Situational Analysis of Pharmacovigilance in a Secondary-Level Hospital in Puebla, Mexico

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DOI: 10.22517/25395203.25788

Abstract

Introduction: In Mexico, pharmacovigilance has been around for a very short time, it began in 1995, only 68 events of Adverse Drug Reactions were reported, 10 years later the figure increases to 7960, however, with the increase in the reporting rate, there is a need to continue evaluating the level of knowledge and attitude of the staff, which gives the opportunity for improvements for quality certification.

Objective: To determine the situational analysis based on the knowledge, attitudes and perception of the health personnel of the third level hospital in the interior of the state of Puebla, regarding the pharmacovigilance process, within 2023.

Methodology: This research was performed through an observational and cross-sectional study, with descriptive, prolective and analytical characteristics, through a validated survey based on guidelines and the Mexican standard NOM-220-SSA1-2016.

Results: It was found that female medical staff corresponds to 9% and male medical staff represents 31%. The position of the staff surveyed was female staff (50%), Medical Staff (45%), and Clinical laboratory staff (5%). The working shift of the hospital, Morning (44%), Evening (16%), Night (17%), Cumulative Day (23%). In the same point of view, the comparision between sex, workshift, and professions, showed interesting results, like women have more knowledge in pharcovigilance than men (*$p<0.05$), the working shift nocturne (***$p<0.001$) have more knowledge than the others, and the nurses have more knowledge than doctors(*$p<0.05$).

Keywords: Pharmacovigilance, adverse drug reactions, adverse reaction reporting system, knowledge and attitude in pharmacovigilance.

Introduction

Knowledge about drug-related toxicity generates concern not only among patients but also among prescribers, dispensers, and health authorities. Adverse drug reactions (ADRs) are a major cause not only of medical consultations but also of hospital admissions and even mortality. In recent years, several drugs have been withdrawn from the market after an unfavorable benefit–risk balance was identified, which had not been detected during their initial authorization (1,2).

Since 1990, the World Health Organization (WHO) and the Uppsala Monitoring Centre have operated as reference bodies for the implementation of pharmacovigilance (1,2). In Mexico, the first pharmacovigilance center was established in 1995, along with the development of specific regulations, such as the Official Mexican Standard NOM-220-SSA1-2016, which regulates the establishment and operation of pharmacovigilance systems (3). This standard, in force since 2016 after several revisions, aims to strengthen the detection, evaluation, and prevention of adverse events (AEs), suspected adverse drug reactions (sADRs), ADRs, and events supposedly attributable to vaccination or immunization (ESAVIs) (3).

Despite these advances, reports remain insufficient. According to a systematic review of 149 articles, by 2014 international pharmacovigilance targets had not been reached, with fewer than 200 reports annually per million inhabitants (4). That same year, 40,499 sADR reports were recorded, and in 2015 a total of 54,795 (4). However, most of these reports came from the pharmaceutical industry rather than from healthcare facilities, reflecting significant shortcomings in the operational implementation of the system (4).

In addition, recurring errors have been identified in the completion of reporting forms, such as incomplete data or the use of initials instead of full names of patients and physicians, which limits the quality of the information collected (4). This situation shows that, although progress has been made in pharmacovigilance regulations, their effective implementation in clinical practice remains limited. Among the main barriers are a lack of knowledge about reporting procedures and a low reporting culture among healthcare professionals.

Materials and Methods

An observational, cross-sectional study with a descriptive and analytical approach was conducted using a previously validated survey (19). The question bank was developed based on the pharmacovigilance guidelines established by the Mexican Ministry of Health, through the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), and in accordance with the criteria of the Official Mexican Standard NOM-220-SSA1-2016.

The survey was structured into three sections. The first assessed staff attitudes using eight items on a five-point Likert scale: 5 (strongly agree), 4 (agree), 3 (neither agree nor disagree), 2 (disagree), and 1 (strongly disagree). The second section evaluated the level of knowledge about pharmacovigilance, consisting of eight items. The total score was obtained by summing the responses. The third section explored barriers or reasons why ADR reports are not submitted, through eight specific questions.

Application Strategy

The survey was administered in person, with prior authorization from the hospital's Teaching Department. It was conducted in the spaces designated by this department, covering different work shifts (morning, afternoon, night, and extended shifts), according to staff availability, on Mondays and Fridays, in accordance with the hospital's internal policies.

Statistical Analysis

A descriptive percentage analysis was performed for qualitative variables (attitudes) and quantitative variables (knowledge), with results plotted using GraphPad Prism® software, version 7.0. For inferential analysis, mean comparison tests were applied: Student's t-test or multiple comparison ANOVA, as appropriate. Comparisons were made between groups defined by sex, work shift, and professional category, with the statistical significance level set at $p < 0.05$.

Ethical Considerations

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and its updates, as well as the Declaration of Tokyo. Compliance was ensured with the provisions of the Mexican General Health Law Regulations on Health Research. The research protocol was approved by the Bioethics Committee and the Research Committee of the Centro de Estudios Superiores de Tepeaca. Participation was voluntary, and confidentiality and anonymity of the data obtained were guaranteed. Data were used exclusively for statistical and scientific purposes.

Results

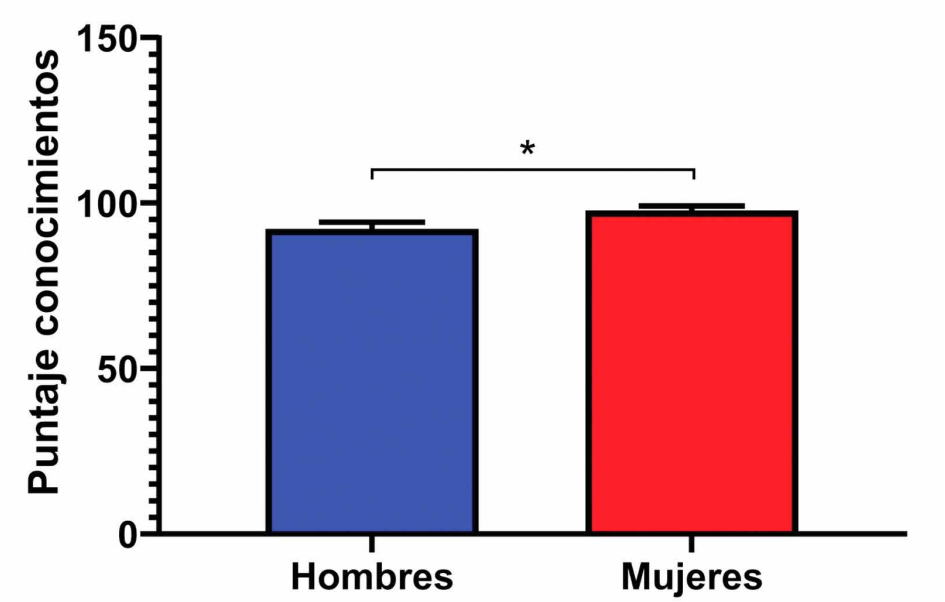
In this study, laboratory staff were included, given that the person in charge of the in-hospital pharmacovigilance unit belongs to this service. The Official Mexican Standard NOM-220-SSA1-2016 establishes that the scope of pharmacovigilance includes all personnel in public and private facilities engaged in prescribing, administering, or supplying drugs or biological products. The sample consisted of n = 129 participants.

Analysis of Age and Staff Knowledge

The mean age of the general hospital healthcare staff was 40.5 ± 12.33 years. Regarding job position, the personnel who completed the survey were distributed as follows: nursing staff n = 64 (49.61%), medical staff n = 58 (44.96%), pharmacy staff n = 0 (0%), and clinical laboratory staff (chemists) n = 7 (5.42%). The total population corresponded to n = 129 (100%) of the healthcare workforce.

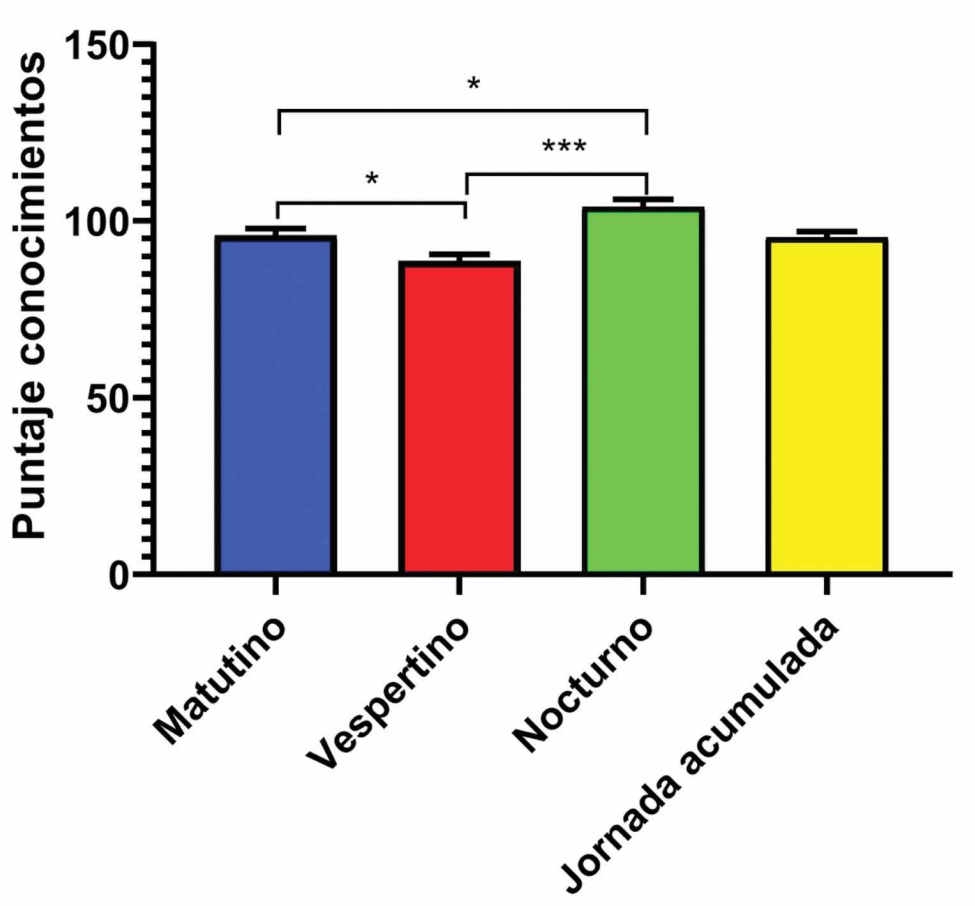
Comparison of Pharmacovigilance Knowledge Level by Sex, Shift, and Profession In this section, it was identified that men, on average, scored 92.16 points, while women obtained an average of 97.76 points; this difference was statistically significant (p = 0.020) (see Figure 1).

Figure 1. Comparison of knowledge levels between men and women. Statistical analysis was performed using the Student's t-test. Prepared by the authors using GraphPad version 7.0.



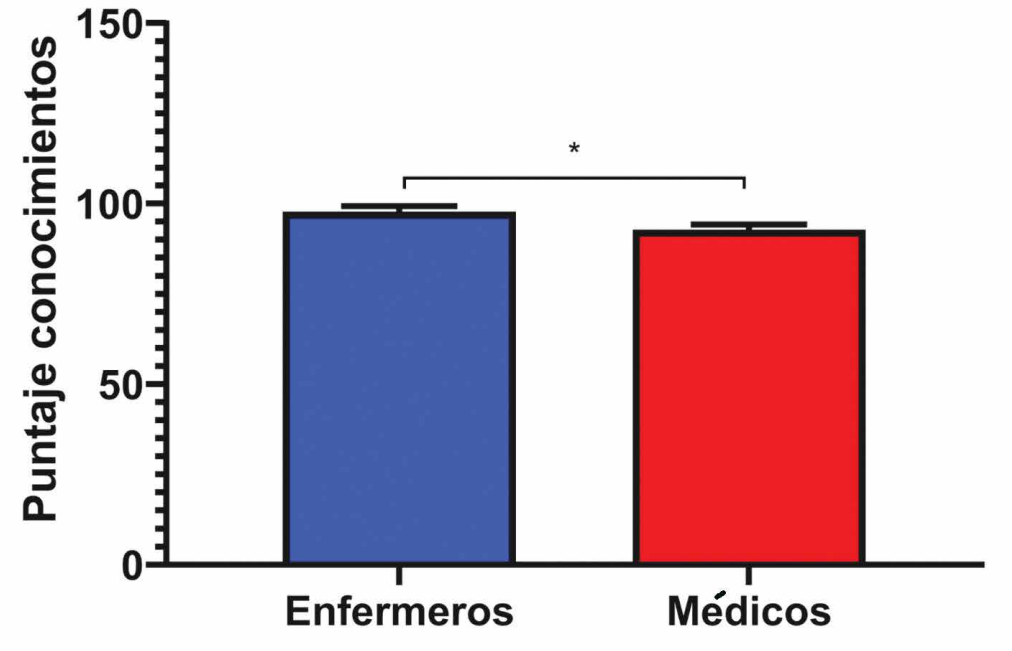
Regarding work shifts, it was observed that night-shift personnel had a higher score than evening-shift personnel (104 vs. 88.7 points, respectively; $p < 0.0001$). Similarly, the night shift showed a higher score than the morning shift (104 vs. 95.9 points; $p = 0.043$). In turn, the morning shift presented a higher score than the evening shift (95.9 vs. 88.7 points; $p = 0.029$) (see Figure 2).

Figure 2. Comparison of knowledge levels across work shifts. Statistical analysis was performed using ANOVA with Tukey's post hoc multiple comparison test. Generated with GraphPad version 7.0.



On the other hand, in the comparison between physicians and nursing staff, it was observed that nurses obtained a higher knowledge score on pharmacovigilance (97.72 vs. 92.79, respectively); however, this difference was not statistically significant ($p = 0.26$) (see Figure 3).

Figure 3. Comparison of knowledge levels between physicians and nurses. Statistical analysis was performed using the one-sample t-test. Generated with GraphPad version 7.0.



Staff Attitude Analysis

Regarding staff attitudes, 57% of respondents considered pharmacovigilance important for their professional practice. Meanwhile, 30% reported being neutral regarding the importance of pharmacovigilance, and 12% indicated that they did not consider it important (see Table 1). In addition, 66% believed that it is not necessary to routinely report adverse drug reactions (ADRs), 24% expressed neutrality, and only 9% considered that routine reporting is feasible (see Table 1).

Table 1. Summary of knowledge questions 1–8.

Question or factor	Favorable (%)	Uncertain (%)	Unfavorable (%)
Greater commitment/obligation is needed from doctors to report adverse reactions.	18.60	13.95	67.44
The Pharmaco vigilance reporting system is not important or significant for my work.	56.59	30.23	13.18
The Pharmaco vigilance report is not of importance or significance for the country.	62.02	24.03	13.95
There are many more important issues within medical practice ahead.	46.51	34.88	18.60
The Pharmaco vigilance report concerns the authorities more than it does health personnel.	64.34	18.60	17.05
I can't find a good reason to routinely report.	66.67	24.03	9.30
The report exposes my clinical practice unnecessarily.	67.44	24.81	7.75
I really don't know how to make a spontaneous adverse reaction report.	55.81	12.40	31.78

The 44% of respondents believe that the process is not bureaucratic, 38% were unable to define whether it is or not, and 15% consider it bureaucratic. This perception is similar when analyzing whether reporting requires a significant amount of time: 35% believe it does not demand much time, 41% were undecided, and 22.5% stated that it does require considerable time (see Table 2).

Table 2. Summary of factors for not reporting, questions 9–16

Question or factor	Favorable (%)	Uncertain (%)	Unfavorable (%)
Only those adverse drug reactions that demonstrate a cause-effect relationship should be reported.	60.47	18.60	20.93
The adverse reactions of a medication are already known when a medication reaches the market, since only safe medications are marketed.	72.87	11.63	15.50
Physicians should contribute to the general advancement of medical knowledge through the reporting of adverse drug reactions.	86.82	6.98	6.20
It is actually very difficult to determine if a medication is responsible for an adverse reaction.	41.86	33.33	24.81
Reporting adverse drug reactions requires a lot of time and attention.	35.66	41.09	23.26
I don't know where to find the Adverse Drug Reactions reporting form.	42.64	22.48	34.88
The report is bureaucratic and complicated.	44.96	38.76	16.28
I consider the report valuable in some cases of legal controversy.	65.12	18.60	16.28

Finally, 77% of respondents believe that only a reward system would motivate physicians to report adverse drug reactions (ADRs). An essential factor is medical education: 83% consider that adequate university training in pharmacovigilance would improve the functioning of the system (see Table 3).

Table 3. Summary of possible solutions, questions 17–24.

Question or factor	Favorable (%)	Uncertain (%)	Unfavorable (%)
Only those adverse drug reactions that demonstrate a cause-effect relationship should be reported.	24.03	50.39	25.58
The adverse reactions of a medication are already known when a medication reaches the market, since only safe medications are marketed.	13.95	7.75	78.29
Physicians should contribute to the general advancement of medical knowledge through the reporting of adverse drug reactions.	87.60	5.43	6.98
It is actually very difficult to determine if a medication is responsible for an adverse reaction.	58.91	24.81	16.28
Reporting adverse drug reactions requires a lot of time and attention.	56.59	24.03	19.38
I don't know where to find the Adverse Drug Reactions reporting form.	72.87	17.05	10.08
The report is bureaucratic and complicated.	84.50	11.63	3.88
I consider the report valuable in some cases of legal controversy.	51.94	17.05	31.01

Discussion

The results obtained show that, despite the existence of specific regulations in Mexico, such as NOM-220-SSA1-2016, significant limitations persist in the knowledge and attitudes of healthcare personnel regarding pharmacovigilance. This situation is consistent with findings reported in other national and Latin American studies (3,4,19).

The mean age of the surveyed personnel was 40.5 ± 12.33 years, which coincides with a study reporting that the average age of healthcare professionals ranges between 38 and 45 years (20). This characteristic is relevant, as it reflects a professionally active population with sufficient experience, but still with deficiencies in competencies related to pharmacovigilance.

The analysis by professional categories revealed a predominance of nursing staff, which is consistent with the usual composition of teams in secondary-level hospitals in Mexico (20,21). Likewise, the higher female representation can be explained by the historical feminization of nursing in Latin America, a phenomenon well documented in sociolabor studies (22).

Regarding knowledge in pharmacovigilance, it is noteworthy that female staff obtained significantly higher scores compared to male staff. This finding could be associated with the greater representation of women in nursing,

which, according to the results, shows higher knowledge than medical staff. This phenomenon has also been reported in studies conducted in Peruvian and Mexican hospitals, where nurses are often more familiar with reporting processes, as they are directly involved in drug administration and monitoring (26,27).

Another relevant finding is that the night shift obtained the highest knowledge scores. This contrasts with existing literature, which usually associates the night shift with heavier workloads and lower participation in administrative processes such as pharmacovigilance (25). However, it may be explained by specific factors of the internal organization of the studied hospital, where there is lower care demand and greater availability for reporting and recording events during that shift.

Importance of Pharmacovigilance and International Context

Pharmacovigilance is an essential discipline for patient safety and the quality of medical care. Its objective is the early detection, assessment, and prevention of adverse drug reactions (ADRs), particularly those not identified during clinical trials (7,8).

The phases of drug development (Phase I to IV) have inherent limitations. In Phases II and III, only 2,000 to 5,000 patients are typically included, which prevents the detection of low-incidence ADRs, long-latency events, or those specific to subpopulations (5,6,8). For this reason, post-marketing pharmacovigilance (Phase IV) is indispensable for identifying adverse events in real-life settings and under heterogeneous clinical conditions.

Globally, ADRs represent a significant cause of morbidity, prolonged hospitalizations, and increased healthcare costs (1,2,9). In countries such as the United Kingdom, the estimated cost of ADRs reaches 847 million dollars annually, while in the United States it exceeds 76.6 billion dollars (4).

Pharmacovigilance in Mexico

In Mexico, the formal development of pharmacovigilance began in 1995 with the creation of the National Pharmacovigilance Center (3,4). However, since its inception, it has faced multiple challenges. Reporting rates have historically been low, and most reports originate from the pharmaceutical industry rather than healthcare centers (4).

In addition, frequent deficiencies have been documented in the quality of reports, including incomplete or invalid data, such as the use of initials instead of names, which limits causality analysis and decision-making (4). A systematic review showed that until 2014 international standards were not

met, with fewer than 200 reports per million inhabitants—far below WHO recommendations (4).

Analysis of Staff Attitudes

A critical finding of this study is staff attitudes toward ADR reporting. Although 57% acknowledge the importance of pharmacovigilance, only 9% consider it feasible to report routinely. This finding reveals a disconnection between theoretical knowledge and clinical practice, which is consistent with reports from previous studies in Mexico, Peru, and Chile (19,26,27).

Furthermore, 77% of participants believe that only a reward system would motivate physicians to report ADRs. This finding is concerning, as it reflects a culture where pharmacovigilance is not perceived as an integral part of patient care but rather as an additional administrative burden.

The perception that reporting is bureaucratic or time-consuming, although not predominant, is still maintained at considerable percentages (15% consider it bureaucratic and 22.5% that it requires too much time), representing a relevant operational barrier.

Relevance of Pharmacovigilance Training

Another key aspect is the recognition of a training deficit: 83% of respondents believe that adequate university-level education would significantly improve the functioning of the pharmacovigilance system. This finding is consistent with national studies warning of the limited presence of formal pharmacovigilance content in the curricula of medicine, nursing, and pharmacy programs (19,20).

Incorporating pharmacovigilance as a cross-cutting competency in university training programs is essential, not only to meet international patient safety standards but also to promote an institutional culture of reporting and pharmacotherapeutic risk management.

Study Limitations

The main limitation of this study is that it was conducted in a single secondary-level hospital, which may restrict the generalizability of the results. However, the findings are consistent with previous studies in similar contexts, which strengthens their internal validity.

Conclusions

This study showed that despite the existence of specific regulations and an acceptable level of knowledge on pharmacovigilance among healthcare personnel, significant barriers to its practical implementation persist in a secondary-level hospital in Puebla, Mexico.

The results indicate that nurses demonstrated higher levels of knowledge than physicians, and that the night shift was associated with better performance in this area. However, the overall attitude toward pharmacovigilance was poor, with a low perception of the need to report routinely and a high reliance on potential external incentives to motivate the reporting of adverse drug reactions.

These conditions reflect weaknesses both in the institutional culture of pharmacovigilance and in the prior academic training of professionals. Therefore, the need to implement comprehensive strategies becomes evident, including:

- Continuing education programs for all healthcare personnel.
- Formal inclusion of pharmacovigilance in health sciences curricula.
- Strengthening internal processes through simplification of reporting systems and promotion of a proactive culture oriented toward patient safety.

Finally, the findings of this study provide the basis for developing an institutional improvement plan focused on staff training, timely identification of adverse drug reactions, and optimization of reporting systems, which is essential to raising the standards of quality and safety in medical care.

Acknowledgments

The authors express their gratitude to Dr. Elizabeth Vega Cárdenas and Dr. Martín Carrasco Varela for their support and the facilities provided for the completion of this research.

Financing: None.

Conflicts of interest: None.

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