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.
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<th>No of hospitals</th>
<th>Adverse events (% of adm.)</th>
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*  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.
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 monitoring patient safety.

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**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.
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 automated 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 healthcare. 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](image-url)
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. 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. 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.
REFERENCE LIST


