Monitoring adverse events in hospitals

Rebecca Baines

MONITORING ADVERSE EVENTS IN HOSPITALS

How safe are hospitals for patients?

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ISBN: 978-94-92679-28-4
NUR: 100

Cover design: proefschriftenprinten.nl
Cover illustration: Markovka
Layout and printing: Print Service Ede

VRIJE UNIVERSITEIT

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ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad Doctor aan
de Vrije Universiteit Amsterdam,
op gezag van de rector magnificus
prof.dr. V. Subramaniam,
in het openbaar te verdedigen
ten overstaan van de promotiecommissie
van de Faculteit der Geneeskunde
op donderdag 8 februari 2018 om 11.45 uur
in de aula van de universiteit,
De Boelelaan 1105

door

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geboren te St. Asaph, Groot-Brittannië

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copromotoren:	prof.dr. M.C. de Bruijne dr. M. Langelaan

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1 Introduction

First do no harm

This is a fundamental principle that medical students, nurses and other healthcare staff are taught and work by. Similar words are also a part of the oath of medical students at their graduation in the Netherlands. However, despite the very best of intentions of healthcare workers, harm to patients caused by health care, is of all times.

Patient safety has been high on the international agenda for several decades since the Harvard Medical Practice Study (HMPS) in 1990 and the report 'To Err is Human' of the Institute Of Medicine (IOM) in 1999.[1,2] The HMPS was the first study to estimate how many patients suffered from health care related harm, through large scaled retrospective patient record review. The IOM report concluded, based upon a number of studies, that between 44,000 and 98,000 hospitalised patients in the US die each year as a result of medical error and that health care providers and governments should set up efforts to improve patient safety.[2] After the HMPS results and the IOM report the world started to realise that hospitals are in potential an unsafe place to be for patients, despite medical and technological progress over the years.

Many countries, as the Netherlands, have followed the HMPS in assessing health care related harm, i.e. adverse events, in hospitals and the results have increased the sense of urgency to take countermeasures to guarantee the safety of patients in hospitals throughout the world (table 1).[1;3-22] These studies are all cross-sectional studies, estimating (national) incidences of adverse events and often the preventability at a certain point in time. The incidence of adverse events varies from 2.9% to 16.6%, of which 22% to 70% are more than likely to be preventable (table 1). In the Netherlands the incidences are on the low side of the spectrum, in comparison with other countries. The differences in range may reflect differences in definitions as well as differences in quality and safety of care.[23]

Initiatives to improve patient safety have followed the publishing of incidences of adverse events and preventable adverse events. As a result, over the last 10 years, large scaled quality and safety campaigns have taken place in many countries all over the world. The adverse event studies have also helped guide prioritising important improvement themes for these large campaigns. In the Netherlands two large scaled quality and safety improvement programmes have taken place from 2004 to 2012. The inevitable question arises if patients are safer now than say 10 or 20 years ago.

On a more detailed level, research is available studying the effects of interventions aimed at more specific patient safety hazards. National follow-up of large scaled adverse events studies to provide a good general sense of the burden of preventable harm to patients caused by health care on the other hand are seldom performed. In the Netherlands we have monitored the level of patient safety during the years alongside the national quality and safety programmes through performing three national adverse event studies.

Table 1: Results of adverse event studies in different countries

Country	Author	Year of admissions	No of admissions	No of hopitals	Adverse events	Preventable adverse events		Potentially preventable death	
					(% of adm.)	(% of adm.)	(% of AE)	(% of deaths)	(% of AE)
Netherlands	Langelaan e.a. 2013	2011/2012	4,048	20	7.1†	1.6‡	22.0‡	2.6‡	-
United Kingdom	Hogan e.a. 2012	2009	1,000	10	-	-	-	5.2‡	39.7‡
Republic of Ireland	Rafter e.a. 2016	2009	1,574	8	10.3†	-	72.7‡	-	-
Portugal	Sousa e.a. 2014	2009	1,669	3	11.1	-	53.2	-	-
Italy	Sommella e.a. 2014	2008	1,501	1	3.3	-	-	-	-
Netherlands	Langelaan e.a. 2010	2008	4,023	20	8.0†	2.9‡	37‡	5.5‡	-
Latin America (5 countries)	Aranaz-Andres e.a. 2011	2007	11,379	58	10.5†	5.5‡	59.0‡	-	-
8 developing countries	Wilson e.a. 2012	2005	15,548	26	8.2*	-	83.0‡	-	-
Spain	Aranaz 2009	2005	5,908	24	8.9†	4.9‡	42.6‡	-	-
Tunisia	Letaief e.a. 2010	2005	620	1	10.0†	-	60‡	-	-
France	Michel e.a. 2007	2004	8,754	71	6.6†	2.3‡	35.4‡	-	-
Netherlands	de Bruijne e.a. 2007	2004	7,926	21	5.7†	2.3‡	40‡	4.1‡	-
United Kingdom	Sari e.a. 2007	2004	1,006	1	10.9*	-	55.0**	-	-
					8.6†	-	31.0‡	-	
Sweden	Soop e.a. 2009	2003/2004	1,967	28	12.3†	8.6‡	70.1‡	-	-
Canada	Baker e.a. 2004	2000	3,745	20	7.5†	-	36.9‡	0.7‡	9.0‡
United Kingdom	Vincent e.a. 2001	1999	1,014	2	10.8	5.6‡	47.9‡	-	-
Denmark	Schioler e.a. 2001	1998	1,097	17	9.0	-	40.4	-	-
New Zealand	Davis e.a. 2002	1998	6,579	13	12.9*	5.2**	37.1**	-	-
Australia	Wilson e.a. 1995	1992	14,179	28	16.6	-	51.2	-	-
United States	Thomas e.a. 2000b	1992	14,052	28	2.9†	6.8‡	-	-	-
United States	Brennan e.a. 1991	1984	30,121	51	3.7†	1.0‡	27.6‡		51.3‡

* Causality 2 or higher
† Causality 4 or higher
** Preventability score 2 or higher
‡ Preventability score 4 or higher

DEFINING, MEASURING AND MONITORING PATIENT SAFETY

Defining patient safety

The definition of patient safety is not a static one. Traditionally patient safety is focussed on the many ways health care organisations can fail and has been defined as the prevention of errors and adverse effects to patients associated with health care by the WHO, or even simpler as the prevention of harm to patients by the Institute of Medicine. Over the years the focus has moved from counting harms after the event to a more integrated view of risk management and prospectively looking at hazards that might give rise to errors, or safety failure before harm has occurred.[24] Recently a different look on patient safety has been emerging and is shifting from focusing on what and why did it go wrong (Safety I) towards what goes right (Safety II). The line of thought behind this is proactive safety management, by focussing on how everyday performance usually succeeds rather than on the occasional failure. Healthcare is resilient to a large extent: clinicians constantly adjust what they do to match the conditions at hand.[25] Both points of view seem to be complementary and important for an understanding of patient safety.

This thesis mainly concentrates on Safety I outcomes: counting and analysing failures through outcomes such as adverse events, preventable adverse events and potentially preventable deaths (see box 1 for definitions).

Box 1: Definitions of adverse events, preventable adverse events and potentially preventable deaths

Adverse event:

1. an unintended injury, which
2. resulted in temporary or permanent disability, death of prolongation of hospital stay, and was
3. caused by health care management rather than the patients disease.

Example adverse event: a patient experiences an allergic reaction after a medication is administered. This adverse event could have been preventable as well as unpreventable. If the patient had not previously had this medication, the allergy was unknown to either patient or hospital and thus the adverse event was unpreventable.

Preventable adverse event: an adverse event is found to be preventable when the given care was inadequate/substandard, i.e. falls below the current level of expected performance for either the health care worker or the health care system.

Example preventable adverse event: continuing on the previous example of an allergic reaction: if the patient had previously experienced the allergic reaction in the hospital and this was marked in the patient record, the adverse event was preventable.

Potentially preventable death: if a preventable adverse event has occurred in a deceased patient, in some cases the preventable adverse event has also contributed to the death of that patient. It is important to emphasize that not all deaths, as the adverse event could also have been totally unrelated to the death of the patient. We use the word 'potentially' because of the multifactorial nature of hospital deaths and the retrospective assessment of the causality.
Example potentially preventable death: continuing on the previous example of an allergic reaction: the patient experienced an anaphylactic shock due to an allergy which was previously known and had been written down in the patient record. The patient died.

Even under the basic assumption that all health care workers are doing their utmost best, the rare exception aside, patients are at risk of experiencing harm when admitted to a hospital. There are several frameworks that describe safety in health care, of which the systems approach of James Reason has been one of the most influential.[24] It provides the insight that (medical) errors happen due to a combination of expectable and inevitable human failure combined with the design of the healthcare system at hand.[26] Reason illustrated that although multiple layers of defence lie between error and harm, flaws can exist in each layer, effectively shown in the Swiss Cheese model. The holes are created by active failures and latent conditions. Active failures are individual unsafe acts, latent conditions are failures of organisation or design caused by decisions made by designers, builders, management, amongst others.[26,27] As humans are fallible, active failures will always happen. Countermeasures are based on the assumption that you can change the local and working conditions under which humans work and it is important to create effective defences and minimise the latent conditions within an organisation. Besides active failures and latent conditions, safety culture is also a factor to take into account in studying the patient safety of an organisation. Safety culture can be defined as the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style of proficiency of, an organisation's health and safety management.[28] Hospital safety culture has been linked to patient safety.[29,30] Thus often many factors underlie a (preventable) adverse event. The challenge is to get insight into as many factors as possible by using multiple methods and subsequently to improve care.

Measuring and monitoring patient safety

The higher purpose or intention of patient safety interventions is to improve outcomes for patients by preventing/reducing harm. It is important to gather information on patient safety and the effectiveness of interventions. The WHO has described different stages in the patient safety research cycle to help to determine which type of activity is needed when continuously

improving patient safety: measuring harm, understanding causes, identifying solutions, evaluating impact and translating evidence into safer care.[37] The measurement method depends on the specific goal of the measurement. We have monitored the level of patient safety through performing three national adverse event studies. In this sense the adverse event studies can be seen as repeatedly performing the first stage of the patient safety research cycle by repeatedly increasing the awareness of patient safety risks and herewith the sense of urgency to improve it. Another goal was to add results to the fourth step of the patient safety research cycle: evaluating the impact, as the national adverse event studies do give a general sense of the state of patient safety at that specific moment.

There are many ways to measure harm, for example through mortality statistics, systematic record review, reporting systems or through safety indicators from existing data sources. Each method has its own advantages and disadvantages.[31] To monitor the national level of patient safety in our country, we chose to repeatedly perform national adverse event studies using systematic record review. Systematic record review is an often used method and especially appropriate for estimating rates of adverse events. An advantage of this choice was that in our country a first measurement using chart review had already taken place.[19,32] As any other method, systematic record review has downsides: a questionable reliability, it is expensive and hindsight bias may form a problem.[31,33,34] Despite these downsides, the strength of chart review is that it contains robust systematic assessment of data in which a well-considered judgement is made by physicians if a patient has experienced harm caused by healthcare, and in retrospect this could possibly have been prevented. This method lies close to clinical practice and is therefore appealing to healthcare workers. Moreover systematic record review is especially appropriate for showing the sense of urgency to take countermeasures to improve patient safety, as the main outcomes of this type of study sort their effect on different stakeholder levels: the policy makers, hospitals and the patient.

Other methods seemed less obvious. Data from reporting systems lack a denominator, are dependent on the willingness of doctors and nurses to report adverse events and do thus not reliably measure adverse event rates. Moreover, a high rate of reported adverse events could reflect an organisation committed to identifying and reducing adverse events. A downside of analysis of administrative data is that automised in depth studying individual cases is not possible and that the clinical context is for a large part lost. Thus the measurements and results would have less meaning for healthcare workers. Moreover, incomplete and inaccurate data is also an underlying problem.[31] Mortality statistics have recently received attention, but have a questionable relation to outcome measures as preventable deaths or preventable adverse events in general.[35] Also, the analysis of mortality is based on administrative data with the same downsides as aforementioned method.

Patient safety movement in the Netherlands

In the Netherlands patient safety has had an increasingly important place on the political and healthcare agenda since 2004. In 2004 a national quality programme was launched: 'Better Faster'. The goal of the programme was improving transparency, efficiency and quality of health care. As part of this programme, 24 of the 93 Dutch hospitals joined a multi-layered programme designed to implement improvements on best practices in patient logistics, patient safety and leadership and organisation development. Part of the Better Faster programme was that the former Shell president Rein Willems was asked for advise on risk management in Dutch hospitals. One of his most important recommendations was the implementation of a certified safety management system (SMS) in all Dutch hospitals.[38] This recommendation was implemented in the following national safety programme, 'Prevent harm, work safely', which started in 2008 and ran until the end of 2012. This comprehensive programme was specifically directed at patient safety and all Dutch hospitals were able to participate. The safety campaign focused on the implementation of a Safety Management System (SMS) and the implementation of interventions on ten specific medical themes, such as prevention of surgical site infection, prevention of central line infections and medication reconciliation.

Adverse events and preventable adverse events have been monitored during the years alongside the national quality and safety programmes, as requested by the Dutch ministry for Health, welfare and sports (figure 1). The first adverse event study assessed the safety in Dutch hospitals in the first year of 'Better Faster', the second and third adverse event study reviewed patient records from the first and last year of the national safety programme 'Prevent harm, work safely'.

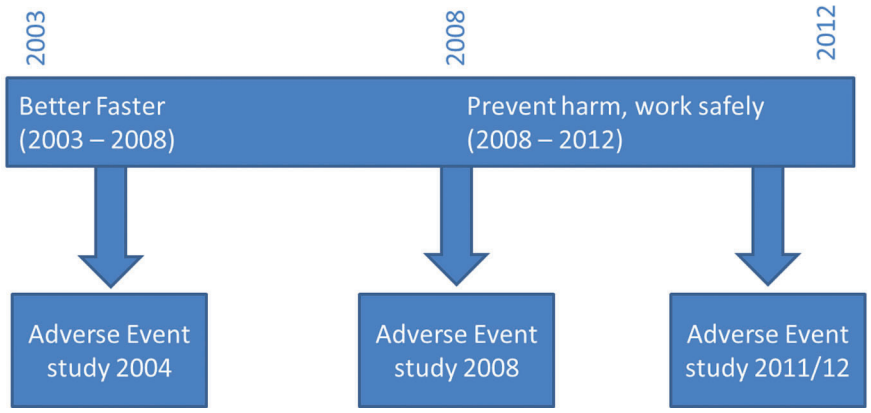

Figure 1: National quality and safety programmes and adverse event studies in the Netherlands

Besides the national quality and safety programmes of the last decade, other developments affecting patient safety in hospitals have also taken place. The most important probably being the introduction of surgical checklists. Use of surgical checklists was especially accelerated following the publication of a study in the Netherlands in 2010 showing that the use of surgical checklists resulted in a reduction of complications, reoperations and hospital mortality in surgical patients, and the presentation of the results of the second national adverse event study showing that surgical adverse events had increased in 2008 in comparison to 2004. [20,36] Moreover the Dutch Health Care Inspectorate has stimulated the development of pre-, peri- and post-surgical guidelines and subsequently also monitored the implementation. In this manner the Dutch Health Care Inspectorate has paid an increasing amount of attention to the surgical process and kept an eye on implementation of guidelines, time-out procedure and checklists.

As a spin-off from the national adverse event studies since 2007 more and more Dutch hospitals are using retrospective patient record review by their own nurses and physicians as part of their quality and safety system. Because this method is carried out by both nurses and physicians, it has other perceived benefits besides the standard main outcome measures. On the one hand nurses and physicians are stimulated to cooperate and act together with an understanding of each other's work. On the other hand patient safety awareness and a positive patient safety culture are stimulated as the results are often discussed in morbidity and mortality reviews and thus contribute to raising a shared sense of urgency and commitment to improvement.

Study design in short

To monitor adverse events and preventable adverse events through time we have performed three national systematic record review studies, using patient records from 2004, 2008 and 2011/2012. In short the used method is presented here. A more detailed description can be found in the upcoming chapters.

The most important outcome measures are adverse events and preventable adverse events. As a sample of patient records is reviewed to assess adverse events, we have numerators as well as denominators and incidences can be calculated. The review method of determining adverse events is comparable to those of other international studies and based on the Harvard Medical Practice Study and the Canadian adverse event study.[1,6] First a nurse screens the patient record by using triggers indicating a potential adverse event. Admissions positive for at least one trigger are further reviewed by a physician. Presence and preventability of an adverse event is determined, based on a standardized procedure and preceded by a number of underlying questions to secure a systematic assessment. Physician reviewers make a decision on the preventability based on a thorough analysis of the information in the/ treatment described in the patient record by systematically assessing whether given care fell below the current level of expected performance for practitioners or systems. Physicians also

scored the clinical process, i.e. diagnostics, surgery, medication etc., and causes related to the adverse event.

To assess the reliability of the used method, part of the sample was reviewed by two nurses or two physicians. Moreover, a number of patient admissions from the 2004 adverse event study were re-reviewed during the 2011/2012 adverse event study.

OUTLINE OF THESIS

This thesis aims to assess trends in adverse events and preventable adverse event rates in the Netherlands through the time period 2004 – 2012, and assess patient safety in more detail for specific care processes and patient groups.

Part I: Monitoring of adverse events and preventable adverse events 2004-2012
In chapters 2 – 4 results are shown of the monitoring of adverse events and preventable adverse events in the Netherlands between 2004 and 2012. In chapter 2 the results of the first two measurements are given, in chapter 3 the results of all three measurements. To assess if hospital care has become safer over the years corrected multilevel incidences are given. It is important to realise that the corrected multilevel incidences are different from the cross sectional data published on the measurements in the national reports.

Chapter 4 discusses a topic that has not previously been researched, but is important in light of the longitudinal character of our monitoring studies: the intra-rater agreement of retrospective record review over time. The physicians reviewers have re-reviewed patient records that they had reviewed during the first adverse event study of 2004 after a period of eight years to assess if they had become stricter or more lenient in their review process over the years.

Research questions:

1 How have adverse event and preventable adverse event rates developed between 2004-2012 alongside a national patient safety programme?
   a What are the changes in adverse event and preventable adverse event rates between 2004, 2008 and 2011/2012?
   b What is the intra-rater agreement of physicians in reviewing patient records for adverse events and preventable adverse events after six years? Is there a difference in judgement of preventability between re-review and original review?

Part II: Descriptive studies illustrating patients and processes at risk of experiencing (preventable) adverse events

In chapters 5-8 results illustrating patient and processes at risk of experiencing adverse events and preventable adverse events are shown, by secondary analyses focussing on specific hypotheses. Chapter 5 discusses records sampled for the adverse event study: inpatient deaths versus patients who are discharged alive. As retrospective patient record review is time consuming and costly, it is important to look into methods that could make systematic record review more effective for either practice of research. In chapter 6 the risk of experiencing an adverse drug event is discussed, accompanied by information on medication groups and processes at risk. In chapter 7 the risk of being treated by multiple physician specialties is assessed, an important topic in light of increasing specialisation in hospital care. Chapter 8 discusses the presence, correctness and timeliness of the discharge letter, an important part of the handover process when a patient leaves the hospital.

Research questions:

1 What can be learned from focussed secondary analyses on the data gathered for the national monitoring of adverse events
   a Does assessing inpatient deaths offer a representative view of the number and type of adverse events in hospitals in comparison to patients who are discharged alive?
   b What is the incidence, nature and potential preventability of medication related adverse events during hospitalisation? What are potential factors associated with the occurrence of medication related adverse events?
   c Is the number of specialties treating a patient associated with the risk of experiencing harm during hospital admissions?
   d To what extent is the presence, correctness and timeliness of discharge letters in hospital records associated with patient and admission characteristics?

The general discussion, chapter 9, provides an overall conclusion and interpretation of the preceding chapters.

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PART I

Monitoring of adverse events and preventable adverse events 2004-2012

2 Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study

Published as:

Rebecca J Baines, Maaike Langelaan, Martine C de Bruijne, Henk Asscheman, Peter Spreeuwenberg, Lotte van de Steeg, Kitty M Siemerink, Floor van Rosse, Maren Broekens, Cordula Wagner. Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study. BMJ Quality & Safety. 2013 Apr;22(4): 290–298.

ABSTRACT

Objective
To determine the change in adverse event rates and preventable adverse event rates over time, identify certain patient risk groups and discuss factors influencing the outcome.

Design
Longitudinal retrospective patient record review study.

Setting and participants
A random sample of 21 hospitals in the Netherlands in 2004 and 20 hospitals in 2008. In each hospital 400 patient admissions were included in 2004 and 200 in 2008.

Main outcome measures
Adverse events and preventable adverse events.

Results
To account for the hierarchical data structure, multilevel analyses were performed to evaluate changes in the rates of adverse events and preventable adverse events. Multilevel analyses of 11,883 patient records (7,887 in 2004, 3,996 in 2008) showed that the rate of patients experiencing an adverse event increased from 4.1% (95% CI 3.3% to 5.1%) in 2004 to 6.2% (95% CI 5.0% to 7.6%) in 2008. The preventable adverse event rate remained relatively stable at 1.8% (95% CI 1.3% to 2.4%) in 2004 and 1.6% (95% CI 1.2% to 2.3%) in 2008. The risk of experiencing a preventable adverse event was increasingly higher for patients admitted to a surgical unit (Odds Ratio 1.54 (95% CI 1.10 to 2.16) in 2004 and 3.32 (95% CI 2.17 to 5.07) in 2008). More than 50% of all adverse events were related to surgery. Indications were found that differences in the risk of experiencing a preventable adverse event between hospital departments were larger in 2008 than in 2004, while differences between hospitals themselves were smaller.

Conclusions
Patient harm related to health care is a persistent problem that is hard to influence. Measuring adverse events over time stresses the continuing urgency and also identifies possible areas for improvement.

INTRODUCTION

Following the Harvard Medical Practice Study (HMPS)[1] many countries have published their own results on adverse event rates.[2-9] In response patient safety interventions and campaigns have been set up to improve patient outcomes by reducing harm related to health care. Evidence of their effect is, however, limited.[10-12] Long term change in adverse event and preventable adverse event rates could provide insight in overall development of patient safety in hospitals.

Measuring adverse events over time on a large scale is important to estimate the overall effect of many efforts to improve patient safety, but is also difficult. It is costly and not all contextual factors that are of influence can be accounted for. Landrigan and colleagues published trends in harm rates in 10 hospitals in Northern Carolina using the IHI Global Trigger Tool (GTT).[13,14] They were unable to find a significant improvement in preventable adverse event rates. The GTT was originally developed to fulfil hospitals' need for a more practical and less labour intensive approach to assess patient safety.[15] In the Netherlands the first national adverse event study took place in 2004 in 21 hospitals using comparable methods as the HMPS and the Canadian adverse event study.[1,4,16] This method is more labour intensive than the GTT, however does allow the physician reviewers to ascertain a broad and structured perspective of a patient, the reviewed admission and the events preceding and following a possible adverse event. Due to the structured questioning method a good assessment can be made of the relationship between harm, health care and preventability.

We have undertaken a second measurement to get a more up to date view and to assess changes in national adverse event and preventable adverse event rates between 2004 and 2008. We also aim to identify potential patient risk groups and to discuss factors influencing the outcome. The results will help hospitals and patient safety initiatives to identify further possibilities for improvement.

METHODS

Design and setting

We performed a longitudinal retrospective patient record review study in 21 randomly sampled hospitals in 2004 and 20 in 2008 out of the total of 93 Dutch hospitals. Eight hospitals were studied in both years. Both samples were stratified for hospital type, university, tertiary teaching and general hospitals, and a proper representation of both urban and rural settings in the samples were verified. Tertiary teaching hospitals in the Netherlands provide specialised care and train doctors. The level of care given is between that given in a university hospital and in a general hospital. Generally speaking, university hospitals and to some extent tertiary teaching hospitals tend to treat more complex patients with more complex

care. To be eligible, hospitals had to have at least 200 beds and an intensive care unit. In each hospital 400 patient admissions were randomly selected in 2004, 200 in 2008. Fifty percent of the records were of patients who were discharged from the hospital after a stay of at least 24 hours. The other fifty percent were of patients who died in hospital. These patients were sampled from all inpatient deaths, regardless of their length of stay. We did not exclude patients admitted with an explicitly palliative care plan, this information was noted down and taken into account during the review process. During analysis overall adverse event rates were corrected for the oversampling of deceased patients, because in our sample 50% of the patients were inpatient deaths and in reality 3%. In the results we weight our 50% back to the actual 3% so the presented results are a representation of the total hospital population of discharged and deceased patients. We followed the same procedure for the distribution of types of hospitals. Patients admitted to the psychiatry department, obstetrics and children under one year were excluded. The design and results of the 2004 study have been published elsewhere.[1,16-21]

Record review

The nursing, medical and, if available, outpatient records of the sample patient admissions were reviewed by trained external nurses and trained external physicians belonging to the specialties surgery, internal medicine and neurology. Consultation with specialties other than their own was available if needed. For the largest part the reviewers in the 2008 study had also participated in the 2004 study. Review of the records took place in 2005/2006, and in 2009/2010 respectively.

The method of determining adverse events was comparable to those of other international studies.[4,8] First a nurse screened the records by using triggers indicating potential adverse events, for example readmissions or hospital acquired infections. Admissions positive for at least one trigger were further reviewed by a physician. Based on a standardized procedure and preceded by a number of underlying questions to secure a systematic assessment, the presence and preventability of an adverse event was determined.

An adverse event was defined by three criteria:

1 An unintended injury;
2 The injury resulted in prolongation of hospital stay, temporary or permanent disability or death;
3 The injury was caused by healthcare management rather than the patient's disease.

An adverse event was found to be preventable when the care given fell below the current level of expected performance for practitioners or systems. The cause of an adverse event as well as its preventability were scored on a six point Likert scale and counted as caused by health care or preventable if the score was 4-6. A score of 4-6 indicated that the reviewer

regarded the event as having a greater than 50% of chance of being caused by health care or preventable. To add more structure to the implicit review process, the causation and preventability score were each preceded by thirteen questions to facilitate the final reviewers' judgment (appendix table 1).

Adverse events that occurred during the patient's index hospital admission and were detected during either the index admission or subsequent admissions over the following 12 month period were counted. Also counted were adverse events related to patient admissions in the same hospital within the 12 months preceding the index admission but which were not detected until the index admission. Consequently patient records of the index hospital admission were reviewed, as were the patient records of patient admissions before and after the index admission. The way the adverse events were counted was the same for both years. Only patient admissions in participating hospitals were evaluated. Out of hospital pre-admission care could not be evaluated.

The review process of the 2004 study was slightly adapted for the 2008 study. In the 2004 study, pairs of physicians independently assessed all records positive for screening criteria in the first stage review. Disagreement about the presence and/or preventability of an adverse event prompted a consensus procedure.[16] Analysis of the data from 2004 showed that physicians within pairs tended to show substantial agreement, however between pairs agreement was much lower.[17] The involvement of a second reviewer and consensus procedure in 2004 apparently did not per se improve the overall reliability. For this reason and due to limited resources we chose to perform a more efficient review process in the 2008 study, as other recent and earlier patient record review studies have also done, in which all records positive for screening criteria were reviewed by one physician.[4,22] To compensate for the loss of discussion between physicians during the consensus procedure, for the 2008 study we more often organized reflection meetings based on discrepancies in records reviewed twice for all reviewers to uphold high quality of the review process.

Additional data on the total Dutch hospital population in 2004 and 2008 and on diagnosis, coded according to the International Statistical Classification of Diseases, 9th revision (ICD-9) for the reviewed patient admissions, was obtained from the national hospital administration database (Prismant).

Reliability

To test the reliability of the review process a random sample equally spread over all hospitals and time was drawn in 2004 and 2008. To ascertain the reliability of screening by nurses 415 records were reviewed twice in 2004, 238 in 2008. To ascertain the reliability of judgments on the presence and preventability of an adverse event, 120 records were reviewed twice by physicians in 2004, 228 in 2008. The second reviewer was blinded for the outcome of the first review. The interrater agreement was expressed as the percentage of records for which there

was agreement on the presence of screening criteria for the nurses and the presence and preventability of an adverse event for the physicians and by the kappa statistic.

Statistical analysis

Patients' descriptive characteristics of the 2004 and 2008 sample were calculated (SPSS 18.0). After weighting for the sample frame the total study sample, that is both discharged and deceased patients, was representative of the total Dutch population of hospitalized patients.

A multilevel logistic regression analysis was performed (MLwin 2.22) in order to analyse changes in the rates of patient admissions with at least one adverse event or preventable adverse event between 2004 and 2008, while at the same time correcting for clustering on the hospital and hospital department levels.[23] The 2nd order PQL estimation method was used. To make results comparable with studies that use rates of adverse events and preventable adverse events per thousand admission days, we also analysed rates per thousand patient days with a multilevel Poisson regression analysis. In the multilevel analyses the eight overlapping hospitals were allowed to co-vary. Adjustments were made for the stratified sample to correct for over-representation of deceased patients and hospital types. To account for the possibility that changes over time were influenced by changes in the patient mix; terms were added to the model for age, sex, urgency of admission, admission to a surgical unit and main ICD9 diagnostic groups. All variables included in the model were centred to reference values for all Dutch hospital admissions in 2008. In previously published adverse event rates, we chose to use less complex analytic models which were easier to interpret and suitable for the descriptive analyses of the baseline study. More complex models were required to compare the two years in this article, by comparison the proportions of the more complex models are systematically lower.

To analyse the changes in group variance for hospital and department levels, we calculated intra-class correlation coefficients (ICCs), the ratio of the between group variance and the total variance. A higher ICC at the hospital level, for example, means a smaller variance for all adverse event rates within the hospitals and a larger variance between hospitals. Odds ratios (ORs) for the co-variables were calculated to ascertain the risk of experiencing an adverse event for specific groups.

The characteristics of the adverse events, such as type of adverse event (surgery, drug/fluid, medical procedure, diagnostic, other clinical management, discharge or other) and degree of disability were analysed in SPSS by pooling the 2004 and 2008 data.

RESULTS

Patient records and sample

In total 11,949 of the 12,400 sampled records were reviewed, 7,926 patient records in 21 hospitals from 2004 and 4,023 patient records in 20 hospitals from 2008. The 451 (3.6%) records that were not reviewed were unavailable or inadequate for review. During analysis 66 patient records were excluded because they could not be linked to the hospital administration database and consequently had missing ICD9 main diagnostic group information. In total 11,883 patient records were analyzed, 7,887 of 2004 and 3,996 of 2008.

Patient characteristics of both samples and total inpatient hospital populations are given in table 1. The total inpatient hospital population stayed relatively stable, with a slight decrease from 1,343,234 patient admissions in 2004 to 1,332,602 in 2008, hospital deaths decreased from 42,329 in 2004 to 35,721 in 2008. The length of hospital stay decreased between 2004 and 2008 in both the sample and the total inpatient hospital population. The percentage of urgent admissions in the 2004 and 2008 sample was comparable. The mean age had increased slightly.

Table 1: Comparison of hospital and patient characteristics of the study samples 2004 and 2008 and the total Dutch inpatient hospital population (source: Prismant) in 2004 and 2008

Hospital characteristics	**Sample 2004***	**Sample 2008***	**Total hospital population 2004****	**Total hospital population 2008****
Inpatient admissions n (% of all patients)	7,887 (0.6)	3,996 (0.3)	1,343.234	1,332.602
Hospital deaths n (% of total sample/ pop)	3,958 (50.2)	1,996 (49.9)	42,329 (3.2)	35,721 (2.7)
Patient admissions**				
- University n (% of total sample/ pop)	1,378 (17.5)	791 (19.8)	179,998 (13.4)	197,269 (14.8)
- Tertiary teaching	2,322 (29.4)	1,197 (30.0)	381,625 (28.4)	584,914 (43.9)
- General	4,187 (53.1)	2,008 (50.3)	781,611 (58.2)	550,419 (41.3)
Patient Characteristics	**Sample 2004*†**	**Sample 2008*†**	**Total hospital population 2004****	**Total hospital population 2008****
Male sex %	49.0	49.9	49.7	49.9
Age y, mean (SD)	57.4 (21.6)	60.0 (20.7)	55.9 (21.7)	56.8 (21.8)
Length of hospital stay d, mean (SD/median)	8.5 (10.4/ 5.0)	6.7 (8.9/4.0)	7.3 (10.4/ 4.0)	6.3 (9.47/3.0)
Urgently admitted patients %	53.8	54.1	46.6	49.5
Hospital departments, %				
- Surgery	24.0	21.9	24.4	23.8
- Cardiology	12.9	11.6	16.1	17.5
- Internal medicine	15.8	16.2	16.1	15.9
- Orthopedics	10.5	11.0	8.7	8.2
- Neurology	7.5	7.7	6.3	6.5
- Lung diseases	7.2	6.2	6.5	7.7
- Ear, nose and throat	4.3	3.7	4.5	3.8
- Urology	4.2	5.2	5.0	5.0
- Other	14.5	13.2	18.8	11.6

Patient Characteristics	Sample 2004*†	Sample 2008*†	Total hospital population 2004**	Total hospital population 2008**
ICD-9 diagnostic groups				
- Neoplasms	10.4	12.2	11.7	11.1
- Nervous system and sensory organs	4.4	3.3	3.6	2.9
- Circulatory system	19.1	20.8	18.8	18.0
- Respiratory system	8.4	8.7	7.6	7.8
- Digestive system	10.9	10.8	10.9	10.0
- Genitourinary	6.5	6.3	6.7	6.4
- Musculoskeletal system and connective tissue	11.2	11.9	9.0	8.6
- Ill defined conditions	8.9	6.3	10.1	13.2
- Injury and poisoning	9.8	9.5	10.0	10.0
- Other ‡	10.3	9.3	11.8	11.9

* Patient admissions of obstetrics, psychiatry, <1 year and <24 hours for non-deceased patients were excluded

** All patient admissions in non-specialty and non-psychiatric hospitals in the Netherlands (source: Prismant). Admissions of obstetrics, psychiatry, <1 year and <24 hours for non-deceased patients were excluded

† Patient characteristics are weighted for overrepresentation of deceased patients and hospital type

‡ Rest category includes smallest groups (3% and under): infectious and parasitic diseases; endocrine, nutritional, metabolic and immunity; blood and blood forming; mental; complications birth; skin and subcutaneous disease; congenital abnormalities; V-codes

Table 2: Rate of:

A. patients who experienced at least one adverse event or preventable adverse event

B. adverse events per 1000 patient days for the total sample and per hospital type (university, tertiary teaching and general). All rates are corrected for the stratified sample and patient mix for the total sample and for the sub-samples. P-values for the difference between 2004 and 2008 rates are given

	Reviewed records		Adverse event		Preventable adverse event	
	2004	2008	2004 (95% CI)	2008 (95% CI)	2004 (95% CI)	2008 (95% CI)
A rate per 100 patients						
Total sample *	7,887	3,996	4.1 (3.3 to 5.1)	6.2 (5.0 to 7.6)	1.8 (1.3 to 2.4)	1.6 (1.2 to 2.3)
- University †	1,378	791	6.2 (4.1 to 9.3)	5.1 (3.5 to 7.4)	1.1 (0.6 to 2.1)	1.3 (0.8 to 2.2)
- Tertiary teaching †	2,322	1,197	3.9 (2.8 to 5.5)	6.4 (4.7 to 8.5)	1.6 (1.1 to 2.5)	1.8 (1.2 to 2.7)
- General †	4,187	2,008	3.7 (2.8 to 4.9)	6.4 (5.0 to 8.2)	2.2 (1.6 to 3.1)	1.6 (1.1 to 2.3)
B rate per 1000 patient days						
Total sample *	7,887	3,996	6.0 (4.8 to 7.5)	10.5 (8.7 to 12.7)	2.4 (1.8 to 3.3)	2.7 (2.0 to 3.7)
- University †	1,378	791	7.8 (5.1 to 12.1)	7.4 (5.3 to 10.3)	1.4 (0.7 to 2.6)	1.8 (1.0 to 3.0)
- Tertiary teaching †	2,322	1,197	5.8 (4.0 to 8.3)	11.2 (8.6 to 14.6)	2.2 (1.5 to 3.3)	3.2 (2.2 to 4.6)
- General †	4,187	2,008	5.6 (4.2 to 7.5)	11.2 (8.9 to 14.1)	3.3 (2.4 to 4.6)	2.6 (1.9 to 3.6)

* Total sample rates are corrected for the stratified sample (deceased patients and hospital type) and patient mix (age, sex, urgency of admission, admission to a surgical unit and main ICD9 diagnostic groups)

† Hospital type rates are corrected for the stratified sample (deceased patients) and patient mix (age, sex, urgency of admission, admission to a surgical unit and main ICD9 diagnostic groups)

Table 3: adverse events (2004 and 2008 data pooled) by clinical process and proportions judged preventable, leading to permanent disability (excluding death) and contributed to death

Classification	No of AEs	Distribution of AEs (column %*)	Preven-table (row %*)	Permanent disability (row %*)	Death (row %*)
Surgery (events related to an operation or occurring within 30 days after an operation)	516	51.7	36.5	5.5	6.2
Drug/fluid (eg, side effects, allergic reactions, anaphylaxis)	271	18.1	22.9	3.3	10.5
Medical procedure (eg, central catheters, endoscopies, pacemakers,)	184	14.7	25.6	6.4	8.0
Diagnostic (eg, missed, delayed or inappropriate diagnostic process)	140	7.0	79.7	6.7	21.7
Other clinical management (including nursing care and allied healthcare)	111	5.7	51.0	0	10.2
Discharge (eg, inappropriate discharge)	5	1.2	100.0	0	0
Other (eg, fall)	29	1.6	64.3	0	14,3
Total	1256	100.0	37.5	4.8	8.6

* Percentages were weighted for oversampling of deceased patients and type of hospital

Rate of patients experiencing an adverse event

The physicians identified one or more adverse events in 663 of the 7,887 reviewed patient admissions for 2004 and in 467 of the 3,996 reviewed patient admissions for 2008, 283 and 198 adverse events respectively were found to be preventable. These numbers are crude unweighted numbers.

Multilevel analysis showed that between 2004 and 2008 the rate of patients that experienced an adverse event, corrected for sampling design and case mix, showed a statistically significant increase from 4.1% (95% CI 3.3% to 5.1%) in 2004 to 6.2% (95% CI 5.0% to 7.6%) in 2008 in the total sample and also in the sub-sample of tertiary teaching hospitals and general hospitals (table 2). The incidence of preventable adverse events remained relatively stable over time in all groups, with 1.8% (95% CI 1.3% to 2.4%) in 2004 and 1.6% (95% CI 1.2% to 2.3%) in 2008.

Rate of adverse events per 1000 patient days

A number of patients experienced more than one adverse event, in total 744 adverse events in 663 patients were found in 2004 and 512 in 467 patients in 2008. In 2004 on average 6.0 (95% CI 4.8 to 7.5) adverse events per 1000 patient days were found, in 2008 10.5 (95% CI 8.7 to 12.7). In 2004 2.4 (95% CI 1.8 to 3.3) preventable adverse events per 1000 patient days were found in 2004 and 2.7 (95% CI 2.0 to 3.7) in 2008. The results per 1000 patient days show the same general view as the rates of patients experiencing (at least) one adverse event or preventable adverse event, but with stronger contrasts (table 2).

Clinical process of adverse events

Of all 1256 adverse events found in 2004 and 2008 together 37.5% was found to be preventable, 4.8% led to permanent disability and 8.6% to death. Of all adverse events 51.7% was related to surgery. Adverse events related to the diagnostic process and discharge were most often found to be preventable, with the diagnostic adverse events also most often leading to death (table 3).

Table 4 shows case descriptions for adverse events and also illustrates the clinical process.

Table 4: Case descriptions for adverse events and preventable adverse events

Non preventable adverse events
Paralysis of vocal cords and respiratory problems after total hip replacement (surgery)
Allergic reaction to medication, not previously known (drug/fluid)
Neutropenic sepsis after chemotherapy in correct dosage (drug/fluid)
Pneumonia after thoracotomy, resulting in artificial ventilation and antibiotics (medical procedure)
Pressure sore on heel, despite adequate preventive measures (other clinical management)
Preventable adverse events
Technical inadequate hip prosthesis, resulting in two repositions and reoperation (surgery)
Patient deceased due to congestive hart failure, as a consequence of intravenous fluid overload not timely diagnosed and treated after operation (surgery)
Inadequate antibiotic treatment for urine tract infection, resulting in death (not corrected after results of culture) (drug/fluid)
Perforation of rectum after enema, leading to abscess, gastrointestinal bleeding and death (medical procedure)
Missed diagnosis pulmonary embolism in a 50 year old female on oral contraceptives after 1 week bed rest for "flu" (diagnostic)
Missed diagnosis of incarcerated femoral hernia, died of intractable septic complications from peritonitis (diagnostic)
Severe hypoxia due to wrongly connected oxygen tube (other clinical management)

Variation at the hospital and hospital department levels

ICC estimates for the hospital and department levels together showed a decrease from 0.138 in 2004 to 0.082 in 2008. This indicated less variation at both levels for experiencing an adverse event in 2008 than in 2004. In other words hospitals and departments became more alike in the risk of experiencing an adverse event.

For preventable adverse events, the ICC at the hospital level and the department level together was comparable in both years, with an ICC of 0.152 in 2004 and 0.149 in 2008. The relative contribution of the department level however increased from 0.025 in 2004 to 0.067 in 2008. This indicates that for preventable adverse events in 2008 there were more differences between departments and less between hospitals in comparison with 2004.

Covariables

Odds Ratios (ORs) for the different groups in our model for adverse events and preventable adverse events in 2004 and 2008 are shown in table 5. Both years show an increase of adverse events and preventable adverse events by age. Patients who were urgently admitted had a lower risk of experiencing adverse events and preventable adverse events. Patients admitted to a surgical unit experienced a higher risk in both years. This risk increased over the years from an OR of 1.54 (95% CI 1.10 to 2.16) in 2004 to 3.32 (95% CI 2.17 to 5.07**)** in 2008 for experiencing a preventable adverse event. Patients who eventually deceased in the hospital were at a higher risk of experiencing an adverse event or preventable adverse event in both years. Various main diagnostic groups showed higher ORs in 2004 and 2008 using 'circulatory system' category as a reference. Of these the digestive system, injury and poisoning, genitourinary and neoplasms were the most pronounced (table 5).

Table 5: Odds ratio's (ORs) for the covariates of a multilevel multivariable model for adverse events and preventable adverse events in 2004 and 2008 adjusting for clustering at the hospital level and hospital department level. Variables included in the model were centered on reference values for all Dutch hospital admissions in 2008

	All AEs OR (95% CI)		Preventable AEs OR (95% CI)	
	2004	2008	2004	2008
Hospital type (ref general)				
- Academic	**1.72 (1.06 to 2.79)**	0.78 (0.51 to 1.20)	0.50 (0.26 to 0.96)	0.80 (0.47 to 1.35)
- Tertiary teaching	1.06 (0.69 to 1.61)	0.99 (0.70 to 1.41)	0.74 (0.47 to 1.16)	1.16 (0.82 to 1.64)
Patients deceased during admission (ref no)	**3.03 (2.40 to 3.84)**	**3.87 (2.95 to 5.08)**	**3.48 (2.45 to 4.95)**	**5.24 (3.41 to 8.05)**
Age (year)	**1.01 (1.00 to 1.02)**	1.00 (1.00 to 1.01)	**1.01 (1.00 to 1.02)**	1.01 (1.00 to 1.02)
Sex (ref male)	0.97 (0.82 to 1.15)	0.97 (0.79 to 1.20)	0.93 (0.73 to 1.20)	1.32 (0.97 to 1.80)
Urgently admitted patients (ref non-urgent)	**0.47 (0.38 to 0.59)**	**0.59 (0.45 to 0.77)**	**0.50 (0.36 to 0.69)**	0.68 (0.46 to 1.02)
Surgical admission-unit (ref non-surgical)	**1.50 (1.14 to 1.97)**	**2.64 (2.00 to 3.48)**	**1.54 (1.10 to 2.16)**	**3.32 (2.17 to 5.07)**
ICD9 diagnosis group (ref circulatory system)				
- Neoplasm	1.07 (0.81 to 1.42)	**1.42 (1.04 to 1.96)**	0.96 (0.63 to 1.48)	**1.75 (1.06 to 2.89)**
- Nervous system and sensory organs	0.82 (0.43 to 1.58)	0.63 (0.26 to 1.52)	1.07 (0.40 to 2.82)	1.58 (0.51 to 4.88)
- Respiratory system	1.26 (0.88 to 1.81)	0.82 (0.54 to 1.24)	**1.81 (1.15 to 2.87)**	1.08 (0.56 to 2.10)
- Digestive system	**1.48 (1.06 to 2.07)**	1.45 (0.97 to 2.16)	**1.74 (1.08 to 2.79)**	**2.48 (1.39 to 4.42)**
- Genitourinary	1.53 (0.98 to 2.38)	0.97 (0.56 to 1.70)	**2.34 (1.32 to 4.15)**	**2.58 (1.26 to 5.27)**
- Musculoskeletal system and connective tissue	0.80 (0.48 to 1.34)	0.77 (0.45 to 1.32)	1.00 (0.49 to 2.02)	1.01 (0.43 to 2.40)
- Ill-defined conditions	0.96 (0.65 to 1.43)	1.02 (0.61 to 1.71)	1.33 (0.76 to 2.33)	1.48 (0.66 to 3.29)
- Injury and poisoning	**1.86 (1.30 to 2.66)**	**1.54 (1.03 to 2.32)**	**2.09 (1.26 to 3.45)**	1.49 (0.79 to 2.82)
- Other*	1.31 (0.93 to 1.85)	1.12 (0.74 to 1.69)	**1.71 (1.04 to 2.79)**	1.33 (0.69 to 2.56)

Bold: significant ORs for that year

* Other: infectious and parasitic diseases; endocrine, nutritional, metabolic and immunity; blood and blood forming; mental; complications birth; skin and subcutaneous disease; congenital abnormalities; V-codes

Reliability

There was substantial agreement of nurses for positive screening criteria in both years, with an agreement of 82% and a kappa statistic of 0.62 (95% CI 0.54 to 0.69) in 2004 and an agreement of 85% and a kappa statistic of 0.65 (95% CI 0.55 to 0.75) in 2008. The agreement between physicians assessment for the presence of an adverse event was fair in 2004 with an agreement of 76% and a kappa of 0.25 (95% CI 0.05 to 0.45), and moderate in 2008 with an agreement of 83% and a kappa of 0.47 (95% CI 0.33 to 0.61). Moderate agreement was also found in both years for the determination of a preventable adverse event (2004 70% agreement, kappa 0.40; 2008 74% agreement, kappa 0.49).

DISCUSSION

We found an increase in adverse event rates and relatively stable preventable adverse event rates in Dutch hospitals between 2004 and 2008. Due to a shorter length of stay in 2008 rates of adverse events per 1000 patient days showed an even stronger increase than the rate of patients experiencing at least one adverse event during an admission. Although more harm related to health care occurred, the amount of adverse events related to substandard care remained stable. More than 50% of all adverse events were related to surgical procedures. The odds of experiencing an adverse event or preventable adverse event clearly was higher for patients admitted to a surgical unit in 2008 than in 2004. It is not quite clear where this relative shift in adverse events originates from. Performing surgical procedures on increasingly older and more complex patients may have been of influence. Our 2004 data however do not contain information on ASA status, which prevents us to look into this all too closely. Patients admitted to a surgical unit or experiencing a surgical adverse event show the same increase in age between 2004 and 2008 as does the total patient group (data not shown). Since 2008 attention for patient safety in surgery has increased a great deal. This not in the least through attention for surgical checklists, which show promising results and may sort an effect in the years after our 2008 measurement.[24-26] Despite the lack of a clear explanation, our results do indicate that there is still apparent room for improvement in the surgical process.

Further results of this study show that urgently admitted patients in both years had a lower risk of experiencing adverse events and preventable adverse events, receiving unplanned treatment apparently does not lead to a higher risk of substandard care. Also differences between departments were larger for the risk of preventable adverse events in 2008 than in 2004. This shows that some departments may have improved patient safety while others were lagging behind.

Our study has several limitations. First of all reviewing physicians depend on information written in the patient record, which is sometimes limited and information revealing an adverse event and its preventability may be lacking. The amount and type of information in the patient record may differ between 2004 and 2008 due to the increasing use of electronic patient records (EPRs) or changes in safety culture, however reviewers did not comment on greater access to relevant information. In 2008 only one hospital in our sample had an almost complete EPRs, all other hospitals were in a transition phase between paper records, scanned paper records and full EPRs, which also differed between departments within hospitals. Electronic patient records intuitively are more to the point and staccato, but then may also miss crucial information. Previous research has found that hospitals with greater automation of a hospital's information system may be related with reductions in mortality, complications and costs.[27]

Another limitation of this study is its reliability. Our study shows moderate interrater agreement for the determination of adverse events, as is also common in previous research.[4,5,8,28] Also the number of physicians that reviewed one patient record differed between the years. As mentioned earlier results of the 2004 study showed that two physician reviewers and a consensus procedure does not lead to a higher interrater reliability.[17] Moreover results of the 2004 study showed that more adverse events were found after the consensus procedure than with two independent reviews by two physicians, indicating that physicians were more reluctant in their judgment of adverse events without support of collegial review. The total effect of using one physician per patient record instead of two (or three) and a consensus procedure however is not clear.

Measuring adverse events over time on a larger, national, scale is not yet widespread. Landrigan and colleagues also found that despite efforts a significant and measurable improvement in preventable adverse event rates over the years is still lacking.[13] In comparison we found remarkably lower adverse event rates than they did with the global trigger tool, however by using an extensive decision framework our method is more specific and strict in only scoring adverse events that are caused by the health care. Benning and colleagues measured adverse event rates as part of a larger evaluation study of the Safer Patient Initiative and also found no significant improvement in preventable adverse event rates.[29] The absence of improvements in preventable adverse event rates in these and our own study raises the question to what extent it is possible to improve preventable adverse event rates.

Many factors influence the results of large patient outcome studies, such as the quality of care, changes in patient case mix, data quality and chance.[30] A large campaign took place in the Netherlands between 2004 and 2008 introducing approaches from other sectors and improving transparency by developing a national set of performance indicators for hospital care.[31] In 24 hospitals improvements in hospital logistics and patient safety took place. However, only three of these hospitals were present in our samples in 2004 and 2008, so a

direct result of this campaign is not expected in our sample. Since 2008 a large national safety campaign started that is specifically aimed at improving patient safety and is directed to all Dutch hospitals. A safety management system and improvements on 10 specific medical themes are being implemented in the hospitals. Given that our study shows higher risks in the surgical process and that recent studies have shown positive results using surgical checklists, current campaigns should include this type of intervention.[24,25]

Our analysis corrected for changes in case mix, although residual confounding by patient complexity cannot be ruled out. For example, indications for treatment and surgery are extended to increasingly older and complex patients. Also less complex patients are increasingly treated in day care, which is not present in our sample, thus leaving more complex patients to be admitted to hospital for treatment. Day treatments increased by 8.4% between 2004 and 2008.[32] This could be a reason for the increase in adverse events in 2008. A global examination of the 2004 and 2008 adverse events however still shows the same classic pattern of adverse events. Still present are preventable adverse events related to hospital acquired infections, hematologic and coagulation problems and chemotherapy.

In conclusion our study shows that patient harm related to health care is a persistent problem that is hard to influence. Due to the above mentioned limitations, comparison of the two years must be made with caution. Improving patient outcomes such as a decrease in preventable adverse events is the goal of most national patient safety programs. Measuring adverse events during more time periods gives information on the current patient safety situation in hospitals and stresses the continuing urgency. It also raises questions on the feasibility of a decrease of the preventable adverse event rates. Our results show that high risks exist in the surgical process, further research is needed to show why these risks increased over time. In other studies surgical checklists have shown promising results to reduce risk to patients. For the future, evaluation of improvement strategies is also important. Further examination of changes to the type of adverse events and preventable adverse events and the clinical process could reap benefits.

APPENDIX

Appendix 1: causation and preventability scoring in the review form

To add more structure to the implicit review process, the causation and preventability score were each preceded by a number of questions to facilitate the final reviewers' judgment. Our review form is originally based on the Canadian adverse event study of Baker et al (2004)[4], with minor adjustments to the Dutch situation. Below are the sections of our review form concerning these preparatory questions as well as the final judgement.

Causation, preparatory questions:

1. Is there a note in the medical record indicating that a health care professional or health care management caused the injury? (No/Yes/Not applicable)
2. Is there a note in the medical record suggesting the possibility of an unintended injury from the patient's disease? (No/Yes/Not applicable)
3. Does the timing of events suggest that the injury is related to the treatment? (Likely/Possibly/Unlikely/Not applicable)
4. Does the timing of events suggest that the injury was related to the lack of treatment? (Likely/Possibly/Unlikely/Not applicable)
5. Are there other reasonable explanations for the cause of the unintended injury? (No/Yes/Possibly/Not applicable)
6. Was there an opportunity prior to the occurrence of the injury for intervention which might have prevented it? (No/Yes/Possibly/Not applicable)
7. Is lack of treatment or delayed treatment a recognized cause of this injury? (Widely recognized/Recognized by other specialists/No/Not applicable)
8. Is the lack of diagnosis or delayed diagnosis a recognised cause of this injury? (Widely recognized/Recognized by other specialists/No/Not applicable)
9. Is the treatment given to the patient a recognized cause of this injury? (Widely recognized/Recognized by other specialists/No/Not applicable)
10. Is this injury a recognized complication of the patient's underlying index disease? (Widely recognized/Recognized by other specialists/No/Not applicable)
11. Was the injury recognized during the index admission? (No/Yes/Not applicable)
12. If 'Yes' Was the appropriate action taken during the Index Admission? (No/Yes/No action needed/Not applicable)
13. If 'Yes' Did the injury respond to the appropriate action? (No/Yes/Possibly/Not applicable)

Causation, final judgement:

14. After consideration of the clinical details of the patient's management, irrespective of preventability, and your response to the questions above – What level of confidence do you have that the health care professional or health care management caused the injury?
    1. (Virtually) no evidence for health care management causation
    2. Slight to modest evidence of health care management causation
    3. Health care management causation not likely (less than 50/50, but 'close call')
    4. Health care management causation more likely (more than 50/50, but 'close call')
    5. Moderate to strong evidence of health care management causation
    6. (Virtually) certain evidence of health care management causation

Preventablity, preparatory questions:

1. How complex was this case? (Very complex/Moderately complex/Somewhat complex/Not complex/Unable to determine)
2. Was the management of the Primary illness (not the adverse event) appropriate? (Definitely appropriate/ Possibly appropriate/Probably appropriate/Definitely not appropriate)
3. What was the degree of deviation of management of the primary illness (not the adverse event) from the accepted norm? (Severe/Moderate/Little/None)
4. What was the co-morbidity of the patient? (Significant co-morbidity/Moderate co-morbidity/Mild co-morbidity/No co-morbidity)
5. What was the degree of emergency in management of the primary illness (not the adverse event) prior to the occurrence of adverse event? (Very urgent/Moderately urgent/Not urgent)
6. What potential benefit was associated with the management of the illness which led to the Adverse Event? (Life saving/Curing/Life prolonging/Symptom relief/Palliation//No potential benefit)
7. What was the chance of benefit associated with the management of the illness which led to the Adverse Event? (High/Moderate/Low/Not applicable)
8. What was the risk of an adverse event related to the management ? (High/Moderate/Low/Not applicable)
9. Is the injury/complication a recognized complication? (No/Yes/Not applicable)
10. What percentage of patients like this would be expected to have this complication? (Unable to determine/ Not applicable/<1%/1-9%/10-24%/>=25%)
11. On reflection, would a reasonable doctor or health professional repeat this health care management strategy again? (Definitely/Probably/Probably not/Definitely not
12. Was there a comment in the medical records indicating a need for follow-up as a result of this Adverse Event? (select all that apply) (No/Counselling/Psychiatric/Rehabilitation/Routine clinical/Other/UTD)
13. Did the patient have any follow-up as a result of this Adverse Event? (No/Counselling/Psychiatric/ Rehabilitation/Routine clinical/Other/UTD)

Preventability, final judgement:

14. Please indicate to what extent there are indications that the event was preventable:
    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

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3 How effective are patient safety initiatives? A retrospective patient record review study of changes to patient safety over time

Published as:

Rebecca J Baines, Maaike Langelaan, Martine C de Bruijne, Peter Spreeuwenberg, Cordula Wagner. How effective are patient safety initiatives? A retrospective patient record review study of changes to patient safety over time. BMJ Quality & Safety. 2015 Sep;24(9):561-71.

ABSTRACT

Objectives
To assess whether, compared with previous years, hospital care became safer in 2011/2012, expressing itself in a fall in preventable adverse event (adverse event) rates alongside patient safety initiatives.

Design
Retrospective patient record review at three points in time.

Setting
In three national adverse event studies, patient records of 2004, 2008 and 2011/2012 were reviewed in, respectively, 21 hospitals in 2004, 20 hospitals in 2008 and 20 hospitals in 2011/2012. In each hospital, 400, 200 and 200 patient records were sampled, respectively.

Participants
In total, 15,997 patient admissions were included in the study, 7,926 patient admissions from 2004, 4,023 from 2008 and 4048 from 2011/2012.

Interventions
The main patient safety initiatives in hospital care at a national level between 2004 and 2012 have been small as well as large scale multifaceted programmes.

Main outcome measures
Rates of both adverse events and preventable adverse events.

Results
Uncorrected crude overall adverse event rates showed no change in 2011/2012 in comparison with 2008, whereas preventable adverse event rates showed a reduction of 45%. After multilevel corrections, the decrease in preventable adverse event rate in 2011/2012 was still clearly visible with a decrease of 30% in comparison to 2008 (p=0.10). In 2011/2012 fewer preventable adverse events were found in older age groups, or related to the surgical process, in comparison with 2008.

Conclusions
Our study shows some improvements in preventable adverse events in the areas that were addressed during the comprehensive national safety programme. There are signs that such a programme has a positive impact on patient safety.

INTRODUCTION

Patient safety has been high on the international agenda for several decades since the Harvard Medical Practice Study (HMPS) in 1990 and the 1999 Institute of Medicine report 'To Err Is Human'.[1] Many retrospective patient record review studies in various countries have followed the HMPS in an attempt to evaluate patient safety. Reported adverse event incidence rates range from 2.9% to 16.6% of all hospital admissions, preventable adverse event rates range from 1.0% to 8.6%.[2-7] These results have increased the demand to take measures to guarantee further the safety of patients in hospitals. Large scale quality improvement and patient safety programmes have started in many countries, such as the Partnership for Patients,[8] the 100,000 Live Campaign in the USA,[9] and the Safer Patient Initiative (SPI) in the UK.[10]

In the Netherlands two large programmes have taken place, the 'Better Faster' programme (2003-2008) in a selection of hospitals and 'Prevent Harm, Work Safely' (2008-2012) aimed at all Dutch hospitals (box 1). To keep track of changes in patient safety at a national level three patient safety measurements with patient records from 2004, 2008 and 2011/2012 have been carried out in the Netherlands. The results of the first adverse event study were, partly, the reason to start the safety programme 'Prevent Harm, Work Safely' from 2008 to 2012.[4] The overall goal of this national programme was to decrease the number of preventable adverse events in Dutch hospitals by 50% through the implementation of a Safety Management System in all hospitals and through improvement modules on 10 more practical clinical themes. Part of the improvements between 2008 and 2012 were directed towards complex, often elderly, patients, the surgical process and medication processes, more specific medication verification and high risk medication, (box 1). The adverse event studies of 2008 and 2011/2012 coincide with the start and the conclusion of the most recent national safety programme (box 1). They have been performed in order to keep track of patient safety in our country.

While many countries have performed one adverse event measurement to assess the status of patient safety, using more than one national adverse event measurement is not widespread. Previously Landrigan and colleagues have used the global trigger tool to assess temporal trends in patient harm,[11] Benning and colleagues have performed repeated adverse event measurements in a smaller patient group as part of their evaluation of the SPI,[10,12] and our research group has previously reported on the results of the first two measurements in the Netherlands.[13] None of these studies have shown that, as a result of sustained attention to patient safety, there have been significant falls in preventable adverse events and widespread reductions in patient harm associated with this.

There are several other methods to measure errors and, possibly, preventable, harm. Yet each has its own strengths and weaknesses.[14] Retrospective patient record review is a thorough assessment of entire patient records and is used especially to obtain information on the incidence, nature, preventability and consequences of adverse events for the whole

population of hospitalised patients. Therefore, it currently seems to be the most suitable method to count the number and preventability of adverse events, and as such useful in assessing the possible effects of the safety programme.

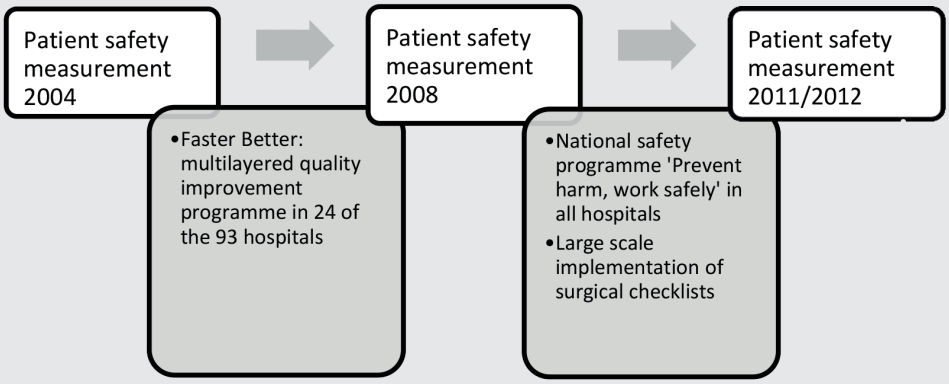
In this paper, we will discuss the results of the 2011/2012 adverse event measurement in relation to the previous two measurements and in light of the large scale efforts to enhance patient safety in the intervening years. This paper asks:

Has hospital care become safer in 2011/2012 in comparison with earlier years, manifesting itself in a reduction of preventable adverse event rates, alongside a national patient safety programme?

Are there shifts in the types of preventable adverse events over time indicating areas in which patient safety has increased or where it is in need of further attention?

Box 1: Context patient safety in the Netherlands 2004 - 2012

PATIENT SAFETY IN THE NETHERLANDS 2004-2012



A number of factors may have influenced patient safety in Dutch hospitals. There have been two specific programmes on quality and safety, while surgical checklists have been implemented on a broad scale. It is impossible to provide a complete overview of factors and initiatives that may have influenced patient safety in recent years. We will describe what we believe have been the largest initiatives at a national level.

2004-2008:

The national programme 'Better Faster' was launched in 2003. Between 2004 and 2008, 24 of the 93 hospitals joined a multi-layered programme aimed to enhance the quality of hospital care and to stimulate performance management.[15] At a national level the aim was to create awareness and introduce approaches from business

and industry into health care. Priority was given to issues of safety, logistics, accountability and innovation. Transparency was introduced in order to guide purchasing decisions and the improvement efforts. A national set of standardised safety indicators for hospital care was developed and maintained by the Health Care Inspectorate.

2008-2012

A national safety programme, 'Prevent Harm, Work Safely' was set up between 2008 and 2012, by the different stakeholders in health care. The overall goal of this programme was to decrease the incidence of preventable adverse events in Dutch hospitals by 50%. All 93 Dutch hospitals were offered support in this programme to implement improvements in patient safety. This safety programme had two pillars. First of all, a Safety Management System (SMS) was implemented in the hospitals. By the end of 2012 all hospitals in the Netherlands were obliged to have an accredited SMS. The basic requirements of a SMS for leadership, management, personnel, patient participation, prospective risk assessment, retrospective risk assessment and improvements were recorded in the Dutch Technical Agreement (NTA 8009) in 2007.[16] In 2011, basic requirements for communication, third party management and management measures were added to the NTA (NTA 8009:2011).[17]

The second pillar consisted of improvement modules on 10 practical clinical themes[18]:

- prevention of post-operative wound infections (POWIs)
- early detection and treatment of critically ill patients
- early detection and treatment of pain
- verification of medicines upon admission and discharge
- prevention of renal failure from the use of iodinated contrast agents [19]
- high-risk medication: parenteral preparation and administration [20]
- optimized care for acute coronary syndrome [21,22]
- prevention of line sepsis and the treatment of severe sepsis
- vulnerable elderly [23,24]
- safe patient transfer

At the same time, Dutch hospitals implemented surgical checklists on a large scale, stimulated by external pressure from the Health Care Inspectorate. In 2007 the Dutch Health Care Inspectorate published a report on the operative process, showing that there was considerable room for improving patient safety [25]. Since 2007 the Dutch Health Care Inspectorate has given greater attention and supervision to the operative process and many perioperative guidelines including time-out procedures have been developed. Studies supported the use of surgical checklists in the Netherlands. In particular, de Vries et al. (2010) showed the positive effects of the use of surgical checklists on post-surgery complications, re-operations and hospital mortality.[26]

METHODS

Study design and population

We performed retrospective patient record review studies using patient admissions from 2004, 2008 and April 1 2011 until March 31 2012, in respectively 21, 20 and 20 hospitals, out of the total of 93 Dutch hospitals. In 2008 and 2011/2012 the same 20 hospitals were included in the sample. Eight of these were studied in all three measurements. The samples were stratified for university, tertiary teaching and general hospitals. Between 2008 and 2011/2012 three general hospitals received their accreditation as a tertiary teaching hospital. Within the strata the hospitals were selected randomly and a proper representation of both urban and rural settings in the samples were verified. Hospitals had to have at least 200 beds, an intensive care unit and an emergency room to be eligible. Therefore, 4 hospitals were excluded, leaving 89 hospitals from which the sample was drawn. In each hospital, 400 patient admissions were selected in 2004, 200 in 2008 and 200 in 2011/2012. In total, up to 16,000 patient admissions were included. Patients admitted to the psychiatry department, obstetrics and children under 1 year were excluded, in order to be comparable with other studies using the same review methods.[3] Fifty per cent of the records were of patients who were discharged from the hospital after a stay of at least 24 h. The other 50% were of patients who died in hospital during admission. This made it possible to estimate the number of preventable deaths as this is a relatively small patient group. These patients were sampled from all inpatient deaths, regardless of their length of stay (LOS). We did not exclude patients admitted with an explicitly palliative care plan. This information was noted down and taken into account during the review process.

Patient record review

The nursing, medical and, if available, outpatient records of the sample patient admissions were reviewed by external nurses and external physicians belonging to the specialties surgery, internal medicine and neurology. Consultation with specialties other than their own was available if needed. Most of the reviewers in the 2008 and 2011/2012 studies had also participated in the 2004 study. As we studied the period from 12 months prior to, and 12 months after, the index admission, review of the records took place in 2005/2006, 2009/2010, and 2012/2013 respectively.

The method of determining adverse events was comparable to those of other international studies.[2,3] First a nurse screened the records by using triggers indicating potential adverse events. Admissions that were positive for at least one trigger were reviewed further by a physician. The presence and preventability of an adverse event was determined based on a standardised procedure and preceded by a number of underlying questions in order to secure a systematic assessment.

An adverse event was defined by three criteria:

1. an unintended injury;
2. the injury resulting in a longer hospital stay, temporary or permanent disability, or death;
3. the injury was caused by healthcare management rather than the patient's disease.

An adverse event was found to be preventable when the care given fell below the current level of expected performance for practitioners or systems. The causation by health care of an adverse event as well as its preventability was scored on a six-point Likert scale after consideration through a set of supportive questions to standardise the procedure and counted as caused by health care or preventable if the score was 4-6. A score of 4-6 indicated that the reviewer regarded the event as having a >50% chance of being caused by health care or being preventable.

Adverse events that occurred during the patient's index hospital admission, and were detected during either the index admission or subsequent admissions over the following 12-month period, were counted. Also counted were adverse events related to patient admissions in the same hospital within the 12 months preceding the index admission but that were not detected until the index admission. Consequently, patient records of the index hospital admission were reviewed, as were the patient records of patient admissions before and after the index admission. The way the adverse events were counted was the same for all periods of measurement.

The physicians assessed which clinical process was related to the adverse event: surgery, drug/fluid, medical procedure, diagnostic, other clinical management, discharge or other. This grouping was based on the grouping of the Canadian adverse event study and does not have a one on one relationship with the themes of the national programme.[3]

The review process of the 2004 study was slightly adapted for the 2008 and 2011/2012 study. In the 2004 study, pairs of physicians assessed independently all records found positive for the screening criteria in the first stage review. Disagreement about the presence and/or preventability of an adverse event prompted a consensus procedure. Analysis of the data from 2004 showed that physicians within pairs tended to show substantial agreement; however, between pairs agreement was much lower. The involvement of a second reviewer and consensus procedure in 2004 did not in itself appear to improve the overall reliability.[27] For this reason, and due to limited resources, we chose, in the 2008 and 2011/2012 studies, to review all records positive for screening criteria by one physician.

This has also been the case for other recent and earlier patient record review studies.[28,29] In our two latter studies, we compensated for the loss of discussion between physicians during the consensus procedure by organising more frequent reflection meetings based on discrepancies in records reviewed twice for all reviewers. This aimed to uphold the high quality of the review process.

Reliability

A random sample, spread equally over all hospitals and time, was taken in 2004, 2008 and 2011/2012 in order to test the reliability of the review process. To ascertain the reliability of screening by nurses 10% of the records were reviewed twice: 415 in 2004, 238 in 2008, and 215 in 2011/2012. To ascertain the reliability of considerations of the presence and preventability of an adverse event, 120 records were reviewed twice by physicians in 2004, 228 in 2008, and 241 in 2011/2012. This was also around 10% of the reviewed records by physicians in 2008 and 2011/2012. In 2004 this was different due to a change in the consensus procedure as described above.[27] The second reviewer was blinded for the outcome of the first review. Positive and negative agreements were assessed for all years pooled together. We showed positive and negative agreements, as these are absolute measures that are more informative, specific, and transparent, compared with a relative measure like a kappa statistic.[30] Positive agreement for the nurses' assessment of the presence of triggers was 86.3% (2004: 84.8%; 2008: 89.0%; 2011/2012: 85.8%), negative agreement 74.0% (2004: 77.0%; 2008:76.0%; 2011/2012: 63.3%). For the physicians' assessment of an adverse event, the positive agreement was 58.5% (2004: 54.9%; 2008: 63.3%; 2011/2012: 56.9%), the negative agreement 81.8% (2004: 66.2%; 2008: 86.9%; 2011/2012: 82.9%). For the physicians' assessment of a preventable adverse event, the positive agreement was 72.9% (2004:75.0%; 2008: 70.6%; 2011/2012: 73.3%), the negative agreement 76.8% (2004: 63.4%; 2008: 76.2%; 2011/2012: 83.3%).

Statistical analysis

Descriptive characteristics for the patient characteristics of the 2004, 2008 and 2011/2012 sample were calculated (SPSS V20). These characteristics were weighted for the sampling frame to make the total study sample representative of the total Dutch population of hospitalised patients. During these calculations, the analysis outcomes were corrected for the oversampling of deceased patients, because, in our sample, 50% of the patients were inpatient deaths, whereas the real figure is 3%. In the results, we weight our 50% back to the actual 3%, so the results presented are a representation of the total hospital population of discharged and deceased patients. We followed the same procedure for the distribution of types of hospitals.[31] The sample weight was the inverse of the probability of being included in the sample owing to the sample design. Descriptive characteristics for the total Dutch hospital population are given in appendix 1.

First, we calculated crude adverse event and preventable adverse event rates weighted for the sampling frame, but without corrections for the clustering of the data or corrections for differences in patient mix between the years. Following this, we calculated standardised adverse event and preventable adverse event rates with corrections through multilevel analysis. All rates will be presented as a rate of patients with at least one adverse event or preventable adverse event per 100 hospital admissions.

To analyse whether hospital care has become safer in 2011/2012, in comparison with earlier

years, adverse event and preventable adverse event rates were assessed using multilevel logistic regression analysis with a three level structure: patient, hospital department and hospital (MLwiN 2.28) including hospital and department as random effects. These included separate year parameters for the mean and higher level variances (covariances). We were able, therefore, to correct for clustering at the hospital and hospital department levels per year.[32] The outcome measures were the number of patients experiencing at least one adverse event, and at least one preventable adverse event. The second-order penalized quasi-likelihood (PQL) estimation method was used, except for the models regarding preventable adverse events, where we used first-order marginal quasi-likelihood (MQL) estimation methods. To account for the possibility that changes over time were influenced by changes in the patient mix, terms were added to the models for age, sex, urgency of admission (urgent/elective) and admission to a surgical unit (yes/no). All variables included in the model were standardised to reference values for all Dutch hospital admissions in 2008, effects of the variables were estimated for each year (appendix 2). We performed Wald tests to assess if differences existed after patient mix corrections in adverse event rates and preventable adverse event rates between the years. We extrapolated total preventable adverse event rates to absolute numbers of preventable adverse events in the Netherlands by multiplying the corrected preventable adverse event rates with the total number of patient admissions in the Netherlands. We chose to use the total number of patient admissions of 2011/2012 for calculations in all years. In this way differences in absolute numbers of patients experiencing preventable adverse events would not be the result of differences in total patient admissions between the years. The Intraclass Correlation Coefficients (ICCs) were calculated for the hospitals and departments per year. The ICC indicates the relative influence of that level on the total variance of the outcome in a year. A higher ICC at the hospital level means a smaller variance for all rates within the hospitals and a larger variance between hospitals. Unfortunately, our sample was not sufficient to show the results on hospital level. Besides, showing the results on hospital level could result in problems with anonymity and confidentiality.

The occurrence of preventable adverse events within specific age groups and the main clinical process related to preventable adverse events (surgery, drug/fluid, medical procedure, diagnostic, other clinical management, discharge or other) were analysed in SPSS for each year, weighting the results for the sampling frame.

To illustrate the types of adverse events and preventable adverse events we found, we also grouped the adverse events into more specific types of adverse events, based on the categories that Landrigan and colleagues used in their study.[11] We calculated, for each year the numbers per 10,000 patients in order to make it possible to show the numbers of the years side by side. The results are shown in appendix 3.

Table 1: The hospital and patient characteristics of the study samples 2004, 2008 and 2011/2012

	Sample 2004*	**Sample 2008***	**Sample 2011/2012***
Inpatient admissions n (% of all patients)	7,926 (0.6)	4,023 (0.3)	4,048 (0.2)
Hospital deaths n (% of total sample/ population)	3,983 (50.3)	1,996 (49.9)	2,025 (50.0)
Patient admissions			
- University hospitals n (% of total sample/ pop)	1,378 (17.4)	794 (19.7)	799 (19.7)
- Tertiary teaching	2,342 (29.5)	1,201 (29.9)	1,642 (40.6)
- General	4,206 (53.1)	2,028 (50.4)	1,607 (39.7)
Patient characteristics	**Sample 2004*†**	**Sample 2008*†**	**Sample 2011/2012*†**
Male sex, %	49.0	49.9	50.2
Age (years), %			
1-18	7.3	5.6	6.0
19-40	13.7	10.9	10.8
41-65	36.4	38.0	37.2
66-79	28.6	28.7	29.2
≥80	14.1	16.9	16.8
Length of hospital stay, days mean (SD/median)	8.5 (10.4/ 5.0)	6.7 (8.9/4.0)	6.3 (14.6/3)
Patients admitted as urgent, %	53.9	54.1	54.6
Hospital departments, %			
- Surgery	23.9	21.8	21.7
- Cardiology	12.9	11.6	10.7
- Internal medicine	15.8	16.2	16.2
- Orthopaedics	10.5	11.0	11.2
- Neurology	7.5	7.7	6.8
- Lung diseases	7.2	6.1	6.9
- Ear, nose and throat	4.3	3.8	3.6
- Urology	4.2	5.1	4.9
- Other	13.7	16.7	18.0
International Classification of Diseases main diagnostic groups, %			
- Neoplasms	10.4	12.1	11.5
- Nervous system and sensory organs	4.4	3.2	3.6
- Circulatory system	19.1	20.6	17.7
- Respiratory system	8.4	8.6	8.7
- Digestive system	10.9	10.7	9.9
- Genitourinary system	6.4	6.2	6.1

Patient characteristics	Sample 2004*†	Sample 2008*†	Sample 2011/2012*†
- Musculoskeletal and connective	11.1	11.8	10.5
- Ill-defined conditions	8.9	6.3	5.3
- Injury and poisoning	9.8	9.5	9.0
- Other	10.2	10.2	12.4
- Missing	0.4	0.7	5.3
Adverse events n (%)	663 (5.7)	467 (8.0)	390 (7.1)
Preventable adverse events n (%)	283 (2.3)	198 (2.9)	108 (1.6)

* Patient admissions of obstetrics, psychiatry, <1 year and <24 hours for non-deceased patients were excluded
† Patient characteristics are weighted for overrepresentation of deceased patients and hospital type

RESULTS

In total, 15,997 patient admissions were included in the study, 7,926 patient admission from 2004, 4,023 from 2008 and 4,048 from 2011/2012 (table 1). The largest shift in patient characteristics in our samples was between 2004 and 2008. Here the mean age increased and the LOS decreased ($p<0.001$). Between 2008 and 2011/2012, patient characteristics stayed relatively stable (table 1). The increase in percentage of tertiary teaching hospitals was due to some hospitals receiving accreditation between 2008 and 2011/2012, and therefore changed from the general to the tertiary teaching hospital category. The data in our sample roughly corresponds with national trends in the hospital population but the trend of a shorter LOS over the years in our sample is stronger than the national trend (source: DHD/KIWA Carity/ appendix 1).

Adverse events

Crude adverse event rates of patients with at least one adverse event increased between 2004 and 2008 ($p<0.001$) and stayed relatively stable between 2008 and 2011/2012 (table 1). Overall, the corrected and standardised adverse event rate in 2004 was 4.0% (95% CI 3.2 to 5.0), which increased to 6.0% in 2008 (95% CI 4.9 to 7.3) ($p<0.01$) and finally stayed relatively stable with 5.7% in 2011/2012 (95% CI 4.7 to 6.8) ($p=0.68$) (figure 1A).

ICC estimates for overall adverse event variance at the hospital and department levels showed a slight, statistically non-significant, decrease. At the hospital level these were 6.5% in 2004, 5.1% in 2008 and 2.6% in 2011/2012. The decrease indicates that the differences between hospitals became smaller. ICCs at the department level were higher, but stayed

relatively stable through the years at 10.6% in 2004, 8.4% in 2008 and 9.7% in 2011/2012. The differences within hospitals, thus between departments, remains relatively stable.

Preventable adverse events

Uncorrected rude preventable adverse event rates showed a 45% decrease of admissions with at least one preventable adverse event in 2011/2012 in comparison with 2008 from 2.9%, 198 out of 4023 patients, to 1.6%, 108 out of 4048 patients (p<0.001). In comparison with 2004 this was a 30% reduction from 2.3% to 1.6% (p<0.001) (table 1). To analyse whether hospital care had become safer in 2011/2012, in comparison with earlier years, multilevel corrections were made for clustered data and possible differences in patient mix between the years. These analyses showed that the decrease in preventable adverse events was no longer statistically significant (p=0.10). The corrected and standardised percentage for preventable adverse events was 1.9% in 2004 (95% CI 1.5 to 2.6), staying relatively stable in 2008 with 2.0% (1.5 to 2.8) (p=0.80), and decreased by 30% to 1.4% in 2011/2012 (95% CI 0.9 to 2.0) (p=0.10) (figure 1B). Extrapolating these rates to total absolute patient numbers in the Netherlands, in comparison to 2008 in 2011/2012 10.070 fewer patients experienced a preventable adverse event.

Because preventable adverse events were such rare events, especially in 2011/2012, the sample was not big enough to capture, reliably, the small variance between hospitals and hence is estimated as zero. Therefore ICCs at the hospital level could not be calculated for preventable adverse events. At the department level, ICCs for preventable adverse events showed more variation in later years: 8.2% in 2004, and a statistically non-significant increase to 14.4% in 2008 and 13.9% in 2011/2012. The differences between the departments thus became larger.

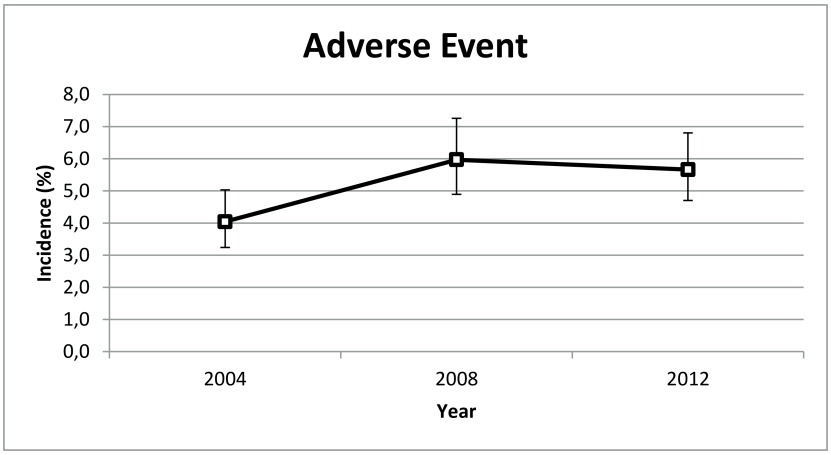


Figure 1A: Multilevel corrected adverse event rates in 2004, 2008 and 2011/2012

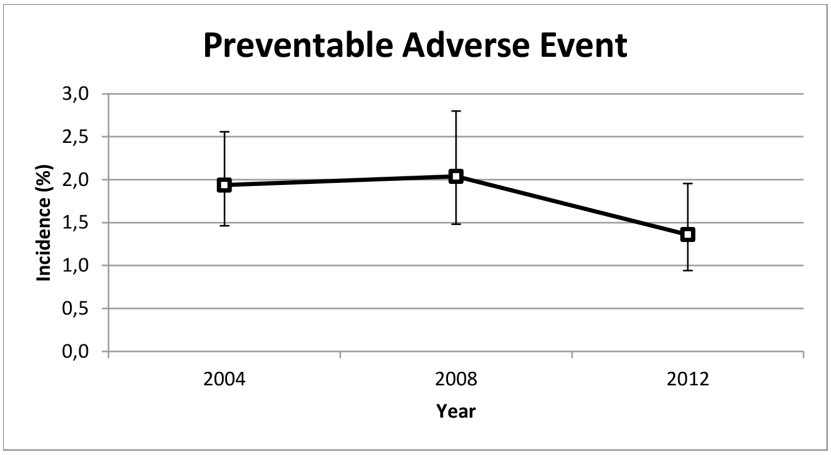


Figure 1B: Multilevel corrected preventable adverse event rates in 2004, 2008 and 2011/2012

We analysed further possible shifts in crude preventable adverse events in the surgical process, medication, diagnostics and the risk of experiencing a preventable adverse event in different age groups, in order to assess whether specific patient safety efforts in the hospitals in the intervening years could be seen in our data. For the large part, the preventable adverse events were related to the surgical process in all years, with respectively 1.0% of all hospitalised patients in 2004, increasing to 1.6% in 2008 and decreasing to 0.7% in 2011/2012

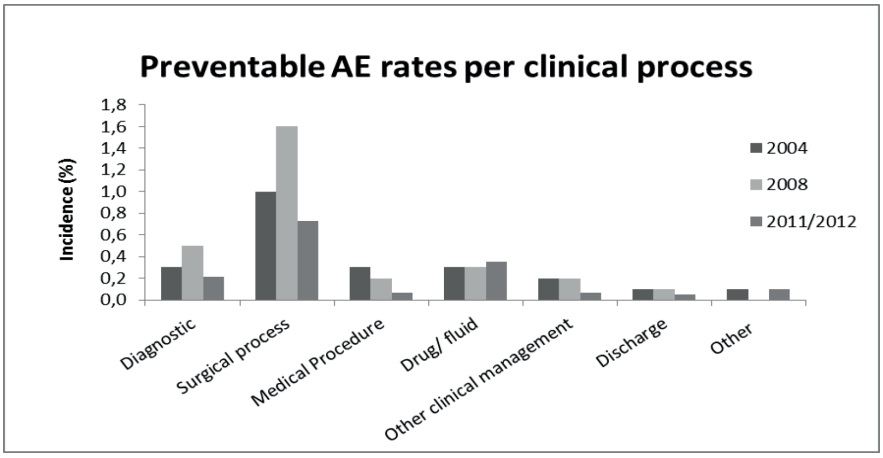


Figure 2: Preventable adverse event (AE) rates per clinical process weighted for overrepresentation of deceased patients and hospital type

(p<0.001 for 2008-2011/2012 and 0.08 for 2004-2011/2012) (figure 2). Preventable adverse events related to drug/fluids were also common and stayed relatively stable through the years, with respectively 0.3%, 0.3% and 0.4% (figure 2). Similarly, preventable adverse events related to the diagnostic process increased from 0.3% in 2004 to 0.5% in 2008 (p=0.03) and then decreased to 0.2% in 2011/2012 (p=0.02), even though there was not a specific theme targeting the diagnostic process (figure 2).

The visible decrease in preventable adverse events in 2011/2012 could be attributed primarily to older patient groups (figure 3), starting in the age group 41-65 and most visible in patients aged ≥80. In 2004, 3.7% of all patients of ≥ 80 years experienced a preventable adverse event, in 2008, 4.4% and in 2011/2012 this decreased to 0.9%. This trend was also visible in the age group 41-65 and 66-79, although less pronounced. In contrast in the age group 19 to 40, the incidence of preventable adverse events slightly increased, from 2.1% in 2008 to 3.0% in 2011/2012 (figure 3). The LOS decreased about equally in each age category over the years (data not shown), and thus cannot explain this decrease in preventable adverse events being detected during hospital stay. The results in elderly patients will be described in more detail in a separate manuscript.

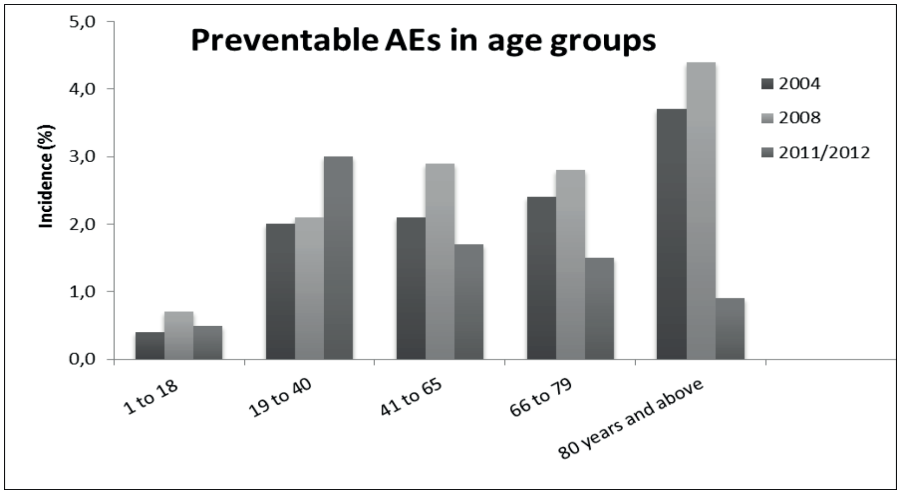


Figure 3: Preventable adverse event (AE) rates per age group

DISCUSSION

Principal findings

We reviewed nearly 16,000 patient records during three national adverse event studies with a thorough assessment of patient admissions in order to estimate overall and preventable adverse event rates. Uncorrected crude overall adverse event rates showed no change in 2011/2012 in comparison with earlier years, and preventable adverse event rates showed a reduction of 45%. After multilevel corrections for clustered data and possible differences in patient mix between the years, the decrease in preventable adverse event rate in 2011/2012 was still clearly visible with a 'decrease' of 30% in comparison to 2008. But this decrease was not statistically significant (p=0.10). This 30% reduction amounts to 10,070 fewer patients experiencing preventable adverse events in the Dutch hospital population. In 2011/2012, fewer preventable adverse events were found in older age groups or related to the surgical process in comparison with 2008. Because the LOS and thereby the chance of an adverse event being detected during hospital admission decreased about equally in all age categories, we believe that the reduction in LOS does not explain the change in adverse events in elderly patients.

As Brown and colleagues have discussed, a common problem for evaluators is that patient outcomes that are affected by an intervention are also influenced by many other factors and many forms of bias may exist.[33,34] Variations in our data are likely to be a summation of variations in the quality of care, variations due to patient case mix, variations in the used definitions/data quality and chance.[35] First of all, the true source of change we would like to capture is the quality of care. A number of factors make it plausible that at least in part the improvement in preventable adverse event rates could be the result of the national patient safety programme and other safety improvement initiatives that have been implemented. The safety programme between 2008 and 2013 was much more elaborate and directed towards all Dutch hospitals in comparison to the programme between 2004 and 2008. This could explain the improvement between 2008 and 2011/2012. Also, the pronounced decrease in preventable adverse events related to the surgical process coincides with the attention given to the surgical process over the last years. This attention has included: pre-surgical, peri-surgical and post-surgical guidelines, surgical checklists and increased attention and supervision by the Dutch Health Care Inspectorate. The decrease in preventable adverse events, furthermore, is mainly visible in older age groups. This coincides with several of the 10 improvement trajectories such as early recognition and treatment of deteriorating patients and the trajectory for the vulnerable elderly. A national report evaluating the improvement modules of the safety programme showed that the process indicators of these two trajectories showed improvements.[36] For the topic 'Early recognition and treatment of deteriorating patients', the goal was to implement a rapid response system. The evaluation

study showed that 17 of the 18 hospitals evaluated had their rapid response team operational by the end of 2012. For the module, screening of vulnerable elderly patients for falls, poor nutrition, physical limitations and delirium, the goals were not completely met, but did show a significant increase over the years.[36] Our results did not show any visible improvements in preventable adverse events related to medication. Two of the ten improvement modules were related to medication: "medication reconciliation at hospital admission and discharge" and "high risk medication". With respect to the use of the medication reconciliation module, the aforementioned evaluation study showed that compliance in the hospitals remained low over the course of the evaluation study, but did show a slightly positive trend.[36] Although all hospitals took part in the national safety programme, the hospitals that participated in the study described in the evaluation report were not the same hospitals as in our record review study. About 19 hospitals participated in the data collection on each module. The overlap in hospitals was very small and the participating hospitals did not collect data for each module. Therefore a complete dataset is not available for use in the current retrospective study.

As figure 2 shows, the rate of preventable adverse events associated with the diagnostic process decreased between 2008 and 2011/2012, even though there was no specific theme targeting the diagnostic process. It is likely that other processes apart from the national safety programme were of influence on the preventable adverse event rates. Of course in these years other initiatives and processes directed towards patient safety and quality of care also took place, as for example new or improved guidelines, local initiatives, training or schooling, etc. The national safety programme however did include more than the 10 themes, such as the implementation of a safety management system in all hospitals. This could have resulted in a more general patient safety awareness.

Secondly, changes in patient mix could have had an influence on the results. Our data show that the largest shift in patient mix is between 2004 and 2008. Then patients were getting increasingly older and had a shorter LOS. But this was less the case between 2008 and 2011/2012. We have corrected in our model as much as possible for changes in patient mix. We doubt though whether we were able to capture patient complexity completely. Despite the indications that the efforts of the national safety programmes may have resulted in a decrease of preventable adverse events, it is still unclear to what extent the programmes exactly contributed to this improvement.

Thirdly, variations in definitions and in the method of measurement used could influence the results. The research method was not exactly the same for all years, as more extensively described in earlier work.[13] This mainly concerned the 2004 measurement, in which a two-stage review process was used instead of a one-stage review process in 2008 and 2011/2012. Also, it is important to realise that changing patient records, such as more and more patient

records becoming electronic, could have an influence on the information that is written down. Information in electronic medical records availability, accessibility and readability of information may be better. However, it also may be that information written down in the electronic records is less comprehensive, as our reviewers made comments on this aspect during our study. This is particularly important as our study is reliant on patient records and the information in these records. Finally, a recent national report shows that patient safety culture in the Netherlands has shown improvements over the years.[37] It is unknown to what extent a changing culture has an effect on what reviewers would find preventable. We, however, hypothesise that, if any effect, more adverse events would be found preventable instead of less.

Strengths and weaknesses

The strength of our study is that we reviewed nearly 16,000 patient records over three periods in time with a thorough, standardised, assessment of patient admissions. Retrospective patient record review is currently still seen by many as the gold standard for obtaining information on the incidence of adverse events and preventable adverse events for the whole population of hospitalised patients.[38] This study has made it possible to keep an eye on patient safety in hospitals and keep patient safety high on the agenda. Despite the considerable number of patient records reviewed over the years, the sample was not large enough to detect a statistically significant decrease in corrected and standardised preventable adverse event rates (p=0.10). This was partly due to the thorough statistical analyses. Because our data were clustered within departments and hospitals, a multilevel analysis was necessary. Although the uncorrected crude overall adverse event rates showed statistically significant improvement, using these rates to draw the final conclusions would overestimate the effect.

Neither was our study set up to describe a causal relationship between the safety programmes and other initiatives over the years and our study outcome, adverse events and preventable adverse events. The method also has a few limitations linked to retrospective patient record review such as hindsight bias, a moderate inter-rater reliability and information bias.[27,39-41] Hindsight bias is not expected to have had a different effect over the years and thus also not specifically on the results of changes in adverse event rates. On the other hand, if our reviewers changed their opinions over a period of years on either the causation by healthcare of specific adverse events, or the preventability, this could also have had an influence on the hindsight bias. Our results might be biased by the adaptation of the review process between 2004 and 2008. The effect of using one physician instead of two and a consensus procedure is not clear. There is an indication that physicians prone to discover and judge presence of an adverse event with support of thorough collegial review.[27] A record review process with two physicians and a consensus procedure could lead to more reported adverse events than a review process with only one reviewer per record.

Practical Implications

This study shows that when monitoring national adverse event rates, there are challenges in reaching enough power to make sufficiently reliable conclusions. We do, however, believe that the benefits of our national adverse event studies are not merely scientific. They are also an important tool for highlighting the need to maintain high levels of patient safety. As such they also have an impact on society at large. Making adverse event and preventable adverse event rates public at three points in time over the last 10 years has helped to prioritise achieving further improvements to the already high levels of patient safety. This is true for hospitals, patients and Dutch professional societies such as for physicians or nurses. On the other hand, the low rates and the lack of potential for improvement may also come with the loss of sense of urgency for patient safety. However, in our experience, with a thorough explanation of the results and their implications for daily practice people can still be motivated. All aspects should be taken into consideration when considering whether to repeat this type of research. Advances in electronic patient records could help make the process of case note review more efficient and thus easier to reach larger samples. Future research could also direct itself towards more specific patient groups or diseases with a high risk of experiencing preventable adverse events, such as patients undergoing surgery. This could overcome some of the methodological problems related to a structured but implicit review and could offer insight into directions for further opportunities for improvement.

CONCLUSION

We found a 45% decrease in crude preventable adverse event rates ($p<0.01$) alongside a national patient safety programme and other patient safety and quality of care initiatives. In addition, we found a 30% decrease in corrected and standardised preventable adverse event rates ($p=0.10$) in the last four years after a 5% increase in the five preceding years ($p=0.80$). A decrease of preventable adverse events was seen in the areas that were addressed during the safety programme. Although these results make it plausible to attribute the positive results to the national programme, they may also in part be the result of other initiatives or based on chance.

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APPENDICES

Appendix 1: Hospital and patient characteristics of the total Dutch inpatient hospital population (source: Dutch Hospital Data/Prismant) in 2004, 2008 and 2011/2012

Hospital characteristics	**Total hospital population 2004***	**Total hospital population 2008***	**Total hospital population 2011/2012***
Inpatient admissions n	1,343,234	1,332,602	1,678,283
Hospital deaths n (% of total population)	42,329 (3.2)	35,721 (2.7)	37,249 (2.2)
Patient admissions n (% of total sample/ pop)			
- University hospitals	179,998 (13.4)	197,269 (14.8)	219,728 (13.1)
- Tertiary teaching	381,625 (28.4)	584,914 (43.9)	744,334 (44.4)
- General	781,611 (58.2)	550,419 (41.3)	714,221 (42.3)
Patient Characteristics	**Total hospital population 2004***	**Total hospital population 2008***	**Total hospital population 2011/2012***
Male sex %	48.7	49.9	49.8
Age y, mean (SD)	55.9 (21.7)	56.8 (21.8)	57.7 (21.6)
Length of hospital stay d, mean (SD/median)	7.3 (10.4/4)	6.3 (9.5/3)	5.4 (7.0/3)
Patients admitted urgently %	46.6	49.5	53.1
Hospital departments,			
- Surgery	24.4	23.8	23.0
- Cardiology	16.1	17.5	17.2
- Internal medicine	16.1	15.9	17.7
- Orthopaedics	8.7	8.2	8.4
- Neurology	6.3	6.5	7.5
- Lung diseases	6.5	7.7	8.5
- Ear, nose, throat	4.5	3.8	3.2
- Urology	5.0	5.0	5.1
- Other	13.1	11.6	9.3

* Patient admissions of obstetrics, psychiatry, <1 year and <24 hours for non-deceased patients were excluded

Appendix 2: Multilevel model preventable adverse event (AE)

	Model AE OR (95% CI)	**Model preventable AE OR (95% CI)**
Inpatient death 2004	2.98 (2.37 to 3.75)	3.26 (2.36 to 4.52)
Inpatient death 2008	4.05 (3.10 to 5.30)	4.90 (3.23 to 7.42)
Inpatient deaths 2011/2012	3.06 (2.31 to 4.06)	4.80 (2.81 to 8.22)
Academic hospital 2004	1.69 (1.05 to 2.73)	0.64 (0.36 to 1.14)
Tertiary teaching hospital 2004	1.04 (0.68 to 1.59)	1.00 (0.63 to 1.59)
Academic hospital 2008	0.83 (0.55 to 1.23)	0.65 (0.37 to 1.14)
Tertiary teaching hospital 2008	0.95 (0.68 to 1.32)	0.93 (0.59 to 1.45)
Academic hospital 2011/2012	1.29 (0.91 to 1.82)	0.60 (0.33 to 1.09)
Tertiary teaching hospital 2011/2012	0.96 (0.72 to 1.29)	0.92 (0.61 to 1.40)
Age 2004	1.01 (1.00 to 1.02)	1.01 (1.00 to 1.02)
Age 2008	1.00 (1.00 to 1.01)	1.01 (1.00 to 1.01)
Age 2011/2012	1.01 (1.00 to 1.01)	1.00 (0.99 to 1.01)
Sex 2004	0.97 (0.82 to 1.15)	0.94 (0.73 to 1.19)
Sex 2008	0.97 (0.79 to 1.19)	1.31 (0.96 to 1.79)
Sex 2011/2012	1.03 (0.83 to 1.28)	1.37 (0.92 to 2.03)
Urgent admission 2004	0.53 (0.43 to 0.65)	0.60 (0.44 to 0.81)
Urgent admission 2008	0.63 (0.49 to 0.81)	0.73 (0.50 to 1.06)
Urgent admission 2011/2012	0.50 (0.38 to 0.65)	0.54 (0.34 to 0.88)
Admission to surgical unit 2004	1.70 (1.31 to 2.20)	1.96 (1.47 to 2.61)
Admission to surgical unit 2008	2.83 (2.19 to 3.67)	3.69 (2.50 to 5.44)
Admission to surgical unit 2011/2012	2.44 (1.86 to 3.21)	2.20 (1.42 to 3.41)
	Model AE variance*	**Model preventable AE variance***
hospital level 2004	0.23	0.26***
department level 2004	0.39	0.29
hospital level 2008	0.18	0.16***
department level 2008	0.30	0.55
hospital level 2011/2012	0.09	X**
department level 2011/12	0.35	0.55
R-squared****	10.1%	12.8%

* Variances are the sum of the variances and covariances of that year

** Variances and covariances could not be calculated and were estimated as zero by model

*** Covariances of 2011/2012 could not be calculated and were estimated as zero by model

**** McKelvey and Zavoina approximation for the explained proportion of variance for multilevel logistic regression [42]

Appendix 3: Type of preventable adverse events (AE) per 10.000 patients for 2004, 2008 and 2011/12

	Type of harm	Preventable AE 2004	Preventable AE 2008	Preventable AE 2011/2012
1	**Cardiovascular system, total**	**41.6**	**32.3**	**29.6**
1.1	Cardiac arrest	0.0	2.5	0.0
1.2	Hypotension	3.8	2.5	4.9
1.3	Hypertension	0.0	2.5	0.0
1.4	Shock	3.8	0.0	2.5
1.5	Arrhythmias or conduction abnormality	5.0	0.0	0.0
1.6	Myocardial ischaemia	8.8	0.0	4.9
1.7	Heart failure	15.1	7.5	9.9
1.8	Aneurysm	0.0	0.0	2.5
1.9	Other cardiovascular event	5.0	17.4	4.9
2	**Respiratory system, total**	**39.1**	**62.1**	**19.8**
2.3	Pneumothorax	2.5	5.0	0.0
2.4	Atelectasis	1.3	0.0	0.0
2.5	Bronchospasm	0.0	0.0	2.5
2.6	Aspiration	7.6	12.4	4.9
2.7	Pulmonary embolus	15.1	24.9	4.9
2.9	Other respiratory event	12.6	19.9	7.4
3	**Renal or endocrine system, total**	**36.6**	**34.8**	**34.6**
3.1	Fluid overload	5.0	5.0	2.5
3.2	Dehydration or oliguria	2.5	5.0	0.0
3.5	Hyperglycaemia	2.5	2.5	2.5
3.6	Hypoglycaemia	2.5	5.0	7.4
3.7	Hyperkalaemia	3.8	2.5	9.9
3.8	Renal insufficiency	5.0	12.4	4.9
3.9	Other renal or endocrine event	15.1	2.5	7.4
4	**Haematologic system, total**	**22.7**	**37.3**	**9.9**
4.1	Haemorrhage	15.1	14.9	2.5
4.2	Thromboembolic venous event	3.8	7.5	2.5
4.3	Haematoma	0.0	7.5	2.5
4.4	Other haematologic event	3.8	7.5	2.5
5	**Gastrointestinal system, total**	**39.1**	**64.6**	**37.1**
5.1	Nausea or vomiting	0.0	2.5	2.5
5.2	Diarrhoea	0.0	0.0	0.0
5.5	Pancreatitis	0.0	0.0	2.5
5.6	Ileus	3.8	22.4	4.9
5.7	Intestinal tract bleeding	10.1	0.0	7.4
5.8	Perforation	10.1	12.4	14.8
5.9	Other gastrointestinal event	15.1a	27.3	4.9

	Type of harm	Preventable AE 2004	Preventable AE 2008	Preventable AE 2011/2012
6	**Neurologic system, total**	**37.9**	**14.9**	**19.8**
6.2	Delirium or encephalopathy	3.8	5.0	2.5
6.3	Seizure	0.0	2.5	2.5
6.4	Stroke or intracerebral haemorrhage	15.1	2.5	4.9
6.5	Coma	0.0	0.0	7.4
6.6	Withdrawal symptoms	2.5	2.5	0.0
6.8	Other neurologic event	16.4	2.5	2.5
7	**Hospital acquired infection, total**	**36.6**	**87.0**	**46.9**
7.1	Catheter-related bloodstream infection	2.5	5.0	2.5
7.2	Sepsis or bacteraemia unrelated to catheter	15.1	54.7	24.7
7.3	Ventilator-associated pneumonia	1.3	0.0	0.0
7.4	Nosocomial pneumonia, not ventilator-related	3.8	9.9	4.9
7.5	Urinary tract infection	6.3	0.0	0.0
7.6	Surgical site infection	1.3	7.5	2.5
7.8	Clostridium difficile colitis	0.0	0.0	2.5
7.9	Phlebitis	0.0	0.0	2.5
7.10	Infected foreign material	2.5	5.0	2.5
7.11	Other hospital acquired infection	3.8	5.0	4.9
8	**Surgical event, total**	**94.6**	**121.8**	**49.9**
8.1	Postoperative haemorrhage	15.1	37.3	2.5
8.2	Postoperative haematoma	2.5	2.5	2.5
8.3	Postoperative abscess	2.5	2.5	2.5
8.4	Laceration or other organ injury	13.9	0.0	4.9
8.5	Unplanned removal of organ after intraoperative injury	0.0	9.9	0.0
8.6	Vascular injury	2.5	0.0	0.0
8.7	Nerve injury	3.8	0.0	0.0
8.9	Wound dehiscence	3.8	2.5	0.0
8.10	Anastomotic leakage	6.3	7.5	2.5
8.11	Postoperative fistula	2.5	0.0	0.0
8.12	Failed procedure	29.0	2.5	29.6
8.13	Unplanned return to surgery	0.0	9.9	0.0
8.14	Other event	12.6	47.2	4.9
9	**Other types of harm, total**	**94.6**	**121.8**	**49.4**
9.2	Pyrexia	0.0	5.0	2.5
9.4	Allergic reaction	0.0	0.0	0.0
9.5	Pressure ulcer	5.0	0.0	0.0
9.6	Rash	1.3	7.5	0.0
9.7	Catheter complication	0.0	0.0	0.0
9.8	Fracture	6.3	2.5	4.9
9.9	Other type of harm	36.6	42.3	22.2

4 Intra-rater agreement in adverse event studies: stability of assessment of adverse events over time

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ABSTRACT

Background

Retrospective patient record review is often used to research adverse events during hospitalisation. If used to monitor patient safety over time, it is important to know if improvements are not caused by for example a more lenient or stricter assessment of adverse events and their preventability. The objective of this article is to assess the intra-rater agreement of physicians in reviewing patient records for adverse events and preventable adverse events after six years

Methods

Retrospective chart review of the same set of patient records with an interval of six years was performed by eight physician reviewers in six hospitals. Agreement scores, specific agreement scores, and Cohen's kappa statistics were assessed.

Results

In total 250 patient records were re-reviewed by eight physician reviewers with a range of 18 to 55 records per reviewer. Total agreements, in comparison with their own scores six years later, were reasonable for assessing the presence of an adverse event with 76.8%, and for the preventability of an adverse event 69.9%. Positive agreement for determining preventability was lowest of all specific agreement scores, with 56.0%, other specific agreements ranged from 71.8% to 80.3%. Cohen's kappa was 0.52 for the assessment of an adverse event and 0.33 for the assessment of preventable adverse events.

Conclusions

We did not find any systematic shifts in judgement over the years. Reviewers of our adverse event studies have not become stricter or more lenient over a six year interval in their judgement of adverse events and their preventability. Random variation is present in the assessment of adverse events as well as their preventability, especially the judgement of the preventabiity of an adverse event seems to be difficult.

BACKGROUND

Since the late eighties and early nineties of the last century retrospective patient record review has been a much used method in estimating national incidences, nature and preventability of adverse events (adverse events) during hospitalization.[1-5] A few studies have reported estimates of adverse events and preventable adverse events at more than one time-point.[6,7] Many studies have looked at the agreement and reliability between different reviewers in adverse event incidence studies, often finding only moderate kappa values. In the Netherlands we have performed three national incidence studies with three to four year intervals as to monitor developments in patient safety.[2,7] If patient safety improves or worsens over time, we have to be sure that this is not caused by for example a more lenient of stricter assessment of adverse events and their preventability. This temporal stability of the assessment of adverse events and preventable adverse events by the same reviewers over time is of importance in the interpretation of this kind of monitoring of adverse event rates. Until now no study has looked into this (long term) intra-rater agreement of adverse event and preventable adverse event assessment. Some of the expert physician reviewers participated in all three of the national incidence studies. Possibly reviewers change their review over the years, influenced by for example a culture shift set on by increased attention for patient safety, or new insights in care changing the judgement of the preventability of adverse events. For this reason, at the time of the third national incidence measurement, we set up an intra-rater agreement study.

Research questions

What is the intra-rater agreement of physicians in reviewing patient records for adverse events and preventable adverse events after six years?

Is there a systematic shift in the assessment of the preventability of adverse events, i.e. are adverse events specifically found to be preventable more or less often during the re-review than during the original review?

METHODS

Study design and population

To explore how stable structured review methods, such as the assessment of adverse events and preventable adverse events, are over the years, our reviewers re-reviewed a small part of the patient records that they had reviewed in previous years. To ascertain the long term intra-rater agreement we chose a purposeful sample of the combination of hospitals and physician reviewers that participated in a previous national adverse event study,[2] and also participated in our third national measurement, in which review took place in 2022/2012. To prevent that reviewers would remember how they had previously reviewed a certain case, we chose to re-review patient records from the first Dutch national adverse event incidence study, in which review took place in 2005/2006, instead of the second national study in which the review took place in 2009/2010. Eight physician reviewers out of 55 that reviewed for the first adverse event study also participated in the third national adverse event measurement and were able to re-review the patient records. In the Dutch national adverse event studies most reviewing physicians are physicians who have just retired, the primary reason for no longer reviewing in the third national adverse event study was no longer enough affinity with clinical practice.

The combination of reviewers and hospitals from the first national adverse event study still participating in the third national measurement made it possible to select records from six hospitals The re-review of the records took place in 2011/2012, during the review period of our third national adverse event measurement.

The requirement for written informed consent was waived by the institutional review board, since the study was retrospective and involved record review only.

Sampling of patient admissions

To guarantee sufficient records with (preventable) adverse events the record sampling was stratified for patient admissions with a preventable adverse event, patient admissions with a non-preventable adverse event, and patient admissions without an adverse event. These strata were constructed based on the results of the first national adverse event study. The sampling was optimized to the following stratified sample per physician per hospital:

- 7 records with preventable adverse events
- 7 records with non-preventable adverse events
- 7 records without an adverse event

Within these strata patient records were randomly chosen as much as possible. However not all physicians had always reviewed a sufficient number of patient records in the hospitals under study during the original review in total or for all strata. This was especially the case for the preventable adverse events, and to a lesser extent for the non-preventable adverse events. In these cases and if possible, the records were replaced with records from the other strata.

From here on we will refer to the review of the first national adverse event incidence study as the "original review" and the second review of these records as the "re-review".

Retrospective patient record review

In the original review the nursing, medical and if available outpatient records of the patient admissions were reviewed by trained external nurses and trained external physicians of the specialties surgery, internal medicine and neurology. Consultation of other specialties than the physicians own was available if needed for the review of a patient record. The method of determining adverse events was comparable to those of other international studies and is summarised in box 1.[1,3] In the original review pairs of physicians independently assessed all records positive for screening criteria in the first stage review. Disagreement about the presence and/or preventability of an adverse event prompted a consensus procedure. In 9% of the reviews a consensus procedure took place.[8,9] As during the second and third national adverse event study the choice had been made to have the patient admissions reviewed by only one physician without a consensus procedure, during the re-review the admissions were also only reviewed by one physician. For the comparison of the intra-rater reliability we chose to use the original independent review of the physicians, before a possible consensus procedure, as this best reflects the judgment of that independent physician.

Box 1: Adverse event and preventable adverse event assessment

First a nurse screened the records by using 16 triggers indicating potential adverse events (e.g. readmission or hospital acquired infection). Admissions positive for at least one trigger were further reviewed by a physician. Based on a standardized procedure presence and preventability of an adverse event were determined. An adverse event was defined by 3 criteria:

- an unintended injury
- resulting in prolongation of hospital stay, temporary or permanent disability or death
- caused by healthcare management rather than the patients disease

Physician reviewers made a decision on the preventability based on a thorough analysis of the patient record by systematically assessing whether given care fell below the "current" level of expected performance for practitioners or systems. If the unintended injury was caused by management (causation), the preventability score was scored on a 6 point Likert scale. An adverse event was considered preventable if the score was 4 to 6, as is also common in other adverse event studies (box 1). To add more structure to the review process, in the original review as well as the re-review, the causation and preventability score were each preceded by 13 questions to facilitate the final reviewers' judgement . Questions preceding the causation score were directed to support the reviewer if the injury was indeed caused by healthcare (management) rather than the patients' disease. Questions preceding the preventability score were directed to support the reviewer in their assessment if the adverse event was indeed preventable. Adverse events that occurred during the index hospital admission

and were detected during either the index admission or subsequent admissions over the following 12 month period were counted.

Causation, preparatory questions

15. Is there a note in the medical record indicating that a health care professional or health care management caused the injury? (No/Yes/Not applicable)
16. Is there a note in the medical record suggesting the possibility of an unintended injury from the patient's disease? (No/Yes/Not applicable)
17. Does the timing of events suggest that the injury is related to the treatment? (Likely/Possibly/Unlikely/Not applicable)
18. Does the timing of events suggest that the injury was related to the lack of treatment? (Likely/Possibly/Unlikely/Not applicable)
19. Are there other reasonable explanations for the cause of the unintended injury? (No/Yes/Possibly/Not applicable)
20. Was there an opportunity prior to the occurrence of the injury for intervention which might have prevented it? (No/Yes/Possibly/Not applicable)
21. Is lack of treatment or delayed treatment a recognized cause of this injury? (Widely recognized/Recognized by other specialists/No/Not applicable)
22. Is the lack of diagnosis or delayed diagnosis a recognised cause of this injury? (Widely recognized/Recognized by other specialists/No/Not applicable)
23. Is the treatment given to the patient a recognized cause of this injury? (Widely recognized/Recognized by other specialists/No/Not applicable)
24. Is this injury a recognized complication of the patient's underlying index disease? (Widely recognized/Recognized by other specialists/No/Not applicable)
25. Was the injury recognized during the index admission? (No/Yes/Not applicable)
26. If 'Yes' Was the appropriate action taken during the index admission? (No/Yes/No action needed/Not applicable)
27. If 'Yes' Did the injury respond to the appropriate action? (No/Yes/Possibly/Not applicable)

Causation, final judgement

After consideration of the clinical details of the patient's management, irrespective of preventability, and your response to the questions above – What level of confidence do you have that the health care professional or health care management caused the injury?

7. (Virtually) no evidence for health care management causation
8. Slight to modest evidence of health care management causation
9. Health care management causation not likely (less than 50/50, but 'close call')
10. Health care management causation more likely (more than 50/50, but 'close call')
11. Moderate to strong evidence of health care management causation
12. (Virtually) certain evidence of health care management causation

Preventablity, preparatory questions

15. How complex was this case? (Very complex/Moderately complex/Somewhat complex/Not complex/Unable to determine)
16. Was the management of the primary illness (not the adverse event) appropriate? (Definitely appropriate/ Possibly appropriate/Probably appropriate/Definitely not appropriate)
17. What was the degree of deviation of management of the primary illness (not the adverse event) from the accepted norm? (Severe/Moderate/Little/None)
18. What was the co-morbidity of the patient? (Significant co-morbidity/Moderate co-morbidity/Mild co-morbidity/No co-morbidity)
19. What was the degree of emergency in management of the primary illness (not the adverse event) prior to the occurrence of adverse event? (Very urgent/Moderately urgent/Not urgent)
20. What potential benefit was associated with the management of the illness which led to the adverse event? (Life saving/Curing/Life prolonging/Symptom relief/Palliation//No potential benefit)
21. What was the chance of benefit associated with the management of the illness which led to the adverse event? (High/Moderate/Low/Not applicable)
22. What was the risk of an adverse event related to the management? (High/Moderate/Low/Not applicable)
23. Is the injury/complication a recognized complication? (No/Yes/Not applicable)
24. What percentage of patients like this would be expected to have this complication? (Unable to determine/ Not applicable/<1%/1-9%/10-24%/>=25%)
25. On reflection, would a reasonable doctor or health professional repeat this health care management strategy again? (Definitely/Probably/Probably not/Definitely not
26. Was there a comment in the medical records indicating a need for follow-up as a result of this adverse event? (select all that apply) (No/Counselling/Psychiatric/Rehabilitation/Routine clinical/Other/UTD)
27. Did the patient have any follow-up as a result of this adverse event? (No/Counselling/Psychiatric/ Rehabilitation/Routine clinical/Other/UTD)

Preventability, final judgement

Please indicate to what extent there are indications that the event was preventable:

7. (Virtually) no evidence for preventability
8. Slight to modest evidence of preventability
9. Preventability not quite likely (less than 50/50, but 'close call')
10. Preventability more than likely (more than 50/50, but 'close call')
11. Strong evidence of preventability
12. (Virtually) certain evidence of preventability

Analysis

To determine the intra-rater agreement and reliability, we calculated the overall agreement and specific agreements, expressing the agreement separately for the positive and the negative ratings, and Cohen's kappa statistics. Besides the more commonly used Cohen's kappa, we decided to also give specific agreements, as de Vet et al. mention this is the most appropriate measure for conveying the relevant information in a 2x2 table and is most informative for clinicians.[10] de Vet et al. describe that Cohen's kappa is a measure of reliability as it is a relative measure relating to the absolute agreement or measurement error of a characteristic to its variation in the sample. Reliability is at stake if one wants to know whether a specific test is suitable for identifying or classifying patients in a certain sample.[10] To answer the question if a reviewer who assessed the presence of a preventable adverse event in the original review, still did so in the re-review, according to de Vet et al. actually requires an absolute measure of agreement. We refer to the paper of de Vet et al. for more details on this subject.[10] Specific agreement measures are the most appropriate agreement measures, as they also show if there are problems for the negative and/or positive scoring and take the prevalence of positive (and negative) scores into account.

The positive agreement is the probability that the reviewer finds an adverse event in the re-review in the same patient admission in which he or she had also found an adverse event to be present in the original review.

Box 2: Various intra-rater agreement and reliability outcome measures for this study

		Re-review	
		AE +	AE -
Original review	AE +	a	b
	AE -	c	d
Agreement (%)		$\frac{a+d}{a+b+c+d}$	
Positive agreement (%): proportion agreement for finding an AE		$\frac{2a}{2a+b+c}$	
Negative agreement (%): proportion agreement for not finding an AE		$\frac{2d}{2d+b+c}$	
Cohen´s Kappa		$\frac{Po-Pe}{1-Pe}$	

As mentioned earlier the review differed between the original review and the re-review, because during the original review patient records were assessed by two physician reviewers and if needed a consensus procedure took place. In the analysis of the intra-rater reliability we chose to use the original independent review of the physicians, before a possible consensus procedure, as we feel this best reflects the judgment of that independent physician. To assess if the outcome is different if we had made a different choice, we performed a sensitivity analyses in which we used the original review after the consensus procedure instead of before.

RESULTS

In total 285 patient records from our first national adverse event study were sampled for this study. For one physician reviewer patient records from three hospitals could be selected, for four reviewers patient records from two hospitals and for three reviewers patient records from one hospital. In total 250 (88%) were re-reviewed by the physicians with a range of 18 to 55 records per reviewer. The records of 35 patients were unavailable either because they could not be retraced by the hospital archives, or because the patient was admitted to the hospital at time of the re-review. Of the 250 patient records that were re-reviewed, in the original review in 60% no adverse event was determined to be present, in 25% a non-preventable adverse event and in 15% a preventable adverse event (table 1). The missing records were equally spread over the three groups related to presence and preventability of adverse events.

Table 1: Patient records sampled from original study and included for re-review

	Sampled from original study (% of total)	Included for re-review (% of total)
Without AE	172 (60.3)	150 (60.0)
Non-preventable AE	70 (24.6)	63 (25.2)
Preventable AE	43 (15.1)	37 (14.8)
Total	285	250

Table 2 and 3 show the 2x2 tables for adverse events and preventable adverse events and corresponding positive and negative agreements.

In the original review the reviewing physicians found 100 adverse events in the 250 patient records. In the re-review physicians found 106 adverse events (table 2). There was an overlap of 74 adverse events in both reviews and 118 patients not experiencing an adverse event, making a total agreement of 76.8%. The positive agreement for both reviews was 71.8%, meaning that in the probability that the reviewer finds an adverse event in the re/review in the same patient admission in which he or she had found an adverse event to be present in the original review was 71,8%. The negative agreement, the probability that the reviewer assessed no adverse event to be present in there/review in the same patient admission in which he or she had found no adverse event to be present in the original review, was 80.3% (table 2). Cohen´s kappa for adverse events was 0,53.

Table 2: Intra-rater agreement of determining the presence of an AE

Adverse event		**Re-review**		
		AE +	AE -	Total
Original review	AE +	74	26	100
	AE -	32	118	150
	Total	106	144	250
Agreement (%)		76.8%		
Positive agreement (%)		71.8%		
Negative agreement (%)		80.3%		
Cohen's Kappa		0.52		

The 74 patient records in which the reviewers had found at least one AE in the original review as well as the re-review were further analysed for the assessment of preventabiity (table 3). For one adverse event the preventability had accidentally not been assessed, thus we only had preventability scores for 73 of the 74 adverse events. In the original review 26 adverse events had been found preventable, in the re-review 24, with an overlap of 14 preventable adverse events and 37 non-preventable adverse events, resulting in an overall agreement of 69.9%. The positive agreement for determining preventability was 56.0%; the negative agreement was 77.1% (table 3). Cohen's kappa for the assessment of preventability was 0.33.

The 2x2 tables for adverse events and preventable adverse events do not show any systematic shifts, as the switch from positive to negative scoring and vice versa (i.e. the numbers in the cells b and c, respectively) is of the same size in the re-review in comparison

with the original review. The differences in assessment seem to be random over both measurements. The total number of adverse events and preventable adverse events was comparable in both measurements.

Sensitivity analyses using the original review after the consensus procedure instead of before, did not show any large differences in agreement or specific agreement scores. Specific agreement scores differed no more than three to four percent. For example the largest difference was found in the negative agreement of preventable adverse events, which was 73.4% instead of 77.1%. Smallest difference was found in the negative agreement of total adverse events, which was 78.5% instead of 80.%.

Table 3: Intra-rater agreement of determining the preventability of AEs

Preventable adverse event		**Re-review**		
		Preventable AE +	Preventable AE -	Total
Original review	Preventable AE +	14	12	26
	Preventable AE -	10	37	47
	Total	24	49	73
Agreement (%)		69.9%		
Positive agreement (%)		56.0%		
Negative agreement (%)		77.1%		
Cohen's Kappa		0.33		

Results per reviewer

Table 4a. & 4b. show results per reviewer. For both adverse events and preventable adverse events the results show inconsistency between the reviewers. For adverse events agreement scores varied 47.4% to 92.0 %, positive agreement from 0% to 92.3%, negative agreement scores from 61.5% to 95.7% and kappa statistics from 0.01 to 0.88 (table 4a). For 50% of the reviewers intra-rater agreement and kappa statistics for preventable adverse events could not be calculated due to small numbers. For the remaining 4 reviewers the agreement scores for preventable adverse events ranged from 50.0% to 91.7%, positive agreement from 0% to 88.9% and negative agreement from 40.0% to 93.3%. Kappa statistics ranged from 0.0% to 8.82% (table 4b).

Table 4 a & b: agreement, positive agreement, negative agreement and Cohen's kappa scores per reviewer for adverse events (a) and preventable adverse events (b)

4a. Adverse event

Reviewer	No of records	Agreement (%)	Positive agreement (%)	Negative agreement (%)	Cohen's Kappa
1	55	80.0	83.6	74.4	0.58
2	25	92.0	50.0	95.7	0.47
3	37	78.4	84.6	63.6	0.50
4	35	65.7	66.7	64.7	0.32
5	18	94.4	92.3	95.7	0.88
6	41	82.9	0	90.7	0.59
7	20	65.0	53.3	72.0	0.26
8	19	47.4	16.7	61.5	0.01
Total	250	76.8	71.8	80.3	0.52

4b. Preventable adverse event

Reviewer	No of records	Agreement	Positive agreement	Negative agreement	Cohen's Kappa
1	28	67.9	0	80.9	0.19
2	1	-	-	-	-
3	22	68.2	63.2	72.0	0.36
4	12	91.7	88.9	93.3	0.82
5	6	50.0	57.1	40.0	0.0
6	0	-	-	-	-
7	3	-	-	-	-
8	1	-	-	-	-
Total	73	69.9	56.0	77.1	0.33

Positive agreement for the intra-rater agreement on preventability was 56%. As preventability scores are judged on a 6-point Likert scale, with a 1-3 score judged as non-preventable and 4-6 score judged as preventable, we also looked how large the differences in preventability scores were between theto time periods (table 4). In 33 of the 73 cases (45.2%) the reviewers gave exactly the same score. In 22 cases the adverse event was judged as non-preventable (score 1-3) in one year and preventable (score 4-6) in the other year. Of these 22 cases where the reviewers assessed the preventability different, in 6 cases (27.2%) the difference in preventability score was 1 point. However, in 13 cases (59.1%) the difference in scoring was 3 points on the preventability scale. Only in one case the shift was from a more extreme score, being "strong evidence of preventability", to the other side of the spectrum, being "(virtually) no evidence for preventability".

Table 5: Preventability scores of all records in which an adverse event was found of the original review and the re-review

Preventability score							
	Re-review						
Original review	**Score 1**	**Score 2**	**Score 3**	**Score 4**	**Score 5**	**Score 6**	**Total**
Score 1	23	1	5	5	1	0	35
Score 2	2	0	1	1	0	0	4
Score 3	3	0	2	2	1	0	8
Score 4	7	1	4	4	3	0	19
Score 5	0	0	0	1	3	1	5
Score 6	0	0	0	0	1	1	2
Total	35	2	12	13	9	2	73

Preventability score: 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

DISCUSSION

Main findings

After six years, intra-rater agreements in our opinion were reasonable for assessing the presence of an adverse event (76.8%), but slightly lower for assessing the preventability of an adverse event (69.9%). Specific agreement scores for the assessment of an adverse event and negative agreement for preventability seemed to be reasonable, with scores ranging from 71,8% to 80.3%. Determining preventability of an adverse event seemed to be the most difficult judgement, as the positive agreement score as well as Cohen's kappa were only fair with 56% and 0,33 respectively. Although there are no other studies to compare positive agreement scores of preventable adverse events with, agreement scores just above 50% does not seem to be a lot more than chance. Apparently, in the overall data judging an adverse event to be preventable is a difficult assessment, but seems to be the result of random variation as no systematic shifts were found. Although numbers of reviewed admissions are small per reviewer, for both adverse events and preventable adverse events the results were not consistent across reviewers.

Our results show that reviewing patient records for adverse events and especially their preventability is a complex assessment. First of all the situation at hand has to be assessed: the reviewer gathers information from the patient record to obtain a complete view of the patient, his or her illness, the delivered care, the communication between caregiver and patient, and underlying argumentation and decision making around diagnosis, treatment and prognosis. Subsequently all this information together must be weighed carefully to be able to make a judgement on the presence and preventability of an adverse event. The preparatory questions preceding the actual causation and preventability score are present to guide the reviewers in their assessment, but are also illustrative of the complex factors a physician must take into consideration when coming to a judgement. Something can go wrong in assessing the situation, as well as in weighing the information, and these factors of course can also interact. If information is overlooked in assessing the situation, the information could be weighed differently and thus may lead to a different judgment. This could have taken place in both years and thus would most likely lead to random variation. A different assessment of the prognosis, which could depend on new medical insights or recognising deviating laboratory values and symptoms, could change the assessment of adequacy of given care. But in this case it would be expected that a systematic shift would have taken place: in the original review more adverse events would have been scored as non-preventable and in the re-review as preventable due to new medical insights. Our data show that changes in judgement of preventability are practically equally distributed among the original review and re-review. Other possible mechanisms could be a change in patient safety culture over the years in our reviewers. Patient safety has got an increasing amount of attention through the years, this may have had an effect on what reviewers see as preventable and what not. We can also not

rule out a learning curve in our reviewers. Altogether, it is clear that it is a complex judgement for reviewing physicians, and dependent on complex deliberation that can be susceptible to small differences in interpretations with possible large consequences for the outcome.

Until now most international research showing results on the reliability and agreement of adverse event measurements has been done by using kappa statistics. These studies show poor to moderate inter-rater reliability for the determination of adverse events and their preventability in the form of kappa statistics [3,5,9,11-14], no study reports on specific agreement statistics and often not even overall agreements. Through the years Cohen's kappa has been under scrutiny because of often paradoxal outcome.[15,16] For example a high level of agreement can be accompanied by a low kappa value. To overcome these problems, de Vet and colleagues have suggested to use different agreement measures[10], and we have accordingly done so for this article. In specific agreements, as in kappa statistics, the prevalence of the outcome measure is of influence, but now it has direct meaning as it is transformed into a probability of agreement for positive and negative ratings.[10]

Our study shows that the assessment of adverse events as well as their preventability has a certain degree of difficulty, and especially the assessment of a preventable adverse event seems to be difficult. Moreover results vary between the reviewers. Kunac and colleagues have found that kappa values of preventable adverse drug events were lower than in the non-preventable adverse drug events.[17] In the study of Kunac the judgement of each reviewer was found to be relatively consistent over time, however their study was conducted over a 12 week period using three reviewers from different specialties: a neonatologist, a clinical pharmacist and a paediatric clinical pharmacist.[17] We measured intra-rater agreement with an interval of six years.

Strengths and weaknesses

This is the first study to give insight into intra-rater agreement of adverse events and preventable adverse events over a long period of time. To our knowledge this has not been assessed before. Strength of our study is that it provides information whether judgement of reviewers changes over time. This is of special interest in the light of studies monitoring adverse events and preventable adverse event rates over time. If patient safety improves or worsens over time, it is important to know if this is not caused for example by a more lenient or stricter assessment of adverse events and their preventability by the reviewers.

Weakness is, as is always the case in patient record review studies, that reviewers are dependent on the information that is written down in the patient records. This may also have been influenced by the fact that over the years many of the patient records in the hospitals have been digitalised and herewith old paper records were scanned, thus although the same information was still in the patient record, the method of access differed to some extent.

CONCLUSIONS

In conclusion, our results show that reviewers of adverse event studies have not become stricter or more lenient over a six year interval in their judgement of adverse events and their preventability. Random variation is present in the assessment of adverse events as well as their preventability. Especially the judgement of an adverse event being preventable seems to be difficult. Our results suggest that in monitoring adverse events over time, changes in adverse event and preventable adverse event rates are not caused by a more lenient or stricter assessment by the reviewers.

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PART 2

Descriptive studies illustrating patients and processes at risk

5 Is researching adverse events in hospital deaths a good way to describe patient safety in hospitals: a retrospective patient record review study

Published as:

Rebecca J Baines, Maaike Langelaan, Martine C de Bruijne, Cordula Wagner. Is researching adverse events in hospital deaths a good way to describe patient safety in hospitals: a retrospective patient record review study. BMJ Open. 2015 Jul 9;5(7):e007380.

ABSTRACT

Objective
Adverse event studies often use patient record review as a way to assess patient safety. As this is a time-consuming method, hospitals often study inpatient deaths. In this article we will assess whether this offers a representative view of the occurrence of adverse events in comparison to patients who are discharged while still living.

Design
Retrospective patient record review study.

Setting and participants
A total of 11,949 hospital admissions, fifty percent of inpatient deaths, the other half of patients discharged while alive. The data originated from our two national adverse event studies in 2004 and 2008.

Main outcome measures
Overall, adverse events and preventable adverse events in inpatient deaths and in admissions of patients discharged alive. We looked at size, preventability, clinical process and type of adverse events.

Results
Patients who died in hospital were on average older, had a longer length of stay, were more often urgently admitted and were less often admitted to a surgical unit. We found twice as many adverse events and preventable adverse events in inpatient deaths than in patients discharged alive. Consistent with the differences in patient characteristics, preventable adverse events in inpatient deaths were proportionally less often related to the surgical process. Most types of adverse events and preventable adverse events occur in inpatient deaths as well as in patients discharged alive, however, they occur more often in inpatient deaths and are differently distributed.

Conclusions
Reviewing patient records of inpatient deaths is more efficient in identifying preventable adverse events than reviewing records of those discharged alive. Although many of the same types of adverse events are found, it does not offer a representative view of the number or type of adverse events.

INTRODUCTION

Retrospective patient record review is a commonly used method for estimating national incidences, nature and preventability of adverse events.[1-5] These studies have led to an increased sense of urgency to improve patient safety and to global directions for hospital safety improvement programmes.

A number of studies have partly or specifically focused on inpatient deaths, to estimate the relationship between an adverse event and death.[2,6-8] These studies report considerable numbers of preventable deaths due to hospital care. Previous studies from our group have also shown higher risks of experiencing preventable adverse events in this specific subgroup.[2,9] This means that through studying inpatient deaths, not only is information on the most serious outcomes of adverse events acquired, but also more indications can be found as to where improvements are possible.

One method will not identify all types of patient safety issues.[10-12] Retrospective patient record review seems especially useful as a means to assess whether negative patient outcomes are brought on by healthcare or healthcare management. However, it does have certain limitations in, for example, analysis of causes or insight into deviations in processes as captured by incident reports. Despite the downsides, retrospective patient record review does provide the best characterisation of the overall rate of harm at a given time.[13] It is however also a very time-consuming and costly method and from this point of view efficiency is welcome. All in all, studying inpatient deaths through adverse event research on the one hand instigates the sense of urgency more than studying the total hospital population because of the serious outcome of preventable deaths. However, inpatient deaths are a relatively small proportion of inpatient admissions; in the Netherlands, inpatient deaths in 2008 made up around 3% of the total inpatient admissions (source: Dutch Hospital Data). So the question arises as to whether the same type of patient safety lessons can be learned from studying inpatient deaths as from studying admissions of patients who are discharged alive with a two stage review process.

For substantiation of previous research and to direct future research, as well to inform hospitals doing their own research on hospital deaths, it is important to know whether studying inpatient deaths is efficient and offers a representative view of the number and type of adverse events in hospitals in comparison to patients who are discharged alive.

METHODS

Study design and population

We used the data from our two previous adverse event studies.[2,9] In the Netherlands, we performed adverse event studies with patient records from 2004 and 2008 to estimate national incidences of adverse events and preventable adverse events. In both measurements, half of the patient admissions were of inpatient deaths and the other half of admitted patients discharged alive, making it an ideal sample to compare the two groups. The hospital samples were stratified for hospital type: university, tertiary teaching and general hospitals. Within these strata, the hospitals were randomly selected and a proper representation of urban and rural settings in the samples was verified. For the 2004 measurement, 21 hospitals were included, and 20 hospitals for the 2008 measurement. Within the hospitals, half of the sample consisted of patient admissions who were discharged alive from the hospital after a stay of at least 24 hours, the other half were inpatient deaths regardless of the length of stay. Within these strata, patient admissions were randomly selected. Patients admitted with an explicit palliative care plan were not excluded, and this information was taken into account during the review process. As is also common in other adverse event studies, the psychiatry department, obstetrics admissions and children younger than one year were excluded. For the 2004 measurement, in each hospital 400 randomly chosen patient admissions were reviewed, and 200 patient admissions for the 2008 measurement. In all hospitals, 50% of patient records were from inpatient deaths, the other 50% from patient admissions discharged alive.

Patient record review

Trained external nurses and external physicians reviewed the nursing, medical, and – if available – outpatient records. The method of determining adverse events was the same in both groups, and comparable to those of other international studies and based on the Canadian adverse event study.[3] First a nurse screened the records by using triggers indicating potential adverse events. One trigger did not apply for deceased patients: “readmission within twelve months after discharge of the index admission”. Admissions positive for at least one trigger were further reviewed by a physician. The physicians belonged to the surgery, internal medicine or neurology specialties, and, if needed, could consult with specialties other than their own. Patient records of the index hospital admission were reviewed, as were the patient records of patient admissions a year before and a year after the index admission. Presence and preventability of an adverse event was determined for all patients, based on a standardised procedure and preceded by a number of underlying questions to secure a systematic assessment.[9] In addition, for the patients who died in hospital, the physician reviewers also assessed whether the preventable adverse events had specifically contributed to the patients’ death, leading to potentially preventable death.

Assessing adverse events

An adverse event was defined by three criteria:

1. An unintended injury;
2. resulting in prolongation of hospital stay, temporary or permanent disability or death;
3. caused by healthcare management rather than the patient's disease.

An adverse event was found to be preventable when the care given was not in compliance with existing professional standards and/or due to shortcomings of a healthcare practitioner, management or system. A six-point Likert scale was used to score the likelihood of cause by healthcare management as well as the preventability. A score of 4-6 indicated that the reviewer regarded the event as having a greater than 50% chance of being caused by healthcare or being preventable. If a preventable adverse event had occurred in a deceased patient, the physicians also assessed whether the preventable adverse event had contributed to the death of that patient. If this was the case it was marked as a potentially preventable death, 'potentially' because of the multifactorial nature of hospital deaths and the retrospective assessment of the causality. With regard to the timing of adverse events, adverse events that occurred during the patient's index hospital admission and that were detected during either the index admission or subsequent admissions over the following 12-month period were counted. Also counted were adverse events related to patient admissions in the same hospital within the 12 months preceding the index admission but which were not detected until the index admission. If an adverse event was identified, questions about the clinical process during which the adverse event occurred were asked, and physicians were able to choose from the following clinical processes: diagnostics, being an incorrect diagnosis or a diagnosis made too late; surgery, during the surgery or within a 30-day post-operative period; drug/fluid; medical procedure; other clinical management, including care given by nurses; discharge and other.

The review process of the 2004 study was slightly modified for the 2008 study. In short, in the 2004 study, pairs of physicians independently assessed all records positive for screening criteria in the first stage review. Disagreement about the presence and/or preventability of an adverse event prompted a consensus procedure.[14] In the 2008 study, all records positive for screening criteria were reviewed by one physician and standardisation of reviews was supported by regular meetings to discuss inter-rater differences based on double-blind reviews in 10% of all records. As we are not comparing the years, we do not feel this adaptation has a major influence on the results of this article. In 2004, between pairs of specialists for adverse events, positive agreement was 54.9% and negative agreement 66.2%. In 2008, for adverse events positive agreement was 56.9% and negative agreement 82.9%.

Exploration of type of adverse events

Complementary to the analysis of adverse events, preventability and related clinical processes, we also wanted to acquire more information on the specific types of adverse events. We therefore classified the type of adverse event or preventable adverse event into more specific subgroups. We based our classification on the classification used by Landrigan and colleagues in their study.[15] Based on the information in the structured review and description of the adverse event, one researcher classified the adverse events. In the cases where the researcher was unsure of the chosen classification, a second researcher also assessed the adverse event and the outcome was compared.

Analysis

The proportions of both samples, the sample of patients discharged alive and the sample of inpatient deaths, were weighted in the same manner for the different proportions of types of hospitals (university, tertiary teaching or general) in the sample in comparison to the total hospital population in our country. All proportions were weighted for the overrepresentation of university hospitals in the sample frame. After weighting, the estimates were representative of the total Dutch population of hospitalised patients, either discharged alive or inpatient deaths. The sample weight was the inverse of the probability of being included in the sample due to the sample design. All statistical analyses were performed in SPSS 20.0.

Summary and descriptive statistics of patient characteristics of inpatient deaths and patients discharged alive were calculated.

Weighted rates of adverse events and preventable adverse events were calculated with 95% confidence intervals (CI). Preventability of adverse events, related clinical process and more specific types of adverse events were assessed for both groups.

All differences between patients discharged alive and inpatient deaths, except for the more specific types of adverse events due to small numbers, were tested using proportion tests for two independent groups, with corrections for the binomial distribution and continuity.

RESULTS

In total, 11,949 of the 12,400 sampled patient admissions were reviewed, 5,990 inpatient deaths and 5,959 patients discharged alive. The 451 patient records that were not reviewed were unavailable or inadequate for review.

adverse events and preventable adverse events were found more than twice as often in inpatient deaths than in the patients discharged alive (table 1). In all admissions, 1,256 adverse events were found in 1,130 patients, 855 adverse events in 762 inpatient deaths, of which 375 were found to be preventable (weighted 46.5%). In patients discharged alive, 401 adverse events in 368 admissions were found, of which 146 were found to be preventable

(weighted 37.7%). Of the inpatient deaths, 5.8% (95% CI 5.2 to 6.5) experienced a preventable adverse event, in patients who were discharged alive this was 2.3% (95% CI 1.9 to 2.7). In 4.5% (95%CI 4.0 to 5.1) of the deceased patients the adverse event contributed to the death of that patient (table 1).

Table 1: Rate of patients, either inpatient death or discharged alive, who experienced at least one AE, preventable AE or preventable death.

	Inpatient deaths§		Discharged alive§	
	N	Weighted (95% CI) %	N	Weighted (95% CI)* %
Adverse event	762	12.5* (11.7 to 13.4)	368	6.1* (5.5 to 6.8)
Preventable AE	344	5.8* (5.2 to 6.5)	137	2.3* (1.9 to 2.7)
Potentially preventable death	265	4.5 (4.0 to 5.1)	-	-

§ For AEs, preventable AEs and preventable deaths unweighted numbers are given, % are weighted for hospital type.

* Significant differences between inpatient deaths and patients discharged alive ($p<0.001$)

Table 2: Descriptives of patient characteristics of the study sample, for inpatient deaths and patients discharged alive

	Inpatient deaths§		**Discharged alive§**		**Significance**
	N	weighted %	N	weighted %	
Inpatient admissions	5,990		5,959		
Patient admissions					
- University hospital	1,179	15.1	993	12.6	<0.001
- Tertiary teaching	1,748	33.3	1,795	34.0	0.215
- General*	3,063	51.6	3,171	53.4	0.013
Male sex	3,217	53.7	2,924	49.0	<0.001
Age in years, mean (median/sd)	73.7 (76.0/13.7)		57.4 (61.0/21.3)		<0.001
Age categories					
- 1-18	35	0.5	433	7.0	<0.001
- 19-40	131	2.0	802	13.3	<0.001
- 41-65	1,264	20.7	2,253	37.9	<0.001
- 66-79	2,238	37.3	1,674	28.2	<0.001
- 80 and older	2,314	39.3	796	13.6	<0.001
Length of hospital stay, days (median/sd)	12.0 (7.0/15.3)		7.7 (5.0/9.6)		<0.001
Urgent admission	5,172	87.0	3,061	52.2	<0.001
Department to which patient was admitted					
- Cardiology	717	12.3	730	12.6	0.535
- Surgery	726	12.2	1,424	23.9	<0.001
- Intensive Care	563	8.8	62	1.0	<0.001
- Paediatrics	12	0.2	209	3.4	<0.001
- Internal medicine	1,755	29.7	899	15.1	<0.001
- Orthopaedics	103	1.7	651	11.3	<0.001
- Neurology	706	11.9	430	7.3	<0.001
- Lung disease	779	13.2	384	6.5	<0.001
- Ear, nose and throat	26	0.4	264	4.3	<0.001
- Urology	68	1.1	280	4.7	<0.001
- Other μ	535	8.5	626	9.9	0.004
Patient admitted to surgical department	1,003	16.5	2,976	49.7	<0.001

§ For patient characteristics unweighted numbers are given, % are weighted for hospital type.

μ Other: all other departments < 3.5%, for example geriatrics, gynaecology, ophthalmology

Patient characteristics differed between inpatient deaths and patients discharged alive. Inpatient deaths were on average older, the largest group falling into the '80 years and older' category in contrast with patients discharged alive, who most often fell into the 41-65 age group. Admission characteristics also differed: patients who died in hospital had on average a longer length of hospital stay and were more often urgently admitted. The department the patient was admitted to also differed between the two groups: inpatient deaths had more often been admitted to the intensive care unit, or the internal medicine, neurology and lung disease departments, but less often admitted to a surgical department such as urology, orthopaedics, ear, nose and throat, and paediatrics (table 2).

We further assessed the clinical process related to preventable adverse events in inpatient deaths and patient admissions discharged alive (figure 1). In inpatient deaths, 27.8% of the preventable adverse events were related to diagnostics, as opposed to 12.9% of the patients discharged alive ($p<0.001$). Adverse events and preventable adverse events of patients discharged alive were proportionally more often related to surgery. In 53.7% of the preventable adverse events, the related clinical process was surgery in patients discharged alive, as opposed to 29.7% of the inpatient deaths ($p<0.001$). This lower proportion of surgical preventable adverse events in inpatient deaths is primarily related to fewer admissions to surgical departments in this group (table 2). When analysing the clinical process related to the preventable adverse events for the subgroup of patients who were admitted to a surgical department, these differences disappear to a large extent. For inpatient deaths, 70.7% of the preventable adverse events is then related to the surgical process, for patients discharged alive, this is 81.6%.

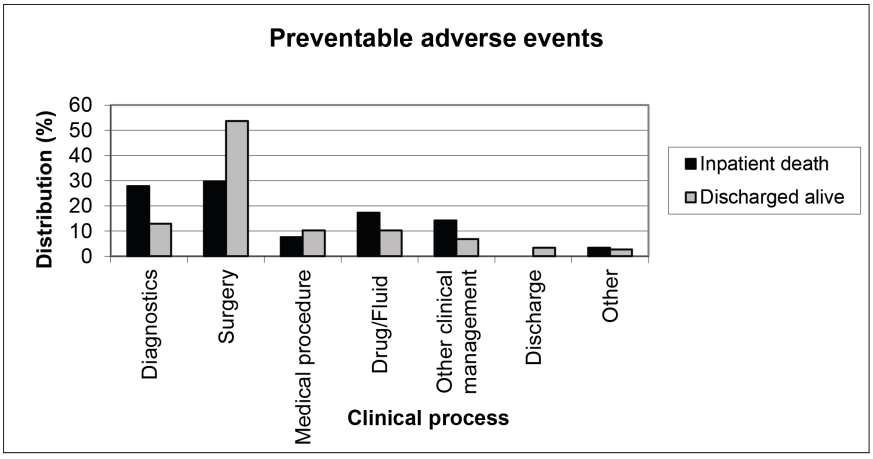

Figure 1: Distribution of clinical process related to preventable adverse events; % are weighted for hospital type

Looking more closely into specific types of adverse events and preventable adverse events, two main differences stand out. Firstly, all main types and almost all subtypes of adverse events and preventable adverse events occur in both groups, but more often in inpatient deaths than in patients discharged alive (table 3). The most pronounced examples of subtypes of adverse events occurring more often in inpatients deaths are: heart failure (32 versus 4), pulmonary embolus (23 versus 4), haemorrhage (29 versus 12), ileus (14 versus 6), perforation (17 versus 3) and stroke or intracerebral haemorrhage (30 versus 4) (table 3). Some of these adverse events were also found relatively often to be preventable in inpatient deaths, 78% of the 23 pulmonary emboli and 71% of the 14 ileus were preventable. Some adverse events are found more often in patients discharged alive: more surgical site infections, nerve injuries after surgery and failed surgical procedures were found during admission.

Secondly, as was the case with the clinical process related to the adverse events, it appears that the distribution between the groups seems to vary. For the main categories, as a proportion of all adverse events, a lower proportion of surgical adverse events and a higher proportion of preventable hospital-acquired infections are found in the population of inpatient deaths in comparison with patients discharged alive (table 3). This again is related to differences in departments to which the patient was admitted between the two groups.

There are a number of preventable adverse event types that occur rarely in patients discharged alive and are found in inpatient deaths, for example aspiration or sepsis/ bacteraemia.

Table 3: Type of harm for all adverse events and preventable adverse events

Type of harm	Inpatient death AE, n	Inpatient death Preventable AE, n	Discharged alive AE, n	Discharged alive preventable AE, n
Cardiovascular system (total column %)§	**96 (11.2%)**	**41 (11.3%)**	**20 (5.3%)**	**5 (3.4%)**
Cardiac arrest	6	1		
Hypotension	3	3	3	1
Hypertension	1	1		
Shock	7	3		
Arrhythmias or conduction abnormality	9	4	4	
Myocardial ischemia	15	7	4	
Heart failure	32	13	4	2
Other cardiovascular event	23	9	5	2

Type of harm	Inpatient death AE, n	Inpatient death Preventable AE, n	Discharged alive AE, n	Discharged alive preventable AE, n
Respiratory system, (total column %)§	**110 (13.2%)**	**48 (12.7%)**	**19 (4.8%)**	**8 (5.4%)**
Pneumothorax	24	3	5	1
Atelectasis	1	1		
Bronchospasm			2	
Aspiration	26	11	2	
Pulmonary embolus	23	18	4	4
Other respiratory event	36	15	6	3
Renal or endocrine system, (total column %)§	**54 (6.0%)**	**32 (7.9%)**	**22 (5.8%)**	**11 (7.5%)**
Fluid overload	7	5	2	1
Dehydration or oliguria	2	2	4	2
Hyperglycaemia	1	1	3	2
Hypoglycaemia	7	3	3	1
Hyperkalemia	5	4		
Renal insufficiency	13	8	4	1
Other renal or endocrine event	19	9	6	4
Haematologic system, (total column %)§	**56 (6.2%)**	**26 (6.6%)**	**19 (5.5%)**	**7 (6.1%)**
Haemorrhage	29	14	12	4
Thromboembolic venous event	12	4	4	2
Haematoma	4	2	3	1
Other haematological event	11	6		
Gastrointestinal system, (total column %)§	**84 (10.0%)**	**48 (12.7%)**	**27 (6.8%)**	**9 (6.1%)**
Nausea or vomiting	1	1	4	
Diarrhoea	2		2	
Pancreatitis			2	
Ileus	14	10	6	2
Intestinal tract bleeding	21	7	3	1
Perforation	17	11	3	2
Other gastrointestinal event	29	19	7	4
Neurologic system, (total column %)§	**52 (6.0%)**	**25 (6.3%)**	**4 (4.5%)**	**11 (7.5%)**
Over sedation			1	
Delirium or encephalopathy	6	4	2	1
Seizure	1		1	1
Stroke or intracerebral haemorrhage	30	11	4	2
Withdrawal symptoms	3	3		
Other neurologic event	12	7	10	7

Type of harm	Inpatient death AE, n	Inpatient death Preventable AE, n	Discharged alive AE, n	Discharged alive preventable AE, n
Hospital-acquired infection (total column %)§	**186 (21.7%)**	**58 (16.1%)**	**73 (17.8%)**	**6 (4.8%)**
Catheter-related bloodstream infection	19	3	3	1
Sepsis or bacteraemia unrelated to catheter	88	34	5	
Ventilator-associated pneumonia	3	1		
Nosocomial pneumonia, not ventilator-related	17	6	7	1
Urinary tract infection	13	4	12	1
Surgical-site infection	11	2	21	2
Clostridium difficile colitis	2		1	
Phlebitis	2			
Infected foreign material	7	4	11	
Other hospital-acquired infection	24	4	13	1
Surgical event (total column %)§	**151 (18.1%)**	**62 (16.9%)**	**142 (34.8%)**	**62 (41.5%)**
Post-operative haemorrhage	48	18	30	9
Post-operative haematoma	3	1	6	2
Post-operative abscess	5	2	7	1
Laceration or other organ injury	14	4	11	7
Unplanned removal of organ after intra-operative injury	6	3	3	1
Vascular injury	3	1	1	1
Nerve injury	1		8	3
Wound dehiscence	5	2	2	2
Anastomotic leakage	16	7	5	1
Post-operative fistula	2		4	2
Failed procedure	12	10	23	14
Unplanned return to surgery	3	1	7	3
Other event	33	13	35	16
Other types of harm, (total column %)§	**66 (7.7%)**	**35 (9.5%)**	**61 (14.8%)**	**27 (17.7%)**
Pyrexia	9	2	8	
Allergic reaction	2		5	
Pressure ulcer	9	3	5	1
Rash	8	3	6	1
Catheter complication	3			
Fracture	5	2	7	4
Other type of harm	30	25	30	21
Total	855 (100%)	375 (100%)	401 (100%)	146 (100%)

§ For types of harm, unweighted numbers are given, for the main groups, % are weighted for hospital type

DISCUSSION

Main findings

Inpatient deaths differ in patient and admission characteristics from patients discharged alive. Patients who died in hospital on average are older, have had a longer length of stay and are more often urgently admitted. Additionally, the department to which the patient was admitted differs between the two groups; for inpatient deaths this is less often a surgical department such as general surgery, orthopaedics, or urology. The number of adverse events and preventable adverse events differ, occurring at least twice as often in inpatient deaths. There are also differences in distribution of the clinical process related to the adverse event and type of adverse events. Consistent with fewer admissions to a surgical department, preventable adverse events in inpatient deaths were proportionally less often related to the surgical process. A few adverse events occur rarely in patients discharged alive: sepsis/bacteraemia and aspiration, most likely because these outcomes often lead to a patient's death. No specific type of preventable adverse event present in patients discharged alive was absent in deceased patients.

Implications for practice, policy and research

Patient record review used in large national adverse event studies, or in hospitals as a part of the quality and safety cycle, are often performed, but are also very costly projects. It is important to know if efficiency can be improved by exclusively sampling or oversampling inpatient deaths.

We found that exclusively sampling or oversampling inpatient deaths does seem an efficient method: fewer patient records need to be studied to identify where safety improvements are possible. Especially when the goal is not specifically the estimation of incidences for the total hospital population, but primarily to obtain as much information as possible on patient safety threats and potential solutions, this seems to be an efficient choice as fewer patient records are required to find one preventable adverse event. This goal is most likely the case for individual hospitals performing chart review as part of their quality and safety improvement cycle. In this case the results of a structured review of complete patient admissions provide information on improvement possibilities specific for that hospital. The results are often discussed in morbidity and mortality meetings, where additional information on the preventable adverse events can be acquired from the involved physicians and nurses. This also may contribute to raising a shared sense of urgency and commitment to improvement. A focus on reviews of deaths is likely to promote interest in the measurement of preventable deaths and perhaps even differences between organisations. However, this will be a difficult undertaking, given the large samples that are needed to do so, while the prevalence of preventable deaths is low and the number of in hospital deaths is limited.

Exclusively studying inpatient deaths may underexpose improvement possibilities,

especially on wards where patients are proportionally less likely to die. So for some wards it would not suffice to only research hospital deaths. Moreover, through chart review, certain types of problems in healthcare will not be found. Other research has shown that different methods often produce complementary information on patient safety and often have little overlap.[10-12,16] Our results also show that types of preventable adverse events in the hospitalised population are heterogeneous and spread across many different infrequently occurring specific types. So for one hospital alone it will not necessarily allow an understanding of patterns of harm, even when focusing on all hospital deaths.

For national studies estimating incidence rates of adverse events and preventable adverse events, reviewing only inpatient deaths will lead to valid information on the number of preventable deaths – these being the most severe kind of adverse events – but not to valid information on incidence rates of preventable adverse events for the total hospitalised population. This limits the usefulness to prioritise improvement possibilities, as assessing only inpatient deaths can lead to a biased view as to which domain is most important to target. On the other hand, omitting patient records of inpatient deaths in a study also does not seem to be a good idea, as specific types of severe adverse events will be overlooked, for example sepsis-bacteraemia or aspiration. Given that the incidence of hospital deaths in most hospitals is around 5%, some oversampling of this subgroup will be necessary in most studies.

Strengths and limitations

To our knowledge no previous study has compared inpatient deaths and hospital admissions discharged alive. The strength of our study is the large representative sample of nearly 12,000 patient admissions, consisting of 50% inpatient deaths and 50% patient admissions discharged alive, reviewed in the same years by the same reviewers, making it an ideal sample for our research question.

Limitations of this study can be seen in the standard limitations of retrospective patient record review studies. Firstly, information bias could occur in retrospective patient record review. It is likely that not all information on adverse events and preventable adverse events has been written down in the patient record. We do think that this form of bias is probably the same for the inpatient deaths as well as for patients discharged alive, since during treatment care providers do not know whether the patient will die. As has been recorded in other studies – and is also the case for our own study – retrospective patient record review of adverse events is subject to moderate reliability.[9,17-19] Lastly, hindsight bias is often mentioned as another problem.[8,20] Hindsight bias is the influence of knowing the outcome and its severity on the judgement of causation and preventability.[8,21,22] The outcome in inpatient deaths, being death, is more severe than the outcome in the group of patients admitted alive, being prolongation of hospital stay, temporary or permanent disability. Thus hindsight bias may be a more serious problem in the sample of inpatient deaths and therefore may have

led to an overestimation of the number of preventable adverse events and adverse events contributing to the death of a patient (preventable death) in this subgroup. In our study however, we do not expect the hindsight bias to be of a large influence on the distribution of the types of preventable adverse events. This bias can only fully be prevented if the reviewers are blinded for the outcome, this however is not possible in large scale retrospective patient record review studies.

In conclusion, studying inpatient deaths with patient record review seems an efficient way to identify preventable adverse events in comparison with patients discharged alive: we found more than double the results in the same number of patient records. To acquire information on as many improvement possibilities as possible, this would seem to be an efficient choice. However, when only studying inpatient deaths, awareness of the fact that some problems remain under- or unexposed is important. And on certain hospital wards, patients rarely die, thus for these wards it would not suffice to only research hospital deaths. When using the results to prioritise where improvement of patient safety is needed, one has to take into account these variations in distribution.

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6 Medication-related adverse events during hospitalisation: a retrospective record review study in the Netherlands

Published as:

Nikki Damen, Rebecca J Baines, Cordula Wagner, Maaike Langelaan. Medication-related adverse events during hospitalisation : a patient record review study in The Netherlands. Pharmacoepidemiology & Drug Safety. 2017 Jan;26(1):32-39. Epub 2016 May 19.

ABSTRACT

Purpose

Medication-related adverse events (MRAEs) are an important priority for patient safety. Results from Dutch AE studies showed that – despite various improvement initiatives - the incidence of preventable MRAEs did not decline. The aim of this study is to describe the characteristics of MRAEs during hospitalizations, using national patient data from records of patients admitted to Dutch hospitals in 2008 and 2011/2012.

Methods

Trained nurses and physicians reviewed the randomly selected records of 8,071 patients admitted to one of 20 hospitals in 2008 or 2011/2012, during a two-stage review process. Patient and admission characteristics were collected. After identification of a MRAE, physicians determined their potential preventability, drug type, related prescribing factors, and potential consequences.

Results

The physicians identified 928 AEs in 857 admissions, of which 218 (15.2%) were medication-related. They judged 55 (18.4%) of these as preventable. Preventability of MRAEs was high in anticoagulant treatment (42.5%). Haematoma (39.0%) and intra-cerebral haemorrhage (25.5%) were common types of anticoagulant-related AEs. Anticoagulant-related AEs were often related to dosage factors (46.9%) and often resulted in an intervention (80.2%), of which 40.2% was judged as preventable.

Conclusions

This study provided detailed information on MRAEs during hospital admissions in the Netherlands. A substantial proportion of AEs was medication-related (15.2%), of which 18.4% was judged to be preventable. As preventability in MRAEs was especially high in anticoagulant treatment (42.5%), those medications are a threat to patient safety. Future research and new safety programs should focus on prevention of AEs related to this medication group.

INTRODUCTION

Patient safety continues to be a major challenge and a high priority in hospitals worldwide. Healthcare-related adverse events (AEs) are common and can be defined as unintended injuries that result in temporary or permanent disability, death, or prolonged hospitalization, caused by healthcare management rather than patients' underlying disease.[1-4]

Medication-related adverse events (MRAEs) occur as a consequence of medication errors or adverse drug reactions and are one of the most common types of healthcare-related AEs.[4-6] In the Netherlands, the first national AE study took place in 2004, in which the extent and nature of AEs and their preventability was evaluated in 21 Dutch hospitals.[7] Results from this study indicated that MRAEs comprise around 15% of all AEs, with almost 30% of them being preventable.[8-10] In addition, MRAEs were associated with considerable longer hospital stays and higher healthcare costs[9], imposing a high burden on patients, caregivers, and the healthcare system. These results were in line with findings from other AE studies[11-14] and also confirmed in systematic reviews and meta-analyses.[5,6]

Over the last years, the prevention of AEs has become an important priority for patient safety in the Netherlands. In 2008, the national program "Prevent Harm, Work Safely" was launched. The overall goal of this safety program was to reduce the number of preventable AEs in Dutch hospitals by 50% through the implementation of a Safety Management System in all hospitals and through improvement modules on 10 clinical themes, including medication processes such as medication reconciliation and high-risk medication.[15]

To keep track of changes in patient safety on a national level, a second and third measurement of the national AE study was conducted in 2008 and 2011/2012. In recent publications, general trends in AEs over time and main categories of preventable AEs have been assessed.[16,17] These studies showed that – despite various safety improvement initiatives such as the safety program - the incidence of preventable MRAEs did not decline over the years. Hence, the aim of the current study is to describe the characteristics of (potential preventable) MRAEs during hospitalizations, using national patient data from records of patients admitted to Dutch hospitals in 2008 and 2011/2012. This information could contribute to the design of future medication safety initiatives.

METHODS

Study design and population

We used the data from two of our previous AE studies[16, 17], in which patient records of hospital admissions in 2008 and 2011/2012 were assessed. Review of these admissions records took place in 2009/2010 and 2012/2013, respectively. In both studies, the same 20 hospitals of the in total 93 Dutch hospitals were included. The hospital samples were

both stratified by hospital type: university, tertiary teaching, and general hospitals. Within these strata, hospitals were randomly selected and a proper representation of urban and rural settings in the sample was verified. Per hospital, for each measurement year about 200 patient admissions were randomly selected: half of these consisted of admissions of patients discharged alive from the hospital after a stay of at least 24 hours, the other half consisted of inpatient deaths regardless of the length of hospital stay. In both studies, only one admission per patient was included. As was also common in other AE studies, records from patients admitted to the psychiatry or obstetrics department, and records of children younger than one year of age were excluded. Detailed information on the design of the studies was published previously.[7,17] Both study protocols were approved a priori by the medical ethics committee of the VU medical center, Amsterdam, the Netherlands.

Patient record review

Trained external nurses and external physicians reviewed the nursing and medical records of included admissions. The method of determining AEs, which was comparable to those of other international studies[18, 19] and based on the Canadian AE study[1], comprised two phases: first, a nurse screened the records by using triggers indicating potential AEs. In the second phase, a physician further reviewed admissions positive for at least one trigger. These physicians belonged to the specialties surgery, internal medicine, or neurology, and AE reviews were assigned based on their specialty. If needed, they could consult with specialties other than their own. Patient records of the index-hospital admission were reviewed, as were the patient records of patient admissions a year before and after the index-admission. Presence of AEs was determined by the physicians, based on a standardized procedure.

An AE was defined by three criteria:

1. An unintended physical or mental injury;
2. The injury resulted in prolongation of hospital stay, temporary or permanent disability or death;
3. The injury was caused by healthcare management rather than the patient's underlying disease.

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

1. (Virtually) no evidence for management causation;
2. Slight to modest evidence of management causation;
3. Management causation not likely (<50/50, but borderline);
4. Management causation more likely (>50/50, but borderline);

5. Moderate to strong evidence of management causation;
6. (Virtually) certain evidence of management causation.

The cause of an AE was counted as caused by healthcare if the score was 4–6.

If an AE was identified, questions about the clinical process during which the AE occurred were asked. Physicians were able to choose from the following clinical processes: diagnostics, surgery, drug, medical procedure, other clinical management, discharge, and other. All AEs in which a drug was chosen to be the main clinical process during which the AE had occurred, were marked as medication-related AEs (MRAEs).

A MRAE was considered to be preventable when the care given fell below the current level of expected performance for practitioners or systems. In accordance with our previous studies, preventability was assessed on the following six-point Likert scale[7,9,16]:

1. Almost no evidence for preventability;
2. Slight to modest evidence for preventability;
3. Modest preventability (<50/50, but borderline);
4. Modest to strong evidence of preventability (>50/50, but borderline);
5. Strong evidence of preventability;
6. Almost certain evidence of preventability.

A score of 4-6 indicated that the reviewer regarded the MRAE as having a greater than 50% chance of being potentially preventable.

To add more structure to the implicit review process, the causation and preventability scores were each preceded by 13 questions to facilitate the final reviewers judgment. In addition, physicians were trained in assessing the causation and preventability prior to reviewing patient admissions, and frequent reflection meetings were organised to uphold a high quality of the review process.

After identification of a MRAE, the physician reviewers determined among others drug type, related prescribing factors, and potential consequences associated with the MRAE.[1] As for the timing of MRAEs, MRAEs that occurred during the patient's index-hospital admission and were detected during either the index-admission (n=147) or subsequent admissions over the following 12-month period (n=13) were counted. Also counted were MRAEs related to patient admissions in the same hospital within the 12 months preceding the index-admission but which were not detected until the index-admission (n=58). Exceptions were made for MRAEs related to hair loss due to cytostatic treatment and neutropenia without fever, as these were common side effects of cancer chemotherapy and therefore not counted as AEs in this study.

STATISTICAL METHODS

Weighting procedure

In accordance with our previous studies, during analyses all proportions were corrected for the oversampling of deceased patients and university hospitals. [8,9,16] In our sample, 50% of the patients were inpatient deaths, whereas in reality this is 3%. In the results we weighted our 50% back to the actual 3%. We followed the same procedure for the distribution of types of hospitals: in our sample 20% of the hospitals were university hospitals, whereas in reality this is 10%. Therefore, in the results we weighted our 20% back to the actual 10%. After weighting for this sample frame, the total study sample — that is, both discharged and deceased patients — was representative of the total Dutch population of hospitalised patients. Detailed information on the weighting procedure was published previously.[7] As a consequence of the weighting process, proportions are not directly comparable to the accompanying crude numbers.

Conducted analyses

Summary and descriptive statistics for patient and admission characteristics were calculated for all reviewed patients, and for all patients who were assessed to have experienced an MRAE. SPSS complex samples were used to calculate weighted rates of patients who had experienced at least one MRAE during the admission, and their preventability (referred to as “MRAEs – admission level” in the accompanying Tables). As it was possible for patients to experience more than one MRAE during a hospital admission, we also assessed the total number of MRAEs and preventable MRAEs (referred to as “MRAEs – adverse event level” in the accompanying Tables). We further analysed medication type. For the drug type most frequently related to a preventable MRAE, we further analysed possible related prescribing factors as well as consequences. All statistical analyses were performed in SPSS 20.0 and STATA 13.

RESULTS

Table 1: Patient and hospital characteristics of the study sample

	Total population		
	N	**unweighted%**	**weighted% †**
Inpatient admissions	8,071		
Hospital admission year			
- 2008	4,023	49.9	49.8
- 2011/2012	4,048	50.1	50.2
Age in years, mean (median/sd)			60.2 (64.0/20.8)
Age categories			
- 1-18	286	3.5	5.8
- 19-40	533	6.6	10.8
- 41-65	2,365	29.3	37.6
- 66-79	2,665	33.0	29.0
- 80 and older	2,222	27.5	16.8
Discharge status			
- Alive	4,039	50.0	95.3
- Inpatient death	4,032	50.0	4.7
Gender			
- Male	4,155	51.5	50.0
- Female	3,916	48.5	50.0
Patient admissions			
- University hospital	1,593	19.7	13.9
- Tertiary teaching	2,843	35.2	44.1
- General	3,635	45.0	41.9
Length of hospital stay, days (median/sd)			6.5 (4.0/12.1)
Urgent admission			
- No	2,496	30.9	45.6
- Yes	5,575	69.1	54.4
Department to which patient was admitted			
- Cardiology	814	10.1	11.1
- Surgery	1,410	17.5	21.7
- Geriatrics	163	2.0	1.1
- Coronary Care Unit	286	3.5	3.3
- Intensive Care	543	6.7	1.9
- Paediatrics	172	21.3	3.4
- Internal medicine	1,720	2.1	16.2
- Orthopaedics	510	2.2	11.1
- Neurology	695	9.9	7.2
- Pulmonology	802	8.6	6.5
- Ear, nose and throat	178	6.3	3.7
- Urology	251	3.1	5.0†
- Other	527	6.5	7.8†

† Weighted for overrepresentation of deceased patients and hospital type

Table 2: Patient and hospital characteristics of medication-related adverse events

	MRAEs (n=204)* n (column %, weighted) †	Preventable MRAEs (n=53)* n (row %, weighted) † ‡
Age categories		
- 1-18	5 (4.2)	0 (0.0)
- 19-40	9 (4.0)	1 (22.6)
- 41-65	47 (25.1)	7 (17.4)
- 66-79	88 (41.3)	24 (17.9)
- 80 and older	55 (25.5)	21 (22.7)
Discharge status		
- Alive	67 (90.9)	11 (17.2)
- Inpatient death	137 (9.1)	42 (30.7)
Gender		
- Male	104 (46.8)	26 (18.1)
- Female	100 (53.2)	27 (18.7)
Patient admissions		
- University hospital	41 (14.5)	8 (14.5)
- Tertiary teaching	57 (36.9)	13 (21.2)
- General	106 (48.7)	32 (17.5)
Urgent admission		
- No	44 (26.1)	8 (14.0)
- Yes	160 (73.9)	45 (20.0)
Department to which patient was admitted		
- Cardiology	19 (8.5)	9 (7.2)
- Surgery	11 (2.2)	3 (9.0)
- Geriatrics	5 (1.4)	2 (9.6)
- Coronary Care Unit	5 (3.1)	3 (7.6)
- Intensive Care	15 (5.8)	4 (29.2)
- Internal medicine	75 (33.4)	13 (6.9)
- Paediatrics	2 (2.0)	-
- Ear, Nose, Throat	2 (1.1)	-
- Pulmonology	28 (15.1)	8 (25.9)
- Neurology	15 (6.9)	4 (34.1)
- Orthopaedics	8 (5.5)	2 (29.0)
- Urology	6 (7.1)	3 (50.1)
- Other	13 (7.8)	2 (23.1)

* MRAE's – admission level

† Weighted for overrepresentation of deceased patients and hospital type

‡ No preventability was shown if numbers of MRAEs were smaller than 5

MRAE=medication-related adverse event

Table 3: Drug type of medication-related adverse events

	MRAEs (n=218)* n (column %, weighted) †	Preventable MRAEs (n=55)* n (row %, weighted) † ‡
Antiasthmatic	1 (0.0)	-
Antibiotic	22 (13.6)	3 (11.2)
Anticoagulant	43 (17.1)	17 (42.5)
Antidepressant	1 (1.8)	-
Antiepileptic	2 (1.1)	-
Antihypertensive	4 (2.9)	-
Antiplatelet	7 (6.3)	1 (1.6)
Antipsychotic	2 (0.1)	-
Chemotherapy	58 (22.0)	3 (0.7)
Cardiovascular	11 (6.9)	5 (4.4)
Diuretic	5 (3.1)	0 (0.0)
Insulin/ oral diabetic	12 (5.0)	7 (34.8)
Potassium	1 (0.0)	-
Morphine/opioid	9 (3.0)	2 (5.3)
NSAID	1 (0.0)	-
Sedative	9 (1.4)	4 (15.5)
Other	30 (15.5)	7 (27.8)
Total	218(100)	55 (18.4)

* MRAEs - adverse event level
† Weighted for overrepresentation of deceased patients and hospital type
‡ No preventability is shown if numbers of MRAEs were smaller than 5
MRAE=medication-related adverse event; NSAID= Non-steroidal anti-inflammatory drug

In total, records of 8,071 patient admissions were included in the study, of which 4,023 of 2008 and 4,048 of 2011/2012. Patient and hospital characteristics of the study sample are described in Table 1.

Medication-related adverse events

The hospital admissions were assessed for the presence of AEs and MRAEs, and their preventability. In the second stage, the physicians identified 928 AEs in 857 admissions, of which 218 (15.2%) in 204 admissions were medication-related. They judged 55 (18.4%) of these MRAEs in 53 admissions as preventable. MRAEs often occurred in patients aged 66-79 years. The preventability of MRAEs was high in patients who died in-hospital, urgently admitted patients, patients admitted to a urology or neurology department, and patients admitted to tertiary teaching hospitals (Table 2).

Table 3 shows that the majority of MRAEs were adverse drug reactions related to cancer chemotherapy (n=58, 22.0%), anticoagulant treatment (n=43, 17.1%), and antibiotics (n=22, 13.6%). Preventability in MRAEs was especially high in anticoagulant treatment (n=17, 42.5%) and insulin/oral diabetics (n=7, 34.8%). MRAEs related to chemotherapy were seldom considered preventable: 0.7% (n=3) of all chemotherapy-related MRAEs.

Anticoagulant-related adverse events

As MRAEs related to anticoagulant treatment were common and often preventable, we further analyzed this type of medication. Although preventability in insulin/oral diabetic-related MRAEs was also found to be high, they only comprised 5.0% (n=12) of total MRAEs (Table 3). Therefore, due to power constraints we did not perform further analyses on this medication type.

Most anticoagulant-related AEs were related to coumarins (n=24, 55.8%) and heparins (n=13, 30.2%) (results not shown in Table). Although numbers were small, most of the anticoagulant-related AEs were among patients of 66 years or older and in patients urgently admitted. The preventability of anticoagulant-related AEs was high in urgently admitted patients and patients admitted to tertiary teaching hospitals. (Table 4).

Haematoma (n=5, 39.0%), intra-cerebral haemorrhage (n=8, 25.5%), and gastrointestinal bleeding (n=9, 12.6%) were common types of anticoagulant-related AEs. Anticoagulant-related AEs were often related to dosage factors (n=14, 46.9%), of which 66.2% (n=7) was judged as preventable. Although therapeutic factors were less often related to anticoagulant-related AEs, their preventability was high (n=4, 90.6%). Anticoagulant-related AEs often resulted in an intervention (n=26, 80.2%), of which 40.2% (n=10) was judged as preventable. In 18.9% (n=2), anticoagulant-related AEs resulted in readmission (Table 5).

Table 4: Patient and hospital characteristics of anticoagulant-related adverse events

	Anticoagulant-related AE (n=41)* n (column %, weighted) †	**Preventable anticoagulant-related AE (n=17)* n (row %, weighted) † ‡**
Age categories		
- 1-18	0 (0.0)	-
- 19-40	1 (0.3)	-
- 41-65	5 (14.0)	2 (60.8)
- 66-79	17 (33.0)	7 (39.0)
- 80 and older	18 (52.7)	8 (40.6)
Gender		
- Male	22 (38.6)	10 (57.0)
- Female	19 (61.4)	7 (33.8)
Discharge status		
- Alive	11 (89.3)	4 (42.6)
- Inpatient death	30 (10.7)	13 (44.1)
Urgent admission		
- No	10 (15.9)	3 (6.5)
- Yes	31 (84.1)	14 (49.6)
Patient admissions		
- University hospital	6 (10.7)	0 (0.0)
- Tertiary teaching	9 (51.2)	4 (59.7)
- General	26 (38.2)	13 (32.1)
Department to which patient was admitted		
- Cardiology	6 (2.1)	4 (65.8)
- Surgery	4 (1.4)	-
- Geriatrics	1 (0.4)	-
- Coronary Care Unit	3 (16.1)	-
- Intensive Care	1 (0.3)	-
- Internal medicine	13 (25.9)	5 (37.0)
- Paediatrics	0 (0.0)	-
- Ear, Nose, Throat	1 (0.3)	-
- Pulmonology	3 (19.6)	-
- Neurology	3 (1.2)	-
- Orthopaedics	2 (0.7)	-
- Urology	4 (32.1)	-
- Other	0 (0.0)	-

* MRAEs – admission level

† Weighted for overrepresentation of deceased patients and hospital type

‡ No preventability was shown if numbers of MRAEs were smaller than 5

AE= adverse event

Table 5: Factors and consequences of anticoagulant-related adverse events

	Anticoagulant-related AEs (n= 43)* n (column%, weighted) †	**Preventable anticoagulant-related AEs (n= 17)* n (row %, weighted) † ‡**
Prescribing factors		
- Administrative/procedure	0 (0.0)	-
- Dosage	14 (46.9)	7 (66.3)
- Therapeutic	6 (10.1)	4 (90.6)
- Delivery	0 (0.0)	-
- Administering	0 (0.0)	-
- Other	22 (20.0)	11 (20.0)
Type of adverse event		
- Shock	1 (0.4)	-
- Heart failure	1 (0.4)	-
- Pulmonary embolism	2 (0.7)	-
- Renal insufficiency	1 (6.8)	-
- Other renal failure	1 (0.4)	-
- Intra-cerebral haemorrhage	8 (25.5)	3 (38.6)
- Thromboembolism	1 (0.4)	-
- Haematoma	5 (39.0)	1 (31.0)
- Gastro-intestinal bleeding	9 (12.6)	4 (14.2)
- Cerebrovascular accident	7 (3.0)	0 (0.0)
- Catheter-related blood infection	1 (0.3)	-
- Pulmonary infection	1 (0.4)	-
- Postsurgical haemorrhage	1 (0.4)	-
- Other	1 (9.9)	-
Consequences §		
- Intervention	26 (80.2)	10 (40.3)
- Impairment at moment of discharge	1 (4.9)	-
- Extended length of stay	4 (5.9)	-
- Readmission	2 (18.9)	-
- Death	18 (12.1)	4 (11.3)
- Outpatient visit	1 (10.8)	-
- Other	2 (11.1)	-

* MRAEs - adverse event level

† Weighted for overrepresentation of deceased patients and hospital type

‡ No preventability was shown if numbers of MRAEs were smaller than 5

§ More than one answer was possible. Therefore the total percentage sums up to more than 100

AE=adverse event

DISCUSSION

In the current study, a substantial proportion of all healthcare-related AEs were medication-related (n=218, 15.2%). Of all 218 identified MRAEs, 55 (18.4%) were deemed to be preventable. Preventability of MRAEs was especially high in anticoagulant treatment (n=17, 42.5%). Haematoma (n=5, 39.0%) and intra-cerebral haemorrhage (n=8, 25.5%) were common types of anticoagulant-related AEs. Anticoagulant-related AEs were often related to dosage factors (n=14, 46.9%) and they often resulted in an intervention (n=26, 80.2%), of which 40.2% (n=10) was judged as preventable.

The results of this study corroborate the findings of previous studies, demonstrating that MRAEs were responsible for 12-37% of all AEs [2,4,9,11-14,17], which was also confirmed in systematic reviews and meta-analyses [5,6,20-22]. In these earlier studies, 30-50% of MRAEs was judged to be preventable, whereas in our study this number was considerably lower (18.4%). The finding that anticoagulant treatment accounted for a substantial proportion of preventable MRAEs was also in line with previous research.[11,13,23-25] As compared to results of the first measurement of the national AE study [9], no visible differences were found in the occurrence of anticoagulant-related MRAEs (18.0% in 2004 vs. 17.1% in this study, respectively) but their preventability slightly decreased from 54.0% in 2004 to 42.5% in our study.

Over the past decades, several interventions have been developed to reduce MRAEs and improve medication safety. In the Netherlands, the national program “Prevent Harm, Work Safely” was launched in 2008 and aimed to reduce the number of preventable AEs in Dutch hospitals by 50%. The program included two improvement modules on medication processes: reducing events that involve high-risk medication and reducing medication errors on admission and discharge.[15]. Baines et al. (2015) concluded that during the safety program no visible improvements in medication safety were established.[16] MRAEs are therefore still a threat to patient safety, and our results indicate that especially on certain high-risk medications, such as anticoagulant treatment, many preventable MRAEs still occur.

Other intervention methods and tools to prevent MRAEs have also been proposed. The most commonly implemented interventions are “computerized physician order entry systems (CPOEs)”, a form of patient management software allowing health care providers to electronically enter patient treatment instructions.[26,27] While CPOE systems are well implemented in most hospitals, a considerable amount of MRAEs was still reported and CPOE systems introduced new types MRAEs as well. [28, 29]. Clinical pharmacy interventions have also been investigated, with a hospital pharmacist interacting and advising the healthcare team.[30,31] Though these interventions contributed to the reduction of (preventable) MRAEs, most of them are costly and time consuming and difficult to provide continuously.[31] Recent research showed that evidence-based drug rules seem promising in preventing MRAEs, but their clinical efficacy is yet to be tested.[32]

Although in the current study anticoagulant-related AEs were the most common types of preventable MRAEs, none of the aforementioned interventions specifically targeted this medication group. Anticoagulant care is considered complex and potential risks of bleeding and thrombosis should always be taken into account. In addition, various healthcare professionals are involved in the treatment of patients, including medical specialists, pharmacists, general practitioners, dentists, and the anticoagulation services. These different healthcare providers need to collectively coordinate anticoagulant care. It was previously argued that suboptimal communication and coordination within this "chain" of healthcare providers is common and associated with adverse patient outcomes.[33] In the Netherlands, several guidelines have been developed addressing these integrated care problems, but one of our recent studies showed that adherence to these guidelines is still trivial.[34] Future research is needed to further examine the complex nature of MRAEs, hereby focussing on hospital-related factors as well as suboptimal integrated care. This knowledge could contribute to the design of future medication safety initiatives, which should especially target the areas with the highest risk of preventable MRAEs, such as anticoagulant treatment.

Strengths and limitations

One of the strengths of the current study is that we reviewed 8,071 patient records over two periods in time based on an international, standardised assessment method of patient admissions. Although assessing patient records on AEs is a difficult process, retrospective chart studies currently offer the best method available to assess the incidence and is considered as the "golden standard".[35] This more implicit method also allows us to focus on a broad range of MRAEs instead of an explicit range of MRAEs and gives a good insight in the general state of medication safety in hospitals.

Retrospective review studies also have disadvantages. The incidence of preventable MRAEs may be underestimated because not all information is available or written down in the patient records.[36] However, hindsight bias may have been overestimated the incidence of MRAEs.[37] Knowing the outcome of an admission may have influenced the judgement of the causality and preventability of MRAEs. We found that anticoagulants still account for a large proportion of the total amount of preventable MRAEs. Unfortunately, we did not register the use of anticoagulants and other medications for *all* included patients. Therefore, a numerator was not available and the incidence of anticoagulant-related AEs could not be calculated.

CONCLUSION

The current study provided detailed information on MRAEs during hospital admissions in the Netherlands. A substantial proportion of AEs was medication-related (n=218, 15.2%), of which 18.4% (n=55) was judged to be preventable. As preventability in MRAEs was especially high in anticoagulant treatment (n=17, 42.5%), those medications are a threat to patient safety. It is therefore recommended that future research and new safety programs focus on the prevention of AEs related to this high-risk medication group.

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7 What are the safety risks for patients undergoing treatment by multiple specialties: a retrospective patient record review study

Published as:

Rebecca J Baines, Martine C de Bruijne, Maaike Langelaan, Cordula Wagner. What are the safety risks for patients undergoing treatment by multiple specialties: a retrospective patient record review study. BMC Health Services Research. 2013 Nov 28;13:497.

ABSTRACT

Background

If multiple medical specialties are involved in treatment there is a danger of increasing risks to patient safety. This is due to the need for greater co-ordination and communication with other specialties, less emergency cover for individual sub-specialties, and a drop in general care and the overview of care. This study aims to determine if the number of medical specialties treating a patient is associated with the risk of experiencing harm during hospital admission.

Methods

We performed a retrospective patient record review study carried out by trained nurses and doctors using a stratified sample of 20 hospitals in the Netherlands. In each hospital 200 patient admissions were included. We related the occurrence preventable adverse events and non-preventable adverse events to the number of specialties treating a patient through a stepwise multilevel logistic regression analysis.

Results

Compared to patients treated by only one specialty, patients treated by three or more specialties had an odds ratio of experiencing an adverse event of 3.01 (95% CI 2.09 to 4.34), and an odds ratio of experiencing a preventable adverse event of 2.78 (95% CI 1.77 to 4.37). After adding characteristics related to the patient and the type of health care, the odds ratio for non-preventable adverse events decreased to 1.46 (95% CI 0.95 to 2.26), and for preventable adverse events to 2.31 (95% CI 1.40 to 3.81). There were no large differences found between the groups relating to the causes of preventable adverse events. However, in patients treated by three or more specialties, the greater number of preventable adverse events was related to the diagnostic process.

Conclusions

The more specialties treating a patient the greater the risk of an adverse event. This finding became more pronounced for preventable adverse events than for non-preventable adverse events after corrections for the characteristics of the patient and their health care. This study highlights the importance of taking the number of specialties treating a patient into account during a hospital admission. More research is needed to gain insight into the underlying causes of inadequate care when multiple specialties are required to treat a patient. This could result in appropriate solutions resulting in improvements to care.

BACKGROUND

Hospitals have become increasingly complex organisations. Scientific and technological progress has been followed by specialisation and further sub-specialisation of the medical profession. Increasing specialisation can have positive as well as negative effects on the care of patients. The care given is more specialised so there is more specific knowledge on, and experience of, specific diseases and treatment options. Specialisation in this way is often seen as a way to improve patient outcomes, especially in surgery.[1,2] On the other hand, increased specialisation may lead to inadequate care and increased risks to patient safety. This is due to an increased need for co-ordination and communication with other specialties, the fragmentation of care, less emergency cover for individual sub-specialties and a drop in general care and the overview of care. An example of how specialisation can lead to greater risks for patients is that doctors within a specific specialty seem to be biased towards diagnosing patients within their own domain.[3] The more specialisation and more specialties treating a patient thus may lead to improved care, but also to extra safety risks for patients. We do not know yet if, indeed, an increased risk exists, and if it does, how large the risk is for patients treated by multiple specialties. Previous research, on, for example, the high risk associated with hospital handovers does suggest that an increased risk for patients treated by multiple specialties could exist.[4,5]

In this article we explore if patients treated by more specialties are at a higher risk of experiencing harm during hospital admissions. A retrospective patient record review to assess adverse events (AEs) provides a unique opportunity to study the above mentioned questions. In this type of research entire patient admissions are reviewed to see if a patient experienced an AE. An AE is seen 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.[6,7] The degree to which an AE is preventable is defined by judging if inadequate care had caused the adverse event. In other words if the care given fell below the current level of performance expected of practitioners or systems. The number of specialties treating a patient and the possible communication and co-ordination problems associated with this could have a role in inadequate care. AEs which could not be prevented are unintended injuries caused by health care in spite of receiving care according to the current level of expected performance (figure 1). This study provides a first indication of whether the number of specialties treating a patient is associated with patients´ risk of experiencing harm during hospital admissions. If an association exists then we will explore the contribution made by inadequate care by comparing the preventable and non-preventable AEs.

METHODS

Design and setting

We performed a retrospective patient record review study from 2009 to 2010 in 20 of the 93 Dutch hospitals.[8] These comprised, four university hospitals, six tertiary teaching hospitals and ten general hospitals. The sample was stratified for hospital type (university, tertiary teaching and general hospitals), representation of urban and rural settings in the samples were verified. Hospitals were eligible if they had at least 200 beds, an emergency room and an intensive care unit.

In each hospital, a stratified sample of 200 admissions from 2008 was selected. Fifty per cent of the records were from patients discharged from the hospital after more than 24 hours. The other fifty per cent was of patients who deceased in hospital. The admissions were selected randomly within these two strata. In our national studies, we chose to oversample hospital deaths in order to be able to assess the rate of preventable deaths.[6] Admissions to the psychiatric department, obstetrics department and admission of children aged less than one year, were excluded.

Record review

The nursing, medical and, if available, outpatient record of the index admissions were reviewed by 39 nurses and 19 medical consultants drawn from the specialties surgery, internal medicine and neurology. Consultation with specialties, other than their own, was available, if needed, for the review of a patient record. The method of determining AEs was comparable to those of other international studies.[7,9] Firstly, a nurse screened the records by using 16 triggers indicating potential AEs, for example, re-admission or hospital acquired infection. During the review process additional data was gathered on the number of specialties involved in the treatment of the patient during the index-admission. The nurses were asked to note down which specialties were involved in the treatment of the patient. The nurses were able to choose from an extensive, though not exhaustive, list of 21 different specialties. These were: cardiology, surgery, dermatology, geriatrics, gynaecology, intensive care, internal medicine, paediatrics, ear, nose and throat, pulmonology, oncology, nephrology, neurosurgery, neurology, ophthalmology, orthopaedics, psychiatry, radiology, rehabilitation medicine, rheumatology and urology. If a specialty involved in treatment was not on this list, the nurses could also choose for the option “other” and write down the specialty. The specialties written down were: gastroenterology, endocrinology, vascular surgery, thoracic surgery, plastic surgery, anaesthesia for pain treatment, infectious diseases, haematology, dental medicine and cardiac surgery. The nurses were instructed to record a specialty as being involved in the treatment if they could find any evidence in the patient record of a consultation or an involvement in the treatment.

Admissions marked positive for at least one of the 16 triggers were reviewed further by a doctor. The presence and preventability of an AE was determined based on a standardised procedure. An AE was defined by three criteria:

1. an unintended injury.
2. resulting in a longer stay in hospital, a temporary or permanent disability, or death.
3. caused by healthcare management rather than the patient's disease.

The medical reviewers took a decision on how far the AE could have been prevented based on a thorough analysis of the patient record by assessing, systematically, whether the care given fell below the current level of performance expected from practitioners or health systems. The cause of an AE, as well as the degree to which it could be prevented, were scored on a six-point likert scale and only counted as caused by health care or preventable if the score was four to six as is common to other studies of AEs.[7,10]

AEs that occurred during the index hospital admission and were detected, either during the index admission, or subsequent admissions over the following 12-month period, were counted. In contrast to previous articles from our research group, AEs related to admissions within the 12 months preceding the index admission and detected during the index admission, were not counted for this article. This was because we had no information on that specific admission and the number of specialties involved in the treatment of the patient.

We linked the admissions included in the sample to the hospital administration database (Dutch Hospital Data) to obtain ICD9 diagnostic information.

Exploring underlying mechanisms

We divided AEs into those which were non-preventable, having a preventability score of one to three, and those which were preventable, having a preventability score of four to six. To add structure to the implicit review process the reviewer's judgement of inadequate care, and thus the presence of a preventable AE, was preceded by thirteen questions. These questions help the reviewers with their assessment of inadequate care, take into account the patient's comorbidity and the complexity of the one or more diseases suffered. The care received by the patient is taken into consideration. We asked: Is the given care appropriate, deviant from the accepted norm, urgent, what is its potential advantage, what is the risk of an AE, is the injury a recognised complication and would other health care professionals repeat the care given? (figure 1).

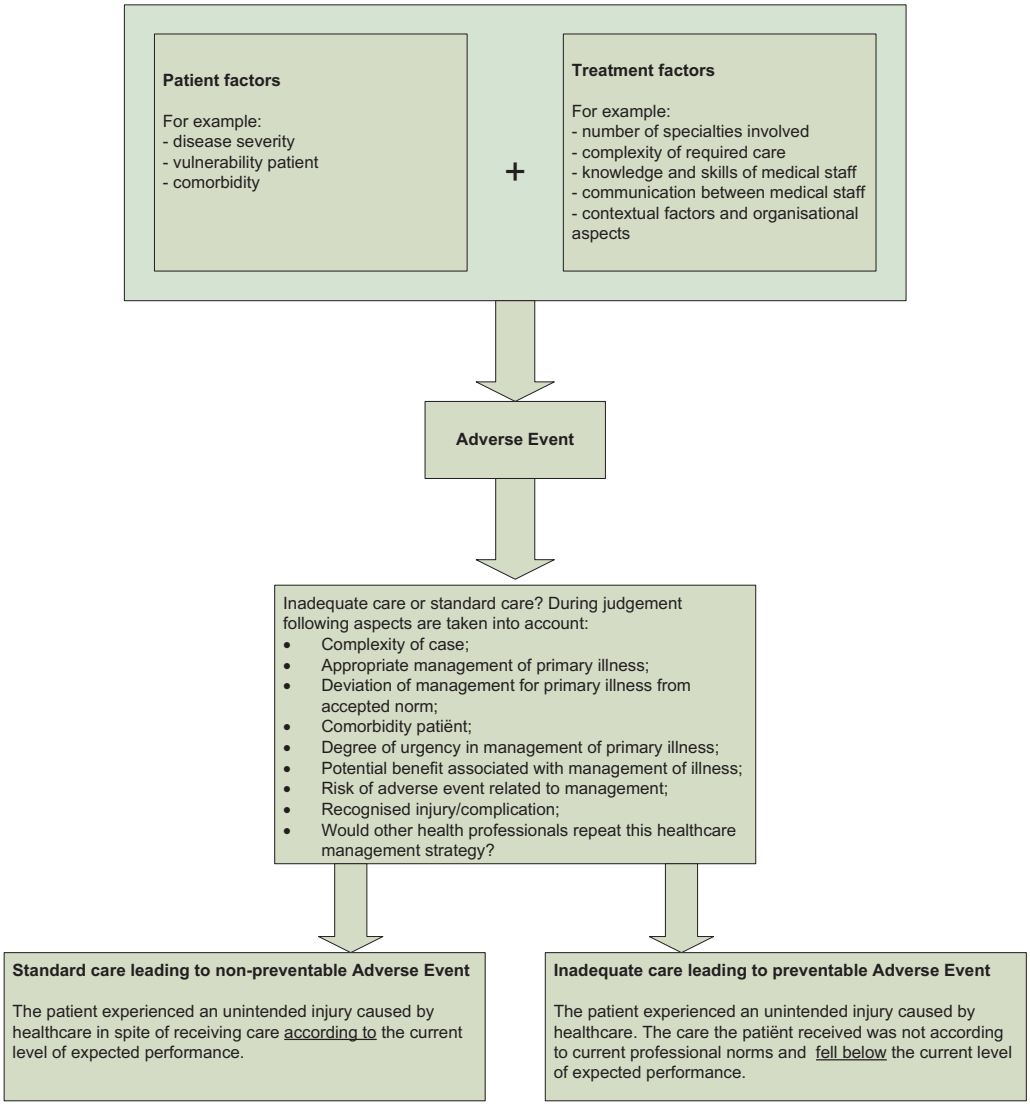

Figure 1: Patient and treatment factors leading to preventable and non-preventable adverse events

In this article we analyse preventable and non-preventable AEs to assess if inadequate care plays a role in AEs with patients treated by multiple specialties. Of course the difference between the two is often not black and white. However, it is important to seek out if the pathway, or part of it, leading to a preventable AE, in patients treated by multiple specialties, is different from the one leading to a non-preventable AE. We believe that the vulnerability of a patient, the complexity of a patient's illness or illnesses, and the complexity of the treatment at hand, are all factors, amongst others, that may contribute to either preventable as well as non-preventable AEs (figure 1). The main difference between both types of AEs however is that, in non-preventable AEs, the patient has received standard care and in spite of this suffered harm. In the origin of a preventable AE, however, inadequate care plays an important role, and at least in part, results in the patient suffering harm (figure 1). For example, if a patient has had a previously unknown allergic reaction to a medication then this patient has received optimal care and in spite of this experienced an unavoidable AE. However, if this patient had previously had an allergic reaction to this medication and this was also written down in the patient's record, then the AE is preventable. This patient has received, inadequate care as, despite the allergy being written down in the patient's record, the medication was given to the patient in question. When more caregivers are involved in the treatment during an admission, there may be a greater chance that information is missed.

When there are an increasing number of specialties involved in the treatment of a patient then we assess if the pathway of preventable AEs is different from non-preventable AEs. We achieve this in our analysis by correcting for factors representing the complexity of the patient and the complexity of the treatment. If the risk of preventable AEs and non-preventable AEs for different numbers of specialties treating a patient do not stay the same, this may indicate a difference in the risk of experiencing inadequate care.

If an AE was identified then a variety of questions were asked about it such as what are the clinical processes related to the AE. The medical reviewer could choose between the following processes: diagnostic, surgical, drug/fluid, medical procedure, other clinical management, discharge, and other. The doctors were also asked to select all the causes that contributed to the occurrence of the AE using the taxonomy of the Eindhoven Classification Model.[11] The model is based on the system approach to accident causation from reason and the skill-rules-knowledge based framework of Rasmussen.[12,13] The main categories of the model are: human (related to deficits in knowledge, skills or rules of conduct); organisational (related to procedures, information transfer, culture and organisational decisions and priorities); technical (related to design, construction, software or material); patient-related (patient characteristics outside the control of health care professionals, for example comorbidity, communicative skills or ethnicity); and other causes.

Statistical Analysis

The number of specialties involved in the treatment of a patient was grouped into '1 specialty', '2 specialties' or '3 or more specialties' for each patient in order to assess if patients with an increasing number of specialties also have an increasing risk of experiencing AEs.

Descriptive statistics on patient and admission characteristics by the number of specialties treating a patient were analysed using SPSS 20.0. After weighting for the sampling frame, the total study sample was representative of the total Dutch population of hospitalised patients. The sample weight was the inverse of the probability of being included in the sample owing to the sample design.

Furthermore, we assessed the association between the number of specialties involved in the treatment of a patient and the presence of preventable and non-preventable AEs through stepwise multilevel logistic regression analysis (MLwin 2.22). Multilevel analysis was used because the data had a hierarchical structure: patients (level 1) were clustered within hospital departments (level 2), and hospital departments were clustered within hospitals (level 3).[14] The 2nd order PQL estimation procedure was used. Variables were added to the model in order to correct for any possible patient and treatment factors influencing the association between the number of specialties involved in the treatment of a patient and the presence of preventable and non-preventable AEs. Model 1 was a naïve analysis with the number of specialties treating a patient as variable. Corrections were made for the stratified sampling method, with regard to deceased patients and the type of hospital. In model 2 corrections were made for the patient characteristics, gender, age and the ICD9 main diagnostic group. The categories that were less common, that is less than three per cent, in our sample were pooled in a rest group. This left us with nine major categories and one rest group. In model 3 we added the health care related characteristics that influence the type of care received in the hospital, such as the transfer to an intensive care unit during admission, surgery during admission, the length of admission and the urgency of admission. All the models were analysed for the outcome preventable AE as well as non-preventable AE, in order to assess the differences in the contribution of inadequate care between the numbers of specialties involved. After corrections we calculated intraclass correlation coefficients (ICCs), the ratio of the between group variance and the total variance. A higher ICC at the department level for instance means a smaller variance for preventable AE rates within the departments and a larger variance between departments.

We analysed the proportions of causes and clinical processes related to preventable AEs in order to assess further the underlying mechanisms.

We performed two sensitivity analyses. For the first sensitivity analysis, we added the Charlson comorbidity index (CI) to the model in model 2 to correct further for patient complexity. The CI is a comorbidity scoring system that includes weighting factors on the basis of the severity of a disease.[15] The CI could only be calculated for 18 out of the 20 hospitals.

The second sensitivity analysis was performed because intensive care was not always counted as a separate specialty, so that not all patients admitted to an intensive care unit had intensive care named as a separate specialty in their treatment. To account for the possibility that intensive care was not a new specialty for patients after they were transferred, we performed a second sensitivity analysis without counting intensive care as a separate specialty.

Interrater specific agreement statistics were calculated, that is the positive and negative agreement.[16] For the assessment of AEs the positive agreement was 63%, the negative agreement 87%. For assessment of the preventability of AEs, the positive agreement was 71% and negative agreement 76%.

RESULTS

In total 4,023 patient records were reviewed. Of these 27 patient records were excluded during analysis because they could not be linked to the hospital administration database and consequently had missing ICD9 main diagnostic group information. During the index admission 269 patients experienced a non-preventable AE, 191 a preventable AE. In total 2,117 patients were treated in only one specialty, 924 by two and 955 by three or more. After weighting for the stratified sample this amounts to 69% patients treated in one specialty, 19% in two and 12% in three or more. In this last group the maximum number of specialties treating a patient was 12 (one patient), but most patients in this group had three (487 patients), four (247 patients) or five (107 patients) specialties.

Patients treated by more than one specialty were older, were admitted for longer, were admitted more often urgently, underwent a surgical procedure less often, were admitted more often to an intensive care unit and were admitted more often to the departments internal medicine and neurology (table 1).

Stepwise multilevel logistic regression analyses showed that the number of specialties treating a patient is associated with the risk of experiencing either a non-preventable AE or preventable AE as is shown in table 2.

Table 1: Hospital and patient characteristics of the study samples for 1, 2 or 3 or more specialties

Hospital and patient characteristics †	One specialty	Two specialties	Three or more specialties	Total
Male sex %, n=2,051	49.3	50.5	52.5	49.9
Age in years, mean (SD)	57.7 (21.0)	64.3 (19.7)	66.6 (17.5)	60.0 (20.7)
Length of hospital stay in days, mean (SD/median)	4.6 (5.3/3.0)	8.3 (8.0/6.0)	16.2 (16.6/12.0)	6.7 (8.9/4.0)
Urgent admissions %, n= 2,727	46.3	69.2	76.5	54.1
Surgery during admission %, n=1,336	48.5	36.6	30.0	44.1
Admission to an intensive care unit %, n=640	3.8	14.4	23.4	8.0
Hospital departments, column %				
- Surgery, n=703	21.6	25.1	18.4	21.9
- Cardiology, n=421	12.4	11.9	6.5	11.6
- Internal medicine, n=863	13.7	20.2	24.5	16.2
- Orthopaedics, n=255	13.2	5.3	7.3	11.0
- Neurology, n=366	5.1	10.9	18.0	7.7
- Lung diseases, n=374	5.9	7.3	6.1	6.2
- Ear, nose and throat, n=91	5.1	0.8	0.4	3.7
- Urology, n=127	6.1	3.4	2.3	5.2
- Other, n=796	10.3	2.6	2.5	13.2
ICD-9 diagnostic groups, column %*				
- Neoplasm's, n=649	12.6	10.9	11.8	12.2
- Nervous system and sensory organs, n=105	3.7	1.9	2.5	3.3
- Circulatory system, n=1,051	17.9	27.6	27.7	20.8
- Respiratory system, n=453	8.7	9.1	8.0	8.7
- Digestive system, n=355	10.8	11.1	9.7	10.8
- Genitourinary system, n=187	6.9	5.2	3.8	6.3
- Musculoskeletal system and connective tissue, n=261	14.1	6.5	6.3	11.9
- Ill-defined conditions, n=242	6.2	5.9	7.6	6.3
- Injury and poisoning, n=320	8.7	11.1	12.5	9.5
- Other ‡, n=374	10.2	10.5	9.9	9.3

† Hospital and patient characteristics are weighted for overrepresentation of deceased patients and university hospitals. n: actual numbers of cases, not weighted.

‡ Other: includes smallest groups (3% and under): infectious and parasitic diseases; endocrine, nutritional, metabolic and immunity; blood and blood forming; mental; complications birth; skin and subcutaneous disease; congenital abnormalities; V-codes. n= actual number, not weighted.

Table 2: Multilevel regression analysis for the association between patients with at least one non-preventable AE or preventable AE during an admission and the number specialties.

No. of specialties	No. of non-preventable AE	Model 1* OR (95% CI)	Model 2* OR (95% CI)	Model 3* OR (95% CI)
One specialty (reference group) (n=2,117)	77			
Two specialties (n=924)	52	1.54 (1.03 to 2.30)	1.51 (1.01 to 2.25)	1.19 (0.78 to 1.83)
Three or more specialties (n=955)	106	3.01 (2.09 to 4.34)	2.90 (2.01 to 4.18)	1.46 (0.95 to 2.26)
	No. of preventable AE	**Model 1* OR (95% CI)**	**Model 2* OR (95% CI)**	**Model 3* OR (95% CI)**
One specialty (reference group) (n=2,117)	51			
Two specialties (n=924)	55	2.15 (1.36 to 3.39)	2.21 (1.40 to 3.48)	2.15 (1.35 to 3.43)
Three or more specialties (n=955)	77	2.78 (1.77 to 4.37)	2.88 (1.83 to 4.54)	2.31 (1.40 to 3.81)

* Model 1: naïve model, corrections for sampling strategy (overrepresentation deceased patients and university hospitals); model 2: model 1 + corrections for age, sex and ICD9 main diagnostic groups; model 3: model 2 + corrections for admission characteristics: admission to intensive care, length of stay, urgency of admission and surgery during admission. n= actual number, not weighted.

Patients treated by three or more specialties during admission had an odds ratio (OR) of 3.01 (95% CI 2.09 to 4.34) for experiencing a non preventable AE and an OR of 2.78 (95% CI 1.77 to 4.37) for a preventable AE. After corrections for patient characteristics (model 2) ORs for non-preventable AEs, as well as preventable AEs, barely changed. Finally, after adding corrections for the characteristics of the treatment (model 3) the association between treatment by three or more specialties and non-preventable AEs decreased to an OR of 1.46 (95% CI 0.95 to 2.26) and for preventable AEs the OR decreased to 2.31 (95% CI 1.40 to 3.81). The same pattern, though less pronounced, was found for patients treated by two specialties during their hospital admission.

After corrections the ICC estimates for preventable AEs at the hospital level were 1.97 and at the department level 11.2, indicating more variation at the department level than at hospital level.

Examples are given in box 1 to illustrate in what way treatment by multiple specialties could have an influence upon the origin of preventable AEs.

Box 1: case descriptions of AEs

Case description

Admission recent myocardial infarction, heart failure, fever and suspected pneumonia in delirium patient with chronic renal insufficiency. Four specialties were involved during this admission (cardiology, geriatrics, internal medicine (main specialty), neurology). Confusion in nursing staff because different specialties (geriatrics and general internal medicine) did not discuss treatment policies and both communicated conflicting medications to the nursing staff, resulting in extra intervention and treatment for the patient. The reviewer scored the preventability as more than likely.

Admission with stomach ache and constipation. Four specialties were involved during this admission (general surgery (main specialty), gynaecology, intensivist, gastroenterology). CTscan showed ileus of the small intestine. Operation however followed ten days later resulting in unfavourable postoperative course. Communication with radiologist in an earlier stage could have led to a faster diagnosis. The reviewer scored the preventability as more than likely.

Admission for epileptic incident. Only one specialty was involved during this admission (neurology). Status epilepticus a month earlier, however after this previous admission no maintenance medication was given due to insufficient consultation internal medicine by neurologist. Adverse event was noticed during following admission. Reviewer scored the preventability as strong evidence of preventability.

Table 4: Distribution of causes related to preventable AEs by the number of specialties. Row percentages are given. For example the first row describes the distribution of causes related to all preventable AEs with one specialty treating a patient. Total percentages can add up to more than 100%, as reviewers could give more than one cause per AE.

Causes related to preventable AEs	Human †	Organisation †	Patient †	Technical †
Number of specialties (row %)				
One specialty, n=54	75.0	20.0	14.5	7.1
Two specialties, n=57	78.3	25.0	39.1	8.7
Three or more specialties, n=80	72.0	24.0	20.0	0
Total, n=191	75.0	21.4	20.4	5.8

† Percentages causes weighted for overrepresentation of deceased patients and university hospitals. n: actual numbers of causes, not weighted.
Reviewers could select more than one causal factor per AE.

We analysed clinical processes and causes related to preventable AEs in order to assess further the underlying mechanisms of preventable AEs (table 4 and 5). In total in 154 preventable AEs human causes were found, in 51 organisational causes, in 59 patient-related causes and in 14 technical causes. After weighting the results for the stratified sample, the causes amounted, correspondingly, to 75.0% human, 21.4% organisational, 20.4% patient-related and 5.8% technical (table 4). No large differences were found in the main causes for the number of specialties treating patients.

With regard to the clinical processes, more preventable AEs were related to diagnostic processes, in patients treated in multiple specialties - especially those treated in three or more - in comparison to those treated in just one. These figures were 32.0% as opposed to 14.3% (table 5). 73.2 % of the preventable AEs in patients treated in just one specialty were related to the surgical process that is the AEs occurred during surgery or within the postoperative period of 30 days. By contrast in patients with three or more specialties the figure was 44.0% (table 5).

A sensitivity analysis adding the Charlson index to correct further for patient complexity in 18 hospitals had no effect and showed practically the same ORs, at that level, for no-preventable AEs as well as preventable AEs.

Sensitivity analyses excluding intensive care as a separate specialty showed the same pattern in association between adverse events and treatment in multiple specialties, only with lower ORs. Patients treated by three or more specialties had an OR of 1.95 (95% CI 2.33 to 5.19) for preventable AEs, after corrections for patient and health care related characteristics (model 3).

Table 5: Distribution of clinical processes related to preventable AEs by the number of specialties. Row percentages are given. For example the first row describes the distribution of clinical processes related to all preventable AEs with one specialty treating a patient.

Clinical process related to Preventable Adverse Event n=206	Diagnostic †	Surgical †	Medication †	Other clinical management †	Other †*
Number of specialties (row %)					
One specialty, n=54	75.0	20.0	14.5	7.1	7.1
Two specialties, n=57	78.3	25.0	39.1	8.7	8.7
Three or more specialties, n=80	72.0	24.0	20.0	0	0
Total, n=191	75.0	21.4	20.4	5.8	5.8

† Clinical process is weighted for overrepresentation of deceased patients and university hospitals.
* Including non-surgical interventions
n= actual number, not weighted.

DISCUSSION

General findings

The number of specialties treating a patient is associated with a patient's risk of experiencing harm during a hospital admission. We found this variation for both preventable and non-preventable AEs. It was most pronounced in patients treated by three or more specialties. These variations were hardly explained by patient characteristics (age, sex, ICD9 major diagnostic group, Charlson index). They were explained in part by health care related characteristics (admission to intensive care, length of stay, urgency of admission and surgery during admission). This was more so for the non-preventable AEs than for the preventable ones. Thus after corrections for patient and health care characteristics the increased risk of harm for patients treated in multiple specialties stayed most visible in preventable AEs. This indicates a difference in that part of the pathway leading to preventable and non-preventable AEs since preventable AEs are related to inadequate care, whereas non-preventable AEs are related to limitations in today's health care.

Our results indicate that inadequate care increases with the number of specialties involved in treatment independent of the complexity of the patient and treatment. However our data cannot confirm this is a causal relationship. After examining the causes of preventable AEs further we could not find evidence of, for example, more organisational or human-related

causes in the different groups of numbers of specialties treating a patient. We did find more preventable AEs related to diagnostics in patients with three or more specialties, and more surgical AEs in patients with only one specialty.

Other research

We did not find any previous studies combining the risk of experiencing AEs and preventable AEs and the number of specialties treating a patient. Links can be made to other areas of research looking at either increasing complexity in hospitals, or focussing on communication errors.

Higashi and colleagues found that, contrary to their expectations, the quality of care increased when the number of chronic conditions suffered by a patient increased.[17] They measured the quality of care by determining the deliverance of the percentage of care included in the indicators of quality care. This contrasts with our results, although these indicators of quality care did not concern outcome measures. Furthermore Nardi and colleagues discuss that complexity is far more than the co-existence of more than one medically diagnosed diseases.[18] Patient complexity involves the intricate interrelation between two or more systems, as for example illness, therapy, cognition, family, and behaviour.[18] From this perspective, patients treated by multiple specialties defines a part of patient and care complexity, but of course not all.

Delivering professional care to a complex patient who needs multiple specialties simultaneously or in a sequence is associated with an increased risk of preventable AEs. Communication failures are often mentioned as a common, if not the leading, cause of patient harm.[19,20] Problems in care due to poor communication between doctors seems likely to contribute often to preventable AEs.[21,22] Research on this topic focuses primarily on the communication related to teamwork in one group or setting.[23] Improving interpersonal communication during consultation, multidisciplinary handovers or multidisciplinary meetings may help. Applying Crew Resource Management (CRM) principles in order to develop a greater situational awareness and recognition of human factors could be of use in these situations. Introducing checklists or briefings may support the use of CRM principles to improve multidisciplinary teamwork. Communication is often just through writing when more specialties are involved, as for instance when a specialty is asked for a consultation. Often questions remain that cannot be pursued easily due to insufficient structure and information.[24] Verbal reports, in combination with written reports, have been shown to be the most effective.[5] Hierarchical differences, conflicting roles and conflicts also need to be taken into account when looking at communication failures.[22]

Not only the communication between professionals, but also the communication between the patient and the different professionals may be associated with preventable AEs. Bartlett et al found in 2008 that patients experiencing preventable AEs were three times more likely to have communication problems themselves.[25] Unfortunately, we did not collect data on all

the patients' communication capabilities, but this factor could also have influenced our results.

Patient risks due to increased specialisation could be reduced by improving communication with both professionals and the patient and by improving handovers. On the other hand, the call for more generalists such as hospitalists or geriatricians may also be seen as a way to decrease the risks. Although we did not find a direct link to patient safety, the introduction of hospitalists have demonstrated improved clinical efficiency and even a reduction of re-admissions[26], shorter hospital stays and a lower risk of mortality.[27]

Strengths and limitations

The strengths of this study are that complete patient admissions have been reviewed by independent qualified nurses and doctors in a structured and detailed manner to ascertain AEs, preventable AEs and underlying processes. In this manner, consecutive events can be studied, taking all available information into account. To our knowledge this is the first study linking AEs and the number of specialties treating a patient. This method cannot find out all the causes of AEs, as reviewers are dependent on information written down in the patient records.[28] This method also has some limitations concerning the number of specialties treating a patient. We could not account for the total number of individual specialists a patient came into contact with due to changing shifts but only the number of different specialties. Secondly, only different medical specialties involving doctors are taken into account in this study, other care givers that come into contact with patients as for example nurses or physiotherapists are not taken into account. Also, even though we have information on the number of specialties treating a patient, we do not have information on the specific contribution they made to the treatment of the patient. It is thus unclear if the specialist was simply consulted by telephone by the senior specialist, or if this specialist had actually seen the patient for a consultation, or if this specialist also had fully participated in the treatment of the patient during the whole admission. Lastly, we do not have information on at what moment the specialties were involved during the admission. In theory, more specialties could become involved after an adverse event has happened. However, looking at the nature of the adverse events, we expect this is less likely than other reasons for involving further specialties as described in our model (fig 1).

In conclusion a greater number of specialties treating a patient is associated with an increased risk of experiencing preventable AEs, which are related to inadequate care. More research is needed to gain insight into the underlying causes and any suitable solutions. We hope this study increases awareness of the fact that patients treated by multiple specialties have a higher risk of experiencing preventable AEs. This awareness can encourage the use of prevention strategies to avoid extra harm to this patient group. These include changes to the organisational structure, improved communication methods and methods to heighten an awareness of the situation.

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8 Association of admission and patient characteristics with quality of discharge letters: posthoc analysis of a retrospective study

Published as:

Maaike Langelaan, Rebecca J Baines, Martine C de Bruijne, Cordula Wagner. Association od admission and patient characteristics with quality of discharge letters: posthoc analysis of a retrospective study. BMC Health Services Research. 2017 Mar 21;17(1):225

ABSTRACT

Background

A complete, correct and timely discharge letter can communicate important information from the hospital to the general practitioner. The adequacy of the letter may vary with the patient and admission characteristics of the patient. Insight in the association between these characteristics and the presence and quality of the discharge letter will give rise to improvement activities for a better continuity of care after discharge.

The objective was to determine the presence, correctness and timeliness of admission information in discharge letters and to determine the association between patient and admission characteristics, including unplanned readmissions and the quality of the discharge letter.

Methods

A Post-hoc analysis of a two-staged retrospective patient record review study was performed in 4,048 patient records in a random sample of 20 hospitals.

Results

Nearly ten percent of the discharge letters are lacking in patient records in Dutch hospitals. In 59.1% of the discharge letters, one or more relevant components are missing. Important laboratory results, relevant information about consultations, answers to the questions of the referrer, changes in medication and follow up are often lacking. Discharge letters are more likely to be missing in elective patient admissions to a hospital, with a shorter length of stay, less comorbidity, and in readmissions. There was a significant variation in missing discharge letters between hospitals and between hospital departments.

Conclusions

The quality of discharge letters varies with patient and admission characteristics.

BACKGROUND

Transitions from inpatient to outpatient care are considered a high risk process in patient safety terms. A discharge letter is intended to summarise events during hospitalisation, and prepare the outpatient physician or other referrer to resume care of the patient. A complete, correct and timely discharge letter can communicate important information back to the general practitioner or other involved outpatient health care workers, prevent adverse events and reduce readmissions to the hospital.[1,2] Adverse events frequently occur in handover moments of care and could have been avoided in most cases. These adverse events might lead to readmissions and to extra costs.[3] A standardized discharge may decrease the number of postdischarge adverse events and rehospitalizations.[4,1] Several studies found that discharge summaries often are not available or lack important information needed to help the general practitioner understand what should be done to avoid postdischarge adverse events. The review of Kripalani et al. showed that approximately 11% of the discharge letters and 25% of the discharge summaries never were received by the primary care physician.[5] Zegers et al. found that the discharge letter was unavailable in 13% of the reviewed patient records and more AEs were found in patient records with poor quality of the discharge letter.[6]

All admissions may not be equally at risk for the absence or poor quality of the discharge letter. However, in-depth insight into specific types of admissions at risk is limited. Weiskopf et al. found that completeness of patient records varied with the underlying health status of the patient as sicker patients tend to have more complete records.[7] Research conducted on the association between admission characteristics and the presence and quality of the discharge letter will give rise to improvement activities for a better continuity of care from hospital to home. However, to our knowledge, no such research has ever been conducted.

The aim of this study was to assess the presence, correctness and timeliness of discharge letters in hospital records. Another aim was to determine the association between patient and admission characteristics, including unplanned readmissions, and the presence of the adverse events.

METHODS

Design

The study design was a posthoc analysis of a retrospective patient record review study performed in a random sample of 20 Dutch hospitals: 4 university, 8 tertiary teaching and 8 general hospitals. From each hospital, a random selection of 100 admissions of discharged patients and 100 admissions of in-hospital deaths was made. Oversampling of deceased patients and patients admitted to a university hospital took place in order to gain sufficient data on these relatively small patient groups. During analysis, the results were corrected for this oversampling to make these representable for the total hospital population. Records from patients admitted to the psychiatry or obstetrics departments were excluded, as well as records from children aged less than one year. The study period was between April 1st, 2011 and March 31st, 2012. The design and methods of this study are described in more detail elsewhere.[8,9]

Record review

The nursing and medical records of the admissions were reviewed by a team of 26 trained nurses and 10 trained physicians in a two-staged structured record review process. The reviewers never reviewed in hospitals where they had ever been employed. In the first stage, a nurse screened the patient records by using 16 screening criteria indicating potential adverse events, including unplanned readmissions. In this stage of the record review, the nurse assessed whether the discharge letter was present in the patient record and the date of sending. In the second stage, one physician reviewed the patient records with one or more positive screening criteria assessed at the first stage. Based on a standardized procedure the physician determined the presence of adverse events and their preventability. An adverse event was defined as an unintended injury among hospitalized patients that results in disability, death or prolonged hospital stay, and was caused by health care management. [8] In the records with at least one positive screening criterion for an adverse event the physicians judged also the correctness of applicable components of the discharge letter if available. Physicians were considered as the experts in judging the contents of the discharge letter. Therefore, the judgement of the correctness of the discharge letter took place at stage 2. In total 4,048 patient records were screened by nurses and assessed for the presence and timeliness of the discharge letter, and 2,632 patient records were reviewed by physicians and judged for the correctness of the applicable components of the letter.

Data were abstracted regarding the presence and correctness of the following components of the discharge letter: name of the patient, date of birth of the patient, date of admission, date of discharge, patient history, most important outcomes of tests, most important laboratory results, information about consultations and the conclusions, conclusions / diagnosis, answers to the questions of the general practitioner / referrer, treatment and

prognosis, complications, treatment after discharge, changes in medication, follow up and appointments, and name and function of the discharging physician.

As official guidelines on components of discharge letters were not available and implemented in the Netherlands, the list of components was based on existing literature and one official guideline on information exchange between physicians and family practitioners [10,11], expert opinions and unofficial guidelines for example from individual hospitals. Physicians also collected data about the timeliness of the discharge letter. Data about the admission characteristics (length of stay, admission department, urgency) were collected from the patient records and from the hospital administrative system.

Statistical analysis

Descriptive statistics about the presence and components of the discharge letter were analysed using Stata 13.0.[12] The relation between the presence and quality of the discharge letter and admission and patient characteristics was analysed with logistic multilevel regression analysis. Multilevel analysis was used because the data had a hierarchical structure: patients (level 1) were clustered within hospital departments (level 2) and hospital departments were clustered within hospitals (level 3).[13] The 2nd order PQL estimation procedure was used.

The presence of the discharge letter and the presence of discharge letter components were set as dichotomous (no/yes) outcome variables. For each component, separate regression analyses were run. The independent admission and patient characteristics were age, discharge status (deceased or discharged), admission urgency (elective/urgent), unplanned readmission (no/yes), one or more positive screening criteria for adverse events (no/yes), adverse event during admission (no/yes), preventable adverse event during admission (no/yes), and hospital type (university/tertiary teaching/general).

The variances of the model were tested for statistical significance using a one-sided Wald test.

ICCs were calculated for the hospitals and departments. The ICC indicates the relative influence of that level on the total variance of the outcome in a year. A high ICC at the hospital level means that there is less heterogeneity within hospitals and a high variation in the presence of the discharge letter between hospitals.[13] The variance at the patient level, the lowest level, is approximated by $\frac{\pi^2}{3}$ to calculate the total variance.[13]

The multilevel analyses were carried out using MLwiN 2.30 and the application “runmlwin” in Stata 13.0.[14,15]

Ethics

The study has been granted ethical approval by the Vrije Universiteit (VU) University Medical Center in Amsterdam, The Netherlands.

Table 1: Hospital and patient characteristics of the study sample.

Hospital characteristics*	
Inpatient admissions (n)	4,048
Hospital deaths n (%)	2,025 (50.0)
Type of hospital n(%)	
- University hospital	799 (19.7)
- Tertiary teaching	1,642 (40.6)
- General	1,607 (39.7)
Patient characteristics*†	
Male sex %	50.2
Age (y), mean (SD)	60.5 (20.9)
Charlson index of comorbidity %	3.7
Score >=3	
Admission characteristics*†	
- Length of hospital stay (d), mean (SD/median)	6.3 (14.6/3)
- Urgently admitted patients %	54.7
- Admission is a readmission	26.7
- Admission is followed by an unplanned readmission	17.7
Hospital departments,	
- Surgery	21.7
- Cardiology	13.7
- Internal medicine	18.7
- Orthopaedics	11.2
- Neurology	6.8
- Lung diseases	6.9
- Ear, nose and throat	3.6
- Urology	4.9
- Other	12.6
Presence of adverse events*†	
- One or more positive screening criteria in record n(%)	2,632 (44.7)
- Adverse events n (%)	390 (7.1)
- Preventable adverse events n (%)	108 (1.6)

* Patient admissions of obstetrics, psychiatry, <1 year and <24 hours for non-deceased patients were excluded.

† Patient characteristics are weighted for overrepresentation of deceased patients and hospital type.

RESULTS

A total of 4,048 patient records were reviewed in 20 hospitals (table 1). These were assessed for the presence of the discharge letter. The reviewers found that the discharge letter was not present in 500 (9.6%) of all patient records.

Table 2 shows that discharge letters are more likely missing in patients electively admitted to a hospital, with a shorter length of stay, and in readmissions. Discharge letters of patients admitted to the neurology departments were more often missing than discharge letters of the cardiology departments. Patient records that were positive for one or more screening criteria had a lower odds for missing the discharge letter than records with all screening criteria negative. Although the association was not significant, the discharge letter was more often present in records with an adverse event (p=0.07) and preventable adverse event (p=0.36).

After correction for covariates the intercept variation for the hospital level and the department level was statistically significant ($p<0.05$). This implies a significant variation in missing discharge letters between hospitals and between hospital departments. The clustering of missing discharge letters in departments (ICC 9.4%) was about one and a half times higher than in hospitals (ICC 6.7%).

In 2,632 patient records at least one positive screening criterion for containing an AE was found. These records were judged on the correctness of different components of the discharge letter. In 59.1% of the discharge letters reviewed by the physician, one or more applicable components were missing. Table 3 shows the absences and quality of discharge letter components. Important laboratory results, relevant information about consultations, answers to the questions of the referrer, changes in medication and follow up are often lacking.

Table 2: Univariate multilevel analyses for the association between missing discharge letters and patient and admission characteristics adjusted for clustering at the hospital level and hospital department level

	OR for missing discharge letter (95% CI)	
Type of hospital		
- University	1.16	(0.57 – 2.35)
- Tertiary teaching	1.21	(0.67 – 2.17)
- General	RC	
Admission department		
- Cardiology	RC	
- Surgery	0.96	(0.59 – 1.58)
- Internal medicine	1.00	(0.64 – 1.58)
- Ear, nose, throat	1.67	(0.82 – 3.40)
- Lung diseases	0.78	(0.45 – 1.35)
- Neurology	0.31	(0.15 – 0.62)**
- Orthopaedics	1.18	(0.66 – 2.10)
- Urology	0.72	(0.34 – 1.54)
- Other	0.52	(0.31 – 0.85)**
Age cat		
- 1-18 years	1.02	(0.55 – 1.88)
- 19-40 years	1.32	(0.85 – 2.03)
- 41-65 years	1.05	(0.79 – 1.39)
- 66-79 years	1.19	(0.91 – 1.55)
- >80 years	RC	
Urgently admitted patients	0.70	(0.56 – 0.87)**
Patients deceased during admission	0.81	(0.66 – 1.00)
Admission is a readmission	1.30	(1.05 – 1.60)*
Admission is followed by an unplanned readmission	0.89	(0.61 – 1.30)
Admission to a non-surgical unit	0.81	(0.60 – 1.09)
Length of hospital stay	0.99	(0.98 – 1.00)*
Charlson index of comorbidity Score >=3	1.35	(0.94 – 1.94)
One or more positive screening criteria	0.67	(0.54 – 0.83)**
Adverse event	0.70	(0.48 – 1.02)
Potential preventable adverse event	0.73	(0.37 – 1.44)

* $p<0.05$

** $p<0.01$

† Other: infectious and parasitic diseases; endocrine, nutritional, metabolic and immunity; blood and blood forming; mental; complications in birth; skin and subcutaneous diseases; congenital abnormalities; V-codes

Table 3: Absence and inadequacy of applicable discharge letter components

Discharge letter components	Absence of applicable components (N=2632) (%)	Component present but inadequate (% of present components)
Name, address and function of receiver	1.4	-
Name and function of receivers of a copy of the letter	34.2	-
Name and date of birth of the patient	0.7	0.4
Address of the patient	0.9	-
Date of admission	1.5	-
Date of discharge or death	2.0	-
Patient history	7.1	3.8
Most important outcomes of tests	6.5	2.8
Most important laboratory results	31.6	1.6
Information about consultations and the conclusions	21.1	4.3
Conclusions / Diagnosis	2.2	3.5
Answers to the questions of the general practitioner / referrer	11.7	0.5
Treatment and prognosis	3.1	3.0
Complications	9.7	3.1
Treatment after discharge	7.1	0.7
Changes in medication	15.2	0.9
Follow up and appointments	10.8	-
Name and function of discharging physician	0.3	-

- Not applicable

The median of the duration of sending the discharge letter after discharge was 7 days (IQ range 1 day – 21 days). 13.6% of all letters did not seem to reach the general practitioner within 31 days after discharge.

In 373 admissions, the admission was followed by an unplanned readmission of which 153 (41.1%) readmissions were within 30 days after discharge. 35 (22,9%) of these patients were readmitted within 3 days after discharge. In 107 of 153 (69.7%) of the unplanned readmissions within 30 days, the discharge letter of the index admission was missing or incomplete at the time of reviewing and consequently at the time of readmission. In patients who were not readmitted to the hospital 45.5% of the letters were missing or incomplete.

DISCUSSION

Our study shows that 9.6% of the discharge letters are lacking in patient records in Dutch hospitals. Discharge letters that are available are often lacking certain components. Just as found in other studies on the completeness of patient record data we found that some components of the discharge letter were more often complete than others.[16] Information on name, address and age of the patient is complete for 98% of the patients. Data on receivers of the letter, relevant laboratory results, consultations and changes in medication are currently only available in 65% to 85% of the patients. If the components are available, our data shows that the information is often correct. Besides the completeness and correctness of the discharge letter, it is of importance that the letter is sent within a reasonable time.

The study also gives an insight into groups with a higher risk of missing discharge letters. Especially patients who are electively admitted, with a shorter length of stay, or readmissions are vulnerable to missing discharge letters. On the other side, discharge letters are more often available in patients with less comorbidity. This is not in concordance with findings in other studies that showed that sick patients have more complete electronic patient records. [7] It also seems that patients who experience an undesirable incident, i.e. an adverse event or experienced one or more positive screenings criteria, are more likely to have a discharge letter sent to their referrer, mainly the general practitioner.

One of the reasons of the incompleteness, incorrectness and untimeliness of the discharge letters may be the lack of an adequate standard outlining the components that each discharge letter should contain and guidelines on the timeliness of sending the discharge letter. Another reason may be a lack of a structural implementation of writing discharge letters in the medical curriculum. An adapted masters education program and a fast electronic sending system of the discharge letter to the general practitioner may decrease the duration of sending the letter.[17]

The rate of missing discharge letters varied significantly between hospitals and between hospital departments. Moreover, the variance on the department level was almost one and a half times higher than the variance on hospital level. This implies that there is more room for improvement in the availability of discharge letters at the department level than at hospital level. The differences between hospitals and departments may be caused by differences in knowledge, dissemination or implementation of communication guidelines, such as the guideline of the Dutch College of General Practitioners or the standard of the Joint Commission on the Accreditation of Healthcare Organizations.[11,10] Implementation of these guidelines is expected to improve the communication between medical specialists and general practitioners. To monitor the implementation of the guideline and the quality of discharge letters audits and feedback of the letters may be successfully.[18]

Strengths and limitations

Several studies examined the presence and correctness of the whole patient record by determination of missing components and the inadequacy of the components.[6,19,7,16] Some of these studies linked this examination to patient characteristics.[7,16] However there are no studies in which the relation of missing discharge letters alone and its components is linked to patient characteristics.

One of the strengths of our study is that reviewing physicians were heavily depended on documentation stored in the patient record and in the hospital administrative system. Despite the fact that we did a thorough in-hospital search for missing discharge letters, some letters may have been missed. However, discharge letters that are not stored on a regular place may not be found by other health care workers which can be a potential risk for adverse events.

Our study has several limitations. First, the presence and the quality of the discharge letter components was only judged in the second stage of the review and therefore in records with at least one positive screening criteria for an AE. The results might be biased if the presence and quality of the components is different between records with and without positive screening criteria. A record with adverse events and preventable adverse events may be subjected to a lower quality of care and a lower quality of record keeping and discharge procedure. However, not all records with positive criteria had an adverse event or preventable adverse event; only 16% of these records contain an adverse event. Therefore a positive screening criterion is not directly associated with a lower quality of care.

Another limitation is that we only recorded the date of sending the discharge letter. From a patient safety perspective it is very informative if and when the discharge letter was received by de general practitioner as he plays an important role in preventing unplanned readmissions. Also, we do not have information on adverse events detected after discharge that might be related to incompleteness, incorrectness or untimeliness of the discharge letter.

CONCLUSION

In conclusion, nearly ten percent of the discharge letters are lacking in patient records in Dutch hospitals. Discharge letters that are available are often lacking certain components. In 70% of the unplanned readmissions, the discharge letter of the index admission was missing or incomplete at the time of readmission. Discharge letters are more likely to be missing in patients electively admitted to a hospital, with a shorter length of stay, with less comorbidity, and in readmissions. It also seems that if something undesirable happened during the admission, discharge letters are more frequent available. Interventions to improve the completeness of the discharge letters should be tailored for and carried out on department level. We hope this study increases awareness of the fact that a substantial group of patients may be at risk for an adverse event, e.g. a readmission as the discharge letter of their admissions are not available or missing information for a good continuity of care. Awareness of this problem can stimulate the writing of complete, correct and timely discharge letters.

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9 General discussion

This thesis aims to assess trends in adverse event and preventable adverse event rates in the Netherlands through the time period 2004 – 2012, and to assess patient safety in more detail for specific care processes and patient groups.

MAIN FINDINGS

Part I: Monitoring of adverse events and preventable adverse events 2004-2012

In total around 16,000 patient records were reviewed in three national adverse event studies using a thorough and systematic assessment of patient records, based on the Harvard Medical Practice Study and the Canadian Adverse Event Study. To assess if the level of patient safety in Dutch hospitals had changed over the years, we assessed the findings through multilevel regression analysis with corrections for clustered data and possible differences in patient mix. These results showed a relatively stable preventable AE rate in 2008 in comparison to 2004 and followed by a statistically non-significant decline of 30% (p=0.10) in preventable adverse events in 2011-2012 in comparison to 2008. This statistically non-significant reduction could primarily be attributed to a lower preventable AE rate in older patients and during the surgical process in 2011/2012 compared to earlier years. In all years the majority of preventable adverse events was related to the surgical process, however the relative contribution increased between 2004 and 2008 and decreased again between 2008 and 2012. Preventable adverse events related to the diagnostic process showed a similar trend. In contrast preventable adverse events related to medication were also common but stayed relatively stable through the years. As can be seen in the intraclass correlation coefficient (ICC) of preventable adverse events, differences between departments were comparable in 2008 and 2011/2012, but were larger than in 2004. This indicates that alongside the national campaigns, some departments may have improved patient safety while others were still lagging behind.

The interrater agreement stayed similar over the years. Part of the 2004 sample was re-reviewed by the same physicians six years later. The results of the intra-rater agreement showed random variation and no systematic shifts, indicating reviewers did not seem to have become stricter or more lenient over the years. Intra-rater agreement scores and kappa statistics were moderate, the intra-rater agreement of preventable adverse events was lowest of all scores.

Part II: Descriptive studies illustrating patients and processes at risk of experiencing (preventable) adverse events

Adding to the current body of evidence on processes or patient groups who are at risk of experiencing (preventable) adverse events, we further looked into a number of topics in relation to adverse events and preventable adverse events: patients who eventually died in

hospital, patients who experienced medication related adverse events, patients treated by multiple physician specialties, and the discharge letter.

Inpatient deaths: Patient and admission characteristics between inpatient deaths and patients discharged alive differed. Patients who died in hospital were on average older, admitted for longer periods of time and admitted more often urgently than patients who were discharged alive. Additionally patients who died in hospital were less often admitted to a surgical department.

Twice as many adverse events and preventable adverse events were found in inpatient deaths than in patients discharged alive. Most types of adverse events and preventable adverse events occurred in inpatient deaths as well as in patients discharged alive, however, were differently distributed. Preventable adverse events in inpatient deaths were for example less often related to the surgical process than in patients discharged alive. This was consistent with differences in admission characteristics, as in inpatient deaths there were fewer admissions to surgical departments.

Medication related adverse events: Our results showed that 15.2% of all adverse events found in 2008 and 2011/2012 were medication related and that only 18.4% of these adverse events were preventable. Although chemotherapy related adverse events were the most common, these were almost never judged preventable. Preventable medication related adverse events were most often found in relation to anticoagulant treatment, of which most were related to dosage or therapeutic factors.

Multiple specialties: The more specialties treating a patient, the higher the risk of experiencing an adverse event or preventable adverse event. This finding was most pronounced in patients treated by three or more specialties. After corrections for patient and health care characteristics the increased risk of harm for patients treated in multiple specialties stayed more visible in preventable adverse events than in non-preventable adverse events. Inadequate care seemed to increase with the number of specialties involved in treatment independent of the complexity of the patient and treatment, but the cross-sectional data cannot confirm a causal relationship.

Discharge letter: In 2011/2012 nearly 10% of all discharge letters were absent in the patient records. In more than half of the discharge letters that were present one or more relevant components were missing such as changes in medication, follow-up, answers to questions of the referrer and important laboratory results. Discharge letters were more likely to be missing in elective patient admissions, patients with a shorter length of stay, less comorbidity, and in readmissions. Results furthermore showed more differences between departments in missing discharge letters than there were between hospitals.

METHODOLOGICAL CONSIDERATIONS

Strengths and limitations of the studies in this thesis.

The most important strengths of the studies included in this thesis relate to:

- A large number of patient admissions, 16,000, were included in this study during three national adverse event studies. This is unprecedented in the field of patient safety, and provided us with the data for a good general sense of the burden of preventable harm caused to patients in hospitals over time.

- The method of systematic record review used, following the Harvard Medical Practice Study and the Canadian adverse event study, is a thorough, standardised assessment of patient admission in which physicians assess consecutive events and make a well-considered clinical judgement of adverse events and preventable adverse events, taking all available information into account. Systematic retrospective record review is still regarded as the method that best characterises the overall rate of harm.[1]

- Our study provides information whether judgement of reviewers changes over time. This is of special interest in the light of studies monitoring AEs and preventable AE rates over time. If patient safety improves or worsens over time, it is important to know if this is not caused for example by a more lenient of stricter assessment of AEs and their preventability by the reviewers. The results described in chapter 4 confirmed that this was not the case.

- The results of the studies have increased the sense of urgency to take countermeasures to guarantee the safety of patients in Dutch hospitals. Although this is more a practical strength than a methodological one, the used method and the specific outcome measures together have created this sense of urgency.

The most important general limitations of the studies in this thesis relate to:

- The Dutch adverse event studies showed moderate inter- and intra-rater agreement in kappa values and specific agreements, as is also common for the interrater agreement in other adverse event studies using this structured but relatively implicit review method. [2-7] This is the case for adverse events as well as preventable adverse events, of which the judgement of preventable adverse events seems to be the most difficult. To support the physician reviewers in their judgement of adverse events and preventable adverse events, preparatory questions preceded the causality and preventability score to guide the assessment, all reviewers were extensively trained, received a comprehensive guide and reflection meetings were often organised.

- Although the sample was large, it was not large enough to detect statistically significant decreases in corrected and standardised preventable AE rates over the years. Realistically a preventable adverse event rate of 0% will not be possible, it is thus the question what the lower limit of preventable adverse events is in any country or hospital. This complicates the challenge of reaching statistical significance even further and for our results may even mean that we have approached this lower limit. If attention for a specific topic is high and improvements are made in that specific area, this may coincide with decreasing attention for another area. In this light it may be more important for the future to get an overview of shifts in type of preventable adverse events, more than shifts in the incidence of preventable adverse events.

- It is likely that not all information on adverse events and preventable adverse events has been written down in the patient record, which may lead to information bias. As is the same for information concerning contributing factors as communication and handovers between health care professionals. Also, over the years the patient record has become more and more digital. Advances in electronic patient records on the one hand could make it easier to perform this kind of study because of heightened availability, accessibility and readability. On the other hand, our reviewers commented on the fact that the information written down in electronic patient records is less comprehensive.

- Hindsight bias is the influence of knowing the outcome of the care process of a patient, on the judgment of the preventability of adverse events, and is of influence in any retrospective patient record review study.[8] Especially the severity of the outcome is of influence, for example knowing that the patient has deceased as a result of an adverse event may increase the chance that the adverse events is assessed as preventable.[9] To help our reviewers minimise the effect of hindsight bias the judgement of preventability is preceded by a number of structured questions. This form of bias however can only truly be prevented if the reviewers are blinded for the outcome. This is not possible in this kind of large scaled adverse event studies.

Internal validity and generalisability

Systematic record review currently provides the best characterisation of the overall rate of harm.[1] A well-considered judgement is made by physicians in a method lying close to clinical practice. The method has high face validity with health care workers.[10]

In all three years, the samples were representative for the total Dutch hospital population after weighting, excluding obstetric admissions, children under 1 and admissions under 24 hours. All proportions were corrected for the oversampling of deceased patients and university hospitals. In our samples, 50% of the patients were inpatient deaths, and in reality this is about 3%. In the results, we weight our 50% back to the actual 3%. The same procedure was followed for the distribution of types of hospitals. This makes the results of the Dutch adverse event studies generalizable to the total Dutch hospital population.

The results of our studies may also be generalizable to other countries. The specific trends in adverse events and preventable adverse events are likely more specific for the Netherlands, however the study also provides information on monitoring preventable adverse events. This information can support other countries in choosing to perform a monitoring study and how to set up such a study. Moreover the results of the more focussed studies looking into patients who eventually died in hospital, patients who experienced medication related adverse events, and patients treated by multiple physician specialties are likely to have a general value.

REFLECTION

Monitoring of adverse events and preventable adverse events 2004-2012

The results we found in regard to the trends in preventable adverse events and adverse events in the Netherlands are encouraging, especially as improvement in specific subpopulations (elderly and surgery) coincided with attention hospitals have given to these topics. Particularly between 2008 and 2012 the surgical process received an increasing amount of attention through surgical checklists, pre, peri and post-surgical guidelines, and attention by the Dutch Health Care Inspectorate.[11-15] Although a causal relation cannot be based on our data, the positive signals in our results combined with the fact that a previous study assessing the effect of implementation of a surgical checklist on surgical complications and mortality found positive results, are promising.[16] Moreover during the safety campaign, care for the complex elderly was also one of the ten medical themes at which interventions were directed and in which subpopulation we found improvements in preventable adverse event rates.

However, as mentioned earlier, hard statistically significant evidence of an improvement in overall patient safety as measured by adverse events and preventable adverse events cannot be supported by our data, as random variation cannot be ruled out. It is further important to realise that not only the quality of health care could have influenced variations in adverse event and preventable adverse event rates, but other factors could also have (partly) sorted

their effect. Over the years the context in health care has changed: on average the length of stay has become shorter and the number of 1-day admissions has increased, while the number of clinical admissions has stayed relatively stable.[17]

Until now only a few other studies of multiple measurements of adverse events have been performed. The most often cited is of Landrigan et al. (2010), who used the Global Trigger Tool to assess temporal trends in rates of patient harm resulting from medical care in 10 hospitals in North Carolina.[18] Their results showed a similar pattern as our study did. They found a reduction in preventable harm that did not reach statistical significance (p=0.06), with no significant change in the overall rate of harms.[18] Wang et al. (2015) recently described national trends in patient safety between 2005 and 2011, for four common conditions, which had received extensive nationwide attention focussed on improving care processes and outcomes. They used a large database of information abstracted from medical records on 21 possible adverse events in patients hospitalised in the United States. Adverse event rates declined substantially among patients hospitalised for AMI or congestive heart failure, but not for pneumonia or conditions requiring surgery.[19] As this study was a database study, no in depth study of the clinical context or assessment of preventability of adverse events could be made.

Often single interventions with a relatively short measurement interval show promising results, where large studies struggle to reproduce the improvements on a large scale over longer periods of time. In a recent study for example, Starmer et al. (2015 NEJM) found changes in preventable adverse event rates using active surveillance after implementation of a handoff programme in nine paediatric hospitals in the US and Canada.[20] Though promising results, it would be interesting to see if such an intervention is sustainable over a longer period of time, when attention for other problems increases and priorities change.

The question rises if systematic record review is a suitable candidate for the monitoring of adverse events and preventable adverse events through time. The outcomes of our and other monitoring studies shows that monitoring adverse event rates through systematic record review also brings along some challenges. In the Dutch adverse event study, despite the considerable amount of in total nearly 16,000 reviewed patient records in three time periods, with already low rates of preventable adverse events the sample was not large enough to detect a statistically significant decrease in corrected and standardised preventable adverse event rates. Random variation therefore cannot be ruled out as the explanation for the non-significant reduction. Shojania & Mheen have mentioned this as a plausible explanation in the light of a Bayesian perspective.[21] However as afore mentioned, other considered methods have their own challenges and systematic record review still seems the best possible candidate. Moreover, it is also important to realise that the benefits of national adverse event

studies are not merely scientific. The results have also been an important tool for stressing the need for attention to patient safety and preventing harm to patients and herewith also have a more societal impact. Repeatedly making preventable adverse event rates public over the last 10-15 years has helped to repeatedly put patient safety on the agenda of hospitals in the Netherlands. The scientific as well as the societal impact should be considered when thinking of monitoring adverse events through time.

In a Health Foundation report on measurement and monitoring of safety, Vincent and colleagues describe that information from different dimensions is needed to get a full picture of organisational (conditions for) safety management and monitoring (figure 1).[22]

1. Past Harm: both psychological and physical measures
2. Reliability: measures of behaviour and systems
3. Sensitivity to operations: information and capacity to monitor safety on an hourly or daily basis
4. Anticipation and preparedness: ability to anticipate and be prepared for problems
5. Integration and learning: the ability to respond to and improve from safety information.

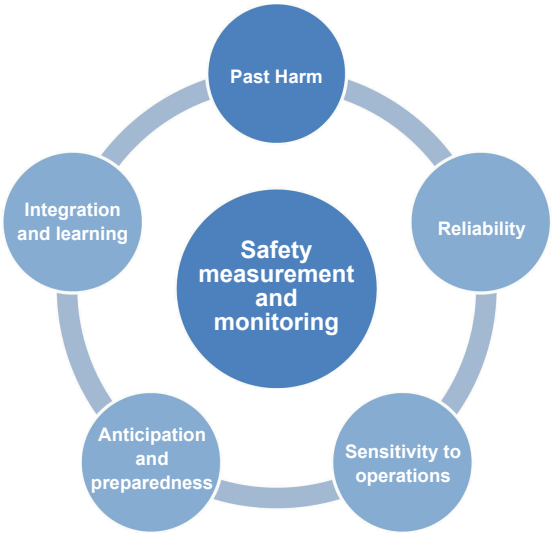

Figure 1: The five dimensions of patient safety measurement and monitoring

Our adverse event studies, by repeatedly reporting on past harm, provide important information on one of these dimensions. Safety I (what and why did it go wrong) as well as the more recent Safety II (what goes right) thinking can be placed within these dimensions. Organisations need outcomes of safety as well as information on preconditions for patient safety. Furthermore the aim of safety I and II is the same: safer healthcare for patients. The focus how to reach this primarily differs, as the focus of patient safety II lies on the resilience of an organisation and what goes right instead of what goes wrong. Outcomes of adverse event studies will stay important, for Safety I and II likewise, as results provide information on presence as well as absence of adverse events.

When choosing a type of measurement, one must take into account the goal, strategy and involved stakeholders. The goal of our study was a more policy driven one: to monitor hospital wide patient safety on a national level. This in light of a comprehensive safety programme in which all Dutch hospitals had to implement an accredited safety management system and additionally improve their clinical practice on ten medical themes known to contribute to harm to patients. If the goal had been obtaining information more specifically on causes of adverse events as to help hospitals in their search for ways to increase patient safety, then the chosen method could have been a different one. As Vincent and Amalberti discuss, adverse event studies provide a very general sense of the burden of "disease". If one for example would want to evaluate specific treatments, or the outcome of a specific intervention, often more specific measures are chosen.[23]

Descriptive studies illustrating patients and processes at risk of experiencing (preventable) adverse events

A large amount of effort has been put into gathering the data for the successive national adverse event studies. These data have also been used to further study patients and processes at risk of experiencing adverse events and preventable adverse events. What can be learned from these focussed secondary analyses?

Studying inpatient deaths with patient record review seems an efficient way to identify preventable AEs in comparison with patients discharged alive and may be a practical new direction for future adverse event studies, as for example the UK has done.[24] However, when only studying inpatient deaths, awareness of the fact that some problems remain under- or unexposed is important, and that on certain hospital wards, patients rarely die.

Delivering care to more complex patients, not surprisingly, often seems to be associated with a higher risk of experiencing preventable adverse events.[25,26] Patients in need of multiple specialties, simultaneously or in sequence, are a good example hereof. As even after corrections the effect remains most visible in preventable adverse events, it is likely that this is not only dependent on the patients complexity and suboptimal care also plays a role. Communication problems between professionals during handoffs, or between the patient and professionals could play a role.[27,28] Handover studies most commonly focus on the

sign out, and rarely evaluate the quality of handover practices.[28] Discharge of a patient from in hospital care is also considered as a high risk process in patient safety terms.[29] The discharge letter is one of the handover methods for the outpatient carer, but are not always sufficient, as important information or the entire discharge letter is often missing. The (preventable) adverse events resulting from this lack of information during transitions in care will not always be visible in the results of the in hospital adverse event studies, as these rely on the information in the patient record of the hospital. These adverse events will only be found in the case that the adverse event leads to a readmission to the same hospital, or through studying patient records of the GP after discharge of a patient.

Although the study was not set up for these specific research questions, it would have been a waste of data and resources not to look into secondary data analysis possibilities. If the specific research questions had been the main research questions, then systematic record review and the specific data collected for the studies may not have been the preferred method to facilitate the particular research questions in all cases. Especially for the studies of multiple specialties treating a patient and adverse events related to medication other or additional research methods could have provided additional meaningful information. Although the results that we have assessed may lack some desired information, information from patient records contain powerful and valuable data and we believe that our studies are a valuable intermediate step in acquiring information on what the next important questions on a topic are.

RECOMMENDATIONS

Recommendations for future research

- Adverse event studies play an important role in highlighting the need to maintain high levels of patient safety in hospitals. However, given the already low rates of preventable adverse events in our country and taking the limited resources into account, it may not seem advisable to perform a fourth generic measurement for patients discharged alive. Future large scaled adverse event studies should therefore be directed at on the one hand specific patient groups at high risk for experiencing preventable adverse events, such as patients undergoing surgery or inpatient deaths. In this case, it is important not to lose attention for patient safety on wards where there are only few hospital deaths, or non-surgical units. On the other hand future studies could optimise the data collection to further facilitate in depth analysis possibilities, besides the assessment of (preventable) adverse events.
- Retrospective patient record review of (preventable) adverse events is performed using a structured method. Inter- and intra- rater agreement scores in our studies, as is also

the case in other research, however remain moderate. Future research could be set up to study the possibilities of making the preventability of adverse events more explicit.

- The results of chapter 7 and 8 warrant further research into communication between caregivers, intramural as well as extramural.
- Patients treated by multiple specialties have an increasing risk of experiencing preventable adverse events, however the underlying causes and suitable solutions should be the subject of further research.
- Continuity of care between the hospital and the primary care setting does not seem to be guaranteed through the discharge letters of patients, putting them at risk for experiencing adverse events and readmissions. Further research is needed directed towards patient safety and transmural care.
- The results of chapter 6 shows that future research is needed to further examine the complex nature of MRAEs, especially focussing on suboptimal integrated care and anticoagulant treatment.

Recommendations for practice and policy

Monitoring of adverse events in the Netherlands shows that there are indications that patient safety is increasing in Dutch hospitals. Although the results cannot be causally linked to the large scaled quality and safety programmes in our country, these positive signals do encourage to continue improvement efforts. Moreover maintaining a high level of patient safety is and will remain a continuous challenge as scientific and technological progress, and older and sicker patients, make hospital care increasingly complex. High quality and safety of patient care should be and remain a self-evident top priority.

Systematic record review provides relevant information on problems and difficulties in the provision of hospital care. The nurses and physicians who performed the reviews for our adverse event studies often commented on the fact that it is also a useful quality measure for hospitals themselves. Currently nearly a quarter of all Dutch hospitals perform systematic record review as a part of their quality cycle, often focussing on hospital deaths. In hospitals not the number of adverse events is the most important outcome, but more the underlying problems leading to preventable adverse events and the focus on learning possibilities. Besides a focus on inpatient deaths, hospitals could also focus on other areas at high risk for experiencing preventable adverse events such as patients undergoing surgery, or even directed towards specific problems such as patients using specific medication types or vulnerable (elderly) patients.

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Summary

This thesis aims to assess trends in adverse event and preventable adverse event rates in hospitals in the Netherlands through the time period 2004 –2012. Furthermore patient safety for specific care processes and patient groups are assessed.

Patient safety has been high on the international agenda for several decades. This started with the publication of the 'Harvard Medical Practice Study' (HMPS) and the Institute of Medicine (IOM) report 'To err is human'. The HMPS was the first to publish rates of adverse events, assessed through retrospective patient record review. An adverse event is seen as an unintended injury that results in temporary or permanent disability, death or prolonged hospital stay, and is caused by healthcare management rather than the patients underlying disease process. Many countries have since then performed their own retrospective patient record review studies, providing a good sense of burden of (preventable) harm caused by health care. These results, amongst others, have increased the sense of urgency to improve patient safety in hospitals. In the Netherlands two large scaled programmes have taken place, the 'Better Faster' programme (2003-2008) in a selection of hospitals and 'Prevent Harm, Work Safely' (2008-2012) aimed at all Dutch hospitals.

Alongside these national programmes the level of patient safety in hospitals in the Netherlands has been monitored through performing three national adverse event studies assessing patient records from 2004, 2008 and 2011/2012. The large number of patient records reviewed, in total over 16,000 patient records, also enabled us to in depth study patients and processes at risk of experiencing adverse events and preventable adverse events.

Part I: Monitoring of adverse events and preventable adverse events 2004-2012

Chapters 2 and 3 describe the results of the three national adverse event studies. Chapter 2 of the 2008 study in relation to the 2004 study, chapter 3 of the 2011/2012 study in relation to 2004 and 2008. Overall in total 16,000 patient admissions were thoroughly assessed in order to estimate adverse event and preventable adverse event rates.

In 2008, in comparison to 2004, an increase in adverse event rates, that is non/preventable adverse events and preventable adverse events together, was found. This while the number of preventable adverse events stayed relatively stable. Efforts of the 'Better Faster' programme were not visible in our results, however only three of the hospitals participating in the 2008 study had participated in this programme.

More than 50% of all adverse events were related to the surgical process. The odds of experiencing an adverse event or preventable adverse event related to surgery were higher in 2008 than in 2004. Performing surgery on increasingly old and complex patients could be of influence, however this cannot be corroborated by the data presented in chapter 2 as there was no data on the ASA-status available in 2004. Receiving unplanned treatment did not lead to an increased risk of substandard care, as in both years urgently admitted patients had a

lower risk of experiencing adverse events and preventable adverse events. The results also showed that differences in risk of preventable adverse events between hospital departments were larger in 2008 than in 2004, indicating that some departments had improved, while others were lagging behind.

Results showed that in 2011/2012 30% less patients experienced preventable adverse events than in 2008, this however was a non-significant decrease (p=0.10). Fewer preventable adverse events were found in older age groups or related to the surgical process in comparison to 2008. Reduction of length of stay and therewith the chance of an adverse event being detected during admission, decreased equally in all age categories, thus is not likely to explain the decrease of preventable adverse events in older age groups. Besides chance, the (non-significant) variation in preventable adverse event rates could be the result of a change in quality of care between the two time periods. This study however cannot support a causal relationship. The fact that the decrease in preventable adverse events coincided with a shift in specific areas receiving attention during the intermediary years is encouraging. Another possible explanation is variation due to patient case mix, although we did correct for patient mix as good as possible in our statistical multilevel models.

Chapter 4 looked into the temporal stability of the physician reviewers' assessment of adverse events and preventable adverse events. It is important to investigate if possible shifts in adverse event rates are possibly affected by a more lenient or stricter assessment of adverse events and their preventability by the reviewers. A number of physicians, who reviewed patient admissions during the 2004 adverse event study, re-reviewed 2004 patient admissions during the 2011/2012 adverse event study. We did not find any systematic shifts in judgement over the years, indicating that our reviewers had not become stricter or more lenient over the years. Random variation was present. Especially the judgement of the preventability of an adverse event seemed to be a difficult assessment.

Part II: Descriptive studies illustrating patients and processes at risk of experiencing (preventable) adverse events.

In the second part of this thesis we have in depth studied patients and processes at risk of experiencing (preventable) adverse events.

Chapter 5 discusses if studying adverse events in hospital deaths is a good way to describe patient safety in hospitals. This is an interesting question in light of sampling patient admissions for national adverse event studies, as well as for hospitals using retrospective patient record review as a tool in their own quality and safety cycle. Adverse events and preventable adverse events occur twice as often in hospital deaths as in patients who are discharged alive. This

makes that exclusively sampling hospital deaths is an efficient manner to identify preventable adverse events and herewith as many improvement possibilities as possible. If doing so, one must be aware that some patient safety issues will be un-, under- or overexposed. On certain hospital wards patients rarely die, so these patient admissions will seldom be looked into in the case of reviewing only hospital deaths. Patients who died in hospital were less often admitted to a surgical unit. Consistent with this finding, preventable adverse events in inpatient deaths were less often related to the surgical process than in patients who were discharged alive. No specific type of preventable adverse event present in patients discharged alive was absent in our sample of inpatient deaths. When using the results to prioritise patient safety improvement possibilities, the variations in distribution should be taken into account.

Chapter 6 further in depth describes characteristics of (preventable) medication-related adverse events during hospitalisation. Of all adverse events 15.2% was medication related and 18.4% of these were deemed preventable. The majority of medication related adverse events were related to cancer chemotherapy, anticoagulant treatment and antibiotics. Medication related adverse events related to chemotherapy were seldom considered preventable. In adverse events related to anticoagulant treatment and insulin/oral diabetic treatment preventability was high. The preventable adverse events related to anticoagulant treatment were most often due to dosage factors. Preventable adverse events related to insulin/oral diabetic treatment were not further analysed due to small numbers.

In **Chapter 7** the risk of experiencing adverse events and preventable adverse events in patients treated by multiple specialties is discussed. Involvement of more specialties treating a patient aims to improve care as more and complementary knowledge and experience is present. The results of this study showed that the number of specialties treating a patient is also associated with a patient's risk of experiencing adverse events and preventable adverse events during hospitalisation. This association was hardly explained by patient characteristics (age, sex, ICD9 diagnostic group, Charlson comorbidity index) and in part explained by health care related characteristics (admission to intensive care, length of stay, urgency of admission and surgery during admission). However after corrections for patient and health care characteristics, the increased risk of harm in patients treated by multiple specialties stayed most visible in preventable adverse events and to a lesser extent in non-preventable adverse events. This suggests that inadequate care increases with the number of specialties treating a patient, independent of the complexity of the patient or treatment at hand. The data used however cannot confirm this is a causal relationship.

Chapter 8 describes that in nearly 10% of all patient admissions the discharge letters are lacking in patient records, putting the continuity of care at risk. The discharge letters that are available are often incomplete. The relevant laboratory results, consultations and changes

in medication were only present in 65% to 85% of the letters. Especially electively admitted patients, patients with a shorter length of stay, or patients who were readmitted were at risk. If a patient admission had been scored positive for screening criteria for an adverse event, it was more likely that a discharge letter was present. Missing discharge letters varied between hospitals and even more so for hospital departments, indicating that interventions for improving discharge letters should be directed towards hospital departments.

GENERAL DISCUSSION

The results regarding the monitoring of adverse events and preventable adverse events between 2004 and 2012 in the Netherlands are encouraging, especially as improvements in specific subpopulations coincided with attention hospitals had given to these topics. Other factors could also have been of influence on the results. Over the years the context of hospital care has also changed, as for example length of stay in hospitals has become shorter, admitted patients have on average become older and the number of day-admissions increased while the number of clinical admissions stayed relatively stable. Also over the years the patient record became more and more electronic.

The outcomes of our study and other studies monitoring adverse events show that monitoring adverse event rates can be challenging. Despite a large sample of in total 16,000 patient records measured over three time periods (8,000, 4,000 and 4,000 respectively), the sample did not detect a statistically significant decrease in corrected and standardised preventable adverse event rates. This means that random variation, i.e. chance, could also be an explanation for the visible reduction. Taking this and methodological considerations into account such as moderate inter- and intra-rater agreement and dependence on information written down in the patient record, the question arises if this method is the most suitable method to monitor adverse events through time. Other available methods however also have downsides. Systematic retrospective record review currently is still the most suitable method to count the number of adverse events and preventable adverse events and herewith the best candidate to assess possible effects of a safety program. The large number of patient records researched in our national adverse event studies also let us in depth study a number of processes and patient groups at risk for adverse events. Moreover it is also important to realise that the benefits of the Dutch national adverse event studies have not merely been scientific. Making adverse event and preventable adverse event rates public over the last decade has been an important tool in stressing the importance of attention for patient safety in Dutch hospitals. All aspects should be taken into consideration when considering whether to repeat this type of research.

RECOMMENDATIONS

Recommendations for future research:

- Future national adverse event monitoring studies: sample specific patient groups at high risk of experiencing preventable adverse events, such as surgical patients, or patients that have deceased in hospital.
- Methods to improve inter- and intra-rater reliability of the judgement of adverse events and the preventability of adverse events.
- Causes and suitable solutions for the high risk of experiencing adverse events in patients treated by multiple specialties.
- Patient safety and transmural care.
- Underlying causes for preventable medication related adverse event, especially for anticoagulant treatment.

Recommendations for practice and policy:

- Perform retrospective patient record review as a part of the quality and safety cycle of the hospital
- Direct retrospective patient record review towards areas at high risk of experiencing preventable adverse events such as patients undergoing surgery, inpatient deaths, vulnerable (elderly) patients or patients using specific types of medication.

Samenvatting

In dit proefschrift worden trends in zorggerelateerde schade en vermijdbare zorggerelateerde schade in Nederlandse ziekenhuizen gedurende de jaren 2004, 2008 en 2011/2012 beschreven. Daarnaast wordt ingegaan op patiëntveiligheid voor specifieke zorgprocessen en patiëntengroepen.

Patiëntveiligheid staat sinds tientallen jaren hoog op de internationale agenda. Startpunt was de publicatie van de 'Harvard Medical Practice Study' (HMPS) en het rapport 'To Err is Human' van de Institute of Medicine (IOM). De HMPS was de eerste studie die incidenties publiceerde van patiënten met zorggerelateerde schade. Dit onderzochten zij door retrospectief in de dossiers van de patiënten te kijken. Zorggerelateerde schade wordt gezien als onbedoelde schade aan een patiënt die resulteert in tijdelijke of permanente schade, overlijden of verlengd verblijf in het ziekenhuis, en wordt veroorzaakt door een gezondheidszorg professional of –organisatie. Vele landen hebben sindsdien hun eigen retrospectief dossieronderzoek verricht naar (vermijdbare) zorggerelateerde schade, waarmee een goede indruk wordt verkregen van het vóórkomen van (vermijdbare) zorggerelateerde schade tijdens een ziekenhuisopname. Deze onderzoeken hebben geleid tot een urgentiebesef om patiëntveiligheid in ziekenhuizen te verbeteren. Mede als gevolg hiervan zijn in Nederland twee grootschalige verbeterprogramma's geweest: 'Sneller Beter' (2003-2008) in een deel van de Nederlandse ziekenhuizen, en 'Voorkom schade, werk veilig' (2008-2012) gericht op alle Nederlandse ziekenhuizen.

In Nederland is de patiëntveiligheid in de ziekenhuizen gemonitord door middel van drie landelijke studies naar zorggerelateerde schade. Ziekenhuisopnames uit 2004, 2008 en 2011/2012 zijn hierbij bestudeerd.

Deel 1: monitoren van zorggerelateerde schade en vermijdbare zorggerelateerde schade 2004-2012

Hoofdstuk 2 en 3 beschrijven de resultaten van de drie landelijke studies naar (vermijdbare) zorggerelateerde schade in de Nederlandse ziekenhuizen. Hoofdstuk 2 gaat in op de meting van ziekenhuisopnames uit 2008 in vergelijking met 2004, hoofdstuk 3 over de 2011/2012 meting in vergelijking met 2004 en 2008. In totaal zijn 16.000 opnames beoordeeld met als doel een schatting te maken van de (vermijdbare) zorggerelateerde schade door de jaren heen.

In 2008 is, in vergelijking met 2004, een toename van de totale zorggerelateerde schade (zowel niet vermijdbare als vermijdbare zorggerelateerde schade) gevonden. Hierbij bleef de vermijdbare zorggerelateerde schade relatief stabiel. Resultaten van de inspanningen van het verbeterprogramma Sneller Beter waren niet terug te zien in onze resultaten, echter slechts drie van de 20 ziekenhuizen die aan de 2008 meting deelnamen participeerden ook aan het verbeterprogramma.

Meer dan 50% van alle zorggerelateerde schade is gerelateerd aan het chirurgisch proces.

De kans om als patiënt tijdens een ziekenhuis opname (vermijdbare) zorggerelateerde schade met betrekking tot het chirurgisch proces mee te maken was hoger in 2008 dan in 2004. Operaties uitvoeren op toenemend oude en complexe patiënten zou hierop van invloed kunnen zijn. Dit kan echter niet bevestigd worden door de data gepresenteerd in hoofdstuk 2, aangezien in de 2004 studie geen gegevens beschikbaar waren over de ASA-status van de chirurgische patiënten.

Niet-electieve zorg levert geen hoger risico op vermijdbare zorggerelateerde schade, aangezien zowel in 2004 als 2008 met spoed opgenomen patiënten een lager risico hadden op het meemaken van (vermijdbare) zorggerelateerde schade. Daarnaast lieten de resultaten zien dat verschillen in risico op vermijdbare zorggerelateerde schade tussen ziekenhuis afdelingen groter waren in 2008 dan in 2004. Dit wijst erop dat in 2008 sommige ziekenhuisafdelingen al een verbeterslag hadden gemaakt, terwijl andere ziekenhuisafdelingen achterbleven.

In 2011/2012 maakten 30% minder patiënten zorggerelateerde schade mee dan in 2008, dit was echter een niet statistisch significant verschil (p=0.10). Bij oudere patiënten of gerelateerd aan het chirurgisch proces werd minder vermijdbare zorggerelateerde schade gevonden in 2011/2012 in vergelijking met 2008. Een afname van de opnameduur en hiermee tijd om vermijdbare zorggerelateerde schade mee te maken, nam gelijk af in alle leeftijdsgroepen. Hiermee verklaart deze afname van de opnameduur waarschijnlijk niet de afname van vermijdbare zorggerelateerde schade in de oudere patiënt. De (niet significante) variatie in vermijdbare zorggerelateerde schade zou het resultaat kunnen zijn van een verschil in kwaliteit van zorg tussen de twee verschillende jaren. Dit onderzoek kan echter een oorzakelijk verband hiertussen niet bevestigen. Het gegeven dat de daling in vermijdbare zorggerelateerde schade samen gaat met een verschuiving in specifieke gebieden die aandacht kregen gedurende de tussenliggende jaren is echter bemoedigend. Een andere mogelijke verklaring is variatie ten gevolge van verschillen in de case-mix, hiervoor is echter zo goed als mogelijk gecorrigeerd in de statistische multilevel modellen.

Hoofdstuk 4 gaat in op de stabiliteit van de arts-beoordeling van zorggerelateerde en vermijdbare zorggerelateerde schade door de tijd heen. Het is belangrijk om na te gaan of (mogelijke) verschuivingen in schattingen van zorggerelateerde schade en de vermijdbaarheid mede ingegeven zijn door een soepelere of juist strengere beoordeling door de arts-beoordelaars. Hiertoe heeft een aantal arts-beoordelaars die voor de 2004 studie patiënt opnames hadden beoordeeld, deze zelfde dossiers 6 jaar later herbeoordeeld tijdens de 2011/2012 studie. De resultaten lieten zien dat er geen systematische verschuivingen in beoordeling was na 6 jaar. Dit wijst erop dat de arts-beoordelaars niet strenger of juist soepeler hebben beoordeeld in het ene jaar in vergelijking met het andere jaar. Random variatie was wel aanwezig, en vooral de beoordeling van de vermijdbaarheid leek lasting.

Deel II: beschrijvende studies die ingaan op patiëntengroepen en processen met een hoger risico op (vermijdbare) zorggerelateerde schade.

In het tweede deel van dit proefschrift worden een aantal diepte studies beschreven die ingaan op risicovolle patiëntengroepen en zorgprocessen.

Hoofdstuk 5 bespreekt of het beoordelen van zorggerelateerde schade bij patiënten die tijdens een opname in het ziekenhuis overlijden een goede methode is om de patiëntveiligheid in ziekenhuizen te beschrijven. Dit is een interessante vraag voor enerzijds het trekken van een steekproef voor landelijke studies naar zorggerelateerde schade, anderzijds voor ziekenhuizen zelf die retrospectief dossieronderzoek gebruiken als een methode binnen hun eigen kwaliteit en veiligheid cyclus. Zorggerelateerde schade en vermijdbare zorggerelateerde schade komen twee keer zo vaak voor in patiënten die tijdens een opname in het ziekenhuis overlijden dan in patiënten die levend uit het ziekenhuis worden ontslagen. Dit maakt dat het exclusief samplen van overleden patiënten een efficiënte manier is om vermijdbare zorggerelateerde schade te identificeren en hiermee ook zoveel mogelijk verbeterpotentieel. Hierbij is het wel van belang dat men zich bewust is dat hiermee een aantal veiligheidsproblemen on-, onder- of overbelicht wordt. Patiënten die tijdens opname in het ziekenhuis overlijden zijn relatief gezien minder vaak opgenomen op een chirurgische opnameafdeling. Samenhangend hiermee komt vermijdbare zorggerelateerde schade gerelateerd aan het chirurgisch proces bij patiënten die tijdens opname in het ziekenhuis overlijden minder vaak voor dan bij patiënten die levend uit het ziekenhuis worden ontslagen. In een landelijke studie als de onze waarbij grote aantallen patiëntdossiers worden bestudeerd, is geen specifieke type vermijdbare zorggerelateerde schade afwezig ten opzichte van levend uit het ziekenhuis ontslagen patiënten. Als de resultaten gebruikt worden om verbetermogelijkheden ten aanzien van patiëntveiligheid in een ziekenhuis of ziekenhuizen te prioriteren, dan is het belangrijk om rekening te houden met het verschil in verdeling van type zorggerelateerde schade tussen de twee groepen.

Hoofdstuk 6 gaat in op karakteristieken van medicatie gerelateerde zorggerelateerde schade tijdens ziekenhuisopnames. Van alle zorggerelateerde schade was 15.2% medicatie gerelateerd, waarvan 18.4% vermijdbaar geacht werd. De meest voorkomende medicatie gerelateerde zorggerelateerde schades hadden betrekking op chemotherapie voor kanker, antistolling en insuline/orale behandeling voor diabetes. Chemotherapie gerelateerde schade werd zelden vermijdbaar geacht. Met name zorggerelateerde schade gerelateerd aan antistolling en insuline/ orale behandeling voor diabetes werd vermijdbaar geacht. Vermijdbare zorggerelateerde schade met betrekking tot antistolling kwam het meest voor ten gevolge van dosis factoren. Vermijdbare zorggerelateerde schade gerelateerd aan insuline/ orale diabetes behandeling werd niet verder geanalyseerd vanwege de kleine aantallen.

Hoofdstuk 7 bespreekt het risico op zorggerelateerde schade en vermijdbare zorggerelateerde schade bij patiënten die tijdens hun ziekenhuisopname behandeld werden door meerdere specialismen. Betrokkenheid van meerdere specialismen bij de behandeling van een patiënt heeft als doel verbeterde zorg doordat in totaal meer en aanvullende kennis en ervaring aanwezig is. De resultaten in dit hoofdstuk laten zien dat het aantal specialismen dat tijdens de opname van een patiënt betrokken is bij de zorg, ook geassocieerd is met het risico op zorggerelateerde en vermijdbare zorggerelateerde schade. Deze associatie werd nauwelijks verklaard door patiënt kenmerken (leeftijd, geslacht, ICD9 diagnostische groepen, Charlson comorbiditeits index), en voor een deel verklaard door zorggerelateerde kenmerken (opname intensive care, opnameduur, spoedopname en operatie tijdens opname). Na correcties voor patiënt en zorggerelateerde kenmerken, was het toegenomen risico op schade nog het meest zichtbaar bij vermijdbare zorggerelateerde schade en in mindere mate bij de niet vermijdbare zorggerelateerde schade. Dit suggereert dat inadequate zorg toeneemt met het aantal specialismen dat een patiënt behandelt, onafhankelijk van de complexiteit van de patiënt zelf. De gebruikte data kan echter geen causale relatie bevestigen.

Hoofdstuk 8 beschrijft dat in bijna 10% van alle ziekenhuisopnames de ontslagbrief mist in het patiëntdossier, waardoor de continuïteit van zorg in het geding komt. De ontslagbrieven die wel aanwezig zijn, zijn vaak incompleet. Relevante lab uitslagen, consulten en wijzigingen in medicatie waren aanwezig in slechts 65% tot 85% van alle ontslagbrieven. Voornamelijk bij patiënten die electief (gepland) waren opgenomen, patiënten met een kortere opnameduur of heropnames hadden een hoger risico op incomplete ontslagbrieven. Als een patiënt opname positief werd bevonden voor screening criteria voor zorggerelateerde schade, was het waarschijnlijker dat een ontslagbrief aanwezig was. Het afwezig zijn van een ontslagbrief varieerde tussen ziekenhuizen en nog meer voor ziekenhuisafdelingen. Dit indiceert dat interventies om aanwezigheid en compleetheid van ontslagbrieven te bevorderen het best gericht kan worden op ziekenhuisafdelingen.

DISCUSSIE

De resultaten met betrekking tot het monitoren van zorggerelateerde schade en vermijdbare zorggerelateerde schade van 2004 tot 2012 in Nederland zijn bemoedigend, vooral omdat vooruitgang in specifieke subgroepen samenvalt met aandacht die de ziekenhuizen aan deze onderwerpen hebben gegeven. Andere factoren kunnen ook van invloed zijn op de resultaten. Door de jaren heen is de context van de ziekenhuiszorg veranderd. Patiënten worden bijvoorbeeld steeds minder lang klinisch opgenomen, klinisch opgenomen patiënten zijn gemiddeld gezien ouder geworden en het aantal dagopnames is toegenomen terwijl het aantal klinisch opnames relatief stabiel is gebleven. Daarnaast zijn de patiëntdossiers door de jaren heen steeds meer elektronisch geworden.

De uitkomsten van onze studie en andere studies laten zien dat het monitoren van (vermijdbare) zorggerelateerde schade een uitdaging kan zijn. Ondanks een grote sample van in totaal 16.000 patiënt opnames gemeten in drie verschillende tijdperiodes, is er geen statistisch significante vermindering aan te tonen in gecorrigeerde en gestandaardiseerde vermijdbare zorggerelateerde schade. Dit betekent dat random variatie, dat wil zeggen toeval, ook een verklaring zou kunnen zijn voor de zichtbare vermindering. Dit in gedachten houdend en rekening houdend met de methodologische overwegingen als matige inter- en intra-beoordelaars betrouwbaarheid en de afhankelijkheid van informatie genoteerd in het patiënt dossier, doemt de vraag op of deze methode de meest passende methode is om (vermijdbare) zorggerelateerde schade door de tijd heen te monitoren. Andere beschikbare methodes hebben echter ook nadelen. Systematisch retrospectief dossieronderzoek is tot op heden de meest geschikte methode om zorggerelateerde schade en vermijdbare zorggerelateerde schade te tellen en is hiermee op dit moment de beste kandidaat om de zorggerelateerde schade door de jaren heen te monitoren. Het grote aantal patiënt opnames dat in totaal bestudeerd is, heeft het daarnaast ook mogelijk gemaakt een aantal diepte-studies op verschillende onderwerpen uit te voeren. Bovendien is het ook belangrijk om te realiseren dat de voordelen van het Nederlandse landelijke onderzoek naar (vermijdbare) zorggerelateerde schade niet alleen van wetenschappelijke aard zijn. Het bekendmaken van zorggerelateerde schade en vermijdbare zorggerelateerde schade op verschillende momenten het afgelopen decennium is ook een belangrijke tool geweest om te benadrukken dat continue aandacht voor patiëntveiligheid in de Nederlandse ziekenhuizen noodzakelijk is. Alle aspecten moeten afgewogen worden wanneer overwogen wordt om dit type onderzoek te herhalen.

AANBEVELINGEN

Aanbevelingen voor vervolgonderzoek:

- Sample bij toekomstige landelijk dossieronderzoek specifieke patiënten groepen die een hoog risico hebben op vermijdbare zorggerelateerde schade, zoals chirurgische patiënten of patiënten die uiteindelijk na opname zijn overleden in het ziekenhuis.
- Onderzoek methodes om inter- en intra-beoordelaarsbetrouwbaarheid bij de beoordeling van vermijdbare zorggerelateerde schade te verbeteren.
- Oorzaken en passende oplossingen voor het verhoogde risico's dat patiënten hebben die behandeld worden door meerdere specialismen.
- Patiëntveiligheid en transmurale zorg.
- Onderliggende oorzaken voor vermijdbare medicatie gerelateerde zorggerelateerde schade, met name antistollingsbehandeling.

Aanbevelingen voor praktijk en beleid:

- Gebruik in ziekenhuizen retrospectief dossieronderzoek naar (vermijdbare) zorggerelateerde schade als onderdeel van eigen kwaliteit en veiligheidscyclus.
- Richt retrospectief dossieronderzoek op gebieden met een hoog risico op (vermijdbare) zorggerelateerde schade zoals patiënten die een chirurgische ingreep ondergaan, patienten die tijdens opname in het ziekenhuis overlijden, kwetsbare (oudere) patiënten of patiënten die bepaalde types medicatie gebruiken.

Dankwoord

Zoveel mensen hebben een bijdrage geleverd aan de totstandkoming van mijn proefschrift dat ik bij voorbaat al weet dat ik mensen ga vergeten, alvast mijn excuses hiervoor.

Allereerst wil ik mijn promotor en copromotoren bedanken: Cordula Wagner, Martine de Bruijne en Maaike Langelaan. Cordula, wat heb ik een ongelooflijke bewondering voor jouw overzicht, dat je kansen ziet in plaats van problemen en jouw kunde om overal verbanden te zien en te leggen. Dat zal je goed van pas komen als directeur van het NIVEL! Martine, dank voor je motiverende begeleiding, je bodemloze put van ideeën en oplossingen, de interessante discussies en natuurlijk ook je persoonlijke interesse. Wat leuk dat ik je benoeming tot hoogleraar nog mee kan nemen in mijn proefschrift! Maaike, dank voor je nuchtere blik en nimmer aflatende motiverende woorden. Daarnaast ook zeker ook voor de fijne samenwerking, soms in de nachtelijke uurtjes analyserend en bellend of we gelijke getallen hadden.

Alle verpleegkundigen en arts-beoordelaars, jullie zijn met teveel om allemaal bij naam te noemen: ik wil jullie allen bedanken voor jullie integriteit, jullie harde werk, mooie discussies en niet te vergeten jullie reislustigheid! Alle hoeken van het land hebben jullie bezocht. Henk Asscheman wil ik nog bij naam noemen, dank voor je aandeel in de trainingen, terugkombijeenkomsten en in het verwerken van de gegevens. Dank ook aan de vele onderzoeksassistenten die de beoordelaars hebben ondersteund in hun werkzaamheden in alle ziekenhuizen.

Alle deelnemende ziekenhuizen wil ik bedanken voor hun deelname en de openheid. Hierbij wil ik zeker ook de medewerkers van de afdelingen kwaliteit & veiligheid, archief en ziekenhuisautomatisering noemen, die het mogelijk hebben gemaakt dat alle 16.000 dossiers beoordeeld konden worden door onze beoordelaars.

Speciaal dank gaat uit naar Maren Broekens, die de studies rondom zorggerelateerde schade coördineerde. Maren, wat ben jij een ongelooflijke doorzetter en veelzijdig, van trainingen geven tot aan planningen maken en expert van Patsafe!

Verder wil ik alle de co-auteurs van mijn artikelen bedanken voor hun bijdrage, in het bijzonder Peter Spreeuwenberg. Peter, dank voor al je statistische ondersteuning!

Graag wil ik ook de leden van de leescommissie bedanken voor het lezen en beoordelen van dit proefschrift: Prof.dr. E.L. Swart, Prof.dr. J. Twisk, Prof.dr. N.F. de Keizer, Prof.dr. I. Leistikow en dr. D.L.M. Zwart.

(Oud-) collega's van de onderzoeksgroep Safety4Patients, een groep vol met enorm gedreven onderzoekers op het VUmc en NIVEL. Ik heb hele mooie herinneringen aan de vrijdagse

schrijfdagen op het NIVEL, soms gevolgd door een bezoekje aan de Ierse pub, congresbezoek, de jaarlijkse kerstdiners bij Martine thuis en zomer BBQs bij Maaike. Mijn kamergenoten van B550: Maren, Hanneke, Floor en Babette, ik had geen fijnere kamergenoten kunnen wensen!

Daarnaast wil ik ook mijn meer recente collega's danken voor hun interesse: oud-collega's van Bureau Patiëntveiligheid & Kwaliteit van het Diakonessenhuis in Utrecht, en mijn huidige werkplek de directie Kwaliteit van zorg & Patiëntveiligheid van het UMC Utrecht.

Lieve paranimfen Annemijn en Floor, wat ben ik blij dat jullie naast mij willen staan tijdens de verdediging!

Lieve (schoon)familie en vrienden. Sommigen dachten misschien dat het er nooit van zou komen, maar het ei is al een tijdje gelegd en de afronding hopelijk nu daar! Dank voor jullie interesse, maar met name voor de afleiding, ontspanning en vermaak!
Lieve ouders en schoonouders, wat voel ik me rijk wetende dat jullie achter me staan!
Lieve zussen. Jullie zijn de fijnste en liefste zussen van de hele wereld!!
Lieve Bram, ik kan echt altijd op jou bouwen, de liefde die ik voor je voel en de steun die ik van je ervaar zijn niet goed in woorden uit te drukken. Lieve Jako en Mia, door jullie kan ik altijd al het andere heerlijk in perspectief zien. Liefste Bram, Jako en Mia, de wereld is zo leuk met jullie!!!

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Rebecca Baines was born on April 15, 1978 in St. Asaph, Great Brittain. In 1996 she graduated high school at Stedelijk Gymnasium Leiden. From 1997 to 2000 she studied veterinary medicine in Utrecht. In 2001 she studied human movement science, specialising in rehabilitation, in 2005 she received her MSc degree.

From 2001 to 2003 she worked at the research and innovation centre in rehabilitation hospital De Hoogstraat in Utrecht on a project focussing on the development of a brief generic instrument to rate participation of rehabilitation patients. From 2003 to 2005 she worked at ZonMw, the Netherlands organisation for Health Research and Development as a junior programme officer. Among others, she supported programmes on Patient Safety, development of Clinical practice guidelines and Rehabilitation. In 2009 she started as a junior researcher at the VU University medical center, department of public and occupational health. She was a member of the research group Safety4Patients, a collaboration between the VU University medical center/ EMGO+ Institute in Amsterdam and NIVEL in Utrecht. Her PhD project was part of the large Dutch patient safety study “Monitor Zorggerelateerde Schade”. In 2013 she also received her MSc degree in Epidemiology at Epidm. In 2014 she exchanged the VU University medical center for NIVEL, where she participated in other research projects on quality of care. From 2015 until 2017 she worked at the department of quality and safety of the Diakonessenhuis in Utrecht as an adviser, primarily focussing on incidents and sentinel events. In 2017 she started working at the University Medical Center Utrecht as a staff adviser focussing on sentinel events.