

# **Patient safety in primary midwifery care**

**Lucie Martijn**

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For reasons of consistency within this thesis, some terms have been standardized throughout the text. As a consequence the text may differ in this respect from the articles that have been published.

The studies presented in this thesis have been performed at the Scientific Institute for Quality of Healthcare (IQ healthcare). This institute is part of the Nijmegen Centre of Evidence Based Practice (NCEBP), one of the approved research institutes of the Radboud University Nijmegen Medical Centre.

The studies described in this thesis (chapters 2 and 4) were financed by the Dutch Ministry of Health, Welfare and Sport (VWS) .

Financial support by the Scientific Institute for Quality of Healthcare (IQ healthcare) for the publication of this thesis is gratefully acknowledged.

ISBN: 978-90-76316-796

Nijmegen, 2013

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Cover design: Jolanda Tielens

Print: GVO drukkers en vormgevers B.V. | Ponsen & Looijen, Ede

# **Patient safety in primary midwifery care**

## **Proefschrift**

ter verkrijging van de graad van doctor  
aan de Radboud Universiteit Nijmegen  
op gezag van de rector magnificus prof. mr. S.C.J.J. Kortmann,  
volgens besluit van het college van decanen  
in het openbaar te verdedigen op woensdag 19 februari 2014  
om 12.30 uur precies  
door

Lucia Maria Martijn

geboren te Cuijk en Sint Agatha op 27 september 1964



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# **Chapter 1**

## **General introduction**

This thesis concerns patient safety in primary midwifery care, with a focus on low risk pregnant women. The introduction will first elaborate on the healthcare system for pregnant women in The Netherlands. Most studies about maternity care in The Netherlands report on its outcomes in terms of morbidity and mortality, but insight into the safety of the preventive and clinical processes is limited. This introduction will first provide a background in primary midwifery care and patient safety. Then the main research questions will be presented. Finally we provide a short overview of the content of the thesis.

## **Primary midwifery care in The Netherlands**

In most developed countries, hospitals have become the predominant setting for childbirth. The number of medical interventions in perinatal care has increased steadily over time, with positive and negative consequences. Many questions have been raised about the benefits, safety and risks for healthy childbearing women.<sup>1</sup> In many parts of the world, midwives are the primary providers of care for childbearing women. Midwifery-led care emphasizes the normality of birth and the continuity of care. Healthcare delivery models including primary midwifery care all comprise of a multi-disciplinary network of consultation and referral with other care providers.<sup>2</sup> In The Netherlands, midwifery care is mainly provided in a primary healthcare setting by teams of midwives in small office-based practices outside hospitals and close to the pregnant women's homes. Dutch midwives take care of the prenatal, birth and postnatal care for women with low-risk profiles based on their obstetric and medical histories.<sup>3</sup> Midwives refer a pregnant woman to obstetric specialists in a hospital when a high risk of complication is expected. They are trained to apply detailed protocols for risk assessment combined with clinical judgment. In The Netherlands, most referral arrangements are specified in an Obstetric Manual, which is a document based on best evidence or consensus between obstetric and midwifery caregivers.<sup>4</sup> In recent years, 20% of pregnant women received complete obstetric care in a hospital due to the detection of a previously defined high risk in their medical or obstetric histories. Some 80% of the pregnant women in The Netherlands had a low-risk pregnancy profile according to the Obstetric Manual and started their prenatal care in a midwifery practice and thus had the possibility of choosing the place of birth – either at home or in hospital with her own midwife.<sup>3</sup>

## **Patient safety**

Patient safety in healthcare has become a major concern worldwide. In essence, patient safety is absence of preventable harm to patients caused by healthcare provision. Many definitions of patient safety have been proposed. The World Health

Organization defines an 'adverse event' as *a process or act of omission or commission that resulted in hazardous healthcare conditions and/or unintended harm to the patient*. A patient safety incident is defined as *an unintended event during the care process that resulted, could have resulted or still might result in harm to the patient*.<sup>5</sup> This latter broad definition includes both unnecessary real and potential harm in the patient; this definition has been used in this thesis.

When an adverse event has occurred, a significant event analysis can be made to determine the preventability of this adverse event. When a clinical decision is not consistent with the recommended clinical guidelines or professional standards, an analysis has to be made to determine the actual risk for adverse outcomes. In both cases, the assessment of patients' safety can only be made on the basis of scientific knowledge, integrated with clinical expertise, about the relation between clinical decisions or practices, and adverse outcomes. Therefore, insight into the incidence and impact of potentially unsafe situations is the first step towards improving patient safety.<sup>6</sup>

## **Patient safety in primary care**

The increased attention to patient safety issues has put pressure on healthcare professionals, organizations and regulators to curtail the extent of unintended harm to patients.<sup>7</sup> Since the well-known report 'To err is human' was published in the United States in 1999, much attention has been paid to patient safety in specialized healthcare and to the registration and examination of safety incidents, particularly in hospitals.<sup>8</sup> There is a paucity of data on patient safety in primary healthcare settings.<sup>9</sup> The patient safety risks in primary care are different from hospital care due to the specific characteristics of primary care.<sup>10</sup> Despite low risk, primary care can cause serious avoidable harm to patients.<sup>11</sup> A priori chances of severe symptoms are low in primary care settings, but the yearly volume of contacts and procedures in primary care is very high.<sup>12</sup> Diagnostic error and treatment comprises may be the incidents with highest risk of harming patients in primary medical care.<sup>13</sup>

In an earlier study of patient safety in primary care, a mix of methods was found to be necessary to identify safety incidents.<sup>10</sup> Retrospective patient record review is a frequently used method to retrieve safety incidents, but the validity of this method depends on the quality of recordkeeping.<sup>14</sup> Incident reporting by healthcare professionals is another method, which is frequently applied, but its validity is highly dependable on the willingness of professionals to report and analyze substandard care. Incidents reported by professionals mostly refer to organizational and communication aspects, although most serious tends to result from errors in diagnostic procedures and treatment.<sup>11</sup> Direct continuous observations have proven

to be especially valuable in detecting near-misses, as they are far less frequently reported or documented in patient charts than actual adverse events.<sup>14</sup> Studies in primary medical care showed that improvement of patient safety should consider the specific characteristics of primary care, including the high yearly numbers of patients and contacts, the perceived low risk of harm, and the broad diversity of conditions and procedures.<sup>12</sup>

### **Professionals' perceptions of patient safety**

Special attention is needed for the perceptual awareness of safety risks by healthcare professionals. Research showed that healthcare professionals felt that the incidence of patient safety incidents in healthcare was substantially lower than is described in literature, despite most had personal experiences of these incidents.<sup>15</sup> This may indicate a discordance between the real extent of the problem and the extent felt by the professionals who could have the largest effect on reducing the problem.<sup>7</sup> Interviews with healthcare professionals in the United Kingdom showed that health professionals understand risk as an intrinsic feature of healthcare delivery, which is routinely integrated in clinical decision making.<sup>16</sup> Risks were generally described in terms of acceptable versus unacceptable and preventable versus non-preventable. Further examination of the differences in the perceptual awareness of risk can advance the knowledge on the possible impact they could have upon patient safety.

### **Patient safety in primary midwifery care**

International empirical evidence on the safety of midwifery-led care for low risk childbearing women is limited.<sup>17</sup> Patient safety in primary midwifery care has not been thoroughly explored before and measures to analyze the patient safety status were not available. Examination of patient safety in maternity care would benefit from a systematic, multi-method approach.<sup>18</sup> A systematic review of patient records is a first and suitable method to retrieve (possible) safety incidents in a low risk population with high numbers of patient contacts. A measure for the review of records of pregnant women should be developed on the base of scientific knowledge, guidelines and clinical experience. Beside well known determinants of general patient safety risk, this measure needs a focus on the specific features of primary midwifery care, namely the continuous risk assessment in low risk pregnancy.<sup>19</sup>

### **What are the risks in primary midwifery care?**

Perinatal mortality is showing a downward trend in The Netherlands, but other European countries have reported a more impressive decline in the mortality rates.<sup>20</sup> Although the impact of the Dutch perinatal system, as described above, is difficult to



substantiate, one study has found adverse effects on perinatal outcomes.<sup>21</sup> On the other hand, a large national study that found no relation between births led by primary care midwives and increased risk of perinatal death in The Netherlands.<sup>22</sup> Indeed, some countries are developing policies to strengthen primary care for pregnant women. For instance, the recent 'Birthplace in England national prospective cohort study' supports a policy of offering healthy women with low risk pregnancies a choice of birth setting. Women planning birth in a midwifery unit and multiparous women planning birth at home experience fewer interventions than those planning birth in an obstetric unit with no impact on perinatal outcomes.<sup>23</sup> Previous research on patient safety among childbearing women in hospital care has been concentrated on care during delivery. Human error and system-based problems related to staffing levels, medication, the use of technical equipment, knowledge, skills and communication have been identified as risk factors during obstetric care.<sup>24,25</sup>

Since there is scant data about patient safety in primary midwifery care, we performed a large systematic study on the basis of record review, incident reports and a pre structured questionnaire on patient safety management. This combination of methods was used to identify incidents, determine the cause and type of incidents and the seriousness of the (potential) harm. The analyses of the safety incidents and identification of specific domains of risk provide midwives with empirical evidence to guide improvement of their practices.

### What are the safety risks for pregnant women living in deprived neighbourhoods?

An analysis of perinatal mortality in The Netherlands shows that the number of unfavourable perinatal outcomes in larger Dutch cities stands out in particular.<sup>26</sup> And non-minority women residing in deprived urban areas have been shown to have a particularly higher probability of experiencing adverse perinatal outcomes.<sup>27,28</sup> There is also emerging evidence that, irrespective of their residential area, patients with a minority cultural and language background are at a greater risk of experiencing preventable adverse events than mainstream patient groups. A comparison of the occurrence, causes and consequences of patient safety incidents in the care for pregnant women in general and pregnant women in a deprived urban area in particular, will enhance the safety for vulnerable pregnant women.

### What are the potential causes of critical incidents in maternity care

Under the Dutch quality Act of 2005, healthcare professionals in The Netherlands have a statutory duty to report 'critical incidents' to the Dutch Health Care Inspectorate, defined as 'any unintended or unexpected quality of care related event

which have resulted in the death or serious permanent injury to a patient or client of the medical facility'.<sup>29</sup> The supervision performed by the Dutch Health Care inspectorate is based on legislation and regulations as well as on 'field standards' set by professional associations themselves. A significant approach for supervision is the evaluation of critical incidents in hospitals or primary care practices.<sup>30</sup>

Since 2010, healthcare professionals in perinatal care, started with the implementation of the National Perinatal Audit in order to make a systematic analysis of perinatal mortality with all health professionals involved. This perinatal audit consists of three pillars: a local, regional and a national audit. A panel of expert caregivers will look for specific patterns or explanations for the mortality. This type of audit in particular leads to recommendations for national policy, such as adaptations of guidelines, training or preventive measures but also increases the awareness of health professionals and promotes cooperation between echelons of healthcare. The first results of the Dutch perinatal audit in 2010, a structural evaluation of perinatal morbidity from 37 weeks pregnancy in The Netherlands, showed that 10% of the evaluated cases are related to substandard care factors.<sup>31</sup>

The challenge is to identify risk domains in both primary and hospital maternity care. Since maternity care in The Netherlands is provided in a multi disciplinary network with a substantial number of referrals from primary care to hospital and back, it is important to analyze safety risks in the complete spectrum of maternity care. It has been observed that a patient safety incident consists of a string of related causes.<sup>32</sup> The evaluation of critical incidents with serious harm for the pregnant woman and child, provides us with information about potential causes of high risk in maternity care in The Netherlands, regardless of where this is provided.

## Outline

This thesis consists of a number of studies concerning patient safety in primary midwifery care in The Netherlands. We start with the provision of a protocol of a large observational study that aimed to provide insight into the current patient safety issues in primary care in The Netherlands (chapter 2). In chapter 3 we described the development of a method to explore the status of patient safety in primary midwifery care. In chapter 4 a first inventory of the incidence, causes and effects of safety incidents in primary midwifery care by means of a review of records from pregnant women is described. Next, we focus on primary care providers' views on patient safety and the possible relation with the occurrence of safety incidents (chapter 5). In chapter 6 we compared the results of the study as described in chapter 4, to the causes and effects of safety incidents in the care for women living in deprived neighbourhoods. Finally, we analyzed critical incidents in maternity care in both

hospitals and primary care, in order to identify potential causes of high risk in the whole spectrum of maternity care (chapter 7).

The following research questions will be addressed:

- |   |  |           |
|---|--|-----------|
| 1 | What is the validity of a measure to identify patient safety risks in patient records in maternity care?         | Chapter 3 |
| 2 | What is the incidence of patient safety incidents in primary midwifery care and which consequences do they have? | Chapter 4 |
| 3 | Are health professionals' perceptions of patient safety related to patient record figures on safety incidents?   | Chapter 5 |
| 4 | Are pregnant women living in deprived area's more at risk to experience a safety incident?                       | Chapter 6 |
| 5 | What are the potential causes of critical patient safety incidents in maternity care?                            | Chapter 7 |

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## **Chapter 2**

# **Patient safety in Dutch primary care: a study protocol**

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Implementation Science 2010; 5: 50.



## Abstract

*Background:* Insight into the frequency and seriousness of potentially unsafe situations may be the first step towards improving patient safety. Most patient safety attention has been paid to patient safety in hospitals. However, in many countries, patients receive most of their healthcare in primary care settings. There is little concrete information about patient safety in primary care in The Netherlands. The overall aim of this study was to provide insight into the current patient safety issues in Dutch general practices, out-of-hours primary care centres, general dental practices, midwifery practices, and allied healthcare practices. The objectives of this study are: to determine the frequency, type, impact, and causes of incidents found in the records of primary care patients; to determine the type, impact, and causes of incidents reported by Dutch healthcare professionals; and to provide insight into patient safety management in primary care practices.

*Design and methods:* The study consists of three parts: a retrospective patient record study of 1,000 records per practice type was conducted to determine the frequency, type, impact, and causes of incidents found in the records of primary care patients (objective one); a prospective component concerns an incident-reporting study in each of the participating practices, during two successive weeks, to determine the type, impact, and causes of incidents reported by Dutch healthcare professionals (objective two); to provide insight into patient safety management in Dutch primary care practices (objective three), we surveyed organizational and cultural items relating to patient safety. We analyzed the incidents found in the retrospective patient record study and the prospective incident-reporting study by type of incident, causes (Eindhoven Classification Model), actual harm (severity-of-outcome domain of the International Taxonomy of Medical Errors in Primary Care), and probability of severe harm or death.

*Discussion:* To estimate the frequency of incidents was difficult. Much depended on the accuracy of the patient records and the professionals' consensus about which types of adverse events have to be recognized as incidents.

## Background

*Primum non nocere* ('first do no harm') has been a maxim of healthcare workers for many centuries. In the past decade, patient safety has been placed high on the societal agenda. This can be seen from high-profile cases of compromised patient safety around the world, policy reports such as *To err is human* in the United States<sup>1</sup>, a growing overall aversion of risk in society, and the fact that healthcare professionals have started to realize that there is a lot to gain in the quality of care by focussing explicitly and systematically on patient safety.

There are many definitions of patient safety and unsafety. The World Health Organization defines patient unsafety as *a process or act of omission or commission that resulted in hazardous healthcare conditions and/or unintended harm to the patient*.<sup>2</sup> Wagner and Van der Wal<sup>3</sup> define a patient safety incident as *an unintended event during the care process that resulted, could have resulted or still might result in harm to the patient*. A more specific unit used in this type of research is the adverse event. Zegers et al.<sup>4</sup> define an adverse event as *an unintended injury that results in temporary or permanent disability, death or prolonged hospital stay, and is caused by healthcare management rather than by the patient's underlying disease process*.

Research into patient safety can be positioned in the broader field of implementation science. When an adverse event has occurred (e.g., the patient died during treatment), a significant event analysis has to be made to determine the preventability of this adverse event. When a clinical decision is not consistent with the recommended procedures (e.g., a clinical guideline or professional standard was not followed), an analysis has to be made to determine the actual risk for adverse outcomes. In both cases, the assessment of patients' safety can only be made on the basis of scientific knowledge, integrated with clinical expertise, about the relation between clinical decisions or practices (e.g., prescribing medication), and adverse outcomes (e.g., worsening of symptoms or prolonged illness). Therefore, insight into the frequency and seriousness of potentially unsafe situations may be the first step towards improving patient safety.

Most attention to patient safety has been directed at hospitals, because hospital care clearly implies high-risk procedures (e.g., surgery and blood transfusion) and a riskful environment (e.g., hospital-acquired infections and pressure ulcers). According to national and international studies, 3% to 17% of the patients in acute care hospitals have one or more adverse events. Patients die due to 5% to 13% of the adverse events.<sup>4-6</sup> Approximately 50% of the adverse events are considered potentially preventable.<sup>4</sup> A Dutch costing study has shown that estimates indicate that the total

of preventable direct medical costs of adverse events in hospitals form a substantial part (1%) of the expenses of the national healthcare budget. The expenses are mainly due to an excessively long stay (including readmissions).<sup>5</sup>

Hospital care, although important, represents only a fraction of a patient's use of the healthcare services.<sup>7</sup> In many countries, including The Netherlands, most patients receive most of their healthcare in primary care settings. Although primary care may imply lower risks for the patient, the large volume of contacts and procedures in this healthcare system implies that incidents can be expected to occur in primary care. For instance, one of the characteristics of primary healthcare is multidisciplinary co-working (e.g., general practitioner (GP) and physiotherapist, general dental practitioner (GDP) and dental hygienist), which implies extended communication and consequences for transferring information.

There are also studies of patient safety that show that incidents in hospital care have their origin in primary care. For example, the Dutch HARM (Hospital Admissions Related to Medication) study showed that the cause of unintended hospital admissions were medication errors in extramural care (i.e., primary care and outpatient clinics).<sup>8</sup> A French national study of adverse events in 2004 revealed that 3.5% of admissions to general medicine departments and 4.5% of admissions to surgical departments were due to events occurring outside the hospital.<sup>9</sup> An English study of 18,820 patients admitted to hospital showed that 6.5% of these admissions were related to adverse drug reactions. Although most patients recovered, 28 (2.3%) died as a direct result of the index adverse drug reaction (as detailed in either the case notes or on the death certificate).<sup>10</sup> A German incidentreporting system for general practices ('Jeder Fehler Zählt') received 188 classifiable reports in the 17 months following its launch in September 2004; 41.5% of these reports were associated with harm to the patient.<sup>11</sup> Errors and preventable adverse events were identified in 24% of 351 outpatient visits in the USA. Harm was believed to have occurred as a result of 24% of the errors, and there was potential harm in another 70%.<sup>12</sup> Note that the patient populations and methods differed, which may have influenced the numbers. For instance, in a French hospital study<sup>9</sup>, patients were actually observed, while the German data<sup>11</sup> were based on a reporting system.

There are, however, scant data about patient safety in primary care in The Netherlands. In a small-scale study in two Dutch general practices, GPs recorded all the adverse events they encountered in their regular office hours during an observation period of five months. During this period, 4,095 patients visited the practice, and a total of 31 adverse events were noted (0.7%). About one-half of the events did not have health consequences, but onethird led to worsening of symptoms, and a few resulted in unplanned hospital admissions.<sup>13</sup> A cross-sectional,

multicentre, observational study employed five coached patients who telephoned the triage nurses of four Dutch GP cooperatives. The study shows that the triage nurses estimated the level of urgency of 69% of the 352 contacts correctly. They underestimated the level of urgency of 19% of the contacts.<sup>14</sup>

In allied healthcare, some incidents resulting in harm to or even death of children are mentioned in The Netherlands and internationally.<sup>15-17</sup> There are also some studies of incidents with spinal procedures of adults. Dissection of the vertebral arteries was the most common problem; other complications included dural tear, oedema, nerve injury, disc herniation, haematoma, and bone fracture. The symptoms were frequently life-threatening, though in most cases the patient fully recovered. In most cases, a spinal procedure was deemed to be the probable cause of the adverse effect.<sup>18-20</sup>

There are hardly any other data about the incidence of incidents in primary healthcare settings in The Netherlands.<sup>21</sup>

## **Aims and objectives**

Current data regarding patient safety in primary care in The Netherlands are needed to identify performance gaps (both under- and over-treatment) and underlying factors, to tailor interventions to deal with the relevant obstacles to and enablers for change, and to set specific targets for improvement. The Dutch Ministry of Health, Welfare, and Sport has developed a policy to improve safety in healthcare, including primary care, and has called for a study to describe the situation at the start of this policy program.

This study protocol concerns a study of patient safety in primary care practices (general practices), out-of-hours primary care centres, general dental practices, midwifery practices, and allied healthcare practices (with physiotherapists, occupational therapists, and/or Cesar-Mensendieck therapists). The overall aim was to provide insight into current patient safety issues. Such insight would help inform national health policy makers and decision makers in the domain. The objectives of this study were: to determine the frequency, type, impact, and causes of incidents found in the records of Dutch primary care patients; to determine the type, impact, and causes of incidents reported by healthcare professionals; and to provide insight into safety management in primary care practices by means of a written survey.

## **Definitions**

Because we did not want to focus only on events that actually caused harm, we used a broader definition of 'incident': an unintended event during the care process that resulted, could have resulted, or still might result in harm to the patient.<sup>3</sup>

However, this is a very broad definition indeed, and it is difficult to use in specific primary healthcare settings. Gaal et al.'s study <sup>22</sup>, based on a web-based survey of 68 general practices, shows that the clinical cases were not uniformly judged as particularly safe or unsafe.

On the basis of our reading of the literature and discussions in the project team, we presented the following description of a patient safety event. We considered both acts of omission and of commission, although not everyone on the project team would consider acts of omission always necessarily a threat to patient safety. We included incidents related to unnecessary harm or risk to the individual patient. We thought of the harm as somatic (e.g., death, pain, infection, and injuries), but included serious psychiatric or mental diseases (e.g., anxiety disorder and stress responses) as well. In cases of risk of harm to the patient (rather than actual harm, such as prolonged recovery), we agreed that the risk had to be scientifically proven or broadly accepted as valid (e.g., by recommendations in guidelines). Patients can contribute to incidents, but we exclude incidents that are completely caused by a patient (e.g., not adhering to therapy). We do not use other terminology, such as adverse events, or near incidents.

We tested our definition in a pilot study, and proved it to be functional. Fifty patient records from each study were judged by at least two reviewers. The proportion of agreement about whether an event should be defined as a patient safety incident was good to very good, varying from 75% (midwifery care) to 100% (out-of-hours primary care).

## **Hypothesis**

While the study is mainly descriptive and explorative, we formulated the following hypothesis: patient safety in primary care is relatively good, meaning that fewer incidents per 100,000 contacts occur in primary care than in hospital care, and fewer of these incidents have major adverse outcomes.

## **Design and methods**

An observational study of patient safety in primary care has shown that a mix of methods is needed to identify incidents in general practice.<sup>23</sup> Therefore, the current study has a retrospective component and a prospective one. The retrospective component concerns a patient record study and a written survey of health professionals. The prospective design concerns an incident-reporting study. Table 1 illustrates the framework for the study.

## Setting

The setting is one of practices, health professionals, and patient records in primary healthcare in The Netherlands.

### *Practices*

Separate studies were carried out in general practices, out-of-hours primary care centres, general dental practices, midwifery practices, and allied healthcare practices (with physiotherapists, occupational therapists, and/or Cesar-Mensendieck therapists). Stratified random sampling of 20 practices was performed for each study, except for the out-of-hours primary care study. Twenty general practices related to four centres (five practices for each centre) were selected for the study of out-of-hours primary care centres. We chose a sample size of 20 practices for each study because it was feasible in the context and budget of the project, and experience has shown that this sample size is large enough to give reliable results.

For a stratified random sample, we used two factors for stratification: practice size and urbanization. We defined a small practice as one with no more than the equivalent of two full-time jobs for primary care health professionals (GPs, et al.), and we defined large practices as having more than the equivalent of two full-time jobs (regarding the type of contract and reimbursement) for primary care health professionals. Trainees and nurse practitioners are not included in this definition. The practices may be part of larger organizational networks, such as multidisciplinary health centres or primary care trusts (for instance, for sharing patient lists, financial risk, legal accountability, support staff, et al.). This wider organizational context was not considered in the sampling in this project. In this study, 'urban' refers to more than 100,000 inhabitants in the area, while 'rural' or 'town' refers to less than 100,000 inhabitants (considering the geographical location of the practice, although the patients may come from other areas). For reasons of logistics, it is acceptable to sample in one geographical area or a few of them in the country. The degree to which these regions represent the country as a whole is described qualitatively in terms of health system and population health.

There are some exceptions to these sampling rules. In allied healthcare, we stratified the distribution of physical, occupational, and exercise therapy practices. There was no stratification of practice size because occupational and exercise therapy practices are always small.

The practices were compensated for the expenses of their activities at a standardized rate within the project. Depending on the study, accreditation and/or feedback about results was possible.

### *Health professionals*

The study considered all staff physically working in each primary care practice, including professionals themselves: GPs, allied healthcare professionals, GDPs, midwives, nurses, practice assistants (with or without clinical tasks), dental hygienists, preventive dental assistants, administrative people, and managers.

### *Patients*

There were no restrictions of the type of patients included, except that they had to be registered or be regular practice attendees. They could attend the practice in person, phone the practice, or be visited at home by a health professional. In the patient record study, contacts had to have taken place one to four months before the selection of patient records. Contacts for collecting incidents in the incident-reporting study had to have taken place during two successive weeks.

An exception to this is the study in midwifery practices. The selection was made amongst women who gave birth in 2008. The study also included women who miscarried, had a premature delivery, or only received care in the postnatal period.

## Reviewer recruitment and training

The patient records were reviewed by teams of researchers and, if necessary, health professionals. The reviewers also examined the type and cause of the incidents found in the patient record study and the incident-reporting study. The selection criteria for the reviewers were: at least five years of postgraduate clinical experience (at least one day a week); a retirement of no longer than five years; and experience or affinity with analysis of incidents.

Health professionals were recruited via personal contacts of the project leaders of each substudy.

The reviewers took an e-learning patient-safety course <sup>24</sup>, starting with a general introduction to patient safety. One module was compulsory, namely, the PRISMA method module.<sup>25,26</sup> We used this method to classify the causes of the incidents into the Eindhoven Classification Model.<sup>27</sup> The study protocol, definitions, and review forms were explained, and examples of incidents were discussed at meetings. Additionally, the reviewers of each study called as many meetings as necessary to clarify the definition of a patient safety incident within their own fields. A pilot test was also used for this purpose. External reviewers were compensated for their review activities at an hourly rate and for expenses.

## Procedures

We collected data from primary care patient records, incident-reporting forms, and surveys. Table 1 gives an overview of the methods and outcome measures.



**Table 1. Overview of methods and outcome measures****Objective 1: To determine the frequency, type, impact, and causes of incidents affecting primary care patients**

Method: retrospective patient record study

Outcome measures: practice type, patient sex, patient age (category), social status of patient, recording of possible communication problems, patient's risk, number of contacts in study year, urgency of the request for help, having seen health professional(s) outside the practice for the same health problem, accuracy of record keeping, question of whether the event was an incident, description of the incident, action(s) taken afterwards.

Analysis of incidents: type of incident, cause (by Eindhoven Classification Model class<sup>27</sup>), actual harm (by the severity-of-outcome domain of the International Taxonomy of Medical Errors in Primary Care<sup>32</sup>), probability of severe harm or death (as judged by the reviewers).

**Objective 2: To determine the type, impact, and causes of incidents reported by healthcare professionals**

Method: prospective incident-reporting study.

Outcome measures: information about the reporting person (e.g., function), patient's year of birth. Patient's sex, description of the incident, action(s) taken afterwards, possible consequences of the incident, and suggestions how to prevent similar incidents in the future.

Analysis of incidents: type of incident, cause (by Eindhoven Classification Model class<sup>27</sup>), actual harm (as defined by the severity-of-outcome domain of the International Taxonomy of Medical Errors in Primary Care<sup>32</sup>), probability of severe harm or death (as judged by the reviewers).

**Objective 3: To get insight into the patient safety management of primary care practices**

Method: written survey

Outcome measures:

Practice characteristics (practice type, number of health professionals in the practice, proportion of patients >75 years old, proportion of patients with low social status, mean number of hours of patient contacts and management tasks per week, and whether the practice has an educational function);

Topics related to quality and safety management (e.g., existence of joint policy, annual report, quality aspects of the annual report, policy plan, quality system, standard procedure for complaints, registration of incidents and near incidents, and method of processing digital data);

Safety culture of the practice (e.g., is it easy to discuss incidents within the practice, learn from each other's mistakes, express concerns about patient care, ask questions for clarity, correct follow-up of incidents, and report concerns about patient safety?).

*Patient record study*

Fifty patient records were randomly selected from the appointment lists one to four months before the selection date for each sub-study (out-of-hours primary care centres excluded), in each of the 20 practices, for a total of 1,000 patient records. Each record was reviewed by one reviewer from the selection date going back one year to determine whether any incidents occurred in that year. We aimed for great sensitivity, meaning that no incidents were to be missed. Details of each incident that the reviewers found were recorded. The details were discussed with another reviewer within the sub-study in case there was any doubt about whether an event was an incident. If consensus was not achieved, one or more other reviewers provided a final judgement on the basis of information from the other two reviewers.

There were some exceptions to this procedure. Because there were fewer patients and a greater frequency of contacts in allied healthcare practices, and because we wanted to guarantee a random selection, the appointment list of one to twelve months preceding the selection date were used for these practices. The screening period of the record was one year, ending at the selection date. Four GP cooperatives with five practices each were selected for the study of out-of-hours primary care centres. Next, a total of 50 patients who had contact with the GP cooperative at least one week before the selection date were randomly selected from each practice. The patient records in the centre (moment of contact) and in the practice (one week before contact to at least eight weeks after contact with the centre) were reviewed. The end of midwifery care had to be in 2008, and the review period for a pregnancy was nine months. Table 2 shows these procedures.

#### *Incident-reporting study*

The incident-reporting study was conducted during two successive weeks, and whenever possible, immediately after the patient record study. The health professionals were asked to report all incidents on standardized forms for the patient record study. If no incidents were reported, the practices were asked whether they did not report at all or if they had not encountered any incidents.

Due to practical limits, this procedure was not feasible in the study of out-of-hours primary care centres. For this study, we used prospectively collected information from the incident-reporting systems that the centres were already using.

**Table 2. Overview of selection and review of patient records**

	<b>General practices</b>
T <sub>-1</sub> : 1-4 months before T <sub>0</sub>	T <sub>0</sub>
T <sub>-2</sub> : 0-12 months before T <sub>-1</sub>	T <sub>0</sub>
	<b>Out-of-hours primary care centres</b>
T <sub>-1</sub> : 1 week before T <sub>0</sub>	T <sub>0</sub>
	T <sub>0</sub> T <sub>-2</sub> : 1 week before to 8 weeks after T <sub>-1</sub>
	<b>General dental practices</b>
T <sub>-1</sub> : 1-4 months before T <sub>0</sub>	T <sub>0</sub>
T <sub>-2</sub> : 0-12 months before T <sub>-1</sub>	T <sub>0</sub>
	<b>Midwifery practices</b>
T <sub>-1</sub> : end of midwifery care in 2008	T <sub>0</sub>
T <sub>-2</sub> : 0-9 months before T <sub>-1</sub>	T <sub>0</sub>
	<b>Allied healthcare practices</b>
T <sub>-1</sub> : 0-12 months before T <sub>0</sub>	T <sub>0</sub>
T <sub>-2</sub> : 0-12 months before T <sub>-1</sub>	T <sub>0</sub>
T <sub>-2</sub> : review period of patient record, T <sub>-1</sub> : date of patient contact with practice or office, T <sub>0</sub> : date of actual visit of reviewer to practice or office to select patient records (early 2009)	

### *Survey*

A questionnaire about organizational and cultural items related to patient safety was sent to a contact person in each practice, but not to the out-of-hours primary care centres. A standard set of questions was designed, and when necessary, extra questions were added to focus more on the specific topics related to the professional circumstances of the different professions. The contact person was asked to fill in the questionnaire and return it to the research group.

The procedures of the patient record study and the incident-reporting study were tested in a pilot study in six practices. The results were discussed in a plenary meeting of all the researchers in order to standardize the procedures as much as possible. The pilot study shows that the methods and instruments, with some modifications, appeared to combine as the most valid method at hand within the budget and relatively short period available for conducting the study of incidents in primary care.

### **Accuracy of figures**

The power calculation was based on the patient record study because this method resulted in the most comprehensive overview of patient safety issues. For the moment, we assumed that the number of records with incidents was 30 in every 1,000 records (3%). It is possible that incidents were clustered within individual practices. To what extent this was true was defined as the intracluster correlation (ICC). Assuming an ICC of 0.05 and an alpha of 0.05, the confidence interval becomes 1% to 5%. This is the range in which the 'true' number of incidents will lie in a sample of 1,000 records.

### **Measures**

Table 1 gives an overview of the methods and outcome measures.

#### *Patient record study*

For each record, the following items were recorded: practice type, patient gender, patient age (in categories), social status of the patient (determined by checking a list of postal codes of areas with a known economic status), recording of possible communication problems, whether the patient was at risk, number of contacts in the review year, urgency of the request for help, having seen more than one professional in the same practice, having seen one or more professionals outside the practice for the same health problem, the accuracy of the record keeping, and whether an incident had occurred. The primary care subgroups were free to add profession-specific questions.

For selected patient records in which an incident had occurred, the following items were added to the case registration form: a description of the incident (setting, incident, outcomes, judgement of the justification), and actions taken afterwards. The registration form was based on a form to be used in general practice care.<sup>28</sup>

#### *Incident-reporting study*

We developed a structured form for reporting incidents that included the following items: type of incident, cause, actual harm to the patient, and probability of severe harm or death.

#### *Survey*

The questionnaire for practices addressed the following aspects: six questions about practice characteristics, 21 questions related to the presence of quality and safety management items (to be answered with 'yes' or 'no'), and 14 questions about the safety culture of the practice (on a five-point Likert scale).

The content of the questionnaire was derived from the *Visitation Instrument Accreditation*<sup>29</sup>, the *Guidance for patient safety in general practice*<sup>30</sup>, and the *Safety Attitudes Questionnaire* (SAQ, ambulatory version)<sup>31</sup>. The measures from the SAQ were translated systematically in a forward and backward translation procedure. If necessary, questions were adjusted to the type of healthcare practice.

### Data processing and data analysis

We analyzed the incidents found in the retrospective patient record study and the prospective incident-recording study by means of type of incident, causes, actual harm, and probability of severe harm or death. Types of incidents-not causes-are related to organization, environmental context (e.g., materials and entrance), communication, prevention, triage, diagnostics, treatment, and/or intervention. We used the Eindhoven Classification Model<sup>27</sup> to classify the causes. We used the 'severity of outcome' domain of the International Taxonomy of Medical Errors in Primary Care<sup>32</sup> to define the severity level of the harm. We classed the probability of severe harm or death as 'very probable', 'probable', and 'not probable'. Table 3 gives an overview of the classifications.

We used SPSS to enter the data in a database. In general, explorative analyses were involved. By this we mean that appropriate summary measures, such as mean and median values, were used. The accuracy of the figures was expressed in terms of 95% confidence intervals. Where necessary, we took into account the fact that the data were nested at the practice level. More details about analyses at the level of the sub-studies will be described in separate papers.

**Table 3. Overview of classifications****Type of incident:**

Related to organization, communication, prevention, triage, diagnostics, and/or treatment.

**Cause(s) of the incident:**

Related to latent conditions (technical or organizational), active errors (human: knowledge-based behaviour, human: rule-based behaviour, human: skill-based behaviour), and other factors (patient related or other type) <sup>27</sup>.

**Harm to the patient:**

Error, but no harm; error resulting in harm to the patient; error resulting in death; error, but harm indeterminate <sup>32</sup>.

**Probability of severe harm or death:**

Very probable, probable, or not probable.

### Ethical approval/confidentiality (privacy)

According to the Dutch Central Committee on Research Involving Human Subjects regulations, only research in which the study participant has to be physically present during the study is subject to the Medical Research Involving Human Subjects Act <sup>33</sup>. Therefore, the committee stated in writing that ethical approval was not necessary. Each participating practice formally consented to participate.

Anonymity of practices, health professionals, and patients was and is of the utmost importance in this study. Several measures were taken to ensure the confidentiality of the collected information. The practices themselves selected the patient records and deleted any specific patient information, such as name, address, and date of birth. The reviewers signed a confidentiality agreement to maintain the secrecy of the information. The reviewers never reviewed in practices where they had ever been employed, and they did not and would never contact the individual patients or physicians. During the data collection, the records were never left unattended. Each record received a unique study number so that the patient's identity remained anonymous. Patient identifiers were kept in the practice and were destroyed on completion of the study.

If a reviewer had any concerns during the review process about unrecognized, potentially deliberate, harmful acts, illegal acts, or repetitive negligent behaviour, he would first of all discuss these concerns with the care provider. If doubt remained, the concerns could be further discussed with the internal ethics committee set up for this study.

### Timeframe

The complete study was planned to take place from January to December 2009. The part of the study described in this protocol was planned for May to December 2009.

## Discussion

There is no doubt that patient safety incidents occur in primary care. The aim of this study was to provide more detailed insight into the current patient safety issues in Dutch primary care in order to learn from current practice and to improve the quality of primary healthcare. It was difficult to estimate the frequency of the incidents. Much depended on the accuracy of the patient records and the lack of professionals' consensus regarding which types of adverse events were to be recognized as incidents. Gaining insight into the types, causes, and consequences of incidents was not too difficult. However, there was not enough information to do so in cases in which the healthcare professional did not realize that an incident had occurred. Hindsight bias comes into play in backward reviewing of patient records and incidentreporting forms.<sup>34,35</sup> In primary care, there are hardly any standardized registration or report systems for incidents. Substantial differences in record-keeping attitudes of professionals in primary care might have influenced the comparability of the results.

Another important factor is that the characteristics of the patient populations differ greatly across the practice types. For instance, in general dental care, most visits will be preventive. Physiotherapy care with a lot of elderly patients and many more contacts per patient, and midwifery care with many check-up visits contrast sharply with the immediate, symptomatically driven attendance at out-of-hours primary care centres. This has its implications for presenting results and probably for the type of follow-up research needed as well.

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## **Chapter 3**

# **Patient safety in midwifery care for low-risk women: instrument development**

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Journal of Midwifery & Women's Health 2012; 57: 386–395.

## **Abstract**

*Introduction:* Few studies have examined the safety of midwife-led care for low-risk childbearing women. While most women have a low-risk profile at the start of pregnancy, validated measures to detect patient safety risks for this population are needed. The increased interest of midwife-led care for childbearing women to substitute for other models of care requires careful evaluation of safety aspects. In this study, we developed and tested an instrument for safety assessment of midwifery care.

*Methods:* A structured approach was followed for instrument development. First, we reviewed the literature on patient safety in general and obstetric and midwifery care in particular. We identified 5 domains of patient risk: organization, communication, patient-related risk factors, clinical management, and outcomes. We then developed a prototype to assess patient records and, in an iterative process, reviewed the prototype with the help of a review team of midwives and safety experts. The instrument was pilot tested for content validity, reliability, and feasibility.

*Results:* Trained reviewers with clinical midwifery expertise applied the instrument. We were able to reduce the original 100-item screening instrument to 32 items and applied the instrument to patient records in a reliable manner. With regard to the validity of the instrument, review of the literature and the validation procedure produced good content validity.

*Discussion:* A valid and feasible instrument to assess patient safety in low-risk childbearing women is now available and can be used for quantitative analyses of patient records and to identify unsafe situations. Identification and analysis of patient safety incidents required clinical judgment and consultation with the panel of safety experts. The instrument allows us to draw conclusions about safety and to recommend steps for specific, domain-based improvements. Studies on the use of the instrument for improving patient safety are recommended.

## Introduction

Patient safety has gained considerable attention following publications questioning the safety of patients in hospitals and publications showing a growing aversion to healthcare risks in society.<sup>1</sup> However, data on the safety of patients in other healthcare settings, including midwifery settings, are not often available.<sup>2</sup> There is nevertheless an increased interest in the effects of a midwife-led care model on quality, safety, and satisfaction.<sup>3</sup> The substitution of midwife-led care for hospitalized care provided by a medical specialist is aimed at normalizing the birth process but requires careful evaluation for successful implementation. A valid instrument to assess the safety of midwife-led maternity care is needed.

In The Netherlands, primary care midwives and 4.2% of primary care physicians are responsible for prenatal care, birth, and postnatal treatment of women with low risks of complications at the start of pregnancy.<sup>4</sup> Midwives refer to obstetric specialists when complications arise or a risk of complications is detected, and detailed guidelines are available for when to refer.<sup>5</sup> In 2008, 80% of pregnant women in The Netherlands received most of their prenatal care via a midwifery practice, and 69% were still in primary midwifery care at the start of the intrapartum period.<sup>6</sup> About 30% of pregnant women in The Netherlands had a home birth, 10% had a hospital birth supervised by a primary care midwife, and the remaining 60% had already been referred to a hospital. When women are referred to a hospital during the intrapartum period, care is transferred to a hospital-based midwife or obstetric specialist. The 60% of births occurring in hospitals were formally supervised by an obstetric specialist, while the percentage of births in secondary care managed and performed by a hospital-based midwife has increased from 8% in 1998 to 26% in 2007.<sup>7</sup> Shortly after giving birth (i.e., 2 hours to 1 day later), most women are referred back to the primary care midwife who cares for them at home during a postnatal period of about a week. These figures show childbearing women to be regularly referred to hospital departments of obstetrics at different stages in their pregnancies, but they do not provide information on the safety of the care involved. The perinatal care system in The Netherlands has a substantial number of home births and is unique among developed countries with both independent primary care midwives and hospital-employed midwives in addition to obstetric specialists providing care for childbearing women. Risk assessment and counseling for even low-risk childbearing women is crucial in all healthcare systems and settings. International evidence on maternity patient safety stresses the importance of good team work, good training, one-on-one care, good management in general and caseload management in particular, suitable guidelines, and learning from incidents.<sup>8</sup> Furthermore, the use of both qualitative and quantitative methods has been shown

to be necessary to draw sound conclusions with regard to patient safety.<sup>9,10</sup> The purpose of this study was to develop an instrument to assess the safety of care for low-risk childbearing women receiving midwife-led care and evaluate the reliability, feasibility, and validity of the instrument. In this article, we describe the content, development, and pilot testing of the instrument.

## Methods

### Definition of patient safety

Drawing on the international World Health Organization definition of patient safety, we adopted a broad definition that encompasses all unsafe practices, with an emphasis on avoidable risk of harm to the patient. By using this broad definition, we included cases with obvious and possible risks, aiming to substantiate safety improvement. A threat to patient safety was defined as an omission or commission that resulted in hazardous healthcare conditions and/or unintended harm to the patient. A patient safety incident was defined as an unintended event during the care process that resulted, could have resulted, or still might result in harm to the patient.<sup>11</sup>

We included acts of omission and commission that related to unnecessary somatic and/or psychological harm or risk. The risk had to be scientifically known or widely recognized. Incidents caused by the women themselves were not included. Legal or moral responsibility were also not considered.<sup>12</sup>

### Identification of domains of safety in midwifery care

Risk domains were identified on the basis of a review of the literature and a theoretical framework. When patient safety in Dutch primary care was previously reviewed, research on primary midwifery care was not available.<sup>13</sup> We scanned MEDLINE, PubMed, and the Cochrane database from 2000 to 2010 for international scientific literature on "safety", "incidents", "low-risk pregnancy", "midwife-led care", and "maternity care". An important part of the literature was summarized in a Cochrane review on the contribution of midwife-led care to the quality and safety of care for childbearing women and concluded that this model contributes to patient safety in terms of fewer interventions, greater one-on-one care, and no increased likelihood for any adverse outcome for women or their infants.<sup>3</sup> Remaining findings of our review are described in the following.

In 2008, 600 maternity care professionals (80% of them midwives) were surveyed about their concerns regarding maternity care in the United Kingdom and indicated a need for better training on the handling of complex maternal health needs, improved management, and better staff planning.<sup>14</sup> An assessment of reported incidents

related to maternal morbidity showed many of the incidents to involve treatment delays or failure to recognize complications.<sup>14</sup> Other published safety research on the care for childbearing women in hospital obstetric departments listed the following as risk domains: staff equipment, medication, medical equipment, knowledge, skills, and communication.<sup>13</sup> Communication is a well-known risk factor in healthcare. Observations of communication in delivery suite teams showed it to be restricted by interprofessional tensions, workload pressure, and environmental design problems.<sup>15</sup> A theoretical framework of risk domains containing clinical and managerial topics was derived from detailed guidelines for midwifery care and practical experience of members of the project team and expert team. This framework was adjusted and completed based on the results of the review of literature and led to the following 5 broad domains of midwifery care with respect to their safety limitations: organization, communication, patient risk factors, clinical management, and outcome.

## Organization

Primary midwifery care in The Netherlands is organized close to women's homes. Given the substantial number of home births and the risk for every childbearing woman of developing acute complications during the prenatal, intrapartum, or postnatal periods, quick availability and accessibility of the healthcare provider to the patients (whether at home or in the hospital) is a prerequisite for safe midwifery care. The literature shows that continuous care for women who are giving birth leads to fewer interventions, better monitoring of the birth period, and less anxiety on the part of parents.<sup>16</sup> Another recent study shows a longer travel time from the home to a hospital maternity unit to be associated with an increased incidence of intrapartum/neonatal mortality and adverse outcomes.<sup>17</sup> In general, care for childbearing women is characterized by the possible need for urgent interventions. Consideration of travel time and possible care delays is thus an important area for patient safety research, and we, therefore, concentrated on attainability and availability as key aspects of the organization of midwifery care.

Most medical professions consider 15 minutes to be an acceptable period for the start of necessary care in general.<sup>18</sup> For hospital care following a non-urgent referral by a primary care midwife, the Dutch governmental guidelines recommend ambulance transportation and the start of necessary hospital procedures within 45 minutes.<sup>19</sup> The literature about urgent obstetric referrals from home to a hospital shows a time frame of 20 minutes to be the upper safety limit.<sup>17</sup> For our assessment instrument, we adopted a 15-minute time frame from the woman's request for help (due to complications during pregnancy or intrapartum care) to the time of arrival of

the midwife in the woman's home. For attainability of hospital care, we adopted a time frame of 45 minutes between referral to the hospital by the midwife and the start of necessary care in the hospital. All delays in these time frames for midwifery care were judged to be unsafe care because of the possible harm that might be caused by the delay.

## Communication

Studies have revealed that poor communication is a well-known risk for patient safety. Communication with regard to patients who have to cross boundaries within the healthcare system constitutes a particular safety risk.<sup>20</sup> Based on literature and evaluation of complaints, we defined communication as a second domain of midwifery care.<sup>21</sup> Several aspects of the communication during the midwifery care process can be distinguished in part because the care involves a multidisciplinary network of consultation and referral with a substantial number of referrals of childbearing women to the hospital and then back to primary midwifery care in particular. Over the years, more and more midwives and practice assistants have started working together in large midwifery practices. Therefore, communication problems within the practice can also give rise to safety problems. All communication procedures between midwives and obstetric specialists, obstetric assistants, pediatricians, maternity assistants, nurses, clinical midwives, and other caretakers should be assessed in patient safety research. Similarly, communication problems between the pregnant women themselves and the attending midwives or practice assistants can result in unsafe situations. Rights and obligations of healthcare providers and clients are defined in the Law on Medical Treatment Agreement.<sup>22</sup> This law also includes the requirements for proper reporting and communication between caregivers themselves and between caregivers and patients. Miscommunication that resulted or might have resulted in physical harm and/or mental harm to the mother was thus considered unsafe care. In this study, identification of suboptimal communication was based on an implicit clinical judgment.

## Patient risk factors

The social, mental, and physical profiles of the pregnant woman also influence the health and well-being of the mother and the perinatal outcome.<sup>23</sup> An important feature of midwifery care should thus be the screening of childbearing women for possible risks together with the integration of this information into the clinical management of the cases and provision of the interventions needed to decrease risk factors. Medical, family, and obstetric histories should be carefully reviewed to identify risk factors that may need consultation or referral to an obstetric specialist.

The involvement of social welfare organizations, efforts to reduce stress, and attention to aspects of an unhealthy lifestyle (e.g., a high body mass index, smoking, alcohol or drug use) should also be assessed in patient safety research. Residents in socially disadvantaged areas have higher perinatal mortality rates than residents elsewhere.<sup>24</sup> Such risk factors were not considered in and of themselves to be a safety risk. They should certainly be taken into consideration to determine the necessary and timely interventions required of the midwife. In this study, detailed referring guidelines provided the standards for assessment to reduce the potential for adverse outcome because of these risk factors.<sup>5</sup>

### Clinical management

The care for childbearing women is largely preventive. Governmental screening programs for pregnant women should therefore be offered and integrated into clinical management procedures, as this enables detection of problems as early as possible. A lack of preventive procedures clearly constitutes a safety risk.<sup>25</sup> Studies of hospital care indicate that medication errors are a well-known cause of patient safety incidents.<sup>1</sup>

Preventive procedures in midwifery care imply the appropriate timing of counseling and requests for prenatal testing. Parents in The Netherlands can have their children tested for Down syndrome and other congenital disorders during pregnancy using prenatal screening for Down syndrome and the 20-week ultrasound.<sup>25</sup> The absence or delay of such procedures is thus considered a safety risk because governmental procedures prescribe that all pregnant women in The Netherlands should be informed in a timely manner about these procedures in order to allow the women to make an informed choice about participation. The counseling with regard to such tests is nevertheless a complex procedure that requires specific training. The complexity of the information for the pregnant women and the impact of the test results imply a certain risk for communication incidents. We therefore considered such communication incidents to be a safety risk. National blood screening of pregnant women for the rhesus D factor, irregular erythrocyte antibodies, and infectious diseases in addition to other blood tests and ultrasounds are part of the standard preventive care for pregnant women in The Netherlands.<sup>25</sup> The proper interpretation of both laboratory and ultrasound results but also their accurate integration into the care process are thus prerequisites for safe care.

We also defined not having the first antenatal consultation after 10 weeks of pregnancy or having less than 12 antenatal consults throughout the total prenatal period as possible safety risks.<sup>26</sup> A late first antenatal checkup or a discontinuity of



care that was not caused by the woman herself and can possibly lead to unsafe situations should thus be assessed as part of patient safety research.

The prescription and management of the medication that Dutch midwives are authorized to administer is also examined as part of this patient safety tool. Failure to prescribe medication as consistent with existing guidelines (e.g., the anemia guideline), insufficient monitoring of hemoglobin status, and failure to assess the effectiveness of prescribed iron supplements can all be considered unsafe – particularly with prolonged maternal anemia.<sup>27</sup>

## Outcomes

Despite differences in national health maintenance care systems, midwifery care is always provided in a multidisciplinary network of consultation and referral with other care providers. Timely and proper risk assessment is thus a key feature of midwifery care. A 2007 national study showed midwifery risk selection results in a relatively small percentage of urgent referrals but generally satisfactory neonatal outcomes for births led by primary-level midwives.<sup>28</sup> A more recent cohort study, however, revealed some unknown risk factors in the referral from midwifery care to obstetric hospital care.<sup>29</sup> Risk factors that are known to relate to perinatal morbidity and mortality are prematurity, intrauterine growth retardation, asphyxia, and congenital abnormalities.<sup>23</sup> Assessment of adequate and timely referral in response to such risk factors and the review of maternal and perinatal outcome is thus a prerequisite for drawing conclusions about patient safety in midwifery care. We therefore defined a suboptimal outcome for either mother or child as a relevant domain in the study of patient safety.

Although suboptimal maternal or prenatal outcomes do not necessarily imply unsafe care, consideration of the absence of proper interventions and/or late referral is important. Dutch midwives are required to register a number of outcome features for both the mother and child in The Netherlands Perinatal Registry.<sup>30</sup> Midwives can reduce safety threats with timely detection and referral to a hospital. The monitoring of outcome factors can thus contribute to a review of the Total care process with respect to timely and proper referral but also the development of interventions to improve suboptimal outcomes. The absence of interventions that should be standard care according to national guidelines should also be assessed in patient safety research. For instance, the absence of ultrasound tests when 'small for gestational age' is recorded in the obstetric history can be considered an unsafe practice when the current pregnancy is also associated with a child who is small for gestational age. Individual variables were created in these 5 domains to identify incidents that require further evaluation. Nevertheless, unfavorable outcomes cannot always be predicted

or always seen to stem from unsafe care. The outcome features and referral procedures should therefore be examined by the users of the instrument in detail before conclusions are drawn about patient safety.

### Development of the instrument prototype

Elaboration of our patient safety domains resulted in 100 items to be dichotomously scored by the review team. A positive item score indicated a possible risk that should be further analyzed for the presence of safety incidents. At the end of the 100-item list, the identified safety incidents are assigned a preliminary category by a reviewer according to cause and according to effect and are assigned to a severity score.<sup>31</sup>

For the organization domain of patient safety, we distinguished 10 risk items, which include time delays in the emergency telephone system, time delays for urgent home visit, and birth with the midwife not present. For the communication domain of patient safety, 12 communication processes with a variety of caretakers who could possibly be involved in the care process were described extensively. For the domain of patient-related risk factors, we defined 23 risk items, which encompassed a variety of areas, including: social factors, lifestyle factors, medication use, family history of risk, obstetric history of risk, and mental disorders. We developed 10 items for the clinical management domain of patient safety; the items concerned procedures related to prenatal testing, laboratory and ultrasound tests, prescription of medication, the first antenatal consultation, and the number of consultations. Finally, 45 items were developed for the outcomes domain of patient safety. This was done in accordance with The Netherlands Perinatal Registry, which requires midwives to report on each birth. For child outcome, we recorded gestational age, birth weight, breech position, asphyxia, and congenital abnormalities. For maternal outcome, we recorded the need for medical support or hospital admission due to incomplete recovery after giving birth arising from anemia, traumatic experience, physical disorders, or mental disorders.

### Evaluation of patient records

In a previous study of patient safety in primary care, several different approaches were shown to be needed to identify safety problems.<sup>32</sup> We therefore developed a separate instrument to review patient records from childbearing women in midwifery care for safety incidents. Advantages of such an instrument are its potentially high validity and the possibility of checking random samples from defined patient populations. A disadvantage of such an instrument could be missing data in patient records, which makes them difficult to interpret. We therefore decided to evaluate the completeness of record keeping. For this, we examined the intake notes during

the first antenatal checkup with regard to the patient's general, medical, family, and obstetric history. The overall quality of record keeping was examined using existing guidelines for the adequate transmission of patient data and proper reporting of the care process by midwives.<sup>33</sup>

### Expert assessment of content validity of instrument prototype

To assess the face and content validity of the patient safety instrument, we discussed all of the items developed for this first version of the instrument with an expert team composed of 2 doctorate-prepared midwives, a patient safety expert, the patient safety project leader, and the midwife project leader. The list of items to be scored was judged to be very extensive and detailed. Based on the research literature and former studies of midwifery care, the expert team recommended the addition of items concerned with social risk factors (e.g., children from more than 2 partners, induced abortion in obstetric history, no partner).<sup>34</sup> The patient safety expert added an item about failure of medical equipment.

The expert assessment of the face and content validity of the instrument prototype produced a first test version with 100 items covering 5 domains of midwifery patient safety. The prototype was then pilot tested in 2 midwifery practices.

### Pilot testing

We assumed that application of a safety assessment instrument to patient records would require trained reviewers with experience in primary care midwifery practice. We thus established a review team consisting of 4 academically trained research midwives. The midwives had at least 5 years of postgraduate clinical experience, were not retired more than 5 years, and had experience or at least an affinity with the analysis of safety incidents. All of the reviewers were explicitly trained to examine the causes of incidents using the Prevention and Recovery Information System for Monitoring and Analyses (PRISMA).<sup>35</sup> The PRISMA provides a quantitative database of incidents and process defects for the development of improvement measures and consists of 3 components: 1) incident description, 2) classification, and 3) translation of the causes to structural measures.

For the second component (classification) of the PRISMA, which draws on the Eindhoven Classification Model, the reviewers were given standardized instructions to determine the type, cause, actual harm, and potentially severe consequences of identified safety incidents. To identify the severity of the actual harm, the 'severity of outcome' domain of the International Taxonomy of Medical Errors in Primary Care was used.<sup>31</sup>

To examine the variation in the review process, 50 patient records were independently reviewed by all reviewers. The kappa procedure, a measure of intraobserver and interobserver agreement, was considered unsuitable for measuring interobserver reliability due to the low rate of incidents, and, therefore, the degree of agreement for the detection of patient safety incidents was calculated.<sup>36</sup>

## Privacy

In this study, anonymity of practices, health professionals, and patients was of utmost importance. Several measures were taken to ensure confidentiality of the collected information. The practices themselves selected the patient records and deleted any specific patient information, like name, address, and day of birth. Reviewers signed a confidentiality agreement to maintain the secrecy of the information. The reviewers never reviewed in practices where they have ever been employed, and the reviewers never contacted individual patients or physicians. During the data collection, the records were never left unattended. Each record received a unique study number so that the patient's identity would not be revealed. Patient identifiers were kept in the practice and were destroyed once the study was finished.

According to the Dutch Central Committee on Research Involving Human Subjects regulations, only research in which the study participant has to be physically present during the study is subject to the Medical Research Involving Human Subjects Act.<sup>37</sup> Therefore, the committee stated in written form that ethical approval was not necessary. Each participating practice formally consented to participate.

If a reviewer had any concerns during the review process about unrecognized potential deliberate harmful acts, illegal acts, or repetitive negligent behavior, these concerns were discussed initially with the care provider. In case of still existing doubt, they could further be discussed with the internal ethics committee that was set up for this study.

## Initial data collection and analysis

Two midwifery practices were selected from the networks of the researchers for pilot testing of the patient safety assessment instrument. One practice was a small, rural practice; the other was a large, urban practice. For each practice, 100 patient records were randomly selected, and a total of 200 records were examined by reviewers using the instrument. All of the identified incidents and unsafe procedures were then assessed, described extensively, and given a preliminary cause classification by the reviewers.

## Results

### Results of pilot testing and adjustment of the instrument

It took 2 reviewers 4 days to judge 200 patient records for possible incidents. The degree of agreement on the presence of a safety incident was 75%. The trained reviewers perceived the scoring list as extensive and complicated. In revising the instrument based on this pilot test, we omitted items that could be assumed to already be a part of the professional competence of midwives. For instance, time delays could be clustered into 3 core items instead of describing all possible telephone and house-call moments of contact. Communication items were clustered in 2 categories – communication inside the midwifery practice and outside the practice. We replaced the list of all possible caretakers involved in communication (e.g., obstetrician, general practitioner) to the safety item list (Appendix 1). The number of patient risk items was also reduced; these items are part of clinical knowledge of experienced midwives. For the same reason, the extensive description of all necessary referral indications according to the current guidelines were reduced to 2 items – referral during pregnancy and referral during or after birth. The detailed clinical management items were replaced, as preventive and diagnostic procedures are assumed to be part of daily practice. Suboptimal outcomes for mother or child generally serve as a trigger for experienced observers and therefore no longer needed a subclassification of possible complications and a description of all congenital abnormalities.

Sufficiently detailed and careful analysis of actual patient safety incidents took much more time than expected. Given that we aimed for great thoroughness, no incident could be missed, and the details of each incident had to be carefully documented. The details of an actual safety incident were discussed with the other reviewer when there was any doubt about whether the event constituted a safety incident. If consensus could not be achieved, the remainder of the review team was called in, followed by the panel of experts to provide a final judgment on the basis of the information provided to the original 2 reviewers.

The pilot testing of the instrument protocol on 200 patient records revealed 4 safety incidents. The panel of experts confirmed the type, cause, actual harm, and possible consequences for each incident. The incidents could be categorized according to the safety domains we identified and the safety items included in our instrument. The literature search and expert validation procedure used here thus produced good content validity. Based on the pilot results, several further adjustments were made to develop a patient safety instrument with high content validity and feasibility. These adjustments are presented in Table 1.

**Table 1. Development of the final instrument from the pilot instrument**

<b>Safety domain</b>	<b>Safety items pilot instrument</b>	<b>Safety items final instrument</b>	<b>Specified safety items (for incident description)</b>
Organization	10	4	6
Communication	12	2	10
Patient risk factors	23	10	13
Clinical management	10	4	6
Outcomes	45	12	33
Total	100	32	68

### Testing of final instrument

The final instrument, the IQ Safety Instrument Midwifery (IQ-SIM), contained 4 organizational items, 2 communication items, 10 patient-related risk factors, 4 clinical management items, and 12 outcomes (Appendix 1). When a possibly unsafe situation was discovered by a reviewer, a more extensive list of specification items was then consulted (the "safety item list" is included in Appendix 1). The IQ-SIM requires an initial dichotomous score indicating the occurrence of a specific safety incident or not, followed by a further description of the incident when one is judged to have occurred.

The face and content validity of the final instrument was discussed by the review team together with the panel of experts. It was concluded that the insights provided by pilot testing were sufficiently incorporated and no further adjustments to the instrument were needed.

The final instrument was next used in 18 midwifery practices, which were randomly selected from a national database. Over a period of 4 months, the review team visited the practices and reviewed 50 randomly selected patient records per practice using the final instrument. The application of the final instrument reduced the review time by half compared to the prototype instrument. Reviewers identified 85 safety incidents of which 24 incidents had a noticeable effect for the women and/or children. We cross-checked our findings by determining the interobserver agreement. Possible variation in the patient record review process across reviewers was examined by having 2 reviewers independently examine 50 patient records selected from the first 5 practices. The degree of agreement was 75%. Review reliability was evaluated and discussed by the expert team, along with some inconclusive cases, in order to gain consensus on the assessment of patient safety. The adjustments made to the instrument protocol produced a final instrument with good applicability, reliability, and feasibility. Both the instrument protocol and the final instrument showed good content validity. All identified safety incidents could be classified using the instrument domains and items of safety.

## Discussion

The quality of midwifery care is an important issue worldwide.<sup>38</sup> Despite research from different perspectives, explicit recommendations to improve perinatal care are difficult to make and substantiate. Validated and systematic safety research in midwifery care allows us to focus on specific risk domains and provide specific improvement procedures and recommendations.

We have developed and pilot tested a new instrument of patient safety in midwifery-led care. In doing this, we identified 5 domains of midwifery safety risk for otherwise low-risk childbearing women. We involved a panel of midwifery and patient safety experts to put the safety domains into a number of safety items and safety limitations. We applied the measure to actual patient records and were able to demonstrate that the final instrument showed high content validity and good feasibility.

While a validated instrument for identifying patient safety concerns in midwifery-led care for low-risk childbearing women is now available, there are some cautions to observe. Trained reviewers with clinical experience in midwifery practice are needed for proper use of the instrument; use of the instrument by students and other inexperienced providers is not recommended. Further validation compared to other study methods in patient safety research is recommended. As our method depends on records of the midwives themselves, other methods like observation and auditing might reveal different safety aspects.

The instrument we developed can be used for quantitative analyses of patient records and to identify unsafe – or possibly unsafe – situations. It can also be used to quantify patient safety in incident reporting systems for practices and the healthcare system in general. The instrument allows us to draw conclusions about safety, based on a root cause analysis, and to recommend steps for specific, domain-based improvements within the midwifery practices themselves, maternity care teams, at the regional level, and at the national level. Given the clearly positive contribution of midwife-led care to the quality and safety of maternal care, the IQ-SIM can help substantiate both research and quality improvement efforts concerned with the healthcare for healthy pregnant women – who constitute the majority of women worldwide.<sup>2</sup>

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## Appendix: IQ Safety Instrument Midwifery (IQ- SIM) and detailed safety item list

This table displays the final instrument being used and contains 2 sections. The first part on the left, IQ-SIM, is used for an initial assessment to retrieve possible incidents. The corresponding second part on the right, the safety item list, is used for detailed dichotomous scoring of these incidents.

<b>IQ-SIM</b>	<b>Yes</b>	<b>No</b>	<b>SAFETY ITEM LIST</b>	<b>Yes</b>	<b>No</b>
<b>Organization</b> Delay in arrival of midwife (more than 15 minutes)  Delay in attainability of hospital care (more than 45 minutes) Delay in ambulance transportation to hospital (more than 45 minutes) Birth with no midwife or maternity assistant present (birth before arrival)			<b>Organization</b> Presence of incident regarding <ul style="list-style-type: none"> <li>personal availability midwife</li> <li>availability midwife by telephone</li> <li>availability hospital</li> <li>availability ambulance</li> <li>Birth with no midwife present (birth before arrival)</li> <li>Birth with no maternity assistant present</li> </ul>		
<b>Communication</b> Communication incident with primary midwifery caregivers (inside practice)  Communication incident with other caregivers (outside midwife practice)			<b>Communication</b> Communication incidents within practice with <ul style="list-style-type: none"> <li>colleague midwife</li> <li>practice assistant</li> <li>student</li> <li>other</li> </ul> Communication incident outside practice with <ul style="list-style-type: none"> <li>gynecologist</li> <li>general practitioner</li> <li>clinical midwife</li> <li>nurse</li> <li>pediatrician</li> <li>other</li> </ul>		
<b>Patient risk factors</b> Presence of general risk factors  Presence of social risk factors			<b>Patient risk factors</b> <ul style="list-style-type: none"> <li>General factors               <ul style="list-style-type: none"> <li>ethnicity non-Dutch</li> <li>language barrier</li> <li>age &lt;20 or age ≥40</li> </ul> </li> <li>Social factors               <ul style="list-style-type: none"> <li>involvement in social care</li> <li>resident of socially disadvantaged area</li> <li>domestic violence</li> <li>sexual abuse</li> <li>children from more than 2 partners</li> <li>abortion in obstetric history</li> <li>no partner</li> </ul> </li> </ul>		

<b>IQ-SIM</b>	<b>Yes</b>	<b>No</b>	<b>SAFETY ITEM LIST</b>	<b>Yes</b>	<b>No</b>
Presence of lifestyle factors			<ul style="list-style-type: none"> <li>• Lifestyle               <ul style="list-style-type: none"> <li>- smoking</li> <li>- alcohol consumption</li> <li>- drug abuse during pregnancy</li> <li>- unhealthy diet</li> <li>- obesity</li> <li>- remarks with regard to high workload</li> </ul> </li> </ul>		
Presence of mental risk factors			<ul style="list-style-type: none"> <li>• Involvement in mental health care, remarks of psychological stress</li> </ul>		
Use of medication			<ul style="list-style-type: none"> <li>• Use of medication</li> <li>• Divergent lab results (HIV, HBsAg, Syphilis, Rhesus D antibodies negative, Irregular antibodies positive, other)</li> <li>• Fertility treatment for this pregnancy</li> </ul>		
Presence of risk factors in family history			<ul style="list-style-type: none"> <li>• Family history               <ul style="list-style-type: none"> <li>- congenital abnormalities in family history</li> <li>- hereditary diseases</li> </ul> </li> </ul>		
Presence of risk factors in obstetric history			<ul style="list-style-type: none"> <li>• Obstetric history               <ul style="list-style-type: none"> <li>- hypertensive disease</li> <li>- post partum hemorrhage &gt; 1000cc</li> <li>- small for gestational age (&lt;P 5)</li> <li>- large for gestational age (&gt;P 95)</li> <li>- premature birth</li> <li>- perinatal death</li> <li>- complicated artificial delivery or caesarean section</li> <li>- psychological disorders</li> </ul> </li> </ul>		
Woman does not follow prescribed therapy and no show			<ul style="list-style-type: none"> <li>• Current pregnancy               <ul style="list-style-type: none"> <li>- does not follow prescribed therapy or no show</li> <li>- uncertain due date after 22 weeks' pregnancy</li> </ul> </li> </ul>		
Presence of referral procedures in this pregnancy			<ul style="list-style-type: none"> <li>• Referral procedures in this pregnancy</li> </ul>		
Presence of referral procedures during/after birth			<ul style="list-style-type: none"> <li>• Referral procedures during birth</li> <li>• Referral procedures after birth</li> </ul>		
<b>Clinical management</b>			<b>Clinical management</b>		
Incidents during preventive procedures			<ul style="list-style-type: none"> <li>• Incidents regarding timely and complete information about prenatal tests</li> </ul>		
Incidents during diagnostic procedures			<ul style="list-style-type: none"> <li>• Incidents due to laboratory tests during process of care</li> <li>• Incidents due to ultrasound procedures during process of care</li> </ul>		
Medication incidents			<ul style="list-style-type: none"> <li>• Incidents due to incorrect prescription, dosage, or administration of medication during process of care</li> <li>• Quality of record keeping               <ul style="list-style-type: none"> <li>- Incomplete</li> <li>- Moderate</li> <li>- Good</li> </ul> </li> </ul>		

<b>IQ-SIM</b>	<b>Yes</b>	<b>No</b>	<b>SAFETY ITEM LIST</b>	<b>Yes</b>	<b>No</b>
Number of contacts, first antenatal visit after 10 weeks' pregnancy or < 12 consults in full antenatal care			<ul style="list-style-type: none"> <li>Number of recorded contacts in the antenatal, intrapartum and postnatal period (home call, telephone consult, consult at practice)</li> </ul>		
<b>Outcomes</b>  Neonatal outcome: Small or large for gestational age  Low Apgar score <7 after 5 minutes Breech birth Congenital abnormalities Hospital admission of this infant          Birth trauma Maternal outcome: Anemia, complicated instrumental delivery or caesarean section          inadequate coping after postnatal period,  traumatic experience of birth, suspicion of depression or psychosis  prolonged hospitalization			<b>Outcomes</b> <ul style="list-style-type: none"> <li>Remarks in patient record regarding;               <ul style="list-style-type: none"> <li>incorrect referral</li> <li>late referral</li> <li>referral due to incorrect procedures</li> <li>absence of referral related to suboptimal outcome</li> </ul> </li> <li>Neonatal outcomes:               <ul style="list-style-type: none"> <li>small for gestational age</li> <li>large for gestational age</li> <li>low Apgar score, &lt;7 after 5 minutes</li> <li>breech birth</li> <li>congenital abnormalities</li> <li>hospital admission for hypoglycemia</li> <li>neurologic problems</li> <li>circulation problems</li> <li>malnutrition</li> <li>infectious diseases</li> <li>problems related to temperature regulation</li> <li>clavicular fracture</li> <li>brachial plexus injury</li> <li>other problems</li> </ul> </li> <li>Maternal outcomes:               <ul style="list-style-type: none"> <li>anemia</li> <li>complicated instrumental birth</li> <li>caesarean section</li> <li>mastitis</li> <li>uterine infections</li> <li>postpartum hemorrhage</li> <li>other infectious diseases</li> <li>wound infections</li> <li>inadequate coping after postnatal period</li> <li>traumatic experience of birth</li> <li>suspicion of depression</li> <li>psychosis</li> <li>prolonged hospitalization</li> <li>other problems.</li> </ul> </li> <li>Failure of technical equipment</li> </ul>		
<b>Cause classification of the incident</b> <sup>35</sup>			<ul style="list-style-type: none"> <li>Related to latent conditions (technical or organizational)</li> <li>Active errors (human: knowledge-based behavior, human: rule-based behavior, human: skill-based behavior)</li> <li>Other factors (patient related or other type)</li> </ul>		

<b>IQ-SIM</b>	<b>Yes</b>	<b>No</b>	<b>SAFETY ITEM LIST</b>	<b>Yes</b>	<b>No</b>
<b>Harm to the woman/child<sup>31</sup></b>			<ul style="list-style-type: none"> <li>• Error, but no harm</li> <li>• Error resulting in harm to the woman/infant</li> <li>• Error resulting in death</li> <li>• Error, but harm indeterminate</li> </ul>		
<b>Probability of severe harm or death<sup>31</sup></b>			<ul style="list-style-type: none"> <li>• Very probable</li> <li>• Probable</li> <li>• Not probable</li> </ul>		
<b>Incident description</b>					



## **Chapter 4**

# **Patient safety in midwifery-led care in The Netherlands**

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Midwifery 2013; 29: 60–66.

## Abstract

*Objective:* To describe the incidence and characteristics of patient safety incidents in midwifery-led care for low-risk pregnant women.

*Design:* Multi-method study.

*Setting:* 20 Midwifery practices in The Netherlands; 1,000 patient records.

*Population:* Low-risk pregnant women.

*Methods:* Prospective incident reporting by midwives during 2 weeks; questionnaire on safety culture and retrospective content analysis of 1,000 patient records in 2009.

*Main outcome measures:* Incidence, type, impact and causes of safety incidents.

*Results:* In the 1,000 patient records involving 14,888 contacts, 86 safety incidents were found with 25 of these having a noticeable effect on the patient. Low-risk pregnant women in midwifery care had a probability of 8.6% for a safety incident (95% CI 4.8-14.4). In 9 safety incidents, temporary monitoring of the mother and/or child was necessary. In another 6 safety incidents, reviewers reported psychological distress for the patient. Hospital admission followed from 1 incident. No safety incidents were associated with mortality or permanent harm. The majority of incidents found in the patient records concerned treatment and organizational factors.

*Conclusions:* A low prevalence of patient safety incidents was found in midwifery care for low-risk pregnant women. This first systematic study of patient safety in midwifery adds to the base of evidence regarding the safety of midwifery-led care for low-risk women. Nevertheless, some areas for improvement were found. Improvement of patient safety should address the better adherence to practice guidelines for patient risk assessment, better implementation of interventions for known lifestyle risk factors and better availability of midwives during birthing care.

## Introduction

In most developed countries, hospitals have become the setting for childbirth. The number of medical interventions in perinatal care has also increased steadily over time, raising many questions about the benefits, safety and risks for healthy childbearing women.<sup>1</sup> In many parts of the world, midwives are the primary providers of care for childbearing women. Midwifery-led care emphasises the normality of birth and the continuity of care. All models of midwifery care are provided in a multi-disciplinary network of consultation and referral with other care providers.<sup>2</sup> International empirical evidence on the safety of midwifery-led care for low risk childbearing women is limited.<sup>3</sup> In The Netherlands, midwifery care is mainly provided in a primary healthcare setting by teams of midwives in small office-based practices outside hospitals and close to the pregnant women's homes. Dutch midwives are responsible for the prenatal, natal and postnatal care for women with low-risk profiles based on their obstetric and medical histories. Midwives refer a pregnant woman to obstetric specialists in a hospital when a high risk of complication is expected. They use detailed protocols for risk assessment combined with clinical judgment. In The Netherlands, most referral arrangements are specified in an Obstetric Manual, which is a document based on best evidence or consensus between obstetric and midwifery caregivers.<sup>4</sup> In 2007, 20% of pregnant women received complete obstetric care in a hospital due to the detection of a high risk in their medical or obstetric histories during early pregnancy.<sup>5</sup> Some 80% of the pregnant women with a low-risk pregnancy profile according to the Obstetric Manual started their prenatal care in a midwifery practice and thus had the possibility of choosing the place of birth – either at home or in hospital with her own midwife.

In recent years, much attention has been paid to patient safety in healthcare and to the registration and examination of safety incidents, particularly in hospitals. There is a paucity of data on patient safety in primary healthcare settings.<sup>6</sup> The Dutch Ministry of Health (VWS) therefore funded a nationwide study to obtain national safety figures for five types of primary care settings: general practices, out-of hours primary care offices, general dental practices, midwifery practices and allied healthcare practices. The overall objectives of the study were to identify the incidence, type and impact of safety incidents among Dutch primary care patients, examine the causes of the safety incidents and compare the rates, types and causes of the safety incidents across the five types of primary care settings.<sup>7</sup> The focus of the study reported on here is on the midwifery part of the aforementioned research. Previous research on patient safety among childbearing women in hospital care has been concentrated on natal care. Human error and system-based problems related to



staffing levels, medication, the use of technical equipment, knowledge, skills and communication have been identified as risk factors during obstetric care.<sup>8,9</sup>

Many definitions of patient safety have been proposed. The World Health Organization defines an 'adverse event' as a process or act of omission or commission that resulted in hazardous healthcare conditions and/or unintended harm to the patient. A patient safety incident is defined as an unintended event during the care process that resulted, could have resulted or still might result in harm to the patient.<sup>10</sup> We adopted this definition and focused on unnecessary physical/mental harm or potential harm for the individual. The risk had to be scientifically documented or broadly recognized as legitimate. The present study was specifically aimed at documenting the number and types of safety incidents in midwifery care for low risk childbearing women.

## Methods

In an earlier study of patient safety in primary care, a mix of methods was found to be necessary to identify safety incidents.<sup>11</sup> A more recent Australian measure of patient safety in maternity care substantiated the benefits of adopting multi-method approach.<sup>12</sup> In the present study, both retrospective and prospective methods were therefore adopted to identify safety incidents in midwifery care. The retrospective component entailed a review of 1,000 patient records. The prospective component involved the reporting of safety incidents across a period of two successive weeks by actively practicing midwives and practice assistants in 20 practices using standardized forms. This combination of methods was used to identify incidents, determine the type of incidents and the seriousness of the harm, which resulted from them. In addition, we gathered information using a pre-structured questionnaire with regard to various organizational and cultural factors related to patient safety from all of the participating practices. The content of this questionnaire was derived from the Safety Attitudes Questionnaire (SAQ).<sup>13</sup> An expert team meeting of researchers and midwives was held to fine-tune the specifics of the midwifery study protocol. The protocol for the general study of safety in primary healthcare practices has already been published.<sup>7</sup>

## Study population

We randomly sampled 1,000 patient records from an estimated mean total population of 5,400 pregnant women for whom midwifery care finished in 2008. The patient records came from a sample of 20 midwifery practices recruited from those Dutch midwifery practices registered with the Royal Dutch Organization of Midwives (KNOV). When selecting the practices, we aimed for stratification with regard to

practice size, degree of urbanization for the practice location and regional representation for The Netherlands. This selection procedure resulted in the inclusion of low risk pregnant women who received prenatal, natal and postnatal care but also women who miscarried, had a referral during their pregnancy or received only postnatal care.

## Measures

For the retrospective inspection of the patient records, a safety assessment instrument was developed on the basis of the literature on patient safety in general and patient safety in obstetric and midwifery care in particular. Given that risk assessment is a key feature of midwifery care, the use of existing guidelines and classification as low, medium or high risk according to the Obstetric Manual were prominent parts of the patient safety assessment instrument. A pilot version of the assessment instrument was developed and reviewed in an iterative procedure by a team of midwifery experts and researchers. The instrument was then pilot tested and shown to be both reliable and feasible.<sup>14</sup> This resulted in the final version of the instrument.

The patient safety assessment instrument provides information with regard to the following: patient age in categories; social-economic status according to postal codes, which indicates advantaged/disadvantaged areas of The Netherlands as defined by the Dutch Ministry of Health<sup>15</sup>; recordings of possible communication problems; patient risk assessment based on obstetric history; current health status; lifestyle factors and any psycho-social problems; quality of record keeping in terms of completeness of records on various standardized parts; number of contacts during care; calls for help due to medical emergency; involvement of various caretakers from primary, secondary or tertiary care; whether or not a safety incident had occurred; and a description of the safety incident with actions taken after the incident.

Possible variation in the patient record review process across reviewers was examined by having two reviewers independently examine 50 patient records selected from the first five practices. The degree of agreement was 75%. The kappa procedure was considered less suitable for measuring the inter-rater reliability because of the low rate of incidents.<sup>16</sup> Review reliability was therefore evaluated and discussed by the expert team along with some inconclusive cases in order to gain consensus on the assessment of patient safety.

For the collection of the prospective patient safety data, participants were asked to record and describe all safety incidents during their daily work across a period of 2 weeks using a standard form. The reported incidents were then assessed by the

reviewers with regard to the following: type of incident, cause, actual harm to the patient and probability of severe harm or death.

## Data analysis

The patient records were reviewed by a team of five research midwives who all had at least 5 years of postgraduate experience and were trained to examine the causes of safety incidents using the Prevention and Recovery Information System for Monitoring and Analyses (PRISMA) method.<sup>17</sup> The main aim of the PRISMA is to establish a quantitative database of safety incidents and process defects for the identification of improvement measures. The PRISMA involves three components: (1) incident description, (2) incident classification and (3) translation of the causes to structural measures.

After the description of the safety incidents, they were classified as concerning one of the following: organization, communication, preventive care, triage, diagnostic procedures or treatment. The causes of the safety incidents were then classified using the Eindhoven Classification Model (ECM), which is part of the PRISMA, as being due to technical failure, organizational failure, knowledge-based and rule-based behavior or other factors including patient-related causes. The PRISMA recommends referring to patient-related factors as little as possible.

Finally, two reviewers independently classified the extent of damage for those safety incidents, which occurred using the 'severity of outcome' dimension of the International Taxonomy of Medical Errors in Primary Care.<sup>18</sup> The extent of harm could be classified as 'necessity of monitoring', 'presence of emotional or temporary damage', 'temporary damage with hospital admission' or 'permanent damage'. The harm classifications were made on the basis of remarks from the patients reported in the records and/or reviewer estimates. The two reviewers also screened the incidents for the likelihood of having caused severe damage or death. The incidents could be classified as 'unlikely' to 'very likely'. Inconclusive results were discussed by the team of researchers and expert midwives.

## Findings

### Sample characteristics

In Table 1, the participating practices are described in terms of practice type and size. The composition of the recruited practices was similar to national figures with respect to practice type and average number of midwives.

**Table 1. Characteristics of participating primary care midwifery practices**

Characteristics	Study sample (n=20 practices)	National Dutch figures <sup>19</sup>
Type of practice	6% solo 11% duo 83% group	5.1% solo 14.1% duo 80.8 %group
Average number of caregivers	2.9 midwives 0.7 locum 0.2 students 0.1 maternity assistants 0.8 practice assistants	
Internship for midwifery students	78%	

In Table 2, the characteristics of the patients from the 1,000 randomly selected patient records are described and compared to national data when available in terms of age, lifestyle factors and information on the care process, which included referrals and birth outcome and postnatal problems.

**Table 2. Patient characteristics of 1,000 randomly selected patient records**

	Study sample (n=1,000 patients from 20 practices) (%)	National Dutch figures (%) <sup>20</sup>
<b>Age</b>		
15-19	1.3	1.7
20-24	9.7	10.9
25-29	26.7	29.5
30-34	39.2	36.2
35-39	19.3	18.8
40-44	3.7	2.8
Residing in a socially disadvantaged area	3.6	7 <sup>21</sup>
Not ethnically Dutch	10.7	19.6
<b>Lifestyle</b>		
Smoking during pregnancy	12.9	7.6 <sup>22</sup>
Alcohol use	0.08	
Drug abuse	0.04	
BMI>30	5	
Remark of high workload	5.7	
Remark of unhealthy diet	1	
<b>Process of care</b>		
Emergency request for help (for instance birth assistance)	66.8	
Referral during pregnancy	36.9	31.1
Referral during birth or directly after birth	26.4	39.7
Hospital admission child	1.4	1.1
SGA<P5	1.9	2.1
LGA >P95	3.8	
Apgar score <7	1.4	1.9
<b>Postnatal psychological problems</b>		
Inadequate coping	6	
Traumatic birth experience (remark in file until 6 weeks pp)	0.6	

There were 14,888 recorded contacts. Compared to the national figures, slightly fewer patients in our sample lived in a disadvantaged area. About 9% fewer patients were non-native Dutch. Considerably more risk factors were noted, particularly smoking and reports of high workloads. For a substantial number of the women (63%), a referral during the pregnancy or birth was required, which is in accordance with national figures. The neonatal outcomes were also comparable to the national Dutch results of primary care. Postnatal maternal psychological problems were mentioned in 7% of the records.

### Safety management and aspects of practices

In Table 3, the questionnaire results for those items concerned with safety management and aspects of the practice are presented. Most of the practices had procedures to assure continuous availability, protect automated data and register complaints. However, only a minority of the practices had a quality monitoring system, incident registration or safety policy.

**Table 3. Safety management and safety aspects of study practices**

Have a complaint procedure	94%
Joint policy for availability	89%
Protection of automated data	72%
Produce annual practice report	61%
Quality considerations in annual report	56%
Have a safety policy	39%
Use a quality monitoring system	22%
Register incidents and near incidents	17%

### Incident reporting

During the 2 weeks of consecutive data collection, 12 of the 20 midwifery practices reported 36 patient safety incidents; 27 were analyzed in greater detail as the other 9 pertained to hospital care and therefore did not involve a midwife. None of the reviewed safety incidents could have caused severe harm or death in the opinion of the reviewers, but 2 of the 27 reported incidents could have caused patient harm. The largest numbers of reported incidents involved either organizational problems (n=11) or communication problems (n=6).

### Patient record review

With regard to completeness of the medical, social, psychological and obstetric histories and registration of the care process in terms of ultrasound outcomes, laboratory reports and – in cases of referral – hospital reports, 87% of the 1,000 randomly selected patient records were judged to be 'good'. Only 13% of the records

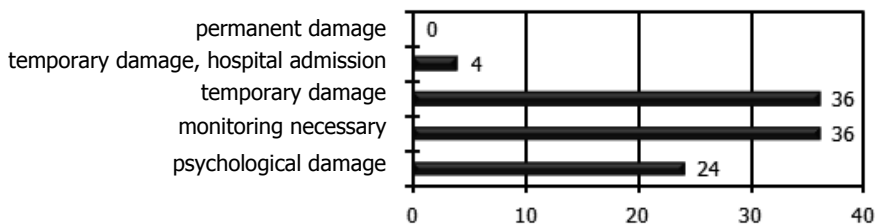
were judged to be of moderate quality. It struck the reviewers that particularly in cases of referral to a hospital during the birth process, a discontinuity in the record keeping with regard to the birth process was often present prior to referral to an obstetric specialist.

For the 14,888 contact moments reported in the 1,000 patient records, 86 safety incidents in 1,000 patient records concerning the 14,888 contact moments were referred to. Applying  $ICC=0.124$  and  $\alpha=0.05$ , a pregnant woman in primary midwifery care has a 8.6% probability to experience a safety incident (95% CI=4.8-14.4). This percentage includes both incidents with and without noticeable effects for the woman and her child.

### Severity of safety incidents

Only 25 of the 86 safety incidents had a noticeable effect on the patient, which meant a 2.5% probability of experiencing a safety incident with a noticeable effect. When the number of contacts was also taken into consideration, the probability of experiencing a safety incident with a noticeable effect on the patient was found to be 0.17% per patient contact. Figure 1 provides an overview of the severity of the noticeable effects on the patient.

**Figure 1. Incidents with noticeable effects (n=25), severity of damage %**



For most safety incidents, only temporary monitoring of the mother and/or child was required. For instance:

Delay in birth care because of an error in the emergency telephone call system, a house call was made 1.5 hrs after the patient informed the midwife because of a term rupture of membranes, condition of mother and child were good.

Patient with an uncomplicated home birth had a haemorrhage post partum, 1500 cc. Patient was not referred to a hospital. On the second day in the puerperal period, the Hb test showed a level of 6.4 mmol/l, iron supplementation was prescribed, patient's clinical condition was good.

In 6 of the 25 cases with a noticeable effect, the safety incident was judged by reviewers to have caused anxiety or some other psychological harm.

Telephone call from a patient with regular contractions did not reach the attending midwife. She arrived at the woman's home at the beginning of the second stage of labor, condition of mother and child post partum were good.  
Midwife arrives 25 minutes after a telephone call with a patient in labor for her seventh child, the child is born 7 minutes after arrival of the midwife.  
Midwifery care was only provided during the puerperal period because of a severe depression with medication in patient's history for which specialist hospital care was necessary. Because of work overload in the practice, only two telephone calls were made to the patient in order to check on the condition of mother and child.

In 9 of the 25 cases of a noticeable effect, the safety incident was judged to cause temporary harm.

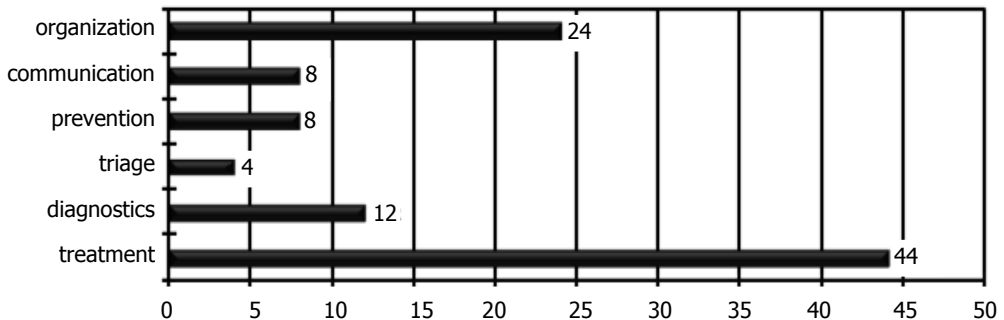
Obstetric history of patient shows a large for gestational age child, > P97,7, BMI of the mother is 34. Patient refuses glucose tests, no additional ultrasounds are made, birth weight of the child born in 2008 is > p97,7. Extra glucose checkups and monitoring of the child during the first hours post partum were necessary.

In only 1 of the 25 safety incidents with a noticeable effect on the patient was hospital admission required. No incidents with permanent harm were reported.

Because of an obstetric history with intrauterine growth restriction (<P10) for the second and third children, midwife consults with obstetric specialist about monitoring of this pregnancy. The patient is allowed to receive prenatal midwifery care, no additional ultrasounds are made until the term period, at 40 weeks pregnancy the patient is referred to the hospital for suspected growth restriction, the child is born in the hospital with a birth weight below P5 and referred to a neonatal specialist.

Figure 2 provides an overview of the causes of the safety incidents identified using the PRISMA method. In the midwifery practices we studied, most of the safety incidents concerned treatment factors or organizational factors.

With regard to the treatment factors, the two reviewers reported inadequate adherence to guidelines for the monitoring of fetal growth for women with a small or large for gestational age child in their obstetric history, insufficient monitoring of fetal growth for pregnant women who are obese or smoke and limited adherence to such guidelines as the KNOV Anaemia Guideline.<sup>23</sup>

**Figure 2. Noticeable incidents (n=25), cause classification %**

In Table 4, the classifications of the safety incidents reported in the patient records are summarized. Table 4 shows particularly problematic domains to be availability, patient risk assessment and communication. The organizational problems most frequently encountered in birth records concerned the presence of a midwife following two emergency calls for help. Inadequate assessment of urgent situations concerning availability of care was judged to occur in 6.4% of the safety incidents and substandard care related to risk assessment in 3.7% of the incidents. In 2.5% of the safety incidents, communication problems were judged to have occurred.

**Table 4. Problems of availability, patient risk assessment and communication associated with safety incidents found in 1,000 patient records**

<b>Risk domains</b>	<b>Percentage of incidents found (n=1,000 patient records)</b>
<b>Availability incident</b>	
Incident availability midwife > 15 minutes	1.9
Incident availability hospital care > 45 minutes	1.1
Incident availability ambulance transport >45 minutes	0.01
Midwife not present or < 15 minutes before time of birth	1.7
Birth assistance not present or < 15 minutes before time of birth	1.7
<b>Communication incident</b>	
Mention of communication problem	1.5
Incident regarding communication in process of care	0.02
Incident regarding personal behavior	0.02
Delay caused by miscommunication	0.09
Client factor regarding communication	0.7
<b>Patient risk assessment incident</b>	
Non-adherence to Anaemia Guideline	1.2
Ignorance of SGA or LGA children in obstetric history	1.4
Ignorance of postnatal depression/psychological problems in medical history	0.04
Incomplete information regarding risk factors in family or medical history	1.0
Late referral according to Obstetric Manual	0.05



As already mentioned, 25 of the 86 safety incidents identified in the patient records were judged to have noticeable consequences for the patient. The probability of severe damage or death was judged to be unlikely for 15 of the 25 incidents; for the other 10 incidents, severe damage or death was judged to have potentially been caused.

## **Discussion and conclusion**

In the 20 midwifery practices examined in this study, we found a 2.5% probability per patient of a safety incident. This is a relatively small percentage of safety incidents. It should not, however, be accepted as the safe reference for midwifery care simply because specific improvement measures may further reduce the chances of a safety incident.

Our results show patient risk assessment to generally be applied in keeping with the Obstetric Manual. The most urgent requests for help were properly handled, and the records showed adequate and frequent checkups during the prenatal, natal and postnatal care process.

Domains found to be 'at risk' for causing a safety incident during midwifery care were the organization of the urgent care process and risk assessment in treatment. Organizational factors influencing mostly the availability of the caregiver also contributed to the risk of safety incidents. Despite written procedures and appointments, midwives appear to hesitate to call in an oncall colleague when two urgent requests for help are received at the same time. Qualitative research examining patient safety in obstetric care has also shown interprofessional communication combined with workload pressures to be a threat to patient safety.<sup>24</sup> Given the importance of physically attending the birth process and the importance of continuity of care for women giving birth, improvement measures to assure the timely presence of the midwife and maternity assistant should result in less anxiety on the part of parents and better monitoring of the birth period.<sup>25</sup> Improving this important feature of midwifery care should also contribute to fewer referrals and interventions aimed at, for example, pain relief and thereby decrease instrumental delivery rates. In addition, the degree of maternal satisfaction with the care will presumably increase.<sup>2</sup>

Underestimation of the level of risk on the basis of the medical or obstetric histories of patients was also found to be a cause of safety incidents. Based on child outcome factors and having a small or large gestational age in particular, the reviewers in our study concluded that the presence of a child with a small or large for gestational age in the obstetric history, did not lead to sufficient monitoring of fetal growth during the current pregnancy. Given the predictive value of birth weight for problems during

pregnancy, birthing and the neonatal period, better monitoring of fetal growth is thus recommended and should lead to better assessment of patient risk during pregnancy.<sup>26</sup>

Another cause of safety incidents in treatment was the lifestyle of the childbearing women and in particular a large BMI and/or smoking. Although lifestyle factors are difficult to influence, evidence-based intervention procedures are available for midwives to use to reduce the prevalence of smoking during pregnancy.<sup>27</sup> In a substantial number of the records of for pregnant women who smoked, no mention was made of use of these intervention procedures despite the possibility of standard notation of this intervention in patient records. Other research in The Netherlands on the offering of smoking cessation support during healthcare has similarly shown only 29% of midwives to apply the proper support instrument for intervention on smoking pregnant women.<sup>28</sup>

For obese pregnant women, relatively few remarks about their weight at the beginning of the pregnancy or during the pregnancy were encountered in their patient records. Additional monitoring of fetal growth for obese women was not standard procedure in most of the midwifery practices in our study.

Dutch midwifery care is known to result in a relatively small number of intrapartum emergency referrals and show satisfactory neonatal outcomes for births led by a primary care midwife.<sup>29</sup> However, the large volume of contact and procedures involved in midwifery care with a high number of referrals to obstetric specialists and referrals back from hospitals for renewed primary midwifery care means that safety incidents can still occur.

The methods used in the present study may have caused both underestimation and overestimation of the safety incidents during midwifery care. The use of a convenience sample of Dutch midwifery practices may have produced a selection bias towards practices, which pay particular attention to patient safety and are therefore more likely to have better procedures for record keeping and engaging in quality improvement activities. Overestimation may have occurred as the research method for reviewing patient records involves very detailed recording of patient features, aspects of the care process, care outcomes and potential safety incidents. Given the importance of safety measurement for quality improvement purposes<sup>30</sup>, we included the potential for safety incidents in the present study.

The retrospective review of patient records and incident reporting forms may have caused a hindsight bias. Differences in record keeping may also have influenced the comparability of results.<sup>31</sup> A great deal of the present analyses depended on the accuracy of the patient records, which were kept. Particularly in cases of referral during the birthing process, it struck the reviewers that a major discontinuity in the

record keeping of the midwifery practices emerged. Notes taken while the woman was still under the care of a midwife before referral to the hospital were not accurately recorded in the patient's record.

The analyzed reported safety incidents could be mostly classified as pertaining to organizational or communication problems. It is reasonable to assume that the focus from midwives regarding incidents is more on evident procedures such as omissions in the daily practice, organization and miscommunication with the patient and other caretakers. However, incident reporting is highly dependent on institutional and unit cultures.<sup>30</sup> By combining the results of three data sources, we were able to minimize the limitations inherent to a particular study method. The quality of obstetric and midwifery care for childbearing women is an important topic in many countries. In The Netherlands, the quality of pregnancy and birth care is a frequently discussed topic in the media. According to the results of the Taskforce Pregnancy and Birth, an Advisory Committee to the Ministry of Health in The Netherlands, both the risk profile of Dutch pregnant women and the quality of the obstetric care system influence perinatal outcomes in The Netherlands.<sup>32</sup> In a recent cohort study, Evers et al.<sup>33</sup> have questioned the quality of the Dutch obstetric care system after finding that the infants of women who were referred by a midwife to an obstetrician during labor had a 3.66 times higher risk of delivery-related perinatal death than the infants of women who started labor under the supervision of an obstetrician. The results of this regional study are nevertheless in contrast to the results of a large national study, which showed no relation between births being led by primary care midwives and an increased risk of perinatal death.<sup>29</sup> The present study is an explicit and systematic audit of patient safety in midwifery care and thus adds to the pool of evidence regarding the safety of midwifery care for low-risk pregnant women.

The analyses of the safety incidents in the present study and identification of specific domains of risk provide midwives with empirical evidence to guide improvement of their practices. Their availability and the continuity of birth care should be improved along with the application of guidelines and patient risk assessment. These recommendations are in accordance with other qualitative research on the safety of maternity services.<sup>34</sup>

In this first study of patient safety during midwifery care in a detailed and systematic manner using the validated PRISMA to analyze the data, we found only a small number of safety incidents. Most of the incidents had no noticeable effect on the pregnant women or their babies. These findings are in accordance with the overall conclusions of the national Patient Safety study. The methods and results of our study can thus be used for the broader implementation and evaluation of the improvement measures, which we recommend.

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## **Chapter 5**

# **Are health professionals' perceptions of patient safety related to figures on safety incidents?**

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Journal of Evaluation in Clinical Practice 2013; 19(5): 944-947.

## **Abstract**

*Objective:* The study aims to explore whether healthcare professionals' perceptions of patient safety in their practice were associated with the number of patient safety incidents identified in patient records.

*Setting:* Seventy primary care practices of general practice, general dental practice, midwifery practices and allied healthcare practices were used in the study.

*Methods:* A retrospective audit of 50 patient records was performed to identify patient safety incidents in each of the practices and a survey among health professionals to identify their perceptions of patient safety.

*Results:* All health professions felt that 'communication breakdowns inside the practice' as well as 'communication breakdowns outside the practice' and 'reporting of patient safety concerns' were a threat to patient safety in their work setting. We found little association between the perceptions of health professionals and the number of safety incidents. The only item with a significant relation to a higher number of safety incidents referred to the perception of 'communication problems outside the practice' as a threat to patient safety.

*Conclusions:* This study indicates that the assessment of professionals' perceptions may be complementary to observed safety incidents, but not linked to an objective measure of patient safety.

## Introduction

Patient safety has become a major concern in healthcare worldwide. There is increased attention paid to patient safety issues, and pressure placed on healthcare professionals, organizations and regulators to curtail the extent of unintended harm to patients.<sup>1</sup> In developed countries, many studies have been conducted in hospital care<sup>2</sup>. The patient safety risks in primary care are different from hospital care due to the specific characteristics of a primary care setting.<sup>3,4</sup> A large observational study on patient safety in primary care was conducted in The Netherlands in 2009.<sup>5-9</sup> This national Dutch study not only mainly focused on the frequency, types and determinants of patient safety incidents, but also surveyed the professionals' perception of patient safety management in the participating practices. We wondered whether these different measures of patient safety were correlated.

Research showed that healthcare professionals felt that the incidence of patient safety incidents in healthcare was substantially lower than the To Err Is Human report claimed, despite most had personal experiences of these incidents.<sup>10,11</sup> This may indicate a discordance between the real extent of the problem and the extent felt by the professionals who could have the largest effect on reducing the problem.<sup>1</sup> Interviews with healthcare professionals in the United Kingdom showed that professionals understand risk as something intrinsic to healthcare; another variable one needs to prepare for.<sup>12</sup> Risks were generally described in terms of acceptable versus unacceptable and preventable versus non-preventable. This study suggests that the further examination of the differences in the perceptual awareness of risk can advance the knowledge on the possible impact they could have upon patient safety.

In this paper, we focused on healthcare professionals' perceptions of patient safety aspects in their work setting. The aim of this study was to explore primary care professionals' perceptions of patient safety and to examine associations of these perceptions with actual number of patient safety incidents identified in their practices.

## Methods

### Study design

This study was part of a larger observational study on patient safety in Dutch primary care practices.<sup>5</sup> The present study was based on an audit of patient records and a written survey among health professionals in participating practices.



## Study population

We recruited 20 practices in four primary healthcare professions: general practices, general dental practices, midwifery practices, allied healthcare practices [physiotherapists, exercise therapist (Mensendieck/Cesar) and occupational therapists]. In each practice, we randomly sampled 50 patient records for inspection, thus 4000 records in total. In addition, we asked one professional in each practice (n=80) to complete a written survey.

## Measures

The measures of the patient record audit have been presented elsewhere and are briefly summarized here.<sup>5-9</sup> We adopted the definition of the World Health Organization that defines a patient safety incident as 'an unintended event during the care process that resulted, could have resulted or still might result in harm to the patient'.<sup>13</sup> We focused on unnecessary physical/mental harm or potential harm for the individual. The risk had to be scientifically documented or broadly recognized as legitimate. Trained observers from the relevant health profession examined retrospectively the patient record for a 1-year period. The method was pilot tested in a small practice test and shown to be reliable, reasonable, consistent and feasible. The written survey for health professions included questions on professionals' perceptions of patient safety, which had been derived from the Safety Attitudes Questionnaire (ambulatory version) and were relevant for officebased primary care practices.<sup>14</sup> Participants were requested to respond to 14 statements on a five-point Likert scale (very agree–very disagree).

## Data analyses

All data were aggregated and analyzed at the level of the health profession. We determined descriptive figures on professionals' perceptions.

The quality of record keeping could have influenced the number of incidents reported. We dichotomized the incidents in 'more' or 'less' than average number of incidents. The cut-off point was the median number of incidents for each health profession. Practices that scored the median or less were grouped into 'less incidents'; practices that scored higher than the median were grouped into 'more incidents'.

Logistic regression analysis models (with binomial distribution and logit link function) were constructed, with the different 'professional perceptions' to predict the incident rate. The statistical analyses were performed using SPSS 16.0 (SPSS Inc., Chicago, IL, USA).

## Results

A total of 70 practices returned the questionnaire (response rate 88%): 17 general practices (85%), 17 general dental practices (85%), 16 midwifery practices (80%) and 20 allied healthcare practices (100%). Table 1 presents descriptive information on the participating practices.

**Table 1. Practice characteristics for each health profession and total (n=70)**

	Health profession			
	General (n=17)	Dental (n=17)	Midwifery (n=16)	Allied healthcare (n=20)
Organization (n (%))				
Solo	2 (12)	9 (53)	1 (6)	9 (45) <sup>1</sup>
Duo	4 (24)	2 (12)	2 (13)	2 (10)
Group	6 (35)	5 (29)	13 (81)	8 (40)
Centre	5 (29)	1 (6)		1 (5)
Average number of professionals	2.8 GPs	1.9 GDPs	2.9 midwives	3.4 therapists
Student training(n%)	16 (94)	5 (29)	12 (75)	8 (40)

<sup>1</sup> Relatively high percentage, mainly due to the high number of occupational therapists and Cesar-Mensendieck therapists.

GP=General practitioners; GDP=General dental practitioners; therapists=physiotherapists, occupational therapists and/or Cesar-Mensendieck therapists

Table 2 shows the total numbers of recorded incidents for each health profession (across all practices which participated in the survey). The numbers of health professions that had more than average number of incidents was 7 out of 17 general practices (41%), 4 out of 17 general dental practices (24%), 6 out of 16 midwifery practices (38%) and 9 out of 20 allied healthcare practices (45%).

**Table 2. Numbers of recorded incidents for each health profession**

	Health profession			
	General (n=17)	Dental (n=17)	Midwifery (n=16)	Allied healthcare (n=20)
Min – max	3-22	0-1	0-9	0-4
Mean (SD)	10.88 (5.011)	0.24 (0.437)	4.00 (2.503)	0.90 (1.252)
Median <sup>1</sup>	11	0	4	0

<sup>1</sup> Used as cutoff for dichotomization in further analyses.

In Table 3, findings concerning perceptions of patient safety are presented. For all health professions, relatively large numbers felt that 'communication breakdowns inside the practice' were a threat to patient safety in their work setting (range 12-41%). The same applied to 'communication breakdowns outside the practice' (10-53%), and 'reporting of patient safety concerns' (29-33%). 'Not adhering to clinical guidelines' was perceived as potentially unsafe in the allied healthcare practices

(20%), as was 'not having common briefings' in the dental practices (25%) and 'not taking responsibility for patient safety' in general practices (18%), compared with the other health professions.

The logistic regression analysis regarding the 14 items on perceptions of patient safety identified one significant association: more perceived 'communication problems outside the practice' was associated with more incidents identified in the patient records [a 0.027; B 0.623; Exp(B) 1.866 (95% CI 1.09–3.20)]. None of the other perceptions was significantly related to numbers of patient safety incidents.

**Table 3. Description of professionals' perceptions of patient safety (% statements indicating potential unsafety)**

Statement	Health profession				Total (n=70)
	General (n=17)	Dental (n=17)	Mid- wifery (n=16)	Allied healthcare (n=20)	
There is widespread adherence to clinical guidelines and evidence-based criteria in this office	0	6	0	20	7
Medical errors <sup>1</sup> are handled appropriately in this office	18	6	25	5	14
In this office, it is difficult to discuss errors	0	0	6	5	3
Briefings are common in this office	6	25	8	7	12
Communication breakdowns inside the practice which lead to delays in delivery of care are common	41	29	20	12	26
Communication breakdowns outside the practice which lead to delays in delivery of care are common	53	35	25	10	40
The levels of staffing in this office are sufficient to handle the number of patients	24	12	13	15	16
I am encouraged by my colleagues to report any patient safety concerns I may have	29	29	33	30	29
The culture in this office makes it easy to learn from the errors of others	0	0	13	11	6
In this office, it is difficult to speak up if I perceive a problem with patient care	0	0	7	11	4
I know the proper channels to direct questions regarding patient safety in this office	12	13	13	17	13
It is easy for personnel in this office to ask questions when there is something that they do not understand	0	0	8	0	2
All the personnel in this office take responsibility for patient safety	18	0	0	0	4
Personnel frequently disregard rules or guidelines (e.g., hand washing, treatment protocols/clinical pathways, sterile field, etc.) that are established for this office	18	12	15	6	13

<sup>1</sup> Medical error is defined as any mistake in the delivery of care, by any healthcare professional, regardless of outcome.

## Discussion

All health professionals related 'communication breakdowns inside' as well as 'outside' the practice with potential unsafety. Professionals also assumed a relation between the 'reporting of patient safety concerns' and safety risk. This study found little association between the number of incidents and the perceptions of professionals.

Although the results are consistent with literature<sup>10-12</sup>, the specific indicator with a statistically significant association, 'more communication problems outside the practice', may be considered as an important finding. Studies have revealed that poor communication is a well-known risk for patient safety.<sup>6,7,15</sup> Communication with regard to patients who have to cross boundaries within the healthcare system, which is common in primary care, constitutes a particular safety risk.<sup>16</sup> The importance of preventing communication problems is thus recognized by health professionals. Improvement strategies with a focus on the awareness of professionals' risky behaviour and supportive tools, for example, in electronic health records, can be helpful to improve communication with other professionals.

The lack of association between health professionals' perceptions of patient safety in the work setting and patient safety incidents derived from patient records may also indicate that the latter were often related to individual clinical decisions and activities. For instance, many of the most serious incidents were related to missed diagnoses and risk factors, or inappropriate clinical reasoning and treatment decisions made by a clinician.<sup>17</sup> On the other hand, it can be argued that work setting factors such as workload and absence of evidence-based guidelines may contribute to such incidents, which is not well perceived by health professionals.

This study was explorative. Although the study described in this paper was part of a large national inventory and the questionnaire had a response rate of 88%, firm conclusions cannot be drawn because of the study size of 80 practices. The measures of patient safety incidents were newly developed and the measure of health professionals' perceptions was not separately validated for primary care in The Netherlands.

The generalizability of the results should be considered with caution due to the included number of professional settings. Even though the sample and recruitment of practices considered factors as practice size and urbanization level, 80 professional settings in primary healthcare in The Netherlands do not lead to a representative view, despite the relatively high number of patient encounters.

Selection bias, that is, an underestimation of the prevalence of patient safety incidents, could have occurred due to the voluntary self-selection of participating practices affecting the results of this study. Despite these limitations, this explorative

study can be useful in further research and in the development of interventions to improve patient safety and quality of care.

This study indicates that the assessment of professionals' perceptions can be complementary to a quantitative report of safety incidents. Combining both perspectives contributes to a better understanding of the full spectrum of patient safety and increases the awareness of health professionals of a possible discrepancy between their own attitude towards patient safety and quantitative results of patient safety studies. As healthcare professionals should implement improvement strategies, insight in their own perceptions in relation to quantitative outcomes is needed.

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## **Chapter 6**

# **Patient safety in primary midwifery care in The Netherlands, an increased risk of safety incidents in an urban area?**

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Submitted.



## **Abstract**

*Purpose:* To provide insight into patient safety in maternal care, we performed a secondary analysis of the incidence of safety incidents and their causes in maternal care in two recent studies.

*Design:* We compared the results of a national study among 1000 pregnant women in the Netherlands to the results of a similar study among 449 pregnant women living in an urban area with deprived neighbourhoods.

*Method:* In the national study, safety incidents were retrospectively identified from patient records. In the urban study, midwives reported incidents. The same methods of documentation, analysis and classification were further used.

*Findings:* In the national study, the pregnant women had a 2.3 % (95% CI 1.0-3.6) probability of a safety incident during the birth period; in the urban study, this was 6.6 % (95% CI 3.3-10.0). In both studies, most of the safety incidents stemmed from organizational factors.

*Conclusion:* A low prevalence of safety incidents was found. Women in a deprived urban area had a higher risk of patient safety incidents than women nationally.

*Implications for practice:* Measures to improve patient safety should focus on the organizational aspects of birth care and prioritize pregnant women from vulnerable groups.

## Introduction

In recent years, much attention has been paid to patient safety in healthcare and to the registration and documentation of safety incidents, particularly in hospitals. In contrast, figures on patient safety in primary healthcare settings are hardly available. Insight into incidents in obstetric and midwifery care is similarly lacking, while the quality of care for childbearing women is an important issue. There's an increased interest in the effects of midwife-led care on care quality, safety, and satisfaction.<sup>1</sup>

The Dutch midwifery model of care is known for its relatively high rate of home-births (19,6% in 2009).<sup>2</sup> Pregnancy care in the Netherlands is characterized by risk monitoring in primary care by a community based midwife as the first point of call for 80% of the pregnant women. If no problems or risks occur, the woman can choose to give birth at home, in a birth clinic or in a hospital (with her own primary care midwife). If increased risk is identified, the pregnant woman is referred during pregnancy (33 %) or during birth (49 %) to a team of hospital based midwives and obstetricians.<sup>2,3</sup>

In recent years, perinatal mortality showed a less impressive decline in the Netherlands compared to other European countries.<sup>4</sup> A secondary analysis of the Euro-PERISTAT study showed that the relatively high perinatal mortality rate in the Netherlands is caused by extremely preterm births. Although the PERISTAT data cannot be used to show that the Dutch maternity care system is safe, neither do they provide indications that the system is unsafe.<sup>5</sup> Nevertheless, it remains important to identify patients with higher risk for safety incidents. Studies showed that the number of suboptimal perinatal outcomes in larger Dutch cities stands out in particular.<sup>6,7</sup>

The Taskforce 'Pregnancy and Birth', an advisory committee for the Dutch Ministry of Health, recommended specific measures to improve the quality of perinatal care for women living in deprived areas and women with an increased social risk profile.<sup>8</sup> Also the WHO agenda on 'Women and Health' reports that in developed countries, the health of girls and women is critically affected by social and economic factors such as access to education, household wealth and place of residence.<sup>9</sup> These findings are in keeping with other international research about non-minority women residing in deprived urban areas that have a particularly higher probability of experiencing adverse perinatal outcomes.<sup>10,11</sup> There is also emerging evidence that, irrespective of their residential area, patients with a minority cultural and language background are at greater risk of experiencing preventable adverse events than mainstream patient groups.<sup>12</sup>

In the present analysis, we compared the occurrence, causes and consequences of patient safety incidents in the care for pregnant women in general and pregnant

women in a deprived urban area in particular. Based on our earlier patient safety research in primary midwifery care we formulated the following hypothesis: Patient safety in primary midwifery care is relatively good, but we expect more patient safety incidents to occur in an urban area due to the neighbourhood deprivation, culture, language and ethnic diversity of the patient population.<sup>13,14</sup> Our secondary analysis thus provides insight into the patient safety of healthy pregnant women in general but also in otherwise healthy pregnant women in a deprived urban area.

## Materials and methods

### Study design

The Ministry of Health in The Netherlands has developed a policy to improve safety in healthcare. Since there was a lack of data on primary care and in order to describe the situation at the start of this policy program, the Ministry asked the Scientific Institute for Quality of Healthcare, Radboud University Nijmegen Medical Centre, to conduct a national study of patient safety in independent primary care, including midwifery care, in The Netherlands.<sup>15</sup> At the same time, The Netherlands Organization for Applied Scientific Research TNO conducted a study on the safety and quality of maternal care in the city of Rotterdam, a large Dutch city with relatively high perinatal mortality rates.<sup>16</sup> The unfavourable perinatal outcomes in large cities are related to living in deprived areas, some cultural backgrounds and a late start of pregnancy care that results in suboptimal use of preventive life style interventions and fewer opportunities for prenatal screening.<sup>17</sup> To target improvement strategies for pregnant women at risk for suboptimal outcomes, the specific causes of these outcomes have to be determined. Incident reporting systems can provide this valuable information.<sup>18</sup> Therefore, a report system of safety incidents by midwives in the Rotterdam area was part of this larger study in Rotterdam. The retrieved incidents were analyzed by means of a standardized method that was also used in the national study.<sup>15</sup> For the purpose of the present study, it was decided to conduct a secondary analysis of the data from these two studies.

### Definition

Many definitions of patient safety events have been proposed. The World Health Organization defines a patient safety incident as *an unintended event during the care process that resulted, could have resulted or still might result in harm to the patient*.<sup>19</sup> This definition was used in both the national and urban studies with a focus on unnecessary physical or mental harm or potential harm with a risk for the individual woman and her child. The assessment of possible risk damage as defined

above, was analysed by trained midwife reviewers in both studies. Experiences of risk or- damage as reported by the mother were not included.

## Study method

The national study adopted a multi-method approach which included a retrospective chart review to retrieve safety incidents in maternal care. We randomly sampled 1000 patient records from a sample of 20 midwifery practices recruited from those Dutch midwifery practices registered with the Royal Dutch Organization of Midwives (KNOV). When selecting the practices, we aimed for stratification with regard to practice size, and regional representation for the Netherlands.<sup>20</sup> Primary midwifery care during pregnancy, birth and the postnatal period were all covered. The main data source was patient records, which were systematically reviewed by a team of five experienced and specially trained midwives. A screening instrument with five risk domains was developed for this purpose. A structured approach was followed for instrument development. First, we reviewed the literature on patient safety in general and obstetric and midwifery care in particular. We identified five domains of patient risk: organization, communication, patient related risk factors, clinical management, and outcomes. The instrument was evaluated by a team of experts in a pilot and practice test for content validity, reliability and feasibility and found to be good. To examine the variation in the review process, 50 patient records were independently reviewed by all reviewers. The kappa procedure, a measure of intra- and inter-observer agreement, was considered unsuitable for measuring inter-observer reliability due to the low rate of incidents and therefore the degree of agreement for the detection of patient safety incidents was calculated (75%).

The study of maternal care in a deprived urban area of The Netherlands was part of a larger evaluation of the quality and safety of perinatal care in the Dutch city of Rotterdam and had a prospective descriptive research design. Patient safety was examined for all maternal care (i.e., birth under the care of a midwife or an obstetrician). Practicing midwives provided the data and all midwifery practices in Rotterdam, Capelle a/d IJssel and Krimpen a/d IJssel were asked to participate in the study. The city of Rotterdam was not fully represented by the 8 participating out of a total of 18 midwifery practices. A special case report form called the Quick Scan – Incident Registration Midwifery (QS-IRM) was developed to register all births and patient safety incidents that occurred during parturition in independent midwifery practices and in hospitals during March through June 2010.<sup>21,22</sup>

## Data analysis

For a valid comparison of the incidence, types of safety incidents and causes/possible causes, we eliminated all data pertaining to obstetricians and thus restricted our analysis to midwifery-led births. This could include the care process in a hospital when supervised by a primary care midwife.

Several methods have been developed to identify the root causes of safety incidents. One of these is the Prevention and Recovery Information System for Monitoring and Analysis (PRISMA method).<sup>23</sup> The PRISMA was initially developed to quantify industry failures and process defects (i.e., safety incidents) to then target for improvement. Later "PRISMA Medical" was developed to identify, describe and classify the root causes of healthcare safety incidents. In both the national and urban studies, all incidents were analyzed and categorized by independent trained reviewers using PRISMA Medical. The classification of the causes of the safety incidents could refer to technical factors, organizational and management factors, human factors and patient-related factors. PRISMA advises avoidance of the use of "patient-related factors" in order to detect primarily process defects in the healthcare system. Following the description of the safety incidents and classification of their possible causes using the PRISMA method, the incidents were next classified for the extent of damage which actually occurred using the "severity of outcome" dimension from the International Taxonomy of Medical Errors in Primary Care.<sup>24</sup>

## Findings

### Study population

In the national study, midwifery practices in deprived neighbourhoods were underrepresented. In the urban study, four of the eight participating midwifery practices were located in deprived areas of Rotterdam. An overview of the characteristics of the patients in the 1000 patient records from the national study and the 449 records from the urban study is presented in Table 1.

Compared to nationally available figures, fewer women from the sample in the national study lived in socially and economically deprived areas and fewer were non-native Dutch. Almost 50% of the women from the sample in the urban study were non-native and almost 33% lived in deprived areas. In the urban study, more pregnant women were under 19 years of age.

**Table 1. Patient characteristics**

<b>Patient Characteristics</b>	<b>National study n=1000 (100%)</b>	<b>Urban study n=449 (100%)</b>	<b>National Dutch figures (PRN,2009)</b>
Age of the pregnant women in years			
15-19	1.3%	2.7%	1.7%
20-24	9.7%	15.1%	10.9%
25-29	26.7%	31.6%	29.5%
30-34	39.2%	33.4%	36.2%
35-39	19.3%	13.8%	18.8%
40-44	3.7%	3.6%	2.8%
45-49	0.0%	0.2%	0.1%
Resident of a social-economic deprived area <sup>27</sup>	3.6%	32.8%	7.0%
Pregnant woman is not native Dutch	10.7%	49.4%	19.6%

## Safety incidents

In the national study, 531 of the 1000 records concerned partial (140) or total (391) birth care by a primary care midwife. Our review of the 531 primary care records revealed 86 safety incidents with 12 of these concerning the birth period. All 12 of these incidents were classified as having a noticeable effect on the patient resulting in a probability of 2.3% (95% CI 1.0-3.6) for a safety incident with noticeable effects for the woman and/or her child during the birth period.

The urban study reported 30 unintended events for 211 births under the care of a midwife. Of these 30 unintended events, 14 were classified as having a noticeable effect on the patient resulting in a probability of 6.6 % (95% CI 3.3-10.0) for a safety incident during the birth period.

In Table 2, the characteristics of the safety incidents revealed using the PRISMA method are summarized. While the pregnant women in the national study had a 2.3% possibility of a safety incident with a noticeable effect, those in the urban study had an almost three times more likely possibility (6.6%) of experiencing a safety incident during the birth period. Most of the detected safety incidents in primary midwife care in both the national study and the urban study were due to organizational factors.

**Table 2. Incident characteristics**

Type of incident	National study (n=12)	Urban study (n=14)
ORGANIZATION		
Lack of space in hospital, late arrival of care providers in hospital		5
Delay in arrival of midwife despite timely call	7	3
PATIENT RELATED FACTORS		
Late call for help		5
TECHNICAL		
Telephone failure	1	1
HUMAN		
Clinical practice not in accordance with guidelines	4	

### Urban study

In the urban sample, the organizational factors concerned the presence of a midwife but also "lack of available hospital or birthing centre space" when the woman did not want to or could not give birth at home. In the urban study, patient-related factors also contributed to 5 of the 14 detected safety incidents. These incidents all concerned a late call for help, despite specific instructions for an early call due to the medical necessity of a hospital birth. Two of these incidents concerned non-native Dutch women.

### National study

In 7 incidents in the national sample, problems with the presence of a midwife were mostly found and then in cases of two urgent requests coming in at the same time but a second midwife not on call for back-up. In 4 incidents the care was not provided in accordance to practical guidelines.

**Table 3. Incident effects**

Effect/ damage	National study (n=531)	Urban study (n=211)
Incidents with noticeable effects	12 (2.3%)	14 (6.6%)
Temporary monitoring, further examination	1 (0.2%)	1 (0.5%)
Anxiety, psychological damage	3 (0.6%)	4 (1.9%)
Temporary damage	3 (0.6%)	1 (0.5%)
Hospitalization	0	2 (0.9%)
No damage	5 (0.9%)	6 (2.8%)

In 1 of the 12 safety incidents, only temporary monitoring (i.e., further examination) of the mother proved necessary. In 3 of the 12 cases, reviewers perceived the incident to result in psychological damage or anxiety – mostly as a result of stress for the woman or the delay of necessary care. Another 3 incidents were judged to result

in temporary damage. And no damage could be identified in the other 5 incidents. None of the 12 safety incidents required prolonged hospital admission or resulted in permanent damage or death.

## **Discussion and conclusions**

We found a relatively small percentage of safety incidents and a very low risk of permanent damage in both of the studies we analyzed. None of the incidents resulted in permanent damage or death (Table 3). In the national study, a pregnant woman had a 2.3% probability of experiencing a safety incident during the natal period while in midwife care; in the urban study, we found an almost statistically significant three times greater probability of experiencing a safety incident. In both studies, organizational factors related to the birth care process were identified as causing the majority of the incidents. In the urban study, patient-related factors also appeared to play a role in the occurrence of safety incidents (Table 2).

Urgent questions for help are an important feature of the care for childbearing women.<sup>25</sup> Primary midwifery care provided close to a women's home *should* guarantee availability and continuity of care. Continuity of care is known to relate to better outcomes for both mother and child.<sup>26</sup> Unlike the national study, the urban study showed a lack of space in hospitals and birthing centres that in turn created safety incidents due to prolonged travel time, emotional stress and delayed start of the necessary care. Patient-related factors such as calling later than agreed upon for birth care also contributed to delays and thus safety incidents. In the literature, travel delays are indeed cited as a risk factor for suboptimal perinatal outcomes.<sup>27</sup> Some possible limitations on the two studies which we analyzed should also be mentioned and taken into consideration in the interpretation of the present results. The comparison of the outcomes for the two studies should be handled with caution because of differences in study designs. It is well known that patient records' research depends on the quality of the record keeping and reveals different types of incidents than the ongoing reporting of adverse events and serious medical errors.<sup>28</sup> This might have caused the difference in the number of incidents that were related to 'care not provided in accordance to practical guidelines'. It is reasonable to assume that care providers themselves are less likely to evaluate their own daily practice. However, the results of the two studies complement each other and can thus contribute to patient safety research.<sup>29</sup>

Four of the eight midwifery practices which participated in the urban study worked in deprived neighbourhoods. Given the clustering of socially deprived geographic areas in a limited number of midwifery practices in The Netherlands, practices located in deprived areas were underrepresented in the national study.<sup>30</sup>



## Practice recommendations

Firm conclusions cannot be drawn on the basis of the present results, but some lessons for improvement of primary midwifery care can nevertheless be learned.

Midwives should focus on optimizing the availability and continuity of care for pregnant women. This can be realized by the midwives within a single practice or in cooperation with midwives in adjacent primary care practices.

For urban areas, midwives can improve patient safety by pointing out the lack of available hospital/birthing centre space to obstetric specialists, paediatricians, policy makers and health-insurance companies.

Evidence suggests that safety can thus be further promoted by routinely collecting data on race, ethnicity and language proficiency but also by enhancing the cultural competency of healthcare providers and the public health role which they play.<sup>11</sup> This is in accordance with the WHO report and justified by the five patient-related safety incidents detected in the present analyses.<sup>9</sup>

It is likely that a more multidisciplinary approach and the implementation of health education programmes in deprived urban areas may have a beneficial effect on perinatal health outcomes.

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## **Chapter 7**

# **Adverse outcomes in maternity care for women with a low risk profile in The Netherlands: a case series analysis**

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BMC Pregnancy and Childbirth 2013; 13: 219.

## Abstract

*Background:* This study aimed to perform a structural analysis of determinants of risk of critical incidents in care for women with a low risk profile at the start of pregnancy with a view on improving patient safety.

*Methods:* We included 71 critical incidents in primary midwifery care and subsequent hospital care in case of referral after 36 weeks of pregnancy that were related to substandard care and for that reason were reported to the Health Care Inspectorate in The Netherlands in 36 months (n=357). We performed a case-by-case analysis, using a previously validated instrument which covered five broad domains: healthcare organization, communication between healthcare providers, patient risk factors, clinical management, and clinical outcomes.

*Results:* Determinants that were associated with risk concerned healthcare organization (n=20 incidents), communication about treatment procedures (n=39), referral processes (n=19), risk assessment by telephone triage (n=10), and clinical management in an out of hours setting (n=19). The 71 critical incidents included three cases of maternal death, eight cases of severe maternal morbidity, 42 perinatal deaths and 12 critical incidents with severe morbidity for the child. Suboptimal prenatal risk assessment, a delay in availability of healthcare providers in urgent situations, miscommunication about treatment between care providers, and miscommunication with patients in situations with a language barrier were associated with safety risks.

*Conclusions:* Systematic analysis of critical incidents improves insight in determinants of safety risk. The wide variety of determinants of risk of critical incidents implies that there is no single intervention to improve patient safety in the care for pregnant women with initially a low risk profile.

## Background

In many parts of the world, maternity care is provided in a multi-disciplinary team or network involving general physicians, obstetric specialists and midwives.<sup>1</sup> In The Netherlands, the start of maternity care is often provided in primary care practices.<sup>2</sup> Midwives refer a pregnant woman to an obstetric department in a hospital when an increased risk of complications is expected. Recent figures show that 80% of all the pregnant women in The Netherlands have a low risk pregnancy profile in early pregnancy and receive primary midwifery care, about 30% of these a priori low risk pregnant women are being referred to a hospital mainly during the third trimester of their pregnancy, and 20% of these women are referred while giving birth.<sup>3</sup> The remaining 30% of the low risk pregnant women remain in primary midwifery care and give birth, either at home (18%) or in a hospital (12%).

Perinatal mortality is showing a downward trend in The Netherlands, but other European countries have reported a more impressive decline in the mortality rates.<sup>4,5</sup> Although the impact of the Dutch perinatal system, as described above, is difficult to substantiate, one study has reported on adverse effects of this system on perinatal outcomes.<sup>6</sup> On the other hand, a large national study found no relation between births led by primary care midwives and increased risk of perinatal death in The Netherlands.<sup>7</sup> A study on maternal outcomes among low risk women with planned home versus hospital births in The Netherlands also showed that low risk women in primary care at the onset of labor with planned home birth had lower rates of severe acute maternal morbidity than those with planned hospital birth.<sup>8</sup>

Several countries are developing policies to strengthen primary care for pregnant women. For instance, the recent 'Birthplace in England national prospective cohort study' supports a policy of offering healthy women with low risk pregnancies a choice of birth setting. All women planning birth at home or in a midwifery led care unit receive fewer interventions than those planning birth in an obstetric unit. There is no impact on perinatal outcomes for women planning birth at home or in a midwifery unit compared to women planning birth in an obstetric unit, except for primiparous women planning birth at home where there is an increase in adverse perinatal outcomes.<sup>9</sup> A Dutch patient record study of patient safety incidents in primary midwifery care showed that incidents in care provided by midwives do occur, but no safety incidents were associated with mortality or permanent harm.<sup>10</sup> The first results of the Dutch perinatal audit, a continuous monitoring of perinatal mortality after 37 weeks of pregnancy in The Netherlands, showed that in 10% of the evaluated cases, care was not provided in accordance with prevailing clinical guidelines and good clinical practice, and was defined as 'substandard care'.<sup>11</sup>

Most studies on perinatal care focus on outcomes such as morbidity and mortality but do not provide information about underlying causes and effects. A case-by-case analysis of care for pregnant women with adverse outcomes provides information on determinants of safety risks. The database of the Dutch Health Care Inspectorate (DHI) contains these cases with care related unexpected untoward outcomes and is therefore a valuable source for analysis of critical incidents. Given the high number of referrals from pregnant women to hospital care in the third trimester or during birth, and the low a priori chance of adverse outcomes in this population, the challenge is to identify risk domains in the care for this majority of pregnant women in The Netherlands regardless of the echelon where this is provided. We focused our analysis on primary midwifery care (and additional primary care providers) for low risk pregnant women and hospital care for these women in case of referral after 36 weeks of pregnancy. The DHI database does not reflect the population at large, but contains cases that were reported by care providers and according to a DHI analysis, are related to a substandard quality of care. In this study we reviewed the critical incidents and final assessment by the DHI in care for women with a low risk pregnancy profile and aimed to analyze main determinants of risk.

## Methods

### Context

The Dutch Health Care Inspectorate has an independent responsibility for supervision of quality and safety in healthcare. The supervision performed by the DHI is based on legislation and regulations as well as on 'field standards' set by professional associations. A significant approach for supervision is the evaluation of critical incidents in hospitals or primary care practices.<sup>12</sup> Under the Dutch Quality Act of 2005, healthcare professionals in The Netherlands have a statutory duty to report 'critical incidents' to the Dutch Health Care Inspectorate, defined as 'an unintended or unexpected healthcare related event that resulted in the death or serious permanent injury to a patient'.<sup>13</sup>

### Study design and sample

The DHI database from 2008 to 2011 contained 357 'perinatal' cases concerning various echelons of perinatal care reported by patients, midwives, general physicians, obstetricians, paediatricians and hospital boards. In the study described in this article, we excluded cases concerning women with a predefined high risk pregnancy profile and cases that were solely related to specialized neonatal care. We included all 89 reports in the database from January 2008 until December 2011 concerning care for women with an early low risk pregnancy profile, under supervision of a

primary care midwife (and additional primary care providers). We also analysed the hospital care for these pregnant women in case of referral after 36 weeks. Further analysis focuses on the 71 reports which proved to be critical incidents as defined by the Dutch Quality Act. The other 18 reports were not specifically related to individual patient care or did not cause severe harm. Most of these remaining 18 reports were referred by the DHI to a committee for handling patients' complaints. The content of the critical incident reports in the DHI database varied, but usually included parts of patient records, reports of interviews with patients and care providers, a variety of root cause analysis reports drawn by special safety committees in hospitals or the primary care providers themselves, and a final assessment by the DHI that focused on the possibility of repeated occurrence and the implementation of improvement measures in a specific hospital or practice.

### Ethical approval

The database of the DHI is accessible to researchers under the following three strict conditions; a signed confidentiality agreement, the information from the database is not identifiable to individual patients and, prior to publication, the DHI grants approval to the manuscript. Our study meets these conditions according to the ethics committee's assessment.

### Measures

In an earlier national patient safety study in primary midwifery care we developed and validated an instrument for the review of records of healthy pregnant women to identify determinants of adverse outcomes and near misses.<sup>14</sup> This instrument is based on patient safety literature in general and obstetric and midwifery care in particular, and on clinical and managerial topics derived from practice guidelines. It reviews possible risk procedures and provides the classification of safety risk determinants in five risk areas where each case can contribute to one or more determinants: healthcare organization, communication about treatment, patient related risk factors, clinical management, and clinical outcomes. Although suboptimal clinical outcomes do not necessarily imply unsafe care, the care provided in these cases was perceived as requiring a detailed retrospective analysis.

The DHI performed a previous analysis of critical incidents in maternity care from 2006 to 2008. The case files were analyzed to determine which factors contributed to the incidents, paying particular attention to care involving multiple caregivers, and care delivered after office hours. Actions and measures taken to prevent repeated occurrence were recorded.<sup>15</sup> The first mentioned instrument was developed for primary care. The DHI analysis also focused on hospital care. We complemented our



instrument with specific DHI questions for primary and hospital care and aimed for an optimal detection of determinants and consequences of high- risk in both echelons of maternal care. (Additional file 1)

## Analysis

A multidisciplinary team of the DHI including perinatal and general DHI professionals analyzed the incidents in the database and assessed the root cause analysis by care providers as well as the implementation of improvement measures to prevent recurrence in a specific hospital or primary care practice. A standardized overall analysis of determinants of risk in the cases that were reported from 2009 until 2011 has not been undertaken by the DHI.

For the analysis as described in this article, two trained reviewers – one academically trained research midwife and one DHI professional – independently analyzed the incidents and the final DHI assessment using the above mentioned instrument. The reviewers were not allowed to request additional information because the cases were closed. Inconclusive results between reviewers were discussed with the two reviewers and with the DHI Inspector.

## Results

### General

#### *Setting*

Our study included 71 critical incidents: 42 (59%) incidents occurred in hospital care, 29 (41%) incidents happened in primary care. Eighteen incidents occurred in care provided by a midwife, six primary care incidents occurred when pregnant women in primary midwifery care consulted a general practitioner (GP). Five of these incidents were related to care in a GP out of office hours services. Four incidents in primary midwifery care were related to auxiliary care by a maternity assistant at home in the postnatal period and 1 incident was related to a public pharmacy.

#### *Outcomes*

In the 71 critical incidents were three cases of maternal death and eight critical incidents were recorded because of severe maternal morbidity. The records described 42 perinatal deaths and 12 critical incidents with severe morbidity for the child.

## Determinants of risk of the critical incident

We identified the determinants of risk as described in our instrument (Additional file 1) that contributed to a greater or lesser extent to the occurrence of the critical incident. Table 1 describes the potential determinants of the incidents.

**Table 1. Classification of determinants of risk in the critical incidents**

<b>Determinants of risk of the critical incident</b>	<b>Critical incidents (n=71)</b>
<b><i>Availability of healthcare provider</i></b>	
Availability of the care provider in charge	20 (28%)
<b><i>Communication</i></b>	
Communication about treatment between care providers within a practice	39 (55%)
Communication about treatment between primary care and hospital caretakers	7 (10%)
Communication with the patient	7 (10%)
<b><i>Clinical management</i></b>	
Referral procedures	19 (27%)
Risk assessment by telephone triage	10 (14%)
Medication procedures	3 (4%)
Technical procedures	9 (13%)

### *Availability of healthcare provider*

The timely availability of responsible care providers was assessed in relation to the timeframe of the urgent question for help, and that from the patient until arrival of the responsible care provider or availability of advice by telephone. In 20 cases there was a delay in the availability in primary or hospital care for more than 15 minutes in case of an urgent question for help.

### *Communication about treatment*

Insufficient communication about treatment between caretakers within a primary practice or hospital was assessed as a potential cause in 39 cases. Communication between the primary and hospital care was a risk in seven incidents. In seven critical incidents communication problems with the patient were identified as a potential cause. These communication problems were described as 'due to a language barrier'.

### *Clinical management*

We analyzed 61 referrals during pregnancy (n=35) and birth (n=26). Twelve referrals during pregnancy from primary care to the hospital were delayed, and five women should have been referred according to practical guidelines but they were referred only after the critical incident occurred. Two women were referred during pregnancy from the hospital back to primary care but should have stayed in hospital

care according to practice guidelines. Three referrals during birth were delayed. The remaining 39 referrals were timely and correct.

The risk assessment by telephone was a potential cause for safety risk in ten cases. In four out of these ten cases, the telephone triage was performed by a midwife, in five cases the triage was performed by a general physician service, and one case occurred in hospital care.

Incidents caused by medication (3) and technical procedures (7) were mainly described in cases that occurred after referral to hospital care.

### *Clinical management during out of office hours*

In our analysis we found that 40 (56,3%) of the critical incidents occurred outside office hours and 31 (43,7%) during office hours. According to a retrospective assessment of the reviewers, 19 (26,8%) incidents may have had a better outcome if they had occurred during office hours. Six of these possibly avoidable out of office hours incidents occurred in primary care (n=29). Three of these primary care incidents occurred in an out of office hours GP service and three in a midwifery practice. In two incidents in the GP service the GP nurse was not able to reach the responsible GP in time because of workload and in one incident the GP did not respond adequately to severe symptoms. In one incident in the midwifery practice the responsible midwife did not respond in time because of another urgent call for help, in one incident the midwife did not visit the patient at home in the late evening despite two calls for help and in one incident a colleague midwife from another practice was not available by telephone.

13 incidents during out of office hours occurred in a hospital. In seven incidents in hospital care a delay occurred in the availability of care providers such as the first or second obstetrician, pediatrician, and the surgery unit team. In four incidents there was a communication problem between the evening and night shift, in two of these cases the pregnant women were incorrectly referred back to primary care. In two incidents the responsible obstetrician was in the hospital during the night but the nurse or clinical midwife hesitated to call.

### **Actions undertaken by the DHI**

The DHI recommended and imposed one or more actions to prevent recurrence and supervise the implementation of such measures. This may vary from adjusting protocols on local or national level, to organizational adjustments or disciplinary actions. Table 2 describes the recommended actions according to the DHI.

In most cases the DHI imposed the improvement of written protocols followed by improving the organization of urgent care and better communication between care providers.

**Table 2. Measured imposed by the DHI to prevent recurrence**

<b>Required improvement</b>	<b>N</b>
Diagnostic procedures and medical treatment	12
Organization of (urgent) care	26
Task description and delineation	14
Record keeping	20
Communication between care providers	24
Structural training	14
Written protocols	39
No measures recommended or recorded	11

## Discussion

We performed a standardized analysis of critical incidents that were related to substandard care in primary midwifery care and subsequent hospital care for women with a low risk profile at the start of their pregnancy. We were able to identify a range of determinants that contributed to the occurrence of critical incidents.

In general, care for childbearing women is characterized by the possible need for urgent interventions.<sup>16</sup> Most professionals in perinatal care consider 15 minutes to be an acceptable maximum delay period to start urgent care in general.<sup>17</sup> Since the delayed availability of the care provider in charge was a potential cause of 20 (n=71) critical incidents, this has to be considered. For instance, it has impact on the planning of geographical distribution of healthcare providers and the organization of hospital care.

Studies have revealed that poor communication is a well-known risk for patient safety.<sup>18</sup> Given the substantial number of instances of miscommunication about treatment between care providers within primary care practices and within teams in maternity wards in hospitals, the first focus of improvement should be on the improvement of internal communication procedures by means of a standardized handover tool. Special attention is needed for Dutch language skills and translation since the existence of a language barrier is a crucial determinant of risk.<sup>19</sup> This can easily be improved by the use of an interpreter.

In patient safety literature, technical failure such as emergency calls and medication errors are well known for their consequences for patient safety.<sup>20</sup> Our evaluation also showed that these factors contribute to the occurrence of critical incidents and are therefore in need of test procedures of emergency call systems and medication safety programs.

Timely referral contributes to safe care for pregnant women. There is a low prevalence of severe pregnancy related problems in primary care and the presentation of these complications by pregnant women can be difficult to interpret. Despite a perceived low risk of harm in primary care, a continuous awareness of a possible presentation of high risk complications especially during pregnancy, should be part of daily practice.

Five out of nine telephone triage related incidents happened in a GP out of office service. Although primary care midwives and maternity wards in hospitals offer 24/7 care, pregnant women also call the out of office GP services with general or pregnancy related problems. A study on the safety in telephone triage in out- of- hours care shows that there's room for improvement of triage in patients who present high risk symptoms.<sup>21</sup> This emphasizes the importance of knowledge about the current state of clinical management and guidelines in care for pregnant women and, in case of doubt, consultation from the GP with the responsible maternity care provider. In addition, pregnant women should be informed to contact their primarily responsible care provider in case of pregnancy related problems.

## Limitations

In our earlier research in primary midwifery care, we described the underestimation of the level of risk on the basis of the medical or obstetric risk (e.g., small for gestational age child in the obstetric history) and lifestyle factors associated with safety incidents.<sup>10</sup> In our current analysis it was not possible to review these factors, since there was no structural notation in the previous root cause analysis by care providers. Further, additional information, such as birth weight, gestational age, and information from the records of primary care in case of referral to a hospital, was not structurally presented by care providers. Since we were not authorized to request for additional information, our current analysis and the description of the incidents in this article were thus restricted to the reports and data that were available in the database. It is difficult to draw firm conclusions about causality and a possible correlation between safety determinants from a case-by-case analysis but our structural approach provided us with some safety highlights.

## Conclusion

We reviewed the critical incidents and the DHI assessment of cases in primary and subsequent hospital care for pregnant women with a low risk profile in early pregnancy. We performed an analysis of cases that were reported to the DHI and that did not reflect the population at large. Since all cases had an unexpected or unintended care related component, we were able to identify determinants of risk

that contributed to the occurrence of the incident. Our standardized analysis provides additional and more valid information compared to the non-systematic evaluation that is currently performed by involved care providers or by the DHI. We used a standardized instrument and aimed for the detection of determinants of high risk. The variety of potential determinants and improvement measures that are recommended, substantiate the conclusion that no easy solutions for patient safety questions exist.

Over the last few years, perinatal care providers implemented a successful perinatal audit system in The Netherlands. Also the DHI recommends improvement measures and supervises the quality and safety of healthcare. Our study shows that the structural implementation of a standardized analysis of unintended or unexpected care related events can provide valuable information to all healthcare providers and improve the awareness towards the influence of safety determinants on the occurrence of a critical incident. Our analysis strengthens the importance of routine data collection on the determinants of safety risks as described in the instrument.

The majority of pregnant women has a low risk profile in early pregnancy and are cared for by primary care midwives. These women are frequently referred during pregnancy and birth and therefor it's important to analyse the complete spectrum of primary and hospital care for these women. Because of a low a priori chance of adverse outcomes in low risk pregnancies, a special focus on critical incidents in this population provides all primary care midwives with valuable information, regardless their involvement in a case. Given the increased willingness to report critical incidents throughout the last years, an analysis of these incidents and a structural report of the findings to primary care midwives, will contribute to the awareness of safety risks and improve the quality of care.

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## **Additional file 1:**

### **Instrument for the review of potential causes of safety risks**

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#### **Determinants of safety risk**

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##### ***Organization***

Delay in arrival/ availability by telephone of responsible care provider (more than 15 minutes)

Delay in attainability of hospital care (more than 45 minutes)

Delay in ambulance transportation to hospital (more than 45 minutes)

Birth with no responsible care provider present (birth before arrival)

##### ***Communication***

Communication incident with care providers (inside practice)

Communication incident with other care providers (outside practice)

Communication incident with patient

##### ***Patient risk factors***

Presence of general risk factors

Presence of social risk factors

Presence of lifestyle factors

Presence of mental risk factors

Use of medication

Presence of risk factors in family history

Presence of risk factors in obstetric history

Woman does not follow prescribed therapy and no show

##### ***Clinical management***

Incidents during preventive procedures

Incidents during diagnostic procedures

Medication incidents

Technical failure

Number of contacts, first antenatal visit after 10 weeks pregnancy or < 12 consults in full antenatal care

Incidents in referral procedures in this pregnancy

Incidents in referral procedures during/after birth

Incidents in risk assessment by telephonic triage

##### ***Outcomes***

###### ***Neonatal outcome:***

small or large for gestational Age, low Apgar score <7 after 5 minutes, breech delivery, congenital abnormalities, birth trauma, hospital admission of the child, severe morbidity, mortality.

###### ***Maternal outcome:***

anemia, complicated instrumental delivery or caesarean section, prolonged hospitalization, inadequate coping after postnatal period, traumatic experience of birth, suspicion of depression or psychosis, severe morbidity, mortality

##### ***DHI***

Investigation by the DHI

Quality of recordkeeping

Records available from primary care and hospital care

Care during out of office hours

Problems with 'chain care' between primary care and hospital care

Measures to prevent recurrence

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## **Chapter 8**

### **General discussion**

## Introduction

In many parts of the world, midwives are the primary providers of care for childbearing women.<sup>1</sup> The perinatal care system in The Netherlands is unique among developed countries with both independent primary care midwives and hospital teams of midwives and obstetricians providing care for childbearing women.<sup>2</sup> In The Netherlands, primary midwifery care is characterized by a large volume of contacts and procedures, a high number of referrals to obstetricians and referrals back from hospitals for follow-up primary midwifery care.<sup>3</sup> The country has a substantial number of home births compared to other developed countries.<sup>4</sup>

Worldwide as well as in The Netherlands, the number of medical interventions in perinatal care is increasing, which raises questions about the benefits, safety and risks for healthy pregnant women.<sup>5</sup> The quality of pregnancy and birth care is a frequently discussed topic in The Netherlands. Advisory committees have identified the organization of perinatal care, adherence to practical guidelines, patient related risks profile and clinical procedures as domains, which contain possible causes of suboptimal care.<sup>6</sup> Since midwives participate in the care for most pregnant women in The Netherlands, understanding the safety risks in midwifery care is essential. Direct evidence on patient safety of primary midwifery care was hardly available when we started the studies presented in this thesis in 2008.

Because a valid, comprehensive, and feasible measure for this type of care was not available, it was difficult to examine patient safety and the frequency and type of safety incidents in primary care. In many cases, patient records are used as primary source of information. In such cases, the validity depends on the completeness and accuracy of the patients records. In addition, consensus does not always exist among professionals as to which procedures should be recognized as 'not safe'. Alternative methods are registration and report systems for safety incidents, but these systems are not standardized and reporting is highly dependent on the willingness of care providers.<sup>7</sup> Hence, there is a need for the development of valid measures to identify the causes and effects of (possible) patient safety incidents in primary midwifery care and recommend empirical based improvement measures.

In this final chapter of the thesis we first present the main conclusions of our research and then we discuss our findings in relation to the national and international scientific literature. We will then consider the strengths and limitations of the studies presented in this thesis and finally make recommendations for daily practice, education, safety management, and healthcare policy.

## Main conclusions

We developed a new instrument for the identification and classification of patient safety incidents in primary midwifery care. Based on a review of the literature, and in an iterative procedure with midwifery and patient safety experts, we identified five broad risk domains for safety incidents in primary midwifery care: healthcare organization, communication, clinical management, patient risk factors and, outcomes. When we applied the instrument, we were able to identify and classify safety incidents, causes and effects, with the use of standardized classification systems.

We subsequently performed a large observational study in primary midwifery care. We examined 1000 patient records, incident reports and healthcare provider perceptions of safety in their practice. The chart audit in midwifery practices identified 86 incidents with 25 of these having a noticeable effect on the patient, which was not severe in most cases. In this study we thus found a 2,5% risk per patient of a safety incident. We found that patient risk assessment by primary care midwives is largely in line with clinical practice guidelines. The most urgent requests for help were adequately handled, and the records showed adequate and frequent checkups. Identified risks were often related to the organization of the urgent care process and patients' life style and medical history.

We used a written survey in primary care professionals to explore the relation between the professionals' perceptions on behavioural and organizational practice in various domains and the actual numbers of safety incidents. We found little association between the number and causes of the incidents and health professionals' perceptions.

Socioeconomic deprivation is a known risk factor for perinatal outcomes.<sup>8</sup> Given the clustering of socially deprived geographic areas in a small number of urban midwifery practices in The Netherlands, we analyzed data on purposefully sampled women in a defined geographical area. We found that the timely availability of midwives during birth care was an important determinant. Additional risk factors that were found were related to cultural background and language proficiency of the pregnant women and capacity problems in hospitals.

Finally, we used our instrument to assess patient safety risk factors in primary midwifery care and successive hospital care in cases that resulted in severe harm to pregnant women and their babies. We found a wide variety of risk factors causing critical incidents. Most prevalent factors were related to timely availability of care providers in urgent care, communication about treatment between care providers within their own practice and with patients with a language barrier, telephone triage and the assessment of patients with high risk symptoms.

## **Methodological considerations**

In general, the studies described in this thesis, are among the first on patient safety in primary midwifery care. We used both prospective and retrospective studies to enhance the validity of our research, using a range of data collection methods: patient record review, incident reporting and a survey among health professionals.<sup>9</sup> A review of patient records yielded other kind of incidents than incident reports by professionals and written surveys.<sup>10</sup> We were able to show results from records of pregnant women, highlights from incident reports by health professionals and we related the actual incidents to professionals' perceptions about patient safety. In addition, direct observation of the care process by independent professionals and auditing could provide additional information. In our national study we were able to perform a large study and review 1000 records in 20 randomly selected midwifery practices that represented all regions in The Netherlands.

Potential bias due to self-selection by participating 'patient safety minded' practices cannot be ruled out. Based on literature we expected more safety incidents to happen in areas with unfavorable perinatal outcomes.<sup>11</sup> Given the clustering of socially deprived geographic areas in a small number of urban midwifery practices in The Netherlands, it was not possible to include a representative number of women from these areas in our national study population so we performed a targeted study with a study population that represented these specific areas.

The study sample of critical incident reports focused on reported cases of substandard quality of care, which should not be regarded representative for patient safety in the country. Although our analysis was limited due to privacy regulations, such that we could not review original patient records, this database contained 71 specific cases with certain elements of substandard care. We were able to perform a thorough analysis of patient safety in midwifery and subsequent hospital care in cases with high risk outcomes.

The Dutch maternity care system is unique compared to other developed countries with both midwives in primary care and obstetric specialists and midwives in hospitals taking care for pregnant women in relatively separate healthcare sectors.<sup>12</sup> Comparisons of safety studies in maternity care in other countries and our study results should therefore be handled with caution.

## **Patient safety research and perinatal care in the Netherlands**

During the data-collection and analysis for the various studies presented in this thesis, studies on the quality and safety of perinatal care were published, mostly based on mortality rates or other outcome features. Based on a cohort study in a defined geographical area, a team of researchers questioned the quality of the Dutch

obstetric care system. The study found that the infants of women who were referred by a midwife to an obstetrician during labour had a higher risk of delivery-related perinatal death than the infants of women who started labour under the supervision of an obstetrician.<sup>13</sup> The results of this study are in contrast with the results of a large national study which showed no relation between births being led by primary care midwives and an increased risk of perinatal death.<sup>2</sup> A recent study on nonurgent referrals in primary midwife-led care during labor showed that there was a considerable rise in nonurgent referrals to obstetrician-led care during labor but perinatal safety did not improve significantly over time.<sup>14</sup> A study on maternal outcomes among low risk women with planned home versus hospital births in The Netherlands also showed that low risk women in primary care with planned home birth had lower rates of severe maternal morbidity than those with planned hospital birth.<sup>15</sup> From 2001 until 2010 the perinatal mortality rate from 37 weeks pregnancy in The Netherlands showed a 39% decrease, but overall perinatal mortality in The Netherlands showed a less impressive decline compared to other European countries.<sup>16</sup> A secondary analysis of the Euro-PERISTAT II study showed that the relatively high perinatal mortality rate in The Netherlands appears to be driven mostly by the relatively high number of extremely preterm births.<sup>17</sup> This was also found in the subsequent Euro- PERISTAT III study.<sup>18</sup> Although the PERISTAT data cannot be used to show that the Dutch maternity care system is safe, neither can they be used to argue that the system is not safe.<sup>17</sup>

According to the results of the Taskforce Pregnancy and Birth, an Advisory Committee to the Ministry of Health in The Netherlands, both the risk profile of Dutch pregnant women and the quality of the obstetric care system influence perinatal outcomes in The Netherlands.<sup>6</sup> A broad inventory of recent research and the description of the major research questions in order to improve the perinatal mortality in The Netherlands in 2010, focused on the 'BIG 4', causing the majority of perinatal deaths; prematurity, asphyxia, intra uterine growth retardation and congenital abnormalities.<sup>19</sup>

The results of recent national audits on perinatal mortality after 37 weeks of pregnancy showed a large variety of causes and effects.<sup>20</sup> Programs to improve outcomes of perinatal care should focus on the development of multidisciplinary guidelines instead of separate guidelines for primary and hospital care, better emergency training for all involved professionals, and structured record keeping. The 'Birthplace in England National Prospective Cohort Study' supports a policy of offering healthy women with low risk pregnancies a choice of birth setting. All women planning birth at home or in a midwifery led care unit receive fewer interventions than those planning birth in an obstetric unit. There is no impact on perinatal

outcomes for women planning birth at home or in a midwifery unit compared to women planning birth in an obstetric unit, except for primiparous women planning birth at home where there is an increase in adverse perinatal outcomes.<sup>21</sup>

We developed new methods to actually review the (possible) safety risks of primary midwifery care for individual pregnant women and their children. Overall we found a low incidence of safety incidents in primary midwifery care, but also a number of generic causes of increased risk, which will be discussed below.

### Patient risk factors

The patient risk profile is determined by medical, social and psychological features. In our safety instrument, we extensively defined possible risk factors for pregnant women. Based on our national safety study we found that the quality of primary midwifery care benefits from special attention for women with patient risk factors in the life style or obstetric history.<sup>22</sup>

We observed that the primary midwifery care for women who smoke during pregnancy can be improved by offering smoking cessation procedures and by better monitoring of the fetal growth. The care for obese pregnant women can be improved by structural recording of body weight at the beginning of the pregnancy and during the pregnancy and additional monitoring of fetal growth.

Underestimation of the level of risk on the basis of the medical or obstetric histories of patients was also found to be a cause of safety incidents. Based on child outcome factors, the reviewers in our study concluded that the presence of a child with a small or large birth weight in the obstetric history, did not lead to sufficient monitoring of fetal growth during the current pregnancy.

We assessed the social risk factors of pregnant women in our study populations and found that special attention is needed in the care for women with a reduced language proficiency. In the analysis of patient safety of midwifery care in an urban area as well as in the study on critical incidents, parents with a reduced understanding of the Dutch language, were more at higher risk of a safety incident. We found notes from midwives about 'calling later than agreed upon' that contributed to delay in urgent birth care. In the analysis of critical incidents we also identified communication problems with the patient a potential cause. These communication problems were described as 'due to a language barrier'.

### Organizational factors

In both our national patient safety study as well as the analysis of patient safety in an urban area and in the evaluation of critical incidents we defined the organization of timely and continuous availability of midwives in urgent (birth) care as a safety

risk. Although it may not be feasible for primary care providers to arrive on time in large rural regions or cities with traffic problems, the timely availability in primary care was also compromised by professionals themselves. Despite written procedures and appointments, midwives appear to hesitate to call in an on-call colleague when two urgent requests for help are received at the same time.

The analysis of the safety of midwifery care in an urban area, showed a lack of space in hospitals and birthing centers to give rise to safety incidents due to prolonged travel time, emotional stress and delayed start of the necessary care. And in a substantial part of the critical incidents a delay in availability in primary or hospital care in case of an urgent question for help, was described.

### **Professional factors**

In our national safety study we found a low prevalence of safety incidents. Our results show that patient risk assessment was generally in line with the Obstetric Manual and current guidelines. The most urgent requests for help were adequately handled, and the patient record notes showed adequate and frequent checkups during the prenatal, natal and postnatal care process. The incidents we actually identified were related to the organization of the urgent care process and the assessment of patient risk factors. On the base of our analysis of the critical incidents in the database of the Dutch Healthcare Inspectorate we identified a delay in the risk assessment and timely referral of women and children with rare and severe complications contributing to severe incidents. Also the telephone triage of pregnant women that present high risk symptoms, can be improved by GP out of office services as well as by midwives. Despite a perceived low risk of harm in primary care, a continuous awareness of a possible presentation of high risk complications especially during pregnancy, should be part of daily practice.

In our national safety study we revealed patient related communication incidents as well as incidents caused by communication about treatment between care providers. The analysis of critical incidents mainly reports on instances of miscommunication about treatment between care providers within primary care practices and within teams in maternity wards in hospitals. The first focus of improvement should be on the internal communication procedures between care providers.

### **Implications and recommendations**

In contrast to primary care, care providers in hospitals are familiar with incident report systems and safety management in hospitals is supported by a special trained staff. In general, all studies presented in this thesis, suggest that periodic audits of patient safety of primary midwifery care are important. Currently, the awareness of



many midwives (and other health professionals) regarding actual safety risks in their practice is low. The evaluation of midwifery care by midwives themselves can increase this awareness. The successful implementation of a multidisciplinary perinatal audit in The Netherlands should not prevent midwives from making a critical evaluation of the care provided within their own practice. Since we found a low prevalence of safety incidents with serious harm to the mother or child, the safety of primary midwifery care benefits from the evaluation of all care provided by midwives because we can learn from actual incidents but also from the evaluation of near- incidents and potential safety risks.

The evaluation of the safety of primary midwifery care in daily practice should focus on the earlier mentioned risk factors identified in our studies. The main patient risk factors were related to life style, the assessment of fetal weight of previous born children and language proficiency. The evaluation of patient records should focus on the actions undertaken for smoke cessation support, structural notation of BMI with extra monitoring of fetal growth, and notation and specific attention with regards to the capability to understand the Dutch language. The number of ultrasound procedures in low risk pregnancies increases steadily over time but it is important to evaluate the number and timing of these ultrasounds for women with a child with a small or large birth weight in the obstetric history.<sup>23</sup>

We identified a number of organizational risk factors with regard to timely availability of midwives in case of two urgent questions for help at the same time. Structural recording and evaluation of the time interval between the call from the mother and the arrival of the midwife increases the awareness towards possible time delay and the necessity to ask a second midwife on call. The discussion about 'lack of space' problems in hospitals with policy makers and other care providers also benefits from detailed record keeping of time delay caused by capacity problems in hospitals.

Professional risk factors in primary care are related to the quality of risk assessment and communication about treatment. Since there is a low prevalence of high risk in primary midwifery care, the safety of midwifery care benefits from the evaluation of the care process in case of presentation of high risk symptoms, regardless of the outcome for mother or child. Healthcare professionals expect more safety risks in the communication about treatment with care providers in other echelons but we recommend a focus on the evaluation of internal communication procedures.

A structured periodic evaluation of the care process should be part of the quality and safety program of each primary care practice. It's also important that the evaluation of midwifery care and possible safety incidents is part of the education of student midwives and training programs for practicing midwives.

We developed study methods for the evaluation of patient safety in primary midwifery care and recommend the implementation of a structural evaluation of the care provided by midwives. Until now, there is little research-based knowledge on the effectiveness of patient safety interventions and procedures in primary midwifery care. We recommend the implementation of patient safety programs with retrospective and prospective methods in midwifery practices and further studies to evaluate the effects of such programs on the quality and safety of primary midwifery care.

## Overall conclusion

We started this chapter with the description of the Dutch perinatal care system. It comprises of a multi-disciplinary network of consultation and referral with other care providers. Primary midwifery-led care emphasizes the normality of birth and the continuity of care.<sup>24</sup> The number of studies on Dutch midwifery primary care has increased since the mid- 1990s and the scope of these studies was not only on the outcome of care provided by midwives but also on women's wishes and expectations.<sup>25</sup> Three years after delivery, most women looked back positively on their birth experience, while about one in seven looked back negatively. Factors that are associated with negative recall included having had an assisted vaginal delivery or unplanned cesarean delivery, referral during labor, pain coping and relief, a negative description of the caregivers, or having had fear for the baby's life or her own life.<sup>26</sup> Primary care midwives have the opportunities to influence most factors that caused these negative experiences. Childbirth is a life event for parents and requires a continuous focus of care providers on women's experiences.

In contrast to other primary care providers, both primary midwifery care and general practice consists of scheduled care and urgent care processes. In general practice, most serious patient safety events are seen with diagnostic delay or failure, in serious diseases.<sup>27</sup> Also patient factors such as comorbidity, polypharmacy, age and language problems contribute to safety incidents.<sup>28</sup> We also found diagnostic delay and patient risks a determinant of safety in primary midwifery care. This might be related to a low priori change of the presentation of severe symptoms in both primary care practice types. General practitioners and primary care midwives should meet the challenge to maintain a person- orientated 'normality of care' view and, at the same time, stay alert to a correct diagnosis of high risk symptoms.

Communication problems about treatment between care providers within hospitals, general practices or midwifery practices, caused safety incidents. This adds to the evidence that poor communication about treatment is more related to healthcare professionals than to the setting in which they provide care. In both primary and

hospital care, we identified the timely availability of urgent care a risk factor for safety incidents. When the care for pregnant women is solely provided in hospital, safety risks in communication and availability will still occur.

Patient factors such as life style and social deprivation demand strong preventive procedures that can best be offered close to women's homes in a public health setting.<sup>29</sup> Primary care midwives can offer this preventive care since they are familiar with families, homes and neighborhoods.

In our studies we found opportunities to improve the safety of primary midwifery care in The Netherlands and maintain the strengths of primary care in a multi-disciplinary network. We have a duty to identify risk areas and improve safety as much as possible. Midwifery practices, and all other healthcare facilities, are subject to mandatory 'systematic monitoring, control and improvement on the quality of care'.<sup>30</sup> Midwives can offer public healthcare interventions close to women's homes, improve availability by better collaboration with other primary care midwives and at the same time improve the assessment of high risk. The perinatal system in The Netherlands with both primary care and hospital based midwives in addition to obstetric specialists taking care of pregnant women and their children, has opportunities for safety improvements in all echelons. Primary care midwives can make a first move. We hope our methods and results will contribute to further research, awareness in midwives of issues of quality and safety of care, but most importantly, to safe care for pregnant women and children in The Netherlands.

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# Summary

**Chapter 1** describes the background and outline of this thesis. It elaborates on the organization of healthcare for pregnant women in The Netherlands. Then recently collected data on patient safety in primary midwifery care, with a focus on low risk pregnant women are presented and discussed. This leads to the research questions for the thesis, which concern the documentation and exploration of patient safety in primary midwifery care.

**Chapter 2** describes the study protocol of a large observational study in primary care in The Netherlands. The study on patient safety in primary midwifery care was part of this larger research project. The overall aim of the study was to gain insight into the current patient safety status in general practices, primary out-of-hours care, general dental practices, allied healthcare practices and midwifery practices. The objectives of this study were: to determine the frequency, type, causes and effects of the incidents found in patient records, to determine the frequency, type, causes and effects of the incidents reported by healthcare professionals and to provide insight into patient safety management in the primary care practices. For this study we combined three different study methods; a retrospective review of 1000 patient records per practice type, a prospective incident report study for two successive weeks and a written survey on organizational and cultural patient safety aspects in the participating practices. We analyzed the incidents we revealed from the patient record study and from incident reports by type of incident, cause, actual harm and probability of severe harm or death.

**Chapter 3** describes the development of a validated measure to detect patient safety risks in midwife- led care for low risk childbearing women. The increased interest of midwife-led care for childbearing women to substitute for other models of care requires careful evaluation of safety aspects. A structured approach was followed for instrument development. First, we reviewed the literature on patient safety in general and obstetric and midwifery care in particular. We identified five domains of patient risk: organization, communication, patient related risk factors, clinical management, and outcomes. We then developed a prototype to assess patient records and, in an iterative process, reviewed the prototype with the help of a review team of midwives and safety experts. The instrument was pilot tested for content validity, reliability and feasibility. A valid and feasible instrument to assess patient safety in low risk childbearing women is available and can be used for

quantitative analyses of patient records, the identification of unsafe situations and, to recommend steps for specific, domain-based improvements.

**Chapter 4** presents the patient safety study we performed in primary midwifery care in 2009 in The Netherlands, as outlined in chapter 2. In the 1000 patient records involving 14888 contacts, 86 safety incidents were found with 25 of these having a noticeable effect on the patient. Low-risk pregnant women in midwifery care had a probability of 8.6% for a safety incident (95% CI 4.8-14.4). In 9 safety incidents, temporary monitoring of the mother and/or child was necessary. In another 6 safety incidents, reviewers reported psychological distress for the patient. Hospital admission followed from 1 incident. No safety incidents were associated with mortality or permanent harm. The majority of incidents found in the patient records concerned treatment and organizational factors. This study suggested that patient safety in primary midwifery care is high. Nevertheless, some areas for improvement were found. Improvement of patient safety should address the better adherence to practice guidelines for patient risk assessment, better implementation of interventions for known lifestyle risk factors and better availability of midwives during birthing care.

**Chapter 5** presents an explorative study on the associations of primary healthcare professionals' perceptions of patient safety with the actual number of patient safety incidents identified in patient records in their practices. The study was performed in 70 primary care practices of general practice, general dental practice, midwifery practices, and allied healthcare practices and was based on the results of the patient record review and a survey among health professionals to identify their perceptions of patient safety. All health professions felt that 'communication breakdowns inside the practice' as well as 'communication breakdowns outside the practice' and 'reporting of patient safety concerns' were a threat to patient safety in their work setting. However, we found little association between the perceptions of health professionals and the number of safety incidents. The only item with a significant relation to a higher number of safety incidents referred to the perception of 'communication problems outside the practice' as a threat to patient safety. This study indicates that the assessment of professionals' perceptions may be complementary to observed safety incidents, but not linked to an patient record based measure of patient safety.

**Chapter 6** describes a secondary comparative analysis of the incidence of safety incidents and their causes in maternal care in two studies. We compared the results of the national study among 1000 pregnant women in The Netherlands to the results of a similar study among 449 pregnant women living in an urban area with deprived neighbourhoods. In the national study, safety incidents were retrospectively identified from patient records. In the urban study, midwives reported incidents. The same methods of documentation, analysis and classification were further used. In the national study, the pregnant women had a 2.3 % (95% CI 1.0-3.6) probability of a safety incident during the birth period; in the urban study, this was 6.6 % (95% CI 3.3-10.0). In both studies, most of the safety incidents stemmed from organizational factors. A low prevalence of safety incidents was found. Women in a deprived urban area nevertheless had a higher risk of patient safety incidents than women nationally. Measures to improve patient safety should focus on both the organizational aspects of urgent birth care and prioritize pregnant women from vulnerable groups.

**Chapter 7** presents a study of critical incidents in maternity care with a view on improving patient safety. We included all 71 critical incidents in primary midwifery care and successive hospital care in case of referral after 36 weeks of pregnancy that were reported to the Health Care Inspectorate in The Netherlands in 36 months. We performed a case-by-case analysis, using a previously validated instrument which covered five broad domains: healthcare organization, communication between healthcare providers, patient risk factors, clinical management, and clinical outcomes. Causes of critical incidents concerned healthcare organization (n=20 incidents), communication about treatment procedures (n=39), referral processes (n=19), risk assessment by telephone triage (n=10), and clinical management in an out of hours setting (n=19). The 71 critical incidents included three cases of maternal death, eight cases of severe maternal morbidity, 42 perinatal deaths and 12 critical incidents with severe morbidity for the child. The wide variety of potential causes of critical incidents implies that there is no single intervention to improve patient safety in maternity care. Key domains for patient safety were prenatal risk assessment, availability of healthcare providers in urgent situations, communication about treatment between care providers, and communication with patients in situations with a language barrier. Systematic analysis of critical incidents enhances learning and improvement of patient safety.



**Chapter 8**, the general discussion of the thesis, presents an overview of the findings which are discussed against the background of the existing literature. Furthermore, the strengths and limitations of the studies in this thesis are discussed, as well as implications for midwifery practice, education and healthcare policy. Finally, advice on further patient safety research in primary midwifery care is discussed.

# Samenvatting

**Hoofdstuk 1** Dit proefschrift beschrijft patiëntveiligheid in de eerstelijns verloskundige zorgverlening in Nederland. Wereldwijd bestaat interesse naar een verloskundig zorgmodel voor zwangeren dat sterk gemedicaliseerde zorg vermijdt maar het is noodzakelijk om inzicht te hebben in de veiligheid van de zorg door verloskundigen. In het eerste hoofdstuk wordt de organisatie van verloskundige zorg voor zwangeren met een laag risico in het begin van de zwangerschap in Nederland beschreven en worden de studies die in het kader van dit proefschrift zijn uitgevoerd toegelicht. De centrale onderzoeksvraag van dit proefschrift luidt: 'Wat is de patiëntveiligheid in de eerstelijns verloskundige zorg in Nederland'.

**Hoofdstuk 2** presenteert het studieprotocol van een brede, observationele studie naar patiëntveiligheid in de eerstelijns gezondheidszorg in Nederland. De studie in de verloskunde, zoals gepresenteerd in hoofdstuk 4, maakte deel uit van deze landelijke studie. Het onderzoek werd uitgevoerd in huisartsenpraktijken, verloskundigen praktijken, tandartspraktijken, huisartsenposten en paramedische praktijken. De studie had tot doel om inzicht te geven in de frequentie, het type, de impact en de oorzaak van incidenten in de eerstelijns gezondheidszorg in Nederland alsmede het patiëntveiligheidsmanagement in de diverse beroepsgroepen in de eerstelijns zorg. De studie bestond uit drie delen: een retrospectief dossieronderzoek van 1000 patiëntendossiers per praktijksoort, een prospectieve studie waarin zorgverleners gedurende twee aaneengesloten weken incidenten konden melden en een schriftelijke vragenlijst over organisatorische en culturele aspecten van patiëntveiligheid in de participerende praktijken. Er is bewust een ruime definitie van incidenten aangehouden, waardoor ook vermijdbare verhoogde risico's zonder schade voor de patiënt werd meegenomen. We analyseerden de incidenten uit de dossierstudie en de gemelde incidenten door zorgverleners naar type incident, oorzaak, werkelijke schade en de waarschijnlijkheid van ernstige schade of overlijden.

**Hoofdstuk 3** beschrijft de ontwikkeling van een instrument om patiëntveiligheidsrisico's in de eerstelijns verloskundige zorg te identificeren. Er was geen valide instrument beschikbaar voor de beoordeling van veiligheid van verloskundige zorg. Dit instrument is ontwikkeld en toegepast in de studies die zijn beschreven in dit proefschrift. Voor de ontwikkeling van dit instrument hebben we algemene literatuur over patiëntveiligheid en literatuur over patiëntveiligheid in de eerstelijns verloskundige zorg beoordeeld. We hebben vijf risico domeinen

geïdentificeerd voor patiëntveiligheid in eerstelijns verloskundige zorg; organisatie van zorg, zorg gerelateerde communicatie, patiënt gerelateerde risicofactoren, medisch handelen en uitkomsten van zorg. Op basis van deze vijf risicodomeinen hebben we een prototype van een analyse instrument ontwikkeld om verloskundige dossiers te screenen op onveilige aspecten. Dit prototype is aangepast in een iteratief proces met verloskundige onderzoekers en experts in patiëntveiligheid. De validiteit, betrouwbaarheid en toepasbaarheid van het instrument zijn getest in een pilot en vervolgens toegepast in de landelijke patiëntveiligheidsstudie. Een valide instrument voor de kwantitatieve analyse van dossiers van zwangere vrouwen in de eerstelijns verloskundige zorg is beschikbaar. Het instrument identificeert onveilige aspecten van eerstelijns verloskundige zorg en faciliteert aanbevelingen voor verbetering van de veiligheid op basis van geïdentificeerde risicodomeinen.

**Hoofdstuk 4** beschrijft een observationele studie naar de patiëntveiligheid in de eerstelijnsverloskundige zorg. We analyseerden 1000 verloskundige dossiers waarin 14888 contactmomenten van verloskundigen met zwangeren stonden beschreven. We vonden 86 veiligheidsincidenten, waarvan 25 een merkbaar gevolg voor de zwangere en/of haar kind hadden. Op basis van deze studie hadden zwangeren met een a priori laag risico in Nederland 8,6% kans op een veiligheidsincident (95% BI 4,8-14,4). Negen incidenten hadden tot gevolg dat moeder en/of kind extra monitoring nodig hadden. Bij zes incidenten ondervonden zwangeren emotionele stress ten gevolge van het incident, één incident leidde tot ziekenhuisopname. Er zijn geen incidenten gevonden met ernstige gevolgen zoals blijvende schade of overlijden. De meeste incidenten waren gerelateerd aan de behandeling of de organisatorische aspecten van de verloskundige zorg. Deze studie wijst uit dat eerstelijns verloskundige zorg veilig is, maar dat er aspecten in de zorg zijn die verbeterd kunnen worden. De veiligheid van verloskundige zorg kan worden verhoogd door de bestaande richtlijnen voor risicoselectie beter te volgen, meer aandacht te geven aan risicofactoren in de leefstijl van zwangeren en de beschikbaarheid van verloskundigen tijdens de bevalling te verbeteren.

**Hoofdstuk 5** presenteert een exploratieve studie naar de relatie tussen de mening van eerstelijns zorgverleners over de patiëntveiligheid in hun dagelijkse praktijk en het feitelijke aantal incidenten dat is gevonden in de patiëntendossiers van deze zorgverleners. De studie werd uitgevoerd in 70 eerstelijns praktijken van huisartsen, tandartsen, verloskundigen en paramedici en is gebaseerd op de resultaten van de dossieronderzoeken en de vragenlijsten naar organisatorische en culturele aspecten van patiëntveiligheid in de participerende praktijken. Alle eerstelijns zorgverleners

veronderstelden dat 'communicatie problemen binnen de eigen praktijk' en 'communicatieproblemen met zorgverleners buiten de praktijk', alsmede het 'rapporteren van onveilige aspecten in de praktijk', een negatieve invloed hebben op de patiëntveiligheid in de praktijk. Wij vonden echter weinig verband tussen meningen van zorgverleners en het aantal incidenten in dossiers. Alleen de veronderstelde relatie tussen 'communicatieproblemen buiten de praktijk' en feitelijke incidenten als gevolg van deze communicatieproblemen, was significant aantoonbaar. Deze studie bevat aanwijzingen dat het betrekken van de mening van zorgverleners ten aanzien van de patiëntveiligheid in de eigen praktijk aanvullend kan zijn aan observationeel onderzoek, maar deze is niet gerelateerd aan de uitkomsten van dossieronderzoek.

**Hoofdstuk 6** beschrijft een secundaire vergelijkende analyse van de incidentie en oorzaken van veiligheidsincidenten in verloskundige zorg tijdens de bevalling in twee studies. We vergeleken de resultaten van de nationale studie bij 1000 zwangeren in Nederland en de resultaten van een soortgelijke studie bij 449 zwangeren in een stedelijke regio met achterstandswijken. De veiligheidsincidenten in de nationale studie zijn retrospectief geïdentificeerd uit de dossiers van zwangeren, de incidenten in de stedelijke regio werden gemeld door verloskundigen. De incidenten in beide studies zijn op gelijke wijze gerapporteerd, geanalyseerd en geclassificeerd. In de landelijke studie hadden zwangeren 2,3% (95% BI 1,0-3,6) kans op een veiligheidsincident tijdens de bevalling, in de stedelijke studie was deze kans 6,6% (95% BI 3,3-10,0). In beide studies was de kans op een incident niet hoog en was er een laag risico op ernstige schade. De meeste incidenten werden gevonden binnen de organisatie van verloskundige zorg. Zwangeren in de stedelijke regio hadden een verhoogde kans op een veiligheidsincident vergeleken met de uitkomsten voor zwangeren in Nederland. Verbetermaatregelen zouden zich moeten richten op organisatorische aspecten van spoedeisende verloskundige zorg en meer specifiek op interventies die toepasbaar zijn voor kwetsbare zwangeren in stedelijke regio's met achterstandswijken.

**Hoofdstuk 7** presenteert een analyse van de patiëntveiligheidsaspecten van ernstige calamiteiten in de verloskundige zorg. Wij analyseerden 71 calamiteiten die zijn opgetreden van 2009 tot 2012 en zijn gemeld aan de Inspectie voor Gezondheidszorg in Nederland. Het betrof zwangeren in zorg van eerstelijns verloskundige praktijken of zwangeren die vanuit de eerstelijns praktijken na 36 weken zwangerschap werden verwezen. We analyseerden alle individuele cases met het eerder gevalideerde instrument dat vijf veiligheidsdomeinen bevat:

organisatie van zorg, communicatie over de zorgverlening, patiënt gerelateerde risicofactoren, medisch handelen en uitkomsten voor moeder en kind. De volgende risicodeterminanten werden gevonden; organisatie van zorg (n=20), communicatie over behandeling (n=39), verwijspcedures (n=19), telefonische triage van risicofactoren (n=10) en behandeling buiten kantooruren (n=19). De 71 calamiteiten resulteerden in 3 cases met maternale sterfte, 8 cases met ernstige maternale morbiditeit, 42 cases met perinatale sterfte en 12 cases met ernstige perinatale morbiditeit. We vonden een breed spectrum van risicodeterminanten en concluderen dat er geen eenvoudige oplossing is om patiëntveiligheid in verloskundige zorg te verbeteren. Belangrijke geïdentificeerde risicodomeinen zijn risicoselectie tijdens de zwangerschap, beschikbaarheid van verloskundige zorgverleners in acute situaties en communicatie met zwangeren die de Nederlandse taal onvoldoende beheersen. De systematische analyse van calamiteiten leidt tot inzicht in risicodeterminanten van patiëntveiligheid in verloskundige zorg, verhoogt het risicobewustzijn van zorgverleners en bevat aanwijzingen voor verbetering van deze zorg.

**Hoofdstuk 8** beschrijft de conclusies van dit proefschrift. Het bevat een overzicht van de bevindingen en beschrijft deze bevindingen tegen de achtergrond van bestaande literatuur. Vervolgens worden de methodologische kanttekeningen van de onderzoeken in dit proefschrift beschreven evenals de implicaties voor de dagelijkse verloskundige zorg, de opleiding van verloskundigen en het beleid voor de eerstelijns verloskundige zorg. Tot slot worden adviezen voor vervolgonderzoek besproken.

# Dankwoord

Tijdens het schrijven van dit proefschrift heb ik veel wetenschappelijke en persoonlijke inspiratie gehad. Ik ben veel mensen dank verschuldigd, een aantal wil ik in het bijzonder noemen.

Mijn beide promotoren Prof. dr. M. Wensing en Prof. dr. S.E. Buitendijk en mijn co-promotor dr. J.E. Jacobs.

Beste Michel, veel dank voor je consequente en vooral, altijd snelle reactie op mijn documenten en vragen. Ik heb regelmatig met promoverende collega-verloskundigen gesproken en een ding is mij duidelijk geworden. De begeleiding die ik van jou én van IQ healthcare heb gekregen is zeker niet vanzelfsprekend. Ik heb veel geleerd van je commentaar op mijn artikelen en van je visie op de gezondheidszorg.

Beste Simone, dank voor je kennis van de perinatale zorg in Nederland, je commentaar en positieve reacties. Toen jij je functie in Leiden aanvaardde zei je tegen me dat je wel tweede promotor wilde blijven omdat 'ik er toch al bijna was'. Voor mijn gevoel had ik nog een lange weg te gaan maar je woorden motiveerden mij enorm.

Beste Annelies, heel veel dank voor je begeleiding maar ook voor je interesse in mijn persoonlijke leven met de combinatie van werk, wetenschap en gezin. We hebben veel samen gezeten voor het landelijke patiëntveiligheidsonderzoek en het IGZ onderzoek. Je kon me altijd weer overzicht geven als de materie te complex dreigde te worden en je hebt me enorm gemotiveerd.

De leden van de beoordelingscommissie Prof. dr. D.D.M. Braat, Prof. dr. J. van der Velden en Prof. dr. R. de Vries wil ik bedanken voor de beoordeling van het manuscript.

Jolanda van Haren, dank voor je onmisbare hulp bij het manuscript en alle werkzaamheden rond de vormgeving van het proefschrift. Jij bent een bron van kennis binnen IQ healthcare. Jolanda Tielens, creatief hockeymaatje, dank voor je inspiratie en ontwerp van de omslag van dit proefschrift.

Alle medeauteurs wil ik bedanken voor het enthousiasme, de inspiratie en het commentaar. Ondanks alle drukke werkzaamheden hebben jullie bijgedragen aan mooie publicaties. In het bijzonder wil ik mijn collega-verloskundige onderzoekers Carola Groenen, Ageeth Schonewille-Rosman en Alieke de Roon-van Immerzeel en bedanken voor de bijdrage aan het tijdrovende dossieronderzoek in de praktijken. Ook ben ik dank verschuldigd aan het onderzoeksteam van de landelijke patiëntveiligheidsstudie in de eerstelijns gezondheidszorg en in het bijzonder aan Mirjam Harmsen en Irma Maasen. Mirjam, je was een prima projectleider die mij als startende onderzoeker veel steun gaf. Irma, ik kon altijd een beroep op je doen, je overzicht en bewerking van alle data was onmisbaar. Marlies Rijnders, Ashley Verlinden en Wilma Otten, mijn medeauteurs van TNO, dank voor je medewerking om de vergelijkende studie tot stand te brengen. Ook een woord van dank aan Renske Wentzel bij de Inspectie voor Gezondheidszorg voor je enthousiaste bijdrage aan de analyses. Als laatste, heel speciaal, Marianne Amelink, dank voor je enorme bijdrage in mijn wetenschappelijke vorming. Als kritische maar zeer betrokken begeleider heb je mijn Master thesis begeleid en vervolgens mocht ik onder jouw vleugels verdergaan met de analyse van calamiteiten. Naast je wetenschappelijke input ben je altijd geïnteresseerd in mijn persoonlijke en professionele leven. Voor mij ben je een voorbeeld- verloskundige die bijdraagt aan de kwaliteit van perinatale zorg en je bent een inspiratie voor veel verloskundigen in Nederland.

In de Verloskundigen Praktijk in Deurne heb ik altijd geweldige collega's gehad. Marja, Anja, Emilie, Linda, Eveline en Wilma, dank voor alle speciale momenten. Ik heb met jullie het plezier, de werklust en alle spreekuren, diensten en visites gedeeld en er is nooit een verkeerd woord gevallen. Het gaat jullie goed in de praktijk in Deurne. Maar ook dank aan alle zwangeren in Deurne die ik heb mogen begeleiden. Het dragen en krijgen van een kind is een topprestatie, een voorrecht om daarbij te mogen zijn.

Dank aan alle inspirerende collega's in de regio en in het land die ik als voortrekkers van de verloskundige zorg heb ontmoet. Ik heb veel inspiratie en kennis gehaald uit deze ontmoetingen. Een paar collega's wil ik in het bijzonder noemen. Erna, mijn maatje van het eerste uur op 't Ooievaarsnest in Heerlen, wat hebben we tijdens de opleiding plezier gehad en als we elkaar nu tegenkomen gaan we gewoon verder waar we gebleven zijn. Mieke B, Mieke A, Antje, Franka, Suze en alle anderen, gelukkig blijven we elkaar zien. Greta, grote kracht achter de wetenschapscommissie van de KNOV, het was heerlijk om met je te werken en geweldig om jou nu als paranimf naast me te hebben.

Ik heb dit proefschrift alleen kunnen schrijven omdat ik een warme cirkel om mij heen heb. Een hockeyteam waar ik stoom kan afblazen en lol kan maken. De vriendinnen van de 'mannen' kookclub, heerlijke gesprekken als de mannen zalig koken en de dames het gewoon gezellig hebben. De fractiegenoten in de gemeentepolitiek en in het bijzonder de DOE!- vrouwen, we hebben het allemaal ongelofelijk druk maar gelukkig vinden we momenten voor inspirerende uitjes.

Met een vader die als motto heeft: 'Nie mauwe mâr Durdauwe' en op respectabele leeftijd twee boeken van historische waarde schrijft en een moeder die gemiddeld drie keer per week een sms stuurt; "Kan ik nog iets voor je doen", dan is het eerder logisch dan bijzonder dat mijn proefschrift voltooid is. Verder lieve Zeeuwse schoonfamilie en een zus en zwager met wie wij de liefde en lol van Maud, Lotte, Pim en Evelien delen, dubbel familie is leuk! Ik heb een heerlijk, warm, stabiel gezin. Hans, je stimuleert me in alles wat ik doe en samen hebben we lieve kinderen met een druk schema vol inspirerende bezigheden. We hebben het goed!



# Curriculum Vitae

Lucie Martijn werd op 27 september 1964 geboren in Cuijk. Na het behalen van het Atheneum diploma aan het Peelland College te Deurne heeft ze de HBO-V in Goes gevolgd. In 1989 behaalde ze haar diploma als verloskundige aan de Vroedvrouwenschool te Heerlen en startte haar verloskundige werkzaamheden in Tilburg. In 1990 vestigde zij zich in de Verloskundigen Praktijk te Deurne waar zij tot 2013 praktiseerde als verloskundige.

In 2006 voltooide zij de Master of Science Midwifery aan AMC/Universiteit van Amsterdam waarna zij in 2007 begon met haar werkzaamheden als beleidsadviseur bij de KNOV. Dit combineerde ze gedurende vijf jaar met de praktijkwerkzaamheden. Daarnaast werd zij in 2009 verloskundig onderzoeker voor het onderzoek naar patiëntveiligheid in de eerstelijns gezondheidszorg bij IQ healthcare/Radboudumc.

Sinds september 2012 werkt ze als beleidscoördinator Zorg bij de afdeling Kwaliteit & Innovatie van Coöperatie VGZ. Lucie is getrouwd met Hans. Samen hebben zij twee kinderen, Pim en Evelien.

## Stellingen

behorende bij het proefschrift van Lucie Martijn

### Patient safety in primary midwifery care

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1. Om de patiëntveiligheid in de eerstelijns verloskundige zorg te verhogen is een structurele evaluatie van alle verleende zorg, ongeacht de uitkomsten, een eerste vereiste. *(dit proefschrift)*
2. De patiëntveiligheid van eerstelijns verloskunde kan alleen worden beoordeeld met een instrument dat specifiek is ontwikkeld voor deze zorg. *(dit proefschrift)*
3. Eerstelijns verloskundige zorg in Nederland is grosso modo veilig, maar verloskundigen mogen niet nalaten deze verder te verbeteren. *(dit proefschrift)*
4. Alle verloskundige praktijken hebben een achterwachtingregeling voor dubbele spoedoproepen, er bestaat echter een drempel voor het daadwerkelijk inschakelen van de achterwachting. *(dit proefschrift)*
5. Kwetsbare zwangeren uit risicogroepen hebben een verhoogde kans op veiligheidsincidenten. *(dit proefschrift)*
6. Er zijn geen eenvoudige oplossingen om ernstige calamiteiten in de perinatale zorg te voorkomen, maar bewustwording van risico's is een eerste stap in de goede richting. *(dit proefschrift)*
7. Het implementeren van een veiligheidsmanagementsysteem binnen de eerstelijns verloskundige praktijken hoort in het curriculum van de opleiding voor verloskundigen.
8. Verwijzing van alle zwangeren met een laag risico op complicaties naar gespecialiseerde medische zorg zal de patiëntveiligheid van de perinatale zorg niet verhogen.
9. Wij leven in een bijzonder land als de dierenambulance met zwaailicht en sirenes mag rijden, maar verloskundigen bij noodoproepen in de file moeten aansluiten.
10. Periodieke analyse van calamiteiten in de database van de Inspectie voor Gezondheidszorg voorafgaand aan een verloskundige dienst leidt tot veiliger zorg.

