

Safety Data for Safer Care: The Importance of International Consensus and Action

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"I am called eccentric for saying in public that hospitals, if they wish to be sure of improvement, must find out what their results are. Must analyze their results to find their strong and weak points. Must compare their results with those of other hospitals...

Such opinions will not be eccentric a few years hence."

E. A. Codman, MD, 1917. (1869-1940)

Abstract

Objective: Interest in comparative quality measurement and evaluation has grown considerably over the past two decades due to several factors, such as recognition of widespread variation in clinical practice, the increased availability of evidence on medical effectiveness, and increasing concern about the cost and quality of healthcare.

Interest in ensuring that healthcare is safe has grown, particularly since 2001 when the Institute of Medicine (IOM) included patient safety as another quality dimension.

This interest in safety is not limited by international borders or by classifications of "more developed" or "less developed" countries. International initiatives at the highest levels of government such as the Organization for Economic Cooperation and Development's (OECD) Health Care Quality Indicators Project and its Patient Safety Working Group, as well as the World Alliance for Patient Safety, highlight the need for international agreement to increase learning on patient safety. However, little is being done to improve the availability and comparability of data/indicators on patient safety within and between countries.

Material and method: In this paper, we describe the work being done by national bodies such as the US Agency for Healthcare Research and Quality (AHRQ), and international organizations such as the OECD and the World Alliance (WHO) to improve safety data with a view to providing safer care. At the same time, we compare this with information existing in Spain on this same question.

Results: The proposal by the OECD attempts to identify suitable measurements to enable comparisons at international level, although several difficulties (availability of data, ethical aspects, organization of the systems) mean that the number of indicators has been reduced. The indicators proposed by the AHRQ, based on several solid information sources, offer a much clearer vision as regards patient safety at national level.

In Spain, there are initiatives for international comparisons using the indicators proposed by the OECD and, at national level, using the proposals by AHRQ, based on the MBDS (minimum basic data set).

Conclusions: The development of patient safety data systems, both at national and international level, still has a long way to go. One important aspect to consider, is the need to involve patients and their associations in the collection and recording of data on patient safety.

Key words: Patient safety. Safety indicators. Quality care.

Resumen

Objetivo: El interés en la medida y en la evaluación de la calidad ha crecido considerablemente a través de las últimas 2 décadas debido a diversos factores, como el reconocimiento de la gran variabilidad existente en la práctica clínica, la mayor disponibilidad de evidencia de eficacia probada y la creciente preocupación sobre el costo y la calidad del cuidado de la salud.

En particular, el interés ha crecido en asegurar que el cuidado de la salud sea seguro, sobre todo desde que en 2001 el Institute of Medicine (IOM) incluyera la seguridad como una más de las dimensiones de la calidad.

Este interés en la seguridad no está relacionado con barreras internacionales o con las particularidades de "mayor desarrollo" o "menor desarrollo" de un país.

Iniciativas internacionales del más alto nivel gubernamental, como las de la Organización para la Cooperación Económica y del Desarrollo (OCDE), el Proyecto de Indicadores de Calidad en Salud (HQIP) y su grupo de trabajo en Seguridad del Paciente o la de la Alianza mundial por la Seguridad del Paciente de la OMS, resaltan la necesidad de un convenio internacional para lograr un mayor aprendizaje sobre la seguridad del paciente.

Sin embargo, poco se ha estado haciendo para mejorar la disponibilidad y la comparabilidad de los datos/indicadores acerca de la seguridad del paciente dentro y entre los países.

Material y método: En este artículo, describimos el trabajo realizado por cuerpos nacionales como la Agencia para la Investigación y la

Calidad de la Asistencia Sanitaria (AHRQ) de Estados Unidos y por organizaciones internacionales como la OCDE y la Alianza Mundial (OMS) para mejorar los datos de seguridad en la búsqueda de proveer un cuidado más seguro, a la vez que contrastamos con la información existente en España sobre esta misma cuestión.

Resultados: La propuesta de la OCDE pretende identificar las medidas apropiadas para favorecer comparaciones en el ámbito internacional, aunque una serie de dificultades (disponibilidad de datos, aspectos éticos, organización de los sistemas) hace que el número de indicadores sugeridos se haya visto reducido. Los indicadores que propone la AHRQ, basándose en varias fuentes de información sólidas, ofrecen una visión más rica respecto a la seguridad del paciente en el ámbito nacional.

En España, existen iniciativas para comparación internacional mediante los indicadores propuestos por la OCDE e, internamente, usando los propuestos por la AHRQ, basándose en el CMBD.

Conclusiones: El desarrollo de los sistemas de datos sobre seguridad del paciente, tanto en el ámbito nacional como en el internacional, tiene aún un largo camino por recorrer. Un aspecto importante a considerar es la necesidad de involucrar a los pacientes y sus asociaciones en la recogida y registro de datos sobre seguridad del paciente.

Palabras clave: Seguridad de pacientes. Indicadores de seguridad. Calidad asistencial.

Introduction

In April 1992, in Halifax, Canada, a 4 year old girl with leukemia was to receive her last chemotherapy treatment session. She had suffered the disease for 2 years, and on that same day she had to receive dental surgery as well as her leukemia treatment. As there were no incompatibilities between her medication and anesthesia, the doctors decided to give the girl all the medications together. Vincristine was given to the girl using a spinal catheter. Vincristine in the subdural space is lethal. The girl died 1 week later. From then on the National Director Committee on Patient Safety in Canada¹ issued a report. Since 1989, 3 patients (from Scotland, Quebec, and Canada) have died for similar causes. Although these errors had been studied in depth, another death was unavoidable due to the lack of knowledge dissemination, that of a 7 year old girl in the BC Children's Hospital in 1997. The director of the Hospital, Mme Linda Cranston announced that the National Health System from Canada had not been able to learn from previous mistakes. Two thousand years after, the Hippocratic Principle –*Primum non nocere* (First, do no harm)– has once again become relevant.² Patient safety is the main objective of quality in healthcare, and it is the result of a set of values, attitudes, competences and interventions from all the professionals of the healthcare system. Because of the inherent risks of healthcare, patient safety is, nowadays, on the agenda of the main international and national organizations associated with healthcare, such as the World Health Organization (WHO), the Joint Commission on Accreditation of Healthcare, and the Quality Agency of the National Health System in Spain. The highest patient safety can be achieved with appropriate knowledge of the healthcare risks, their elimination, prevention and protection from those which we know exist. The design of a specific indicators scheme on patient safety must include com-

plications and adverse events, as well as serious events that could result in harming the patient.³⁻⁵

Interest in comparative quality measurement and evaluation has grown considerably over the past 2 decades, due to factors such as the recognition of widespread variation in clinical practice, the increased availability of evidence on medical effectiveness, and increasing concern on the cost and quality of health care. This interest has led to several national, as well as international, efforts to report what is known about clinical quality care using science-based indicators generated from a variety of data sources.⁶⁻⁸ Since the WHO 2000 World Health Report, which ranked the health system performance of 191 countries on the basis of 5 composite indicators, including disability-adjusted life expectancy, equity, financing, and system responsiveness, international comparisons have generated considerable discussion and debate.⁹⁻¹² Concerns have focused on the conceptual and methodological difficulties inherent in comparing health system performance at any level, both within and between countries, as well as how the results of such comparative analyses are communicated and used by policymakers.¹¹ Dilemmas at the conceptual level relate to the need for a valid performance measurement system that separates determinants of health that lie outside the health system from those that are attributable to the delivery of health care.¹³ Methodological issues, particularly in cross-national comparative analyses, focus on the comparability of indicators across countries with respect to data specifications and data availability, as well as the interpretability of health indicators in the light of differences in a cultural context and health care delivery systems.^{7,9-14}

This paper describes several exemplary data-based efforts taking place within national and international bodies that attempt to address this “gap” in safety data, namely:

- The US National Healthcare Reports, published by the US Agency for Healthcare Research and Quality (AHRQ)
- The OECD's Health Care Quality Indicators Project and its Patient Safety Working Group.

Purpose of the reports

A snapshot comparison of the OECD Health Care Quality Indicators (HCQI) Project and the US National Healthcare Quality Report is presented in Table 1. The OECD HCQI Project, initiated in 2001, is currently the only ongoing international project aimed at measuring quality of care across a range of health care conditions, such as cancer, diabetes, cardiovascular disease; across a range of dimensions of health care quality, such as effectiveness, patient safety and responsiveness or patient centeredness; and across a range of patient needs, such as preventive health, curative care, living with disability and coping with end of life. The Project's work on a broad set of indicators in new disease areas, such as primary care and prevention, patient safety and mental health, is groundbreaking in that –in some instances– it is the first effort aimed at developing an international consensus around what is essential to measure in health care quality for those

Table 1. A Snapshot Comparison of the OECD Health Care Quality Indicators Project and the US National Healthcare Quality Report

Characteristic	OECD HCQI	US AHQR
Origin	Request by member countries	Legislative mandate to develop 2 reports to congress on health care quality and health disparities
Purpose	Identify measures appropriate for cross national comparison	Develop a set of indicators appropriate for profiling health care quality at national level, including trends over time
	Assess measurements and data comparability	Examine differences at sub-national level
	Resolve methodological comparability issues, where possible	Examine variations by socioeconomic status
	Disseminate information about the measures to member countries	Disseminate information to a wide audience
Conditions covered	Cancer	Cancer
	Vaccine preventable diseases/ immunizations	Diabetes
	Asthma	ESRD
	Heart disease (AMI/Stroke)	Heart disease
	Waiting time for surgery	HIV/AIDS
	Risk factors (smoking)	Maternal child health
		Mental health
		Respiratory disease
		Nursing home and home health care
Number of measures	13	148 in the first (2003) NHQR
Type of indicators	Process and outcome	Process and outcome
Development process	Technical experts with vetting by ministers of member countries	Interagency working group (technical experts) with vetting by private sector organizations and clearance by US government
Development of a framework	Examined frameworks of participating countries	Examined other national efforts to develop consensus on measures (HP2010)
	Built on existing international comparisons (Commonwealth and Nordic Ministers Council working group)	Contracted with the US Institute of Medicine for development of a framework
	Built on US Institute of Medicine framework	
Primary criteria for selecting measures	Importance of the indicator	Importance of the indicator
	Scientific soundness	Scientific soundness
	Feasibility to generate data on an ongoing basis	Feasibility to generate data on an ongoing basis
Dissemination	Technical working papers	Reports to congress
	Inclusion of selected measures in OECD data base	Measure specifications included in national quality measures clearinghouse
		Development of condition-specific and state-specific reports
		Data available on the web

OECD HCQI: Organization for Economic Cooperation and Development's –Health Care Quality Indicators Project; US AHQR: United States Agency for Health'care Research and Quality.

conditions. The effort at deriving an initial set of indicators for the HCQI Project has spanned four years, involving extensive consensus building across the 23 participating countries and detailed analysis on the comparability of data across different country data sources. The HCQI Project was developed originally under the OECD's Health Project, a multi-disciplinary effort begun at the OECD in 2001. The work on quality indicators was developed at the request of member countries interested in improving performance measurement of health system outputs that could be used in conjunction with the OECD's well developed database on health care spending, utilization and mortality levels. The *HCQI Project Initial Indicators Report* and *HCQI Project Conceptual Framework Paper* were released in March 2006 [1].

During that same time period, within the US, the development process was well underway for the first-ever National Healthcare Quality Report and its companion, the National Healthcare Disparities Report (NHQR and NHDR). The mandate for these annual congressional reports was set forth in the 1999 enabling legislation for the AHRQ.¹⁵ A wide-scale effort, the development of the NHQR engaged the technical and substantive input of nine federal agencies and organizational units within the Department of Health and Human Services (DHHS) [2] as well as a range of state public partners and private sector organizations. Now in its fourth year, the NHQR offers a well-established, consensus-based set of health care quality measures across five dimensions of quality—effectiveness, safety, timeliness, patient centeredness. The report examines effectiveness of care across nine clinical condition areas—cancer, diabetes, end stage renal disease, heart disease, HIV/AIDS, maternal and child health, mental health, respiratory diseases, and nursing home and home health care. In terms of the number of measures and dimensions of care reviewed, they are the broadest examination of quality ever completed in the United States or any other major industrialized country.¹⁶

Tracking Safety at National Level: US National Reports

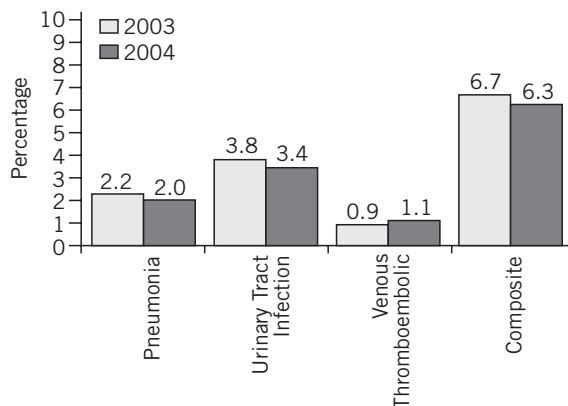
The US National Healthcare Reports were the first ever truly national and ongoing monitoring of data on patient safety produced in the US. If the aim of the first US National Healthcare Reports was to present data on trends in quality and disparities in safety across vulnerable groups, the issue of tracking trends and how disparities were changing over time for safety were different. This has to do with the data sources used for tracking safety. The data sources for the US National Healthcare Reports on patient safety include:

- Healthcare Cost and Utilization Project (HCUP) databases bring together the data collection efforts of State

[1] These papers are available from the OECD at: www.oecd.org/health.

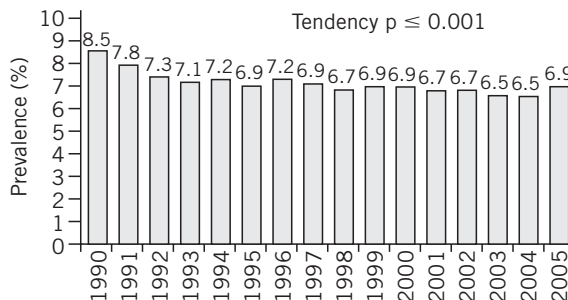
[2] There are now 12 federal agencies and organization units within US DHHS working on the US National reports.

Figure 1. **Postoperative complication rates—No progress nationally*.**



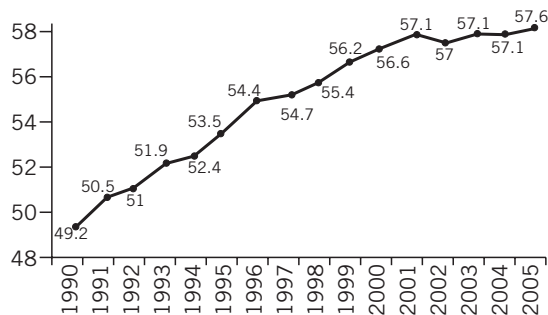
*Surgical patients with postoperative pneumonia, urinary tract infection, and venous thromboembolic event and composite, 2003 and 2004 (Source: US NHQR, 2006; Medicare Patient Safety Monitoring System).

Figure 2. **Prevalence of patients with infection*.**



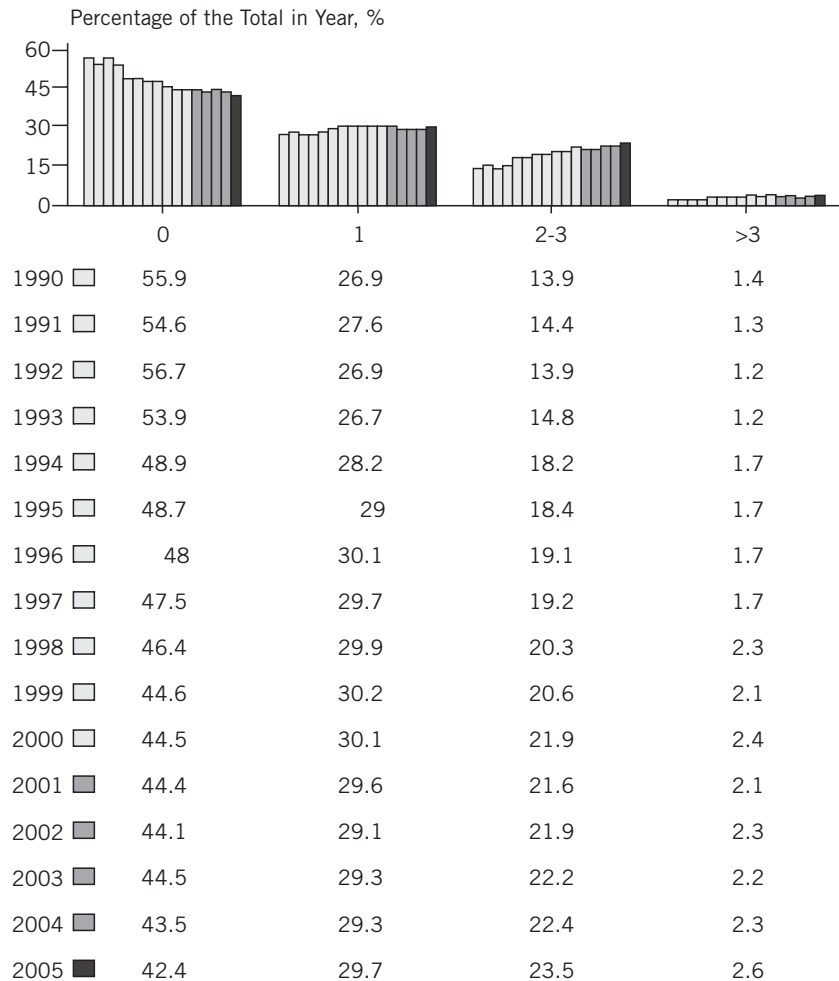
*EPINE, 1990-2005.

Figure 3. **The average age of the patients studied*.**



*EPINE, 1990-2005.

Figure 4. Number of intrinsic risk factors, 1990-2005.



government data organizations, hospital associations, private data organizations, and the Federal Government to create a national information resource of discharge-level health care data. The number of participating States increased to 37 in 2003

– Medical Expenditure Panel Survey (MEPS) comprises 3 component surveys: the Household Component (HC), the Medical Provider Component (MPC), and the Insurance Component (IC). The MEPS Household Component, the core survey, is an interviewer administered CAPI (computer assisted personal interview) household survey. The data for the 2006 US National Healthcare Reports are primarily from the following sections of the 2000 and 2003 MEPS-HC

– Medicare Patient Safety Monitoring System – This source uses chart abstraction using an electronic data collection tool. Once medical records are selected from the sample, abstractors use explicit clinical criteria to examine the process of care, ascertain the occurrence of specific adverse

events, determine that the event is an adverse event, and assess patient risk factors

– Medicare Quality Improvement Organization (QIO) Program – Under the direction of CMS, the Quality Improvement Organization Program consists of a national network of 53 QIOs responsible for each US State, territory, and the District of Columbia. Their data are collected according to data collection tools developed by QIOs or related organizations. The systematic random sample size and measurements vary between years

These various data sources have yielded an increasingly clear picture of patient safety at national level in the US. In particular, the 2006 National Healthcare Quality Report highlights the fact that rates of postoperative complications have not been improving when examining data from 2003 and 2004 (Figure 1). In Spain, cross infections have remained stable in the last decade (Figure 2), due to the increase in: the age of healthcare users (Figure 3), intrinsic risk factors (Figure 4), as well as the

more complex healthcare that we have nowadays, which has also led to an increase of the extrinsic risk factors (Figure 5).¹⁷

Moreover, the safety of patients in US hospitals varies according to where the hospital is located. Infections acquired during hospital care (nosocomial infections) are one of the most serious safety concerns. A common hospital-acquired infection is a wound infection following surgery. Hospitals can reduce the risk of wound infection after surgery by making sure patients get the right antibiotics at the right time on the day of their surgery. Variation was seen among States in the overall timing of prophylactic antibiotics. In 2004, the all-States average was 57.7% and ranged from 39.6% to 71.3% (Figure 6).

Finally, safety can also depend on factors at patient level. Many complications that arise during hospital stays cannot be prevented. However, rapid identification and aggressive treatment of complications may prevent these complications from leading to death. This indicator, also called “failure to rescue,” tracks deaths among patients whose hospitalizations are compli-

cated by pneumonia, thromboembolic event, sepsis, acute renal failure, shock, cardiac arrest, and gastrointestinal bleeding or acute ulcer. In all 3 years tracked in the 2006 National Healthcare Disparities Report, the rates of in-hospital deaths following complications of care were significantly higher among Asians and Pacific Islanders compared with Whites (Figures 7 and 8).

The Need to Improve Data Internationally: The OECD HCQI Project and Patient Safety

The OECD embarked on a new phase of the HCQI Project to work with countries prospectively on improving data systems in five priority areas, including patient safety.¹⁸ In order to focus its work on these 5 areas, the OECD developed a data availability questionnaire for a set of 85 indicators that were recommended in 5 separate reports by international experts. These 85 indicators were recommended as they met a set of strict criteria of scientific soundness and

Figure 5. Number of extrinsic risk factors, 1990-2005.

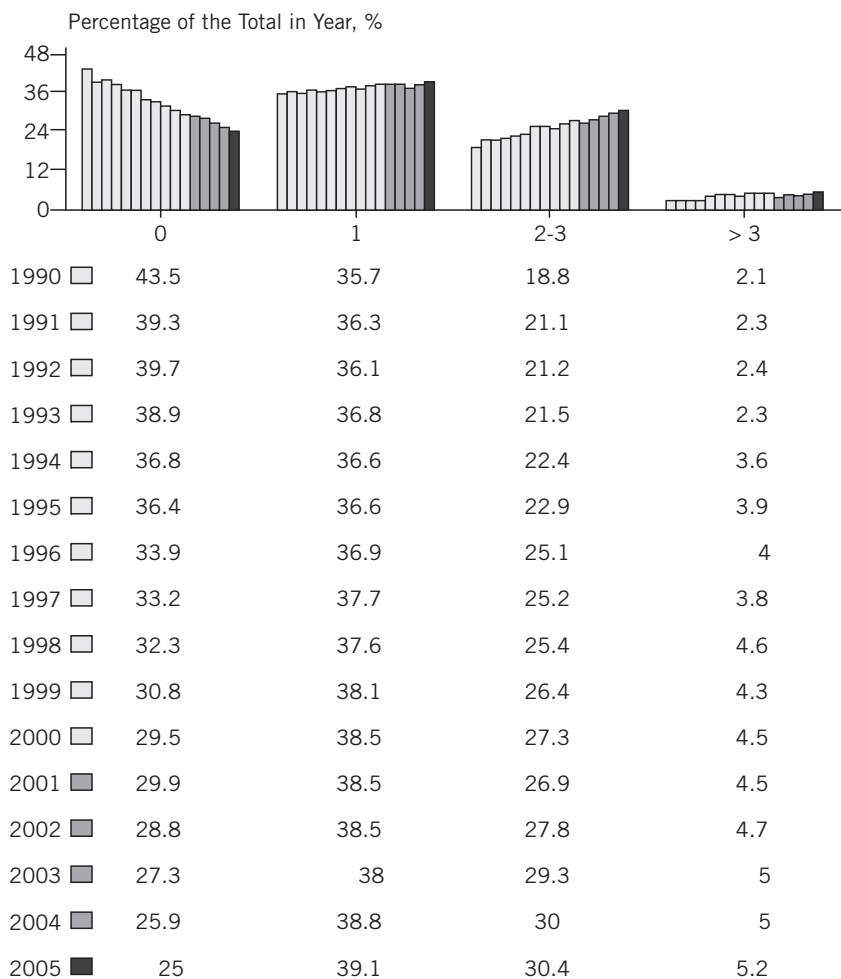
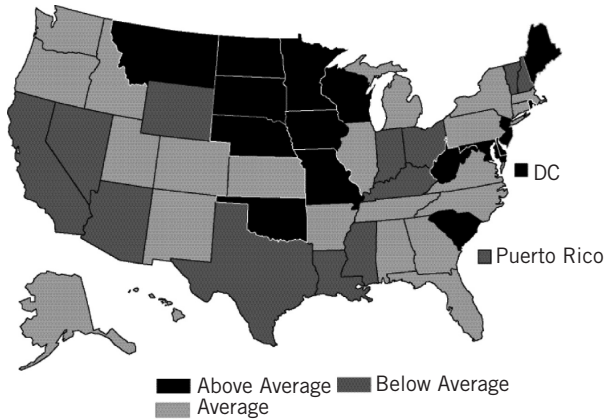


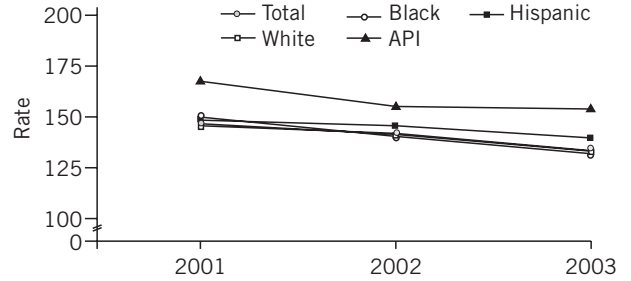
Figure 6. Safety varies with geography*.



*Appropriate timing of antibiotics received by adult Medicare patients having surgery, by State, 2004 (Source: US NHQR, 2006; Medicare QIO Program).

clinical and policy importance. In 2005, information was gathered from countries on data availability of the 85 indicators in the 5 areas. The results of that survey showed that 23 indicators could be constructed from available data from 10 or more countries. Nine of these 23 indicators were in the priority area of patient safety. The OECD undertook to form a Patient Safety Expert Group, which met for the first time in Dublin, Ireland, hosted by the Irish Department of Health

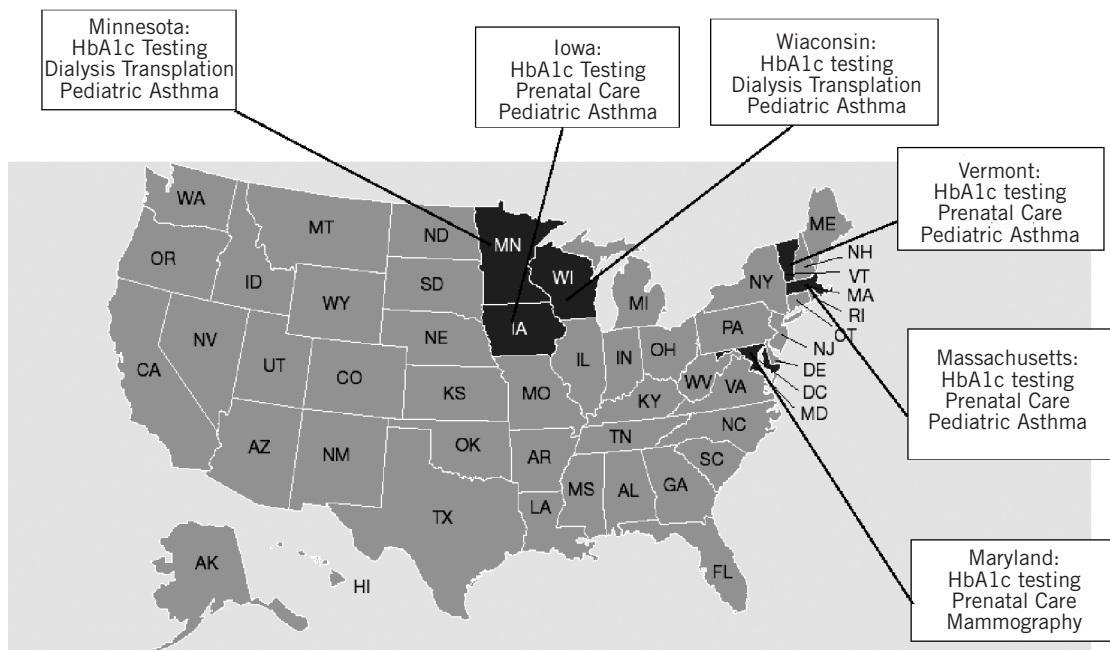
Figure 7. The impact of race on safety.



Deaths per 1000 patients following complications of care by race/ethnicity, 2001-2003 (Source: US NHDR, 2006; HCUP State Inpatient Databases disparities analysis file, 2001-2003).

and Children. This seminar, the first ever multi-country conference in the OECD on patient safety data systems, attempted to address 3 issues: a) getting patient safety data systems on the agenda; b) developing a concrete work plan for improving patient safety data systems and international comparability of patient safety data; and c) addressing how countries should think about linking data to action to improve patient safety.

Figure 8. Performance summaries in the US National Reports, by State: indicating high performers.



In terms of getting patient safety data systems on the agenda, it is clear from leading experts in the UK, US, and elsewhere that a national structure is needed to coordinate patient safety data efforts. Given that many patient safety “events” (adverse events, complications of care, etc) are relatively rare events, it is extremely important that data be collected in a uniform manner across hospitals, states, provinces and regions and centrally analyzed. It is also clear that these data systems must be seen as useful to the stakeholders involved in producing the data. Feedback mechanisms and dissemination tools must be used to broadcast, in a timely fashion, patient safety problems and how they can be fixed. It is also clear that a major area of the patient safety data agenda that has been entirely unaddressed by virtually every country in the OECD, is the involvement of patients in patient safety data system development. As Sir Liam Donaldson, President of the World Alliance on Patient Safety, stated in his address on day 2 of the Conference, patients must be at the center of the patient safety movement. Currently, virtually no country in the OECD has a regular, uniform, official vehicle for incorporating patient reports of adverse events into their regular patient safety data systems.

It is clear from the OECD’s survey on patient safety data availability and from the presentations at this Conference that there are a number of opportunities for improving patient safety data systems worldwide. In particular:

- *There is currently no international database on patient safety.* At the most basic level, there is no international database that is currently collecting data from countries internationally on an ongoing basis on patient safety that could serve as a tool for national benchmarking and learning

- *There is very limited data that is immediately comparable across countries.* There are few countries that track these patient safety indicators, such as adverse events and medical errors, in the same way. However, the OECD’s patient safety data availability survey also shows that there are areas of promise, particularly in the potential use of hospital administrative data

- *Where there is available data, a range of factors inhibits their use for international benchmarking and learning.* In some areas, such as hospital complications of care, there is a reasonable level of data availability. However, the specific data systems conventions and structures that are in use, as well as the legal context for data systems, inhibit any international comparability

The use of safety indicators, adapted from the Agency for Healthcare Research and Quality (AHRQ)¹⁹⁻²², have been suggested in Spain, and this could be done from the CMBD or Minimum Data Set (Tables 2-8), which has the reference data from the National Health Service in Spain, and could be useful to assess improvements in patient safety.

Conclusion

It is clear that the initial work undertaken by the OECD in the HCQI Project and the US in developing the work on improving patient safety data systems at both the national and

Table 2. Mortality

Observed mortality, awaited mortality (fit mortality), and observed/awaited ratio in:

- Medical GRDs mortality
- Surgical GRDs mortality
- Urgent episodes mortality
- Programmed episodes mortality

Table 3. Surgical Complications

- Wound or anastomosis dehiscence
- Hemorrhage or hematomas after surgery
- Central and peripheral nervous system complications after surgery
- Physiological and metabolic disorders after surgery
- Postoperative septicemia, abscess or wound infection
- Urinary tract postoperative complications
- Postoperative cardiac complications except infarction
- Mechanical complications of implants, except organ implants
- Postoperative pneumonia
- Acute confusion or coma after surgery
- Shock after surgery or during surgery due to anesthesia
- Acute myocardial infarction after surgery
- Perforation after surgery
- Postoperative respiratory complications
- Digestive hemorrhage or after non-digestive surgery

Table 4. Sentinel Complications

- ABO incompatibilities
- Central nervous system abscess
- Gas gangrene
- Post-anoxia brain injury
- Medical complication due to gas embolism
- Rh incompatibility reaction
- Acute reaction to a foreign substance/surgical instrument

Table 5. Hospital complications of total number of episodes.

- Aspiration pneumonia
- Other organs complications after surgery
- Anesthesia and other drugs with central nervous system depressant properties
- Miscellaneous complications
- Decubitus ulcer
- Thrombosis and thromboembolism
- Complications due to drugs

Table 6. **Obstetric Indicators**

High-risk childbirth: caesarean with complications
 High-risk childbirth: vaginal birth with complications
 Low-risk childbirth: caesareans with complications
 Low-risk childbirth: vaginal birth with complications
 Miscarriage/abortion with complications

Table 7. **Neonatal Indicators**

Neonatal traumatism
 Perinatal hypoxia
 Brain hemorrhage
 Neonatal infection

Table 8. **Re-Admissions**

Emergency readmission 30 days after surgery
 Emergency readmission 30 medical days
 Emergency readmission 30 days with same surgical ICD
 Emergency readmission 30 days with same medical ICD

international level has a long way to go. Even at the national level, most countries (such as the US) cannot report any progress in reducing rates of adverse events such as postoperative complications. Indeed, as the OECD experience shows, many countries should probably expect rising rates of patient safety events as they institute more comprehensive systems of surveillance, and train surveyors and coders on what to record. Finally, in all of this there is an incredibly important point, in that virtually no country worldwide does an adequate job in terms of involving patients in collecting and recording patient safety data. It is essential to change our cultural thinking. We need to focus our attention on the patient. And we need their collaboration, even to modulate the information and its treatment, which must be gathered in reports and the safety indicators. Some evidence is presented here: the OECD Dublin seminar opened with a presentation by Mrs. Margaret Murphy, a patient advocate from Ireland, who argued in her presentation that it is only in learning from individual patient experiences that we can improve our data systems to the point that they support patient safety improvements. Ms. Murphy's son, Kevin, was the victim of a series of missed diagnoses, lost opportunities and inappropriate medical care that ended up costing him his life in 1999. There was a wide variety of shortcomings in the care that Kevin received for his condition, including the selective and incomplete transfer of information between key caregivers, the absence of an integrated pathway, ignoring clear clinical signs that were not in

line with the existing diagnosis (Kevin developed neurological issues), the weekend environment of the hospital when Kevin was finally admitted where junior staff were left on their own all played a part. Ms. Murphy outlined a set of recommendations from her, and her son's experience that are relevant for improving patient safety data systems:

- Acknowledging the reality as experienced by patients is fundamental if patient-based data is to be used to solve safety problems. Patient-centered care is intended to be just that. Robust data collection needs to include patient input
- Patients therefore need to be included in targeted ways in the process of developing patient safety data tracking systems
- More work is needed to move patient safety data systems to the point where they can reveal root causes of safety problems (ie, the real issues that need to be addressed) and where they can drive quality assurance to improve outcomes for patients
- There is an absolute need for improved patient safety data systems to result in measurable improved outcomes for patients

Ms. Murphy showed a copy of Kevin's death certificate as an example of an "official" element of data. Nowhere does it indicate that the cause of Kevin's death was a set of medical errors. Ms. Murphy's powerful call to international patient safety experts everywhere is to move patient safety data systems to the point where errors, adverse events and complications of care are called as such, and tracked openly. Only then, as she points out, will progress be made in improving patient safety.

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