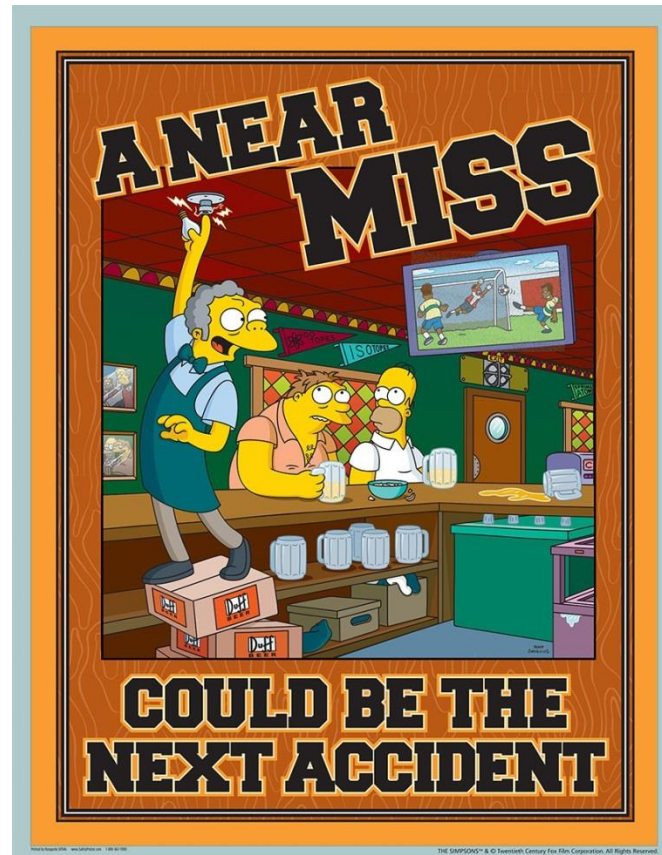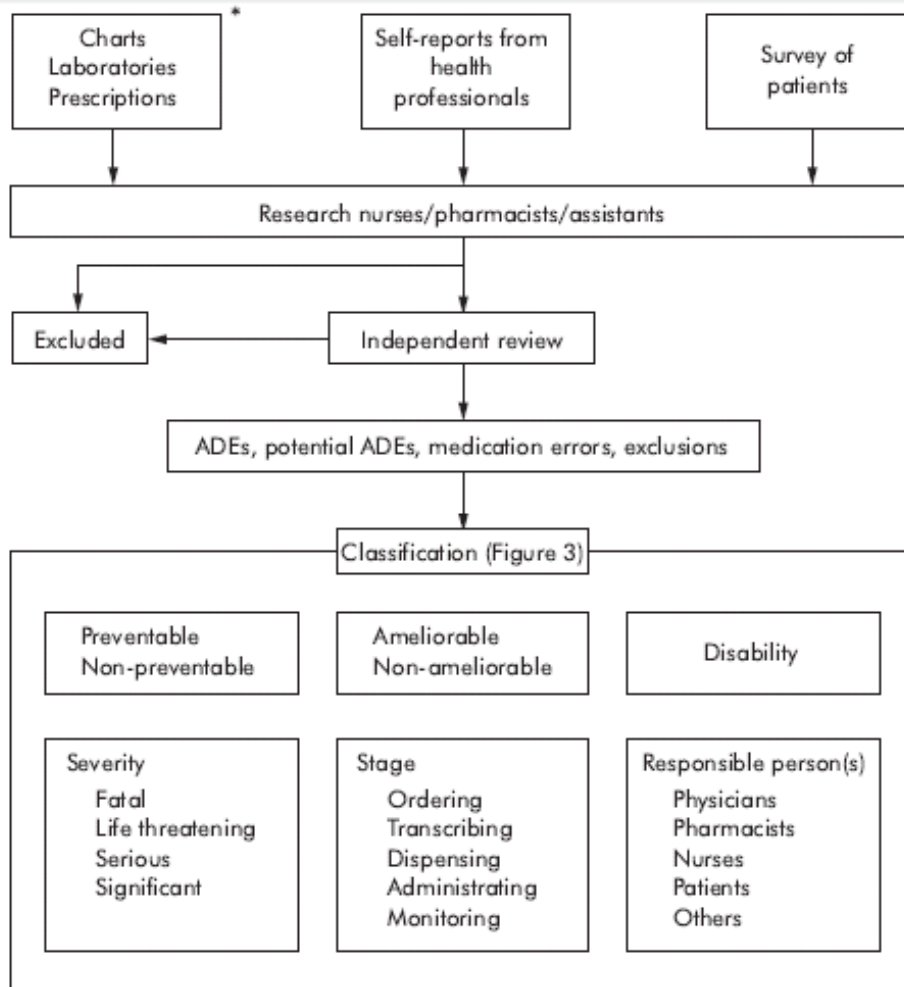# Identifying the risk and assessing the frequency and severity of the risk

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

How can we identify risks?

Adverse drug events and medication errors: detection and classification methods
T morimoto, T K gandhi, A C seger, T C hsieh, D W Bates
Qual saf health care 2004;13:306–314.
Doi: 10.1136/qshc.2004.010611

General process for finding adverse drug events (ADEs), potential ADEs, and medication errors. *Computerized or not.

How can we identify risks?

- **Patient safety rounds**

    - Interviews, dialog and observations
    - Identify and discuss current and potential risks.

- **Global trigger tool**
    - A number of records is reviewed for the so-called triggers. If a trigger is present, it should be considered a warning sign and the records are examined in more detail.

- **Patient complaints and compensations**

How can we assess and learn from the incidents?
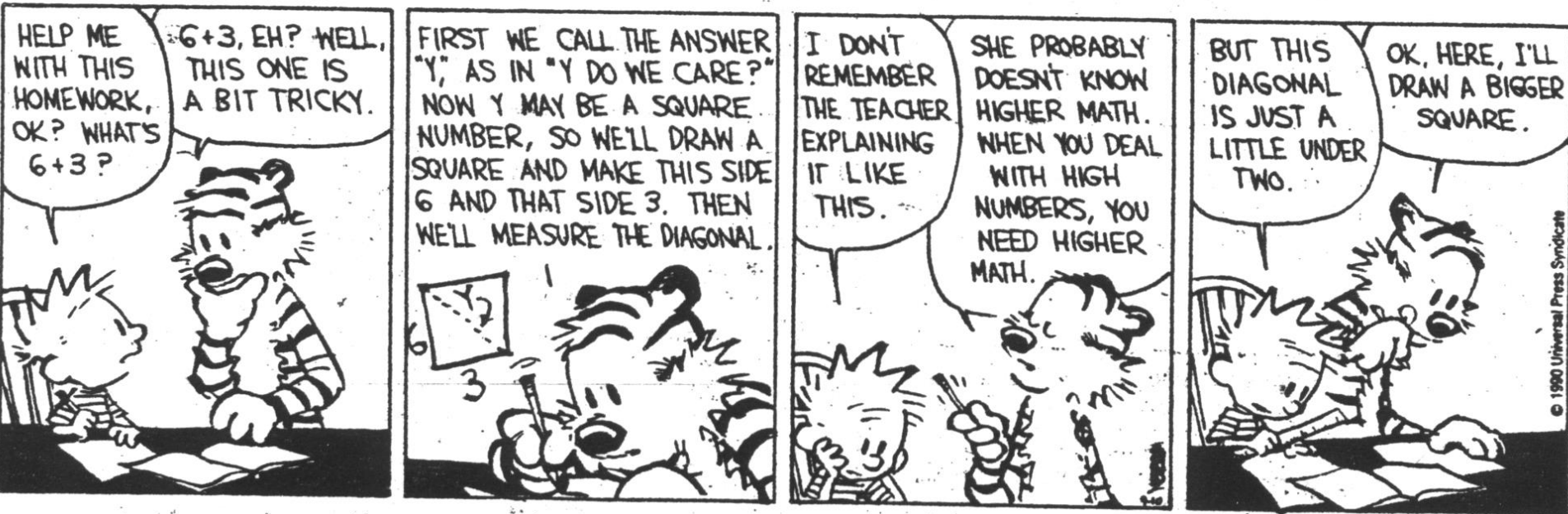
It depend on how you look at the problem

Age of safety management

Age of human factors

Age of technology

1850   1900   1950   200 0
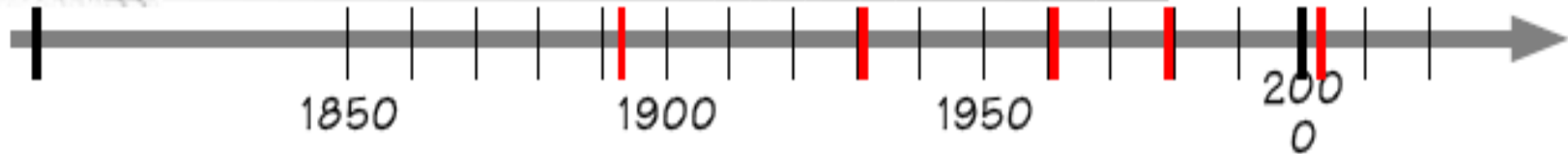
Simple linear model
Independent causes,
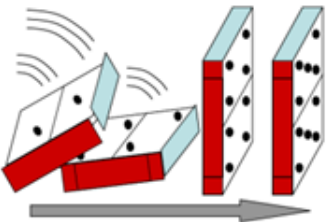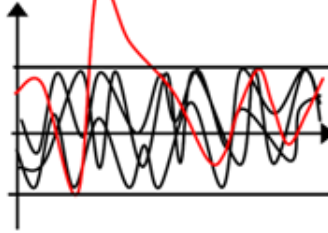Failures, malfunctions

Sequential

Complex linear model
Interdependent causes
(active + latent)

Epidemiological

Non-linear model
Tight couplings, coincidences,
resonance, emergence

Systemic

Three generations of accident models

Accident model	Metaphor	Management principle	Nature of cause	Response type
Sequential Accident development is deterministic (cause-effect links) "Domino"		"Error" management	Causes can be clearly identified (root cause assumption)	Eliminating or containing causes will exclude accidents
Epidemiological Accidents have both manifest and latent causes. "Swiss cheese", "Bowtie"		Performance deviation management	Blunt end / sharp end deviations have clear signatures	Deviations leading to accidents must be suppressed
Systemic Variability can be helpful as well as disruptive. "Functional resonance"		Performance variability management	Sources of variability can be identified and monitored	Some variability should be amplified, some reduced

In order to learn from mistakes, we need an error classification

- Standardization

- Filter the relevant information

- 'Translator'

Components in error classification Primary classification

- Impact—the outcome or effects of medical error and systems failure, commonly referred to as harm to the patient.

- Type—the implied or visible processes that were faulty or failed.

- Domain—the characteristics of the setting in which an incident occurred and the type of individuals involved.

- Cause—the factors and agents that led to an incident.

- Prevention and mitigation—the measures taken or proposed to reduce incidence and effects of adverse occurrences.

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Conceptual Framework for the International Classification for Patient Safety

| Classification (1), Concept (2) Class (3), Semantic Relationship (4) | Patient (5), Healthcare (6) Health (7) | Safety (8) Patient Safety (13) |

Contributing Factors/Hazards (28)

Influences → ← *Informs*

Hazard (9), Circumstance (10) Event (11), Agent (12), Violation (16), Error (17), Risk (18), System Failure (46)

Incident Recovery

Patient Characteristics (30)

Patient Safety Incident (15)

Incident Type (29)

Incident Characteristics (32)

Attributes (31)

Attributes (31)

Healthcare Associated Harm (14), Reportable Circumstance (19), Near Miss (20), No Harm Incident (21), Harmful Incident (Adverse Event) (22), Adverse Reaction (33), Side Effect (34) Preventable (35)

Influences → **Detection (36)** ← *Informs*

Incident Recovery

Influences → **Mitigating Factors (37)** ← *Informs*

Informs ← **Patient Outcomes (38)**   **Organizational Outcomes (40)** → *Informs*

Harm (23), Disease (24) Injury (25), Suffering (26) Disability (27), Degree of Harm (39)

Accountable (44) Quality (45)

Ameliorating Actions (41)

Influences ← → *Informs*

Actions Taken to Reduce Risk (42) *(left vertical bar)*

Actions Taken to Reduce Risk (42) *(right vertical bar)*

System Resilience (Proactive & Reactive Risk Assessment)

Resilience (43)

More than words

Conceptual Framework for the International Classification for Patient Safety

Technical Report January 2009

World Health Organization   Patient Safety

Risk assessment

Risk assessment programme overview
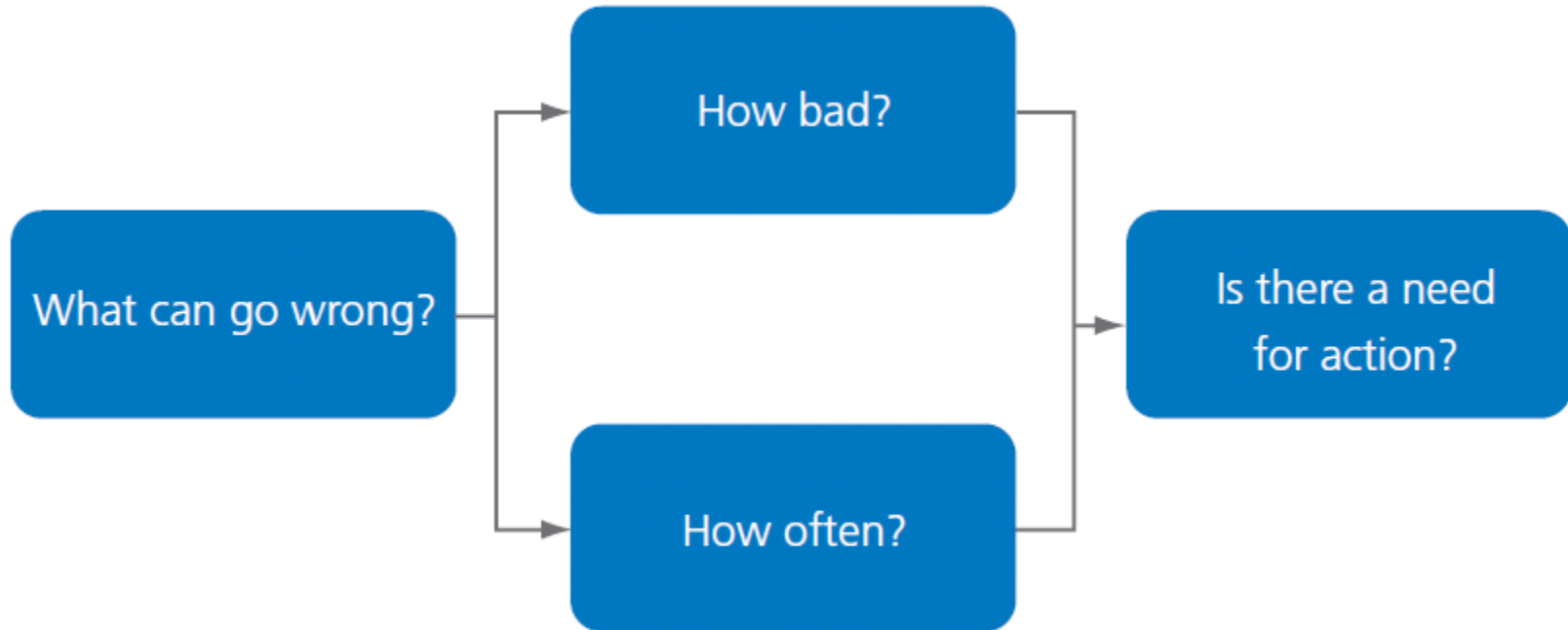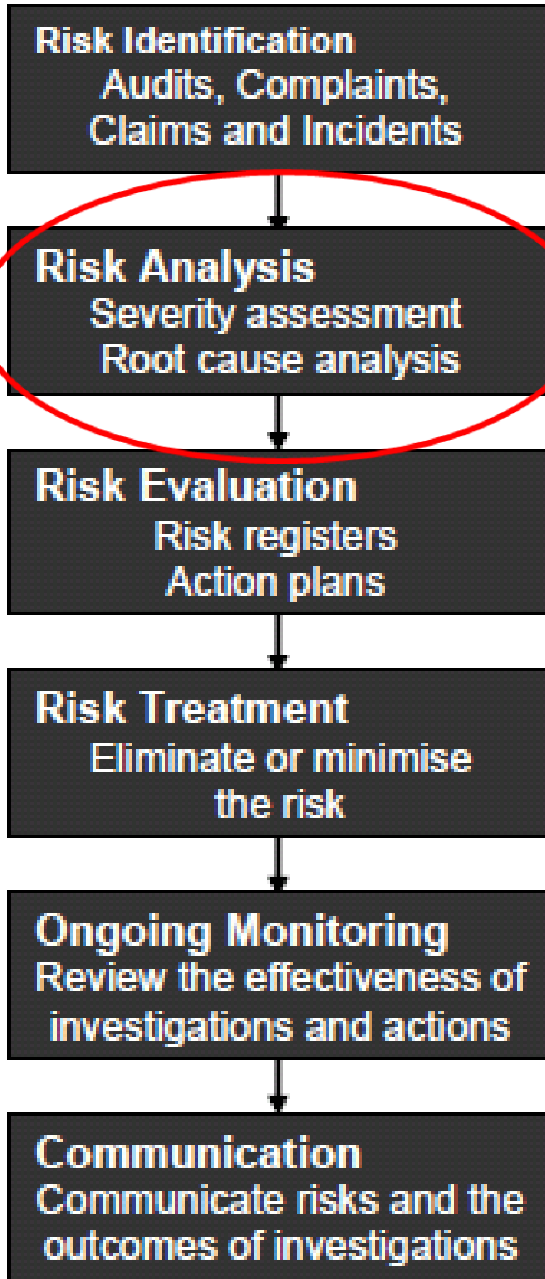National Patient Safety Agency. November 2006 ©

Table 1. Patient safety culture maturity levels

Maturity Levels	Approach to Improving Patient Safety Culture
Pathological	No systems in place to promote a positive safety culture
Reactive	Systems are piecemeal, developed only in response to occurrences and/or regulatory or accreditation requirements
Calculative	Systematic approach to patient safety exists, but implementation is patchy and inquiry into events is limited to circumstances surrounding specific event
Proactive	Comprehensive approach to promoting a positive safety culture exists; evidence-based intervention implemented across the organization
Generative	Creation and maintenance of a positive safety culture are central to mission of the organization; organization evaluates the effectiveness of interventions and drains every last drop of learning from failures and successes and takes meaningful action to improve

Adverse Event Management Process

Risk Identification
Audits, Complaints, Claims and Incidents

Risk Analysis
Severity assessment
Root cause analysis

Risk Evaluation
Risk registers
Action plans

Risk Treatment
Eliminate or minimise the risk

Ongoing Monitoring
Review the effectiveness of investigations and actions

Communication
Communicate risks and the outcomes of investigations

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Severity assessment

Action Required

1	**Extreme risk** – immediate action required – Reportable Incident Brief (RIB) for all SAC 1 incidents must be forwarded to the DoH within 24 hours. A Privileged Root Cause Analysis (RCA) investigation must be undertaken for all Clinical SAC 1 incidents with a report being submitted to the DoH.
2	**High risk** – need to notify senior management. Detailed investigation required. Ongoing monitoring of trended aggregated incident data may also identify and prioritise issues requiring a practice improvement project.
3	**Medium risk** – management responsibility must be specified – Aggregate data then undertake a practice improvement project. **Exception** – all financial losses must be reported to senior management.
4	**Low risk** – manage by routine procedures – Aggregate data then undertake a practice improvement project.

NB – An incident that rates a SAC 2, 3 or 4 should only be reported to the DoH if there is the potential for media interest or requires direct notification under existing DoH legislative reporting requirements or NSW DoH Policy Directive.

		CONSEQUENCE			
LIKELIHOOD		**Serious**	**Major**	**Moderate**	**Minor**	**Minimum**
	Frequent	1	1	2	3	3
	Likely	1	1	2	3	4
	Possible	1	2	2	3	4
	Unlikely	1	2	3	4	4
	Rare	2	3	3	4	4

Example from a Danish hospital – Action on different incidents

Type of accident	Classifikation	Method
Suicide		Root cause analysis
Medicine errors	SAC = 3 SAC < 3	Root cause analysis Local analysis
Confusion Surgery		Root cause analysis
Incidents	Faktuel score 2 Potentiel score 3	Aggregeted root cause analysis
Complaints and compensation		Journal audit

Adverse Event Management Process

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løbe over flere linjer

Risk Identification
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Communicate risks and the
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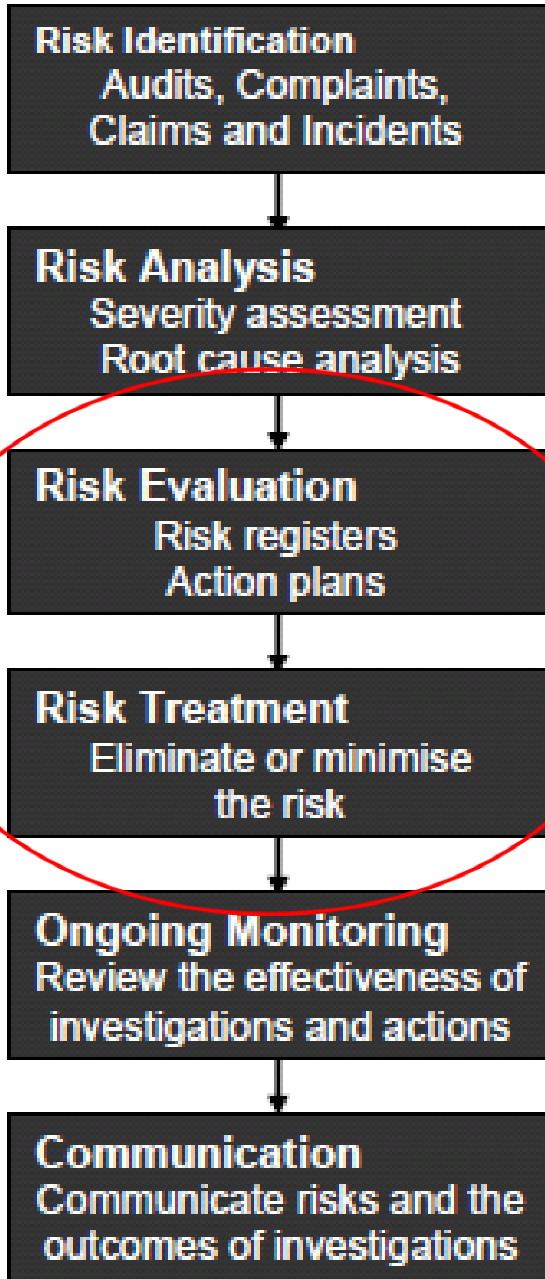
Risk evaluation and action

Human Error Type	Typical Forms	Common Prevention Strategies
Slip / Lapse	• Double capture • Omission • Interference • Perceptual Confusion	• Minimise interruptions • Forcing functions • Colour-coding, highlighting differences • Checklists, memory aids
Rule-Based Mistake	• Strong-but-wrong • Exception to rule • Cognitive overload	• Minimise / highlighteexceptions • Provide feedback • Manage workload
Knowledge-Based Mistake	• Confirmation bias • Out of sight, out of mind • Encystment • Vagabonding	• Decision support • Team work & CRM training

Risk Identification
Audits, Complaints,
Claims and Incidents

Risk Analysis
Severity assessment
Root cause analysis

Risk Evaluation
Risk registers
Action plans

Risk Treatment
Eliminate or minimise
the risk

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Review the effectiveness of
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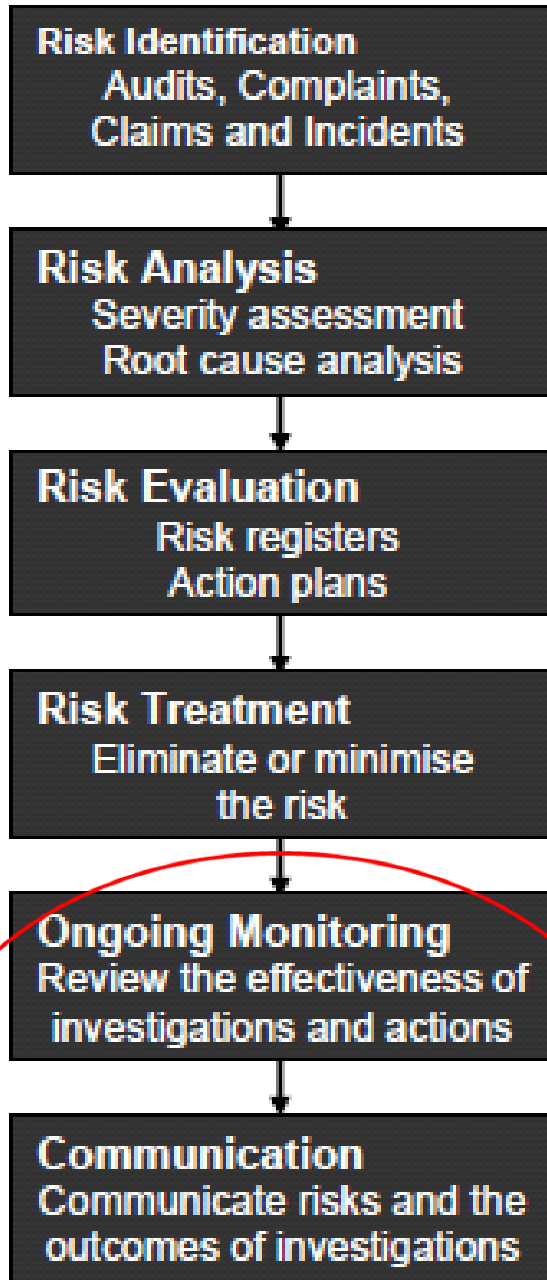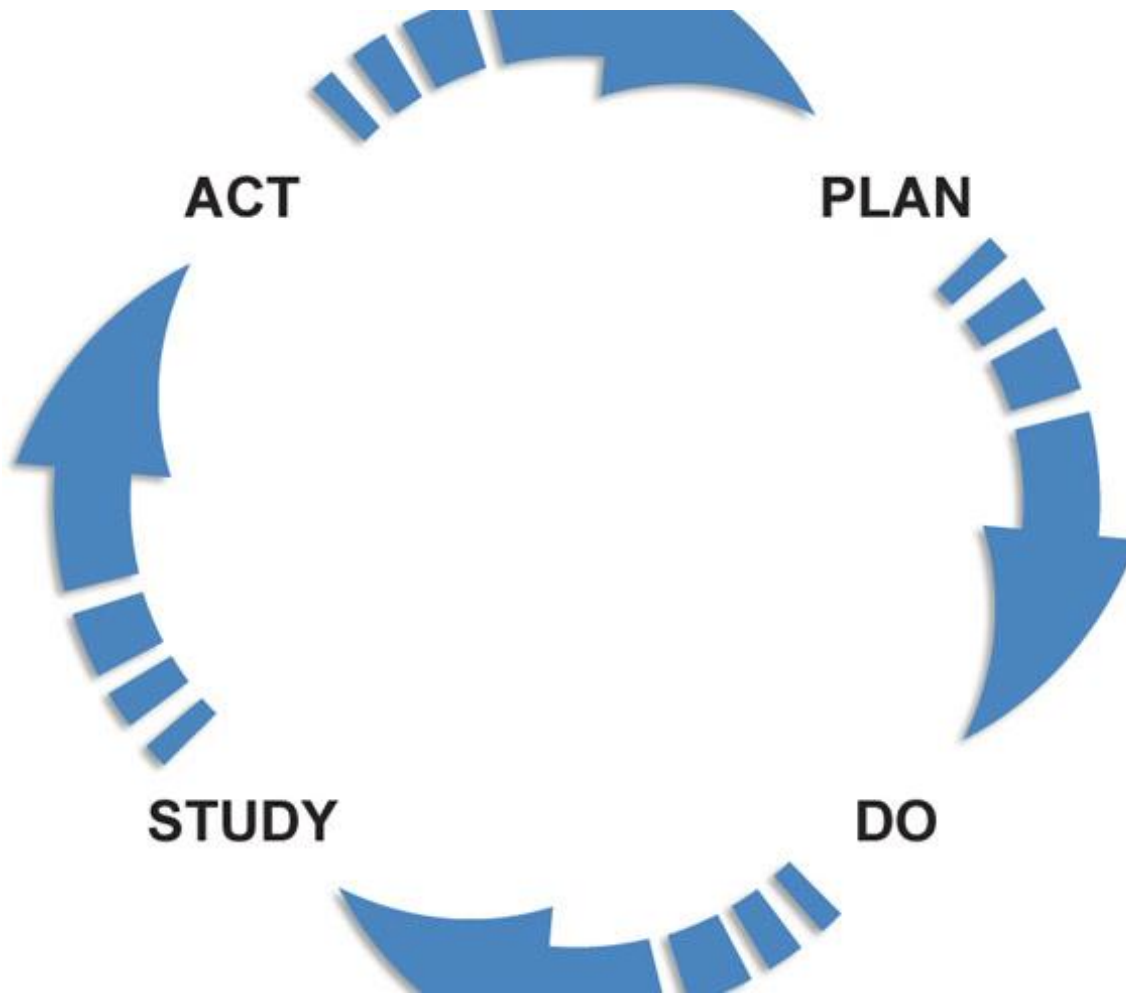# Adverse Event Management Process
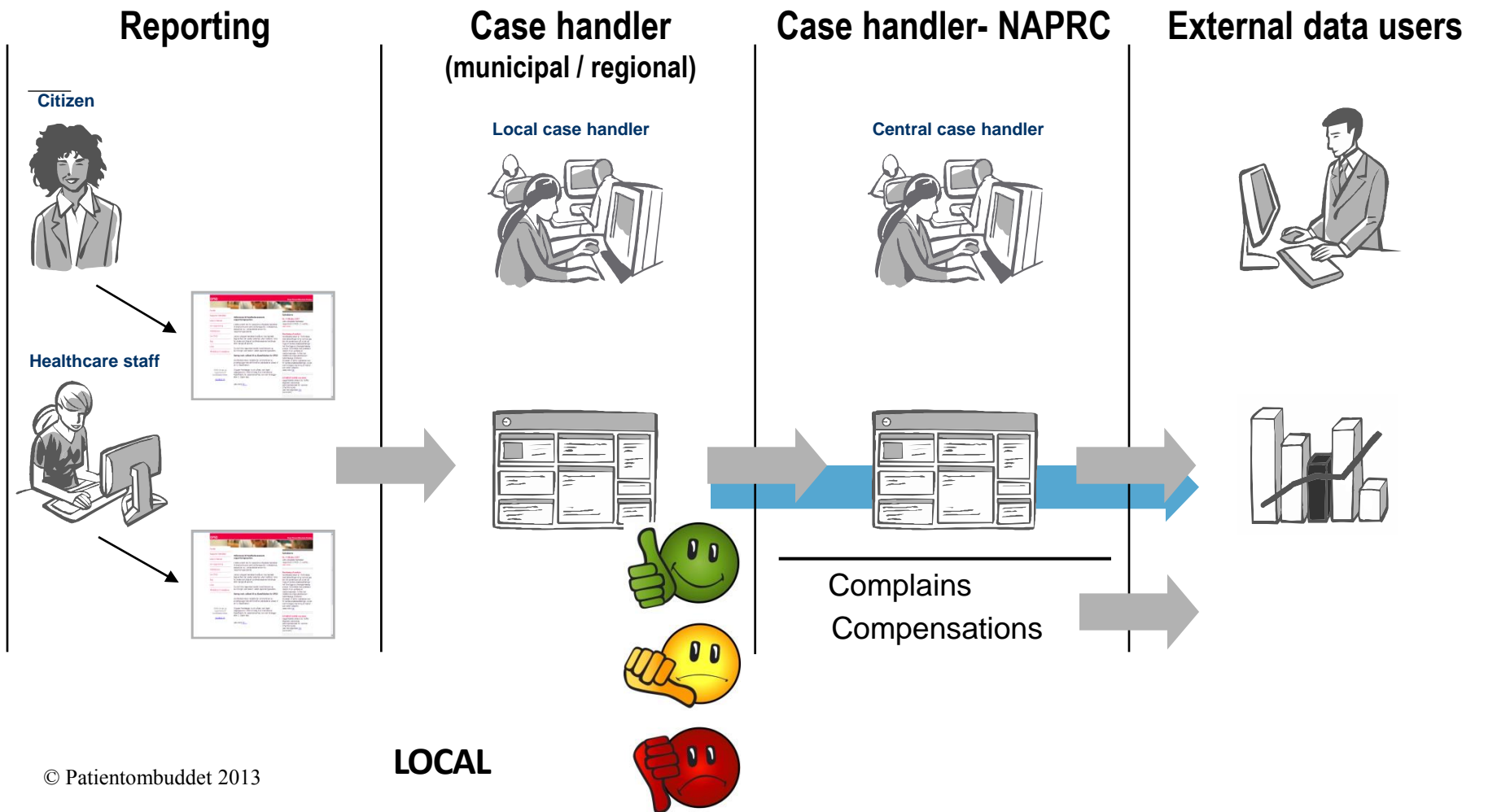
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1. **PLAN:** Plan a change or test of how something works.

2. **DO:** Carry out the plan.

3. **STUDY:** Look at the results. What did you find out?

4. **ACT:** Decide what actions should be taken to improve.

5. **Repeat as needed until the desired goal is achieved**

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Eksempel – The Danishs Case flow

NATIONAL

Reporting	Case handler (municipal / regional)	Case handler- NAPRC	External data users

Citizen

Healthcare staff

Local case handler

Central case handler

Complains
Compensations

LOCAL

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Source of error analysis - from beginning to end

Step 1:
Select the topic or issue.

Step 2:
Establish the analysis team.

Step 3:
Develop workflow and identify risk areas

Step 4:
Identify the underlying causes.

Step 5:
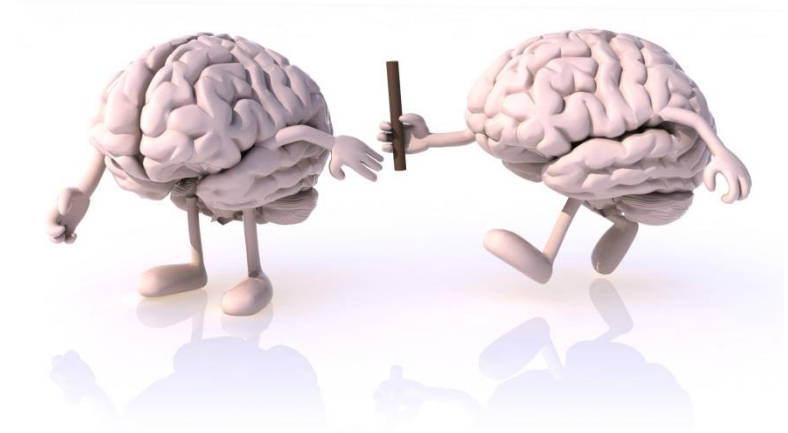Prepare action plans and monitoring plan.

Step 6:
Produce source of error analysis report

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TIME TO LEARN

FEJLKILDEANALYSE
METODEBESKRIVELSE

Patientsikkerhed
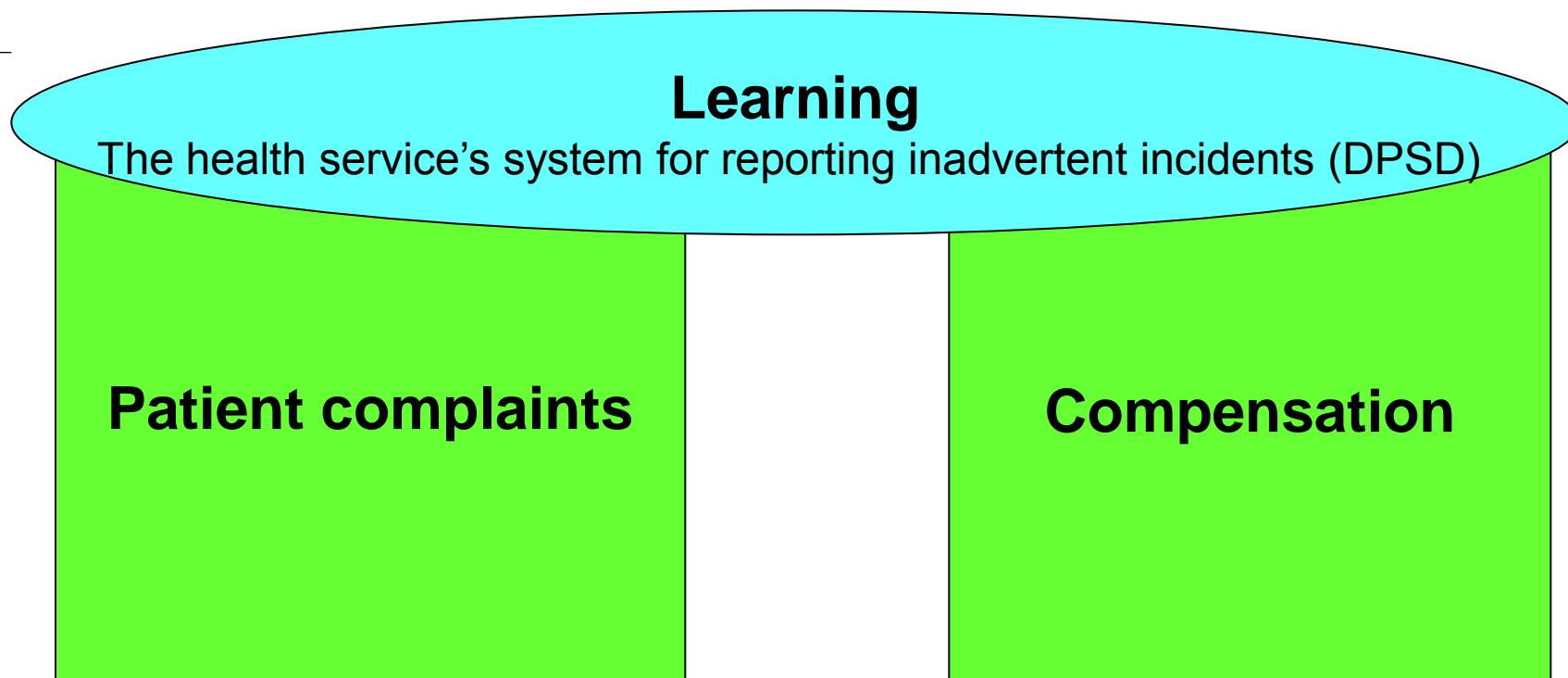
Act on Patient Safety

— Frontline personnel in hospitals and in the primary care sector are obligated to report adverse events to a national reporting system
Patients and relatives may report adverse events.

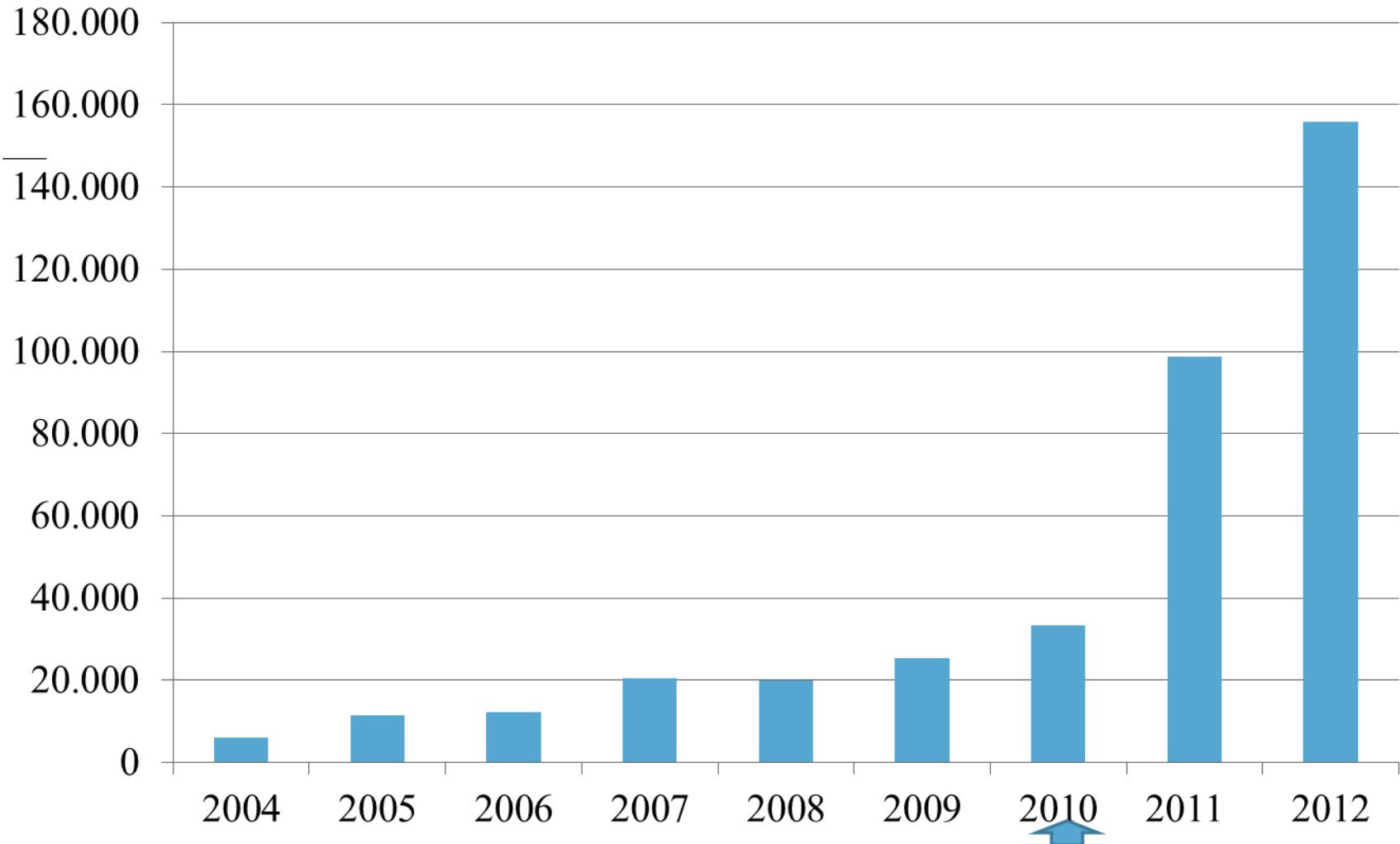Regions and municipalities are obligated to act on the reports.

The Danish National Agency for Patients' Rights and Complains is obligated to communicate the learning nationally.

The purpose of the reporting system is to learn, not punish.

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Learning
The health service's system for reporting inadvertent incidents (DPSD)

Patient complaints

Compensation

Adverse events reported in 2012 in percent WHO international classification for Patient Safety (ICPS)	Municipals	Regional	Private	Other regional
Adminstrative processes	1,9			
Blood and blood components	0			
Buildings and infrastructure	0,1			
Gases and air for medical use	0			
Individual-team-organisation	0			
Infection	,1			
Clinical processes	1,3	19,9	8,5	22,7
Communication og documentation	2,9	17,8	12,4	18,9
Medication	68,8	23,9	40,3	29,4
Medication equipment	0,3	4,3	4,7	1,1
Patient accidents	21,6	6,7	8,3	0,7
Self-harm, suicide attemps or suicide	0,1	0,9	0	0,1
Other incident type	1,5	3,1	3	1,2

Defined as: Medication Incidents include, for example prescribing the wrong drug or wrong dose, administering the wrong preparation or strength, and medication at the wrong time.

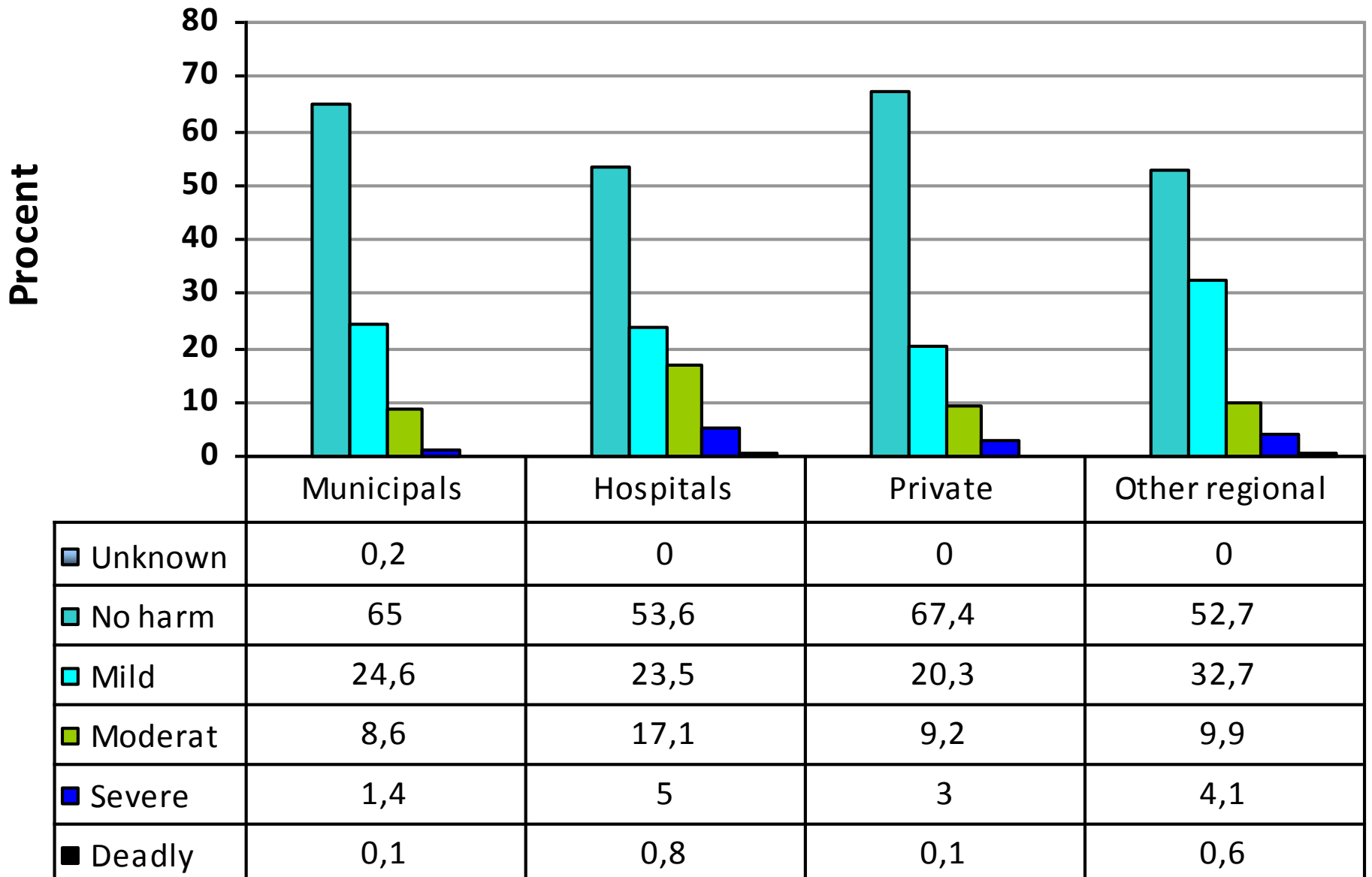![Patientombuddet - The Danish National Agency for Patients' Rights and Complaints]

Medication Incidents - Process

Medication Incidents - Problem

Defined as: Wrong dose due to improper strength and / or quantity. Wrong time. Not given. lack of discontinuation

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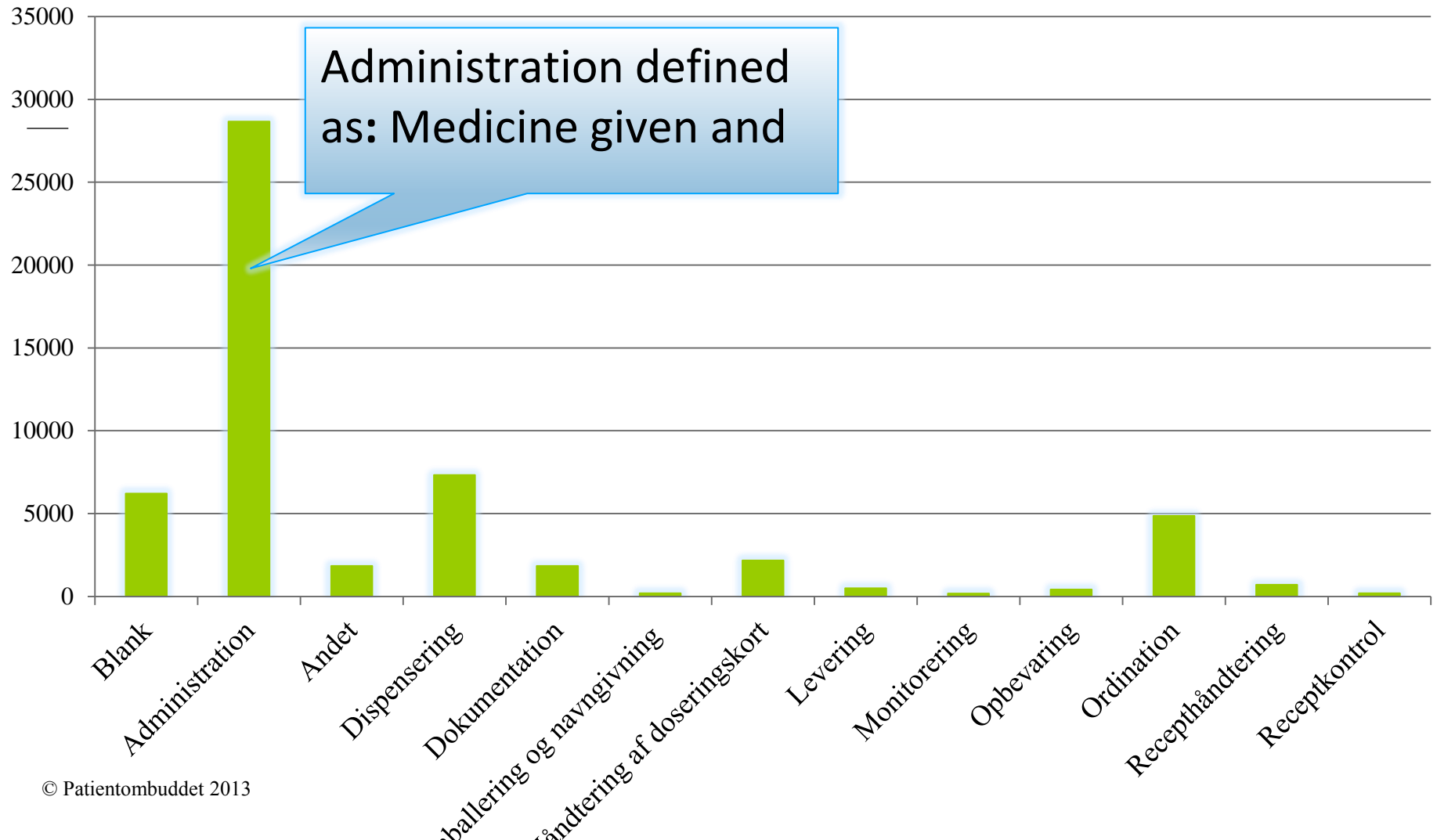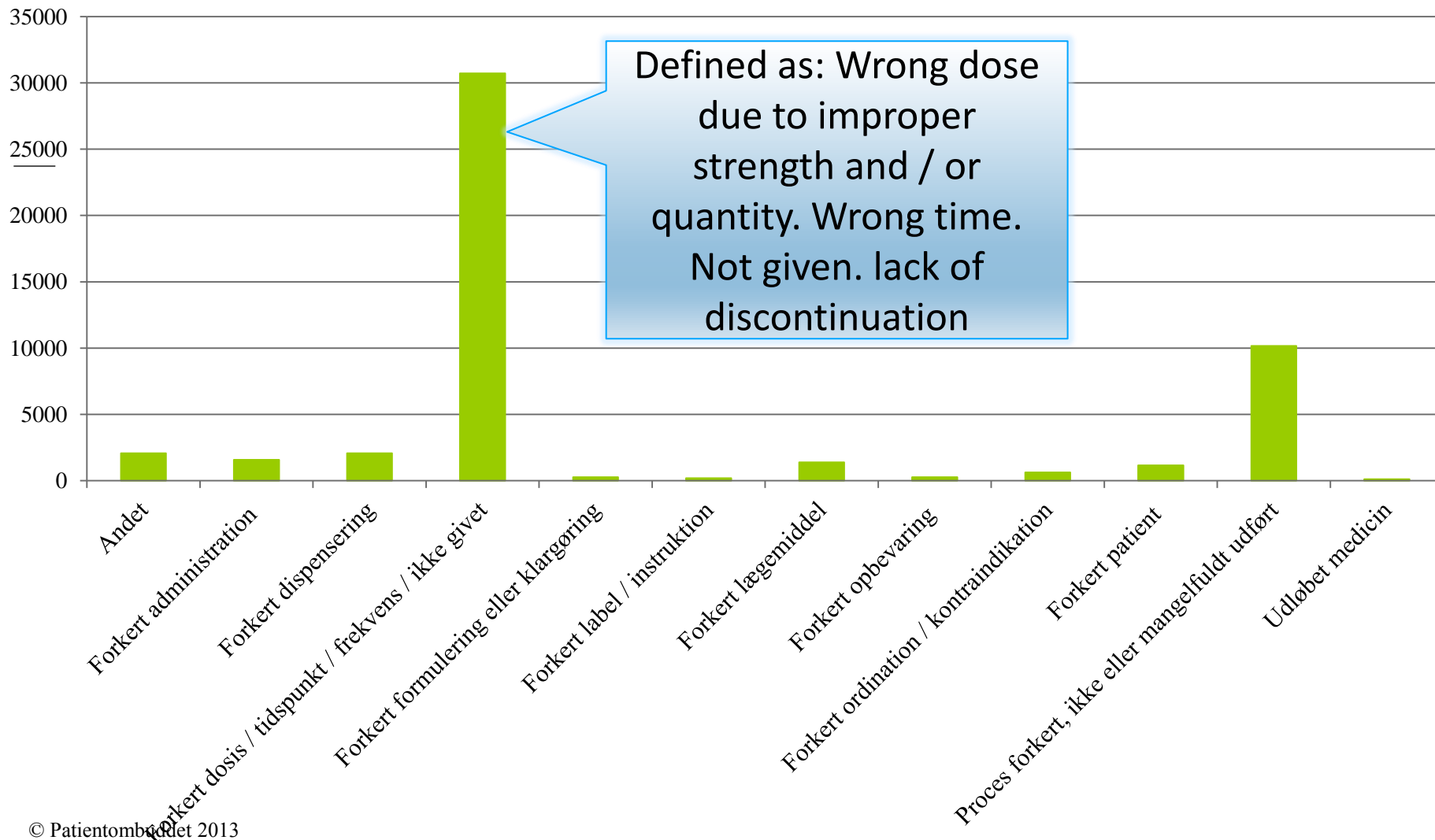
Severity	Harm
No harm	No harm
Mild	Slight transient injury that does not require increased treatment or increased management efforts
Moderat	Transient injury requiring hospitalization or treatment by a medical practitioner or increased management efforts or for hospitalized patients increased treatment.
Serious	Permanent injuries requiring hospitalization or treatment by a medical practitioner or increased management efforts or for hospitalized patients increased treatment, or other injuries that require urgent life-saving treatment.
Deadly	Deadly

Adverse events reported in 2012 in percent

	Municipals	Hospitals	Private	Other regional
■ Unknown	0,2	0	0	0
■ No harm	65	53,6	67,4	52,7
■ Mild	24,6	23,5	20,3	32,7
■ Moderat	8,6	17,1	9,2	9,9
■ Severe	1,4	5	3	4,1
■ Deadly	0,1	0,8	0,1	0,6

Incidents – assessed every week

- The incidents classified as 'dead'

- Medicine incidents classificed as;
  - moderate
  - serious
  - dead

Publications

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

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THANK YOU

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