



Dansk Selskab for  
**PatientSikkerhed**

# Further work on diagnostic safety

Charlotte Frensdved

Dansk Selskab for  
Patientsikkerhed

**PS!**

# Opportunities for follow up

- Acute illnesses
  - Orthopedic surgery (trauma)
  - Medical diseases (heart, lungs, infections)
  - Error in diagnosis in connection with deterioration during hospital stay (e.g. after rapid response team)
- Cancer
- Other chronic diseases
- Psychiatry

# Sweden:

Patients with reported preventable harm in primary health care and emergency departments

- Psychiatric disease nearly doubled the risk of being a reported case of preventable harm
- The preventable harm in this group was to 46% diagnostic errors of somatic disease.

Fernholm, R., Holzmann, M.J., Wachtler, C. *et al.* Patient-related factors associated with an increased risk of being a reported case of preventable harm in first-line health care: a case-control study. *BMC Fam Pract* **21**, 20 (2020). <https://doi.org/10.1186/s12875-020-1087-4>

## RESEARCH ARTICLE

## Open Access

### Patient-related factors associated with an increased risk of being a reported case of preventable harm in first-line health care: a case-control study



Rita Fernholm<sup>1\*</sup>, Martin J. Holzmann<sup>2,3</sup>, Caroline Wachtler<sup>1</sup>, Robert Szulkin<sup>1,4</sup>, Axel C. Carlsson<sup>1</sup> and Karin Pukk Härenstam<sup>5</sup>

#### Abstract

**Background:** Patient safety issues in primary health care and in emergency departments have not been as thoroughly explored as patient safety issues in the hospital setting. Knowledge is particularly sparse regarding which patients have a higher risk of harm in these settings. The objective was to evaluate which patient-related factors were associated with risk of harm in patients with reports of safety incidents.

**Methods:** A case-control study performed in primary health care and emergency departments in Sweden. In total, 4536 patients (cases) and 44,949 controls were included in this study. Cases included patients with reported preventable harm in primary health care and emergency departments from January 1st, 2011 until December 31st, 2016.

**Results:** Psychiatric disease, including all psychiatric diagnoses regardless of severity, nearly doubled the risk of being a reported case of preventable harm (odds ratio, 1.96;  $p < 0.001$ ). Adjusted for income and education there was still an increased risk (odds ratio, 1.69;  $p < 0.001$ ). The preventable harm in this group was to 46% diagnostic errors of somatic disease.

**Conclusion:** Patients with psychiatric illness are at higher risk of preventable harm in primary care and the emergency department. Therefore, this group needs extra attention to prevent harm.

**Keywords:** Primary health care, Emergency medical services, Emergency care, Medical errors, Mental health disorders, Psychiatric illness, Patient harm, Preventable harm, Adverse Events

# Opportunities for follow up

- Further analysis of incidence and patterns
- Causes? (sociological/anthropological methods?)
- Development and testing of interventions/tools
- Measurement of diagnostic safety
- Changes in systems and organisation

# Analysis of adverse events

- Dansk Patientsikkerhedsdatabase
  - ~ Lex Maria (but includes all degrees of severity (no harm – severe harm and death + patients can report))
- Compulsory (non-punitive) reporting of adverse events (patient safety incidents) by health care workers
- 300.000+ events collected every year by The Danish Patient Safety Authority
- No classification of diagnosis-related adverse events

# Analysis of adverse events

- Free text search for "diagno\*" revealed 236 events - 5 year-period
- Another random sample of 100 events with problemcodes "delayed assesment" – "delayed reaction to test-results"
- Includes all degrees of severity – many 'no harm'
- Majority of events in both groups turned out to be diagnosis-related



## Analyzing the Diagnostic Process

The CBS taxonomy enables data analyses along the process of care that help identify where breakdowns most commonly occur. Each of the 12 steps described below presents focal points for more detailed analysis and opportunities for provider training and systems improvements.

 **58%**  
of cases involve  
assessment  
failures

### INITIAL DIAGNOSTIC ASSESSMENT

Covers the patient's presentation with a complaint, through the physician's assessment, differential diagnosis, and test orders. Factors that trigger malpractice allegations are primarily related to voids in the physician's evaluation of the patient's history and cognitive processing related to presentation, differential diagnosis, and test ordering.

- 1. Problem Noted, Care Sought**  
Issues: Access, including or seeking issues impede the patient from raising a relevant health problem, or delays him or her from seeking care for a recognized problem.
- 2. History and Physical Conducted**  
Issues: The patient's (personal and family) history is not fully recorded or updated; the physical examination is absent or inadequate.
- 3. Patient Assessed and Symptoms Evaluated**  
Issues: The patient's complaints or symptoms are not thoroughly addressed.
- 4. Differential Diagnosis Established**  
Issues: A narrow diagnostic focus, failure to establish a differential diagnosis, or reliance on a chronic condition or previous diagnosis.
- 5. Diagnostic Test(s) Ordered**  
Issues: The ordering of appropriate tests/imaging/labs is impeded by an incomplete or biased assessment.

### TESTING AND RESULTS PROCESSING

From the scheduling, performance, and interpretation of diagnostic tests, through the management of the test results. The factors that trigger malpractice allegations are primarily related to breakdowns in clinical systems for test result management, the cognitive skills related to interpretation, and communication of results to the ordering physicians.

 **29%**  
of cases involve  
testing  
failures

- 6. Tests Performed**  
Issues: Ordered test/imaging is not performed, performed incorrectly, or specimen is mislabeled or mishandled.
- 7. Test Interpreted**  
Issues: Report of findings are determined to be incomplete or inaccurate; abnormal findings not ruled out.
- 8. Test Results Transmitted to/Received by Ordering Physician**  
Issues: Receipt/review of test result by ordering physician is not completed, or is significantly delayed.

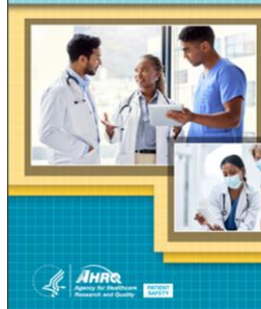
### FOLLOW UP AND COORDINATION

Encompasses decisions made and actions taken after assessment and testing, including consultations and communication. The factors driving malpractice allegations are primarily related to failure to involve specialty consultation and breakdowns in communication among caregivers and between caregivers and the patient.

 **46%**  
of cases involve  
follow-up  
failures

- 9. Physician Follows Up with Patient**  
Issues: Findings are not communicated to the patient, follow-up testing is not arranged, or follow-up is not documented.
- 10. Referrals/Consults**  
Issues: Appropriate referrals to specialists (or consults) are not made or adequately managed, or identification of the physician responsible for ongoing care is unclear.
- 11. Patient Information Communicated Among Care Team**  
Issues: Failure by one or more provider to fully review or share patient information that influences ongoing diagnostic process.
- 12. Patient and Providers Establish Follow-up Plan**  
Issues: Patient fails to adhere to the follow-up plan, including appointments and treatment regimen.

## Measure DX: A Resource to Identify, Analyze, and Learn From Diagnostic Safety Events



## Agency for Healthcare Research and Quality, AHRQ

## Appendix H. Diagnostic Error Evaluation and Research (DEER) Taxonomy

Where in the Diagnostic Process	What Went Wrong
1. Access/Presentation	<ol style="list-style-type: none"> <li>a. Failure/delay in presentation</li> <li>b. Failure/denied care access</li> </ol>
2. History	<ol style="list-style-type: none"> <li>a. Failure/delay in eliciting critical piece of history data</li> <li>b. Inaccurate/misinterpreted/overlooked critical piece of history data</li> <li>c. Failure in weighing critical piece of history data</li> <li>d. Failure/delay to follow-up critical piece of history data</li> </ol>
3. Physical Exam	<ol style="list-style-type: none"> <li>a. Failure/delay in eliciting critical physical exam finding</li> <li>b. Inaccurate/misinterpreted/overlooked critical physical exam finding</li> <li>c. Failure in weighing critical physical exam finding</li> <li>d. Failure/delay to follow-up critical physical exam finding</li> </ol>
4. Tests (Lab/Radiology)	<p><b>Ordering (traditionally called "pre-analytic phase")</b></p> <ol style="list-style-type: none"> <li>a. Failure/delay in ordering needed test(s)</li> <li>b. Failure/delay in performing ordered test(s)</li> <li>c. Error in test sequencing</li> <li>d. Ordering of wrong test(s)</li> <li>e. Tests ordered wrong way</li> </ol> <p><b>Performance (traditionally called "analytic phase")</b></p> <ol style="list-style-type: none"> <li>f. Sample mix-up/mislabeled (e.g., wrong patient/test)</li> <li>g. Specimen delivery problem</li> <li>h. Technical errors/poor processing of specimen/test</li> <li>i. Erroneous lab/radiology reading of test</li> <li>j. Failed/delayed reporting of result to clinician</li> </ol> <p><b>Clinician Processing (traditionally called "post-analytic phase")</b></p> <ol style="list-style-type: none"> <li>k. Failed/delayed follow-up of (abnormal) test result</li> <li>l. Error in clinician interpretation of test</li> </ol>
5. Assessment	<p><b>Hypothesis Generation</b></p> <ol style="list-style-type: none"> <li>a. Failure/delay in considering the diagnosis</li> </ol> <p><b>Suboptimal Weighing/Prioritizing</b></p> <ol style="list-style-type: none"> <li>b. Too little consideration/weight given to the diagnosis</li> <li>c. Too much weight on competing/coexisting diagnosis</li> </ol> <p><b>Recognizing Urgency/Complications</b></p> <ol style="list-style-type: none"> <li>d. Failure/delay to recognize/weight urgency</li> <li>e. Failure/delay to recognize/weight complications of a diagnosis</li> </ol>
6. Referral/Consultation	<ol style="list-style-type: none"> <li>a. Failure/delay in ordering referral/consult</li> <li>b. Failure/delay in obtaining/scheduling ordered referral</li> <li>c. Error/suboptimal quality in diagnostic consultation performance</li> <li>d. Failed/delayed communication/follow-up of consultation</li> </ol>
7. Follow-up	<ol style="list-style-type: none"> <li>a. Failure/delay in timely follow-up/rechecking of patient</li> <li>b. Failure to refer patient to close/safe setting/monitoring</li> <li>c. Failure/delay in needed monitoring or lab (BP, INR, repeat CXR)</li> <li>d. Failure/delay in communicating findings among healthcare providers</li> </ol>

Acknowledgment: Dr. Gordon Schiff, Harvard Medical School. Used with permission.

# Preliminary results

- Many lab-associated events (6-8)
  - referrals got lost
  - things gone wrong in the lab
  - communications of results
- Many
  - Missed 'referrals/consults' (10)
  - Failure/delay in 'communication among healthcare providers' (11)

Original 2019-analysis of malpractice claims

Initial diagnostic assessment					Testing and results processing			Follow up and coordination			
80 %					27 %			33 %			
1	2	3	4	5	6	7	8	9	10	11	12
Problem noted – Care sought	History and Physical Conducted	Patient Assessed and Symptoms Evaluated	Differential Diagnosis Established	Diagnostic Test(s) Ordered	Tests Performed	Tests Interpreted	Test Results Transmitted to/ Received by Ordering Physician	Physician Follows up with Patient	Referrals/ Consults	Patient Information Communicated among Care Team	Patient and Providers Establish Follow up Plan
1%	23%	52%	44%	38%	2%	25%	0%	7%	24%	4%	1%




# Analysis of adverse events – next step?

- Dansk Patientsikkerhedsdatabase
- Sample of adverse events with severe harm/death
- How many are related to diagnosis?

# Sweden

- 4830 cases of preventable harm were identified
- 2208 (46%) were due to diagnostic errors

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

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### 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.

### ARTICLE HISTORY

Received 4 September 2018  
Revised 18 March 2019  
Accepted 30 April 2019

### KEYWORDS

General practice; diagnostic errors; emergency and out-of-hours care; patient safety; primary healthcare

# UK


Patient safety incident reports (10 years, 2005–2015) collected from the National Reporting and Learning System.

Reports describing severe harm/death in acute medical unit were identified.

Results: A total of 377 reports of severe harm or death were confirmed. **The most common incident types were diagnostic errors** (n : 79), medication-related errors (n : 61), and failures monitoring patients (n : 57).

Incidents commonly stemmed from lack of active decision-making during patient admissions and communication failures between teams.

## Learning from patient safety incidents involving acutely sick adults in hospital assessment units in England and Wales: a mixed methods analysis for quality improvement

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### Summary

**Objective:** Six per cent of hospital patients experience a patient safety incident, of which 12% result in severe/fatal outcomes. Acutely sick patients are at heightened risk. Our aim was to identify the most frequently reported incidents in acute medical units and their characteristics.

**Design:** Retrospective mixed methods methodology: (1) an a priori coding process, applying a multi-axial coding framework to incident reports; and, (2) a thematic interpretative analysis of reports.

**Setting:** Patient safety incident reports (10 years, 2005–2015) collected from the National Reporting and Learning System, which receives reports from hospitals and other care settings across England and Wales.

**Participants:** Reports describing severe harm/death in acute medical unit were identified.

**Main outcome measures:** Incident type, contributory factors, outcomes and level of harm were identified in the included reports. During thematic analysis, themes and metathemes were synthesised to inform priorities for quality improvement.

**Results:** A total of 377 reports of severe harm or death were confirmed. The most common incident types were diagnostic errors (n = 79), medication-related errors (n = 61), and failures monitoring patients (n = 57). Incidents commonly stemmed from lack of active decision-making during patient admissions and communication failures between teams. Patients were at heightened risk of unsafe care during handovers and transfers of care. Metathemes included the necessity of patient self-advocacy and a lack of care coordination.

**Conclusion:** This 10-year national analysis of incident reports provides recommendations to improve patient safety including: introduction of electronic prescribing and monitoring systems; forcing checklists to reduce diagnostic errors; and increased senior presence overnight and at weekends.

### Keywords

Clinical, emergency medicine, health service research, medical error/patient safety, medical management, other emergency medicine, other statistics and research methods, quality improvement

Received: 16th November 2020; accepted: 28th June 2021

### Introduction

Patient safety incidents occur in 6% of patient cases acutely admitted to hospital, with 12% resulting in severe or fatal outcomes.<sup>1</sup> In 2004, the Royal College of Physicians advocated acute medical units to relieve pressures on emergency departments<sup>2</sup> and improve patient outcomes.<sup>3</sup> Ten years later, a single Irish hospital study has reported decreased mortality since the introduction of an acute medical unit (a 60% reduction in relative risk for individual patients).<sup>4</sup> It is still the case that, despite major redesign of care delivery, little is known about patient safety incidents occurring in acute medical units.

Handovers and care transfers, diagnostic cognitive overload and staffing levels may be important factors.<sup>5</sup> For example, a UK team conducted a single site observational study (four one-week periods over 18 months involving 36 staff and 71 patients) identifying delays in 44% of admissions.<sup>6</sup> An observational and interview study from the same team demonstrated 46% (318/688) of medication charts contained errors, the majority of which involved omission of medication. This study highlighted variances in medication history-taking including a lack of collaborative histories before prescribing.<sup>7</sup> These data correlate with the findings of a 2008 narrative review

# Future

- Further analysis of incidence and patterns
- More knowledge about causes
- Testing of interventions/tools
- Testing of tools for measuring diagnostic safety
- Changes in systems and organisation

# Society to improve diagnosis in medicine



SOCIETY to IMPROVE DIAGNOSIS  
in MEDICINE

- Founded 2011
- Initiator of the 2015-report from the Institute of Medicine – Improving Diagnosis in Health Care
- Platform for knowledge
- Initiates research
- International conferences



Mark Graber  
Founder and President  
Emeritus - Society to  
Improve Diagnosis in  
Medicine (SIDM)

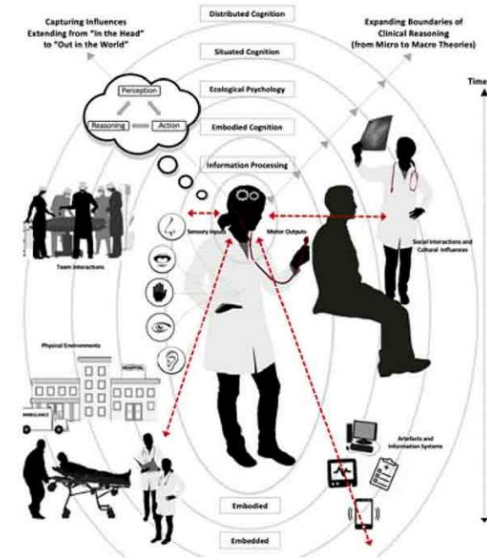
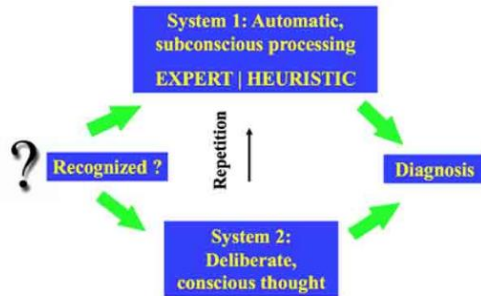
# The situative perspective:

2000

Diagnosis as information processing  
“In the head”

2020

Diagnosis as a social,  
situated process  
“In the world”



From: Graber, M Progress understanding diagnosis and diagnostic errors: thoughts at year 10. *Diagnosis*, Volume 7, Issue 3, Pages 151–159, DOI: <https://doi.org/10.1515/dx-2020-0055>. – with permission from Mark Graber and Michelle Daniel (drawing).

# Diagnostic excellence



*Hardeep Singh professor of Health Policy, Quality and Informatics, Center for Innovations in Quality, Effectiveness and Safety, Department of Veteran Affairs, Houston, Texas.*

## New Care Models: “LEDE” Organizations

*LEDE = Learning & Exploration of Diagnostic Excellence*



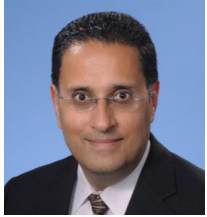
Singh H, Upadhyay DK, & Torretti D. [Developing health care organizations that pursue learning and exploration of diagnostic excellence: An action plan](#). *Acad Med*.

15

Singh H, Upadhyay DK, & Torretti D. [Developing health care organizations that pursue learning and exploration of diagnostic excellence: An action plan](#). *Acad Med*.



# Feedback - to calibrate how clinicians think



Jama 2019:

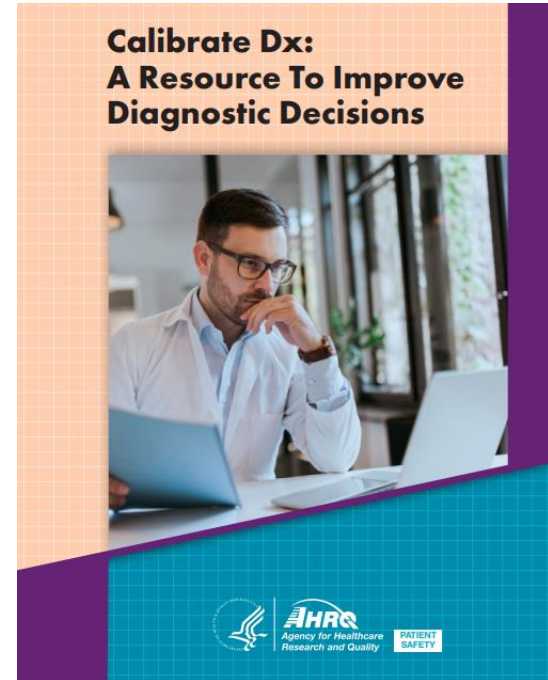
The Path to Diagnostic Excellence Includes  
Feedback to Calibrate How Clinicians Think

“Clinicians must learn about the ultimate accuracy of their diagnoses, as well as the processes that led them to those diagnoses (eg, which tests were ordered and whether they should have been) or why diagnostic performance was suboptimal.”

<https://jamanetwork.com/journals/jama/fullarticle/2724792>

<https://www.ahrq.gov/patient-safety/settings/multiple/calibrate-dx.html>

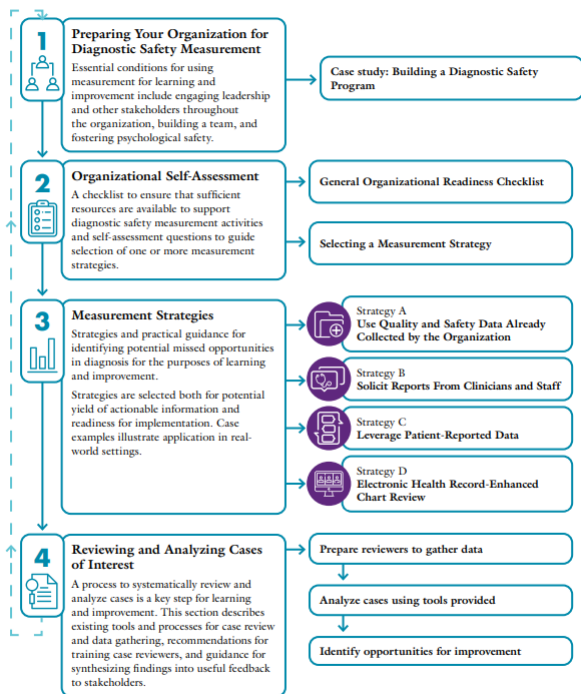
<https://qualitysafety.bmj.com/content/early/2021/05/10/bmjqs-2020-012464>



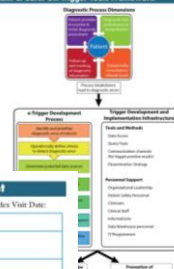
Agency for Healthcare  
Research and Quality

# Measuring diagnostic safety

## Overview of the Resource



Appendix C. Safer Dx Trigger Tools Framework



A.S. Garg, M. Mehta, P. Thomas et al. / *Applied Ergonomics* 2019, 78, 101–109

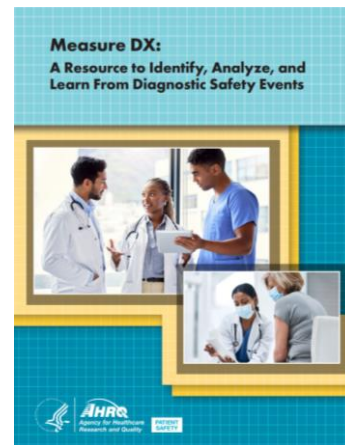
### Appendix E. Safer Dx Process Breakdown Supplement

Study ID#	Reviewer	Review Date	Index Visit Date
What was the initial diagnosis?			
<p>Was the chief complaint or presenting symptoms at initial presentation?</p> <p>Was the chief complaint related to the diagnosis error?</p> <p><input type="checkbox"/> Yes    <input type="checkbox"/> No</p>			
<b>Premiside Characteristics</b>			
Please identify all setting personnel involved in the error(s) and rate the importance of their contribution.			
Setting Involved (code list, scoring code)	Personnel Type (code list, pages 1-2)	Personnel Involved (code list, specialty codes)	Contributory Role Rating (code list, scoring scale)
1.			
2.			
3.			
4.			
What factors prompted the error discovery? (select all that apply)			
<input type="checkbox"/> Discussed at part of planned follow up <input type="checkbox"/> Failure of original symptoms or signs to resolve <input type="checkbox"/> New symptoms or signs <input type="checkbox"/> Evolution of the original symptoms or signs <input type="checkbox"/> Patient insistence/persistence on pursuing another diagnosis <input type="checkbox"/> New data		<input type="checkbox"/> Fresh eyes looking at the original picture <input type="checkbox"/> Information after patient died (i.e., family alleges diagnosis error) <input type="checkbox"/> Yes/Other, please describe: <input type="checkbox"/> Not able to be determined <input type="checkbox"/> Patient admitted to hospital, placed safety <input type="checkbox"/> Patient facility <input type="checkbox"/> Outside facility	
In the episode of care most closely associated with the error, was any differential diagnosis documented?			
If "Yes," was the differential diagnosis acted upon?			
Was the correct diagnosis considered in the differential diagnosis at the initial presentation of the health problem?			

Appendix H. Diagnostic Error Evaluation and Research (DEER) Taxonomy

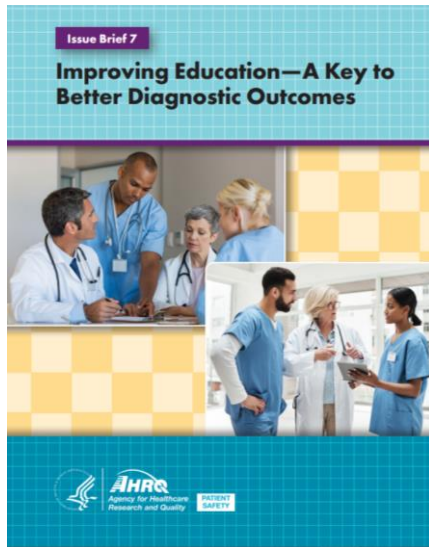
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**Acknowledgments:** The Gordon Schiff Humanoid Medical School, UMass Lowell, with members



**Oversættes til dansk**

# Diagnostic process – education program



## Improve Communication and Teamwork Among Providers by Using the TeamSTEPPS® for Diagnosis Improvement Course



Module 1: Introduction



Module 2: Diagnostic Team Structure



Module 3: Communications



Module 4: Leadership



Module 5: Situation Monitoring



Module 6: Mutual Support



Module 7: Putting It All Together

<https://www.ahrq.gov/teamstepps/diagnosis-improvement/index.html>

Dansk Selskab for PatientSikkerhed **PSI!**

# Future plans

- Emergency Department in Odense, Denmark
- NHS patient safety
- Hardeep Singh
- Other international partners



International Forum on  
**QUALITY & SAFETY**  
in **HEALTHCARE**  
**COPENHAGEN**



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### Vigtige datoer

- 1. november - 7. december 2022  
Rabatkampagne for danske deltagere – opnå rabat på 20-30%
- 7. december 2022  
Call for Posters deadline
- 8. marts 2023  
Early Bird deadline

Læs mere på [patientsikkerhed.dk/internationalforum2023](https://patientsikkerhed.dk/internationalforum2023)