Patientombuddet

The Danish National Agency for Patients' Rights and Complaints

Trends and Strategies in Patient Safety and training in the EU and globally

Pia Knudsen, Ph.D. Pharm,
Senior Patient Safety Officer

- 5 packs of morphine 0.4 mg / mL are ordered
- The person who packs the goods do not scan or double check the medicine and pack 3 packets morphine 0.4 mg / ml and 2 packets of morphine 40 mg / mL
- Packaging design and color of both strengths are equal
- The medicine is received and is the right goods on the delivery note
- The medicine is put in place without checking the strength of morphine in all the 5 packages.
- The medicine is taken without checking the strength, as the ward usually only has 0.4 mg / mL
- The patient was given the wrong strength morphine

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It is about preventing that the next patient experience the same mistake

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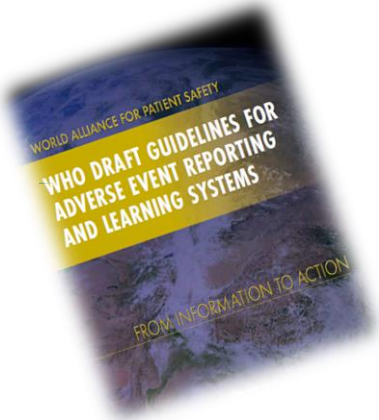
The recommendations from WHO, World Alliance for Patient



The four core principles underlying the guidelines are:

- ✓ [illegible]
- ✓ **A reporting system must produce a visible, useful response to justify the resources expended and to stimulate reporting.**

The motivation to implement a reporting system

- Benchmarking on Patient Safety
- Media attention - political pressure.
- Accreditation Programmes for hospitals
- EU recommendation 2009
- Legislation

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Choosing components for a reporting system

Components of a reporting system

The organizational framework
Where is the responsibility placed?

- Health regulatory bodies
- Professional regulatory bodies
- Local health organisations

Reporting Systems for adverse events in EU member states	National	Regional	Local (stand alone)	Local (connection to a central system)
BELGIUM			X	
CROATIA	X			
CZECH REPUBLIC	X			
DENMARK	X			
ESTONIA	X		X	
GERMANY	X	X		
HUNGARY	X			
ITALY	X	X		X
LATVIA			X	
NORWAY	X			
POLAND			X	
SLOVAKIA	X			
SPAIN	X	X		X
SWEDEN	X			
UNITED KINGDOM	X			

Toolbox for Reporting and Learning Systems for adverse events . Patient Safety and Quality of Care Working Group of the European Commission Reporting and Learning System Subgroup – Draft dec. 2013

Components of a reporting system

How do you want to implement the system?

- Pilot project
- Step by step
- All at the same time

How was the reporting system implemented	Member states
There was established a pilot project	Czech Republic, Hungary, Italy, Norway and Spain
There was made a step by step implementation	Belgium, Croatia, Czech Republic, Hungary, Norway and Spain
It all started at the same time	Denmark and Slovakia

Toolbox for Reporting and Learning Systems for adverse events . Patient Safety and Quality of Care Working Group of the European Commission Reporting and Learning System Subgroup – Draft dec. 2013

Process features of national reporting systems

What events are to be reported – and how?

- Adverse events
  - Preventable / non-preventable
  - Deadly
  - Serious
  - Near misses
- Illegal actions that lead to a AE?

- Structured reporting ><Narrative reports

- What is the expected product?
- How will the classification scheme facilitate analysis that will produce the desired outcome?
- What types of data are available?
- Are reporters expected to have carried out an investigation and analysis of the event?
- The more detailed and elaborate the classification system is,the more expertise will be required, and the costlier the system will be to maintain.

Process features of national reporting systems

Who are the reporters?

- Hospital
- Ambulance setting
- Mental health settings
- Primary care
  - Social care settings
  - Residential/home settings
  - Pharmacies
  - General practitioner
  - Dentists
- Patients / relatives

EU Member State	Healthcare professionals	Patients	Relatives	Public
BELGIUM	X			
CROATIA	X	X		
CZECH REP	X			
DENMARK	X	X	X	
ESTONIA	X			
HUNGARY	X			
ITALY	X			
LATVIA	?			
NORWAY	X			
SLOVAKIA	X			X
SPAIN	X			
SWEDEN	X			

Toolbox for Reporting and Learning Systems for adverse events . Patient Safety and Quality of Care Working Group of the European Commission
Reporting and Learning System Subgroup – Draft dec. 2013

Process features of national reporting systems

Methods for submitting reports ?

- Mail
- Fax,
- Phone
- Internet

Reporting systems outside Europe

- USA
  - Local
- CANADA
- AUSTRALIA

The motivation to report adverse events

1. Build a safety culture.
2. Lead and support your staff.
3. Integrate your risk management activity.
4. Promote reporting.
5. Involve and communicate with patients and the public.
6. Learn and share safety lessons.
7. Implement solutions to prevent harm.

According to the Institute of Medicine, *"the biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm*

Components of a reporting system – Voluntary or mandatory nature?

- Trust that people are committed to patient safety thinking and want to convey learning

- Used the law or guideline to regulate the reporting

EU Member State	Healthcare professionals	Patients	Relatives	Public	Regulated by law
BELGIUM	Voluntary	No	No	No	No
CROATIA	Mandatory	Voluntary	No	No	Yes, partial
CZECH REP	Voluntary	No	No	No	No
DENMARK	Mandatory	Voluntary	Voluntary	No	Yes
ESTONIA	Mandatory	No	No	No	Yes, partial
HUNGARY	Voluntary	No	No	No	No
ITALY	Mandatory	No	No	No	Yes, partial
LATVIA		No	No	No	No
NORWAY	Mandatory	No	No	No	Yes
SLOVAKIA	Voluntary		No	Mandatory	No
SPAIN	Voluntary	No	No	No	No
SWEDEN	Mandatory	No	No	No	Yes

Toolbox for Reporting and Learning Systems for adverse events .
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Reporting and Learning System Subgroup – Draft dec. 2013

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Components of a reporting system – Confidentiality

- the confidentiality of the organisation in which the event took place
- the confidentiality of the patient involved
- the confidentiality of the reporter (usually member of staff).

Components of a reporting system – Anonymity

- Rapporteur is anonymous throughout the process

- The patient's identity are anonymous, while the rapporteurs identity is stored and secured by making the identity confidential

- The anonymisation happens when event is transferred to the central system

- Manual or automatic anonymisation after making an analysis

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Case – willingness to report

When administrating the medicine toda… a patients medication. The patient… e 100 mg instead of 50 m…

The pati…

h… prevent it from

We… es concerning medicine, including the han… staff meeting.

It is essential to have a blame-free culture, which is free of sanctions, if health professionals should be motivated to report adverse events with enough detail to analyse and prevent the incident.

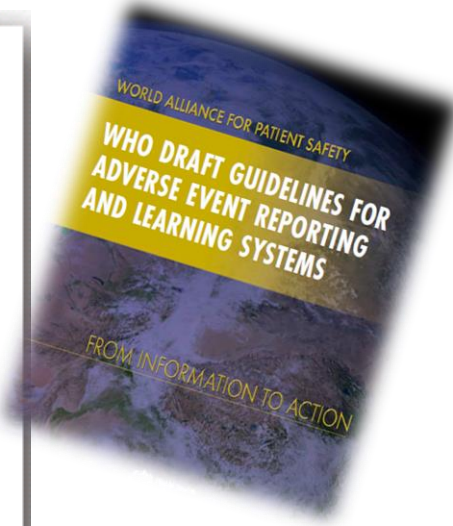
EDUCATION

"The patient in the next bed is highly infectious. Thank God for these curtains."

How was training in rapportering of adverse events organized in the beginning?	No training	Starff meetings	Reporting form is self-explanatory	Training of all health professionals	Specialists trained and educated other health professionals	E-learning	Instructional / guidelines on reporting
BELGIUM		X	X		X		X
CROATIA			X				X
CZECH REPUBLIC	X		X		X		
DENMARK		X	X		X		X
ESTONIA							
HUNGARY		X	X		X	X	
ITALY		X		X		X	X
LATVIA							
NORWAY	X	X					X
POLAND							
SLOVAKIA	X						X
SPAIN		X			X	X	X
SWEDEN	X						

Table 1 Characteristics of Successful Reporting Systems (7)

Non-punitive	Reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting.
Confidential	The identities of the patient, reporter, and institution are never revealed.
Independent	The reporting system is independent of any authority with power to punish the reporter or the organization.
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and are trained to recognize underlying systems causes.
Timely	Reports are analysed promptly and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.
Systems-oriented	Recommendations focus on changes in systems, processes, or products, rather than being targeted at individual performance.
Responsive	The agency that receives reports is capable of disseminating recommendations. Participating organizations commit to implementing recommendations whenever possible.



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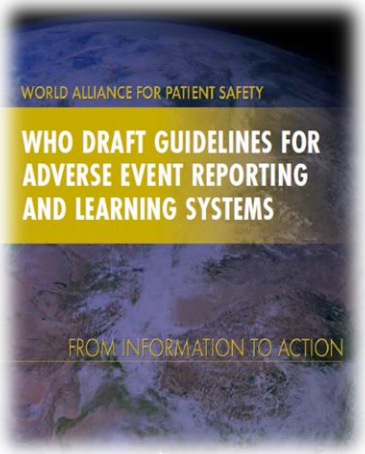
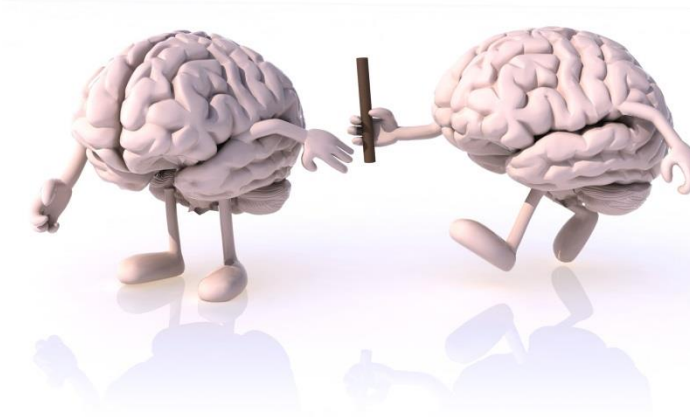


The recommandations from WHO, World Alliance for Patient

”Reporting is only of value if it leads to a constructive response. At a minimum, this entails feedback of findings from data analysis.”



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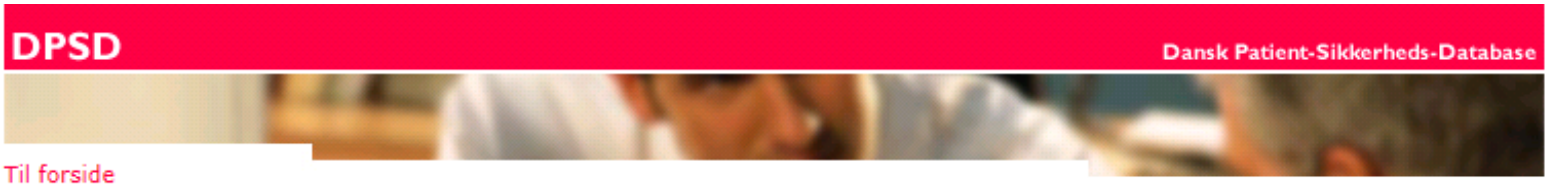
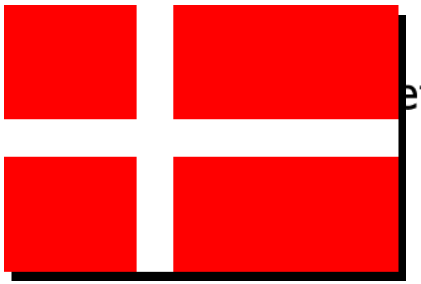
The Danish Patient Safety Database





Denmark

Population

5,6 million (2012)

Area

43,098 square kilometres

Capital

Copenhagen

Denmark is divided into five regions and 98 municipalities

Welcome to the National Agency for Patients' Rights and Complaints

What is the National Agency for Patients' Rights and Complaints?

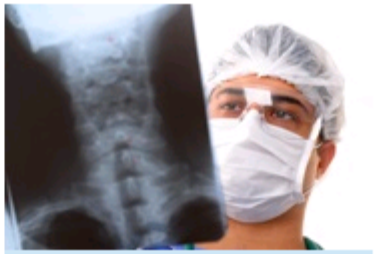
The National Agency for Patients' Rights and Complaints functions as a single point of access for patients who wish to complain about the professional treatment in the Danish health service.

The National Agency for Patients' Rights and Complaints also deals with complaints about the disregard of patient rights and complaints about the Patient Insurance Association's decisions over compensation.

The National Agency for Patients' Rights and Complaints is responsible for the administration of the system for reporting inadvertent incidents within the health service, and helps to make sure that the knowledge gained from these incidents and patient and liability suits is used preventatively.

The National Agency for Patients' Rights and Complaints offers guidance on rights to healthcare in other countries in accordance with Danish legislation, EU regulations and other international agreements.

Tasks



Patient complaints

Complaints concerning professional healthcare, patient rights and coercion in psychiatry.

Compensation

Appeals against decisions from the Patient Insurance Association about compensation for patient injuries and damage from medicine products.

Learning

The health service's system for reporting inadvertent incidents (DPSD) is attached to the National Agency for Patients' Rights and Complaints.

International Health Insurance

International Health Insurance offers guidance on rights in accordance with EU rules, etc., during travel/residence in the EU etc.

Organization

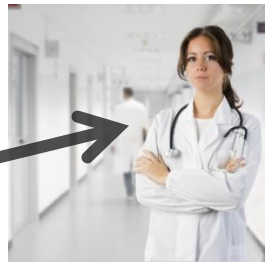
§ 199 2) The National Agency for Patients' Rights and Complaints receives reports from the regions and municipalities on adverse events and create a national register for it.
The National Agency for Patients' Rights and Complaints analyze and disseminate knowledge to the health care on the basis of the received reports.
The National Agency for Patients' Rights and Complaints shall make the report available to the Board of Health for the health guidelines work, see § 214, paragraph. 1

Organisation

DIRECTOR

International Health Insurance

ADMINISTRATION AND SERVICE



LEARNINGCENTER

DPSD

Psychiatric appeals board

disciplinary board

COMPLAINT-CENTER

COMPESATIONS-CENTER

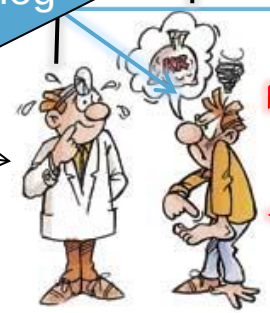
Patient Injury Complaints Board

Medical Injury Complaints Board

Patient Insurance Association

Patientforsikringen

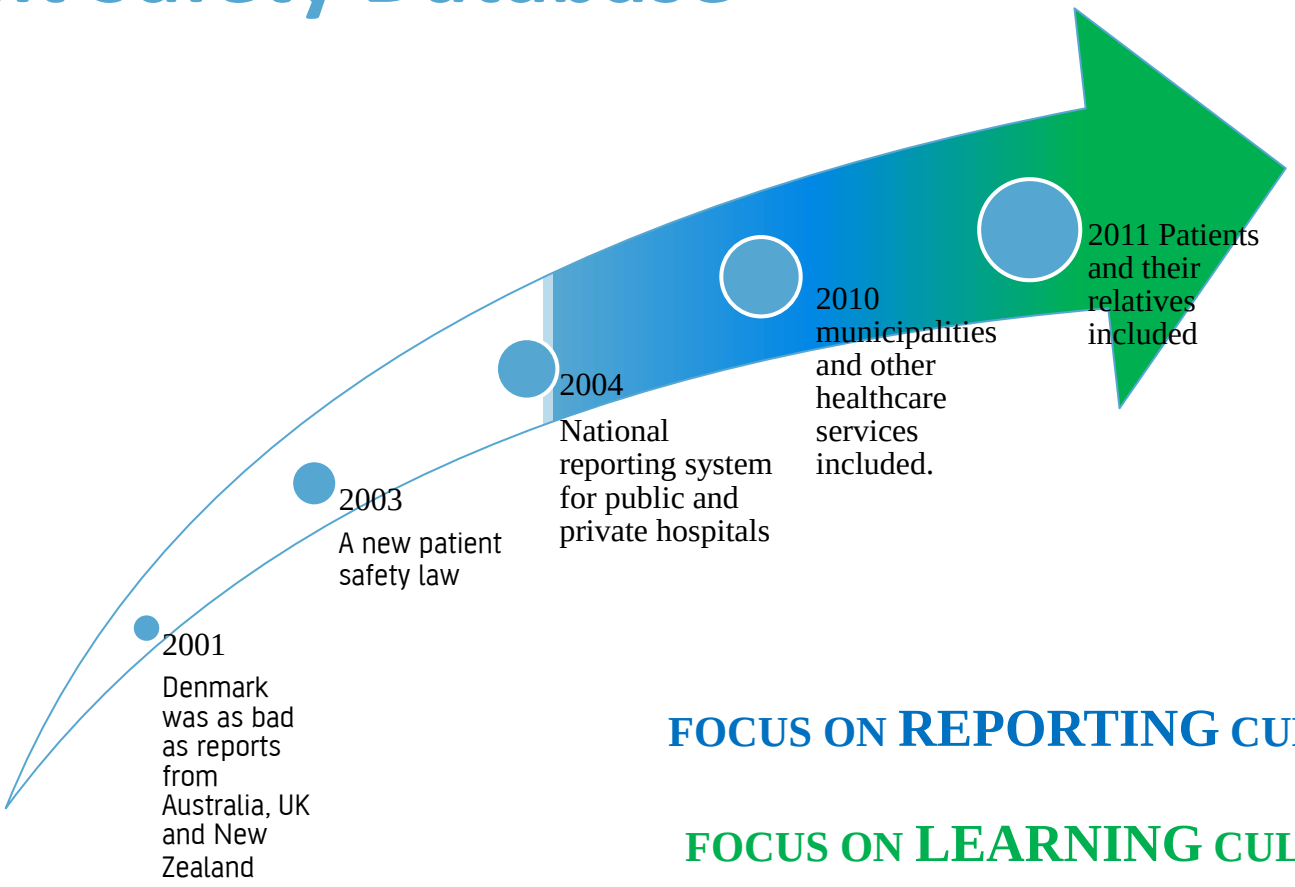
Dialog



Sundhedsstyrelsen

NATIONAL BOARD OF HEALTH

The story behind the Danish Patient Safety Database



FOCUS ON REPORTING CULTURE

FOCUS ON LEARNING CULTURE

In English

Organization

Projects

Contact

Tools

Act on Patient Safety

About the Danish Society for Patient Safety

The Danish Society for Patient Safety is a non-profit organization working to ensure that patient safety is an aspect of all decisions made in Danish health care. Established in 2001 we have pioneered patient safety and health care quality, not only in Denmark but internationally as well.

With partners, domestic and international, we have implemented a wide range of quality projects in hospitals and primary care, as well as legislative work. We provide advice to legislators and stakeholders, arrange study tours and conferences, suggest standards for safe operation, create consensus and initiate projects.

How we work

Our projects are improving the quality of care through the 'model for improvement'. We strive to develop and build a quality improvement and patient safety focused culture and build long-term sustainability and capability to support the improvements. Our main focus is to:

- Gather, spread and develop knowledge and initiatives
- Provide advice to legislators & stakeholders
- Arrange study tours and conferences
- Sugges standards for safe operation
- Do campaigns and lobbyism
- Create consensus
- Initiate projects

The board of the Society consists of representatives from a wide range of stakeholders in Danish health care: the health care professionals, patient and research organizations, the pharmaceutical and medical device industry, the hospital owners and Local Government Denmark. This composition offers a great possibility for all parties to work together for the common patient safety interest. For a closer look on the members of the

Beth Lilja *(left) is the CEO of the Danish Society for Patient Safety*

Ulla Astman *is the chairman of the board of The Danish Society for Patient Safety.*
She is also the president of the council of the North Denmark Region.

Employees - contact info

Links to organisations in the board:

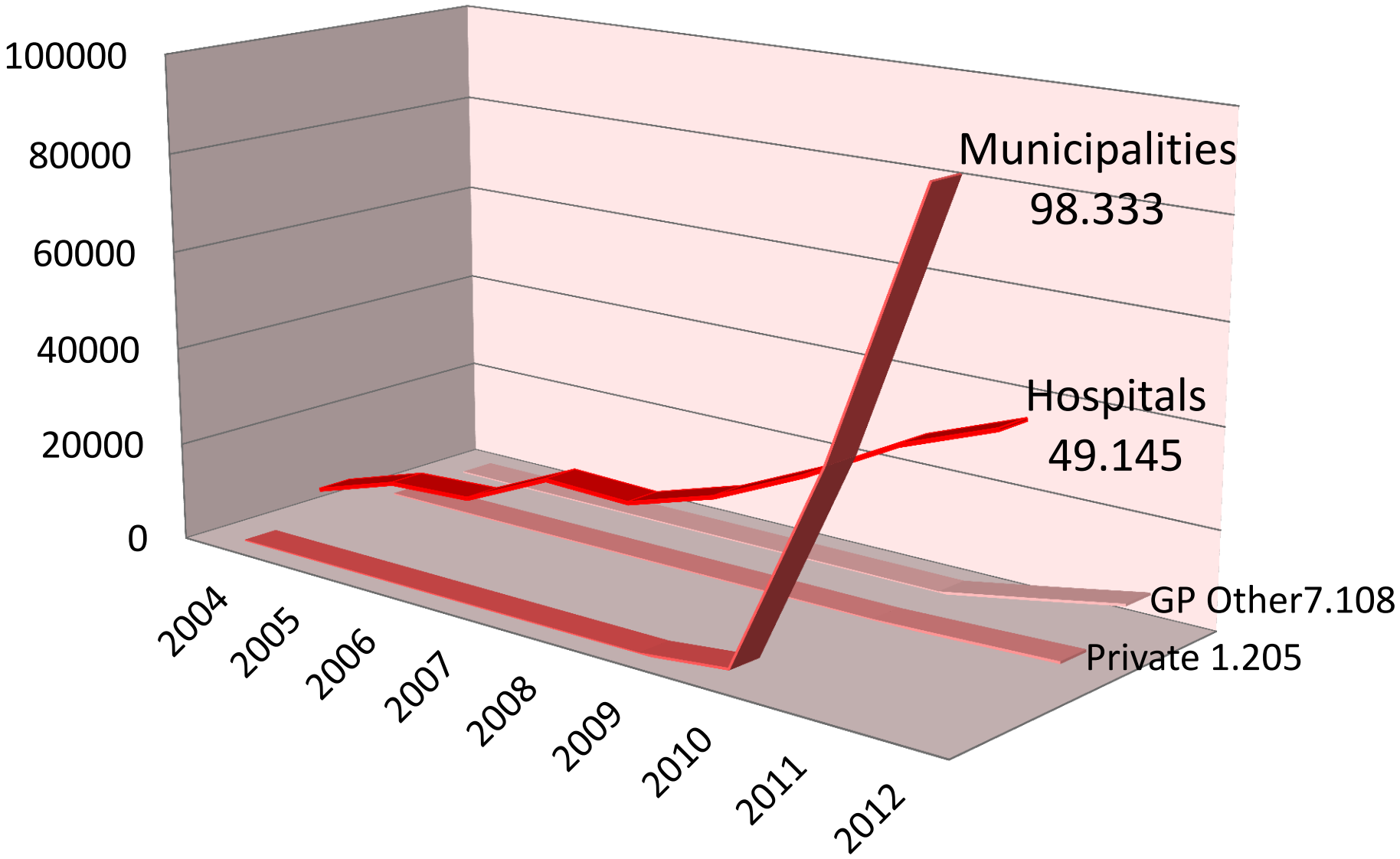
Danish Regions

The five regions

Danish Medical Association

Danish Nurses Organisation

Developments in the number of reported adverse events 2004-2012



Characterization of the Danish reporting system

- **Mandatory**
  A health care professional who becomes aware of an adverse event shall report such an event.

- **Confidentiality**,
  Discloser of information about reporting health care professional's identity to anybody is not allowed.

- **Sanction-free**,
  A health care professional shall not be subjected to disciplinary investigations or measures by the employing authority, supervisory reaction by the National Board of Health or criminal sanction by the courts

- **Shall**
- Authorized healthcare professionals and persons acting on these responsibilities (eg, a medical secretary who take blood tests on a patient)
- Ambulance staff
- Pharmacists
- Pharmacy staff

Can

- Patients and relatives

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The Danish National Agency for Patients' Rights and Complaints

What must be reported ?

Hospital services:

All adverse events are reportable, regardless of the factual consequences for the patient.

The practice and the pre-hospital care:

All adverse events that occur in the sector transitions and use of medical devices are subject to reporting. In addition, infections are reportable.

Patientombuddet
The Danish National Agency for Patients' Rights and Complaints

What must be reported ?

Regional housing & the municipal health services:

All adverse events that occur in connection with medication and sector transitions. In addition, patient accidents and infections reporters.

Adverse events in the other categories are reportable if;

- The patient dies
- Patients suffer permanent disability
- When doctor must be called, hospitalization or intensively increasing treatment
- When several patients need increased care or when increasing treatment must be facilitated

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What must be reported ?

Pharmacy sector:

All adverse events that occur in the sector transitions are subject to reporting.

Adverse events in the other categories are reportable if;

- The patient dies
- Patients suffer permanent disability
- When doctor must be called, hospitalization or intensively increasing treatment
- When several patients need increased care or when increasing treatment must be facilitated

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Location classification in the reporting system

Hospitals

Other regional areas

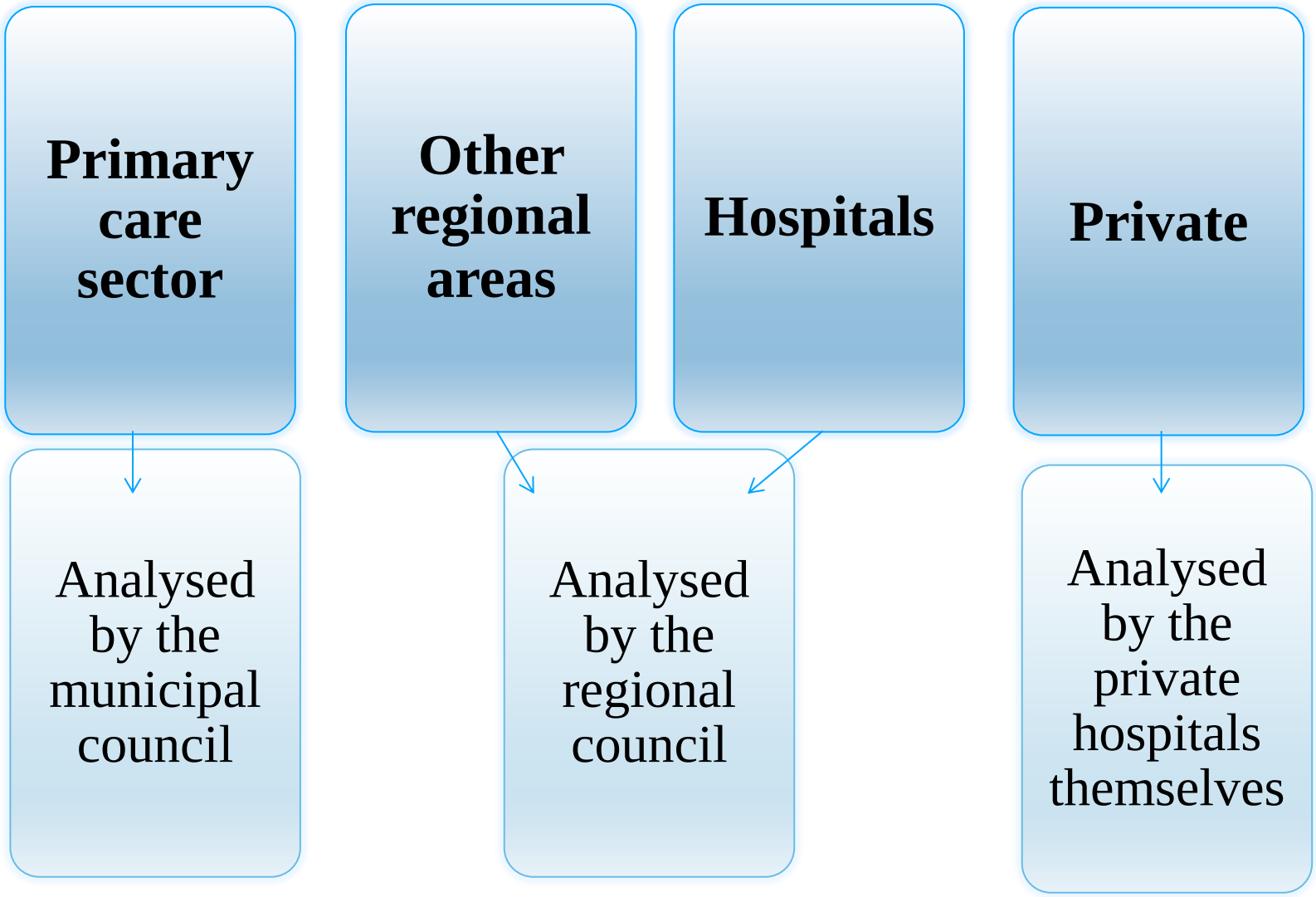
- **GP**
- **Therapists and chiropractors**
- **Dentists and dental hygienists**
- **Pharmacies**
- **Regionale housing**
- **Specialists**
- **Midwives**
- **Psychologists**
- **Doctor on call**
- **Pre-hospital og ambulances**

Private hospitals and hospices

Location classification in the reporting system

Primary care sector

- **Nursing homes**
- **Home Care**
- **Housing for citizens with disabilities**
- **Social housing**
- **Care centers**
- **Training**
- **Home nurse**
- **The public dental**
- **Nurses**
- **Addiction treatment**
- **Prevention Centre**
- **Others**



5 regions and 98 municipals

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Case flow

Reporting

Citizen

Healthcare staff

Case handler (municipal / regional)

Local case handler

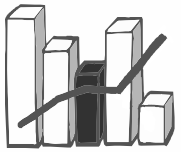
Case handler- NAPRC

Central case handler

Complains

Compensations

External data users



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The Danish National Agency for Patients' Rights and

Publications

- Alerts
- Attentions
- Theme reports
- Newsletters
- Annual Report
- Info for users
- Presentations
- Seminars

THANK YOU

Pia Knudsen,
Ph.D. Pharm,
Senior Patient Safety Officer

The Danish National Agency for Patients' Rights and Complaints

Telephone
+45 7228 6600

E-mail
pia@patientombuddet.dk

Web
www.patientombuddet.dk

Finsensvej 15
2000 Frederiksberg
Denmark