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Patterns of errors and weaknesses in the diagnostic process: retrospective analysis of malpractice claims and adverse events from two national databases

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ABSTRACT

Background Diagnostic errors (DEs) are a significant global patient safety issue, often associated with increased morbidity and mortality due to overlooked, delayed, or incorrect diagnoses. Our aim was to study the occurrence of DEs and adverse events (AEs), patient-related harm to identify vulnerable steps in the diagnostic process.

Methods A retrospective analysis of data from two public, national databases—National Health Care Compensation Claims Database (2009–2018) and Danish Patient Safety Database with AEs (2015–2020). Vulnerable steps in the diagnostic process were identified using a scoring tool developed by The Controlled Risk Insurance Company.

Results In the analysis of patient compensation claims, 14.5% of all settled cases (n=90 000) were classified as due to a DE, with a 59% compensation rate for DEs, twice the rate compared with other compensated cases (25%). DEs constituted 29% of all compensated cases. Death due to DEs was 8.3% (n=680 cases), 1.8 times higher compared with other cases and DEs resulted in higher degrees of disability.

In the overall reported AEs, 0.3% of AEs were fatal and 1.7% AEs caused severe patient harm, per year. In a representative sample of AEs with a severe or fatal consequence (n=269), 33% were due to DEs.

The initial clinical assessment was a cause or contributor to the DE in 80% of the compensation cases and in 83% of the severe or fatal AEs. The follow-up and coordination phase were a cause in 33% of compensation cases and 46% of severe or fatal AEs.

Conclusions Errors and AEs in the diagnostic process are prevalent and a significant patient safety issue in Danish healthcare. This study identifies vulnerable steps in the diagnostic process, with patterns correlated to different degrees of severity, and highlights steps for future improvements efforts needed to mitigate the risk of DEs.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The diagnostic process is complex, prone to errors and linked to significant patient harm and increased healthcare resource use. Measuring the frequency and impact of diagnostic errors remains difficult.

WHAT THIS STUDY ADDS

⇒ This study identifies vulnerable steps in the diagnostic process, showing that errors during initial clinical assessment and decision-making carry a higher risk of serious harm compared with those in the diagnostic testing phase.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings can guide healthcare policy-makers, stakeholders and professionals in focusing improvement efforts to mitigate the risk of diagnostic errors and help achieve diagnostic excellence, enhancing education in diagnostic and clinical reasoning, fostering and supporting better communication and feedback among healthcare workers and improving technical systems for safe communication of test results.

INTRODUCTION

A prerequisite for receiving correct treatment and care in the healthcare system is a correct diagnosis, that is, an accurate and timely explanation of the patient's health problem(s) and communicating the diagnosis to the patient.[1] The consequences for the patients can be serious with increased morbidity and mortality,[2–4] and overlooked, delayed or misdiagnosis is an important area of patient safety and preventable patient harm worldwide.

Patient safety events related to the diagnostic process can be the consequence of multiple and complex causes—individual cognitive failures by the clinicians and/or organisational system factors. The diagnostic process is complex with inherent uncertainty, spanning over time and in different settings, involving different health professionals. This makes it vulnerable to errors with a risk of adverse consequences to the health of the patient(s), patient safety and with increased

use of financial and human resources in the healthcare system.[1]

The 2015 report Improving Diagnosis in Health Care by the National Academy of Medicine in the USA[1] highlighted that research in the diagnostic process had been underprioritised. This is a key report describing the magnitude of diagnostic errors (DEs). Currently, international estimates of the occurrence of DEs still vary according to evaluated type of data, clinical setting, patient category and country.[1 3–6] More knowledge about the occurrence of DE, patterns of weaknesses in the diagnostic process and the degree of patient-related harm is needed, as current estimates of occurrence and burden might only demonstrate 'The tip of the iceberg'.[7]

Our goal was to enhance understanding of occurrences within the Danish healthcare system and describe vulnerable steps in the diagnostic journey. This knowledge can guide future improvement efforts with the aim of reducing the risk of DEs and enhancing patient safety.

MATERIAL AND METHODS

Study design

We conducted two retrospective, descriptive studies with data and analysis of case reports from two Danish national databases.

Study 1, in 2019, The Danish Society for Patient Safety (PS!) and The Danish Patient Compensation Association (DPCA) performed an analysis of all settled cases in DPCA's national healthcare compensation claims database from 2009 to 2018. Cases were included if the patient was entitled to financial compensation for the harm experienced in the healthcare system based on a DE (overlooked, delayed or missed).

First, a quantitative analysis was performed to evaluate the prevalence of DEs in the DPCA data, categorising the DEs according to main ICD-10 disease groups. Hereafter, a qualitative analysis of settled cases recognised as DEs was performed to provide insight into possible causes and patterns behind the DEs. The cases were systematically and individually analysed by three experienced medical doctors using a diagnostic scoring tool developed by Controlled Risk Insurance Company (CRICO) (see below).

Study 2, in 2023, PS!, DPCA and The Danish Patient Safety Authorities (STPS) performed an analysis on adverse events (AEs) reported to the Danish Patient Safety Database (DPSD). This is an official national, compulsory, anonymised and non-punitive reporting system for all healthcare workers, patients and relatives. The AEs in the DPSD registry are coded according to ICPS (The conceptual framework for the international classification for patient safety (who.int)). The overall aim of the AE reporting system is to gain learning from the events both locally and on a national level. All Danish healthcare workers have, according to the Health Act,[8] an obligation to report AEs, but for patients and relatives, the reporting is on a voluntary basis. The overall reported AEs are equally distributed across the country according to population size of the region, and AEs are reported from all sectors of the Danish healthcare system. It is well recognised that some departments or institutions have a higher reporting rate than others. The DPSD is a cross-sectional and anonymised database. Both the patients experiencing the AEs and the reporter are anonymised, and the cases are closed after 3 months by a local risk manager. Anonymisation of the patients makes it impossible to merge data with other Danish patient registers, for example, cause of death register, electronic healthcare journals over time, patient claim registers.

In this study, AEs were analysed systematically and independently by two experienced medical doctors. First, assessing whether the AE was related to the diagnostic process or not. Thereafter, the diagnostic scoring tools CRICO were applied (see below). In both studies, the medical doctors evaluated and scored the cases independently. Subsequently, all medical doctors met and viewed all cases to reach consensus through discussion, both on the appearance of a DE or not, and to classify the diagnostic steps involved.

Data material with extraction, inclusion and exclusion criteria

Study 1: DPCA data

The DPCA operates according to Danish law (the Act on Complaints and Compensations 995/2018) as a no-fault compensation system and is separated from the disciplinary system. The system is free of charge to patients and healthcare professionals alike and covers all public and private authorised healthcare in Denmark.[9]

Most DE cases were recognised according to 'the specialist rule'—where the diagnostic process was assessed to deviate from specialist standard, whereby harm could have been avoided by an experienced specialist acting differently. A case could also be recognised if the patient experienced a complication assessed as more serious than expected or rare. The specialist rule does not necessarily require a basis for professional criticism of the involved healthcare professionals, which is handled by another public authority, separating the compensation system from the system giving professional criticism.

Cases included all information in the patient's health record and in most cases an expert assessment, evaluating whether the patient had been harmed by the DE, and thereby would be eligible for compensation.

For the qualitative analysis, 225 cases were selected, with the following criteria: reported from a public hospital or the primary public healthcare sector; an expert assessment had been performed; and the case was acknowledged according to the 'the specialist rule'. The case selection was aimed at an equal distribution of gender, age and geographical distribution—and an equal representation of the three most dominant International Classification of Diseases (ICD-10) groups from the quantitative analysis was sought. The sample was selected to be as diverse as possible and was thus not statistically representative of the

total DPCA data material. Data extraction was performed on 20 December 2018.

Study 2: the AE data from the national DPSD

The STPS provided national data on AEs from 2015 to 2020.

The AEs in DPSD are categorised according to the ICPS in one of 20 main event categories, attributed with a process and problem code, date, free text with a short description of the event, and with a reporter or local risk manager evaluated degree of severity (no harm, mild, moderate, serious to fatal). The degree of severity does not represent the long-term assessment of the final harm score of an AE.

Unfortunately, the Danish implementation of the ICPS does not include a process code for 'DEs'. Therefore, three different search strategies were designed to extract AEs with a higher probability of comprising a diagnosis-related problem. In all three samples, AEs reported by patients and relatives were excluded, as they were considered to represent a different type of data entry compared with AEs reported by healthcare professionals, and thus to be more suitable for a separate analysis.

The following search criteria were applied:

Sample 1: Extraction of events with the following word combinations in the free text description; Diagnos* + delayed or overlook or not detected"; "lack of diagnos*"; "no diagnos* made"; "misdiagnos*"; "Error in diagnos*"; "Error+diagnos*", in the text description, across all the event categories. All medication-related events were excluded. This search entailed 2355 events from which a sample of 235 (10%) random cases were extracted. Data extraction was performed on 8 November 2021.

Sample 2: Extraction of events with the following problem codes: "delayed reaction to test results" and "delayed evaluation". This search entailed 1827 cases with extraction of a sample of 184 (10%) random cases. Medication-related events were included (n=4). Data extraction was performed on 8 March 2022.

Sample 3: A representative sample was extracted out of all 21 306 randomly sorted AEs reported to the DPSD between 2015 and 2020 registered with a serious or fatal consequence, including medication-related events. The sample size was calculated with a 90% confidence and 5% margin of error resulting in 269 events. Of these AEs, 32 cases were excluded from further evaluation: 8 AEs due to an insufficient amount of information in the case description, 21 AEs as they dealt with suicide or suicide attempts and 3 AEs that were reported by patients or relatives. Data extraction was performed on 13 April 2023.

Applied diagnostic scoring tools

The analysis tool developed by the American organisation (CRICO—The Risk Management Foundation of the Harvard Medical Institutions Incorporated) was chosen, as this tool was developed for scoring of malpractice claims in the USA.[10] After permission from CRICO, it was adapted to Danish conditions. The CRICO tool divides the diagnostic process into three phases; (1) initial diagnostic assessment, (2) testing and results processing and (3) follow-up and coordination. The tool has a total of 12 steps (see figure 1). During their review, the medical doctors marked one or more of the 12 steps when the step(s) were assessed to be a cause or contributor to the DE or AE.

3 Phases		CRICO 12 steps in the diagnostics process
Initial diagnostic assessment	1	Problem noted - patient seeks help in the health care system
	2	Medical history and clinical evaluation
	3	Clinical assessment and evaluation of symptoms
	4	Differential diagnosis established/considered
	5	Diagnostic test (s) ordered
Testing and result processing	6	Diagnostic examinations/tests performed
	7	Interpretation of test result(s)
	8	Transmitting/Communicating test results to the prescribing clinician or other relevant health care worker
Follow up and Coordination	9	Follow up with the patient by the clinician / health care system
	10	Referrals or Consultings
	11	Sharing patient information among Health care workers
	12	Establisment of plan and follow up between patient and Health care system

Figure 1 The CRICO (The Risk Management Foundation of the Harvard Medical Institutions Incorporated) scoring tool[10] with the 12 steps in the CRICO classification adapted to Danish conditions with adaptations in step 8 (added relevant healthcare worker) and 9 (added healthcare system).

Statistical analysis

Descriptive statistical analyses were used to present distribution and frequencies of DEs and AEs. Stata V.17 was used for statistical analysis (StataCorp. 2023. Stata Statistical Software: Release 18., StataCorp)

RESULTS

The quantitative analysis of the patient compensation data

In the period 2009–2018, approximately 90 000 treatment injury (TI) cases were settled in the DPCA, with approx. 13 000 cases classified as being due to a DE (14.5% of all settled cases in the period) and with 7629 acknowledged DEs entitled to financial compensation (59% acknowledgement rate for DEs). The approx. 77 000 settled TIs, not classified as a DE (85.5% of settled cases) and with 18 848 acknowledged and entitled for compensation (24.5% acknowledgement rate). The acknowledgement and compensation rate for DEs was more than twice as high compared with other TIs. DEs constituted 29% of all recognised and compensated injuries in the period (7629 out of a total of 26 477 cases).

DEs often have serious consequences for the patients, with death due to the injury being the most serious

Table 1 The main International Classification of Diseases-Tenth revision (ICD-10) disease groups for the acknowledged diagnostic error cases in the Danish Patient Compensation Database evaluated in the quantitative analysis

The most common ICD-10 disease groups in recognised diagnostic errors			
ICD-10 main group	Percentage (%)	Cumulated (%)	Top 3 (% of their main ICD-10 group)
DS: Injury/lesions	31.2	31.2	DS62: Fractures of hand and wrist (11%)
			DS63: Dislocations/distortions in joints/ligaments in the hand (8.7%)
			DS46: Lesions of muscles/tendons in the shoulder (8.2%)
DC: Cancer/neoplasms	21.7	52.9	DC5: Malignant neoplasm of breast (27.3%)
			DC6: Malignant neoplasms of female genital organs (14.5%)
			DC3: Malignant neoplasms of respiratory and intrathoracic organs (14.3%)
DM: Musculoskeletal system	10.9	63.8	DM5: Other dorsopathies (31.1%)—especially disc herniation
			DM7: Other soft tissue disorders (14.2%)—pain of the extremities
			DM1: Arthrosis (14.1 %)
DI: Diseases of the circulatory system	7.4	71.2	DI21: Acute myocardial infarction (17.1%)
			DI63: Cerebral infarction (12.8%)
			DI71: Aortic aneurysm and dissection (7.3%)
DK: Diseases of the digestive system	4.0	75.2	DK56: Paralytic ileus and intestinal obstruction without hernia (10.4%)
			DK35: Acute appendicitis (10.1%)
			DK62: Other diseases of anus and rectum (6.5%)
DN: Diseases of the genitourinary system	3.1	78.3	
DD: Benign tumours	3	81.4	
DG: Diseases of the nervous system	2.7	84.1	
Others	15.9	100	

The top three International Classification of Diseases- Tenth revision (ICD-10) diseases according to their percentage in the main ICD-10 group.

patient outcome. Death due to DEs constituted 8.3% of the recognised DEs (680 cases in the 10-year period), 1.8 times higher compared with other recognised TIs in the period.

In the DPCA data, all cases are settled with a 'degree of disability', normally with a maximum of 100%, rarely up to 120%. The degree of disability after a DE is also higher compared with other TIs; degree of disability 100%–120% (DEs=1.6%; TIs=0.7%); 50%–99% (DEs 7.8%; TIs 3.0%) and lower for 0%–59% (DEs 90.6%; TIs 96.3%).

Most common ICD-10 disease groups

Categorisation according to main ICD-10 disease groups was undertaken for the 7629 acknowledged DEs. Five main ICD-10 disease groups constituted 75% of all acknowledged DEs (table 1). The five most common main ICD-10 groups were: injury/lesion contributing 31.2%; cancer/neoplasms 21.7%; musculoskeletal system 10.9%; diseases of the circulatory system 7.4% and diseases of the digestive system 4%.

The qualitative analysis of the patient compensation data

In the qualitative analysis, 225 acknowledged DEs were systematically reviewed, with exclusion of 12 cases assessed by the medical doctor as not being diagnosis-related.

The initial diagnostic assessment phase (steps 1–5) in CRICO was the most frequently involved, with 80% of cases having a cause or contributing factor in this phase. Many cases had more than one marking in steps 1–5, with 52% of all cases in step 3 (clinical assessment and evaluation of symptoms), 44% in step 4 (differential diagnosis established/considered) and 38% in step 5 (diagnostic test(s) ordered) (table 2, last column).

The subsequent testing and result phase (steps 6–8) was involved in 27% of the cases, with step 7 (interpretation of test result) in 25% of the cases, mostly related

Table 2 The classification and distribution of diagnostic errors and diagnosis-related adverse events according to the CRICO scoring tool

	Adverse events sample 1	Adverse events sample 2	Adverse events sample 3	The patient compensation data
Total number of cases	235	184	269	225
Excluded cases	19	8	32	0
Number of evaluated AEs with diagnostic tools N	216	176	237	225
AEs not related to the diagnostic process N (%)	34 (15)	58 (33)	159 (67)	12
Diagnostic safety events N (%)	182 (84)	118 (67)	78 (33)	213
Total number of scores	216 (1.18 per case)	167 (1.41 per case)	125 (1.6 per case)	455 (2.1 per case)
Degree of severity				
% of the total sample (fatal/severe/moderate/mild /no harm)	1/7/24/23/44	2/8/23/23/43	17/83/0/0/0	
% of the diagnosis-related AEs (fatal/severe/moderate/mild/no harm)	1/8/26/24/41	3/10/22/25/39	14/86/0/0/0	

		% of n=182		% of n=118		% of n=78		% of n=213	
Initial diagnostic assessment									
Step 1	Problem noted—the patient seeks help in the HCS	2	11%	3	21%	14	83%	1	80%
Step 2	Medical history and clinical evaluation	1		2		13		23	
Step 3	Clinical assessment and evaluation of symptoms	4		9		40		52	
Step 4	Differential diagnosis established/considered.	2		6		10		44	
Step 5	Diagnostic test(s) ordered	3		2		6		38	
Testing and result processing									
Step 6	Diagnostic examinations/tests performed	47	64%	9	60%	13	28%	2	27%
Step 7	Interpretation of test result(s)	8		3		10		25	
Step 8	Transmitting/communicating test results	10		0		5		0	
Follow-up and coordination									
Step 9	Follow-up with the patient	7	35%	39	56%	24	46%	7	33%
Step 10	Referrals or consultations	7		7		5		24	
Step 11	Sharing patient information among HCWs	21		8		17		4	
Step 12	Establishment of plan and follow-up between patient and HCS	1		2		0		1	

Patient compensation data from the period 2009–2018 and adverse event data from DPSD from 2015 to 2020. Sample 1=Adverse events extracted with free text diagn* in combination with extra word. Sample 2=Adverse events extracted with problemcodes#. Sample 3=Random representative sample of Severe or fatal adverse events.
Each case can have more than one marking in the diagnostic process (steps 1–12), as a main or contributing cause, the sum of percentages, therefore, exceeds 100%. The origin of the data material, search criteria and analysis process differ between the three samples, and they are not comparable and reflect different perspectives of diagnostic errors and patterns of weaknesses in the diagnostic process. In the Danish Patient Safety Database (DPSD) for the adverse events, if reviewers were unable to assess the diagnostic steps involved, due to lack of information in the often very short description, these cases were not scored, sample 1 (N=16), sample 2 (N=5) and sample 3 (N=2). In the analysis of the Patient Compensation data, there were no restriction according to maximum number of scores, however it was agreed on limiting the number to the most important contributing cause/phases.
CRICO, Controlled Risk Insurance Company; HCS, healthcare care system; HCW, healthcare worker.

Table 3 Number of adverse events (AEs) reported to the Danish Patient Safety Database (DPSD) from 2015 to 2020 demonstrated according to assessed severity and the AEs registered as medication-related AEs

Adverse events reported to the Danish Patient Safety Database 2015–2020							
	2015	2016	2017	2018	2019	2020	Total
Total number of reported AEs (N)	178241	179474	182266	186674	212061	182539	1121255
Medication-related events N (% of total AEs)	97291 (55)	96203 (54)	98483 (54)	102724 (55)	117857(56)	97283 (53)	609841 (54)
Degree of severity registered N (% of total AEs)	178223	179451	182266	186606	212035	178496	1117011
Fatal	516 (0.3)	490 (0.3)	422 (0.2)	454 (0.2)	524 (0.2)	589 (0.3)	2995 (0.3)
Severe	3702 (2.1)	3629 (2)	3168 (1.7)	2551 (1.4)	2736 (1.3)	2525 (1.4)	18311 (1.6)
Moderate	17873 (10)	18000 (10)	19015 (10.4)	16967 (9.1)	18520 (8.7)	16513 (9.3)	106888 (9.6)
Mild	44674 (25.1)	47144 (26.3)	47469 (26.1)	43958 (23.6)	50525 (23.8)	41747 (23.4)	275517 (24.7)
No harm	111458 (62.5)	110188 (61.4)	112126 (61.5)	122676 (65.7)	139730 (65.9)	117122 (65.6)	713300 (63.9)

Data extraction: 9 March 2023.

to misinterpretation of imaging (X-rays, ultrasound and CT/MR-scans) or abnormal diagnostic test results not leading to the appropriate treatment or to further diagnostic evaluation.

The follow-up and coordination phase (steps 9–12) was involved in 33% of the cases, with step 10 (referral or consulting) in 24%, where the physician should have consulted a colleague or referred to another medical specialty.

The analysis of AEs from the Danish Patient Safety Database

In the 6-year period (2015–2020), approximately 1.1 million AEs were reported to the DPSD, on average 186876 AEs per year, with an average of 55% being medication-related AEs (table 3). According to the assessed severity of the AEs, on average 0.3% of cases were fatal, 1.7% were associated with severe harm, 9.6% with moderate harm, 24.7% with mild harm and 63.8% of cases with no patient harm.

Qualitative analysis of samples 1 and 2 of AEs

In the two samples of AEs obtained using a specific search strategy, the results reflect the appropriateness of the search strategy, with a high proportion of events assessed as related to the diagnostic process, 84% and 67% in samples 1 and 2, respectively. Analysed with CRICO, table 2 columns 1 and 2, most diagnostic AEs in samples 1 (64%) and 2 (60%) had a cause or contributor in the testing and result processing phase (steps 6–8). The follow-up and coordination phase (steps 9–12) were involved in 35% and 56% of the AEs in samples 1 and 2, respectively.

In the 186 AEs with a mark in the diagnostic testing phase (steps 6–8), the type of diagnostic tests involved were diagnostic imaging (35%), laboratory blood tests (26%), pathology (20%), microbiology (9%) and others (9%). The degree of severity in most AEs in samples 1 and 2 was categorised as moderate to no harm in 91% and 86% of the cases, respectively (see table 2).

Qualitative analysis of sample 3, severe and fatal AEs

To describe the occurrence and patterns of DEs among all AEs with either a severe or fatal consequence, a random sample of 269 AEs (1.2% of cases with severe or fatal consequence between 2015 and 2020 (N=21306)) were analysed. 32 AEs were excluded from analysis with CRICO (see Method section for exclusion criteria). Thus, 237 AEs with severe or fatal consequences were assessed, with 78 (33%) AEs assessed as related to the diagnostic process and 159 AEs (67%) as not diagnosis-related.

The most common reported AE to the DPSD is medication-related AEs, constituting 55% of all AEs in the period 2015–2020, but medication-related AEs only constituted 22% (n=53) in the representative sample of AEs with severe and fatal consequences.

The CRICO tool was applied to 78 diagnosis-related AEs. In 83% of the cases, a cause or contributor was marked in the initial diagnostic assessment phase (steps 1–5), table 2 column 3, with the clinical assessment and evaluation of symptoms (step 3) being marked in 40% of the cases.

The follow-up and coordination phase (steps 9–12) was involved in 46% of the AEs, with especially step 9 (follow-up with the patient) and step 11 (sharing patient information among healthcare workers) being vulnerable steps marked in 24% and 17% of the cases, respectively. The testing and result processing phase (steps 6–8) were involved in 28% of the cases.

DISCUSSION

This study describes the occurrence and patterns of DEs and weaknesses in the diagnostics process using two types of national and public data sources—recognised and

compensated patient claims and AEs. The two types of data sources complement each other well by elucidating different aspects of and challenges in the diagnostic process. We identify significant steps in the diagnostic process prone to errors. This illustrates relevant targets for future improvement interventions, with a potential for mitigating the risk of DEs and increasing patient safety in the diagnostic process.

The real incidence of DEs and diagnosis-related AEs is challenging to measure.[11 12] The reported incidences vary according to country, source of analysed data, hospital setting and applied definition of a DE.[4] Most research has been retrospective analyses on smaller or selected cohorts based on, for example, patient claims, or autopsies, or performed on selected disease categories.[13–18]

We have applied a diagnostic scoring tool found applicable on a similar data type,[3 19 20] with our retrospective analysis supporting previous findings—that DEs and diagnosis-related AEs are frequent and constitute a major patient safety problem in Danish Health Care. DEs were frequent in the DPCA database, constituting 14.5% of all settled cases and 29% of all cases eligible for financial compensation. Both the recognition rate, the severity, the degree of disability and compensation sum were higher for DEs compared with other treatment injuries. These results are comparable to other studies,[5 21] and Newman-Toker *et al*[3] published similar results from nearly one-third of patient claims in US healthcare, where 21% of closed cases concerned DEs, but 34% among the high severity claims.

Newman-Toker *et al* found failure in the clinical judgement to be the leading identified cause of serious misdiagnosis-related harms, responsible for >85% of cases.[3] This is in line with our results—both in the patient compensation cases and the severe or fatal AEs—with 80% and 83% of the cases, respectively—having a cause or contributing factor in the initial clinical assessment of the patient. A similar pattern was reported by Schiff analysing 583 clinician-reported cases of DE.[22] Of these, 162 errors (28%) were rated as major, 241 (41%) as moderate and 180 (31%) as minor or insignificant. Using the DEER taxonomy tool to determine where the diagnostic process broke down, they found that error in clinician assessment accounted for 32% of 583 cases (including hypothesis generation, weighing or prioritising, and recognising urgency or complications). In a subgroup analysis of major DEs (n=162), a larger proportion, 43% were found to be related to clinician assessment. Similar results were also found in a study by Gupta *et al* from 2018, where 22% of compensated malpractice claims were diagnosis-related, with a 1.83 higher risk of disability, 2.33 times higher risk of death and a higher amount paid in compensations.[15]

Overall, in the AEs database, medication-related AEs constituted on average 55% of *all* AEs per year, regardless of severity, and are the most common reported AE. However, among the severe and fatal AEs in our random sample, DEs were more frequent than medication-related AEs. In a Swedish study,[5] including severe safety incidents in emergency departments and primary healthcare, the authors found 44% and 64%, respectively, being diagnosis-related compared with only 1.6% and 9.1% being medication-related. The relation between DE and harmful AEs is well known and was recently confirmed in a systematic literature search including 80 026 patients. The study concluded that at least 0.7% of adult admissions involve a harmful DE.[23] These results overall support that the consequences of DEs are often more serious than other AEs/treatment errors and with a higher severity/consequence of a DE, the initial clinical assessment is often involved in the DE.[3 13 15] Based on the results of AEs from 2015 to 2020, on average 500 AEs were fatal, and 3050 AEs were severe per year, and with 33% in our random sample being diagnosis-related, this will correspond to approx. 165 deaths and 1006 severe AEs per year being diagnosis-related in Denmark (population of approx. 5.8 million in 2020). These numbers are only based on reported events, and it is well recognised that under-reporting of AEs is an issue.[24 25] The numbers are not applicable for demonstrating the exact incidence of the severe and fatal diagnosis-related events in Denmark.

In the DPCA data, we identified five main ICD-10 groups constituting 75% of all recognised DEs. Similar disease groups were found in a Swedish study,[5] while slightly different groups were identified by Newman-Toker *et al*.[3] Newman-Toker *et al* describe 'the big Three' diseases accounting for approx. 75% of the high severity cases (cancer 37.8%; vascular events 22.8% and infections 13.5%). However, different classification systems have been applied: Clinical Classification Software[26] versus ICD-10; in the latter, infections are not a separate group.

The analysis of AEs in samples 1 and 2 is valuable (even though most of them are of no or low severity), as it gives important insight into other vulnerable steps in the diagnostic process, especially adding more knowledge in relation to the diagnostic testing and processing part. The analysis of these AEs illustrates the importance of and the need for strengthening the processes and technical systems related to delivering, receiving and reacting on diagnostic test results.

In the follow-up and coordination phase (steps 9–12), errors were often due to lack of referral or consulting with a colleague or to lack of sharing information or data between healthcare workers or with the patient. As highlighted in the key report—Improving Diagnosis in Health care from 2015[1]—our analysis supports the importance of developing secure health information technologies and structural processes to ensure safer communication both between healthcare workers and to the patient. Currently, different Electronic Patient Journal systems in Denmark hinder secure sharing of patient data, especially between the primary and secondary healthcare sector, whereby transitions become a great risk factor.

Research in DEs and diagnostic safety is still sparse, with a lack of clear and internationally agreed definitions and good data monitoring solutions. Even though diagnosis-related AEs are frequent, and among the severe and fatal

AEs more frequent than medication-related AEs, no classification or process code exists to improve monitoring of diagnosis-related AEs in the Danish Patient Safety Database. These limitations in data and different registration methods reduce the comparability between studies and countries. There is a need for developing, for example, technologies and trigger tools for more practical, accurate, real-time data collection of diagnosis-related AEs and errors, to support data-driven improvement initiatives and to monitor the effect of the implemented solutions.

The initial clinical judgement is a critical step for preventing the most severe DEs and AEs. This emphasises the need to improve education in clinical/diagnostic reasoning, knowledge about cognitive bias (diagnostic bias), medical uncertainty and development of feedback systems to help clinicians achieve diagnostic excellence.[27–33] Achieving diagnostic excellence is about making a correct and timely diagnosis, using the fewest resources, maximising patient experiences, managing and communicating uncertainty to the patients, and tolerating watchful waiting whenever unfocused treatment may be harmful.[32] The healthcare system, the structural framework and the working environment play a significant role in creating the best circumstances for diagnostic thinking, thereby minimising the risk of cognitive bias. A strong healthcare organisation with a focus on strong feedback systems, psychological safety and good communication supports clinicians' cognitive work and their ability to handle the uncertainty inherent in the diagnostic process.[30 34] Public health policy makers, hospital managers, clinicians and healthcare educators ought to strengthen both graduate and postgraduate teaching in the diagnostic process and develop technical support solutions for diagnostic decision-making (eg, artificial intelligence or computer-based tools) and strengthen a supportive structural framework for the complex diagnostic process.

Strengths and limitations

The strength of our study is the use of two types of national and public data sources complementing each other well by illustrating the diagnostic process from different perspectives, degrees of severity and patient harm. The patient compensation data are unique in an international context, as the database collects national data, in a 'no fault' and public, free of charge, compensation system. While this system can support a higher reporting frequency of patient complaints, the data are still limited, not providing a true estimate of the incidence of DEs in Danish healthcare. Patient complaints data only represent the 'tip of the iceberg' and cannot identify which disease categories are most prone to DEs. Most likely, DEs may occur in all specialties, settings, all disease categories and both in common and rare diseases,[5 18] although rare diseases and atypical courses of diseases are probably more at risk.

Limitations related to AE data can also be stated as only representing another 'part of the iceberg', due to both under-reporting to the database and the lack of a code in the database to extract relevant diagnosis-related cases. The applied extraction and search criteria can be stated as a suitable specificity-orientated search strategy, with a high percentage being diagnosis-related, but the search method does not catch all cases. The patterns of the most vulnerable steps in the diagnostic process in our AE analysis are influenced by the search criteria. Reporting of AEs is also biased, by many and complex factors, the patient safety and psychological safety culture at the institution. Some staff groups, specialties and departments report more than others. Reporting is affected by workload/business and personal factors, for example, feeling insecure or missing the purpose of reporting events. Many reported AEs from an institution cannot necessarily be interpreted as bad but may just as well be the result of a strong patient safety culture with great engagement in learning and improving from mistakes.

CONCLUSIONS

This study analyses two national data sources revealing frequent DEs and diagnosis-related AEs in Danish healthcare. These errors pose a significant patient safety risk. We identified critical steps prone to errors and focus areas for future improvements. Our results highlight the need for better education in diagnostics and clinical reasoning, as well as continuous feedback to and between healthcare workers achieving diagnostic excellence. Improved technical support systems to secure safe communication, transmission, receiving and action on test results. Despite limitations like under-reporting, our findings stress the importance of robust data collection and systematic improvements to reduce DEs.

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Patient consent for publication Not applicable.

Ethics approval No ethical approval from the Danish ethics committee was required for the analyses. All AEs are registered in a non-identifiable anonymised way in the Danish Patient Safety Database, and all data handling and analysis were performed on-site at the institution of The Danish Patient Safety Authorities. The data from the Danish Patient Compensation Association were handled by researchers after signing a confidentiality and data security declaration.

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