**Patient Safety in the Emergency Department:**
*Exploring and applying principles from high risk industries*

The central aim of this thesis is to explore how principles of organisational learning, organisational culture, and High Reliability Theory can be applied to increase the safety of patients in the Emergency Department (ED). In short the following research questions were positioned (Chapter 1).

- Can learning from incidents be accomplished by root cause analyses of liability claims?
- How is safety culture related to the implementation of system defences and self-reported safety levels?
- Can classroom-based Crew Resource Management training instil the non-technical skills and safety culture that is deemed necessary in order to develop into a highly reliable organisation?

The principle of organisational learning was operationalised by means of exploring root cause analyses of liability claims. We were interested in whether liability claim files could additionally lead to learning from incidents (Chapter 2). Organisational culture, especially safety culture, is one of the factors influencing safety. We were interested in which safety dimensions determined the implementation of system defences (Chapter 3) and self-reported safety (Chapter 4).

Another important principle to enhance patient safety is to adopt characteristics of high reliability organisations. These organisations are primarily focused on optimal teamwork amongst their employees. Optimal use of non-technical skills, such as communication or teamwork, is a prerequisite for optimal teamwork. Starting with a classroom based training to raise awareness, we wanted to investigate whether our training programme had potential to change non-technical skills (NTS) and whether our training programme ultimately had the potential to make healthcare safer. For that purpose, we developed a model to measure non-technical skills (Chapter 5), and we used that model to measure the effect of crew resource management (CRM) training on non-technical skills (Chapter 6). Finally, we conducted a review to see whether these types of classroom-based training can potentially alter patient safety culture (Chapter 7).
Chapter 1 outlines the contextual setting of the research described in this thesis as well as explains some of the fundamental insights of safety science in the quest for more reliable organisations, i.e. organisational learning, organisational culture, and High Reliability Theory. The chapter ends with a brief synopsis of the research questions answered in this thesis.

Chapter 2 explored whether liability claims files are feasible as source to learn from incidents. Feasibility was defined by reliability, applicability and validity. PRISMA-Medical was used as a tool for root-cause analyses on all closed and settled claim files from the year 2001 and 2002. Fifty incidents occurring at 31 EDs were found in 47 files. 114 root causes were found, on average 2.3 per incident. Zero technical, 29.0% organisational, 66.7% human-related, and 4.4% patient-related factors were found. Reliability, measured by the interrater-agreement, for classification of root causes was good (kappa= 0.78). Preventive measures following from PRISMA’s classification-action matrix were: improving completion of available sources of information, improving structures of communication and training staff to prevent failures due to the wrong implementation of tasks or due to errors in reasoning. Regarding the applicability, the application of PRISMA-medical is relatively time consuming, but the main problem was the large time involved between the occurrence of incidents, their detection and their reporting at the liability insurer. Additional information about the context and organisational and technical information can therefore hardly be gathered. Validity of the root cause profile of diagnostic claims is considered moderate due to a lack of information about technical and organisational causes of errors. Therefore the root cause profile was incomplete for organisational factors in comparison with other studies. Feasibility of PRISMA for retrospective analyses of closed claims may be improved if system-based reasoning by the liability insurers and hospital staff is enhanced.

Chapter 3 investigates the association between eleven patient safety culture dimensions and the implementation of seven organisational patient safety defences in the ED. The safety defences were formulated by the largest medical liability insurer in the Netherlands. Safety defences were 1. a resident orientation programme must be present for all new residents, 2. residents have to be educated about diagnosis and treatment of several commonly misdiagnosed and maltreated conditions, 3. skills of residents have to be evaluated directly after training and continuously twice a year regarding; medical knowledge, technical skills, documentation, and communication/
social skills, 4. treatment protocols about fractures and tendon injuries have to be present at the ED unit and have to be updated every three years, 5. All medical records of patient who were seen at the ED the previous day have to be checked during patient record review meetings, 6. supervision appointments and rules have to be formed adequately, and 7. radiologists, surgeons/ supervisor and residents have to take part in daily X-ray result reviews. Data on the degree of implementation of the seven organisational patient safety defences were gathered via a cross-sectional survey filled in by the head of the unit.

Data about safety culture were gathered in 33 EDs by means of the Dutch version of the Hospital Survey on Patient Safety Culture (HSOPSC), which measures eleven dimension of patient safety. Analyses showed that several culture dimensions were negatively or positively associated with the implementation of the patient safety defences. Two patient safety culture dimensions were most frequently associated with the implementation of organizational patient safety defences. ‘Hospital management support’ appeared to be a facilitator with respect to the presence of protocols, resident orientation programmes, X-ray result reviews and patient record reviews. ‘Hospital handoffs and transitions’ were associated with less frequently correct implementation of structured supervision, resident orientation programmes, X-ray results reviews and patient record reviews. Results suggest that well perceived culture dimensions might inhibit improvements by lack of a sense of urgency as well as facilitate improvements by inducing feelings of support for organisational changes and improvements.

Chapter 4 describes the patient safety culture of Dutch EDs, describes which safety culture dimensions determine self-reported safety, and explores differences between nurses and physicians. The dataset from Chapter 3 was used containing 480 Nurses, 159 physicians, and 91 other professionals. In unadjusted analyses, all dimensions of safety culture were positively associated with the reported level of patient safety. Six of these associations with patient safety were statistically significant in multivariate models and after adjustment for the clustering of responses at the department level (‘teamwork across units’, ‘frequency of event reporting’, communication openness’, ‘feedback about and learning from errors’, ‘hospital management support for patient safety’, and ‘overall perception of safety’). Differences between nurses and physicians were found on two dimensions (‘frequency of event reporting’ and ‘ hospital management support for patient safety’). Physicians tended to grade patient safety higher than nurses whilst having
Chapter 5 describes the development of the Explicit Professional Oral Communication (EPOC) tool to measure and quantify the use of non-technical skills observed by means of direct observations. In an iterative process we translated, tested and refined an existing checklist from the aviation industry, in the context of healthcare, notably EDs and ICUs. The EPOC comprises six sub dimensions and three main dimensions. Assertiveness forms the dimensions Self. Working with others, Task-oriented leadership, and People-oriented leadership form the dimensions Human Interaction. Situational awareness and Planning and Anticipation form the dimension Anticipation on Environment. Each dimension is specified into several concrete items reflecting verbal behaviours. We evaluated the Intraclass Correlation (ICC) overall and for every dimension of the EPOC. The EPOC was evaluated in four EDs and six ICUs.

In the ED and ICU, respectively 378 and 1144 individual, and 51 and 68 simultaneous observations of individual staff members were conducted. All EPOC dimensions were observed frequently, except for Assertiveness. Overall interobserver-reliability was high with an ICC of 0.91 (95% CI 0.84 - 0.95). Per dimension the interobserver-reliability was 0.90 (95% CI 0.80 - 0.95) for Human Interaction (HI) and 0.85 (95% CI 0.75 - 0.91) for Anticipation on Environment (AoE). It was not possible to assess the interobserver-reliability for Assertiveness. For the six sub-dimension the ICCs varied between .53 and .95. We conclude that the EPOC is reliable in two highly different settings. By quantifying professional behaviour the instrument facilitates measurement of behavioural change over time. The results suggest that EPOC can also be translated to other settings.

Chapter 6 evaluates the effect of a classroom-based CRM training at EDs on non-technical skills. Therefore, we conducted a pragmatic controlled before-after trial with two EDs in the intervention group and two EDs in the control group.

ED nurses and physicians at the intervention sites received a two day interactive, classroom-based training. Direct observations were made to assess non-technical skills of ED nurses and physicians by means of the EPOC
scoring form. Three outcome measures were analysed: Human Interaction, Anticipation on Environment, and an overall EPOC score. Linear and logistic mixed model analyses were performed. Models were corrected for the outcome measures HI, AoE and overall EPOC at baseline, days between training and observation, and patient safety culture and error management culture at baseline.

A statistically significant increase after the training was found on HI (β = 0.27, 95% CI 0.08 - 0.49) and the overall EPOC score (β = 0.25, 95% CI 0.06 - 0.43), but not for AoE (OR = 1.19, 95% CI .45 - 3.15). This means that approximately 25% more explicit communication was shown after CRM training. This implies that CRM has the potential to increase patient safety by reducing communication flaws, which play an important role in healthcare-related adverse events.

Chapter 7 reports the results of a systematic review of the effect of classroom-based CRM trainings on safety culture. Studies were identified in PubMed, Cochrane Library, PsycINFO, and ERIC up to 19 December 2012. The Methods Guide for Comparative Effectiveness Reviews was used to assess the risk of bias in the individual studies. Twenty-two manuscripts were included for review. Training settings, study designs, and evaluation methods varied widely. Most studies reporting only a selection of culture dimensions found mainly positive results, whereas studies reporting all safety culture dimensions of the particular survey found mixed results. On average, studies were at moderate risk of bias. Evidence of the effectiveness of CRM training in healthcare on safety culture is scarce and the validity of most studies is limited. The results underline the necessity of more valid study designs, preferably using triangulation methods.

Chapter 8 summarises the main findings of the studies and the methodological considerations of the studies in this dissertation. Furthermore, chapter 8 provides recommendations for practice and for future research.

Concerning the question whether learning from liability claims files is possible, we found that the process of the liability claim is too focused on the liability of the individual healthcare worker which makes it difficult to learn about possible organisational latent failures that contributed to the incident. The delay between the occurrence of the incident and reporting to the insurer makes this extra hard. Acquiring insight into the context at that particular time is considered a precondition to be able to understand why things went wrong. Another methodological considerations of importance is
that claims from 2001 and 2002 reflect the way of thinking of that time, which can be different compared to recent thinking about patient safety as the patient safety movement in the Netherlands started from the second half of the ‘00s.

The second main question concerned safety culture and the predictive value of its dimensions on implementation of system defences and self-reported safety. Analyses revealed that two patient safety dimensions were most frequently associated with the implementation of organizational patient safety defences: ‘Hospital management support’ and ‘hospital handoffs and transitions’. Concerning the latter, complacency may play a role, as one might tend to overlook the opportunities for improvement if one thinks one is already doing a good job.

Furthermore, six out of eleven patient safety culture dimensions were positively associated with the level of self-perceived patient safety: ‘teamwork across units’, ‘frequency of event reporting’, ‘communication openness’, ‘feedback about and learning from errors’, ‘hospital management support for patient safety’, and ‘overall perceptions of patient safety’. Analyses revealed that physicians tend to grade patient safety significantly higher than nurses when having the same scores for ‘frequency of event reporting’ and ‘hospital management support for patient safety’.

The main methodological considerations for these two studies would be that the outcomes and safety culture scores are self-reported. There is always a chance that answers are over- or underestimating safety and that one respondent may be more or less critical than another. A solution would be to use triangulation methods to describe safety culture. This provides the opportunity to investigate values and underlying assumptions rather than merely artifacts. Plus, it provides the opportunity to look into more dimension than predefined by the questionnaire. Using a triangulation method will also help to come up with ideas of what processes and accompanying structures an organisation has to implement in order to create a higher level of safety. Another important consideration is that, based on our observation that safety culture differs across countries, hospitals and department, corrections for clustering of responses must be made.

A recommendation resulting from the discussion of the findings and methodological consideration of main question 1 and 2 therefore would be that safety investigators have to focus on the context in which adverse events happened. This recommendation holds for practice as well as future research.
Researchers also have to use a triangulation method when appropriate and possible.

Regarding the third main question on CRM we have found that, as far as it concerns the ‘human interaction’ category of the EPOC observation tool, training may increase the number of non-technical skills that are used by as much as 25%. However, our systematic review on the effect on safety culture showed no conclusive results. Single- or multi-centre studies with uncontrolled designs all found changes in safety culture dimensions to some extent. The few studies with a control site did not find any changes. Whether this is the result of more custom-made trainings in uncontrolled studies, publication bias or a real effect of the trainings must be further explored. The importance of management support regarding culture change through CRM training has also been demonstrated. Where uncontrolled CRM found evaluations a large effect on safety culture either a hospital management was present that supported CRM uptake or there was a local team of key-figures devoted to implementing the training, or both. A recommendation therefore is that hospital management has to proclaim patient safety as a priority and provide resources accordingly.

Methodological considerations regarding the study on CRM reflect to the necessity to evaluate on more than one level of effect. We tried to study attitudes (level II of Kirkpatrick’s model), but the questionnaire that we used possessed no useful dimensions. We evaluated level III of Kirkpatrick’s model, behaviour, and found that cognitive processes, such as situation awareness, is not fully gained in the model. Probably questionnaires are more useful to measure these. In addition, we do not know if effects are sustained. An implementation plan would probably be helpful in this regard. Furthermore, level IV of Kirkpatrick’s model, organisational outcomes, is hard to measure. In safety culture, we found a marker of organisational evidence, but more elegant would be to measure patient outcomes.

Based on our finding on the third main question we would recommended to embed non-technical skills training into every-day practice and training curricula and to invest in methods to support the uptake of learned non-technical skills in practice. For future studies, evaluations of a complex intervention implemented in an organisation need a multilevel approach, context description, comparison groups, and a combined use of qualitative and quantitative measures.
We conclude that a focus on context and the use of triangulation will give us a better picture of the existing safety culture, and enhance our understanding of how things went wrong, which interventions might work, how interventions work, and the way they have to be implemented. With a profound focus on context and safety culture, when striving for organisational learning and high reliability, gains will probably be larger and the chances higher that effects will be sustained.