Chapter 1:
Introduction
This thesis focuses on patient safety in older hospitalised patients and has two main 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 hip fracture patients. This patient group was chosen as an exemplary group for vulnerable hospital patients undergoing a surgical procedure and rehabilitation process. This first chapter provides a brief overview of the field of patient safety (research) in general and the developments in patient safety over the last fifteen years in Dutch hospitals. Furthermore, this chapter includes a description of the Risk Governance Framework and how it is used as an overall framework for the studies described in this thesis.

PATIENT SAFETY AND DEFINITIONS

Attention for patient safety in hospitals was raised with the publication of the report ‘To err is human: building a safer health system’ by the Institute of Medicine in the United States of America (USA) in 1999 [1]. This report claimed that between 44,000-98,000 patients in the US alone died each year as a result of medical error and raised awareness that action should be taken to improve patient safety. The World Health Organization (WHO) describes patient safety as “the prevention of errors and adverse effects to patients associated with health care” [2]. In this thesis we use the following definition of patient safety: “the (virtual) lack of (any risk of) injury to the patient as a result of actions of health care workers which are not according to the professional standard and/or by shortcomings of the care system” [3].

One of the most accepted methods to gain insight into the level of patient harm in hospitals is the use of retrospective record review studies [4]. For these studies, a standardised methodology and review form are used by trained reviewers to examine patient records on the occurrence of adverse events (AEs). An AE can be defined as an unintended injury that results in temporary or permanent disability, death or prolonged hospital stay, and is caused by healthcare management rather than by the patient’s underlying disease process [5]. A review by De Vries et al. showed that for Western countries in general, a mean overall incidence of AEs in hospitals was 9.2%, of which almost half were classified as preventable [6]. A preventable AE can be defined as an AE that results from an error in management due to failure to follow accepted practice at an individual or system level. Accepted practice is ‘the current level of expected performance for the average practitioner or system that manages the condition in question’ [7]. Preventable AEs are of specific interest for patient safety because this is where improvements can be made to prevent them in the future. A common first step to investigate patient safety is therefore to study the incidence, causes and preventability of AEs in a country.
DEVELOPMENT OF PATIENT SAFETY IN THE NETHERLANDS

In the Netherlands, there has been increasing attention for patient safety over the last fifteen years. One of the first initiatives was the ‘Sneller Beter’ programme [in English: ‘Better Faster’] launched in 2003. Sneller Beter consisted of three main pillars: 1) create awareness for safety, 2) develop indicators for safer and better care and 3) an improvement programme on quality, innovation and effectiveness. One of the first important products of Sneller Beter was a report by Rein Willems in 2004 [8]. As the president of Shell Holland at the time, he was asked to use his safety knowledge and experience from the high-risk petrochemical industry to assess safety in Dutch hospitals and how this was embedded on a management level. After visiting several hospitals, he concluded that there was a lack of safety management in hospitals. He therefore recommended that all hospitals should implement a safety management system, including risk-inventory, incident reporting and analyses and a management system to plan and monitor improvement initiatives [8].

As mentioned before, the third pillar of Sneller Beter was a large-scale improvement programme with projects in 20% of Dutch hospitals to achieve improvements for patients and healthcare professionals. The hospitals participating in this pillar received external support and guidance to apply improvement techniques such as working with breakthrough collaboratives and process redesign. The improvement projects mainly focused on logistics and safety, but overarching themes such as leadership and patient participation were also included. The process-evaluation of the overall Sneller Beter programme and the specific evaluation of the third pillar showed that many of the improvement goals were not reached within the time frame of the programme [9]. Contributing factors for these outcomes included the ambitious goals of the programme, a perceived increase of undesirable outcomes because of improved registration, the limited possibilities to copy practices into other local settings and the lack of data for the evaluation of the programme. On the other hand, Sneller Beter did show positive outcomes, such as increased awareness for quality and safety, the increasing number of improvement projects and the possibility for shared learning between hospitals and disciplines [10].

A second landmark within the Dutch patient safety development was the publication of the results of the first Dutch Adverse Events Study [11]. In this study, retrospective record review of almost 8000 patient records in 21 Dutch hospitals was used to get insight into the level of patient harm. Zegers et al. showed that one or more AEs were found in 5.7% of all Dutch hospital admissions in 2004, and preventable AEs occurred in 2.3% of admissions [12]. In-depth analyses showed an increase in the proportion of AEs, preventable AEs
and degree of disability with age. More than half of all AEs and over one-third of preventable AEs were related to surgical procedures. The extrapolation of the results to a national level showed that between 1482 and 2032 potentially preventable deaths occurred in Dutch hospitals in this year.

The publication of these findings led to a discussion on patient safety in hospitals on multiple levels, which resulted in a prominent place for patient safety on the policy agenda. As a next step, a nationwide improvement programme was developed, another landmark in the Dutch patient safety development. This programme, called the VMS Safety Programme, included the implementation of a safety management system in each hospital as well as improvement on ten specific high risk themes, such as care for frail older patients [13]. The safety management system is a tool to monitor and continuously improve on quality and safety by systematically reducing reported risks and deficiencies. This safety management system is now required by national standard and should be functional in each hospital since 2012. It includes several general elements such as creating risk awareness among employees, participation of patients, retrospective and prospective risk analyses and continuous improvement. The second element of the VMS Safety Programme, the selection of the specific high risk themes for improvement, was based on the outcomes of the Dutch Adverse Events Study [11]. It included themes such as care for frail older patients, medication verification at admission and discharge and early detection and treatment of pain. The VMS Safety Programme was evaluated in 2013 [14]. Results showed that the implementation of the ten themes was improved but substantial differences were found between hospital departments in the extent to which they adhered to the guidelines within the themes. The experienced complexity of a theme influenced the level of implementation and adapted care to specific patients made a 100% adherence not desirable. Insight into results on the themes and providing feedback on performance were considered essential for the implementation of a theme. Since the start of the VMS Safety Programme, two more retrospective record review studies have been conducted to monitor the changes in AE rates in Dutch hospitals. The results of these studies showed a reduction of 45% in the crude, and 30% in the corrected preventable AE rate from 2007 to 2011/2012 [15]. Also, the data showed a substantial decrease in the incidence of preventable AEs over time in older patients, especially patients of 80 years and older [16].

**RISK MANAGEMENT IN HOSPITAL CARE**

Healthcare providers work in a complex environment and incidents can have serious consequences for patients. Therefore, another important step to improve patient safety is to take a step back in the processes and to look at the risks within the environment and the causes that may lead to undesired
outcomes. Several models explaining the causation of incidents have been developed, such as the well-known accident-causation model of Reason [17]. The idea behind this model is that there are multiple layers of defences to prevent a failure from resulting in an actual incident with potentially negative consequences. Many work processes in healthcare nowadays have built-in defences, such as a medication double check. These barriers aim to prevent that failures will reach the patient. However, these barriers too can fail and under specific circumstances the weaknesses in the defences of all layers align, which makes that failures actually reach the patient and can result in patient harm.

Figure 1: IRGC’s Risk Governance Framework [18,19]
To further improve patient safety, additional information on risks and harmful outcomes in healthcare is needed to strengthen the barriers. An integrated approach and broad focus on risk management may be beneficial to achieve this. This overall approach has been applied previously in other high-risk industries, such as the petrochemical industry, in which organisations are deliberately and prospectively managing risks. This approach implies that there has to be a common understanding of risks and a sense of urgency based on knowledge about the nature and scale of the consequences. One of the frameworks used in industry which may also be applicable to healthcare is the Risk Governance Framework developed by the International Risk Governance Council, see figure 1 [18,19].

**RISK GOVERNANCE FRAMEWORK [18,19]**

The Risk Governance Framework was developed by the International Risk Governance Council (IRGC) to explain the concept of risk governance for application by policy makers, regulators and risk managers [18,19]. The IRGC 2005 White Paper ‘Risk Governance – Towards an Integrative Approach’ describes this model in detail and provides practical guidance on how to analyse and cope with risks. The framework includes definitions relevant for the research described in this thesis and the interpretation of the results [18, page 4]. A risk refers to “an uncertain (generally adverse) consequence of an event or activity with respect to something that human beings value. Risks are often taken for opportunities associated with initiating activities or applying technologies”. Governance “refers to the actions, processes, traditions and institutions by which authority is exercised and collective decisions are taken and implemented”. The combination of these concepts leads to the term risk governance which “deals with the identification, assessment, management, evaluation and communication of risks in the context of plural values and distributed authority. It includes the totality of actors, rules, conventions, processes and mechanisms and is concerned with how relevant risk information is collected, analysed and communicated, and how management decisions are taken. […]” [18, page 4]. Risk governance has an important role within the Risk Governance Framework because, according to the IRGC, it is needed to minimise negative consequences of risks while new opportunities are introduced and used.

IRGC’s Risk Governance Framework comprises of five closely linked phases and can be used in situations where there is the potential for deficits in risk governance structure and processes. It helps to understand, analyse and manage important risk issues. The framework takes into account the societal context of both the risk and decision, in addition to the standard elements of risk handling, risk assessment, management and communication.
The five phases of the framework are the following:

The **pre-assessment** phase includes ‘early warning and framing’ of the risk to come to a structured definition of the problem and insight into potential ways to handle it. This means that the different perspectives of the stakeholders on a risk need to be clarified and that the issues that should be looked at are defined. The pre-assessment forms the baseline for the assessment and management of the risk.

The goal of the **risk appraisal** phase is to develop and synthesise the knowledge base to decide whether a risk should be taken and which options are available for the avoidance, mitigation, reduction or handling of the risk. It includes a scientific risk assessment and concern assessment. The scientific risk assessment is about the factual, physical and measurable characteristics of the risk. This also includes the probability of occurrence. The concern assessment includes an analysis of the associations and perceived consequences as seen by different stakeholders.

In addition to the scientific evidence, other important factors should be taken into account for the evaluation of risks, these can be societal values, economic interests and political considerations. These factors are considered in the **tolerability and acceptability judgement** phase. Eventually, the evaluation of a risk should include the acceptability (risk reduction can be considered unnecessary) and (in)tolerability (should the risk be pursued with appropriate risk reduction measures because of its benefits or avoided).

The fourth phase, **risk management** involves “the design and implementation of the actions and remedies required to avoid, reduce, transfer or retain the risks” [18, page 18]. It includes several elements, namely the generation, assessment, evaluation and selection of appropriate risk-reduction options. But also the implementation of the selected measures, monitoring of the effectiveness and if needed, decision reviewing.

Finally, **communication** is important throughout the Framework; effective internal and external communication is an essential prerequisite for trust in risk management. After making a risk management decision, the rationale should be clearly explained to the stakeholders so they are able to make informed choices about the risk and the risk management.

In this thesis, the Risk Governance Framework is used to systematically investigate the risks related to hospital care for a specific patient group. This Framework was chosen for this purpose because it provides a systematic approach to risks and has shown added value in other high-risk industries.
In this thesis, we focus on (older) hospitalised patients in general to uncover the general risks and their causes and investigate the differences in root causes of incidents between hospital departments. In addition, older hip fracture patients were chosen as an exemplary vulnerable patient group to systematically investigate the risks in a subpopulation. Also, this population was used to study the effectiveness of potential strategies for improvement of patient safety.

There are several reasons for the focus on older hip fracture patients as an exemplary vulnerable patient group. First, hip fracture patients are usually of high age and studies have shown an increase with age for the proportion of AEs, preventable AEs and degree of disability as a consequence of the (preventable) AE [12,20]. Second, the population in the Netherlands is ageing which means that there will be more older patients and these older patients will also live longer [21]. This means that the group of patients being exposed to a relatively high risk of AEs will increase as well. Third, older patients often suffer from multimorbidity; they have more than one disease or condition and often use a lot of medication, this further complicates treatment. Fourth, more than half of the AEs in the Dutch AE study was related to surgical procedures, which means that patients who undergo surgery, such as older hip fracture patients, are at risk of suffering from AEs when all these factors are combined. In addition to the surgical procedure itself, these patients have to go through a care process in which many different care providers are involved. Many patients with a hip fracture have a variety of medical comorbidities, they usually undergo operative repair of the fracture and face a long rehabilitation process. Unfortunately, the outcomes of this whole care process are disappointing for many patients. There is an increased likelihood of morbidity, disability and mortality [22,23]. Also, a negative effect of hip fractures on health-related quality of life and activities of daily living has been shown [24].
OUTLINE OF THIS THESIS AND RESEARCH QUESTIONS

The first part of this thesis describes two studies relevant for the pre-assessment phase of Risk Governance and they are conducted among a general (older) hospital population. More specifically, the overall objective addressed in part one is to provide an overview of the risks and their causes for patient safety in a general (older) hospitalised patient population. This part also focuses on the root cause profile for incidents and whether these differ between types of hospital departments. In the second part of this thesis the phases of the Risk Governance Framework are systematically used to study the risks, causes and possibilities for risk-reduction in hospitalised hip fracture patients of 65 years and older. More specifically, the overall objectives of this thesis are 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
Chapter 1

Part one: Risks and causes

Chapter two

To establish the risk of (preventable) adverse events in older hospitalised patients in the Netherlands, we performed secondary data analyses on the first Dutch Adverse Events Study. The aim is to answer the following research question:

1. What are the differences in scale, nature, causes and preventability of AEs in hospitalised patients of 65 years and older compared with younger patients?

Chapter three

An incident-reporting study was conducted to get insight into the types of incidents and their root-causes in different hospital departments to establish whether surgical patients are exposed to specific risks when compared to incidents occurring at internal medicine and emergency departments. In chapter three the following research questions are addressed:

2. A: What is the number of incidents reported in emergency medicine, surgery and internal medicine?
   B: What are the types of incidents, consequences for patients and root causes of reported incidents at unit level?
   C: Are there differences in types and causes of incidents between types of units?
Part two: risks and interventions for older hip fracture patients

Chapter four

The second part of this thesis focuses specifically on older hip fracture patients. The phases of the Risk Governance Framework were systematically addressed during this in-depth study. In chapter four the focus is on the **pre-assessment** in relation to this specific patient group. It provides an overview of the specific risks for this patient group as perceived by the stakeholders involved in the care chain. The following research question is addressed in chapter four:

3. How do different stakeholders perceive the risks in the care chain for older hip fracture patients?

Chapter five

In chapter five the design of a comprehensive study on risks in older hip fracture patients is described. This study includes a comprehensive integrated intervention programme to improve patient safety in older hip fracture patients using the Risk Governance Framework.

Chapter six

The phase after pre-assessment is **risk appraisal** in which risk and concern assessment are important elements. Insight into these elements is necessary for the evaluation and characterisation of the risks (**tolerability and acceptability judgement**). A retrospective record review study was conducted to provide a quantitative overview of the risks and adverse outcomes in older hip fracture patients. The following research question is addressed with this study:

4. What is the scale, nature, preventability and causation of AEs amongst older hip fracture patients?
**Chapter seven**

In addition to the goal of a general risk overview, the data of the retrospective record review study were used to look at the relationship between the quality and adequacy of the medical records in relation to unintended outcomes for this patient group. The medical record is an important element of written communication between care providers. In addition to the risk appraisal phase of the Risk Governance Framework, chapter seven therefore addresses the communication between care providers in relation to the risks for older hip fracture patients. Communication is the central element between all phases within the Risk Governance Framework. The following research question is answered in chapter seven:

5. Are the general quality and adequacy of the medical record related to the occurrence of complications, AEs and preventable AEs?

**Chapter eight**

For the risk management phase, an integrated intervention programme was designed for implementation in hospital wards. The idea behind this intervention programme was that improved communication between the care providers and with the patient/informal carer can potentially prevent unintended harm. Three interventions were implemented as part of this study: the SBAR-communication tool [25] a patient leaflet with information for the period after discharge and a patient safety card [26]. The interventions are described in more detail in following chapters of this thesis. There were two central research questions during this phase. The first was aimed at following the process and potential changes between nurses and (ward) physicians after the introduction of the SBAR in the wards. This study involved the nurses and physicians working on the surgical wards and the focus was therefore broader than just the patients admitted with a hip fracture.

6. Does the introduction of the SBAR-communication tool lead to a more complete discussion of relevant patient status information between the nurse and physician during the morning rounds on surgical wards?
**Chapter nine**

The research questions for the integrated intervention programme (*risk management phase*) were limited to older hip fracture patients and are answered in chapter nine:

7. How is it, in the total care chain for older hip fracture patients, possible to reduce risks and unintended arm, and to ensure that complex care processes proceed more safely? This research question was divided into three sub-questions for the separate interventions:

   a. What is the effectiveness of the SBAR communication tool on unintended events and avoidable harm during hospital stay? (Intervention A)

   b. What is the effectiveness of a patient safety card with guidelines for patients and their families on signalling errors and patient trust in health care? (Intervention B)

   c. What is the effectiveness of a discharge information leaflet for patients which includes evidence based information on the most common complications and contact details for the period after discharge? (Intervention C)

Table 1 provides an overview of how the different phases of the Risk Governance Framework were included in this thesis, the study goals, study populations, data and outcome measures of each study.
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<th>Ch.</th>
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<td>Pre-assessment (problem framing)</td>
<td>To compare the incidence, preventability, clinical process category and causes of (preventable) AEs between younger and older (65 years and older) hospitalised patients.</td>
<td>Hospitalised patients (18 years and older).</td>
<td>Secondary analysis of reviewed records of 7917 patients from the first Dutch adverse events study (retrospective record review)</td>
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<td>3</td>
<td>Pre-assessment (problem framing)</td>
<td>To establish the variation in unit based reporting between emergency medicine, surgery and internal medicine in types of incidents and their root-causes.</td>
<td>Incidents reported by hospital staff.</td>
<td>2028 patient safety incidents and their root-cause analysis: - 522 incidents emergency medicine - 881 incidents surgery - 625 incidents internal medicine</td>
<td>Incidence, types and root-causes of reported incidents.</td>
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<td>4</td>
<td>Pre-assessment</td>
<td>To provide an overview of the perceived risks in the care chain for older hip fracture patients.</td>
<td>Stakeholders involved in the care process for older hip fracture patients.</td>
<td>Survey among nurses (n=30), general practitioners (n=6), nursing home physicians (n=5), physical therapists (n=8), nursing home attendants (n=3), dietician (n=1) and paramedics (n=2)</td>
<td>Risks identified for the following phases in the care chain: -transfer to the hospital -admission and pre-operative -operation -post-operative -discharge -rehabilitation</td>
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<td>5</td>
<td>Design</td>
<td>Design of a randomised controlled trial with three interventions aimed at improving patient safety for older hip fracture patients by implementing three interventions to improve communication and transfer of information.</td>
<td>Hospitalised hip fracture patients of 65 years and older.</td>
<td>Proposed data collection: - Admission information/questionnaires - Telephone follow-up interviews - Retrospective record review</td>
<td>Primary outcome measures: incidence of complications, AEs, preventable AEs and functional mobility six months after discharge. Secondary outcome measures: length of hospital stay, quality and completeness of the patient record and patient use and satisfaction with the instruments.</td>
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### Table 1: Continued

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<td>6</td>
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<td>To provide insight into the scale, preventability, causes and prevention strategies of AEs in patients of 65 years and older who are admitted to the hospital with a primary diagnosis of hip fracture.</td>
<td>Hospitalised hip fracture patients of 65 years and older.</td>
<td>Retrospective review of 616 records of hip fracture patient admitted to four Dutch hospitals in 2007.</td>
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<td>7</td>
<td>Risk-assessment and appraisal and Communication</td>
<td>To establish if the quality of the patient record and the adequacy of written handover information are related to the occurrence of complications, AEs and preventable AEs.</td>
<td>Hospitalised hip fracture patients of 65 years and older.</td>
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<td>Graded quality of patient record. Number of adequately registered items in the patient record in general and for specific handover moments using the I PASS the BATON structure. Complication, AEs and preventable AEs.</td>
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<td>To evaluate the completeness and structure of the information transfer between nurses and physicians during the daily ward rounds after the introduction of the SBAR-communication tool in three surgical wards in Dutch hospitals.</td>
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<td>9</td>
<td>Risk management</td>
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<td>188 hip fracture patients of 65 years and older in the intervention groups and 107 patients in the control group.</td>
<td>Randomised Controlled Trial. Retrospective record review study of included patients in intervention and control groups. Questionnaires and telephone interviews with patients in intervention groups.</td>
<td>Primary outcome measures: incidence of complications, AEs, preventable AEs and functional mobility six months after discharge. Secondary outcome measures: length of hospital stay, quality and completeness of the patient record and patient use and satisfaction with the instruments.</td>
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18. IRGC (2012). An Introduction to the IRCG Risk Governance Framework. IRGC, Lausanne. EN


