Chapter 1

Introduction, research questions and methodology
Medical residents are key figures in delivering care and an important target group for patient safety education. The studies described in this thesis primarily focus on the development and the effects of patient safety education for residents. Moreover, insight is provided into the factors influencing residents’ participation in patient safety improvement.

This introductory chapter provides an overview of the background of patient safety research and patient safety education with a national and an international character. The research questions and methodology of this thesis are also outlined in this chapter. The following themes are successively addressed in this chapter: growing attention for patient safety; occurrence of errors; definition of patient safety education; role of residents in health care; patient safety and curricular reformations; theoretic framework of thesis; scope of thesis; study design; and outline of thesis.

1.1 Growing attention for patient safety

Adverse events in health care have been the subject of numerous studies over the past ten years. Since the report “To err is human” was published in 2000, there has been a remarkable increase in attention for patient safety research. This report by the Institute of Medicine (IOM) demonstrated that in American hospitals 44,000 to 98,000 patients die each year as a result of medical errors. This means that in the United States of America (USA) medical errors cause more deaths than motor vehicle accidents, breast cancer, or AIDS. In the years following, the extent of adverse events in hospitals was investigated in many other countries. In 2008, de Vries et al. published a systematic review assessing the overall incidence of in-hospital adverse events in the developed world. Eight patient record review studies were included in this review, representing a total of almost 75,000 patient records. De Vries et al. found that the median overall incidence of in-hospital adverse events was 9.2%. Of these events, 7.4% were lethal and 43.5% were preventable. Since the extent of harm due to adverse events became visible and the gravity of the problem was recognized, the need to improve patient safety has been expressed in policy plans in many countries. In line with the increased sense of urgency, institutes were formed in many countries to lead, support and monitor patient safety improvements, for example the National Patient Safety Foundation (NPSF) in the USA, the National Patient Safety Agency (NPSA) in England and Wales and the Australian Patient Safety Foundation (APSF).

In the Netherlands, patient safety has become an important issue as well. At the request of the Dutch ministry of Health, the chief executive officer (CEO) of Royal Dutch Shell presented a report in 2004 with advice about risk management for Dutch hospitals. This report was based on the petrochemical industry’s many years of experience with safety management, adjusted to the health care setting. One of the recommendations in this report was to implement a certified patient safety management system (VMS, veiligheidsmanagement systeem) in all Dutch hospitals before January 2008. This system includes risk-analysis, a system for blame-free event reporting, analysis of events and a management system to plan and monitor interventions to enhance patient safety. In line with this recommendation, the VMS safety program has been initiated by the Dutch Hospitals Association (NVZ, Nederlandse Vereniging van Ziekenhuizen), the Dutch...
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Federation for University Medical Centers (NFU, Nederlandse Federatie voor Universitair medische centra), the Dutch Society of Medical Specialists (OMS, Orde van Medisch Specialisten), the Netherlands Centre of Excellence in Nursing (LEVV, Landelijk Expertisecentrum Verpleging & Verzorging) and the Netherlands Nurses and Carers (V&VN, Verpleegkundigen & Verzorgenden Nederland). Ninety-three Dutch hospitals are implementing this program, which aims at a 50% reduction of preventable harm in hospital care. In addition, the Advisory Council on Health Research (RGO, Raad voor Gezondheidsonderzoek) advised the ministry on the need for patient safety research in Dutch hospitals. In 2005 a large research program was started, initiated by the Dutch Society of Medical Specialists (OMS, Orde van Medisch Specialisten), to gain more insight into the incidence, nature, impact, preventability and costs of adverse events and near misses.

1.2 Occurrence of errors

The human error problem can be viewed in two ways: 1] the person approach; and 2] the system approach. The long-standing person approach is widely used and focuses on the unsafe acts of people at the ‘sharp end’: for example nurses, physicians, surgeons, anesthetists and pharmacists. The person approach focuses on the errors of individuals, blaming them for forgetfulness, inattention, or moral weakness. The system approach conversely recognizes that humans are fallible and that errors are to be expected. It concentrates on the conditions under which individuals work, and tries to build defenses to avert errors or mitigate their effects. An error is seen as a consequence rather than a cause, having its origin not so much in the human nature, but rather in systemic factors. These include recurrent error traps in the workplace, as well as the organizational processes that cause them.

To explain the causation of accidents from the point of view of the systems approach, Reason’s Swiss Cheese Model is often cited (figure 1). This model demonstrates that there often are weaknesses in a process. These weaknesses may be related to active or latent conditions. Latent conditions are created by the delayed consequences of technical and organizational actions and decisions. They arise from decisions made by designers, builders, procedure writers and top-level management. All such strategic decisions have the potential for introducing pathogens into the system. Active failures, on the other hand, occur at the level of the frontline providers, ‘the sharp end’, and they have immediate consequences. They may be action slips or failures (e.g. picking the wrong medicine), cognitive lapses or mistakes (e.g. forgetting to carry out a procedure) or violations involving deliberate departures from safe operating practices, procedures or standards.

In the Swiss Cheese Model, the weaknesses of a process are visualized by holes in different slices of cheese. In reality, however, these holes are continually opening, shutting, and shifting their location. Usually, accidents only happen when holes in many layers momentarily line up to permit a trajectory of accident opportunity. The presence of holes in just one slice normally does not cause an adverse outcome, because high technology systems have many defensive layers (the layers of cheese) that protect potential victims and assets from local hazards. Some defenses are engineered (alarms, physical barriers,
etc), others rely on people (surgeons, anesthetists, etc), and others yet again depend on procedures and administrative controls. Education is also considered to be a defensive layer, as it can contribute to increased awareness, knowledge and skills in order to promote safety behavior. Among the challenges involved in achieving tangible improvements in patient safety, integrating this subject matter into medical education is considered of great importance.

**Figure 1. Swiss Cheese Model, Reason (1995)**

*This figure was adapted from the Dutch report “Here you work safely, or you don’t work here. Better faster - safety in health care” (in Dutch: “Hier werk je veilig of je werkt hier niet. Sneller beter - de veiligheid in de zorg”) by Rein Willems, executive officer at the Royal Dutch Shell (2004).

**1.3 Definition of patient safety education**

Patient safety education focuses on the acquisition of knowledge, attitudes and skills to support changes in behavior to deliver safer care. A major part of the patient safety principles involve non-technical skills and therefore are not necessarily discipline-specific. In this section, three major patient safety educational topics are explained in more detail: 1] reporting of incidents; 2] human factors engineering; and 3] information transfer between health care workers and towards patients.

1] Voluntary and non-punitive reporting of unintended or unexpected events which might or did lead to harm for one or more patients can be a valuable method to gain insight into the occurrence and causes of incidents and to identify risk factors which should be acted upon to improve safety. Systems for reporting incidents have demonstrated their usefulness in other high-risk sectors, such as aviation and petrochemical industry, where they resulted in measurably safer processes. There are three principal conditions for creating an effective reporting system: 1) health care workers must be aware of the importance of reporting incidents; 2) they need to know how to report an incident; and 3) they must be able to recognize risky situations. Education is perceived as a major incentive
to meet these conditions and to achieve an active reporting culture, which may contribute to a reduction of risks in patient care.\textsuperscript{23,27-30} In this thesis, we pay special attention to the education of residents concerning incident reporting and analysis.

2] The need to understand basic error science and human factors science and their applications deserves particular mention. It is considered important to learn about the interactions between systems, individuals and their environments, as this provides insight into cognitive dissonance, human fallibility and the importance of being humble. A basic understanding of human factors theory should, for example, explain the significant effects of sleep deprivation and fatigue in the generation of errors.\textsuperscript{21}

3] Communication failure is an important underlying cause of adverse events.\textsuperscript{31,32} Communication failures occur in many forms: failure to recognize language or health literacy barriers to patient/family understanding, failure to read back verbal orders, failure to transmit important patient information when handing a patient over to the care of another physician, untimely reporting of critical test results, and inappropriate use of abbreviations in writing patient records. Communication skills are also often found wanting when physicians need to talk with a patient or a patient’s family following a preventable adverse event.\textsuperscript{33} Most patients and patient families want an acknowledgement that a preventable adverse event occurred, a commitment to thoroughly investigate what happened, a commitment to take appropriate steps to prevent future occurrences, and an apology. That, however, may prove to be difficult for a physician lacking specific training in the development of communication skills, especially those relating to apology.\textsuperscript{21}

1.4 Role of residents in health care

The term ‘residents’ or ‘registrars’ in this context refers to medical graduates: physicians who finished medical school and who may or may not be in training to become a medical specialist. In the Netherlands, residents who are in training to become a medical specialist are allied to one of the eight Dutch academic medical centers. During their training they work in the academic setting and have multiple residencies at other teaching hospitals. For several reasons residents are a particularly important target group for education on patient safety principles. Firstly, residents provide much of the direct patient care. Secondly, they are considered a fragile link in the care process; research has revealed that a lack of working experience and high work-pressure among residents increases hazardous situations.\textsuperscript{30,34} Thirdly, research showed that medical trainees across a broad range of training levels, degrees and specialties had a limited knowledge of patient safety,\textsuperscript{27} and that physicians in general have a relatively low incident reporting rate.\textsuperscript{35} A final argument for training residents in patient safety is that they are considered to be a group which can contribute long-lasting benefits, as these physicians are at the beginning of their career and they are the specialists of the future.

1.5 Patient safety and curricular reformations

Soon after the extent of harm due to adverse events became visible, the lack of attention for patient safety principles in medical education was acknowledged as well. In response, the need for integrating patient safety principles into medical education was expressed.\textsuperscript{21,36-38} Around the start of the new millennium, major reforms were set in motion
to improve medical specialist training. A review by Teunissen (2009) of initiatives in the United Kingdom (UK), the USA, Canada, Denmark and the Netherlands showed that a shift towards learner-centered, competency-based education driven by desired outcomes of learning was promoted.

An increased attention for patient safety can also be distinguished in the frameworks which describe the competencies a physician should have. Several frameworks have been developed, which can be used for the development and assessment of medical curricula. In this section, two of these frameworks are explained in greater detail: 1] the Canadian Medical Educational Directives for Specialists (CanMEDS); and 2] the United States Accreditation Council on Graduate Medical Education (ACGME).

The CanMEDS of the Royal College of Physicians and Surgeons of Canada (RCPSC) distinguishes seven roles at which a physician must be competent to become a good doctor: 1] communicator; 2] collaborator; 3] manager; 4] health advocate; 5] scholar; 6] professional; and 7] medical expert, which unites the first six competencies. Each of these roles is made up of specific elements and can be broken down into smaller components for teaching, learning, observation, interaction and assessment. A selection of these elements is explicitly related to specific safety improvement skills, as is demonstrated in table 1. These roles and elements are not specialty-specific and they should preferably be taught in multi-disciplinary groups, as this is expected to enhance the learning process.

In the USA, a comparable model for medical educational development was introduced. In 1999, the ACGME introduced six competency domains: 1] patient care; 2] medical knowledge; 3] practice based learning and improvement; 4] interpersonal and communication skills; 5] professionalism; and 7] systems-based practice. In particular, educational interventions to train competences in ‘practice-based learning and improvement’, ‘communication skills’ and ‘systems-based practice’ were explicitly described in relation to patient safety.

The Central College of Medical Specialties in the Netherlands (CCMS, Centraal College Medische Specialismen), along with the medical boards of Canada, Australia, New Zealand and Denmark, adopted the CanMEDS framework, and it is used as the initial concept for all medical education, undergraduate as well as graduate. Besides, in the Netherlands, the Dutch Federation for University Medical Centers (NFU) appointed patient safety as one of the topics that needs to be addressed within discipline-exceeding education for graduate medical trainees. Concurrently, the need for research on patient safety educational needs, educational content and effects of education was expressed. In line with this, the Medical Center Alkmaar (MCA, Medisch Centrum Alkmaar), VU University Medical Center (VUMc, VU medisch centrum) in Amsterdam and Utrecht University Medical Center (UMCU, Universitair Medisch Centrum Utrecht) cooperated to develop and organize patient safety courses for residents. The current thesis focuses on the patient safety courses of these Dutch hospitals.
Table 1. CanMEDS roles and elements in relation to patient safety

<table>
<thead>
<tr>
<th>CanMEDS role</th>
<th>Defined patient safety element</th>
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<tbody>
<tr>
<td>1] Communicator</td>
<td>-shared decision making; efficiency; accuracy; conveying effective oral and written information for patient care; use of expert verbal and non-verbal communication; appropriate documentation -disclosure of errors or adverse events</td>
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<td>2] Collaborator</td>
<td>-recognizing one’s own roles and limits -collaborative care, culture and environment; shared decision making; sharing of knowledge and information; effective teams; multi-professional health care</td>
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<tr>
<td>3] Manager</td>
<td>-supervising others; administration; consideration of justice, efficiency and effectiveness in the allocation of finite health care resources for optimal care; priority setting -quality assurance and improvement; information technology for healthcare</td>
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<tr>
<td>4] Health advocate</td>
<td>-patient safety</td>
</tr>
<tr>
<td>5] Scholar</td>
<td>-moral and professional obligation to maintain competence and be accountable -self-assessment; identifying gaps in knowledge -reflection on all aspects of practice; giving feedback; teacher-student ethics, power issues, confidentiality, boundaries; learning together -evidence-based medicine</td>
</tr>
<tr>
<td>6] Professional</td>
<td>-self awareness; self-assessment -integrity and honesty; medico-legal frameworks governing practice; disclosure of errors or adverse events -commitment to professional standards</td>
</tr>
<tr>
<td>7] Medical expert</td>
<td>-principles of patient safety and avoiding adverse events -knowing limits of expertise -application of ethical principles for patient care</td>
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1.6 Theoretic framework of thesis

As outlined in section 1.3 of this chapter, patient safety education primarily aims at changing the attendants’ behavior. One of the models that can explain behavioral change is the social psychological Theory of Planned Behavior (TPB) of Ajzen (1988). This model consists of four elements, which directly or indirectly influence behavioral change. These elements are: 1] attitude towards behavior; 2] subjective norm; 3] perceived behavioral control; and 4] behavioral intention.55 Ajzen defines behavior as an individual’s observable response in a given situation with respect to a given target. The attitude towards behavior is an individual’s positive or negative evaluation of self-performance of a particular behavior. It is determined by the total set of accessible behavioral beliefs, linking the behavior to various outcomes and other attributes. The subjective norm is defined as an individual’s perception of social normative pressures, or of the beliefs of relevant others that he or she should or should not perform such behavior. Perceived behavioral control indicates an individual’s
perceived ease or difficulty to perform a particular behavior. It is assumed that perceived behavioral control is determined by the total set of accessible control beliefs. The behavioral intention is an indication of an individual’s readiness to perform a given behavior, which is assumed to be the immediate antecedent of behavior.\textsuperscript{55} Ajzen states that behavior is a function of compatible intentions and perceptions of behavioral control. Behavioral intention is based on attitude toward the behavior and subjective norm, with each predictor being weighted for its importance in relation to the behavior and the population of interest. Perceived behavioral control is expected to moderate the effect of intention on behavior, such that a favorable intention produces the behavior only when perceived behavioral control is strong (figure 2). Multiple studies indicated that the TPB has relevance for studying the behavior of health care providers as well.\textsuperscript{56,57} By educating residents in patient safety issues, we expect to influence the antecedents of behavior in order to improve patient safety behavior. Expanding residents’ knowledge and skills and offering possibilities to exercise specific patient safety improvement behavior hopefully influences their behavioral attitudes, subjective norms and perceived behavioral control, thus influencing their intentions and their ability to improve safety in daily practice. Apart from this, the fact that residents are working in complex systems with other people - patients, nurses, supervisors and many others - and are dependent on existing organizational structures, also influences their behavior with respect to patient safety.

\textbf{Figure 2.} Theory of Planned Behavior, Ajzen (1988)

\begin{center}
\begin{tikzpicture}
  \node [draw] {Behavioral attitude} [yshift=1cm]
  \node [draw, right of=behavioral attitude, xshift=1cm] {Subjective norms} [yshift=-1cm]
  \node [draw, right of=subjective norms, xshift=1cm] {Intention} [yshift=-2cm]
  \node [draw, right of=intention, xshift=1cm] {Behavior} [yshift=-2cm]
  \node [draw, below of=subjective norms, yshift=-2cm] {Perceived behavioral control}
  \draw [->] (behavioral attitude) -- (subjective norms);
  \draw [->] (subjective norms) -- (intention);
  \draw [->] (intention) -- (behavior);
  \draw [->, dashed] (behavior) -- (perceived behavioral control);
\end{tikzpicture}
\end{center}

\textbf{1.7 Scope of research}

The aim of this thesis is to provide insight into the development and effects of patient safety education for residents, with special focus on incident reporting. According to Kern \textit{et al.} (1998), educational development is a process consisting of six consecutive steps (figure 3), initiated by a perceived need.\textsuperscript{58} Assessment of learning needs (step 1) and analysis of desired behavior (step 2) are important at the start of any educational training and appear to be precursors of effective educational interventions.\textsuperscript{59} Subsequent steps focus on shaping the educational intervention: defining the learning goals (step 3),
selecting the subject of teaching (step 4) and selecting educational methods (step 5). A final essential step is the evaluation of the educational intervention (step 6) which can guide further improvement of the education. All these steps are addressed within the current thesis.

Consequently, we designed a curriculum using four main didactic principles to stimulate the learning process and achieve behavioral changes: 1] Education needs to be closely related to clinical practice, and wherever possible it needs to be incorporated in the attendants’ daily practice, because what people learn in one context, will not necessarily apply in another setting. 2] Adult learning theorists have recognized that an interactive environment with multi-specialty small groups stimulates the learning process by enabling optimal learning from peers. 3] Education in multiple sessions is often more effective than education consisting of a single session. 4] Assessment stimulates learning.

**Figure 3.** Six step approach for curriculum development in medical education, Kern *et al.* (1998)
The primary research questions and the related sub-questions of this thesis are:

I. How should patient safety education for residents be designed?
   A. What patient safety educational methods and content are described in the literature?
   B. What do residents and supervisors consider important for patient safety education for residents, and how can this be integrated into the development of a patient safety course for residents?
   C. How do course participants evaluate the design of the patient safety course?

II. What are the effects of patient safety education for residents?
   A. What effects of patient safety education for residents are described in the literature?
   B. How does a patient safety course influence residents’ knowledge, skills, attitudes, intentions and behavior?

To better understand the patient safety improvement behavior of residents we also examine the third and last research question:

III. What influences residents’ behavior to improve patient safety?
   A. Which barriers and promoting factors are experienced by residents in taking action to improve patient safety?
   B. Which solutions do residents have for taking away the barriers and stimulating patient safety improvement behavior?

1.8 Study design

Six studies were conducted to address these research questions. In this section, the focus and methods of each study are described in brief. An overview of the data collection methods and outcome measures per study is presented in table 2.

1. We systematically reviewed existing literature on patient safety education for residents. We investigated which teaching methods were used, which specific contents were taught, how the educational interventions were evaluated and what effects were described following the education.
2. By means of questionnaires, we investigated residents’ and supervisors’ perspectives on patient safety performance and patient safety educational needs. The outcomes of this enquiry were used for the development of our patient safety course for residents.
3. We carried out a pilot study to examine the longer-term impact of a patient safety course for residents on their attitudes, intentions and behavior towards the reporting of incidents. For this study, residents were asked to fill out questionnaires at three moments in time: before the course, immediately after the course and six months after the course was given.
4. We investigated the effects on incident reporting in greater depth by using a controlled design study, including more participants and objective outcome measures. Besides the assessment of attitudes, intentions and behavior, we also investigated the effects of education on residents’ knowledge and skills concerning the reporting of incidents.
5. We assessed residents’ intentions and actions for patient safety improvement and their reactions towards the design of the patient safety course. To learn more about residents’ patient safety behavior, we also assessed the factors they experienced as contributing to taking action. For this study, semi-structured interviews with residents were conducted.

6. The perceived barriers to and solutions for incident reporting by residents were investigated by means of focus group sessions.

Table 2. Overview of data collection methods and outcome measures

<table>
<thead>
<tr>
<th>Study</th>
<th>Chapter</th>
<th>Data collection methods</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>Systematic review of the literature, Best Evidence Medical Education (BEME) guidelines</td>
<td>Design and effects of patient safety education for residents</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>Questionnaires for residents and supervisors</td>
<td>Patient safety climate and patient safety educational needs</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>Questionnaires for residents</td>
<td>Residents’ incident reporting attitudes, intentions and behavior</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>Questionnaires for residents, hospital incident reporting systems, incident reporting cards filled out by residents</td>
<td>Residents’ incident reporting knowledge, skills, attitudes, intentions and behavior</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>Questionnaires for residents and interviews with residents</td>
<td>Patient safety improvement intentions and behavior of residents and contributing factors</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
<td>Focus group discussions with residents</td>
<td>Barriers and solutions to incident reporting by residents</td>
</tr>
</tbody>
</table>

1.9 Outline of thesis

The results of the studies are presented in chapter 2 up to and including chapter 7. The chapters are written as separate articles and can be read independently of each other. As a consequence, the content of chapters in some parts shows overlap. In chapter 2 we describe a systematic review of the literature about evaluations of patient safety education for residents. Chapter 3 demonstrates a patient safety educational needs assessment among residents and supervisors, and describes the development of our patient safety course for residents. In chapter 4 we evaluate a patient safety course for residents by focusing on their incident reporting attitudes, intentions and behavior. Chapter 5 describes the evaluation of a patient safety course for residents by focusing on knowledge, skills, attitudes, intentions and behavior concerning incident reporting. Chapter 6 focuses on residents’ intentions and actions after patient safety education, in a broader view than just incident reporting. Besides, this chapter pays attention to the factors influencing residents patient safety behavior and residents’ reactions towards the design of the patient safety course. In chapter 7 our investigation of the barriers to and
the solutions for incident reporting by residents is outlined. Finally, a summary of results of all six studies and an overall discussion with recommendations for future research and implications for practice are given in chapter 8. Table 3 gives an overview of the research questions and the chapters in which they are addressed.

Table 3. Overview of research questions and chapters in which they are addressed

<table>
<thead>
<tr>
<th>Research question</th>
<th>Corresponding chapter</th>
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</thead>
<tbody>
<tr>
<td>I. How should patient safety education for residents be designed?</td>
<td>2, 3 &amp; 6</td>
</tr>
<tr>
<td>A. What patient safety educational methods and content are described in the literature?</td>
<td>2</td>
</tr>
<tr>
<td>B. What do residents and supervisors consider important for patient safety education for residents, and how can this be integrated into the development of a patient safety course for residents?</td>
<td>3</td>
</tr>
<tr>
<td>C. How do course participants evaluate the design of the patient safety course?</td>
<td>6</td>
</tr>
<tr>
<td>II. What are the effects of patient safety education for residents?</td>
<td>2, 4 - 6</td>
</tr>
<tr>
<td>A. What effects of patient safety education for residents are described in the research literature?</td>
<td>2</td>
</tr>
<tr>
<td>B. How does a patient safety course influence residents’ knowledge, skills, attitudes, intentions and behavior?</td>
<td>4 - 6</td>
</tr>
<tr>
<td>III. What influences patient safety behavior of residents?</td>
<td>6 &amp; 7</td>
</tr>
<tr>
<td>A. Which barriers and promoting factors do residents experience in taking action to improve patient safety?</td>
<td>6 &amp; 7</td>
</tr>
<tr>
<td>B. Which solutions do residents have for taking away these barriers and stimulating patient safety behavior?</td>
<td>6 &amp; 7</td>
</tr>
</tbody>
</table>
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