Patient safety in primary and emergency care

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To my parents, Lasse and Karin

ABSTRACT

This thesis explores aspects of risk and safety in health care. Patient safety is about preventing harm to patients. A perspective of resilience is used, which is a proactive approach to making care safer. Resilient organisations recognise the fact that work is done in a complex and adaptive system that can be improved, not only by studying what goes wrong, but even more so by studying what works well. The thesis adds to previous research by studying patient safety in first-contact care, primary health care and the emergency department, resulting in new knowledge that could be used to make care safer.

We investigated reported preventable harm and serious safety incidents in primary health care and in emergency departments (Study I). In these contexts, diagnostic error was the most common type. A diagnostic error is when a patient does not receive the correct diagnosis within a reasonable timeframe when there were clear opportunities to establish the correct diagnosis. The consequence is delayed adequate treatment. There is limited knowledge of the panorama of diagnoses that are involved in diagnostic errors. We explored the diagnoses that were most frequent in this material. Cancer was the most common missed diagnosis in primary health care, in particular colorectal cancer, and fractures were the most common missed diagnoses in the emergency departments.

Furthermore, little is known about patient-related risk factors for preventable harm. We explored factors associated with an increased risk of reported preventable harm, or serious safety incidents, in primary health care and in the emergency departments (Study II). The most prominent risk was psychiatric disease. This was, to our knowledge, the first study in an out-patient setting, with all types of psychiatric diseases.

This thesis also examines what patients and health care professionals perceived as the major risks in primary health care and what solutions they would prefer (Study III and IV). Solutions generated from the people in the system are likely to be more accurate and easier to implement than top-down solutions. In Study III, qualitative analysis of free-text answers to structured questionnaires was performed. The results were used to build a survey for Study IV, where specified risks and solutions were rated according to importance. Regarding risks, the areas that were thought to need most improvement were continuity of care, communication and knowledge. Solutions included: information about what to do when tests were fine, but symptoms remained, so called safety-netting; the use of a nationwide medication record online; and a personal doctor with a restricted number of patients per doctor, to facilitate continuity of care.

These studies support future work for safer and more resilient health care. There were suggestions from the level of the general practice up to the national level. Further research should test interventions that proactively support systems in improved accuracy in diagnosis and correct medication, for example, an intervention to improve continuity of care or to practice safety-netting. Proactive interventions like these could probably improve the resilience of the system in question.

LIST OF SCIENTIFIC PAPERS

I. Fernholm R, Pukk Härenstam K, Wachtler C, Nilsson GH, Holzmann MJ, Carlsson AC. Diagnostic errors reported in primary healthcare and emergency departments: A retrospective and descriptive cohort study of 4830 reported cases of preventable harm in Sweden. *European Journal of General Practice 2019; 25:3, 128-135*

II. Fernholm R, Holzmann MJ, Wachtler C, Szulkin R, Carlsson AC, Pukk Härenstam K. Patient-related factors associated with an increased risk of being a reported case of preventable harm in first-line health care: a case–control study. *BMC Family Practice, 2020;21:1-8.*

III. Fernholm R, Holzmann MJ, Malm-Willadsen K, Pukk Härenstam K, Carlsson AC, Nilsson GH, Wachtler C. Patient and provider perspectives on reducing risk of harm in primary health care: a qualitative questionnaire study in Sweden. *Scandinavian Journal of Primary Health Care, 2020; online 24 Jan, 1-9.*

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CONTENTS

1 LIST OF ABBREVIATIONS

ED   Emergency department

GP   General practitioner

NAM   National Academy of Medicine

OR   Odds ratio

PHC   Primary health care

QI   Quality Improvement

RCA   Root Cause Analysis

WAD   Work-as-done

WAI   Work-as-imagined

WHO   World Health Organization

2 DEFINITIONS AND COMMONLY USED CONCEPTS

Ambulatory care	Primary health care and the emergency department
Patient safety	Prevention of errors and adverse effects to patients associated with health care
Safety I	A system is safe if as little as possible – and preferably nothing – goes wrong. In other words, if there are no accidents or incidents.
Safety II	A system is safe if as much as possible goes well.
Safety incidents	Incidents of harm or near misses (near harm).
System 1	System 1 refers to a way of fast thinking, mostly based om pattern recognition and sometimes called our "auto-pilot".
System 2	System 2 refers to a slower way of thinking that is more analytical and usually less prone to error.
Resilience	A system is resilient if it can adjust its functioning prior to, during, or following events (changes, disturbances, and opportunities), and thereby sustain required operations under both expected and unexpected conditions.

3   PROLOGUE

Patient safety is the subject of this thesis. The focus is on primary health care (PHC) and care in the emergency department (ED). The fact that patients can be harmed when they seek health care is frustrating and should not happen when it is possible to avoid. I will in this thesis explore different aspects of safety and possibilities for making care safer, through the lens of resilience. Resilience in health care is the ability to deliver good and safe care under varying conditions and has a proactive approach. Preventable harm can for example come from health care associated infections, avoidable falls, medication errors or delayed diagnoses. Meeting patients that have been harmed by health care has motivated me to focus on the area of patient safety. Below is an example of diagnostic delay that should not need to happen (fictional case based on several reports of preventable harm).

Thomas was a man in his mid-sixties who came to a General Practitioner (GP) practice. He didn't have a personal GP and met with a locum physician, a temporary doctor. The doctor was working for just two weeks at the practice before moving on. Thomas had had some trouble with depression on and off. Now his stomach was bothering him. The doctor examined him quickly, no rectal exam, and ordered some laboratory tests. Thomas felt a bit neglected but didn't speak up. He did not receive advice about what to look out for and when he should come back. Thomas waited for the lab results for a week or so but since he didn't hear anything, he assumed the lab work had been fine. The stomach kept bothering him. Finally, after 3 months, he sought care again. Now the previous lab results were brought to attention, with anaemia and signs of iron deficiency. Colonoscopy was made 4 weeks after the second visit. Thomas had colon cancer. Computer tomography of the stomach showed that the cancer had spread to the liver.

I began to learn more about patient safety and exploring safety has made me realise that the health care system is a large and highly complex system, harbouring smaller complex systems within. During my doctoral studies I have come to a greater understanding of the complexity and adaptability of the health care system. Also, the necessity for the patient to take a central role in work with quality and safety has grown strong for me over the years. The language used in the thesis is chosen to facilitate spread outside of the academia.

4   BACKGROUND

4.1   Patient safety and resilience

A simple definition of patient safety according to the World Health Organization (WHO) is the prevention of errors and adverse effects to patients associated with health care [1]. In this thesis, on the subject of patient safety, the framework of resilience is used. A definition of resilience is that a system is resilient if it can adjust its functioning prior to, during, or following events (changes, disturbances, and opportunities), and thereby sustain required operations under both expected and unexpected conditions [2]. It is a framework that takes into consideration that health care takes place in an adaptive complex system. Resilience also uses the perspective of being proactive when it comes to safety. The framework is therefore chosen because it can be a valuable tool for making care safer.

Health care is an example of a complex system [3]. With complex systems one usually means that there are many different components which interact with each other and that the outcome is hard to predict. The health care system is a large and highly complex system, harbouring smaller complex systems within. The system is also an adaptive system by nature. When addressing safety, it is important to view the aspects of system safety since it will widen the understanding of the reasons for harm. Thereby, the countermeasures can be more appropriate and proactive. Harm is seldom due to a specific person, but more often due to a type of situation that keeps repeating itself.

There are other frameworks, for example to analyse errors and address contribution factors that are identified, often via Root Cause Analysis (RCA) [4]. That type of framework has also been called safety-I to emphasise the traditional view of safety opposed to the perspective of resilience that is called safety-II [5]. Erik Hollnagel points out the difference between safety-I and safety-II [2]. Safety-I is about avoiding things going wrong, focusing on finding the cause of harm and fix it. Safety-II is about seeing to that as much as possible goes right, by learning from everyday success in order to make the system safer. Regarding diagnoses it can be interpreted as striving for as high as possible percentage of correct diagnoses in a timely manner. In safety-II, a system is resilient if it can adjust to different kinds of disturbances and still work with good results. A system has properties of resilience when it has the ability to "bounce back" and remain safe under different conditions. Safety-II does not replace safety-I but complements it and brings with it a more proactive view on safety. Not only systems can have properties of resilience, but individuals can also be more or less resilient. An individual can handle setbacks and difficulties with more or less appropriate strategies and thereby handle a situation with more or less success.

When discussing resilience, there is a need to mention work-as-imagined (WAI) and work-as-done (WAD) [5]. Work-as-imagined is the work as it is supposed to be performed, to "work by the book". Work-as-imagined can be difficult or impossible to do because of the information overload that is present in health care, because patients can have more than one condition or because of lack of resources. Work-as-done is how the work is done in real life, with all the adjustments that the health care professionals need to do in order to get the job done. In PHC many patients are elderly and have multimorbidity and polypharmacy which makes it difficult to standardise care and to work according till WAI. To work for safer health care, one needs to realise the concept of work-as-imagined and work-as-done. To simply remind people to do the correct thing has a very small effect on safety. In contrast, if work-as-done is known, measures to make the care safer can have a greater impact [5].

Safety is often seen as a component of quality of care. Quality and safety in health care are intertwined and safe care is an important aspect of quality [6]. If the care is not safe, the patient could get harmed in her or his contact with health care. Apart from the tragedy of harming the patient, the confidence in health care can decrease [7], with the result of people in need not seeking health care.

4.2   Patient safety and types of harm

Patient safety is according to WHO defined as the prevention of errors and adverse effects to patients associated with health care [1], as mentioned above. Classic areas of concerns regarding patient safety have been medication errors, unsafe surgical care procedures, unsafe injections practices, health care associated infections, falls and inappropriate treatments. In PHC medication errors and diagnostic errors are the two types of errors resulting in the most severe consequences [8]. Medication errors are common and have been subject to many studies during the past decades while diagnostic errors have not received the same attention. However, diagnostic error is a fast-growing area in patient safety, with ambulatory care as major contributors of cases, as a result of their context as the first contact with health care when new symptoms arise. This thesis study both medication errors and diagnostic errors, where the latter requires more background being newer in the flied of research.

Former Institute of Medicine (IOM) and now National Academy of Medicine (NAM) defines diagnostic error as the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient [9]. Preventable harm due to diagnostic error is thus when the treatment is delayed to the extent that the patient suffers harm, in the case that there were clear opportunities to establish a correct diagnosis [7]. In 2015 the report Improving Diagnosis in Health care was published by NAM [10],

and exposed the problem of diagnostic error. In Sweden, diagnostic errors constitute approximately 10-20% of all serious preventable harm and in the context PHC and EDs, diagnostic errors make up more than 40% [11]. In PHC many patients seek with symptoms rather than with clear cut diagnosis, which could be an explanation for the high percentage of diagnostic errors. The ED setting is to some extend similar to PHC in that respect and diagnostic errors constitutes a major part of preventable harm [12]. An obvious and important difference is the PHC's possibility to use continuity of care as an instrument for safer care.

There are several reasons for increased importance of diagnostic errors. First, our ability to investigate and establish different diagnoses has improved over the last decades. Second, treatments are increasingly effective. We can now treat acute myocardial infarction, stroke, cancer and many types of infections in ways that were not possible a few decades ago. Therefore, the consequences of late diagnosis are more severe. Third, with the pattern of travel nowadays, delayed diagnoses of infectious diseases have potentially greater impact now than earlier. Forth, there is a great cost associated with both under- and over-diagnosis [13]. Finally, the consequeces of diagnsotic errors are often more severe than the consequeces of other types or errors [9].

Diagnostic errors are unfortunately difficult to measure [7]. The time frame of "timely" can differ immensely if we talk about acute myocardial infarction or colon cancer. Each case must be evaluated to see if the patient has experienced harm because a late or wrong diagnosis and that there were apparent missed opportunities for the right diagnosis to be made in a timely manner.

4.2.1 The diagnostic process

The diagnosis is essential to the practice of medicine. The diagnosis explains the patient's health problems, gives information about prognosis and what treatment should be given the patient. The diagnostic process is a process that usually starts with limited information and gathers information along the way, and it is therefore sometimes called the diagnostic trajectory, as information and certainty increase by time.

The diagnostic process begins with a person that has symptoms of a health problem and seeks health care (Figure 1). Information is gathered through medical history, physical exam and diagnostic testing. Often there are more people involved than just the doctor and the patient; maybe a consultant, maybe a radiologist, maybe a nurse or maybe a family member. In the process the information is interpreted, and a working diagnosis is made that is communicated to the patient. Treatment is given, which can result in new information that might adjust the diagnosis and treatment (red arrow in Figure 1). Finally, the patient has an outcome. There can be a break-down in all different parts of the dianostic process [14], and contributing factors can be cognitive, system-related, or non-remedial, often overlapping [15].
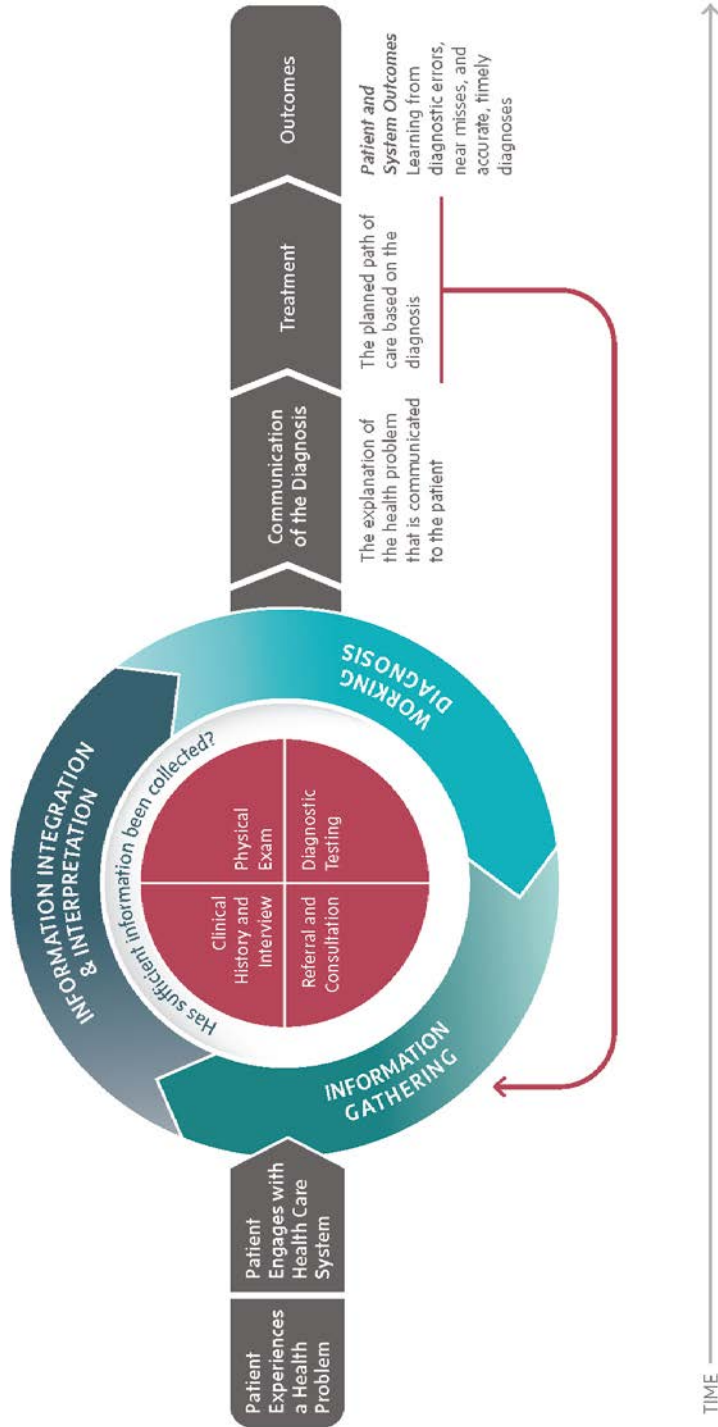
Figure 1. The diagnostic process [9]. (Published with permission from the National Academy of Medicine)

4.2.2 Diagnostic reasoning

A diagnostic error can be a result of failure in the diagnostic reasoning and decision making. The base of diagnostic reasoning is medical rationality which include critical thinking, intellectual ability, knowledge and individual characteristics [16]. Rationality is according to Merriam-Webster Dictionary defined as "the quality or state of being rational or being agreeable to reason" [17].

Decision making can be understood as either non-analytic or analytic, often called system 1 and system 2 or the dual-process model [18, 19], displayed in Table 1. In system 1, the non-analytic, decision making is fast, intuitive, and based on pattern recognition. It is very time efficient, but it is also thought to be prone to error and vulnerable for biases [20]. System 2 is analytic, more time consuming, more precise, but can also be affected by different kinds of biases. The latter is especially true if a person is only reasoning with themselves, not testing the possibilities of alternative diagnoses in discussion with others. The human brain tends to look for arguments that confirm our first theory, resulting in the misconception that we are thinking analytically, but we are just searching for arguments to justify our initial theory [21]. Critical thinking is thus best done in teams [22].

Table 1. Properties of system 1 (non-analytic) and system 2 (analytic) [20].	
System 1	**System 2**
Fast	Slow
Effortless	Effortful
Unconscious	Conscious
Automatic	Controlled
Everyday decisions	Complex decisions
Heuristic	Analytic

System 1 is used more by experienced medical health care professionals and system 2 is used more by the less experienced [23]. System 1 can work by pattern recognition where the clinician can recognise a diagnosis that one has

seen before. For example, a woman with frequent, painful urination receive the diagnosis of urinary bladder infection, even though it can be symptom of chlamydia. If the clinician had a patient the day before with chlamydia the clinician can more easily remember to ask questions for the medical history to avoid missing chlamydia. The non-analytic system is comfortable and since the human brain is lazy by nature, we tend to spend a lot of time in system 1. The danger is when we are not aware of when we are using system 1 and when we are using system 2 [20]. We need to be aware of that and alternate between the systems whenever it is appropriate.

To actively consider alternative diagnoses, system 2 is usually needed [23]. If the clinician gets stuck in system 1, there are ways to force oneself into system 2. For example, "the rule of three", meaning that the clinician hypothesize three possible diagnoses to explain the patient's symptoms. Control questions can be used; What suggests another diagnosis? What else could it be? Could there be more than one problem? In PHC the doctor usually has a diagnosis in mind very fast and often trusts his gut feeling [24]. Quick and convenient – but maybe it is the wrong diagnosis.

4.2.2.1 Biases that affect diagnostic reasoning

There are different types of biases that can affect the clinician in the medical decision making and those are discussed in this section [23]. There is the *group-thinking effect* that makes the clinician more prone to think what others are thinking [25]. The human usually feels safer when fitting in with a group. This effect becomes stronger the more people that agree on a subject. So, if something is said during rounds or is written in the chart, that tends to be understood as true. Medical reasoning can also be negatively affected by "*cognitive fixation*", meaning to get stuck in the initial hypothesis and not revaluate the decision, also called the *anchoring effect* [26]. The patient might then receive the wrong diagnosis. Another important factor that affects diagnostic reasoning is how well calibrated the doctor is to his abilities. *Overconfidence* in diagnostic ability can lead to incorrect diagnoses and *low confidence* can lead to defensive medicine. Good calibration is important for optimal diagnostic reasoning [27].

Availability error means that the clinician is prone to think that the diagnosis is one that the clinician has seen recently [28]. For example, respiratory symptoms that are interpreted as asthma and medication is prescribed. Later the diagnosis turns out to be heart failure or thrombosis. *Confirmation bias* causes the clinician to try to confirm an early hypothesis. For example, the patient might have googled his symptoms and arrives to the doctor with an already formed hypothesis. *Affection error* means that medical reasoning can be affected if the clinician likes a patient too much, like a family member. For example, the clinician does not want to find serious illness in a family member or is embarrassed to perform a complete physical examination.

Attribution error is when the clinician has notions about a patient beforehand, for example, if it is known that the patient drinks excessive amounts of alcohol and therefore the elevated liver enzymes are not investigated for other possible causes. *Satisfaction of search* means that the clinician stops searching as soon as one possible explanation is found, a common reason for diagnostic errors in radiology [29]. For example, the radiologist seeing a pneumonia on the x-ray stops looking (often unconsciously) and miss an osteolytic metastasis on the clavicula. *Diagnostic momentum* is when a diagnosis is said or written in the chart and the belief in the diagnosis becomes stronger and stronger even though the evidence can be scarce [28]. The clinician wants to work fast and it is easy to use selective perception and selective information gathering to fit the diagnosis with the initial hypothesis. That leads to *premature closure*. To have knowledge of the different types of biases can make the clinician better at critical thinking [23].

4.2.2.2 Further factors affecting diagnostic reasoning

An important element for the medical reasoning and medical decision-making is medical knowledge, including *knowledge of probability* [23]. The epidemiology of PHC affects the probability of different diagnoses. If a patient seeks help for joint pain in PHC, little is gained from testing rheumatic blood-work if there is no evident inflammation in the joints. Another factor that plays a role in diagnostic reasoning is good ability to communicate. *Communication* between health care professionals has tangible effects on patient safety and the risk for diagnostic errors, like the language misinterpretations in responses to referrals and radiology results. Unfortunately, standardised language is seldom used [30]. Communication is also of utter most importance when it comes to hand-off and transfer of care and also between health care professionals and patients.

The risk for wrong or delayed diagnosis also increases if one trusts the *prospective memory* [31]. That means that the doctor tells himself to do something later on but have no specific trigger for remembering to do it. This kind of postponed actions are especially vulnerable for distractions. As a GP, one sees many patients in a day and interruptions are very common. For example, when a doctor meets a patient that could have cancer and needs a referral, the doctor may think "I will send the referral after the next patient because I'm running behind my schedule". Then the doctor gets distracted by a phone call or a colleague who needs to ask a question.

Cognitive work is about dynamic attention (what to focus on, when, to the expenses of what), knowledge (how to learn, store, activate and use knowledge), and strategic factors (how to handle limitations and goals in the organisation where the work is done) [32]. Health care has apparent *cognitive challenges*;

stressful work environment, multi-tasking and relaying on prospective memory. It this environment is easy to be affected by cognitive pitfalls like the anchoring effect. In addition, there are *individual factors* like education, experience, tiredness (which severely affects the executive function of the brain), hunger, thirst, ability to think critically, emotional state, tolerance for cognitive pressure, tolerance for group pressure, over-confidence and finally stress, both short-term and long-term [23]. *Time pressure* affects the quality of the medical reasoning negatively, but it is actually not the true restraint of time that is important, but the experience of time pressure [33]. If you feel stressed the quality of your decisions will be lower. Stress leads to "tunnel vision", paralysis and shallow information gathering, affecting the ability to decide on the correct diagnosis [34, 35].

Team factors are also important for diagnosis [36]. There are usually more people involved in a diagnosis than just the patient and the doctor. There are nurses, consultants, laboratory staff, family members and so on. The team is often not as visible in PHC as in a hospital. If these teams, many times temporary teams, do not work well together, there is a risk for diagnostic error. To work well together the team needs to have shared mental models. The idea is that team performance improves if team members have a shared understanding of the task that is to be performed and their part of the team [37]. That improves the so called sensemaking which is important for teams as well as for patients [38, 39].

Moreover, *systemic factors* play an important role when it comes to patient safety and diagnostic errors [40]. They include work environment and ambient conditions (availability of care, patient engagement, diagnostics like laboratory and radiology, consultants, coordination of care and routines for follow-up). The *patient* plays a central role in the diagnostic process [41], with the knowledge of all the symptoms and for carrying vital information through the care process. While many of the members in the diagnostic team change during the diagnostic process, the patient remains. The patient is also the one that cares the most that the diagnosis is correct.

4.3   Reports of harm and incident analysis

In Sweden, patients that have experienced harm can report to a nation-wide insurance company, owned by the Regions (the local governmental level in Sweden that is responsible for publicly-financed health care and public transportation). The company is called Landstingets Ömsesidiga Försäkringsbolag (LÖF). The incident is evaluated by health care professionals trained in incident analysis to see if there has been preventable harm, and in those cases the patient will be financially compensated. Health care facilities also report safety

incidents (incidents of harm or near misses). Health care are obliged by law to analyse and report serious safety incidents to the authorities. The reports from health care are called lex Maria. The Regions and single health care facilities also have their own reporting systems. Incidents are analysed as a mean of learning and improving the systems. Some RCA made by the Regions are reported online to a national database as an opportunity for learning. However, there is literally no data source that gives information about all harm.

A way to analyse safety incidents is RCA, constructed to use the perspective of safety I [4]. When a patient has been harmed in health care an RCA can shed light on the different causes that contributed to the harm, for example, why a diagnostic error has occurred. However, it is difficult to analyse cause and effect in complex systems since there often are many causes that could have contributed to the outcome. RCAs tends to be used in a linear way, not considering the plasticity of reality. With a safety II-perspective the RCA can be modified for a deeper understanding of the situation or one could conduct a "positive root cause analysis" to explore why a situation worked out well. That perspective can be a source of learning about the system and a way to improve the system. It can sometimes be hard to distinguish the boundaries of the system to be included in the RCA, since the different systems in health care are open systems and dependent on one another, as well as dependent on their context. In establishing the diagnosis, the information needed can be spread between systems, among health care professionals, in different electronic health record systems and between primary and secondary care. The RCA needs to include all parts involved in the diagnostic process, which often can pose a challenge in performing the analysis.

Another known model for analysing errors is the Swiss-cheese model, widely used but with variations in interpretations [42]. It is a model of barriers that describes how latent conditions combined with active failures can lead to harm [43]. When a patient suffers from preventable harm there are usually several things that did not go as planned, symbolised by the holes in the slices of cheese. In the Swiss-cheese model the focus is on finding erroneous situations to be able to correct them, like the concept of safety I. Related to diagnostic error this model can be used proactively to build in safety barriers in the system, like safe routines for follow-up on lab results. The patient can also be a barrier to harm by reading his electronic health record online and make sure that a referral is carried out, or that lab results are reported back to the patient.

4.4　　Rationals for the thesis

Preventable harm is an issue of interest in most countries and targeting preventable harm could lead to major quality improvement (QI) in care and could also be cost-effective [44]. An aspect of safe care is that the patient receive a correct diagnosis in a timely manner leading to adequate treatment [9]. Patients with new symptoms and unknown diagnosis seek ambulatory care, like PHC or the ED. Therefore, ambulatory care wrestles with a high density of decision-making regarding diagnoses and a higher risk of diagnostic errors than other settings. It is known that diagnostic errors is a major issue in these settings [7, 9], but only a few studies have explored the diagnoses involved [45, 46]. The gap regarding diagnoses involved is addressed in Study I. Knowledge of which diagnoses are involved could facilitate safety work.

There are known risks of harm in health care. Transfer of care is one and lack of continuity of care is another [9]. Older patients and patients with many medications have a higher risk of harm [47]. In addition, patients with serious mental illness have shown to have an increased risk of harm in hospitals [48]. Apart from that, there is a gap regarding which patients have an increased risk of experiencing harm in ambulatory care. If we know the patient-related factors associated with higher risk of preventable harm, appropriate proactive measures can be designed to make care more resilient. We explored which patient-related factors that were associated with a higher risk of preventable harm and serious safety incidents (Study II).

To take measures for safer care is not easy, especially to implement the measures in daily work. If the solutions for a safer care are influenced by the opinion of patients that have experienced harm, and by the health care professionals working in health care, the implementation can be facilitated [49]. There are some studies regarding what health care professionals think could improve safety, for example improved communication [50, 51]. In addition, patients have pointed out patient-centred ways to improve safety [52]. However, there is still a gap regarding what health care professionals, and especially patients that have experienced preventable harm, believe to be the most important risks and preferred solutions for these risks. We explored views of patients and health care professionals in Study III-IV. Safety research has mainly been reactive over the past decades. We wanted to search for proactive means to mitigate risks. In Study III-IV we looked for answers about where we should focus our efforts and what we should prioritise to do, in order to achieve a safer and more resilient care.

5   AIMS

The overall objective of the thesis was to study aspects of safety in PHC and the EDs.

The specific aims of the studies were:

- To study which diagnoses that are affected when it comes to diagnostic errors in PHC and the EDs (Study I).

- To study which patient-related factors are associated with a higher risk of preventable harm in PHC and in the EDs (Study II).

- To explore the views of patients and health care professionals in PHC regarding patient safety issues and possible solutions for a safer care (Study III).

- To explore how patients and health care professionals in PHC ranked specified risks and solutions for patient safety issues (Study IV).

6 MATERIAL AND METHODS

6.1 Setting

Swedish PHC and EDs are merged in Study I and II. When patients experience new health problems in form of new symptoms, they usually seek help from PHC. If they believe the condition is serious or give rise to aggravated symptoms, they seek the ED. So, in these contexts there are a high density of decisions making concerning diagnoses because the clinicians are exposed to unsorted patients [53]. In PHC in Sweden the patient chooses a personal doctor or a GP-practice. The GP has a gate-keeping function and makes referrals to specialised care.

The epidemiology in these contexts is important to consider. In PHC the serious diagnoses are rare. There is a constant "noise" of symptoms from the patients. When a serious disease occurs, the symptoms usually present themselves together with symptoms of other conditions of that patient, which can conceal the severity of the situation. To pinpoint the serious diagnoses in PHC can be a true challenge, like finding a needle in a haystack. In the ED there is a different spectrum of symptoms and diseases, even though it can overlap with PHC. In this context the serious diagnoses are more common while the patients still seek with new symptoms and many times with unknown diagnoses.

Finally, the upcoming reorganisation of Swedish health care (from 2018 and ongoing) needs to be mentioned. The Swedish government has the intention to support the regions, relevant government agencies and organisations in the coordinated development of a modern, equitable, accessible and efficient health care service, focusing on PHC. The program is called "The coordinated development for good quality, local health care – A primary health care reform" [54]. It will focus the care closer to the patient. The intention is good but will probably result in not yet foreseen risks of harm, as any major organisational change.

6.2 Material

The two largest nationwide accessible registries of data containing information about harm and serious safety incidents in health care were used (Study I-II). The first registry, or database, consisted of patient-reported incidents, that had been assessed by medical experts as preventable. The second registry, or database, consisted of health care-reported serious safety incidents. All harm and incidents reported during the years 2011 throughout 2016 from PHC and EDs were used, yielding a large amount of data, reported both from patients and from health care.

For the qualitative study and the survey study (Study III-IV), exploring the views of risks and solutions, patients with experience of preventable harm in PHC and health care professionals working in PHC took part. An overview of the studies included in the thesis is seen in Table 2.

Table 2. Studies included in the thesis				
Study number	**Aim**	**Material**	**Method**	**Year**
Study I	To study which diagnoses that are affected when it comes to diagnostic errors in PHC and the EDs	Patient-reported harm and health care-reported safety incidents	Cross-sectional study (historical cohort)	2011-2016
Study II	To study which patient-related factors are associated with a higher risk of preventable harm in PHC and in the EDs	Patient-reported harm and health care-reported safety incidents	Case-control study	2011-2016
Study III	To explore the views of patients and health care professionals in PHC regarding patient safety issues and possible solutions for a safer care	Patients with experience of harm and health care professionals	Qualitative study	2018
Study IV	To explore how patients and health care professionals in PHC ranked specified risks and solutions for patient safety issues	Patients with experience of harm and health care professionals	Survey study	2018

6.3   Methods

When exploring reported harm and serious safety incidents, the methods used were observational. We used a cross-sectional study with an historical cohort (Study I), to describe what kind of harm were present in PHC and the ED. To study factors that were associated with increased risk of harm a case-control study was used (Study II).

To explore the views of patients and health care professionals, a qualitative content analysis of free text answers to structured questionnaires was preformed (Study III). With the results from the qualitative analysis, one survey to patients and one to health care professionals were constructed. In this survey study the respondents answered how big they thought specified risks were from 0 to 10, and they ranked specified solutions to mitigate risks (Study IV).

7   SUMMERY OF RESULTS

7.1   Study I

7.1.1   Type of harm

There were 507 cases, all PHC, from the health care-reported database. Of them, 64% were related to diagnostic errors and 9.1% were medication errors. There were 3,066 cases from the patient-reported harm database from PHC. Of them, 44% were related to diagnostic errors. Medication errors were identified in 1.6% cases. From the ED there were 1,322 cases from the patient-reported database, of which 44% were related to diagnostic errors and 2.2% were related to medication.

7.1.2   Diagnostic errors

Of all diagnostic errors in the health care-reported database from PHC, cancer constituted 37%. The top three types were colorectal (22.0%), skin (17.0%) and kidney or bladder cancer (13.0%). Of non-cancer diagnoses, heart disease constituted 8.4% where most cases were myocardial infarction (56%). Fractures constituted 7.1% of the cases. Infections constituted 6.8%; these were mostly sepsis (23%), pneumonia (18%), and tuberculosis (14%). In the patient reported database from PHC, cancer constituted 23%. The three most common types were colorectal (17.0%), skin (12.0%) and lung cancer (8.4%). Of non-cancer diagnoses, fractures constituted 13%, infections constituted 11% and rupture/injury of muscles or tendons constituted 10%. The two databases were not combined because they constitute two varied samples with data collected for different purposes and different degrees of seriousness.

Of all diagnostic errors in the ED from the patient-reported harm database, fractures constituted 24%. These were mostly hand and wrist fractures (29%). Rupture/injury of muscles or tendons constituted 19%; these were mostly tendons of the fingers (28%), tendons of the rotator cuff (15%), and the Achilles tendon (13%). Infections constituted 10%, mostly appendicitis (41%).

7.2   Study II

In total, 4 536 patients and 44 949 controls were included the study. The cases had a higher degree of comorbidities (cardiovascular disease, psychiatric disease and cancer) than the controls. The controls were matched for age, sex, and residential area.

Patients with psychiatric diagnoses had a nearly two-fold higher risk of being a reported case of preventable harm (Odds ratio (OR), 1.96; p < 0.001). The preventable harm was mostly somatic harm as oppose to psychiatric harm/

suicide, primarily involving diagnostic errors (46% of all preventable harm in this category was due to diagnostic errors, the smaller categories were harm from falls, surgical complications, medication-related and health care associated infections). Adjusted for income and education there was still an increased risk (OR, 1.69; p < 0.001).

Differences in income and education had some impact on the risk of preventable harm. The risk in the highest income group (highest quartile) was slightly lower (OR, 0.86; p < 0.01) than that in the lowest quartile. The highest educational level (postgraduate) had a lower risk (OR, 0.51; p < 0.01) than the education level of ≤9 years of school.

7.3   Study III

There were 22 patients and 59 health care professionals that responded to the questionnaire. Three categories were experienced as central to patient safety: continuity of care, communication and competence, the later including skills, capacity and qualification. Sub categories are seen in Figure 2 below.
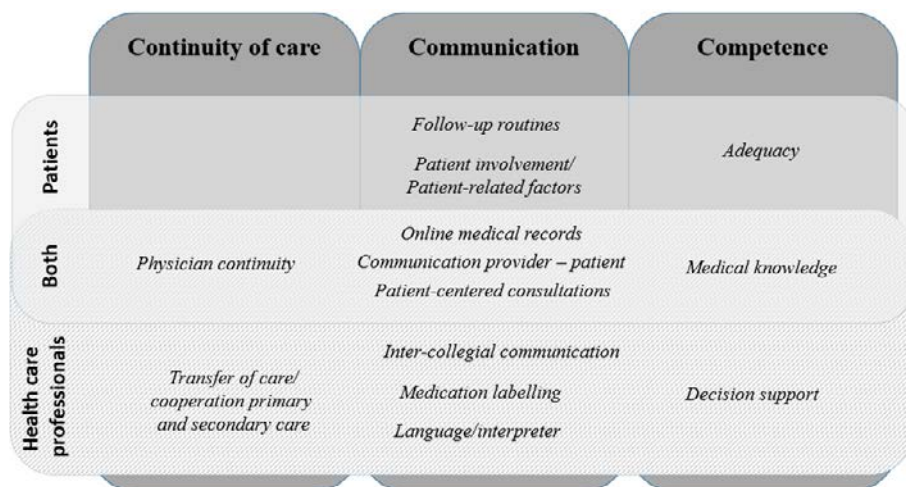

Figure 2. Categories and sub categories in qualitative analysis of free-text answers regarding areas important for patient safety in health care.

Patients identified physician continuity, to see the same doctor repeatedly, as important. The patients had a vague sense of risk when care was experienced as fragmented. Patients also drew attention to problems concerning routines for follow-up. Patients felt they were left with the responsibility to make sure that follow-up took place. Patients also described patient-related factors as

an understanding of risks, for example that the patient waited too long before seeking care. The patients felt that the doctor did not listen to them, did not know what to do and that a major risk constituted of that the doctor did not examine them in the right way or not at all. The patients experienced that the doctors lacked competence. It is not known if the doctors did have the competence but failed in communicating it or if there were an actual lack thereof.

Health care professionals also identified poor physician continuity as a risk. In addition, they drew attention to the risk with transfer of care and that online medical records were critical to patient safety. Good communication between the health care professionals and the patient was stressed as important preferably in the form of patient-centred consultations. Finally, team work was mentioned as important for safety.

The overarching theme for the patients was the experience of being neglected, and for health care professionals the overarching theme was continuity of care.

7.4   Study IV

There were 80 patients and 939 health care professionals that responded to the survey. Response rates were 26% for health care professionals and 19% for patients. The respondents were spread over the country, with varying distance to health care. Risks rated highest among patients were lack of knowledge, that the doctor can be careless or make cognitive mistakes and lack of continuity of care. Risks rated highest among health care professionals were; the lack of a national on-line medication platform, poor cooperation between primary and secondary care, that the same medication substance can have different trade names, stress, and lack of continuity of care. Most risks received similar rating regardless if it concerned diagnostic errors or medication errors.

Both patients and health care professionals rated continuity of care as a highly important factor for safer care. Perceived knowledge was mostly believed to be important from the patients' perspective. There was a difference between patients and health care professionals regarding the importance of knowledge that was not seen regarding continuity of care.

The patients emphasised the importance of a nationwide online medication record, to be thoroughly examined and routines for what to do if tests were fine but symptoms persisted. To achieve better continuity of care, the professionals wanted the patients to have their own GP and that there were a restricted number of patients per doctor. From secondary care they wanted medication review and prescriptions before discharge and clarifications of responsibilities. The health care professionals wanted to use written individual plans for the diagnostic process, test-results and other information.

8 DISCUSSION

8.1 Main findings in relation to aims

There are some diagnoses that are more common than others when studying diagnostic errors in ambulatory care and those are cancer in PHC and fractures in the ED (Study I).

Patients with psychiatric diagnoses have higher risk to be a case of reported preventable harm or involved in a serious safety incident, and especially at risk for diagnostic errors (Study II).

Patients and health care professionals agree about the importance of continuity of care to make health care safer but many patients that have experienced preventable harm feel neglected (Study III).

Risks rated high among patients were experienced lack of knowledge of the doctor and lack of continuity of care. Risks rated high among health care professionals were poor cooperation between primary and secondary care, stress, and lack of continuity of care. As solutions patients prioritised information about what to do if tests were fine but symptoms remained, and that GPs should examine them thoroughly. Health care professionals prioritised better continuity of care by way of a personal GP with a restricted number of patients per doctor (Study IV).

8.2 Comparison with literature

The findings in Study I confirm findings in earlier studies that emphasise that diagnostic errors constitute a major problem in PHC and EDs [7, 8]. However, this study provides new information on the diagnoses that are most frequently involved. When it comes to which diagnoses that are affected by diagnostic error, there are some data from PHC in the United States regarding cancer diagnoses [45]. In our material colorectal cancer is the most common type of cancer while prostate cancer was reported as most common in the United States study. In the ED, the diagnostic distribution of missed diagnoses was similar to those of earlier studies [46], regarding fractures; however, our study provided more detail on the types of fractures.

In Study II it is shown that patients with psychiatric disease have an increased risk to be a reported case of preventable harm or to be involved in serious safety incidents. Previous studies have shown that patients with psychiatric diagnoses are at higher risk of patient safety events [48]; however, these studies mostly included patients with schizophrenia and were conducted within the United States hospital setting, a setting that may not be generalisable to European conditions. In the present study, we included all psychiatric diagnoses in a European setting of first-contact care.

We show that all kinds of psychiatric disease, in an ambulatory setting, are associated with higher risk of harm. To our knowledge, the type of harm affecting the patients with psychiatric diagnoses in PHC has not been studied previously. In this study harm is mainly somatic harm and for the most part due to diagnostic errors of somatic disease. Several large studies have confirmed that people with mental illness die prematurely and have higher rates of comorbidities than the general population [55, 56]. One reason for this may be "diagnostic overshadowing", a process by which physical symptoms are misattributed to mental illness [57].

It could be argued that risk of harm could increase if a patient seeks health care often and therefore is more exposed to health care, for example because of high morbidity. However, patients with psychiatric illness seek health care later than other patients, resulting in more advanced disease by the time of diagnosis [58]. In our study, the most common type of harm in this group of patients was diagnostic error, which should be less likely if the patient presents later, with more evident symptoms.

In Study III and IV we explore beliefs of different groups of health care professionals in PCH and the beliefs of patients who have experienced preventable harm. Clinician views have been studied earlier to some extent [50, 59], but patient views are more sparsely studied [60]. Particularly unique was the opportunity we had to study patients with experience of preventable harm.

In Study III, the patients conveyed that they felt neglected during the patient-provider encounter, that they were not listened to and that there should have been a better physical examination. This can be seen as an aspect of communication and has not been researched in detail before. However, studies from PHC have shown that the safety climate and openness of communication had the largest potential for improvement [61]. Maybe health care professionals did not communicate why specific examinations, diagnostic tests or x-rays were not made, thus failing to create a shared understanding in the patient-doctor encounter. Patients also experienced lack of medical knowledge as a major risk while health care professionals did not emphasise that aspect. It is possible that the experienced lack of knowledge also could reflect poor communication; that the clinician has the knowledge but that is not communicated to the patient. Health care professionals did identify lack in knowledge in colleagues as a potential problem, but not that they lacked knowledge themselves. This might reflect the "blind spot bias" [62, 63] - it is difficult to see your own shortcomings.

The health care professionals and the patients understood many of the risks as caused by poor continuity of care. That is in accordance with earlier studies that identified continuity issues such as poor communication between primary

and secondary care, and suggested standardised discharge summaries and more rigorous systems for follow-up of abnormal test results [50, 59]. Lack of continuity of care in PHC has been raised as a serious threat to safe care [64]. Furthermore, good continuity has been shown to result in fewer hospital admissions [65, 66] and lower mortality [67].

In Study IV, the same areas were pointed out as in Study III. Lack of continuity of care and poor communication were rated as important risks, which is in alignment with previous studies [51, 65]. Stakeholders' priorities concerning patient safety risks and solutions have received little attention so far, especially in patients exposed to preventable harm. Some studies including GPs and patients have suggested interesting patient-centred recommendations for improving patient safety, including patient-centred communication, timely appointments, active monitoring, teamwork and better work environment [51, 52], but these suggestions did not specifically come from patients that had experienced harm in PHC. In the present study, patients who had experienced harm considered lack of physician knowledge as a problem and wanted the doctor to examine them thoroughly. Health care professionals ranked risks and solutions with some similarities to a dataset from the UK [50, 59], like poor cooperation between primary and secondary care. The current study also points out the risk of lack of a national on-line medication platform and the need for clarification of the mission of PHC with a maximum number of patients per doctor.

8.3 Methodological considerations

Methods used in patient safety research include studying of malpractice claims and other patient-reported incidents, incident reports from health care, root cause analyses, chart reviews, questionnaires and interviews. Since each method only can answer some types of research questions, combining different methods can give a better understanding of a problem [68]. Mixed methods approach is therefore used in this thesis. This section intends to add to the methodology discussion offered in the separate studies, not repeating them. All methods and studies suffer from limitations and research has unfortunately showed poor reproducibility [69].

8.3.1 Study I and II

8.3.1.1 Choice of study design

Study I, of the diagnoses involved in diagnostic errors, was a cross-sectional study using a historical cohort. The design is suitable for estimating prevalence of a condition. It is also relatively cheap and easy to perform. The method was used because it could give a good description of which diagnoses that were

involved in diagnostic errors. However, a cross-sectional study only provides a snapshot of reality, even if the material for our snapshot was collected for six years.

Study II, regarding which patient-related factors that could increase the risk of harm, was a case-control study. A case-control study is still an observational study by design, but are particularly suitable for studying risk factors associated with rare conditions (like reported preventable harm) [70]. There is no need to worry about loss to follow-up and associations can be established. It will have better scientific value than a cross-sectional study because matching to controls is possible. The method was used to be able to tell if there were any factors in the patients that were associated with an increased risk of being a reported case of harm or involved in serious safety incidents.

8.3.1.2 Limitations

A disadvantage with an observational design like a cross-sectional study is that the patient cannot be followed longitudinally and causation cannot be inferred [71]. Case-control studies are also observational studies. The causal component is difficult to establish even if a cause-effect relationship between risk factors and disease many times are inferred from the results in these kinds of studies. Cross-sectional and case-control studies are susceptible to bias because of the retrospective nature of the data and the lack of control that the researcher has over items of interest.

The two nationwide registries earlier mentioned were used. Regional registers exist but we did not have access to those which is a limitation. Reported cases are also known to be "the tip of the iceberg" [72], and might not be representative of all cases. Harm from surgical or other visible injuries are easier to detect than for example a delayed diagnosis. In our material from ambulatory care harm from surgery was not common; however, if the cases had been collected via record reviewing, we could have acquired a broader sample of harm. Unfortunately, record reviewing is labour intense and since we were interested in serious harm, which is considered a rare event, using data based on reported harm seemed appropriate.

Selection bias can be an issue when the material should be a representative sample of a larger population. Our population had experienced serious preventable harm or been involved in serious safety incidents in contact with PHC or the ED. We used the mentioned nationwide databases and the selection bias consists of which cases have been entered into the databases. There is probably a systematic skew toward the more serious cases of harm and there are many cases that are probably never reported, both serious and not so serious.

A major limitation in the case-control study is that there is no nationwide source of diagnoses from PHC, so we had to use the diagnoses from secondary care, including hospitals and specialised out-patient care. The diagnoses included those from psychiatric out-patient clinics. This results in a lack of the mild cases, that has never received a psychiatric diagnosis outside of PHC.

Another draw-back is that the data for Study I and II were not originally collected for the studies. They were incidents of harm or risk of harm, reported from patients and from health care. This fact results in the obvious draw-back of the structure and content of the material. We had to adjust the research in part by what information was available, for example there was seldom data on characteristics of the health care professional involved in the incident. Moreover, from the health care-reported data, we only used the data from PHC, not the EDs. The data from health care-reported incidents was not delivered in digital form and to convert the information to digital form was very labour intense, so we limited our efforts to PHC. The setback of that being that we did not have as much information from the EDs as from PHC, making conclusions harder to make with regards to the EDs.

8.3.1.3 Strengths

The mentioned limitations were, to some extent, mitigated by the large material of cases through national registries that represented all of Sweden, and a large number of controls that enabled statistical power. Confounding bias is not in place in Study I, since we have a descriptive cross-sectional study where we do not generate hypothesis about causes. We do not test associations between exposures and outcome. Information bias refer to the collection of information about the cases included in the cross-sectional study. Using standardised and validated methods is important. The information we collected were age, sex, diagnosis, if harm had been experienced in PHC or in the ED and type of harm. None of that information was collected by self-reporting, like answering a questionnaire, but rather collected from data entered in the databases by trained professionals using the electronical health record. The information bias in the study should be acceptably low.

Ascertainment bias occurs when there is inaccurate ascertainment of the disease/event of interest. In our study, that would be the ascertainment of preventable harm and type of harm. The coding of type of error was made by trained health care professionals working with patient safety which hopefully mitigated that bias. Description of how the evaluation of preventable harm was supposed to be done was well defined and was recorded with International Classification of Diseases version 10 (ICD-10) codes. The inter-rater reliability was 92%.

The validity in the case-control study (Study II) is dependent on the representative selection of both the cases and the controls. In this study, the cases are those in the nationwide databases, with the limitations mentioned above. The controls were matched for sex, age and residential area, and came from the same cohort, the nationwide data of residents in Sweden. It is important in case-control studies that controls come from the same cohort so that they have the same chance to be detected as cases. The residential areas were small, about 1000 inhabitants per area. We also used 10 controls per case to strengthen the design.

The association between patient-related factors and reported safety incidents, was estimated by OR, using conditional logistic regression models for the matched case–control data. OR is preferred because it quantifies the strength of the association, in relation to other factors in the study. We looked at crude as well as adjusted analyses. The crude analyses were interesting because when we meet patients, they are "crude", they are not "controlled" for different factors. Therefore, if patients with psychiatric disease experience an even greater risk of harm if they have low income and low education, that information might not help you if you do not ask those questions in the clinical setting.

The learning opportunities from Study I and II, being observational studies, are not as great as would be potentially possible with an experimental design. However, when experimental designs are not possible or ethical, good lessons can be made from observational studies.

8.3.2   Study III

8.3.2.1   Choice of study design

Study III, regarding what health care professionals and patients thought of safety risks in PHC, was a qualitative study. It was based on free-text answers to a structured questionnaire with open-ended questions and the answers were analysed qualitatively with content analysis. Qualitative research is an exploratory scientific method. It gathers non-numerical data, it describes and relate meaning. The learning that can come from qualitative research is of great value and detail. Qualitative methods can answer questions that quantitative research cannot and can give a nuanced picture of a problem, such as what factors and circumstances that may lead to an error. The qualitative base was appropriate for the research question, to find out the views of patients and health care professionals. Qualitative methods have better possibilities to understand the context of a problem and are more flexible for an exploratory analysis of a problem [73].

8.3.2.2 Limitations

A disadvantage of content analysis is that it is time consuming. The method chosen was adequate for the research question but if focus groups or interviews had been made, solely or in combination with the questionnaires, more information could have been obtained.

The subjectivity that is in the nature of qualitative research can make it difficult to detach from the data and to avoid bias. Bias will lead to a distortion of reality and affect the validity and reliability of findings, described below [73]. There are two main types of biases in qualitative research, participant bias and researcher bias. Participant bias stems from that the participates/respondents respond to the questions based on what they think the right answer might be or what is socially acceptable (social acceptability bias), rather than what they really think. It is important that the questions are formulated so that the participants feel accepted no matter what they answer. Moreover, there can be a friendliness bias meaning that participants may agree to questions to complete an interview. The friendliness bias can be mitigated via open-ended questions. There can also be a habituation bias when participants provide the same answers in response to similarly-worded questions. Finally, there can be a sponsor bias if the participants are opinionated about the sponsor of the research. The researcher needs to maintain neutral when formulating the questions.

Researcher bias is when the researchers unknowingly interpret data to meet a hypothesis or only include data that they think is relevant, called confirmation bias. The researchers strengthen what they thought in the first place [73]. Furthermore, the researchers can introduce bias through the order the questions are asked, called question-order bias. Participants can judge and compare questions based on their response to earlier questions. It is important to ask general questions first and specific questions later. Finally, leading questions and wording bias can affect the answers and it is important to keep the questions simple and avoid words that could introduce bias. Furthermore, the researchers need a deep knowledge of the problem domain, and at the same time have understanding of how the pre-knowledge can affect the analysis [73].

A limitation in this study was that the patients and the health care professionals did not receive the exact same questionnaire, which may reflect a lower dependability of our study. We chose different questions because we thought that it would be easier for the patients to respond if they reflected over the harm that they had experienced. In the use of a written questionnaire we received a material that was not with as much depth as focus groups or interviews probably would have been.

8.3.2.3 Strengths

The method is reductive but can at the same time obtain information at a higher logical level. Furthermore, the method can disregard the context that produced the text which we tried to mitigate, by only using researchers that work in the same setting (e.g. PHC). We recognised the possibility that the researchers pre-understanding might have affected the analysis and might have added meanings, not actually justified by the data. The pre-understanding can enable, but also restrict, the learning that can result from such a study. The coding was validated via the senior researcher in the team who coded part of the material without knowledge of earlier coding by the other two researchers. With the answers received, we did see saturation; that new areas were not mentioned in the end of the analysis, strengthening the value of the study and making the findings more relevant to use. We studied the same context, e.g. PHC, that we wished to learn more about.

To keep the participant bias low, we used open-ended questions. The social acceptability bias is probably low in these kinds of questions regarding patient safety. The friendliness bias is thought to be low since the questions were not formulated so one could agree. Moreover, sponsor bias is probably low since the study was supported by the Region Stockholm which is the care deliverer in the region.

Researcher bias is always in place in qualitative studies. The answers by the respondents are to be grouped and analysed objectively but the researcher has a preunderstanding that can be difficult to separate oneself from. To mitigate that bias there were three researchers working with the material and discussing meaning of the answers. Question-order bias could have been in place since we did have the most general question last. We did in the last question to health care professionals, however, ask "Please give other suggestions on how to reduce the risk of patient harm in primary care (within all areas)". We tried to avoid leading questions with the use of open-ended questions.

Recruitment of participants is one of the strengths of the study. Patients that had experienced harm were recruited randomly from the patient-reported registry. The health care professionals all worked in the Region Stockholm which includes rural as well as urban areas with different distance to health care. The health care professionals included physicians as well as nurses and practice managers to broaden the perspective.

We took inspiration from earlier questionnaires that were conducted for the same purpose and we discussed with the authors about their reflections of advantages and disadvantages of their study design [50, 59]. In these previous studies, the authors tried to use their questionnaire not only to health care professionals but

also to patients. However, they were unable to use of the answers because the patients did not seem to understand the questions that were asked. Therefore, we asked our patients what they thought of their personal experience of harm. We had the advantage of having a sample of patients that had experienced preventable harm due to a diagnostic error or a medication error in PHC. We received valuable answers with the draw-back that the patients did not answer the same questions as the health care professionals did. A limitation we created ourselves was that we excluded patients that had passed away due to the harm. We choose to do so, as it could be emotionally difficult for the relatives to be approached with the questionnaire.

8.3.3 Study IV

8.3.3.1 Choice of study design

In Study IV we asked patients and health care professionals to rank specified risks and solutions to patient safety issues. The method of a survey study is adequate when the opinions or thoughts of many people are needed. The survey was created so that the answers could be statistically processed.

8.3.3.2 Limitations

In this study there was a low response rate (26% for health care professionals and 19% for patients), which limits the possibility to draw conclusions from the material. The persons that do not respond to a survey usually differ significantly and systematically from those who do respond. Instead of spreading a link to the survey we chose to collect e-mail addresses and have a known response rate, that unfortunately became low. In the group of health care professionals, we sent out two reminders but in the patient group we only sent out one reminder, out of respect for those not wanting to be reminded of the harm experienced.

Response rate is of great importance in survey studies. The response rate in survey studies has dropped over the years which is unfortunate, but low response rates do not always correlate to lower study validity [74]. Most important with a high response rate is when the material needs to be representative of a larger population in order to yield useable results. In this study we explored the opinions of patients and health care professionals, and the portion that answered has probably thought more about these issues of safety than those that did not answer. The results point to where focus and resources might best be directed and therefore the low response rate might not affect the validity as much as in a purely epidemiological study. However, the low response rate is a major limitation and the survey needs to be further tested in a setting where better response rate is to be expected.

Sampling bias is related to the way the respondents are selected. In our survey we chose patients randomly and nationwide but used a convenience sample for health care professionals. However, we tried to have health care professionals with representation from the whole country. A type of response bias can occur if a survey has many questions, there can then be a fatigue at the end that can make the reliability of the last answers lower. There is also an increased risk that respondents do not follow through and answer all questions. In the survey the patients had 15 questions (rating risks and options) and the health care professionals 42, posing an evident risk for being too extensive.

Habituation bias can have affected the answers since there were questions formulated very similar but dealt with diagnostic errors or medication errors. Another response bias is that responders might want to answer the most "correct" answer, called demand characteristics bias. In our survey the questions were not formulated to imply a correct answer but there was a possibility that some respondents felt that they should rate every problem high. The questions could have been formulated in a different manner, like 10 problems and you can only rate one of them a 10, one a 9, one an 8, and so forth, forcing the respondents to rank the problems compared to each other.

In this survey we first asked how big they thought a problem was, then they were to rank possible solutions by drag-and-drop for that problem. Then we went on to the next problem. When we had asked about all problems regarding medication we asked in the same manner about diagnostic errors. The respondents might have been affected by what they had answered in the part about medication and had a bias to similar responses about diagnostic errors. The questions could have been randomised but then there would have been a risk that the respondents would not be clear about if the question was about medication errors or diagnostic errors. The solutions that were to be ranked are written in an order and there is a risk in online surveys that option that you read first is picked more often.

8.3.3.3 Strengths

The face validity of a survey is of course crucial. The questions used in this survey was constructed on the base of the qualitative study (Study III) to support the relevance of the questions. The response rate was low but the more respondents there are, the more likely that valuable information can be obtained, and we had over 1000 respondents so the results could point toward areas for further research. However, the survey needs further validation.

8.4   Implications for health care

Thomas and his colon cancer, described in the prologue, can be seen as a synthesis of what the studies in this thesis portrait. We are part of a complex system where some groups of patients are extra vulnerable. The individual patient might not be resilient, and our system has flaws and fails sometimes to help our patients. Thomas had colon cancer, but the diagnosis was delayed. He had a history of depression. He felt neglected. The doctor felt stressed and no rectal examination was made. There was a lack of continuity of care. Thomas did not receive advice about what should prompt him to come back. No one looked at the lab results that arrived after the doctor had moved to the next practice. The result showed anaemia, but no one noticed.

To work proactively with safety and strengthen continuity of care can already be recommended (Study III-IV) and other studies [64]. Specific diagnoses, like colorectal cancer, were seen to be common among serious diagnostic errors (Study I). Possible ways to improve safety and resilience could be the use of a clear and written plan for follow-up, with advice on what to do if symptoms persist, so called safety-netting [75], and a personal GP with a restricted number of patients per doctor to facilitate continuity of care (Study III-IV). There could also be taken measures for reducing the risk of diagnostic errors for patients with psychiatric disease (Study II), maybe a contact nurse for this patient group to improve patient centred care and lower the risk of no-shows during follow-ups. These measures could be tested as ways to make the diagnostic process more resilient. Different solutions are probably needed in different settings, but system improvement will be required [9].

Some new knowledge needs more studies to validate the findings before implementation and other knowledge is ready for practice. To implement best evidence is usually done by QI efforts but it can be hard to conduct QI in PHC because of stressful environment and lack of knowledge [76]. Furthermore, the plasticity and complexity of the health care system make work in QI and patient safety difficult. The context and the demands change constantly, and it is of great importance that we build resilient processes and implement solutions for safer care, preferable in co-production with patients.

Resilient solutions regarding safety and other improvements could be described as a boat ride (Figure 3). In the boat we have the patient and the health care professionals (in reality they are in plural). Together they embark on the journey of QI for a safer care. However, they need to be aware of other boats (other QI projects), navigation marks, buoy beacons (possible ways to navigate) and rocks in the sea (obstacles).

The wind is blowing from the north (disturbances, external pressures of management, budget cuts and to see many patients per day) and from the south (contradicting goals, to follow evidence-based medicine and deliver person-centred, high quality care). The passengers on the boat need to design improvements that will work, that will sustain and endure in this context. Sometimes the wind is stronger than usual and might change direction quite sudden. To add life wests to the passengers could keep them safer (and more resilient). The life wests could represent good work environment with the necessary slack to be able to bounce back from different kinds of strains.

The first step in QI-work is to map the practice/hospital ward/ ED. The mapping is usually focused on which health care professionals there are, which patients come there, what the purpose of the work is and what the processes and the patterns are (including the results). With the glasses of resilience and work-as-done this mapping will have to be done somewhat differently. Apart from a deep understanding of the WAD, there also needs to be an understanding of what pressures and incentives that exist. The rest of the QI journey also needs the be dealt with through the lens of resilience to lead to sustainable results.

Figure 3. The journey of quality improvement for a safer care

Different kinds of patient factors, doctor factors and system factors are variables that float around in our three-dimensional system of care. To be resilient we need to recognise WAD and that we all make mistakes, despite our good intentions. Our own shortcomings can be particularly hard to see since we seem to have a filter function disguising them, called the blind spot bias [62]. Are we willing to see our own part in the system, contributing to errors, even though tradition and culture tell us that health care professionals are supposed to be correct and have all the answers? PHC is so diverse so working with safety can pose certain challenges. While it is possible to use check-lists in an operating room, not much of PHC can be standardised enough for check-lists to work. The approach of resilience and safety-II is more applicable in this setting.

8.5   Implications for research

Clinical cognition is not fully understood and needs further exploring. More research is needed to clarify how our medical reasoning and decision-making works, and when and why they may fail. Under what circumstances do medical reasoning work at its best? Probably not a single clinician at a time. Different kinds of team work seem to enhance the ability for good medical decision-making.

These studies have several implications for future research in the area. Diagnostic error is the most common serious safety event in PHC, and the time is ripe for action research. Solutions that use modern information communication technology and maybe artificial intelligence could be interesting. Electronic health record-based triggers can already be used to detect potential delays in cancer diagnosis [77, 78].

Transition of care, and fragmented information in large, put the patients at risk of harm and as seen in this thesis, patients with psychiatric diseases are at extra high risk. Both continuity of care and patient engagement can be ways to make care safer and more resilient. The action research should maybe start there. The diagnoses with the most severe consequences for the patients should be prioritised, seen to malpractice claims in the United States that was cancer, vascular events and infections [79]. In the PHC setting cancer was the most common among serious diagnostic errors [12].

The risk for diagnostic errors could be mitigated through improved diagnostic safety-netting, defined as "Information shared with a patient or their carer designed to help them identify the need to seek further medical help if their condition fails to improve, or if they have concerns about their health" [80]. Primary and emergency care will always deal with a high degree of uncertainty and to involve the patients and their carer in safety-netting could be a

way to increase the resilience of the diagnostics process. The safety-netting advice should include the existence of uncertainty, what exactly to look out for, how exactly to seek further help and what to expect about time course [75]. Implementation of structured safety-netting advice could be a way to improve communication and shared situational awareness. There is some research about preferred structure [81, 82], but action studies are needed both to evaluate how to implement safety-netting and the effect of properly applied safety-netting advice [83].

There have been studies trying to reduce diagnostic errors well described in a review article from 2019 [84]. Quite a few studies in the ED setting have been performed, including computer assistance or checklist via an audit system, with effect in some of the studies [85, 86]. However, few studies have been performed in PHC. Checklists have been tried in PHC without convincing results [87]. In one study there was a decrease in loss-to-follow-up via a computerised trigger system [88]. There have been attempts with early diagnostic suggestions in the electronic health record [89, 90], and regarding medication errors there has been studies of educational training, structured process change, review methods, and patient education [91]. To our knowledge, no intervention has had a wide spread.

9   CONCLUSION

Our findings indicate that the most frequently missed diagnoses were cancers in PHC and fractures in the ED. Patients with both mild and severe psychiatric illness were at higher risk of preventable harm in first-contact health care. Patients, as well as health care professionals, understood risks and how to reduce risks as related to three main categories: continuity of care, communication and competence. As solutions patients prioritised routines for what to do if tests were fine but symptoms persisted, the use of a nationwide medication platform on-line and that the GP should examine them thoroughly. Health care professionals prioritised better continuity of care by way of a personal GP with a restricted number of patients per doctor, and to improve communication with patients by using individual written plans.

These studies support future work for a safer and more resilient health care with a more proactive approach. There are suggestions from the level of the GP practice up to the national level. With focus on continuity of care, better communication and knowledge, solutions can be tested. In addition, the inclusion of the perspectives of patients and health care professionals could increase the possibility of developing and implementing relevant counter-measures for safety risks in PHC. The solutions that patients and health care professionals prioritise and agree on should probably be tested first.

Still, more research is needed to explore effective interventions for safer care. When new types of solutions for better and safer care are tested, they need to be thoroughly studied and evaluated. The next step could be to test interventions that proactively support a system in improved accuracy in diagnosis and correct medication, for example, an intervention to improve continuity of care [67] or practice safety-netting [83]. That could probably improve the resilience of the system in question.

10   EPILOGUE

This journey has been valuable for me in many ways. I have had the time to deepen my knowledge within patient safety and to work with interesting people in numerous projects. I have gained new perspectives on safety while I have learned about the scientific field. Hopefully, I have contributed to the field and become a better doctor during the process. I believe that health care is currently stepping up regarding the issue of safety in PHC and the ED. I am excited to see what the next decade will bring.

11   SVENSK SAMMANFATTNING

Patientsäkerhet innebär skydd mot vårdskada. Den här avhandlingen handlar om patientsäkerhet och använder resiliens som perspektiv. Resiliens innebär att ha ett systemperspektiv och att inte bara lära av vad som går fel, utan framför allt lära av vad som går bra för att göra sitt system säkrare. På så sätt arbetar resilienta system proaktivt med säkerhet. Den här avhandlingen bidrar till forskningsfältet genom att studera patientsäkerhet i primärvård och på akutmottagningar, och den nya kunskapen skulle kunna användas för att göra vården säkrare.

Vi undersökte allvarliga vårdskador och risk för allvarlig vårdskada i primärvården och på akutmottagningar, och kunde konstatera att diagnostiska fel var den vanligaste kategorin. Med diagnostiskt fel avses att en patient inte fått rätt diagnos i rimlig tid för att kunna få adekvat behandling och att det ska ha funnits uppenbara möjligheter att ställa rätt diagnos. Den finns en kunskapslucka gällande vilka diagnoser som vanligen berörs när det kommer till diagnostiska fel. I vårt material var cancer vanligast i primärvården och frakturer var vanligast på akutmottagningarna (studie I).

Vi studerade sedan vilka patientrelaterade faktorer som var associerade med ökad risk för rapporterad vårdskada, eller risk för allvarlig vårdskada, i primärvård och på akutmottagningar. Vi fann att patienter med psykiatriska diagnoser hade en ökad risk att drabbas, framför allt i form av försening av allvarliga somatiska diagnoser (studie II).

Den sista delen av avhandlingen handlar om vad patienter och personal anser vara de största riskområdena inom primärvården och vilka lösningar de skulle föredra. Gällande risker framträdde kontinuitet, kommunikation och kunskap som de viktigaste att förbättra. När det kom till lösningar lyftes vikten av information om vad man ska göra när prover och undersökningar är bra men symtom kvarstår, en nationell digital läkemedelslista som såväl vårdpersonal som patient och apotek kan logga in på, och en egen husläkare med listningstak för en förbättrad kontinuitet (studie III-IV).

Dessa studier stöder fortsatt arbete för en säkrare och mer resilient vård. Resultaten i studierna ligger till grund för förslag från vårdcentralsnivå upp till nationell nivå. För att underlätta implementering och för att öka chanserna för goda resultat kan de lösningar som patienter och personal var överens om testas först, gärna i former av medskapande med patienter. Fokus bör ligga på kontinuitet, förbättrad kommunikation och kunskap. Nästa steg skulle kunna vara att testa interventioner som proaktivt stödjer system till förbättrad diagnostik och korrekt medicinering, till exempel en intervention som stärker kontinuitet eller som använder sig av specifika råd för när, var och hur man bör söka vård på nytt (safety-netting). Sådana proaktiva interventioner skulle antagligen öka resiliensen i det aktuella systemet.

12   ACKNOWLEDGEMENTS

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