

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



THE SimPatIE – Project

- The SIMPATIE (Safety Improvement for Patients In Europe) project was among the accepted proposals for co-financing in the call for proposals from the European Commission on 'Public Health – 2004' (OJ 2004/C52, 27th February 2004)
- The SIMPATIE project started the 15th of February 2005. It had a duration of two years
- The Project was led by CBO in Holland and organised in several Work Packages, one was led by the European Society for Quality in health Care
- The objective of the project was to use Europe-wide networks of organizations, experts, professionals and other stakeholders to establish, within two years, a common European set of vocabulary, indicators, internal and external instruments for improvement of safety in health care
 - **Establish a set of evidence-based evaluated safety of care indicators to be applicable for use in clinical settings in European health care**

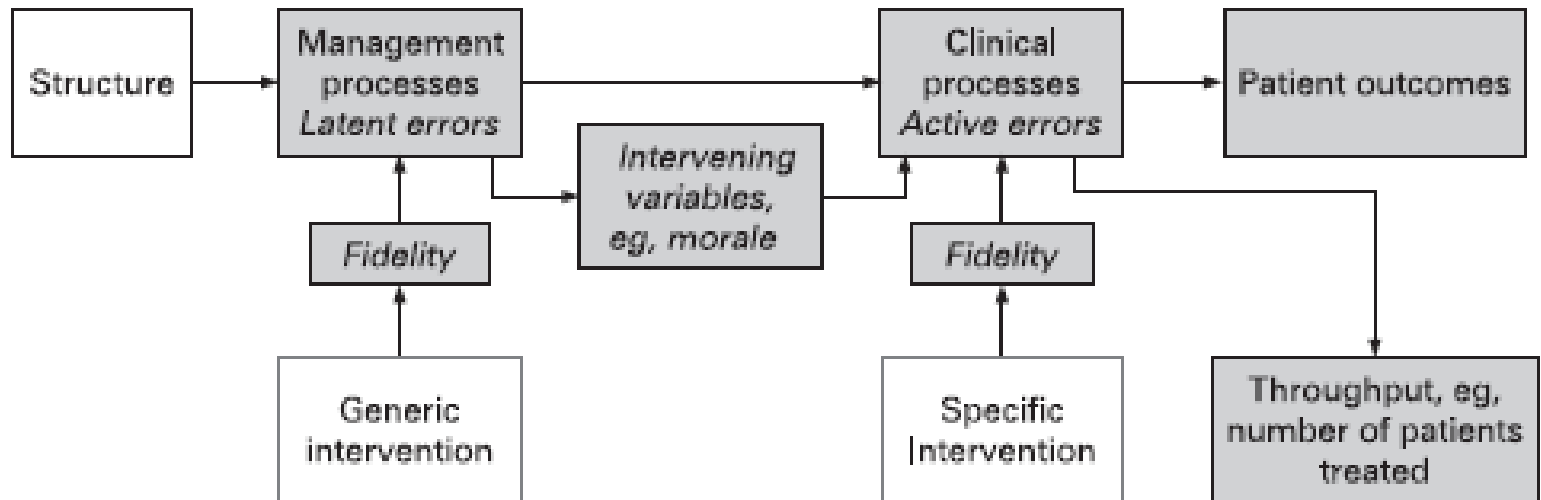


Work Process

| | |
|----------------------------|--|
| Planning phase | <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 safety2. Select and organise the developmental team and assign task |
| Developmental phase | <ol style="list-style-type: none">3. Provide an overview of existing evidence, methods and practices for potential safety of care indicators4. Select process, structure and outcome indicators (and standards)<ul style="list-style-type: none">• Identify confounding factors (risk adjustment)• Establish consensus and rating procedures5. 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 |
| 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 |



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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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 |

1. Agency for Healthcare Research and Quality (AHRQ) - Australian Council for Safety and Quality (ACSQ) - Canadian Institute for Health Information (CIHI) - Joint Commission on accreditation in Health Care (JCAHO) - Organisation for Economic Co-operation and Development (OECD)

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?

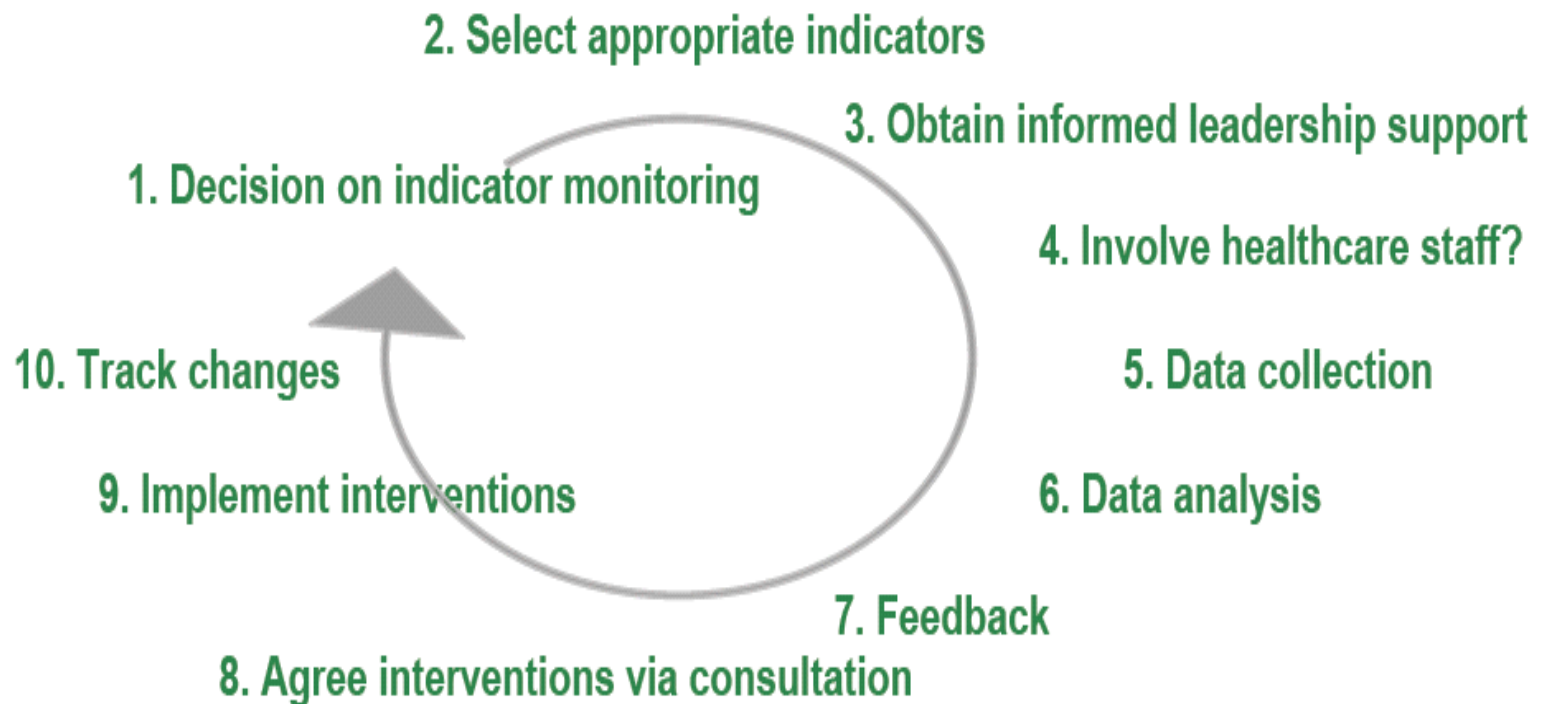
- Patient safety is an outcome of many factors, especially safe practices within the framework of a safe system - what ultimately determines safety is a safer care environment during the patients' whole "journey of care"
- Indicators could be based upon the RAND-Cooperation logic: "If....Then"¹
 - Example: 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





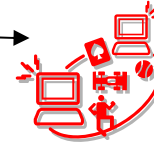
Assessment planning



Computerized data reporting by responsible clinicians at clinical units and departments

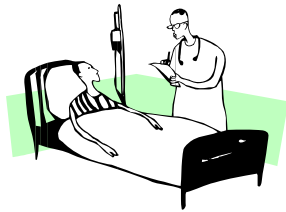


Datatransmission via internet



Clinical database

Clinical observations and data registration



Data analyses by a clinical epidemiologist



Regular feedback to clinical departments and unit

SAFETY IMPROVEMENT

Yearly feedback of risk adusted data



Local clinical audit



National clinical audit

Publication



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

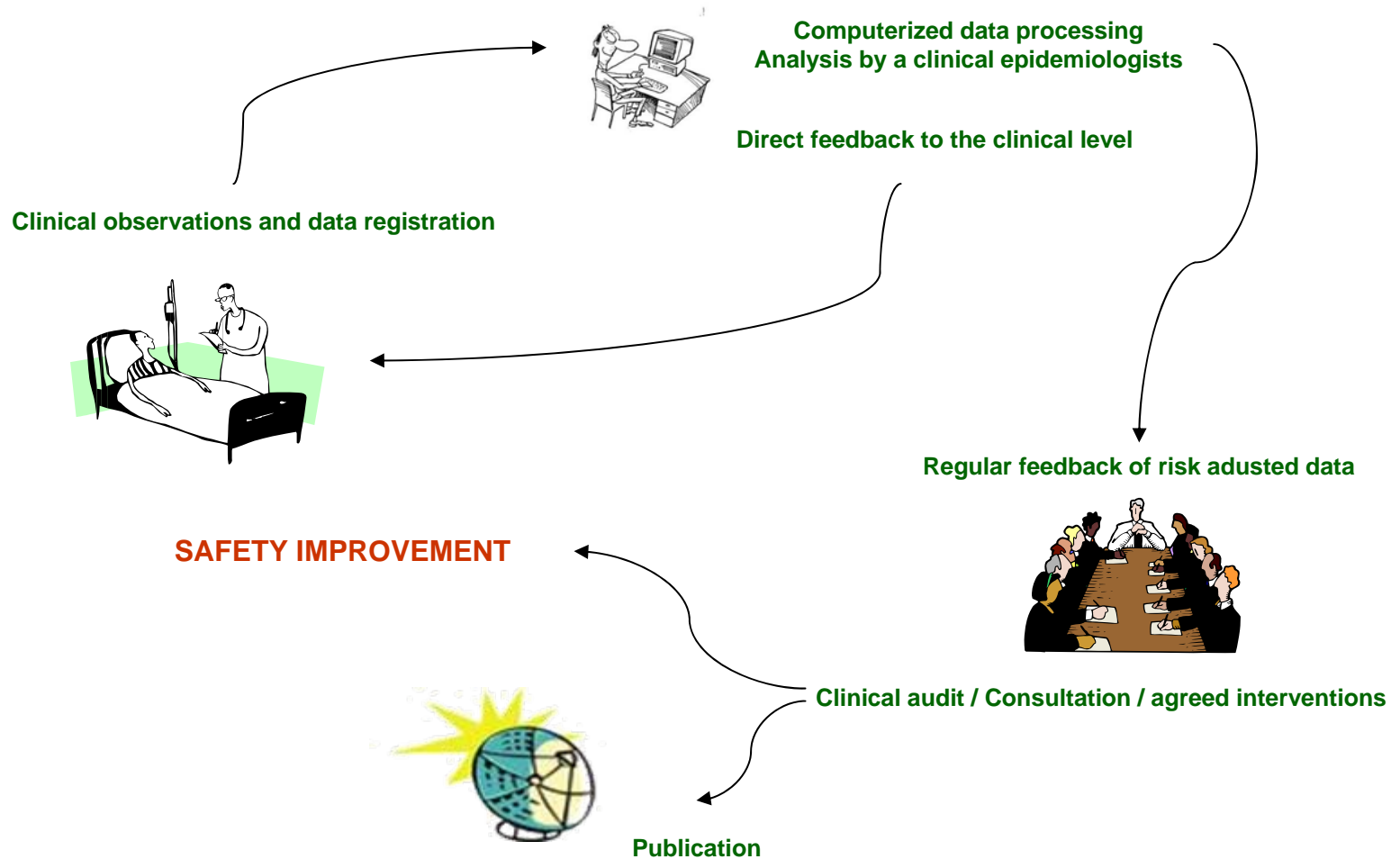
In patient safety assessment, components relating to the medical care system can/should be isolated. This is accomplished by controlling for significant confounding factors that contribute to the outcome

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



Continuously PSIs assessment



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

