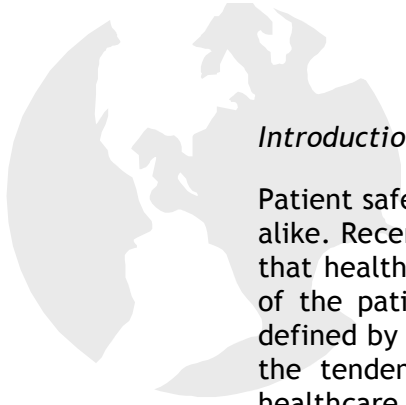




PATIENT SAFETY - CONCEPT AND INITIATIVES

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Introduction

Patient safety is a serious concern in most developed and developing countries alike. Recent studies consistently show, in an increasing number of countries, that health care errors occur in around 10% of hospitalizations.¹ The concept of the patient safety is described with many operational definitions - each defined by the research context. In general, the term *patient safety* describes the tendency to provide conditions and interventions for patients in the healthcare settings that would enable and ensure the desirable outcome. The broadness of this concept embraces both medical and non-medical errors that can incur during the patient stay at the healthcare setting.

Although in many cases, the hospital visit and the patient safety are usually associated with the patient-physician relationship, to a large extent, besides the expertise, professionalism and ethical principles of the medical personnel, the preparedness and level of equipment of the healthcare setting plays crucial role in the outcome of certain intervention; this is another angle of the complex health systems' relations: patient-institution relationship.

Nevertheless, the scientific literature shows that the healthcare sector is a decade or more behind other high-risk industries in its attention to ensuring basic safety for its key players (both patients and health professionals).² Aviation for example, has focused extensively on building safe systems since World War II; between 1990 and 1994, the U.S. airline fatality rate was less than one-third the rate experienced in mid century.³ In 1998, there were no deaths in the United States in commercial aviation; in health care, preventable injuries from care have been estimated to affect between three to four percent of hospital patients.⁴



The concept of patient safety

Since the start of medical practice in its first forms, it is known that unforeseen adverse outcomes of medical treatment can cause harm to patients; intentionally or not, the harm incurred in the already unequal relationship of doctor-patient plants a seed of distrust and disturbed confidence. In order to step in the way of intentional misuse of their position, in 4th century BC, Greek healers modulated a preventive phrase in the well-known Hippocratic Oath obliging them to "prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone."⁵ Still, despite the scientific boom in research and use of scientific evidence in medical practice during the late 19th and 20th century, the data on adverse effects of medical treatment and undesired outcomes were neither collected nor systematically stored and processed, to offer solid base for development of a more profound approach for their prevention; instead, only an anecdotal approach was taken by some commissioned studies.⁶

The concept of patient safety happens to be a relatively recent initiative, as a response to the generally low level of awareness and knowledge about the frequency and magnitude of avoidable adverse outcomes in healthcare industry; the first serious approach to this issue was given in 1990s, when reports in several countries revealed a staggering number of patient injuries and deaths each year.⁷

Since the conception of the idea, the patient safety got its many definitions, most of which however, emphasize the reporting, analysis and prevention of medical errors and adverse healthcare events, but also the near-miss events, administrative and non-medical errors that incur during the patient visit to healthcare setting. Patient safety initiatives include application of lessons learned from business and industry, advancing technologies, education of providers and the public, and economic incentives.⁸ According to some sources, the term is often applied to falls, medication errors, and sometimes even more far-reaching concepts such as patient education, etc.⁹

However, there is a recognized growing unwillingness of governments to leave patient safety to their health care systems or to the institutions and providers who make up the health care system; instead they turn to the option of regulating it with a legislative document.¹⁰

Besides the concerns raised by the national health systems, a number of civil society initiatives commenced as an expression of their anxiety over the issue; in almost every country - the developed ones without exception and most of the developing ones - organizations or movements exist and actively work on monitoring, prevention or even prosecution of medical errors. Yet, the battle is not to be fought single-handed, or even worse - one-sided. The concept of patient safety is not intended to broaden the divide between the patients and medical practitioners - on contrary, it is intended to encourage and even enforce collection and analysis of data on medical errors and adverse outcomes that will enable avoidance of the same malpractice in similar cases in the future. If the concept advocates for decreasing the adverse effects, it should place honours to both patients and medical professionals if it wants an honest and profound change of knowledge, attitudes, beliefs and practices (KABPs).

The Patient Safety vs. the Willingness for Disclosure

The classic *understanding* of risk management and theories that embed this concept are to a large extent focused on single-sided approach, teaching the healthcare workers in this instance to relieve patients but if possible to avoid admitting responsibility or discussing medical errors or malpractice; not only that physicians around the world do not discuss these issues with patients, but they are in many cases refraining from debating and sharing own mistakes and mishaps with colleagues and peers. This is understandable, given the complexity of most situations that cause injury and the unreliability of determining whether an error occurred.¹¹ But it also has created a wall of silence surrounding poor outcomes.¹² This allows for widening of the gap between already unequally positioned physician and patient in their relationship, bringing the physician-patient relationship closer to the paternalistic side of the spectrum.

Patient safety in Action: International initiatives and national policies

Given the short span of the existence of patient safety paradigm and its still not well-established place on the policy agenda, there are only a small number of countries that have given it a full attention, through development and application of related policies. The leaders are again the international community and the developed countries; the initiatives of international organizations will be looked at, and also examples will be drawn from Denmark, UK and the United States, pointing out some of their very innovative measures and approaches to overcoming the reporting stigma that exists in the health professional community when it comes to reporting medical errors.

WHO World Alliance on Patient Safety

In October 2004, World Health Organization (WHO) launched the World Alliance for Patient Safety in response to a World Health Assembly Resolution urging WHO and Member States "(1) to pay the closest possible attention to the problem of patient safety; (2) to establish and strengthen science-based systems, necessary for improving patients' safety and the quality of health care, including the monitoring of drugs, medical equipment and technology".¹³ The Alliance raises awareness and political commitment to improve the safety of care and facilitates the development of patient safety policy and practice in all WHO Member States. Each year, the Alliance delivers a number of programmes covering systemic and technical aspects to improve patient safety around the world; one such programme is the Patients for Patient Safety (PFPS) Programme, that ensures the perspective of patients, consumers and family members around the world are ingrained within the work of the Alliance.¹⁴

European Union

As patient safety was becoming more and more a healthcare priority, not only for the national healthcare systems, but also for the patients seeking healthcare in other member states under the patient mobility mechanism, in 2005, the EU Member States

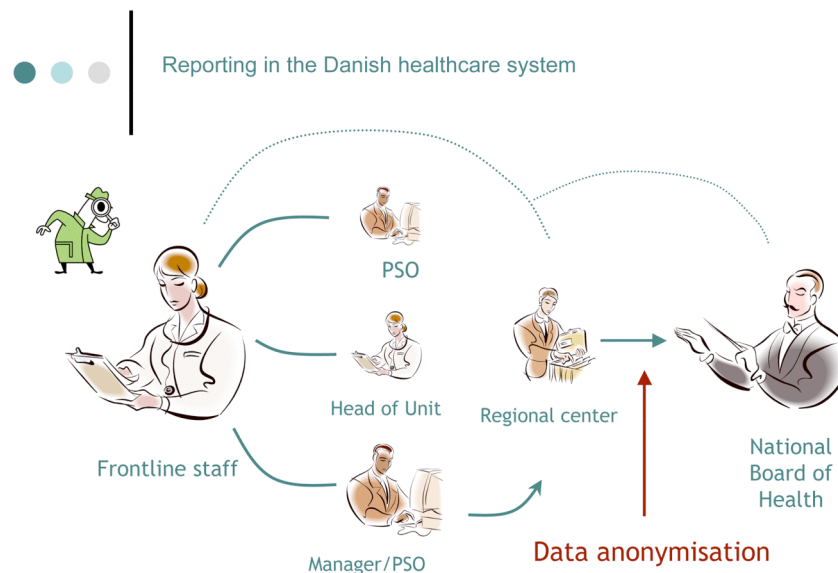
established a mechanism to discuss and take forward the patient safety; special working group was set up under the High Level Group on Health Services and Medical Care to identify priority areas for action, as the Union has committed to facilitate and support its Member States in their work and activities related to reporting and dealing with the medical injuries and adverse events. The recommendations of the High Level Group point out that reporting and learning systems in this field would permit information on problems and solutions to be shared throughout Europe; at the same time, EU patient safety network or forum, working with other international organisations, could provide focus for efforts to improve the safety of care for patients in all EU Member States, through sharing information and expertise.¹⁵

Under the Luxembourgian presidency of EU, in April 2005, the European Commission DG for Health and Consumer Protection issued the Declaration "Patient Safety - Making it Happen!" widely known as the Luxemburg Declaration. The Declaration calls for active involvement of EU institutions, in establishment of EU forum to discuss issues regarding patient safety, in cooperation with other patient safety initiatives, like the WHO Alliance on Patient Safety, and it recommends to the national authorities to establish national forums, to ensure full and free access to personal health information to patients, to optimise the use of new technologies, and above all to work towards creating a culture that focuses on learning from near misses and adverse events as opposed to concentrating on "blame and shame" and subsequent punishment.¹⁶

Denmark

It is the National survey on patient's experiences performed in Denmark that has opened a policy debate on the issue of patient safety - the survey showed that 18% of all interviewees had experienced medical error, of which medication and surgery made almost half; compared to other developed countries - Australia and New Zealand 13%, Britain 11%, France 8.9%, Canada 7.5%, this result seemed like a call to action for the Danish authorities; adding to it the study by Andersen et al in which almost one third of medical professionals are considering the change of profession because of fear of being involved in adverse events¹⁷, the patient safety issue was put high on the political agenda with priority on finding a suitable way to address it through effective policy.

As a result, Denmark became the first example of a country that introduced nationwide mandatory reporting of medical errors and adverse outcomes. The Danish Act on Patient Safety¹⁸ enacted by the Danish Parliament in 2003, sets the ground for obligatory reporting of adverse events by the frontline personnel to a national reporting system; the famous Article 6 of this Act¹⁹, which reads "A health care professional reporting an adverse event shall not as a result of such reporting be subjected to disciplinary investigations or measures by the employing authority, supervisory reactions by the National Board of Health or criminal sanctions by the courts", is opening a space for professional yet sincere debate grounds for gathering, analyzing and communicating the knowledge of adverse events, in order to reduce the number of such events in the healthcare system. In January 2004 the national reporting system was set in place, obliging not only the frontline personnel to report, but also the hospital owners to act on the reports and the National Board of Health to communicate learning from the reports, after making data anonymous, and in that way lifting it to the meta analytical level. More details of this reporting system are available from the National Board of Health and Danish Society for Patient Safety (DSFP).²⁰



United Kingdom

Unlike the unique mandatory reporting system in Denmark, the United Kingdom introduced voluntary reporting of healthcare errors. The reporting system is under the NHS National Patient Safety Agency, established in 2001, with a mandate to identify issues related to patient safety; in 2005, the Agency expanded to incorporate the National Clinical Assessment Service and the National research Ethics Service.

The specificity of the UK reporting system is that it has several specific instances, referred to as "confidential enquiries", with routine investigation initiatives; those include among other, the maternal and child health (mother or infant deaths, deaths of persons under 16), and patient outcome and death, including death of mentally ill persons, perioperative and other unexpected medical deaths. In the British case, as well, the individual data is confidential, enabling increased participation from both the patient and involved health professional.²¹

To this end, the National Confidential Enquiries Strategy determines the purpose of the enquiries in general ("...to investigate the contribution of deficiencies in care to serious adverse patient outcomes; to identify areas where clinical practice needs to be improved and to make appropriate recommendations for changes that will improve outcomes for patients...") and sets up the priority for three enquiries of outmost importance for the UK health system: on Maternal and Child Health (CEMACH), Patient Outcome and Death (NCEPOD), and Suicide and Homicide by People with Mental Illness (NCISH).²²

Still, the 2007 report of the NCEPOD on patient outcome and death "Trauma: Who cares?" reported that less than half of the studied patients received good care, and that 13.4% of cases received inappropriate initial hospital response, with a high likelihood of the overall care for those patients being compromised.²³

United States

In its 1999 report, the Institute of Medicine (IOM) recommended a nationwide mandatory reporting system for collection of standardized information by state governments about adverse events that result in death or serious harm. The report suggests that the reporting should initially be required of hospitals and eventually of other institutional and ambulatory care delivery settings.²⁴

Almost immediate response came from the concerned professional organizations, like the Anesthesia Patient Safety Foundation (APSF) which responded to the report by expressing serious concerns about the practicality and utility of the IOM's recommended reporting system: "Mandatory reporting systems in general create incentives for individuals and institutions to play a numbers game. If such reporting becomes linked to punitive action or inappropriate public disclosure, there is a high risk of driving reporting "underground" and of reinforcing the cultures of silence and blame that many believe are at the heart of the problems of medical error and patient safety. This would be particularly true to the extent that "innocent" providers could be unfairly accused."²⁵

After long debates and controversies over it, in 2005 the US Congress passed the Patient Safety and Quality Improvement Act.²⁶ Under the new plan, hospitals would be encouraged to report their mistakes confidentially to groups that will be known as patient safety organizations. The groups could then contract with the hospitals to analyze their mistakes and develop ways to prevent errors. The federal government would play the role of coordinator, developing the computer network used by the safety groups to collect and analyze the data. Reports remain confidential, and cannot be used in liability cases. Consumer groups have objected to the lack of transparency, claiming it denies the public information on the safety of specific hospitals.²⁷

Another alternative for improvement of the patient safety in the US, argued by the Harvard School of Public Health scholars is the establishment of health courts for medical injury compensation, as part of the administrative compensation system. Mello et al explain that a *health court* has five core features; (i) injury compensation decisions are made outside the regular court system by specially trained judges; (ii) compensation decisions are based on a standard of care that is broader than the negligence standard; (iii) compensation criteria are based on evidence from the scientific literature; (iv) this knowledge, coupled with precedent, is converted to decision aids that allow fast-track compensation decisions for certain types of injury; and (v) *ex ante* guidelines also inform decisions about how much for economic and non-economic damages should be paid.²⁸

The transfer of the medical injury compensation from tort system to administrative compensation system, is under discussion, with questions still remaining to be answered, such as how much this or the mandatory reporting system alike would create a burden on the bureaucracy and if this used financial and human capacity could be utilized in a more effective way to decrease patient injuries and trauma.

Epidemiological data from medical-legal claims can be used, for both identifying rare but unacceptable events of malpractice or medical injuries²⁹, and to look at possibilities to prevent more often incurring cases of compromising health of the patient; yet the balance should be set in the way not to make an oversized system

from which the benefit would be hard to measure or difficult to implement. Some initial research on this topic has been done recently.³⁰

Measuring patient safety - Indicators

There are many ways to measure patient safety; a vast body of literature explores the number of medical injuries, ambulatory, surgical and medication adverse events. However, the absolute numbers of these events do not show the degree of injury or severity of the adverse outcome. The Agency for Healthcare Research and Quality (AHRQ) of the US Department of Health and Human Services has made one of the elaborate attempts to measure the patient safety. The AHRQ system defines the patient safety indicators (PSIs) as a set of measures that screen for adverse events that patients experience as a result of exposure to the health care system, and which are preventable by changes at the system or provider level.³¹ The AHRQ system defines two levels of PSI: *provider level* (adverse events incurred in patients that received their initial care and experienced the complication of care within the same hospitalization), and *area level* (where the initial care and the complication happened in different healthcare settings). The proposed PSI indicators, reported on a voluntary basis measure the accidents from decubitus and transfusion reaction, to birth and obstetric trauma and postoperative complications, such as hip fracture, sepsis, hemorrhage and pulmonary embolism, as well as unwanted events of death in low-mortality diagnostic related groups (DRGs).

Yet, the existing research in this field of mapping and quantifying the medical adverse events in the direction of reducing preventable accidents and malpractice should be furthered by its conversion into policy and implementation into practice. The political agendas of governments should be pressed and influenced to embed and act upon the research and records supplied by their healthcare systems.

Patient safety practices

Despite being still only a concern with many debates surrounding the necessity of establishment of reporting system and reaching consensus over its proper form (mandatory vs. voluntary), the patient safety issues are looked at and acted upon by a large number of organizations that internationally promote patient safety issues. Such initiatives are everyday work for the patient advocates, patient organizations and self-help groups alike.

The flagship among them is the Patient-Centred Healthcare Declaration of the **International Alliance of Patient Organizations (IAPO)**, according to which "*the essence of patient-centred healthcare is that the healthcare system is designed and delivered to address the healthcare needs and preferences of patients so that healthcare is appropriate and cost-effective.*" The Declaration, based on its five principles (respect, choice and empowerment, patient involvement in health policy, access and support, and information) calls for greater patient responsibility and optimal usage, that leads to improved health outcomes, quality of life and optimal value for healthcare investment.³²

Another among the pioneers in this area is the **WHO Patients for Patient Safety Programme**, dedicated to reduction of medical errors and injuries harmful to the patients. In their London Declaration, brought in March 2006, the patients from all

over the world have committed to: devising and promoting programs for patient safety and patient empowerment, driving constructive dialogue with all stakeholders concerned with the patient safety, advocating for and establishing reporting systems worldwide on healthcare harm and defining the best practices for dealing with the healthcare injuries and unwanted events.³³

Partnership for Patient Safety (p4ps) is a patient-centred initiative to advance the reliability of healthcare systems worldwide, through initiating focused partnerships and joint ventures with organizations and individuals that share p4ps core values and objectives of achieving a healthcare system that is authentically patient-centred and systems based. The p4ps, which is an Illinois corporation established in 2000 by some of the leading figures in patient safety in the US, has established the Consumers Advancing Patient Safety (CAPS) in 2003, as a non-profit initiative.

Consumers Advancing Patient Safety (CAPS) has a mission for working towards achieving healthcare that is safe, compassionate and just. In their 10 Principles, Values & Beliefs, besides promoting system-oriented and patient-centred healthcare, they encourage open and honest communication, partnership and collaboration, but also accountability and forgiveness, and appreciation and positive-mindedness, strongly relying on the human nature of the health professionals and self-correcting mechanisms naturally embedded into our existence.³⁴

Conclusion

Patient safety cannot be exclusively brought in connection with the patient-physician relationship; this relationship represents an important but not a single element of the medical treatment process. The knowledge, experience and ethical principles of the health professionals can be most effectively used in bondage with the accessibility of at least a minimum working conditions of the healthcare setting, which means a lot more than just equipment, medical and non-medical supplies.

One of the basic rights of patients - access to healthcare, which is a basic precondition for commencement of the debate on patient safety - should not be limited to the accessibility to healthcare professionals, but rather to include all the infrastructure and environment needed for the medical professionals to responsibly and duly perform their work.

Further, the culture of silence and the potentials of punishment for medical error should be given much bigger attention, as a factor contributing to higher figures in medical injuries, resulting from repetition of same or similar accidents. Evidence-based medicine and clinical protocols are good example of a preventive mechanism through intended use of the best current evidence in making decisions about the care of the individual patient, yet things should be looked at from a wider perspective, as there are cases when the evidence-based medicine can contribute little if it can at all.

The proposed individualization of the healthcare, through the patient-centred healthcare and similar concepts proposing adjustability of healthcare to the need of the patient, in no way means individualization of the healthcare system; systemic approach to the improved patient safety through providing safe enough environment for exchange of practice, will also contribute for protection of the diligent medical practice, sometimes shadowed by the distrust accumulated from tacit experiences.

Nevertheless, cooperation on all levels on the issue of patient safety is needed to improve patient care; from governments and healthcare givers to patients and members of their family. Patient safety to a large extent depends on effective and sustained policies and initiatives, and this should be constantly highlighted to the governments, which hold the power to make and implement those policies. But apart from the political will and dedication, a strong commitment is needed from the healthcare system and all its components, in breaking the vow of silence, improvement of communication and compliance, giving a consideration to the doctor-patient relationship as one among human being to human being.

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¹⁴ WHO Patient Safety webpage, <http://www.who.int/patientsafety/en/>

¹⁵ High Level Group on Health Services and Medical Care

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