

Summary

Background and study aims

Patient safety in healthcare is a major issue throughout the world. In the past decades, many countries examined the occurrence of adverse events in their hospitals. In the Netherlands, the rate of adverse events was 5.7% of all hospital admissions in one year. Approximately 40% of the adverse events were judged to be preventable and 13% contributed to permanent disability, including death.

Despite the rising interest in the safety of patients worldwide, there is still comparatively little knowledge on the *causes* of adverse events, near misses and other unintended events. To achieve an increase in patient safety, interventions should tackle the dominant underlying causes of unsafe events. Further, it is believed that hospitals have to improve the patient safety culture among their staff. A positive safety culture can determine, for example, how carefully healthcare providers follow protocols and the ease with which one can ask a colleague for help. Moreover, if there is a safety culture where people are open about unintended events and report them, they have the opportunity to learn from the mistakes and it is possible to make improvements and thus increase patient safety. The intuitive appeal that safety performance depends on the safety culture among staff is, however, not yet supported by firm evidence from scientific studies.

The aim of this thesis is to get insight into the causes of unintended events in hospitals and, more specifically, the role of the safety culture in the causation of unintended events.

This information can be useful for the design of interventions to improve patient safety and may also give direction to future research. Moreover, data about the nature and causes of unintended events in hospitals may help stakeholders (healthcare workers, hospital managers and policy makers) realise how human behaviour and organisational and technical contextual factors together cause unintended events and this may contribute to a more open culture of dealing with and reporting of safety problems.

In addition, methodological aspects of tools to examine causes of unintended events and safety culture have been investigated. Not only in order to interpret the results of the studies in this thesis, but also because the tools are widely used in hospitals in the Netherlands and abroad.

Methods

Three studies have been performed to answer our research questions: a patient record review study on adverse events, an unintended event reporting study and a study on patient safety culture.

Patient record review

A retrospective patient record review study was conducted in 21 hospitals in the Netherlands to examine adverse events that occurred during hospital admissions in 2004. Trained physicians reviewed the medical, nursing and, if available, outpatient record of all sampled admissions that contained triggers (clues) for adverse events. The presence of one or more triggers was judged in advance by trained nurses. For each patient record two physician reviewers determined independently the presence, consequences, and degree of preventability of the adverse events, based on a standardised procedure and review form. The methods of determining adverse events were based on previous adverse event studies in other countries.

The physicians reviewed 7926 patient records and identified 744 adverse events. Part of the review procedure, and of specific relevance for the current thesis, was an assessment of the underlying causes and prevention strategies of each adverse event, as judged by the physician reviewers. For 736 of the 744 adverse events there were data on causal factors.

Unintended event reporting and PRISMA

A study was performed to examine the root causes of unintended events at 28 hospital units in 20 hospitals in the Netherlands. The units were of three different types, together representing the core of hospital care: emergency medicine, surgery and internal medicine.

Healthcare providers were asked to report all unintended events that occurred in their units on a report card or (more elaborate) report form. The study period was five to fourteen weeks per unit. In order to identify the causes underlying the reported unintended events, the events were analysed with a root cause analysis tool (PRISMA) by one member of a team of five experienced researchers. Once or twice a week a researcher visited the hospital unit to collect the written reports and ask the healthcare providers questions about the reported events in short interviews.

PRISMA

PRISMA, an acronym for Prevention and Recovery Information System for Monitoring and Analysis, is a tool to analyse the causes of unintended events. Unintended events are analysed by means of causal factor trees. At the top of the causal tree a short description of the event is placed, as the starting point for the analysis. Below the top event, all involved direct causes are mentioned. These direct causes often have their own causes. By continuing to ask “why” for each event or action, beginning with the top event, all relevant causes are revealed. In this way a structure of causes arises, until the root causes are identified at the bottom of the tree. The root causes are classified with the Eindhoven Classification Model (ECM). This taxonomy distinguishes five main categories of causes: technical, organisational, human, patient related and other factors, which can be subdivided into 20 subcategories.

Patient safety culture measurement

Patient safety culture was measured with the Dutch translation of the Hospital Survey on Patient Safety Culture (HSOPS), named COMPaZ (Cultuur Onderzoek onder Medewerkers over de Patiëntveiligheid in Ziekenhuizen). The questionnaire consists of 51 items, including background variables. Healthcare providers rate the items on a five-point scale of agreement (strongly disagree, disagree, neither, agree and strongly agree) or frequency (never, rarely, sometimes, most of the time, always).

Data on patient safety culture were collected in three different sub studies. To examine the psychometric properties of COMPaZ, data of the Dutch ‘Better Faster’ study were used: 583 respondents from 23 units in eight hospitals. To examine the clustering of responses at unit and hospital level, this dataset was completed with data from the Dutch ‘Safety Management System’ study, resulting in 1889 completed questionnaires from 87 units in 19 hospitals. Finally, to examine the role of patient safety culture in the causation of unintended events, COMPaZ was administered in the units that participated in the unintended event reporting study (see above). In each unit, the patient safety culture questionnaire was filled out prior to the start of the reporting study. A total of 542 questionnaires were completed by healthcare providers from 28 units in 20 hospitals.

Main findings

Causes of unintended events (Chapter 2 and 3)

Adverse events examined using patient record review (Chapter 2)

Chapter 2 provides an overview of causes of adverse events and potential prevention strategies, examined with patient record review by experienced physicians. In most of the 736 adverse events that the physicians identified, human errors were involved (in 61% of the adverse events). These were predominantly knowledge-based and rule-based errors, for example: incorrect reasoning or not verifying if all necessary instruments are present before the start of a procedure. In 39% of the adverse events, patient related factors were involved. In 14% of the adverse events, organisational factors (mostly inadequate transfer of knowledge) contributed to the adverse event, in 4% technical factors (mostly material defects) and in 19% other factors. Adverse events with organisational factors were relatively often preventable (93%) and resulted relatively often in permanent disability (20%), particularly adverse events caused by inadequate or unavailable protocols.

Strategies that were suggested to prevent adverse events were primarily quality assurance/ peer review, evaluation of safety behaviour, training and improvements of procedures. For the adverse events with human and patient related causes, reviewers predominantly recommended quality assurance/ peer review. Adverse events caused by organisational factors were considered preventable by improving procedures.

Unintended events examined using event reporting (Chapter 3)

Chapter 3 gives insight into the nature and causes of unintended events in a risky hospital department, the emergency department. A total of 522 unintended events were reported by healthcare providers in ten emergency departments. Half of the events directly reached the patient, most often resulting in inconvenience or suboptimal care. PRISMA root cause analysis of all events that were reported at the emergency departments showed that most root causes were human (60% of the root causes), followed by organisational (25%) and technical causes (11%). Patient related factors and factors in the category 'other' occurred rarely. Unintended events related to materials and equipment were relatively often caused by technical factors. Incorrect data and substitutions were most often caused by human errors, while organisational

factors contributed most to unintended events related to protocols and regulations.

Nearly half of the root causes were external (46%), meaning that an individual's behaviour, technical factors or organisational factors at an outside hospital department or in another organisation contributed to the unintended event (e.g. laboratory, consulting services, ambulance services etc.). A quarter of all unintended events were classified as events related to some stage in the collaboration with other hospital departments. The problems in this collaboration with other departments and outside services can also be seen in the phase of care in which unintended events mainly come about -medical examinations and tests-, since a lot of tests are performed by other departments.

Inter-rater reliability of constructing causal trees and classifying root causes (Chapter 4)

Chapter 4 reports on the inter-rater reliability of the method that we used for the analyses of reported unintended events: PRISMA. With PRISMA, the root causes of events are examined by describing the event in a causal tree and classifying the root causes with the Eindhoven Classification Model (ECM).

A total of 300 unintended event reports were sampled from a database of 2028 events. The reports were previously analysed with PRISMA by experienced analysts and were re-analysed by another analyst for the reliability study. Half of the sample was used to compare the descriptions of root causes and the number of root causes per causal tree. The other half was used to determine the inter-rater reliability of the classifications of root causes.

The agreement between two independent raters in their descriptions of root causes was satisfactory: 54% (full) agreement, 17% partial agreement and 29% no agreement or no equivalent available. The inter-rater reliability of the number of root causes was moderate ($\kappa=0.46$). The inter-rater reliability of classifying root causes according to the ECM was substantial at all levels of the taxonomy, from the highest category level ($\kappa=0.71$) to the lowest subcategory level ($\kappa=0.63$). Most discrepancies occurred in classifying external root causes into one of the three external root cause categories.

In short, PRISMA analysts formulated quite similar root causes and agreed considerably on the classifications given to the root causes, but they varied in the *number* of root causes identified for each unintended event.

Validity of the patient safety culture questionnaire (Chapter 5 and 6)

Psychometric properties (Chapter 5)

In Chapter 5 of this thesis, the underlying dimensions and other psychometric properties of the safety culture questionnaire COMPaZ are analysed. Confirmatory factor analyses were performed to examine the applicability of the 12-factor structure of the original American questionnaire (HSOPS) to the Dutch data. This resulted in some low reliability scores. Explorative factor analyses were performed to examine whether another composition of items and factors would fit the data better. With this method 11 factors were drawn: *Teamwork across hospital units; Teamwork within units; Adequate shift changes; Frequency of event reporting; Non-punitive response to error; Communication openness; Feedback about and learning from error; Supervisor/manager expectations and actions; Hospital management support for safety; Adequate staffing and Overall perceptions of safety*. The internal consistency (Chronbach's α) of the factors was acceptable ($0.58 < \alpha < 0.79$).

The construct validity was good: the moderate correlations of the factors showed that there are no two dimensions measuring the same construct. As expected, all factors correlated with the outcome variable *Patient safety grade* (staff evaluation of the overall patient safety as excellent, very good, acceptable, poor or failing).

The composition of the factors was very similar to that of the original questionnaire. There were only small shifts of items across factors and two of the American factors (*Feedback & communication about error* and *Organisational learning – continuous improvement*) turned out to combine into a six-item dimension in the Dutch structure (*Feedback about and learning from error*). The other dimensions consisted of two to five items. Two items of the original questionnaire were removed. One was removed because it did not have a sufficient factor loading on any of the factors and one because it lowered the internal consistency of a factor.

Clustering of responses at unit and hospital level (Chapter 6)

The results in Chapter 6 support the claim that COMPaZ (HSOPS) measures culture and not just individual attitudes. Intraclass correlations (ICC) at unit level ranged from 4.3% to 31.7%, representing considerable unit level variation for all dimensions. For three dimensions of patient safety culture there was also significant clustering of responses at hospital level: *Feedback about and learning from error* (ICC=6.2%); *Teamwork across hospital units* (ICC=4.4%) and *Non-punitive response to error* (ICC=4.5%).

In the multi-response model, there were no highly correlated dimensions, indicating that each dimension measures a unique aspect of patient safety culture. The strongest correlations were found at unit level; correlations at individual level were smaller and more homogeneous in size. The effects at hospital level were too small to calculate correlations, when controlling for variation at individual and unit level. This is also an indication that the hospital level is not the most important level regarding patient safety culture. The detection of clustering of responses within units confirms the claim that COMPaZ measures group culture and not just individual attitudes.

The role of patient safety culture in the causation of unintended events (Chapter 7)

It is known that patient safety varies between hospital units. The safety culture among healthcare providers in the hospital units is believed to influence safety performance. In Chapter 7, we examine if the relationship between work area (specialty) and patient safety outcomes is mediated by the safety culture in the units. If safety culture mediates the relationship, it explains why units vary in performance. Safety culture then accounts for the relation between work area and outcomes: differences in outcomes between specialties are in fact caused by the different safety cultures within the units.

The overall patient safety culture (measured with COMPaZ) in the units was not related to any of the outcomes (types of unintended events and causes). We found only a few significant relationships between some safety culture dimensions and outcomes. Three of the 11 safety culture dimensions showed significant mediation of the effect of work area on safety outcomes: 1) *Non-punitive response to error* mediated the relation between work area and the occurrence of events related to medication events and between work area and the frequency of organisational causes; 2) *Hospital management support*

mediated the relation between work area and the occurrence of events related to materials/equipment, events related to collaboration with residents/consultants and technical causes; 3) *Frequency of event reporting* (willingness to report) was the most important mediating factor, mediating all relationships that were examined because of their potential for mediation effects.

We concluded that our results could not support the claim that safety culture is a key factor affecting patient safety. The safety culture present within hospital units could not clearly explain differences in safety outcomes between unit types. The findings suggest that the current policy emphasising the importance of safety culture might be somewhat misplaced. It seems that the pace and complexity of the work itself, inherent to the different work areas, is more important for patient safety than the safety culture among unit personnel. Nevertheless, there might be other aspects of safety culture or other safety outcomes that were not measured in our study but that do significantly relate to each other.

General discussion

In the general discussion (Chapter 8) of this thesis, the main findings and methodological strengths and limitations of the studies are summarised and discussed. Moreover, implications for practice and recommendations for future research are given.

System approach

We found a predominance of human causes in both the patient record review study on adverse events and the event reporting study on unintended events. However, we certainly do not believe that in order to increase patient safety, researchers and policy makers should focus on human behaviour only, without considering the setting under which the healthcare providers work. The system that surrounds healthcare providers has to be adjusted to the people working in it. It should be less provocative for making errors and should have barriers for the inevitable errors; preventing them from resulting in patient harm. Our study results also gave an indication for the importance of this system approach: many unintended events were caused by a combination of latent factors (technical or organisational) and active (human) factors.

Recommendations for practice to improve patient safety

- *Taking on the system approach, e.g.:*
 - Design for standardisation and simplicity;
 - Make it easy to do the right thing;
 - Include users in the design or procurement of materials and equipment;
 - Assess the risks of changes.
- *Using event reporting:* event reporting can provide elaborated information concerning the circumstances and underlying causes of unintended events. Specific recommendations:
 - A combination of event reporting with additional interviews of involved personnel;
 - Research beyond unit boundaries, uncovering not only internal causal factors but also causal factors in other units;
 - Recurrent event reporting periods (e.g. each quarter of a year a period of two weeks).
- *Using PRISMA:* PRISMA analysts formulate quite similar root causes and can reliably classify the root causes into one of the categories of the Eindhoven Classification Model (ECM). However, they vary in the number of root causes used in the causal tree. Specific recommendations:
 - Increase training in the disclosure of all relevant root causes of an event: tracing additional causal factors and dismantling all causes in the causal tree into separate root causes;
 - Adjust the ECM by removing the distinction between the three types of external factors and combining them into one category.
- *Using COMPaZ/HSOPS:* the safety culture in hospital units as measured by COMPaZ/HSOPS did not show to have a strong relationship with safety outcomes. However, the questionnaire can reveal differences between units on several dimensions. COMPaZ/HSOPS can be used as an additional source of information about safety issues and it can be a means for hospital staff to think about patient safety.

Recommendations for future research into the causes of unintended events

- *Using more than one method at the same time:* research methods vary in the ability to uncover certain types of unintended events and types of causes. A combination of methods will more likely enable researchers to study adverse

events as well as near misses, nursing as well as medical events, and to find active as well as latent causal factors.

- *Examining the common cause hypothesis*: future research is needed to examine the resemblance of the causal factor structures of unintended events and adverse events in the healthcare setting.
- *Focussing research on specific topics*: our study has provided clues for more specific research on certain topics:
 - *Collaboration between hospital units*, particularly for the emergency department: e.g. collaboration between the emergency department and laboratory and radiology;
 - *Medication events*, especially for internal medicine and surgery units: e.g failures in setting out medication, forgetting to give a prescribed medicine, giving the wrong dose or setting a wrong run-in speed of (fluid) medicines;
 - *Organisation of healthcare*: care processes should be examined critically, and illogical or impractical steps should be removed or rearranged.

