### ADVERSE EVENTS – DANGEROUS BUT PREVENTABLE

**Carmen ANGHELUTĂ, MD**  
Medic primar SPM, NSPHMDHB

#### Harm to patient safety in medical services

Although one of the basic Hippocratic principles of medical practice is „Primum non nocere”, modern medicine is confronted with a real „epidemic” of damages and even death of patients as a consequence of errors within the medical services. The adverse events represent one of the most frequent prejudice source to patient health, representing a major source of morbidity and mortality in the entire world. Health systems from the majority of countries make efforts to develop patient safety improving systems, by studying the adverse events that took place in different medical services, by evaluating the potential risks associated to medical care, by developing a safety culture and creating a national frame of patient safety policies within the health system.

#### Patient safety glossary

The European Commission defines patient safety as lack of harm or of potential harm to the patient, in relationship with the health system. A variety of circumstances determine the occurrence of a diversity of errors, dependent on the impact that it determines. At the same time, patient safety enters in the attention area of a variety of personnel categories, such as clinicians, risk managers, administrators, etc. This multidisciplinary approach determined the necessity to adopt a glossary of terms unanimously accepted and understood. A project financed by de European Commission defined a set of terms used by the EU countries. We are presenting below some of the more frequent used terms. [1]

**Adverse events** can be defined as unintentional and unwanted damage to health, harm, morbidity, temporary or permanent disability or even the patient’s death, caused by weak performance or even the lack of medical care.

**Sub-event** is an adverse event that has the capacity to produce harm but didn’t produce consequences due to the adequate and in time identification and correction.

**Sentinel-event** – reflects serious harm of patient’s health and the probability that the event investigation reveals serious problems of policies and procedures within the health organization, lack of interest for safety, organization with risk degree in the provision of services. Such an event signals the necessity of immediate investigation and adoption of adequate correction measures.

It’s unanimously accepted that a lot of errors can be prevented and require the introduction of radical changes in the modality of providing the medical services, in order to respond to the major objective of patient safety.

#### Types of errors

The most frequent errors are those of **diagnosis** (delay in establishing the diagnosis, not-indicating the appropriate tests and analysis, **treatment** prescription of drugs administration, contraindications, delays in administration, etc), **prevention** (lack of prophylactic treatment, lack of monitoring and surveillance) or other causes (nosocomial infections, problems related to the medical equipment, organization of health services, lack of communication between medical personnel, etc). Given the complexity of causes that generate errors, the multiple categories of clinicians, specialists, administrators, decision-makers involved in the possible generation of errors, the interest in this phenomenon and and the improvement of patient safety is very big. In addition, the new strategies of providing safe medical services is based as well on the awareness and involvement of the patients in the integrated approach to the problem, in plans of organizational changes of health services. [2]

In hospitals, due to the complexity of services, to the technologies used, to the high degree of services request, to the multiple human resources involved, conditions are created for a probability of risk occurrence, and, as a consequence, of errors. Most of the available studies at this moment of time are addressed to hospitals, but errors can occur in any type of medical service. Besides the errors registered in hospitals are those from outpatient services, primary care, community services, pharmacies etc, so that the alarming figures referring to the patients being affected in hospitals represent only a small part of the possible adverse accidents with their dramatic consequences upon the patients, medical staff and costs within the system.

Categories of errors can be different so that in primary care and ambulatory services the most frequent errors can be those...
of diagnosis and medication, less those related to treatment, interventions, and medical equipments. However, taking into consideration the large number of consultations and prescriptions in these services, the number of errors and affected patients is probably very high.

**The magnitude of the problem**

This era of preoccupation for patient safety was opened in the '90 when some studies done in USA showed that medical errors appeared more frequently than estimated. In 1999, through “To err is human- building a safer health system” study, elaborated by the Institute of Medicine form USA (IOM), was revealed to specialists and the large public a dramatic phenomenon, supposed but unrevealed, discussed by the clinicians behind closed doors: medical errors have a huge frequency and produce more victims than road accidents, breast cancer or AIDS.

The mentioned IOM report was based on two studies done one in the hospitals from Colorado and Utah, and the other in New York. These studies, like most that concern medical errors that determine harm to the health or life of patients, had as object of study patients from hospitals. The conclusions show that 3.7% from cases suffered an adverse event. From these, 3.6% developed a permanent disability and 13.6% died as a consequence of medical errors. In the study from Utah and Colorado, the proportion of adverse events was 3.7, respectively 2.9%, and 6.6% from these patients died. In both studies more than 2/3 from medical errors was avoidable. By extrapolating the study results to 33.6 million of admissions in USA hospitals in 1997 resulted that in one year die because of medical errors between 44000 – 98000 persons, exceeding the number of death attributable to the 8th cause of death in USA. The estimated costs associated to medical errors (productivity loss, patient’s personal financial loss, and disability and health system costs), at national level in USA have a value between 17 and 29 billion USD, from which about half are the expenditures of the sanitary system. Other studies show that errors of medication are the most frequent, about 2 out of 100 patients admitted in USA hospitals being confronted with such an incident and increasing the costs per admission with about 4700 USD. At country level this cost increase would represent 2 billion USD per year. In addition to these costs are the opportunity costs, meaning costs that are unavailable for other objectives and patients that would need these financial allocations. Therefore, both health systems and patients are paying supplementary for services that were not properly provided.

Beyond the human physical and psychological suffering of the patients or the drama due to loss of life, another big loser as a consequence of medical errors is the health system. The medical staff has to suffer, as well, both after losing the confidence of patients and because of guilt and frustration due to the lack of the capacity to provide the necessary and good medical services for patients. At society level other looses in terms of productivity, absence from school, decrease of the level of population health status are registered.

The authors of the study consider that it is unacceptable for patients to suffer after their interaction with the health system that is festinated to offer cure and health. Therefore o complex strategy of interventions at all levels is proposed – government, service providers, the industry of medical technique and drugs, health professionals, patients, in order to decrease the preventable errors. [2]

The report “To err is human” produced a deep impact upon the attitude of health organizations, international organizations, patients. In 2000, in Great Britain, the NHS report in 2000 showed that 400 patients were seriously harmed or died as consequence of such incidents connected to the utilization of medical equipments and about 10000 patients have suffered adverse effects as a result of drug use. This report, named “An organization with a memory” analyzed the level and types of errors that have caused death or the serious harm of patients’ health and introduced the concept of system analysis in order to understand the causes of errors, recommending active measures of changing the organizational culture and of introducing the reporting and learning systems. In 2004 WHO launched the program “World Alliance for Patient Safety” that requests all countries to pay more attention to patient safety issues and brings examples regarding the best practices for patient safety.

In 2005 The Council of Europe adopted the „Statement for patient safety” that recognize as key objective the improving of healthcare quality and patient safety, and in 2009 adopted the „Council recommendation concerning the patient safety including the prevention and control of associated infection”. In most European countries numerous research programs were conducted to determine the level of adverse events and their types. In 2005, in Spain a study on hospital admissions was made, that showed that 9.3% of patients experienced an adverse event, and of these 42.8% were preventable. Regarding the types of adverse events, according to the study mentioned above, the largest errors are due to medication (37.4%), nosocomial infection (25.34%) and procedural errors (25.04).

**Approach to errors from a system perspective**

The traditional approach to analysis of accidents in the health services is the individual.

Traditional thinking considers that qualified personnel cannot commit errors, so errors occur because of individuals’ incompetence and deserve punishment.

Over time, most Western countries have introduced quality standards for medical training, licensing and certification of professionals and for accreditation of the provided medical services in order to increase quality of health services, credibility and professionals’ responsibility. These measures were not sufficiently protective, so that patient safety is still critical, which lead to an increased responsibility of health professionals to learn from errors and develop systems to provide safety for patients.

Organizations such as hospitals operating in an environment of safety hazards develop defense barriers to come between hazards and a potential victim. These defense systems include physical barriers, security features, alarm and also barriers related to the management, organization, procedures, controls etc.

Experiences of other industries, such as aviation or nuclear power, show that the roots of error must be sought not only
at the individual level, but at the system level. This theory of accidents in complex systems, as demonstrated by James Reason is based on the finding that in jobs with potential dangers accidents’ production is a typical pattern. The fact that different people are involved in the same type of accidents indicates that the generation of accidents has causes at the level of that work place. Systems crack and organizational culture determines a typical lack in the safety mode of action of individuals. [4]

Healthcare organizations, especially hospitals are complex systems in which a variety of components interact - staff, patients, infrastructure, technology, drug suppliers, supplies, etc., which form a complicated structure, less predictable. The complexity of health services includes diversity of patients, medical staff, the relationships between patients and medical staff, administrative, community relations, diversity of tasks of each person, changes in the physical environment of health care, changes in rules and procedures, implementing new technologies, specialization of medical personnel etc.

So often on the patient's path within the medical system a chain of defects can occur; they are not apparent, but may lead to patient harm. Although defects are "hidden" they might determines errors 'active' at the sharp - end causing the harm of the patient.

These deficiencies can be found at any level of the system: organization, management, training, medical equipment and, on the other hand, at the direct interface with the system usually acts a single person (Figure 1).

When an accident occurs, otherwise determined by hidden causes, the first person found guilty is the one being in direct contact with the patient. Moreover, it often starts from the false premise that the person who was wrong intentionally chose the wrong path. This is the traditional punitive approach to punish the one that was wrong without analyzing the causes that generated the individual mistake. Reactive behaviors of health professionals and health organizations, the media, society in general are hiding errors, blame and punishment. This type of procedure is unfair, unnecessary and results in the hiding of the phenomenon and the perpetuation of the possibility to repeat the error anytime, anywhere.

Invoking human error is the easiest approach. But as shown by experience, sometimes the best trained specialists commit the most serious mistakes. Moreover, the errors do not occur by chance, but often are the result of a faulty action, which came into habit. Basically, the same circumstances can cause the same effects, regardless of the persons involved. In risk management the exclusive approach of issues such as negligence, forgetfulness, lack of attention, lack of compassion do not solve the problem. The literature describes two types of errors: active errors caused by errors or procedural violations that have immediate impact on the victim and usually are first investigated and latent errors, which do not produce a direct effect in themselves, until certain conditions are met locally or active mistakes are made, finally causing a catastrophe. This category includes the decisions of design, construction, procedures or management decisions. For example the decision on limited allocation of financial and human resources might determine in time and specific conditions to produce a serious accident (by accumulation and the intervention of active factors - active faults by excessive fatigue, lack of personnel, lack of materials and equipment) [5]

Good practice in analyzing the causes of errors reveals many factors that influence behaviors and practices of medical services. The individual factors such as behavioral or psychological factors and vocational training represent only one category of factors involved in a workplace as health services. The systemic approach does not mean that individuals are absolved of the responsibility or discipline in their work where negligence or malice was proven.

Single focus on individual guilt leads to neglecting and ignoring causes and risk factors in the health system and losing the opportunity to correct and to learn from experience.

The system analyses could approach all the quality aspects described by Donabedian – structure, process, outcome.

The experience of organizations from the United Kingdom regarding error analysis has identified several important factors to be investigated in the analysis of the causes (Root Cause Analysis). The NHS believes that the following factors are the most influential in the medical care field:

- Institutional context
- Organizational and management factors
- Working environment factors
- Team factor
- Individual staff factors
- Factors related to medical activity
- Patient characteristics

A systemic approach for investigating errors will allow the determination and analysis of dysfunctional organizational factors related to process, teamwork, management, financial difficulties or other factors that could lead to accidents [5].

In addition, giving up a blaming culture, the development of a culture of safety, openly discussing the risks, disclosure by reporting errors and learning from mistakes lead to the identification and adoption of safety systems in the health field. At the same time, individuals in such an organization are also fully
responsible for their professional and ethical practice in work relations with the other health professionals and with patients.

**Basic principles of patient safety**

Patient safety and the quality of health services are related to one another but patient safety has developed into almost a new discipline, which fundamentally transformed healthcare services worldwide. In order to provide safe health services in a hospital or any medical facility there is a need to accept the following premises: in providing health care services there are risks (such as risks regarding the structure or process) that can be prevented and there is an expressed desire from the part of the organization to identify and analyze those errors or risks for patients.

The fundamental principles underlying patient safety are represented by the prevention or reduction of the potential errors and minimizing the consequences of adverse events. Safety is obtained from the interaction of system components that is much more than identification of the preventable errors or the absence of the adverse events. That is the identification process, the risk analysis and risk management in order to make safer the healthcare services for patients and minimize risk.

Basically, the most important mechanisms of intervention are developing a culture of safety and investigation and analysis of adverse events and sub-events for learning and intervention.

**Understanding the phenomenon - by measuring patient safety**

*The Patient Safety Indicators*

Reducing medical errors can not be achieved without a good knowledge of their causes and nature. Currently many healthcare organizations experienced a multitude of possibilities for the identification and understanding of the errors, the potential of their apparition and use of experiences for learning and methods to improve quality and reduce errors.

One of the methods used for understanding the risk level and types of errors is the definition and collection of some indicators of medical errors. Indicators of adverse events must be relevant to patient safety and easy to use by health services.

The Agency for Healthcare Research and Quality (AHRQ) provides for the hospitals in the U.S.A sets of indicators to be used in current clinical assessment, based on ICD 9 diagnosis codes and orient the hospitals in determining the information, the potential complications and adverse events that have occurred during hospitalization. Hospitals evaluate their own performance and AHRQ monitors and makes comparisons between hospitals, regions, populations, assess trends, providing evidence for measures to improve patient safety. The lists of patient safety indicators are continuously updated and AHRQ reports are made public. [6]

OECD has also selected several areas for which were defined patient safety indicators used in studying health services from various states and recommended for comparison between different services. The main areas are:

- Hospital infections,
- Surgical and post-surgical complications
- Obstetrics
- Sentinel events [7].

A literature review conducted by WHO experts, in 2009 has selected those accidents that cause damage to patients and had an increased frequency and a severe impact, but with high potential for improvement:

- Infections associated with medical care
- Assistance for pregnant women
- Drug-related adverse events
- Medical equipment related adverse events
- Unsafe injections
- Unsafe blood products
- Diagnostic errors
- Errors of anesthesia and surgery
- Fall of patients in medical units [8].

*Sentinel events* are events that should not occur being called "never events" and constitute a special category. The term includes events that lead to very serious damage to the patient's health or even death and are clearly identifiable and measurable and usually preventable. In many hospitals and health systems a list of these events was adopted, that must be reported for correcting, controlling and avoidance of recurrence of the risk. Those events are also called „catastrophic events” to attract the attention on the drama they produce but also on the potential risk of that organization; this risk is caused by the disregarding of patient safety culture and procedures. The organizations where such events occur, must take measures for fundamental change of organization, culture, procedures in order to avoid risks and increase safety.

The UK National Health System has adopted in 2009/2010 the list of adverse events (Never Events) and the annual report informs about the level of these indicators and examines how security policies are used by medical services.

The basic list of these events includes:

- Surgery for other parts of the body than those intended
- Forgetting an instrument into the patient after surgery
- Using a wrong way of administration for chemotherapy
- Non detection of an incorrect placement (air passages) of an oral or nasal-gastric probe before using them - the introduction of fluids-
- Suicide of patient by using incompressible tubes/cables
- Escaping from a secure perimeter of mental illness patients
- Maternal death because of postpartum hemorrhage after cesarean surgery
- Administering intravenous potassium chloride solutions in an inadequate concentration [9].

The Agency for Health Care Research and Quality classified into six categories of causes such events which determine serious damage or death to patients:

- Surgical (e.g. surgery of other parts of the body, the patient's death during surgery or immediately after surgery)
- Medical products or equipment (e.g. drugs or contaminated equipment)
D. Using the claims data

This type of analysis is useful also, because it contains clinical patient data and other possible administrative and context data. It is more useful if is based on electronic file. Sometimes claims data can indicate false adverse events.

The best practice experience related to patient safety

There are many models to improve the patient safety. It is agreed that patient safety is everybody business of those working in the health field, including the beneficiaries – the patients. Consequently the common identified areas for best practice are addressing national policy levels, health organizations and patient’s level.

The US model

After the report “To Err is human – Building a safer health system”, important measures have been introduced at the national level:

- establishing a national focus - Agency for Healthcare Research and Quality – to create leadership, research, tools and protocols to increase the knowledge base about safety, information and technical support for health services providers;
- identifying and learning from errors by developing a nationwide public mandatory reporting system by encouraging health care organizations and practitioners to develop and participate in voluntary reporting system;
- raising performance standards and expectations for improvements in safety through the actions of oversight organizations, professionals and purchaser of health care;
- Developing safety systems in health care organizations to ensure safe practices (safety culture, patient’s involvement, etc).

There is a fundamental change of healthcare organizations in the way of behavior and discussing about medical errors, prevention of errors, analyses of system brakes and failures – there is a strong believe that system failures and not bad people are at the root of the accidents.

The American Congress is allocating $ 50 million annually for patient safety research to AHRQ and health care organizations. There is a major interest at the national level for this priority including at the level of the main stakeholders: Joint Commission International on Accreditation of Healthcare Organization (JCAHO), hospitals, medical centers, doctors, nurses, pharmacists, patients, etc. Many pilot projects for safety practices – „safe surgery check list”, „medication safety”, prevention of hospital infections, etc and also projects for organizational transformation – improving communication, team work, to reach high standards of reliability, honesty (“high reliability organization”) have been implemented.

Despite of significant improvements in reducing important errors, AHRQ recognize the difficulty of existing barriers produced by the fear of malpraxis liability, unwillingness to discuss or admit errors, the high diversity and complexity of medical specializations and practices, the lack of leadership at the level of healthcare organizations. The strategic plan for the

- Management of the patient (e.g. wrong hospital discharge of a child given to other people than the parents)
- Care management (e.g., medication error, dose, concentration, time administration, route of administration, blood incompatibility with hemolytic reaction, maternal death related to labor in low-risk pregnancy, stress ulcer, etc.)
- Hospital-related events (electric shock, inappropriate use of gas, burns, fall)
- Criminal events (seduction, sexual assault, death of a patient or member of staff inside the hospital).

Adoption of the list, reporting obligation, the devastating effect on patients put a high pressure on health system to eliminate these preventable errors. Beginning with 2007 Medicare has stopped reimbursement for the treatment of preventable errors, including the Sentinel events, inflating this way the actual responsibility of health care providers for patient safety and quality of medical services. [10]

B. Retrospective medical records review

It is one of the most used methods for detecting the incidence level of adverse events, especially when there are no base line studies at the country or hospital level, offering clinical and safety events data. In the last ten years, many of the studies performed by European hospitals used this technique. But the variability of data is high both in terms of content and quality. Many data related to the patient pathway or transfer, administrative data might be missing or incomplete. Because the majority of the records are paper based, the process of collecting and analysis is time and resources consuming.

C. Voluntary or mandatory incident reporting

A national IT reporting system of incidents is becoming the principal method used in many countries, being recommended by national and international organizations. It is based on self-reporting of the event by the hospital. The collected data is including information related to the environment and the medical system. Some of the events might not be reported. The safety culture must be developed within the organization (recognise the existence of the errors in the medical practice and disclose them, training in errors analyse techniques, make the recommendations for improvements as well as an adequate IT support to generate useful reports regarding the accidents). The basic principles of an efficient IT incident reporting system are: mandatory reporting focused on learning, confidentiality, punitive free. To succeed in introducing such a reporting system, a legal and institutional frame must be created. This frame has to support the staff to report by offering confidentiality and non-punitive protection in order to encourage the reporting. Many countries developed a dedicated legislation which is regulating the format of the report, the procedure to use the data from the system, the mandatory obligation for reporting of the medical staff and management, the secure confidentiality of the staff and patients, the prohibition of using data from the system for administrative and disciplinary measures. Denmark law – Danish Patient Safety Act- is a good example, because this law is marking clear borders between the safety events reporting system (which is design for learning process and increase safety measures) and the claims system or health insurance system [11].
next years is focused on introducing the best safety practices in all the medical services, electronically records of the patients for ensuring the continuity of information, training for team work, development of the safety culture, safety medication, etc [11].

European Commission view

The „Council Recommendation on patient safety, including the prevention and control of healthcare associated infections” is formulating recommendations and detailed measures for the member states. The recommendations are based on results of studies performed by member states, studies asked by the Commission (RAND), Euro barometer survey on perception of medical errors, recommendations made by High Level Working Group for Patient Safety, World Alliance and results of projects EuNetPas, SIMPATIE and others.

The main recommendations are:

• The Governments of the member states will support the patient safety policies and programs by:
  - designating the competent authority or authorities or any other competent body or bodies responsible for patient safety on their territory;
  - embedding patient safety as a priority issue in health policies and programmes at national as well as at regional and local levels;
  - supporting the development of safer and user-friendly systems, processes and tools, including the use of information and communication technology;
  - regularly reviewing and updating safety standards and/or best practices applicable to healthcare
  - encouraging health professional organizations to have an active role in patient safety including a specific approach to promote safe practices to prevent the most commonly occurring adverse events such as medication-related events, healthcare associated infections and complications during or after surgical intervention.

• Empower and inform the citizens and patients
  - involving patient organizations and representatives in the development of policies and programmes on patient safety
  - disseminating information to patients
  - patient safety standards which are in place;
  - risk, safety measures which are in place to reduce or prevent errors and harm;
  - complaints procedures and available remedies and redress
  - development of core competencies in patient safety namely, the core knowledge, attitudes and skills required to achieve safer care, for patients.

• At the level of the education and healthcare organizations:
  - multidisciplinary patient safety education and training of all health professionals, other healthcare workers and relevant management and administrative staff in healthcare settings;
  - risk and safety measures in place to reduce or prevent errors and harm, including best practices, and promoting their involvement;
  - development of core competencies in patient safety namely, the core knowledge, attitudes and skills required to achieve safer care, for dissemination to all healthcare workers and relevant management and administrative staff;
  - providing and disseminating information to all healthcare workers on patient safety standards, risk and safety measures in place to reduce or prevent errors and harm, including best practices, and promoting their involvement;

• At the health system and health providers:
  - establishment of reporting and learning systems fair and non punitive and encouraging the reporting of medical staff to:
  - determine exact and complete data about the adverse events
  - creation of a favorable transparent and no-blaming environment for reporting and learning
  - create a clear separation and confidentiality of the reporting and learning system and the other system of claims and disciplinary measures
  - establishing clear legal responsibilities of the staff

In addition the EU Commission is making detailed recommendations for prevention and control of the health care associated infections, which is one of the major causes of adverse events. [12]

UK Model

The National Agency for Patient Safety from Great Britain developed a frame to guide the healthcare organizations to adopt the main actions for improving patient safety. (“Seven steps to patient safety”). This frame is making recommendations resulted from the best experiences which actually worked in patient safety and includes guidelines, tools and education programs. Shortly, the seven steps are:

• Step 1: developing a culture of safety
  - It is assumed that safety has is the fundament of the healthcare services, and become a priority for the management and staff. There is a very good communication of the staff with the management and within teams. The safety climate of the work is developing confidence, transparency, no blame behaviors; the environmental factors which are influencing the work and performance in stressful conditions are analyzed and took into consideration (high workload, stress, fatigue, etc)

• Step 2: Lead and support the staff
  - A strong leadership is needed in order to develop the vision and specific safety policies, the working plans, to ensure a good communication within the organization, to develop training and education for safety and to ensure support for the team work,

• Step 3 Integrate the risk management activity
  - Development of the risk management capacity to identify, evaluate and analyze the potential risks in the organization. Specific instruments are recommended (probabilistic risk assessment, risk matrix, failure modes and effects analysis etc)

• Step 4 Promote reporting
  - A reporting and learning system has been provided to the healthcare organization by NPSA; the system is anonym and confidential and has the data set established by NPSA. The statistical analyze is performed at the central data and the results are made available for learning process to the healthcare providers to implement safety practices.
• Step 5 Involve and communicate with patients and the public
Involving the patients becomes an obligation of the organization to ensure safety. The personal perception and experience, the promotion of dialog are bringing important aspects in developing safety procedures. The methods used for involving patients: workshops, anonymous reporting, developing safety solutions, etc.

• Step 6 Learn and share safety lessons.
It is more important to find how and why the accident was possible and not who is guilty for it. There are recommended methods to determine the causes of accidents (root cause analyses, fish bone diagram, etc).

• Step 7 Implement solutions to prevent harm
Design the solution and implement them is the final objective for avoiding future accidents. Learning from others experiences, support of management and introducing in practice the researches results are some of the methods recommended.

Potential solutions for the healthcare system in Romania
It is difficult to appreciate the incidence of adverse events and the level of safety culture in the health care organizations from Romania, because scarcity of studies on adverse events and organizational safety culture.

We could have some interesting indications about the Romanian health system, evaluating the existence or non-existence of some key recommendations from the document „European Commission Council Recommendation on patient safety, including the prevention and control of healthcare associated infections - Impact assessment”. Considering the existence of a national policy frame for patient safety, the existence of a national authority for patient safety, functional reporting system blame free and permitting learning, involvement of the professional staff for developing and using best safety practices, development of a safety culture, etc it becomes obvious these are not implemented within the healthcare system in Romania. Unfortunately almost all the criteria are missing and there is a big gap related to the implementation of the safety measures in the EU countries, which have important achievements in the last years.

An immediate and priority attention is necessary both from the authorities and professional staff. High level decision makers need to understand that their support is necessary to change the focus on safety of patients and that the efforts to increase safety have a positive impact on the patients’ health and costs of care. Safety services means avoid accidents, preventions of complications, decrease of direct and indirect costs and improvement of patient satisfaction.

The subject is a kind of taboo. The sensitivity of the problem consist on one hand from the necessity to take urgent actions to reduce the adverse events (unfortunately in the last years the headlines of the newspapers have announced a lot of catastrophic events in hospitals) and on the other hand an important barrier – the existence of the blaming culture at the level of the society, mass media, central and local administration which is blocking the „declassification” of the subject.

The international experience shows that reform and reorganization policies for improving quality, accreditation, standardization of clinical processes, etc partially improved the safety of the services. Safety is an internal feature of the services and it depends of a good organization, infrastructure, equipment, professional behavior, human relations. These concepts should start to be part of the Romanian specialists thinking. Considering the characteristic of the Romanian health system - the perpetual reform and reorganization – the new requirements for safety might be seen as supplementary efforts and responsibilities and could be rejected.

Consequently, parallel measures have to be applied. At the national level, the Government has to introduce safety patient policies and to technical and financial support the implementation. Also, the professional staff from the healthcare services has to be involved.

The approach of the professional staff has to harness human potential of experts and their natural behaviors of interaction and cooperation. A huge contribution for a radical change of the health organizations for improvement of patient safety might be brought by the professionals, if they are well informed, empowered, mobilized and natural grouped by their own professional and social affinities. In this way they could work very well and find the best solutions. Professional leaders on different specialties could be the catalysts for creation and implementation of best models and the promoters for implementing by the others. The acceptance of new practices would be easier adopted if is initiated from inside of specialties by well known experts or from peers, rather than imposed by the administration.

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