, resulting in two repositions and re-operations.</td>
</tr>
<tr>
<td>Inadequate nasal intubation by tonsillectomy, resulting in tear off concha, bleeding and re-operation.</td>
</tr>
<tr>
<td>Spinal anaesthesia with non-treated hypertension, resulting in hypotension, coma and contributed to death.</td>
</tr>
</tbody>
</table>
More than half of the AEs attributable to anaesthesiology, plastic surgery and orthopaedics were judged to be preventable (Table 5.1). AEs attributable to vascular surgery (33.3%), anaesthesiology (22.2%), heart/thorax surgery (19.2%), and plastic surgery (18.2%) contributed more often to permanent disability including death.

Table 5.1 Surgical AEs (n=367) by specialty and proportions with preventability, permanent disability (excluding death) or deaths

<table>
<thead>
<tr>
<th>Specialties</th>
<th>No. AEs</th>
<th>Preventable (%)</th>
<th>Permanent disability (%)</th>
<th>Deaths (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthesiology</td>
<td>9</td>
<td>60.0</td>
<td>22.2</td>
<td>0</td>
</tr>
<tr>
<td>Plastic surgery</td>
<td>6</td>
<td>54.5</td>
<td>18.2</td>
<td>0</td>
</tr>
<tr>
<td>Orthopaedics</td>
<td>41</td>
<td>52.2</td>
<td>4.3</td>
<td>4.3</td>
</tr>
<tr>
<td>Gynaecology</td>
<td>12</td>
<td>50.0</td>
<td>14.3</td>
<td>0</td>
</tr>
<tr>
<td>General surgery</td>
<td>162</td>
<td>44.9</td>
<td>1.6</td>
<td>7.9</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>3</td>
<td>40.0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dentistry/oral surgery</td>
<td>7</td>
<td>33.3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Heart/thorax surgery</td>
<td>41</td>
<td>32.0</td>
<td>7.7</td>
<td>11.5</td>
</tr>
<tr>
<td>Urology</td>
<td>21</td>
<td>30.8</td>
<td>0</td>
<td>3.8</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>14</td>
<td>26.7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>41</td>
<td>25.0</td>
<td>19.0</td>
<td>14.3</td>
</tr>
<tr>
<td>Ear, nose and throat</td>
<td>10</td>
<td>14.3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>367</td>
<td>40.5</td>
<td>4.6</td>
<td>5.8</td>
</tr>
</tbody>
</table>

* percentages were weighted for oversampling of deceased patients and of patients admitted to a university hospital

Surgical AEs were mainly related to surgical procedures (83.1%) (Table 5.2). Some surgical AEs were related to non-surgical procedures (5.5%), for instance urinary tract infection by bladder catheterisation and lung bleeding after insertion of a Swann Ganz catheter. 3.7% of the surgical AEs were drug related, such as wrong type of medication, under- or overdoses of medication, or adverse drug reactions. Surgical AEs related to ‘other clinical management’ (2.8%) were related to insufficient post operative care, for example inadequate administration of gastro-enteral feeding resulting in aspiration and drop out of liver abscess drain resulting in sepsis. Examples of diagnostic related surgical AEs (2.5%) in this study were ‘missed intra-abdominal perforation’ which resulted in a sepsis, ‘missed incarcerated inguinal hernia’, and ‘missed appendicitis’ which resulted in a readmission. Surgical AEs related to surgical procedures were less often judged to be preventable compared to surgical AEs related to other clinical procedures.
Surgical AEs by clinical procedure

<table>
<thead>
<tr>
<th>Classification</th>
<th>No. (%)</th>
<th>Preventability (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical procedures (Operative procedures)</td>
<td>292 (83.1)</td>
<td>34.7</td>
</tr>
<tr>
<td>Other procedures (e.g. central catheters, endoscopies, pacemakers, intervention radiology)</td>
<td>19 (5.5)</td>
<td>55.6</td>
</tr>
<tr>
<td>Drug (e.g. side effects, allergic reactions, anaphalaxis)</td>
<td>13 (3.7)</td>
<td>50.0</td>
</tr>
<tr>
<td>Other clinical management (including nursing and allied health care)</td>
<td>15 (2.8)</td>
<td>100</td>
</tr>
<tr>
<td>Diagnostic (e.g. missed, delayed or inappropriate diagnostic process)</td>
<td>22 (2.5)</td>
<td>100</td>
</tr>
<tr>
<td>Discharge (e.g. inappropriate discharge)</td>
<td>2 (1.2)</td>
<td>100</td>
</tr>
<tr>
<td>Other (e.g. fall)</td>
<td>4 (1.2)</td>
<td>50</td>
</tr>
<tr>
<td>Total</td>
<td>367 (100)</td>
<td>40.5</td>
</tr>
</tbody>
</table>

*percentages were weighted for oversampling of deceased patients and of patients admitted to a university hospital

The 292 AEs related to surgical procedures were classified by pathological categories and were associated with 596 injuries (Table 5.3). Most frequent injuries were inflammation/infection (39.3%); bleeding/haematoma (23.1%); injury by mechanical/physical-chemical cause (22.1%); and other functional impairment (16.5%), like urine retention, respiratory insufficiency, renal insufficiency, anuria, strangulation ileus, and dystrophy of the hand after an operation for carpal tunnel syndrome. Surgical AEs with a percentage of preventability were pressure ulcers, injury by mechanical/physical-chemical cause, fistula forming, shock, and ischemia/heart failure. Surgical AEs with injuries like shock and ischemia/heart failure contributed more often to permanent disability including death.
Table 5.3 Surgical AEs by pathological category (n=596)* and their degree of preventability and disability

<table>
<thead>
<tr>
<th>Pathological category</th>
<th>No.</th>
<th>Preventable</th>
<th>Permanent disability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Column %**)</td>
<td>(Row %**)</td>
<td>(including death)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(Row %**)</td>
</tr>
<tr>
<td>Inflammation/infection</td>
<td>136 (39.3)</td>
<td>25.7</td>
<td>11.1</td>
</tr>
<tr>
<td>Bleeding/haematoma</td>
<td>72 (23.1)</td>
<td>25.8</td>
<td>6.3</td>
</tr>
<tr>
<td>Injury by mechanical/physical-chemical cause</td>
<td>46 (22.1)</td>
<td>68.3</td>
<td>6.1</td>
</tr>
<tr>
<td>Other functional disorder</td>
<td>49 (16.5)</td>
<td>35.6</td>
<td>15.8</td>
</tr>
<tr>
<td>Accumulation/leakage of body fluids</td>
<td>46 (12.2)</td>
<td>45.5</td>
<td>14.7</td>
</tr>
<tr>
<td>Abnormal wound healing (e.g. wound dehiscence/ delayed fracture healing/pseudartrosis/stenosis)</td>
<td>39 (12.0)</td>
<td>31.3</td>
<td>6.3</td>
</tr>
<tr>
<td>Symptoms without diagnosis (e.g. fever, pain)</td>
<td>7 (4.1)</td>
<td>16.7</td>
<td>0</td>
</tr>
<tr>
<td>Fistula forming</td>
<td>18 (4.0)</td>
<td>54.5</td>
<td>9.1</td>
</tr>
<tr>
<td>Shock</td>
<td>47 (3.9)</td>
<td>54.5</td>
<td>50.0</td>
</tr>
<tr>
<td>Necrosis/infarction</td>
<td>44 (3.8)</td>
<td>40.0</td>
<td>40.0</td>
</tr>
<tr>
<td>Thrombosis/Embolism</td>
<td>25 (3.5)</td>
<td>30.0</td>
<td>40.0</td>
</tr>
<tr>
<td>Ischemia/heart failure</td>
<td>40 (2.9)</td>
<td>50.0</td>
<td>42.9</td>
</tr>
<tr>
<td>Pressure ulcers</td>
<td>8 (2.9)</td>
<td>71.4</td>
<td>0</td>
</tr>
<tr>
<td>Rejection/allergy/other immunological reaction</td>
<td>2 (1.4)</td>
<td>0.0</td>
<td>0</td>
</tr>
<tr>
<td>Other/non-specified category</td>
<td>9 (3.7)</td>
<td>40.0</td>
<td>10.0</td>
</tr>
</tbody>
</table>

* physicians could register more injuries per AE
** percentages were weighted for oversampling of deceased patients and of patients admitted to a university hospital

Causes and prevention strategies for surgical adverse events
Causal factors of surgical AEs were judged to be predominantly human (65.2%) and patient related (35.3%), and less often organisational (12.7%), and technical (4.4%) (Figure 5.1). Of all surgical AEs with organisational causal factors, 90.2% were judged to be preventable. 55.7% of all surgical AEs with human factors; 31.9% of all surgical AEs with patient related factors and 28.6% of all surgical AEs with technical factors were judged to be preventable.
Figure 5.1 Frequency of causal factors (n=456)** for surgical AEs (n=367) and preventable surgical AEs (n=150)

* percentages were weighted for oversampling of deceased patients and of patients admitted to a university hospital

** physician reviewers could register more than one causal factor per AE

The physician reviewers recommended 442 potential prevention strategies for all 150 surgical AEs that were judged to be preventable (Table 5.4). For more than 70% of the surgical AEs, quality assurance/peer review was mentioned as a direction for the prevention of these AEs. Other frequently recommended prevention strategies were training for improvement of skills (58.9%), evaluation of the current way of behaving regarding safety (51.4%), and improving procedures (40.6%).

Table 5.4 Recommended potential strategies (n=442) to avoid preventable surgical AEs (n=150)

<table>
<thead>
<tr>
<th>Potential prevention strategy [21]</th>
<th>No. preventable AEs*</th>
<th>Frequency (%)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality assurance/peer review</td>
<td>111</td>
<td>72.9</td>
</tr>
<tr>
<td>(Continuously monitoring quality and assessment of health care workers performance by individuals in the same field)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training</td>
<td>78</td>
<td>58.9</td>
</tr>
<tr>
<td>(improving (re) training programmes for skills needed)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Table 5.4 continues -
- table 5.4 continued -

<table>
<thead>
<tr>
<th>Potential prevention strategy</th>
<th>No. preventable AEs*</th>
<th>Frequency (%)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation (evaluating the current way of behaving regarding safety)</td>
<td>84</td>
<td>51.4</td>
</tr>
<tr>
<td>Procedures (improving formal and informal procedures)</td>
<td>65</td>
<td>40.6</td>
</tr>
<tr>
<td>Motivation (positive behaviour modification)</td>
<td>41</td>
<td>30.2</td>
</tr>
<tr>
<td>Information and communication (improving available sources of information, communication structures and medical record keeping)</td>
<td>33</td>
<td>17.3</td>
</tr>
<tr>
<td>Technology/equipment (e.g. redesign of technical devices)</td>
<td>11</td>
<td>9.3</td>
</tr>
<tr>
<td>Personnel (Increasing amount of personnel)</td>
<td>4</td>
<td>3.1</td>
</tr>
<tr>
<td>Upscaling (handling the problem at a higher organisational level)</td>
<td>4</td>
<td>1.8</td>
</tr>
<tr>
<td>Financial investment (Financial investments in required areas)</td>
<td>3</td>
<td>1.5</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>3.6</td>
</tr>
</tbody>
</table>

* physicians could register more prevention strategies per AE
** percentages were weighted for oversampling of deceased patients and of patients admitted to a university hospital

Discussion

Occurrence and nature of surgical adverse events
In this study, AEs attributable to surgical specialties, assessed in the Dutch Adverse Event Study, were explored in more detail. Of all AEs, 65% were attributable to surgical specialties of which 41% were considered to be preventable. 11% of all surgical AEs resulted in permanent disability including death. Previous studies also showed that surgical AEs were more common than non-surgical AEs: 51% of all AEs were attributable to surgical care in Australia to 77% in the UK [9; 10].
In this study, AEs attributable to surgical specialties were mainly related to surgical procedures (83%). Surgical interventions by their nature are associated with a degree of risk [17]. The most frequently registered injuries as a result of surgical procedures were inflammation/infection (39%), bleeding/haematoma (23%) and injury by mechanical/physical-chemical cause (22%). Of the surgical AEs that resulted in injury by mechanical/physical-chemical cause, 68% was judged to be preventable. Physician reviewers considered that an inaccurately performed procedure was a main contributing factor for injuries by puncture or perforation of other organs, like nerves, vessels and bowels. Moreover, specific techniques that are not carried out conform the state of the art resulted in AEs such as leakage and wound dehiscence. Also inadequate application of new techniques, like endoscopic procedures, and procedures that demand specific expertise and experience (vessel surgery) resulted in AEs.

Similar to the results of previous record review studies of ten years ago [13; 14], in our study infection, bleeding and injury by mechanical/physical-chemical cause form the largest group of injuries as a result of surgical AEs. The high amount of infections raises the question whether evidence-based prophylactic protocols and infection prevention guidelines have been successfully implemented [13; 14].

**Causal factors and potential prevention of surgical adverse events**

Causal factors of surgical AEs were judged to be predominantly human causes (65%) and less often organisational (13%) or technical (4%). However, almost all (90%) surgical AEs with organisational causes were judged to be preventable. According to the high percentage of human causes, the recorded potential prevention strategies to reduce surgical AEs were mainly focussed on improvement of the performance of healthcare professionals. Examples of well-known interventions are given in Box 5.2, which offer practical solutions to achieve the frequently recorded potential prevention strategies in our study.

We have not conducted an exhaustive review of the literature to identify the best practices to reduce surgical AEs. Instead, we present the commonly used interventions based on evidence-based literature (systematic reviews) and ongoing clinical trials.

Methods for *quality assurance/peer review* are patient record review, examination of all hospital deaths (necrology commission), morbidity and mortality conferences, and reporting and analysing of incidents and AEs [22-25]. The methods should be incorporated systematically in the daily work of health care providers and should be supported by the medical staff and
management. Assessment and analysis of AEs will increase the awareness for unsafe situations and will strengthen the performance of the physicians.

Box 5.2  Examples of well-known interventions to achieve the recorded prevention strategies

<table>
<thead>
<tr>
<th>Main potential prevention strategies recorded by physician reviewers (see Table 4)</th>
<th>Examples of well-known interventions to achieve the recorded prevention strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality assurance/ peer review (Continuously monitoring quality and assessment of health care workers performance by individuals in the same field)</td>
<td>Patient record review [22; 25] Systematic examination of all hospital deaths with or without autopsy results (necrology commission) Morbidity and mortality conferences [23; 24] Incident reporting [22]</td>
</tr>
<tr>
<td>Training (improving (re) training programmes for skills needed)</td>
<td>Training for improvement of skills and for implementation of new techniques (e.g. simulation training) [26-28] Better training and supervision of residents [17]</td>
</tr>
<tr>
<td>Evaluation (evaluating the current way of behaving regarding safety)</td>
<td>Multisource feedback to assess performance [29] Portfolio of competence and performance [30]</td>
</tr>
<tr>
<td>Procedures (improving formal and informal procedures)</td>
<td>Localizing specific surgical procedures and surgeries to high-volume centers [31; 38] Appropriate use of antibiotic prophylaxis to prevent surgical site infection [33; 38] Improve handwashing compliance to prevent infections [39; 40] Better application and control of existing protocols and guidelines for infection prevention (sterilization of instruments; minimum number of persons in the operation theatre; reduction of door movements during operation) [15; 32; 34]</td>
</tr>
<tr>
<td>Information and communication (improving available sources of information, communication structures and medical record keeping)</td>
<td>Operation room briefing with team communication checklist [35; 36] Application of aviation-style crew resource management to improve teamwork [37] Improvement of completeness and adequacy of patient information and record keeping [41]</td>
</tr>
</tbody>
</table>
A frequently recorded strategy in our study was more training for improvement of skills and implementation of new techniques and appropriate supervision of trainees. The risk of AEs decreases with the experience of surgeons [17]. Several studies showed that simulation training shortens the learning curve on for example real laparoscopic procedures compared to traditional training methods [26-28].

Potential interventions for the evaluation of the current way of behaving regarding safety are multisource feedback systems and using portfolios for the assessment of the competence and performance of healthcare professionals [29; 30]. Multisource feedback, using questionnaire data from patients, medical colleagues, and residents, can be used to assess key competencies such as communication skills, medical expertise, and ability to continually learn and improve [29]. Portfolio is a dossier of evidence collected over time that demonstrates a health professional’s education and practice achievements [30]. Evaluating competencies and performance of individual professionals should lead to a better performance and positive attitude to improve patient safety.

Physician reviewers indicated that potential interventions to improve procedures should focus on: concentration of certain procedures [31] and timely consultation of other specialists. With increasing subspecialisation in surgery, the need for cross referral between consultants is increased [17]. Specific procedures to reduce (post operative) infections are: consistently apply antibiotic prophylaxis and sterilization of instruments [15; 32; 33]; and better control of existing protocols and guidelines in the operation theatre (hand disinfection, number of persons in the operation theatre, number of door movements, sterilization of instruments) [34].

Interventions to promote information exchange and communication in operation theatre teams are operation theatre briefings with team communication checklists, or medical team training [35-37]. The operation theatre briefing is a preoperative time-out procedure with team communication checklists for the operation team and takes one to two minutes. The WHO developed the Surgical Safety Checklist that compromises a set of basic tasks and should be completed or confirmed prior, during or after completion of the operation and will improve the communication between all members of the surgical team [15]. Medical Team training, based on the crew resource management principle, aims to improve patient safety by optimizing teamwork in high risk environments such as operation rooms. Generally, the
focus of CRM training is on communication, decision-making, leadership and situation awareness [37]. Implementation of (a combination of) interventions may lead to more insight into unsafe situations, improvement of the safety culture and an increase of the safety in surgical care. Some interventions are already included in the training of health care professionals, but should be more focused on safety problems.

**Strengths and limitations**

In the Netherlands, a nationwide routine reporting system of complications by surgeons and surgical residents was started to get insight into the occurrence of complications in the Netherlands. However, the routine reporting system underestimates the occurrence of minor adverse outcomes compared to the retrospective record review method [19; 42]. A possible explanation is that patient records also contain information about adverse outcomes related to health care by nurses or other caregivers. Also the surgeons’ and residents’ willingness to report will determine the scale and nature of the reported complications. Another study, in the UK, showed that with incident reporting by health care workers hospital wide events like intra- and postoperative adverse outcomes were underreported compared to the record review method [22]. In general, patient record review of hospitalised patients is by far the most applied and thoroughly studied method for the assessment of the occurrence and nature of AEs [43].

The record review method has, however, some limitations. Because the record review method depends on the completeness of the information that is recorded in the patient record, the amount of identified surgical AEs in this study could be underestimated [45]. The inter-rater agreement for the judgement of AEs was fair for the assessment of AEs (κ=0.25) and their preventability (κ=0.40) [18]. Moreover, record review may not be the most accurate method to get insight into causal factors like technical and organisational factors. Because technical and organisational factors are less often reported in the patient record, they may have been underreported in this study [21].

There were also other limitations not related to the record review method. It was not possible to calculate surgical AE rates per specialty, since responsibility periods within patient admissions were not registered. The admission department gives a poor reflection of all specialties responsible for patient care and associated AEs during a admission. For this reason we chose to take into

*Chapter 5*
account all AEs attributable to surgical specialties rather than those AEs occurring in patients initially admitted to surgical departments. Moreover, the aim of the Dutch Adverse Event Study was to measure a national hospital-wide AE incidence rate. The in-depth analysis of surgical AEs from the national study is hampered by the small number of AEs for some sub categories. The results of the categories with a small number of AEs should be interpreted with caution.

**Recommendations for future research**

To get more insight into organisational and technical factors of surgical AEs, an approach that combines record review with prospective methods in which clinical staff is interviewed about the origin of the AEs, will give a more appropriate and complete insight of the route causes of AEs. The combination of record review and interviews with the clinical staff can compensate for the lack of information in patient records [44]. In future studies on the occurrence of surgical AEs, it may be interesting to register the responsibility periods for each specialty per admission to calculate AE rates per responsible specialty. Finally, not all prevention interventions mentioned in Box 5.2 are evidence-based practices or are evaluated for surgical care. Future evaluation studies should examine the effects of these potential prevention strategies and especially for surgical specialties.

**Conclusion**

Two-third of all AEs in the Dutch Adverse Event Study was attributable to surgical specialties. Potential strategies to improve surgical care should focus on better control of existing protocols and guidelines, training of health care workers and getting insight into and learn from unsafe situations and safety incidents. This may improve both the safety culture and the safety of surgical care. In reaction to the results of the national study, several stakeholders of the Dutch health care sector jointly formulated a safety action campaign to reduce the occurrence and consequences of AEs [46]. Prevention of postoperative infections is one of the aims of the campaign. Other elements of the campaign are reporting and analysing incidents, morbidity and mortality conferences, reviewing patient records, (team)training, and evaluation of the Individual Functioning of Medical Specialists (IFMS) [46].
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NVZ vereniging van ziekenhuizen, Orde van medisch specialisten (Orde), Landelijk Expertisecentrum Verpleegkundig en Verzorging (LEVV), Verpleegkundigen en Verzorgenden Nederland: patient safety campaign: prevent adverse events, work safely in Dutch hospitals (in Dutch). 2007
Appendix 5.A  Definitions and outcome measures

Description 18 screening criteria for potential adverse events [11]
1. Unplanned admission before index admission (admission reasons are related to the index admission)
2. Unplanned readmission after discharge from index admission
3. Hospital-incurred patient injury (Permanent or temporary injury obtained (acquired) during index admission)
4. Adverse drug reaction
5. Unplanned transfer from general care to (an) intensive care (unit)
6. Unplanned transfer to another acute care hospital (after unexpected deterioration of the patient)
7. Unplanned return to the operating room
8. Unplanned removal, injury or repair of organ during surgery
9. Hospital-acquired infection or sepsis
10. Other patient complication
11. Development of neurological deficit not present on admission
12. Unexpected death
13. Cardiac or respiratory arrest
14. Injury related to abortion or delivery
15. Inappropriate discharge to home
16. Dissatisfaction with care documented in the medical record
17. Documentation or correspondence indicating litigation
18. Any other undesirable outcome not covered above

The determination of an adverse event was based on three criteria [11]:
1. an unintended (physical and/or mental) injury which
2. results in temporary or permanent disability, death or prolongation of hospital stay, and is
3. caused by health care management rather than the patient’s disease

To determine whether the injury was caused by health care management or the disease process a 6-point scale was used:
1. (Virtually) no evidence for management causation
2. Slight to modest evidence of management causation
3. Management causation not likely (less than 50/50, but ‘close call’)
4. Management causation more likely (more than 50/50, but ‘close call’)
5. Moderate to strong evidence of management causation
6. (Virtually) certain evidence of management causation

Causation scores of 4 to 6 were classified as adverse events.

The degree of **preventability** of the adverse events was measured on a 6-point scale:

1. (Virtually) no evidence for preventability
2. Slight to modest evidence of preventability
3. Preventability not quite likely (less than 50/50, but ‘close call’)
4. Preventability more than likely (more than 50/50, but ‘close call’)
5. Strong evidence of preventability
6. (Virtually) certain evidence of preventability

Adverse events with a preventability score of 4 to 6 were defined as preventable.
Adverse events among hospitalised patients
Chapter 6

The inter-rater agreement of retrospective assessments of adverse events does not improve with two reviewers per patient record.

This article was accepted as:
Zegers M, De Bruijne MC, Wagner C, Groenewegen PP, Van der Wal G, De Vet HCW. The inter-rater agreement of retrospective assessments of adverse events does not improve with two reviewers per patient record. Accepted for publication in the Journal of Clinical Epidemiology.
Abstract

Objective
To evaluate the inter-rater agreement of the record review process of the Dutch Adverse Event study, which we aimed to improve by the involvement of two independent physician reviewers per record instead of one including a consensus procedure in case of disagreement.

Methods
The inter-rater agreement *within* pairs of physicians (independent review between physician A+B) and *between* pairs of physicians (independent review between physician A+B and C+D) was measured to evaluate the record review process with two physicians including a consensus procedure, with 4,272 and 119 records respectively.

Results
The inter-rater agreement *within* pairs of physicians was substantial for the determination of AEs with a kappa of 0.64 (95% CI 0.61 to 0.68). The inter-rater agreement *between* pairs of physicians was fair for the determination of AEs with a kappa of 0.25 (95% CI 0.05 to 0.45).

Conclusion
A record review process with two physicians per record including a consensus procedure to assess AEs is not more reliable than a record review process with one physician. Retrospective estimates of incidence of AEs from record review studies should be interpreted with caution. Improvement of the method is necessary for monitoring incidence of AEs over time at a national level.
Introduction

Patient record review of hospital admissions is by far the most widely applied and thoroughly studied method for measurement of patient safety [1-10]. It is a standard method by which adverse events (AEs) of clinical care and their degree of preventability are measured and it forms the basis for patient safety policy in several countries [11]. This method was proven valid to identify AEs and estimate their incidence in hospitals nationwide [2]. However, previous AE studies showed poor to moderate inter-rater agreement for the determination of AEs and their preventability [1-3;5;7-10]. Therefore, standing on the shoulders of our predecessors and keeping the method and instruments maximally comparable, we have tried to improve the inter-rater agreement of the measurement of AEs and their preventability within the Dutch Adverse Event study.

Inter-rater agreement refers to the consistency of ratings or to the ability of various raters to reach the same conclusion about a specific case [2; 12]. Strategies to enhance inter-rater agreement are standardisation of the measurement and consensus procedure between the reviewers [12; 13]. To improve the inter-rater agreement for the assessment of AEs in the Dutch Adverse Event study all records were independently reviewed by two physicians instead of one and in case of disagreement, the two physicians discussed and reconsidered their review to obtain consensus. We hypothesized that the involvement of two physicians per patient record including a consensus procedure would give a more reliable assessment of AEs and their preventability. Within the Dutch Adverse Event Study a reliability study was conducted to evaluate the inter-rater agreement of the patient record review. The objective was twofold. First, to examine the inter-rater agreement of the original review by two independent physician reviewers before the consensus procedure. This is called the inter-rater agreement within pairs of physicians (physician A versus B). Second, to examine the inter-rater agreement of the complete record review process, including the consensus procedure, with a second pair of physicians. This is called the inter-rater agreement between pairs of physicians (physician A+B versus C+D). The Harvard Medical Practice Study in the US and the Australian study on the occurrence of AEs also involved two physician reviewers and the Australian study also used a consensus procedure in case of disagreement between the two physicians [3; 10]. However these studies only evaluated the inter-rater agreement of the original review within pairs of physicians (physician A and B) and not of the ultimate
decisions made by a pair of physicians. To gain insight into the reliability of the record review procedure with two physicians per patient record including a consensus procedure in case of disagreement, the inter-rater agreement between pairs of physicians is more relevant and has not yet been studied thoroughly.

Methods

Study design and setting
A retrospective patient record review study was conducted to determine the incidence and preventability of AEs among hospitalised patients in the Netherlands [14]. The method of this study was based on a protocol and instruments originally developed by the Harvard Medical Practice Study. They studied the incidence of AEs in New York state hospitals in 1984, based on analysis of information in patient records [3; 15]. This method, with modifications, was used in subsequent studies in Australia, the United Kingdom, New Zealand, the United States, Denmark, France and Canada [1; 5; 8; 10; 15-19]. This reliability study was conducted as part of the Dutch Adverse Event study. We have described the design and method of our main study in more detail elsewhere [14]. A random sample of 7,926 patient records, originating from 21 randomly selected Dutch hospitals, was reviewed using a three-stage retrospective patient record review process by trained nurses and physicians between August 2005 and October 2006 (Figure 6.1) [20]. The sample of records (n=7,926) was stratified for discharged and deceased hospital patients: 3,943 records of discharged patients and 3,983 records of deceased patients in 2004. A large subsample of deceased hospital patients was included to determine the occurrence of potentially preventable deaths in hospitals more precisely than in previous studies [20].

Original record review process
In the first stage of the three-stage review process, a nurse screened the patient records by using 18 screening criteria indicating potential AEs. One or more criteria were fulfilled in 4,317 patient records, of which 65% were from deceased patients and 35% were from discharged patients. These were forwarded to the second stage of the review process for a medical review by two physicians independently to determine whether an AE had occurred and whether the AE had been preventable. An adverse event (AE) was defined as an
unintended injury among hospitalised patients that results in disability, death or prolonged hospital stay, and was caused by health care management. Preventability of an AE is defined as health care that fell below the current level of expected performance for practitioners or systems (Appendix 6.A) [1; 5; 10; 15].

The patient records were independently reviewed by two physicians of the same specialty (general internists, general surgeons, neurologists or paediatricians). The physician reviewers had to focus on their own expertise. Records with, for example, screening criteria related to surgical events were reviewed by two surgeons. Moreover, records with screening criteria related to multiple specialties were reviewed by two different specialists.

In case of disagreement about the presence of an AE and/or degree of preventability between the two independent reviews of the physicians, they started a consensus procedure (stage 3). In this consensus procedure the physicians considered and discussed both reviews and reconsidered their reviews to obtain consensus. When they failed to reach agreement, a third trained reviewer gave a final judgement based on information of the first two reviews [14]. In 663 hospital admissions one or more adverse events were identified (Figure 6.1) [20].

Reliability study

**Measurement inter-rater agreement within pairs**

The inter-rater agreement of the original review between physician A and B (before consensus procedure), defined as the inter-rater agreement within pairs of physicians, was determined for 4,272 records; 45 records were excluded, because the AEs had occurred outside the participating hospitals (thus in another hospital) or were not related to the sampled admission (Figure 6.1).

**Measurement inter-rater agreement between pairs**

To assess the inter-rater agreement of the complete review process by pairs of physicians, including the consensus procedure and if applicable a third review, a stratified random sample of 119 records was selected for an independent review by a second pair of physicians (physician C and D) (Figure 6.1). Physician C and D independently reviewed the selected records and in case of disagreement, they started a consensus procedure and if applicable, a third reviewer gave a final judgement. Only records reviewed by two internists or two surgeons were selected.
Figure 6.1 Flow chart of the record review process

* 45 records were excluded, because the AEs had occurred outside the participating hospitals (thus in another hospital) or were not related to the sampled admission
** Consensus procedure about the presence of an AE and/or preventability

Because the inter-rater agreement may vary for records that did and did not need a consensus procedure to decide about the presence of AEs, the sample was stratified for records with or without a consensus procedure between
physician A and B. As the majority of records did not show an AE, for efficiency reasons we aimed to include about an equal number of records with and without an AE in the sample (Table 6.1).

<table>
<thead>
<tr>
<th>Strata</th>
<th>Result review process physician A and B</th>
<th>Evaluation agreement within pairs: all stage 2 records (n=4,272)</th>
<th>Evaluation agreement between pairs: stratified sample (n=119)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AE - C-</td>
<td>No AE was found; direct agreement</td>
<td>81.4%</td>
<td>38.6%</td>
</tr>
<tr>
<td>AE + C-</td>
<td>AE was found; direct agreement</td>
<td>9.8%</td>
<td>28.6%</td>
</tr>
<tr>
<td>AE - C+</td>
<td>No AE was found; consensus procedure* (and if applicable third review) was necessary</td>
<td>3.1%</td>
<td>9.2%</td>
</tr>
<tr>
<td>AE + C+</td>
<td>AE was found; consensus procedure* (and if applicable third review) was necessary</td>
<td>5.7%</td>
<td>23.5%</td>
</tr>
</tbody>
</table>

* consensus procedure between physician A and B about the presence of an adverse event

**Physician reviewers and training**

In this study 55 trained physicians reviewed records in several different hospitals (average 5.2 hospitals per physician). The eligibility criteria for physicians to act as reviewer were: more than ten years post graduate general clinical experience, good reputation among colleagues, no longer than five years retired, experience or affinity with analysis of incidents, complaints and errors of clinical care, and availability for at least one day per week.

The physicians followed a one-day training in small groups (max 12 participants), led by one researcher and one experienced physician. During the training, the study protocol, definitions and electronic review forms were explained and examples of (preventable) AEs were discussed. The reviewers practised with cases and the review forms and they were provided with a review manual in which the research protocol, instruments and definitions were defined [14].

During the study, the physicians could consult an expert panel of medical specialists for questions about accepted clinical practice. After one month of reviewing, the reviewers had a half-day training session to discuss their problems concerning the review process and reviewers were updated with the latest insights about the review process. These training sessions were
organised frequently during data collection. The discussed problems were collected and noted in a regularly updated Frequently Asked Questions (FAQ) document, which was spread via post and mail to all reviewers.

Statistical analysis
The judgement about the presence of an AE and degree of preventability were measured on a six-point scale (Appendix 6.A). We used a score of at least four (>50% chance that medical management caused the AEs) to indicate the presence of AEs. For preventability we used a score two or higher (at least slight to modest evidence that the AE was preventable) [20]. The inter-rater agreement within pairs of physicians (physician A and B) and between pairs of physicians (physician A + B and C + D) was measured for the determination of AEs and for the determination of the degree of preventability of the AEs. Because no preventability score could be given for records without AEs, the inter-rater agreement for preventability was only estimated for records in which both (pairs of) physicians found an AE. The inter-rater agreement between pairs of physicians was adjusted for the stratified sampling procedure with respect to the oversampling of records with AEs and the oversampling of the presence of a consensus procedure.

The inter-rater agreement was expressed as a kappa (κ) statistic with 95% confidence intervals (CIs) and as the percentage of records for which there was agreement. A κ-value between 0.00-0.20 was classified as ‘slight’; between 0.21-0.40 as ‘fair’; between 0.41-0.60 as ‘moderate’; 0.61-0.80 as ‘substantial’; and between 0.81-1.00 as ‘almost perfect’ [21].

Data were analysed using SPSS 14.0 for Windows.

Results

Inter-rater agreement within pairs of physicians
The inter-rater agreement within pairs of physicians (physician A and B) was determined for 2,757 (65%) records of deceased patients and for 1,515 (35%) records of discharged patients. The inter-rater agreement for the determination of AEs was substantial (κ = 0.64, 95% CI 0.61 to 0.68). Also for the determination of their preventability the inter-rater agreement was substantial (κ = 0.72, 95% CI 0.66 to 0.79) (Table 6.2).

Physician A and physician B separately determined 592 and 621 AEs before a consensus procedure (Table 6.2). After discussion and reconsideration of their
reviews in a consensus procedure more AEs were determined (n=663). Figure 1 shows that 373 (213+105+55) records were discussed in a consensus procedure between physician A and B about the determination of AEs and/or degree of preventability or were finally judged by a third physician reviewer. This procedure resulted in 243 (213+30) AEs. Of all detected AEs 37% (243/663) were determined after consensus procedure.

Table 6.2  Agreement and kappa statistic of duplicate review process within pairs of physicians (physician A+B)

<table>
<thead>
<tr>
<th>Physician A</th>
<th>Adverse event</th>
<th>Preventable adverse event</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Absent</td>
<td>Present</td>
</tr>
<tr>
<td>Absent</td>
<td>3,479</td>
<td>201</td>
</tr>
<tr>
<td>Present</td>
<td>172</td>
<td>420*</td>
</tr>
<tr>
<td>Total</td>
<td>3,651</td>
<td>621</td>
</tr>
<tr>
<td>Agreement (%)</td>
<td>91.3</td>
<td></td>
</tr>
<tr>
<td>Kappa statistic (95% CI)</td>
<td>0.64 (0.61-0.68)</td>
<td>0.72 (0.66-0.79)</td>
</tr>
</tbody>
</table>

* the inter-rater agreement for preventability was estimated in records in which both physicians found an AE. For 3 cases the preventability score was missing

Inter-rater agreement between pairs of physicians
The inter-rater agreement between pairs of physicians (physician A+B and C+D) was determined for 77 (65%) records of deceased patients and for 42 (35%) records of discharged patients. The inter-rater agreement was fair for determination of presence of AEs (κ = 0.25, 95% CI 0.05 to 0.45) and for determination of preventability of AEs (κ = 0.40, 95% CI 0.07 to 0.73) (Table 6.3). The second pair of physicians determined less AEs (n=40) than the first pair of physicians (n=62) (Table 6.3). For 46 records there was no agreement between the pairs of physicians. For 21 (46%) of these records a consensus procedure was needed between physician A and B.

The inter-rater agreement for AE determination and their preventability between pairs of physicians was lower than the inter-rater agreement within pairs of physicians. The kappa value for the AE determination was lower than the kappa value for the determination of the preventability of AEs.
Table 6.3 Agreement and kappa statistic of duplicate review process between pairs of physicians (physician A+B and C+D)

<table>
<thead>
<tr>
<th>Physician A+B</th>
<th>Adverse event</th>
<th>Preventable adverse event</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Absent</td>
<td>Present</td>
</tr>
<tr>
<td>Absent</td>
<td>45</td>
<td>12</td>
</tr>
<tr>
<td>Present</td>
<td>34</td>
<td>28*</td>
</tr>
<tr>
<td>Total</td>
<td>79</td>
<td>40</td>
</tr>
<tr>
<td>Agreement (%)</td>
<td>75.6**</td>
<td></td>
</tr>
<tr>
<td>Kappa statistic (95% CI)</td>
<td>0.25 (0.05-0.45)**</td>
<td>0.40 (0.07-0.73)</td>
</tr>
</tbody>
</table>

* the inter-rater agreement for preventability was estimated in records in which both pairs of physicians found an AE. For 1 case the preventability score was missing
** adjusted for sampling frame

Subgroup analysis
To get an indication of determinants for high or low agreement for the assessment of AEs we performed a post-hoc analysis of the inter-rater agreement separately for subgroups of records. The inter-rater agreement within pairs of physicians was higher for records of discharged patients compared to records of deceased patients. For records reviewed by two neurologists the inter-rater agreement within pairs of physicians was higher compared to records reviewed by two internist, surgeons or paediatricians. The inter-rater agreement within pairs of physicians was higher for records that were reviewed by two physicians who reviewed both many records compared to records reviewed by physicians who both reviewed less records. However, all these differences in kappa values were not statistically significant (Table 6.4).

We also analysed the inter-rater agreement between pairs of physicians for subgroups of records. The inter-rater agreement between pairs of physicians was also higher for records of discharged patients ($\kappa = 0.55, 95\% \text{ CI } 0.16$ to $0.94$) compared to records of deceased patients ($\kappa = 0.14, 95\% \text{ CI } -0.09$ to $0.36$). For records reviewed by two internists the inter-rater agreement was higher ($\kappa = 0.27, 95\% \text{ CI } -0.01$ to $0.55$) compared to records reviewed by two surgeons ($\kappa = 0.17, 95\% \text{ CI } -0.14$ to $0.47$). The inter-rater agreement between pairs of physicians for records with a consensus procedure between physician A and B was lower ($\kappa = 0.07, 95\% \text{ CI } -0.43$ to $0.58$) than the records without a consensus procedure ($\kappa = 0.23, 95\% \text{ CI } 0.01$ to $0.45$). However, most of these kappa values
had wide confidence intervals because of the small number of records in these sub group analyses, meaning that these results were not statistically significant.

Table 6.4  Inter-rater agreement within pairs of physicians for AE determination for subgroups of records (n=4,272)

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>N</th>
<th>Kappa (95% CI)</th>
<th>Agreement (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records of discharged patients</td>
<td>1,515</td>
<td>0.68 (0.62-0.73)</td>
<td>92.3</td>
</tr>
<tr>
<td>Records of deceased patients</td>
<td>2,757</td>
<td>0.62 (0.58-0.67)</td>
<td>90.7</td>
</tr>
<tr>
<td>Records reviewed by 2 internists (n=25)</td>
<td>2,757</td>
<td>0.64 (0.59-0.68)</td>
<td>91.7</td>
</tr>
<tr>
<td>Records reviewed by 2 surgeons (n=20)</td>
<td>1,011</td>
<td>0.63 (0.57-0.70)</td>
<td>88.9</td>
</tr>
<tr>
<td>Records reviewed by 2 neurologists (n=5)</td>
<td>372</td>
<td>0.77 (0.65-0.88)</td>
<td>96.0</td>
</tr>
<tr>
<td>Records reviewed by 2 paediatricians (n=5)</td>
<td>59</td>
<td>0.25 (-0.19-0.69)</td>
<td>91.5</td>
</tr>
<tr>
<td>Records reviewed by mix of 2 physicians</td>
<td>73</td>
<td>0.56 (0.32-0.78)</td>
<td>84.9</td>
</tr>
<tr>
<td>Records reviewed by 2 physicians who reviewed ≥143</td>
<td>2,738</td>
<td>0.68 (0.64 - 0.73)</td>
<td>92.7</td>
</tr>
<tr>
<td>Records reviewed by 2 physicians who reviewed &lt;143</td>
<td>377</td>
<td>0.63 (0.51 - 0.75)</td>
<td>91.8</td>
</tr>
</tbody>
</table>

* the median number of reviewed records per physician was 143; 1,157 records were excluded from this analysis because they were reviewed by a pair of physicians who reviewed more and less than 143 records

Discussion

We hypothesized that the involvement of two physicians per patient record, including a consensus procedure in case of disagreement between their reviews, would improve the reliability of the review process to assess AEs. However, the inter-rater agreement of the complete medical review process (inter-rater agreement between pairs of physicians), including the consensus procedure, was only fair, although the inter-rater agreement within pairs of physicians was substantial.

More consensus procedures during the study between the same physicians has probably led to more simultaneous reviews which increased the inter-rater agreement within pairs of physicians. The Dutch Adverse Event study measured the incidence of AEs at a national level. For geographical reasons, physicians often reviewed in the same region and hospitals. After a number of independently reviewed records, physicians had consensus procedures to
obtain consensus in case there was disagreement. If physicians reviewed in the same hospital, they may often have had consensus procedures with the same colleagues. The second pair of physicians (physician C+D) reviewed in another region and had seldom or never consensus procedures with physicians of the first pair (physician A+B). The within pair consensus procedure produced a pair-specific improvement in agreement but not in overall reliability between pairs of physicians who were part of different discussions. It even had negative consequences for the inter-rater agreement between pairs of physicians. Perhaps the consensus procedure did not improve the inter-rater agreement of assessment of AEs, because there was not enough mixture of reviewers within and across pairs. A possible explanation for the fact that a consensus procedure did not improve the assessment is that for a group judgement task (in this study the discussion between the two physicians during a consensus procedure), discussion is primarily used as a justification for the members’ original positions rather than contributing any input to a group decision [22]. However, we did not find dominant physician reviewers who convinced other physician reviewers more often during consensus procedures. The physician reviewers evaluated the double review procedure and the consensus procedure to be meticulous and instructive. However, this comfort is deceptive and may lead to unwarranted confidence in the result [22].

The results also showed that more AEs were found after the consensus procedure than with two independent reviews by the two physicians. One-third of all AEs (37%) were determined using a consensus procedure about the presence of AEs and/or their preventability. This implies that it was hard for the physician reviewers to judge about the presence of AEs and that physicians were more reluctant in their judgement without support of a collegial review.

Another finding was the higher kappa value for the assessment of preventability than for the assessment of AEs. An explanation is that the inter-rater agreement of preventability could only be estimated for records in which both (pairs of) physicians found an adverse event. Another explanation is that in the Dutch study the threshold for preventability was two and higher (Appendix 6.A). Previous studies that maintained four and higher as a threshold for preventability scores showed lower kappa values for the assessment of preventability.

Poor inter-rater agreement could be caused by a lack of information or knowledge necessary to appropriately determine AEs [23]. Judgements require not only up to date clinical knowledge, but also consideration of standards of
care and the recognition of distinction between adverse events and unintended outcomes caused by the disease or patient condition [24]. The determination of AEs and their preventability in this study is based on a structured implicit method that relies on expert judgement. The structured part is that reviewers are guided in determining AEs and their preventability. The review is, however, implicit in that the reviewers are asked to judge on basis of relatively uncodified knowledge, held in their minds and perhaps tailored to the circumstances of a specific case [25]. The measurement procedure in implicit review requires the reviewers to form their criteria and apply them, and thus a source of variability is included in the measurement of reliability. Explicit methods for AEs assessment based on clearly defined criteria showed higher inter-rater agreement than implicit methods [25]. However, explicit methods are only applicable in the case of selected, homogeneous samples of cases. In the Dutch Adverse Event study, admissions were selected hospital-wide with a wide variation of diagnosis and treatments. Many hospital patients suffer from multiple and complex diseases and need complex treatment. A “gold standard” on good clinical practice is often lacking for each unique individual patient in his context. In addition, the AEs showed a wide range of origins and outcomes. So even if the standardised review process was perfectly applied by all reviewers, one would still expect a certain amount of disagreement about presence of AEs.

Poor inter-rater agreement could also be caused by lack of review experience. The inter-rater agreement was higher for records reviewed by physicians with more experience (assessed by the number of reviewed records) compared to records reviewed by physicians with less experience. On average, a small group of neurologist (n=5) reviewed more records per reviewer than the group internists (n=25) or surgeons (n=20). The inter-rater agreement of records reviewed by neurologists was higher than the inter-rater agreement of records reviewed by internists or surgeons. The judgement about the presence of AEs probably became more standardised within a smaller group of reviewers.

Low inter-rater agreement may imply an over- or underestimation of AEs in the national study on the occurrence of AEs in Dutch hospitals. Policy makers, hospital managers and health care workers should be aware of this and interpret the results with caution. The moderate reliability of the review process is a well known problem of record review studies to identify AEs and their preventability, in which kappa values ranged from 0.2 to 0.6 [3; 5; 7; 9; 10]. The Harvard Medical Practice Study and the Australian study also involved
two physicians for the medical review [3; 10]. They found a kappa value of 0.61 and 0.55 for the AE identification, respectively. However, these studies only evaluated the inter-rater agreement within pairs of physicians. In our study the inter-rater agreement within pairs of physicians was substantially higher than the inter-rater agreement between pairs of physicians. Thus, the inter-rater agreement presented in the previous studies limited to within pair agreement between two physicians could be an overestimation. However, the value of kappa depends upon the prevalence of AEs [26; 27]. Good care, meaning low AE rates, is likely to be associated with lower values of kappa [25]. This impairs comparison of kappa values between populations.

Our study had some limitations. We included more patient records of deceased patients than patient records of discharged patients in the reliability study. The proportion deceased and discharged patients in the Dutch hospital population is 3% versus 97% and in the sample for the determination of the inter-rater agreement between pairs of physicians 65% versus 35%. The post-hoc analyses showed that the inter-rater agreement for records of discharged patients is much better than for records of deceased patients. Therefore the kappa values of the inter-rater agreement between physicians may be underestimated in this study. However, because of the small number of records in the subgroup analysis for discharged and deceased patients and the wide 95% confidence intervals, we refrained from adjustment for the oversampling of deceased patients.

Secondly, we selected 119 records to evaluate the inter-rater agreement between pairs of physicians including consensus procedure. The number of records was too small for appropriate analysis of the inter-rater agreement for subgroups of records.

Finally, we involved 55 physicians, which is more than in other studies. The more the heterogeneity in the raters and the conditions studied, the lower the reliability will be [6]. Table 6.4 showed that the inter-rater agreement for the internists (n=25) was lower than the inter-rater agreement for the 5 neurologists who reviewed all records with neurological events. Also the inter-rater agreement for physicians who reviewed more records was better than the inter-rater agreement for physicians who reviewed less records. However, for logistic reasons, many raters will be needed to estimate the incidence of AEs at a national level.
The involvement of a second physician and implementation of a consensus procedure did not improve the reliability of the patient record review method for the measurement of AEs. In future record review studies on the occurrence of AEs, one physician reviewer per record may be considered and makes the study much cheaper.

The suboptimal reliability of patient record review to identify AEs should be further improved in order to monitor patient safety in hospitals and hospital departments over time at national level. To improve the reliability a more explicit method based on specified and detailed checklists (using standards) for specific departments or patient groups may offer a solution. An approach which combines record review with prospective methods, in which clinical staff is interviewed about the origin of the AE, may also help to improve the inter-rater agreement to assess AEs. The team of physicians could be extended with more specialists from different disciplines, e.g. cardiologists and neurosurgeons. However, the overall number of reviewers should be reduced in order to increase the experience per reviewer and to facilitate intensive training and standardisation of the process. A wider spread of reviewers over hospitals across the country may help to avoid artificial enlargement of the inter-rater agreement within pairs of physicians. Also more training sessions during the study with all physician reviewers together should be organised devoted to comparison of reviews to standardise the review process and to enhance the overall inter-rater agreement.

**Conclusion**

Although judgement of presence of AEs is difficult, retrospective patient record studies currently offer the best method available to assess the incidence of AEs and their preventability, nature and types [6]. The results of record review studies provide urgently needed insight in the current state of patient safety and possibilities for improvement of patient safety and are therefore generally highly appreciated.

Involvement of two physicians per patient record and consensus procedure in case of disagreement between physicians did not improve the inter-rater agreement of patient record review for the assessment of AEs. However, a record review process with two physician reviewers per record and a consensus procedure led to more reported AEs than a record review process with only one physician reviewer per record. If the aim is to investigate quality
improvement, two reviewers may be preferred over one, to maximize the amount of information for quality improvement. But for routine assessment of AEs, one physician reviewer per record may be considered and makes the assessment of AEs more efficient and cheaper. Retrospective estimates of incidence data of AEs should be interpreted with caution. Improvement of record review is necessary for monitoring incidence of AEs over time at a national level.
References


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Adverse events among hospitalised patients


Appendix 6.A  Definitions and outcome measures [14; 20]

Description **18 screening criteria** for potential adverse events

1. Unplanned admission before index admission (admission reasons are related to the index admission)
2. Unplanned readmission after discharge from index admission
3. Hospital-incurred patient injury (Permanent or temporary injury obtained (acquired) during index admission)
4. Adverse drug reaction
5. Unplanned transfer from general care to (an) intensive care (unit)
6. Unplanned transfer to another acute care hospital (after unexpected deterioration of the patient)
7. Unplanned return to the operating room
8. Unplanned removal, injury or repair of organ during surgery
9. Hospital-acquired infection or sepsis
10. Other patient complication
11. Development of neurological deficit not present on admission
12. Unexpected death
13. Cardiac or respiratory arrest
14. Injury related to abortion or delivery
15. Inappropriate discharge to home
16. Dissatisfaction with care documented in the medical record
17. Documentation or correspondence indicating litigation
18. Any other undesirable outcome not covered above

The determination of an **adverse event (AE)** was based on three criteria:

1. an unintended (physical and/or mental) injury which
2. resulted in temporary or permanent disability, death or prolongation of hospital stay, and is
3. **caused by health care management** rather than the patient’s disease.

To determine whether the injury was caused by health care management or the disease process a 6-point scale was used:

1. (Virtually) no evidence for management causation
2. Slight to modest evidence of management causation
3. Management causation not likely (less than 50/50, but ‘close call’)
4. Management causation more likely (more than 50/50, but ‘close call’)

Adverse events among hospitalised patients
5  Moderate to strong evidence of management causation
6  (Virtually) certain evidence of management causation

The degree of **preventability** of the AEs was measured on a 6-point scale:
1  (Virtually) no evidence for preventability
2  Slight to modest evidence of preventability
3  Preventability not quite likely (less than 50/50, but ‘close call’)
4  Preventability more than likely (more than 50/50, but ‘close call’)
5  Strong evidence of preventability
6  (Virtually) certain evidence of preventability
Adverse events among hospitalised patients
Chapter 7

Adequacy of patient records

An indicator of the quality of care or a source of bias in retrospective patient safety studies?

This article was submitted as:
Zegers M, De Bruijne MC, Spreeuwenberg P, Wagner C, Groenewegen PP, Van der Wal G. Adequacy of patient records: an indicator of quality of care or a source of bias in retrospective patient safety studies?
Abstract

Background
Patient record review of hospitalised patients is by far the most applied and thoroughly studied method to assess adverse events in hospitals. Since the assessment of adverse events with record review relies exclusively on data from patient records there is a serious risk for information bias.

Objectives
To assess the relation between the assessment of adverse events and the presence of record components and the adequacy of record contents.

Methods
This study was part of the Dutch Adverse Events Study in which 7,926 hospital admissions of 21 Dutch hospitals were analysed with a structured record review method. The occurrence of adverse events, the availability of record components and the quality of the record contents (completeness, readability and adequacy of the recorded information) were determined. Their association was analysed using multilevel logistic regression analyses.

Results
The absence of record components was associated with lower adverse event rates, suggesting that missing records components lead to an underestimation of adverse events. However, inadequacy of record contents was associated with higher adverse event rates, implying that the quality of record contents is associated with the quality of care.

Conclusion
To improve patient safety, the availability of patient information and the quality (completeness, adequacy, accessibility and exchange) of recorded information in patient records needs to be improved and standardised. This will benefit both the quality of the health care process and the monitoring of patient safety.
Introduction

The primary aim of recording information in patient records is to support the delivery of good health care. Patient records support clinical decision-making and contribute to the communication between health care workers and to the continuity of care. It is an important source for patient information for health care workers, like residents, physicians asked for consultation and physicians on call. Thereby, it is also a valuable source for scientific research, quality assurance and transparency of the delivered care [1]. Structured patient record review of hospital admissions is by far the most widely applied and thoroughly studied method to assess patient safety in hospitals [2-8]. In several retrospective record review studies, patient records have been systematically reviewed to estimate the occurrence of adverse events and to better understand potential causes and contributory factors [9-17].

Since the assessment of adverse events with record review relies exclusively on data from patient records there is a serious risk for information bias. The diligence with which information is recorded may influence the visibility of adverse events. Clinicians of high diligence may record more data and thereby expose themselves to detection of more adverse events [18]. Incomplete, inadequate, illegible, or untraceable information may make it more difficult to detect adverse events and may thus be associated with lower rates of adverse events and could therefore bias the results of retrospective record review studies. On the other hand, poor adequacy of patient records may be a cause or a consequence of poor quality of care and may thus be associated with higher rates of adverse events.

In the Dutch Adverse Event Study, the presence and quality of the documented information in the patient records was assessed in detail. In this article we investigated:

1 the availability of record components and the quality of recorded information in the records reviewed within the Dutch Adverse Event Study;
2 the variation in the quality of the records between hospitals and between hospital departments;
3 the association between the occurrence of adverse events and the availability of patient record components and the quality of recorded information.
Methods

Study design and setting
We have performed a retrospective patient record review study in a random sample of 21 Dutch hospitals: 4 university, 6 tertiary teaching and 11 general hospitals. From each hospital, we randomly selected 200 admissions (>24 hours stay) of discharged patients and 200 admissions of deceased hospital patients in 2004 (or less if the total of patients who died in 2004 was lower). The study was carried out between August 2005 and October 2006. We selected admissions of 2004 to obtain a complete overview of the patient information, including a 1-year period after discharge or death of the patient. The design and methods of this study are described in more detail elsewhere [19].

Structured review of patient records for the assessment of adverse events
The nursing and medical records of the sampled admissions were reviewed by a team of 66 trained nurses and 55 trained physicians with a structured record review process. The reviewers never reviewed in hospitals where they have ever been employed. In the first stage, a nurse screened the patient records by using 18 screening criteria indicating potential adverse events. In the second stage, two physicians independently reviewed the patient records with one or more positive screening criteria. Based on a standardised procedure they determined the presence of adverse events. An adverse event was defined as an unintended injury among hospitalised patients that results in disability, death or prolonged hospital stay, and was caused by health care management [19]. In total, 7,926 patient records were reviewed. The physicians identified one or more adverse events in 663 hospital admissions [20].

Assessment of adequacy of patient records
In the first stage of the review process, the nurses assessed the presence of record components and the quality of the record contents (including completeness, readability and adequacy of the recorded information) of the sampled patient records, existing of the nursing record (with the nursing notes, physician orders and if applicable the medication list) and the medical record (with the medical notes, report of medical history and physical examination, discharge letter, and if applicable the procedure reports, diagnostic imaging results and laboratory/pathology-anatomy test results). Finally, the nurses gave an overall report mark between 1 and 10 for the nursing record (n=7,926).
In the second stage of the review process, the physician reviewers assessed the adequacy of the medical records that were positive for one of the screening criteria (n=4,317) and registered inadequacies such as ‘the admission reason was not clearly described’, and ‘lack of clarity regarding decisions and changes in policy’. Finally, the physicians gave an overall report mark between 1 and 10 for the medical record.

**Statistical analysis**

Descriptive statistics about the availability and quality of the patient record components were analysed using SPSS 14.0. To assess the variation in the overall quality of the nursing and medical record between hospitals and between hospital departments, a multilevel linear regression model was estimated with the overall report mark (range from 1 to 10) for the nursing and the medical record as outcome variable. Intra class correlations (ICCs) were calculated to express the variation in the report mark of the nursing and medical record. The variances were tested for statistical significance using a one sided Wald-test [21; 22].

The association between adverse events and the availability of record components and the quality of the record contents was analysed with multivariate logistic multilevel regression analysis with a random intercept at hospital and hospital department level and with the presence of adverse events (yes/no) in the patient record as a binominal outcome variable. The independent variables were the availability of record components (binomial), the adequacy of the record contents (binomial), and an overall report mark for the nursing and medical record. The logistic multilevel model was adjusted for several covariates: age, discharge status (deceased or discharged), admission urgency (elective, urgent or transfer from another hospital), readmission (yes/no), and hospital type (university, medical tertiary teaching or general hospitals). The contribution of the availability and adequacy of the record components and the overall report mark of the patient record to the occurrence of adverse events was expressed with odds ratio’s (ORs) with 95% confidence intervals (CIs). The multilevel analyses were carried out using MLwiN 2.0 software.
Results

Presence and adequacy of the patient record components reviewed by nurses

The nurse reviewers registered that of all 7,926 patient records in 108 (1%) patient records the nursing record and in 104 (1%) records the medical record were unavailable (Table 7.1). These patient records were however included in the study, because the nurse and physician reviewers noticed that there was enough information for a good record review to judge about the presence of adverse events.

In 79% of the patient records the medication list was available. In some hospitals, the medication lists were archived at the hospital pharmacist department after discharge and for logistic reasons these medication lists were not used in the review process. However, information on drugs prescribed and used by the patient was also available in the nursing progress notes, the medical record and discharge letter.

Table 7.1 Presence of patient record components and inadequacy of record content assessed by nurse reviewers

<table>
<thead>
<tr>
<th>Record components</th>
<th>Present (%)</th>
<th>Inadequate (%)</th>
<th>Illegible (%)</th>
<th>Incomplete (%)</th>
<th>Other (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing record (n=7,926)</td>
<td>98.6</td>
<td>9.6</td>
<td>nm</td>
<td>nm</td>
<td>nm</td>
</tr>
<tr>
<td>Physician orders</td>
<td>92.5</td>
<td>10.1</td>
<td>2.4</td>
<td>5.3</td>
<td>2.4</td>
</tr>
<tr>
<td>Medication list (if applicable)</td>
<td>78.8</td>
<td>13.9</td>
<td>1.2</td>
<td>10.7</td>
<td>2.0</td>
</tr>
<tr>
<td>Medical record (n=5,171)*</td>
<td>98.7</td>
<td>23.4</td>
<td>7.7</td>
<td>14.8</td>
<td>0.9</td>
</tr>
<tr>
<td>Report of medical history and physical examination at admission</td>
<td>80.5</td>
<td>12.4</td>
<td>3.9</td>
<td>7.6</td>
<td>0.9</td>
</tr>
<tr>
<td>Discharge letter</td>
<td>86.9</td>
<td>5.2</td>
<td>nm</td>
<td>nm</td>
<td>nm</td>
</tr>
<tr>
<td>If applicable:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure reports</td>
<td>82.0</td>
<td>2.3</td>
<td>nm</td>
<td>nm</td>
<td>nm</td>
</tr>
<tr>
<td>Diagnostic imaging results</td>
<td>72.9</td>
<td>1.2</td>
<td>nm</td>
<td>nm</td>
<td>nm</td>
</tr>
<tr>
<td>Laboratory/pathology-anatomy reports/test results</td>
<td>79.9</td>
<td>2.3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

nm = not measured

* the nurses reviewed the adequacy of 5,171 medical records. In case the nurses found enough screening criteria in the nursing record, they did not screen the whole medical record.
The nurse reviewers judged that 23% of the medical records and 10% of the nursing records were inadequate. The inadequate medical records were described as incomplete (15%) and illegible (8%). In 10% of all patient records the physician orders and in 14% the medication list was inadequate. Documentation deficiencies related to the physician orders and medication list were for example: not signed by the physician; documentation was unclear and disorderly; or the medication list was handwritten. In 12% of the patient records, the report of medical history and physical examination at admission was inadequate, because for example: the patient was not approachable, only a preoperative screening was done, or only a screening at the emergency department was available.

Table 7.2 shows that the absence of record components was negatively associated with the occurrence of adverse events. This finding was significant for the presence of the nursing record, physician orders and laboratory/pathology-anatomy test results. Inadequacy of patient record parts was positively associated with adverse events. Thus, inadequate patient information was associated with more adverse events. This finding was significant for the adequacy of the discharge letter.

Table 7.2  Association between absence and inadequacy of patient record components assessed by nurse reviewers and the presence of adverse events assessed by physician reviewers, analysed with multilevel logistic analysis and corrected for covariates

<table>
<thead>
<tr>
<th>Record components</th>
<th>Absence (%)</th>
<th>OR (95% CI)</th>
<th>Inadequate (%)</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing record (n=7,926)</td>
<td>1.4</td>
<td>0.3 (0.1-0.9)*#</td>
<td>9.6</td>
<td>1.1 (0.9-1.5)</td>
</tr>
<tr>
<td>Physician orders</td>
<td>7.5</td>
<td>0.7 (0.5-0.9)*</td>
<td>10.1</td>
<td>1.0 (0.8-1.4)</td>
</tr>
<tr>
<td>Medication list (if applicable)</td>
<td>21.2</td>
<td>0.9 (0.8-1.1)</td>
<td>13.9</td>
<td>1.2 (1.0-1.6)</td>
</tr>
<tr>
<td>Medical record (n=5,171)</td>
<td>1.3</td>
<td>0.7 (0.3-1.5)#</td>
<td>23.4</td>
<td>1.2 (0.8-1.6)</td>
</tr>
<tr>
<td>Report of medical history and physical examination at admission</td>
<td>19.5</td>
<td>0.8 (0.6-1.2)</td>
<td>12.4</td>
<td>1.1 (0.7-1.6)</td>
</tr>
<tr>
<td>Discharge letter</td>
<td>13.1</td>
<td>0.9 (0.7-1.2)</td>
<td>5.2</td>
<td>1.5 (1.1-2.1)*</td>
</tr>
<tr>
<td>If applicable:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure reports</td>
<td>18.0</td>
<td>0.9 (0.6-1.4)</td>
<td>2.3</td>
<td>1.4 (0.6-3.5)</td>
</tr>
<tr>
<td>Diagnostic imaging results</td>
<td>27.1</td>
<td>0.9 (0.7-1.3)</td>
<td>1.2</td>
<td>1.5 (0.5-5.2)</td>
</tr>
<tr>
<td>Laboratory/pathology-anatomy reports/test results</td>
<td>20.1</td>
<td>0.7 (0.5-0.9)*</td>
<td>2.3</td>
<td>1.9 (0.5-6.4)</td>
</tr>
</tbody>
</table>

* p-value <0.05
# we selected for the availability of the nursing and medical record. Records without nursing and medical record regarded admissions with a short length of stay.
**Adequacy of the medical records reviewed by physicians**

In the second stage of the review process, physician reviewers judged that overall 20% of medical records were inadequate or incomplete. Table 7.3 shows the inadequacies per medical record component. In 11% of the records, other reports, like medication list, operation/procedure report, diagnostic imaging results, laboratory/pathology-anatomy test results, reanimation report or autopsy report, were not available or incomplete. In the ‘other’ category (2%), documentation deficiencies like information of the general practitioner was missing, notes about allergy were missing, moment and circumstances of death were missing, and complications (e.g. bleeding, sepsis) were not mentioned in the medical record (only in the nursing record).

Table 7.3  Inadequacies of the medical record assessed by physician reviewers* (n=4,317) and the association with the occurrence of adverse events analysed with multilevel logistic analysis and corrected for covariates

<table>
<thead>
<tr>
<th>Medical record inadequate or incomplete</th>
<th>Total (%)</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20.0</td>
<td>1.5 (1.3-1.9)**</td>
</tr>
<tr>
<td>Report of past medical history and physical examination at admission inadequate or incomplete</td>
<td>12.4</td>
<td>1.3 (1.0-1.7)**</td>
</tr>
<tr>
<td>Other reports not available or incomplete</td>
<td>11.0</td>
<td>1.7 (1.3-2.1)**</td>
</tr>
<tr>
<td>Discharge letter not available</td>
<td>10.7</td>
<td>1.0 (0.7-1.3)</td>
</tr>
<tr>
<td>Lack of clarity regarding decisions and changes in policy</td>
<td>8.3</td>
<td>2.0 (1.5-2.6)**</td>
</tr>
<tr>
<td>Discharge summary not adequate, because*:</td>
<td>7.9</td>
<td>1.9 (1.5-2.4)**</td>
</tr>
<tr>
<td>- Discharged diagnose is missing</td>
<td>2.8</td>
<td>1.9 (1.2-3.0)**</td>
</tr>
<tr>
<td>- Prognosis is missing</td>
<td>2.1</td>
<td>1.5 (0.9-2.7)</td>
</tr>
<tr>
<td>- Treatment policy is missing</td>
<td>3.5</td>
<td>1.7 (1.1-1.5)**</td>
</tr>
<tr>
<td>- Agreement of supervisor is missing</td>
<td>0.9</td>
<td>1.2 (0.5-2.8)</td>
</tr>
<tr>
<td>Notes on procedure related to adverse event inadequate</td>
<td>6.9</td>
<td>3.2 (2.5-4.3)**</td>
</tr>
<tr>
<td>Lack of clarity regarding who was responsible for decisions and changes in policy</td>
<td>5.8</td>
<td>2.5 (1.8-3.4)**</td>
</tr>
<tr>
<td>Lack of clarity when changes in policy were made</td>
<td>5.5</td>
<td>1.7 (1.2-2.4)**</td>
</tr>
<tr>
<td>Admission reason not clearly described</td>
<td>4.0</td>
<td>1.3 (0.86-2.0)</td>
</tr>
<tr>
<td>Other</td>
<td>2.2</td>
<td>1.5 (0.9-2.6)</td>
</tr>
</tbody>
</table>

* physicians could register more options per record

** p-value <0.05

Table 7.3 shows that inadequacies of the medical record components judged by the physician reviewers were associated with the occurrence of adverse
Thus, inadequate patient information was associated with more adverse events.

**Overall quality of patient records**

**Variation in the quality of patient records between hospitals and hospital departments**

The overall report mark for the nursing records judged by the nurses was 6.96 (95% CI 6.94-6.98). The overall report mark for the medical records judged by the physicians was 6.79 (95% CI 6.76-6.81). The variation in the report mark of the nursing and medical record between hospitals and hospital departments was analysed with a multilevel linear regression model. The report mark for the nursing and medical record varied significantly between hospitals and between hospital departments (Table 7.4). The variation in the report mark of the nursing record was higher on hospital level (ICC of 5.0%) than on hospital department level (ICC of 1.6%), implying larger differences in the adequacy of the nursing records between hospitals than between hospital departments. The variation in the report mark of the medical record was higher on hospital department level (ICC of 12.6%) than on hospital level (ICC of 7.6%).

<table>
<thead>
<tr>
<th>Table 7.4</th>
<th>Variation and intra class correlation coefficients (ICCs) of the report mark of the nursing and medical records at patient, department, and hospital level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient level</td>
<td>Department level</td>
</tr>
<tr>
<td>Variance (SE)</td>
<td>Variance (SE)</td>
</tr>
<tr>
<td>Nursing record</td>
<td>2.8 (0.05)*</td>
</tr>
<tr>
<td>Medical record</td>
<td>0.79 (0.02)*</td>
</tr>
</tbody>
</table>

* p-value <0.05

**Relation between the overall quality of patient records and adverse events**

The association between adverse events and the report mark for the adequacy of patient records was studied with a multilevel logistic regression model. There was a negative association between adverse events and the report mark for the nursing and medical record. So, a higher score for the nursing and medical record was associated with a lower adverse event rate: OR = 0.89 (95% CI 0.85-0.92) and OR = 0.78 (95% CI 0.71-0.85) for the adequacy of the nursing and medical record respectively. The adverse event variation between hospitals reduced after entering the variable report mark for adequacy of the nursing and medical record in the multilevel model (reduction of 7.2% and 9.5%...
respectively). This implies that between 7 to 10% of the adverse event variation between hospitals can be allocated to the adequacy of the patient record (Appendix 7.A).

**Discussion**

The patient record is the most frequently used source of information about the quality of care [23]. In this study, the association between the presence and the quality of patient record components and the occurrence of adverse events was studied. It was found that the absence of record components was associated with lower adverse event rates. Thus, missing record components leads to an underestimation of adverse events in record review studies. However, inadequate contents of records were associated with higher adverse event rates. Also, a higher overall report mark for the nursing and medical record was associated with a lower adverse event rate, suggesting that in our study the effect of inadequate record contents was stronger than the effect of missing record parts. So, the quality of information recorded in the patient record seems to be a predictor of the quality of care.

Of all previous adverse event studies, only the Australian study reported on the association between the identified adverse events and the completeness of the patient record. Similar to our findings, they found that the proportion of admissions associated with adverse events was higher in those records with no components missing compared to records with missing components. They did, however, not measure the association between the quality of the recorded information and the occurrence of adverse events [14].

The overall report mark for the medical and nursing record varied significantly between hospitals and between hospital departments. The variation in the report mark for the nursing record was higher between hospitals than between hospital departments. Most of the hospitals have one format for the nursing record for all hospital departments. However, there is no national standard for the nursing record, which might explain the higher variation between hospitals. There is neither a national standard for the medical record and most of the specialties within hospitals have their own format. This might explain the higher variation in the report mark for the medical record between hospital departments.
Strengths and limitations

Several studies examined the validity and reliability (observer-bias) of the retrospective patient record review method to assess the occurrence of adverse events [2-8; 12; 15]. However, the examination of information bias by missing record components and by inadequacy of the information recorded in these components was explored less often. There are no studies in which the relation between the adequacy of patient records and adverse event rate was examined with logistic multilevel regression analysis corrected for several covariates. Only the Australian adverse event study gave descriptive data about the completeness and adequacy of the patient records related to adverse event rates [14].

Our study has some limitations. There is no national standard for record-keeping in Dutch hospitals. All hospitals and specialties have their own standard [1]. So, the reviewers had no gold standard for the judgement of the adequacy of the patient record. The nurse and physician reviewers’ judgement was based on their clinical expertise. The judgement of the completeness and adequacy of the patient record was, however, extended and done systematically according to a format. In addition, a general weakness of the retrospective record review method is hindsight bias [24]. The presence of severe adverse events may influence the judgement of the adequacy of the patient record. Physician reviewers judged about both the adequacy of the patient record and the presence of adverse events. Therefore, the association we found between the adequacy of the medical records judged by the physician reviewers and the occurrence of adverse events could be overestimated. However, the nurse reviewers are less affected by hindsight bias, since they registered the presence and adequacy of the patient record components, but did not judge about the presence of adverse events. The association between the overall report mark for the nursing record judged by the nurses and the presence of adverse events judged by the physicians was statistically significant. The association between the presence and adequacy of the different record components judged by the nurses and the occurrence of adverse events was not for all record components statistically significant, but all pointed in the same direction as the associations based on physician judgements. The results of this study are robust and challenging and should be confirmed in future studies.
Implications for practise to enhance patient safety

This study shows that between 7 to 10% of the adverse event variation between hospitals could be allocated to the adequacy of the patient record. Therefore, improvement of the adequacy of the registration of patient information and standardisation of the design of the patient record are desirable to improve the adequacy, accessibility and the exchange of patient information which may lead to safer care. This could be promoted by improvements in the record design such as having preformulated checklists which can partly alert the health care worker to what is expected and partly allow recording by checkmarks that indicate what was done or found and what was not [23]. Further, an integrated patient record for all healthcare workers and keeping all records relating to a patient in a single patient record rather than divided on several hospital departments or sites of care could improve the adequacy, availability and exchange of patient information [17].

In the Netherlands, a national standard with specific and detailed guidelines for the documentation of patient information uniform for all hospitals and specialties is lacking. In 2007, an investigation of the Netherlands Health Care Inspectorate also concluded that patient records of Dutch hospitals were extremely varied and incomplete. They reported that some information was not recorded, while other information was included in several (sometimes disparate) copies. The Inspectorate urged hospitals to make a national, unequivocal, efficient and accessible format for the documentation of information in the patient record and to implement this format in 2008 [25].

The national guidelines for registration of information in patient records should be incorporated within the training of nurses and physicians and should be used for accreditation and visitation of hospitals. As an example, the Dutch hospitals can use the evidence-based record keeping standards for inpatients developed by the British Royal College of Physicians (RCP) [26].

Recording information is both burdensome and time-consuming. The implementation of an electronic patient record hospital-wide will contribute to the standardisation, ease of recording, completeness and availability of patient information. The electronic patient record will improve the accessibility and the exchange of patient information between specialties and hospital institutions and benefits the possibilities for monitoring patient safety, because the information is available shortly after discharge or death of the patient for record review [25]. In addition, electronic patient records are more complete than hand written records because of the possibility to integrate multiple data sources, e.g. laboratory test results and medication data. However, the data in
the electronic medical record is entered by humans and therefore prone to error and bias [27]. Implementation of an electronic patient record will only have the desired effect if the recording of patient information is standardized. “A mess computerised is a computerised mess” [26]. Implementation of a national standard for registration of patient information in electronic records will thus benefit both research and the quality of health care.

**Implications for future research**
Future research should confirm the findings of this study and the influence of hindsight bias. Hindsight bias could be avoided by independent assessment of the occurrence of adverse events and the presence and adequacy of patient record components. In future retrospective record review studies, the presence of all record components is recommended to avoid underestimation of adverse events. Which record components are most related to adverse events should be investigated more to optimize the study protocol for record review studies.
References


20 Zegers M, De Bruijne MC, Wagner C, et al. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. Qual Safety Health Care, accepted for publication


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Appendix 7.A

The relation between the presence, adequacy and report mark of the medical and nursing record and the occurrence of adverse events was analysed with multilevel regression analysis. Multilevel analysis was used because the data had a hierarchical nature: the adequacy of the medical and nursing records (level 1) was clustered within hospital departments (level 2) and hospital departments were clustered within hospitals (level 3). Clustering of data (no independent observations) violates a major assumption of traditional regression analysis. Multilevel models are used to analyse hierarchical structured data and variation can be split between levels [21; 22].

Table 7.A.1 Multivariate multilevel logistic regression analysis of the relation between the report mark for the nursing and medical record and AEs

<table>
<thead>
<tr>
<th></th>
<th>Estimates</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nursing record</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Model 1: with random intercept at hospital level and department level and covariates, without adequacy nursing record</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept (SE)</td>
<td>-2.81 (0.10)*</td>
<td></td>
</tr>
<tr>
<td>Variance at hospital level (SE)</td>
<td>0.12 (0.07)*</td>
<td></td>
</tr>
<tr>
<td>Variance at department level (SE)</td>
<td>0.32 (0.08)*</td>
<td></td>
</tr>
<tr>
<td><strong>Model 2: with random intercept at hospital level and department level and covariates and with adequacy nursing record</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept (SE)</td>
<td>-2.82 (0.10)*</td>
<td></td>
</tr>
<tr>
<td>Coefficient for report mark nursing record (SE)</td>
<td>-0.12 (0.04)*</td>
<td>0.89 (0.85-0.92)</td>
</tr>
<tr>
<td>Variance at hospital level (SE)</td>
<td>0.11 (0.06)*</td>
<td></td>
</tr>
<tr>
<td>Variance at department level (SE)</td>
<td>0.32 (0.08)*</td>
<td></td>
</tr>
<tr>
<td>Proportional reduction of variance at hospital level (compared to model without adequacy nursing record)</td>
<td>7.2%</td>
<td></td>
</tr>
<tr>
<td>Proportional reduction of variance at hospital department level (compared to model without adequacy nursing record)</td>
<td>0.5%</td>
<td></td>
</tr>
</tbody>
</table>

- table 7.A.1 continues -
### Table 7.A.1 continued

<table>
<thead>
<tr>
<th>Medical record</th>
<th>Estimates</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model 1: with random intercept at hospital level and department level and covariates, without adequacy medical record</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept (SE)</td>
<td>-1.98 (0.10)*</td>
<td></td>
</tr>
<tr>
<td>Variance at hospital level (SE)</td>
<td>0.11 (0.06)*</td>
<td></td>
</tr>
<tr>
<td>Variance at department level (SE)</td>
<td>0.26 (0.08)*</td>
<td></td>
</tr>
<tr>
<td><strong>Model 2: with random intercept at hospital level and department level and covariates and with adequacy medical record</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept (SE)</td>
<td>-2.01 (0.10)*</td>
<td></td>
</tr>
<tr>
<td>Coefficient for report mark medical record (SE)</td>
<td>-0.25 (0.04)*</td>
<td>0.78 (0.71-0.85)</td>
</tr>
<tr>
<td>Variance at hospital level (SE)</td>
<td>0.10 (0.06)*</td>
<td></td>
</tr>
<tr>
<td>Variance at department level (SE)</td>
<td>0.25 (0.07)*</td>
<td></td>
</tr>
<tr>
<td>Proportional reduction of variance at hospital level (compared to model without adequacy medical record)</td>
<td>9.5%</td>
<td></td>
</tr>
<tr>
<td>Proportional reduction of variance at hospital department level (compared to model without adequacy medical record)</td>
<td>4.4%</td>
<td></td>
</tr>
</tbody>
</table>

* p-value <0.05
Chapter 8

General Discussion
A national population-based study on the occurrence of adverse events in Dutch hospitals was carried out because of a lack of empirical data. The main objective of the study was to measure the incidence, nature, severity and preventability of adverse events among hospitalised patients in the Netherlands. This in turn would create a sense of urgency to improve patient safety. Insight into the scale and nature of adverse events can be used for prioritising patient safety interventions, setting research priorities and formulating a patient safety programme. The main findings are presented in this thesis. Furthermore, two methodological aspects of the record review method to assess adverse events have been investigated in more detail. Therefore, the following research questions were formulated:

1. "What is the incidence of adverse events among Dutch hospital patients and what are the nature, severity and preventability of these adverse events?"

2. "To what extent do rates of (preventable) adverse events vary between hospitals and hospital departments?"

3. "What are the causes, occurrence and nature of surgical adverse events and potential strategies to prevent them?"

4. "Does the inter-rater agreement of retrospective assessments of adverse events improve with two physician reviewers per patient record?"

5. "Is the adequacy of patient records an indicator of the quality of care or a source of bias in retrospective patient safety studies?"

In this Chapter, the main findings and the methodological considerations of the study are summarised and discussed. Moreover, recommendations are given for policy makers, hospital managers and healthcare providers in order to reduce the scale of adverse events. The societal impact of the study is also described. Finally, recommendations for future research are proposed.
Main findings

The incidence, nature, severity and preventability of adverse events in Dutch hospitals
The results presented in Chapter 3 show that in 5.7% (95% CI 5.1 to 6.4) of all randomly selected hospital admissions one or more adverse events occurred. Of all adverse events, approximately 40% was judged to be preventable and 13% contributed to permanent disability, including death. When extrapolated to the national level, approximately 76,000 patients experienced one or more adverse events and 30,000 patients suffered from a preventable adverse event in 2004. The proportion of adverse events, their severity and preventability, increased with age. The adverse event rate was significantly higher in university hospitals than in general hospitals. Although not statistically significant, the rate of preventable adverse events was lower in university hospitals than in general and medical tertiary teaching hospitals. Fifty-four percent of all adverse events was related to surgical procedures; 17% was related to non-surgical procedures; 15% to adverse drug events and 6% to diagnostic procedures. Almost all adverse events, relating to diagnostic procedures, were judged to be preventable (84%).
Among hospital patients who died, the incidence of adverse events was 10.7% (95% CI 9.8 to 11.7) and 48% of these were judged to be preventable. The incidence of preventable adverse events contributing to death among deceased hospital patients was 4.1%. When extrapolated to the national level, between 1,482 and 2,032 potentially preventable deaths occurred in Dutch hospitals in 2004. Almost half of the deceased patients, who suffered from a preventable adverse event that contributed to their death, had an estimated potential life expectancy of more than 1 year, had the potentially preventable adverse event not occurred.
The adverse event incidence rate is at the lower end of the range of results from previous record review studies in other developed countries, which range from 3% to 17%. However, a comparison of the Dutch incidence rate with incidence rates of previous studies is hampered because of differences in definitions and methodology between the studies. In addition, the calculation of the incidence rate of adverse events and the type of reviewer vary between studies [1; 2].
The higher incidence rate of adverse events with a lower preventability, which occurred in university hospitals, may be explained by the level of care given in university hospitals and the complexity of treatment for their patients
compared to tertiary teaching and general hospitals. The higher proportion of adverse events among elderly patients may be explained by the clinical complexity of their care rather than discrimination based on their age [3]. Elderly patients experience an increased risk of adverse events because they often suffer from multiple co-morbidities, are treated with combinations of medication and usually need complex care. More than half of the adverse events were related to surgical procedures. Surgical procedures are by their nature associated with a degree of risk [4].

**Variation in rates of adverse events between hospitals and hospital departments**

Chapter 4 gives an insight into the variation in rates of adverse events between hospitals and hospital departments. After correction for patient, department and hospital characteristics, rates of adverse events varied significantly between hospitals and even more between hospital departments, meaning that patient safety differs between hospitals and hospital departments. This implies that patients are better off in some hospitals than in others in terms of their risk of an adverse event. The rates of preventable adverse events varied only significantly between hospital departments and the clustering of preventable adverse events in hospital departments was more than twice as high as in hospitals. In conclusion, there is more room for improvement in patient safety at the hospital department level than at the hospital level. Prevention strategies and safety programmes should focus on both levels. Directing all interventions at the hospital level, the centralised approach, may not be the best approach to improve patient safety. Efforts to make improvement on a decentralised (department) level seem more worthwhile. The results in Chapter 4 show that the median odds ratio for preventable adverse events was 1.46 and 1.74 for hospitals and hospital departments respectively, meaning that the differences between hospitals and hospital departments present a higher risk of adverse events than co-morbidity (OR=1.40).

The inter-hospital variance in adverse events was mainly explained by hospital type. Patient mix and department type did not reduce the inter-hospital variance in adverse events, contrary to the general perception that differences in rates of adverse events between hospitals are strongly related to differences in patient mix. The fact that inter-hospital variance actually increased after including patient mix and department type indicates that these variables masked some of the inter-hospital variance. The inter-hospital department
variance in both adverse events and preventable adverse events was mainly explained by differences in patient mix and department type. Monitoring of adverse events should be carried out at both hospital and hospital department levels, because hospitals with a low rate of adverse events may have departments with high rates of adverse events. Until now, efforts to measure, report and monitor the performance of health care and the effects of safety programmes are focusing on the hospital level. However, hospital managers and policy makers should be aware of unsafe hospital departments and not only of unsafe hospitals. Measurement at the department level is more appropriate in order to formulate specific interventions tailored to the problems of departments.

The occurrence, nature, and causes of surgical adverse events and potential prevention strategies

In Chapter 5, the adverse events attributable to surgical specialties were analysed in more detail. Of all adverse events found in the Dutch Adverse Event Study, 65% was attributable to surgical specialties, of which 10% resulted in permanent disability, including death. Approximately 41% was considered to be preventable. Surgical adverse events were mainly related to surgical procedures (83%). The most frequently found pathological outcomes of surgical adverse events were: inflammation/infection (39%); bleeding/haematoma (23%); injury by mechanical/physical-chemical cause (22%); and other functional impairment (17%). Sixty-eight per cent of the surgical adverse events that resulted in injury by mechanical, physical or chemical cause, was judged to be preventable. Physician reviewers judged that an inaccurately performed procedure was a major contributing factor to injuries by puncture or perforation of other organs, such as nerves, vessels and bowels. Moreover, specific techniques that are not carried out in accordance with state of the art procedures resulted in adverse events such as leakage and wound dehiscence. Furthermore, inadequate application of new techniques, such as endoscopic procedures, and procedures that demand specific expertise and experience, for example vessel surgery, resulted in adverse events. Previous studies also showed that surgical adverse events were more common than non-surgical adverse events [5-10]. Similar to the results of previous record review studies of ten years ago [9; 10], our study showed that infection, bleeding and injury due to a mechanical, physical or chemical cause formed the largest group of injuries as a result of surgical adverse events. The high rates of infection raises the question whether evidence-based prophylactic protocols
and infection prevention guidelines have been successfully implemented [9; 10].

Physician reviewers judged that most of the surgical adverse events (65%) were a result of human causes and less often by organisational (13%) or technical (4%) causes. However, almost all (90%) of surgical adverse events caused by organisational factors were judged to be preventable. According to the high percentage of human causes, the potential prevention strategies recorded by the physician reviewers were mainly focused on improvement of the performance of health care professionals. Physician reviewers recorded that potential prevention strategies to minimise the occurrence of adverse events attributable to surgical specialties should focus on quality assurance/peer review, training for improvement of skills, evaluation of the current way of behaving regarding safety, and the improvement of procedures.

**Inter-rater agreement between physician reviewers for the assessment of adverse events**

We hypothesised that the involvement of two physicians per record, including a consensus procedure in case of disagreement, would give a more reliable assessment of adverse events and their preventability, than with just a single physician reviewer. The findings in Chapter 6 show that the kappa value for the independent assessment of adverse events and their preventability by two physicians (before consensus procedure) was substantial, $\kappa = 0.64$ and $\kappa = 0.72$, respectively. The complete record review procedure, including a consensus procedure if applicable, was evaluated with a second pair of physicians. The kappa values between two independent *pairs* of physicians were fair, $\kappa = 0.25$ for the assessment of adverse events, and $\kappa = 0.40$ for the assessment of their preventability. Thus, a record review process with two physicians per record is no more reliable than a record review process with one physician. This implies that involving two physicians for the assessment of adverse events, including a consensus procedure, gives a false feeling of higher reliability.

The results in Chapter 6 also show that more adverse events were found with two physician reviewers, including a consensus procedure, compared to the independent reviews by the two physician reviewers separately. This indicates that it was hard for the physician reviewers to judge whether an adverse event was present and that physician reviewers were more reluctant in their judgement without the support of a collegial review.

The higher inter-rater agreement within pairs, compared to the inter-rater agreement between pairs of physicians, might be explained by the fact that the
physician reviewers, for logistical reasons, reviewed in the same region and thus often had consensus procedures with the same physician reviewers. This might have led to a pair-specific improvement in the inter-rater agreement within pairs of physicians, but not to an improvement of the overall inter-rater agreement between pairs of physicians. Perhaps the consensus procedure did not improve the inter-rater agreement of assessment of adverse events, because there was not enough mixing of reviewers within and across pairs. The physician reviewers evaluated the double review procedure and the consensus procedure to be valuable and instructive. However, this perception is deceptive and may lead to unwarranted confidence in the result [11].

**Association between the completeness and adequacy of the patient records and adverse events**

Chapter 7 shows that the absence of record components, for example medication overview and procedure reports, was associated with lower rates of adverse events, implying that missing record components may have led to an underestimation of adverse events. Besides, inadequate content in patient records was associated with higher rates of adverse events. Also, a lower overall report-mark for the nursing and medical record was associated with a higher rate of adverse events. Thus, the adequacy of patient record contents seems to be a predictor of the quality of health care.

The overall report-mark for the medical and nursing record varied significantly between hospitals and between hospital departments. Between 7% and 10% of the adverse event variation between hospitals could be allocated to the adequacy of the patient record. Therefore, an improvement in the registration of patient information, standardisation of the design of the patient record, and availability of patient records, are desirable to improve the quality, accessibility and the exchange of patient information, which may lead to safer care.

**Methodological considerations and implications for future patient record review studies**

The methodological limitations of the record review study, that could have lead to an over- or underestimation of adverse events, have been discussed in the previous Chapters. The main methodological aspects are summarised below and the implications are given for preventing bias in future patient record review studies.
Missing records and missing content within records
A potential source of bias is missing records, or missing contents within records. In Chapter 2 it is described that in this study, the patient records were selected from the hospital information system in order to guarantee a random selection of the records and to ensure the inclusion of records that were not present in the hospital archive because they were, for example, used for litigation or disciplinary procedures or for training of medical students. In the Harvard Medical Practice Study (HMPS) the rate of adverse events in the missing records was measured by means of a follow-up study. The rates of adverse events in the follow up study were lower than in the initial study [5]. In our study, 383 patient records (5%) of all selected admissions were unavailable or excluded for several reasons (Chapter 3). A follow-up study to assess the rate of adverse events in the missing records was not possible because of financial reasons.

In some participating hospitals in this study it was not feasible to collect the outpatient record of all selected admissions, as they were stored in many different archives. Missing outpatient records has probably led to an underestimation of the rate of adverse events. The rate of adverse events in patients with an outpatient record did not, however, significantly differ from patients without an outpatient record, 4.9% (95% CI 3.6 to 6.7) versus 5.9% (95% CI 5.2 to 6.7) respectively.

The results in Chapter 7 show that the absence of record components was associated with lower rates of adverse events, meaning that missing record components may have led to an underestimation of adverse events. Which record components are most related to adverse events should be investigated more extensively to optimise the study protocol for patient record review studies. An integrated patient record for all healthcare professionals, keeping all record components relating to a patient in a single record, rather than divided between several hospital departments could improve the completeness and availability of patient information. The implementation of an electronic patient record may also contribute to the completeness and availability of patient information. These efforts will benefit both patient safety and the assessment of adverse events.

Inter-rater agreement
Moderate inter-rater agreement is a well known problem of record review studies to assess the occurrence of adverse events and their preventability. In this study we tried to improve the inter-rater agreement between physician
reviewers by involving two physician reviewers per record, and a consensus procedure in case of disagreement, instead of a single physician. The results of the reliability study in Chapter 6 show, however, that the inter-rater agreement of the record review method did not improve. In future record review studies one physician reviewer per record might be sufficient and will make the study method more efficient and cheaper. However, the results in Chapter 6 also show that more adverse events were found using two physician reviewers. So, two physician reviewers are desirable to gather more information about the scale of patient harm for the improvement of patient safety.

The inadequate reliability of patient record review to identify adverse events should be improved further, in order to monitor patient safety in hospitals over time at a national level. Suggestions to improve the inter-rater agreement are a more explicit review form based on specified and detailed checklists using standards for specific departments or patient groups [12]. In addition, the team of physician reviewers could be extended with more physicians from different specialties, e.g. cardiologists, neurosurgeons and anaesthetists. However, the overall number of reviewers should be reduced to increase the experience per reviewer in order to improve their learning curve, and to facilitate more intensive training in order to standardise the review process.

Hindsight bias
Hindsight bias is a general weakness of all retrospective studies and means that knowing the outcome and its severity may influence the judgement of the appropriateness of the quality of care and the degree of preventability [13; 14]. This may have led to an overestimation of the degree of preventability of adverse events judged by the physician reviewers [4]. In addition, the potentially preventable deaths, and the life expectancy of the deceased patients if the adverse event had not occurred, were determined retrospectively (Chapter 3). It is difficult to estimate the life expectancy as if the error had not been made [15]. Hindsight bias could be avoided by blinding reviewers to the aspects being compared, for example measuring the quality of the healthcare procedure and the patient outcomes separately [16]. However, the latter is hardly feasible in practice.

Measurement of causes
Record review is suitable for the assessment of the incidence rates of adverse events and their type and nature. However, patient records are less suitable for identifying causes of adverse events, such as underlying failures in the process
or structure of care [17]. It is hard to get information about all the contributing factors by reading the patient record only. Human actions are regularly reported in a patient record and therefore human causes are most visible for physician reviewers. One can imagine that healthcare providers are less inclined to note technical or organisational factors in the medical or nursing record of an individual patient. This can be an explanation for the relatively small amounts of technical and organisational factors found in our study (Chapter 5). In conclusion, organisational and technical causal factors may be underreported [18].

Methods such as incident reporting and interviewing healthcare workers are more suitable for the assessment of the causes of adverse events. Moreover, an approach which combines the record review method with prospective methods, in which clinical staff is interviewed about the origin of the adverse event, will give a more appropriate and complete picture of (preventable) adverse events and their causes. This approach compensates for the lack of information in patient records [12; 19-21]. The involvement of clinicians is also an important issue for the ownership of the results, and therefore for the professional acceptability of subsequent patient safety initiatives [12]. The costs of this combined method are, however, higher than standard record review and this method is more time-consuming. However, it potentially brings more valid data about the causal factors of adverse events [19].

Adverse events after discharge

Adverse events revealed after discharge were captured if they resulted in a readmission to the hospital. If the patient was not readmitted, because, for example, the patient died at home or went to other healthcare providers such as the general practitioner, the adverse event was not discovered unless it was recorded in the hospital’s outpatient record. This could lead to an underestimation of the occurrence of adverse events as a result of hospital care. It was not possible to estimate the number of adverse events that were not captured in this study, but most adverse events that cause major disability probably require hospitalisation [5]. To gather more information about the patient after discharge, patient information from the general practitioner could be involved in future studies of adverse events. Extending the record review method with more sources of information from other healthcare providers will, however, increase the costs, complexity and feasibility of the method.
Implications for practice for improving patient safety in hospitals

The epidemiological data about the occurrence and nature of adverse events in hospitals identified in the Dutch Adverse Event Study are a source of information for prioritising patient safety efforts to prevent patient harm. According to the framework of Donabedian and Reason, described in the introductory Chapter of this thesis, prevention strategies can be divided into generic and specific interventions [22; 23]. Based on the results of the patient record review study, efforts described in the literature and ongoing trials, the following general strategies and specific interventions for improvement of patient safety are proposed.

General patient safety strategies

**Improvement and standardisation of the patient record**

Chapter 7 of this thesis shows that inadequate patient records were associated with higher rates of adverse events and the quality of the patient record varied significantly between hospitals and hospital departments. Thus, the improvement and standardisation of the registration of patient information in patient records, their accuracy, completeness, legibility, and availability, may enhance the safety of the healthcare process. A national standard for the patient record will assist both the healthcare process and the process of monitoring patient safety. This national standard should be incorporated into the training of health care professionals. The implementation of an electronic patient record may contribute to the standardisation, completeness, ease of recording, accessibility, availability and exchange of patient information. The electronic patient record may also improve the chances of monitoring patient safety, because the information is immediately available for record review after discharge or the death of the patient. The implementation of an electronic patient record will only have the desired effect if the recording of patient information is standardised [24]. “A mess computerised is a computerised mess” [25].

**Achieving insight into unsafe situations by identifying and learning from unintended events by healthcare professionals**

Healthcare professionals should identify and learn systematically and continuously from unsafe situations, incidents, complications and adverse events. Analysing and learning from unintended incidents and their underlying causes give insight into their performance and into the organisation of the
healthcare process. It will also make the healthcare workers feel more responsible for addressing these incidents and will promote preventive actions to reduce incidents in the future [26; 27].

There are acknowledged methods for identifying unintended events including: incident reporting, record review, morbidity and mortality meetings, and through a necrology committee. The nurse and physician reviewers who collected data for the Dutch Adverse Event Study recommended that reviewing patient records to analyse adverse events should be incorporated into the tasks and training of healthcare workers, because it is a valuable tool for achieving an insight into their performance and that of their colleagues. Reporting of, and learning from, unintended incidents by healthcare workers provides insight into unintended events and also helps to indentify underlying contributing factors, for example organisational and procedural failures. In the Netherlands, a framework for reporting incidents has been developed [28]. Morbidity and mortality meetings are standardised weekly meetings with the medical staff in which complications and deaths that occurred are investigated and the contributing factors are discussed. These meetings are an important and powerful educational tool [29]. Finally, a systematic examination of all hospital deaths by a necrology committee, with or without autopsy results, will give an insight into adverse outcomes and inappropriate care. Unexpected findings found during an autopsy are an excellent way of refining clinical judgement and identifying any misdiagnosis [30]. Nevertheless, autopsy rates have declined in recent years both world-wide and in the Netherlands as well [31].

The methods described above are less suitable for the assessment of the incidence rates for adverse events, but are valuable methods for evaluation of professional treatment and peer review between colleagues. This may increase the awareness of unsafe situations and patient harm. The methods described already exist. However, a more systematic application or reintroduction of these methods, or a combination of them, is necessary in order to continuously learn from incidents and improve patient safety. Continuously reporting and learning from unintended events may create a more open and blame free safety culture wherein reporting and discussing patient safety problems will become commonplace for all healthcare professionals, including physicians.

*Improving the patient safety culture and leadership through the training of healthcare workers*

There is an increasing amount of patient safety research and evidence-based practices to improve patient safety. These research findings should be
translated into practice and be diffused to hospitals, health professionals and managers. Healthcare professionals should be educated in how they can contribute to make health care safer [27]. The aim of patient safety training is to raise their awareness, role and responsibility for identifying, recognising, understanding and resolving patient safety problems. Incorporating patient safety education into clinical training programmes is a key mechanism for improving patient safety [30; 32]. The Institute of Medicine (IOM) recommended that training in patient safety should occur early in undergraduate and graduate medical education programmes and continue throughout medical education. Healthcare workers should be trained in multiple activities that can be directed towards understanding the causes of adverse events and ultimately their responsibility and potential role in promoting patient safety, including team training programmes, information technology improvements, incident reporting and learning programmes. Changing of individual attitudes and the safety culture of an organisation may result in an improvement of patient safety [30; 32].

**Detecting unsafe hospital departments**
The findings in Chapter 4 show that rates of adverse events varied between hospitals and even more between hospital departments. Thus, when improving patient safety we should focus on unsafe hospital departments and not only on unsafe hospitals. Studying unintended events with, for example, incident reporting, record review or routine hospital administrative data, should be carried out at both levels. Analysing unintended events at the department level is more appropriate for formulating specific interventions tailored to the safety problems at the hospital department level. Interventions at the level of the hospital department can be tailored to the specific needs of a department, while only a small number of the departments within a hospital may gain from interventions implemented at the hospital level. The governing board and the medical staff of hospitals should identify and monitor departments with high levels of adverse events and should offer assistance to unsafe departments through the implementation of prevention strategies. Hospital managers can use monitoring information at the department level for prioritising efforts to improve patient safety and financial resources.

**Specific prevention interventions**
Besides structural, general strategies, specific interventions to improve patient safety are needed, directed at the problems of patient safety identified in the
Dutch Adverse Event Study. The results of the Dutch Adverse Event Study showed that 65% of all adverse events were related to surgical specialties (Chapter 5); the occurrence, preventability and severity of adverse events increased with age; and that most of the adverse events that were related to diagnostic procedures, were judged to be preventable (Chapter 3). Prevention activities should focus on these areas in order to reduce the scale and severity of adverse events.

**Surgical adverse events**

The findings in Chapter 5 show that surgical adverse events mainly resulted in wound infections (39%). Evidence-based actions that are described in literature for the prevention of postoperative infections are: the consistent application of antibiotic prophylaxis and sterilisation of instruments, the reduction of door movements during the operation, having a minimum number of people in the operation room, and perioperative actions. In the Netherlands, hygiene guidelines to prevent infections are described by the Working party on Infection Prevention (WIP) [33]. These existing guidelines should be applied better, used more consistently and controlled more often.

We described in Chapter 5 that causal factors for surgical adverse events were judged to be predominantly human causes (65%). An extensive overview of examples of well-known interventions to prevent surgical adverse events is given in Chapter 5. These interventions focus on both technical and non-technical skills of healthcare professionals, such as more skills training and implementation of new techniques, team training, and the improvement of available sources of information and communication structures.

Recently, the Netherlands Health Care Inspectorate reported on the quality of the operative process and the risks associated with laparoscopic surgery [34-36]. The Inspectorate detected a lack of standardisation, incomplete or inaccessible patient data, poor adherence to hygiene standards and gaps during transfer of care in both the pre- and intra-operative stages of surgery. They concluded that: the communication, transfer - or handover - and coordination of the operative process should be improved; there should be more attention for the safe use of medical materials and equipment; and the risk for infection should be reduced. In addition, they found that the level of experience with laparoscopic surgical techniques varies widely in Dutch hospitals. Laparoscopic surgical techniques should be standardised through the development of national guidelines, protocols, a formal quality system, and training requirements for all basic laparoscopic techniques.
In the Netherlands, several interventions aimed at reducing surgical adverse events have been implemented or are being developed and validated, such as the ‘SURgical PAatient Safety System’ (SURPASS)-checklist, medical team training, the development of guidelines, simulation training, and the improvement of compliance with hygiene standards. In recent years, the time-out procedure, including debriefing, has been implemented in order to improve the communication between all members of the surgical team. This procedure is, however, limited to the operation room [37]. The SURPASS-checklist is a multidisciplinary checklist that covers the entire surgical patient pathway, instead of just the operative phase. The effectiveness of the checklist in reducing adverse events and improving patient safety is being studied [38]. Crew resource management (CRM), derived from the aviation industry, aims to improve situational awareness by improving communication, teamwork and safety culture of team members. CRM is currently being implemented in the intensive care and emergency departments in the Netherlands and is being adapted for the training of integrated surgical teams [39]. Simulation training is increasingly being used for improving the technical and non-technical skills of healthcare professionals, like laparoscopic surgical techniques, teamwork and communication skills. However, evidence-based literature about the effectiveness of simulation training is limited [40; 41].

Frail elderly
The results in Chapter 3 show that the occurrence, preventability and severity of adverse events increased with age. Because the population of elderly patients will increase over the coming decades, it is important to focus patient safety interventions on elderly patients. The use of multidisciplinary teams, including nurse specialists, clinical pharmacists and geriatricians, in the care of frail elderly patients is an opportunity to improve the quality and safety of health care in this high-risk population [42]. In addition, potential prevention strategies should focus on improving the transfer of information and communication both between healthcare professionals and between healthcare professionals and patients. And the care process after discharge from the hospital to home, nursing home or other locations should be improved to prevent adverse events and readmissions [43; 44]. However, while a variety of preventive approaches have been proposed, the available evidence is limited [42].
**Diagnostic process**

The findings in Chapter 3 show that most of the adverse events that were related to diagnostic procedures were judged to be preventable. Potential strategies for minimising the scale and impact of adverse events related to the diagnostic process cited by the WHO Working group on patient safety are redesigning the healthcare system. These strategies aim to decrease the dependence on human memory, provide a better infrastructure for learning from diagnostic-related adverse events, optimise healthcare procedures in order to minimise the harmful impact of diagnosis errors and delays, and finally to train healthcare professionals to improve their cognitive skills and awareness of common biases and disease-specific pitfalls. However, no randomised trials exist of successful interventions to prevent adverse events related to the diagnostic process [42].

**The societal impact of the study**

The Dutch Adverse Event Study was the first study that assessed the national incidence of adverse events in Dutch hospitals. The main aim of the study was to raise a sense of urgency among healthcare professionals, hospital managers and policy makers to reduce the occurrence of adverse events. After publication of the results in a national report in April 2007 [45], patient safety came high on the political agenda. The day after the publication of the results there was a debate about the results in the second chamber of the Dutch parliament and the minister of health announced the aim of reducing the number of potentially preventable adverse events and deaths in Dutch hospitals by 50% in 5 years. Associations of physicians, nurses and hospitals, supported by the Netherlands Health Care Inspectorate and the Ministry of Health, developed a patient safety action campaign for Dutch hospitals called ‘Prevent harm, work safely’ in order to improve patient safety and to achieve the aim of reducing the occurrence of potentially preventable adverse events and deaths by 50% in 5 years [46]. The campaign will run from 2008 till 2012 and consists of a certified safety management system, a selection of existing patient safety activities and ten topics to improve patient safety (Box 8.1) [46]. The ten topics of the safety campaign are partly based on the results of the Dutch Adverse Event Study.

A vital part of the safety management system is to identify risks and initiate efforts to manage those risks in order to continuously improve the quality of care. The five basic elements of the safety management system in hospitals are: the formulation of a safety policy and strategy; the creation of a safety...
culture; safe incident reporting; proactive risk-analysis of high-risk processes; and to continuously improve patient safety. The aim is that all Dutch hospitals have implemented a safety management system by the end of 2008. The Netherlands Health Care Inspectorate will supervise the implementation and the effects of the safety management system in hospitals.

In conclusion, the Dutch Adverse Event Study raised the awareness among policy makers, hospital managers and healthcare professionals for the need to improve patient safety. The results of the Dutch Adverse Event Study were used as input to formulate the safety action campaign. Despite the fact that the incidence rate of adverse events in Dutch hospitals is at the lower end of the range of incidence rates of adverse events shown in previous international studies, stakeholders realise that patient safety in Dutch hospitals needs to be improved.

Box 8.1 Ten topics of the Dutch safety campaign ‘Prevent adverse events, work safely in Dutch hospitals’

<table>
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<tr>
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<th>1</th>
<th>Prevention of postoperative infections</th>
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<td></td>
<td>2</td>
<td>Prevention of central line related adverse events (infections, sepsis and iatrogenic tissue damage)</td>
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<td>3</td>
<td>Early detection of patients with at risk vital functions</td>
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<td>4</td>
<td>Prevention of medication-related adverse events with specific attention for handover moments</td>
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<td></td>
<td>5</td>
<td>Prevention of adverse events in elderly patients, with specific attention for: detection and prevention of delirium, fall prevention, prevention of loss of mobility and prevention of and resolving under-nutrition</td>
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<td></td>
<td>6</td>
<td>Prevention of death due to an acute myocardial infarction</td>
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<td>7</td>
<td>Prevention of unnecessary suffering of patients from pain</td>
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<td>8</td>
<td>Prevention of incidents with the preparation and administration of high risk medication</td>
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<td>9</td>
<td>Prevention of exchanges of patients and exchanges within patients (e.g. wrong site surgery)</td>
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<td></td>
<td>10</td>
<td>Prevention of contrast-induced or medication-induced renal failure</td>
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**Recommendations for future research**

In the introductory Chapter of this thesis, the patient safety research process of the WHO working group on patient safety was described. The process is an ongoing cycle and consists of five steps, which may be carried out concurrently [47]:

1. Measuring adverse events.
2. Understanding the underlying causes.
3. Identifying methods of prevention.
4 Developing safety programmes.
5 Evaluating safety programmes and implemented interventions.

The study in this thesis addresses the first step of this cycle and is focused on the scale and nature of in-hospital adverse events. The recommendations for future research below regard the remaining steps of the cycle and give new input to the first step of the cycle.

**Step 2: Better understanding of the underlying causes**
We mentioned in the section ‘methodological considerations’ that record review is less suitable for identifying the root causes and contributing factors of adverse events. Future studies aiming to identify the causes are needed and should use methods that are more suitable for the assessment of the causes of adverse events. After the Dutch Adverse Event Study, a study on the causes of near misses and adverse events was initiated within the Dutch patient safety research programme [48]. To study the causes more precisely, incident reporting was combined with interviewing healthcare professionals in order to get more insight into the underlying causes [49; 50]. Compared to the proportion of causes found in the Dutch Adverse Event Study (Chapter 5), technical and organisational causes were more often detected in the study on causes and it gave more specific clues for the improvement of the organisational and technical aspects of the healthcare process.

More research should be done on the extent to which organisational and technical factors can prevent human errors. The relation between these factors and the occurrence of adverse events is less clear. Further research is needed on how organisational factors interact with human factors, such as fatigue or lack of adequate training, thus contributing to adverse events [42].

In addition, more research to explain the remaining variation in adverse event rates between hospitals and hospital departments (Chapter 4) would help to find ways to improve patient safety. Organisational factors that might explain the remaining variance are: safety culture; level of experience and skills of medical personnel; total staffing; and availability and quality of facilities.

**Step 3: Identifying and evaluating interventions to improve patient safety**
Evidence-based interventions should be identified and implemented in order to resolve patient safety problems and to reduce the burden of adverse events. However, the amount of evidence-based patient safety interventions is limited [42]. The effectiveness of several prevention interventions on patient safety should be measured. For example, does improving the transfer of information
and communication between healthcare professionals, education of healthcare professionals, and implementation of the electronic patient record, reduce the scale of adverse events in hospitals? Is there a relationship between safety culture and clinical outcomes? More research should be carried out to quantify the relation between safety interventions and the rates of adverse events [42]. According to the findings in this thesis there are several factors of special interest for reducing the burden and severity of adverse events in hospitals. Special attention should be paid to: identifying and evaluating interventions for surgical adverse events, for adverse events related to diagnostic procedures and in particular to the frail elderly patients. Several recommended interventions for reducing the burden of adverse events due to surgical care mentioned in Chapter 5 are not evidence-based. Future studies must examine the effectiveness of interventions such as team training, operative debriefing, and training for the improvement of skills. Because most of the surgical adverse events resulted in infection, future research should investigate if the current infection prevention guidelines are sufficiently formulated and implemented and should examine the compliance to infection prevention guidelines. No randomised trials exist of successful interventions for preventing adverse events related to the diagnostic process [42]. Identifying and evaluating interventions to improve the diagnostic process is highly recommended. The WHO Working group on patient safety has advised, among other things, that research could be concentrated on: cognitive failures in making the correct diagnosis; the follow-up on the results of diagnostic tests; the use of information technology in the diagnostic process; and the need for training of professionals to improve their diagnostic capability [42]. Within the Dutch patient safety research programme, a study has been launched to reveal weak elements in the diagnostic process and to determine their causes. In addition, the study focuses on the relation between personal and circumstantial factors and the diagnostic process. The study will provide insight into the nature and severity of suboptimal diagnostic events and will provide additional insight into the reasons why and where in the diagnostic process suboptimal events occur. This information will provide an indication for possible interventions [51]. More research is needed to investigate the organisation of care for elderly patients. Research is needed on the development and evaluation of interventions to improve information transfer and communication between healthcare professionals and improving the care process after discharge to reduce the risk of preventable readmissions. Recently, the research programme ‘Patient Safety and Complex Care’ has been launched. The programme includes
the evaluation of three intervention studies to improve the process of care for elderly patients: the implementation of the patient safety card to strengthen the role of patients and their family in preventing errors and patient harm; implementation of bundles of evidence-based recommendations for common complications to improve the care process after discharge; and the implementation of the SBAR tool to improve the information transfer and communication among healthcare professionals within hospitals. The situational briefing model SBAR, which comprises elements including the situation, background, assessment, and recommendation, might be an effective framework for structuring critical communication between healthcare professionals [42; 44].

**Step 4: Developing safety programmes**
As a reaction to the results of the Dutch Adverse Event Study, a patient safety action campaign has been formulated and launched. The campaign consists of the implementation of a certified safety management system, a selection of existing patient safety activities and ten clinical areas for improvement of patient safety [46]. How to improve patient safety in these ten clinical areas has not been completely formulated in the programme. One of the aims of the campaign is to identify and implement evidence-based safety interventions to fulfil these ten clinical topics. Evidence-based practices from the preceding stage and ongoing trials and projects could provide input for the completion of the safety campaign.

**Step 5: Evaluating safety campaigns and interventions: monitoring adverse events in hospitals**
The systematic and ongoing monitoring of trends and patterns of adverse events is necessary in order to evaluate the effect of the national patient safety action campaign and prevention interventions in Dutch hospitals. Only methods that calculate adverse event rates are suitable methods to monitor adverse events over time, for example record review and surveillance of patient safety indicators and the hospital standardised mortality ratio (HSMR).

It is most appropriate to measure a possible reduction in the assessed adverse event rate, and the potential preventable hospital deaths in the Dutch Adverse Event Study, by using the same method and thus replicating the record review method. The instruments and results from the Dutch Adverse Event Study can be used for the development of a valid method to monitor adverse events. Monitoring should be done by external, independent reviewers to generate
reliable data about the performance of hospitals. Based on this study, the methodological improvements are: ensuring complete patient records; the development of a more explicit review form; the involvement of more physician reviewers from different medical specialties; and the reduction of the overall number of reviewers in order to increase the experience per physician reviewer and to facilitate a more intensive training programme in order to standardise the review process. The opportunities to give feedback on the results to the healthcare providers, in order to enhance their awareness for patient safety problems and to stimulate them to take actions to improve safety, should be examined further.

Another method of monitoring adverse events in hospitals is the development of patient safety indicators which establish standards resulting in consistency and uniformity for the measurement of patient safety across multiple organisations [30]. The indicators provide information on patient safety using routine hospital administrative data, such as admission duration, the percentage of infections and complications, and the amount of readmissions. Since 2003, performance indicators for Dutch hospitals were defined and implemented supported by the Netherlands Health Care Inspectorate and are still in development [52]. The application of patient safety indicators using routine reported hospital administrative data to monitor adverse events should be validated in future research [42; 53].

The HSMR has been used increasingly as an indicator to assess and monitor differences in performance between hospitals over time. This method compares mortality rates between hospitals, adjusted for patient mix and hospital characteristics and is based on routinely collected hospital administrative data [54; 55]. However, the systematic review of Pitches et al. (2007) concludes that risk-adjusted mortality rates are not yet a valid and consistent predictor of the quality of care [56]. In addition, the HSMR method measures quality of care at the hospital level, but the findings in Chapter 4 show that we should focus on unsafe hospital departments and not only on unsafe hospitals. A limitation of both performance indicators and the HSMR compared to the record review method is that there is no judgement about the degree of preventability of the recorded unintended events or mortality rates. Incident reporting is used increasingly to monitor incidents and adverse events in hospitals [57]. Incident reporting is, however, less suitable for monitoring trends of adverse events. This method assesses single events that are not linked to denominators, thereby restricting the ability to estimate incidence rates and make comparisons across subgroups or over time. In addition,
incident reporting does not provide an accurate reflection of harm to patients and has to overcome the fear of malpractice [58-60].

**Back to step 1: (Re)measuring adverse events**

The patient safety research process is an ongoing cycle. Continuously enhancing patient safety should be supported by recent data about patient safety. Measuring adverse events should be an ongoing activity in patient safety research. Suggestions for future research are the measurement of adverse events outside the hospital and patient safety research at a European level.

Most international studies on the occurrence of adverse events were carried out in the hospital setting, because the risks associated with hospital care are high. However, hospital patients represent only a small proportion of the total population at risk. In the Netherlands, no epidemiological figures about the occurrence of adverse events outside the hospital are available, with exception of the Hospital Admission Related to Medication (HARM) Study. In this study, the occurrence and risk factors of medication-related hospital admissions were measured [61]. Studies are needed to raise the awareness of patient safety problems in other healthcare settings by estimating the scale of adverse events in settings such as primary health care, nursing homes, mental health care, home care and pharmacies. Outpatient centres and general physicians’ offices serve thousands of patients daily. Recent literature highlights concerns about outpatients as well, but there are very few data on the extent of the problem outside hospitals [20; 26].

Patient safety is high on the political agenda of the European Union (EU). Projects are initiated to, among other things, encourage and enhance collaboration in the field of patient safety between the EU Member States. These include: the development of quality approaches and strategies at the EU level for healthcare institutions; the establishment of a common set of vocabulary, indicators, internal and external instruments for improvement in patient safety; to support the development of national policies and programmes on patient safety; to share knowledge, experience and best practice at an European level; and to develop and promote research on patient safety [62; 63]. Co-operation on patient safety at the EU level is needed to improve patient care for all citizens across the EU. The development and regulation of patient safety in EU countries and the integration of quality management systems and safety management systems in European countries are interesting topics for future research. Patient safety policies, requirements...
and standards should be formulated and evaluated at an European level. Subsequently, uniform methods and definitions could be developed to measure and compare the variance in incidence rates of adverse events in European countries.
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Adverse events among hospitalised patients

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Adverse events among hospitalised patients
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Adverse events among hospitalised patients
Summary
Background and aims of the study

Unsafe health care is a major source of morbidity and mortality among hospitalised patients throughout the world. Enhancing patient safety starts with measuring the nature and scale of patient harm. Insight into the scale and nature of the problem should raise the awareness of healthcare professionals and policy makers that situations of patient harm caused by unsafe health care are not isolated cases, but are probably more common and widespread. Measuring the scale and nature of adverse events may create a sense of urgency to reduce the scale of adverse events systematically. Epidemiological data about adverse events in Dutch hospitals were lacking. Insight into the scale, preventability and causes of adverse events is a prerequisite for developing and prioritising safety interventions and research efforts in order to reduce the burden of harm to patients and to enhance patient safety in Dutch hospitals.

To address the need for empirical information about the adverse events among hospitalised patients, the Dutch Adverse Event Study was initiated. The objectives of the record review study were to assess the incidence, nature, severity and preventability of adverse events among hospitalised patients in Dutch hospitals, and to analyse the variation in the rates of adverse events between hospitals and hospital departments. Furthermore, adverse events attributable to surgical specialties were analysed in more detail. In addition, two methodological aspects of the record review method were examined: the inter-rater agreement between physician reviewers for the assessment of adverse events and the association between the adequacy of patient records and the occurrence of adverse events.

The main findings and methodological aspects of the Dutch Adverse Event Study are described in this thesis.

Methods

Chapter 2 describes the study methods and instruments of the Dutch Adverse Event Study, which were based on previous international record review studies. Between August 2005 and October 2006, a three-stage retrospective patient record review study was carried out in a stratified random sample of 21 Dutch hospitals: 4 university, 6 tertiary teaching, and 11 general hospitals. With a standardised electronic review form 66 trained nurses and 55 trained
physicians reviewed the records of 7,926 randomly selected hospital admissions: 3,943 admissions of discharged patients and 3,983 admissions of hospital patients who died in 2004. A large sub-sample of deceased hospital patients was included to determine the incidence of potentially preventable deaths more precisely compared to previous international studies.

In the first stage of the review process, the nurse reviewers screened all patient records using 18 screening criteria indicating potential adverse events and they measured the adequacy of the patient records. In the second stage, two physician reviewers independently reviewed the records that were positive for one of the 18 screening criteria. They assessed the presence, preventability, nature and severity of adverse events. An adverse event is an unintended injury that results in temporary or permanent disability, death or prolonged hospital stay and that is caused by healthcare management rather than by the patient’s underlying disease process. A preventable adverse event is the result of healthcare management below the professional standards and by healthcare system failures. The identified adverse events were classified by specialty and clinical process. Also, the causes, potential prevention strategies and the adequacy of the patient records were recorded.

If there was disagreement about the presence and/or preventability of an adverse event between the two physician reviewers, they started a consensus procedure to obtain consensus (stage 3). If they could not reach consensus, a third trained physician reviewer gave a final judgement. Previous studies have shown that the inter-rater agreement for the assessment of adverse events and their preventability by physician reviewers was poor to moderate. We aimed to improve the inter-rater agreement with, among other things, the involvement of two independent physician reviewers per patient record including a consensus procedure in case of disagreement, instead of a single physician reviewer. To assess the reliability of the final judgement of an adverse event, so including the consensus procedure and a third review if applicable, a stratified random sample of 119 records was reviewed by a second pair of physicians.

Main findings

The incidence, nature, severity and preventability of adverse events in Dutch hospitals

The results presented in Chapter 3 show that in 5.7% (95% CI 5.1 to 6.4) of all selected hospital admissions one or more adverse events occurred. Of all
adverse events, approximately 40% was judged to be preventable and 13% contributed to permanent disability, including death. When extrapolated to the national level, approximately 76,000 patients experienced one or more adverse events and 30,000 patients suffered from a preventable adverse event in 2004. The proportion of adverse events, their severity and preventability, increased with age. The adverse event rate was significantly higher in university hospitals than in general hospitals. Although not statistically significant, the rate of preventable adverse events was lower in university hospitals than in general and medical tertiary teaching hospitals. More than half (54%) of the adverse events was related to surgical procedures; 17% was related to non-surgical procedures; 15% to adverse drug events and 6% to diagnostic procedures. Almost all adverse events related to diagnostic procedures were judged to be preventable (84%).

Among hospital patients who died, the incidence of adverse events was 10.7% (95% CI 9.8 to 11.7) and almost 48% of these were judged to be preventable. The incidence of preventable adverse events contributing to death among deceased hospital patients was 4.1%. When extrapolated to the national level, between 1,482 and 2,032 potentially preventable deaths occurred in Dutch hospitals in 2004.

The adverse event incidence rate in Dutch hospitals is at the lower end of the range of results from previous record review studies in other developed countries, which range from 3% to 17%. However, a comparison of the Dutch incidence rate with incidence rates of previous studies is hampered because of differences in used definitions and methodology between the studies. In addition, the calculation of the incidence rate of adverse events and the type of reviewer vary between studies.

Variation in rates of adverse events between hospitals and hospital departments

Chapter 4 gives insight into the variation in rates of adverse events between hospitals and hospital departments. After adjustment for patient, department and hospital characteristics, rates of adverse events varied significantly between hospitals and even more between hospital departments, meaning that patient safety differs between hospitals and hospital departments. This implies that patients are better off in some hospitals than in others in terms of their risk of an adverse event. The rates of preventable adverse events varied only significantly between hospital departments and the clustering of preventable adverse events in hospital departments was more than twice as
high as in hospitals. In conclusion, there is more room for improvement in patient safety at the hospital department level than at the hospital level. Prevention strategies should focus on both levels. Directing all interventions at the hospital level, the centralised approach, may not be the best approach to improve patient safety. Efforts to make improvement on a decentralised (department) level seem more worthwhile. Monitoring of adverse events should be carried out at both hospital and hospital department level, because hospitals with a low rate of adverse events may have departments with high rates of adverse events. Measurement at the department level is more appropriate in order to formulate specific interventions tailored to the problems of departments.

**The occurrence, nature and causes of surgical adverse events and potential prevention strategies**

The adverse events attributable to surgical specialties were studied in Chapter 5 in more detail. Of all adverse events found in the Dutch Adverse Event Study, 65% was attributable to surgical specialties. Approximately 41% was considered to be preventable and 10% resulted in permanent disability including death. Surgical adverse events were mainly related to surgical procedures (83%). The most frequently found pathological outcomes of surgical adverse events were: inflammation/infection (39%); bleeding/haematoma (23%); and injury by mechanical/physical-chemical cause (22%). Physician reviewers judged that 65% of the surgical adverse events were caused by human factors and less often by organisational (13%) and technical (4%) factors. However, almost all (90%) surgical adverse events caused by organisational factors were judged to be preventable. According to the high percentage of human causes, the potential prevention strategies recorded by the physician reviewers to reduce the scale of surgical adverse events were mainly focused on improvement of the performance of health care professionals. They recorded that potential prevention strategies should focus on quality assurance/peer review, training for improvement of skills, evaluation of the current way of behaving regarding safety, and the improvement of procedures. An extended overview of examples of well-known interventions to prevent surgical adverse events is given in Chapter 5. These interventions are focused on both technical and non-technical skills of healthcare professionals.
Inter-rater agreement between physician reviewers for the assessment of adverse events

In Chapter 6, the methods and results of the reliability study are described. We hypothesised that the involvement of two physicians per record including a consensus procedure in case of disagreement would give a more reliable assessment of adverse events and their preventability, than with just a single physician reviewer. The findings in Chapter 6 show that the kappa value for the independent assessment of adverse events and their preventability by two physicians (before consensus procedure) was substantial, $\kappa = 0.64$ and $\kappa = 0.72$, respectively. The complete record review procedure, including a consensus procedure if applicable, was evaluated with a second pair of physicians. The kappa values between two independent pairs of physicians were fair, $\kappa = 0.25$ for the assessment of adverse events, and $\kappa = 0.40$ for the assessment of their preventability. Thus, a record review process with two physicians per record is not more reliable than a record review process with one physician.

The results in Chapter 6 also show that more adverse events were found with two physician reviewers compared to the independent reviews by the two physician reviewers separately. This indicates that it was hard for the physician reviewers to judge whether an adverse event was present and that physician reviewers were more conservative in their judgement without the support of a collegial review.

The higher inter-rater agreement within pairs, compared to the inter-rater agreement between pairs of physicians, might be explained by the fact that the physician reviewers, for logistical reasons, reviewed in the same region and thus often had consensus procedures with the same physician reviewers. This might have led to a pair-specific improvement in the inter-rater agreement within pairs of physicians, but not to an improvement of the overall inter-rater agreement between pairs of physicians. The physician reviewers, however, evaluated the double review procedure and the consensus procedure to be valuable and instructive.

Association between adverse events and the completeness and adequacy of the patient records

The relation between the occurrence of adverse events and the adequacy of the patient record is examined in Chapter 7. The findings in Chapter 7 show that the absence of record components, for example medication overview and procedure reports, was associated with lower rates of adverse events. This implies that missing record components may have led to an underestimation of
adverse events. However, inadequate content in patient records was associated with higher rates of adverse events. Also, a lower overall report-mark for the nursing and medical record was associated with a higher rate of adverse events. Thus, the adequacy of patient record contents seems to be a predictor of the quality of health care.

The overall report-mark for the medical and nursing record varied significantly between hospitals and between hospital departments. Between 7% and 10% of the adverse event variation between hospitals could be allocated to the adequacy of the patient record. Therefore, an improvement in the registration of patient information, standardisation of the design of the patient record, and availability of patient records, are desirable to improve the quality, accessibility and the exchange of patient information, which may lead to safer care.

**General discussion**

In the general discussion (Chapter 8) of this thesis, the main findings and the methodological considerations of the study are summarized and discussed. Moreover, the societal impact of the study is described and recommendations for policy makers, hospital managers and healthcare providers in order to reduce to scale of adverse events are given. Finally, recommendations for future research are proposed.

**The societal impact of the study**

The Dutch Adverse Event Study was the first study that assessed the national incidence of adverse events in Dutch hospitals. The main aim of the study was to raise a sense of urgency among healthcare professionals, hospital managers and policy makers to reduce the scale of adverse events. After publication of the results in April 2007, patient safety obtained a higher position on the political agenda. The minister of health announced the aim of reducing of the number of potentially preventable adverse events and deaths in Dutch hospitals by 50% in 5 years. To achieve this aim, the associations of physicians, nurses and hospitals, supported by the Netherlands Health Care Inspectorate and the Ministry of Health, developed a patient safety action campaign in Dutch hospitals to improve patient safety in hospitals.
Implications for practice to improve patient safety in hospitals
Based on the results of the Dutch Adverse Event Study, efforts described in the literature and ongoing trails, the following general strategies for reducing the scale of adverse events are proposed in Chapter 8:
- improvement and standardisation of the patient record;
- achieving insight into unsafe situations by identifying and learning from unintended events by healthcare professionals;
- improving the patient safety culture and leadership through the training of healthcare workers;
- detecting unsafe hospital departments in order to formulate specific interventions tailored to the problems of hospital departments.

The results of the Dutch Adverse Event Study showed that 65% of all adverse events were related to surgical specialties, that the occurrence, preventability and severity of adverse events increased with age and that most of the adverse events related to diagnostic procedures were judged to be preventable. Prevention activities should focus on these areas in order to reduce the scale and severity of adverse events. Specific interventions that are directed at these patient safety problems are described in Chapter 8.

Recommendations for future patient safety research
At the end of Chapter 8 recommendations for future patient safety research are given. The recommendations are focused on:
- better understanding of the underlying causes of adverse events;
- identifying and evaluating interventions to improve patient safety;
- developing safety programmes based on evidence-based interventions;
- evaluating safety campaigns and interventions: monitoring adverse events in hospitals;
- (re)measuring adverse events: measurement of adverse events outside the hospital and more research about patient safety at the European level.
Samenvatting (Summary in Dutch)
Achtergrond en doelstellingen van het onderzoek

Onveilige gezondheidszorg is wereldwijd een belangrijke bron van morbiditeit en mortaliteit bij ziekenhuispatiënten. Het verbeteren van de patiëntveiligheid begint met het meten van de aard en omvang van onbedoelde zorggerelateerde schade (adverse events). Kennis over de aard en omvang van het probleem zou het bewustzijn van gezondheidszorgprofessionals en beleidsmakers moeten vergroten, evenals het inzicht dat gevallen van onbedoelde schade veroorzaakt door onveilige gezondheidszorg niet op zichzelf staan, maar waarschijnlijk meer algemeen en wijdverbreid voorkomen.

Het meten van de aard en omvang van onbedoelde schade kan leiden tot een urgentiegevoel om de omvang van onbedoelde schade systematisch te verminderen. Epidemiologische gegevens over onbedoelde schade in Nederlandse ziekenhuizen ontbraken tot dusverre. Inzicht in de omvang, aard, vermijdbaarheid en oorzaken van onbedoelde schade is een voorwaarde voor het ontwikkelen en prioriteren van preventieve interventies en onderzoeksdoelstellingen om de omvang en gevolgen van onbedoelde schade te beperken en de patiëntveiligheid in Nederlandse ziekenhuizen te vergroten.

Omdat empirische gegevens ontbraken is een landelijke dossierstudie opgestart naar de omvang van onbedoelde schade in Nederlandse ziekenhuizen. De doelstelling van het dossieronderzoek was het meten van de omvang, aard, vermijdbaarheid en ernst van de gevolgen van onbedoelde schade bij patiënten en het analyseren van de variatie van onbedoelde schade tussen ziekenhuizen en ziekenhuisafdelingen. Vervolgens is meer specifiek gekekend naar onbedoelde schade gerelateerd aan snijdende specialismen. Daarnaast zijn twee methodologische aspecten van het dossieronderzoek onderzocht: de interbeoordelaarsbetrouwbaarheid tussen artsenbeoordelaars voor het beoordelen van onbedoelde schade en de associatie tussen de kwaliteit van de diagnostische voering en het voorkomen van onbedoelde schade.

In dit proefschrift zijn de belangrijkste bevindingen en methodologische aspecten van de landelijke dossierstudie naar onbedoelde schade beschreven.

Methoden

Hoofdstuk 2 beschrijft de methode en meetinstrumenten van de landelijke dossierstudie naar onbedoelde schade, welke gebaseerd zijn op voorgaande internationale dossierstudies. Het retrospectief dossieronderzoek is uitgevoerd
tussen augustus 2005 en oktober 2006 in een gestratificeerde aselecte steekproef van 21 Nederlandse ziekenhuizen: 4 academische, 6 topklinische en 11 algemene ziekenhuizen. In deze ziekenhuizen zijn de dossiers van in totaal 7926 aselect geselecteerde opnames beoordeeld: 3943 opnames van ontslagen patiënten en 3983 opnames van overleden patiënten in 2004. Om de omvang van potentieel vermijdbare sterfte nauwkeuriger te schatten in vergelijking met voorgaande studies is in deze studie een grotere steekproef van overleden patiënten getrokken.

De dossiers zijn systematisch in drie fasen beoordeeld door 66 getrainde verpleegkundigen en 55 getrainde artsen met een gestandaardiseerd elektronisch beoordelingsformulier. In de eerste fase van het dossieronderzoek hebben de verpleegkundigen alle dossiers gescreend op de aanwezigheid van 18 aanwijzingen (triggers) voor onbedoelde schade en hebben zij de kwaliteit van de dossiervoering beoordeeld. In de tweede fase zijn de dossiers met triggers onafhankelijk beoordeeld door twee artsen. De artsen beoordeelden of er sprake was van onbedoelde schade en vervolgens de aard, ernst en de mate van vermijdbaarheid van de onbedoelde schade. *Onbedoelde schade* is gedefinieerd als een onbedoelde uitkomst voor de patiënt die is veroorzaakt door de geleverde zorg en/of door het zorgsysteem in plaats van door het onderliggende ziekteproces van de patiënt met schade voor de patiënt zodanig ernstig dat er sprake is van tijdelijke of permanente gezondheidsbeperking, verlengde opnameduur of overlijden van de patiënt. *Vermijdbare schade* is onbedoelde schade die is ontstaan door het onvoldoende handelen volgens de professionele standaard en/of door tekortkomingen van het zorgsysteem. De gevonden onbedoelde schade werd geclassificeerd naar verantwoordelijk specializement en betrokken klinisch deelproces. Daarnaast werden de oorzaken, potentiële preventie strategieën en de kwaliteit van de dossiervoering beoordeeld. Indien de beoordelingen van de twee artsen over de aanwezigheid en de vermijdbaarheid van onbedoelde schade niet overeen kwamen werd er een consensusprocedure opgestart waarin de artsen probeerden tot consensus te komen (fase 3). Indien de twee artsen niet tot overeenstemming kwamen, valde een derde getrainde arts het definitieve oordeel.

In voorgaande studies was de interbeoordelaarsbetrouwbaarheid tussen artsen voor het beoordelen van de aanwezigheid van onbedoelde schade en de vermijdbaarheid slecht tot matig. We hebben in deze studie geprobeerd de interbeoordelaarsbetrouwbaarheid te verbeteren door onder andere alle dossiers in de tweede fase onafhankelijk te laten beoordelen door twee artsen in plaats van één arts, inclusief een consensusprocedure indien de

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beoordelingen niet overeen komen. Om de betrouwbaarheid van de gehele beoordelingsprocedure te beoordelen, dus inclusief de consensusprocedure en een derde beoordelaar indien van toepassing, is er een steekproef van 119 dossiers onafhankelijk beoordeeld door een tweede koppel artsen.

Belangrijkste bevindingen

De omvang, aard, ernst en vermijdbaarheid van onbedoelde schade in Nederlandse ziekenhuizen
In hoofdstuk 3 wordt beschreven dat in 5,7% (95% BI 5,1 tot 6,4) van alle geselecteerde ziekenhuisopnames een of meerdere gevallen van onbedoelde schade is gevonden. Van alle onbedoelde schade werd 40% als vermijdbaar beoordeeld en heeft 13% mogelijk bijgedragen aan permanente gezondheidsbeperking, inclusief overlijden. Geëxtrapoleerd naar Nederland zou dit neer komen op ongeveer 76.000 patiënten die onbedoelde schade hebben ondervonden in 2004. Bij 30.000 patiënten had de schade mogelijk voorkomen kunnen worden. De omvang, ernst en mate van vermijdbaarheid van de onbedoelde schade nam toe met de leeftijd. De omvang van onbedoelde schade was significant hoger in academische ziekenhuizen dan in algemene ziekenhuizen. De omvang van vermijdbare schade was lager in academische ziekenhuizen dan in algemene en topklinische ziekenhuizen, echter deze bevinding was niet statistisch significant. Meer dan de helft (54%) van de onbedoelde schade was gerelateerd aan chirurgische ingrepen, 17% was gerelateerd aan niet-chirurgische ingrepen, 15% aan medicamenteuze behandeling en 6% aan het diagnostisch proces. Bijna alle onbedoelde schade (84%) gerelateerd aan het diagnostisch proces werd beoordeeld als vermijdbaar.

De incidentie van onbedoelde schade bij de in het ziekenhuis overleden patiënten bedroeg 10,7% (95% BI 9,8 tot 11,7), waarvan bijna 48% als vermijdbaar werd beoordeeld. Bij 4,1% van de overleden patiënten heeft de vermijdbare schade mogelijk bijgedragen aan het overlijden van de patiënt. Geëxtrapoleerd naar Nederland zou dit neer komen op 1482 tot 2032 patiënten waarbij potentieel vermijdbare schade mogelijk heeft bijgedragen aan het overlijden van de patiënt in 2004.

Het percentage onbedoelde schade in Nederlandse ziekenhuizen bevindt zich aan de onderkant van de range van de resultaten van voorgaande dossierstudies in andere Westerse landen (range van 3% tot 17%). Echter, de
vergelijking van het percentage in Nederlandse ziekenhuizen met de percentages uit de voorgaande studies wordt belemmerd door verschillen in definities en methoden tussen de studies. Daarbij varieert de berekening van het percentage onbedoelde schade en het soort beoordelaar tussen de studies.

**Variatie in onbedoelde schade tussen ziekenhuizen en ziekenhuisafdelingen**
Hoofdstuk 4 geeft inzicht in de variatie in de omvang van onbedoelde schade tussen ziekenhuizen en ziekenhuisafdelingen. Na correctie voor patiënt, afdeling en ziekenhuiskenmerken varieerde de omvang van onbedoelde schade significant tussen ziekenhuizen en zelfs meer tussen ziekenhuisafdelingen, hetgeen betekent dat de patiëntveiligheid verschilt tussen ziekenhuizen en ziekenhuisafdelingen. Dit impliceert dat patiënten beter af zijn in sommige ziekenhuizen dan in andere ziekenhuizen wat betreft hun risico op onbedoelde schade. De omvang van vermijdbare schade varieerde alleen significant tussen ziekenhuisafdelingen en de clustering van vermijdbare schade op ziekenhuis-afdelingsniveau was twee keer zo hoog als op ziekenhuisniveau. Kortom, er is meer ruimte voor verbetering van patiëntveiligheid op afdelingsniveau dan op ziekenhuisniveau. Preventiestrategieën zouden gericht moeten zijn op beide niveaus. Het richten van alle interventies op ziekenhuisniveau, de centrale aanpak, lijkt niet de beste methode te zijn om patiëntveiligheid te verbeteren; interventies met een decentrale benadering (op afdelingsniveau) lijken het meest geschikt. Het monitoren van onbedoelde schade zou op beide niveaus, op ziekenhuis- en afdelingsniveau, plaats moeten vinden, omdat ziekenhuizen met een laag percentage onbedoelde schade afdelingen zouden kunnen hebben met een hoog percentage onbedoelde schade. Het meten van onbedoelde schade is mogelijk effectiever op afdelingsniveau, omdat hierdoor interventies ontwikkeld kunnen worden die toegesneden zijn op de specifieke problemen op afdelingen.

**De omvang, aard en oorzaken van onbedoelde schade gerelateerd aan snijdende specialismen en potentiële preventie strategieën**
Onbedoelde schade gerelateerd aan snijdende specialismen is nader bestudeerd in hoofdstuk 5. Vijfenzestig procent van alle onbedoelde schade gevonden in de landelijke dossierstudie was gerelateerd aan snijdende specialismen. Bijna 41% werd als vermijdbaar beoordeeld en 10% heeft bijgedragen aan permanente gezondheidsbeperking, inclusief overlijden. Chirurgische onbedoelde schade was voornamelijk gerelateerd aan
chirurgische ingrepen (83%). De meest voorkomende pathologische uitkomsten ten gevolge van chirurgische onbedoelde schade waren: ontsteking/infectie (39%); bloeding/hematoom (23%); en onbedoelde schade tengevolge van mechanische/fysisch-chemische oorzaken (22%). De artsen beoordeelden dat 65% van de chirurgische onbedoelde schade werd veroorzaakt door menselijke oorzaken en minder vaak door organisatorische (13%) en technische (4%) oorzaken. Echter bijna alle (90%) chirurgische onbedoelde schade werd als vermijdbaar beoordeeld. Overeenkomstig met het hoge percentage menselijke oorzaken werden door de artsenbeoordelaars voornamelijk potentiële preventie strategieën gericht op het verbeteren van het handelen van de gezondheidszorg professionals aanbevolen om de omvang van chirurgische onbedoelde schade te verlagen. Ze gaven aan dat potentiële preventie strategieën gericht zouden moeten zijn op kwaliteitsbewaking/intercollegiale toetsing, training om benodigde vaardigheden te verbeteren, reflectie van de huidige gedragspatronen met betrekking tot veiligheid en de verbetering van procedures. In hoofdstuk 5 wordt een uitgebreid overzicht gegeven van voorbeelden van bekende interventies om chirurgische onbedoelde schade te voorkomen. Deze interventies zijn gericht op zowel technische als niet-technische vaardigheden van gezondheidsprofessionals.

Interbeoordelaarsbetrouwbaarheid tussen artsen voor het beoordelen van onbedoelde schade

Hoofdstuk 6 beschrijft de methoden en resultaten van de betrouwbaarheidsstudie. De hypothese was dat het beoordelen van dossiers onafhankelijk door twee artsen, inclusief een consensusprocedure indien er geen overeenstemming is, in plaats van één arts de betrouwbaarheid van het beoordelen van onbedoelde schade en de vermijdbaarheid zou verhogen. Uit de bevindingen in hoofdstuk 6 blijkt dat de kappa waarde voor de onafhankelijke beoordelingen van onbedoelde schade en de vermijdbaarheid door twee artsen (vóór de consensusprocedure) goed was, respectievelijk κ = 0.64 and κ = 0.72. De gehele beoordelingsprocedure, inclusief de consensusprocedure, werd geëvalueerd met een tweede koppel artsen. De kappawaarden tussen twee onafhankelijke koppels van artsen was matig, κ = 0.25 voor de beoordeling van onbedoelde schade en κ = 0.40 voor de beoordeling van vermijdbaarheid. Dus een beoordelingsprocedure met twee artsen per dossier is niet betrouwbaarder dan een beoordelingsprocedure met één arts. De resultaten in hoofdstuk 6 laten ook zien dat er meer onbedoelde
De schade werd gevonden met twee artsen inclusief een consensusprocedure in vergelijking met de onafhankelijke beoordelingen van twee artsen apart. Dit geeft aan dat het moeilijk was voor de artsenbeoordelaars om te oordelen over de aanwezigheid van onbedoelde schade en dat de artsenbeoordelaars terughoudender waren in hun oordeel zonder steun van een collega beoordelaar. De hoge interbeoordelaarsbetrouwbaarheid binnen een artsenkoppel vergeleken met de interbeoordelaarsbetrouwbaarheid tussen artsenkoppels zou kunnen worden verklaard door het feit dat de artsenbeoordelaars door logistieke redenen vaker in dezelfde regio’s beoordeelten en dus vaker consensusprocedures hadden met dezelfde artsenbeoordelaars. Dit zou kunnen hebben geleid tot paar-specifieke verbetering van de interbeoordelaarsbetrouwbaarheid binnen artsenkoppels maar niet in een verbetering van de algehele interbeoordelaarsbetrouwbaarheid tussen koppels van artsen. De artsenbeoordelaars evalueerden echter de dubbele beoordeling van de dossiers inclusief de consensusprocedure als waardevol en leerzaam.

De relatie tussen onbedoelde schade en de volledigheid en kwaliteit van de patiëntendossiers

De relatie tussen het voorkomen van onbedoelde schade en de kwaliteit van de dossiervoering is onderzocht in hoofdstuk 7. De bevindingen in hoofdstuk 7 laten zien dat de afwezigheid van dossieronderdelen, bijvoorbeeld het medicatieoverzicht of de verslagen van ingrepen, geassocieerd was met een lager percentage onbedoelde schade, hetgeen betekent dat ontbrekende dossieronderdelen kunnen leiden tot een onderschatting van de omvang van onbedoelde schade in dossieronderzoek. Echter, inadequate patiëntgegevens in de dossiers was geassocieerd met een hoger percentage onbedoelde schade. Ook was een lager rapport cijfer voor het verpleegkundig en medisch dossier geassocieerd met een hoger percentage onbedoelde schade. Dus de adequaatheid van de patiëntengegevens in dossiers lijkt een voorspellende waarde te hebben voor de kwaliteit van zorg. Het gemiddelde rapportcijfer voor het medisch en verpleegkundig dossier varieerde significant tussen ziekenhuizen en ziekenhuisafdelingen. Tussen 7 en 10% van de variatie in de omvang van onbedoelde schade tussen ziekenhuizen kan worden toegewezen aan de kwaliteit van het dossier. Daarom is verbetering van de kwaliteit van de dossiervoering en de registratie van patiënteninformatie, standaardisatie van de opbouw van het patiëntendossier en de beschikbaarheid van de dossiers wenselijk voor het verbeteren van de
Adverse events among hospitalised patients. This would possibly be able to contribute to the improvement of the quality of care.

**Algemene discussie**

In the general discussion (chapter 8) of this thesis, the most important findings and methodological considerations of the research are summarized and debated. Furthermore, the societal interest in the research is described and recommendations are given for policymakers, hospital managers and healthcare professionals for the reduction of the extent of unintended harm. Finally, recommendations are made for future research.

**Het maatschappelijk belang van het onderzoek**

The national dossier study was the first research where the national incidence of unintended harm in Dutch hospitals was measured. The most important goal of the research was to increase the urgency feel of healthcare professionals, hospital managers and policymakers to reduce the extent of unintended harm. After the publication of the results in April 2007, patient safety became high on the political agenda to stand. The minister of Public Health announced the goal to reduce the extent of potential avoidable damage and death in Dutch hospitals by 50%. To achieve this goal, the professional organizations of doctors, nurses and hospitals, supported by the Inspectorate for Healthcare and the ministry of Public Health, have drawn up a joint action plan to improve patient safety in Dutch hospitals.

**Aanbevelingen voor de praktijk ter verbetering van de patiëntveiligheid in ziekenhuizen**

Based on the results of the national dossier study and initiatives described in the literature and in ongoing studies, in chapter 8 the following strategies are proposed for the reduction of the extent of unintended harm:
- improvement and standardization of the patient dossier;
- analyzing and learning from unintended events by healthcare professionals;
- verbeteren van de patiëntveiligheidscultuur en leiderschap van gezondheidszorgprofessionals door onderwijs;
- identificeren van onveilige ziekenhuisafdelingen met als doel het formuleren van specifieke maatregelen gericht op de problemen die spelen op afdelingsniveau.

De resultaten van de landelijke dossierstudie naar onbedoelde schade lieten zien dat 65% van alle onbedoelde schade gerelateerd was aan snijdende specialismen, dat de omvang, vermijdbaarheid en ernst van onbedoelde schade toenam met de leeftijd en dat het merendeel van de onbedoelde schade gerelateerd aan het diagnostisch proces als vermijdbaar was beoordeeld. Deze patiëntgroepen en klinische deelgebieden zijn van bijzonder belang bij de formulering van preventieve interventies om de omvang en ernst van de gevolgen van onbedoelde schade te verminderen. In hoofdstuk 8 zijn specifieke interventies beschreven die gericht zijn op deze patiëntgroepen en klinische deelgebieden.

Aanbevelingen voor toekomstig onderzoek naar patiëntveiligheid

Aan het einde van hoofdstuk 8 zijn aanbevelingen gedaan voor toekomstig onderzoek naar patiëntveiligheid. De aanbevelingen zijn gericht op:
- meer inzicht verkrijgen in de oorzakelijke factoren van onbedoelde schade;
- identificeren en evalueren van interventies ter verbetering van de patiëntveiligheid;
- samenstellen van veiligheidsprogramma’s gebaseerd op evidence-based interventies;
- evaluatie van geïnitieerde veiligheidscampagnes en interventies: monitoren van onbedoelde schade in ziekenhuizen;
- (her)meten van onbedoelde schade: meten van onbedoelde schade buiten het ziekenhuis en meer onderzoek naar patiëntveiligheid op Europees niveau.
Adverse events among hospitalised patients
Dankwoord

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Adverse events among hospitalised patients
Curriculum Vitae

The author of this thesis, Marieke Zegers, was born on May 17, 1978 in Nijmegen, the Netherlands. After graduating at Dominicus College in Nijmegen in 1996, she started her academic training in Biological Health Science and in Health Policy, Economics and Management at the University of Maastricht and obtained in 2004 her master’s degree.

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She completed her master’s degree in Epidemiology at the VU University Medical Center in Amsterdam in 2007.

Since January 2009, she is working at NIVEL on a national survey about quality of life of cancer patients and their health care experiences and needs during their illness.