Summary

Background and aims of the study

Diagnostic error in medicine is an important topic in the field of patient safety. In the international literature, it is estimated that diagnostic errors occur in 5-15% of the patients admitted to the hospital. Diagnostic errors are more often considered to be preventable and are more severe than other error types. Furthermore, it turns out that out of all medical error types, patients are the most worried about getting misdiagnosed, since being misdiagnosed often means receiving an incorrect treatment on top of missing out on the correct treatment. In order to be able to reduce the number of diagnostic errors in medicine, studying the causes is a prerequisite. Existing studies have shown that the causes of diagnostic errors are mostly cognitive, however system related causes also play a role.

Although the research in the field of patient safety has increased substantially over the last decade, research on diagnostic error received comparatively little attention. This could partially be explained by the complexity of this error type and the difficulty to study diagnostic error. Furthermore, diagnostic errors are not easily reduced by implementing widespread interventions in the health care system, because it is mostly cognitive factors that underlie diagnostic errors. Both the high preventability and the severity of the consequences indicate that diagnostic errors are a particularly important error type to study and to develop interventions against.

The main aim of the studies described in this thesis is to provide insights in the diagnostic reasoning process and diagnostic error.

1. The incidence of diagnostic adverse events are studied and the causes are compared to the causes of other adverse event types.
2. Faults in the diagnostic reasoning process of dyspnea patients are studied. The weaknesses are related to the occurrence of diagnostic errors and patient harm and their causes are examined.
3. Selective information gathering and selective information processing in the diagnostic reasoning process is examined and related to the occurrence of diagnostic error and patient harm.
4. Subjective workload and work experience are related to adverse outcomes in the diagnostic reasoning process. Furthermore, the factors influencing subjective workload are explored.
5. The application of an evidence-based decision rule to diagnose patients with a suspicion on pulmonary embolism.

Methods

Record review study 1

Two record review studies were conducted to answer the research questions. The first record review study involved a three-stage record review study carried out in a stratified random sample of 21 Dutch hospitals. The review method to determine the occurrence of adverse events was based on previous international adverse events studies. With a standardized electronic review questionnaire, the patient records of 7926 patients were reviewed. Nurses determined whether there were triggers for adverse events, and subsequently two independent physicians reviewers determined whether an adverse event had occurred as well as the type of adverse event, the degree of preventability, the causes and the consequences for the patient. In the 7926 patient records, 744 adverse events were identified of which 80 were diagnostic adverse events. The diagnostic adverse events were compared with the other adverse event types on the incidence, causes, preventability and consequences.

Record review study 2

In order to obtain more specific insights into the diagnostic reasoning process a second more elaborate research method was developed, including a patient record review focused on the diagnostic reasoning process of dyspnea patients and diagnostic error as well as data about the reasoning process, subjective workload and work experience.

With a Delphi method, the optimal diagnostic process for patients with shortness of breath (dyspnea) was determined. Based on the optimal diagnostic process a questionnaire was developed which was used to review the patient records of the dyspnea patients. In total 247 patients were included in the study by the treating physicians. Physicians indicated the initial differential diagnoses and their perceived workload after deciding to admit the patient to the hospital. After discharge the patient records were reviewed by expert internist, identifying faults in the reasoning process as well as diagnostic errors and patient harm. Subsequently, the treating physicians were interviewed about the faults in the reasoning process. Based on the record review and the interviews, the causes of the reasoning faults were determined and classified by the model of unsafe acts of James Reason. This model distinguishes intended and unintended actions. Intended actions included mistakes (the intended action was incorrect) and violations (deliberate deviations from the protocol). Unintended actions

involved slips (unintended deviation from a correct plan) and lapses (unintended deviation from a correct plan due to memory failure). In addition, record errors were distinguished (an action was performed correctly but not noted down in the patient record).
Furthermore, the work experience of the treating physicians was acquired.

Main findings

What is the incidence rate of diagnostic adverse events and how do the consequences, the preventability and the causes compare to other AE types?

Chapter 2 describes the results of a population-based study on the occurrence of diagnostic adverse events in hospitals in the Netherlands. In 0.4% (95% CI: 0.21- 0.59%) of all patients admitted to the hospital, the patient was harmed due to a diagnostic error. Diagnostic adverse events involved a substantial proportion of all adverse events that occurred in the Netherlands (6.4%, 95%CI: 4.3- 8.5%), especially of the preventable adverse events (13.4, 95%CI: 8.4-18.4%). Diagnostic adverse events were considered to be preventable in 83.3% of the cases (95% CI: 70.4- 96.2%), which was significantly more often than for other adverse event types. In addition, the consequences of diagnostic adverse events were considered to be more severe than for other types of adverse events, i.e. higher mortality-rate.
In the large majority of the cases a human cause was present (96.3%, 95% CI: 92.0-100%). In particular, compared to other adverse event types knowledge-based causes occurred frequently as well as causes involving insufficient assessment of the situation before taking action (31%) and insufficient monitoring of the patient during the whole process (22%).

What are the most common faults that occur in the diagnostic reasoning process?

a) What reasoning faults occur in the diagnostic process?

The results described in Chapter 4 described a study of a more complex and vulnerable patient group. The diagnostic process of patients presenting with shortness of breath (dyspnea) was followed using a record review which was specifically developed to study the diagnostic reasoning process. This study showed that in 66% of the cases, faults in the diagnostic reasoning process occurred, for example not all relevant information was gathered during the history taking and physical examination, too many or insufficient laboratory

results were requested. These faults most often occurred in the data-gathering stages of the diagnostic process, i.e. history taking, physical examination, application of laboratory test and additional tests and biopsies.

b) What are the causes of those faults?

Each of these faults was discussed with the treating physician and the causes were classified with Reasons model of unsafe acts. Mistakes (58%) occurred most frequently, meaning that physicians thought they were acting correctly, but in fact were not. Slips, failure in executing a task you intended to do (14%) and lapses, forgetting to perform an intended task (12%) occurred regularly as well. Violations, deliberate deviations from the protocol, were rare (4%). In addition, record errors (when physicians did perform a certain test/examination, but did not note it down in the patient record) occurred in 12% of the cases.

c) What are the (possible) consequences of diagnostic reasoning errors?

Fortunately, in most cases reasoning faults did not lead to a diagnostic error or to patient harm, although when more of reasoning faults occurred, the likelihood of a diagnostic error and patient harm increased significantly. Cases with both a diagnostic error and patient harm, which are comparable with diagnostic adverse events, occurred in 3.2% (95% CI: 1.0-5.4%) of the patients who were admitted to the hospital with dyspnea. Diagnostic errors occurred in 13.8% (95% CI: 9.5-18.1%) of the cases, while the patient was harmed in 11.3% (95%CI: 7.4-15.2%).

To what extent does selectivity in the diagnostic reasoning process occur and what are the consequences?

In the diagnostic reasoning process the occurrence of cognitive biases is expressed as selective information-gathering and selective information-interpretation. Chapter 5 studied the extent to which physicians are selective in their diagnostic reasoning process. During the diagnostic process, physicians were often selective in their information-gathering and information-interpretation (45.7% of the cases 95%CI: 39.5-51.9%). Physicians often focused one main diagnosis while insufficiently ruling out other possible diagnoses or co-morbidity. Selective information gathering occurred most often (33.2%), while selective information-processing most often led to diagnostic errors with and patient harm. Not considering a correct diagnosis early in the reasoning process was related to more diagnostic errors. In addition, physicians were less likely to consider abdominal diseases (e.g. appendicitis) than thoracic diseases (e.g. pneumonia) when patients presented with dyspnea. Abdominal diseases were more likely to get missed.

What is the relationship between workload, work experience and faults in the diagnostic reasoning process, diagnostic error and patient harm?

Chapter 6 studied the influence of subjective workload and physicians' work experience on faults in the reasoning process and adverse outcomes i.e. diagnostic errors and patient harm. In an everyday clinical setting, workload and work experience were both significantly related to the occurrence of adverse outcomes, i.e. diagnostic error and/or patient harm (workload: p=0.01and work experience p=0.017). Interestingly, irrespective of the physicians work experience, all physicians were affected by the subjective workload and more adverse outcomes took place. Conversely, the occurrence and the number of reasoning faults in the diagnostic process was not significantly related to different levels of workload and work experience.

Are evidence-based diagnostic decision rules applied in order to diagnose a patient with a suspicion on pulmonary embolism?

The use of evidence-based decision rules to support physicians during the diagnostic process is increasing. For diagnosing pulmonary embolism, a validated decision rule was developed by the Christopher research group and is implemented in the Netherlands.[1] In the study described in Chapter 7, the use of this evidence-based decision rule was investigated in everyday clinical practice. In a majority of the cases, the evidence-based decision rule was not correctly followed (79% 64 out of 80 patients, 95% CI: 70-88%). In 51% (41 patients) no diagnostic tests or insufficient diagnostic tests were used and PE could have been missed. In 28% (22 patients) the diagnostic tests were not applied according to the Christopher decision rule. It seemed that physicians were following their own estimate of the likelihood to determine their diagnostic strategy as opposed to the evidence-based decision rule.

General discussion

Incidence of diagnostic error and the signal detection theory

Generally, international research showed that diagnostic errors occur in 5-15% of the patients.[2,3] Diagnostic adverse events occur less frequently because not all diagnostic errors contribute to patient harm although the population-based incidence rate had not been studied before. The diagnostic adverse events that were found in the population-based study (Chapter 2) represents the top of the

iceberg by only selecting cases in which the a faulty reasoning process by the physician, or technical or organizational failure led to a diagnostic error which harmed the patient. In addition, the selected sample was representative of the hospital population while in many other studies a subgroup with a higher risk on diagnostic error is studied.[2-4]

In Chapter 4, the reasoning process was studied in more detail and showed that not all faulty reasoning led to a diagnostic error and diagnostic errors were not always related to a faulty process.

In Figure 1, the diagnostic process is described in terms of the signal detection theory (see also Chapter 1). This theory shows how people make decisions under conditions of uncertainty. The signal detection theory assumes that under conditions of uncertainty the important information (signal) that the operator needs to detect is embedded in the irrelevant information (noise).[5,6] With this theory we can explain how in the study described in Chapter 4, faulty reasoning does not always affect the decision to diagnose a disease in such a way that it leads to diagnostic errors. A physician begins establishing a diagnosis by gathering information about the patient's symptoms and complaints. The amount of information (evidence for a particular diagnosis) that a physician needs to accumulate in order to decide that the patient has the disease, is called the threshold. The threshold for deciding whether or not a patient has a disease does not generally depend on one aspect of e.g. the history taking. On the other hand, when a patient presents atypically, the decision criterion (threshold for determining the disease is present) can be reached when the patient does not have the disease. This explains why a correct reasoning process can still lead to diagnostic errors, as was found in Chapter 4 of this thesis. Furthermore, throughout the whole diagnostic process several pieces of information are being accumulated and interpreted, and if this occurs incorrectly, a disease might go undetected because the threshold for establishing a disease (decision criterion) is not met.

The causes of diagnostic error

The findings described in this thesis indicated that lack of knowledge or inadequate application of knowledge plays a substantial role in the occurrence of diagnostic adverse events and diagnostic error. This suggests that in case of a diagnostic error, physicians did not have all the necessary knowledge available or they did not apply this knowledge correctly. This is however, not as straightforward as it seems, and there might be reasons why these knowledge-

based errors occur.[7] Underlying factors such as insufficient situational awareness, time-pressure and incomplete handovers might also play a role.[4,8-10] To be able to develop interventions to reduce diagnostic error, more specific factors on why physicians do not apply the knowledge they have, and what specific knowledge is lacking. Some of the factors influencing to the diagnostic reasoning process were addressed in Chapters 5-7.

Selectivity in the diagnostic reasoning process can be considered as a result of physicians being subject to cognitive biases. For the diagnosis that the physician is considering, the decision criterion becomes more liberal (high specificity, but low sensitivity) and this diagnosis is therefore more likely to be established by the treating physicians. Conversely, the decision criterion for the alternative diagnoses will be more conservative (low specificity, but high sensitivity) and those diagnoses are therefore less likely to be established by the treating physician. This argument is also supported by the interviews that we conducted with the treating physicians about the faults in the diagnostic reasoning process. They often stated that they did not to test for a certain disease because they already had a likely alternative.

Similarly the decision criterion to establish a diagnosis can be biased due to high levels of workload. When experiencing a high workload, physicians might adjust their decision criterion to a more liberal one e.g. they consider their working diagnosis more quickly as confirmed than in situations in which they have more time available to examine a patient.

In Chapter 7 we showed that the Christopher evidence-based decision rule for diagnosing pulmonary embolism is not correctly followed by physicians and that physicians tended to follow their own intuition rather than the decision rule. Not following a valid decision rule should only be done when there is a clear indication, such as not exposing a patient to a CTa when the patient has renal insufficiency, since the CTa might lead to more severe kidney failure. However, the physician should apply the evidence-based decision rule in the cases in which such a contraindication is not present since the decision rule would lead to the optimal number of correct diagnoses when applied to the majority of the patients.

Overall, physicians seem not aware of their reasoning faults and the biases that they are subject to.[11,12] This could be explained by overconfidence, which is a frequently mentioned problem in the literature of diagnostic reasoning and diagnostic error.[3,13] Particularly physicians with little work experience do not realize when they are wrong.[12] Therefore, possibilities to reduce reasoning

errors involve meta-cognitive training in which strategies such as, prospective hindsight, 'consider the opposite', and 'what diagnosis can I not afford to miss' are proposed.[3,14-16] Similarly, reflective practice in which physicians are critical of their own reasoning process might contribute to a reduction in diagnostic errors.[17] These strategies have not yet been widely implemented. The studies described in this thesis suggests that this is needed. The causes of diagnostic error and the factors that influence the diagnostic reasoning process show that the diagnostic process is a complex process and possibilities to improve this process should involve various interventions, both improvement strategies focused on the physicians reasoning process as well as implementation strategies and system changes.