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 to 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

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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

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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 the 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 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**

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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.

**Summary**
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