

Patient Safety Indicators

Challenges and Experiences

from the SimPatIE project

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Why assess patient safety?

- Initiatives to improve patient safety have **high priority** among health professionals and politicians in most developed countries
- A growing body of experience and evidence suggests that the daily practice of care **does not correspond to the standards** that the medical profession itself puts forward
- The exact incidence and prevalence of patient safety quality problems are **unknown**
- Currently, however, assessment of patient safety problems relies mainly on **case-based methodologies**. The evidence for their efficiency and reproducibility, proving that safety of care has improved with their usage, is questionable
- Does better organisation and management of medical care allow hospitals to improve and **spend their health care expenses more wisely?**
- It has been documented that performance and outcome measures can improve the quality of care. Such measures have supported accountability and transparency, helped to make judgements and set priorities, enabling comparison over time between providers and the effectiveness of interventions

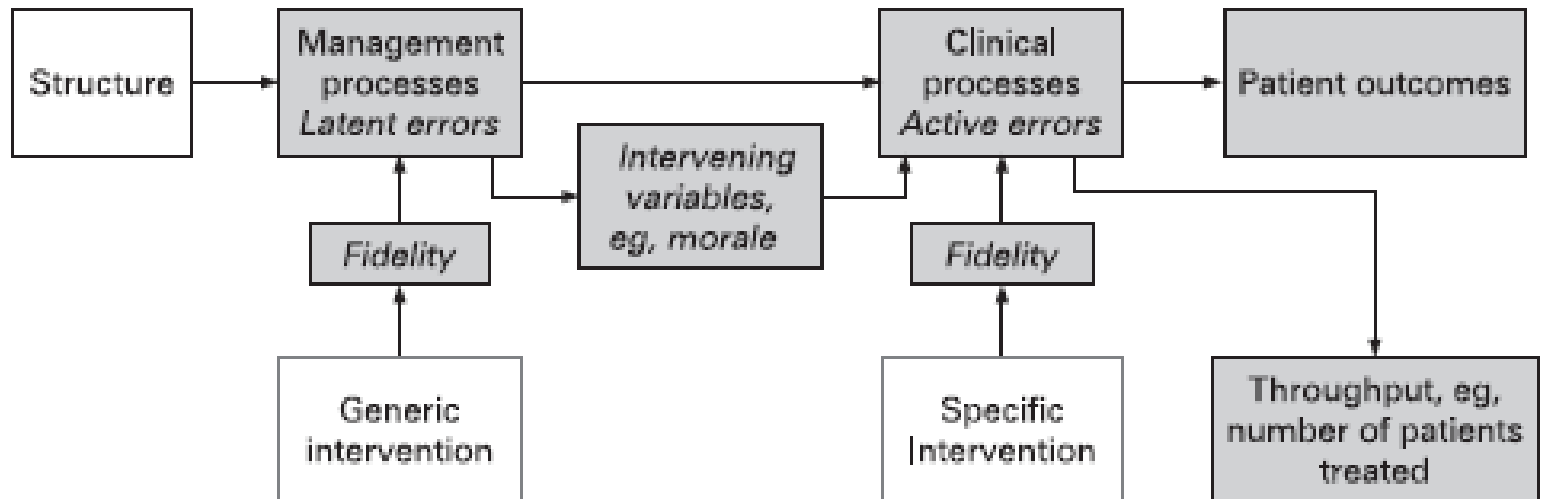


Work Process

<p>Planning phase</p>	<ol style="list-style-type: none"> 1. Chose the area of patient safety to develop <ul style="list-style-type: none"> • Establish frame work and importance (high volume, cost, variation, feasibility) • Identify opportunities for improvement of safety 2. Select and organise the developmental team and assign task
<p>Developmental phase</p>	<ol style="list-style-type: none"> 3. Provide an overview of existing evidence, methods and practices for potential safety of care indicators 4. Select process, structure and outcome indicators (and standards) <ul style="list-style-type: none"> • Identify confounding factors (risk adjustment) • Establish consensus and rating procedures 5. Characterize the indicators <ul style="list-style-type: none"> • Define indicators by their aspects of patient safety and aim • Identity the setting, the target problem or population • Determine inclusion and exclusion criteria • Define risk adjustment strategy • Identify data sources • Describe data collection procedures
<p>Test phase</p>	<ol style="list-style-type: none"> 6. Evaluate the selected patient safety indicators 7. Validate the Psychometric properties 8. Adjust indicator characterisations – recommend validated indicators



Conceptual Framework - Assessment of Patient Safety



Active errors are those whose effect are directly experienced²

Latent errors involve adverse consequences that may lie dormant in the system becoming apparent only when they combined with other facets to penetrate a systems defences²



1. C Brown et al. An epistemology of patient safety research: a framework for study design and interpretation. Part 3. End points and measurement. *Qual. Saf. Health Care* 2008;17;170-177
2. Reason Human error. New York: Cambridge University Press. 1990

Definition of a PSI

PATIENT SAFETY INDICATORS ARE MEASURES THAT DIRECTLY OR INDIRECTLY MONITOR PREVENTABLE ADVERSE EVENTS

SimPatIE

- Safety of care indicators can be defined as measures assessing a particular healthcare process, structure or outcome, and as measuring tools, screens or flags used as guides to monitor, evaluate, and improve the quality of care, clinical support services and organisational functions affecting safety of care
- Safety of care indicators are quality indicators, which prove to be valid within the specific framework of interpretation



Decided focus of the Indicators

Taking into account the frequency and severity of safety of care problems, as well as the existence of evidence-based interventions towards problems, three indicator areas for hospital-related safety of care indicators were chosen:

- **Institution-wide indicators;**
defined to address general safety of care characteristics of healthcare organizations e.g. hand washing, culture of safety, HSMR
- **theme-specific indicators**
defined to flag preventable processes or outcomes, related to specific clinical themes, e.g. surgical complications, medication errors, obstetrics and falls
- **diagnosis-specific as well as other specific safety of care indicators**
defined to flag specific patient safety issues e.g. decubitus ulcer



Decided types of Indicators

- **Structural indicators**
describe the type and amount of resources used to deliver programs or services. They relate to the presence of e.g. number of staff, money, beds, buildings, education
- **Process indicators**
describe what the provider did for the patient and how well it was done, processes are the series of interrelated activities undertaken to achieve a certain objective
- **Outcome indicators**
describe states of health or events that follow care and that may be affected by safety
- **Sentinel indicators versus rate-based indicators** (frequency)
Individual event level / Aggregated event level
- **Institutional versus system level Indicators**



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Test phase	<ol style="list-style-type: none">6. Evaluate the selected patient safety indicators7. Validate the Psychometric properties8. Adjust indicator characterisations – recommend validated indicators



Characterisation of PSIs

SCHEME FOR CLASSIFICATION OF PATIENT SAFETY INDICATORS	
DIMENSION OF CLASSIFICATION	DESCRIPTION
Title	
Sheet no.	
Description	
Indicator category	
Source(s)	
Evidence Supporting the Criterion of Patient Safety	
Data definitions	
Denominator Description	
Numerator Description	
Data Source	
Care Setting	
Professionals Responsible for Health Care	
Lowest Level of Health Care Delivery Addressed	
Level of Determination of Patient Safety	
Allowance for Patient Factors	
Stratification by Vulnerable Populations	
Standard of Comparison	
Extent of Measure Testing	
Scoring	



Evaluation of the Indicators

EVALUATION QUESTIONNAIRE			
Dimension	Definition		Score
Relevance and Appropriateness	Are areas of significance covered (severity and frequency) in terms of patient safety within its specified domain (population and/or organisation)?		1-3 Low degree of relevance 4-6 Medium degree of relevance 7-9 High degree of relevance
Validity and Reliability	Is the instrument satisfactory in terms of: -Construct validity (Evidence-based) -Internal consistency -Exhaustiveness/exclusiveness -Reliability		1-3 Low degree of validity 4-6 Medium degree of validity 7-9 High degree of validity
Feasibility	How is the: -Availability of data -Clinical burden of data collection		1-3 Low degree of feasibility 4-6 Medium degree of feasibility 7-9 High degree of feasibility
SCORING SHEET			
Title of the evaluated instrument:			
Scores			Any additional comments
Relevance and Appropriateness	Validity and Reliability	Feasibility	
Score from 1-9	Score from 1-9	Score from 1-9	Free text



Implementation was recommended according to four categories

1. Immediately workable 'throughout' the European healthcare systems
2. Immediately workable 'in parts' of the European healthcare systems
3. At present not workable for implementation in Europe -
Recommendation for future decision on implementation or
4. Not suitable as a PSI for recommendation in Europe



Recommended PSI (1)

INDICATOR CATEGORY AND NAME	SOURCE ¹	APPLICATION ²
INSTITUTION-WIDE Patient Safety Indicators		
Measuring Hospital Standardised Mortality Rates	SimPatIE	2
Transition of Care – Patients’ Understanding of the Purpose of their Medication	SimPatIE	2
Institution-Wide Use of Cultural Assessment	SimPatIE	1
Surveying the Development of the Patient Safety Culture	SimPatIE	1
THEME-RELATED Patient Safety Indicators: “INFECTION CONTROL”		
Hospital-Acquired Infection Registration – Post Operative Wound Infections	SimPatIE	2
Wound Infection	OECD, CSP	1
Ventilator Pneumonia	OECD	2
Hand Hygiene - Measured by Alcohol Consumption	SimPatIE	1
THEME-RELATED Patient Safety Indicators: “SURGICAL COMPLICATIONS”		
Complications of Anaesthesia	AHRQ, CIHI, OECD	2
Postoperative Sepsis	AHRQ, OECD	1
Postoperative Haemorrhage or Haematoma	AHRQ	1
Postoperative Physiologic Metabolic Derangements	AHRQ	2
Postoperative Respiratory Failure	AHRQ	2

1. Agency for Healthcare Research and Quality (AHRQ) - Canadian Institute for Health Information (CIHI) Complication Screening Programme (CSP) - Joint Commission on accreditation in Health Care (JCAHO) Organisation for Economic Co-operation and Development (OECD) - The Danish National Indicator Project (NIP)
2. Application: 1. Immediately workable throughout the European healthcare systems & 2. Workable in parts of Europe

Recommended PSI (2)

INDICATOR CATEGORY AND NAME	SOURCE ¹	APPLICATION ²
THEME-RELATED Patient Safety Indicators: “MEDICATION ERRORS”		
Transfusion Reaction	AHRQ, CIHI OECD	2
Wrong Blood Type	OECD	2
Electronic Trigger Tool - Surveillance of Adverse Drug Events	SimPatIE	2
THEME-RELATED Patient Safety Indicators: “OBSTETRICS”		
Obstetric Trauma – Vaginal Delivery without Instrument	AHRQ, JCAHO	2
Obstetric Trauma – Vaginal Delivery with instrument	AHRQ, CIHI, OECD	2
Birth Trauma – Injury to Neonate	AHRQ, CIHI, OECD	2
THEME-RELATED Patient Safety Indicators: “IN-HOSPITAL FALL”		
Postoperative Hip Fracture	AHRQ, CIHI, OECD	1
In-Hospital Hip Fracture or Fall	OECD,CSP	1
DIAGNOSIS-SPECIFIC AS WELL AS OTHER SPECIFIC Patient Safety Indicators		
Decubitus Ulcer	AHRQ, CIHI, OECD	1
Assessment of Suicidal Risk in Schizophrenic Patients	NIP	2
Assessment of Side Effects of Anti-Psychotic Treatment	NIP	2

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2. Application: 1. Immediately workable throughout the European healthcare systems & 2. Workable in parts of Europe

Not Recommended PSI (1)

INDICATOR CATEGORY AND NAME	SOURCE ¹	APPLICATION ²
INSTITUTION-WIDE Patient Safety Indicators		
Death in Low-Mortality DRGs	AHRQ	3
Patients Experiencing Adverse Events	SimPatIE	3
Patients Informed about an Adverse Event by the Staff	SimPatIE	3
Patient Experiences of Adverse Events Management	SimPatIE	3
THEME-RELATED Patient Safety Indicators: “INFECTION CONTROL”		
Selected Infections due to Medical Care	AHRQ, OECD	4
Hand Hygiene - Staff’s Compliance with Guidelines for Use of Jewellery	SimPatIE	4
THEME-RELATED Patient Safety Indicators: “SURGICAL COMPLICATIONS”		
Foreign Body Left during Procedure	AHRQ, CIHI, OECD	4
Postoperative Pulmonary Embolism or Deep Vein Thrombosis	AHRQ, CIHI, OECD	4
Accidental Puncture or Laceration	AHRQ, OECD	3
Wrong Site Surgery	JCAHO, OECD	3
Medical Equipment-Related Adverse Events	JCAHO, OECD	3
Patients Experiencing Harmful Surgical Adverse Events	SimPatIE	3

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2.3. At present not workable for implementation in Europe – Recommendation for future decision on implementation and 4 .Not suitable as a PSI for recommendation in Europe

Not Recommended PSI (2)

INDICATOR CATEGORY AND NAME	SOURCE ¹	APPLICATION ²
THEME-RELATED Patient Safety Indicators: “MEDICATION ERRORS”		
Medication Error (Did not fulfil the criteria as an indicator, therefore deleted)	JCAHO, OECD	-
THEME-RELATED Patient Safety Indicators: “OBSTETRICS”		
Obstetric trauma – Caesarean Delivery	AHRQ, OECD	3
Problems with Childbirth	ACSQ, OECD	3
THEME-RELATED Patient Safety Indicators: “IN-HOSPITAL FALL”		
Patient Falls	JCAHO, OECD	4
” DIAGNOSIS-SPECIFIC AS WELL AS OTHER SPECIFIC Patient Safety Indicators		
Failure to Rescue	AHRQ	4
Iatrogenic Pneumothorax	AHRQ	3

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Summary Results

- A total of 24 indicators were recommended for use in Europe:
 - **9 indicators were recommended for implementation across EU**
 - 6 indicators from were from known indicator programmes, mainly originating from the AHRQ and OECD
 - 3 were newly established SimPatIE indicators
 - **15 safety of care indicators were recommended for application in parts of EU**
 - 9 indicators from were from known indicator programmes, mainly originating from the AHRQ and OECD
 - 4 were newly established SimPatIE indicators
- 23 indicators were rate-based and 1 was a sentinel indicator flagging 'wrong blood type'
- Application of a number of these indicators are regarded sensitive to bias caused by patient disease severity, comorbidities and/or lifestyle factors



Challenges

- As the indicators were evaluated for feasibility, aspects such as **data availability, quality of administrative data, resources available for indicator monitoring, organisation of data collection, legal systems concerning data collection of individual data** etc. were identified as areas characterized by **great variation** in the European countries
- As these aspects were not covered by the aim of the project, they **remain to be investigated and systematically** uncovered for Europe, if the recommendations on safety of care indicators are to be used for other purposes other than local monitoring of safety of care, e.g. national or European benchmarking.



Hurdles in applying PSIs

- Underreporting - identification of problems and when to report¹
- Coding practices - ICD 9 /10 and 1. & 2 diagnosis¹
- How to interpret variations in results when comparing; Do they mirror true differences in PS and / or variation in coding and data quality?¹
- Examination of the sensitivities, specificities, positive predictive values, and positive likelihood ratios of five surgical AHRQ PSIs revealed that sensitivities and PPVs were moderate²
- What is the relation between organisational processes and clinical processes and like wise between clinical processes and outcomes³
- What is the value of outcome measures? *What does the number of planes crashed tell about the safety of flying?*

1. Saskia Drösler et al. Application of patient safety indicators internationally: a pilot study among seven countries. *International Journal for Quality in Health Care*, April 2009; pp. 1–7
2. Patrick S. Romano et al. Validity of Selected AHRQ Patient Safety Indicators Based on VA National Surgical Quality Improvement Program Data. *Health Serv Res.* 2009 Feb;44(1):182-204. Epub 2008 Sep 17.
3. C Brown et al. An epistemology of patient safety research: a framework for study design and interpretation. Part 3. End points and measurement. *Qual. Saf. Health Care* 2008;17;170-177



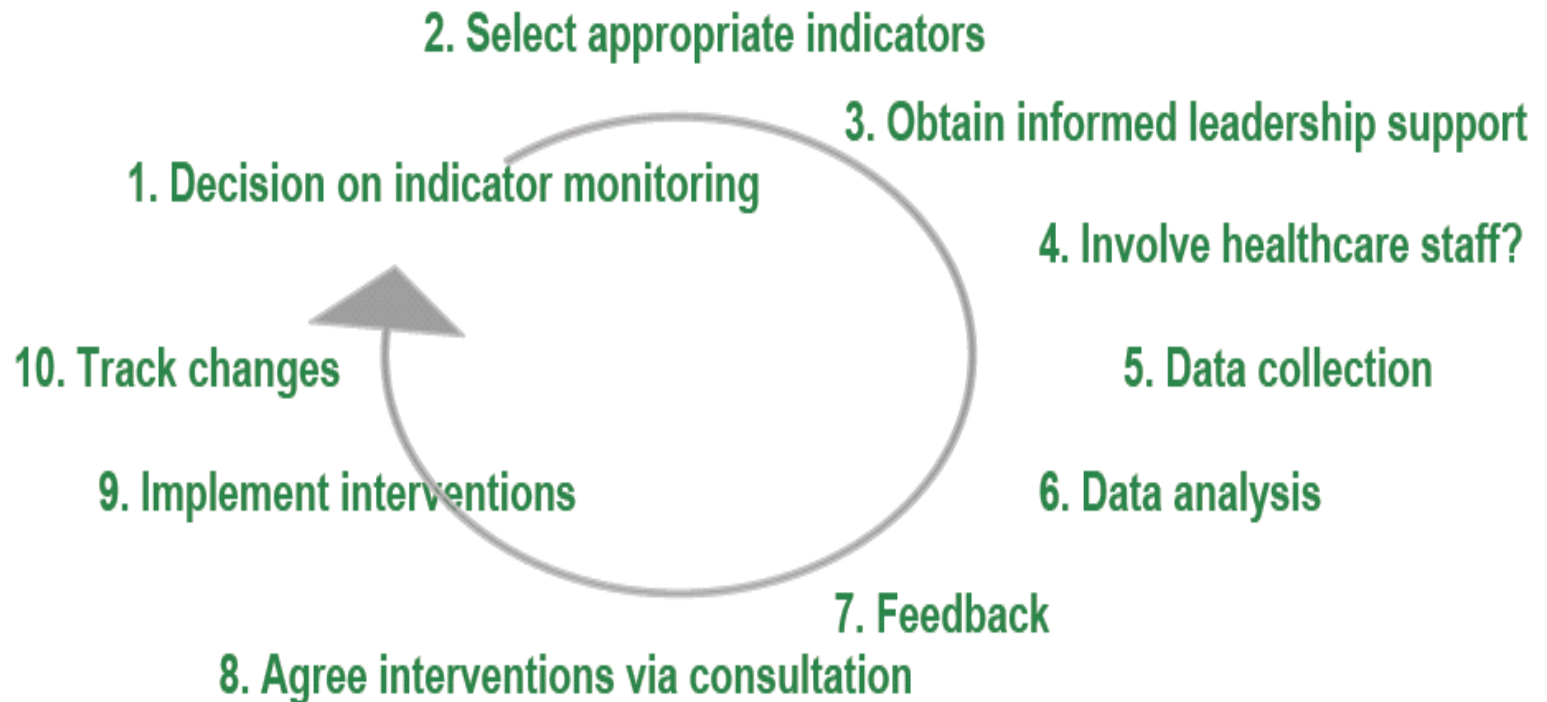
What did we learn?

- Patient safety is an outcome of many factors, especially safe practices within the framework of a safe system - what ultimately determines safety is a safer care environment during the patients' whole "journey of care"
- Indicators could be based upon the RAND-Cooperation logic: "If....Then"¹
 - Example: If it is documented in the patient file, that the patient was given antibiotics then the patient must have a lab test stating an elevated level of infection, then the an in-hospital infection is identified
- The assessment of process should be carried out through both qualitative and quantitative methods - Triangulation could be a mean to broader understanding of lapses in PS
- Establishing an over view of a PS area must be based upon a number of aggregated PSI results covering organisational and clinical processes
- To establish easy and low cost continuous surveillance sophisticated data registration, evaluation, validation, and cross professional co-op is needed – it takes time!

1. www.RAND.org



Assessment planning



Conclusions SimPatIE Indicators

- 41 PSIs were selected and recommended as;
 - 9 PSIs immediately workable throughout EU health care systems
 - 15 PSIs immediately workable in parts of the EU health care systems
- Based upon; Administrative data, patients surveys, patient files
- More information; www.simpatie.org



Risk adjustment

In patient safety assessment, components relating to the medical care system can/should be isolated. This is accomplished by controlling for significant confounding factors that contribute to the outcome

In most cases, multiple factors contribute to a patient's risk or harm

Outcome measures must be adjusted for factors outside the health system influence if fair comparisons are to be made



Patient Safety at the EU Level - 2006



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COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

**Recommendation Rec(2006)7
of the Committee of Ministers to member states
on management of patient safety and prevention of adverse events in health care**

*(Adopted by the Committee of Ministers on 24 May 2006
at the 965th meeting of the Ministers' Deputies)*

”Recommends that governments of member states, according to their competencies:

.....

vi. develop reliable and valid indicators of patient safety for various health-care settings that can be used to identify safety problems, evaluate the effectiveness of interventions aimed at improving safety, and facilitate international comparisons”

.....



European Society
for Quality in Healthcare

The Patient Safety Indicators should

- Be used to help hospitals identify potential adverse events that might need further study
- Provide the opportunity to assess the incidence of adverse events using administrative data found in the typical discharge record
- Document the level of patient safety – development in PS?
- Provide transparency
- Support accountability
- Help make judgments and set priorities
- Be usable for comparisons (benchmarking; time - organizations)
- Support quality improvement, regulation, and accreditation
- Support patient choice of providers

