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Point of view

Medication errors in hospitals: Bioethical issues

Erros de medicação em hospitais: considerações a partir da Bioética

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Introduction

Medication error is any preventable event that can actually or potentially lead to inappropriate use of medication. This means that the misuse may or may not cause harm to a patient, whether the drug is under the control of a health professional, the patient, or a consumer. The error may be related to professional practice; to products used in healthcare; to procedures; to communication problems, including prescriptions, labels, packaging, and names; to preparation; to dispensation; to distribution; to administration; to education; and to the monitoring and the proper use of medications.[1]

Bioethics proposes carrying out a complex, interdisciplinary, and shared reflection on the adequacy of the actions involved in life and living.[2] Thus, reflection on the possibility of occurrence and damage resulting from medication errors, as well as methods for identification and assessment, should include a broad perspective of the issues involved. It should also include the group of professionals that can contribute to their proper understanding, allowing the discussion of this problem in its multiple aspects.

The need to share this information and these points of view involves a process of effective communication between all involved sectors: professionals, patients, family members, and managers. The establishment and preservation of a relationship of trust among all those involved should be a key feature for the success and continuity of adequate monitoring of reported medication errors. These activities must be interpreted as a guarantee of safety for patients, professionals, and institutions.

In relation to the main issues regarding ethical implications related to medication errors, considering the error severity, the type of error, and the drugs involved, we highlight the recording of medication errors in patients' records, the communication between professionals, the disclosure of the error to the patient and/or family, and the reporting of an error that has caused damage.

Recording of the medication error in the patient's medical record

The patient's medical record, according to the Federal Council of Medicine, is a single document consisting of a collection of

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information, recorded signs, and images generated from facts, events, and situations about the patient's health and the care he/she received that has medical, legal, scientific, and confidential features, enabling the communication between members of the multidisciplinary team and continuity of the care provided to the individual.[3]

The medical record, from the point of view of the Federal Council of Pharmacy, is the appropriate instrument for the documentation of each professional involved in the patient's care in the institution, and can also be used to determine the co-responsibility of every healthcare professional involved in case of need for legal defense.[4]

During the course of hospitalization, data regarding the patient's daily evolution, with date and hour, description of all procedures to which the patient was submitted, and identification of all professionals that provided care are included in the medical record.[5] During a mean hospital stay of eight days in a general teaching hospital, on average 75 different professionals deal with a patient's medical chart.[6]

The complete, correct, and legible completion of medical records is the guarantee of an adequate recovery of the information contained for future treatment, research, and teaching activities.[7]

The inadequate documentation or lack of information in the medical records related to drugs used before and during hospitalization may be related to the occurrence of incidents that cause damage, as the records are the source of the information necessary to establish specific and adequate care for each patient. For instance, in the case of a patient with a history of penicillin allergy, the omission of such information in the records could cause harm by the inadvertent administration of this medication.[8]

After the occurrence of medication error, the healthcare professional should record the incident, reporting the drug involved, aiming at implementing measures for the patient, as well as preventing new errors with the same characteristics from occurring.[9]

The reporting of medication error on the medical chart should be limited to the description, as reliable as possible, of the facts and circumstances involved. The best way to do so is to include the time and place of occurrence, the drug involved, the dose, route of administration, whether there were consequences for the patient, and the measures that were taken when the situation was discovered. This must be included as is any other information regarding the evolution of patient care . The report should be as impartial as possible, and should avoid establishing a prior judgment on the guilty part. Based on this set of information, these associations may be analyzed later by those responsible.

Professionals are often afraid to record medication error. The failure to record these conditions increases the risk for the patient and for the professionals themselves. Adequate and continuous documentation of all data related to patient care is a demonstration of interest and good faith on the part of the professionals involved.

It is noteworthy that the medical record, with all the data that compose it, belongs to the patient and should always be available. Institutions are responsible for the proper preservation of this document. When the medical record is requested by the patient or his/her legal representative, those responsible for keeping it should facilitate the provision of certified copies of the relevant information.[10]

Reporting of medication errors among professionals

The culture of infallibility, very often present in healthcare education, may lead to the non-communication of errors that occur during professional activities. Activities to prepare the professional to deal with errors are not developed during professional training. Errors are wrongly directly related to the idea of guilt, generating feelings of shame, failure, and lack of knowledge.[11] Thus, through institutional notification programs, hospitals can work through the issues involved with the error, in an educational manner, with all the professionals involved in the medication system. This becomes even more necessary in university hospitals, by including undergraduate and graduate students, in addition to the residents of several fields of health care.

These institutional notification programs should be associated with others that promote a culture of lifelong learning, in order to ensure effective communication among members of the healthcare team. The integration of the multidisciplinary team shifts the focus from the isolated individual activity to the sharing of knowledge and interdisciplinary actions.[12] Drug use starts with the prescription made by the physician, but it requires the presence and participation of pharmacists, nurses, and other health care professionals involved in patient care. These activities, when integrated, provide valuable assistance and improve the quality of patient care.[13]

In large hospitals, medication error notification can be haphazard, occurring only in certain units or containing little information of poor quality. It is important to mention that the unification of information reduces ambiguity. This information needs to be shared through a collaborative process of communication involving all institution employees. Thus, it is possible to identify patterns in the errors, and therefore, promote to changes to correct the different stages of the medication system involved in the errors.[14]

It is also appropriate to have a multidisciplinary committee in hospitals capable of articulating and coordinating programs and activities aimed at medication error prevention. This committee should be composed of physicians, pharmacists, nurses, risk managers, and representatives of the management area. Moreover, depending on hospital characteristics, this collegiate can also include a representative of the bioethics committee or quality department.[15]

The occurrence of errors is inherent to any human activity. The important thing, from the institutional point of view, is to have adequate means for their communication, evaluation, and correction of the involved processes. It is essential to establish an environment of trust among the professionals involved, so that communication occurs effectively and continuously. This trust must also be associated with the evaluation process, where the focus is to identify risks and gaps in the medication system. The corrective measures may include changes in the system itself, as well as educational measures for the care team.

Error disclosure to the patient and/or family

According to the standards of hospital accreditation organizations, patients should be informed about unexpected results during their treatment. The disclosure of errors is a commitment to the truth and respect of the patient's self-determination.[16]

The disclosure of an error should be understood as the communication between a health professional and a patient, or a family member or legal representative, that reports on the occurrence of this situation. The professional, in addition to the disclosure, should discuss what happened, and describe an association between the error and its consequences. This information must be communicated in such a way that the patient can properly understand it.[17]

Studies indicate that, in cases of errors, especially those that caused damage, patients express four needs: 1) to learn the truth about the event and its occurrence, 2) to have the assurance that the health institutions will assume their responsibilities, 3) to receive an apology from the institution, that must acknowledge the negative consequences for the patient, and 4) to receive a personal apology from the professional involved. However, often full disclosure is not provided for fear of lawsuits, and apologies are not given, as some professionals consider them as an admission of guilt.[18]

There is no consensus regarding the apology on the part of the professional. It is a therapeutic necessity for the professional himself/herself, demonstrating humility, humanity, fallibility, and regret. A sincere apology can help the patient psychologically, and, moreover, can enable forgiveness. Regarding the professional, the apology may lessen the guilt and shame related to the error.[18] It is noteworthy the fact that this kind of attitude should be genuine, because when performed only to follow protocol, it can result in a reaction that will be counterproductive.

The beliefs and values of patients and families facing the errors influence their responses. Health professionals need to see the issue from the perspective of those who suffered the error. This empathetic attitude helps to understand the culture of patients and assists professionals in the communication with them. Each patient or family member may have a different expectation in relation to the same explanation of what happened, an apology, and the certainty that the error will not happen again. Likewise, each patient will have a different view about the notion of forgiveness associated with the reported error.[19]

Reporting a medication error and associated damage

Very often a health professional will experience an internal conflict between revealing or not revealing bad news to the patient or their relatives. Bad news is any sudden and harmful change to the notion of a person's future. Medication errors, according to the magnitude of its impact, can be seen as bad news. The association of damage to the occurrence of an error can make the patient anxious, depressed, and traumatized. Likewise, depending on the severity, it can also emotionally affect the professionals involved in the error.[18]

A study on the attitudes of patients and physicians regarding the disclosure of medication errors demonstrated that patients have varying opinions about the right to be informed about errors that caused no damage. Some patients believe that they must be alerted to situations that might occur, while others imagine that they would be disturbed by this news. Among the physicians, the opinions also diverged: some claimed that this disclosure may decrease the trust of patients, and others believed that the disclosure is an opportunity to talk about what happened.[20]

The ethical dilemma in this situation of no immediate harm is related to the professional's obligation to inform considering the benefit or harm associated with this disclosure. From a deontological perspective, communication is perceived as mandatory, regardless of the presence of associated damage. This obligation of disclosure is also associated with the obligation of being truthful. Other considerations can also be made. There is the possibility to evaluate the damage/benefit relation associated with the disclosure itself and with the profile of the patient and his/her family. It is important that the type of conduct to be carried out in this situation of no immediate damage associated with a medication error is included in an institutional policy.

When damage occurs associated with medication errors, the evaluation of the ethical aspects also changes. According to the patients' conception in the aforementioned study, all errors that cause harm should be disclosed. This disclosure can demonstrate honesty and increase trust in the physician. It can be understood as a confirmation that patients are receiving complete information about everything that is happening in their treatment. From the perspective of physicians, errors that cause damage must also be disclosed. However, doctors may experience three situations where, even though the damage has occurred, the disclosure might not: when the damage is trivial, when the patient shows no concern or is unable to understand that an error occurred, or when the patient does not want to know about the error.[20]

The exception related to the question of non-disclosure when the damage is trivial implies establishing a classification for the magnitude of the damage involved. Considering this perspective, the occurrence of trivial damage would be treated as an absence of harm situation. This classification, if deemed appropriate, should also be included in an institutional policy, preventing this decision from being taken individually and according to different criteria. The basis for this exception is the assessment of the damage/benefit described above.

The second exception is based on very subjective criteria. The evaluation that the patient is not concerned or does not have the ability to understand that the error occurred is very difficult and subject to questioning. This position can be understood as a paternalistic professional conduct towards the patient.

When patients express their wish not to know, they are legitimately exercising their autonomy. They can impose this limit to the professional's obligation to inform. This must be properly registered on the chart, together with a description of the situation itself. The provider can ask the patient whether

he/she designates a family member or another person to whom the consequences of the situation can be disclosed and discussed. This shows the interest of professional to inform and maintain confidentiality, respecting the patient's decision to not know.

When a decision is made not to disclose the occurrence of the error, regardless of the associated damage, all professionals involved in patient care will be in an uncomfortable situation. This discomfort may be due to the non-disclosure itself, as well as the attitude in response to the patient's questioning. This omission can become a deliberate deception or distortion of the truth. The difficult part is to establish the boundaries between one type of situation and the other. The belated discovery that an error has occurred, caused damage, and was not disclosed, affects the relationship between health professionals and patients.[21] This reduction or breach of the bond of trust is extremely harmful and opens the possibility that other actions may be performed by the patient or his family in order to seek some compensation, be it of any kind. Thus, the question that professionals must face is when and what the best way is to make this disclosure.

The disclosure of information associated with the error should follow some basic principles of practitioner and patient communication. The disclosure must be made in a suitable environment and not in hallways or rooms shared by other patients and families not involved in the situation. This prevents other people, who do not need to know this information, from wondering about the occurrence of similar situations during their care. The professional must have all necessary information and should be accompanied by other professionals involved in patient care whenever possible. Likewise, the patient should be asked if he/she wants someone else to attend this meeting. If necessary, the provider may request the help of another colleague with more experience, whenever difficulties for the patient or their family, if they are present, are anticipated. At the disclosure, the facts should be presented gradually, in understandable language, observing the patient's reaction. If the patient asks questions, they should be answered simply and objectively, within the limits of the patient's questioning. The provider must maintain an adequate attitude of listening, without a behavior that demonstrates that this is only being done defensively. There should be concern about the post-news period, in order to assess what support can be given to the patient and his/her family.[22]

The worst-case scenario associated with finding a medication error is that in which the patient has died as the consequence of the error. In this situation, the disclosure should follow the same precautions described above, but with the understanding of the error severity and especially the difficulty that the family may experience to understand and recognize this situation.

Professionals must receive adequate training for reporting errors to patients and/or family through readings, observations, and practical activities involving this type of situation. The disclosure should include empathy and knowledge, always taking into account the perspective of the patient's dignity.[18] Learning to communicate errors, to make an apology, and ensure that the needs of the patients involved are recognized, as well as addressing the impact of errors with honesty, must be part of the education of all health professionals.[19]

Final considerations

Medication errors should be neither trivialized, nor magnified; they should be adequately addressed in all their personal, professional, and institutional consequences. Acknowledgment of the real possibility of their occurrence, risk assessment, review of the medication system steps, implementation of institutional policies for error reporting, and training and disclosure of medication errors is the course to be followed. Recognizing that errors may occur implies that measures should be taken.

The commitment of the entire team of healthcare professionals and the institution itself will be decisive, not to deny the existence of errors, but to appropriately cope with them when they occur.

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