

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.