Chapter 10: General discussion
In this thesis we investigated the risks, causes of unintended events and priorities for improvement of patient safety in (older) hospitalised patients and studied potential differences between hospital unit types. In addition, the Risk Governance Framework (see Figure 1 in Introduction) was used to systematically study the scale, nature, causes, possibilities for prevention and management of the risk of unintended outcomes in vulnerable patients, namely older hip fracture patients. The final chapter of this thesis offers a summary and appraisal of the main findings. In addition, methodological considerations are discussed and implications for practice, policy and future research are proposed.

MAIN FINDINGS

Part one: Risks and causes

To get an overview of the risks of (preventable) AEs in (older) hospitalised patients in the Netherlands we re-analysed the data of the Dutch Adverse Events Study. The results of this analysis (chapter 2) showed that AEs and preventable AEs occurred significantly more often in hospitalised patients of 65 years and older (6.9% AEs; 2.9% preventable AEs) when compared to hospitalised patients under 65 years of age (4.8% AEs; 1.8% preventable AEs). The AEs in the older patient group were more often related to medication. Also, the root cause human knowledge-based behaviour related, which means the inability to apply existing knowledge to a new and complex situation, contributed more often to the occurrence of an AE in older patients compared to younger patients. These outcomes confirmed that special attention is needed to improve patient safety for older patients.

In addition, in a prospective observational study, we investigated the types and causes of patient safety incidents in emergency departments, internal medicine and surgical units and explored the differences between them (chapter 3). The unit-based incident reporting showed differences between the units in the types and causes of incidents reported. This provided us with specific information per unit-type, such as the relatively high number of medication related incidents in surgical units when compared to emergency department units.

The results of both studies show that many risks, incidents and causes can be identified in hospital care, but that they are different for age groups and types of units. Therefore it is important to not only focus on improving patient safety on a hospital level, but to also focus on specific patient groups and units.

Part two: Risks and interventions for older hip fracture patients

For the majority of the other chapters in this thesis we focused on older hip fracture patients to systematically study the risks for undesired outcomes and
test methods to manage them. Although this focus on a specific patient group limits the generalisability of the findings, this choice made it possible to rule out an important proportion of variation between patients and unit types. Older hip fracture patients are seen as one of the vulnerable patient groups because they are usually of high age, often with a fragile health status with multimorbidity and high medication use, which was the case in our study as well. They have to go through a complex care process after admission for the hip fracture which makes good communication and close monitoring of these patients even more important [1-4].

**Pre-assessment**

Chapter 4 describes the pre-assessment phase of risk framing for this patient group. We investigated the risks that may lead to undesired outcomes as perceived by the different stakeholders involved in the care process for older hip fracture patients. The majority of the risks identified by the stakeholders occurs in the post-operative period in the hospital. Complications, such as pressure wounds, delirium, pneumonia and wound infections were mentioned most often. Many risks were related to the process of care, including problems around discharge, transfers within the hospital and the operative procedure itself.

**Risk appraisal, tolerability and acceptability judgement**

For a more precise estimate of the adverse events, their causes and prevention strategies for older hip fracture patients, we used a retrospective record review study specifically designed for this group (chapter 6). This study confirmed the vulnerable status of this patient group, since an AE was identified in 19% of the patients and a preventable AE in 8% of the patients. These numbers are considerably higher than the incidence in the general hospital population of 65 years and older and they show that improvements in care for this patient group are needed. Most AEs were related to the surgical procedure and human causes contributed to more than half of the AEs. The most often selected prevention strategies by the medical experts reviewing the records were training and close monitoring of quality of care and the health professional’s performance.

In addition, a detailed analysis was performed on the quality of the medical record and on the adequacy of written handover information (chapter 7). Previous studies have suggested that handover moments and communication in general are high risk elements in the care process [5-7]. To establish whether the focus on improvement of communication as a risk management strategy could be of potential value for older hip fracture patients, we investigated if the quality and adequacy of written handover information in the patient record was related to several measures of patient safety. An analysis of the records
reviewed in the retrospective study revealed that complications and AEs were identified significantly more often in patient records with a lower mean grade for quality, but there was no significant association with preventable AEs. When looking at the handover moments in more detail, we found that many items were not adequately registered, but there were no significant associations with the occurrence of complications, AEs and preventable AEs. Nevertheless, this study showed that there is room for improvement in terms of quality and registration of (handover) information in the patient record.

**Risk management**

The final chapters of this thesis describe various interventions to potentially manage the risks for older hip fracture patients. The three tested interventions were all related to communication and transfer of information: either between care providers or between care providers and the patient. The interventions used were the SBAR-communication tool, an information leaflet for patients with important information on the most common complications after discharge and the patient safety card for patients with suggestions on how they can contribute to safer care during hospitalisation [8-11].

In chapter 8 we evaluated the completeness of information transfer between nurses and physicians during the daily ward rounds after the introduction of the SBAR-communication tool in three surgical wards. The observations of the discussion between the nurses and physicians showed that the rounds were usually led by the physician with a limited role for the nurses. Many SBAR-items (Situation, Background, Assessment, Recommendation) were often included in the patient discussion, but the timing and confirmation of required actions were usually absent. It is recommended that these items are more explicitly included; the confirmation that actions are correctly understood by the receiving person (in this case usually the nurse) is important for safe care. Another recommendation from this study is to give nurses a more pronounced role during the daily ward rounds since they are in close contact with the patient during the day and are able to provide the physician with valuable information. However, changing usual practice during the daily ward rounds will require a lot of effort and practice since the participants seem very accustomed to their role.

Finally, in chapter 9 the results of a randomised controlled trial on the potential effectiveness of the three interventions to manage and reduce risks are described. Due to the insufficient number of patients included in the trial, the high loss-to-follow-up, problems with the randomisation procedure and the limited use of the interventions, no meaningful comparisons could be made between the intervention groups. Despite the careful preparation of the trial, practical
issues prevented a methodologically sufficient outcome. It can be questioned whether the RCT design is the most appropriate for these types of patient safety improvement interventions. More pragmatic designs or randomisation at ward level should be considered in future studies into the effectiveness of patient safety interventions aimed at improving communication.

**Applicability of Risk Governance Framework [12,13]**

To our knowledge, the current study is one of the first to systematically identify and manage risks in a specific patient group with the Risk Governance Framework. The use of this framework had several advantages. First, it provided guidance in systematically addressing the risks for a specific patient group from different perspectives. Many studies on patient safety focus on a general hospital population and establish an adverse event rate by using retrospective record review. Retrospective record review is an important method to provide insight into the level of patient safety but the main focus is the medical perspective. In our study, the use of the Framework guided us in systematically identifying risks from different perspectives by including a broad risk assessment. Communication in the Risk Governance Framework means effective internal and external communication about risk management decisions. In our study, we have used communication as the starting point for risk management by implementing three interventions that are related to communication. This has provided us with the result that timing and confirmation of required actions in interprofessional communication is often lacking and that it was difficult to actively involve vulnerable hip fracture patients to improve safety. Overall, the framework provided support to guide the research through the different phases to establish the problem and to appraise, judge and manage the risks involved.

However, some issues have to be taken into account when considering how we applied the framework. The judgement and appraisal phase is an important phase within the Framework. In this thesis the judgement that the high rate of preventable AEs is intolerable and unacceptable is mainly based on the comparison with incidences in other patient populations. It is likely that these high risk rates are judged as unacceptable by all stakeholders involved, but we did not establish this formally. A more in-depth analysis on the level of risk that is acceptable for this patient group would be an interesting next step. This analysis should not only consider the risks from a medical perspective, but mainly focus on the wishes and welfare of patients. In the current study it was not feasible to assess the socio-economic impact, for example with a cost-effectiveness study. We also did not systematically address the social concerns, for example the extent to which we should focus on medical treatment for older patients or consider other options that may have more value to the older patients themselves.
Methodological considerations

Strengths related to the studies in this thesis

There are several strong elements for the studies included in this thesis. First, the use of the Risk Governance Framework resulted in a comprehensive overview of the risks for a vulnerable patient group from multiple perspectives. Second, multiple data sources were used to come to these findings: patient records, care provider questionnaires, interviews with patients and information from observations during the daily ward rounds. Third, we used different research methods, namely retrospective record review, structured interviews, questionnaires, observations and a randomised controlled trial. In general, assessing safety in healthcare has specific challenges both in how to define harm and how to measure it. Defining harm is often difficult because the cause and effect relation is difficult to establish; patients are generally ill when they come into the hospital which makes it challenging to separate harm due to healthcare from harm due to illness. Second, treatments in itself can be harmful for patients such as chemotherapy. Third, harm cannot always be detected immediately or it may be become apparent gradually. Fourth, if a patient is harmed it does not necessarily mean that there are shortcomings in healthcare, even with care delivered as intended a patient may get an pneumonia [14]. In addition, Pronovost provided an overview of the difficulties with measuring harm; adverse events are uncommon, definitions vary, surveillance systems for safety often rely on self-reporting, the population at-risk are often unknown and the time period for exposure is often unidentified [15]. The different methods and data sources used in this thesis have enabled us to look at safety from multiple perspectives, therefore partly addressing the issues with the cause and effect relation, the role of healthcare provision and ways to measure harm. This approach has also enriched the data, e.g. the observations during the daily ward rounds and patient interviews gave us insight into the difficulties with the use of the interventions during the RCT. Without these data, the data of the RCT would have been less informative as the only conclusion would then be that the RCT did not go as intended, but without the underlying reasons. Fourth, three different interventions were used in the RCT and the care providers in the different wards were involved in the modification of the interventions. The interventions were aimed at the care providers and patients and the interaction between them, including multiple communication moments. Even though we were unable to show changes in outcomes, the whole process has provided us with valuable information on how to further develop and implement these types of interventions. Active involvement of care professionals and long-term implementation are two lessons learned from our studies.
Limitations related to the studies in this thesis

There are also several limitations for the studies presented in this thesis. The first is related to the execution of the RCT. Despite all our efforts, the recruitment process was difficult and did not result in a sufficient number of patients. Initially, the nurses in the participating wards were supposed to include patients into the study. Soon after the start of the project, it became clear that this was not feasible which meant that the researchers had to do the inclusion themselves which took a lot of time and resulted in missing patients. Each ward was visited at least once a week, but still patients were missed. This change also meant that we were aware of the intervention group the patient was allocated to and this, potentially, could have influenced the results. Also, the loss-to-follow up was high because patients did not want to participate any longer or had deceased, which meant incomplete data on the outcome measures. Second, in retrospect, the RCT-design was perhaps not the most feasible design for these types of interventions. The RCT-design requires strict control regardless of the setting. Even though the multiple-arm RCT is a valuable and often used study design when several treatment strategies have to be tested [16,17], it can be questioned whether this is also the most appropriate design for the interventions in our study. Perhaps the uptake of the interventions would have been better if they were tailored to the specific needs and wishes of each ward, which was not possible within the current study. More pragmatic designs or randomisation at cluster level are recommended for future studies., Third, we have used retrospective record review for outcome measurement in different studies. Because of the structured and highly standardised review procedure the risk of bias is reduced, even though the risk of hindsight bias remains an important factor (knowing the outcome and its severity may influence the judgement, such as on the quality of care and preventability) [18,19]. Another issue to consider is that patient records are not always complete and therefore relevant information may be missing. Using medical records for retrospective record review also limits the results to the medical perspective, while we established that many risks are related to the whole care chain. In addition, the inter-rater agreement between the reviewers was moderate, which is a well-known problem of this research method [20-22]. Usually, retrospective record review is conducted in a two-stage process in which records are first screened by a nurse using ‘triggers’ (such as unplanned readmission) and positively screened records go through to a second review stage by a physician. In our study for older hip fracture patients we used a one-stage process in which all records were reviewed by a physician reviewer; we considered all of these patients at high risk making the first stage redundant. Although this complete review of all selected patient records is a strong point of the current study, it may have had consequences for the comparability with other retrospective record review studies; perhaps the high percentage of (preventable) AEs in
our study can be partly explained by the fact that the physicians reviewed all records. On the other hand, almost all reviewers in our study participated in the Dutch adverse events study and were therefore familiar with the methodology and outcome measurement. Finally, patients could have been involved more for the patients’ perspective on perceived risks and how they should be addressed. Due to the ageing population and the tendency to continue to live independently, the number of older patients coming into the hospital is likely to rise. Technological advances make it possible to increasingly treat medical issues, but the patients’ perspective is needed to find a balance between medical possibilities and the best option for the patient. To illustrate, recent research among a group of independently living Dutch persons of 75 years and older showed that they focus more on risks threatening their wellbeing and independent living situation than medical risks [23].

**Generalisability of the findings**

The results presented in chapter 2 showed that the incidence of AEs and preventable AEs is considerably higher in older hospitalised patients than in younger patients. Also, in chapter 6 we found that the percentages of AEs and preventable AEs in older hip fracture patients were higher than in the general population of hospitalised patients of 65 years and older. These results confirm that special attention in terms of safety is required for this patient groups and that they, in some ways, are different from the younger and general older hospital population.

Although not investigated in this thesis, some of these results are likely to also apply to other (vulnerable) patients groups undergoing surgery. For example, the importance of complete and adequate transfer of information in the patient records, but also the transfer of information during the daily ward rounds, is relevant for safety in all patients. But it is especially important in vulnerable patients since it is likely that shortcomings will sooner lead to unintended outcomes in these patients than in patients who have a less vulnerable health status.

The limited use of the patient-interventions (information leaflet for discharge and patient safety card) can be partly explained by the choice of patient group: during the contact-moments with the patients it became clear that many patients were not feeling well enough to use the instruments or that they had forgotten about them. It is possible that these interventions will be used more actively by patients of younger age or in a better health situation because they feel more up to it.
The retrospective record review study on hip fracture patients was conducted in four hospitals in the Netherlands, these include all existing hospital types (one university, two tertiary teaching, one general). Treatment for hip fractures in the Netherlands is fairly standardised, which makes it plausible that these results are of general value to improve care for this patient group. However, for the interventions (SBAR, information leaflet for discharge and patient safety card) we have seen that a uniform approach was not effective and that the local setting is important for the adaptation and implementation. Therefore, the results with these interventions have to be studied in more detail in other settings and outcomes are likely to depend on the local context.

Recommendations

Based on this thesis, several recommendations can be made for practice, policy and future research.

Recommendations for practice

Awareness of the vulnerability and potential risks for older hospitalised patients requires attention. This has already been an important topic in improvement of care for over a decade. One example is the inclusion of the theme ‘vulnerable older patients’ as part of the national safety improvement programme in the Netherlands [24]. This goal includes a screening-bundle for all clinical patients above the age of 70 years and preventing loss of function due to hospital admission. Nevertheless, other topics, such as medication related problems and patient involvement need to be further developed.

Our studies show that care for older hip fracture patients can be improved. They are at additional risk of suffering from preventable AEs and at least some of these could be prevented by further training and improving the performance of individual health care providers. Possibilities for improvement can include more training on how to deal with the specific needs of this patient group (such as the high medication use), involving other care providers (such as a geriatrician) for a comprehensive geriatric assessment of the patient and early attention and screening for specific risk factors that may negatively influence the outcomes of care.

Throughout the different studies we have seen that improvement in different forms of communication is possible and necessary. This includes the transfer of information during the daily ward rounds, but also the quality, completeness and adequacy of written information in the patient record. Several issues have been partly addressed in recent years with, for example, the introduction of electronic patient records in hospitals. The electronic patient records provides possibilities for a more standardised registration and exchange of patient information [25].
Recommendations for policy

As described above, the national safety improvement programme in the Netherlands included frail older hospitalised patients as one the focus groups. It is recommended that this policy focus on vulnerable patient groups is continued since the number of vulnerable patients is likely to increase in the upcoming years. Improvement on a national level can potentially be facilitated by setting requirements for accreditation by specific training for hospital staff in how to deal with older vulnerable patients. A second recommendation relates to recent policy changes in the Netherlands. Older people are expected to live at home longer. One of the consequences of this policy is that the proportion of older patients represented at the emergency department rises [26]. Many emergency departments have difficulties in coping with these rising numbers of older patients, resulting in longer waiting times and problems with finding a suitable place for further rehabilitation of the older patient. As far as we know, no studies have yet been published about the potential consequences of this policy change for older hip fracture patients, it can have a negative influence on the outcomes for this patient group.

A third recommendation is to uniform registration in electronic patient records because this may increase the standardisation, completeness and adequacy of important information required for safe care during the hospitalisation. In addition, facilitating safe exchange of relevant patient information between the different organisation within the care chain is recommended.

Recommendations for future research

This was, to our knowledge, the first study to use the Risk Governance Framework for a systematic investigation of the risk assessment, appraisal, judgement and management for a specific patient group in a healthcare setting. Our first recommendation for future research is that this framework should also be applied to other patient groups and in other settings to test the usefulness, especially in relation to the introduction of new risks. Examples can include new operation techniques or the introduction of new types of medication. These studies should aim to include the elements of the framework that are missing in the current study, such as a cost-analysis. It is recommended that different research methods are used to gather rich data to facilitate interpretation.

Second, it would be interesting to test the applicability of the framework on an individual patient level in which the phases are used to come to a comprehensive assessment of the patient status with a complete overview of risks and how to manage them. The wishes of the patient can then be assessed on an individual level and be leading in risk management.
Third, a more in-depth analysis of the factors that make this patient group so vulnerable to (preventable) AEs would be of added value for future improvements. The retrospective record review study has provided broad suggestions for improvement, but more insight into the causes and possibilities for improvement are needed. This should address the perspective of all stakeholders involved, including the patient.

Fourth, the implementation of the interventions did not go according to plan in the current study. In recent years, there is increasing attention for instruments such as SBAR and it has shown to lead to possible results in some studies in different settings [27-31]. However, implementation takes a lot of time and requires careful consideration of the local context, needs and preferences. Research on the improvement potential and successful methods of implementation is needed. Also, researchers should carefully consider whether the RCT-design is feasible for these types of interventions; the advantages and disadvantages of other study designs to measure the outcomes should be studied.

Finally, more research is needed on patient involvement in patient safety in general and specifically on involvement of older patients.

**CONCLUSIONS**

Overall, we can conclude that the Risk Governance Framework provides a valuable framework to systematically assess, appraise, judge and manage the risks for specific patient groups in healthcare. This thesis showed that older hospitalised patients in general, and older hip fracture patients in specific, have an increased risk of AEs and preventable AEs which means that safety of care for these patients should be improved. Effective communication is important for safe care and this is not always the case in the care process. The transfer of information during daily ward rounds is not always complete and structured and improvements can be made in the patient records as well. We tested several interventions for potential improvement of care, but had to conclude that due to methodological issues it was not feasible to draw solid conclusions from the randomised controlled trial. Therefore, other methods to study the effect of these quality and safety improvement interventions are recommended.
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