Risk Management Considerations and Multiple Responsibilities in Medical Pharmaceutical Practice

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Abstract

In the health field, risk assessment of health damage is a basic component in the control and maintenance of human health. Risk management is defined as the technique of assessing and preventing accidental losses through insurance, and safety measures by making the right decisions and ensuring accountability. The responsibility of those in the medical-pharmaceutical field is permanent and multiple, on several levels, and named as follows: professional responsibility towards the patient, legal responsibility, administrative responsibility, economic responsibility, and social responsibility. Accountability in decisions is ongoing all the time and is a constant, daily, and multi-layered activity. The double responsibility of the doctor and the pharmacist is very important: to the patient and to the community. The society holds physicians accountable for the high cost of health care. Public health programs, warn that the rate of increase in medical costs is growing faster than national income. Still, patients, who are becoming more and more informed about medical issues - are also demanding more diagnostic procedures, more drugs, more medical care, and more hospitalizations.

Keywords: risk management, risk in the medical practice, responsibilities, medical-pharmaceutical activity, medical management

Introduction

The study of risk assessment and risk modeling is a broad and complex activity that requires multidisciplinary knowledge approaches from different fields such as

medical, sociological, economic, technological, or political. Risk assessment can lead to decisive influences on decision-making, analysis of responsibilities, and the success of strategies adopted in all the fields under consideration [1]. In the health field, risk assessment for health impairment is a basic component in the control and maintenance of human health [2]. Risk management is defined as the technique of assessing, minimizing, and preventing accidental losses through insurance and safety measures by making the right decisions and ensuring accountability [2]. In the health field, risk management activities are essential in keeping the health of the population under control.

A standardized approach to risk management involves the following steps [3]:

- Risk and opportunity identification is the process of discovering, recognizing, and describing risks and opportunities.
- Risk and opportunity analysis, systematization, and prioritization, which is the process of understanding the nature of risk and opportunity and determining the level of risk.
- Addressing risks and opportunities.
- Implementing recessionary measures to address risks and opportunities.
- Verification of the effectiveness of the measures applied.
- Learning from experience and generalizing actions that have proven effective-continuous improvement.

For a young man or woman aspiring to medical or pharmacy school, it is difficult to understand the multitude and dimensions of the responsibilities he or she will have to assume in medical practice to meet the requirements of risk management.

General Responsibilities In The Medical Practice

All those who have dedicated their lives completely to the medical field and focused seriously on medical or pharmaceutical practice remember the multiple responsibilities of their professional lives. The fulfillment of responsibilities in decision-making takes place all the time and is a constant, daily, and multiple activity on several levels. We can thus identify the following types of responsibilities [2]:

- Professional (ethical) responsibility towards the patient, which must be paramount, fully understood, and assumed;
- Legal liability (civil liability, criminal liability), which must always be taken into account, without influencing the total fulfillment of professional responsibilities [4];
- Administrative responsibility for medical expenses, which nowadays has become a huge responsibility to the community due to the high cost of medical care;

- Social responsibility: "Medicine is not only a profession but also a highly respected social activity"[5].

The double responsibility of the doctor and the pharmacist is very important: towards the patient and the community. The community holds physicians accountable for the high cost of health care and public health programs and warns that the rate of increase in medical costs is growing faster than national income, but patients, who are becoming more informed about medical issues, are also demanding more diagnostic procedures, more drugs, more medical care, and more hospitalizations [2]. But can we think of the fight against disease only in terms of cost-effectiveness? What are the limits that can be reached to respect the human value of medical acts and, at the same time - their efficiency? (Efficiency = the ratio of costs to benefits for humans). When we are asked to shorten the patient's hospital stay, who will defend the doctor against their demands, given the possible risks of an unexpected course of illness or of omitting or repeating tests? Fear of such claims and of the legal consequences leads some doctors to abuse some scans, which are often expensive and unnecessary, further increasing the cost of healthcare unnecessarily. The following are justifiably suggested: controlled studies in the health sector (studies comparing different hospitals or population groups), outpatient medical services (much cheaper than hospital medicine which costs up to 60% of the health budget), and more preventive action. Objectively speaking, medical progress toward human well-being must go hand in hand with a profitable economy, and the doctor has the difficult role of maintaining the balance between these two conditions [2, 6]. From a legal point of view, some of the essential principles and responsibilities contained in the ISO 31000:2018 standards have been formulated [3]. These obligations include [7]:

- Collection and dissemination of patient safety information.
- Provisions on certification and recertification of patient safety organizations (PSOs).
- Creation of a patient safety database.
- Facilitate the development of consensus among healthcare providers, patients, and other stakeholders on patient safety and recommendations for improving patient safety.
- Provide technical assistance to countries that have (or are developing) medical error reporting systems.
- Assist states in developing standardized data collection methods and collecting data from state reporting systems for inclusion in the patient safety database.

The fundamental objective was to enhance overall patient safety at the national level by encouraging voluntary reporting of adverse events that affected patients [7]. Policymakers concluded that better patient safety could be achieved by systematically

collecting data on medical errors. Awareness of these error data by healthcare providers and administrators would lead to the prevention of errors and an overall reduction in their recurrence [8].

Results and Discussions

Risk Management Consideration

If we want to ensure that risks are not left to chance and to look at them in terms of their implications, then we are talking about risk management. The possibility of a risk occurring is given by the probability of the risk occurring. Theoretically, this probability is between 0 and 100%. If it is 0%, the risk does not exist or does not occur, and if it is 100%, the risk becomes a certainty. In the healthcare system, it is necessary to consider the risks in such a way that the percentage of existing risks is minimal. Good risk management involves systematically going through steps such as those in Figure 1:

Figure 1 The risk management cycle

1. Risk management planning or risk management strategy set refers to the general establishment of how to approach risks: organizational framework, general risk approach philosophy (risk appetite), functional structure for risk management (responsibilities, accountabilities, committees, procedures), etc.;
2. Risk identification, i.e. the application of methodologies to identify as objectively as possible events, incidents, and causes of possible risks, then to validate them in terms of relevance, and finally to classify risks in order to prioritize subsequent actions;
3. Qualitative risk analysis, which involves analyzing the identified risks from at least two perspectives:

a. Causes and effects, i.e. establishing the causes of the risk, estimating the effects, and the consequences of their occurrence;

b. Risk exposure involves assessing the extent to which the risk affects the state of normality in terms of impact and likelihood of occurrence, i.e. taking into account certain tolerance thresholds set by the organization, thus generating reports and summary statements on risk vulnerability (Risk Register).

4. Quantitative risk analysis follows on from qualitative risk analysis and involves quantifying the costs generated by the existence and/or occurrence of risks. It is an effort to identify what is called the "estimated monetary value" of risk or the cost of risk. It is a very important step for judicious budgeting of contingency plans, response planning, or risk response.

5. Risk response planning, which includes response planning and how to deal with 'red' risks. There are several approaches to dealing with risks, ranging from actions to mitigate impact or likelihood to deciding to transfer the risk to a third party.

6. Implementation of planned actions.

7. Risk monitoring and control, which consists of tracking identified risks and monitoring the effectiveness of risk responses. The establishment of effective reporting mechanisms is a prerequisite for this stage. Obtaining early warning of emerging risks is only possible if monitoring and control really work.

Responsibilities And Risks In The Medical Practice

Medicine is not only a science but also an art, and medical practice is an art that involves the knowledge and proper application of scientific data. The doctor has a responsibility to deal competently and devotedly with the patient, but he cannot predict everything, nor can he offer an absolute guarantee of a cure. Medical practice is full of contingencies and risks. Risks are inherent in any field where uncertainties are common and decisions are made on the basis of probabilities [2, 7].

The doctor assumes responsibilities and risks in all his work. He has responsibilities when he makes a diagnosis, when he makes a therapeutic decision, or when he prescribes a medicine. There is no medicine without side effects. Of course, there is also an estimated risk, whereby in modern medicine we evaluate the performance of a medical act, the prescription of drugs (whatever their therapeutic or diagnostic value), against the risk of side effects. When the positive value dominates, the doctor can take the risk of application, but only after serious reflection [2].

One example is a blood transfusion when it is essential for the patient's life or health. In this case, we run the risk of causing (in 5-10% of cases) the subsequent occurrence of post-transfusion hepatitis, caused by one of the hepatitis viruses that exist in the donor's blood, undetected by current technical possibilities (and therefore not eliminated).

The estimated risk is also taken into account for difficult but necessary surgery. In these cases, the surgeon must obtain the informed consent of the patient or, if this is not possible, of the family. It is justifiable and ethical, that in such circumstances, the risks should be shared with the patient. To this end, it is useful for the doctor to ask for the patient's signature. But in certain unforeseen or emergency situations or during surgery, the surgeon must decide for himself according to his conscience and competence. This raises the following question: is it really advisable to disclose to the patient all the possible risks of such a medical act? We are in an area with great problems of interpretation, uncertainty, and guidance. However, it is not possible or desirable to expose the patient to all the risks of a medical act [9].

In some Western countries, particularly in North America, but also in Europe, patient information about the risk of the medical act is carried out without omission in order to prevent any complaints from the patient. As a result, a crisis of trust has developed between doctor and patient and a degeneration of medical practice into so-called defensive medicine, i.e. medicine for the doctor's defense. The causes are the multiple complaints and legal actions against doctors for malpractice by dissatisfied patients. Lawyers who specialize in lawsuits against doctors contribute to these actions by seeking out and exploiting the smallest patient complaints. In fact, doctors in these countries, especially those exposed to medical risk (surgeons, anesthetists, orthopaedists, and gynecologists), defend themselves against these lawsuits in various ways:

- By prescribing 50-60% more tests than usual in order to protect themselves from patients' demands, increasing the cost of medical services;
- By informing patients of all possible risks, especially surgical ones, until the so-called patient faints or gives up the proposed surgery;
- By insuring doctors against the risk of complaints from patients and protecting them against lawsuits with patients. The large amount of insurance shows how much medical liability can cost doctors and how damaged trust in the doctor-patient relationship is. The burden of so many risks in modern medical practice can thus be appreciated by multiple examples.

Possible Risks And The Responsibilities Of The Physician

These types of risks are related to the doctor and the responsibilities the doctor has regarding qualifications, work, and personal behavior. Therefore, some doctors create risks for themselves through incompetence or unconsciousness (sancta simplicitas!), negligence, or fraud. All of these fall under so-called malpractice, in Anglo-Saxon, which means incompetent, fraudulent practice, which attracts sanctions (administrative or criminal) from the College of Physicians. It lays down rules of highly humane behavior, from which today's medical deontology is inspired.

Three types of doctors with serious medical misconduct were analyzed [2]:

- Doctors with moral misconduct ranging from lack of concern for the patient to gross negligence;
- Doctors who are not capable of responsible work due to mental illness (mental illness) or drug addiction (alcoholism, etc.);
- Incompetent doctors who are below the standard of current knowledge are aware or unaware of their lack of knowledge and their lack of progress in the development of modern medicine [10].

All these attitudes represent serious risks for patients and for medical practice which no longer imply particularities of medical practice, but individual entities, doctors with such deviations, who form a minority within the medical staff.

Such situations fall under the doctor's legal responsibilities (civil and criminal), classified into different categories: professional negligence, professional negligence, professional incompetence, etc., as presented in the literature [11].

Possible Risks And The Responsibilities Of The Pharmacist

Pharmacists have their own responsibilities that do not generally circumvent the principles of medical ethics [12]. The pharmacist's work has the same purpose as that of the doctor, so even if the moral principles of work are common, they must be tailored to the profession, specifying that the doctor-pharmacist deontological relationship should not be understood as a relationship of subordination but of collaboration that serves a single purpose, that of ensuring the health of a country [11, 12].

Pharmacists have the obligation and responsibility to provide timely drug support to the pharmaceutical network, patients, and the population in need at the appropriate technical and scientific level [11, 12].

The pharmacist must give priority to the preparation and dispensing of emergency prescriptions. In special cases, the pharmacist is obliged to respond to emergency requests outside working hours. The pharmacist shall, to the best of his or her knowledge, provide emergency assistance to patients in cases where they are unable to receive immediate medical assistance from a doctor; the pharmacist shall refer to the competent medical institution and inform the doctor of the measures taken on his or her own initiative.

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The pharmacist must fill medical prescriptions and assist persons with medicines equally for any patient, except for emergency medical prescriptions, in which cases priority in filling and dispensing is provided.

The pharmacist must apply uniform methods of preparing medicines to ensure uniformity of execution and presentation; the aim is to prevent patient doubts or suspicions about the quality of the medicine (uniform shape and size, uniformity of appearance, color, taste, smell, etc.). The pharmacist must avoid any expression of doubt and mistrust in the presence of the patient regarding the attending physician or medical prescriptions. If the pharmacist notices an incomplete or wrong formula in the prescription or when an ingredient needs to be replaced, he will contact the prescribing doctor to agree on how to solve the case. If the doctor cannot be contacted and the administration of the medicine cannot be postponed, the pharmacist will make the necessary change under his or her own responsibility and write the adjustment on the prescription, subsequently informing the doctor of the changes.

Pharmacists are not allowed to recommend medicines or any other therapeutic methods, except for hygiene products. Pharmacists must refer patients to a doctor to obtain the necessary indications. The two collaborators, the doctor, and the pharmacist, must prevent polypharmacy and understand the psychology of the patient and/or groups who misuse medicines; they must carry out systematic and constant preventive actions based on the principles of ethical behavior [12].

Physicians and pharmacists must behave in a collaborative, respectful, and supportive manner towards colleagues and other collaborators. It is forbidden to blame or denigrate colleagues by making negative judgments about their medical qualifications or work in front of patients, family members, legal representatives, or medical staff; it is also forbidden to make any expression or act that endangers trust in the doctor or pharmacist or in their professional work. The necessary criticism must be based on objective evidence in an organized setting in order to have a positive effect [12].

The doctor and pharmacist are obliged to guide and control the work of their subordinate staff at all times, which must be carried out in accordance with principles, consistency, and accuracy. Medical and pharmaceutical scientific work must be based on moral principles and respect for human beings. It is forbidden to artificially cause disease in healthy people or to intentionally maintain a state of disease for the purpose of scientific research [11, 12].

Medication Errors

Medication errors have long been cited as a cause of patient harm, this includes incorrect administration of medications, incorrect dosing, and administration of medications to which patients have documented allergies. [13, 14]. While the responsibility certainly rests with individuals to verify the correct medication, correct dosage, and patient allergies before ordering and administering medications, this

topic was also addressed in "To Err is Human" and is an area for system-wide improvement. The emergence and widespread implementation of electronic medical records (EMRs) have been imperative for the development of safeguards against medication errors. EMRs could verify the correct dose based on the patient's weight, check dosing frequency, and provide an alert if an ordered medication conflicts with the patient's allergy list [15]. These are protection systems at the time the doctor orders medication; EMRs also provide levels of protection for fellow nurses. Many hospitals have implemented a barcode scanning system in which the patient's identification bracelet has a barcode that must be scanned to verify the identity and accuracy of medications before they are administered by the nurse [16, 17]. Finally, many hospitals have increased pharmacist availability and visibility as an additional measure to prevent medication errors; this includes 24-hour telephone consultation with the pharmacist, pharmacist review and approval of all medication orders, and the physical presence of a clinical pharmacist in higher-risk medicine areas such as intensive care and emergency medicine [18, 19].

All of these system-level protections aim to meet the goal outlined in "To Err is Human" - to minimize the possibility of human error by creating a multi-layered system of protection around providers and patients. To prevent sentinel events, a hospital system must first accept that human error is inevitable and, to some extent, unavoidable. As outlined in Err is Human, the focus must shift from blaming individuals for human error to instead developing a multi-faceted system and culture of protection around providers and patients. Successful examples of this approach include standardizing patient handoffs and perioperative checklists, using EMRs to verify medication accuracy, and increasing pharmacist visibility and involvement. In general, successful hospital systems for patient safety share one essential trait - a positive, supportive, and collaborative culture that encourages every employee, patient family member, and individual patient to participate [20, 21, 22].

Measures To Reduce Risks In Medical Practice

What needs to be done to reduce risk in medical practice, both medical risk and the risk resulting from the poor activities of a medical minority?

First and foremost, the most important are preventive solutions at the educational level, from graduate to postgraduate level, through the medical press, books, meetings, control actions, and preventive actions at the administrative and ethical level (through the College of Physicians and through the College of Pharmacists). The concept of continuous professional training of doctors must be given a moral obligation, and the incompetent doctor is not only morally but also legally guilty. It is also useful to analyze the new ethical problems raised by the progress of modern medicine (prenatal genetic diagnosis and genetic surgery, prolonged resuscitation, etc.) and the ethical solutions envisaged. Minimal-risk diagnostic techniques should be used.

New drugs should not be used without knowing their risks and without obtaining the patient's informed consent for a particular treatment.

A peer review should be carried out whenever the patient's situation requires it. The social and economic responsibility of the contemporary doctor must be known. In addition, the ethical rules of scientific research in clinical medicine must be known and applied. On the other hand, there is the "identification of the black sheep" of medicine and their sanctioning in accordance with socialist medical ethics and legislation.

Reducing The Medical–Pharmaceutical Risk By Continuous Professional Training

The College of Physicians and the College of Pharmacists can provide the organizational framework for taking measures for continuous training, professional information with the latest scientific knowledge, with new methods and techniques to avoid risks in medical practice.

- We could not end this incursion into the medical practice risk issue and responsibilities without emphasizing the need for continuous professional training, which we consider not only an important solution for reducing the medical practice risk but also an *essential moral obligation of the physician and pharmacist*.
- The desire for training must be present in each physician or pharmacist in order to deserve their title. Therefore, we must always be unpleased with ourselves, with our everyday work, our reading, or our knowledge regarding the patients and our tasks, reflecting upon the daily activities and accuracy that we have completed.
- Only a vast experience, a life lived between the suffering and symptoms of the patients from the hospital and in the core of the medical social issues of the field, will allow us to gain that complex value that characterizes the physician with clinical experience and large perspectives, who is at the same time a clinician and epidemiologist.
- At clinical experience new daily readings must be added in order to maintain high professional competence and to reduce at minimum the risk for the patient in medical practice. Even the success of using computers in the clinic depends on the accuracy of the data collected by the clinician, which is introduced in the computer. In the opposite situation, on the contrary: “garbage in, garbage out”. The physician’s professional quality matters as well as the accuracy of the collected data and the correctly used terminology.
- In reducing the medical risk, it is also important to consider the professional quality of the sanitary staff. Therefore, we agree with the above-quoted opinion that “a very good experienced nurse is better than a computer or a computerized

automatic system". In the clinic, we often used the observation and opinion of an experienced nurse regarding the diagnostic and prognosis of a patient. And the nurse's answer was often a useful light on the dark road of diagnosis or prognosis.

- On the other hand, close collaboration must be maintained with the patient and correct information of the patient by an appropriate dose of data, adjusted to the condition of the patient. The patient–physician relationship must be reinforced and educated since nowadays has become poor. In the past, patients had more confidence in their physician rather than in medicine, meanwhile today the faith in medicine increases while the faith in the physician decreases and the physician's responsibility towards the patient increases.
- The medical risk will never be completely eliminated, and therefore, our inner restlessness as physicians remains permanent in front of the patient.

Conclusion

Risk management in medical practice is a complex and necessary activity both for patients and for doctors and pharmacists. Risk reduction is vital for patients, for ensuring the health of the population, and for increasing the longevity of the population. Risk reduction for physicians and pharmacists is a basic requirement in the performance of medical activities, not only in ensuring their professional protection but also in protecting patients and proving efficiency and effectiveness in ensuring the health of the population.

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