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Selecting Indicators for Patient Safety at the Health Systems Level in OECD Countries

John Millar, Soeren Mattke
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JOHN MILLAR, SOEREN MATTKE AND THE MEMBERS OF THE OECD PATIENT SAFETY PANEL

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[1] John Millar, of the Canadian Institute for Health Information, was chair of the OECD Patient Safety Panel. Soeren Mattke, OECD Secretariat, was convenor of the panel and a co-author of this report. The remaining members of the OECD Patient Care Panel and co-authors of this report were: Margardia França, Instituto da Qualidade em Saúde, Portugal, Pia Maria Jonsson, National Board of Health and Welfare, Sweden, Vin McLoughlin, Department of Health and Ageing, Australia, and David Somekh, European Society for Quality in Healthcare. David Bates, Harvard Medical School and Brigham and Women's Hospital, US, contributed to the Discussion section. Brief biographies of the chair and Panel members are to be found in Annex 2.

SUMMARY

1. This report presents the consensus recommendations of an international expert panel on indicators for patient safety. Using a structured review process, the panel set out to select indicators to cover the five key areas: areas hospital-acquired infections, sentinel events, operative and postoperative complications, obstetrics, and other care related adverse events. This report proposes 21 indicators as follows:

Area	Indicator Name
Hospital-acquired infections	Ventilator pneumonia
	Wound infection
	Infection due to medical care
	Decubitus ulcer
Operative and post-operative complications	Complications of anaesthesia
	Postoperative hip fracture
	Postoperative pulmonary embolism (PE) or deep vein thrombosis (DVT)
	Postoperative sepsis
	Technical difficulty with procedure
Sentinel events	Transfusion reaction
	Wrong blood type
	Wrong-site surgery
	Foreign body left in during procedure
	Medical equipment-related adverse events
	Medication errors
Obstetrics	Birth trauma - injury to neonate
	Obstetric trauma – vaginal delivery
	Obstetric trauma - caesarean section
	Problems with childbirth
Other care-related adverse events	Patient falls
	In-hospital hip fracture or fall

The report describes the review process and provides a detailed discussion of the scientific soundness and policy importance of the 21 indicators.

RESUME

2. Ce rapport présente les recommandations consensuelles d'un groupe d'experts internationaux sur les indicateurs relatifs à la sécurité des patients. En suivant une méthodologie détaillée, le groupe d'experts a entrepris de sélectionner des indicateurs devant couvrir cinq grands domaines : infections nosocomiales, événements sentinelles, complications opératoires et post-opératoires, obstétrique, autres événements indésirables liés aux soins. Ce rapport propose les 21 indicateurs suivants:

Domaine	Nom de l'indicateur
Infections nosocomiales	Pneumopathies nosocomiales sous ventilation artificielle
	Infections des plaies
	Infections liées aux soins médicaux
	Escarres
Complications opératoires et post-opératoires	Complications de l'anesthésie
	Fracture de la hanche post-opératoire
	Embolie pulmonaire ou thrombose veineuse profonde post-opératoires
	Infection post-opératoire
	Difficulté technique en cours d'opération
Evénements sentinelles	Réaction à la transfusion
	Erreur de groupe sanguine
	Erreur de site opératoire
	Oubli d'un corps étranger dans le champ opératoire
	Evénements indésirables liés à l'équipement médical
	Erreurs de médication
Obstétrique	Traumatisme de la naissance
	Traumatisme obstétrical vaginal
	Traumatisme obstétrical - césarienne
	Accouchements difficiles
Autres événements indésirables liés aux soins	Chutes du patient
	Fracture de la hanche ou chute à l'hôpital

3. Le rapport décrit la méthodologie employée et démontre, arguments à l'appui, la viabilité scientifique et l'importance stratégique des 21 indicateurs retenus.

TABLE OF CONTENTS

Tables

INTRODUCTION

Background

4. This paper presents proposals for indicators of patient safety. This is one of five areas which have been identified by the OECD as having priority for the development of quality indicators (see Box 1) An Expert Group consisting of government officials and academic experts from the participating countries was tasked with identifying a shortlist of potential indicators in close collaboration with the Secretariat. Given resource constraints, this work was limited to reviewing existing indicators in Member countries rather than developing new indicators. This Technical Paper summarizes the proceedings and indicator recommendations of the Patient Safety Panel and incorporates comments from Member countries on an earlier report of the Panel. The first section describes the panel's methods of indicator selection and the second part the recommended indicators. The third section concludes with a discussion of the comprehensiveness and cohesiveness of the indicator set. A comprehensive discussion of all recommended indicators and short biographies of the Panel members can be found in Annex 1 and Annex 2, respectively.

Box 1. The OECD Quality Indicator Project

The technical quality of medical care, long regarded as a professional responsibility rather than a policy issue, now rivals cost and access as the foremost concern of health policymakers. A growing body of evidence suggests that the daily practice of care does not correspond to the standards that the medical profession itself puts forward. In addition, improving quality of care presents itself as an avenue to restraining the growth of medical expenditures by reducing costly complications and unnecessary procedures. In other words, better organisation and management of medical care would allow countries to spend their health care dollars more wisely. To improve care for their citizens and to realise these potential efficiency gains, policymakers are looking for methods to measure and benchmark the performance of their health care systems as a precondition for evidence-based health policy reforms. As published international health data sets such as OECD Health Data currently lack comparable measures for the technical quality of national health systems, there is, so far, little possibility of such international benchmarking. To fill this gap, the OECD Health Care Quality Indicators Project (HCQI) has brought together 21 countries[2], the World Health Organization (WHO), the European Commission (EC), the World Bank, and leading research organisations, such as the International Society for Quality in Health Care (ISQua) and the European Society for Quality in Healthcare (ESQH). An expert group representing these countries and organizations has identified five priority areas for initial development of indicators: cardiac care, diabetes mellitus, mental health, patient safety, and prevention/health promotion together with primary care

[2] The participating countries are Austria, Australia, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Japan, Mexico, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom (U.K.) and the United States (U.S.)

Methods of Indicator Selection

Conceptual Approach

5. To ensure comprehensive coverage of the most relevant domains of patient safety panel by the selected set of measures, the Patient Safety Panel decided that the final indicator set ought to cover the following five core domains of patient safety:

- Hospital-acquired infections;
- Sentinel events;
- Operative and postoperative complications;
- Obstetrics; and
- Other care related adverse events.

Box 2. Selection Criteria for Quality Indicators

Following the recommendations for indicator evaluation developed by the U.S. Institutes of Medicine, the Expert Group and all expert panels agreed on the following three selection criteria for indicators (Hurtado, Swift, and Corrigan, 2001). First, it had to capture an important performance aspect. Second, it had to be scientifically sound. And third, it had to be potentially feasible.

The importance of an indicator can be further broken down into three dimensions:

- Impact on health. What is the impact on health associated with this problem? Does the measure address areas in which there is a clear gap between the actual and potential levels of health?
- Policy importance. Are policymakers and consumers concerned about this area?
- Susceptibility to being influenced by the health care system. Can the health care system meaningfully address this aspect or problem? Does the health care system have an impact on the indicator independent of confounders like patient risk? Will changes in the indicator give information about the likely success or failure of policy changes?

The scientific soundness of each indicator can also be broken down into two dimensions:

- Face validity. Does the measure make sense logically and clinically? The face validity of each indicator in this report is based on the basic clinical rationale for the indicator, and on past usage of the indicator in national or other quality reporting activities.
- Content validity. Does the measure capture meaningful aspects of the quality of care?

The feasibility of an indicator reflects the following two dimensions:

- Data availability. Are comparable data to construct an indicator available on the international level?
- Reporting Burden. Does the value of the information contained in an indicator outweigh the cost of data collection and reporting?

As the panels were not able to make a definite statement about data availability for an indicator in all OECD countries, feasibility was given less weight in the decision process. The participating experts were asked to express their opinion as to whether it was likely, possible or unlikely to find comparable data on the international level for each indicator. If data availability was regarded as unlikely, an indicator was dropped, unless strong conceptual reasons existed to retain it.

All panels also agreed that every member would rate each indicator individually on a scale from one to nine for the scientific soundness and importance dimensions, as originally proposed by the RAND Corporation (Kerr et al., 2000). The panel would then discuss the indicator, potentially ask its members to reconsider their original ratings and make a final decision. Scores from seven to nine reflected support of the indicator, scores between one and three rejection of the indicator and scores between four and six ambivalence towards an indicator. The panel decided that all indicators with a final median score above 7.0 for both importance and scientific soundness and at least possible feasibility should be considered suitable and all indicators with a median rating of 5.0 or below for importance or scientific soundness should be rejected. The remaining indicators, i.e. the ones that fit neither cut-off criterion, were thoroughly discussed by the panel, leading to their adoption or rejection on a case-by-case basis.

Results of the Indicator Selection Process

6. A total of 59 indicators from seven different sources were identified by the Secretariat, submitted by the Expert Group or proposed by members of the Patient Safety Panel. The indicator sources are described in Table 1. Each panellist was asked to identify 20 measures they felt had the greatest prospects of being selected. Through a series of conference calls and email discussions, the Patient Safety Panel converged on a final list of 21 indicators that are listed in Table 2. A detailed discussion of their importance and scientific soundness can be found in Annex 1.

Discussion of the Cohesiveness and Comprehensiveness of the Proposed Indicator Set for the Area of Patient Safety

General Comments

7. Measures of other aspects of quality have been developed for some time, and they are increasingly widely used and accepted. However, it has proved more challenging to identify measures for patient safety that can be widely used, for a variety of reasons. Some of these are that serious adverse events are relatively infrequent, but perhaps more important is that current detection systems which rely on self-report miss most of them. Another key detection approach involves using billing codes, and under-coding of these problems is frequent. In addition, it is sometimes challenging to determine whether a specific event represents something that should be counted.

8. Many studies now demonstrate that patient safety is an international problem. For example, large studies in the United States, New Zealand, Australia, Canada, and the United Kingdom have all identified high rates of adverse events, and smaller studies in many other countries have found important safety issues.

9. Understandably, the public in most countries is very concerned about safety, and would like to be able to assess how safe the care it is or will be getting is. Moreover, historically there have been few incentives for providers to deliver safer care, and strong disincentives for revealing safety problems, which may in part be why the fact that there are major issues with safety in health, went relatively unnoticed for so long.

Specific Comments

10. As a result, there is now a major need to begin to measure safety on an on-going basis, though it is less clear about how best to do it. This committee was charged with selecting measures that would best allow the assessment of safety in an on-going way, given the current available knowledge.

11. One way to categorise safety events is whether they should never (or nearly never) occur, or whether they do occur sometimes, but at a finite rate that should be minimised. Some of each of these are included in the measure set, but it might be helpful to separate them. That would make it possible to aggregate the events that never occur to create a somewhat more stable rate. Examples of events that should never occur include wrong-side and wrong-site surgery, and death from medication error. Examples of safety events that will continue to occur at a finite rate are surgical site infections and development of bedsores.

12. This measure set includes only measures that focus on specific clinical outcomes. While this was likely a conscious choice, another approach is to use measures that apply at an organisational level, for example whether a hospital or practice is utilising computerised prescribing, or has implemented practices demonstrated to reduce the rate of ventilator-associated pneumonia. In addition, all the indicators address hospital events.

Comments Regarding Individual Measures:

- For some of the measures, such as death of serious complications from medication errors, under-coding has been ubiquitous. It is still worthwhile to use this as a measure, but it is important for policymakers to recognise that the rate identified by this does not necessarily represent the rate of the problem.

- For many other measures such as postoperative pulmonary embolism or deep vein thrombosis and postoperative sepsis, secondary review is required of individual cases if it is desirable to assess whether any individual event actually represents a patient safety event.

- Several of the measures overlap, for example death or serious complications from medication errors and medication error, transfusion reaction and wrong blood type, and infection due to medical care and postoperative sepsis. In some instances, only one of each of these measures should be used, and in others the differences should be resolved, but it will be worthwhile overall to examine the remainder for overlaps and duplications and eliminate or merge these indicators as necessary.

13. It is important to recognise that even the aggregate of these measures does not provide anything like a complete picture of patient safety, and will thus represent the "tip of the iceberg.' For many areas, such as missed diagnosis, we simply do not yet have reliable measures. In the medication area, only deaths or serious complications related to medication errors are included. While those severe events are more likely to be recorded, they only represent a small proportion of the overall events. For example, death occurs in less than one percent of all adverse drug events, and the other severe complications included in the indicator are, fortunately, equally rare. The aggregate burden to society of the less severe adverse drug events, however, is almost certainly vastly greater than that of the severe ones, because they too will lead to additional diagnostic and therapeutic procedures and extension of hospital stays, but not to permanent and easily visible harm to patients. That being said, to date there is no good measure for adverse drug events that can be widely applied across even one nation. Thus, while the current measure set represents a good selection, it is tilted heavily toward the most severe events, which occur at sufficiently low rates that

point estimates may be unstable, and it will be important to revisit this set over time. Examples of safety events that do occur at relatively high rates and are included in the set are surgical site infections and decubitus ulcers.

14. Internationally, there has been great interest in identifying the major safety issues, and at facilitating progress. In the US, there have been a number of important recent efforts. The National Quality Forum has released its list of "never events," 27 events that should never happen, and the also its release of 30 safe practices, practices that have been demonstrated to or are widely believed to improve care. The measures included here map well to the never events, and the safe practices report, although the latter is not focused on safety measures specifically, but rather on what institutions can do. In addition, the Institute of Medicine has recently convened a committee on Patient Data Safety Standards, which will be releasing a report later this fall. In other countries, there has been particularly widespread activity in the United Kingdom, but also in Australia for example.

22. Many of these indicators rely on data that have been entered for administrative (billing and accounting) purposes and have not been rigorously assessed for various dimensions of data quality such as accuracy, reliability and reproducibility.

15. Consideration of these recommendations suggests a number of areas that might represent good targets for future measures. Some of these might be level of nursing staffing per level of acuity, whether pharmacists participate actively in the medication use process, and whether a core set of data are routinely transmitted in a transition from one type of care to another. Standards for these areas do not yet exist, but they are likely to represent fertile ground for future standards development, given that for example a fairly strong association between mortality and level of nursing staffing, and adverse events appear to be especially common after transitions. Of course, development of a standard for nursing staffing would be highly controversial, and would be especially difficult to do at the international level given the many differences between care systems.

16. In conclusion, although this represents an outstanding set of measures, it is important to recognise that this set will require considerable refinement over time. It will be important to recognise that a low rate of problems on these measures does not necessarily mean that safety at an individual site is good, because of the "tip of the iceberg" phenomenon mentioned earlier. Furthermore, any system that relies on billing codes should consider what the incentives are to institutions regarding using codes that will be flagged. It is likely that as electronic health records become more widely used that it will eventually be possible to detect safety events with considerably greater sensitivity and specificity than is possible today. Overall, this set of measures represents an exciting development, and their use should be tested in a variety of countries.

Table 1. Indicator Sources

Set Name	Description
AHRQ Safety Indicators	This measure set was developed by UCSF for the US Agency for Healthcare Research and Quality (AHRQ). Safety measures were developed using 1) a background literature review, 2) structured clinical panel reviews of candidate indicators, 3) expert review of diagnosis codes, and 4) empirical analyses of potential indicators. These indicators are all derived from hospital administrative data. A full report contains many more indicators that were not selected.
AHRQ/CIHI Safety Indicators	AHRQ safety indicators adapted for use in Canada by the Canadian Institute for Health Information (CIHI).
Aus. Council for Safety and Quality	The Australian Council for Safety and Quality in Health Care has developed indicators for sentinel events (binomial, catastrophic, symptomatic of system failure) which have been agreed by all Australian Health Ministers. These indicators were selected as these events cause serious harm to patients and have the potential to undermine public confidence in the health system, warrant robust investigation and analysis. The information systems issues are being worked through in each state/territory to enable reporting of these indicators.
Complications Screening Programme BIH	This measure set was developed at the Beth Israel Hospital (BIH) in Boston, US The BIH Complications Screening Programme algorithm uses discharge abstract data to identify complications that raise concerns about the quality of hospital care. This set includes 27 complication-rate indicators to screen for patterns that could be prevented by improving the processes of care.
JCAHO IMSystem: Infection Control	The Indicator Measurement (IM) System was developed by the Joint Commission on Accreditation of Healthcare Organisations (JCAHO). It is designed to incorporate continuous performance measurement into the accreditation process, and provide periodic feedback to health-care organisations. This indicator set measures adverse patient outcomes in infection control.
JCAHO sentinel events	This measure set is a collection of sentinel events that the US Joint Commission on Accreditation of Healthcare Organisations collects through a voluntary reporting process.

Table 2. Summary table of recommended set

Area	Indicator Name	Numerator	Denominator
Hospital-Acquired Infections			
	Ventilator pneumonia	Ventilated inpatients who develop pneumonia.	Inpatient (ICU/Non-ICU) ventilator days.
	Wound infection	Patients experiencing a wound infection (ICD-9 998.51 and 998.52). Secondary diagnosis only.	All hospitalised patients
	Infection due to medical care	Discharges with ICD-9-CM code of 999.3 or 996.62 in any secondary diagnosis field per 100 discharges.	All medical and surgical discharges. Exclude patients with any diagnosis code for immuno-compromised state or cancer.
	Decubitus ulcer	Discharges with ICD-9-CM code of 707.0 in any secondary diagnosis field per 100 discharges.	All medical and surgical discharges. Include only patients with a length of stay of more than 4 days. Exclude patients in MDC 9 or patients with any diagnosis of hemiplegia, paraplegia, or quadriplegia. Exclude patients admitted from a long-term care facility.
Operative and Postoperative Complications			
	Complications of anaesthesia	Discharges with ICD-9-CM diagnosis codes for anaesthesia complications in any secondary diagnosis field per 100 discharges.	All surgical discharges. Exclude patients with codes for poisoning due to anaesthetics E855.1, 968.1-4, 968.7 AND any diagnosis code for active drug dependence, active nondependent abuse of drugs, or self- inflicted injury.
	Postoperative hip fracture	Discharges with ICD-9-CM code for hip fracture in any secondary diagnosis field per 100 surgical discharges.	All surgical discharges. Exclude patients who have musculoskeletal and connective tissue diseases (MDC 8). Exclude patients with principal diagnosis codes for seizure, syncope, stroke, coma, cardiac arrest, poisoning, trauma, delirium and other psychoses, or anoxic brain injury. Exclude patients with any diagnosis of metastatic cancer, lymphoid malignancy or bone malignancy, self-inflicted injury. Exclude patients 17 years of age and younger.
	Postoperative pulmonary embolism or deep vein thrombosis	Discharges with ICD-9-CM codes for deep vein thrombosis or pulmonary embolism in any secondary diagnosis field per 100 surgical discharges.	All surgical discharges. Exclude patients with a principal diagnosis of deep vein thrombosis. Exclude all obstetric admissions (MDC 14 and 15). Exclude patients with secondary procedure code 38.7 when this procedure occurs on the day of or previous to the day of the principal procedure.
	Postoperative sepsis	Discharges with ICD-9-CM code for sepsis in any secondary diagnosis field per 100 discharges in the population at risk.	All elective surgical discharges. Exclude patients with a principal diagnosis of infection, or any code for immuno-compromised state, or cancer. Include only patients with a length of stay of more than three days. Exclude all obstetric admissions (MDC 14 and 15).

Area	Indicator Name	Numerator	Denominator
	Technical difficulty with procedure	Discharges with ICD-9-CM code denoting technical difficulty (*e.g.*, accidental cut, puncture, perforation or laceration during a procedure) in any secondary diagnosis field per 100 discharges.	All medical and surgical discharges. Exclude all obstetric admissions (MDC 14 and 15).
Sentinel Events			
	Transfusion reaction	Discharges with ICD-9-CM codes for transfusion reaction in any secondary diagnosis field per 100 discharges.	All medical and surgical discharges.
	Wrong blood type	Number of haemolytic blood transfusion reaction resulting from ABO incompatibility.	All transfusions.
	Wrong-site surgery	Number of procedures on the wrong patient, wrong side of the body, or wrong organ.	All procedures.
	Foreign body left in during procedure	Discharges with ICD-9-CM codes for foreign body left in during procedure in any secondary diagnosis field per 100 surgical discharges.	All medical and surgical discharges.
	Medical equipment-related adverse event	Number of patient deaths or major permanent losses of function associated with a problem with medical equipment.	Not applicable[3]
	Medication error	Number of patient deaths, paralysis, coma, or other major permanent loss of function associated with a medication error.	Not applicable[4]
	Death and complications from medication error	Number of patient deaths or serious complications (CNS damage with squeal, myocardial infarction, pulmonary embolism, blood disorders) likely to be caused by medication errors.	Not applicable[5]

3 The original developer of this indicator conceived it as sentinel event indicator, i.e. it would reflect events that should never happen. Consequently, the original definition has no denominator. However, if the indicator were applied to the health system level, an appropriate denominator would have to be used to be able to compare rates across countries.

4 The original developer of this indicator conceived it as sentinel event indicator, i.e. it would reflect events that should never happen. Consequently, the original definition has no denominator. However, if the indicator were applied to the health system level, an appropriate denominator would have to be used to be able to compare rates across countries.

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Area	Indicator Name	Numerator	Denominator
Obstetrics			
	Birth trauma - injury to neonate	Discharges with ICD-9-CM codes for birth trauma in any diagnosis field per 100 live-born births.	All live-born infants. Exclude infants with a subdural or cerebral haemorrhage (subgroup of birth trauma coding) AND any diagnosis code of preterm infant (denoting a birth weight of less than 2,500 g and less than 37 weeks gestation). Exclude infants with injury to skeleton (767.3, 767.4) AND any diagnosis code of osteogenesis imperfecta (756.51).
	Obstetric trauma - vaginal	Discharges with ICD-9-CM codes for obstetric trauma in any diagnosis or procedure field.	All vaginal delivery discharges. Include instrument assisted delivery.
	Obstetric trauma - caesarean section	Discharges with ICD-9-CM codes for obstetric trauma in any diagnosis or procedure field per 100 caesarean deliveries.	All caesarean delivery discharges.
	Problems with childbirth	Maternal death or serious morbidity associated with labour or delivery.	Total number of labour and deliveries.
Other Care Related Adverse Events			
	Patient fall	Number of patient falls that result in death or major permanent loss of function as a direct result of the injuries sustained in the fall.	Not applicable.
	In-hospital hip fracture or fall	Patients experiencing an in-hospital hip fracture OR fall as defined by the CSP: secondary diagnosis only and excluding patients with trauma or metastatic cancer as any diagnosis; excluding patients with principal diagnosis of seizure, syncope, stroke, coma, cardiac arrest, or poisoning; excluding patients in MDC 8.	Inpatients undergoing major surgery OR minor or miscellaneous surgery OR invasive cardiac procedures OR invasive radiologic procedures OR endoscopy OR medical patients OR all patients as defined by the CSP.

ANNEX 1: DETAILED DISCUSSION OF THE RECOMMENDED INDICATORS

Hospital-Acquired Infections

Ventilator Pneumonia

Operational definition

17. **Source:** JCAHO IMSystem: Infection Control (AHRQ, 2002).

Numerator: Ventilated inpatients who develop pneumonia.

Denominator: Inpatient (ICU and Non-ICU) ventilator days.

18. Data requirement: Administrative data.

Importance of the indicator

19. Clinical significance: Ventilator-associated pneumonia (VAP) is a leading cause of morbidity and mortality in the ICU. Incidence of VAP varies greatly, ranging from 6-52% of intubated patients depending on patient risk factors. Overall VAP is associated with an attributable mortality of up to 30%.

20. Policy importance: Patient safety has become a major quality issue since the formation of the National Patient Safety Foundation by the American Medical Association in 1996, although the clinical magnitude of the problem was already identified in 1991 by the Harvard Medical Practice Study (Brennan *et al*., 1991). Similar national organisations, responding to the same issue are AIMS (Australian Incident Monitoring System) and NPSA (National Patient Safety Agency) in the UK.

21. Susceptibility to being influenced by the health care system: Collard and Saint (2001) review four evidence based practices that carry the potential to reduce the incidence of VAP in patients receiving mechanical ventilation, including randomised clinical trials.

Scientific soundness of indicator

22. Face validity: Given the grave consequences of VAP and the efforts that ICUs undertake to prevent them, VAP rates appear to be a plausible indicator of patient safety. However, the literature identifies only a small number of explicit processes of care that have been proven in randomised clinical trials for preventing this complication.

23. Construct validity: Like for many safety indicators, the greatest threat to validity is differential reporting.

Wound Infection

Operational definition

24. **Source**: Complications Screening Programme.

Numerator: Patients experiencing a wound infection (ICD-9 998.51 and 998.52). Secondary diagnosis only.

Denominator: All hospitalised patients.

Importance of the indicator

25. Clinical significance: The occurrence of a wound infection can have clinical consequences that range from minor insignificant inflammation to considerable pain and suffering, wound disruption, septicaemia and even death. Re-operation and prolonged hospitalisation are often required.

26. Identification of process/outcome as quality problem: The incidence of wound infection can be reduced by proper pre-, intra- and post-operative care, in particular strict hygiene. It is long known that hospital staff tends to neglect simple measures like hand washing and use of disinfectants.

27. Policy importance: Given the high cost of hospital care, it is of great importance to reduce the incidence of such adverse events.

Scientific soundness of the indicator

28. Face validity: As various clinical processes are proven to be linked to wound infections, this is a plausible measure.

29. Content validity: It may be difficult to get consistent, accurate documentation of the severity of wound infections.

Operational issues

30. Data availability: It is unlikely that standardized comparable data to support this indicator are available consistently across OECD countries.

Infection Due to Medical Care

31. **Source**: AHRQ Safety Indicators.

Numerator: Discharges with ICD-9-CM code of 999.3 or 996.62 in any secondary diagnosis field per 100 discharges.

Denominator: All medical and surgical discharges. Exclude patients with any diagnosis code for immuno-compromised state or cancer.

32. Data requirements: Administrative data.

Importance of the indicator

33. Clinical significance: Infections related to medical care can be a very serious problem in some cases leading to death. Often patients experience pain and other discomfort.

34. Identification of process/outcome as quality problem: As nosocomial infections are often preventable, the occurrence of infections in the course of medical care is an important measure of the quality of care.

35. Policy importance: As infections also prolong pain and suffering and the duration of hospitalisation, this indicator also has important economic and legal policy implications.

36. Susceptibility to being influenced by the health care system: Many infections acquired in the course of medical care are preventable by proper hygiene, rational use of antibiotics and other measures.

Scientific Soundness of the Indicator

37. Face validity: The occurrence of nosocomial infection is widely acknowledged to be a valid measure of health care quality. This measure has been recommended in the US by the Complications Screening Programme, the University HealthSystem Consortium and the American Nurses Association.

38. Content validity: The ICD codes chosen are reasonable but there may be considerable variation in the coding practices.

Operational issues

39. Availability of interpretive data: There is no standard for interpreting results

40. There is a need for case-mix adjustment across countries.

41. Data availability: Most jurisdictions should be able to provide data on hospitalised patients.

Decubitus Ulcer

42. **Source**: AHRQ/CIHI Safety Indicators.

Numerator: Discharges with ICD-9-CM code of 707.0 in any secondary diagnosis field per 100 discharges.

Denominator: All medical and surgical discharges. Include only patients with a length of stay of more than 4 days. Exclude patients in MDC 9 or patients with any diagnosis of hemiplegia, paraplegia, or quadriplegia. Exclude patients admitted from a long term care facility.

Importance of the indicator:

43. Clinical significance: The occurrence of a decubitus ulcer in a hospitalized patient has a serious negative impact on the individual's health and often leads to a much prolonged hospital stay.

44. Identification of process/outcome as *quality problem*: Decubitus ulcers can be prevented with good quality nursing care.

45. Policy importance: In addition to being a good measure of quality, the economic impact of extended hospital stays makes this indicator important for both financial and quality improvement policies.

46. Susceptibility to intervention: Decubitus ulcers are preventable with good quality nursing care.

Scientific soundness of the indicator:

47. Face validity: Decubitus ulcers or bedsores are a common complication of inadequate care for immobilized patients. Thus, the indicator has great clinical plausibility as a patient safety measure.

48. Construct validity: While the indicator is well operationalized, the biggest threat to construct validity is the inability to precisely distinguish between pre-existing and hospital-acquired decubitus ulcers on the basis of administrative data.

Operational issues

49. Data availability: Most jurisdictions should have reliable data for hospitalised patients.

Operative and Postoperative Complications

Complications of Anaesthesia

Operational definition

50. **Source**: AHRQ/CIHI Safety Indicators (AHRQ, 2002; Auerbach *et al*., 2001; Auerbach and Islam, 2001).

Numerator: Discharges with ICD-9-CM diagnosis codes for anaesthesia complications in any secondary diagnosis field per 100 discharges.

Denominator: All surgical discharges. Exclude patients with codes for poisoning due to anaesthetics E855.1, 968.1-4, 968.7 AND any diagnosis code for active drug dependence, active nondependent abuse of drugs, or self- inflicted injury.

51. Data requirements: Administrative data.

Importance of indicator

52. Clinical significance: Death due to anaesthesia has become rare (such as to rival the safety record achieved in other high risk industries such as aviation). By contrast morbid events, *i.e.* complications related to anaesthetic care are much more prevalent, ranging from postoperative nausea through to equipment failure (leading for example to hyperventilation with potentially serious morbidity such as stroke or AMI). Many such events (apart from the obvious ones given above) may be difficult to classify as preventable or avoidable.

53. Policy importance: Patient Safety has become a major quality issue since the formation of the National Patient Safety Foundation by the American Medical Association in 1996, although the clinical magnitude of the problem was already identified in 1991 by the Harvard Medical Practice Study (Brennan *et*

al., 1991). Similar national organisations, responding to the same issue are AIMS (Australian Incident Monitoring System) and NPSA (National Patient Safety Agency) in the UK.

Scientific soundness of the indicators

54. Face validity: The AHRQ evidence report that was compiled to back up the measure provides support that various procedural improvements, like pre-anaesthesia checklists, can reduce errors. Others, however, like intense intra-operative monitoring, failed to produce better outcomes. Further, the studies reviewed to support this indicator have mainly been observational without control group, reducing the face validity of the indicators.

55. Construct validity: The key problem here would seem to be the difficulty in classifying the majority of adverse events as preventable or avoidable. Adequate criteria appear not to be available. There may also be underreporting in administrative data.

Operational Issues:

56. Evidence supporting indicator validity: The indicator has recently been developed and is not yet in operational use. There are insufficient data to comment on indicator validity.

Postoperative Hip Fracture

Operational definition

57. **Source**: AHRQ/CIHI Safety Indicators.

Numerator: Discharges with ICD-9-CM code for hip fracture in any secondary diagnosis field per 100 surgical discharges.

Denominator: All surgical discharges. Exclude patients who have musculoskeletal and connective tissue diseases (MDC 8). Exclude patients with principal diagnosis codes for seizure, syncope, stroke, coma, cardiac arrest, poisoning, trauma, delirium and other psychoses, or anoxic brain injury. Exclude patients with any diagnosis of metastatic cancer, lymphoid malignancy or bone malignancy, self-inflicted injury. Exclude patients 17 years of age and younger.

Importance of the indicator

58. Clinical significance: This indicator captures the incidence of postoperative hip fractures (as distinct from hip fractures occurring in non-surgical settings) and is intended to reflect the quality of post-operative care. As hip fracture can have devastating consequences including pain, loss of function and, sometimes, death, it has immense clinical significance. When hip fracture occurs in the post-operative period it can reflect inappropriate prescribing by medical staff (*e.g.*, use of long-acting sedatives) or inadequate nursing procedures (*e.g.*, lack of patient monitoring and bedrail use).

59. Policy importance: As postoperative hip fractures can cause pain, suffering, prolonged hospital stays and additional surgical interventions, monitoring this indicator is important for pursuing quality improvement, economic, legal and ethical policies.

60. Susceptibility to intervention: The incidence of post-operative hip fracture can be reduced through the monitoring of this indicator in the context of a quality improvement programme aimed at encouraging appropriate post-operative prescribing and good nursing practices.

Scientific soundness of the indicator

61. Face validity: Although it may be impossible to completely eliminate postoperative falls leading to hip fracture, through appropriate prescribing and use of pain relief medication and good nursing care, these should be kept to a minimum.

62. Content validity: For surgical cases the coding quality has been found to be high, even though there may also be underreporting in administrative data.

Operational issues

63. Data availability: Administrative data on postoperative hip fractures should be readily available in most OECD countries.

Postoperative Pulmonary Embolism(PE) or Deep Vein Thrombosis(DVT)

Operational definition

64. **Source**: AHRQ/CIHI Safety Indicators.

Numerator: Discharges with ICD-9-CM codes for deep vein thrombosis (DVT) or pulmonary embolism (PE) in any secondary diagnosis field per 100 surgical discharges.

Denominator: All surgical discharges. Exclude patients with a principal diagnosis of DVT. Exclude all obstetric admissions (MDC 14 and 15). Exclude patients with secondary procedure code 38.7 when this procedure occurs on the day of or previous to the day of the principal procedure.

Importance of the indicator

65. Clinical significance: The occurrence of postoperative PE/DVT can range from mild symptoms to devastating clinical consequences including pain, respiratory distress, and death.

66. Policy importance: Because PE/DVT can cause unnecessary prolongation of hospital stays as well as unnecessary pain, suffering and death, this indicator has important financial and quality improvement implications.

67. Susceptibility to being influenced by the health care system: PE/DVT can be prevented through the appropriate use of anticoagulants and other preventive measures.

Scientific soundness of the indicator

68. Face validity: Given the numerous measures undertaken to reduce postoperative PE/DVT, this indicator has clinical plausibility.

69. Content validity: Coding of those events should be unambiguous, but PE/DVT is known to frequently go undiagnosed. Thus, health system with better monitoring practices may be mislabelled as having unusually high event rates.

Operational issues

70. Data availability: Administrative data on PE/DVT should be available in most OECD countries.

Postoperative Sepsis

Operational definition

71. **Source**: AHRQ Safety Indicators.

Numerator: Discharges with ICD-9-CM code for sepsis in any secondary diagnosis field.

Denominator: All elective surgical discharges. Exclude patients with a principal diagnosis of infection, or any code for immuno-compromised state, or cancer. Include only patients with a length of stay of more than three days. Exclude all obstetric admissions (MDC 14 and 15).

Importance of the indicator

72. Clinical significance: The occurrence of sepsis following surgery is a severe complication with a mortality rate of up to 30%. Even less severe cases will require prolonged ICU treatment for organ failure. As many cases of postoperative sepsis can be prevented, primarily through a reduction of hospital infection rates, this indicator is a good measure of quality.

73. Policy importance: This indicator is relevant to both quality improvement and cost containment, as prolonged hospital stays due to postoperative sepsis have considerable economic impact.

74. Susceptibility to being influenced by the health care system: Many cases of postoperative sepsis can be prevented through the appropriate use of prophylactic antibiotics, good surgical site preparation, careful and sterile surgical techniques and good post-op care.

Scientific soundness of the indicator:

Face validity: Sepsis after elective surgery is considered a severe complication. It usually results from less severe infective complications, such as urinary tract infections, pneumonia and would infection, which should be avoided and/or properly treated. Consequently, this indicator is a plausible patient safety measure.

Content validity: Given the dramatic nature of this complication, it is usually reliably coded in administrative data sources/

Operational issues

75. Data availability: Data should be available in most OECD countries.

Technical Difficulty with Procedure

Operational definition

76. **Source**: AHRQ Safety Indicators (AHRQ, 2002).[6]

Numerator: Discharges with ICD-9-CM code denoting technical difficulty (*e.g.*, accidental cut, puncture, perforation or laceration during a procedure) in any secondary diagnosis field per 100 discharges.

Denominator: All medical and surgical discharges. Exclude all obstetric admissions (MDC 14 and 15).

77. Data requirement: Administrative data.

Importance of indicator

78. Clinical significance: While for example accidental cut, puncture, perforation or laceration during a surgical procedure is a recognised risk, for example of abdominal surgery, elevated rates of such complications may indicate systems problems, such as inadequate surgical training or fatigued surgeons.

79. Policy importance: Patient Safety has become a major quality issue since the formation of the National Patient Safety Foundation by the American Medical Association in 1996, although the clinical magnitude of the problem was already identified in 1991 by the Harvard Medical Practice Study (Brennan *et al.*, 1991). Similar national organisations, responding to the same issue are AIMS (Australian Incident Monitoring System) and NPSA (National Patient Safety Agency) in the UK.

80. Susceptibility to being influenced by the health care system: Traditionally such adverse events were dealt with by peer review procedures, the effectiveness of which in reducing future frequency of adverse events has not been proven. It remains to be seen whether national schemes such as those already referred to will eventually demonstrate more convincing effects.

Scientific soundness of the indicator

81. Face validity: There has been considerable dispute over what to include and not to include in this measure (Iezzoni *et al.*, 1994).

82. Construct validity: No convincing evidence on validity is available from previous studies.

Operational issues

83. Data availability: Data on PE/DVT should be available in most OECD countries.

6. The Evidence-based Practice Centre (EPC) at University of California – SF and Stanford University with the University of California Davis contracted with AHRQ to review and improve the evidence-based related to potential indicators that can be developed from administrative data. A major source of data are the CSP (complications screening programme) developed by Lisa Iezzoni *et al.*, 1992).

Sentinel Events

Transfusion Reaction

Operational definition

84. **Source**: AHRQ/CIHI Safety Indicators.

Numerator: Discharges with ICD-9-CM codes for transfusion reaction in any secondary diagnosis field per 100 discharges.

Denominator: All medical and surgical discharges.[7]

Importance of the indicator

85. Clinical significance: The administrations of blood to the wrong person may have serious effects. The risk of adverse outcome from erroneous transfusion rivals or exceeds current estimates of the risk of acquiring infectious disease by transfusion (Linden *et al*., 2000). According the same authors the systems must be redesigned to allow minor fluctuations in human performance, especially in routine tasks. The use of systems designed to prevent specific errors may be helpful (such as convenient access to standard operating procedures instructions in work areas, a blood component lock system that will not allow the access of a component unless there is patient wristband and blood component match, etc.).

86. Recent studies on human error in medicine followed methods derived from the experience gained while analysing large-scale technological disasters (Eagle *et al.*, 1992; Reason, 1990). They recognised that medical, like technological, accidents nearly always require the conjunction of two types of failures: active failures, mistakes happening while performing a task, and latent failures, or management system errors. The latter ones are more difficult to perceive, because they constitute silent failures residing inside a system until a human error allows their expression into a major accident (Baele *et al.*, 1994). According to this author the detection and the correction of the latter type failure, ideally before the occurrence of accidents, is more efficient in improving the overall quality of a system than any action aiming only active failures. Clinician panellists from AHRQ consider that this indicator very likely reflects actual medical errors. As is expected, this indicator proved to be very rare with less than 1 per 10 000 cases at risk (McDonald, 2002).Scientific soundness of the indicator

87. Evidence supporting indicator validity: This indicator was originally proposed by Iezzoni *et al*. (1992) as part of the Complications Screening Programme (CSP "sentinel events"), along with gas gangrene, CNS abscess, anoxic brain injury, accidental puncture or laceration, wound dehiscence, and foreign body left in (all of which were omitted from this indicator). It was also included as one component of a broader indicator ("adverse events and iatrogenic complications") in AHRQ's original HCUP Quality Indicators. It was proposed by Miller *et al.* (2001) in the original "AHRQ PSI Algorithms and Groupings," although their definition also includes minor transfusion reactions (999.8), which was omitted from this indicator (McDonald *et al*., 2002).

Operational Issues

88. Some countries have been made efforts to quantify the magnitude of the non-infectious risks of transfusions include the voluntary SHOT programme; the New York State Department of Health mandatory

7. The panel recommends changing the denominator to all transfusions.

reporting programme of transfusion – related incidents, accidents and errors; the French Haemovigilance System; and the Belgium SANGUIS Group (Callum, 2001). However, the data may not be available in countries without similar programmes.

Wrong Blood Type[8]

Operational definition

89. **Source**: Australian Council for Safety and Quality.

Numerator: Number of haemolytic blood transfusion reaction resulting from ABO incompatibility.

Denominator: All transfusions.

Importance of indicator

90. The chance of a patient suffering a fatal transfusion reaction due to ABO-incompatibility is roughly equivalent to the risk of acquiring HIV infection from a blood transfusion (AHRQ, 2001). Half of the reported deaths due to major complications of transfusion in United Kingdom and the United States are a consequence of the transfusing the wrong blood to a patient. In the UK and Ireland, between October 1996 and September 1998, 366 reports of death or major complications of transfusions were reported and the most common (52%) adverse event was giving the wrong blood to the patient (Callum *et al.*, 2001). According to the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) statistics the three major root causes of transfusion events are: Orientation/training, Patient identification and care planning (JCAHO, accessed 2004).

Scientific soundness of the indicator

91. The administration of blood to the wrong patient remains the leading cause of acute haemolytic transfusion reactions and subsequent death. Acute haemolytic transfusion reactions due to ABO incompatibility remain the leading cause of the deaths associated with blood collection or transfusion, and the administration of blood to the wrong person is the cause of most acute haemolytic transfusion reactions (Jensen and Crosson, 1996).

92. Some countries have been made efforts to quantify the magnitude of the non-infectious risks of transfusions include the voluntary SHOT programme; the New York State Department of Health mandatory reporting programme of transfusion – related incidents, accidents and errors; the French Haemovigilance System; and the Belgium SANGUIS Group (Callum *et al.*, 2001). However, the data may not be available in countries without similar programmes.

Wrong-Site Surgery

Operational definition

93. **Source**: JCAHO sentinel events (JCAHO, accessed 2004).

8. The panel acknowledges that only one indicator for transfusion reactions should be put forward. The choice between the two indicators may be determined by actual reporting practices and thus data availability.

Numerator: Number of procedures on the wrong patient, wrong side of the body, or wrong organ.

Denominator: All procedures.

94. Data requirement: Administrative data.

Importance of the indicator

95. Clinical significance: "Wrong-site surgery" has received international prominence as a sentinel event, with Dennis O'Leary, current JCAHO President stating "even one wrong-site surgery is one too many". Although it is accepted that there is gross underreporting it is still not a common event. For example only 16 cases were reported to JCAHO in 1998 and 58 in 2001. Although we do not know for certain, it is likely that increased reporting reflects greater awareness rather than significantly increased incidence of the problem. The consequences of error can be severe, but to provide an idea of the magnitude of the problem, it is estimated that 1 in 4 orthopaedic surgeons may make such an error once in 25 years of practice.

96. Identification of process/outcome as quality problem: Such sentinel events, even though they are rare, may provide insight into substantial system failures that allow those events to happen. These failures ought to be uncovered by root cause analysis that tries to determine the proximal reasons for catastrophic events with the intent to prevent future mishaps. This concept has successfully been applied in aviation and manufacturing industries to improve safety and reliability of operations. In medical care, mistakes in verification of patient identity, miscommunication between staff members, mistakes in medical records and lack of standardised procedures are among identified causes.

97. Policy importance: Patient Safety has become a major quality issue since the formation of the National Patient Safety Foundation by the American Medical Association in 1996, although the clinical magnitude of the problem was already identified in 1991 by the Harvard Medical Practice Study (Brennan, 1991). Similar national organisations, responding to the same issue are AIMS (Australian Incident Monitoring System) and NPSA (National Patient Safety Agency) in the UK.

98. Susceptibility to being influenced by the health care system: There is insufficient evidence to allow comment.

Scientific soundness of the indicator

99. Face validity: The consequences of such an event give great plausibility to this indicator.

100. Construct validity: It is difficult to judge whether this particular construct has specific problems, because there is insufficient research evidence.

Operational issues

101. Generally, like many patient safety measures, this indicator may suffer from underreporting.

Foreign Body Left in During Procedure

Operational definition

102. **Source**: AHRQ/CIHI Safety Indicators (AHRQ, 2002).

Numerator: Discharges with ICD-9-CM codes for foreign body left in during procedure in any secondary diagnosis field per 100 surgical discharges.

Denominator: All medical and surgical discharges.

103. Data requirement: Administrative data.

Importance of the indicator

104. Clinical significance: Errors relating to the failure to remove surgical instruments at the end of a procedure (*i.e.* needles, knife blades, electrosurgical adaptors, safety pins or sponges) are no less common than the better known mishaps such as wrong-site surgery. However, many cases of retained foreign body do not cause harm, although some clearly do. Therefore JCAHO sentinel event policy specifically mentions that "unintentionally retained foreign body without major permanent loss of function" does not require reporting. Although surgeons and operating room teams rely on the practice of sponge, sharp and instrument counts as a means to eliminate detained foreign bodies, practices are not standardised. Equally, data on the extent of the problem is scanty. In one study of malpractice claims over a 7-year period it was cited as representing 1% of all claims, sure to be a gross underestimate of the actual incidence.

105. Identification of process/outcome as quality problem: As for many safety measures, the magnitude of the problem is difficult to assess because of underreporting. However, even single events may signal a serious system failure that should be addressed.

106. Policy importance: Patient safety has become a major quality issue since the formation of the National Patient Safety Foundation by the American Medical Association in 1996, although the clinical magnitude of the problem was already identified in 1991 by the Harvard Medical Practice Study (Brennan, 1991). Similar national organisations, responding to the same issue are AIMS (Australian Incident Monitoring System) and NPSA (National Patient Safety Agency) in the UK.

107. Susceptibility to being influenced by the health care system: There is only one known study demonstrating indirect evidence of the effectiveness of sponge and instrument counts. There are hints that process redesign in surgical procedures could lead to improvement for example errors in sponge counts are attributed to team fatigue, difficult operations, sponges "sticking together" or staff accepting apparently incompatible counts without re-checking.

Scientific soundness of the indicator

108. Face validity: As indicated above, studies demonstrating the effectiveness of interventions are hard to find, but the event seems a clinically plausible indicator of system failure.

109. Construct validity: Without sufficient research evidence, it is difficult to judge whether this particular construct has specific problems. In a general sense, like many patient safety measures, it may suffer from underreporting.

110. Evidence supporting indicator validity: Notwithstanding the lack of research evidence, retained foreign body has featured in indicators proposed by the developers of the Complications Screening Programme, in AHRQ's original HCUP quality indicators. Based on expert consensus panels, McKesson Health Solutions, a healthcare consultancy, included this indicator in its CareEnhance Resource Management Systems quality module.

Medical Equipment-Related Adverse Events

Operational definition

111. **Source**: JCAHO sentinel events.

Numerator: Number of patient deaths or major permanent losses of function associated with a problem with medical equipment.

Denominator: All hospital admissions.

Importance of the indicator

112. Clinical significance: Events related to medical equipment can be divided into two categories: user error and equipment failure. Health device inspection and preventive maintenance by biomedical or clinical engineering departments have high face validity as an important patient safety practice in reducing equipment failure (Shojania *et al.*, 2001).

113. Equipment failure can trigger an accident or it may complicate the recognition and treatment of other problems. The equipment failure itself may occur due to a variety of causes, such as equipment defect, improper set-up or maintenance, or environmental factors. That failure is rarely the sole cause of the adverse device event. Other factors combine with equipment failure to result in the accident (Bruley, 2000).

114. According to Joint Commission Sentinel Event Statistics[9] medical equipment-related is the fourth major sentinel event in Home Care (JCAHO, accessed 2003). There are some methods to analyse and prevent the consequences of a medical equipment failure. Computer simulation methods offer a "safe" environment to study individual response to critical incidents and other unplanned incidents such as equipment failure. They are potentially useful for training anaesthetics and for quality assessment programmes (Doyle, 2002). Bruley refer the necessity of a system for collection of accurate information so that an effective initial analysis can be performed, hopefully leading to early resolution, or lead to undertaking of an effective investigation (Bruley, 2000). Use of checklists is another practice that helps ensure equipment readiness, particularly for equipment that is needed in critical situations and/or where equipment failure may have dire consequences (Shojania *et al.*, 2001).

Scientific soundness of the indicator

115. Medical technology and medical devices play major roles in the diagnosis and treatment of patients in health care facilities. Therefore, each health care facility should assure that a newly acquired technological advance does not pose safety hazards to patients and that the end of the device's useful life is anticipated so that quality does not decrease and dangers to patients do not increase due to equipment obsolescence. Successfully applying of Quality Assessment principles, consistent with each phase in the life of medical technological devices, should ensure equipment of high quality and thus benefit a health care facility and its patients (Keil and Wiedmann, 1984).

116. In a recent report to Congress the US Food and Drug Administration stated that under requirements of the Safe Medical Devices Act medical device manufacturers reported a total of 980 device-related deaths in 1998. In a presentation to the Association for the Advancement of Medical Instrumentation a representative of FDA Centre for Devices and Radiological Health stated that one-third of the 80 000 incident reports it receives annually may involve medical equipment use error. Since, medical technology is

9. Total number of Sentinel Events reviewed by the Joint Commission since January 1995: 2085.

an integral component of health care delivery system, efforts to improve patient safety and quality healthcare delivery must take into account the omnipresence of medical technology (ACCE, accessed 2001).

117. Evidence supporting indicator validity: No studies to date have developed a widely used standardised protocol for equipment maintenance for clinical engineering departments, largely because the lack of standardisation of endpoints renders assessing the relative value of any particular maintenance protocol impossible. Nonetheless, equipment failure does result in a small fraction of clinical events and thus is an important safety intervention (Shojania *et al.*, 2001).

Medication Errors[10]

Operational definition

118. **Source**: JCAHO sentinel events.

Numerator: Number of patient deaths, paralysis, coma, or other major permanent loss of function associated with a medical error

Denominator: Not applicable.

Importance of the indicator

119. Medication errors are known to be common but preventable events that occur in both inpatient and outpatient settings. Conclusions from a study show that the drug class most commonly associated with preventable adverse drug events was analgesics, followed by sedatives and antibiotics (Bates *et al*., 1995). While many medication errors are probably undetected with few or no consequences for patient health, some others result in serious patient morbidity or mortality. Studies have already found that half of medication errors occur at the stage of drug ordering (Bates, 1995; Kaushal, 2001) although direct observation studies indicate that many errors also occur at the administration stage (Allan and Barker, accessed September 2003).

120. According to Joint Commission Sentinel Event Statistics medication error is the third major event in General Hospitals and in Hospital Emergency Department, the fourth in Free-standing Ambulatory Care, the second in Home Care and the fifth in Psychiatric Hospital and in the Psychiatric Unit in General Hospital[11] (Joint Commission on Accreditation of Healthcare Organizations, accessed September 2003).

121. According the same organization the three major root causes of medication errors are, in importance order: Orientation/training (60%), Communication (50%-60%) and Availability of Information (20%-30%).

122. The health care system can improve this quality problem: literature supports Computerized Physician Order Entry Systems with Clinical Decision Support Systems beneficial effect in reducing the frequency of a range of medical errors; studies about unit-dosing show a positive impact on error reduction (Shojania *et al*., 2001).

10. Medication errors refer to errors in processes of ordering, transcribing, dispensing, administering, or monitoring medications.

11. Total number of Sentinel Events reviewed by the Joint Commission since January 1995: 2085.

Scientific soundness of the indicator

123. Face validity: The common nature of medication errors and the clinical severity of the complications captured by this indicator provide it with great plausibility. Several studies have demonstrated success with computerized identification of adverse drug events.

124. Content validity: The indicator is based on incident reporting systems, which are not able to provide accurate epidemiological data. These systems are an important and relatively inexpensive way of getting information on errors and adverse events. Studies suggest that only 6% (Shojania *et al*., 2001) of adverse drug events are identified through traditional incident reporting or a telephone hotline. Also incident reporting has hindsight bias, lost information, lost contextual clues and seems to capture a different set of events when comparing with chart review and traditional risk management. Nevertheless incident reporting appears to be growing in importance in the medical area.

Operational issues

125. Other care sites outside hospitals should be considered for study and review such as nursing homes, ambulatory care and patient self managed care.

126. In some OECD countries, incident reporting and consequent analysis are not protected from legal action and discovery, possibly resulting in underreporting to avoid litigation. The data are also unlikely to be available in the absence of mandatory reporting systems.

Obstetrics

Birth Trauma - Injury to Neonate[12]

Operational definition

127. **Source**: AHRQ/CIHI Safety Indicators.

Numerator: Discharges with ICD-9-CM codes for birth trauma in any diagnosis field per 100 live-born births.

Denominator: All live-born infants. Exclude infants with a subdural or cerebral haemorrhage (subgroup of birth trauma coding) AND any diagnosis code of preterm infant (denoting a birth weight of less than 2,500 g and less than 37 weeks gestation). Exclude infants with injury to skeleton (767.3, 767.4) AND any diagnosis code of osteogenesis imperfecta (756.51).

12. The panel decided to use Perinatal death/loss of function (SY058) as fallback for SY019 if data are not widely available for the later. SY058 comes from JCAHO sentinel events. It measures the number of perinatal deaths unrelated to a congenital condition in an infant having a birth weight greater than 2500 grams.

Neonatal deaths could occur out of the hospital following discharge; however, this indicator captures the in-hospital deaths. This indicator may require further discussion as the WHO has data concerning the deaths of neonates in all settings.

128. Data requirements: Administrative data – hospital morbidity data collection.

Importance of the indicator

129. Clinical importance: A US study of newborns who had a discharge diagnosis of birth trauma found that only 25% had sustained a significant injury to the head, neck, or shoulder (Hughes *et al.*, 1999). The remaining patients either had superficial injuries or injuries inferior to the neck. Towner *et al.*(1999) linked California maternal and infant discharge abstracts from 1992 through 1994, but they used only infant discharge abstracts to describe the incidence of neonatal intracranial injury, and they did not report the extent of agreement between the two.

130. Policy importance: Birth trauma can lead to prolonged disability of the infant requiring substantial resources for rehabilitation and care.

131. Susceptibility to being influenced by the health care system: Birth trauma injury is preventable. Occurrence of mortality or morbidity in childbirth may be due to system failure, poor antenatal treatment, or poor obstetric practice.

Scientific soundness of the indicator

132. Face validity: This indicator has been widely used in the obstetric community, although it is most commonly based on chart review rather than administrative data. It was proposed by Miller *et al. (2001)* in the original "AHRQ INDICATOR Algorithms and Groupings," although their definition also includes injury to the brachial plexus (767.6), which was excluded from this INDICATOR. Based on expert consensus panels, McKesson Health Solutions included a broader version of this indicator (767.xx) in its CareEnhance Resource Management Systems, Quality Profiler Complications Measures Module.

133. Content validity: The indicator appears to be well operationalized. However, it may be necessary to exclude or adjust for additional high-risk conditions to ensure comparability of this indicator across countries.

Operational issues

134. Data availability: Administrative data should be available from most OECD countries.

Obstetric Trauma[13] – Vaginal Delivery

Operational definition

135. **Source**: AHRQ/CIHI Safety Indicators.

Numerator: Discharges with ICD-9-CM codes for obstetric trauma in any diagnosis or procedure field.

Denominator: All vaginal delivery discharges. Include instrument assisted delivery.

136. Data requirements: Hospital morbidity data collection

13. Obstetric trauma includes uterine rupture, fracture of pelvis, including coccyx, laceration or haematoma of cervix, vagina, vulva, perineum and anus.

Importance of the indicator

137. Impact on health: In a stratified probability sample of vaginal and Caesarean deliveries, the weighted sensitivity and predictive value of coding for third- and fourth-degree lacerations and vulvar / perineal haematomas (based on either diagnosis or procedure codes) were 89% and 90%, respectively (AHRQ, 2003). Third and fourth degree perineal laceration can produce significant long term morbidity of women undergoing childbirth (JCAHO, accessed 2002).

138. Policy importance: This indicator is intended to flag cases of potentially preventable trauma during vaginal delivery. It is estimated in the US that 235.7 per 1,000 population is at risk for this complication (AHRQ, 2003). Complications to delivery can have an ongoing burden on the hospital system in increased length of stays and readmissions for repair for some obstetric trauma.

139. Susceptibility to being influenced by the health care system: Obstetric trauma during delivery is often preventable. The percentage of deliveries involving third and fourth degree lacerations is a useful quality indicator of obstetrical care and can assist in reducing the morbidity from extensive perineal tears.

Scientific soundness of the indicator

140. Face validity: A version of this indicator (third- or fourth-degree perineal laceration) has been adopted by the Joint Commission for the Accreditation of Healthcare Organisations (JCAHO) as a core performance measure for "pregnancy and related conditions". Based on expert consensus panels, McKesson Health Solutions included the JCAHO indicator in its CareEnhance Resource Management Systems, Quality Profiler Complications Measures Module. Fourth degree laceration, one of the codes mapped to this indicator, was included as one component of a broader indicator ("obstetrical complications") in AHRQ's original HCUP Quality Indicators (Johantgen *et al.*, 1998).

141. Content validity: The indicator appears to be well operationalized. However, it may be necessary to exclude or adjust for additional high-risk conditions to ensure comparability of this indicator across countries.

Operational issues

142. Although AHRQ/CIHI Safety Indicators collects data for obstetric trauma separately for instrument assisted and non-instrument assisted vaginal deliveries (SY021) the panel decided to combine these two measures.

143. Data availability: Administrative data should be available from most OECD countries.

Obstetric Trauma - Caesarean Section

Operational definition

Source: AHRQ Safety Indicators.

Numerator: Discharges with ICD-9-CM codes for obstetric trauma in any diagnosis or procedure field per 1,000 caesarean deliveries.

Denominator: All caesarean delivery discharges.

Importance of the indicator

144. Impact on health: In a stratified probability sample of vaginal and caesarean deliveries, the weighted sensitivity and predictive value of coding for third- and fourth-degree lacerations and vulvar/perineal haematomas (based on either diagnosis or procedure codes) were 89% and 90%, respectively (AHRQ, 2003). Third and fourth degree perineal laceration can produce significant long term morbidity of women undergoing childbirth (JCAHO, accessed 2002).

145. Policy importance: This indicator is intended to flag cases of potentially preventable trauma during caesarean delivery. The percentage of deliveries involving third and fourth degree lacerations is a useful quality indicator of obstetrical care and can assist in reducing the morbidity from extensive perineal tears. Complications to delivery can have an ongoing burden on the hospital system in increase length of stays and readmission for repair for some obstetric trauma.

Scientific soundness of the indicator

146. Face validity: A version of this indicator (third- or fourth-degree perineal laceration) has been adopted by the Joint Commission for the Accreditation of Healthcare Organisations (JCAHO) as a core performance measure for "pregnancy and related conditions". Based on expert consensus panels, McKesson Health Solutions included the JCAHO indicator in its CareEnhance Resource Management Systems, Quality Profiler Complications Measures Module. Fourth degree laceration, one of the codes mapped to this indicator, was included as one component of a broader indicator ("obstetrical complications") in AHRQ's original HCUP Quality Indicators (Johantgen *et al.*, 1998).

147. Content validity: The indicator appears to be well operationalized. However, it may be necessary to exclude or adjust for additional high-risk conditions to ensure comparability of this indicator across countries.

Operational issues

148. Data availability: Administrative data should be available from most OECD countries.

Problems with Childbirth[14]

Operational definition

149. **Source**: Australian Council for Safety and Quality.

Numerator: Maternal death or serious morbidity associated with labour or delivery.

Denominator: Total number of labour and deliveries.

150. Data requirements: Hospital morbidity data collection

14. The panel considered an alternative measure capturing maternal complications, Maternal Death and decided to keep it as a fallback indicator should data collection for the selected indicator prove difficult. Maternal death is part of the JCAHO sentinel events indicator set and is defined as the number of intrapartum (related to the birth process) maternal deaths.

The WHO has developed a maternal death indicator.

Importance of the indicator

151. Impact on health: Death or serious complications from delivery are catastrophic events and their impact is undisputed.

152. Policy importance: Serious complications of delivery have become rare in industrialised countries but may still indicate system failures, if they occur. Comparative information from other countries would help policymakers to determine whether a safety problem is this area exists.

153. Susceptibility to being influenced by the health care system: Proper pre- and perinatal care and monitoring should be able to avoid such complications.

Scientific soundness of the indicator

154. Face validity: Given the grave consequences, the indicator appears to be a plausible measure.

155. Content validity: The comparability of this indicator will depend on consistent definitions for and reporting practices of complications across countries. The indicator is restricted to deaths in hospitals occurring as a direct result of childbirth and not pregnancy.

Operational issues

156. Data availability: Administrative data should be available from most OECD countries.

Other Care-Related Adverse Events

Patient Falls

Operational definition

157. **Source**: JCAHO sentinel events.

Numerator: Number of patient falls[15] that result in death or major permanent loss of function as a direct result of the injuries sustained in the fall.

Denominator: All hospital admissions.

Importance of the indicator

158. Clinical significance: Falls are costly and clinically important problems (Englander *et al.*, 1996). They prolong hospital says and increase resource utilisation (Bates *et al.*, 1995). Studies show that falls are a common cause of morbidity and the leading cause of nonfatal injuries and trauma-related hospitalisations in the United States (Shojania *et al.*, 2001). Falls are common among elderly hospital in-patients of any countries with serious consequences and with 13(?)-14% of patients sustaining fractures. Also falls also

15. A fall is defined as unintentionally coming to rest on the ground, floor, or other lower level, but not as a result of syncope or overwhelming external force.

represent a change in the clinical point of elderly in addition to increased costs to the system (Bates *et al.*, 1995).

159. According to Joint Commission Sentinel Event Statistics patient fall is the first major sentinel event in Long Term Care and the third major sentinel event in Home Care[16] (Joint Commission on Accreditation of Healthcare Organisations, accessed September 2003). According the same organisation the three major root causes of medication errors are, in importance order: Orientation/training, Communication, and Patient assessment. Organisational environment may contribute to fall risk in both hospitals and community or institutional settings. Other numerous risk factors for falls in older people are identified and reviewed (Shojania *et al.*, 2001).

160. Factors associated with fall risk in the hospital setting may differ from those in community-dwelling or institutional settings. Falls are among the most common incidents reported in institutions. However reports may underestimate the true occurrence and facts. Falls are usually the result of the interaction of many factors and consequently the usual medical model in which the outcome is related to a single disease or etiologic factor is seldom applicable (Hindmarsh and Estes, 1989). Also the focus on the chronic disease in the elderly diminishes the importance of falls as source of morbidity and mortality in the population over 65 years of age.

Scientific soundness of the indicator

161. Evidence supporting indicator validity: Studies show that intervention can decrease the risk of falls (Bates *et al.*, 1995). While considering that the objective of eliminating falls completely is unrealistic, there is evidence that interventions to reduce specific risk factors resulted in a 30% reduction in falls over one year in a prospective community cohort (Tinetti *et al.*, 1993).

162. Factors associated with fall risk in the hospital setting may differ from those in community-dwelling or institutional settings. Falls are among the most common incidents reported in institutions. However reports may underestimate the true occurrence and facts. Falls are usually the result of the interaction of many factors and consequently the usual medical model in which the outcome is related to a single disease or etiologic factor is seldom applicable (Hindmarsh and Estes, 1989).

163. Some studies have associated falls with the use of benzodiazepines, diuretics, hypnotics, antidepressants, laxatives, vasodilators and other medication. However these findings have been inconsistent (Bates *et al.*, 1995). Other associations of falls with decreased mobility, poor balance, and impaired vision showed importance of the reliability of clinical records.

Operational issues

164. The profile of fallers in hospitals differs from that of fallers in the community. Thus, other care settings besides hospitals should be considered for this indicator. Lack of recording could be common and may result in inaccurate data. Risk adjustment for severity of illness and comorbidity should be considered.

In-Hospital Hip Fracture or Fall

Operational definition

165. **Source**: Complications Screening Programme.

16. Total number of Sentinel Events reviewed by the Joint Commission since January 1995: 2085.

Numerator: Patients experiencing an in-hospital hip fracture OR fall as defined by the CSP: secondary diagnosis only and excluding patients with trauma or metastatic cancer as any diagnosis; excluding patients with principal diagnosis of seizure, syncope, stroke, coma, cardiac arrest, or poisoning; excluding patients in MDC 8.

Denominator: Inpatients undergoing major surgery OR minor or miscellaneous surgery OR invasive cardiac procedures OR invasive radiologic procedures OR endoscopy OR medical patients OR all patients as defined by the CSP.

Importance of the indicator

166. Clinical significance: Falls are a leading cause of adverse event in acute care hospitals. Up to 20% or 1 in 5 elderly people fall during recovery from illness (many patients "at risk" because of untoward medication effect, rehabilitation, etc.). Falls are associated with functional disability and injury, increased length of stay, and risk of nursing home placement from hospital. Patient falls are also a significant liability issue for hospital risk-management, because many falls and their damaging consequences are preventable. Falls may be caused by the persons' health status, response to medication or anaesthesia, external factors (wet floor, etc.) or other factors. Reducing risk of falls is an important quality of care issue for hospitals (Oliver *et al.*, 2000).

167. The incidence of hip fracture is related with demographic factors (and others) such as: age, gender, racial difference, rural *vs.* urban, institutional *vs.* community dwelling and family history. Two thirds of all hip fractures occur among women. Hip fracture incidence rate from different countries within Europe appear to vary substantially with highest incidences found in Northern Europe and the lowest in Mediterranean area. Highest rates are found in white populations and lower rates are found in Asian and developing countries. Rural population have lower incidence than urban population. Institutionalised elderly people also have higher rates (CCAA, accessed 2003; SNAP, 1997).

168. Policy importance: Prevention of falls is an important factor in hospital management. It's an important aspect for patients, hospital managers, and visitors. Failure to provide safe conditions in hospital, and a safe environment can lead to falls, which may result in injuries. These injuries may lead to complications and decrease in mobility. In other hand, falls may have impact in patient's perception of safety and psychological well-being.

Scientific soundness of the indicator

169. Evidence supporting indicator validity: A study from Lichtenstein *et al.* (1994) conducted a study in Canadian province of Saskatchewan from 1983 through 1985. They found six factors independently associated with a significant increased risk of in-hospital hip fracture: impaired vision; assisted ambulation, confusion, psychotropic drug use, lowest height tercile and prior in-hospital fall.

170. Needleman *et al.* (2002) considered in-hospital fall or fracture as an "Outcome Potentially Sensitive to Nursing," based on input from their Technical Expert Panel, but discarded it because the "event rate was too low to be useful." The American Nurses Association, its state associations, and the California Nursing Outcomes Coalition have identified the number of patient falls leading to injury per 1,000 patient days (based on clinical data collection) as a "nursing-sensitive quality indicator for acute care settings" (McDonald *et al.*, 2002).

Operational issues

171. The profile of fallers in hospitals differs from that of fallers in the community. Thus, other care settings besides hospitals should be considered for this indicator. Lack of recording could be common and may result in inaccurate data. Risk adjustment for severity of illness and comorbidity should be considered.

ANNEX 2: MEMBERS OF THE PANEL

John Millar (Chair)

172. Dr. John Stanley Millar is the Vice President for the Canadian Institute for Health Information. He graduated with a degree in Medicine from the University of British Columbia. He joined the BC Ministry of Health in January 1985, as a Medical Health Officer/Trainee, received his MHSc in Community Medicine in 1986, and his FRCP(C) in 1988. He served as Medical Health Officer of the Northern Interior and Cariboo Health Units from September 1987, until moving to Nanaimo and the Central Vancouver Island Health Unit in 1988 as Medical Health Officer/Director. He remained there until his appointment as Provincial Health Officer in 1993 in which post he continued until November, 1998. Dr Millar serves on the Board of Directors of the Manitoba Centre for Health Policy and on the Institute Advisory Board for the Institute of Population and Public Health of the Canadian Institutes for Health Research. He's currently a member of the National Steering Committee on Patient Safety of the Royal College of Physicians and Surgeons of Canada. He formerly served on the Federal Minister of Health, Allan Rock's Science Advisory Board and on the Hon David Anderson's Committee for an Information System for the Environment. He is an Adjunct Professor in the Department of Epidemiology and Community Medicine at the University of Ottawa. Dr Millar is an honorary life member of the Canadian Public Health Association. He has for several years been a member of the F/P/T Advisory Committee on Population Health and has contributed to the First and Second Reports on the Health of Canadians and other publications. Dr. Millar is past Chair of the Council of Chief Medical Officers of Health for Canada, a reviewer for the National Health Research Development Programme and the Social Sciences and Humanities Research Council and a member of the Canadian Policy Research Network.

Pia Maria Jonsson

173. Dr. Pia Maria Jonsson received her medical degree from the University of Tampere in Finland, and her Ph.D. in Health Systems Research from Karolinska Institute, Dept. of Public Health Sciences, in Stockholm, Sweden. She is currently the Principal Administrative Officer at the Swedish National Board of Health and Welfare, Division of Health Care and Medical Services. In addition, she is the project director of Sweden's Health Care Reports, and a member of the national committee for the quality registers in Sweden. Previously, she was a Special Advisor at the Ministry of Health and Social Affairs (1997-98), a Principal Secretary of the National Committee on Gender Disparities in Health Care (1995-96), and a Senior Research Associate at the Swedish Institute for Health Services Development (Spri), Depts. of Health Economics and Medical Informatics (1987-94).

Margarida Madalena Martins França,

174. Margardia França is the Executive Director of the Instituto da Qualidade em Saúde (IQS), the Portuguese national frame on health continuous quality improvement implemented legally on April 1999. She graduated with a degree in law and also earned a Master in Health Administration and Economics and a Post-graduation on Hospital Administration. She began her career in the Portuguese National Health System as a hospital administrator, and spent three years as an executive on the Board of a regional acute hospital. Before assuming her role on IQS she worked with the Central Health Administration (Direcção Geral da Saúde) setting up the Hospital Accreditation Programme within the partnership with the King's Fund Health Quality Service. Since the inception of the IQS she has been the executive manager. This project started on

September 1999 with 7 acute hospitals and includes 20 hospitals at the present date. Within this national project two acute hospitals have already received full accreditation already and one provisional accreditation while others are in progress. As executive director of the IQS, Margarida França has been working and participating in other projects on the health quality assessment and continuous improvement as well on the definition of the national policies and projects on health quality and financial funds at national level.

Vin McLoughlin

175. Dr. Vin McLoughlin is Assistant Secretary of the Health Priorities Branch at the Australian Department of Health and Ageing, where she is responsible for coordinating and managing initiatives designed to improve the safety and quality of health care services in Australia. Previously she was on secondment from the Australian Government as a consultant on health policy to the OECD's Social Policy Division to look at the mechanisms that selected countries are using to identify evidence-based medicine and health outcomes approaches and apply them to policy and financing decision-making processes. From 1992-1998 McLoughlin was responsible for the management of the General Practice Strategy. She chaired the Ministerial Review of the General Practice Strategy. Dr McLoughlin has worked in the health care industry for almost 20 years, both in the UK and Australia. She has been involved in 'on the ground' services planning and the provision of services as well as in epidemiological research and in policy (both national and local) spanning the acute and community sectors.

David Somekh

176. Dr. David Somekh is a forensic psychiatrist, psychoanalyst and experienced clinician in management who retired from the NHS two years ago to devote himself to a “portfolio” existence as a management consultant, expert witness and quality advisor. He was a member of AQH Council from 1988-2002 (Chair of the executive from 1995). AQH was the only U.K. organisation dedicated solely to Quality in health care and with a multi-professional membership. Pump primed by the Department of Health for three years, 1989-1991, it was registered as a Charity in 1993. In 2002 it merged with IQA, the Institute for Quality Assurance (a member of EOQ) to become the Health and Social Care group of IQA. Dr. Somekh served as the UK member of the Advisory Committee of ISQuA (International Society for Quality Assurance) from 1995-1997, and a member of the Management Committee of the National Centre for Clinical Audit (NCCA) from 1997-1999. As Chair of AQH he was a member of Council of the European Society for Quality in Health care (since its inception in 1998) and the executive member responsible for communications since 2000. He has been director of London ESQH office specialising in Patient Safety since Oct.2002.

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