Development and Evaluation of a Computerised Decision Support System for use in pre-hospital care

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Abstract

The aim of the thesis was to develop and evaluate a Computerised Decision Support System (CDSS) for use in pre-hospital care.

The thesis was guided by a theoretical framework for developing and evaluating a complex intervention. The four studies used different designs and methods. The first study was a systematic review of randomised controlled trials. The second and the last studies had experimental and quasi-experimental designs, where the CDSS was evaluated in a simulation setting and in a clinical setting. The third study included in the thesis had a qualitative case study design.

The main findings from the studies in the thesis were that there is a weak evidence base for the use of CDSS in pre-hospital care. No studies have previously evaluated the effect of CDSS in pre-hospital care. Due to the context, pre-hospital care is dependent on protocol-based care to be able to deliver safe, high-quality care. The physical format of the current paper-based guidelines and protocols are the main obstacle to their use. There is a request for guidelines and protocols in an electronic format among both clinicians and leaders of the ambulance organisations. The use of CDSS in the pre-hospital setting has a positive effect on compliance with pre-hospital guidelines. The largest effect is in the primary survey and in the anamnesis of the patient. The CDSS also increases the amount of information collected in the basic pre-hospital assessment process. The evaluated CDSS had a limited effect on on-the-scene time.

The developed and evaluated CDSS has the ability to increase pre-hospital patient safety by reducing the risks of cognitive bias. Standardising the assessment process, enabling explicit decision support in the form of checklists, assessment rules, differential diagnosis lists and rule out worst-case scenario strategies, reduces the risk of premature closure in the assessment of the pre-hospital patient.
Original papers

The thesis is based on the following studies, which are referred to by Roman numerals in the text:

**Study I**


**Study II**


**Study III**


**Study IV**


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## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>3</td>
</tr>
<tr>
<td>Original papers</td>
<td>4</td>
</tr>
<tr>
<td>Study I</td>
<td>4</td>
</tr>
<tr>
<td>Study II</td>
<td>4</td>
</tr>
<tr>
<td>Study III</td>
<td>4</td>
</tr>
<tr>
<td>Study IV</td>
<td>4</td>
</tr>
<tr>
<td>Content</td>
<td>5</td>
</tr>
<tr>
<td>List of abbreviations</td>
<td>7</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>8</td>
</tr>
<tr>
<td>1. Introduction</td>
<td>9</td>
</tr>
<tr>
<td>2. Background</td>
<td>10</td>
</tr>
<tr>
<td>2.1 Patient safety in pre-hospital care</td>
<td>10</td>
</tr>
<tr>
<td>2.2 Decision making and human error</td>
<td>12</td>
</tr>
<tr>
<td>2.2.1 Judgement and decision-making theories</td>
<td>12</td>
</tr>
<tr>
<td>2.2.2 Dual process theory</td>
<td>13</td>
</tr>
<tr>
<td>2.2.3 Decision-making in emergency care</td>
<td>19</td>
</tr>
<tr>
<td>2.2.4 Decision-making in the pre-hospital emergency setting</td>
<td>20</td>
</tr>
<tr>
<td>2.2.5 Human errors</td>
<td>23</td>
</tr>
<tr>
<td>2.3 Decision support systems</td>
<td>28</td>
</tr>
<tr>
<td>2.3.1 Protocol-based care</td>
<td>29</td>
</tr>
<tr>
<td>2.3.2 Computerised decision support system</td>
<td>32</td>
</tr>
<tr>
<td>3. Rationale for the thesis</td>
<td>36</td>
</tr>
<tr>
<td>4. Aim of the thesis</td>
<td>36</td>
</tr>
<tr>
<td>5. Material and methods</td>
<td>39</td>
</tr>
<tr>
<td>5.1 Research theory perspective</td>
<td>39</td>
</tr>
<tr>
<td>5.1.1 Critical realism</td>
<td>39</td>
</tr>
<tr>
<td>5.2 Methodological framework</td>
<td>42</td>
</tr>
<tr>
<td>5.2.1 Developing and evaluating complex interventions</td>
<td>42</td>
</tr>
<tr>
<td>5.2.2 Definition of complex interventions</td>
<td>42</td>
</tr>
<tr>
<td>5.2.3 The content of the framework</td>
<td>43</td>
</tr>
<tr>
<td>5.3 Study designs</td>
<td>47</td>
</tr>
<tr>
<td>5.4 Setting and participants</td>
<td>47</td>
</tr>
<tr>
<td>5.5 Data collection</td>
<td>50</td>
</tr>
</tbody>
</table>
5.5.1 Literature search........................................................................................................ 50
5.5.2 Observation of digital video tapes.............................................................................. 51
5.5.3 Participant observations............................................................................................. 51
5.5.4 Interviews ................................................................................................................ 51
5.5.5 Sampling of documents ............................................................................................. 52
5.5.6 Ambulance medical records ...................................................................................... 52
5.6 Estimation of sample size .............................................................................................. 53
5.7 Data analysis ................................................................................................................ 53
5.8 Ethical considerations ................................................................................................... 54

6. Findings ............................................................................................................................ 56
6.1 Summary of results (I-IV) ........................................................................................... 56
6.2 Development of the CDSS ........................................................................................... 56
6.3 The evidence base for the use of CDSS in pre-hospital care (I) ............................... 61
6.4 The features of protocol-based care in pre-hospital settings (III) ......................... 62
6.5 The feasibility of using a CDSS in a pre-hospital organisation (III) ..................... 63
6.6 Effect of CDSS on compliance with pre-hospital guidelines and the systematic assessment framework among ambulance nurses (II, IV) .......... 64
6.7 Effect of CDSS on time spent on the scene among ambulance nurses (II, IV) ....... 65

7. Discussion ............................................................................................................................ 66
7.1 Reflections on the findings ............................................................................................ 66
7.1.1 Effect of CDSS on patient safety in pre-hospital care ............................................ 66
7.1.2 Potential risks of using a CDSS in pre-hospital care ............................................. 72
7.1.3 What are the features of an optimal CDSS in a pre-hospital setting? .................... 73
7.2 Methods ......................................................................................................................... 74
7.2.1 Validity and reliability ............................................................................................. 74

8. Conclusions ......................................................................................................................... 76
9. Implications ......................................................................................................................... 77
10. Future research ............................................................................................................... 77
Summary in Swedish ........................................................................................................... 79
11. References ......................................................................................................................... 81
**List of abbreviations**

ABCD = Airway, Breathing, Circulation and Disability  
AMLS = Advanced Medical Life Support  
AN = Ambulance Nurses  
ATLS = Advanced Trauma Life Support  
CDM = Centre for Defence Medicine  
CDSS = Computerised Decision Support System  
CMO = Context + Mechanism = Outcome  
COPD = Chronic Obstructive Pulmonary Disease  
CPR = Cardio-Pulmonary Resuscitation  
DSS = Decision Support System  
DST = Decision Support Tool  
EBP = Evidence-Based Practice  
ECG = Electrocardiogram  
ED = Emergency Department  
EHR = Electronic Health Records  
EMT = Emergency Medical Technicians  
IRR = Inter-rater Reliability  
ITS = Interrupted Time Series  
JDM = Judgement and Decision Making  
OST = On Scene Time  
PBC = Protocol-Based Care  
PHTLS = Pre-hospital Trauma Life Support  
PSP = Patient Safety Practice  
RCT = Randomised Controlled Trials  
ROW = Rule Out Worst-case scenario  
RPD = Recognition-Primed Decision Model  
SU = Stroke Unit
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1. Introduction

The context of pre-hospital care is characterised by decision-making in an unstable environment, a long distance from medical support, a high level of acuity, a lack of clinical information and a wide range of clinical conditions (Wireklint Sundström, 2005; Bigham et al., 2012). Ambulance staff have had to make more and more demanding decisions, as much of the advanced care previously performed at hospital has been moved to the pre-hospital setting (Bigham et al., 2011). These contextual factors contribute to the fact that pre-hospital care is a high-risk discipline when it comes to patient safety. Unfortunately, patient safety issues are poorly investigated in pre-hospital care (Meisel et al., 2008). The limited research in the area suggests that errors in decision-making and clinical judgement are the dominant threats to patient safety in the pre-hospital setting (Atack & Maher, 2010; Fairbanks et al., 2008; Wang et al., 2008; Lammers et al., 2012; Price et al., 2012). However, bias in the decision-making process is probably one of the most common causes of medical errors in all kinds of clinical work (Bucknall, 2010). The development of clinical guidelines has been a method both to support the decision-maker in patient assessment and to promote evidence-based practice. Evidence-based guidelines have the ability to enhance the quality of care (Lugtenberg et al., 2009). The implementation of the guidelines is crucial to the outcome and compliance with guidelines is sometimes very poor, both in the pre-hospital setting (Figgis et al., 2010; Woollard et al., 2001; Rittenberger et al., 2005; Fisher & Vinci, 1995; Bosse et al., 2011) and in hospital (Gagliardi et al., 2011). One way to promote increased compliance is to integrate guidelines in different kinds of Computerised Decision Support System (CDSS) (Latoszek-Berendsen et al., 2010). CDSS can increase compliance with guidelines and improve patient safety in hospital settings and in primary care (Kawamoto et al., 2005; Garg et al., 2005). The effect of CDSS on patient safety is to standardise the decision-making process. The effect of a standardised decision-making process is that different clinicians assess and treat patients equally and make a comparison of methods possible (Morris, 2002). There are also studies that reveal a more complex picture, with a wide range of effects of CDSS, ranging from small improvements to large effects (Shojania Kaveh et al., 2009). The various results suggest that a CDSS is a complex intervention, sensitive to the context in which it is intended to operate (Ovretveit et al., 2011). It is crucial that the implementation of a decision support system is preceded by a detailed scientific evaluation. The aim of the present thesis is to use the guidelines in the methodical framework, Developing and Evaluating Complex Interventions (Campbell et al., 2000; Craig et al., 2008), to develop and evaluate a CDSS for use in the pre-hospital context.
2. Background

2.1 Patient safety in pre-hospital care

In 2000, the Committee on Quality of Health Care in America, Institute of Medicine released the report “To Err Is Human: Building a Safer Health System” (2000). The report was a wake-up call for health providers and researchers all over the world. It revealed that up to 98,000 people died in 1997 as a result of medical errors in American hospitals. A recent study estimates that there are more than 400,000 preventable harmful incidents a year that contribute to the death of hospitalised patients in American hospitals (James, 2013). From an international perspective, it is estimated that one in 10 patients admitted to an acute care hospital are exposed to a harmful incident (Runciman et al., 2007). Being a patient in an acute care hospital is associated with 33,000 deaths per 100 million people a year (Runciman et al., 2007). The figures are probably equally alarming in Sweden. A study conducted by the National Board of Health and Welfare (2011) reports that 8.6% of patients treated in hospital experience some sort of harmful incident. This was equivalent to 100,000 patients every year in Sweden. The areas with the highest injury rates were surgery, internal medicine and primary care. The main causes of injury were surgery (51.8%), medical treatment (26.8%) and diagnostic failure (11.9%). A report by the Swedish Association of Local Authorities and Regions (2012) found that 14% of examined patient notes included harmful incidents. The most common causes were health-care-associated infections, followed by medical and pharmaceutical concerns and surgery. It was estimated that 5% of the harmful incidents were a serious threat to the patient. None of the reports included pre-hospital care.

The goal of research on Patient Safety Practice (PSP) is to prevent harmful incidents in health care (Dy et al., 2011). The terms and key concepts of patient safety are described in a framework by Runciman et al. (2009). The framework describes patient safety as “the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum”, where a harmful incident (adverse event) is classified as “an incident that resulted in harm to a patient”. Error is defined as the “failure to carry out a planned action as intended or application of an incorrect plan”. Errors are further divided into errors of commission, which are described as doing the wrong thing, and omission, which are described as failing to do the right thing at either the planning or the execution phase. Violation is a “deliberate deviation from an operating procedure, standard or rule” (Runciman et al., 2009). The Institute of Medicine (2001) divided quality improvement in health care into six aims, where safe care is one and the first of
the aims. The others are effective care, patient-centred care, timely care, efficient care and equitable care (Institute of Medicine, 2001).

The rate of harmful incidents in pre-hospital care in Sweden is unknown and there has also been a lack of error reports in the international literature (Sayre, 2002). The Canadian Patient Safety Institute, together with the Emergency Medical Services Chiefs of Canada, has examined patient safety in the pre-hospital setting (Bigham et al., 2011). The aim was to identify the central issues related to patient safety in pre-hospital care in the United States and Canada. The most important issues were clinical Judgement and Decision-Making (JDM) among pre-hospital workers. Other studies support this view of the main threat to patient safety in pre-hospital care (Atack & Maher, 2010; Fairbanks et al., 2008; Wang et al., 2008). One suggestion for the reasons is that pre-hospital providers do not have the education or the tools to make good judgements in such a complex context (Atack & Maher, 2010). Paramedics in Canada are providing more and more complex and time-sensitive patient care; examples include a new Cardio-Pulmonary Resuscitation (CPR) process for cardiac arrest, myocardial infarction identification and transport bypass protocols, early stroke identification and therapeutic interventions in trauma (Bigham et al., 2011). Sweden has seen similar developments in pre-hospital care (Suserud, 2003). It has been argued that training alone may be inadequate to ensure that paramedics and ambulance nurses are competent when performing complex protocols and making clinical decisions on diagnosis and treatment and this may contribute to patient safety issues (Bigham et al., 2011). The importance of guidelines and protocols is recognised and studies also suggest that guidelines incorporating flexibility to include clinical decisions and judgement may be more appropriate if coupled with timely medical supervision, comprehensive training and feedback (Bigham et al., 2011; Atack & Maher, 2010). Compliance with guidelines and protocols in the pre-hospital setting is another issue of concern. Several studies reveal that compliance with guidelines among the pre-hospital care providers is sometimes low (Figgis et al., 2010; Woollard et al., 2001; Rittenberger et al., 2005; Fisher and Vinci, 1995; Bosse et al., 2011).

The threats to pre-hospital patient safety are unique and underestimated and more research on pre-hospital patient safety issues is needed (Cone, 2007). A need for research in areas such as education, error reporting, safety culture, decision-making, human errors and quality improvement interventions has been identified (Bigham et al., 2012; Meisel et al., 2008).

One reason for the lack of studies of patient safety issues in pre-hospital care could be the complexity of studying PSP. Compared with more traditional clinical trials, such as the evaluation of drugs, PSP is regarded as more complex and PSP interventions have more levels at which the interventions can be applied (Brown et al., 2008a). The interventions are frequently applied at the
organisational level rather than at the patient or individual level (Dy et al., 2011). The theoretical aspects of PSP research are poorly described and there is a need to describe features typical of PSP research, such as settings, participants, clinical behaviours and interventions (Brown et al., 2008a). In January 2011, Sweden introduced new patient safety legislation. The new law gives the caregivers responsibility for pursuing active patient safety work and preventing injury and errors in health care. The caregivers are also obliged to investigate events that have caused injury or threatened to cause injury (Ministry of Health and Social Affairs, 2011).

2.2 Decision-making and human error

2.2.1 Judgement and decision-making theories

To be able to develop and test a CDSS, it is proposed that the developer needs a substantial knowledge of the way people really make decisions (Patel and Bates, 2003; Patel & Kaufman, 1998). There are many examples of CDSS interventions which have been a failure because the developer did not consider decision-making in the real world (Institute of Medicine, 2000). A CDSS which does not match the way people actually make decisions is not likely to work in an unstable clinical setting (Patel & Bates, 2003). Even in the evaluation of a CDSS intervention, the theory of decision-making is important. The theory can help the researcher to identify the factors in the process that contribute to the success or failure of the intervention (Foy et al., 2011). Judgement and Decision-Making (JDM) has been the subject of research for many years. Experimental psychology has produced a large number of studies in the field. Other areas, such as economics, political science, law, nursing and medicine, have also shown an interest in JDM (Patel et al., 2002). The literature can be somewhat confusing, as there are many different theories and terminology relating to JDM (Buckingham & Adams, 2000). The reason for the confusing terminology in JDM could be that every discipline creates its own terms and regards the decision-making within that discipline as unique and not transferable to other settings (Buckingham & Adams, 2000).

The theories of JDM have been categorised into three main domains, normative, descriptive and prescriptive (Thompson & Dowding, 2002). The normative theories originated from statistical, mathematical and economic science (Patel et al., 2002). The normative theories focus on finding logical strategies for making good decisions (Shaban, 2005). The normative theories have three main types of model. Two are the expected utility and subjective expected utility. The rationale behind the models is to calculate the ratio of chance in relation to the cost, thereby maximising the gain (Patel et al., 2002). The models originate from studies of gaming. Another normative approach is
the Bayesian models, which are statistical models for calculating the probability that an event will occur (Shaban, 2005). The models offer a way of comparing and improving the decision-making in a mathematical model. The expected utility, subjective expected utility and Bayesian models have become the standard for optimal decision-making in the normative school (Patel et al., 2002). However, there is also criticism of the normative theories. The main criticism is that these models take no account of real problems in clinical settings (Patel et al., 2002). In particular, the work of Kahneman and Tversky (1974) challenged the normative school by revealing that people do not make decisions in a normative way. People instead use heuristics in decision-making. Humans have a limitation when it comes to information processing and the normative theories do not take account of the environments and the context in which the decisions are made (Patel et al., 2002).

The criticism of normative decision-making led to new theories of decision-making. These theories had their roots in psychology and behavioural science (Patel et al., 2002). The descriptive theories start by surveying and describing the nature of human decision-making. The theories attempt to answer the question of how people make decisions in a natural environment. The descriptive theories do not consider the quality of the decisions but only describe the process (Shaban, 2005). Most of the descriptive theories are based on experimental studies in laboratories (Lipshitz et al., 2001). The criticism of descriptive models is that they tend to overlook the fundamentally rigid nature of decision-making. Health-care practice is driven by standards such as health, quality of care and expertise (Falzer, 2004). Prescriptive decision theories were introduced in the 1980s, with the aim of helping people to make good decisions in the real world (Bell et al., 1988). To realise this goal, the prescriptive theories had to investigate how people make decisions (descriptive theories) and build decision-making models from that starting point. The focus is to help people make better decisions (Falzer, 2004). Prescriptive theories use multiple approaches. Decision analysis and decision trees are common models for improving the clinical decision-making in medicine and nursing. The development of clinical guidelines, policies and decision support systems also involves methods from the prescriptive theories (Falzer, 2004).

2.2.2 Dual process theory

Research in the descriptive paradigm has produced several models of the way people make decisions. One of the most recognised models is dual process theory. In fact, there are several theories under this umbrella term. What the theories have in common is the idea that people have two different approaches to processing information, System 1 and System 2 (Evans, 2008). There is currently significant agreement on the features that distinguish the two types of
cognitive procedure and this is confirmed by Kahneman (2003). The characteristics of System 1 are that the cognitive process is supported by encapsulated processes. The thinking in System 1 does not require access to the central working memory and this makes the decision processes rapid and automatic (Evans, 2008). Instead of analytical reasoning, System 1 works with processes labelled intuition, the construction of mental maps (schemata), pattern matching, short cuts and rules of thumb, also called heuristics (Croskerry, 2009a). The System 1 processing is described as emotionally stimulated and also ruled by habits. This makes the processing in System 1 difficult to control or modify (Kahneman, 2003). It is also suggested that the reasoning process in System 1 is dependent on context (Croskerry, 2009a). The idea of two types of thinking process can be seen in other decision-making theories, such as Hammond’s Cognitive Continuum Theory (Cader et al., 2005). Hammond’s theory is based on social judgement theory, which argues that the correctness of a person’s judgement in a situation depends on the weighting the individual assigns to information cues coming from that situation (Cader et al., 2005). Hammond claims that people are capable of different modes of decision-making, which include both intuitive and analytical reasoning and the use of the different strategies depend on whether the task is well structured or poorly structured (Cader et al., 2005). Cognitive research has described several different processes which are involved in System 1 reasoning. 

Heuristics, according to Tversky and Kahneman (1974), are used in clearly defined situations or, as Hammond put it, well-structured situations. By using heuristic reasoning, people are able to process subjective information based on intuitive experience. Heuristic reasoning is further divided into three different types of process.

Representativeness heuristics is when the decision-maker uses base-rate data to make judgements (Cioffi, 1997). For example, when assessing a patient with dyspnoea and a history of Chronic Obstructive Pulmonary Disease (COPD), the ambulance nurse uses previous experience of COPD patients and establishes at an early stage in the assessment process that the patient’s dyspnoea is due to COPD. The decision is based on the frequency of previous experience of similar patients. The ambulance nurse takes a short-cut in the assessment process.

Accessibility heuristics is divided into two types of reasoning. The first is the availability of the way a probable hypothesis can be brought to mind. A situation that is different, easily imagined and exact will be more readily available than a situation that is more unemotional. The process is dependent on the decision-maker’s experience of similar situations (Patel et al., 2002). The second type of accessibility is mental simulation, described as when the decision-maker uses
mentally simulated events and selects the most negative alternative (O'Neill, 1995).

Anchoring and adjustment heuristics is when the decision-maker establishes an anchor point based on previous experience and knowledge and then makes adjustments from this anchor point (Cioffi, 1997).

As in the COPD patient example, the ambulance nurse established an initial diagnostic hypothesis (anchor) early in the assessment process and then used the rest of the assessment to confirm (adjust) the hypothesis.

Another term used to explain the reasoning process in System 1 is intuition. The role of intuition in JDM has been particularly explored in nursing research (Benner & Tanner, 1987). The term “intuition” has been described in several different ways and there is a lack of consensus about the terms (Cert & Wilcockson, 1996). Intuition has been characterised as a process in which it is not possible to explain or understand why a decision has been made (Thompson & Dowding, 2001). However, intuition is described as rapid, unconscious and automatic decision-making, dependent on the decision-maker’s experience. Intuition has also been described as the feature which distinguishes the novice from the expert (Benner, 1982). Kahneman (2003) describes intuition as “judgements that directly reflect impressions and are not modified by System 2”. Cioffi (1997) argues that intuition is related to heuristics and can be partly explained by heuristics. Crandall and Getchell-Reiter (1993) investigated nurses at a neonatal intensive care unit who were supposed to have an intuitive ability to predict whether or not the patient was in need of antibiotic therapies. The researchers used an interview technique called critical decision method (Klein et al., 1989) and were able to identify the clues the nurses used to predict septicaemia in patients. Crandall and Getchell-Reiter argue that the nurses did not use intuition. Instead, they used experience of early signs of patients at risk of septicaemia. The results of the study could subsequently be used to formulate guidelines for antibiotic therapies. The process of using past experience by comparing the current situation with previously experienced situations stored in the memory is described in another study (Cioffi, 2001).

The problem with intuition as a concept is the vague definition and the sense of something mystical and unexplainable phenomena. Perhaps the use of past experience is what intuition is all about.

The use of schemata is also a process proposed to be related to System 1 reasoning. People use different kinds of schemata. Some are pre-programmed sequences of actions, such as walking, and have been labelled motor schemata. Motor schemata are used in routine actions of which the person has a great deal of experience (Byrne, 2013). One example from the pre-hospital setting could be the expert ambulance nurses’ inserting intravenous cannulae.
To be able to convert complex information from the world around into meaningful constructs, the decision-maker unconsciously uses perceptual schemata to compare new information with past experience (Byrne, 2013). The use of these mental models or schemata has been found to reduce the problem of limited working memory by treating complex information as a collection of individual pieces (Byrne, 2013).

The expert ambulance nurse who uses a predetermined model in the assessment of a critically ill patient could be an example of the use of perceptual schemata. The schemata could be divided into the assessment in a first survey with assessments of Airway, Breathing, Circulation and Disability (ABCD) (alphabetical reasoning) and a second survey of further assessments and examinations.

The descriptions of System 2 processes differ a great deal from the processes involved in System 1. System 2 reasoning has been labelled analytical. It is in situations that include uncertainty and poorly defined tasks that System 2 appears to be the dominant thinking process (Evans, 2008). The reasoning in System 2 requires access to the central working memory, unlike System 1 processes which are knowledge based. This means that the process is slow and has limited capacity (Reason, 1990). Research has also shown that System 2 reasoning is dependent on the decision-makers’ individual differences in intelligence and working memory capacity, whereas System 1 reasoning is not dependent on individual differences to an equal extent (Evans, 2008). In contrast to System 1 reasoning, the analytical approach is not supposed to be dependent on context (Croskerry, 2009a). The extent to which the two systems are involved in a task is very much dependent on the decision-maker’s past experience. People with a great deal of experience in the domain (experts) have a richer selection of schemata (Schmidt & Boshuizen, 1993). This means that the expert can use System 1 reasoning much more than the novice and, as a result, can make faster, more accurate decisions (Byrne, 2013). The novice’s lack of stored schemata is also probably the reason for the novice’s difficulty in focusing on important structures and the opportunity for fast pattern recognition processes, which is characteristic of the expert (Patel et al., 2002). Kahneman (2003) argues that expert decision-makers often perform better when they use System 1 processes than when they use comprehensive analysis. The expert’s reasoning is suggested to be more data driven in comparison with the novice. The novice’s reasoning is more hypothesis driven, where the hypothesis guides data collection and explanation (Patel et al., 2001). The differences in reasoning also make the bias different. The novice makes errors of commission because of his/her inability to distinguish relevant from irrelevant information and the expert is more prone to omission errors related to heuristic shortcuts (Patel et al., 2001).
The model in Figure 1 provides the theory with a schematic overview of reasoning in dual process theory. The figure shows that JDM often includes both types of reasoning. There is a dynamic alternation between the two systems, but the type 1 system is dominant (Croskerry, 2009b). For example, the repetitive performance of a task using System 2 reasoning can transfer the reasoning to an automatic System 1 reasoning. Type 1 reasoning can override type 2 reasoning about irrational behaviours. The reason can be fatigue, stress and sleep deprivation, for example. Type 2 reasoning could override Type 1 in a rational manner (Croskerry, 2009a). For example, memory aids such as checklists and reminders can trigger an override to type 2 reasoning (Ely et al., 2011).

One reason for the expert’s (an expert is defined as a person with more than 10 years’ domain-specific experience) superior decision-making can be found in Klein’s (1999) work on naturalistic decision-making and his Recognition-Primed Decision Model (RPD), which is a variant of the dual process model. In naturalistic environments, Klein and associates have investigated the decision process of expert decision-makers in situations which involve the need for rapid decisions in unstable and dynamic environments. They have, for example,
studied the decision-making of fire captains, tank platoon leaders, aircraft captains and captains of military ships. The model describes how people use experience to produce a chain of patterns and explains how people can make rapid decisions without comparing different options; they instead use the patterns to highlight the most relevant information, see the goals and identify typical reactions according to the situation. They can then make a decision by comparing the situation with the patterns (Klein, 1999). RPD research has also revealed that people who are forced to make very rapid decisions have used mental simulations of how they should make decisions in a different situation (Klein, 2008). The RPD model describes a mix of both an intuitive and an analytical approach (Systems 1 and 2). Using only intuitive methods is too risky, as the patterns could be inconsistent, and using only analytical methods can be too slow (Klein, 2008).

The model shows two processes (Klein, 1999). A basic strategy in routine situations is when the decision-maker recognises the situation as typical and of a routine nature. He/she immediately knows which type of goals to set, which cues to look for, what to expect in the future and the typical way of responding. If the situation is of a non-routine nature, the decision-maker has to pay more attention to diagnosing the situation by gathering more information, as the situation does not match a typical case. In more unfamiliar cases, the decision-maker imagines the course of action to evaluate a single option. The decision-maker in an unstable environment never compares options at the same time (Klein, 1999).

What the RPD model can add to dual process theory is the fact that expert decision-makers in situations of high acuity and time pressure use System 2 reasoning minimally and do not compare options with one another.

A theory which explains the expert’s reasoning in medicine is the “Stage Theory of Clinical Reasoning” (Schmidt et al., 1990). The theory describes the transition of the medicine student from novice to expert. In a novel situation, the novice uses pathophysiological knowledge in clinical reasoning, but, after seeing more patients, the pathophysiological knowledge is gradually replaced by simplified mental models called illness scripts in the model. Through experience, the clinicians develop more and more illness scripts based on earlier experience of patients and clinical situations. Decision-making in routine cases by expert clinicians is therefore rapid and automatic. The process involves script search, script selection and script confirmation (Schmidt et al., 1990). The use of the illness scripts enables the expert clinicians to process the clinical information in a pre-existing linear mode with a fixed order. It makes the decision-making rapid, automatic and without comparing options to one another (Schmidt & Boshuizen, 1993). In solving more complex clinical problems, the expert clinicians use more analytical processes (System 2) and the reasoning is more
similar to the reasoning of the novice, using pathophysiological knowledge (McLaughlin et al., 2008).

2.2.3 Decision-making in emergency care

The RPD model is suggested to fit well in emergency care (Croskerry, 2002). All kinds of emergency care have been labelled unstable, due to their uncontrolled volume of patients, variable level of acuity, lack of information, time sensitivity, stress and fatigue (Kovacs & Croskerry, 1999, Croskerry, 2002). The cognitive strategies used in emergency care have been shown to be similar between nurses and doctors (Crow et al., 1995). The way clinicians collect and process information is the same. The only difference is the goal of the processes. The nurses search for clues which can explain the patients’ conditions and the doctors search for clues for a medical diagnosis (Crow et al., 1995). Clinicians involved in emergency care use several different methods in the decision-making process, all fitted in the dual process theory (Croskerry, 2009a). The similarity of the initial assessment of the critically ill patient between in-hospital and pre-hospital emergency care makes it possible to use studies from in-hospital emergency care clinical reasoning as a framework for the reasoning in pre-hospital care (Alexander, 2009). The most common methods in clinical JDM have been described as follows.

Pattern recognition is labelled as a common strategy in emergency care. A combination of significant symptoms produces pattern recognition of a specific disease. The clinician’s past experience of the symptoms is an important feature in pattern recognition. In this context, pattern recognition can be similar to the process of anchoring (Croskerry, 2002).

The exhaustive method is defined as a strategy typically used by novice clinicians. The clinicians scan the patient for all possible data in order to produce diagnoses. The strategy is slow and ineffective and can also be used by more experienced clinicians afflicted by stress or fatigue (Croskerry, 2002).

The hypothetico-deductive method is probably the most extensively studied and influential model of clinical decision-making (Patel et al., 2002). The first stage in the model is hypothesis generation, where the clinicians produce an early hypothesis based on patient history, a physical examination, vital signs and the clinicians’ past experience. Representative heuristics and availability heuristics are important processes in the initial assessment. The next stage in the model is hypothesis evaluation, where the clinicians use strategies to confirm or evaluate the hypothesis. The last stage is hypothesis verification and, after verification, the clinician can draw up a treatment plan for the patient (Kovacs & Croskerry, 1999). In emergency situations, in the assessment of the critically ill or injured
patient, clinicians involved in emergency medicine appear to abandon the hypothetico-deductive method in favour of the alphabetical model (algorithms), such as the ABCDs of resuscitation (for examples, see Box 1). The assessments in these cases are more protocol based (Aleksandra et al., 2012).

Another common decision-making strategy in emergency care is the Rule Out Worst-case scenario (ROW) (Croskerry, 2002). The clinicians start the assessment by looking for signs of critical condition. The cognitive processes are a combination of pattern matching and availability heuristics (Croskerry, 2002). For example, the ambulance nurse who assesses a patient with symptoms of chest discomfort starts with a physical examination to eliminate serious conditions such as unstable angina, acute myocardial infarct and aortic dissection.

2.2.4 Decision-making in the pre-hospital emergency setting

As mentioned before, errors in the decision-making process are probably the main threat to patient safety in pre-hospital care (Bigham et al., 2012). There are few studies which have investigated the pre-hospital care provider’s JDM. The few studies of pre-hospital JDM reveal a similarity in the cognitive methods used in the pre-hospital setting to methods used in in-hospital emergency care (Alexander, 2009; Jensen et al., 2011). The main difference between in-hospital and pre-hospital emergency care is suggested to be the environment where the JDM is executed (Jensen, 2011). For example, in the pre-hospital setting, the clinicians had to make an improvised caring space (Wireklint Sundström, 2005). Other decision points typical of pre-hospital care are the level of care tempo, decisions about where the assessment and treatment should be performed (on the scene, on route, at hospital) and decisions about the level of care (leave patient at home, transfer patient to primary care, nearest Emergency Department (ED) or some kind of specialist centre) (Wireklint Sundström, 2005). At an early stage, the pre-hospital clinicians learn the schemata of the typical ambulance mission which involves receiving the call, arriving at the address, performing an on-the-scene assessment, performing an initial patient assessment, transporting the patient to the ambulance, performing further assessments and treatment on route, arriving at hospital and handing over the patient (Jensen, 2011). The JDM process starts the moment the ambulance clinicians receive the call. Based on information from the dispatch centre, the ambulance clinicians use past experience to imagine the scenario (Wireklint Sundström, 2005). To use the concept of the RPD model (Klein, 1999), they mentally simulate the expected scenario. The reason for this process is suggested to be an effort to be mentally prepared and shorten the cognitive starting run (Wireklint Sundström, 2005). Research is also described anchoring and adjustment heuristics in this phase of the ambulance mission.
when the clinicians use the information from the dispatch centre to plan for a specific condition (Wireklint Sundström, 2005). Another study (Alexander, 2009) confirms the use of anchoring and adjustment heuristics very early in the assessment process. Research has revealed that the phase during the ambulance mission which imposes the greatest demands on the clinicians is the on-the-scene phase. Outside the ambulance, the clinicians have to deal with inconsistent settings and are given the least cognitive support (Jensen, 2011). In the patient assessment, the ambulance clinicians use cognitive models similar to clinicians’ in-hospital emergency settings (Alexander, 2009). The models of System 1 and System 2 thinking are in use (Jensen, 2011). It appears to be the patient’s level of urgency that determines whether System 1 or 2 is used. In situations in which the patient shows symptoms of failure in vital functions, a schedule-based, automatic approach is more common in comparison with more stable situations where there is time for more analytical reasoning (Wireklint Sundström, 2005; Leblanc et al., 2012).

Another feature suggested to distinguish the pre-hospital JDM from the in-hospital setting is the frequent use of cognitive tools such as guidelines, protocols and algorithms in the JDM process (Jensen et al., 2011). This particular form of reasoning is labelled System 2-by proxy. The System 2-by proxy strategy includes elements of algorithmic reasoning and ruling out the worst case scenario (Jensen, 2011). In a study (Jensen, 2011) using talk-aloud protocols, it was shown that System 2-by proxy reasoning was dominant among Canadian advanced care paramedics. The System 2-by proxy reasoning was used in 137 decisions, System 1 reasoning in 78 decisions and System 2 reasoning in 60 decisions (Jensen, 2011). The use of early experience has also been suggested to be a typical strategy in pre-hospital JDM (Burrell et al., 2013; Hosea, 2002; Pugh, 2002). However, the use of experience is fundamental in all strategies in System 1 reasoning (Schmidt & Boshuizen, 1993). A simulation study (Smith et al., 2013) showed that experienced pre-hospital clinicians use clinical information in a more effective manner to reach a field diagnosis. They also perform more assessments and interventions compared with the novice. The reason for the difference is probably that the experienced pre-hospital clinicians have more stored schemata based on earlier experience which they use to interpret information (Smith et al., 2013). The ambulance mission has also been characterised by pronounced teamwork. The way the teamwork functions can determine which JDM strategies are used, as well as the quality of the decisions (Wireklint Sundström, 2005).

A feature which has been described as important in JDM processes in emergency settings is the so-called letter courses (Aleksandra et al., 2012). The first course of this kind was the Advanced Trauma Life Support course (ATLS), which was introduced in the USA in the late 1970s (Johansson et al., 2012). The corresponding pre-hospital course is the Prehospital Trauma Life Support (PHTLS) (2011) course. In emergency situations, emergency clinicians
tend to leave the hypothetico-deductive reasoning and instead use the algorithmic reasoning suggested in the letter models (Aleksandra et al., 2012). It is not only in trauma cases that similar models have been used. The medical analogue to ATLS is Advanced Medical Life Support (AMLS) and there have also been courses for the pre-hospital setting (Dalton, 2010). The concept of the models is to divide the assessment into a series of well-defined tasks. The assessment starts with a first survey, where airway, breathing, circulation and disability are assessed and, if needed, treated. The assessment continues with a second survey including patient history, establishment of main symptoms, focused examination, establishment of a field diagnosis and treatment (PHTLS, 2011, Dalton, 2010) (for a pre-hospital example, see Box 1). It has been shown that, by educating pre-hospital clinicians in the PHTLS concept, the mortality among trauma victims has been reduced (Johansson et al., 2012). Similar evidence of AMLS effectiveness is lacking, but there is reason to believe that the concept could also benefit the pre-hospital medical patient (Stiell et al., 2007).
Box 1. Alphabetical reasoning in an assessment framework

<table>
<thead>
<tr>
<th>Primary survey</th>
<th>Airway</th>
<th>Airway assessment and treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Breathing</td>
<td>Assessment of spontaneous breathing</td>
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<td></td>
<td></td>
<td>Assessment of breathing rate (estimated)</td>
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<tr>
<td></td>
<td></td>
<td>Assessment of breathing quality</td>
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<tr>
<td></td>
<td></td>
<td>Assessment of cyanosis</td>
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<tr>
<td></td>
<td>Circulation</td>
<td>Assessment of external bleeding</td>
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<tr>
<td></td>
<td></td>
<td>Assessment of pulse rate (estimated)</td>
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<tr>
<td></td>
<td></td>
<td>Assessment of localisation of pulse</td>
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<tr>
<td></td>
<td></td>
<td>Assessment of skin</td>
</tr>
<tr>
<td></td>
<td>Disability</td>
<td>Assessment of pupil size and reaction to light</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assessment of strength of extremities</td>
</tr>
<tr>
<td>Anamnesis</td>
<td>Question formulation</td>
<td>What symptoms have been observed?</td>
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<tr>
<td></td>
<td></td>
<td>When did symptoms start?</td>
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<tr>
<td></td>
<td></td>
<td>What makes symptoms worse or better?</td>
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<tr>
<td></td>
<td></td>
<td>What is the character of the symptoms?</td>
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<tr>
<td></td>
<td></td>
<td>Localisation or radiating?</td>
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<tr>
<td></td>
<td></td>
<td>Severity of symptoms?</td>
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<td></td>
<td></td>
<td>Duration of symptoms?</td>
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<td></td>
<td></td>
<td>Allergies?</td>
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<td></td>
<td></td>
<td>Medical history?</td>
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<td></td>
<td></td>
<td>Present medication?</td>
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<tr>
<td></td>
<td></td>
<td>Last oral intake, elimination?</td>
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<tr>
<td></td>
<td></td>
<td>Events preceding the symptoms?</td>
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<tr>
<td>Secondary</td>
<td>Determine the chief complaint</td>
<td></td>
</tr>
<tr>
<td>survey</td>
<td>Focused examination based on the chief complaint</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Determine field diagnosis</td>
<td></td>
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<tr>
<td></td>
<td>Treatment</td>
<td></td>
</tr>
</tbody>
</table>

2.2.5 Human errors

“To Err Is Human: Building a Safer Health System” is the title of the Committee on Quality of Health Care in America, Institute of Medicine’s influential report on patient safety (2000). The title of the report indicates that errors are an important feature of being a human. As long as humans are
involved in a system, errors are bound to occur (Reason, 2000). Reason (1995) argues that organisations must be conscious of the course of error and build a layer of defence in the organisation to avoid errors among front-line providers. In his _generic organisational accident model_ (Reason, 1990), Reason divided errors into _active failures_, which are the errors of people at the “sharp end” of an organisation. In health care, these are errors committed by doctors, paramedics and nurses in direct contact with the patient (Reason, 2000). However, the most important errors are _latent failures_, which he describes as a sickness in the organisation which leads to front-end active failures. He further says that, in every organisation, there are a number of defence layers to prevent active failures. If these layers contains holes, like those in slices of Swiss cheese, which are constantly opening, shutting and shifting, so that the location and the holes are temporarily lined up, an opportunity for an error can pass through the organisation (Reason, 2000). Examples of latent failures can be poorly adapted working hours, poorly adapted cognitive support, lack of resources, a poor safety culture and so on (Reason, 1995).
Figure 2. Generic organisational accident model applied to a pre-hospital care system (after J. Reason)

The generic organisational accident model could be used to identify the reasons why pre-hospital clinicians sometimes make errors in JDM. By screening the pre-hospital literature, eight latent and active failures were found as a possible reason for error in JDM (see Figure 2).

- Inadequate external education (Atack & Maher, 2010)
- Lack of experience (Atack & Maher, 2010)
- Inadequate internal education (Atack & Maher, 2010)
- Poorly adapted equipment (Atack & Maher, 2010; Bigham et al., 2011)
- Poorly adapted cognitive tools (Bigham et al., 2011; Bigham et al., 2012)
- Lack of feedback (Atack & Maher, 2010; Brice et al., 2012)
- Fatigue, stress, environmental factors (Patterson et al., 2012)
- Motivation and morale (Patterson et al., 2010)
- Errors of cognition (Bigham et al., 2011; Bigham et al., 2012; Brice et al., 2012)

Reason (1995) defines an active failure as “the failure of planned actions to achieve their desired goal”. He estimates that 90% of accidents in hazardous technologies have their origin in human error. He further divides errors into slips and lapses and mistakes. Slips and lapses are errors related to failures which
have their origin in failures of memory. The errors often occur in routine and automatic processes involving System 1 reasoning. The plan is good, but it is in the execution of the plan that failure occurs. The reason for slips and lapses can be distractions and interruptions during a task (Reason, 1995). In the case of mistakes, however, it is the plan which is inadequate, but the execution proceeds as planned. This makes mistakes far more difficult to identify than slips and lapses. He further divides mistakes into rule-based mistakes, which are mistakes which are due to the decision-maker’s stored schemata not fitting the task, and knowledge-based mistakes, which are described as mistakes in situations which are new to the decision maker. In knowledge-based mistakes, analytical System 2 reasoning is involved in the process, which makes the reasoning slow and resource limited (Reason, 1995).

According to Reason (2002), errors of omission are probably the most common human error type of all kinds. These errors have their origin in heuristic reasoning (System 1), which is the use of shortcuts and rules of thumb (Tversky & Kahneman, 1974). In situations where a task step is involved in a high informational load, which is demanding for the short-term memory, there is a risk that the task step will be omitted (Reason, 2002). Task steps that are functionally isolated also risk being omitted. Further, task steps at the end of a series of steps risk being omitted. This is also called premature exit or premature closure and, where two task steps are similar, the last task step is often omitted. Interruption is a common cause of the omission of task steps (Reason, 2002). As mentioned before, heuristic reasoning is regarded as a common strategy, especially in emergency medicine (Croskerry, 2002), but heuristics have also been shown to be prone to bias (Tversky & Kahneman, 1974). Croskerry (2002) identified 30 different sources of cognitive bias in emergency settings. The majority of the bias is due to the omission of task steps related to problems in heuristic reasoning. Important cognitive biases are as follows.

- **Aggregate bias** is when clinicians treat the individual patient differently from what has been decided for a group of patients in clinical guidelines, for example. The consequence is that the patient is assessed and treated differently from the standard and is exposed to unnecessary tests and assessments (Croskerry, 2002).

- **Anchoring bias** is when the clinicians decide on a diagnosis or hypothesis too early in the assessment process and spend the rest of the assessment confirming the diagnosis. There is a real risk that the clinicians will ignore important information in favour of information which confirms the initial hypothesis. This bias can lead to premature closure. Anchoring is a risk when the clinicians have been provided with an early hypothesis from other health-care personnel involved with the patient (Croskerry, 2002). For example, there is a risk of anchoring
when ambulance personnel in the hand-over phase at the ED report in diagnosis terms (Alexander, 2009). With this knowledge, there may also be a possible risk of anchoring when the ambulance personnel are provided with a suspected diagnosis by the dispatch centre. This phenomenon is called diagnostic momentum (Croskerry, 2002).

- **Ascertainment bias** occurs when the clinician’s reasoning is influenced by expectation. For example, when a patient with nocturnal dyspnoea also has symptoms of ankle oedema, the clinicians expect the reason for the dyspnoea to be congestive heart failure. This bias can lead to the collection of pseudo-information and the neglect of some other information. This bias can be a reason for premature closure (Croskerry, 2002).

- **Availability bias**; in heuristic reasoning, there is a tendency to treat the most available information as the most relevant information. If the clinicians recently assessed a patient with chest pain due to unstable angina pectoris, there is a risk that the clinicians will treat the next patient with similar symptoms in the same manner because the schemata is easily available (Croskerry, 2002).

- **Representativeness bias** is when the clinician judges the patient’s symptoms on the way these symptoms are usually assessed, based on previous experience. Clinicians use base rates and probability in their reasoning. The risk of the strategy is premature closure (Croskerry, 2002).

- **Sutton’s slip** is a strategy of “going where the money is”. This is when the clinicians bet on the most probable reason. In emergency medicine, this strategy is regarded as a good strategy, but there is a risk that the betting is wrong and leads to a premature closure (Croskerry, 2002).

- **Vertical line failure** occurs when the clinicians are too rigid and fail to think outside the box. Most conditions in emergency care benefit from a vertical line approach, but, in more uncommon and complicated cases, there is a need for clinicians to step outside the box in order not to miss or delay diagnoses (Croskerry, 2002).

The cognitive bias among ambulance personnel, in particular aggregate bias, anchoring, availability and unavailability biases, appears to be similar to the bias in the in-hospital emergency setting, together with vertical line failure (Alexander, 2009). A simulation study (Alexander 2009) has shown that ambulance personnel anchor to a significant aspect, or a few significant aspects, very early in the JDM process. The anchoring in the study was so strong that the participants collected very little information to confirm the diagnoses. The study participants showed an inability to use mnemonic-driven data collection, which leads to a disorganised patient assessment and history taking (Alexander, 2009). A common strategy among the study participants was ROW but without actually ruling out the worst-case scenario. A lack of adequate schemata for the situation in the study is probably the reason for the bias (Alexander, 2009), so-
called rule-based mistakes (Reason, 1995). This is the result of only one study and there is a need for more studies of cognitive problems in the pre-hospital setting (Cone, 2007). An example of cognitive bias is shown in Box 2. The case has been described after an interview with a highly experienced Swedish ambulance nurse.

Box 2. Example of JDM error in the pre-hospital setting.

| The ambulance team receive an emergency call on the beeper. It is late afternoon and they have had a busy shift with several emergency calls. From the dispatch centre, they receive some information about the patient. It is a woman in her sixties with breathing problems. She is allergic but healthy apart from that. The team is near the address and gets there in a few minutes. They meet the patient outside her house. She has severe dyspnea and tachypnea. The ambulance nurse starts the history gathering. The patient is from a foreign country and they have some communication problems depending on both language issues and the dyspnea. The patient says that she has abdominal pain but thought it was from a hernia and she talks about an X-ray she had undergone yesterday and that she is allergic. She is cyanotic with low saturation and has a high pulse rate. At this moment, the ambulance nurse decides to treat the patient as having anaphylaxis and gives the patient a dose of 0.3 mg of adrenaline. He also gives the patient 10 litres of oxygen. Transport to the ED begins. The patient improves during the transport, the cyanosis disappears and she has better saturation. The patient still has a high respiration rate and abdominal pain. In the handover phase at the ED, the ambulance nurse reports that he has treated the patient as having anaphylaxis and the treatment has had a good effect. Later at the ED in connection with further examinations including an electrocardiogram, it is found that the patient has had a cardiac infarction. The infarction was the reason for the abdominal pain and the dyspnea. The patient was sent to the catheterisation laboratory. |

2.3 Decision support systems

This thesis uses three different decision support terms. The terms “Decision Support Tool (DST)” and “Decision Support System (DSS)” are different terms for the same thing. The definitions include a broad perspective of decision support ranging from simple paper-based algorithms to advanced information technology and can have both a paper-based and an electronic format. Perrault (1999) describes a DSS as an instrument supporting diagnoses, treatment plans, guidelines and best practice. The DSS also has an administrative function for coding and documentation. The present thesis focuses on the features of the Computerised Decision Support System (CDSS). The term “computer” is a synonym for information and communication technologies. Decisions are the management of the individual patient and support is defined as the aiding of decisions (Greenes, 2007).
2.3.1 Protocol-based care

According to a concept analysis (Ilott et al., 2006), Protocol-Based Care (PBC) is an umbrella term which includes clinical guidelines, protocols and algorithms, care pathways, procedures and patient group directives. The objective for the procedures is to promote Evidence-Based Practice (EBP) and to standardise the care. PBC is also a way to expand autonomy among some groups in health care, for example, nurses and ambulance personnel, and for the assessment and verification of the competence needed to perform certain tasks. According to concept analysis, clinical guidelines are a rated set of recommendations to assist clinical JDM and are based on the best clinical evidence. Protocols and algorithms are defined as comprehensive written instructions on how to complete a specific task and care pathways are defined as a description of the whole passage for a typical patient with a specific diagnosis from admission to discharge. A care pathway can include clinical guidelines and/or protocols and/or algorithms nested at points along the pathway (Ilott et al., 2006).

Clinical guidelines have been described as prescriptive models to assist clinical practitioners to make decisions about patients with particular symptoms, diseases or conditions (Rycroft-Malone, 2002). The health-care system has used guidelines for 30 years. The development of clinical guidelines was a reaction to a large variation in clinical practice, documentation and an interest in health-care economy. The early guidelines were often designed by a group of experts, but nowadays guidelines are an important tool to promote EBP (Latoszek-Berendsen et al., 2010). Recommendations in guidelines are linked to scientific research and these specific guidelines have been labelled evidence-based guidelines (Lugtenberg et al., 2009). The level of evidence varies in different guidelines and the level of evidence has been classified through different systems (Latoszek-Berendsen et al., 2010). Although guidelines are comprehensive and can contain a large amount of text, some guideline developers have also translated the guidelines into algorithms. Algorithms are described as guidelines in a compressed and manageable format, designed to aid clinicians in the JDM process in a busy environment (Patel et al., 2001). Checklists are another form of DSS. Checklists have been used in certain high-security areas such as the aviation industry, the nuclear power industry and in the military environment for many years (Thomassen et al., 2011). In health care, checklists have not been implemented extensively (Bosk et al. 2009). The main goal of checklists is to promote patient safety by reducing errors of omission (Reason, 2002).

The use of clinical guidelines had been shown to benefit the quality of health care. A systematic review (Grimshaw & Russell, 1993) of the effectiveness of clinical guidelines revealed that, of 59 studies, all but four detected a significant improvement in quality of care after the introduction of guidelines. The crucial
factors for success were the clinical context and the methods for developing, disseminating and implementing the guidelines (Grimshaw & Russell, 1993). Other studies indicate that clinical guidelines can be an effective tool for improving patient outcome. In a study aiming to investigate the effect of a high level of compliance with evidence-based guidelines for acute coronary syndrome, the results indicate that a high level of compliance is related to a high survival rate. The authors also suggest that compliance with guidelines could be used as a measurement of quality of care (Peterson et al., 2006). In a study of evidence-based guidelines in the Netherlands, the use of guidelines had a strong effect on the process of care, but the effect on patient outcome was weaker (Lugtenberg et al., 2009). One possible reason is that the process of care is easier to measure than outcomes such as morbidity and mortality (Pronovost & Lilford, 2011). In conclusion, the use of clinical guidelines has had a positive effect on the process and structure of care. The direct effect of guideline use on patient outcome has been much more difficult to establish.

The main problem with clinical guidelines and other kinds of DSS has been found to be the implementation (Gagliardi et al., 2011). Several attributes that have an effect on compliance have been identified. There have, for example, been differences in compliance, depending on the type of health problem with which the guidelines deal. Acute conditions have been found to have higher compliance than chronic problems (Gagliardi et al., 2011). The quality of the evidence and the way the information is presented (format) have also been factors contributing to compliance (Grol & Grimshaw, 2003). Another suggestion relating to the issue of weak compliance is that the guideline developer did not consider natural cognitive processes when the guidelines were developed (Gagliardi et al., 2011). There have been many suggestions for ways of increasing guideline compliance. Many of these interventions had a limited effect. For example, education and information on the guidelines have a very short and weak effect on compliance (Grol & Grimshaw, 2003). One feature which has been shown to increase guideline compliance is reminders (Grol & Grimshaw, 2003). Reminders have been an effective tool in preventing omissions of all kinds. An effective reminder needs to contain some important features in order to be effective. The reminder needs to catch the decision-maker’s attention; the reminder should provide a checklist of what has been done, the reminder should not cause unwanted or additional problems and the reminder has to be positioned as closely as possible in time and the location where the task is executed (Reason, 2002). The format of the guidelines has been identified as an important factor when it comes to the effect of guidelines on JDM (Rycroft-Malone J, 2010). Typical paper-based guidelines have been difficult to use in a busy clinical setting. They have usually contained a great deal of text and the format has not always been adapted for use explicitly in front of the patient (Morris, 2002). Various forms of information presentation
have been found to have different effects on cognition. A study performed by Patel et al. (2001) compared the decision-making among experts and novices when they used clinical guidelines in a typical text-based format with guidelines in an algorithmic format. The participants found it much easier to organise the information using the algorithms. The algorithms functioned as a reminder for the expert decision-maker and were an important tool for bridging knowledge gaps among the novices. The algorithmic guidelines helped the study participants to focus on relevant information and the collection of unnecessary information was reduced (Patel et al., 2001). The result suggests that the format of guidelines and the presentation of information are important. In a comprehensive study, Rycroft Malone et al. (2010) investigated the impact of PBC in the UK. They found several factors which have an impact on the use of guidelines and protocols. The feature with the highest impact was also the format of the guidelines, together with the location and the visibility of the guidelines, the personnel’s experience and education, where nurses use them more than doctors and novices more than experts and the flexibility of the standardised care approaches also has an impact on the way they were used (Rycroft-Malone J, 2010). There is also a review which has shown that guidelines integrated in a computerised system had a better effect compared with traditional paper-based guidelines (Kawamoto et al., 2005).

In addition to problems with compliance, PBC has been shown to have other potential limitations. One is that the recommendations in the guidelines are wrong and the result can be that the patient does not receive the best care. Another possible limitation could be that patients’ needs are not the only priority. Other factors such as cost, special interests and social factors may have influenced the guideline developer (Morris, 2002). Guidelines which are inflexible could also have a negative effect on the individual patient, if there is no scope to take personal circumstances into account (Morris, 2002). Further, guidelines are supposed to be time consuming and to have a negative effect on clinical work (Steven et al., 1999). Finally, it has been suggested that all information technology can change human performance and there could be a risk that the use of clinical guidelines can negatively impact clinicians’ professional development (Patel et al., 2002).

Pre-hospital care is an area in health care which is very much dependent on PBC (Jensen, 2011). Several reasons have been proposed. Ambulance providers are dependent on standing orders in order to perform tasks which otherwise require a physician’s directive. The pre-hospital work is performed a long distance from medical support; the personnel handle many different symptoms and conditions in changing environments and with different levels of education and experience (Cone, 2007). This context necessitates step-by-step medical supervision in treatment protocols and algorithms (Lang et al., 2012). The unique context also requires the development of guidelines which should cover
a large number of clinical conditions, should be suitable for use in varying and demanding environments and suit personnel with varying education and experience (Cone, 2007). There is a need for research on guideline development and the use of computerised decision support in the pre-hospital setting (Cone, 2007).

Even in the pre-hospital setting, evidence-based guidelines have the ability to benefit patient outcome (Atary et al., 2010), but studies also indicate that compliance with guidelines is sometimes low in pre-hospital care (Figgis et al., 2010; Woollard et al., 2001; Rittenberger et al., 2005; Fisher and Vinci, 1995; Taira et al., 2010). The reason for this poor guideline compliance in the pre-hospital setting is unknown, but there is reason to believe that factors similar to those in other health-care settings influence compliance. A systematic review (Ebben et al., 2013) has identified a wide range in compliance with pre-hospital guidelines varying from 7.8% to 95%. The guideline recommendations with the poorest compliance were treatment recommendations related to myocardial infarction and cardiac arrest. Monitoring guidelines had greater compliance compared with treatment plans (Ebben et al., 2013). In addition to problems with compliance, there are other problems when it comes to pre-hospital PBC. Research has found that the majority of the evidence in pre-hospital guidelines is based on research in the in-hospital setting and there is a lack of validation for applications in the pre-hospital setting. It is estimated that only 4% of the recommendations in pre-hospital guidelines are supported by high-quality evidence (Lang et al., 2012). Another problem that has been identified in connection with PBC in the pre-hospital field is the lack of control due to the context which is characterised by rapid decision-making. Identifying the use of guidelines and protocols among pre-hospital providers has been a problem (Cone, 2007).

### 2.3.2 Computerised decision support systems

The aim of a CDSS in a health-care setting is to make data assessment easier and/or to obtain optimal JDM among clinicians. Another task of a CDSS is to select knowledge which is relevant and in the end produce recommendations for action (Greenes, 2007).

CDSS have been divided into two broad classes, passive and active systems (Greenes, 2007). In passive systems, the processing in the system is not patient specific. They instead make relevant data more accessible and assist the decision-maker by organising the data in manageable forms. Examples of a passive system can be the translation of a paper-based clinical guideline to a computer format (Hajioff, 1998). Computer-based guidelines appear to offer benefits compared with paper-based guidelines. There is, for example, evidence that clinicians assess electronic information more frequently than paper-based
information (Prgomet et al., 2009). Another example of passive systems is Electronic Health Records (EHR). In their simplest form, EHR are a repository for patient data in digital form (Häyrinen et al., 2008). EHR have several goals, one of which is to standardise the document architecture. A method for accomplishing this is to use an associative grouping of elements (Greenes, 2007). One example is to group the anamnesis in past medical history, signs and symptoms, allergies and so on. Another goal is to structure the data entry. This can be accomplished using two methods, the use of flow charts, which constitute data entry in a step-by-step fashion, and the use of frameworks, where the data structure represents a model of a fixed situation (Greenes, 2007). An EHR has also been defined as time oriented, where the data are presented in chronological order, and problem oriented, where each problem is described according to the information, assessments and treatment plan (Häyrinen et al., 2008).

One feature of an active system is that patient-specific data are used to provide decision support. A wide range of methods is used in active systems. The more common methods include the use of alerts and reminders. Alerts are a notification of a situation which requires attention. The system is triggered by background events, such as abnormal tests and medication allergies. A reminder has the same purpose, but it is triggered by process steps and time (Greenes, 2007). More complex systems use statistics, mathematical calculations, diagrams and tables to assist the clinicians in the JDM. For example, probabilistic and data-driven classification uses Bayesian statistics to calculate the probability of a diagnosis by using patient data such as the presence of, the absence of, age, gender and so on. Another method in this class of systems is decision analysis using decision trees (Greenes, 2007). The prerequisite for the models is access to a certain amount of data. In unstable settings, such as all kinds of emergency care, the data are often insufficient (Croskerry, 2002). The models used in unstable settings have often been heuristic modelling and expert systems. These models are based on an attempt to match human expertise and reasoning processes. An important feature of these models is the knowledge of cognitive processes (Greenes, 2007). Research has shown that experts in clinical decision-making use pre-existing linear constructions in a fixed order when processing patient information (Schmidt & Boshuizen, 1993). Frameworks, flowcharts, clinical guidelines, grouping of elements and rule-based systems are examples of techniques in these models (Greenes, 2007). Rule-based systems are often used in patient management systems. The conclusions in rule-based systems often apply simple Boolean logic; matching pieces of data with specific conditions and drawing conclusions according to simple, predefined rules (Greenes, 2007). The basic composition of Boolean logic consists of IF AND OR NOT (Hajioff, 1998). If the patient has condition A, action X is recommended and so on. The algorithms of CardioPulmonary Resuscitation (CPR) are an example of a simple rule-based algorithm (Figure 3).
Many CDSS contain many models at different levels in the system. Different kinds of active system are, for example, built into EHR systems (Greenes, 2007).

Simple systems appear to have a greater effect on compliance with recommended care compared with active systems (Grol & Grimshaw, 2003). The reasons are probably that simpler passive systems are more likely to be accepted by clinicians compared with the more advanced active systems and they are also probably safer than active systems (Hajioff, 1998).

CDSS are well investigated in the hospital setting and in primary care. There are several systematic reviews investigating the effect of CDSS on patients and the performance of health-care personnel (Kawamoto et al., 2005; Garg et al., 2005; Tan et al., 2005; Sintchenko et al., 2007; Shojania Kaveh et al., 2009). These reviews indicate that CDSS can improve assessment ability, increase compliance with recommended care and, as a result, improve patient safety. As in studies of the effect on clinical guidelines, the effect on patient outcomes such as morbidity and mortality has been low. The reason is probably the same; patient outcomes are difficult to measure and, to attain reasonable power, the studies must include many patients (Brown et al., 2008c). The use of CDSS in the in-hospital emergency setting produces similar results. There are few studies evaluating patient outcomes. Most studies evaluate process of care effects and, among these studies, the use of CDSS shows a benefit of 63% (Sahota et al., 2011). However, the use of CDSS appears to have a marked effect on patient safety. CDSS have several features which can increase patient safety. The explicit use of CDSS is regarded as the main effect on patient safety (Morris, 2002). For example, mobile handheld technology appears to have a greater effect on the process of care than stationary technology (Prgomet et al., 2009).
The explicit use of CDSS standardises clinical decision-making and, as a result, it gives patients an equal assessment and treatment of higher quality and makes a comparison between methods feasible (Morris, 2002). Both paper-based DSS and CDSS can include the information needed in most clinical situations, but CDSS can provide much more information than is possible in paper format (Latoszek-Berendsen et al., 2010). The main strategies for reducing errors and adverse events have been systems that can improve communication between clinicians involved in patient assessment and treatment, make knowledge and information more available, provide key pieces of information (for example, the dose of a drug), function as a checklist in real time, support with monitoring and offer decision support (Bates & Gawande, 2003). CDSS have been found to be effective if they work as a part of the clinical workflow, if the decision support is given at the same time as the decision-making and that recommendations are provided (Kawamoto et al., 2005).

The use of CDSS is also supposed to involve risks. If, for example, information is designed in a rigid way and fails to respond to differences between patients, this can contribute to errors in clinical decision-making (Morris, 2002). When beginners and junior staff use guidelines and CDSS, it is suggested that the development of clinical reasoning is impeded. On the other hand, the appropriate use of a CDSS works as an effective learning tool for clinical decision-making (Patel et al., 2000). The design of guidelines and CDSS is critical for their success in clinical practice. If the information provided is unclear, the clinical personnel are forced to fill in the logic gaps and the experience of the clinicians will determine the level of patient care (Morris, 2002). Both the patient and the caregiver expect the care to be tailored to patient needs. If a CDSS fails to provide variations between patients, it is not thought to be useful (Morris, 2002). Patel et al. (2002) argue that CDSS mediate the human performance. CDSS can have a positive effect. For example, an effective CDSS can help the decision-maker to gather information in a more systematic, efficient way. However, a CDSS can also have a negative effect. This refers to the risk that the CDSS will slow down the development of changes in knowledge and skills. The frequent use of information technology can result in permanent changes in decision-making, for both bad and good (Patel et al., 2002). Studies have shown (Kushniruk & Patel, 2004; Patel et al., 2000) that the experienced decision-maker (expert) uses the CDSS structure and is able to complete the task using the structure, while a novice uses the CDSS to prompt and gather too much irrelevant information, which results in incorrect decisions. The expert appears to use guidelines and algorithms as a problem-solving process, whereas the novice uses the same system as an educational device (Patel et al., 2000).
3. Rationale for the thesis

Pre-hospital emergency care is administered in an unstable environment with a wide range of medical conditions, changing level of urgency and a long distance from medical support and it is provided by clinicians with different educations and experience. In recent years, the focus in pre-hospital care has been changing from a traditional scoop-and-run practice to more complex assessment and treatment plans. To work in this context, the pre-hospital clinicians are dependent on guidelines and protocols in the execution of pre-hospital care. Unfortunately, compliance with guidelines has been found to be poor in the pre-hospital setting. All this contributes to pre-hospital care possibly being defined as a high-risk process in terms of patient safety. In other health-care settings, the introduction of computerised decision support has been found to have the potential to improve patient safety by increasing compliance with the recommended process of care, standardising the care and facilitating the transition of information, to mention only a few points. However, information technology is made up of complex interventions and can also cause harm if these interventions are not thoroughly evaluated in the specific context in which they are used.

4. Aim of the thesis

The overall aim of the thesis was to develop and evaluates a CDSS for use in pre-hospital emergency care. The specific aims are guided by the methodological framework called Developing and Evaluating Complex Interventions (Campbell et al., 2000, Craig et al., 2008). This means that the study’s aims and the overall aim can be distinct. For an overview, see Table 1.

The specific aims were:

- To identify the evidence base for CDSS in the pre-hospital setting (Study I)
- To examine the features of protocol-based care in the pre-hospital setting (Study III)
- To examine the feasibility of a CDSS in a pre-hospital setting (Study III)
- To describe the context in which the CDSS was evaluated (Study III)
- To conduct a pilot test of a novel CDSS in a safe environment and investigate the effect of the CDSS on compliance with guidelines and on-the-scene time (Study II)
- To evaluate the effect of a CDSS on compliance with the systematic assessment framework of the medical patient and the effect of the CDSS on the on-the-scene time in a pre-hospital clinical environment (Study IV)
Table 1. Overview of included studies and their relationship to the methodological framework

<table>
<thead>
<tr>
<th>Study</th>
<th>Study aim</th>
<th>Thesis aim</th>
<th>Framework phase</th>
<th>Design</th>
<th>Sample</th>
<th>Data analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>The aim was to investigate the DST’s impact on pre-hospital patient assessment.</td>
<td>Identify the evidence base for DSS and CDSS in the pre-hospital setting</td>
<td>1</td>
<td>Systematic review</td>
<td>Two studies were eligible for the study</td>
<td>Descriptive</td>
</tr>
<tr>
<td>II</td>
<td>The aim of the study was to evaluate the effect of the CDSS on compliance with regional prehospital guidelines and OST.</td>
<td>Pilot-test a novel CDSS in a safe environment and investigate the effect of the CDSS on compliance with guidelines and OST.</td>
<td>2</td>
<td>Randomised controlled trial in a simulation environment</td>
<td>N=60 ambulance nurses</td>
<td>Descriptive statistics, Independent t-test, Pearson’s χ² test, Kolmogorov-Smirnov statistics, Mann-Whitney U test</td>
</tr>
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</table>
| III   | The aim of the study was to describe how guidelines and protocols are used in a pre-hospital context, who uses them, why they are or are not used and under which circumstances they are used. | 1) To examine the features of protocol-based care in the prehospital setting  
2) To examine the feasibility for a CDSS in a pre-hospital setting.  
3) To describe the context in which the CDSS was evaluated. | 1 and 2          | Qualitative case study                  | N=43 personnel employed in a Swedish ambulance organisation | Qualitative template analysis |
| IV    | The aim of the study was to evaluate the effect of the CDSS on the basic assessment process of patients with medical emergencies and the effect of the CDSS on OST. | To evaluate the effect of a CDSS on compliance with the systematic assessment framework of the medical patient and the effect of the CDSS on the OST in a pre-hospital clinical environment | 3               | Interrupted time series                 | N=1 Emergency medical technicians  
N=9 Ambulance nurses  
N=371 patients were eligible for the study | Descriptive statistics, Independent t-test, Chi-square tests, Durbin-Watson test, Linear regression |
5. Material and methods

5.1 Research theory perspective

5.1.1 Critical realism

The nature of quality improvement and safety in health care makes different demands from the theoretical perspective than the four dominant research paradigms in nursing research can provide. To date, the dominant research paradigms in nursing are positivist, post-positivist, interpretive and critical theory (Weaver & Olson, 2006). The kind of science required in quality and safety is realistic science, which deals with the complexity of a real world (Batalden et al., 2011). Batalden and Davidoff (2007) identified five knowledge areas critical for quality and safety. They are generalisable scientific evidence, context awareness, performance measurement, plans for change and execution of planned changes. When examining the knowledge areas, it is obvious that a purely positivistic or a purely interpretive view of knowledge is not enough in studies of quality improvement and patient safety. The positivistic and post-positivistic views are described as objective, there are meanings and meaningful realities independent of whether or not we are conscious of it (Crotty, 1998). The world of positivism is a scientific world and does not have so much in common with the world of ordinary life. It is a world in which objects can be observed by measurement and quantification in an experimental environment. Positivism has been described as an empirical epistemology where science consists of data from observed patterns and regularity (Cruickshank, 2012). Evidence-based practice (EBP) is the norm for quality of care in health care (Runciman et al., 2007). The epistemology in EBP is influenced by positivistic/post-positivistic theories. The gold standard of clinical evidence is data from Randomised Controlled Trials (RCT) (Ashcroft, 2004). The advantage of the RCT design is the ability to control for external factors which can explain the result (Kazdin, 2003). The goal is to produce data which can be generalised to a whole population. Experimental research can be used in some but not all of the knowledge areas described by Batalden and Davidoff (2007). There is criticism of the use of experimental paradigms unilaterally in the evaluation of complex interventions (such as patient safety interventions). The main criticism is that experimental studies reduce a complex intervention to a series of mechanical steps and fail to show the entire complexity of the
intervention (Pawson and Tilley, 1997). The data produced in closed systems, like an experiment, cannot necessarily be transferred to an open system with a different situation, patient or population (Cruickshank, 2012). The critical theory research paradigm is sceptical of all claims of knowledge. Knowledge and reality are constructed in the interaction between humans and their world and are developed in a social context (Crotty, 1998). The participatory action research typical of the paradigm (Weaver and Olson, 2006) could fit well in some of the knowledge areas described by Batalden and Davidoff (2007), such as the execution of planned changes.

The direct opposite of positivism is the interpretive paradigm. The interpretive paradigm studies phenomena through the eyes of people’s lived experience. Ontologically, it is based on relativism, with the view that all knowledge is subjective (Weaver & Olson, 2006). One problem with the interpretive paradigm as a theoretical perspective when conducting research in the fields of quality and safety is the focus of individual perspectives. Quality and safety interventions work in a social context. There is an on-going debate about the trend in nursing research towards more descriptive studies. The concerns about this trend are a future lack of studies that provide strong evidence for practice and are beneficial to the patient (Hallberg, 2006).

To be able to study the five knowledge areas described by Batalden and Davidoff (2007), the use of mixed methods is required. Critical realism is a theoretical perspective that has been suggested as appropriate in order to explain mixed method research (Maxwell & Mittapalli, 2010).

Critical realism can be traced back to the German philosopher, Immanuel Kant (1724-1804). Kant’s critical theory falls somewhere in between the rational tradition and the empirical tradition. Kant established that time, space, causality and other elements in the empirical tradition cannot exist as an independent reality but can only exist as forms of possible experience (Losch, 2009). The modern form of critical realism is divided into the German tradition, with philosophers such as Oswald Kulpe (1862-1915) and Carl Stumpf (1848-1936) at the forefront, and American critical realism, with Roy Wood Sellars (1880-1973) as the most influential American philosopher (Losch, 2009). However, the most influential view of critical realism in modern mixed methods research is probably the thoughts of the British philosopher, Roy Bhaskar (1944- ). One example in which Bhaskar’s realist philosophy is used is in the field of programme evaluation (Pawson & Tilley, 1997). At the beginning of his work, Bhaskar himself did not use the term “critical realism”. Instead, he used the two terms transcendental realism and critical naturalism. Other people subsequently labelled the two terms “critical realism” and Bhaskar accepted this (Losch, 2009). Bhaskar’s critical realism is originally based on three items: transcendental
realism; critical naturalism; and emancipatory critique (Bhaskar, 1997), followed later by a fourth: dialectic (Bhaskar & Archer, 1998). Transcendental realism says that the reality is complexly covered and science has to examine these covers beyond what we can immediately see and feel. Critical naturalism proposes that human activities cannot only be examined in closed systems (experiment) because the response of human beings is unpredictable. Emancipatory critique suggests that the way we perceive society is dependent on underlying mechanisms and structures. The dialectic position is that causality can only result from investigating the relationship of one causal power to another (Roberts, 2001).

Critical realism combines an ontological realism (a real world exists independently of our awareness) with an epistemological constructionism (the understanding of the world is a construction from human beings’ own perspective and standpoints) (Maxwell & Mittapalli, 2010). In other words, critical realism can be defined as ontologically objective but epistemologically subjective. In an evaluation of complex interventions, critical realism provides an alternative view of causality to the positivistic regularity theory of causality and the variance theory of interpretative paradigm (Maxwell & Mittapalli, 2010). Critical realism replaces both causality theories with a model “in which objects and social relationships have causal powers which may or may not produce regularities and which can be explained independently of them” (Maxwell & Mittapalli, 2010) (p.155). Pawson and Tilley summarise the realist view of causality with the formula Context+Mechanism=Outcome (CMO configuration) (Pawson & Tilley, 1997) and explain the “logic of realist explanation” as follows. “The basic task of social inquiry is to explain the interesting, puzzling, socially significant regularities (R). Explanation takes the form of positing some underlying mechanism (M) which generates the regularities and thus consists of propositions about how the interplay between structures and agency has constituted the regularity. Within realist investigation, there is also investigation of how the workings of such mechanisms are contingent and conditional and thus only fired in particular local, historical and institutional contexts (C)” (Pawson and Tilley, 1997) (p.71).
Table 2. Frameworks and theories used in the thesis

<table>
<thead>
<tr>
<th>Frameworks</th>
<th>Theories</th>
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<tbody>
<tr>
<td><strong>Philosophical framework</strong></td>
<td></td>
</tr>
<tr>
<td>Critical realism (Bhaskar)</td>
<td></td>
</tr>
<tr>
<td><strong>Methodological framework</strong></td>
<td></td>
</tr>
<tr>
<td>Development and evaluation of complex interventions (Campbell et al., Craig et al.)</td>
<td>Human error (Reason)</td>
</tr>
<tr>
<td></td>
<td>Dual process theory (Croskerry and others)</td>
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</table>

5.2 Methodological framework

5.2.1 Developing and evaluating complex interventions

The present thesis is guided by two methodological frameworks produced by Campbell et al. (2000) and the revised and extended framework produced by Craig et al. (2008). The frameworks describe how to design and evaluate complex interventions.

5.2.2 Definition of complex interventions

Complex interventions are defined as interventions which include multiple interacting components. An intervention can be complex in different dimensions. The framework gives examples of five different dimensions of complexity; the number of interacting components, the number and difficulty of behaviours required by those delivering or receiving the intervention, the number of groups or organisational levels targeted by the intervention, the number and variability of outcomes and the degree of flexibility or tailoring of the intervention permitted (Craig et al., 2008). An example of a complex intervention is the development and evaluation of a CDSS (Campbell et al., 2000). However, most evaluations of patient safety can be defined as complex interventions (Brown et al., 2008b).

Another way of defining complexity is to further describe and place in order the level of complexity by determining the interrelatedness of components of a system (Kannampallil et al., 2011). In this model, the complexity of a system is divided into four levels of complexity.
The first level includes few components and a low level of interrelatedness. It is a simple system which is relatively easy to understand and predict (Kannampallil et al., 2011). An example of a system of this kind is when an ambulance nurse copies patient information from a handwritten note to an EHR.

The next level of complexity is when the system includes many components but has a low level of interrelatedness. The increased complexity is due to the large number of components, but the relationships between the components remain low (Kannampallil et al., 2011). An EHR used by different groups of health-care staff is one example of this kind of system.

The third level of complexity is when the system includes few components but has a high degree of interrelatedness. A system of this kind is relatively complex. These systems are reasonably easy to describe due to the small number of components, but they are difficult to predict and manage (Kannampallil et al., 2011). A CDSS used in pre-hospital care could be an example of this kind of system. There are relatively few components (the ambulance team and the patient), but the components have a high degree of interrelatedness (e.g. computer interface, usability, structure, user compliance, acceptance, work culture and so on).

The last level includes both many components and a high level of interrelatedness. These are the most complex systems and they are difficult to both describe and predict (Kannampallil et al., 2011). A system for organising pre-hospital leadership at a mass casualty event could be an example of a system with this level of complexity.

To be able to evaluate complex systems, the researcher has to identify the components and the relationships between them (Kannampallil et al., 2011).

There is also criticism of the definition of complexity. The criticism is that all interventions include complex parts and dividing interventions into simple or complex interventions offers the researcher more help to define and understand the intervention (Petticrew, 2011). When evaluating a complex intervention, the researcher can have a simpler perspective and choose to evaluate parts of the intervention. It is therefore possible to simplify a complex intervention. In a description like this, it is unnecessary to divide interventions into complex or simple, because it is the researcher’s perspective that determines the level of complexity (Petticrew, 2011).

5.2.3 The content of the framework

The framework suggests the development and evaluation of a complex intervention in four stages. These stages are not linear or cyclical, but there should be an interaction between the different stages (Craig et al., 2008). An overview of the content of the framework is schematically presented in Figure
4 and an overview of the included studies can be found in Table 1. The present thesis uses the first three stages described in the framework. The last stage, which includes the implementation process, is not included in this thesis.

Figure 4. Overview of the methodological framework and the included aims. The present thesis includes all the phases apart from implementation.

1. The first stage is the development stage. This stage has three main goals. They are to identify the evidence base for the intervention. The recommended approach is systematic reviews. If fresh reviews have already been conducted in the targeted area, they can be used, but in most cases a systematic review has to be conducted by the researcher. The aim of the review is to evaluate the existing evidence for the effectiveness of the intervention (Craig et al., 2008). In the present thesis, Study I was a systematic review designed to identify the evidence base for DSS and CDSS in the pre-hospital setting. The next purpose of the development stage is identifying/developing the appropriate theory. To choose an appropriate theory, it is important to be able to describe the logic behind the chosen intervention and answer the question of “why this intervention should work”. The theory can increase generalisability and build a cumulative understanding of the nature of change (Foy et al., 2011). Two theories were chosen with two different goals. Reason’s human error theory (1990) was chosen to explain why the development and evaluation of a CDSS is needed in pre-hospital care. Dual process theory was chosen to explain the study results and how a CDSS can increase patient safety. The final goal in the development phase is modelling process and outcomes. In this stage, it is important to start thinking about the implementation. Studies which can show the rationales for the intervention fit in here. Is it possible to implement the intervention? What
kind of obstacles can the intervention encounter (Craig et al., 2008)? In this stage of the framework, Study III aimed to show the rationale for a CDSS in pre-hospital care.

2. The next stage in the evaluation process is assessing feasibility and piloting methods. The goal of this phase is to test the intervention for acceptability, testing variables and study protocol and sample size calculations (Craig et al., 2008). The methods in this stage can be quantitative or qualitative or preferably a mixture of methods. One method to accomplish part of this goal is medical simulation. To realise the framework goal in this phase, Study II had the role of piloting the CDSS. Firstly, in a simulation study, it is possible to test the intervention in a safe environment. Before the intervention is evaluated in the field with real patients, simulation can detect elements in the intervention which could potentially cause harm. Secondly, simulation is a good method for optimising the study protocol (Brindley & Dunn, 2009). In a simulation study, the researchers can detect usability issues, measurement problems and the participants’ acceptance of the intervention and it can also be the basis for sample size and power calculations. In order fully to understand barriers to participation, qualitative studies are suggested as a complement to the experimental study (Craig et al., 2008). Study III was a qualitative case study with the aim of exploring the feasibility of a CDSS in the investigated ambulance organisation and it also performed the role of a deep context description of the setting in which the CDSS was evaluated. Context descriptions would be considered important if the result of quality improvement and patient safety interventions could be transferred to other settings (Kaplan et al., 2012). Case studies are a method with the potential to detect both barriers and motivation for the intended intervention (Baker, 2011).

3. In this stage, the intervention is evaluated in a clinical setting. According to the framework, experimental or quasi-experimental designs are suitable in this phase (Craig et al., 2008). There are many designs to choose from, but the Randomised Controlled Trial (RCT) is regarded as the strongest design, with its ability to control for confounders (Craig et al., 2008). There are also cases when randomisation is impossible, unethical or impractical (Brown et al., 2008b). In the present thesis, for example, only two CDSS were available. With only two devices, an RCT design was not possible. In those cases, the researcher has to consider less strong evaluation designs. The Interrupted Time Series (ITS) is a strong quasi-experimental design. Study IV had an ITS design and was the clinical evaluation of the CDSS in the thesis. In the ITS study, data are collected on several occasions over time before and after an intervention is introduced. This design allows the researcher to control for secular trends, cyclical effects, duration of the intervention effect and random fluctuations (Ramsay et al., 2003).
Another important issue is which end-point to use in the evaluation. The framework of developing and evaluating complex interventions (Craig et al., 2008) does not discuss end-point issues. An end-point discussion can instead be found in the literature on patient safety research and quality improvement. To be able to choose the right end-point, the researcher must be aware of the level on which the intervention might work. Reason (2000) divides human errors into “latent errors”, which are errors produced on an organisational level, and “active errors”, which are described as errors committed by health-care providers in their contact with the patient or the system. It is important to bear in mind that “active errors”, such as poor clinical judgement, may originate in the system (see Figure 2). The system should be configured to support the clinicians in the decision-making process and provide them with the tools and educations they need to make good decisions (Morris, 2002). Although the present thesis deals with the problem of “active errors”, patient outcomes are tempting end-points. However, patient outcome as an end-point has several problems. Patient outcome such as mortality has been found to be very difficult to interpret, as there are many confounders and a comparison between hospital and treatment methods is difficult to make (Pronovost & Lilford, 2011). The problem of interpreting the results is probably the same for other patient outcomes, such as morbidity, length of hospital stay and complications. Another problem with patient outcome is the large number of patients needed to attain reasonable power (Brown et al., 2008c). In a small-scale project like a thesis, such large studies are not always possible. One popular and recommended outcome for measuring quality of care is compliance with the process of care. Measuring compliance can be a surrogate for patient outcome and measuring compliance is also a method for identifying clinical errors (Brown et al., 2008c). Clinical error has been defined as the failure to apply the correct standard of care (Reason, 2000) and compliance with the process of care may directly reflect these errors (Richard & Peter, 2010). To maintain the validity when using a variable such as compliance with the process of care, it is important that the end-point is empirically correlated to an outcome (Brown et al., 2008c). For example, when using compliance with an assessment process in pre-hospital care, it is important to be able to find evidence that this particular assessment process has a positive effect on patient outcome. Another problem with compliance with the process of care is reliability. In many cases, these measurements include some subjectivity and different raters can make different judgements. Strategies to strengthen the reliability can be reviewer training, measurement of inter-rater reliability and masking (Brown et al., 2008c).

In the two experimental studies included in the thesis, the process of care was the primary end-point. In Study II, compliance with assessment and treatment plans described in the local and regional pre-hospital guidelines was the primary
end-point. In Study IV, the primary end-point was compliance with the systematic assessment framework for patients with medical complaints described in local and regional pre-hospital guidelines. OST was used as a secondary end-point in both studies. The aim of measuring OST was to see whether the CDSS had reasonable usability. If OST increased a great deal when using the CDSS, the system could compromise patient safety.

4. The last step in the evaluation is the implementation phase. This thesis did not actively study the implementation of a CDSS. However, by publishing the results in scientific literature, the research can help to improve the implementation process (Craig et al., 2008).

5.3 Study designs

This thesis comprises four studies influenced by the methodological framework known as Developing and evaluating complex interventions (Campbell et al., 2000, Craig et al., 2008) (Table 1). The four studies have different research designs. The first is a systematic review guided by the Cochrane Handbook of Systematic Reviews of Interventions (Higgins JPT, 2008). The design in Study II is a randomised controlled trial in a simulation environment. The third study has Realistic Evaluation (Pawson & Tilley, 1997) as its methodological framework and uses case study methods (Yin, 2009) as the research design, while the fourth study has an interrupted time series design (Wagner et al., 2002).

5.4 Setting and participants

The participants in Studies II, III and IV were all employed in an ambulance organisation in south-western Sweden. This district has a population of 285,329 inhabitants and was served by 28,109 ambulance missions in 2010. The area of the district is estimated to be 2,500 square miles and the main hospital is placed in the centre of the district. Two types of personnel are employed in the organisation, Emergency Medical Technicians (EMT), who have a shorter education and do not perform all the types of treatment in the organisation, and Ambulance Nurses (AN), who are registered nurses with various kinds of specialist education.

Study II was conducted on three occasions in the spring of 2012. The ambulance personnel, who came from all seven ambulance stations in the organisation, were taking part in a full day of continuous education and were invited at the same time to take part in the study. The inclusion criteria were registered nurse employed in an ambulance service district in south-western Sweden (n = 93) and willingness to participate in the study. Sixty of the 93
eligible nurses invited to participate in the study accepted the invitation. The trial took place at the Centre for Defence Medicine (CDM) in Gothenburg, Sweden. The CDM incorporates a simulation centre with more than 10 years' experience of medical simulation for educational purposes. Personnel from the CDM operated the manikin during the trial. The Laerdal Stavanger, Norway, SimMan 3G was used. The composition of participants in Study II is presented in Table 3.

Table 3. The composition of participants in Study II

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (n = 30)</th>
<th>Control group (n = 30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD)</td>
<td>39.33 (7.32)</td>
<td>39.67 (6.70)</td>
</tr>
<tr>
<td>Number of males</td>
<td>19</td>
<td>22</td>
</tr>
<tr>
<td>Number of females</td>
<td>11</td>
<td>8</td>
</tr>
<tr>
<td>Mean total years as nurse (SD)</td>
<td>9.13 (5.69)</td>
<td>10.80 (4.31)</td>
</tr>
<tr>
<td>Mean total years as nurse in ambulance (SD)</td>
<td>6.20 (3.77)</td>
<td>6.83 (3.75)</td>
</tr>
<tr>
<td>Number of participants with specialist nursing course in:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ambulance</td>
<td>21</td>
<td>23</td>
</tr>
<tr>
<td>Anaesthesia</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Intensive care</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>No specialist course</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Mean number of previous simulation sessions (SD)</td>
<td>4.7 (2.15)</td>
<td>5.4 (2.16)</td>
</tr>
</tbody>
</table>

There were no significant differences between the groups in any variable.

Study III was performed in the same organisation at two ambulance stations, one station with an urban catchment area and one station with a more rural catchment area with generally longer transportation distances. Three of the participants represented the leaders of the organisation and 28 ANs and two EMTs represented the ambulance personnel (Table 4).
Table 4. Background data of participants in Study III

<table>
<thead>
<tr>
<th>Semi-structured interviews</th>
<th>Number of participants</th>
<th>Mean age (range)</th>
<th>Gender</th>
<th>Education</th>
<th>Mean years in ambulance service (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant observation; rural station</td>
<td>n = 3</td>
<td>Male n = 2 Female n = 1</td>
<td></td>
<td>Doctor n = 1 Nurse n = 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n = 11</td>
<td>42 (32-58)</td>
<td>Male n = 7 Female n = 4</td>
<td>Ambulance nurse n = 10 Emergency medical technicians n = 1</td>
<td>14 (1-34)</td>
</tr>
<tr>
<td>Participant observation; urban station</td>
<td>n = 16</td>
<td>42 (32-58)</td>
<td>Male n = 13 Female n = 3</td>
<td>Ambulance nurse n = 15 Emergency medical technicians n = 1</td>
<td>12 (2-32)</td>
</tr>
<tr>
<td>Focus group; rural station</td>
<td>n = 8</td>
<td>42 (33-50)</td>
<td>Male n = 6 Female n = 2</td>
<td>Ambulance nurse n = 8</td>
<td>12 (5-28)</td>
</tr>
<tr>
<td>Focus group; urban station</td>
<td>n = 5</td>
<td>44 (36-54)</td>
<td>Male n = 3 Female n = 2</td>
<td>Ambulance nurse n = 5</td>
<td>14 (10-25)</td>
</tr>
</tbody>
</table>

The setting in Study IV was a single ambulance station in the same organisation. The station’s catchment area can be described as rural, but the ambulance operates missions in both rural and urban areas. Most of the patients are transported to the nearest hospital, which is located 37 kilometres from the ambulance station. The ambulance performed 1,900 missions in 2012. All the regular personnel at the station participated in the study. The regular staff consists of nine ambulance nurses and one EMT. Of them, six were male and four female. The average age was 45.9 years (range 34-60) and the average experience of pre-hospital care was 16.9 years (range 2-35). A total of 371 patients were included in the study. The characteristics and disposition of the included patients can be found in Table 5.
Table 5. Included patient characteristics and disposition in Study IV

<table>
<thead>
<tr>
<th></th>
<th>Pre-intervention (n=175)</th>
<th>Post-intervention (n=196)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean age (SD)</strong></td>
<td>66.7 (19.9)</td>
<td>69.7 (20.5)</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Male (%)</strong></td>
<td>43.4</td>
<td>54.1</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Female (%)</strong></td>
<td>56.6</td>
<td>45.9</td>
<td></td>
</tr>
<tr>
<td><strong>Diagnostic category</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular symptoms</td>
<td>19.4</td>
<td>21.9</td>
<td>0.84</td>
</tr>
<tr>
<td>Neurological symptoms (%)</td>
<td>28.0</td>
<td>29.4</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal symptoms</td>
<td>15.4</td>
<td>15.8</td>
<td></td>
</tr>
<tr>
<td>Affected general conditions (%)</td>
<td>2.3</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>Affected circulation including failing heart conducting system (%)</td>
<td>9.1</td>
<td>7.1</td>
<td></td>
</tr>
<tr>
<td>Infections (%)</td>
<td>4.6</td>
<td>6.6</td>
<td></td>
</tr>
<tr>
<td>Endocrine system symptoms (%)</td>
<td>1.7</td>
<td>2.0</td>
<td></td>
</tr>
<tr>
<td>Allergic symptoms (%)</td>
<td>1.7</td>
<td>0.5</td>
<td></td>
</tr>
</tbody>
</table>

5.5 Data collection

5.5.1 Literature search

The search for literature in Study I started with electronic searches in the following databases from January until April 2010: (1) Cochrane Reviews (up to January 2010); (2) Cochrane Controlled Clinical Trials (1979 to January 2010); (3) Cinahl (1986 to January 2010) and (4) Pubmed/Medline (1926 to January 2010). There was no restriction in terms of language or year of publication. The electronic search was performed by using a combination of the following MeSh terms: emergency medical services, emergency medical technicians, emergency treatment, emergency medicine, ambulances, air ambulances, first aid, military medicine, emergency medical service communication systems, decision support systems (clinical), decision making (clinical), decision support techniques, decision making, computerised patient record, decision making (patient), clinical protocols and emergency treatment and text terms: prehospital, pre-hospital, paramedic, ambulance, out-of-hospital, out of hospital, EMS, EMT, emergency services, emergency medical service, emergency technician, emergency practitioner, emergency dispatch, first responder, emergency rescue, emergency triage, patient assessment. In addition to the electronic search, manual searches were performed in 18 relevant journals, nine pre-hospital homepages, two databases for conference abstracts, fifteen databases for present clinical trials and reference lists of relevant studies.
The literature search in Study III was performed in the following databases: Cochrane Reviews, Cochrane Controlled Clinical Trials, Cinahl and Pubmed/Medline from 1990 to 2011. The search was confined to articles in English and Nordic languages. The following search terms were used: practice guidelines AND protocol based care AND guideline adherence OR compliance OR use AND attitude of health personnel or decision making.

5.5.2 Observation of digital video tapes

To evaluate the ambulance nurses’ performance with and without the CDSS, observations of digital video tapes were made in Study II. The performance was rated using a rating protocol designed for the study. Two of the authors subsequently analysed the digital videos to determine the final scores for simulation case A and simulation case B. The final scores were based on an average score from the two raters for each step in the protocol. The raters were not blinded to the group to which the digital video tapes belonged.

5.5.3 Participant observations

In Study III, 30 participant observations were made. An MSc student made 15 observations at a rural ambulance station and the author of the thesis made 15 observations at an urban ambulance station. In conjunction with the observations, short semi-structured interviews were carried out with the aim of clarifying some questions during the observations. The observations were guided by an observation protocol based on the theoretical framework. The protocol was based on the nine phases of typical ambulance missions: receiving the call, arriving at the address, performing an on-scene assessment, performing an initial patient assessment, transporting the patient to the ambulance, performing further assessments and treatment on route, arriving at hospital and handing over the patient. For every phase, the protocol contains some questions. For examples: How did the team discuss the case? How did it look at the scene? Which decisions were made? Did they use any protocol or guidelines? Did the team discuss the protocol and guidelines? What kind of assessment was performed? The sampling process can be described as unsystematic, even though the researchers were participants in the ambulance missions that took place.

5.5.4 Interviews

In Study III, three semi-structured interviews were held with leaders of the ambulance organisation involved in the development, implementation and maintenance of the organisation’s guidelines and protocols. The interviewees were selected using an eligibility sampling process. The interviews were guided
by an interview protocol based on the study’s theoretical framework. Examples of questions included: *What is your role when it comes to the organisation’s guidelines and protocols? Can you describe the implementations process? How do you think protocols and guidelines are used in the organisation?*

Two focus group interviews were also performed, one at the rural ambulance station and one at the urban ambulance station. The second focus group interview can be described as an “analytical” focus group (Leverence et al., 2007). It was conducted at the urban station and, with the help of the participants, it aimed to refine preliminary data from the earlier phases and, at the same time, function as a member check. Moreover, the focus group interviews were guided by an interview protocol based on the study’s theoretical framework and results from the other phases of the study (conjectured CMO configurations). The focus group interviews were led by one of the authors and were assisted by two co-authors who made notes and asked complementary questions (Wibeck, 2010).

5.5.5 **Sampling of documents**

Sampling of relevant documents, such as guidelines and protocols, was performed in Study III. The search for relevant documents was made by screening the ambulance organisation’s homepage.

5.5.6 **Ambulance medical records**

To evaluate the study participants’ compliance with assessment guidelines in the pre-intervention and the post-intervention phases in Study IV, the ambulance medical records were analysed using a rating protocol designed for the study. The rating protocol was composed of assessment interventions to execute in the assessment of a patient with a medical complaint described in the local and regional pre-hospital guidelines. The eligible records were searched for in the organisation’s medical record database. The inclusion criterion was patients with symptoms of medical emergencies. This included patients with symptoms of chest discomfort, breathing problems, neurological symptoms, allergic symptoms, abdominal pain, affected circulation including failing heart conducting system, affected general conditions, infections and endocrine system symptoms. The exclusion criteria were patients aged < 18 years, patients suffering from trauma or poison, patients transported between hospitals, patients who were pregnant and patients with no circulation and breathing. The rating was performed by one of the study authors who was blinded to the study phase to which the records belonged.
5.6 Estimation of sample size

Before the final RCT (Study II), a pilot study comprising 12 participants was performed. The result of the pilot study was used for sample size calculation. The results showed an effect size of 1.1. With a significance level of $p = 0.05$ and a power of 80%, it was estimated that the study needed 15 participants in each group.

Although sample size calculation is difficult to perform in interrupted time series (Ramsay et al., 2003), the result from a simulation-based power calculation was used (Zhang et al., 2011) for sample size estimation in Study IV. The result of the simulation shows that, with twelve data points in the baseline phase and twelve data points in the intervention phase, there is more than 80% power to detect an effect size of 1.0 or more, depending on the degree of autocorrelation (Zhang et al., 2011).

5.7 Data analysis

The goal of Study I was to perform a meta-analysis by pooling data across included studies. No meta-analysis was possible, as only two studies with different outcomes were included. Instead, the results were presented in a descriptive narrative form.

In Study II, the independent t-test and Pearson’s chi-2 test were used to test the equity between the two groups. Kolmogorov-Smirnov statistics were used to assess the normality of the data. The Mann-Whitney U test was used to compare results between the groups.

For demographic data in Study IV, descriptive statistics were used. To determine the distribution of eligible patients between the pre- and post-intervention phases, an independent t-test was used for continuous data and chi-square tests for categorical data. To analyse the difference between the pre- and post-intervention phases, the regression was tested for autocorrelation in the residuals using the Durbin-Watson test. The estimation of changes in level and trend in Study IV was made using a segmented regression. The formula for the regression can be specified as:

$$\gamma_t = \beta_0 + \beta_1 \times \text{time}_t + \beta_2 \times \text{intervention}_t + \beta_3 \times \text{time after intervention}_t + e_t$$

For the dependent variable mean percentage of compliance, the formula can be explained as: $\gamma_t$ is the mean percentage of compliance per week $t$; indicating time in weeks at time $t$ from the start of the observation period; intervention is
an indicator of time t occurring before or after the CDSS, which was implemented at week 13 in the series. Intervention is a dummy variable with 0 before CDSS and 1 after CDSS. Time after intervention is a continuous variable counting the number of weeks after the intervention at time t, coded 0 before the CDSS and 1-12 after the CDSS. In this model, $\beta_0$ estimates the baseline level of the outcome, mean percentage compliance per week, at time zero (intercept); $\beta_1$ estimates the change that occurs with each week before the intervention (i.e. the baseline trend); $\beta_2$ estimates the level change immediately after the intervention and $\beta_3$ estimates the change in the post-intervention slope, compared with the weekly trend before the CDSS. The sum of $\beta_1$ and $\beta_3$ is the post-intervention slope (Wagner et al., 2002). The same regression model was used for the variable OST.

Realistic evaluation (Pawson & Tilley, 1997) (Study III) is a theory-driven approach where theory guides the researcher through the evaluation process. The process in Study III consisted of four evaluation steps; the first step was a literature screening and creation of a theory, in the next step, a conjectured Context, Mechanism, Outcome (CMO) configuration was created based on the theory. A CMO configuration explains the influence of the mechanisms embedded in the context on outcome. In the third step, the conjectured CMO configuration was tested by data collection and, in the last step, a refined CMO configuration was presented. Although realistic evaluation is a theory-driven approach, a template analysis style (Crabtree & Miller, 1999) was used in the analysis of interviews, guidelines, protocols and observation protocols at every stage. A code manual based on the theoretical framework of the study was developed. The interview guide and the observation protocols were also based on the framework. The data from every phase were analysed separately and, through an accumulation process, the CMO configuration was rebuilt until the final refined CMO configuration was constructed.

### 5.8 Ethical considerations

Research in emergency care is demanding when it comes to obtaining research ethical principles. The informed consent process is challenging because of the time framework where the research that is conducted can be narrow and also because the patients can be in a vulnerable situation. These contextual factors necessitate a thorough ethical evaluation in the planning and execution of research in the emergency setting (Schmidt et al., 2004).

It is important from an ethical point of view to start a research project with a comprehensive literature search. The result of the literature search provides information about several factors needed for an ethical evaluation of the
planned research project. First, has the subject been investigated before? If there is already evidence of the effect of the intervention, it is unethical to expose patient and personnel to further research. Second, a literature search and synthesis provide hints on the effect of an intervention. Research on interventions with estimated small benefits is unethical. Third, a literature search also provides information of potential risks associated with the intended intervention and ways of avoiding exposing study participants to hazards (Runciman et al., 2007).

Although there is a lack of evidence related to the effect of CDSS in pre-hospital care, there was a partly ethical aspect behind the decision to conduct the first test of the CDSS in a safe simulation environment. The simulation was able to determine that the system would be reasonably safe for further evaluation in a clinical setting. The WMA Declaration of Helsinki (2008) makes it clear that, in research involving human subjects, the objectives must outweigh the risk for the study participants.

The only study in the thesis which involves real patients is Study IV. In the WMA Declaration of Helsinki (2008), it is stated that all research that involves patients must be evaluated constantly throughout the project in order to ensure both safety and quality. The ITS design promotes close monitoring as the variables were assessed every week during the study period (Wagner et al., 2002). The patients assessed and treated by the study participants in Study IV were not regarded as study participants and this was the reason for the decision not to request informed consent from the patients. The rationale behind this decision was that no new type of assessment or treatment was used on the patients. The recommendations in the CDSS were the same as those described in the local guidelines. They were simply presented to the staff in a different format.

When it comes to the collected design in Studies II and IV, a limited number of individuals were closely evaluated. There was a risk that the participants might feel criticised in their professional role. Since the law on the ethical review of research involving human beings (Law 2003; 46 0) is applicable here, the research was approved by the Regional Ethics Committee, Gothenburg, Sweden (Dnr: 1133-11). All the informants and study participants signed up voluntarily for Studies II, III and IV, with all the requirements for informed consent, their own safety, confidentiality and trust. They were informed that they were free to withdraw from the study at any time and that the study data relating to that participant would be erased.

The study was partly sponsored by Ortivus AB, who kindly provided the hardware and software platform for the CDSS. Ortivus AB also implemented the CDSS according to the authors’ design and intentions. No financial
transactions were involved in the co-operation and no limitations were made in terms of the presentation of results and so on from the studies.

6. Findings

6.1 Summary of results (I-IV)

The main findings in the studies in this thesis are that there is a weak evidence base for the use of CDSS in pre-hospital care. No studies have previously evaluated the effect of CDSS in pre-hospital care. Due to the context, the pre-hospital care is dependent on protocol-based care in order to deliver safe, high-quality care. The physical format of the current paper-based guidelines and protocols is the main obstacle to their use. There is a request for guidelines and protocols in an electronic format from both clinicians and leaders of the ambulance organisations. The use of CDSS in the pre-hospital setting has a positive effect on compliance with pre-hospital guidelines. The largest effect is in the primary survey and in the anamnesis of the patient. The CDSS also increased the amount of information collected in the basic pre-hospital assessment process. The tested CDSS had a limited effect on OST.

6.2 Development of the CDSS

The CDSS used in the thesis was developed between Ortivus AB and the author of the thesis in collaboration. The development process started with a literature screening of literature describing cognition and human error, especially literature relating to cognition and errors among clinicians in unstable settings, such as emergency settings. The literature was also screened for studies of the use of different kinds of information technology, both paper-based and computer-based technology. The literature screening resulted in ten features that are regarded as important for a novel CDSS in a pre-hospital setting:

- The CDSS should be a *simple/passive system*
- The CDSS should be based on a model recognised by ambulance clinicians
- The CDSS should be an *expert system*
- The CDSS should prevent *premature closure*
- The CDSS should include a *worst case scenario* strategy
- The CDSS should organise the information in a logical manner
- The CDSS should be handheld
- The CDSS should provide support through checklists and reminders
- The CDSS should be linked to pre-hospital clinical guidelines
- In addition to decision support, the CDSS should include a medical record.

The developed CDSS used in Studies II and IV can be defined as an expert system and guides the users through a systematic assessment process based on the content of the Advanced Medical Life Support (AMLS) system (Dalton, 2010). The CDSS is handheld (Panasonic Toughbook©) and uses the MobiMed 4.0 pre-hospital eHealth platform© from Ortivus AB. The CDSS consists of four main areas.

First survey: The goal of the first survey is to assess and treat life-threatening conditions. It starts with an assessment of the airways and continues with an assessment of breathing, circulation, and disability. During the assessment, the ambulance staff can choose to receive support when it comes to assessing and treating problems in the different areas by clicking on algorithms (see screenshots 1 and 2).

Screenshot 1. First survey
History: When the first survey is finished, the CDSS continues with focused history collection. The CDSS guides the ambulance staff through a battery of questions. The questions start with signs and symptoms and continue with questions relating to onset, palliation, quality, radiation, severity, time, allergies, medications, past medical history, last oral intake and events prior to illness (see screenshot 3).
Chief symptoms: After finishing the history collection, the ambulance staff have to choose the patient’s chief symptom. Examples of symptoms are chest discomfort, breathing problems, abdominal pain and altered mental status. When a chief symptom has been chosen, the CDSS provides a list of further focused medical assessments based on the symptom (screenshot 4).

Field diagnosis: The last page in the CDSS is field diagnosis. Here, the CDSS provides a list of field diagnoses based on the chief symptom. Every field diagnosis is linked to the local pre-hospital guidelines where the ambulance staff can obtain information about diagnoses and also obtain access to treatment plans.
The CDSS is also linked to a medical record system. All the actions performed in the CDSS are documented in the system. The documentation comprises ticking boxes and free text fields. When the patient assessment is complete, a medical record can be printed out for use in the hand-over phase. Unfortunately, we were not able to configure the CDSS with the ordinary pre-hospital records system and this is a major disadvantage of this CDSS.

The personnel using the CDSS in Studies II and IV were instructed to use the CDSS in the on-scene phase, when they made the first assessment, to the hand-over phase. It was the nurse who was responsible for the care who used the CDSS structure. The other person in the team performed specific assessment interventions at the request of the nurse responsible for the patient.
6.3 The evidence base for the use of CDSS in pre-hospital care (I)

The evidence base for the use of paper-based or electronic DSS in the pre-hospital setting is insufficient. No study whatsoever has evaluated the effect of CDSS. The limited data indicate that the use of paper-based DSS makes it possible to increase diagnostic accuracy and reduce the time to definitive care.

The initial database screening identified 5,929 citations. After excluding studies in the first screening and removing duplicates, 59 citations remained. The search in magazines, conference abstracts, ongoing studies, homepages, theses and reference lists produced an additional 14 citations. Full-text screening was performed for 73 articles. Of these, 33 studies were eligible for final screening and 31 studies were excluded because of their study design. Only two trials fulfilled the inclusion criteria. No studies were found which evaluated computerised decision support. Among the excluded studies, there were eleven studies that compared a paper-based DSS with a prospective or retrospective control group. All these studies demonstrate positive results that favoured the DSS. The studies show improved diagnostic accuracy, lower mortality and reduced time to definitive care. The risk of selection bias in the excluded studies was considered large.

Among the included studies, one study evaluated a paper-based algorithm to support diagnoses among patients with neurological symptoms (Cincinnati Pre-hospital Stroke Scale). The number of eligible patients who were appropriately referred to the Stroke Unit (SU) by the EMS group was an outcome. There was a statistically significant result in favour of the group using the algorithm. Of 109 eligible patients, 68 patients (62.4%) were referred to the SU compared with nine of 56 (16.1%) eligible patients in the control group (RR = 4.09; 95%CI = 1.84 to 5.59). The study also provided data on how many eligible stroke patients received thrombolysis at the SU. In the intervention group, eight of 44 (18.2%) received thrombolysis and, in the control group, 0 of 22 (0%) received thrombolysis (p < 0.05). The study also measured the time from when the ambulance arrived at the scene to the hospital door. The intervention group spent four minutes less time in transport (p < 0.05).

The other included studies evaluated a decision support system involving the use of a continuous telemetry system and decision support by a thrombolysis eligibility questionnaire and text message from a senior cardiologist. The median time in minutes from call to thrombolysis time was compared between patients receiving a recommendation for pre-hospital thrombolysis and controls receiving thrombolysis in hospital. The median time in the intervention group was 53 minutes compared with 108 minutes in the control group. There was a difference of -55 minutes (p < 0.05).
6.4 The features of protocol-based care in pre-hospital settings (III)

Protocol-based care is widely accepted and important in pre-hospital care. The physical format of guidelines and protocols is the feature which has the greatest influence on use.

The data from Study III indicate that ambulance personnel have a positive attitude to the use of guidelines and protocols. They regard protocol-based care as an absolute necessity and its existence is not questioned. They also regard the guidelines and protocols as a way of making the care more uniform and giving the ambulance team a common structure to work with. This perception is the same for both the experienced ambulance nurses and the more inexperienced ones. The guidelines are seldom used explicitly in the patient assessment. When guidelines are used explicitly, this is done to check and repeat some medical doses. One exception is when the patient could be the subject of a clinical pathway. The protocols in those cases are in the form of checklists where the ambulance personnel tick off inclusion criteria, assessment steps and treatment steps. Following guidelines too literally is thought to be a threat to creative thinking. The view is that it is not possible to follow the guidelines in every situation and it is not possible to create a guideline for every situation in the pre-hospital setting.

The main obstacle to the use of guidelines and protocols in the evaluated ambulance organisation was the physical format of the guidelines. The poorly adapted format originated from the development process of the guidelines where no professionals with context knowledge were involved in the process. One sign of format problems is the fact that many ambulance nurses make their own variation on guidelines, in paper form but most commonly in electronic form. Homemade guidelines in paper form can be files with a mixture of medical tables, algorithms and useful information. It is more common for the personnel to have the guidelines in their own smartphones. These guidelines are available during every phase of an ambulance mission. Another obstacle to the use of guidelines is the lack of evidence in the guidelines. In spite of the fact that the ambulance nurses think that the guidelines have a positive effect on the outcome, the guidelines are seldom regarded as evidence based. Table 6 gives a summary of the results in CMO configurations.
Table 6. Summary of results from Study III presented in CMO configurations

<table>
<thead>
<tr>
<th>Context</th>
<th>Mechanism</th>
<th>Outcome</th>
</tr>
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<tbody>
<tr>
<td>C1: The pre-hospital work is accomplished a long distance from medical support; the personnel handle many different symptoms and conditions in changing environments and they have different levels of education and experience.</td>
<td>M1: The guidelines are developed in a process in which people with in-depth context knowledge are excluded.</td>
<td>O1: Guidelines with a format poorly adjusted to the context. O2: Guidelines with limited explicit use. O3: Development of homemade guidelines. O4: Lack of organisational control. O5: Explicit use of guidelines in file format creates a sense of unprofessionalism.</td>
</tr>
<tr>
<td>M2: Structured implementation strategy for the guidelines at local level.</td>
<td>O1: The personnel are well informed about the guidelines and their content. O2: The personnel take a positive view of the guidelines. O3: Both inexperienced and experienced personnel use them. O4: Improved team function.</td>
<td></td>
</tr>
<tr>
<td>M3: Difficulty developing guidelines which cover every possible situation.</td>
<td>O1: Deliberate deviation from guidelines. O2: Ethical conflicts.</td>
<td></td>
</tr>
<tr>
<td>M4: The ambulance mission is divided into five separate phases.</td>
<td>O1: Different need for support in the different phases. O2: Request for a system which covers all phases.</td>
<td></td>
</tr>
</tbody>
</table>

6.5 The feasibility of using a CDSS in a pre-hospital organisation (III)

There is a high level of feasibility for the implementation of a CDSS in the present ambulance organisation.

Both clinicians and stakeholders responsible for the organisation request a decision support system in electronic format (CDSS) but with different purposes. The varying need for support during the different phases in an ambulance mission has resulted in a request for a system that is able to collect all the different guidelines and protocols in a single system. It should be possible to use the system directly in the first contact with the patient and start the documentation at the same time. There is also a need to be able to start the documentation of the pre-hospital medical records early in the assessment.
process. The ambulance personnel in the study did not think that these requests could be realised in paper format. From the organisation’s perspective, there is a need to have control of compliance with the guidelines. There is a lack of feedback from the present system. Deviations from guidelines probably exist, but they are never reported and the quality of the pre-hospital patient records is therefore unsatisfactory. One way to improve compliance with the guidelines is to have a greater degree of control. It is suggested that electronically based guidelines connected to patient records would give this control.

6.6 Effect of CDSS on compliance with pre-hospital guidelines and the systematic assessment framework among ambulance nurses (II, IV)

A CDSS has the potential to increase guideline compliance. The strongest effect is in the assessment and treatment in the first survey and in the anamnesis of the patient. Compliance with the general systematic assessment framework also increased using the CDSS.

The result from Study II showed that the use of the CDSS had a relatively strong effect on guideline compliance. In the case of the critically ill sepsis patient, the group supported by the CDSS had a median compliance with the regional pre-hospital guidelines of 80% in comparison with the control group, which had a median compliance of 60% (p=< 0.001). The strongest effect on compliance was in the primary survey phase, with compliance of 82% in the CDSS group and 52% in the control group (p=< 0.001), and in the anamnesis of the patient, where the CDSS group showed compliance of 83% compared with the control group, with compliance of 50% (p=< 0.001). When it comes to monitoring, further examinations and therapeutic interventions, there was no significant difference between the two groups. In the assessment and treatment of the less acute COPD patient, the result was similar. Compliance with guidelines was 80% in the CDSS group and 60% in the control group (p=< 0.001). As in the sepsis case, there were significant differences in the primary survey phase and in the anamnesis of the patient.

In the clinical evaluation, the use of the CDSS increased compliance with the systematic assessment framework described in the local and regional guidelines by 10% (p=< 0.001). As a result, the use of the CDSS increased the number of performed assessment steps (Figure 4).
6.7 Effect of CDSS on time spent on the scene by ambulance nurses (II, IV)

It is difficult to draw any firm conclusions about the effects of the CDSS on OST, as the simulation study and the clinical study produced different results. One reason for this could be that, in the simulation study, the participants had only 40 minutes’ training on the CDSS before the study. In the clinical study, the education before the intervention phase consisted of a full day of lectures and training. In the clinical study, the participants used the CDSS on several occasions every working shift. This CDSS probably had a limited effect on OST after training and some practical use of the CDSS.

In Study II, there was an increase in the median time spent on the scene in both scenarios. In the scenario with the critically ill sepsis patient, the median OST was 10.19 minutes in the CDSS group compared with 5.40 minutes in the control group (p=< 0.001). The time to the administration of oxygen and infusion was also significantly longer in the CDSS group. The same tendency was seen in the COPD scenario, where the median total time and time to the administration of salbutamol and ipratropium was increased in the CDSS group (p=< 0.001).

The clinical study did not show any significant increase in OST when the CDSS was in use. The OST was already increased in the baseline phase during the study. The coefficient for the pre-intervention slope was 0.188 (p=0.001) in the most parsimonious model (Figure 5). The reason for this is unknown.
7. Discussion

7.1 Reflections on the findings

7.1.1 Effect of CDSS on patient safety in pre-hospital care

This present thesis has an explicit system approach in the sense that errors in Judgement and Decision-Making (JDM) are a consequence of latent failure rather than human causes (Reason, 2000). The system approach has three goals and they are to design the system to prevent errors, to make error visible and to alleviate the consequences of errors when they are not detected (Thomas, 2000). As shown in Figure 2, there are several potential reasons for errors in the JDM process and the development of cognitive tools is only one of several strategies to prevent cognitive errors. Examples of complementary strategies are training on theories of reasoning and medical decision-making, simulation training, feedback, metacognition, decoupling, reflection, mindfulness and group decision strategy (Croskerry et al., 2013b). Study III suggests that the current cognitive tools are poorly adapted to the pre-hospital context and this
can lead to active failures among the ambulance clinicians in the organisation. Reason (1990) points out that most active failures are due to failures in the organisation to impose the requirement to perform safe actions on the front-end executers. It is in the on-the-scene assessment and treatment process that most of the decisions are made by the pre-hospital clinicians and it is also during this phase of an ambulance mission that the clinicians have the least clinical support (Jensen et al., 2011). This knowledge suggests that it is in the on-the-scene phase that the ambulance clinicians are most vulnerable to cognitive errors. The result from Study III revealed that, due to the physical format of the pre-hospital guidelines and protocols, explicit use is not possible in the on-the-scene phase. The ambulance personnel in the study were highly motivated to follow the recommendations provided by the organisation, but the guideline and protocol format made the use of them difficult. The poorly adapted format of the guidelines and protocols in the investigated ambulance organisation is an example of a latent failure which can produce active failures at the front end. The explicit use of guidelines and protocols is regarded as an important feature in the execution of safe health care (Morris, 2002).

The ambulance nurse in the example in Box 2 is highly experienced and respected. This is in line with research which shows that experts are not immune to committing cognitive errors (Patel et al., 2011). Experts are prone to commit premature closure, rapidly reaching a conclusion and ignoring evidence in support of opposing hypotheses. The errors in the JDM process have their origin in System 1 reasoning. The ambulance nurse in Box 2 used anchoring and adjustment heuristics (Croskerry, 2002) very early in the mission. When he received the meagre information from the dispatch centre, he heard the word “allergic”. Even in the history gathering, the word “allergic” emerged several times. He used “allergic” as an anchor point and spent the rest of the assessment confirming the hypothesis and ignoring other information, such as the abdominal pain. The heuristic bias led to the omission of task steps, which is the most common cognitive error (Reason, 2002), in the assessment process with premature closure as a consequence. He started potentially dangerous treatment without further questions and examinations, such as lung auscultations, electrocardiogram and a head-to-toe examination. Even in Study II, there were signs of premature closure due to System 1 reasoning. For example, the control group working with the standard paper-based guidelines started the treatment with salbutamol and ipratropium on the patient with dyspnoea after only three minutes and 10 seconds, often before a thorough history was taken and auscultation of the lungs was performed. Such a short time for assessment cannot reasonably rule out other causes of the patient’s condition. The reason was probably representativeness heuristics or availability heuristics (Croskerry, 2002), as there is a real probability that a patient with dyspnoea and a history of COPD may experience a remission of COPD, but there is also a smaller probability that the symptoms have other causes, such as
congestive heart failure. Study III demonstrates that ambulance clinicians in the evaluated organisation seldom use guidelines or protocols in the initial assessment. This means that, in the initial JDM process, System 1 reasoning is the dominating reasoning process (Croskerry et al., 2013a). In emergency care, System 1 reasoning is a good strategy in most of the cases and, in life-threatening conditions, System 1 reasoning can be life-saving, but it is also prone to bias. The most common JDM errors in pre-hospital care appear to be aggregate bias, anchoring, availability and unavailability biases and vertical line failure (Alexander, 2009). Bias in JDM happens to both the novice and the more experienced clinician, but the types of bias differ depending on the experience level of the clinicians (Patel et al., 2001). The less experienced clinicians are more prone to commit mistakes, defined by Reason (2002) as errors where the clinician’s stored schemata are insufficient, so-called rule-based mistakes, or when the situation is new, defined as knowledge-based mistakes.

Dual process theory can be a valuable model to explain how and where in the JDM process the CDSS can reduce the risk of cognitive errors (Croskerry, 2009a) (see Figure 1). Cognitive errors can occur when the decision maker fails to identify the situational signals indicating that the System 1 primed reaction needs to be overridden by a System 2 approach (Stanovich & West, 2008). The situational signals in the examples in Box 2 could be a busy shift with a high tempo, short preparation time, communication difficulties and multiple symptoms. An override of this kind is labelled rational override in the model. The CDSS in Studies II and IV can prevent System 1 errors by forcing an override to System 2 using a cognitive forcing strategy (Croskerry et al., 2013b). In the examples in Box 2, the use of the CDSS in the assessment process could stimulate a rational override to System 2 reasoning by forcing the ambulance nurse to continue the history gathering, determine a chief complaint, execute further examinations due to the chief complaint and provide the ambulance nurse with a differential diagnosis list and ROW strategies. The CDSS can also prevent the omission of task steps in the assessment process by providing the ambulance nurse with a passive reminder (Reason, 2002), where the nurse can go back in the system to verify that all the task steps in the assessment process have been executed. In Studies II and IV, the groups using the CDSS gathered significantly more information in the assessment process. This is evidence of the potential of the CDSS to promote rational override. Using the same strategy, the CDSS can also prevent an irrational override from System 2 to System 1 due to stress, cognitive overload, fatigue and environmental factors.

An override from System 2 to System 1 can also occur after the repetitive performance of a task (Croskerry, 2009a). This kind of override is sensitive to cognitive errors if the override occurs too soon. This suggests that an
ambulance nurse with intermediate experience is prone to cognitive errors if he/she overrides to System 1 reasoning without the requisite experience. In these cases, the CDSS can force the ambulance nurse to stay in the System 2 mode of reasoning.

Novice ambulance nurses are more prone to commit knowledge-based mistakes. Mistakes are errors where the clinician’s stored schemata are insufficient or lacking. Mistakes are therefore more common among inexperienced clinicians (Reason, 2002). The system could possibly reduce the risk of mistakes by providing the clinicians with appropriate schemata. Although the CDSS can be classified as an expert system, it imitates the expert’s reasoning. A common strategy among novice clinicians in emergency care is exhaustive methods (Croskerry, 2002). The method is hypothesis driven rather than driven by information. The clinicians scan the patient for a large number of possible conditions. The problem with the method is that it is time consuming and there is a risk that the patient will be exposed to unnecessary examinations. Gathering too much information can overload the working memory and the risk of knowledge-based mistakes is increased (Croskerry, 2002). The CDSS can support the novice ambulance nurse by providing him/her with procedural knowledge, such as general assessment rules, Rule Out Worst-Case Scenario (ROWS) strategies, checklists and stopping rules (Croskerry et al., 2013b), but this requires the explicit use of the CDSS.

The explicit use of a CDSS in pre-hospital care perhaps involves a need for a change in the ambulance team’s way of working. The assessment process could be more like the organisation of a hospital trauma team. The hospital trauma team is led by a team leader who is responsible for the care of the patient. The team leader organises patient care, makes major decisions and delegates work to others. The team leader is assisted by a person who performs hands-on evaluations and reports findings to the team leader (Aleksandra et al., 2012). The context in the pre-hospital setting differs a great deal from that in the hospital setting. The ambulance team normally comprises two team members, while a hospital trauma team can have as many as 15 members (Aleksandra et al., 2012). The ambulance team needs to use an adjusted variant of the trauma team’s organisation. The team leader in the ambulance team is the person responsible for the care of the patient. The team leader organises the assessment, guided by the CDSS structure. The other team member performs most of the hands-on evaluations at the request of the team leader and reports the findings. In some assessment interventions, the two need to co-operate, in connection with ECG measurements, for example. The team leader can perform the history gathering and make decisions relating to further assessment and treatment. The team leader is also responsible for the documentation. To be able to work effectively with a CDSS, the ambulance team needs team
training. Medical simulation has been found to be a good tool for team training (Gaba, 2004).

Study II showed that the CDSS had the greatest effect on compliance in the primary survey phase and in the anamnesis of the patients, but, when it comes to monitoring the patients, there were no differences in compliance between the group using the CDSS and the controls. These results confirm earlier research which reveals that monitoring has greater compliance in pre-hospital care in comparison with compliance with treatment plans (Ebben et al., 2013). High compliance in the primary survey must be regarded as important to patient safety, as it is in this phase that immediate life-threatening conditions must be identified and treated (Dalton, 2010). Moreover, the anamnesis is regarded as a critical component in the assessment of patients with respiratory distress, for example (Delbridge et al., 2003). As has already been stated, in the event of life-threatening conditions, rapid, unconscious System 1 reasoning can save lives. Is it then possible to use a CDSS in the first survey? In some situations, it is probably too time consuming to use an electronic support system when the patient has failures in vital organs. However, in these cases, the ambulance clinicians can use the CDSS as a reminder when the patient is more stable. In Study II, the group using the CDSS in the assessment process performed significantly more chin lifts to create a free airway and this intervention can be regarded as important. An algorithmic approach to pre-hospital airway management is regarded as a valuable tool for ensuring pre-hospital patient safety (Wang et al., 2005).

Protocol-based care is an important feature of pre-hospital care. The result from Study III demonstrates this. The pre-hospital context makes the pre-hospital clinician dependent on protocol-based care. In Sweden, every ambulance has to be staffed by at least one registered nurse, but there is no requirement for supplementary specialist education in pre-hospital care (National Board of Health and Welfare, 2009). This means that it is possible to work in a Swedish ambulance with limited education in emergency care and no education in pre-hospital emergency care at all. The system is highly dependent on support from cognitive tools, such as guidelines, protocols and algorithms. There are signs that protocol-based care is more effective compared with online medical control in the pre-hospital setting when it comes to decision support (Rottman et al., 1997). The disadvantage of the paper-based format was clearly demonstrated during the field observations in Study III, especially in cases where the patients were included in a clinical pathway. In those cases, the ambulance clinicians had to use several different protocols, stored in different places. Having all the documents logically stored in an electronic format would have obvious benefits in the process of care. Protocol-based care is indispensable as a strategy to prevent aggregate bias (Morris, 2002). The use of
a paper-based system has limitations when it comes to organising the information in a manner that promotes explicit use. When using a paper-based DSS, there is a risk that clinicians will have to fill in logical gaps and the system will not relieve the pressure of cognitive overload. There are several illustrations of the impact explicit decision support systems have on patient safety and quality of care. Explicit methods streamline the care and make different clinicians use the same process of care. Explicit methods also provide a foundation for the assessment of other clinical methods (Morris, 2002).

In addition to increasing compliance with recommended care, CDSS can influence patient safety in other ways. In Study IV, the effect of CDSS on compliance with the general pre-hospital assessment process was measured. A structured patient assessment framework has been found to benefit quality of care in several ways. It has a positive effect on patient outcome by strengthening documentation, communication, care implementation and patient and clinician satisfaction (Munroe et al., 2013). Research has found that clinicians using a CDSS in the assessment and decision-making process are more focused on problem solving with simple propositions and the cognitive changes are sustained even after the CDSS is removed (Patel et al., 2000). The reason for the cognitive change is probably the way the information is processed, stored and presented (Patel and Currie, 2005).

Another potential benefit of the use of CDSS in the pre-hospital setting is the transfer of information. Research has shown that there is a substantial risk of information being lost in the handover phase (Carter et al., 2009). The ambulance clinicians’ reports in the handover phase are an important piece in the emergency physicians’ JDM process and there is a need for more detailed and timely pre-hospital information (Aleksandra et al., 2012). In Study IV, the participants documented more information in the pre-hospital records, relating to the patient assessment, compared with the baseline period. Using the documentation in the CDSS as a support in the handover phase could potentially reduce the loss of information. A CDSS connected to an electronic medical record could also organise the information in a manner that better reflects the patient assessment. To being able to start the documentation at the same time as the assessment could also reduce the information loss. In the present system, the ambulance personnel produce the final documentation a long time after the initial assessment. When it comes to transferring information from the organisation to the ambulance clinicians in the field, the CDSS could also have advantages compared with paper-based information. For example, a CDSS could contain alerts and reminders of on-going studies and provide the clinician with inclusion and exclusion criteria in algorithmic form. It should also be possible for the medical director in the organisation to run different forms of campaign, such as when a new drug or a treatment regimen is introduced. The CDSS also has the potential rapidly to reach the clinicians in
the field with other important information, such as steering patients to a different ED due to overload at the nearest ED, information about roads being closed, traffic situations and on-going public gatherings and so on.

7.1.2 Potential risks associated with the use of a CDSS in pre-hospital care

A CDSS can also potentially produce harm. The most obvious error is that the recommendations provided by the CDSS is incorrect (Morris, 2002). It is important that the recommendations in a CDSS are based on the best available evidence. In general, pre-hospital guidelines have a low evidence base (Lang et al., 2012). A poorly designed interface is also a threat to patient safety. Interfaces that are unclear or irrational can result in errors even among very experienced users (Huckvale et al., 2010). It is therefore important that people with context knowledge are involved in the development process (Study III). Another potential risk when using a CDSS is that all information technology can slow down the development of clinical skills (Patel et al., 2000). This particular risk is regarded as low with the CDSS used in Studies II and IV. The CDSS is a passive system; it does not provide decision support by calculating risk or probability. Instead, the CDSS supports decision-making by organising the assessment process in a system which should be familiar to all clinicians working in pre-hospital emergency care. One obvious risk with the use of the present system is the risk of vertical line failure. This occurs when the clinicians are too rigid and follow a predetermined process too literally (Croskerry, 2002). In emergency care, protocol-based reasoning benefits the patient in most cases, but, on some occasions in complicated and unusual cases, it is important for the clinicians to reason more widely than the protocol suggests (Croskerry, 2002). To prevent vertical line failure, the system needs to include a reasonable amount of flexibility. The participants in Study III expressed a need for flexibility in the present guidelines. The tricky part is to decide how much. A system with unlimited flexibility runs the risk of not standardising the process of care at all. A system which is poorly designed and does not match the normal working processes can produce harm in several ways. If the system forces the clinicians to change the normal work flow, this can result in a less effective process (Gooch & Roudsari, 2011). In pre-hospital care, a system of this kind could increase the OST. In some emergencies, the time spent on the scene can negatively influence the patient’s outcome. One example is the case of severe trauma (Gonzalez et al., 2009). The results from Study II indicate that OST increased when the CDSS was in use, but Study IV was not able to show any significant differences between pre- and post-use of the CDSS. The reason could be the short training on the CDSS in Study II and extended training and education on the CDSS means that the effect on OST is minor.
7.1.3 What are the features of an optimal CDSS in a pre-hospital setting?

Unfortunately, there is a lack of research on design features important to the success of CDSS (Main et al., 2010). However, the goal for a CDSS should be explicit use, if the effect on patient safety is to be strong (Morris, 2002). To accomplish this in the pre-hospital setting and especially in the sensitive on-the-scene phase, a handheld device is a necessity. A tablet computer is a suitable format outside the ambulance. Some participants in Study III have the pre-hospital guidelines stored in their own smartphones. The advantage is that they are able to use the guidelines explicitly in the direct patient assessment. The disadvantage is that the guidelines do not have a format suited to smartphones and this means that they can be difficult to operate. Another potential disadvantage is the small screen on the smartphone which makes a contribution to user friendliness. The participants in Study III also used their smartphones to search for information on the internet. This suggests that the internet is a valuable source of information in the pre-hospital setting. However, the internet has been found to be a poor source of information in the in-hospital emergency setting and it should be studied before being accepted as a reliable tool for clinical decision-making (Krause et al., 2011). One important feature of a CDSS is that the system supports the users’ everyday work practice (Rahimi et al., 2009). To achieve this goal, the developer of the system needs to have a substantial knowledge of the working process in the context in which the CDSS is going to be used or, even better, the end user can be involved in the development process (Berg, 2001).

One major drawback of the CDSS in the study was the fact that we were not able to configure the CDSS EHR system to the standard pre-hospital EHR. The reason was that the study did not obtain permission from the IT Department in the participating hospital to make the necessary changes to the standard EHR system. The result was that the participants in Study IV were unable to use the CDSS to finish their patient records. Instead, they had to copy the information in the CDSS to the ordinary records manually on a computer at the ED. This probably led to a reduction in motivation to use the CDSS. Research has shown that a major feature of a CDSS is that the system should not be dependent on the clinician’s initiative to use it (Kawamoto et al., 2005; Garg et al., 2005). The ambulance personnel in Study IV were obliged to produce a patient record. If the record were integrated in the CDSS and, by using the CDSS, they were immediately able to start the documentation and in many cases able to finish the record before the handover phase at the ED, the system could provide decision support automatically as part of the ambulance personnel’s natural work flow. The participants in Study III expressed a need for systems where the documentation could be created early in the assessment process and at the same time support the clinicians.
In addition to including an EHR, there is other information which should be included in a pre-hospital CDSS. In the present paper-based system, information had to be collected in several different places. A system which included all the information needed at work would be ideal for pre-hospital care. This system should be able to include information about all the phases of an ambulance mission (Study III).

7.2 Methods

7.2.1 Validity and reliability

The main threat to validity in Study I is selection bias. This threat was handled using a comprehensive search strategy which included a hand search of grey literature (Hopewell et al., 2007). The selection process included a methodological quality assessment using an assessment instrument (Network, 2010). The method in Study I was rigid and followed the process described in the *Cochrane Handbook of Systematic Reviews of Interventions* (Higgins JPT, 2008). Based on earlier research on the risk of using non-randomised trials in systematic reviews (Deeks et al., 2000), a decision was made to include only RCTs in Study I. Non-randomised studies have a tendency to over- or underestimate the effect of interventions (Deeks et al., 2000). This resulted in a weak knowledge of the impact of DSS on pre-hospital care, as only two studies met the inclusion criteria. The project would probably benefit more from another types of review, such as the *Realist review* (Pawson et al., 2005). The systematic review based on RCT can support the project with firm evidence on whether or not the intervention works. The realistic review can instead provide the project with a deeper understanding of the intervention and how, why and under what circumstances it could work.

The risk of selection bias in Study II was managed by randomly assigning the participants to the study (block randomisation). The effect of repeating the tests was a potential threat in Study II. By randomising the participants to starting with either patient case A or B, the threat could be minimised. One limitation in Study II was that it was not possible to blind the raters to the group to which the participants belonged (it was easy to see whether or not they used the CDSS). To strengthen the protocol and increase the reliability of the measurement, the protocol was tested in a pilot study comprising 12 participants. The inter-rater reliability (IRR) was calculated to determine consistency between two raters. The IRR for the raters was found to be \( \kappa = 0.80 \). Generalisation is difficult in studies of complex interventions. Study II is a laboratory study and there is a risk that the behaviour of study participants in the laboratory setting does not reflect behaviour in the real world (Kazdin,
The laboratory setting had the advantage that it was possible to assess the outcome in depth by analysing digital videotapes. An even greater advantage of the laboratory setting is the opportunity to maintain constant factors that can vary widely in a natural setting (Kazdin, 2003).

One of the cornerstones of quality research is reflectivity (Malterud, 2001). It encompasses the issues of how the researcher’s earlier experience, preconceptions, attitudes and beliefs can affect the results. Reflectivity must be used in every step in the research process to enable the effect of the researcher to be assessed (Malterud, 2001). Reflectivity was considered important in Study III, as the first author had been employed in the evaluated organisation. This was regarded as a threat to objectivity. The authors in Study III dealt with the threat using multiple strategies. To begin with, a template approach was used (Crabtree & Miller, 1999). This means that a theoretical framework based on previous research (Rycroft-Malone J, 2010) was used throughout the research process (Pawson and Tilley, 1997). The interview protocols and the observation protocols were detailed and based on the theoretical framework. The analysis of the gathered material was also guided by the theory using a code manual based on the theoretical framework. Further, the observations of one of the ambulance stations performed by a student were guided by the same observation protocol and a comparison could be made between observations by the two observers. In the focus group interviews, the first author was assisted by two co-authors. One of the focus groups also performed the function of member checking (Creswell, 2007). In the analysis of the data, the first author worked in close collaboration with one of the co-authors.

In addition to reflectivity, the internal validity was maintained by a process of theory triangulation, pattern matching against the theoretical framework, data triangulation (archival data; interview data; participatory observations), member checking and data accumulation. The external validity was maintained by an effort to describe details of context and the reliability by an effort to describe the details of the research process (Baker, 2011).

Instrumentation could have been a threat to internal validity in Study IV. To minimise the threat, the study used only one rater who was blinded to the time periods to which the rated medical records belonged and the records were also randomised in time periods (weekly). There was a risk of attrition in the study, as the study was on-going for seven months. However, there was no significant difference in the number of eligible patients the participants were handling between the pre- and post-intervention phases. In an ITS study, it is not possible to control for selection bias. Instead, the design makes it possible to control for secular trends, cyclical effects, duration of the intervention effect and random fluctuations (Ramsay et al., 2003). The measurement was pilot tested. Two authors separately rated 10 identical records and an IRR was
calculated by using Cohen’s k. The IRR was found to be $\kappa = 0.75$. The primary variable is based on data extracted from electronic health records (EHR). There is a substantial risk of data loss and that the information in the EHR may not entirely reflect reality (Chan et al., 2010). To strengthen the opportunity to transfer the data to other settings, Study III has the function of deep context description (Øvretveit, 2011).

8. Conclusions

The results from the studies in the thesis revealed that:

- The use of paper-based decision support can increase the diagnostic accuracy and shorten the time from symptoms to definitive care in pre-hospital care
- There are no studies which evaluate the effects of computerised decision support systems in a pre-hospital setting before this thesis
- Due to the context, pre-hospital care is dependent on protocol-based care
- The main obstacle to using guidelines and protocols in the pre-hospital setting is the physical format of the guidelines which are poorly adapted to the complex setting in which pre-hospital care is administered. The reason for the poorly adapted tools is that people with knowledge of the context are excluded from the development process
- There is a need for protocol-based care in an electronic format
- The use of a CDSS with integrated pre-hospital guidelines increases compliance with guidelines
- The CDSS has the greatest effect on guideline compliance in the first survey and history taking
- The use of a CDSS has a positive effect on compliance with the systematic assessment framework
- The use of a CDSS has a limited effect on the time the ambulance teams spend on the scene
9. Implications

The results of the present thesis can be used to guide stakeholders in ambulance organisations on strengthening the effect of protocol-based care, preventing cognitive bias and increasing patient safety. Ambulance organisations using guidelines and protocols in a manner similar to that described in Study III should consider integrating the documents in an electronic system. As this is the first evaluation of a CDSS in the pre-hospital setting, we recommend using a passive system which organises the assessment and treatments into a single system. The system should include passive reminders where the clinicians can check that all the necessary steps in an assessment and treatment process have been carried out. It is an important feature to prevent premature closure where parts of the assessment are omitted. This is probably the main threat to patient safety in pre-hospital care.

Without further research, systems which include active and more sophisticated decision support, such as knowledge-based or rule-based systems, should be avoided. It is also important that end users participate in the development of guidelines and CDSS. Due to the complex context in which pre-hospital care is administered, efforts should be made to guarantee user friendliness.

To promote explicit use, the pre-hospital EHR should be integrated into the system. It is important to make the system a natural part of the ambulance clinician’s work flow. The system should also include all the documents that are used in the organisation, such as the main guidelines, drug dose schedules, pathway protocols, triage protocols and specific algorithms.

10. Future research

As the studies in the present thesis are pioneering work, there is a need for more research on the effect of CDSS on pre-hospital care in the future. Even if the effect of CDSS on in-hospital care is evaluated in hundreds of studies, the knowledge base of the true effects of CDSS is regarded as low. It is possible to use experience from CDSS in other health-care settings, but it is unsuitable to transfer this experience directly to the pre-hospital context, as pre-hospital work has some typical features that are not seen in other settings. In the future, there is a need for studies which investigate the nature of cognition in pre-hospital care. There is a need for more knowledge of the way ambulance clinicians make decisions. There is also a need for more knowledge of human
error issues in the pre-hospital context. When do the ambulance clinicians make errors, with which patients, in which situation is the risk greatest and so on? There is also a need for the development and evaluation of more sophisticated systems which include active components. Future evaluations of pre-hospital CDSS should also include patient outcomes such as mortality and morbidity. In addition to experimental studies, qualitative studies are needed to explore the effect of CDSS on pre-hospital work and the effect of CDSS on clinician-patient relationships. Because of their complexity, the future development and evaluations of CDSS for use in the pre-hospital setting should be carried out in a multidisciplinary team including researchers from cognition science, experts in human error and ergonomics, researchers from computer science and researchers from the pre-hospital field. The implementation of a CDSS should be made using traditional quality improvement techniques, such as the PDSA cycle. In the implementation stage, researchers with experience of the quality improvement field should be involved.
Forskning visar att det största hotet mot patientsäkerheten i prehospital akutsjukvård är misstag begångna i bedömningen av den akut sjuka eller skadade patienten. Orsaken till kognitiva misstag kan finnas i den komplicerade kontexten där prehospital akutsjukvård utövas. Vården utövas långt från medicinsk support, vårdarna måste hantera en stor viss av medicinska tillstånd hos patienter i alla åldrar. Miljön kan många gånger vara utmanande och ambulanspersonalen har skiftande utbildning och erfarenhet. Kontexten gör ambulanspersonalen beroende av riktlinjer och protokoll som styr vården. Forskning har visat att följsamheten till riktlinjer har varit svag i den prehospital miljön. Ett sätt att stärka följsamhet och stödja beslutsfattande har inom andra områden i sjukvården varit införandet av datoriserade beslutsstöd men forskningen har gett en komplett bild av dessa systems effekter. Resultaten föreslår att datoriserade beslutsstöd, liksom all form av informationsteknologi, är att betrakta som komplexa interventioner och ska systematisk utvärderas innan de införs i vården.

Syftet med denna avhandling var att utveckla och utvärdera ett datoriserat beslutsstöd för ambulanssjukvård.

Avhandlingen använde sig av ett metodologiskt ramverk för utvecklande och utvärdering av komplexa interventioner. Studie I var en systematisk litteraturstudie med syfte att undersöka den vetenskapliga grunden för införandet av datoriserade beslutsstöd i prehospital akutsjukvård. Delstudie II utvärderade den första versionen av ett datoriserat beslutsstöd i en randomiserad studie i simulerings miljö. Följsamhet till riktlinjer och tid på plats hos patienten var de två variabler som testades i två olika patientfall. I delstudie III undersöktes hur riktlinjer och protokoll används i den utvärderade ambulansorganisationen. Syftet var också att undersöka behovet av riktlinjer och protokoll i ett elektroniskt format och undersöka om några hinder skulle finnas för införandet av ett datoriserat beslutsstöd finns. Studien hade också
funktion som en djupare kontextbeskrivning. Metoden i studie III var ”case study methodic” med data insamlingsmetoder som enskilda intervjuer, deltagande observationer, insamling och analys av dokument och fokusgrupp intervjuer. Den sista delstudiens syfte var att utvärdera den sista versionen av beslutstödet i en klinisk studie. Designen var tidsserie studie där deltagarnas följsamhet till den i riktlinjer beskrivena bedömningsprocessen samt tid på plats hos patienten måttas varje vecka tre månader innan införandet av beslutstödet och tre månader efter införandet.


Det utvecklade och utvärderade beslutstödet kan förbättra den prehospitala patientsäkerheten genom att minska risken för kognitiva misstag. Genom att standardisera bedömningsprocessen och genom att tillhandahälla stöd i forma av checklistor, bedömningsregler, differentialdiagnoslistor och uteslut värsta scenario strategier minska risken för förhastade beslut.


II. References


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