From the Harvard Medical Practice Study to the Luxembourg Declaration. Changes in the approach to patient safety. Closing remarks

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Abstract

Since the Harvard Medical Practice Study was published in 1991 the growing mass of international literature has demonstrated that medical adverse events can cause iatrogenic illnesses, prolonged hospitalisations and increased costs.

In 1999-2001, reports made by the Institute of Medicine (IOM) in the USA, the Department of Health (DoH) in the UK and the Australian Patient Safety Foundation (APSF) stressed the necessity for creating a safer environment and a reporting culture throughout healthcare systems. They also emphasized the need for researchers to investigate means of turning policies into practice. Since their publication a lot of effort has gone into collecting data on adverse events and near misses.

As a result, in 2001, the AHRQ published a Health Technology Assessment report on best practices for patient safety. While in Australia national meetings have been dedicated to address important issues across the whole spectrum of healthcare. In the UK the Audit Commission has published a report that is also focused on medication safety: "A spoonful of sugar".

In 2004 the World Health Organisation promoted a Patient Safety Alliance; while in April 2005 the Standing Committee of European Doctors organised a Conference in Luxembourg called "Patient safety - Making it happen!". The issue of patient safety is therefore seen as a priority by EU institutional bodies and by many European health stakeholders.

Key words: patient safety, adverse events, medical errors

The roots of patient safety

In the last decade patient safety has become a major issue for public health experts.

Since the first systematic study on medical adverse events in 1991 [1,2], a growing mass of international literature [3-9] has shown that healthcare services are meant to cure patients, but sometimes they can also harm them. Moreover, mislead medical interventions have important economic consequences, as they cause iatrogenic illnesses, prolong hospitalisations and increased costs [10].

Renowned pioneers have already highlighted this issue: Florence Nightingale in 1860, and Ernest A. Codman in 1910, both proposed different methods for monitoring and comparing surgical outcomes and hospitals performances [11].

In 1858 Florence Nightingale started a campaign to set standard statistics for civil hospitals. In doing this she introduced rules for adjustment in health outcomes research [12], thus she can be considered as the first advocate for an epidemiological approach to errors.

The American Surgeon Ernest A. Codman, in 1910, proposed a more clinical approach to the study of surgical performance, based on a careful analysis of case histories. He called this the "End Results Idea":

«every hospital should follow every patient it treats, long enough to determine whether or not the treatment has been successful, and then to inquire "if not, why not" with a view to preventing similar failures in the future» [13].

He applied his methods in 1911, when he opened his own private hospital, with the "End Results" being monitored, published and disseminated:

«So I am called eccentric for saying in public: that hospitals, if they wish to be sure of improvement

1. Must find out what their results are.
2. Must analyse their results, to find out their strong and weak points.
3. Must compare their results with those of other hospitals
[….]
8. Must welcome publicity not only for their success, but for their errors…

Such opinions will not be eccentric a few years hence » [14]:

In fact Codman's call hasn't been answered for a long time.

On the contrary, the fear of litigation, which has for more than a century been a source of concern for doctors, nurses and hospital insurers, has reinforced the silence surrounding medical mistakes.

These fears have played a major part in the defensive attitude of healthcare professionals. The "first wave of malpractice" began in the US in around 1850, and the general acceptance by jurists of Contingency Fee Agreements have encouraged this trend, which has been widespread since 1930 [15]. Before this "wave", in the last decades of the 19th century and the first of the 20th, American surgeons regularly published case reports that included the admission of errors causing death or morbidity to patients. In 1934 the New England Journal of Medicine reported that approximately 20,000 lawsuits had been brought against physicians, and for the authors a major cause of suits was the remarks of other physicians, who unintentionally condemned their colleagues [16]. Doctors started "keeping a cautious tongue": mistakes were largely delegated to courtroom hearings, surgery reports, or mortality and morbidity conferences, while if sued physicians were urged to stay close-mouthed and not to talk to anyone about the case, especially the plaintiff [15].

Some authors suggest that doctors often keep a cautious tongue even amongst each other, and that regulatory peer processes are not that effective in detecting medical errors, nor in sanctioning professional rudeness [17-19].

These deficiencies in self-regulation and in critical attitudes have been analyzed by Neil McIntyre and Karl Popper [20], who say that errors in medicine often go undiscovered or hidden, with negative consequences for both patients and for the growth of knowledge. They declare that the old professional ethics are built on the view that scientific knowledge can be certain knowledge, that knowledge grows by accumulation, and that it can be acquired and stored in a person's mind. *«These ideas create an environment favourable to the emergence of authorities (…) An authority is not expected to err* (…) *Thus the old ethics lead to intellectual dishonesty»*.

The "old ethics" described by McIntyre and Popper has lead to a culture of perfection and infallibility in the medical class [21]. The result, as Leape suggests, is that physicians are discouraged in talking about their errors, because they feel that the admission of errors would lead them to censure, surveillance, or worse, to the loss of their reputation [22].

The epidemiological approach to errors

The fear of liability and the medical "infallibility culture" are probably the primary basis for hiding errors in healthcare. However, according to Leape, there is another reason for this silence: serious injuries caused by errors are not part of the everyday experience of physicians and nurses, but are perceived as unusual and isolated events. Consequently, the magnitude and importance of medical injuries are not acknowledged [22].

The first steps in the "patient safety history", making errors more visible, have been made. Subsequently the need for assessing the size of adverse events in medical treatment, according to validated scientific methodologies, has been met. In 1984, one year after McIntyre and Popper's article, Brennan and Leape et al. commenced the first systematic study regarding the incidence of adverse events in hospitalised patients:"The Harvard Medical Practice Study" (HMPS). In HMPS 30.121 medical records of patients admitted to 51 acute care hospitals in New York State in 1984 were reviewed [1,2]. Adverse events (AE), injuries caused by medical management rather than disease process, were reported in 3.7% of admissions and 27.6% of the adverse events were considered to have been avoidable if normal standards of care had been followed. Most of these adverse events caused minor injuries, but 2.6% resulted in permanent disabilities, while 13.6 % led to the death of the patient.

HMPS has been the principal benchmark to estimate the extent of medical injuries occurring in hospitals [23,24], even though data on error rates have been available for at least a decade [25]. Moreover, most estimates of the economic costs of errors are based on data obtained using the HMPS methodology [10, 26].

Following on from the HMPS, similar studies were conducted worldwide: "The Quality in Australian Health Care Study" (QAHCS) [3], "The Utah and Colorado studies" (UTCOS) [4], the UK [7], New Zaeland [8] and Canadian [9] studies. Descriptive characteristics and principal findings of these studies are listed respectively in Table 1 and 2.

Despite the dissimilarity of findings, all of the studies showed a substantial rate of AE. Nevertheless, there are contrasting perspectives with regards to the interpretation of the results. According to some scholars the rate of medical errors could be overestimated in these studies, particularly those concerning deaths caused by "errors" [27-29]. Contrarily, others suggest that the overall numbers of medical errors are underestimated in these studies, as retrospective investigations of iatrogenesis focus only on injuries, which represent the "tip of the iceberg"

[30]. Moreover, other researches using different methodologies found higher rates of preventable AE [31].

In any case, these studies represent a very important step in the patient safety movement, as their results publicize the severity of the problem of iatrogenesis and support the idea that many of the errors can be avoided in healthcare.

Milestones and policies for improvement: US, UK and Australian experiences

Like most scientific publications, the studies cited above didn't have visible effects on the policy makers' agendas [10, 32].

This is probably due to the fact that epidemiologic studies on errors provided estimates on the incidence of AE, without really presenting solutions.

TABLE 1. Principal retrospective studies on the incidence of adverse events

COUNTRY and YEAR	AUTHORS	STUDY NAME AND REFERENCES	SAMPLE SIZE SETTING
USA, 1984	Brennan et al. Leape et al.	"Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I". *NEJM* 1991;324:370-6. "The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II". *NEJM* 1991;324:377-84.	30.121 randomly selected patients Patients discharged from 51 acute hospitals in New York State
USA, 1992	Thomas et al. Thomas et al.	"Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado". *Med Care* 2000;38:261-271. "Hospital Ownership and Preventable Adverse Events". *J Gen Intern Med* 2000;15:211-9.	15.000 randomly selected patients Patients discharged from 28 hospitals in Colorado e Utah, in 1992
AUSTRALIA (New South Wales and South Australia), 1994	Wilson et al. Wilson et al.	"An analysis of the causes of adverse events from the Quality in Australia Health Care Study". *Med J Aust* 1999;170:411-5. "The quality in Australian health care study". *Med J Aust* 1995;163:158-71.	14.000 randomly selected patients Patients discharged from 28 randomly selected hospitals in Australia
UNITED KINGDOM, 1998	Vincent et al.	"Adverse events in British hospitals: preliminary retrospective record review". *BMJ* 2001;322:517-9	1.014 randomly selected patients Patients discharged from 2 acute hospitals in London
NEW ZEALAND, 1998	Davis et al.	"Adverse events in New Zealand public hospitals: principal findings from a national survey". Wellington: NZ Ministry of Health; 2001. Occasional paper n.3	6.579 randomly selected patients Patients discharged from 13 acute hospitals in New Zealand
CANADA, 2002	Baker et al.	"The Canadian adverse events Study: the incidence of adverse events among hospital patients in Canada". *JAMC* 2004;170:1678-86.	3.745 randomly selected patients Patients discharged from 4 acute hospitals in Canada

Table 2. The incidence, preventability and seriousness of adverse events (% of admissions)

Study name	AE (%)	Preventable AE (%)	Minor or moderate injuries (%)	Major injurirs, Disability (%)	Death (%)
Harvard Medical Practice Study (1)	3,7	27,6	70,5	2,6	13,6
Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado (4)	2,9	32,6 in Utah 27,5 in Colorado	90,2	3,2	6,6
Quality in Australian Healthcare Study (5)	16,6	53	46,6	3	4,9
Adverse Events in British hospitals (7)	10,8	48	19	6	8
Adverse Events in New Zealand Public Hospitals (8)	12,9	35	80,6	1,8	4,5
The Canadian Adverse Events Study (9)	7,5	36,9	34,7	3,1	15,9

Perhaps in response to this, recent reports prepared by different organisations in the US, UK and Australia, have recommended actions to guarantee patient safety.

Among these, the report by the Institute of Medicine (IOM): *To Err is Human: Building a Safer Health System* [10] has been reflected not only in US policies, the media and by the general public during in 1999-2000 [33], but also within the scientific community [34,35].

In the first chapter of the book, the authors make an estimate of the overall consequences of medical errors in the United States. Much of the data presented are drawn from HMPS and UTCOS.

Of the overall consequences of medical errors, one the most shocking concerns the rate of yearly avoidable deaths in the US, which ranges from 44,000 to 98,000.

This number becomes even more relevant when compared to deaths for motor vehicle accidents, breast cancer or AIDS, three causes that receive far more public attention and resources.

Therefore, one of the key messages in the IOM's Report is that in healthcare attention and resources should be commensurate with the scale of the problem.

Another key message in the IOM's report is that most errors are the result of faulty systems, rather than faulty people. Leading on from this assumption, the authors propose a series of recommendations involving new policies and practices to enhance patient safety in American hospitals.

With regards to policies, IOM called for a nationwide effort to include the establishment of a Centre for Patient Safety within the Agency for Healthcare Research and Quality (AHRQ), to expand the reporting of adverse events and errors, to develop safety programs in healthcare organisations, and to intensify efforts by regulators, healthcare purchasers and professional societies.

Centralised agencies for safety have considerably helped in reducing risks in other *milieus* like aviation and industry.

These centres collect and analyse data on accidents by means of incident reporting systems, (e.g. the Aviation Safety Reporting System –ASRS- for aviation), disseminate their results and find solutions for problems.

According to IOM, healthcare also needs a Centre for Patient Safety, to be founded inside the Agency for Healthcare Research and Quality (AHRQ). In the US, agencies devoted to patient safety already exist: the National Patient Safety Foundation (NPSF), the Institute for Safe Medication Practices (ISMP) and the Joint Commission on Accreditation for Healthcare Organizations (JCAHO) - which focuses on medication and hospital safety programs.

The forthcoming Centre for Patient Safety should work as a link between existing agencies, harmonise actual reporting systems, find common causes of errors and propose evidence-based best practices for patient safety.

In relation to practice, IOM does advise on some of the principles for the design and management of safety systems in healthcare organisations. They include providing leadership, respecting human limits in process design, promoting effective team functioning, anticipating the unexpected and creating a learning environment.

IOM's proposals however need to be implemented. In particular, one of the basic issues in collecting data on errors is the reporting system's confidentiality.

Today, the voluntary reporting of accidents or errors is hindered by the fear of litigation. But patients, as well as the lay public, have the right to be informed about the quality of the healthcare they receive. Moreover, unsurprisingly, safety policies and practices have a cost, even if in the long run they are expected to help reducing needless expenses.

According to IOM's committee, an initial annual funding (around $ 50 million) as well as a growth in funding level will be necessary to communicate to researchers, states, professional groups and healthcare organizations that this will be a sustained effort. However, in the absence of a significant long term commitment to funding, researchers are unlikely to reorientate their focus to patient safety.

After "To Err is Human" was published, IOM's proposals were promptly recognised by the US Federal Government, and in 2000 the US President Bill Clinton directed the Quality Interagency Coordination Task Force to evaluate IOM's recommendations. Almost immediately the Federal Government established a Center for Quality Improvement and Patient Safety at the AHRQ.

Several programs dedicated to patient safety were funded as follows: $20M to AHRQ for research into the causes and remedies of errors with a special focus on informatics and Internet technology; $33 million to the Food and Drug Administration for enhanced reporting, $47.6M to Veterans Affairs to increase patient safety training for staff and $75.1M for an order entry system and bar-coding; $64M to the Department of Defense to introduce electronic medical records and finally $12M for an automated order entry system for pharmaceuticals. [36]

In the wake of the United States substantial efforts, other countries have responded with their own reports on medical errors, recommendations and actions.

In the UK the Department of Health (DoH) published two different reports on policies for patient safety in 2000 and 2001, titled "An organisation with a memory" [37] and "Building a safer NHS for patients" respectively [38].

In these reports the DoH advocates the creation of a safer environment through the English NHS, by means of a widespread learning culture throughout all healthcare services at both the organisational and operational levels. The DoH has missed many opportunities to improve the NHS's "memory" on safety issues, as there are many different systems for data collection systems in place for the identification of errors however they are not connected to each other. For instance, obstetricians in the UK regularly carry out "confidential enquiries" into all maternal deaths, and since the establishment of Confidential Enquiry into Maternal Deaths (CEMD), maternal death rates have fallen dramatically [39]. Also the National Confidential Enquiry into Perioperative Deaths (CEMD), established in 1987 has helped to reduce deaths after surgery [40]. However, confidential enquiries take time in order to analyse the data and disseminate the findings and recommendations. Moreover, participation in enquiries is voluntary, which means that a lot of data on accidents has probably been missed.

Other means to enhance patient safety in NHS are clinical audits and risk management practices. Since 1991 clinical audit has been mandatory for English doctors [41], but relatively few audits on adverse events and medical accidents have taken place [42]. Also since 1993, risk management activities have been strongly encouraged within the NHS [43], but often they are not linked to clinical audit or quality improvement programmes [40].

In "An organisation with a memory" the DoH recommends the creation of a single overarching mandatory reporting scheme for adverse events and near misses, incorporating all NHS organisations, including general practitioners and dentists treating patients in primary care. Information gathered through the reporting system should be integrated with patients complaint and litigation data, and patients inputs on how to enhance safety and quality in healthcare should be actively sought.

For the DoH to achieve an acceptable level of reporting it will be of the utmost importance to encourage a reporting and questioning culture with-in the NHS and to send regular feedback to all healthcare professionals.

The other DoH report, "Building a safer NHS for patients", defines the English Government's plans for promoting patient safety following the indications in "An organisation with a memory".

One of the first actions singled out in "Building a safer NHS for patients" is the establishment of a National Patient Safety Agency, that will collect and analyse data on accidents from different data sources, send regular feedback to healthcare organisations, find solutions to prevent injuries, specify national goals and establish mechanisms to track progress. The DoH report also calls for a rationalisation of current inspection systems.

"Building a Safer NHS for patients" concludes with an implementation timetable for all of the key targets and milestones described in the report and defines the actions that need to be achieved during 2001-2005. It provides the national targets for four key categories of serious recurring adverse events:

- to reduce the number of patients dying or being paralysed by maladmistered spinal injections to zero;
- to reduce the frequency of adverse events in obstetrics and gynaecology by 25%;
- to reduce the number of serious medication errors by 40%;
- to reduce the number of deaths of mental health patients which occur as a result of hangings from non collapsible beds or shower curtain rails to zero.

Another fundamental contribution is provided by the Australian Patient Safety Foundation (APSF) with the report: "Iatrogenic injury in Australia" [32] that was originally submitted in August 1999 but published in August 2001, after the IOM's and the DoH's reports.

In Australia, like in the US and UK, important means for reporting and monitoring iatrogenic injuries have been in operation for more than a decade.

One of the first initiatives in this sense was the Australian Incident Monitoring Study (AIMS).

AIMS was set up in 1988 by the new-born APSF, and started as a national voluntary anonymous reporting system, specifically for anaesthesia-related incidents [44]. It has being used, or trialled, by twelve medical specialties. More recently AIMS+, a new simpler, electronic and more comprehensive version of AIMS was introduced.

Another available means to obtain information on iatrogenic injuries is the medical record review, which has already been used for the QAHCS in Australia.

APSF proposes that a randomised sample of all hospitals in each State should be compared amongst jurisdictions and over of time with

respect to a "composite indicator", representing a "basket" of adverse events. This would be possible by introducing a new software based process: the Australian Medical Record Analysis System (AMRAS). AMRAS will provide information about the frequency and costs of adverse events, allowing evidence-based priorities to be set up, while AIMS and AIMS+ will provide complementary information on the underlying human and system-based causes of incidents, which are not provided in the medical records.

Since 1995, a Generic occurrence classification (GOC) has been in operation to collect and analyse data on AE identified by AMRAS, AIMS, AIMS+, complaints, morbidity and mortality studies and by medico-legal investigations. GOC was planned to classify adverse events and to elicit their salient features, place them into context and record their contributing factors. Thanks to this new integrated approach it was possible to identify the "top 250" events and define priorities of intervention. The actual aim of APSF is the identification of the first 1000 problems that give rise to iatrogenic injuries.

From policies to evidence based practices

The activities undertaken by IOM, DoH and APSF have given a strong impetus to researchers to bridge policy into practice.

In 2001, the AHRQ published a Health Technology Assessment report on best practices for patient safety [45]. Practices with the strongest supporting evidence (Figure 1) are generally clinical interventions aimed at decreasing the risks associated with hospitalization, whereas practices drawn primarily from nonmedical fields (e.g., use of simulators, bar coding, computerized physician order entry, crew resource management) need additional research to elucidate their value in healthcare environments.

It is worth remarking how according to AHRQ "Asking that patients recall and restate what they have been told during the informed consent process" is an evidence-based practice for safety.

Also in Australia, as a result of data collection and analysis on errors, national meetings have been dedicated to important issues across the whole spectrum of healthcare – nosocomial infections, adverse drug events, thromboembolism, informed consent and falls [32].

In the UK the Audit Commission has published a report that also focuses on medication safety: "A spoonful of sugar" [46]. This report underlines the importance of the patients' role in medication safety, as proper self-administration of medicines can enhance the quality of medication as well as the patients' compliance after discharge. The Audit Commission also recommends enhancing the pharmacists and nurses role in the medication process and warns of the risks of staff shortages. According to the Audit Commission the system order entry for physicians' prescriptions and original pack dispensing should be introduced as soon as possible by NHS healthcare providers.

The international organisations perspective

Reports and health policies in the US, UK and Australia underline the importance of sustainable action at the local, Federal, State and International levels. These three countries have already participated in exchange programs for patient safety research in order to share problems, findings and methodologies. Their pioneering experiences are now spreading worldwide.

In 2004 the World Health Organisation (WHO) promoted a Patient Safety Alliance [47] while in the Organisation for Economic Co-operation and Development (OECD) initiatives were dedicated to the creation of indicators for patient safety, one of the five priority areas identified for the development of quality indicators [48].

Box 1. Practices with the strongest supporting evidence for patient safety

- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk
- Use of perioperative beta-blockers in appropriate patients to prevent perioperative morbidity and mortality
- Use of maximum sterile barriers while placing central intravenous catheters to prevent infections
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent postoperative infections
- Asking that patients recall and restate what they have been told during the informed consent process
- Continuous aspiration of subglottic secretions (CASS) to prevent ventilator-associated pneumonia
- Use of pressure relieving bedding materials to prevent pressure ulcers
- Use of real-time ultrasound guidance during central line insertion to prevent complications
- Patient self-management for warfarin (Coumadin™) to achieve appropriate outpatient anticoagulation and prevent complications
- Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and surgical patients
- Use of antibiotic-impregnated central venous catheters to prevent catheter-related infections

Source: AHRQ, 2001

In April 2005 the Standing Committee of European Doctors (CPME) organised a European Conference: "Patient safety- Making it happen!" in Luxembourg. This conference resulted in the creation of the Luxembourg Declaration, which consists of recommendations for the enhancement of patient safety targeting EU Institutions, National Authorities as well as all healthcare providers [49].

Patient safety is therefore seen as a priority by EU institutional bodies and by many European health stakeholders.

Many of the recommendations in the Luxembourg Declaration are coherent with US, UK and Australian guidelines [50] (ie: to create national databases for adverse events, introduce risk management routines, develop guidelines and indicators as a part of a quality assessment system in the health care sector), especially those addressed to Member State Authorities.

In actual fact, in the Luxembourg Declaration the importance of single Nation projects, like the National Patient Safety Agency in the UK, and the Society for Patient Safety in Denmark is remarked upon.

A harmonised strategy should nevertheless be pursued at the EU level.Thus a European Forum to discuss patient safety issues, as well as an EU solution bank to compare policies and practices for patient safety will help to increase information exchange between countries.

Closer cooperation with WHO to enhance the creation of a worldwide common vocabulary and a set of indicators to measure healthcare services outcomes is therefore needed.

EU Institutions will also have to play an active role in patient safety, i.e. to make sure that EU regulations of medical goods and related services will be designed with patient safety in mind.

Contributions for patient safety are thus needed at the WHO, European, and National institutional levels; however, healthcare professionals and patients must be involved in the process.

All the main documents dedicated to patient safety strongly support the need for a non punitive culture, focused on learning from errors rather than on blaming professionals [50-52].

To encourage reporting and learning from errors, an appropriate means of feedback to professionals is a *condicio sine qua non.*

Moreover, to change the medical "infallibility culture" patients and the public must be made more aware of clinical risks.

To achieve this it will be of the utmost importance to study alternative dispute resolutions for the healthcare system. No fault compensation systems in New Zealand [53-56], as well in northern Europe [57,58] are giving encouraging results, furthermore the German experience of the *GutachterKommissionen* [59] and the French "Commissions de conciliation" [60] are providing successful tools for patients complaints management.

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