

## Diagnostic errors reported in primary healthcare and emergency departments: A retrospective and descriptive cohort study of 4830 reported cases of preventable harm in Sweden

Rita Fernholm<sup>a</sup> , Karin Pukk Härenstam<sup>b</sup>, Caroline Wachtler<sup>a</sup>, Gunnar H. Nilsson<sup>a</sup>, Martin J. Holzmann<sup>c,d</sup> and Axel C. Carlsson<sup>a</sup>

<sup>a</sup>Division of Family Medicine and Primary Care, Department of Neurobiology, Care Sciences and Society, Karolinska Institutet, Huddinge, Sweden; <sup>b</sup>Department of Learning, Informatics, Management and Ethics, Medical Management Centre, Karolinska Institutet, Stockholm, Sweden; <sup>c</sup>Department of Medicine, Karolinska Institutet, Stockholm, Sweden; <sup>d</sup>Functional area of Emergency Medicine, Karolinska University Hospital, Huddinge, Stockholm, Sweden

### KEY MESSAGES

- Of the reported preventable harm cases in primary healthcare and emergency departments, 46% were due to diagnostic errors.
- In primary healthcare, diagnostic errors mainly occurred in different types of cancer.
- In the emergency departments, diagnostic errors mainly occurred in fracture cases.

### ABSTRACT

**Background:** Diagnostic errors are a major patient safety concern in primary healthcare and emergency care. These settings involve a high degree of uncertainty regarding patients' diagnoses and appear to be those most prone to diagnostic errors. Diagnostic errors comprise missed, delayed, or incorrect diagnoses preventing the patient from receiving correct and timely treatment. Data regarding which diagnoses are affected in these settings are scarce.

**Objectives:** To understand the distribution of diagnoses among reported diagnostic errors in primary health and emergency care as a step towards creating countermeasures for safer care.

**Methods:** A retrospective and descriptive cohort study investigating reported diagnostic errors. A nationwide cohort was collected from two databases. The study was performed in Sweden from 1 January 2011 until 31 December 2016. The setting was primary healthcare and emergency departments.

**Results:** In total, 4830 cases of preventable harm were identified. Of these, 2208 (46%) were due to diagnostic errors. Diagnoses affected in primary care were cancer (37% and 23%, respectively, in the two databases; mostly colon and skin), fractures (mostly hand), heart disease (mostly myocardial infarction), and rupture of tendons (mostly Achilles). Of the diagnostic errors in the emergency department, fractures constituted 24% (mostly hand and wrist, 29%). Rupture/injury of muscle/tendon constituted 19% (mostly finger tendons, rotator cuff tendons, and Achilles tendon).

**Conclusion:** Our findings show that the most frequently missed diagnoses among reported harm were cancers in primary care and fractures in the emergency departments.

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## Introduction

Diagnostic errors can be categorized as missed, delayed, or incorrect diagnoses that prevent a patient from receiving correct and timely treatment [1,2].

Primary healthcare (PHC) and emergency care are settings with a high degree of uncertainty regarding patients' diagnoses. Diagnostic errors occur when

**CONTACT** Rita Fernholm [rita.fernholm@ki.se](mailto:rita.fernholm@ki.se) Department of Neurobiology, Care Sciences and Society, Karolinska Institutet, Alfred Nobels allé 23, D2S-141 83 Huddinge, Sweden

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there are apparent missed opportunities for the right diagnosis [2]; for example, when pathological laboratory findings or alarm symptoms are ignored.

In 2015, several articles pointed out the problems associated with patient safety in primary care and the need for more research as part of the LINNEAUS collaboration [3–9]. A large review of patient safety in PHC from 2016 established that diagnostic and medication errors resulted in the most serious harm to patients [10], while the types of preventable harm in emergency care have received little attention.

Knowledge of which diagnoses are involved in diagnostic errors is essential to develop countermeasures for safer healthcare. From these settings, data on which diagnoses are missed, delayed, or incorrect are scarce. Therefore, our aim is to explore the distribution of diagnoses among reported diagnostic errors in the PHC and emergency department (ED) settings.

## Methods

### Study design

A retrospective and descriptive cohort study investigating the reported diagnostic errors was applied. A nationwide cohort was collected from two databases: the safety-incident database that handles serious healthcare-facility-reported safety incidents and the patient-reported harm database that handles patient-reported injury claims.

### Ethics

The study was approved by the Ethics Committee of Stockholm, Sweden (registration number 2017/447-31/1). All data were handled confidentially, and the results are presented in a non-identifiable way on a group level.

### Setting

The study was performed in Sweden from 1 January 2011 until 31 December 2016. The setting was first-line healthcare, including primary healthcare and EDs. PHC is usually the first point of contact for medical care. EDs provide emergency care around the clock in hospital settings and deliver first point-of-care treatment that complements PHC.

### Databases

The first database was the nationwide safety-incident database, consisting of serious healthcare-facility-reported safety incidents. Swedish law requires

healthcare providers to investigate and report serious safety incidents to the Health and Social Care Inspectorate (IVO). These reports are called *Lex Maria* reports and they include all incidents in which the provider has noted the occurrence of serious preventable harm or a risk of serious preventable harm. In this context, 'serious' indicates a patient safety risk that could lead to long-lasting non-negligible damage to the patient, needing significantly increased care, or to the patient's death. The reports, which the IVO assessed as 'satisfactorily investigated' during the study period, were included in this study. These reports were selected because they included sufficient information. Reported cases in this database are often serious, with a mortality of approximately 28% as a direct or indirect consequence of the safety incident.

The second database was the nationwide patient-reported harm database. In Sweden, preventable harm is compensated by a nationwide non-punitive malpractice carrier and insurance company, Landstingens Ömsesidiga Försäkringsbolag (LÖF). This study included all cases from PHC and EDs that were assessed as preventable by the company's medical experts. Reported cases in this database are usually less serious with a mortality rate of approximately 3% as a direct or indirect consequence of the safety incident.

### Inclusion criteria

We included all cases in which patients had experienced serious safety incidents or preventable harm, reported by a healthcare provider or a patient to one of the two databases. From the safety-incident database, only primary care was included.

### Exclusion criteria

All Swedish residents have a unique personal identification number provided by the Swedish Tax Agency. This identification number was used to enable accurate linkage to the reports of harm and safety incidents. Cases in which the patient could not be identified were excluded. After assessment by the research team, the cases that were assessed as non-preventable, such as non-preventable suicides, were also excluded. A non-preventable suicide was defined as that in which the patient had not contacted a healthcare provider before his or her death.

### Data extraction, coding, and agreement

*The safety-incident database.* From each report, the category of harm (see Supplement 1) was coded. The

category was chosen based on descriptive text in the report. The proportion of agreement in categorizing the types of harm was 96% among three senior physicians (authors RF, CW, and KPH) assessing 50 reports. If a diagnosis was missed/delayed/incorrect, it was extracted in the form of the ICD-10 (International Classification of Diseases, 10th revision) code of that diagnosis. The extractor (one) was a physician and GP (author RF), who used the diagnoses already in the report.

*The patient-reported harm database.* The insurance company, after assessment and decision of the claim, codes every claim into ICD-10 codes. Coding is performed by a nurse and a medical secretary, both specifically trained in coding, with full access to all medical material in the process. The company routinely performs internal checks of the quality of coding, whereby the chief medical officer of the company in retrospect and without knowledge of the original coding, codes a random sample of claims. At the latest internal check, the company coding was accurate on 46 of 50 claims. In the material, there was a code for diagnostic errors, as a category of harm, and codes for the diagnoses involved in the diagnostic errors.

### Statistical analysis

Descriptive statistical analyses of age and sex, with mean, standard deviation, and range were performed

using STATA version 14.2 (StataCorp, College Station, TX, USA).

## Results

Cases included in the present study are shown in Figures 1 and 2.

### Primary healthcare

The safety-incident database included 507 cases (all primary healthcare). Of these, 322 cases (64%) were related to diagnostic errors, 76 (15%) were suicides, and 46 (9.1%) were medication errors.

The patient-reported harm database consisted of 3066 cases from PHC. The patient-reported material showed 1358 cases (44%) of diagnostic errors. Medication errors were identified in 22 (1.6%) of the PHC cases. No suicides turned up in this material. The key characteristics of the reported cases from PHC are shown in Table 1.

The total number of cases from PHC was 3508 as 65 cases that appeared in both databases, of which 50 were due to diagnostic errors.

### Emergency departments

The patient-reported harm database from the EDs consisted of 1322 cases, of which 578 cases (44%)

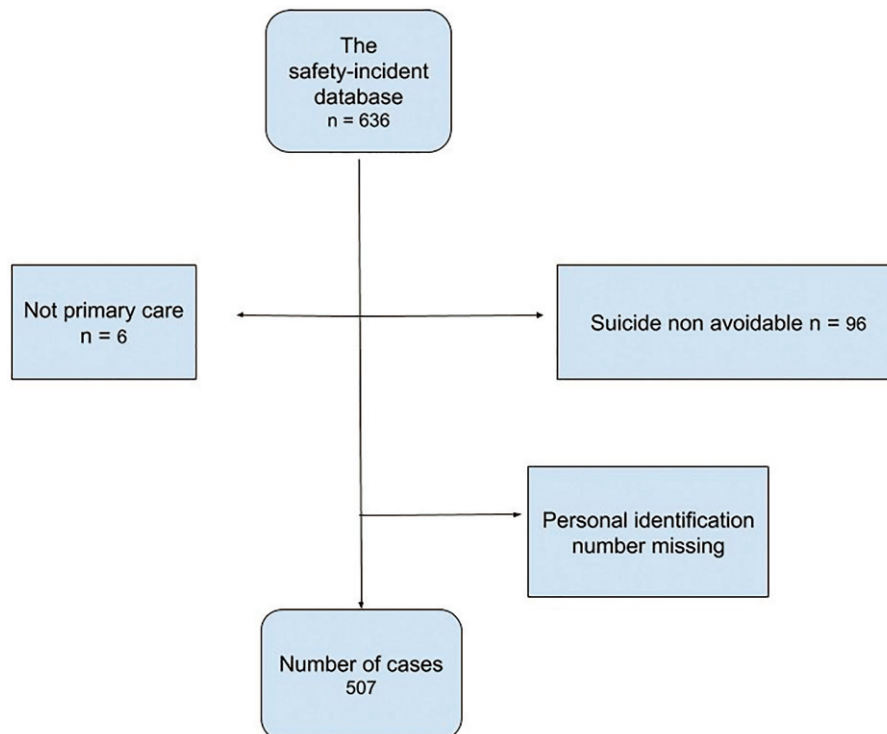
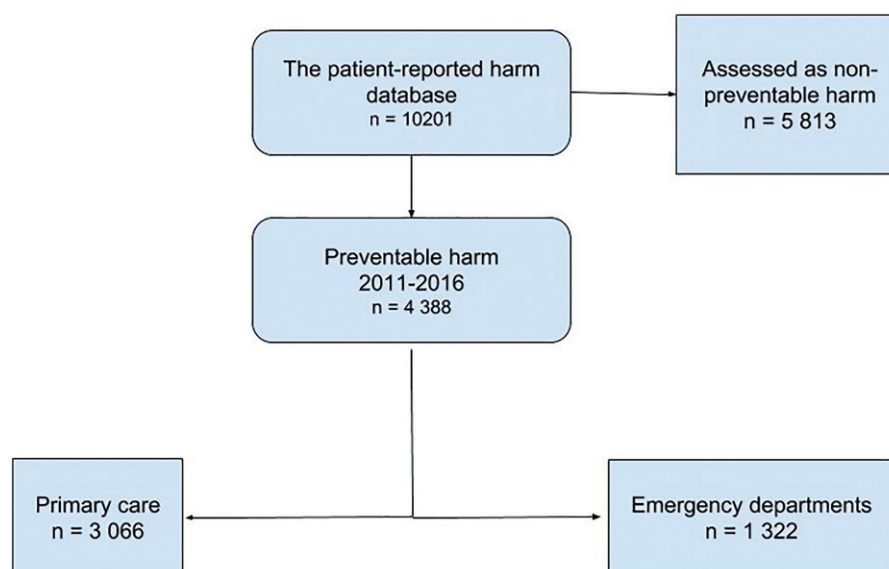


Figure 1. The safety-incident database.



**Figure 2.** The patient-reported harm database.

**Table 1.** Key characteristics of serious safety events and reported preventable harm in primary care and the emergency department.

	Primary care				Emergency department			
	The safety-incident database		The patient-reported harm database		The patient-reported harm database			
Number of cases	507		3066		1322			
Characteristics	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%		
Patient characteristics								
Age, years								
Mean	55	N/A	49	N/A	46	N/A		
SD	23	N/A	19	N/A	22	N/A		
Range	0–98	N/A	1–80	N/A	0–93	N/A		
Female	246	49	1833	60	685	52		
Adverse outcome								
Sick leave <3 months			812	26	319	24		
Sick leave >3 months			948	31	291	22		
Disability 1–15%			1131	37	632	48		
Disability 16–30%			43	1.4	9	0.7		
Disability >30%			24	0.78	22	1.7		
Death			102	3.3	45	3.4		
Temporary disability	68	13						
Increased need for care	124	24						
Permanent disability	175	35						
Death	140	28						
Missed or delayed diagnosis	322	64	1358	44	578	44		

were diagnostic errors. Medication errors were identified in 2.2% of them. There were two (0.15%) suicides reported. The key characteristics are shown in Table 1.

Overall, the number of cases was 4830 (65 overlaps), of which 2208 (50 overlaps) (46%) constituted diagnostic errors.

### Diagnostic distribution

*Primary healthcare, the safety-incident database.* Of all diagnostic errors, cancer constituted 37%. The top six types were colorectal (22.0%), skin (17.0%), kidney and

bladder (13.0%), prostate (7.6%), lung (6.8%), and breast cancer (5.9%).

Of all non-cancer diagnoses, heart disease constituted 8.4%; most cases were myocardial infarction (56%). Fractures constituted 7.1% of the cases. Infections constituted 6.8%; these were mostly sepsis (23%), pneumonia (18%), and tuberculosis (14%). Type 1 diabetes constituted 4.3% and pulmonary embolism 4.0% (Table 2).

*Primary healthcare, the patient-reported harm database.* Of all diagnostic errors, cancer constituted 23%. The five most common types were colorectal (17.0%),

**Table 2.** Diagnostic errors in primary care.

	Primary care			
	The safety-incident database		The patient-reported harm database	
Number of cases	322		1358	
Characteristics	<i>n</i>	%	<i>n</i>	%
Patient characteristics				
Age, y				
Mean	55	N/A	49	N/A
SD	23	N/A	21	N/A
Range	0–90	N/A	0–98	N/A
Female	159	49	739	54
Adverse outcome				
Sick leave <3 months			289	21
Sick leave >3 months			505	37
Disability 1–15%			452	33
Disability 16–30%			27	2.0
Disability >30%			17	1.3
Death			68	5.0
Temporary disability	38	12		
Increased in care need	87	27		
Permanent disability	154	48		
Death	43	13		
Missed or delayed diagnosis				
Cancer	118	37	299	23
Colorectal	26 (22%)		50 (17%)	
Skin	20 (17%)		37 (12%)	
Fractures	23	7.1	168	13
Hand/wrist	Unknown		62 (37%)	
Foot			23 (14%)	
Lower leg			15 (8.9%)	
Hip			12 (7.1%)	
Other			< 4%	
Infections	22	6.8	146	11
Skin/soft tissue	2 (9.1%)		21 (14%)	
Sepsis	5 (23%)		5 (3.4%)	
Heart disease	27	8.4	50	3.7
Myocardial infarction	15 (56%)		23 (46%)	
Ruptured tendons	6	1.9	139	10
Achilles	3 (50%)		37 (27%)	
Rotator cuff	0		28 (20%)	
Diabetes type I	14	4.3	5	0.4
Pulmonary embolism	13	4.0	14	1.0

skin (12.0%), lung (8.4%), kidney and bladder (6.4%), and breast cancer (6.4%).

Of all non-cancer diagnoses, fractures constituted 13%; these were mostly hand and wrist fractures (37%). Infections constituted 11%; these were mostly skin and soft tissue infections (14%), Lyme disease (10%), scabies (10%), and osteomyelitis (5%). Rupture/injury of muscles or tendons constituted 10% and mostly involved the Achilles tendon (27%) and rotator cuff (20%) (Table 2).

The two databases were not combined because they constitute two varied samples with data collected for different purposes and degree of seriousness, as described above.

*Emergency departments, the patient-reported harm database.* Of all diagnostic errors, fractures constituted 24%. These were mostly hand and wrist fractures (29%); other fractures are shown in Table 3. Rupture/injury of muscles or tendons constituted 19%; these were mostly tendons of the fingers (28%), tendons of the rotator cuff (15%), and the Achilles tendon (13%).

Infections constituted 10%, mostly appendicitis (41%) (Table 3).

## Discussion

### Main findings

We found that 46% of reported preventable harm in PHC and EDs were due to diagnostic errors. Diagnostic errors in PHC mainly concern cancer, particularly colon and skin, and in EDs mainly fractures, particularly hand and wrist.

### Strengths and limitations

The major strength of this study was the large sample size. Also, the company that collects the patient-reported harm uses a non-punitive system, thus, leading to less reporting bias. Most of the data are patient-reported, and thereby reflect patients' perspectives of what is serious enough to report.

**Table 3.** Diagnostic errors in the emergency departments.

	Emergency departments	
	The patient-reported harm database	
Number of cases	578	
Characteristics	<i>n</i>	%
Patient characteristics		
Age, y		
Mean	44	N/A
SD	21	N/A
Range	0–93	N/A
Female	283	49
Adverse outcome		
Sick leave <3 months	123	21
Sick leave >3 months	149	26
Disability 1–15%	258	45
Disability 16–30%	6	1.0
Disability >30%	12	2.1
Death	30	5.2
Missed or delayed diagnosis		
Fractures	138	24
Hand and wrist	40 (29%)	
Foot	16 (12%)	
Vertebra	10 (7.2%)	
Hip	9 (6.5%)	
Lower leg	7 (5.1%)	
Other	< 4%	
Ruptured tendons	107	19
Fingers	30 (28%)	
Rotator cuff	16 (15%)	
Achilles	14 (13%)	
Infections	58	10
Appendicitis	24 (41%)	

This study has several limitations. Harm is often under-reported [2]; however, the large sample size can mitigate the bias of that limitation. Actual rates of preventable harm are unknown, however, chart reviews in Sweden suggest that 9.2% of hospital admissions resulted in a preventable adverse event [11], indicating that the actual numbers are much higher than what is reported. We saw a low number of medication errors in the study data compared to other studies, probably because of under-reporting. Accurate detection of medication errors might require chart review. There may be bias in the reporting of harm, for example, there are some known differences in gender and age [12]; however, in our study this bias is largely unknown. We could not adjust for socioeconomic status and comorbidity of the patients as we did not have access to this data.

Diagnostic errors are easier to identify in hindsight [2]. In the present study, medical experts evaluated the missed opportunities to establish the right diagnosis, however, the retrospective nature of the evaluation remains a limitation.

Finally, when generalising the findings on colorectal cancer to other countries, one should keep in mind that types and the extent of screening vary widely all over Europe, and Sweden only conducts screening in certain parts of the country.

### **Interpretation of the study—the results in relation to existing literature**

This study confirms earlier studies that emphasize that diagnostic errors constitute a major problem in the field of primary and emergency care [2,10,13,14]. However, this study provides new information on the diagnoses that are most frequently involved.

This is the first study in PHC to investigate the distribution of diagnoses among reported diagnostic errors. Earlier studies have assessed diagnostic errors in PHC for some specific diagnoses. Data from PHC in the US [15], indicate that prostate cancer is the most frequently missed cancer diagnosis, while it is the sixth most commonly missed cancer diagnosis in Sweden (despite being the most common type of cancer). None of the countries has an established screening programme; however, a prostate-specific antigen concentration is commonly measured in both, and the two countries may differ in how the diagnosis is registered. In our data, colorectal cancer was the most common diagnosis displaying diagnostic errors. Others have observed an association between missed colorectal cancer diagnosis and incomplete workup of rectal bleeding [16,17] or poor coordination of care across multiple providers [18]. Some sex-related differences existed in the self-reported material from PHC, with more female than male patients, in alignment with previous studies suggesting that medical errors are more common in the treatment of female patients [12], even after adjustment for the fact that women seek more healthcare.

In the ED, the diagnostic distribution of missed diagnoses was similar to those of earlier studies [15] regarding fractures; however, our study provides more detail on the types of fractures (Table 3). Fractures are common diagnoses in the ED, and this probably contributes to the rates of diagnostic errors. Some earlier studies in the ED setting have suggested that the leading reasons for breakdowns in the diagnostic process are failures to order an appropriate diagnostic test, obtain an adequate medical history, and perform a thorough physical examination [13].

### **Implications for research and healthcare**

In primary care, future research should focus on identification of contributing factors for diagnostic errors, in particular for colorectal cancer. In the ED, future research should develop and implement strategies for improved follow-up of patients with trauma and suspicion of fractures [19]. Finally, further studies are

needed to clarify whether specific patient groups are at an increased risk of harm due to diagnostic errors.

## Conclusion

Our findings show that the most frequently missed diagnoses among reported harm were cancers in primary care and fractures in EDs. These findings can be applied as information for countermeasures for safer healthcare.

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## Ethics

The study was approved by the Ethics Committee of Stockholm, Sweden (registration number 2017/447-31/1). All data were handled confidentially, and the results are presented in a non-identifiable way on a group level.

## Disclosure Statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper. Dr Holzmann holds a research position funded by the Swedish Heart-Lung Foundation (grant 20170804). The sponsors had no role in the design or conduct of this study.

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## ORCID

Rita Fernholm  <http://orcid.org/0000-0002-6764-8827>

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