Exploring patient safety in home healthcare

– a resilience engineering approach

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- a resilience engineering approach

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ABSTRACT

The overall aim of the thesis is to increase knowledge and understanding of patient safety in home healthcare.

This thesis has an explorative mixed-methods design, with both qualitative (Papers I and II) and quantitative (Papers III, IV and V) methods. Data for Papers I and II were collected at three specialised home healthcare units. The aim for Paper I was to explore patient safety in home healthcare from the multidisciplinary teams and clinical managers’ perspective. Data collection for the study was done through seven individual and nine focus group interviews, a total of 51 participants, and analysed with qualitative content analysis. The aim of Paper II was to explore the medication management process. The data collection was done by observing the medication management process for 27 days, 9 days per unit, and through interviews with the healthcare professionals who had been observed. Data was collected in iterative phases and analysed with grounded theory.

The aim of Paper III was to develop a trigger tool for structured retrospective record review to identify adverse events and no-harm incidents and their preventability that affect adult patients admitted into home healthcare. Another aim was to describe how the development was conducted. During the development, the trigger tool was tested twice, using 60 and 600 records, respectively, from ten different organisations from nine different regions across Sweden. The same 600 randomised home healthcare records were used for Papers IV and V. The aim of Paper IV was to explore the incidence, types and preventability of adverse events using the trigger tool. For Paper V the aim was to explore cumulative incidence, preventability, types and potential contributing causes of no-harm incidents using the trigger tool. Studies III, IV and V were analysed with descriptive statistics.

The results showed that the clinical managers and the multidisciplinary teams considered patient safety as associated with their common mind-set of safe care, based on a well-established care ideology. This mindset included the establishment of a trustworthy relationship with patients and relatives. At the same time, provision of care in a home was characterised by weighing values against each other, between risks and patients’ and relatives’ autonomy and wishes. Other typical contradictory values were between collecting measurements for different quality registers (directives from policy-makers as a measure of
quality and safety), or taking time for patient needs. Strategies and behaviours, such as not following routines, to get around problematic processes were the result of conflicting goals that either promoted or prevented patient safety (Papers I and II). Results from Study III showed that the empirically tested triggers identified more triggers compared to several other studies and thus formed a rich material for validation. More than a third of the patients in home healthcare were affected by adverse events (37.7%), most of which were deemed preventable (71.6%). Most adverse events (69.1%) were temporary and led to that the patient required extra healthcare visits or led to a prolonged period of healthcare. The most common adverse events were “healthcare-associated infections, falls and pressure ulcers (Study IV). Almost every third patient (29.5%) was affected by a no-harm incident, one-fifth of which were deemed preventable (21.2%). The most common types of no-harm incidents were “fall without harm,” “deficiencies in medication management,” and “moderate pain”. “Deficiencies in medication management” were deemed to have a preventability rate (98.4%) twice as high as “fall without harm” (40.9%) and “moderate pain” (50.0%). The most common potential contributing cause of “fall without harm” was “deficiencies in nursing care, i.e., delayed, erroneous, omitted or incomplete care”. For “deficiencies in medication management” and “moderate pain” the most common contributing cause was “delayed, erroneous, omitted or incomplete treatment”. Of the total number of no-harm incidents, the most common contributing causes were “deficiencies in nursing care, treatment or diagnosis” and “deficiencies in communication, information or collaboration” (Paper V).

The conclusion is that patient safety is generally strengthened by the fact that clinical managers and multidisciplinary teams have a common approach to safety built on an internationally and national well-established care ideology, which forms a “dyad” with safe care. In home healthcare, patient safety is formed by the team creating a trustworthy relationship with patients and their families and involving them as partners in their own care. Additionally, the trigger tool and associated manual adapted for home healthcare may be a valid method for identifying cumulative incidence, types, preventability and contributing causes for adverse events and no-harm incidents. Such patient safety knowledge can be used to develop valid process indicators for systemic failures, as well as outcome indicators for structured evaluation and lead to proactive patient safety work in home healthcare.

*Keywords*: patient safety, home healthcare, adverse events, no-harm incidents, preventability, contributing causes.
SVENSK SAMMANFATTNING

Avhandlingens övergripande syfte är att öka kunskap och förståelse av patientsäkerhet inom hemsjukvård.

Avhandlingen har en explorativ design med både kvalitativ (studie I och II) och kvantitativ (studie III, IV och V) forskningsansats. Data för studie I och II samlades in på tre verksamheter som bedriver specialiserad hemsjukvård. Syftet med studie I var att utforska de multidisciplinära teamens och de kliniska chefernas perspektiv på patientsäkerhet.

Datainsamling för studie I gjordes via sju individuella- och nio fokusgruppsintervjuer med totalt 51 deltagare och analyserades med kvalitativ innehållsanalys. Syftet med studie II var att utforska läkemedelshanteringsprocessen. Datainsamlingen gjordes genom att observera läkemedelshanteringsprocessen i 27 dagar, 9 dagar per verksamhet. Data samlades även in via intervjuer med den vårdpersonal som hade observerats och analyserades med grounded theory.

Syftet med studie III var att utveckla ett markörbaserat verktyg för strukturerad retrospektiv journalgranskning och tillhörande manual för att identifiera skador, vårdskador (=undvikbara skador) och tillbud som drabbar vuxna patienter inskrivna i hemsjukvården samt att beskriva metodutvecklingen. Under utvecklingen testades det markörbaserade verktyget två gånger i 60 respektive 600 journaler från tio olika verksamheter som bedriver hemsjukvård från nio olika regioner i Sverige. Samma 600 randomiserade hemsjukvårsjournalerna användes för datainsamling till studie IV och V. Syftet med studie IV, var att med det markörbaserade verktyget identifiera skador och vårdskador och för studie V att identifiera tillbud och dess bidragande orsaker. Studierna III, IV och V analyserades med deskriptiv statistik.

Resultaten visade att grunden för patientsäkerhet var att kliniska chefer och de multidisciplinära teamen hade en gemensam syn på säker vård och stärktes av att teamen skapade en tillitsfull relation med patienter och närstående samt involverade dem som samarbetspartners i egen vård. Samtidigt innebar att vårda i ett hem vanligtvis att väga olika värden mot varandra, till exempel att minska risker mot att respektera patienters och närståendes autonomi och vilja. Andra typiska motstridiga värden var att ta tid för att få information av patienterna till kvalitetsregister, (direktiv från beslutsfattare som mått på kvalitet och säkerhet), eller att lägga tiden på patientens behov. Strategier och beteenden, som
att inte följa rutiner, för att komma runt problematiska processer var ett resultat av motstridiga värden som antingen främjade eller hindrade patientsäker vård (studie I och II). Resultat från studie III visade att de empiriskt testade markörerna identifierades fler gånger jämfört med flera andra studier och utgjorde därmed ett rikt material för validering. Över en tredjedel av patienterna i hemsjukvården drabbades av skador (37.7%) varav de flesta bedömdes vara undvikbara, det vill säga vårdskador (71.6%). De flesta skador (69.1%) var temporära och ledde till att patienten fick göra extra besöka i öppenvård eller akutmottagning eller ledde till förlängd sjukvårdsperiod. De vanligaste skadorna var ”vårdrelaterade infektioner, ”fall” och ”trycksår” (studie IV). Nästan var tredje patient (29.5%) drabbades av tillbud varav en femtedel bedömdes vara undvikbara (21.2%). De vanligaste typerna av tillbud var ”fall utan skada”, ”brister i läkemedelshantering” och ”måttlig smärta”. ”Brister i läkemedelshantering” bedömdes ha dubbelt så hög undvikbarhet (98.4%) som ”fall utan skada” (40.9%) och ”måttlig smärta” (50.0%). Den vanligaste möjliga bidragande orsaken till ”fall utan skada” var ”bristande omvårdnad”, det vill säga att den var ”försenad, felaktig, utebliven eller ofullständig”. För ”brister i läkemedelshantering” och ”måttlig smärta” var den vanligaste bidragande orsaken ”försenad, felaktig, utelämnad eller ofullständig behandling”. Av det totala antalet tillbud, var vanligaste möjliga bidragande orsakerna ”brister i omvårdnad, behandling eller diagnos” och ”brister i kommunikation, information eller samarbete” (studie V).

Slutsatsen är att patientsäkerhet, stärks generellt av att kliniska chefer och multidisciplinära team har ett gemensamt synsätt på säkerhet, som baseras på en internationell och nationell väletablerad vårdideologi, som bildar en ”dyad” med säker vård. Patientsäkerhet, i hemsjukvård, bildas av att teamen skapar ett tillitsfullt förhållande med patienter och närstående samt involverar dem som samarbetspartner i sin egen vård. Ytterligare en slutsats är det markörbaserade verktyget med tillhörande manual anpassat för hemsjukvård kan vara en valid metod för att identifiera vårdskador, tillbud och bidragande orsaker. Sådan kunskap inom patientsäkerhetsområdet kan användas för att utveckla giltiga processindikatorer för systemfel, samt resultatindikatorer för strukturerad utvärdering och leder till ett proaktivt patientsäkerhetsarbete inom hemsjukvård.

Nyckelord: Hemsjukvård, patientsäkerhet, tillbud, skador, vårdskador, bidragande orsaker.
LIST OF PUBLICATIONS

This thesis includes the following papers which will be referred to in the text based on their Roman numerals.

I. **Lindblad M**, Flink M, Ekstedt M. Exploring patient safety in Swedish specialized home healthcare - an interview study with multidisciplinary teams and clinical managers. *BMJ Open* [accepted 2018 15 October].


III. **Lindblad M**, Schildmeijer K, Nilsson L, Ekstedt M, Unbeck M. Development of a trigger tool to identify adverse events and no-harm incidents that affect patients admitted to home healthcare. *BMJ Quality and Safety* 2017;0:1–10 [First published online 29 Sept 2017]


V. **Lindblad M**, Unbeck M, Nilsson L, Schildmeijer K, Ekstedt M. A proactive patient safety approach to identify no-harm incidents in home healthcare: a cohort study using trigger tool methodology. *In manuscript*
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<th>Acronym</th>
<th>Description</th>
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<tr>
<td>AE</td>
<td>Adverse event</td>
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<tr>
<td>EHR</td>
<td>Electronic health record</td>
</tr>
<tr>
<td>MMP</td>
<td>Medication Management Process</td>
</tr>
<tr>
<td>NCC MERP</td>
<td>National Coordinating Council for Medication Error Reporting and Prevention</td>
</tr>
<tr>
<td>PPV</td>
<td>Positive predictive value</td>
</tr>
<tr>
<td>RN</td>
<td>Registered nurse</td>
</tr>
<tr>
<td>RE</td>
<td>Resilience engineering</td>
</tr>
<tr>
<td>RRR</td>
<td>Retrospective record review</td>
</tr>
<tr>
<td>TT</td>
<td>Trigger tool</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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INTRODUCTION

The aim of this thesis is to increase knowledge and understanding of the phenomenon of patient safety in home healthcare. Healthcare in the home was chosen as a context based on the fact that it is a rapidly expanding form of care where more and more advanced care can be given. It can lead to new challenges, prerequisites and risks in the area of patient safety that are important to identify. At the same time, research on patient safety within home healthcare is limited.

In the framing of this thesis I have chosen resilience engineering, a systems theory approach, inspired by today’s safety research. Safety researchers believe that a systems perspective should be applied to safety in complex organisations such as healthcare as an aid to understanding and to improving patient safety work. This thesis key concept is thus patient safety and resilience engineering. These concepts are inherent in the thesis subject as well as established in the main subject for this doctoral thesis, technology and health. The thesis contains two research studies, “Patient safety in specialised home healthcare” (Papers I and II) and “Develop and test a trigger tool to identify adverse events (AEs) and no-harm incidents affect adults patients in home healthcare” (Papers III, IV and V).

The growth of home healthcare is due to several factors that interact, including the development of the growing and ageing population that is living longer with chronic and complex disorders, and the resulting economic pressure on healthcare systems. Together, the medical and technological innovation, and the trend for reduced numbers of hospital beds, have emphasised the need for healthcare being provided in patients’ homes. Today, home healthcare is one of the fastest growing forms of healthcare worldwide. At the same time, as mentioned above, the knowledge about patient safety in this context is limited. What we know is that patient safety has received major attention due to evidence that harm to patients, related to healthcare received, brings serious implications for patients’ well-being, morbidity and mortality, as well as incurring costs to the health system and society. These studies, as well as many others about patient safety has been conducted in hospital care. Patient safety has been more infrequently studied in home healthcare settings and is not as well understood as in another settings due to the context-dependent nature of patient safety.

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Additionally, it has become clear over the last decade that patient harm occurs not only because of an individual care provider doing things incorrectly, but rather that the system of healthcare is so complex that the outcome for each patient depends on a range of factors.\textsuperscript{12} Patient safety is a feature created by the interaction that takes place in organizations (systems), interactions between people, technology, processes, laws, etc.\textsuperscript{13} Hence, patient safety research should be based on a dynamic and systemic approach, in which all parts of a system and their internal relationships are of interest, rather than the individual components.\textsuperscript{14,15}
BACKGROUND

This chapter begins with a description of the key concepts, Patient safety definition and Theoretical framework: resilience engineering, a system approach. This is followed by: Methods to identify patient safety; Home healthcare and specialised home healthcare (an overview of the context studied in the thesis), and ends with: To care and care at home.

Patient safety definitions

Patient safety as a concept is relatively new, even though the phenomenon, “first, do no harm” has existed since ancient times in healthcare. The term was actualised with the report “To Err is Human”. The report found that AEs were related to different underlying factors in the healthcare system more than human mistakes.

Worldwide there are organisations, centres and networks with expert knowledge in patient safety such as the World Health Organization (WHO), the US Institute for Health Improvement, the Australian Patient Safety Foundation, the UK Health Foundation and the Danish Society for Patient Safety. These organisations work to spread scientific knowledge gained through research in the field of patient safety and they design, test and disseminate systems (policies, guidelines, publications, etc.) for safety aimed at reducing patient injury.

WHO is a global organisation that has member states worldwide (Africa, America, South East Asia, Europe, Eastern Mediterranean, Western Pacific), which facilitates the spread of common international knowledge and understanding of patient safety. WHO works actively with member countries in their health development processes. Therefore, for the purposes of this thesis, the WHO definition of patient safety, and the definitions that exist in Sweden, have been chosen. The definitions have similarities and differences both between countries and within the countries.

WHO defines patient safety as follows: “Patient safety is the absence of preventable harm to a patient and reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment”.

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WHO has also published a framework for international classification for patient safety with key concepts, preferred terms and practical applications in this area. The framework aims to facilitate learning within and between organizations and to increase understanding of systems resilience. It also includes a glossary of patient safety terms, where patient safety is defined as: “The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum”. In this framework, it is also stated that patient safety is an essential part of the broader concept of quality, which are critical issues in the healthcare system.

Sweden adopted a definitive definition of patient safety and related concepts (patient safety terminology) for the first time in 2005 in the National Board of Health and Welfare, Management system for quality and patient safety in health care. Patient safety was defined there as: “Protection against adverse events”, and the definition of AE was “suffering, discomfort, bodily or mental harm, illness or death caused by the healthcare system and which is not an inevitable consequence of the patient’s condition”.

A new Patient Safety Act has been introduced aimed at clarifying the healthcare responsibilities within patient safety. There is the same definition of patient safety as in the National Board of Health and Welfare term bank. On the other hand, there is a difference in the AE definition. Here the term “preventable” appears in the definition, as well as a definition of serious AE. AEs are referred to in the Act as: “bodily or mental harm or illness, as well as deaths which could have been prevented if adequate measures had been taken in the patient’s contact with healthcare”, which refers to healthcare harm. “Serious AE” refers to an AE, such as 1) is permanent and not minor, or 2) has led to a significantly increased need for care or the death of the patient”.

The National Board of Health and Welfare has also added an explanatory text about patient safety on their website, which can be translated as follows: “Safe care in which the rate of AE is low, is the utmost requirement to create good care. Good care is characterised as being that which is knowledge-based, effective, safe, patient-focused, effective, equal and accessible. It is the overall work that leads to a good quality of care. A high level of patient safety is characterised by patient and staff involvement in patient safety work, the existence of a good patient safety culture and prevention of AE through an active risk prevention approach”.
Table 1 shows a list of patient safety terms from the WHO framework glossary and the National Board of Health and Welfare. As not all the terms listed in the table are included in both glossaries, or are otherwise not comparable, there are some empty boxes in the table.

<table>
<thead>
<tr>
<th>Terms</th>
<th>WHO’s definitions</th>
<th>Sweden’s definitions</th>
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</thead>
<tbody>
<tr>
<td>Patient safety</td>
<td>The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum</td>
<td>Protection against preventable harm</td>
</tr>
<tr>
<td>Harmful incident (adverse event)</td>
<td>An incident which resulted in harm to a patient</td>
<td>Suffering, physical or psychological harm or disease as well as death that affects a patient</td>
</tr>
<tr>
<td>Healthcare associated harm</td>
<td>Harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury</td>
<td></td>
</tr>
<tr>
<td>Preventable</td>
<td>Accepted by the community as avoidable in the particular set of circumstances</td>
<td>An event that could have been prevented if adequate actions had been taken during the patient’s contact with healthcare</td>
</tr>
<tr>
<td>Contributing factor</td>
<td>A circumstance, action or influence that is thought to have played a part in the origin or development, or to increase the risk, of an incident</td>
<td>An event that could have caused something undesirable</td>
</tr>
<tr>
<td>No-harm incident</td>
<td>An incident which reached a patient but no discernible harm resulted.</td>
<td>An event that could have caused something undesirable</td>
</tr>
<tr>
<td>Resilience</td>
<td>The degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents.</td>
<td></td>
</tr>
<tr>
<td>Risk</td>
<td>The probability that an incident will occur</td>
<td>The possibility of the occurrence of a negative event</td>
</tr>
</tbody>
</table>

The basic principle of patient safety is to protect patients from being harmed and that they are protected from exposure to risks in healthcare. In both definitions, patient safety is a process (reduction/protection) and a result (minimum harm/no harm). A message can be distinguished in both terminologies: the fewer AEs patients are exposed to in an organisation, the safer organisation and vice versa.

**Theoretical framework: resilience engineering a system approach**

The traditional approach to safety has been to analyse what has gone wrong with a focus on the role of the individual. This patient safety approach is usually applied as the “blame and shame” perspective at the individual professionals.
According to Reason, human mistakes can be seen from two perspectives, the individual or the system. If the organisation is based on the individual perspective when an error occurs, the responsibility and the debt are placed on an individual, and the deviation is treated as a moral problem. An individual responsibility can cause fear, shame and guilt for the accused person. A system perspective, however, is based on the fact that there may be deficiencies in the organisation even in a well-functioning organisation. Humans are not infallible and the system can contribute to an act of human error. With safer systems, it is expected to be harder to make mistakes and easier to undertake tasks correctly.

Research and other influences (social development) have led to a changed vision of how to achieve greater safety in healthcare. It has become increasingly evident that safety must be understood from a system perspective, which takes into account the system’s dynamics and complexity and that the system consists of a large number of parts, where the individual is only part of the system. Home healthcare is an example of a complex adaptive system, which is characterised by the presence of large numbers of individuals in the system who interact with each other and with different factors. That is, integration and interaction between people, technology and organisation (processes, guidelines, etc.). The integration and interaction affect the presence or absence of safety.

Resilience engineering (RE) is a system approach that takes into account the complex variability of a system and focuses on how people manage to achieve good results under varying conditions. “Resilience is the essential ability of the system to adjust its functioning prior to, during or following both expected and unexpected events, and thereby sustain the required strategies under varying conditions”.

RE has four essential cornerstones which represent resilience in organisations; the ability to respond, monitor, anticipate and learn. Resilience in home healthcare includes the ability to: 1) know what to do, i.e. how to respond to various situations, disruptions or disturbances in the actual situation; 2) know how to monitor what happens, that is knowing what to look for, the ability to adjust actions to address the critical issues in the situation; 3) know how to anticipate or know what to expect in developments, signs or opportunities such as potential changes and their consequences for the future; 4) know how to learn from experience, successes as well as failures, and to understand both what happened and why.
The RE approach aims to find new ways to improve patient safety and lead towards a more proactive approach to safety, according to Hollnagel et al. 26 A so-called “Safety-II” perspective. A Safety-II perspective means focusing on what goes right in a system compared to the more traditional retroactive perspective, the so-called “Safety-I” perspective, which has focused on what has gone wrong in the system.

**Safety-I, learning from what goes wrong vs. Safety-II, learning from what goes right**

With the Safety-I perspective, the focus is on what went wrong (AEs), on risks identified and that there is a logical reason why AEs occur. In this perspective, bad outcomes and good outcomes depend on different causes. Safety-I tries to prevent accidents from happening by checking or eliminating what may go wrong. Safety-I’s linear explanations, as a causal link to why AEs occur, often lead to simple explanations, such as human error or technology failure, and miss other factors that are not as visible but may be of major importance to patient safety. For example, if the number of AEs decreases after intervention has been taken, this can be seen as evidence that the measures have had the desired effect.

The Safety-II perspective focuses on what is going right; AEs and risks do not arise due to a deviation or malfunction, but due to unexpected combinations of a normal variability. Safety-II accepts the dynamics of a complex adaptive system, and thus tries to prevent AEs from occurring by improving system resilience. The system will support healthcare professionals so that intended and acceptable results occur as often as possible and that the number of opportunities for risks and AEs occurring are minimised. 26

Within Safety-II, patient safety improvements in home healthcare include the understanding of how daily work is actually done and involves learning from both successful adaptations and failures. 14 25 The actual performance of work-as-done is different from the idealised view of work-as-imagined. Work-as-imagined does not consider the varying conditions under which everyday work is performed, whereas work-as-done reflects what the individuals actually have to deal with. 27

The proactive Safety-II perspective focuses on learning from everyday events to be able to understand the patterns in the system’s function. This is contrary to the retroactive Safety-I
perspective which focuses on learning from the very rare (fewer) serious events. Table 2 illustrates differences based on the different perspectives.

<table>
<thead>
<tr>
<th>Table 2. Differences between Safety-I and –II</th>
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<tbody>
<tr>
<td><strong>Safety – I</strong></td>
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<tr>
<td>Definition of safety</td>
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<td>Understanding of Safety</td>
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<tr>
<td>Explanation of safety</td>
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<tr>
<td>Human perspective</td>
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<tr>
<td>Cornerstone, patient safety management</td>
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<tr>
<td>Resilience organisation</td>
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Safety-II, as well as the RE approach, is the prevailing “paradigm” in patient safety but Safety-I coexist with Safety-II as a complement and increase the system’s ability to improve patient safety.

**Methods to identify patient safety**

This section gives a brief description of nationally adopted methods used in home healthcare to assess patient safety i.e. quality registers and incident reporting systems, methods that are also statutory in healthcare. This overview is not exhaustive but gives examples of efforts to assess patient safety as a background to the retrospective record review (RRR) using trigger tool (TT) due to the aim of Paper III being to develop and test a TT. A further description about RRR using a TT can be found in the Methods chapter.

Patient safety can be identified and measured by different methods which yield different outputs. The measures are derived from the various aims, data collecting methods and dimensions of care processes in patient care. The aim of patient safety work, in addition to making healthcare safer, is that it should lead to learning in the organisation. Using reliability and validity methods is a first step in the learning process, but there are few and they are limited in relation to specific context as home healthcare.
It is a global challenge to find common standardised methods for identifying patient safety in home healthcare. Although home healthcare organizations collect data on patient safety, common standardised methods and computer systems are lacking, which makes learning difficult. WHO claimed that systematic and continuous collection of patient safety data is crucial for understanding the extent of learning and to provide a basis for improving, evaluating, implementing and developing patient safety at home.

It is statutory that the healthcare provider is responsible for giving patients and relatives the opportunity to participate in patient safety work. The views of patients and relatives on healthcare are an important source of improvement. The methods used today include patient surveys (attitudes, expectations and experiences) and telephone interviews. Patients may also refer to the Patient Board (Patientnämnden) with complaints and comments, and these data may form the basis of the healthcare provider’s quality and patient safety improvements.

**Healthcare quality registers**

Generally, healthcare quality includes dimension such as effectiveness, timeliness, safety, equity, efficiency, and patient centeredness. Patient safety is one of the pillars of all quality work. Quality registers are used globally and are considered to be a valuable method for ensuring, for instance, care processes in various diagnoses and follow-up of clinical practice guidelines. However, there are few who use the patients themselves as sources of information so the registry does not reflect what is important for them. Another patient safety issue is inadequate reporting and accessibility between different stakeholders.

In Sweden, it is stated by law that each region/county and municipality must establish a quality management system and in Sweden there are a large number of national quality registers (111 registers in 2018) in specific areas. The registers provide knowledge about how care and care work and can be improved. They contain individual-based data on problems, measures and outcomes that enable factors such as learning and improvement work; factors considered necessary in a modern healthcare system. In 2008, a report showed that the quality of home healthcare (processes such as availability, results, visits and costs) in the quality records were incomplete and thus neither comparable nor
informative. After that, the home healthcare quality register was developed continuously with the help of financial support from the state.

The Health Care status report published in 2018 for municipal healthcare included quality registers such as Senior Alert (assessments of pressure ulcer, fall hazard, malnutrition, etc.), the Swedish palliative register, and the National Diabetes Register. There were some registers e.g. dementia wound, behavioural and psychiatric, that it was impossible to analyse due to insufficient coverage (too few persons registered). The analysis carried out showed that the registers were rarely used either in healthcare or research. Drug reviews were often planned as a preventive measure against risk for falls, while hip fractures were the most common cause for elderly people needing hospital care. Furthermore, there was no clear association between drug prescriptions and drug reviews with regard to the results of prescription of inappropriate drugs. Stroke and obstructive pulmonary disease were common diseases in home healthcare. From 2019, the municipalities are asked to begin reporting to the registry on healthcare measures.

**Incident reporting system**

An incident reporting system (also called patient safety reporting system) is one of the most widely used methods around the world to improve patient safety in the healthcare system. As mentioned earlier, it is also statutory that incident reporting will be in Swedish healthcare. As in other reporting systems, “incident reporting” is the objective of improving patient safety by learning from system deficiencies. This system was introduced in healthcare and aimed to reach the same level of resilience and reduction in negative outcomes that other high-risk organisations had reached. Nevertheless, there is little evidence that the incident reporting contributes to safer care, and if it is better than other reporting systems.

It is widely accepted today that shortcomings in patient safety are largely related to deficiencies in the system, but a relatively recent study suggests that it is not easy to change people’s approach. That study showed that the content of the incident reports still focused on describing deficiencies in individuals (patients, families, caregivers, healthcare staff) who were involved, and that the system perspective was lacking. In many countries, a climate exists that makes it necessary for an individual to be blamed for whatever reason.
A climate that blames the individual has been demonstrated in several studies, including the context of a fear of reporting. Even lack of feedback can lead to underreporting. When feedback does not occur, incidents are perceived as a “non-priority task” and writing reports is perceived as waste of time.

There is little research on the precise knowledge that is gleaned from incident reports and how this possible knowledge leads to guidance in practice. According to Marcae, the focus on learning needs to be strengthened and not only by introducing new routines and regulations which has been a common occurrence of incidents. Learning is a complex social process where participation, dedication and reflection are core components to stimulate innovation and enable transfer of knowledge to system-wide improvements. Incident reports have the possibility to increase learning and identify improvement areas but also need to be complemented by other methods in order to understand the reported event.

In order for reporting to be beneficial for patient safety, healthcare staff are required to document and report incidents. When feedback and communication of incidents reports is poor, and there is a tendency towards a blame culture, a decrease in reported incidents has been observed.

**Retrospective record review using trigger tool**

Retrospective record review (RRR) of healthcare admissions is a widely adopted and structured method, proven to measure AE rate both in research and clinically. The RRR method often finds AEs that would otherwise go unnoticed when using, for example, incident reporting systems. The RRR method either uses a set of criteria for screening or a TT. The Global Trigger Tool (GTT), developed by the Institute for Healthcare Improvement, USA, is one of the most frequently used RRR methods. This tool has been used and adapted worldwide in different kinds of settings, mostly for in-hospital care. The purpose with the GTT is to identify patient harm, from the view of the patient, and to follow if improvements decrease the AEs over time. Sweden and Norway are countries that use the method at a national level. The RRR method is argued to be an
established method proven to identify AEs that go unnoticed when using, for example, incident reporting. 62

In Sweden, GTT has been adapted to Swedish conditions and began to be used in in-hospital care in 2008. Today, most emergency hospitals in Sweden are involved and since 2012 there is a database where the results from all hospitals are entered. 67 The adaptation is partly due to the assessment of preventability, in accordance with the definition of AE in the Patient Safety Act, 19 but also aims to include AEs related to both acts of either omission or commission. In the Nilsson et al study, 69 the national incidence of AEs over a four-year period shows that the AE rate in Swedish somatic hospitals has decreased from 2013 to 2016. RRR proved to be a useful method for monitoring patient safety over time, to assess effects and analyse challenges such as increased off-site care. 69 The studies that have measured the AE rate in home healthcare have used the RRR method using screening criteria and most studies are from the US home healthcare system. 8 9 70-72 The most common AEs in this context were: falls; healthcare-related infections; and pressure ulcers. The occurrence of AEs indicated a rate of 13%. 8 9

**Home healthcare organisation**

The mission of home healthcare and organisational structure, differs both within and between countries. There are major variations in what is provided, to whom and how it is best financed, 1 for instance, due to differences in cultures, values, history and economic conditions. 73 In several EU countries (Belgium, France, Italy, Portugal, Spain and Great Britain), the health and social services system has a shared responsibility for providing home healthcare to citizens, based on “the nature of the service provided at home”, either health or socially related. While other countries, including Sweden, Denmark and Finland, have resisted the transfer of the main body to one organisation, i.e. the municipalities, for a more coherent care chain. Patients’ increasingly comprehensive care needs, provided by several healthcare providers from different organizations, require a more coherent care chain to achieve good quality and patient-safe care. 73

The Swedish Health Care Act 43 defined home healthcare as: healthcare when given in the patient’s home or equivalent, which continues over time, and that it comprises habilitation, rehabilitation and where aids are offered. Home healthcare does not include the home care
services organisations with unlicensed staff administering social care in accordance with
the Social Services Act. The Health Care Act and the Social Services Act are
framework laws, which means that municipalities and county councils have freedom to
organise home healthcare to each region’s shifting needs. So, even in Sweden, home
healthcare, and what is to be provided and to whom, differs across the country.

Care for patients in need of home healthcare can include various healthcare initiatives,
which means that different professionals (physicians, registered nurses, physiotherapists,
etc.) and assistant nurses work in home healthcare. By law, the municipality’s
responsibility extends up to the registered nurses (RNs) level and the county council must
allocate to the municipalities the medical resources required. The municipalities and county
councils have a joint responsibility for establishing a coordinated individual care plan for
each patient for increased co-operation between healthcare providers. Home healthcare is
also integrated with social care by delegating home healthcare tasks, meaning drug
administration can be done by unlicensed social care staff.

Frequently occurring terms in home healthcare are used to represent different overall
content. Elemental home healthcare (enkel hemsjukvård) describes healthcare services in
the home that can, if needed, be delegated to social care. Basic home healthcare (basal
hemsjukvård) means that the patient requires a level of care that includes access to nurses
and physicians during the daytime, where the needs for medical and nursing efforts are
more complex. Specialised/advanced home healthcare (specialiserad/avancerad
hemsjukvård) includes access to RNs and physician around the clock. Within
specialized/advanced home healthcare, care can include medically and nursing-composed
decisions and treatments, symptom control as well as infusions/transfusions.

The transfer of home healthcare services from the county councils to the municipalities has
been gradual and is still ongoing. This has been achieved through tax shifting and local
agreements about the content. Over the past two decades, about two-thirds of the
municipalities have taken over this responsibility. The content of home healthcare, which
differs between municipalities, involves differences in age, diagnosis and healthcare needs.
An example of this is that some municipalities have taken over responsibility for all ages,
from 0 years and over, to others who have taken over responsibilities from 18 years of age.
and over. The municipalities and county councils are also allowed to choose whether they will outsource health and social services to private healthcare providers based on changes in national regulations. The purpose of this law was to increase patient freedom to choose providers, availability of specialised medical and nursing interventions in the home, and safety at the end of life, as well as to relieve emergency wards at hospitals.

**Specialised home healthcare**

Specialised home healthcare in Sweden is an expanded form of traditional, palliative home healthcare. Traditional, palliative home healthcare was intended for dying cancer patients, who were given access to an ambulatory multidisciplinary team around the clock in their homes. This assignment has been expanded over time due to changes and developments that have taken place in healthcare and society (as mentioned earlier in this thesis). The widened assignment gave patients with different diagnoses the possibility to be referred to this kind of care when basic home healthcare was insufficient and as an alternative to hospital care. This kind of care can be provided by either municipalities or county councils.

**To be cared for and provide care in the home**

Patients in home healthcare are often high consumers of both health and social care meaning that provision of care is performed intermittently in the home by different healthcare providers employed by different care providers and regulated by different laws (i.e., the Social Services Act and the Health and Medical Services Act). These patients have a wide range of different diagnoses (somatic and psychiatric), symptoms and care needs. Commonly they have multi-morbidity, meaning that the same patient has several debilitating diseases (chronic illness, dementia, arthritis, mental illness, etc.) with multiple specialists involved in their treatment and care. Patients also need palliative care that may vary over time. All this includes complex medical needs and/or the need for advanced medical devices, resource-intensive operations (actions) or very frequent care needs.

There are many good reasons for care to be given at home and many patients prefer the home over other options. In the home, the patient retains his or her independence, family ties, social networking and experiences better control over his/her life. Although the home has many advantages, studies have revealed specific challenges in home healthcare related to patient safety problems and risks; challenges that interact and link patients,
relatives and care providers with each other. The studies are mainly from the US home healthcare context. The complexity of home healthcare, as described earlier, makes it difficult to know the cause of patient harm. Therefore, it is important to highlight challenges and risk areas. Below is a description of some patient safety issues and risk areas which comes from research findings within the home healthcare setting. The following describes areas within the physical environment, technology, medication, communication and coordination.

Performing care in a place that is not designed for care but for a home means that care is carried out in varied work environments with specific challenges. The most common AEs in home healthcare are infections, falls and medication errors, i.e. mistakes during the medication management process. Unhygienic spaces and uncontrolled environments can exist that increase the risk of infection for the patient. That study shows that 3.5 percent of home healthcare patients developed infections that led to emergency care or hospitalisation and infections caused 17 percent of unplanned hospitalisations among patients receiving home healthcare. The situation is further complicated when responsibility for infection control (e.g., central lines, urinary or haemodialysis catheters) falls, for the most part, to the patient and relatives themselves. Therefore, it is important to educate patients and relatives as well as all the different healthcare providers to handle complex tasks in the home healthcare setting. Research has also shown that risk assessment for cases is not performed routinely. Other risks in the home include e.g., rugs and thresholds which increase the risk of fall. Healthcare providers can give advice about how to reduce risks, but when the care is performed within the patient’s own home, it is the patient and relatives who decide whether or not to follow the advice. For healthcare providers, it is important to maintain the feeling of a home for the well-being of the patient, while at the same time creating an appropriate working environment. Patients value the feeling of being safe as much as the feeling of trust. Healthcare providers in home healthcare should have the ability to reduce risks and maintaining the patient’s and relatives trust and autonomy.

The development of medical devices has increased the possibility for more and more patients to be cared for at home while creating new risks. Relatives often take a major responsibility to support patients with complex healthcare tasks that should be performed
around the clock. For example, it may be drug handling, in the form of tablets, injections and infusions, wound care and the handling of medical devices. Often relatives are older, with limited knowledge of the healthcare tasks they perform, which can lead to stress, fatigue and other health problems. Mistakes under the medication management process, i.e., medication errors, are well-known threats to patient safety in home healthcare settings. Research has shown that healthcare professionals can experience relatives as an added workload and find it hard to see them as an equal part in patient care.

The administering of medication to patients at home involves both the health and social service sectors. The delegation of the medication administration from licensed care providers to unlicensed care providers is a patient safety issue considered to be incompatible with practice. It is felt that there is no time for follow-up and RNs feel obliged to delegate in order to streamline their job. Unlicensed care providers also vary in their skills level and competence regarding such core strategies as safe technique, medication administration and infection prevention.

Additionally, deficient communication is a well-known patient safety issue and is interlinked with an increased risk for patient harm. The lack of communication and coordination between the many different care providers is an aggravating factor in the care of patients from a holistic perspective. A shared electronic health record (EHR) can promote this. The National Board of Health and Welfare claimed that the premise of safe and secure home healthcare involves staff having continual access to the EHR system, especially when a patient has multiple healthcare providers from different organizations. However, these intentions are still far from realised. Patients gladly do what they can to overcome deficiencies, by sharing information and checking whether the care providers are involved in their last care visit. They therefore also act as a barrier to wrongdoings, while one of the challenges is that patients and healthcare staff usually do not use the same “language”. Human misconceptions and misunderstanding in information transmission can further complicate coordination and increase risks. This is a well-known patient safety issue for RNs in home healthcare and they seek for improvements to safer communication paths. As mention above, the process of providing care in home healthcare is, in general, an interdisciplinary teamwork. In a literature review by Gharaveis et al., it was shown that appropriate team structure, empowered team members and effective communication
facilitate patient safety but also valuable of almost all aspects of care e.g. assessment, efficiency and problem-solving.

**Rationale**

In summary, the knowledge and understanding of patient safety in home healthcare is limited, while an increasing number of severely frail patients with complex healthcare needs, including the need for advanced technical devices, are cared for at home. Home healthcare has fundamentally different conditions to perform safely in the daily work than in-hospital care. Thus, there is a reason to believe that new challenges and risks arise in the patient safety area. Additionally, patient safety is context dependent and there is both a lack of knowledge of how patient safety is addressed and a lack of systematic measurement adapted for home healthcare. Patient safety data is crucial for understanding and learning as well as to provide a basis for improving patient safety in home healthcare. Using reliable and valid methods for identifying risks and failures is warranted.

The resilience engineering approach opens up for a proactive view to improve patient safety as a complement to traditional methods. From this perspective, several data collection methods are considered essential in order to reach an understanding of how daily work actually is done, and involves learning from both successful adaptations and failures. Exploring how patient safety is manifested and experienced in the home healthcare context, and how safety performance is achieved and learned under normal conditions, is the foundation for the understanding of how risks and failures occur. Retrospective record review using a trigger tool is proven efficient as a means to identify adverse events in in-hospital care. It might be feasible to develop or adapt a trigger tool also for the home healthcare context, as such tools are lacking. In line with a proactive approach to safety it is also imperative to identify fragility in the system that possibly might contribute to failures or incidents as well. This thesis has sought to contribute with increased knowledge to achieve this in the home healthcare context.
**AIM**

The overall aim is to increase knowledge and understanding of patient safety in home healthcare.

**Specifics aims**

*Study I*

To explore how patient safety is described and addressed in specialised home healthcare from the perspectives of multidisciplinary teams and clinical managers.

*Study II*

To explore what constitutes the complexity of the medication management process in specialised home healthcare and how healthcare professionals handle this complexity.

*Study III*

To develop a trigger tool for the identification of both adverse events and no-harm incidents affecting adult patients admitted to home healthcare and to describe the methodology used for this development.

*Study IV*

To explore the origin, incidence, types and preventability of the AEs that occur in patients receiving home healthcare.

*Study V*

To explore cumulative incidence, preventability, types and potential contributing causes of no-harm incidents that affect adult patients admitted to home healthcare using a trigger tool methodology.
METHODS

This chapter contains a detailed description of the methods used in the two studies included in this thesis. The thesis has an explorative design with both a qualitative (Papers I & II and part of Paper III) and a quantitative (Papers III, IV and V) research approach. Data for Papers I and II were collected at three specialised home healthcare units. Data for Papers III, IV and V were based on the medical records of 600 patients from ten different home healthcare organisations in nine regions across Sweden. An overview of the methodological approaches of the five studies is presented in Table 3.

Table 3 Overview of the studies in the dissertation

<table>
<thead>
<tr>
<th>Study no.</th>
<th>Title</th>
<th>Context/participants</th>
<th>Data collection</th>
<th>Data analysis</th>
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</thead>
<tbody>
<tr>
<td>I.</td>
<td>Exploring patient safety in Swedish specialised home healthcare - an interview study with multidisciplinary teams and clinical managers</td>
<td>Multidisciplinary teams and clinical managers from three specialised home healthcare units</td>
<td>Semi-structured individual and focus groups interviews</td>
<td>Content analysis</td>
</tr>
<tr>
<td>II.</td>
<td>Safe medication management in specialised home healthcare – an observational study</td>
<td>Three specialised home healthcare units</td>
<td>Observations of the medication management process and interviews with staff</td>
<td>Grounded theory</td>
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<tr>
<td>III.</td>
<td>Development of a trigger tool to identify adverse events and no-harm incidents that affect patients admitted to home healthcare</td>
<td>41 experts in home healthcare, patient safety, retrospective record review methodology and/or trigger tool design including physicians and registered nurses from ten home healthcare organizations and 600 randomly selected records</td>
<td>1) literature review and interviews, 2) a modified Delphi process 3) two retrospective record review tests of an adapted trigger tool for home healthcare</td>
<td>Descriptive statistics</td>
</tr>
<tr>
<td>IV.</td>
<td>Adverse events in patients in home healthcare: a retrospective record review using trigger tool methodology</td>
<td>600 randomly selected records from ten home healthcare organizations</td>
<td>Retrospective record review using at trigger tool</td>
<td>Descriptive statistics</td>
</tr>
<tr>
<td>V.</td>
<td>A proactive patient safety approach to identify no-harm incidents in home healthcare: a cohort study using trigger tool methodology</td>
<td>600 randomly selected records from ten home healthcare organizations</td>
<td>Retrospective record review using at trigger tool</td>
<td>Descriptive statistics</td>
</tr>
</tbody>
</table>
Data collection Papers I and II

Context and participants for Papers I and II

The studies were carried out at three county council-based units conducting specialised home healthcare within three different geographical areas in one of Sweden’s larger metropolitan districts. The data were collected between October 2013 and December 2014. The studied units had the overall medical responsibility for their patients, including coordination of care with their patients’ other healthcare providers. From January 2013, it became possible even for patients referred for specialised home healthcare in the regions studied in this thesis to have the freedom to choose provider as stipulated by the Act on System of Choice. Their geographical areas and the number of patients with different diagnoses increased sharply as a result. This law has previously been described in the Introduction, section: Home healthcare.

The three units were selected for their sociodemographic differences, such as areas with different income and ethnic background. When the studies were conducted, the units each had between 80 and 200 enrolled patients. Common patient diagnoses were numerous types of cancer, in both the curative (curable) and palliative (non-curable) phase, as well as various cardiovascular, lung- and neurological diagnoses. It was also common for any one patient to have several different diagnoses, known as multi-morbidity, and with multiple specialists involved in treatment and care. The patients’ complex diagnoses and symptom levels meant that their needs and care interventions (medical and nursing) could change rapidly and often. It was common for patients to need advanced medical devices and drug treatments. Most patients’ drug therapies usually included several different “as needed” medications, that is, drugs taken when symptoms occur, including for example analgesics and anxiolytics.

The care was provided by a multidisciplinary team, with RNs and physicians available 24 hours a day. The teams consisted of four to six physicians, 20 to 30 RNs and one person from the related paramedical specialties of social worker, physiotherapist, occupational therapist and dietician. One of the facilities also had eight nursing assistants. Each unit had one head of department and one or two unit managers (clinical management). Since these units earlier only had provided palliative home healthcare based on the Internationally and
national well-established palliative care ideology, they continued after the expansion to base their care on that ideology regardless of patient diagnosis. The cornerstones of palliative care can be summarised as proximity, holistic view, knowledge and empathy. Care should be based on continuity, good communication and support given according to the wishes of the patient and relatives, as far as possible. The palliative care ideology is here after named the care ideology.

**Implementation of Papers I and II**

The head of department of each respective unit was fully informed about the study and permission was sought, and granted, for the implementation of the study. Subsequently, the unit managers were also fully informed and gave their approval. Finally, the multidisciplinary teams received oral information at workplace meetings and via written information through their work email, and were informed that they could decline from being observed or interviewed. Notices about the studies were also posted in strategic positions within each unit.

Data collection and transcription of data for both studies was carried out by the researcher of this thesis (ML) together with the main academic supervisor (ME). During the initial phase, a period lasting six months, time in the three units was spent observing and undertaking interviews in order for the researchers to become as natural a part as possible of the study environment. The researchers wanted to explore and gain insight into the unit’s routines, patient care needs, day-to-day activities, and to observe how unit managers and multidisciplinary teams carry out their daily practical work. The researchers also attended meetings, took part in routines, compilations from the incident reporting systems, documents (meeting notes, introductory programs) and EHRs. Thereafter, data collection took place in three iterative cycles and parallel sessions for both studies (Table 4). Data collection for Study I was conducted using semi-structured interviews and for Study II through observation of the medication management process (MMP) as well as interviews.
Table 4. Overview of the research process and iterative cycles within Studies I and II

<table>
<thead>
<tr>
<th>2013 Initial phase</th>
<th>2014 Iterative cycles of data collection and analysis</th>
<th>2015-18 Closing phase</th>
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<tbody>
<tr>
<td>Following the different professionals during their working day and talking with key people</td>
<td>Pilot study of interview schedule</td>
<td>Analysis</td>
</tr>
<tr>
<td></td>
<td>Observation of the medication management process (MMP) and interviews with managers and care teams</td>
<td>Analysis</td>
</tr>
<tr>
<td></td>
<td>Analysis</td>
<td>Observation and scientific article writing</td>
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Paper I – interviews

Seven individual and nine focus-group interviews were conducted with the multidisciplinary teams and clinical managers resulting in a total of 51 participants. The aim of the interviews was to get the informants to express their own views and perspectives to gain a rich and broad understanding of patient safety.  

An interview schedule was initially tested in a pilot study which led to minor adjustments. The interview schedule was based on open questions in order to open up for discussion issues such as: “Explain why patient safety matters to you”; and “Based on your experience, what factors prevent or promote patient safe care in your daily work?”. In the interviews with clinical managers, questions were added also about how the unit was organised.

The research team wanted to capture a broad and varied perspective of patient safety for which the participation of all disciplines was valuable. The composition of the focus groups, and the choice of individual interviews with clinical managers, assumed that participants would feel comfortable enough to have “free discussions” and be able to describe their feelings and thoughts without being constrained by any potential hierarchical structures. Subsequently, physicians were invited to physician-only group interviews and the other disciplines to mixed groups (Table 5). With one of the physicians, an individual interview was held because the physician was unable to attend the focus group interview but had asked for an interview. In an “individual” interview, two unit managers participated because they both had a work day that day and wanted to participate together. Participants from different units were not mixed in the same group. Each team member and clinical
manager was invited to participate in the interviews. Based on the discussions and answers that materialised, exploratory techniques that were either verbal (such as “What more do you think about it?”, “Can you develop your answer a little more?”) and non-verbal (e.g. humming, nodding) were used by the researcher to gain clarity and increase the understanding of what was being said. The role of the researcher in each interview was to listen, ask questions, keep the discussion on the “right track” and make sure everyone got the chance to talk. An early focus group interview and four of the individual interviews were made jointly by both ML and the more experienced ME, in order for ML to gain training and experience. Subsequently, ML conducted six focus group interviews alone. In addition, two focus group interviews and three individual interviews were undertaken by ME only.

Interviews were conducted in the units in separate rooms during normal work hours. Each focus group consisted of four to six participants and the length of interview ranged between 60 and 90 minutes. Individual interviews varied between 30 and 60 minutes in length. Interviews were recorded and transcribed verbatim.

<table>
<thead>
<tr>
<th>Table 5. Overview of the interviews</th>
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<tr>
<td><strong>Unit A</strong></td>
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<td><strong>Focus group interviews</strong></td>
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<td><strong>Individual interviews</strong></td>
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<td><strong>Total</strong></td>
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Registered nurse=RN, Allied health staff = social worker, physiotherapist, occupational therapist or dietician
Data collection was conducted through observations of the MMP, including interviews with those being observed at the three units. The decision to study MMP occurred as a natural result when it became apparent during the initial phase of the research process (Table 4), that both clinical managers and multidisciplinary teams considered drug-related AEs as the biggest threat to patient safety. This also proved to be the most frequently reported area in all three units’ incident reporting systems. The decision to conduct observations was based on the opportunity to study naturally-occurring events in the routine daily work, in the real-life situation where the event occurs, which could contribute to a deeper understanding of the dynamics within any given clinical context.  

Observations were made as described above for three cycles (Table 4), each cycle consisting of three observation days (6 to 8 hrs/day) per unit. A total of 27 observation days were spread out over nine days per unit. The aim of the observations was to gain knowledge and understanding of what team members actually do and how they deal with a complex task, such as MMP.

Observations were based on two strategies: observing the places where drugs were handled and discussed, and shadowing (Arman 2012) the team members involved in MMP. Observation of places could, for instance, be a medicine storage area where RNs prepare the patients’ prescribed medicines for distribution. Other places could be at team meetings or discipline-specific meetings where patient cases were discussed. Shadowing has been defined as “following people, wherever they are, whatever they are doing” (p. 301). Shadowing was based primarily on the work of the RNs because their duties are largely related to medicines and they are in a key position to identify and correct errors before the patient is affected. The manager of each respective unit had asked the permission of the on-duty RN before the start of the observation session. Those who agreed were observed (shadowed). In the case where any of the RNs declined to participate, and the question proceeded to the next, no data exist. A total of 27 RNs were observed. The observations were made during different work shifts and also during home visits in the patients’ home. Informed consent was obtained by the nurse from patients, as well as from any relatives or other persons who were at home at the time of observation, before the observer went into the patient’s home. None of the patients declined to participate.
The observations were not intended to cause a disturbance during work activities or meetings. Therefore, interviews were conducted after the observed situations and when RNs were travelling between home visits. In addition to interviews with the RNs being shadowed, other key persons were interviewed, e.g. those who had participated in an observed meeting. Key persons could for instance be a clinical manager, physician, patient safety officer or coordinator. The aim of the interviews was to clarify and deepen the understanding of MMP as well as to understand how those involved acted in the situations observed. Audio recordings were made during the observations, and field notes and summaries were written. Recorded conversation during observations and interviews was transcribed verbatim. Notes and summaries were written during and immediately after completion of each observation period.

**Data analysis Papers I and II**

*Paper I – content analysis*

The transcribed interviews were analysed using qualitative content analysis, based on an inductive approach.\(^{106}\)\(^{107}\) The choice of inductive qualitative content analysis was based on the fact that it is an analytical method that allows for analysis of both manifest and latent content with high interpretation degree, to create an understanding of complex phenomena such as patient safety, and for achieving realistic conclusions.\(^{109}\) In addition, the methodological inductive approach is recommended when there is limited knowledge about that which is being studied, in this case, patient safety in home healthcare.\(^{106}\)\(^{107}\) It is characterised by a search for patterns at different levels of abstraction and interpretation.\(^{107}\)

The analysis began with the transcribed interviews being read through several times by the research group (ML, MF, ME), to get a sense of the entire dataset. Thereafter, meaning units were identified, i.e. parts of text expressing an opinion or experience of the patient safety phenomenon. The analysis was continued by condensing the meaning units to codes with a low abstraction level. The codes could be a word or sentence formulated to provide an understanding of the data. In the next step, the codes were compared based on differences between, and similarities within, each other and sorted into 19 subcategories as the basis for further development. The subcategories were compared, sorted, interpreted and abstracted into one main theme and four categories. The four categories have a low
degree of interpretation and abstraction. The main theme is an interpretation and has a higher degree of abstraction, which winds like a “red thread” through the categories. The entire analysis process was conducted in one movement across the whole-parts-whole as the qualitative approach advocates. The codes, categories and themes were discussed in relation to the transcript until consensus was reached in the research group.

**Paper II – grounded theory**

The data were analysed using a constructivist grounded theory approach inspired by Charmaz interpretation of the classic grounded theory statements by Glaser and Strauss. In contrast to Glaser and Strauss, who separated the researcher from the studied objects, Charmaz acknowledge that grounded theories are constructed, in an interaction between the researchers, and influenced by the studied world. The basic assumption of the constructivist approach is that the abstractions that stems from the analysis, are constructed "pictures" of the world that is studied, rather than exact copies of it. This methodology is useful for gathering data in real life, and is especially well suited for explorative, ethnographic studies and interviews. This methodology allows the researchers to study processes and experiences where it happens, in fact, to enable the researcher to understand what the core issues are for the participants.

In line with the methodology outlined by Charmaz, analysis started as soon as the observations were made. Memo-writing, i.e. memorandum notes, was done for personal use, to catch fleeting thoughts and ideas during or after the data observation sessions. The first analytical step was the initial encoding of data, where each line-by-line, or incident-by-incident, event was given a label. The research group (ML, MF, ME) began by comparing and coding events that were similar to each other, followed by tagging events that were not similar. The next step was focused coding, where the initial codes that provided information and perspective for the phenomenon of the MMP were tested against data. During coding, “memos” were made, to describe how preliminary interpretations were made in order to be able to go back and compare ideas and questions that arose during the coding. New insights were generated while reviewing data and rethinking what was implicit in the previous coding. The analysis was a dynamic analysis process where the researchers constantly went back and forth in the data, where data were compared to other data, and codes were also compared to data. The codes were grouped, and theoretically
abstracted, and subsequently synthesised into four categories that retained their specific links to the data, as illustrated by cases and citations in the results. Both at collection and during analysis, the research group reminded each other about having openness towards the data and to try to ignore any preconceptions to enable the possibility of seeing what was new that could be discovered. Several joint meetings were held throughout the analysis process where an analytical and reflective approach to the codes and categories was taken until consensus was reached.

**Data collection Papers III, IV and V**

Data collection of papers III, IV and V were conducted in 2016 with the RRR method using an adapted trigger tool (TT) of 600 randomly selected records from ten home healthcare organisations across Sweden. Paper III describes the development of the TT and how the triggers were tested twice, and AEs and no-harm incidents identified in the 600 records were analysed with results being presented in Papers IV and V, respectively.

The development of the TT was realised in a three-steps manner, in close collaboration with experts with different skills, using: 1) a literature review and interviews; 2) a five-round modified Delphi process including face-to-face meetings with group discussions, and (3) two RRR tests of the TT before Delphi rounds 2 and 3, respectively. A flowchart of the development and validation process is presented in Figure 1.
Figure 1. Flowchart of the development and validation process of the home healthcare trigger tool RRR, retrospective record review.
Literature review and interviews for the identification of triggers and risk areas

To begin with, risk areas were identified in home healthcare based on interviews and the literature review. Two focus group interviews were conducted, where one group consisted of four physicians and the other of seven RNs. Twelve individual interviews were conducted; four with RNs, two with physicians, three with district RNs, two with patients and one with a relative.

The same semi-structured interview schedule was used in all interviews with questions such as: “Describe your opinion of safe care”, “What risks do you think exist when patients are cared for at home?” The interviewed healthcare staff members were also given the opportunity to review the somatic in-hospital list of triggers for RRR \(^{67}\) in order to add relevant triggers for home healthcare and to remove any that were deemed non-relevant. A summary of their suggested list of triggers was made and the interviews were analysed with content analysis. The research group (ML, KS, LN, ME, MU) also made a thorough review of the national and international literature on existing retrospective review methods from different contexts.

Based on the data collected, the research team formulated a project manual, with an appended trigger manual, with 26 triggers that represented risk areas. The trigger manual was intended as a decision support mechanism for future record reviews and included triggers with definitions and descriptions. An example from the trigger manual, showing how the triggers were described and defined, is presented in Table 6.

<table>
<thead>
<tr>
<th>Table 6 Example of a trigger definition and description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse drug event/Adverse drug reaction</strong></td>
</tr>
<tr>
<td>Definition</td>
</tr>
</tbody>
</table>

**What to keep in mind and be aware of when reviewing the record and assessing events**

- Even if the adverse drug reaction is a known side effect, a negative effect on the patient as per the above should be seen as a positive trigger and adverse event.
- When a certain drug is known to always cause a specific reaction (for example, neutropenia following cytostatic treatment), this counts as an adverse event only if the negative effect has been unusually strong and caused extraordinary measures and treatment efforts.
- Drugs may be double documented in different systems for records and documentation; changes in order entries may fail to be updated if drug review is not performed.
- If an anaphylactic reaction requiring treatment should arise, this should be seen as an adverse event, even if the patient has a full recovery after the acute phase.
- Be aware of drugs that often cause side effects in the elderly: cardiovascular drugs, anticoagulants, drugs affecting the central nervous system (psychotropic drugs, morphine-like analgesics, anticonvulsants), antibiotics, cytostatic agents, anti-inflammatory or anti-diabetic drugs.
- Drugs used to ameliorate negative effects of drugs include particular antidotes, such as naloxone (intravenous against overdoses of opiates) and flumazenil (against overdoses of benzodiazepines). Dexrazoxan is an antidote against cytostatic agents of the anthracycline family and used, for example, upon extravasation, to reduce tissue damage.
- If a drug is given to a patient with known sensitivity, without harm arising, this is to be seen as a no-harm incident.
- Are conditions in place for safe drug administration in the home?
- Have adequate measures been taken to avoid mix-up of drugs, erroneous administration etc.?
- Are there routines on delegation and have they been followed?
- At delegation - is there a sign-off list in the home?
- Is there a correct, up-to-date list of drugs in the home? Experience tells us that multiple drug lists occur and raise a risk for no-harm incidents and/or adverse events.
- Have measures been taken to reduce the risk for mix-up of drugs?
- Have risky combinations of drugs been used?

**Adverse events/no-harm incidents that can be identified**

| Allergic reactions, skin reactions (blistering, rash, itching), mucous membrane damage in gastrointestinal tract, effect on central nervous system, kidney, liver or other organs, as well as dizziness, hypotension, heart arrhythmia, hypoglycaemia, confusion, kidney failure, altered consciousness, fainting, respiratory insufficiency, apnoea, shock or death. Falls. Life-threatening acute respiratory insufficiency or shock, or death from these causes. |
| Traceable no-harm incidents: |
| wrongly administered drug (dose, administration route, wrong patient) or non-intentional interruption in medication that has not given rise to an adverse event |
| an order entry that does not correspond to administration (if changes in the drug list have not been observed), that has not given rise to an adverse event |
| the existence of multiple concurrent drug lists in the home is a no-harm incident if no adverse event can be identified |

**Preventability**
The event should be seen as preventable if:

- drugs are given despite contraindication or known sensitivity
- impaired function of kidney or liver has not been taken into account
- the risk of an unfavourable effect has not been taken into account and no justification exists for prescription of interaction substances
- the risk of an unfavourable effect from too low or too high concentrations has not been taken into account and no justification exists
- treatment with opiates or benzodiazepines has caused symptoms that mean an antidote must be given (naloxone, flumazenil)
- follow-up of drug treatment or drug review has not been performed in an adequate way, with assessments and actions, or
- the allergy history has not been reviewed or if a known allergy has not been taken into account

**Modified Delphi process**
The Delphi process is considered a valuable methodology in research studies aimed at getting a panel of experts with different skills to achieve a degree of consensus on a specific topic. This is consistent within this study aim during the developing of the TT. The research team wanted to receive structured feedback and test the TT in close cooperation with a mix of experts with appropriate knowledge from different contexts within the aims.
of the study. The modification the research group applied to the Delphi process was to use a combination of participant anonymity (written feedback) and non-anonymity (face-to-face meetings, which is in contrast to the classic method which advocates anonymity. Two of the rounds consisted of physical meetings and the other three rounds consisted of written (via email) and/or oral (by phone) feedback from the review team or the entire Delphi panel.

Between the Delphi rounds, the research team analysed and revised the triggers and project manual based on feedback and discussions from each round. The revised trigger manual and the project manual were then sent back to the Delphi panel in order that the panel could discuss whether to change, add or delete triggers, reference values and trigger definitions, as well as to consider whether relevant risk areas were adequately covered or not.

**Recruitment of review teams and the Delphi panel**

Purposive sampling was used for the Delphi panel participants to represent a wide range of views from different expert areas: clinical professionals from home healthcare (the review teams), the National Board of Health and Welfare, the Swedish Association of Local Authorities and Regions, and relevant sections within the Swedish Society of Nursing and the Swedish Medical Association (Paper III, Appendix B, Table B: 1). The members of the research group were also participants in the Delphi panel, which consisted of a total of 41 participants.

Review teams were recruited via phone contact or by email through the patient safety network of the Swedish Association of Local Authorities and Regions. Home healthcare services from all 21 regions/county councils throughout Sweden were offered the chance to participate. Seven review teams from the municipal home healthcare and three from council-funded home healthcare chose to participate. Where home healthcare services chose not to participate, this was largely due to lack of time and economic tightening. Each review team consisted of one to three nurses and one to two physicians, a total of 28 persons.
Training for the review teams

In connection with the first Delphi round, a mandatory one-day training in the RRR method, using a TT for all of the review team members, was conducted. The majority of the teams had no previous experience with trigger-based record review. Before the day of training, and independently of each other, each person in the review team reviewed the same practice records (six items) in order to exchange experiences and discuss the assessments during the training day. In addition to that exercise, and a theoretical session, the training day also included a consensus process. The review team then agreed on the interpretation of definitions and the application of triggers, AEs and no-harm incidents, as well as the assessment of preventability, but also inclusion and exclusion criteria. Furthermore, strategies were discussed as to how the review process could be made more reliable and efficient. As a result of discussions during the training day, three new triggers were added: “pressure ulcer”, “escape from home/special accommodation” and “absence of in-depth drug review”.

The retrospective record review process

Two RRR tests were performed using 60 and 600 records, respectively, with a different number of triggers for each, i.e. 35 in the first and 38 in the second, as a stage in the development of the TT. For the second test, it was estimated that at least one AE would occur in 17% of admissions and calculated that a sample of 600 randomly selected records would be sufficient to estimate the cumulative incidence of injuries with a confidence interval of 95% ± 3.01%.

Selection procedure and inclusion- or exclusion criteria

Home healthcare admissions in 2015, where the patient was 18 years of age or older, were deemed eligible for random sampling. Each record was reviewed for a period of a maximum of 90 days starting from the date the patient was enrolled in home healthcare. To ensure that the random selection was conducted in precisely the same way for each review team, one of the researchers conducted the randomisation using a digital randomisation tool based on the number of admissions in 2015.
**Inclusion criteria for AE and no-harm incident**

- The AE or no-harm incident occurred during the index admission, that is, within 90 days after enrolment in home healthcare, regardless of caregiver.

- The AE or no-harm incident derived from caregivers outside home healthcare (outpatient care, social care or in-hospital care) occurred within 30 days prior to the index admission and was detected during the index admission.

**Exclusion criteria for AE and no-harm incident**

- AE and no-harm incident which causes symptoms and is detected more than 90 days after enrolment in home healthcare should not be included

- AE and no-harm incident that has occurred, been detected and for which treatment was completed before enrolment in home healthcare.

**A two-step review process**

The record review was conducted in a two-step process, a primary and a secondary review, each with its own review manual. In addition to the trigger manual, the project manual was available as a decision support at both steps. In most review teams, the RN(s) carried out both the primary and secondary reviews and then discussed the assessments with the physician until they reached consensus. In some of the teams, it was one or more physicians who performed both the primary and secondary review of some of the records. Due to the occurrence of different EHR systems in the municipality and county council, a few of the municipal review teams did not have immediate access to all parts of the records, but these parts were requested as needed. The search related both to triggers in the actual text of the record, such as the patient having fallen and the action taken, and to triggers found in structured data such as, for example, laboratory values and drugs.

In the primary review, the reviewer, without time constraints, searched for triggers in all records and documentation. For each trigger, an assessment was made if it was associated with a potential injury or if an incident had occurred or not. The reviewer also documented how many times each trigger was found and the patient’s demographic data. Only records
where at least one trigger indicated possible injury or incident continued to a secondary examination.

In the secondary review, every possible undesired event was examined separately. In order to qualify as an AE or a no-harm incident, an assessment was made on a four-point Likert scale (1 = the injury/incident was not caused by the healthcare/social care; 2 = the injury/incident was unlikely to be caused by healthcare/social care; 4 = the injury/incident was most likely caused by healthcare/social care; 3 = the injury/incident was caused by healthcare/social care). A similar 4-point scale was used to assess the preventability of the AE or a no-harm incident. The severity of the AE or the no-harm incident, was assessed on the basis of two different scales: the National Coordinating Council for Medication Error Reporting and Prevention, NCC MERP,\(^{114}\) which is used in trigger-based record review; and the scale used in the Harvard Medical Practice study, HMPS.\(^5\) Also documented were, for example, the type and where the AE or no-harm incident originated from (home healthcare, inpatient care, primary care or social care). During the review process, support was available for the review teams from the research group.

**Delphi round 1**

At the first Delphi round, which was a physical meeting, discussions were based on the initial trigger manual, the study manual, risk areas and the Swedish somatic in-hospital manual for RRR method using a TT.\(^{67}\) Discussions were initially in smaller groups and then all groups were gathered for discussion and reflection. This process resulted in a TT containing 35 triggers. One trigger was removed (“Transfusion”), ten triggers were added and 13 triggers were slightly renamed.

Thereafter, the revised trigger manual was sent with 35 triggers to the review team for a first record review.

**The first retrospective record review – 60 records**

In the first RRR test, a total of 60 non-randomly records were reviewed according to 35 triggers, in four modules (Care, Laboratory, Medication, and Continuity and transition). The purpose of this first review was not only to test the comprehensibility and usability of the triggers and study manual, but also to see if it was possible to assemble accurate patient
lists via the patient administrative systems of the respective healthcare providers. The study manual included, for example, AE and no-harm incident descriptions, definitions, and inclusion and exclusion criteria.

**Delphi round 2**

Delphi round 2 consisted of the review team being given extensive feedback on the first record review, both via email and/or telephone, and at the compulsory education that was conducted before the second record review.

**Second retrospective record review – 600 records**

In the second and main RRR test, the review teams reviewed 600 randomly selected records. The initial list contained 38 triggers divided into four modules: General triggers (22 items), laboratory triggers (5), medication triggers (6), and continuity and transition triggers (5). The project manual included a detailed description of the review process.

**Reliability and validity in the review process**

The first review process was evaluated for reliability between two reviewers (inter-rater reliability). Ten percent of the records in the second test were double-checked for the purposes of assessing the consistency between the two reviewers’ assessments regardless of whether or not a record went through to the secondary review.

The two reviewers first reviewed the same record individually and then made a consensus assessment. For each double-reviewed record, the review team submitted the review they made individually, and a jointly completed review template. The joint review was the version that was included in the results. No double review was performed in the secondary reviews. All primary and secondary reviews were submitted to one of the research team members (MU) who checked that the review teams followed the manual and trigger definitions and descriptions. Any issues that arose, and differences detected, were sent back to the respective review team for clarification and possible revision.

**Delphi round 3**

Delphi round 3, which was also the last step in the review process for the review team, was to assess the clinical relevance, comprehensibility and usability of each trigger on a 4-point
scale (1 = to a low degree, 2 = to a relatively low degree, 3 = quite a bit, and 4 = to a large extent). In addition, written comments for each trigger could be added.

The research team analysed the reviews of the triggers and sorted them into four categories: “keep”, “unclear whether it should be kept or not”, “merged” and “remove” to support discussions in the upcoming Delphi Round. The sorting into categories was based on an overall assessment which included each trigger’s positive predictive value (PPV) (cut-off <50% suggested removal) and respective index points (calculated from the Likert scale) for clinical relevance, comprehensibility and usability together with consideration of the written comments. The revised project manual and trigger manual were then sent out to the Delphi panel to be discussed during Delphi round 4.

**Delphi round 4**

Delphi round 4 was a meeting with the Delphi panel. During the meeting, each individual review team evaluated verbally the second RRR while the research group made notes. Subsequently, the entire Delphi panel discussed triggers, definitions and descriptions based on clinical relevance, comprehensibility and usability, as well as which triggers should be retained, renamed, removed or merged. Discussions were held by consensus in the Delphi panel and then compiled by the research group. The last revised trigger list consisted of 23 triggers that were sent to the Delphi panel via email.

**Delphi round 5**

Delphi round 5 was a written feedback from the Delphi panel regarding the 23 triggers. The Delphi panel accepted the changes after the fourth Delphi round and the final version consisted of 23 triggers.

**Data analysis Papers III, IV and V**

Data analysis for Papers III, IV and V was based on the second, main RRR of 600 records using 38 triggers. In all papers, data were analysed descriptively using frequency, percentages, mean deviation (95% confidence interval) and median with interval data (range).
In Paper III, the PPV for each trigger was calculated by the number of times each trigger identified an AE, divided by the total number of times the trigger was found, multiplied by 100. An index for each trigger’s clinical application, comprehensibility and usability was calculated by dividing each trigger’s value of either 3 or 4 on a four-point Likert scale (for each trigger and each keyword) by the number of respondents per trigger (Paper III).

Additionally, in Paper III an assessment of the agreement between members of the primary review team was also made by using Cohen’s *kappa coefficient*. A complete match between reviewers would result in a score of $k = 1$. In the absence of agreement between reviewers, $k$ is equal to 0 (Table 7).

<table>
<thead>
<tr>
<th>k value</th>
<th>Degree of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.20</td>
<td>Low</td>
</tr>
<tr>
<td>0.21 - 0.40</td>
<td>Moderately low</td>
</tr>
<tr>
<td>0.41 - 0.60</td>
<td>Moderately high</td>
</tr>
<tr>
<td>0.61 - 0.80</td>
<td>High</td>
</tr>
<tr>
<td>0.81 - 1.00</td>
<td>Very high</td>
</tr>
</tbody>
</table>

In Papers IV and V, comparison between groups was calculated using the Mann-Whitney U test or the Chi-square distribution. Differences between groups were considered statistically significant if $p$-values were <0.05.

**Ethical considerations**

The research study “Patient safety in specialised home healthcare” (Papers I and II) was a multicentre research project and approved by the Ethical Review Board in Stockholm (2012/1384:31). The research study “Development of a trigger tool to identify adverse events and no-harm incidents that affect patients admitted to home healthcare (Papers III, IV and V) was approved by the Ethical Review Board in Linköping (2014/150-31 and 2016/45-32). Ethical principles for research have been taken into account and are based on the four main requirements: information, consent, confidentiality and usage requirements (Swedish Research Council and Declaration of Helsinki).

In the research project “Patient safety in specialised home healthcare”, participants received written and oral information on implementation and purpose. They were informed that the
participation was voluntary and that at any time during the study they could cancel their participation without giving any explanation. Information was also provided on how the results were to be used and the responsible person’s contact details. The results are presented in such a way that no individual participant or activity can be identified. The data are kept locked away, with no unauthorised access.

In the research project “Development of a trigger tool to identify adverse events and no-harm incidents that affect patients admitted to home healthcare”, it was the head of department of each of the respective units who gave permission for the review team to have access to patient records without the patients’ knowledge; in other words, a waiver to confidentiality was observed. There could have been a risk that patients would have felt uncomfortable and vulnerable if they had known that their records were being used for research purposes. For the consideration of the patients, no one in the research team had access to any patient identities. The units were not only included in the research study, but they also received a compilation of data from their own unit(s), provided by the research group, for use in internal quality work. The research team carried out the described measures although there is support in the Patient Data Act \textsuperscript{116} that the patient cannot decide whether or not his or her own record should be included in research. The principle is that only the head of department of a healthcare providing unit involved in the care of the patient is authorised to receive information about the patient. The patient is also entitled by law to block her/his record from other healthcare providers. However, if the research was approved by an ethics committee, which this project had been, the patient cannot block access to the records.
RESULTS

In this chapter, the main results of the two studies included in the thesis are presented. First: “Patient safety in specialised home healthcare” (Papers I and II), and second “Develop and test a trigger tool for identify adverse events and no-harm incidents affect adult patients in home healthcare” (Papers III, IV and V).

Papers I and II

The care ideology facilitated a consensus on patient safety as it contributed to common values and ways of thinking for the clinical managers and multidisciplinary teams on how care should be planned, prioritised and performed. Patient safety was considered to go “hand in hand” with the care ideology, as a part of a whole and not as a separate goal in itself (I). Based on the care ideology, a highly prioritised goal for the multidisciplinary teams was to satisfy the patient’s desire to receive care at home and to maintain the home as a home. One strategy among many to fulfil this goal was the delegation of medication administration to the unlicensed staff in the municipal social care. This was commonplace as unlicensed care providers had the opportunity to visit a patient several times a day in contrast to home healthcare resources (I, II). Another dilemma was the varied healthcare environments as homes, naturally, are designed to be a home rather than a healthcare environment. This meant there were limited opportunities to follow aseptic guidelines and also were the cause of strenuous work postures (I, II). For example, the home could have cramped, unhygienic spaces, lack of clean work surfaces, or prying pets. Both clinical managers and multidisciplinary teams felt that the possibility to influence the working environment within the home was virtually non-existent (I).

Another factor in promoting patient safety was to create sustainable and trustful relationships with patients and relatives to stimulate participation and active involvement. Therefore, a high-priority goal was to give patients and their relatives’ time for conversation and to be listened to, and that their knowledge, feelings and thoughts were taken seriously. It was necessary not only to understand each patient’s resources and weaknesses, but also the considerations patient and relatives felt were important, rather than what was deemed important from a purely medical, nursing or rehabilitation perspective (I). Patients and relatives were therefore vital resources for, and partners with, the teams (I, II).
It was hence natural that the power was predominantly with the patient. This can be seen as meaning the power within a home belongs to the person who lives there. This meant that prevention of psychological harm, such as lack of respect, violation of autonomy and integrity, had the same priority as the prevention of physical harm. That perception affected how the multidisciplinary teams handled and prioritised risks. This meant, for example, that the patient’s preferences and desires could be weighed against any other risks that were apparent. A balance was sought between the gain in preventing a potential harm compared to the gain of respecting the patient’s autonomy and integrity. Patients with cognitive impairment and/or who lived alone were a risk group where it was challenging to find strategies that allowed the patient to be cared for at home without being exposed to excessive risk (I, II).

The studied units had the overall medical responsibility for their patients, including coordination of care with their patients’ other healthcare providers. The multidisciplinary teams reported that the overall responsibility was seen as both a safety and a relief from patients’ and relatives’ perspectives. At the same time, the extensive flow of information from the patients’ various healthcare providers, with different responsible bodies, professions and care levels, proved a challenge for the teams when coordinated systems were missing. The electronic health record (EHR) system, shared only with other county council-driven healthcare providers in the region, was an important tool in the information transfer, although it also generated risk. It had, for example, an insufficient capacity for reminders and warning systems and inconsistent documentation procedures between healthcare providers. This resulted in documentation which was fragmented and time-consuming to find, and which led to information not being found. The information transfer with other healthcare providers, such as social care, where shared record systems were non-existent, was largely made by using notepads or post-it notes in the home. The lack of information transfer obstructed the multidisciplinary team’s undertaking to provide comprehensive care, and instead created a lack of trust for patients and relatives.

Information related to medication management was identified as the largest risk area in all three studied units (I, II). Patients and relatives took the bulk of the responsibility for being information carriers between the various healthcare providers, for example by informing about changes in prescriptions for drugs. However, this also posed a risk as the patient or relative may have misunderstood some information. When altered drug regimens were
missed or misunderstood, the patient could potentially have received a double dose, or may not have received the intended drug, or failed to receive medication at all (II).

Both clinical managers and multidisciplinary teams perceived the verbal internal and external information transfer as a necessary complement to the written documentation (I, II). The internal verbal transfer of information ranged from unstructured “corridor talk” to structured, scheduled team meetings. Verbal information exchange with external healthcare providers was equally important but finding sustainable solutions proved more difficult. In such cases, the coordinator was not only an important link but also a barrier to information error. The coordinator provided the multidisciplinary team with access to the medical records and acted as a “detective” in finding current information and current prescriptions (I).

The multidisciplinary team’s various skills, and their close cooperation, enabled the care to be personalised and given using a holistic approach. However, both clinical managers and multidisciplinary teams expressed concern about the difficulty in maintaining the broad range of skills needed for patients’ varying diagnoses, complex symptom patterns, and the vast array of advanced medical devices and pharmaceutical treatments (I). The team meeting was a valuable place to exchange experience and knowledge, both within and beyond professional boundaries, and provided a wider knowledge base than the knowledge held by each individual. Among other things, it helped reduce the sense of vulnerability of the team members during home visits where they were usually alone in providing care, without “close” collegial support, and quick decisions needing to be made (I). Minimization of the risks that could arise when care was given remotely for the greater part of the day was dependent, to some extent, on the capacity of patients and relatives to be active participants. For instance, they often took responsibility for monitoring and evaluating the effect of treatment, as well as supervising and practically managing any medical devices (II). The minimization of risks was also dependent on the skills and competence of the social care services. As mentioned above, the delegation of drug delivery to the unlicensed care providers in social care was a strategy to meet the patient’s desire for care at home. This was a necessary undertaking, but one which at the same time was of concern to RNs. Advanced drug treatment is a complicated process to be delegated to unlicensed care providers in social care. The RNs’ worries consisted of the potential problems for the large
number of social care organisations, with high staff turnover and a lack of formal medical knowledge, of being able to follow delegation routines (including follow-up and knowledge transfer). The RNs were unsure if patients would receive the right drug, at the right dose, at the right time (II). The patient safety work was characterised by safety strategies, such as compromises, bridging strategies and priorities, based on the desire of patients and relatives to support a care process which is as safe as possible. These safety strategies were necessary to work around problematic processes, but at the same time they could create new, more or less obvious risks. The risks arose when the strategies were, for the most part, individual interim solutions without systematic evaluation and where collegial learning failed (I, II).

The units were commissioned by the regional county council directives to regularly measure healthcare quality by registering approximately 40 quality indicators. Data for registering quality indicators was collected regularly, largely through structured questioning of patients during home visits. Both clinical managers and multidisciplinary teams felt that many quality indicators did not reflect patient safety because they were general and not adapted to the needs of the patient. This meant that the collection of data into quality indicators restricted the multidisciplinary team’s freedom to adapt healthcare based on the care ideology and needs of the patient. The clinical managers had been invited by the regional county council to participate in the selection of quality indicators, but felt that their views on which indicators were to be measured had not been taken into account. The multidisciplinary team’s incentive to implement the registrations was based largely on knowing that a penalty could be charged to the units unless the specified quality levels were reached. In cases where quality indicators were useful for patient care, the multidisciplinary teams needed to document data both in the EHR and the quality register because they were not compatible with each other.

According to both clinical managers and multidisciplinary teams, the incident reporting system was an ongoing patient safety work, as reporting back led to learning and gave rise to discussions about patient safety. Although the multidisciplinary teams felt that clinical managers encouraged reporting, it was given low priority because the system was experienced as both time-consuming and “complicated”. A common preventive action for incidents was to produce new guidelines. Each unit studied had about thirty different
guidelines solely for the medication management process. While the aim of the guidelines was to improve patient safety, the multidisciplinary teams perceived them as complicated, multi-step routines necessitating trade-offs and workarounds. The clinical managers were well aware of the multidisciplinary team’s departure from the routines. They considered the departures as inevitable and allowed the team members themselves to decide when it was necessary to follow or deviate from the unit’s own guidelines.

**Papers III, IV and V**

A flowchart of the RRR 600 randomly selected home healthcare records is provided in Figure 2.
In the 600 reviewed home healthcare records, 47.6% of the patients were men and 53.3% were women, with an average age of 78.2 years. The most common diagnoses were malignancy and cardiovascular disease. A little less than half of all patients lived alone (44.2%) and the most common reason for enrolment in home healthcare was that patients needed help with medication management. For other demographic data, see Papers III and IV. The 38 empirically tested triggers were identified 4,031 times in 518 (86.3%) of
the 600 reviewed home healthcare records. This resulted in 6.7 triggers per journal (median 4, range 1-54). The inter-rater reliability between first record reviewers regarding which records would proceed to second review was \( \kappa = 0.801 \).

The total PPV for all triggers was 41.7% (range 0.0-96.1% per trigger), of which 25.4% was for AEs and 16.3% for no-harm incidents. The three triggers having the highest PPV were “Fall” (96.1%), “Documentation for inadequate coordination, communication and information” (88.9%), and “Adverse drug event/Adverse drug reaction” (85.0%). The triggers identified AEs and no-harm incidents with varying degrees of severity, ranging from an incident that reached the patient but did not cause any AE, to AEs that resulted in the patient’s death. The triggers most commonly associated with permanent AEs or death of a patient were, “Deviation from normal course after invasive procedure/surgical treatment”, “Adverse drug event/Adverse drug reaction” and “Unplanned contact with a physician and/or a registered nurse” (III).

After the second record review, the teams rated each of the triggers respectively for clinical relevance, comprehensibility and usability using a four-point Likert scale. The Likert scale responses were converted to an index which, for clinical relevance, had the range 0.5-1.0, for comprehensibility 0.67-1.0, and for usability 0.5-1.0. Triggers with a low PPV, i.e. less than 50%, were infrequent. For example, “Treatment” and “Deep vein thrombosis and/or pulmonary embolism” had PPV values of 0% and were subsequently removed from the trigger list.

Patients with severe or multiple diseases often had disease-related deteriorations in their laboratory values. Furthermore, laboratory triggers were seldom detected while any linked events were mostly detected by other triggers. Consequently, the module Laboratory value with its five triggers was removed. In total, 13 triggers were removed and three triggers were merged into one. Some of the remaining trigger definitions and descriptions were refined with the aim of achieving a trigger tool with increased validity, thereby reducing the risk of false-positive trigger outcomes. Thus, the outcome after the fifth Delphi round was a list of triggers containing 23 items divided into three modules: Care; Medication; and Continuity and transition (III).
In the 600 records, 356 AEs were detected in 226 patients (37.7%, 95% CI 33.0 to 42.8). This resulted in one (interval 1-7) AEs per patient. Of the 356 AEs, 255 (71.6%, 95% CI 63.2 to 80.8) were estimated to have been preventable in 174 patients. Eighty-three (13.8%) patients were affected by more than one AE, of which 53 (9.0%) of these were considered to have had more than one preventable AE. There was no difference in the occurrence of AEs between patients over the age of 80 and younger patients (P = 0.12), or between men and women (P = 0.72) (IV). The three most common AEs were “Healthcare-associated infection” (n = 72, 20.2%), “Fall” (n = 66, 18.5%), and “Pressure ulcers” (n = 62, 17.4%). Of the “Healthcare-associated infections”, 46 (63.6%) were considered to be preventable, for “Fall” it was 29 (43.9%) and for “Pressure ulcers”, 52 (83.9%).

Most of the AEs were estimated to be over 70% preventable. Of all AEs (356), 271 (76.1%) were from home healthcare, 44 (12.4%) from hospital care, 23 (6.5%) from social care and 12 (3.4%) for outpatient care. The remaining six (1.7%) did not contain any evidence of origin. There was no difference in preventability (P = 0.97) between AEs arising from home healthcare or other care. It was calculated that, for every 100 patients, 59.3 AEs were identified of which 42.5 were preventable. For a calculation of 1,000 patients, the corresponding numbers would be 8.7 and 6.3 (IV).

The assessment of severity of AEs, based on the NCC MERP scale, showed that 246 (69.1%) of all patient AEs resulted in a temporary AE requiring additional care visits or extended care time. Of these, 187 (76.0%) were considered to be preventable. Three (0.8%) of the AEs contributed to the death of patients, one of which was considered preventable. Assessment of severity based on the HMPS scale showed that 213 (59.8%) of all AEs were of a minor nature and patients recovered within a month. Of these, 149 (69.9%) AEs were considered to be preventable (IV).

The total number of identified no-harm incidents was 313, affecting 177 (29.5 %) patients with a median of three (range, 1-16) no-harm incidents per affected patient. Of these, 198 (63.2 %) no-harm incidents were considered preventable and affected 127 (21.2 %) patients. The number of patients affected by more than one no-harm incident was 66 (11.0 %), with 35 (53.0 %) affected by more than one preventable no-harm incident. The number of no-harm incidents per 100 patients was 52, and the corresponding number for
preventable no-harm incidents was 33. The number of no-harm incidents and preventable no-harm incidents per 1,000 patient days was 7.7 and 4.9, respectively. There was no difference in the rate of no-harm incidents between men and women (p = 0.61), or between patients aged 80 years or older and younger patients (p = 0.84) (V).

The most common type of no-harm incident was “Fall without harm”, n = 127, (40.6 %), considered preventable, n = 52 (40.9%) to a lesser extent than other types of no-harm incidents. The second most common was “Deficiencies in medication management”, n = 62, (19.8 %), resulted in patients not receiving the correct prescribed dose of their medication (instead receiving too much, too little, or not at all). “Deficiencies in medication management” were deemed to have a preventability rate n = 61 (98.4 %) twice as high as those of “fall without harm” and “moderate pain”. The third most common “moderate pain” n = 24, (7.7%) deemed to have a preventability rate of n = 12 (50.0 %). Other common types of no-harm incident were e.g. moderate constipation n = 14 (4.5 %), deficiencies in communication and coordination n=12 (3.8 %) and “moderate psychological impairment” n = 12 (3.8 %), deemed to have a preventability rate of 92.8 %, 100% and 83.3% respectively. There was no difference in outcome for the two most common types of incidents, “Fall without harm” and “Deficiencies in medication management” between men and women (p = 0.14 and p = 1.0, respectively) or between patients aged 80 years or older and patients younger than 80 years (p = 0.19 and p = 0.54, respectively). “Moderate pain” was more common among men than women (p = 0.04) and also more common among patients younger than 80 years than those aged 80 years or older (p = 0.04) (V).

The total documented interventions and potential contributing causes could be higher than the number of no-harm incidents since the reviewers could choose more than one intervention and contributing causes for each no-harm incident. The most common documented interventions were “Extra blood samples, procedures, nursing care and treatments” (n = 129). Other documented interventions included “Delays in assessments, investigations and treatments” (n = 35) and “Extra visits to outpatient care” (n = 23). For a large proportion of the no-harm incidents no interventions were documented (n = 120). Of the total no-harm incidents, 259 (82.7 %) derived from home healthcare and 51 (16.3 %) from caregivers outside home healthcare. The most common type of no-harm incident
originating from care providers outside home healthcare was related to “Deficiencies in medication management,” n = 18 (35.3%).

For all no-harm incidents, their potential contributing causes were divided into different areas. They are described below in descending order, from the most common potential contributing cause area to the least common. Many of the potential contributing causes were related to “Deficiencies in nursing care, treatment and diagnostics”, n = 629 (47.9 %), i.e. “Delayed, erroneous, omitted or incomplete care”, n=168 (26.7 %). The next area was “Deficiencies in communication, information and collaboration”, n = 257 (19.5 %) i.e. between different care providers, n = 54 (21.0 %). Following, the area “Deficiencies in the organization”, n = 204 (15.5 %) included that the “Routines/guidelines were lacking, deficient or have not been observed” n = 81 (39.7 %). “Deficiencies in the medication management process”, n = 168 (12.8 %) was related to the “Prescription – delayed, erroneous, omitted or incomplete”, n = 62 (36.9 %). For the potential contributing cause to “Technical device issues”, n = 19 (1.4 %), related to “Medical equipment, tool, handling errors or lacking knowledge on use”, n = 12 (63.2%). Finally, there was the area “Other”, n = 37 (2.8 %) i.e. not apparent from record, n = 33 (89.2 %).

The three most common types of no-harm incidents, and their most common potential contributing causes were analysed. For “Fall without harm”, the most common potential contributing cause was “Nursing care” (n = 66) and “Observations” (n = 48) i.e. delayed, erroneous, omitted or incomplete nursing care or treatment. For “Deficiencies in medication management”, the most common contributing causes were “Treatment – delayed, erroneous, omitted or incomplete” (n = 63) and “Deficient performance of task” (n = 46). The most common potential contributing cause for “Moderate pain” were “Treatment –” (n = 15) and “Nursing care” (n = 10) “– delayed, erroneous, omitted or incomplete” (V).
DISCUSSION

This chapter includes a discussion of results and interpretation of results influencing of the theory resilience engineering perspective, a methodological discussion following the conclusions, implications for practice and future research.

Discussion of results

Patient safety in specialised home healthcare, Papers I and II

Patient safety was engineered through being inherent in a well-established care ideology which formed a common mind-set between members in the multidisciplinary teams and clinical managers about patient safety, while keeping the patient perspective in mind. In this context, the care ideology, which served as a guiding principle in patient safety work, could also pose risks. The multidisciplinary teams stated that the care provided in the daily work is characterised by weighing goals against each other; a balancing act, adapting to shared responsibility, being authoritarian and preventing risks while preserving the active participation, autonomy and integrity of patients and close relatives. Prevention of psychological harm, which violated autonomy and integrity, had the same priority as preventing physical harm. For example, the routines for checking patient “as needs” medications (opioids, benzodiazepine) before delivery occasionally failed, meaning that the maximum prescribed dose was delivered every week, sometimes unnecessarily. The RNs described how the large amounts of stored drugs worried them, but that confiscating the drugs was difficult without interfering with the patient’s autonomy and integrity. Depending on what was given highest priority in the specific situation, risks could be of a lower and higher target, respectively, than care ideology. A strong care ideology can therefore be both a facilitator and an obstacle to patient safety, depending on which target was given the highest priority. In resilient organisations people are regarded as resources and, based on experience, skills, and tasks, “goal sacrificing” could engineer patient safety.

Nevertheless, RNs experience a dilemma when it appears that a balanced, shared decision-making between a professional and a patient is required for safe drug management, while maintaining and protecting the relationship. A shared responsibility without a common understanding and without well-defined limits of responsibility and authority can thus affect patient safety. Resilient organisations have the ability to adapt to
unpredictable situations and remain intact and functional despite a threat to patient safety in “the sharp end”, that is, the point where the patient and healthcare meet. In this study, the clinical management gave the multidisciplinary teams the freedom to plan home visits without question, and time for conversation was given the same priority as other tasks, e.g. caring tasks such as giving pain relief. The management’s ability to support professionals at “the sharp end” is necessary for improve patient safety.

In a natural manner, the care ideology also promoted a person-centred care, meaning that patients and relatives were treated as equal partners in their own care. Person-centred care has been a healthcare target for several years but with inadequate implementation. By contrast, in this study there has been difficulty in involving patients as equivalent partners, partly due to communication problems and the attitudes of healthcare professionals. In this context, person-centred care in general was seen as a facilitator for patient safety. Patients and relatives were partners with the multidisciplinary teams, took responsibility for tasks themselves such as handling technical devices; care tasks which in institutional care environments are performed by healthcare professionals. They also reported valuable information that contributed to learning about risks. At the same time, risks may increase when patients and relatives are not adequately informed about what they should pay attention to, such as what to monitor, assess and evaluate and what they should report back. The patient’s and relatives’ active role in sharing information and expert knowledge on their experience of the disease, may be an underestimated resource for a resilient healthcare system.

In this study, the policy-makers (macro-level) were not included but their directives that the units were to register quality indicators affected the work at the meso- (clinical managers) and micro-levels (multidisciplinary teams). Both the multidisciplinary teams and the clinical managers felt that quality indicators did not reflect their views on patient safety or quality improvements to any significant extent. They considered that the registrations stole time because they rarely adapted to care based on the needs of the patient and their relatives, i.e. against the care ideology, and did not coincide with how a complex home healthcare system is coordinated in an efficient and safe way. The Incident Reporting System is another macro-level system for the purpose of promoting patient safety. The system has been used with great success in other industries and is a globally accepted
method of healthcare even though there is limited evidence of its contribution to safety. In this study, it was found that a common intervention following incident reports was to produce new guidelines. For example, each study unit had about 30 guidelines related to MMP, which in many cases were perceived as complex multi-step routines by the multidisciplinary teams. Standardisation of work processes has been used as a method of increasing safety and efficiency of care. In this study, as in previous studies, trade-offs and workarounds from guidelines were common strategies in daily work. Standardisations predict a causal link, that care is predictable and that AEs can be prevented by rules and guidelines. In contrast to the RE approach, where both risks and safety come from the same processes in the organisation, and the outcome is due to variations and conflicts of interest. Strategies and behaviours to circumvent practical problematic work processes have shown that either one promotes or impedes patient safety. McDonald et al found that managers felt that adherence to standards promotes patient safety, which contrasts with the results of this project where clinical managers were aware that the multidisciplinary teams made trade-offs to promote patient safety.

The usability of the incident reporting system in improving patient safety has been questioned within the increasing complexity of healthcare. Criticism has been aimed partly with the view that it does not reflect reality because there is an under-reporting and, secondly, that the system is used to count AEs, risks and incidents, which takes the focus away from the analysis. These are the analyses that contribute to effective and meaningful changes and organisational learning. In order to show that patient safety has improved in home healthcare, reliable and valuable methods are needed that will enable the study of the dynamic complexity of the system at different levels. In this study, guidelines and quality assessments were aimed at promoting patient safety from a macro-level perspective, restricting the freedom of the micro-level to adapt to challenges, and providing safe care based on care ideology and patient needs. This indicates that if standardisation is to be used as a tool for promoting patient safety, it must be adapted to a culture based on patient values and taking into account the calculated risks. According to McCarthy and Blumenthal, policy makers could support safety culture by linking safety goals to safety culture goals as part of a supportive learning collaboration.
Both for quality register and incident reporting systems, which have the nature of a Safety-I perspective, it takes time before feedback was given to the units. As a complement to these systems, the studied units had introduced daily safety debriefing team meetings that have the nature of a Safety-II perspective. These safety debriefing meetings became a way to learn from failures and risks that were close in time. These meetings gave an opportunity to prevent AEs before they occurred and exchange experiences and competences across disciplinary boundaries. This contributed to “a complementary knowledge base” that was broader than every individual’s knowledge. During the course of the study, these meetings also tended to act as reactive reports on things that have happened, instead of a proactive forward-looking discussion with regard to how risks can be anticipated and prevented. Team meetings were held before home visits, which were very task-intensive periods, and which could be a contributing factor to the lack of reflection and discussion. The ability of healthcare professionals to reflect on safety issues and risks, and to remember all the different situations over time at the same time as when the work should be done is limited. Learning from both successful adjustments and failures is important for building resilience in the organisation. Reflecting and sharing experiences is characteristic of resilient organisations and is favourable for organisational learning. Team members had face-to-face meetings several times a day, which were of a proactive nature on patient safety issues. Previous studies have shown that proactive communication is a way to minimise medication errors and promote patient safety. The disadvantage, however, is that such “ad hoc communication” is rarely documented in EHR, which prevents horizontal learning within the multidisciplinary team as well as vertical learning between clinical managers and multidisciplinary teams. By using both a Safety-I and Safety-II perspective, a broader picture of patient safety will result, where the whole becomes greater than the sum of the parts.

In this study, it emerged that each unit’s responsibility for patient safe care was, in practice, a shared responsibility between different professions, care providers from different organisations, as well as patients and their relatives. As a result, information and communication were two particularly important patient safety areas. The EHR was an essential information transfer key tool, but the shortcomings in usability, reliability and functionality were challenging. These shortcomings meant that both the clinical managers and the multidisciplinary teams felt that the written information needed to be
complemented with verbal communication, both within their own organisation and across organisation borders. In other studies, patients have been shown to do what they can to bridge information deficiencies, 97 which was consistent with findings in this study. The multidisciplinary teams felt that patients and relatives took great responsibility to be a permanent “gatekeeper”. The coordinator of each unit was perceived as an effective barrier to the risks within information sharing and communication and served as a coordination centre for internal and external communication and data transfer. The coordinator was usually an RN with long experience in home healthcare. Experts with profound knowledge and understanding contribute to resilience through the ability to capture early signs of problems, anticipate development and organise resources to prevent further deterioration. 139 The common EHR implemented by all publicly funded healthcare providers in the studied region facilitated communication and information transfer between these healthcare providers; while healthcare providers with other principals, municipalities, private healthcare providers and social services, had other record systems. Coordination between different stakeholders is in itself a source of complexity that requires explicit coordination mechanisms. 140

**Develop and test a trigger tool to identify adverse events and no-harm incidents affecting adult patients in home healthcare, Papers III, IV and V**

The findings of the second project in this thesis are that adapted triggers with definitions and decision support, developed to identify AEs and no-harm incidents that affect patients admitted to home healthcare, may constitute a valid method for patient safety and quality improvement work in home healthcare.

The use of trigger occurrence and PPVs is a common way to validate TT 62 consistence with this study. The empirically-tested triggers constitute a large material for validating; triggers were found 4,031 times in 600 records. More triggers were identified per record (6.7) than has been found in previous RRR studies where between 2.2 and 4.7 triggers per record were found. 141-143 The occurrence and PPV of triggers varied widely in this study which compares well with the results of other studies regardless of setting and patient population. 29 66 144 145 The high overall PPV found in the current study could have resulted, at least in part, from the no-harm incidents that were also included. Furthermore, as prevalence greatly influences PPV, a high overall PPV value may be a reflection of the high
prevalence of AEs and no-harm incidents. Unfortunately, details of which PPV is acceptable for a trigger, as well as for the RRR method, are lacking in the literature. In order to provide support for the Delphi panel discussions, the triggers found in the final TT (23 triggers) were processed by the research group, and data were analysed, which organised triggers into four categories (“retain,” “ambiguous,” “merge,” and “remove”). Each trigger’s AE/no-harm incident outcomes were used to make an overall assessment for category allocation. PPVs (cut-off < 50% suggestion for removal) and the respective index scorings (computed from the Likert scale) for clinical relevance, comprehensibility and utility were also used in the assessment, as were written comments.

Some triggers such as “Healthcare-associated infection” and “Pressure ulcer” were AEs themselves which led to a low PPV for some no-harm incidents. As far as is known, there are only a few studies using the RRR method to assess AEs in home healthcare. In the current study, more triggers related to falls and drugs were found than in the earlier studies. This can be explained partly by the way that home healthcare is organised, and which patient groups are included, which looks very different from one country to another. In addition, most patients in the current study had malignancy and the most common need was drug assistance. Nevertheless, each trigger indicates a potential AE or no-harm incident and therefore every trigger should be noted. The trigger list (38 triggers) which was tested in the 600 records, and the final trigger list (23 triggers), were constructed according to Swedish TT methodology, allowing no-harm incidents to be included (National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index categories C and D). Including no-harm incidents was considered valuable from a patient perspective when it gives information about gaps in work processes and as a means for proactive patient safety work.

In this study, we found that AEs affected over a third of the patients, most of which were deemed to be preventable. Studies investigating AEs in home healthcare, and with which to compare the current findings, are sparse but the incidence of AEs found in the present study (37.7%) is much higher than the 4%-13% reported by other studies. However, there are considerable difficulties encountered when comparing AE rates between RRR studies. There may be a bias in the data produced, regardless of methodology, which may be caused by several factors, including: study setting, AE definitions, documentation quality, case-
mix, time frames for inclusion, threshold for causation scale, representativeness of the sample and the fact that some studies only recorded one AE per patient. Variations in judgement may be affected by factors such as the level of reviewer skill, differences in the application of screening criteria/triggers and definitions, reviewer’s own experiences and prevailing views, and levels of training and education in the particular RRR methodology. All of these factors affect both validity and reliability. Another challenge is to compare home healthcare setting AE rates with those for in-hospital care, as the home healthcare provider may not be in a position to continuously observe the patient and the healthcare environment and therefore events and information will be unknown to healthcare providers.

The current finding that healthcare-associated infections, falls, pressure ulcers and skin breakdown are the most common AEs is largely consistent with results from a review of 1,200 Canadian home care records. AEs such as infections and pressure ulcers place an added burden on home healthcare organisations with their limited access to RNs and physicians. The fact that these AEs are common in both home healthcare and in-hospital care implies that all sections of healthcare should be alerted to the most common AEs and the use of appropriate preventive measures. The research team decided to not to classify “medication-related AEs” as a separate AE group, since medication is considered here as a contributing cause of AE. In this study, medication-contributing caused AEs can be found among falls, severe constipation and oral candidiasis consistent with other studies. Current findings showed that more than half of all AEs caused minimal impairiment, with recovery occurring within a month. This contrasted somewhat with the findings of Sears et al, where one-quarter of the AEs were related to slight impairment whereas half of AEs resulted in moderate-to-serious impairment or death. One explanation for the difference could be that the present study found a greater overall number of AEs, in fact three times as many as Sears et al where AEs that did not require the use of additional healthcare resources were excluded. Interventions in connection with AEs are resource-consuming and therefore a burden to healthcare. However, in order to establish a broader and more proactive approach to patient safety, the research group felt it was important to include AEs that caused temporary harm without requiring extra visits or a prolonged healthcare period.
As mention above, studies investigating AEs in home healthcare are limited and studies investigating no-harm incidents barely exist. In this study, there was no major difference in the frequencies of AEs (356) and no-harm incidents (313). The most common type of no-harm incident was “Fall without harm” and less than half were deemed as preventable. In home healthcare, patients are largely autonomous and the environment is hard to control or standardise compared with in-hospital settings. For example, it is difficult to remove stairs, thresholds or carpets without the consent of patients and relatives. For that reason, a collaboration with patients and their relatives, and that there is a common understanding of risks, is a requirement for prevention from fall (as well as prevention of other risks) in home healthcare. Studies demonstrate that patients and their relatives are a critical resource in identifying risks and to prevent or mitigate incidents, which rarely are accounted for in the medical records or the incident reporting systems. This further indicates that the number of both AEs and no-harm incidents in home healthcare are highly underestimated.

The second most common type of no-harm incident “Deficiencies in medication management” was deemed preventable to as high a degree as 95.4%. This is twice as high a preventability rate than “Fall without harm”, and “Moderate pain”, the third most common type of no-harm incident. Similarly to this study, Schildmeijer et al found that the most common no-harm incidents were related to drug therapy, with a high rate of preventability (87.9%).

“Deficiencies in medication management” resulted in that the patients did not receive the correct prescribed dose (too much, too little, not at all). Even in a controlled environment such as a surgical department, omission of the prescribed medication dose was the second most common no-harm incident (23.6 %). Although largely unexplored, there is reason to believe that deficiencies in medication management is a huge risk area, or contributing cause, to no-harm incidents, especially in home healthcare, where many different actors are involved in the medication management process. Additionally, qualitatively good documentation is critical to RRR, as the result is dependent on the existence of sufficient qualitative documentation to determine whether a no-harm incident has occurred and to assess its nature and preventability. In this study, for a large proportion of the no-harm incidents, no interventions were documented which may lead to an underestimation of no-harm incidents.
Further findings, the most commonly reported potential contributing cause to no-harm incidents was delayed, erroneous, omitted or incomplete nursing care and treatment. Given that the combination of many minor flaws in the care of a patient, more often are related to serious events, than any single dramatic failure, it is important to be aware of the underlying mechanisms for these deficiencies. These findings indicate a need to investigate how individuals and teams are supported and improve working conditions, organizational conditions and workplace culture. Another potential contributing factor was lack of and deficient routines and guidelines or that they have not been observed. In a complex system where the circumstances constantly change there is a risk that standardised guidelines does not work very well. Safety is not a constant, but must be created by the professionals and different actors in the system. Resilient behaviour in such an environment may be to switch between two opposite ways of working; on the one hand, to comply with standardised rules and guidelines, and on the other hand, to constantly adjust the activity to shifting situations that fall outside the given rules and guidelines.

**Discussion of methods**

This thesis has an explorative, mixed-methods approach, which can also be described as a qualitative-quantitative methodological triangulation. Since the purpose of this thesis is to extend existing knowledge, an explorative approach has been used which demands the use of both qualitative and quantitative methods. The mixed-methods approach is employed through the combination of: focus group-interviews and individual interviews (I); observation including interviews (II); Delphi process (III); and RRR using a TT methodology (III, IV and V). All are methods that are well established in research.

**Trustworthiness of Papers I and II**

Assessment of the study’s scientific trustworthiness encompasses four dimensions suggested by Lincoln and Guba: transferability, credibility, confirmability and dependability.

Transferability refers to which extend the findings can be applied to other contexts. In order to enhance transferability, the three different units were selected in order to capture socio-demographic differences in, for instance, country of birth and income. A rich description of
the included units, organisation, culture, work processes and environment is provided so that readers to evaluate the applicability of data to other settings.

Credibility refers to validity or confidence in the truth of the findings, and involves aspects of how data is gathered and the analysis and interpretation of them. The data collection was done in iterative cycles. Questions that arose in the analysis were later discussed in the research group and gave a deeper insight into the phenomenon that could be used in the next interview or observation. This method has been used successfully in previous research. Interviews were used as the data source for Paper I and were analysed by content analysis. It is a useful method of analysis when you want a deeper understanding of the individual’s subjective experience of a phenomenon and when there is limited knowledge in the area which complies with the purpose of patient safety within home healthcare. Observations were used as the data source for Paper II and analysed with grounded theory, an analytical method that is well suited for acquiring knowledge about complicated processes and interactions. The drug handling process is a recognised complex process where many interactions occur.

The so-called “Hawthorn effect” is discussed as a threat to credibility, which concerns consequent awareness of being studied, and the possible impact on behaviour which means that the participants in this study may have changed their behaviour or their way of working once they knew they were being studied. One way to reduce the Hawthorne effect was to spend sufficient amount of time in all three units before starting with the data collection as a means by which let the participants get used to the fact that the researchers were there, were asking questions and observing their work.

Sample size is debated in qualitative research and there were fewer participants than expected in each focus group. Nevertheless, a rich and profound understanding of patient safety was gained as we gathered data from different units, the participants’ involvement, and the fact that all disciplines from the team were represented, i.e. the setting- and participants’ triangulation. Different data collection techniques were used, to strengthen credibility, such as audio recordings, field notes and memo-writing, to increase the credibility of data. The entire research group were involved in the analysis and interpretation of data, e.g. researcher triangulation.
Confirmability refers to the objectivity of data and should reflect the participants’ perspectives and not those of the researchers. A potential threat to confirmability in qualitative research, as with this study is that the researcher is a part of the instrument and it can be hard to be objective. There is a risk that the researcher interprets data according to his or her own preconceived opinions and experiences and may miss important nuances and details. The researchers have tried to counteract this by going back and forth in the data throughout the entire research process to make sure nothing was overlooked. Also discussed were codes, categories and themes in relation to the transcript until consensus was reached. Reflections on prejudices, experiences and assumptions were also shared in an open climate, and through a self-critical attitude. Additional ways to strengthen confirmability have been to increase the transparency of the interpretations made using representative quotes from interviews and accurate descriptions of events from the observations shown in each theme.

Dependability refers to the reliability of data and would the results be comparable if the study was repeated in similar setting, with similar participants. Meeting the dependability criterion could be difficult but the researcher should at least strive to reach it by giving a description rich enough to allow the reader to verify data throughout the research process. This is what the researchers have been looking for. However, no audit trail of the process from coding to themes exists, which can be considered a weakness. Moreover, a detailed description has been given by the research process, setting and participants. For Paper I, the “SRQR checklist” was also used to assess qualitative research at the submission process.

**Reliability and validity of Papers III, IV and V**

Assessment of the scientific reliability of quantitative studies is basically the same as in qualitative studies, although other concepts are used: validity (measuring what was intended to measure) and reliability (reliability of a measurement) and generalisation. Paper III used both the qualitative approach (Delphi process) and quantitative approach (RRR method) whereas the remaining articles (Papers IV and V) used only a quantitative approach (RRR).
In the development of TT, a Delphi process was used and for the selection of the Delphi panel, purposive sampling was used to capture a wide range of expert areas. An expert group should consist of people with different skills and knowledge in the area, consistent with the Delphi panel composition in this study, which consisted of 41 experts in home healthcare, patient safety, RRR methodology and/or TT design.

The Delphi process has been applied previously in a number of modified ways consistent with this study. The anonymity of participants is considered a key factor in the Delphi process but the literature is divided about the importance of anonymity. In this study, a combination of participant anonymity (written feedback) and non-anonymity (face-to-face meetings) was used based on earlier positive experiences. At the face-to-face meetings, each respective trigger was discussed in terms of clinical relevance (face validity) comprehensibility (readability) and utility which resulted in joint decisions. It was found that the discussions during the face-to-face meetings gave more input to the trigger development compared to the written feedback. Controlled feedback was also used at each stage of the rounds and this is considered to be a key strength in the Delphi process.

Another modification was made in that five rounds were used compared to the usual two or three. The criticism of many rounds has been that the participants’ interest and engagement will decrease but, in the present study, the involvement increased over time, especially after the RRR part, when many of the Delphi panel members had used the triggers on real data. Included also was the decision to test the TT in RRR as a part in the development process and as a way to increase the possibility of implementation. It was also a way to evaluate the triggers on empirical experiences which has been done in only a few Delphi studies previously.

To further strengthen validity and reliability the review teams, at the end of the second RRR test, rated each respective trigger for clinical relevance, comprehensibility and utility, respectively, on a four-point Likert Scale. In addition, each member of the review teams, (fourth Delphi round), verbally evaluated the second RRR test, and the Delphi panel discussed the triggers, definitions and descriptions until consensus was reached. Great efforts have been made to describe in these pages as thoroughly and transparently as possible all the steps undertaken in the Delphi process, the review process and the
development of TT. Nevertheless, generalisations may be of limited value if the reader does not recognise the home healthcare organisation as described in this study.

As the review was part of the validation process, the review teams were included due to their interest in patient safety. All those who were interested in participating were included; in total, ten review teams from different regions around Sweden. The research team did not use a stratified sample of the records for all patients enrolled in home healthcare. Instead, 600 records from ten different home healthcare organisations were randomly selected which represents a good representation of Swedish home healthcare and provides an overview of AEs and no-harm incidents occurring in home healthcare. Inter-rater reliability was assessed in the primary review. At least ten percent of the records were double-reviewed. Classen et al showed that inter-reviewer agreement could be improved by a single training session later followed by a two-hour formal training session. In the present study, to ensure result validity and reliability, all review team members underwent a mandatory one-day education in the methodology. Additionally, each member of the review team independently reviewed six training records in order to achieve reliable reviews. This was followed by a consensus process with all teams, including discussions regarding trigger outcome, assessments of AEs and preventability. Furthermore, the review process was standardised in a written project manual. Thorough monitoring was made by the review teams of all primary and secondary reviews regarding completeness and adherence to the trigger definitions and study manual. In order to strengthen the validity, it was decided that one of the RRR experts in the research team (MU) should monitor all audits and provide written and/or oral feedback to the review teams.

In this study, we had a patient perspective and therefore chose to include all documented AEs and no-harm incidents discovered during the review, regardless of whether or not the event originated from another of the patient’s care providers. The research team also chose to have a 90-day (maximum) review period to capture a broad perspective on patient safety in Swedish home healthcare, contrary to the usual 20 minutes in-hospital records review which has been criticised for being too short. Several studies have also reported that AEs have often occurred after admission and that older patients, as well as those with greater co-morbidity, are generally at increased risk. With today’s shorter hospital stays, patients are selected for continued care at home and the RRR method for home healthcare services
provides information about the continued care, following the patient’s entire healthcare chain.

For the RRR method, the result is, as mentioned above, dependent on the existence of sufficient qualitative documentation \(^ {150}\) to determine whether an AE or no-harm incident has occurred and to assess its nature, preventability and severity. Some review teams reported that the documentation, in some records, was of low quality which may have led to an underestimation of AEs and no-harm incidents. On the other hand, the review teams were familiar with patients and settings which could have led to an overestimation when they had information in addition to what was documented in the records. It is probably true to say that making entirely objective assessments is very difficult for the review teams and a certain measure of subjectivity should therefore be considered inevitable. However, the research team considered that being involved in the setting, and in the patients in home healthcare, was a major advantage in making adequate assessments.

In this study, all AEs and no-harm incidents related to both commission and omission of care are included. This is in contrast to the original GTT version which only includes care related to commission, i.e. the active delivery of care, and not to failures in care processes, i.e. omission of care. \(^ {64}\) Excluding omission of care causes organisations to miss systems related to patient safety and miss many opportunities to learn and thereby not get an overall picture of the situation. In a proactive patient safety work, both perspectives (commission and omission) are equally important and in line with a Safety-II perspective. \(^ {26}\) In this study, it was found that no-harm incidents are often related to system failures, for example deficient MMP and lack of routines. This is an important result that points out that routines and guidelines to protect the patient have failed. No-harm incidents also indicate risks that may lead to AEs. We also included assessment of the prevention of AEs and no-harm incidents, in line with the Swedish definition of healthcare \(^ {19}\) and the Swedish GTT methodology. \(^ {67}\) Prevention is not included in the original GTT version, which includes only events that are an accidental consequence of healthcare, whether it was preventable or not. \(^ {64}\) Including assessment of preventability can cause more AEs or no-harm incidents to be included that are related to the patient’s illness or complaint, which may not be preventable. This in turn can lead to preventive resources being put into wrong types of AEs or no-harm incidents.
There is a consensus in the literature that the RRR method found more AEs compared with other methods although multiple methods are preferred. Based on a review it emerged that there is a surprising lack of validity for the RRR method in relation to the global attention it has received in both research and clinical activities. Lack of validity need not be the same as lack of efficiency, but the tool needs to be used more where the aim is to include validity.

The TT system generates information at a systems level with the intention of providing information on rate of AEs to enable system changes to be evaluated. This is in line with both a Safety-I and Safety-II perspective, respectively. Based on the RE approach including Safety-II, the organisation needs to target its organisational designs, processes and technologies to provide effective patient safety improvements and improved resilience. This indicates that the RRR method is valuable in improving patient safety and providing increased knowledge and learning in the field.

A criticism of the RRR method using a trigger tool in the field of in-hospital care has been that it is a retroactive method, providing information after care has been given and most often after the patient has been discharged (Health quality and safety commission 2013). According to Shimada et al, a functional TT system should be designed so that information is given at the same time as patient care and delivered quickly so as to be clinically meaningful. The RRR method can be a proactive tool in patient safety work by planning implementation based on meeting the above requirements. This can be done by having a clear purpose and goals, as well as careful timing, so that review, analysis and reporting can be done in real time, e.g. within the same day or week. Feedback can be made to all stakeholders at the same time for discussion and reflection with a plan on how to take and introduce interventions. Home healthcare itself allows for clinical feedback to be given while the patient is still registered as it generally has longer care times than in-hospital care. To our knowledge no studies exist, nationally or internationally, that have investigated AEs and no-harm incidents in home healthcare using TT methodology.
CONCLUSIONS

This chapter provides a general conclusion of the findings, followed by a brief reflection over how resilience engineering may contribute to increased knowledge and understanding of patient safety. Clinical implications and future research are also addressed.

General conclusion

Patient safety is generally strengthened by the fact that clinical managers and multidisciplinary teams have a common approach to safety built on an internationally and national well-established healthcare ideology, which forms a “dyad” with safe care. In home healthcare, patient safety is formed by the team creating a trustworthy relationship with patients and their families and involving them as partners in their own care. Patient safety in home healthcare is characterised by contradictory targets competing against each other, threatening patient autonomy and wishes. Depending on which goal and value is given highest priority, patient safety can be promoted or strengthened. Achieving different degrees of patient safety and risk is a natural part of home healthcare. The degree of safe care and risk is in a symbiosis that is influenced by the various types of interacting home healthcare services that vary according to the prerequisites and conditions. Another conclusion is that the trigger-based record review method, when adapted for home healthcare, can contribute to a systematic and valid method for improving patient safety. Overall, the common knowledge gained from healthcare adverse events, no-harm incidents and contributing causes can be used to develop process indicators for system errors, as well as performance indicators for structured evaluation, and lead to proactive patient safety work in home healthcare.

From a resilience engineering approach

In line with the resilience engineering approach, this thesis has used both Safety-I and Safety-II methods to explore patient safety in home healthcare. Overall, the different data collection methods and analyses have contributed to an in-depth knowledge and understanding of how the work is actually carried out and why that differs from how the work is imagined, as well as that both failures and non-failure events can result from the same processes. Even when there are small changes and variations in some parts in the
system, these can cause major changes in patient safety and contribute to risks and AEs. These findings harmonise well with the RE approach. The various interacting aspects of home healthcare (people, skills, management, technology, routines, etc.) that extend beyond organisational boundaries can be both limiting and supportive to patient safety. Inadequate support systems (e.g., journal and incident reporting systems) can assist information transfer and coordination of care, as well as to make learning in patient safety difficult.

Findings indicate, that from a macro-level perspective patient safety is strengthened through a Safety-I approach (guidelines and quality assessments) which limits the freedom of clinical managers and the multidisciplinary teams to adapt care based on their own viewpoint, thus setting limits for safe care. This indicates that if standardisation is to be used as a tool to promote patient safety, it must be aligned with a culture based on patient values and goals, where calculated risks are taken into account. At the same time, resilient behaviour in such an environment may be to switch between two opposite ways of working; on the one hand, to comply with standardised rules and guidelines, and on the other to constantly adjust the activity to shifting situations that fall outside given rules and guidelines.

Learning from experience, successes as well as failures, is an essential cornerstone in the RE approach. Necessary strategies and behaviours are devised by team members to circumvent the day-to-day problematic work processes which lead to either a strengthening or weakening of patient safety. To improve patient safety in work processes within home healthcare, such as the medication management process, team members’ strategies can be integrated into continuous learning, while also maintaining safety limits, instead of safety being based more or less on ad hoc solutions. Clinical managers could strive to increase resilience in processes by allocating time for reflection to increase awareness and preparedness to handle complexity and fluctuating conditions in everyday work. Such learning sessions could also incorporate discussions on how to handle the boundaries between participation, autonomy and integrity for patients and family caregivers, and to share competence between discipline boundaries. Home healthcare requires structured but flexible team work, which places great emphasis on both individual and collective skills.
In the development of a trigger tool aimed to improve patient safety, conducted in close collaboration with experts from the various areas of patient safety, home healthcare and the RRR method, it is important to utilise the knowledge of different stakeholders already during the planning stage of a project. This is in order to gain in-depth knowledge so that improvements are adapted to the conditions, consistent with the RE approach. By identifying the types and frequencies of AEs, new knowledge is created and action can be taken so that the AEs do not occur again, which is in line with a Safety-I perspective. However, measurement alone does not lead to patient safety without the events also being carefully analysed, and learned from, in order for appropriate adaptations and measures to be taken, being a Safety-II perspective.

Further findings indicate that no-harm incidents and contributing causes are a valuable source to improve patient safety. No-harm incidents and contributing causes may not be as “visible” when they represent variations in home healthcare but may be of great importance to patient safety. These factors point out system failures, e.g. lack of routines and failures in work processes which may lead to AEs. Risks arise due to unexpected combinations of a normal variability. For the patient, relatives, society and healthcare it is valuable to insert proactive interventions before an AE occurs. The RE approach states that the inclusion of such knowledge, which gives clues about failures in work processes, increases the ability to improve patient safety; safer work processes make it harder to make mistakes and easier to do tasks correctly.

**Clinical implications**

For policy-makers (macro-level) who engage in structure and reforms for a safe home healthcare, the findings in this thesis may be of value. Weaknesses in the existing medical records, and the absence of a medical records system common across organisational boundaries, contribute to daily risks in the patient safety area. This is a major and wide-ranging patient safety issue that extends beyond organisational boundaries and needs to be solved at the highest levels of management in the healthcare sector.

This thesis may also have relevance for clinical managers (meso-level) and professionals (micro-level) in home healthcare. Learning from both reactive and proactive patient safety information is a way of engineering resilience, and improving patient safety, in home
healthcare. Safety debriefing team meetings are a valuable resource for highlighting patient safety issues in real time. But safety debriefing meetings, per se, do not automatically induce learning. In order for an organisational learning to take place, the meeting must be prioritised, the purpose clarified, and the meeting structure carefully planned. In a unit where activities are constantly ongoing, and where healthcare providers work in shifts, it is a challenge to find solutions that can be adapted to the workflow. The experience of patients and their relatives in handling advanced technical equipment, as well as assessing, monitoring and evaluating their own care, should be taken into consideration to increase learning. Inviting patients and relatives to these debriefing meetings every now and then would most likely offer an invaluable contribution to engineering resilience in the organisation.

Furthermore, home healthcare is in need of valid and reliable methods to improve patient safety. The developed and adapted trigger tool described in this thesis may constitute one such method. Additionally, this trigger tool could contribute as a useful complement to other safety systems, for instance the incident reporting system which is not a systematic method. If a manager makes the decision to conduct a retrospective record review using this trigger tool, I would urge him/her to take the opportunity to include a review of no-harm incidents and contributing causes which give valuable information about failures in routines and work processes before AEs occur. Learning from such information may engineer the performance of resilience which could also provide opportunities to develop valid process indicators for systemic failures, as well as outcome indicators, for structured evaluation. Further, it also lead to proactive patient safety work in home healthcare, in adherence with the Patient Safety Act.

**Future research**

Although this research has contributed to knowledge and understanding of patient safety in home healthcare, it is only a beginning and there is much more to explore in the subject in this context. The two perspectives on safety, Safety-I and II should co-exist for the foreseeable future. Safety researchers must take responsibility to combine Safety-I and II methods in a structured and systematic manner in order to improve performance in patient safety work and to develop reliable and valid methods.
These findings showed that the medication management process is a daily practical patient safety issue that affects a large number of patients, as both AEs and no-harm incidents. Additionally, we do not know to what extent and how the strategies and behaviours used to circumvent the issues in medication management are related to the promotion or hindrance of safe patient care. Thus, further investigation of how to improve the medication management process is warranted. There is a need also to design procedures for improved documentation and the transfer of information. Such procedures, together with solutions to visually enhance important information in the patient record, can lead to improvements in the identification and prevention of no-harm incidents and AEs with regard to medication management processes. Furthermore, a detailed analysis of the problems associated with omission of care is needed in order to raise awareness of “blind spots” that are especially difficult to monitor. It is also important to pay attention to, and learn from, healthcare events and tasks that go well as a method of increasing the possibility to develop ways to support, augment and encourage such outcomes.

It would also be worthwhile to further investigate and test the final trigger tool developed in this thesis. This trigger tool needs to be validated on a larger scale, and to have the social care patient records included to a greater extent, which will encourage the possibility to find effective interventions across organisational boundaries. Additionally, there is a need to explore patient safety from a multilevel view and to include policymakers, patients and relatives’ perspectives and experiences of patient safety in home healthcare. This would no doubt extend the knowledge and understanding of patient safety from a holistic point of view.

Lastly, this thesis has touched on many questions and, from my point of view, we must continue to address the challenges of improving patient safety in novel and innovative ways. It is time to change our approach to healthcare, and home healthcare, and to rethink our use of hitherto accepted concepts such as person-centered care, participation and risk. As healthcare is increasingly being performed in the home, where the experience is fundamentally different to that of in-hospital care, patient safety is necessarily being reshaped. Therefore, the application of a multilevel approach is called for which includes the perspectives of caregivers across the specialist-home healthcare continuum.
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