### Patient Safety in Primary Allied Health Care

# What Can We Learn From Incidents in a Dutch Exploratory Cohort Study?

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**Background:** Research on patient safety in allied healthcare is scarce. Our aim was to document patient safety in primary allied healthcare in the Netherlands and to identify factors associated with incidents.

**Design and Subject:** A retrospective study of 1000 patient records in a representative sample of 20 allied healthcare practices was combined with a prospective incident-reporting study.

**Measures:** All records were reviewed by trained researchers to identify patient safety incidents. The incidents were classified and analyzed, using the Prevention and Recovery Information System for Monitoring and Analysis method. Factors associated with incidents were examined in a logistic regression analysis.

**Results:** In 18 out of 1000 (1.8%; 95% confidence interval: 1.0–2.6) records an incident was detected. The main causes of incidents were related to errors in clinical decisions (89%), communication with other healthcare providers (67%), and monitoring (56%). The probability of incidents was higher if more care providers had been involved and if patient records were incomplete (37% of the records). No incidents were reported in the prospective study.

Conclusions: The absolute number of incidents was low, which could imply a low risk of harm in Dutch primary allied healthcare. Nevertheless, incompleteness of the patient records and the fact that incidents were mainly caused through human actions suggest that a focus on clinical reasoning and record keeping is needed to further enhance patient safety. Improvements in record keeping will be necessary before accurate incident reporting will be feasible and valid.

**Key Words:** adverse events, patient safety, patient records, allied healthcare, administration

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Patient safety has been placed high on the societal agenda, although till to now research focused predominantly on hospital care. The Netherlands has a strong primary care setting, resulting in a large volume of contacts. However, contrary to family practice, there is hardly any concrete information on patient safety in primary allied healthcare (allied healthcare provided by professionals working in the primary care setting).

A literature search on patient safety issues in allied healthcare provided only a few studies. Malpractice reports from all kinds of physical therapy (PT) settings in the United States have shown that the incidence of medical errors is low<sup>9</sup> and mainly associated (77%) with treatment-related issues. A survey study conducted among occupational therapists in geriatric and rehabilitation settings in the United States identified misjudgment, lack of preparation, and lack of experience as the top 3 causes of practice errors. 10 When looking more specific to primary care setting, a recent Dutch explorative study (descriptive literature review and interviews with stakeholders) concluded, that unnecessary and redundant treatment, exercise in high-risk patients, inadequate hygiene, and joint mobilizations/manipulations could be risk factors of adverse events.<sup>8</sup> This was affirmed in anecdotal reports with incidents after spinal manipulation in children<sup>10–14</sup> and adults. 15-17 So far, no studies have been found on the prevalence and types of incidents in primary allied healthcare.

One of the characteristics of primary healthcare in the Netherlands is multidisciplinary collaboration (eg, family physician and allied health therapists), which implies a necessity for alignment and clear communication. Adequate record keeping is a prerequisite for transparent, efficient, and safe care <sup>18</sup> and seems to decrease the risk exposure to potential malpractice. <sup>19</sup>

In this study, we aimed to improve our insights of safety-related issues and focused on 3 allied healthcare disciplines: PT, occupational therapy (OT), and Cesar/Mensendieck exercise therapy (ET), which is ET focusing on body awareness. The aims of this study were (1) to document the prevalence, impact, and causes of incidents and (2) to explore risk factors related to these patient safety incidents.

#### **METHODS**

#### **Design and Setting**

This study was part of a larger observational study on patient safety in primary care in the Netherlands. Identical safety studies were conducted among Dutch family practices, out-of-hours primary care centers, dental practices, and midwifery practices. <sup>18</sup> As a mix of methods is needed to identify incidents, <sup>20</sup> we choose a retrospective patient record review as most appropriate for estimating rates of adverse events, <sup>21</sup> and prospective event reporting for the detection of latent errors. <sup>22</sup> The same incident definition was used in both studies: "an unintended event during the care process that resulted, could have resulted or might still result in harm to the patient." <sup>23</sup>

#### **Preliminary Study**

In preparation for this study, a questionnaire was developed to test the feasibility of the patient record study and to trace the possible nature of incidents. We asked allied healthcare professionals about their experiences with (potentially) unsafe situations in the past years in their practice. The presented list with potentially related items on organization of care, communication, high-risk patients, diagnosis/ intervention, and outcomes was based on the literature.<sup>8,24</sup> A link to an electronic questionnaire was sent by email to 500 allied primary care practices: a sample out of all addresses from the 3 professional organizations in the Netherlands. Therapists were asked to assess the relevance of the items and the likelihood that information could be detected in the patient records. The response rate was 262 (52%). Therapists linked (potentially) patient unsafe situations mostly to patient-related aspects, followed by lack of safe equipment as well as an inadequate history and/or missed red or yellow flags (warning signs of possible serious pathology) in the patient history. The therapists estimated that unsafe situations could adequately be identified in patient records, except for the safety of the use of equipment and material. Finally, therapists were able to point out whether they were willing to participate in the study.

#### **Participants**

The study included 20 primary allied healthcare practices in the Netherlands. On the basis of the total number of PT, OT, and ET practices in Dutch primary care, the proportional selection was determined at 11 PT, 6 ET, and 3 OT practices. Moreover, we stratified for the degree of urbanization (half city and half country site) and only for PT on practice size [7 large ( > 5 PTs) and 4 small], because OT and ET are always small practices. A secretary without knowledge about the study content appointed professionals in the practices who were willing to participate in the preliminary study (N=50) from a randomly ordered list, using the grouping criteria.

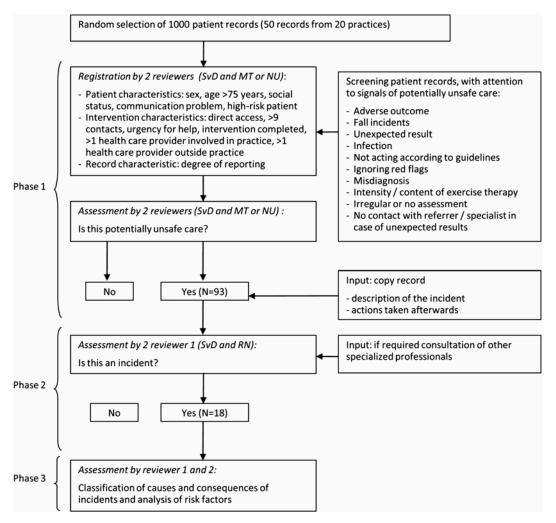
#### **Retrospective Patient Record Study**

We randomly selected 50 records of each of the 20 practices from the appointment lists 1 to 4 months before the selection date (total 1000 records). The selection process ensured a proportional spread across the different therapists. Depending on the total number of appointed patients per therapist in practice, each "xth" record per therapist was selected. Each patient record, including correspondence and

exercise schedules, was made anonymous by the therapist, before it was reviewed. For chronic patients (treatment longer than 1 year for a single diagnosis) records were reviewed from the selection date to 1 year prior. The degree of reporting was classified based on consensus in the project group: a record was considered "good" if the information on the diagnostic and therapeutic process was complete conform the guideline reporting; "moderate" if parts of the diagnostic or therapeutic process had not been specified in the patient record and "poor" if the therapeutic or diagnostic process in the record was missing or if information on both parts was considered to be too scarce.

The review procedure was tested in 3 pilot practices (1 for each discipline), resulting in a few small alterations to the review form. Moreover, in this phase the reviewers were extensively trained in the review procedure and differences in scores were discussed.

The record review procedure consisted of 3 phases (see Fig. 1). In the first phase, reviewers assessed the sampled records. One experienced physical therapist (S.v.D.) reviewed all records using the predefined criterion list. Each practice visit she was accompanied by a researcher (M.T.) with allied healthcare background or a medical student Noortje uphoff (N.U.), all trained in the procedure. The reviewers registered on a review form potential risk factors defined by the project group based on the preliminary study and literature on incidents<sup>8,18,24–27</sup> (see Table 1). Risk factors included patient characteristics [sex, age > 75 y, social status, high-risk patients (history of cardiovascular, lung, or cancer disease) and communication problem], intervention characteristics (intervention completed, direct access, > 9 contacts, urgency for help, > 1 healthcare provider involved in practice and > 1 healthcare provider involved outside the practice), and record characteristic (good/moderate/poor record keeping). All patient records were completely screened by both practice visitors with special attention to the following components: adverse outcome, fall incidents, infection, or other unexpected results. Moreover, we checked not acting according to the guidelines (if available); ignoring red flags; misdiagnosis; the intensity; and content of ET (especially in high-risk patients); irregular or no assessments (objective or subjective) and no contact with referrer or other specialists. All records with only 1 score pointing into the direction of unsafe situations were copied and proceeded to phase 2. These records were assessed for potential incidents by 2 experienced physical therapists (S.v.D. and R.N.), and if necessary, consultation took place with specialized professionals. In the third phase, the same therapists (S.v.D. and R.N.) tentatively classified the causes of the incidents, the consequences and the analysis of risk factors for the cases classified as definitive incidents. Fifty records (first 10 selected cases in first 5 practices) were independently accessed (S.v.D. and R.N.) to determine the interrater reliability in phase 1. Several arrangements were made to ensure the confidentiality of the information. Patient information was already deleted in the selected records by the therapists, therapist names were not included in the database, and reviewers and researchers signed an agreement to guarantee the confidentially of the information.



**FIGURE 1.** Record review procedure.

#### **Prospective Incident-reporting Study**

Immediately after the patient record study, all therapists of the participating practices were invited to report all unintended events during a period of 2 successive weeks. Therapists were instructed how to report all unintended events, and were stimulated to report even when they were unsure whether an event fell within that definition. They received written information on definitions of patient safety, adverse events, and incidents in advance, and more information was also available on the website. <sup>28</sup> If no incident occurred during the reporting period, therapists were asked to return a form in any case, so as to complete the study.

#### **Data Analysis**

Descriptive statistics and frequency tables were used to describe the population (patients and practices) and the causes of the incidents. The returned forms from the incident-reporting study were assessed to check whether these could be marked as an incident according to the stated definition.

#### **Causes of Incidents and Consequences**

We applied the Prevention and Recovery Information System for Monitoring and Analysis (PRISMA) method to analyze incidents by means of causal factor trees. <sup>29,30</sup> It was used as a foundational component for the conceptual framework for the World Health Organization World Alliance for Patient Safety's International Classification for Patient Safety. 31–33 At the top of the causal factor tree a short description of the event is placed, as the starting point of the analysis. Below the top event, all direct causes involved are mentioned. By continuing to ask "why" for each event or action, the majority of causes are revealed. The identified root causes are classified with the Eindhoven Classification Model of PRISMA.<sup>29,30</sup> The Eindhoven Classification Model taxonomy distinguishes 5 main categories of causes: technical, organizational, human, patient-related, and other, which can be subdivided into subcategories. The reviewers (S.v.D. and R.N.) received extensive training in the PRISMA method.<sup>34</sup>

The consequences of the incidents were classified using the "severity of outcome" dimension of the International Taxonomy of Medical Errors in Primary Care.<sup>35</sup>

**TABLE 1.** Characteristics of Patient Records

	Patient Records, N = 1000 (%)	Incident Records, N = 18 (%)
Patient		
Sex (woman)	622 (62.2)	14 (77.8)
Age $> 75 \text{ y}$	99 (9.9)	4 (22.2)
Social status (low)	30 (3)	2 (11.1)
Communication problem (yes)	26 (2.6)	2 (11.1)
High-risk patient (yes)*	105 (10.5)	2 (11.1)
Intervention		
Intervention completed (no)	540 (54)	13 (72.2)
Direct access (yes) <sup>†</sup> > 9 contacts <sup>‡,§</sup>	194 (19.4)	2 (11.1)
> 9 contacts <sup>‡,§</sup>	530 (53)	12 (66.7)
High urgency for help (yes)	40 (4)	1 (5.6)
> 1 healthcare provider involved in practice	225 (22.5)	10 (55.5)
> 1 healthcare provider involved outside the practice	869 (86.9)	18 (100)
Record		
Moderate/poor record keeping	366 (36.6)	12 (66.7)

<sup>\*</sup>High-risk patient: (having had) heart problems, lung problems, or cancer.

#### **Analysis of Risk Factors**

We used logistic regression to study possible association between risk factors and the occurrence of incidents (dependent variable: "Yes an incident" vs. "No incident"). First, possible bivariate associations of all risk factors were examined with  $\chi^2$  tests. Given the low number of incidents, we needed to reduce the number of variables in the model. Variables occurring in less than 20% of the incident cases were therefore excluded, assuming that the incidence would be too low to obtain reliable estimates in a logistic regression model. The remaining factors were examined in a stepwise procedure in which the risk factor with the highest P value was removed, whereupon the model was run again. This step was repeated until no risk factors with P > 0.20 had been left in the model. Results from the logistic regression model were expressed as Odds ratios (OR) including 95% confidence interval (CI). Associations were considered statistically significant if P < 0.05.

#### **RESULTS**

#### **Study Population**

We included 11 PT (550 records), 6 ET (300 records), and 3 OT practices (150 records). Nine were solo practices (45%). Most therapists (37%) were in the age category 26 to 35 years, followed by age category 46 to 55 years (29%), and

36 to 45 years (27%). On average 3.4 therapists worked per practice and 63% were women. The participating professionals in the practices and the patient records characteristics sex, age, direct access, and the number of contacts comprised a representative sample when compared with national reference data. Only the average number of treatments per episode/year in the PT practices differed: 21 visits in this study versus 12 in the normative data due to outliers (median = 9). Table 1 presents an overview of the characteristics for the total sample and the subsample of records with incidents. Reference data of OT practices was not available.

## Prevalence of Incidents in Retrospective Patient Record Study

During the first phase of the record review 93 cases with potential unsafe care were detected. It is noteworthy that only in 63% of the records the degree of reporting was "good," in 31% "moderate," and in 6% "poor." Therefore, it was sometimes difficult or even impossible to track incidents. The interrater reliability was high: (94% agreement; Cohen  $\kappa$ : 0.83). After the assessment in phase 2, 18 cases out of 1000 (1.8%) were classified as patient safety incidents (95% CI: 1.0-2.6): 13 (2.4%) in PT records (CI: 1.1-3.6), 4 (1.3%) in ET records (CI: 0.0-2.6), and 1 (0.7%) in OT records (CI: 0.6-2.0). Of the 20 practices there were 11 practices without incidents, 4 with 1 incident [2 PT, 1 OT, and 1 ET practice(s)], 2 ET practices with 2 incidents, 2 PT practices with 3 incidents, and 1 PT practice with 4 incidents, which means that some practices were more predetermined for incidents than others.

#### **Prospective Incident Reporting Study**

All professionals in the 20 practices participated in the incident reporting study. In total, 7 incident report forms were returned from all 3 kinds of allied healthcare practices. However, evaluation showed no incidents according to the assigned definition. In all cases, the described events occurred in the home situation of the patient and were not directly related to the intervention and/or question for help, that is, a patient who had been involved in a car accident, or a report of a patient who fell from a wheelchair during a restaurant visit.

#### **Causes of Incidents and Consequences**

Table 2 describes the classification of the causes of incidents. Almost all incidents had multiple causes. In 17 out of the 18 incidents at least 1 of the reasons was linked to human behavior. "Knowledge-based behavior" was predominantly involved (16 incidents, 89%). In all these cases there was a wrong or unclear diagnosis resulting in an incorrect intervention combined with lack of evaluation and response to unexpected results. Incidents related to "monitoring" (human rule-based monitoring) were mainly related to problems in monitoring a process or patient status (14 incidents, 56%). Incidents related to the organization of care (12 incidents, 67%) were connected to "transfer of knowledge" (organization transfer of knowledge).

Eight out of the 18 incidents did not result in actual harm. Ten events (56%) did have consequences for patients:

<sup>&</sup>lt;sup>†</sup>Direct access implies that patients came to the healthcare provider without referral.

<sup>&</sup>lt;sup>‡</sup>In the Netherlands, Dutch National Insurance compensates 10 hours per year for occupational therapy. This means that some treatments are for 15 minutes, another for 1.5 hours. In this study occupational therapy is displayed at the number of contacts (and not at the number of hours).

<sup>§</sup>In the Dutch National Insurance a cutoff of more than 9 treatments is used for chronic care in allied healthcare.

A record was considered "moderate" if parts of the therapeutic process or the diagnostic process had not been specified in the patient record. A record was rated as "poor" if the therapeutic or diagnostic process in the record was missing or if information on both parts was considered to be too scarce.

TABLE 2. Underlying Causes of Incidents According to the PRISMA-medical Version (N = 18)

Category	Code	Description		%
Organizational				
External	O-ex	Failures beyond the control/responsibility of the organization	1	5.6
Knowledge transfer	OK	Failures related to communication with other care providers	12	66.7
Protocols	OP	Failures related to quality and availability of protocols	0	0
Management priorities	OM	Conflicts between production needs and safety	0	0
Culture	OC	Failures resulting from a collective approach and its attendant modes of behavior	1	5.6
Human				
External	H-ex	Human failures beyond the control/responsibility of the organization	0	0
Knowledge behavior	HKK	Failures in clinical decisions	16	88.9
Qualifications	HRQ	Incorrect fit between an individual's training and task	0	0
Coordination	HRC	A lack of task coordination within the organization	4	22.2
Verification	HRV	Failures in assessment before starting the intervention	1	5.6
Intervention	HRI	Failures that result from faulty task planning and execution	8	44.4
Monitoring	HRM	Failures in monitoring a process of patient status	10	55.6
Slips	HSS	Failures in performance of highly developed skills	1	5.6
Tripping	HST	Failures in whole-body movements	0	0
Patient-related	PRF	Failures related to patient characteristics or conditions, which are beyond the control of the treatment	1	5.6
Other	X	Other	0	0

in 2 incidents an extra intervention was needed, 2 caused emotional harm, 2 temporary physical harm, 2 patients had to be admitted to the hospital, and 2 incidents resulted in permanent harm. Table 3 describes examples of incidents with causes and consequences.

#### **Risk Factors of Incidents**

Table 4 shows the relationship of the 11 prognostic variables with incidents. The variable ">1 healthcare provider involved outside the practice" was removed because it was present in nearly all cases (86.9%) and therefore not discriminative. Bivariate analyses showed that low social status, communication problems, > 1 healthcare provider involved in the practice, and moderate/poor record keeping were significantly related to incidents. Owing to low frequency, 5 factors were excluded and the remaining 6 variables were included in the stepwise multivariable analyses: sex, age > 75, intervention not completed, > 9 contacts, > 1 healthcare provider involved in practice, and moderate/poor record keeping. On the basis of the P < 0.20, 3 independent variables remained in the final model, of which 2 were statistically significant: treatment by more than 1 healthcare provider in the practice (OR: 3.86; CI: 1.48-10.03) and moderate/poor record keeping (OR: 3.04; CI: 1.16-8.29).

#### **DISCUSSION**

Patient safety incidents were found in 1.8% of the records in allied healthcare practices. Although the percentage suggests a low risk, we found consequences for some of the patients, which should have serious implications for the involved healthcare providers. The high number of incomplete patient records that we found may have resulted in an underestimation of incidents. This is an essential factor because we found that besides treatment by more than 1 healthcare provider in the practice, just incomplete patient records increased the risk of incidents. Almost all incidents were caused by poor knowledge, lack of monitoring and

evaluation, no response to unexpected results, and inadequate communication with other healthcare providers. All these factors are also related to the availability and adequateness of information in the records.

Compared with similar studies in general practice<sup>38</sup> and out-of-hours primary care, <sup>39</sup> the frequency of incidents was low. It is difficult to compare these results with similar studies in the field of allied healthcare, as to our knowledge no similar studies have been conducted so far. At this moment, we conclude that for the individual patient this study shows that primary allied healthcare is safe. Nonetheless, more efforts should be made to avert incidents, because each incident has an impact on the individual involved and may result in high healthcare costs.

In this study, many patients were not treated according to guidelines and intervention results were not adequately monitored and evaluated. These aspects have already been signaled as risk factors for patient safety in other studies.<sup>8,24</sup> It is conceivable that patient care was also unsafe as a result of withholding more appropriate care and unnecessary long intervention periods. Within the used definition of incidents, these cases are not detected, and therefore in future a broader evaluation could be useful. Poor record keeping seems to be a hindering factor in the transfer of care. These results correspond with findings of Mira et al, 40 who showed that the patient's perspective on adverse events is highly related to doctor rotation and good knowledge transfer. Other studies also showed the relationship between poor record keeping and adverse events<sup>4</sup> and an increases risk to potential malpractice.<sup>19</sup> To understand the implicit clinical judgment, good reporting is a key factor for the clinicians themselves and for communication between clinicians. 41 A striking finding in the preliminary study and a survey among general practitioners is that professionals themselves appoint the risk of unsafe care to patient-related characteristics, <sup>24</sup> rather than reflecting on their own professional behavior. In the profound analysis of causes of incidents it appeared that errors were mainly related to knowledge-based behavior,

TABLE 3. Examples of Incidents in Allied Healthcare Practices

Causes of Incidents	Consequences of Incidents	Examples of Incidents
OK, HKK	Temporary harm	A patient with a hip dysplasia has to carry out an intensive exercise program. Despite increasing symptoms of decreased exercise tolerance the physical therapist did not adapt the program, resulting in a bursitis. Owing to that the patient was forced to stop with the exercise program and became hindered in his functioning in daily life
HKK, OK, HRI	Extraintervention necessary	A woman visited the physical therapist with a tendinitis of foot flexors with a lot of pain. Intervention included massage, rest, and cooling advice. After 2 treatment sessions, the pain suddenly increased. Patient contacted her general practitioner and further investigation showed there was a march fracture
OK, HKK, HRI, HRM	Admission to the hospital	A patient has had been in a car accident, resulting in a patella luxation. After treatment in the hospital, patient got a cast for 6 weeks. After removing the cast, the intervention by the physical therapist focused on improving mobility and stability. Patient was treated daily for 2 months with increased symptoms: instability, inflammation, and "giving way" of the knee. Four months later, an MRI showed a rupture of the anterior and posterior cruciate ligaments and the medial collateral ligaments. It is unclear whether the diagnosis was missed in the beginning or occurred during the exercise treatment, but it is evident that the therapist has treated extensively without progress and has not responded to a different course and "red flags"
OK, HKK, HRI, HRM, HRC	Emotional harm	Diagnosis doctor and exercise therapist: low back pain with radiation. There is frequent use of multiple healthcare providers. Treatment exists of long-term massage therapy (×48) with no change in symptoms, no assessment, and no description of communication with other healthcare providers. It is known that massage promotes a passive coping style. In addition, massage is not a defined expertise of an exercise therapist
OK, HKK, HRI, HSS	Permanent harm	A man with arm complaints after a stroke lives in a nursing home and is familiar with aphasia and dementia. The physical therapist was asked to see if the arm function could be improved. Patient was treated once and the next day the arm was less functional and swollen. The therapist classified these symptoms as a normal reaction to the intervention. Two days later, by the persistence of swelling and loss of arm function, an x-ray showed an arm fracture

HKK indicates human knowledge-based behavior; HRC, human rule-based coordination; HRI, human rule-based intervention; HRM, human rule-based monitoring; HSS, human skill-based slips; MRI, magnetic resonance imaging; OK, organization transfer of knowledge.

clinical reasoning, and inadequate monitoring of treatment results or reflection on what could have been expected. These findings are congruent with other studies. 10,39,42–45 The main

problem was that therapists were unaware of incidents and causes, and unsafe situations were, therefore, not remarked or reported by themselves. Besides the unawareness of

TARIE 1	Rivariate and	Multivariable	Logistic	Dograccion	Analysis for	Dick Eactors	of Incidents
IADLE 4.	bivariate and	iviuitivariable	LOGISTIC	Regression	Anaivsis for	RISK FACTORS	or incidents

	Bivariate Ana	alysis	Regression Analysis	
Risk Factor	OR (95% CI)	P	OR (95% CI)	P
Patient				
Sex (woman)	0.46 (0.15–1.42)	0.169	0.43 (0.14–1.35)	0.150
Age > 75	2.66 (0.86–8.26)	0.077	, , , , , , , , , , , , , , , , , , ,	
Social status (low)	4.25 (0.93–19.41)	0.042*		
Communication problem (yes)	4.99 (1.08–22.92)	0.022*		
High-risk patient (yes) <sup>†</sup>	1.06 (0.24–4.70)	0.932		
Intervention				
Intervention completed (no)	2.45 (0.79–6.34)	0.118		
Direct access (yes) <sup>‡</sup>	0.51 (0.117-2.25)	0.369		
> 9 contacts <sup>§,  </sup>	1.79 (0.66–4.81)	0.241		
High urgency for help (yes)	1.42 (0.18–10.96)	0.734		
> 1 healthcare provider involved in practice	4.45 (1.73–11.43)	0.001**	3.86 (1.48–10.03)	0.006**
Record				
Moderate/poor record keeping ¶	3.54 (1.32–9.53)	0.008**	3.04 (1.16-8.29)	0.03*

<sup>\*</sup>Significance P < 0.05.

<sup>\*\*</sup>Significance P < 0.01.

<sup>†</sup>High-risk patient: (having had) heart problems, lung problems, or cancer.

Direct access implies that patients came to the healthcare provider without referral.

<sup>§</sup>In the Netherlands, Dutch National Insurance compensates 10 hours per year for occupational therapy. This means that some treatments are for 15 minutes, another for 1.5 hours. In this study occupational therapy is displayed at the number of contacts (and not at the number of hours).

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OR (95% CI) indicates odds ratio 95% confidence interval.

riskful behavior, the absence of reported incidents in the prospective study could also be related to the short period of incident reporting. However, incident reporting is not common in allied healthcare and therapists do not focus on safety issues in daily practice, which should be improved.

#### Limitations

Retrospective analyses depend on the data quality and have their limitations. First, the poor quality of the patient records hindered the detection and the assessment of incidents and the risk of unsafe situations might be larger than shown in this study. Second, in the incident analysis, we only focused on the allied healthcare patient records; patient records from other professionals were not checked. Therefore, although we acknowledged the possibility that errors were also made by other professionals in the chain of care, it was not possible to check these. Third, we only focused on incidents with possible harm for the patient and not on ineffectiveness or unnecessary care. Fourth, it was not always possible to find a causal relationship between the intervention and the (risk of) harm. Finally, positive selection bias on practice level could have lowered our estimate of the incident rate, because registration for participation was voluntary.

Despite the limitations, this study offers a first overview of the frequency, causes, and determinants of incidents in primary allied healthcare and gives a fairly good indication of the Dutch situation.

#### What Can Be Learned?

Although limited by the quality of reporting in patient records, this first exploratory study provides in-depth information about incidents in primary allied healthcare. This information is useful for the development of focused interventions to improve patient safety and quality of care.

To increase awareness of patient safety issues in allied healthcare, incident reporting should be implemented, with not only focus on riskful patient characteristics, but also on riskful professional behavior of therapists. The PRISMA analysis pointed out that clinical reasoning was crucial. Necessary scientific knowledge is formalized in guidelines, so implementation of guidelines can be an adequate tool to decrease variation in quality of care and increase safety. 46,47 However, for patient-centered interventions adequate monitoring of the treatment result and a reflexive attitude is essential. Therefore, event reporting and incident discussion as a learning tool might be an appropriate way to reconsider the knowledge and improve patient safety.<sup>48</sup> Reflexive attitudes and clinical reasoning skills might be improved by peer review, which is based on learning in practice. 49,50 Moreover, in future, electronic patient records with integrated reminders for comparison with guidelines and evaluation will offer opportunities to monitor patient safety and quality of care.

In the next research step more attention will have to be paid to barriers and facilitators of record keeping and clinical reasoning, because these are key factors in safety. Larger practice-based observational research with mixed method strategies is necessary to get an overview of all risk factors and to find out why one practice or professional is at greater risk than another.

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