

Establishing a Set of Patient Safety Indicators

Safety Improvement for Patients in Europe

SlmPatIE - Work Package 4

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“Learn from yesterday, live for today, hope for tomorrow.
The important thing is not to stop questioning.”

Albert Einstein

Summary

The objective of this work package (WP4) of the SImPatIE-project was the development of a vocabulary and an internal indicator set for patient safety. This report describes the work done to establish the patient safety indicators (PSIs).

The ESQH-office for Quality Indicators in Aarhus, Denmark was the lead partner of WP4. An expert group consisting of European representatives of project partners, stakeholders and external experts was established for the achievement of the aims of WP4.

The PSIs were derived through a formalised consensus process based on literature review, targeted information gathering, and expert consultation taking into account previous work done by the project partners and international quality and patient safety organisations

A literature search was performed. We searched for nationwide and international indicators programs known in a cross-European context. Literature for developing new indicators was also identified.

We developed a Stepwise Assessment Framework Approach (SAIFA) to select, characterise and evaluate the new PSIs and the existing indicators we wanted to review. The framework was based on the definition of the term “patient safety indicator” and the vocabulary framework developed by SImPatIE, WP4 and was followed by a characterisation and an evaluation of the PSI. Indicators were characterised using the developed “Schemes for Characterisation of Indicators”. Eight experts from six nations evaluated the PSIs on a scale ranging from 1 to 9 for “Relevance”, “Validity and Reliability”, and “Feasibility”. Statistics for each dimension of the indicator formed the basis of recommendations in four categories from “recommended to be used throughout EU” to “not recommendable for implementation in EU”.

A number of 28 known indicators, which have been clinically applied are described and evaluated. Also 14 new PSIs are characterised and evaluated by the expert group. Description of the PSIs can be found on www.simpatie.org. The PSIs are related to risk reduction and harm reduction and cover the dimensions; process and outcome. The PSIs are divided into subsets: “Institution Wide Measures”, “Specific Measures” and “Theme Related Measures” covering the themes: “infection control”, “surgical complications”, “medication errors”, “Obstetrics”, and “Fall”.

The existence of differences including aspects of organisational and clinical culture and sub cultures related to e.g. specialities and professions and also differences related to national, regional and local aspects led us to discommend a common “package” of PSIs for implementation in the EU at present. The consensus process was successfully completed leading to a recommendation of nine of 12 new SImPatIE PSIs whereas 16 of 30 PSIs from existing programmes were recommended for implementation in parts or throughout EU. Implementing the PSIs must be based upon thorough assessment of suitable data, considerations of interpretation, and publication of results.

Monitoring and surveillance of patient safety using PSIs depend on data that are varied along a number of dimensions. However, as the quality of administrative data vary across Europe embarking on the actual patient safety assessment activities using the PSIs across Europe entails additional work.

Introduction to WP4

Measures of aspects of quality of care have been developed and they are increasingly used in Europe being the promising answer to the demands for increased transparency and accountability while creating the basis for improvement and prioritisation in health care systems.

Patient safety has long been recognised as a dimension of quality of care and organisational performance. Care has become more and more complex over time, as the uses of technology as well as the number of effective treatments available have increased. Healthcare professionals are thus involved in increasingly complex care and the possibilities for adverse events have increased.

Patient safety is an outcome of many factors. While patient safety is the ultimate goal, belonging to “good outcomes” what ultimately determines safety is a safer care environment during the patients’ process of care.

Adverse events are systematically and frequently reported in European countries and analyses are made in order to learn from incidents and improve safety. This is resource consuming work, which creates a major need to measure dimensions of safety on an ongoing systematic basis, implement learning organisations, demonstrate ongoing safety improvement, determine when lapses in patient safety occur, and document positive effect of the efforts made. The quality improvement work is the role model of such an ongoing systematic monitoring, as it has proven to make the quality of process, structure and outcome visible.

Quality and patient safety studies providing evidence of the frequency of use of different tools are very few. In Western health care the most commonly used continuous quality improvement tools reported across a range of studies are: brainstorming, cause-effect diagrams, flow diagrams, and data collection tools such as forms for recording observations, and data display or analysis tools. Guidelines, protocols, and organisational procedures has been found to be the most commonly reported generic tools either for implementing the latest research or as part of continuous quality improvement projects to institutionalise changes tested by project teams (1). The World Health Organization (WHO) synthesis found incident report data collection and analysis, root cause analysis, and crew resource management to be the most often reported in health care (1).

Thus there is a major need to assess patient safety on an ongoing basis, systematic collection and analyses of PSIs can help prevent future “unsafe” actions of care and, in the long term, their adverse effect.

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Objectives

The objective of the SlmPatIE project is 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. The project is divided into eight so-called work packages that all aim for more specific objectives that together contribute to the overall project objective.

The objective of this work package was the development of a vocabulary and an internal indicator set for patient safety that is to be a part of a final project toolbox for improving patient safety. This report describes the work done to establish a set of recommendable PSIs.

Organisation

The ESQH-office for Quality Indicators in Aarhus, Denmark was the led partner of this work package (WP4). It was led by Prof. Jan Mainz, medical director of the Danish Institute for Quality and Accreditation in Healthcare, supported by Dr. Paul Bartels, medical director of the Danish Indicator Project. Overall project management and scientific work was executed by Master of Health Science Solvejg Kristensen.

The expert group consisted of representatives of project partners and external experts. Members of the expert group were:

- MD, PhD. A. Bourek, University Center for Healthcare Quality, Masaryk University, Czech Republic
- Dr. I. Callanan, Vice President of the Irish Society for Quality and Safety in Healthcare
- Dr. K. Essinger, President, HOPE Subcommittee on Co-ordination (Appointed by HOPE)
- Dr. J. van Everdingen, chief medical officer of CBO (Appointed by CBO)
- Dr. J. Hansen, The Danish National Board of Health
- Dr. M. Kallewaard of the Association of Medical Specialists (Appointed by CBO)
- Dr. B. Lilja, Director of the Danish Society for Patient Safety, Denmark
- Dr. G. Magueres (Appointed by HAS)
- Prof. Dr. med. G. Ollenschläger, Guidelines International Network (G-I-N)
- MD, PhD R. Suñol, Director of Avedis Donabedian Foundation (FAD).

Results to be achieved

The results to be achieved by the work package were:

- Defining a vocabulary related to patient safety, considering language, health care system organisation and economy and cultural issues across Europe (described in another report)
- Establishing a set of indicators / outcome measures that can be used in efforts to improve patient safety both at the system and organisation level
- Developing a brief rating assessment instrument for external application to provisional outputs

Deliverables fulfilled

The work package delivers:

- A set of definitions of terms related to patient safety and a framework to illustrate the core terms of the vocabulary (described in another report)
- A set of indicators for use in efforts to improve patient safety

- A brief rating assessment instrument for external application to provisional outputs

Overall approach taken

The work of WP4 was initiated and coordinated by the ESQH-office for Quality Indicators in Aarhus.

The expert group met in February 2006 with the purpose of introducing SImPatIE and WP4. SImPatIE project manager Benno van Beek, CBO took part in the meeting. The following presentations were given:

- Overall SImPatIE Project Plan and Organisation, by project manager Benno van Beek, CBO.
- Related Work of Work Package 5, by Dr. Georges Marguerez
- Introduction to Indicators Including Qualifications and Characterisation by Prof. Jan Mainz
- Proposed Schemes for Classification and Evaluation of Indicators by Prof. Jan Mainz
- Patient Safety Indicators, by Dr. Paul Bartels
- Specific Issues of Definition and Methodology and an Overview of Available Materials and Ongoing Work on Taxonomy/Vocabulary, by Dr. Paul Bartels

A detailed work plan for WP4 was established and tasks were assigned.

The overall working method in the expert group has been telephone conferences. Development has been initiated and decisions made in a formalised consensus process. The method of developing the indicators is described in details later.

Prior to the meeting of the expert group an extensive literature search was initiated using the search terms: “Patient safety”, “Vocabulary”, “Glossary”, “Taxonomy” and “Indicator”. PubMed <http://scholar.google.dk/> were searched. The literature search was repeated and extended in the process of the work and finalised towards the end of 2006. It was based on a review of similar studies and carried out by the Danish ESQH-office.

A literature review was carried out by the by the Danish ESQH-office in order to identify all relevant sources for the description of concepts and terminology related to patient safety and indicators. The review included work by the Council of Europe (CoE), European Communities (EC), Organisation for Economic Co-operation and Development (OECD), Agency for Healthcare Research and Quality (AHRQ), European Community Health Indicator Monitoring (ECHIM), The Nordic Indicator Group etc. It was decided to take all identified available material – European and international - into account in the development of the indicators. Details of the literature/background sources related to the development of the PSIs are given later. A full reference list can be found at the end of the report.

Introduction to Indicators

The assessment of patient safety can be carried out through both qualitative and quantitative methods (2). The quantitative approach uses indicators and epidemiological methods of analysis to systematically quantify distinct aspects of patient safety.

Qualitative analysis of adverse events and organisational practice in patient safety has proved to be a rich source of detailed information, which has increased knowledge of causation, preventability, and safe practices. The quantitative approach is necessary; it enables comparisons over time, between providers, and of effectiveness of interventions.

In terms of methodological demands for selection, validation, and characterisation of PSIs, they must be considered as a specific type of quality indicators, which focus on aspects of patient safety.

Defining an indicator

Indicators can be defined in different ways (3):

- As measures assessing a particular healthcare process or outcome
- As quantitative measures used to monitor and evaluate the quality of health care provider institutions including clinical and support functions
- 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 patient outcomes

Purpose of the use of indicators

Indicators provide a quantitative basis for clinicians, organisations and planners aiming at achieving improvements in care and the processes by which care is provided.

Indicator measuring and monitoring serve many purposes making it possible to:

- Document the quality of care
- Make comparisons and benchmarking over time between places (e.g. units, hospitals)
- Make judgments and set priorities (e.g. choosing a hospital or surgery or organising medical care)
- Support accountability, regulation, and accreditation
- Support quality improvement
- Support patients' choice of providers

The use of indicators enables professionals and organisations to monitor and evaluate what happens to patients as a consequence of how well professionals and organisational systems function to answer the needs of patients. However, indicators are not a direct measure of quality. As quality is multi-dimensional, understanding quality requires many different measures.

Indicators are based on standards of care. These can be evidence-based and derive from academic literature (e.g. COCHRANE Collaboration, literature syntheses, meta-analyses or randomised-controlled trials). When scientific evidence is lacking, indicators can also be determined by an expert panel of health professionals in a consensus process based on their experience. Thus, indicators and

standards can be described according to the strengths of scientific evidence of their ability to predict outcomes (4;5).

Key characteristics of an ideal indicator

An ideal indicator has the following key characteristics:

- Is based on agreed definitions and is described exhaustively and exclusively
- Is highly or optimally specific and sensitive, i.e. detecting few false positives and false negatives
- Is valid and reliable
- Discriminates well
- Relates to clearly identifiable events for the user (e.g. if meant for clinical providers it is relevant to clinical practice)
- Permits useful comparisons
- Is evidence-based

Each indicator must be defined in detail with explicit data specifications in order to be specific and sensitive.

Indicators may vary in their validity and reliability. Validity is the degree to which the indicator measures what it is intended to measure, i.e. the result of a measurement corresponds to the true state of the phenomenon being measured. A valid indicator discriminates between care otherwise known to be of good or bad quality and concurs with other measures intended to measure the same dimension of quality.

Reliability is the extent to which repeated measurements of a stable phenomenon by different data collectors, judges or instruments at different times and places get similar results. Reliability is important when using an indicator to make comparisons among or within groups over time. A valid indicator must be reproducible and consistent.

Indicators should be based on the best available evidence which can be described as the integration of the best research evidence with clinical expertise and patient values. The strengths of evidence of an indicator will determine its scientific soundness or the likelihood that improvement in the indicator will produce consistent and credible improvements in the quality of care (6).

Rate-based versus sentinel indicators

A rate-based indicator uses data on events expected to occur with some frequency. These can be expressed as proportions or rates (proportions within a given time period), ratios or mean values for a sample population.

To permit comparisons among providers or trends over time, proportions or rate-based indicators need both a numerator and a denominator specifying the population at risk for an event and the period of time over which the event may take place.

A sentinel indicator identifies individual events or phenomena that are intrinsically undesirable and such indicators always trigger further analysis and investigations. Each incident will trigger an

investigation. Sentinel events represent the extreme of poor performance and they are generally used for risk management (7).

Indicators related to structure, process, and outcome

Indicator can be related to structure, process or outcome of healthcare. Structure denotes the attributes of the settings in which care occurs. This includes the attributes of material resources (such as facilities, equipment and financing), of human resources (such as the number and qualifications of staff), and of organisational structure (such as medical staff, organisation, methods of pure review, and methods of reimbursement).

Process denotes what is actually done in giving and receiving care, i.e. the practitioners' activities in making a diagnosis, recommending or implementing treatment or other interaction with the patient.

Outcome measures attempt to describe the effects of care on the health status of patients and populations. Improvements in the patient's knowledge and salutary changes in the patient's behaviour may be included under a broad definition of outcome and some may represent the degree of the patient's satisfaction with care.

For a process indicator to be valid its use must previously have been demonstrated to produce a better outcome. Similarly, using structural indicators for quality assessment is only possible if structural components have been shown to increase the likelihood of either a good outcome or a process that has previously been shown to yield better outcomes. Therefore it is necessary to establish such relationships between any particular component of structure or process that is used to assess quality. These linkages may be based on scientific literature. If little evidence exists professional experience concerning these linkages can be distilled using consensus message. Only clinical indicators which are evidence-based have had the linkage between structure or process and patient health outcomes confirmed. The ability to assess the quality of medical, technical care is bound to the strengths and weaknesses of clinical science (8).

Generic and disease-specific indicators

Generic indicators measure aspects of care relevant to most patients while disease-specific indicators are diagnosis-specific and measure particular aspects of care related to specific diseases. Most generic and disease-specific indicators focus on structure, process or outcome.

Generic indicators may be difficult to interpret – especially when making comparisons among hospitals or providers as there may be profound differences in patient mix. Disease-specific outcome indicators can be used to compare hospitals and plans when data are risk-adjusted. Confounding factors such as prognostic factors for specific diseases are likely to be found in the scientific literature for these diseases thereby indicating the need for risk adjustment (9-11).

Indicators related to type of care, function and modality

Indicators can be classified according to type of care, function, and modality. Indicators classified by type of care may be preventive, acute or chronic. Function of care can relate to screening, diagnoses, treatment, and follow-up. The modality by which care can be delivered relates to physical examination of the patient, laboratory or radiology studies or prescription of medication (11-13).

Risk adjustment

In most cases, multiple factors contribute to a patient's survival and health outcome. Therefore, outcome measures must be adjusted for factors outside the health system influence if fair comparisons are to be made. In quality assessment, components relating to the medical care system should be isolated. This is accomplished by controlling for significant confounding factors that contribute to the outcome. Factors that are frequently included in risk adjustment models include patient demographic, psycho-social characteristics (such as age, sex and functional status), lifestyle factors (smoking and alcohol consumption), and severity of the illness that is the focus of measurement, health status and co-morbid conditions. Risk adjustment is essential prior to comparing patient outcomes across hospitals or providers.

Risk adjustments may be most important for outcome indicators. There are also other methods to ensure that other differences among patient groups are not influencing comparisons of process or outcome indicators – e.g. the population of patients for whom the indicator is measured can be carefully restricted. Alternatively, stratified analyses can be performed to examine specific types of patients within a small and overall sample (11;14;15).

Specific Characteristics of Patient Safety Indicators

Definitions aims and interpretation

PSIs are defined by their purpose, which is monitoring preventable adverse events – directly or indirectly (16;17).

PSIs are thus quality indicators (18), which prove to be valid within the specific framework of interpretation and refer to preventable events or medical errors.

- In terms of structure and process indicators: are healthcare organisational features, practices or interventions, with evidence of effects on exposure to preventable risk factors (e.g. safety culture, hand washing practices, screening of schizophrenic patients for suicidal risk)
- In terms of outcome: harm which is or may be conceived to be caused by preventable events: death, temporary or permanent disability (19;20).

The most important contribution of indicator monitoring to patient safety is the potential for quantitative surveillance. Currently assessment of patient safety problems and appropriate interventions relies mainly on case-based qualitative methodology as reporting systems and root-cause analysis. While these widely used tools have proved to be essential for establishing and supporting a clinical culture of safety, evidence of their effectiveness and efficacy is still uncertain (21;22).

Monitoring of relevant indicators such as mortality rates, true rates of adverse drug events or safety culture is a necessary prerequisite to rational priority decisions concerning patient safety interventions (23).

The interpretation of PSIs as absolute measures of patient safety for benchmarking or accountability purposes is demanding in terms of method development. Firstly because of the probabilistic nature of the relationship between exposure (structure-process) and harm (outcome), and secondly because of the interactions between system and patient factors influences outcome values as mortality rates.

The few categories of directly measurable preventable adverse events (wrong sided surgery, wrong blood type, in-hospital suicide) occurs so infrequently, that corresponding indicators has the characteristics of sentinel indicators (24) with very limited value in monitoring changes over time or for benchmarking purposes at the clinical (hospital) level. However, these indicators have been found to be useful at the system (national-regional) level (e.g. as part of the recommended PSIs from OECD (25).

Therefore assessment of patient safety status by indicators requires access to multiple sources and kinds of data (26) and has the characteristics of screening for safety problems, rather than making a definitive diagnosis (27;28).

Example: Rate-based indicator

Death due to anaesthesia has become rare, by contrast morbid events, i.e. complications related to anaesthetic care such as anaesthetic overdose, reaction, or endotracheal tube misplacement are much more prevalent causing harm to the patient to a different extend. Safety should be assessed at the aggregated patient level.

Example: Sentinel indicator

Although surgeons and operating room teams rely on the practice of counts of sponges, sharp and instrument as a means to eliminate detained foreign bodies, practices are not standardised and every single events may signal a serious system failure that should be addressed. Thus safety should be assessed at the individual patient level.

Areas for development and use of patient safety indicators

As with quality indicators in general the effectiveness of PSIs depends on selection of proper clinical areas of measurement in terms of frequency, severity as well as the existence of evidence-based interventions towards patient safety problems.

When these factors are taken into account (29;30) four main areas for hospital-related PSIs can be identified:

- Generic indicators which monitors organisation-wide patient safety characteristics
- Indicators monitoring hospital-acquired infections
- Indicators monitoring preventable surgical complications
- Indicators monitoring medication safety

Supplemented by a number of condition specific areas (e.g. bedsores, falls)

Definition of a “Reporting System” according to WP4

A system which is designed to contain reports on adverse events. On the basis of reports analysis and communication of known causes and risk situations is possible. The system can contain reports on human and technical errors as well as organisational circumstances, which affects the occurrence of adverse events in the health care process. Reporting systems include input from all stakeholders – providers and service users.

Example of a developmental area:

Reporting systems of adverse events as a basis for developing PSIs

A reporting system, which is used systematically for reports of adverse events, will contain a wide variety of information on reports of different events – different in type, frequency, severity and actions resulting from analysis.

At first each report will represent an incident perhaps even a sentinel event. Events which are rated rare but severe – could be a candidate sentinel indicator event.

Some events in the reporting system database are alike; such events form thematically clusters and they provide essential information for the selection of adequate rate-based patient safety indicators.

Institution-wide patient safety indicators

Consists of indicators which address general patient safety characteristics in all types of healthcare organisations and covers both primary care and hospitals:

- Measures of staff safety culture (structural indicators)
- Standardized mortality rates (outcome indicators)
- Fraction of patients experiencing adverse events (outcome indicators)

Because of their generic nature these indicators are mainly useful in surveillance of organisational interventions or characteristics.

Standardized mortality rates are well-established and validated as indicators of patient safety problems (31;32) but require access to developed administrative healthcare databases and sophisticated analysis of data.

Safety culture assessment and patient experience of adverse events seem promising both in terms of relevance and feasibility, but evidence of validity of these indicators is still limited (33-36).

Indicators monitoring hospital-acquired infections:

Indicators monitoring hospital-acquired infections consist of:

- Rate-based indicators based on registration (direct or through patient administrative data collection systems) of various types of hospital acquired infections (37;38) e.g.:
 - Surgical wound infections
 - Ventilator pneumonia
 - Catheter based UTI
- Probability function assessment of hospital acquired infections
- Structural indicators covering infection control measures (e.g. rate of consumption of hand – disinfectants per 1000 bed days) (39)

The registration-based indicators are well characterized in terms of limitations of validity and feasibility (40;41).

Probability function assessment of hospital-acquired infections is validated and seems less prone to bias than direct registration, but requires advanced health care IT systems (42-44).

Indicators monitoring preventable surgical complications:

Indicators monitoring preventable surgical complications (45) consist of:

- Risk adjusted mortality rates
- Postoperative infection rates
- Postoperative rates of haemorrhage or thrombosis
- Readmission rates
- Rate of processes which reduces risk of complications (peroperative antibiotics, antithrombotic prophylaxis)

These indicators are validated, well-established and characterized.

Indicators monitoring medication safety

Construction of relevant and valid indicators monitoring medication safety has posed specific problems because of the very high incidence of medication errors (46).

Presently published indicators consist of:

- Rate of adverse drug events assessed by trigger tool methodology (47-50).
This type of outcome indicators has been validated for surveillance of the effects of interventions to improve medication safety within an organisation. The indicators are less useful for benchmarking purposes because of standardisation problems.
- Patients understanding of purpose for taking medications.
This questionnaire based indicator is a part of the Care Transitions Measure and is closely related to the process of medication reconciliation at discharge.

Example: Generic indicator

Communication and transfer of information between healthcare settings and between professionals and patients are essential aspects of patient safety. Especially care transition processes are known to be vulnerable regarding patient safety. Understanding the purpose of the medication can impact compliance. Adherence to medications is important as lack of compliance can have fatal consequences for the patient. Thus the quality of staff patient communication regarding patients understanding of the purpose of their medication when leaving hospital is an adequate generic measure of patient safety.

Example: Disease-specific indicator

Schizophrenic patients have a known higher risk of suicidal behaviour especially in the time right after discharge from hospital. Thus assessment of suicidal risk at discharge is an adequate disease-specific measure of patient safety.

Specific issues of data quality, validity and reliability of PSIs

In terms of reliability the value of PSIs in organisational learning seems dependent on a high sensitivity of the indicator, while specificity may be of main concern if the indicator is used for public accountability (51;52). The evaluation of PSIs is therefore strongly dependent on the intended use.

The level of the PSIs which monitors harm (e.g. rates of mortality and infections) is usually sensitive to bias caused by the severity of the disease, comorbidities and lifestyle factors. Validity of these indicators is therefore depended on simultaneous collection of patient-related data appropriate for risk adjustment. Empirical evidence suggests that administrative data are not satisfactory in this respect (53;54) especially when used at clinical (hospital) level.

Experience with direct collection of medical record-based data (primary data) seems to partly alleviate this problem. There is however still ambiguity in the clinical definitions with resulting risk of bias in e.g. recording of wound infections which requires caution in interpretation of

benchmarking studies. Moreover demands in terms of resources and organisation in direct collection of clinical data limit the scale of this approach (55).

Newer developments in the field of medical informatics in the form of automated detection systems based on primary data from laboratory- pharmacy-, and hospital administrative systems show promising results in unbiased assessment of infection rates (56) and medication safety (automated trigger tool methodology) (57). The methodology requires sophisticated resources in terms of informatics and reliable system wide patient identification.

Description of the Work

Objectives of European Patient Safety Indicators

The patient safety indicators (PSIs) should be useful in:

- Surveillance and monitoring of the impact of patient safety activities – e.g. monitoring effects of interventions by reduced harm.
- Identify unsafe processes of care and eventually also unsafe patient outcomes
- Monitor safety consequences of organisational changes in processes and/or structures on the health care system

Furthermore the PSIs should capture important safety aspects, be scientifically sound and feasible, as recommended in the literature (58) and from the expert group.

The PSIs are meant for use of professionals. The results achieved when the PSIs have been applied can be of use for both professionals e.g. clinicians, organisations and planners aiming at achieving improvements in care and the processes by which patient care is provided and laymen e.g. patient and potential patients.

Organisation

The work presented was developed in interplay between the ESQH-office for Quality Indicators in Aarhus and the members of the established expert group of WP4. Participating expert group members and external experts assigned by an expert group member in the work concerning the PSIs were:

- MD, PhD. A. Bourek, University Center for Healthcare Quality, Masaryk University, Czech Republic
- Dr. I. Callanan, Vice President of the Irish Society for Quality and Safety in Healthcare
- Dr. K. Essinger, President, HOPE Subcommittee on Co-ordination (Appointed by HOPE) in cooperation with Dr. J. Ahlberg, Medical director, LÖF, Patientforsaking, Sweden
- R. Gijssen, MSc., Health care researcher, epidemiologist in cooperation with J. de Koning, MPH, PhD, Senior health care researcher, project leader (Appointed by CBO, Holland)
- Dr. M. Kallewaard of the Association of Medical Specialists (Appointed by CBO)
- Dr. B. Lilja, Director of the Danish Society for Patient Safety, Denmark in cooperation with Dr. J. Anhøj, the Danish Society for Patient Safety
- Dr. G. Maguerez (Appointed by HAS, France), Dr. med C. Thomeczek, Senior Researcher, Managing Director, the German Agency for Quality in Medicine (AQuMed / AEZQ) Joint Institution of The German Medical Association and the National Association of the Statutory Health Insurance Physicians representing Prof. Dr. med. G. Ollenschläger of the Expert Group

Prof. Jan Mainz, medical director of the Danish Institute for Quality and Accreditation in Healthcare and Dr. Paul Bartels, medical director of the Danish Indicator Project from the ESQH-office in Aarhus participated in the expert group. Project management and scientific work was executed by Master of Health Science Solvejg Kristensen.

Methodology

The PSIs/outcome measures were derived through a formalised consensus process beginning at the expert group meeting in February 2005 followed by mail contact and telephone conferences.

A step wise – adjusted – method known from development of clinical indicators was chosen in developing the PSIs (59). The planning phase was: choosing areas to evaluate and organising the measurement team, whereas the development phase was: providing an overview of existing indicators and evidence, selecting indicators, and designing measurement specification.

During the initial expert group meeting consensus was reached on a definition of a PSI, it was also decided to focus on a set of indicators for risk and harm reduction both reviewing existing indicators and developing new ones. The expert group decided on specific areas for the PSIs, and tasks were assigned.

An extensive literature search was initiated using the search terms: “Patient safety”, “Indicator”, “Risk” and “Harm” to identify nationwide and international PSIs or indicator programs. The search terms were used single and in all possible combinations. To know if the indicators had been used and evaluated in a clinical setting we extended the search using the terms; “Test*”, “Usage”/“Use”, “Apply” and “Valid*”. PubMed and <http://scholar.google.dk/> were searched. The literature search was started in the beginning of 2006, and repeated and extended in the process of the work, it was finalised by the end of 2006. It was carried out by the ESQH-office in Aarhus.

Indicators or indicator programmes of the organisations mentioned below were reviewed to determine whether they were suitable for characterisation and evaluation according to the “Stepwise Assessment Framework Approach”:

- Australian Council for Safety and Quality in Health Care (ACSQHC)
- Agency for Healthcare Research and Quality (AHRQ)
- The Good Medical Department, Denmark (DGMA)
- International Compendium of Health Indicators (WHO, OECD, Eurostat and ECHIM)
- Institute of Healthcare Improvements (IHI)
- Joint Commission on accreditation in Health Care (JCAHO)
- Nordic Indicators (NI)
- Performance Assessment Tool for Quality improvement in Hospitals (PATH)
- The Danish National Indicator Project (NIP)
- Performance Indicators on Patient Safety and effectiveness for Dutch Hospitals.

The literature search identified the following methods suitable for the basing of indicators:

- Measuring Hospital Standardised Mortality Rates
- Hospital Acquired-Infection Registration
- Quantitative Patient Safety Cultural Assessment
- Patients Satisfactions’ Surveys
- Electronic Trigger Tools

The literature search supported by the initial expert group meeting identified the following themes suitable for basing indicators upon:

- Hand hygiene
- Transition of care
- Medication errors
- In-hospital fall
- Infection control
- Surgical complication

We developed a “Stepwise Assessment Framework Approach” to select, characterise, and evaluate new PSIs as well as reviewing the existing indicators. The “Stepwise Assessment Framework Approach” is described in details later.

To assess whether an indicator qualified, it had to match the definition of an indicator. Also it had to fit into one of the boxes in the table of the core terms of the vocabulary, stating the relation to process or outcome as well as to preventability. Further details can be seen in the report of WP4 on the development of the SImPatIE Patient Safety Vocabulary.

To characterise the indicators (both the reviewed and new) Scheme for Characterisation of Indicators was developed, also a Brief Assessment Instrument was developed for external application. Both instruments were developed by the ESQH-office in Aarhus according to recommendations in the literature, experience, and similar schemes (60;61). The Scheme for Characterisation of Indicators and the Brief Assessment Instrument were pilot tested on a few PSIs. Discussion, comments, and evaluation of the performance of the two methods was made in an expert telephone conference and adjustments were made accordingly. In the section describing the Stepwise Assessment Indicator Framework Approach both instruments are shown.

Characterised indicators were discussed in a telephone conference of the expert group; suggested changes leading to consensus were made. The indicators were then redistributed to the expert group for evaluation.

Indicators (both the existing and the new) were evaluated by individual members of the expert group using the “Scoring Sheet” integrated in the Brief Assessment Instrument. Evaluation of the PSIs was carried out according to three dimensions (Relevance and Appropriateness, Validity and Reliability and Feasibility) of the indicator on a scale ranging from 1 to 9. Scores were divided into; 1-3 Low degree, 4-6 Medium degree and 7-9 High degree. Ratings on each of the three dimensions of each PSI were added and percentiles, mode, minimum and maximum scores calculated and frequencies of scores displayed graphically. On the basis of these statistics the expert group discussed recommendations for application in Europe in telephone conferences. Making these recommendations the expert group focused on the scientific properties mentioned; the group discussed aspects such as resources available, organisation in individual EU countries, legal systems etc. in connections with the dimension Feasibility. However these aspects are not systematically uncovered Europe wide.

Patients perspectives were represented in work of WP4 in different ways; the organisation “Action against Medical Accidents” (AWA), an independent English charity promoting better patient safety and justice for people who have been adversely affected by a medical accident were represented in the over all project meetings. Also a representative of AWA reviewed and commented the characterisation of the PSIs, a set number of five PSIs, and a draft of this report.

The Organisation HOPE commented on a draft of this report.

To coordinate between the work of WP4 and the other work packages at least one representative of the ESQH-office in Aarhus continuously took part in telephone conferences, overall project meetings, steering group meetings, and congresses.

The Stepwise Assessment Indicator Framework Approach

The developed Stepwise Assessment Indicator Framework Approach to select, characterise, and evaluate appropriate indicators is illustrated below. If the indicator does not fulfil all the required demands of a step, it is deleted and not taken any further. The steps are described below.

1. Selecting the indicator

Making sure the indicator addresses relevant and significant patient safety issues: it qualifies as an indicator according to the definition in Table 1, and it can be placed within the bold frame in Table 2.

Table 1. Definition of a Patient Safety Indicator:

<p>Patient safety indicators are measures that directly or indirectly monitor preventable adverse events</p>

Table 2. Step 1: Identifying the type of indicator

PROCESS	Actual event	Near miss (sub-event)
	Non preventable event	Preventable event (Adverse event)
OUTCOME	Harm: Adverse outcome	No Harm

If the indicator does not fulfil the required demands of step 1, it is deleted.

Step 2. Characterising the indicator

To characterise the indicators Scheme for Characterisation of Indicators is used. It is vital for this step that both the numerator and the denominator are defined.

Table 3. Step 2: Characterising the Indicator

PSI (number): (Title)	
Overall origin of the PSI relating to the organisation	
Dimension	Description
Description of Specific Aspects of Patient Safety	Provides a concise statement of the specific aspects of patient safety, the patient population, providers, setting(s) of care, and time period that the measure addresses.
Aim of the PSI	Gives a concise description of the aim of the specific PSI.
Level of Determination of Patient Safety	Identifies the level at which safety can be assessed (i.e., at the individual patient level or the aggregate patient level).
Source(s)	Describes the specific sources of the PSI
Evidence Supporting the Criterion of Patient Safety	Describes the type(s) of supporting evidence appropriate for the measure domain.
Extent of Clinically Testing	Describes the extent of testing of the measure including reliability and/or validity testing.
Evidence of Clinically use of Standards	Describes the extent of standards used clinically, and which standards were used according to the objective of the indicator.
PSI Category	Specifies whether the indicator is: <i>Institution-wide PSIs</i> <i>Theme Related PSIs:</i> “Infections Control” “Surgical Complication” “Medication Errors” “Obstetrics” “In-Hospital Fall” <i>Diagnose Specific as well as other Specific PSIs</i>
Data Definitions	Describes the data definition in detail
Denominator Description	Provides the <i>general</i> specifications of any clinical component that is the basis for inclusions and exclusions in the denominator.
Numerator Description	Provides the <i>general</i> specifications of any clinical component that is the basis for inclusions and exclusions in the numerator.
Data Source	Identifies the data source(s) necessary to implement the measure
Identifying the institutional context	Placing the indicator in an institutional context. E.g. it is also relating to quality improvement work and/or accreditation
Care Setting	Classifies the settings for which the measure applies
Professionals Responsible for Health Care	Classifies the professional(s) who is/are responsible for health care
Lowest Level of Health Care Delivery Addressed	Classifies the lowest level of health care delivery to which the measure (in its current use) applies

Allowance for Patient Factors	Identifies the type of analytic considerations made for the measure based on patient factors or characteristics (e.g., High-risk/vulnerable subgroups, Other subgroups [e.g., age cohort], Case-mix adjustment, Paired data at the patient level, Risk adjustment).
Stratification by Vulnerable Populations	Describes the populations vulnerable to health care patient safety problems that are separately identified for sampling
Standard of Comparison	Classifies the type and time frame of the comparison according to whether the comparison is external (at a given point-in-time or of a time trend), internal, or to a prescriptive standard.
Scoring	Identifies the method used to score the measure (e.g., Categorical, Continuous Variable, Count, Frequency Distribution, Non-weighted Score/Composite/Scale, Rate, Ratio, Weighted Score/Composite/Scale).

Step 3. Evaluating the indicator – a brief rating assessment instrument for external application

Indicators were evaluated by each individual member of the expert group using the scoring sheet integrated in the Brief Assessment Instrument.

Table 4. Step 3: Evaluating the indicators using the Brief Assessment Instrument

SCORING MATRIX			
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			Additional Comments/ Overall Evaluation
Relevance and Appropriateness	Validity and Reliability	Feasibility	
Score from 1-9	Score from 1-9	Score from 1-9	Free text

If the indicator does not fulfil the required demands of step 3 it is deleted. Only indicators meeting all demands in the “Stepwise Assessment Framework Approach” have been fully characterised, evaluated, and recommended.

Step 4. Recommendations for use of the indicator in Europe

Registering and analysing the PSIs has to be feasible. It is crucial, therefore, to aim for a limited set of PSIs that when possible can draw upon existing registries or databases within hospitals and be used for benchmarking. It would be an illusion to think that all aspect of patient safety could be adequately captured in such a set of PSIs.

As the expert group was not able to make definite statements about exact data availability and quality for all the PSIs in all European countries it strived to take cross-cultural registration practices into account in making recommendations for PSI application. The PSIs are divided into four sets dependent on whether the expert group found them:

1. Immediately workable throughout the European health care systems
2. Immediately workable in parts of the European health care 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

Established Patient Safety Indicators

Below a list of the PSIs, which have been established, that is characterised and evaluated by the WP4 Expert Group, is shown. A full description of the PSIs following the SAIFA is available on www.simpatie.org.

Table 5. List of established Patient Safety Indicators by WP4

INDICATOR CATEGORY AND NAME	TYPE
INSTITUTION-WIDE PSIs	
1. Measuring Hospital Standardised Mortality Rates	New
2. Death in Low-Mortality DRGs	Review
3. Patients Experiencing Adverse Events	New
4. Patients Informed about an Adverse Event by the Staff	New
5. Patients Experiences of Adverse Events Management	New
6. Transition of Care – Patient’s Understanding of the Purpose of their Medication	New
7. Institution-Wide use of Cultural Assessment	New
8. Surveying the Development of the Patient Safety Culture	New
THEME RELATED PSIs: “INFECTION CONTROL”	
9. Selected Infections due to Medical Care	Review
10. Hospital Acquired-Infection Registration – Post Operative Wound Infections	New
11. Wound Infection	Review
12. Ventilator Pneumonia	Review
13. Hand Hygiene - Measured by the Alcohol Consumption	New
14. Hand Hygiene - Staff’s Compliance with Guidelines for use of Jewellery	New
THEME RELATED PSIs: “SURGICAL COMPLICATIONS”	
15. Complications of Anesthesia	Review
16. Foreign Body left during Procedure	Review
17. Postoperative Pulmonary Embolism or Deep Vein Thrombosis	Review
18. Postoperative Sepsis	Review
19. Postoperative Haemorrhage or Haematoma	Review
20. Postoperative Physiologic Metabolic Derangements	Review
21. Postoperative Respiratory Failure	Review
22. Accidental Puncture or Laceration	Review
23. Wrong Site-Surgery	Review
24. Medical Equipment-related Adverse Events	Review
25. Patients experiencing Harmful Surgical Adverse Events	New

Table 5. List of established Patient Safety Indicators by WP4 (cont.)

INDICATOR CATEGORY AND NAME	TYPE
THEME RELATED PSIs: “MEDICATION ERRORS”	
26. Transfusion Reaction	Review
27. Wrong Blood Type	Review
28. Medication Error (Does not fulfil the criteria as an indicator, therefore deleted)	Review
29. Electronic Trigger Tool - Surveillance of Adverse Drug Events	New
THEME RELATED PSIs: “OBSTETRICS”	
30. Obstetric Trauma – Vaginal Delivery without Instrument	Review
31. Obstetric Trauma – Vaginal delivery with instrument	Review
32. Obstetric trauma – Caesarean Delivery	Review
33. Problems with Childbirth	Review
34. Birth Trauma – Injury to Neonate	Review
THEME RELATED PSIs: “IN-HOSPITAL FALL”	
35. Postoperative Hip Fracture	Review
36. In-Hospital Hip Fracture or Fall	Review
37. Patient Falls	Review
DIAGNOSE SPECIFIC AS WELL AS OTHER SPECIFIC PSIs	
38. Decubitus Ulcer	Review
39. Failure to Rescue	Review
40. Iatrogenic Pneumothorax	Review
41. Assessment of Suicidal Risk in Schizophrenic Patients	New
42. Side Effect of Anti-Psychotic Treatment	New

Evaluation of the PSIs

Eight experts from six nations evaluated the PSIs. The expert group initially conducted a structured review of each PSI and an independent assessment of each indicator evaluating the three dimensions: “Relevance”, “Validity and Reliability” and “Feasibility” of the indicators. The methodology for the structured review and the evaluation was given using the “Scheme for Evaluation of Indicators”. This evaluation was followed by a number of one hour telephone conferences, which served to discuss the PSIs, ensuring common understanding of the definitions and phrasing, and propose and decide on alterations and refinements. Only alteration for the new developed PSIs were made. Where it was found necessary descriptions of the PSIs were altered and re-circulated among the experts and the PSI was discussed again. The individual ratings on a scale ranging from 1 to 9 for each of the three dimensions of each PSI were also shared in telephone conferences.

As all PSIs had been rated, statistics for each dimension of the indicator was worked out and send to the expert group. The statistics formed the basis of the consensus decisions of recommendations for

implementation of the PSIs according to the four categories previously described. Examples of statistics provided the experts are shown below.

Table 6. Example of statistics bases on the ratings of the three dimensions for one PSI

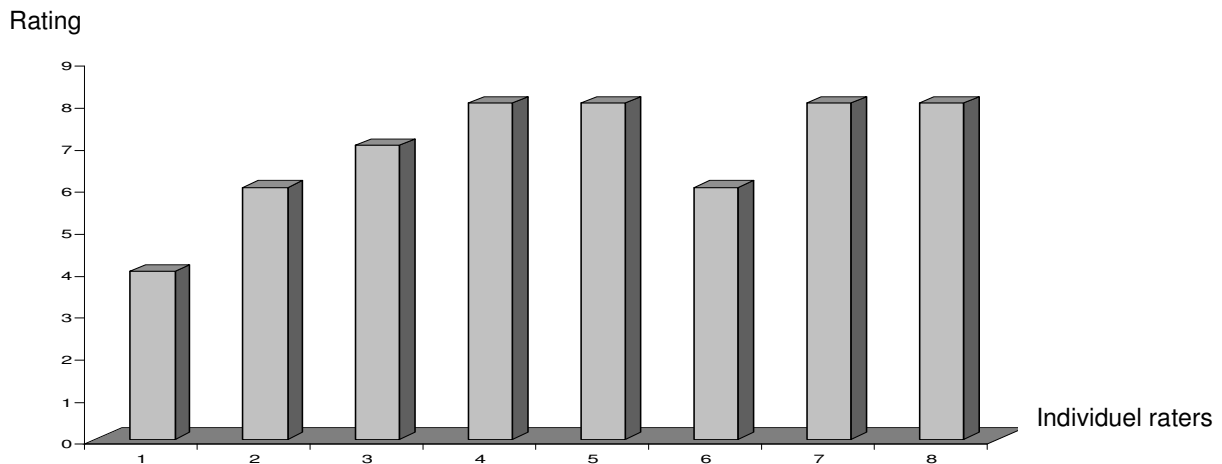
		Relevance and Appropriateness	Validity and Reliability	Feasibility
Number of ratings		8	8	8
Median		7,50	5,50	5,00
Mode		8	4 [#]	5
Percentiles	25	6,00	4,00	3,25
	75	8,00	6,75	5,00

Multiple modes exist. The smallest value is shown

Table 7. Example of statistics bases on the ratings of relevance and appropriateness for one PSI

Score	Frequency	Percent
Score 4: Medium degree of relevance and appropriateness	1	12,5
Score 6: Medium degree of relevance and appropriateness	2	25,0
Score 7: High degree of relevance and appropriateness	1	12,5
Score 8: High degree of relevance and appropriateness	4	50,0
Total	8	100,0

Diagram 1. Example of distribution of the ratings for “Relevance and Appropriateness” for one PSI



Recommendations for application of the PSIs established PSIs in Europe

The expert group’s consensus decisions on applications of the PSIs are shown in the table below. Recommendations are made according to the four possibilities described under step 4 above.

Generally the expert group found that the use of PSIs represent significant advances provided that a number of conditions described in the section on “Specific Characteristics of Patient Safety Indicators” of this report are fulfilled. For various PSIs restrictions in the uses of the PSIs were recommended, please see table 9 below for these restrictions. The relative importance of each of the three dimensions proved to differ by individual PSIs.

Nine rate-based PSIs were recommended for implementation across Europe and 15 PSIs were recommended to be applied in parts of Europe, one of which was sentinel.

Four PSIs (number 3, 4, 5 and 25) were recommended as “At present not workable for implementation in Europe – Recommendation for future decision on implementation”. The expert group highly recommends methodological development of these four indicators in validation of the patient satisfaction survey instrument fundamental for the PSIs.

A number of the PSIs monitor patient harm. These PSIs are regarded sensitive to bias caused by patient disease severity, comorbidities and lifestyle factors. Validity and reliability of these data therefore depend on extensive collection of patient-related data and appropriate risk adjustment. The ambiguity of data definitions in e.g. recording of wound infections or prognostic factors in surgical patients points to problems in interpretation of data; especially if PSIs are to be used for external accountability.

Though comparability across Europe is necessary to develop patient safety, the use of PSIs imply methodological problems as the quality of indicator data was found to vary along a number of dimensions across institutions and nations in Europe. The expert group therefore recommends additional work concerning homogeneous and comparable data (data definitions) and investigation of indicator sensitivity and specificity.

Table 8. Recommendations of application of the Patient Safety Indicators (To be continued)

INDICATOR CATEGORY AND NAME	APPLICATION*
INSTITUTION-WIDE PSIs	
1. Measuring Hospital Standardised Mortality Rates	2
2. Death in Low-Mortality DRGs	3
3. Patients Experiencing Adverse Events	3
4. Patients Informed about an Adverse Event by the Staff	3
5. Patients Experiences of Adverse Events Management	3
6. Transition of Care - Patient's Understanding of the Purpose of their Medication	2
7. Institution-Wide use of Cultural Assessment	1
8. Surveying the Development of the Patient Safety Culture	1

1. Immediately workable throughout the European health care systems. 2. Workable in parts of Europe. 3. At present not workable for implementation in Europe – Recommendation for future implementation or decision on implementation. 4. Not suitable for implementation.

Recommendation with restriction, please see Table 9, below for more details.

Table 8. Recommendations of application of the Patient Safety Indicators (cont.)

INDICATOR CATEGORY AND NAME	APPLICATION*
THEME RELATED PSIs: “INFECTION CONTROL”	
9. Selected Infections due to Medical Care	4
10. Hospital Acquired-Infection Registration – Post Operative Wound Infections	2
11. Wound Infection	1#
12. Ventilator Pneumonia	2#
13. Hand Hygiene - Measured by the Alcohol Consumption	1
14. Hand Hygiene - Staff’s Compliance with Guidelines for use of Jewellery	4
THEME RELATED PSIs: “SURGICAL COMPLICATIONS”	
15. Complications of Anesthesia	2
16. Foreign Body left during Procedure	4
17. Postoperative Pulmonary Embolism or Deep Vein Thrombosis	4
18. Postoperative Sepsis	1
19. Postoperative Haemorrhage or Haematoma	1
20. Postoperative Physiologic Metabolic Derangements	2
21. Postoperative Respiratory Failure	2
22. Accidental Puncture or Laceration	3
23. Wrong Site-Surgery	3
24. Medical Equipment-related Adverse Events	3
25. Patients experiencing Harmful Surgical Adverse Events	3
THEME RELATED PSIs: “MEDICATION ERRORS”	
26. Transfusion Reaction	2
27. Wrong Blood Type	2
28. Medication Error (Does not fulfil the criteria as an indicator, there fore deleted)	-
29. Electronic Trigger Tool - Surveillance of Adverse Drug Events	2#
THEME RELATED PSIs: “OBSTETRICS”	
30. Obstetric Trauma – Vaginal Delivery without Instrument	2#
31. Obstetric Trauma – Vaginal delivery with instrument	2#
32. Obstetric trauma – Caesarean Delivery	3
33. Problems with Childbirth	3
34. Birth Trauma – Injury to Neonate	2#

1. Immediately workable throughout the European health care systems. 2. Workable in parts of Europe. 3. At present not workable for implementation in Europe – Recommendation for future implementation or decision on implementation. 4. Not suitable for implementation.

Recommendation with restriction, please see Table 9, below for more details.

Table 8. Recommendations of application of the Patient Safety Indicators (cont.)

INDICATOR CATEGORY AND NAME	APPLICATION*
THEME RELATED PSIs: “IN-HOSPITAL FALL”	
35. Postoperative Hip Fracture	1
36. In-Hospital Hip Fracture or Fall	1
37. Patient Falls	4
DIAGNOSE SPECIFIC AS WELL AS OTHER SPECIFIC PSIs	
38. Decubitus Ulcer	1
39. Failure to Rescue	4
40. Iatrogenic Pneumothorax	3
41. Assessment of Suicidal Risk in Schizophrenic Patients	2
42. Side Effect of Anti-Psychotic Treatment	2

1. Immediately workable throughout the European health care systems. 2. Workable in parts of Europe. 3. At present not workable for implementation in Europe – Recommendation for future implementation or decision on implementation. 4. Not suitable for implementation.

Recommendation with restriction, please see Table 9, below for more details.

Table 9. Recommendations and restrictions regarding implementation of the Patient Safety Indicators

PSIs RECOMMENDED IMPLEMENTED THROUGHOUT EUROPE
<p>PSI 7. Institution-Wide use of Cultural Assessment <i>The general restrictions concerning data comparability apply, please see above.</i></p>
<p>PSI 8. Surveying the Development of the Patient Safety Culture <i>Comparison between units, departments and nations is only suitable provided that the same method of measuring is used.</i></p>
<p>PSI 11. Wound Infections <i>Data definitions, data quality, and availability vary across institutions and across Europe, which makes this PSI unsuitable for nation wide comparison or benchmarking under the current conditions.</i></p>
<p>PSI 13. Hand Hygiene - Measured by the Alcohol Consumption <i>This PSI is only suitable for nation wide comparison or benchmarking provided the existence of comparable data registration practice.</i></p>
<p>PSI 18. Postoperative Sepsis <i>This condition might be under-reported, which influences the data quality and comparison between units, departments and nations.</i></p>
<p>PSI 19. Postoperative Haemorrhage or Haematoma <i>The general restrictions concerning data comparability apply, please see above.</i></p>
PSIs RECOMMENDED IMPLEMENTED IN PARTS OF EUROPE
<p>PSI 1. Measuring Hospital Standardised Mortality <i>Data quality and availability varies across Europe. The data definition of the PSI is recommended to be altered according to data availability in each country, which makes this PSI unsuitable for cross-nation comparison under the current conditions.</i></p>
<p>PSI 4. Transition of Care - Patient's Understanding of the Purpose of their Medication <i>The general restrictions concerning data comparability apply, please see above.</i></p>
<p>PSI 8. Hospital Acquired-Infection Registration – Post Operative Wound Infections <i>This PSI is only suitable for nationwide comparison provided the existence of comparable data registration practice.</i></p>
<p>PSI 10 Ventilator Pneumonia <i>Data must be risk adjusted prior to comparing patient outcomes across hospitals or providers. Also data is recommend adjusted for time. This PSI is only suitable for nationwide comparison provided the existence of comparable data registration practise</i></p>
<p>PSI 13. Complications of Anesthesia <i>The general restrictions concerning data comparability apply, please see above.</i></p>
<p>PSI 18. Postoperative Physiologic Metabolic Derangements <i>The general restrictions concerning data comparability apply, please see above.</i></p>

Table 9. Recommendations and restrictions regarding implementation of the PSIs (Cont.)

PSIs RECOMMENDED IMPLEMENTED IN PARTS OF EUROPE
<p>PSI 19. Postoperative Respiratory Failure <i>The general restrictions concerning data comparability apply, please see above.</i></p>
<p>PSI 24. Transfusion Reaction <i>Data quality for this PSI varies across Europe. This PSI is highly dependent upon a specific reliable database. Administrative data are not viewed reliable enough to base this PSI upon.</i></p>
<p>PSI 25. Wrong Blood Type <i>The general restrictions concerning data comparability apply, please see above.</i></p>
<p>PSI 28. Electronic Trigger Tool - Surveillance of Adverse Drug Events <i>Data quality and availability varies across Europe. This PSI is highly dependent upon a well developed health informatics system. The data definition of the PSI is recommended altered according to data availability in each country, which makes this PSI unsuitable for cross EU comparison under the current conditions.</i></p>
<p>PSI 29. Obstetric Trauma – Vaginal Delivery without Instrument <i>This PSI is only recommended implemented in countries where case mix and comorbidity can be addressed. Comparison between units, departments and nations is only suitable provided the existence of comparable data definitions and scoring method.</i></p>
<p>PSI 30. Obstetric Trauma – Vaginal delivery with instrument <i>This PSI is only recommended implemented in countries where case mix and comorbidity can be addressed. Comparison between units, departments and nations is only suitable with the provision comparable data definitions and scoring method.</i></p>
<p>PSI 33. Birth Trauma – Injury to Neonate <i>This PSI is only recommended implemented in countries where case mix and comorbidity can be addressed. Comparison between units, departments and nations is only suitable provided that comparable data definitions and scoring method can be procured.</i></p>
<p>PSI 34. Postoperative Hip Fracture <i>The general restrictions concerning data comparability apply, please see above.</i></p>
<p>PSI 35. In-Hospital Hip Fracture or Fall <i>The general restrictions concerning data comparability apply, please see above.</i></p>
<p>PSI 37. Decubitus Ulcer <i>Comparison between units, departments and nations is only suitable provided comparable data definitions, registration and scoring method. This PSI is only suitable for nation wide comparison provided comparable data registration practise</i></p>
<p>PSI 41. Assessment of Suicidal Risk in Schizophrenic Patients <i>The general restrictions concerning data comparability apply, please see above.</i></p>
<p>PSI 42. Side Effect of Anti-Psychotic Treatment <i>The general restrictions concerning data comparability apply, please see above.</i></p>

Aspects to be considered concerning application of the PSIs

In connections with the rating of the dimension; “Feasibility” of each PSI the expert group discussed aspects such as data availability, the quality and features of administrative data present available, resources available, organisation of data collection in individual EU countries, legal systems concerning data collection individual data etc., however these aspects are not systematically deepened and uncovered by WP4 for EU, but we found common traits leading to questions, which need to be followed up upon, if one wants to use the PSIs for comparison over time or even benchmarking building up a European databank. Some of these questions need to be taken carefully into account when planning to use the PSIs for comparison over time – some are more relevant if one wants to consider benchmarking. The questions uncovered in need of further investigation are:

- How is the quality of administrative data – does it match the definitions of the PSIs? Are further definitions needed to make the PSIs suitable for use? E.g. some obstetric PSIs refer to a specific method; “Delivery with instrument”, the use of instruments needs more detailed definition – Also for example for the PSIs on Decubitus ulcer and on infections no further definitions on the pathology is given, it is important to have common definition on both pathology and methods etc. The expert group discussed these aspects and differences in best practice were present both within specialities, professionals and nations in EU, for correct use of the PSIs the quality for the data must be comparable.
- How do local/national differences in opinions, perceptions, attitudes, beliefs, values, norms, assumptions influence decisions among clinicians, hospital managements, policy makers and planners etc. on embarking on systematic collection of personal data – focusing on the frequency of adverse events and errors for the sake of using PSIs to develop patient safety?
- What resources are needed in individual hospitals/nations of Europe to embark on using the PSIs for comparison or even for benchmarking?
- How is the data collection organised (centralised/decentralised)?
- Do individual hospitals/nations have informatics and reliable systems?
- How the availability of administrative data is – is it sufficient in its current form?
- How do individual national legal systems allow data collection – especially with regard to data related to individuals?
- Not all European countries work with ICD-10 or DRG coding, how can this be handled for the PSIs where coding applies in case of benchmarking?

Patient Perspectives

Patients perspectives were represented in work of WP4 in different ways, firstly the organisation “Action against Medical Accidents” (AWA), an independent English charity promoting better patient safety and justice for people who have been adversely affected by a medical accident were represented in the over all project meetings, secondly five Institution-Wide PSIs were commented by a patient representative from AWA taking into account the experiences gathered by the organisation. Also the representative was asked to review and comment the characterisation of the PSIs and a draft of this report. Thirdly a range of international and national patient interest groups and organisation representatives participated the SImPatIE Consensus Conference in Luxembourg.

The following were asked for the five PSIs:

- Understanding; is the PSI explained to a degree ensuring patient understanding the aim/measure of the PSI?
- Relevance; Does the PSI provide relevant information for the patients in terms of patient safety (Do you believe it captures relevant aspect of care provided / if no: how can the measure be improved?)
- Feasibility of the PSI; would public results of the PSI assist the patient in the assessment of an institution and the choice of care provider?

As to the question of the understanding of the PSIs, one general comment was given: “The descriptions of the indicators are generally very technical and long. It could be rewritten in a much simpler way that patients would be more likely to understand”.

An extract of the comments made for the five PSIs on the questions of relevance and feasibility of the PSIs is shown beneath.

PSI 1. Measuring Hospital Standardised Mortality Rates

“Yes, I am sure that patients would find a consistent measure of hospital standardized mortality relevant. I believe that this PSI may well be useful to patients in helping make choices about care providers, where they are interested in making choices....”

PSI 3. Patients Experiencing Adverse Events and PSI 4 Patients Informed about an Adverse Event by the Staff

“...Yes this information is relevant – both the reported number of incidents and the way that the incident has been dealt with after the event. we believe from the point of view of patients as a whole, to have some indicators which are based on patients’ own experience rather than data collected from the provider. This is important from a credibility point of view.”

PSI 6 Transition of Care – Patients Understanding of the Purpose of their Medication

“...Yes, this is very relevant due to medication errors (as well as ‘compliance’) being a well known frequent problem. Communication is vital in helping ensure that both the clinician and the patient have an understanding of what is going on and why, and provides a ‘safety check’”

PSI 8 Surveying the Development of the Patient Safety Culture

“We believe there should be PSIs for cultural issues, but these need to be more specific (for example the informing patients/relatives of adverse events)...However, we would strongly recommend the adoption of PSIs for different elements of patient safety culture (so long as there is genuine consensus on what constitutes a good patient safety culture)”.

“Mistakes are a fact of life. It is the response to the error that counts.”

Nikki Giovani, Africa-American Poet, b. 1943

Main Conclusions and Recommendations

The work of WP4 was initiated to recommend an internal indicator set to be used in efforts to improve patient safety both at the system and organisation level and a brief rating assessment instrument for external application to provisional output.

Based on literature review, targeted information gathering and expert consultation, taking into account previous work done by the project partners and international quality and patient safety organisations a European expert panel worked in a structured consensus process to fulfil the purposes of the work package.

Patient safety is a complex, important and a high priority area across health care systems in Europe. Patient safety improvement requires cooperation and mutual organisational learning at the system level, which entails changes that cut across units, professions, levels of hierarchy, and nations.

PSIs measure the extent to which set targets are achieved. They are expressed as numbers, rates or averages that can provide a basis for clinicians, risk managers, organisations and planners aiming at achieving improvement in all-round patient safety. Provided the data sources of the PSIs are accessible in a feasible way, reliable, and valid, the PSIs are inexpensive and easy to use, and they provide reliable estimates of rates of preventable adverse events. Thus PSIs are valuable as a higher-level safety performance measure.

The Stepwise Assessment Indicator Framework Approach (SAIFA) to select, characterise, and evaluate indicators and a set of 42 clinically multi-facetted PSIs were established covering aspect of the system and the organisational level. A Brief Assessment Instrument was developed and presented as part of the SAIFA. “The Brief Assessment Instrument” is suitable for use with other measures than PSIs.

A number of 28 existing known indicators, which have been clinically applied was described and evaluated. Also 14 new PSIs were characterised and evaluated by the expert group. Description of the PSIs can be found on www.simpatie.org. The 28 existing known indicators mainly originate from AHRQ and OECD. For the indicators of AHRQ, OECD and others we refer to the original extensive literature. The SImPatIE PSIs are meant for clinical use by single providers, whereas the OECD indicators are aimed at use by the health care system, in this way the PSIs of SImPatIE and OECD supplement another.

The SImPatIE PSIs are specifically selected to capture instances representing preventable adverse events in the inpatient setting. The PSIs cover patient risk and harm related to aspects of structure, process and outcome in the categories: Institution-wide Measures, Theme Related Measures (“*Infections Control*”, “*Surgical Complication*”, “*Medication Errors*”, “*In- Hospital Fall*”, “*Obstetrics*”) and Diagnose Specific as well as other Measures. The PSIs cover a wide spectrum ranging from surveillance of cultural assessment to measurement of standardised mortality rates.

The consensus process of the WP4 expert group was successfully completed leading to a recommendation of nine out of 12 new SimPatIE PSIs whereas 16 of 30 PSIs from existing programmes were recommended for implementation in parts or throughout EU. The PSIs from existing programmes have all been clinically applied.

As the same principles of patient safety apply equally to both primary care and hospitals and to all health professions as well as to health promotion, prevention, diagnosis, treatment, rehabilitation, and other aspects of health care, some of the PSIs might be highly relevant and usable in other settings than aimed at in the present context. However this must be investigated in detail.

The established PSIs present a set of possible measures of patient safety. The themes and areas covered by this set are not intended to be exhaustive in the development of patient safety. E.g. within the area of measures of medication errors no indicators for “sound-alike” and “look-alike” medications are established. Though we find it highly relevant to work with these themes to improve safety, more suitable methods than PSIs can be found, and we support work in progress by project partners. The PSI concerning patients understanding of their medication at discharge from hospital can be seen as a supplement to medication reconciliation, which is part of the High 5s Initiative. In this context we recommend the continuous use of PSIs supplemented by other measures and initiatives to improve safety. Each institution must carefully plan, develop, and evaluate patient safety.

Due to patient safety cultural differences, which includes aspects of organisational and clinical culture and sub cultures e.g. related to specialities and professions as well as cultural differences related to national, regional and local aspects we do not recommend a common “package” of PSIs for implementation in EU. Prior to embarking on actual patient-safety assessment activities using the PSIs, a systematic strategy should be established at an institutional or regional level to measure, report, and use information. Implementing the PSIs must be based upon thorough assessment of suitable data, considerations of interpretation and use, and publication of result, especially considering that patients should participate in decisions about their health care, while recognising that health-care workers should provide patients and potential patients with adequate and clear information about potential risks and consequences.

In connections with the rating of the dimension; “Feasibility” of each PSI the expert group discussed aspects such as data availability, the quality and features of administrative data present available, resources available, organisation of data collection in individual EU countries, legal systems concerning data collection individual data etc., these aspects are not systematically deepened and uncovered by WP4 for EU, but we found common traits leading to questions, which need to be followed up upon, if one wants to use the PSIs for comparison over time or even benchmarking building up European Patient-Safety-Indicator-Database. Some of these questions need to be taken carefully into account when planning to use the PSIs for comparison over time – some are more relevant if one wants to consider benchmarking. The questions uncovered in need of further investigation are:

- How is the quality of administrative data – does it match the definitions of the PSIs? Are further definitions needed to make the PSIs suitable for use?
- How do cultural differences (e.g. opinions, perceptions, attitudes, beliefs, values, norms, assumptions and expectations) concerning adverse events and errors among clinicians, hospital management, policy makers and planners etc. influence the decision of embarking on systematic collection of personal data for the sake of using PSIs to develop patient safety?

- What resources are needed in individual hospitals/nations of Europe to embark on using the PSIs for comparison or even for benchmarking?
- How is the data collection organised (centralised/decentralised)?
- Do individual hospitals/nations have informatics and reliable systems?
- How the availability of administrative data is – is it sufficient in its current form?
- How do individual national legal systems allow data collection – especially with regard to data related to individuals?
- Not all European countries work with ICD-10 or DRG coding, how can this be handled for the PSIs where this coding applies in case of benchmarking?

In the work process of WP4 we uncovered that several member states work with different PSIs. We discussed the use of the PSIs and we believe that several of the used PSIs are suitable for spreading and using in Europe to a larger extent than what we found is the case today, thus we recommend a common European Patient-Safety-Indicator-Library containing information on indicators relevant for developing and monitoring patient safety. Such a European Patient-Safety-Indicator-Library must as a minimum be:

- well organised and coordinated across member states
- elaborated
- continuously up dated

to be useful and fulfil its purpose of cross nation knowledge sharing and cooperation.

A literature review shows that monitoring and developing patient safety is impossible without the use of patient safety indicators to assess effectiveness, efficacy and effect of interventions. Thus comparison using PSIs is highly recommendable and necessary, although the use of the recommended 28 PSIs implies methodological problems as the feasibility and quality of indicator data are varied along a number of dimensions across institutions and nations in Europe we estimate, that a subset of the indicators are usable in each EU country. Developing PSIs is an ongoing process in itself.

Additional work concerning homogeneous and comparable data and investigation of indicator sensitivity and specificity remains necessary prior to embarking on actual patient safety assessment activities using most of the PSIs for Europe wide common development here by supplying clinicians, risk managers, policymakers, and researchers with ongoing, comprehensive, and reliable data on patient safety. The methodology requires sophisticated resources in terms of informatics and reliable system wide patient identification and data processing. We strongly recommend that future projects on patient safety monitoring follow up and investigate these aspects to develop assessment of effectiveness, efficacy and effect of interventions.

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