Chapter 05 / Capítulo 05

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Patient safety and pharmacovigilance: nursing's role in the prevention of adverse events / Seguridad del paciente y farmacovigilancia: rol de enfermería en la prevención de eventos adversos

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ABSTRACT

Introduction: the paper analyzed patient safety as a priority axis of health systems and linked it to pharmacovigilance as a central strategy to balance the risk-benefit of drugs. The problem was contextualized on the basis of WHO resolutions and ANMAT pharmacovigilance reports in Argentina, which made it possible to measure the magnitude and avoidable nature of numerous adverse events.
Development: the main international normative milestones were described, including the World Health Assemblies and patient safety goals, as well as the Global Action Plan 2021-2030, focused on a systemic approach. The paper presented specific actions proposed by WHO, such as correct patient identification, improved communication, safety of high-risk medications, safe surgery, infection prevention and reduction of harm from falls. Evidence on low adherence to safe practices, particularly hand hygiene and event reporting, was also reviewed, and the role of the healthcare team, with a focus on nursing, as the last barrier to harm was highlighted.
Conclusions: the study concluded that patient safety constituted an inescapable component of the quality of care and of the ethical and legal responsibility of health personnel. It was emphasized that only the integration of pharmacovigilance, international guidelines and daily nursing practice, within the framework of an organizational culture of safety, made it possible to sustainably reduce adverse events and move towards safer and more humanized health systems.

Keywords: Patient Safety; Pharmacovigilance; Nursing; Adverse Events; Safety Culture.

RESUMEN

Introducción: el trabajo analizó la seguridad del paciente como eje prioritario de los sistemas de salud y la vinculó con la farmacovigilancia como estrategia central para equilibrar el riesgo-beneficio de los medicamentos. Se contextualizó el problema a partir de las resoluciones de la OMS y de los informes de farmacovigilancia de la ANMAT en Argentina, que permitieron dimensionar la magnitud y el carácter evitable de numerosos eventos adversos.
Desarrollo: se describieron los principales hitos normativos internacionales, incluyendo las Asambleas Mundiales de la Salud y las metas de seguridad del paciente, así como el Plan de Acción Mundial 2021–2030, centrado en un enfoque sistémico. El trabajo presentó las acciones específicas propuestas por la OMS, como la correcta identificación del paciente, la mejora de la comunicación, la seguridad de los medicamentos de alto riesgo, la cirugía segura, la prevención de infecciones y la reducción de daños por caídas. Asimismo, se revisó evidencia sobre la baja adherencia a prácticas seguras, en particular la higiene de manos y la notificación de eventos, y se destacó el papel del equipo de salud, con foco en enfermería, como última barrera frente al daño.

Conclusiones: el estudio concluyó que la seguridad del paciente constituyó un componente ineludible de la calidad asistencial y de la responsabilidad ética y legal del personal de salud. Se subrayó que solo la integración de la farmacovigilancia, los lineamientos internacionales y la práctica cotidiana de enfermería, en el marco de una cultura organizacional de seguridad, permitió reducir de manera sostenible los eventos adversos y avanzar hacia sistemas de salud más seguros y humanizados.

Palabras clave: Seguridad del Paciente; Farmacovigilancia; Enfermería; Eventos Adversos; Cultura de Seguridad.

INTRODUCTION

Patient safety has become a priority for health systems worldwide over the past few decades. The World Health Organization (WHO) defines Patient Safety (PS) as the absence of preventable harm and the reduction of the risk of harm to an acceptable minimum. In this regard, the 72nd World Health Assembly committed to advancing universal health coverage by integrating patient safety as an essential component through frameworks for action that guide policies, practices, and evaluations to prevent harm during care. This approach recognizes that adverse events cause not only suffering and mortality but also high economic costs for systems, as evidenced in high-income countries, where a considerable proportion of adverse events are considered preventable.

In this context, pharmacovigilance plays a central role. The Pan American Health Organization (PAHO) defines it as the set of actions aimed at ensuring an adequate risk-benefit balance for medicines throughout their life cycle, contributing to their rational use and minimizing risks to patients. In Argentina, reports from ANMAT's Pharmacovigilance Department, such as the 2017 annual report, allow us to gauge the magnitude of adverse drug reactions (ADRs) and provide key demographic and epidemiological information for decision-making. These data show that patient safety is not a recent concern but a complex issue that has become increasingly visible since the first WHO resolutions on the subject, such as the 55th World Health Assembly, which already warned of the impact of adverse events.

Based on this background, the WHO has proposed system-centered international patient safety models and goals, which include concrete actions such as proper patient identification, improved communication, high-risk medication safety, safe surgery, prevention of healthcare-associated infections, and reduction of harm from falls. More recently, the World Action Plan for Patient Safety 2021–2030 further emphasizes the need to consolidate a culture of safety in healthcare institutions. In this context, the role of healthcare personnel, particularly nurses, is strategic in identifying, preventing, and reporting adverse events, especially in critical processes such as medication administration. This study fits into this scenario by analyzing patient safety from a comprehensive perspective, with an emphasis on nursing practice and strategies to reduce the risks associated with care.

DEVELOPMENT

Chapter I

The WHO defines Patient Safety (PS) as the absence of preventable harm to patients and the reduction of the risk of causing them permanent or temporary harm to an acceptable minimum. To this end, at the 72nd World Health Assembly, it proposed achieving global health coverage

in support of patient safety by establishing a framework for the main parties to join forces and implement initiatives to comprehensively protect patients, thereby avoiding preventable harm during their care.

PAHO defines pharmacovigilance as the balance between risk and benefit throughout the entire drug pathway, encompassing various branches of public health risk analysis and management that contribute to the rational use of medicines and thereby prevent and minimize risks to patients.

The Department of Pharmacovigilance of the Argentine Republic published an annual report in 2017 that compiles statistical data on adverse drug reactions (ADRs) by province, enabling the collection of demographic and epidemiological data for follow-up and accounting for regional statistics.[1]

The issue of patient safety is not new; it has been developing over the years. As indicated at the 55th World Health Assembly in 2002, the high costs of events that result in material losses, and the priority of surveillance and maintenance to ensure patient safety.

The consequences of patient safety failures: studies in first-world countries indicate that high rates of adverse events could be preventable, accounting for millions of dollars in annual hospitalizations and deaths due to healthcare-related adverse events.[2]

Chapter II

The patient safety model is focused on the healthcare system and is based on the following specific actions, established by the WHO in 2007.

1. Correctly identify patients.
2. Improve effective communication.
3. Improve the safety of high-risk medications.
4. Ensure surgery is performed on the right site, with the correct procedure, and on the right patient.
5. Reduce the risk of healthcare-associated infections.
6. Reduce harm caused by falls.

Adding these actions together, the 74th World Health Assembly approved the Strategic Action Plan for Patient Safety 2021-2030, which aims to enhance safety in the design, procedures, and evaluation of health systems worldwide. This plan includes seven strategic objectives and five specific actions that form a framework for instilling a culture of patient safety.

In health, patient safety (PS) and quality of care are pillars in institutions for the continuous improvement of healthcare practice. After the WHO established international goals, institutions planned to prepare professionals and non-professionals in the culture of patient safety. This is understood as a set of organized and coordinated activities that enable professionals to engage in safe behaviors in their daily practice, supported by environments that reduce incidents and adverse events. They involve all the studies, practices, and actions that institutions implement to reduce or eliminate risks related to healthcare.[3]

By saying reduction and not abolition, we assume the existence of potential harm that is implicit in healthcare acts, which may be associated with professionals, but also with other associated factors, such as knowledge of the state of the disease as the object of care, as well

as the quality of care.

Vasconcelos et al.[4], in their descriptive cross-sectional study of adherence to hand hygiene among the nursing team in the intensive care unit, concluded that adherence was very low (47,8 %). There was no adherence at the moment "before performing aseptic procedures." The "after" moments showed higher adherence rates.

State in their article that risks during work performance are inherent in any human activity and define patient safety as the condition that ensures that workers, patients, visitors, infrastructure, and equipment within a healthcare facility are free from risk or danger of accidents, focusing their study on patient identification, active communication, safety in the medication administration process, safety in procedures, reduction of healthcare-associated infections, recording of sentinel event analysis, and the creation of a culture within the organization.[5] in their work, Application of nursing intervention activities.

Healthcare personnel play a crucial role in promoting patient safety, as they are constantly involved in patient care. On the other hand, if this care is not provided in a quality manner, it can lead to errors and compromise patient safety. An error is understood as an unintentional act, by omission or commission, that is inappropriate for the intended effect or result.[6]

Nursing plays a key role in identifying and preventing adverse events related to medication administration. As a last line of defense, it can also provide information through reporting systems, thereby raising awareness among other professionals.

CONCLUSIONS

The review conducted allows us to conclude that patient safety is an essential component of quality healthcare and an ethical, legal, and technical responsibility of the entire healthcare team. Far from being a recent concern, it is an issue in constant development that has gained visibility since the WHO resolutions and the frameworks for action promoted by international and national organizations. Data provided by pharmacovigilance, especially in relation to adverse drug reactions, show that a significant proportion of adverse events are preventable and that they involve suffering, mortality, and high costs for health systems, reinforcing the urgency of systematic and organized intervention.

System-centered safety models, international patient safety goals, and the Global Action Plan 2021–2030 offer a concrete roadmap for reducing risks, focused on correct patient identification, improved communication, high-risk medication safety, safe surgery, infection prevention, and fall injury reduction. However, their effectiveness depends on building an authentic culture of safety in institutions, understood as a set of values, attitudes, and practices that promote safe behaviors, recognize the possibility of error, and encourage organizational learning.

In this scenario, the role of nursing is strategic. Due to their constant contact with patients and active participation in critical processes such as medication administration, hand hygiene, and monitoring of adverse events, nursing staff become the last line of defense against harm. However, evidence indicates significant gaps in adherence to safe practices, such as hand hygiene and incident reporting, underscoring the need to strengthen training, supervision, and teamwork.

In summary, moving toward safer care requires integrating pharmacovigilance, international

guidelines, and everyday nursing practice into a systemic and comprehensive approach. This involves promoting work environments that facilitate compliance with protocols, encourage reporting without blame, and prioritize the patient as the center of care. Only in this way will it be possible to sustainably reduce adverse events and consolidate safer, more efficient, and more humanized health systems.

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FINANCING

None.

CONFLICT OF INTEREST

None.

AUTHORSHIP CONTRIBUTION

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