Summary
GENERAL BACKGROUND AND AIMS

Healthcare providers work in a complex high-risk environment and incidents can have serious consequences for patients. Despite the high quality of care delivered in the Netherlands, unsafe healthcare remains a source of harm for patients. Therefore, over the last fifteen years, there has been increasing attention in the Netherlands for patient safety in hospitals. Many national and local initiatives were undertaken to improve safety for patients and monitoring studies investigating the incidence of adverse events showed a decline in the preventable adverse event rate between 2004 and 2011/2012 in Dutch hospitals.

This thesis focuses on patient safety among hospitalised patients in general and older hospitalised hip fracture patients in specific. It has two aims, first, to identify risks, causes of unintended events and priorities for improvement of patient safety in older hospitalised patients and to study potential differences between hospital unit types. Second, to systematically study the risks and the effectiveness of different interventions to improve patient safety in older hospitalised hip fracture patients. The Risk Governance Framework, developed by the International Risk Governance Council was used as the framework for the second part of this thesis. The risk governance framework consists of several phases; pre-assessment, risk appraisal, tolerability and acceptability judgement, risk management and communication as a central element between all phases.

The specific objectives of this thesis were to gain knowledge and insight in:

- Assessment, appraisal and preventability of the risks on unintended events and avoidable harm for (older) patients in general and older patients with hip fractures in specific
- The potential causes underlying these risks on unintended events and avoidable harm
- Moments of sub-optimal information transfer and communication between care professionals in hospitals and between care professionals and patients/informal carers
- Risk-management by testing the effectiveness of a patient safety intervention programme to reduce avoidable harm in older hip fracture patients
Part one: Risks and causes

In chapter 2 the incidence, preventability, clinical process category, consequences and causes of adverse events (AE) are described. An AE is defined as an unintended injury among patients that results in disability, death or prolonged hospital stay, and is caused by health care management. A preventable AE is an AE resulting from an error in management due to failure to follow accepted practice at an individual or system level. Data from the first Dutch adverse events study were reanalysed to investigate whether differences exists between hospitalised patients of 65 years and older and younger patients on the previously mentioned outcomes. This study consisted of a three-stage retrospective structured, medical record review of 7,917 records of patients admitted in 21 Dutch hospitals in 2004. The results of these analyses show that AEs and preventable AEs occur significantly more often in older patients (6.9% [95% CI 5.9-8.0%] and 2.9% [95% CI 2.3-3.7%] respectively) than in younger patients (4.8% [95% CI 4.0-5.7%] and 1.8% [95% CI 1.3-2.4%] respectively). In older patients, the adverse events were more often related to medication (20.1% versus 9.6%) (p<0.01). An exploration of the causes revealed that the inability to apply existing knowledge to a new and complex situation contributes more often to the occurrence of adverse events in older patients than in younger patients (36.4% vs. 24.3%) (p<0.05). This led to the conclusion that older hospitalised patients have an increased risk on unintended outcomes and harm than younger patients. It is therefore recommended to further train hospital staff in geriatric medicine with a specific focus on medication.

Chapter 2 shows that improving safety in older hospitalised patients is important and necessary and that additional training could be one of the possibilities to achieve this. However, more detailed insight into causes that lead to patient safety incidents could provide further clues for improvement and also whether these apply in general throughout a hospital or that they may be different between unit types. In chapter 3 we further investigated this in a prospective observational study in ten emergency medicine units, ten internal medicine units and ten general surgery units in 20 hospitals in the Netherlands. In total, 2028 incidents reported by hospital staff were analysed, of which more than half had some consequences for patients such as prolonged hospital stay and longer waiting times. Differences were found between the unit types (emergency department, internal medicine, general surgery) in incidents reported. Emergency units reported more incidents related to collaboration; surgical and internal medicine units reported more incidents related to medication use. These differences between unit types indicate that looking at incidents at unit-level provides valuable and specific information which can be used for improvement.
Part two: Risk governance framework: older hip fracture patients

The second part of this thesis focuses specifically on older hip fracture patients as an exemplary group of vulnerable patients. The phases of the risk governance framework were systematically addressed for older hip fracture patients in the studies described in this section. Chapter 4 describes the outcomes of a small survey-study amongst care providers involved in the care chain for older hip fracture patients as part of the pre-assessment phase. This patient group typically consists of vulnerable patients at a higher age, they have to go through a surgical procedure and can have a difficult rehabilitation with often disappointing results. In the survey, care providers involved in this care chain, such as ward nurses, physical therapists, nursing home physicians, etc, were asked to name the main risks they perceive for this patient group within the complete care chain. In total, the survey was filled out by 55 care providers and they perceive complications such as delirium and wound infections as the main risks. In addition, risks related to the organisation of care were mentioned, including delayed operations and the unavailability of rehabilitation options for patients. These results suggest that improvements can be made within the care chain and should not only focus on care provision itself but also on the organisation of care for this vulnerable patient group.

Chapter 5 describes the design of a comprehensive study to test the effectiveness of three patient safety interventions in older hip fracture patients. The first intervention was aimed at improving communication between care providers using the SBAR (Situation, Background, Assessment, Recommendation) communication tool. The second intervention was directed at stimulating the active role of the patient within the care process with the introduction of a patient safety card. The third intervention consisted of a leaflet for patients with information on the most common complications for the period after discharge. Primary outcomes measures were the incidence of complications, AEs and preventable AEs, mortality rate within six months after discharge and functional mobility six months after discharge. Secondary outcome measures were length of hospital stay, quality and completeness of information transfer and patient satisfaction with the instruments. The aim of the study was to investigate whether these interventions would lead to an improvement of patient safety in older hip fracture patients.

In chapter 6 more detailed information was gathered on the extent to which suboptimal hospital care contributed to the often disappointing outcomes in hip fracture patients of 65 years and older. The scale, preventability, causes and prevention strategies of AEs in patients, aged 65 years and older, admitted to the hospital with a primary diagnosis of hip fracture were studied as part of the pre-assessment, risk-assessment and tolerability and acceptability phases of
the risk governance framework. A retrospective record review study of 616 hip fracture patients admitted to four different hospitals in 2007 was conducted by trained medical specialists. The results showed that 19% of the patients in this study experienced one or more AEs and 8% experienced a preventable AE. The majority of the AEs (70%) was related to the surgical procedure and 67% resulted in an intervention or additional treatment. In more than half of the AEs human causes were involved, followed by patient factors (40%). These high percentages of AEs and preventable AEs show that care for older hospitalised hip fracture patients can be improved. More training and quality assurance were suggested strategies to improve the outcomes in this vulnerable patient group.

As part of the risk-assessment and appraisal and communication phases of the risk governance framework we conducted an in-depth analysis on the written communication between care providers available in patient records. In chapter 7 the data of the retrospective record review study of 616 hip fracture patients were analysed to establish the quality of the patient record and the adequacy of written handover information and whether these are related to the occurrence of complications, AEs and preventable AEs. Completeness of the information available in the patient record was assessed by the reviewers using the I PASS the BATON structure (Introduction, Patient, Assessment, Situation, Safety concerns, Background, Actions, Timing, Ownership, Next). Complications (p<0.05) and AEs (p<0.001) were found significantly more often in patient records with a low grade for the quality, but there was no significant association for preventable AEs. For the different handover moments, the I PASS the BATON structure was often incomplete. However, there was no significant association between the number of adequately registered I PASS the BATON-elements and the occurrence of complications, AEs and preventable AEs. This study showed that improvement of the quality of the patient record is necessary for hip fracture patients of 65 years and older.

After establishing in the previous chapters that improvements in patient safety are necessary for older hip fracture patients, the final two studies in this thesis are conducted to test whether three patient safety interventions (SBAR, information leaflet and patient safety card) are effective in reaching this goal. This is part of the risk management phase within the risk governance framework. Chapter 8 describes the implementation of the SBAR-tool and aims to evaluate potential changes in the completeness and structure of information transfer between nurses and physicians during daily ward rounds. The SBAR-tool was adjusted for use on each of three participating surgical wards in Dutch hospitals. To measure the transfer of information between nurses and physicians during the daily ward rounds an observation protocol was developed. Monthly observations were conducted on each of three wards from September 2008
until September 2009. In total, 43 daily ward rounds were observed in which 729 general surgical patients were discussed by the care providers participating in the rounds. The rounds were usually led by physicians and the role of the nurses was relatively limited. The observations showed substantial variation between wards in the time to discuss a patient and the tasks performed during the rounds. Using the SBAR-structure, the Situation was discussed for 86.9% of the patients, the Background for 77.0%, the Safety Concerns as part of the Assessment for 77.6% and the Recommendations/actions for 87.2% of the patients. The specific timeframe for a required action was addressed for 33.7% of patients and for 5.7% actions were reported back for confirmation. These results led to the conclusion that many of the SBAR-items were often included in the patient discussions during the daily ward rounds, except for timing and confirmation of required actions. Inclusion of these items is important for a complete verbal handover of information, but changing the usual way in which daily ward rounds are conducted requires more than only introducing a tool such as SBAR. Active involvement of the nurses and physicians of the wards during this process is recommended.

In chapter 9 the outcomes of the randomised controlled trial to test the effectiveness of SBAR, the information leaflet for patients and the patient safety card are described. A total of 188 hip fracture patients of 65 years and older were included into the four interventions groups (only SBAR, SBAR + patient safety card, SBAR + patient information leaflet, SBAR + patient safety card + patient information leaflet). The control group consisted of 107 patients. Three Dutch hospitals participated in the intervention study, another hospital provided the control patients. Inclusion took place between July 2008 and September 2009, follow-up ended in April 2010. Because of the insufficient number of patients included in the trial, the high-loss to follow-up, problems with the randomisation procedure, unintended exposure to the interventions and the limited use of the interventions, the outcomes of the trial should be interpreted with caution. It was therefore not possible to draw conclusions about the effectiveness of the three interventions, although the exploratory analyses showed no significant differences on the primary and secondary outcome measures. Despite the careful preparation and testing before the start of the trial, practical issues prevented a methodologically sufficient outcome. For future studies it is recommended to use more pragmatic designs to test these types of patient safety interventions aimed at improving communication or to randomise on cluster level instead of the individual patient level. Also, the trial should be preceded by an elaborate feasibility study.
GENERAL DISCUSSION

This thesis shows that many risks, incidents and causes can be identified for the general (older) hospital population and for hip fracture patients of 65 years and older in specific. To improve patient safety it is important to not only address this at the hospital level, but to also focus on specific patient groups and hospital units because risks, incidents and underlying causes are likely to differ. Another conclusion is that hip fracture patients of 65 years and older are a vulnerable patient group at increased risk for AEs and preventable AEs, contributing to patient harm and poor outcomes. The risk governance framework of the International Risk Governance provided valuable guidance to systematically identify risks and to test interventions to potentially manage these risks. When using the different phases of the framework, it results in a broad overview of risks from multiple perspectives, the confirmation of the importance of communication between all those involved and guidance in how to approach the risk management. However, the risk governance framework is often used when considering the introduction of new technologies or activities that may come with substantial risks and impact whereas we focused on usual practice in a fairly standardised care chain. Also, it is difficult to come to a conclusion on the tolerability and acceptability of the risks uncovered in our study. From a patient perspective, these are all unacceptable since they may result in patient harm. However, it is impossible to create a risk-free environment, incidents will always occur.

The general discussion of this thesis ends with some recommendations. First, for practice we recommend to increase awareness on the vulnerability and potential risks for older hospitalised patients. Also, elements of care for older hip fracture patients can be improved to improve outcomes, such as improvement in the different forms of verbal and written communication between care providers.

For policy, we recommend the continuation of the focus on improving patient safety in hospitals. It is also recommended to address the issues that arise due to the policy changes in long term care: when older people are expected to live at home longer, this will have consequences for acute health care organisation; the proportion of older people presented at the emergency department will rise and many of them will be admitted to the hospital. Finally, it is recommended that uniform registration in electronic patient records is facilitated and supported because this may increase the standardisation, completeness and adequacy of important information required for safe care during hospitalisation. In addition, steps should be made to facilitate safe exchange of relevant information between care organisations within the care chain.
For future research we recommend to test the applicability of the risk governance framework in other patient groups and settings, such as the introduction of new operation techniques. It would also be interesting to test the framework on an individual patient level to come to a comprehensive assessment of risks and how to manage them in a specific case. When looking at older hip fracture patients, additional investigation into the factors that make this patient group vulnerable and at high risk of (preventable) AEs is recommended. Also, careful consideration and investigation of appropriate research designs to test patient safety interventions could advance patient safety research. And finally, more research is needed on patient involvement in patient safety in general and on involvement of older and vulnerable patients in specific.