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Review Article

The Risk Management in the Pharmacological Therapy: Organizational Approaches, Tools Regulators, Projects and Best Practices

Maria Carmen Agnello*

Department of Biological, Chemical, and Pharmaceutical Sciences and Technologies, University of Palermo, Italy

***Corresponding author:** Maria Carmen Agnello, Department of Biological, Chemical, Pharmaceutical Sciences and Technologies, University of Palermo, Italy. Tel: +39095444225; E- Mail: agnello.carmen@libero.it

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Abstract

This article analyzes the management of adverse event events in drug therapy, from a patient-oriented perspective and to the quality of health services, priority healthcare targets in EU and EFTA countries. On the basis of an economic socio-economic assessment, the set of organizational approaches, regulation, programming and projects started in a twofold perspective. The first concerns the prevention and repression of deviant behaviors in the marketing of drugs in systems. The second perspective addresses the case of LASA drugs in order to identify the methodological tools for standardizing patient safety-oriented activities and behaviors. To conclude, it is noted that the path to improving the risk management of drug therapy can not be considered as completed and therefore further corrective and improvement interventions are needed in the creation of a virtuous circuit, both in terms of health protection and care safety.

Keywords: Deviant Behavior; Legal Framework; Medicines LASA; Organizational Improvement Approaches; Risk Management Medicines

Introduction

The management of adverse events consequential damages from errors in drug therapy, patient safety and quality of health services are a priority objective in the health care setting, from the countries of the EU and EFTA, international organizations and the European institutions. These errors are the cause of damage and more frequent, as may occur during each phase of the process of medication management. In prescribing, dispensing, preparation, administration and consumption of drugs, the risk of medication errors are exposed both patients and health professionals, which can result in severe damage to the health.

In this way, it is necessary to consider the impact of socio-economic of these adverse events in the management of the therapies. In the United States, medication errors, concern had increased; causing at least one death per day [1]. The frequency of adverse reactions is similar in the countries with high and countries with low and middle income, where the decrease of years as a result of medication errors had a greater impact [2]. These mistakes have an economic impact to health systems for a total cost of $ 42 billion a year, 1% of global healthcare expenditure. In this regard, it is necessary to take into account the whole system of management of the pharmacological therapy, at every stage, from the preparation to the prescription, dispensation, administration, and recruitment in particular, the adverse event in this circuit, it may be the final outcome of a concatenation of errors arising from a plurality of factors, which can be prevented by involving different skills [3].

The Integrated Management of The Medicine: The Phases, The Critical Matters and the Approaches

In the socio-economic context exposed to a people-oriented approach, it is necessary to identify the set of measures that can prevent and repress the occurrence of adverse events caused by mistakes in drug management. In the first place, it is necessary

to identify the factors that favor the occurrence of errors or that create the deficiencies latent in the management of medication. In that regard, are detectable errors in the phase of preparation, storage, management and, in particular, conservation of stocks, can deteriorate or alter the integrity of the pharmaceutical product. Additional risks are present at the time of the prescription of a drug arising from the completeness of the collected information from the doctor relating to diagnosis, indications and contraindications, concomitant therapies, the therapeutic efficacy and tolerability of the drug. Finally, are identifiable risks related to administration of the treatment, related to the identification of the patient, the mode of writing of the prescription, the identification of the medication and the correct dosage to be administered? The present article, the analysis of the routes and of the measures applied in order to reduce the risk related to the administration of drugs through different organizational approaches aimed not only at protecting the health, but also to ensure the safety of care.

This requires a blend of actions and measures, envisaged at the level of soft regulation and hard regulation, which have multiple consequences, both social and economic, of prevention and to preserve the health budgets from the costs arising from such adverse events. At first, it was applied the approach to identify and overcome the critical problems existing through the traceability of the drug chain, identifying and grouping the factors that affect the occurrence of the error, through the monitoring of the whole management cycle. In a second time, according to a preventive approach, it is tried to prevent the detrimental event, by applying different measures, in order to implement the level of information and to raise the threshold of attention, on the part of any operator involved in every single phase.

Both approaches require more efficient health systems, and in particular the implementation of programmatic measures, procedures and best practices, which can guarantee each patient the appropriate drug at the right dosage and at the right time. In this context, the implementation of the Regulated Act implies a participatory extension capable of involving the members of the Regions, the institutions concerned (AIFA, ISS), national experts of professional orders, scientific societies, universities, research organizations and other organizations Public and private. At an organizational level, an increasing importance has the application of technology through models and processes geared to implementing patient safety in this sector.

The Legal Frame Work: The Prevention and Repression of Deviant Behaviour

The World Health Organization (WHO) has launched the initiative "Global Patient Safety Challenge on Medication Safety", with the main objective to tackle and overcome the critical issues of health systems, through strategies to foster the appropriateness of prescriptions and adherence therapeutic protection of patients and safety of care. The initiative of the WHO intervenes in the specific systems of therapy, inviting the member States to implement the level of information and awareness of the risks associated with the misuse of drugs. This requires a greater attention to the health care professionals towards patients and in the different mode.

At the European level, are expected a series of legislative measures designed to ensure the safety features of medicinal products. To this end, it is necessary to harmonies within the Europe the severity of safety, in order to pinpoint and prevent these risks and therapeutic at the same time, to ensure the balance of the internal market of medicinal products. The phenomenon of deviant interest concerns the falsification of medicinal products, threat to the health of the citizens of the EU. In the light of the spread of the falsification of medicinal products is required prior assessment of the risk, can exclude the categories of drugs that do not have the mandatory features yet. These characteristics should not be introduced for medicinal products or non-prescription unless, in exceptional circumstances, an assessment can demonstrate that there is a risk of falsification. Risk assessments should consider aspects such as the price of the medicine, the cases of the past of falsified medicines reported in the Union and in third countries, the implications of a falsification for public health. The directive on falsified medicinal products, in force since January 2013, has instructed the Commission to establish measures to prevent deviant behaviour through the control of the authenticity of medicinal products, the quality of the ingredients and the active ingredients and the correct dosage.

In the implementation of the above directive, the Commission has published the delegated regulation no. 2016/161, which sets out the details of the "safety features" that will be compulsory for medicinal products, in order to ensure the authenticity and security in the supply chain of medicines. In order to protect patients from the risks of falsified medicines and the consequences of prescription errors, the regulation indicates the security features for the authentication of medicines: a unique identifier. A further preventive measure relates to the system for prevention of tampering, aimed at ensuring the integrity of the packaging of medicinal products. The regulation identifies the mode of verification of the authenticity of medicinal products and the persons in charge to run it. The authenticity of medicinal products is guaranteed by a system of upstream control, and downstream, to integrate risk controls carried out by the wholesalers. The medicines are subject to systematic verification at the point of distribution.

The medicines most at risk of falsification (returned or not distributed directly by manufacturers, from the holders of the marketing authorization, or by persons acting on their behalf) are verified by the wholesalers. The authenticity of medicinal products is ensured by comparing the unique identifier on the package with the legitimate unique identifiers contained in a system of stores, established and managed by stakeholders with supervision by the

competent national authorities. As a result of the regulation, which will apply starting from 2019, the medicines will be authenticated before being administered to the patients, preventing the distribution of falsified medicinal products but also other common errors, such as the provision accidental medicines, expired or withdrawn from the market. In addition, the supply chain the European pharmaceutical will be scanned, through a system of archives that will connect manufacturers, wholesalers, pharmacists and hospitals, improving information flows and simplifying procedures for the recall and return of medicinal products.

At the national level, the Ministry of Health has followed a twofold objective is to implement both the control and preventive measures. In reference to the first profile, the Ministry of Health has made up of organs with specific control tasks, such as the technical commission on clinical risk with DM 5/3/2003, and activated at the Directorate General of health Planning, Levels of assistance and ethical Principles of the system, the National Observatory for monitoring of sentinel events, if received, through the Information System of Monitoring SIMES, the reports of such adverse events, including those related to the event of "Death, coma or serious damage derived from errors in drug therapy. At the national level, the Ministry of Health has followed a twofold objective is to implement both the control and preventive measures. In reference to the first profile, the Ministry of Health has made up of organs with specific control tasks, such as the technical commission on clinical risk with DM 5/3/2003, and activated at the Directorate General of health Planning, Levels of assistance and ethical Principles of the system, the National Observatory for monitoring of sentinel events, if received, through the Information System of Monitoring SIMES, the reports of such adverse events, including those related to the event of "Death, coma or serious damage derived from errors in drug therapy.

In reference to the second profile, national and international level have been widespread Recommendations and guidelines, in order to prevent the damage derived from errors in drug therapy. In the present case, the recommendations are information tools, which are used in the clinical field, in order to increase awareness of the potential danger In Italy, regional contacts, the concerned institutions, experts, scientific societies, universities, research institutions, and other public and private organizations, have developed from the 2005 guidelines, to provide to health workers information about hazardous conditions, the cause of serious and fatal consequences to patients, indicated the actions to be taken to prevent adverse events [4].

In this regard, the Ministry of Health has drawn up and made available to the recommendation no. 1, 2005, which regulates the correct use of concentrated solutions of potassium chloride and other concentrated solutions containing potassium and recommendation no. 7 of 2007 for the prevention of death, coma or damage resulting from errors in the pharmacology, which has provided for a system of dual control, for a series of drugs identified high-risk or high level of attention. The implementation of these recommendations is subject to monitoring of the implementation at the company level by the National Agency for Regional Health Services, following a preliminary study carried out by the Italian Society of Hospital Pharmacy and Pharmaceutical Services of Healthcare organizations Of particular importance, it should be noted the Manual for the quality and safety of care in the use of drugs, "Recommendations, Integrations, and Training", which contains the main documentation, which is necessary for furthering the improvement of the quality and safety of care in the context of the use of the drugs [5].

The application at the public and private health facilities of such tools based on scientific evidence and similar documents drawn up in England, the United States, Canada and Australia, have a significant role in the implementation of the security levels of the professional activities and the adoption of specific corporate measures aimed at preventing and reducing the number of adverse events. In the context of healthcare federalism in the national health system, the regional context is characterized by the growing importance attributed to security and clinical risk management in the administration of medicines [6]. In that regard, are identifiable as specific measures that have intervened in specific strategic areas at risk of deviant behaviour, such as the Centralization of the buying-in tenders through dynamic purchasing systems and centralization of purchases, the management of the logistics of the central warehouse and the management of medicines at the regional health care structures.

The Case Study of the Medications Lasa; Projects and Best Practices

Between the medication errors more frequent there is the use of drugs "LASA" is the acronym of "look-alike/sound-alike", which indicates that the drugs, which can be exchanged with other for the similarity of the graphics and/or phonetics of the name, and for packages of similar size and in the color such as to induce in error during the phases of medication management, both in hospitals and in the territory, The appearance of greater importance is the information and raising the awareness of stakeholders on the urgent need to prevent the errors related to the use of drugs LASA and provide methodological tools to standardize the activities and behaviors that are oriented to the Safety of the patients. The Ministry of Health within the framework of the activities aimed at improving the quality of health services, initiated the Project "Drugs LASA and patient Safety", to increase awareness of the possibility of error in the use of those drugs, which can be confused with other for the similarity of the graphics and/or phonetics of the name [7]. The method used has provided for the activation on the website of the Ministry, starting from November 2008, a section dedicated to the Project "Drugs LASA and patient Safety", (http://www.salute.

gov.it/qualita/qualita.jsp). During the first phase of the Project carried out a survey for the collection of information necessary for the assessment of the degree of knowledge of the issue on the national territory. As a result of the investigation, compiled a Report highlighting the critical issues concerning safety in the use of drugs LAAS in the field hospital and territorial. The information gathered allowed to draw up a first list of medications LASA, according to the information received in the course of the hearings-November 2008 - May 2009, and updated and shared with the AIFA, as at 31 December 2010. With the recommendation for the prevention of errors in therapy with drugs LASA in August 2010, it was pursued the goal of providing guidance to prevent the exchange between drugs with phonetic similarity and graphics in the name, as well as the similarity in the packaging and raise awareness among health professionals and the various factors involved in the management of medication to ensure that they are put in place appropriate measures to avoid the exchange of drugs.

The Recommendation applies to medicines LASA used in the hospital and in the community and to healthcare professionals involved in the management of medication, in the hospital, in the territorial services of the ASL, in the Pharmacies of the community, in the studies of general medicine doctors and of the paediatricians, family as well as to the Directorates of health-care Companies and pharmaceutical companies. The Recommendation may find application in healthcare Facilities, in the RSA and rest Homes, in Hospice Facilities, private rehabilitation and care, on ambulances, at the residence of the patient, and wholesalers of medicinal products. As exposed, and on the basis of recent acquisitions in the area of security she management of medicines LASA, as reported in the literature nationally and internationally, some health-care Companies have launched projects and initiatives involving scientific Societies and professional associations. In this regard, at the end of the patient identification and the traceability of medicines has been issued a draft patient Identification and Traceability of medicines, taken by NIRM (Folder Nursing Computerized). The objective is the traceability of the medication the healthcare facility, which can verify the batch of the drug administered, but also to assess aspects of administrative management, such as the cost of drugs per patient and each phase up to the administration to the patient. In the context of the improvement of the quality of health services, the Pharmacy Service and the Simple Structure of Departmental Risk Management of the Azienda Ospedaliero-Universitaria di Parma have created the information sheet "How To: The Prevention of Errors in Therapy Related to the Use of Drugs LASA". This instrument was adopted in order to simplify the communication to professionals on the topic of clinical risk management. The document also contains examples and drawings that facilitate the understanding of the text exhibited in the notice board of the department. In the "How to" describes what the drugs LASA are and the actions to take in each stage of medication management to prevent the exchange, by placing in a separate way these medicines and highlighting the similarity.

To this end, it has been designed a Label for the Alert to be affixed on the packaging of medicines LASA in the cupboards and pharmaceuticals, and on the trolley of the therapy. The "How to" illustrates the path that allows health workers to Report the Presence of Drugs Laas in the department using a card and submit it to the Pharmacy. These reports of medication LASA received will be included in a database that will be used to establish the list of the company of the medications LASA to monitor and update, as required by Recommendation n.12. As far as the drugs LASA, it is essential that information and training on the subject conducted by Universities, Local Authorities, professional associations, scientific Societies, as well as the action of sensitization carried out by the AIFA at the pharmaceutical Companies, in order to develop uniform criteria of safety for the drugs from re-entering Italy and for any changes to those present on the pharmaceutical market. Also, the list of medications LASA extrapolated from the national database on the part of the ministry is a useful tool as a repository of reports, as well as to plan short-term actions at central, regional and in-company, also through the elaboration of lists of medications LASA to monitor and periodically update. In the context of the improvement of the quality of health services, the Pharmacy Service and the Simple Structure of Departmental Risk Management of the Azienda Ospedaliero-Universitaria di Parma have created the information sheet "How To: The Prevention of Errors in Therapy Related to the Use of Drugs LASA". This instrument was adopted in order to simplify the communication to professionals on the topic of clinical risk management.

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Projects towards the Organizational Improvement

The risk from drug therapy poses the problem of a vision system of the process, to guide the security procedures of the homogeneity and the direct management of such situations. The critical issues present in the majority of health care realities, such as the different organizational, the presence of tools not standardized and the lack of computerization of the processes to detect the need of a comparison and exchange of experiences, in order to orient to the homogeneity of the procedural and organizational quality. The presence of diverse experiences in hospital and territorial and of the accreditation process requires a methodological basis, in order to adopt safer practices. On the one hand, the adoption of the Recommendations has proved effective in reducing the number of adverse events, for the other direction, it is necessary that the process of dissemination of such recommendations will be fostered at the level of corporate management, including through appropriate regional programmers that envisage the improvement of the computerization of health Facilities and constant monitoring. The training of the operators is a lever for organizational in the management of the risk of therapy-pharmaceutical and manual, and the course FAD on the risk of clinical pharmacists in collaboration with the Federation of Order of Pharmacists (FOFI), has made an informational tool, prepared on the basis of the previous experiences of the Ministry of Health.

As regards the problem of drugs LASA, will be crucial information and training carried out by Universities, Local Authorities, professional associations, scientific Societies, and the awareness-raising carried out by the AIFA in order to develop uniform criteria for safe medicines of new entry and any changes to those present on the pharmaceutical market. Also, the list of medications LASA extrapolated from the national database will be a useful tool as a repository of reports, to plan interventions at the central level, regional and corporate, including through the elaboration of a list of drugs to monitor and periodically update.

The program on the Pharmacist of the Department in the field of oncology, in collaboration with the Italian Society of Hospital Pharmacy and Pharmaceutical Services of Health-care Companies, represents an innovative approach, based on the available literature highlights how the presence of the Pharmacist, the Department is able to reduce adverse events, with economic consequences positive for the savings on health care costs and pharmaceuticals, and the reduction of the duration of hospital stays and a better quality of care. The final document of the program highlights the necessary information for pharmacists, business managers and health-care professionals involved in the management of medication, not only to manage the risk from treatment but also to implement this new organizational model.

Conclusion

At the conclusion of the above, it is noted that the path towards the optimization of risk management by drug therapy, despite having made some progress presents areas that require further corrective or improvement in order to achieve a virtuous circle is to protect the health and safety of the care.In a specific case of pharmacological innovation, it may be a higher level of risk. As such, it is necessary to ensure an alignment between pharmacological innovation and organizational innovation aimed at achieving the highest level of patient safety.

At the organizational level of a hospital, there is a need for improved logistics evolution, in inventory management, integrated with purchasing management. The integration of supply and logistics has a significant impact on the organizational system where it is necessary to implement information through information flow systems, between pharmacy and departments.

This is in line with the growing application of ICT in this field. To ensure quality standards and to prevent the risk,related to prescription and drug, smart cupboards and carts and the use of computerized folders and robotic automated equipment is growing rapidly [8]. These remedies can combine patient safety and high performance in higher - risk therapeutic areas, such as the preparation and distribution of chemotherapeutic drugs, syringe filling, or safe handling of cytotoxic drugs.

Contributions of Study

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2. In the United Kingdom in 2000, the majority of the events depend on the errors related to the incorrect use of medicines, National Patient safety. Another study carried out in 1116 hospitals in the us in 2001, has shown that the errors in therapy occurs in approximately 5% of patients hospitalized in a year. According to a survey in the US shows that most of the adverse events with regard to the requirement and are interested in medicines ipogligemizzanti (28,7%), cardiovascular (18,6), anticoagulants (18,6), and diuretics (10,1%)

3. World Health Organization. WHO launches 'Nine patient safeties, solutions'?

4. The documents, available on the website of the Ministry, will be subject to further implementation and monitoring, with the cooperation of the Institutions involved.

5. http://www.salute.gov.it/qualita/qualita.jsp

6. The Regional working group on clinical Risk from drugs. Recommendation for Safety in the drug therapy no.2. "The process of recognition and reconciliation, a drug a proper prescription and safe." The Region of Emilia-Romagna May 2011.

7. The e-mail box Terapiaesicurezzapazienti@sanita.it it is designed for the reception of the information on the issue related to the safety in use of medicines LASA. The documents, available on the website of the Ministry (http://www.salute.gov.it/qualita/qualita.jsp), will be subject to further implementation and monitoring, with the cooperation of the Institutions involved.

8. The canadian Intelligent Hospital Systems has all-Robotic system able toFill the syringes and the infusion bags With the correct doses of the drugs.