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Impact of the Role of the Clinical Pharmacist on the Underreporting of Adverse Drug Reactions at a Peruvian hospital

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Abstract

Background: The clinical pharmacists play a key role in the Pharmacovigilance System. They are integrated to the health team performing pharmacotherapeutic follow-up (PF), drug information, at third level care hospital. The objective of this study was to assess the impact of the clinical pharmacists' role in increasing the reporting of suspected adverse drug reactions (SADRs) after including in-service training (IST) in their role, as well as to characterize the reported ADRs. **Methods:** A longitudinal study was performed, reports of SADRs received through medical interconsultations were evaluated, before and after applying IST, in 2 periods: January 2017 to June 2018 and July 2018 to December 2019. **Results:** Interconsultations after IST were increased by 168,4%; of these, 75 were ADRs reported to the Dirección General de Medicamentos, Insumos y Drogas (DIGEMID). Internal Medicine and Pneumology services reported more SADR in both periods. There was significant statistical difference in ADRs' causality ($P = .001$) and type ($P = .009$). Severe ADRs highlighted after IST (4 vs 12). The most affected organ and system in both periods was skin and appendages. **Conclusion:** The reporting of SADRs augmented, reflected in an increase in medical interconsultations as a modality of SADR notification, after including IST to the role of the clinical pharmacist, allowing the development of convenient FP, which led to the evaluation of SARs. A higher number of serious ADRs were reported.

Keywords

adverse drug reactions reporting/monitoring, other or MD < education, clinical services, medication safety

Introduction

The marked underreporting by health centers professionals does not reflect the true incidence of adverse drug reactions (ADRs), especially fatal ones.[1] It has been found in a meta-analysis study that the frequency of ADRs can occur in 16.88% of patients during hospitalization.[2] However, some authors have reported figures greater than 90% underreporting,[3] mainly due to lack of knowledge of various aspects of pharmacovigilance.[4] The magnitude of underreporting is unknown or highly variable among countries, even in established pharmacovigilance centers, in the World Health Organization (WHO) International Pharmacovigilance Program countries receive 200 to more ADR reports per million population annually.[5] Adequate spontaneous reporting allows the generation of safety alerts, quality information, signal detection, among others.[6] Consequently, addressing underreporting should be the task of all centers where pharmacovigilance is performed, identifying problems and applying strategies to improve attitudes and behaviors of health professionals.[7,8] Hospital pharmacists with clinical experience can contribute to this change, to make significant achievements.[9]

The increase in clinical pharmacy services worldwide,[10-12] especially those that are integrated into the health system and have a variety of clinical decision support tools, help to achieve safe and effective pharmacotherapy.[12-15] Supporting therapeutic safety through active pharmacovigilance improves the quality of ADR reporting.[16] In many countries, the comprehensive training of pharmacists under the

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residency program provides the necessary competencies for their integration into the health system, allowing the development of their role in the pharmacovigilance system; it has even been shown that clinical pharmacists provide integrated care that can improve the quality of pharmacological treatment.[17-19]

In Peru, according to the General Health Law (1997), reporting of ADRs by health professionals is mandatory. According to the Dirección General de Medicamentos, Insumos y Drogas (DIGEMID), in 2020, it has obtained a total of 8200 reports, which would represent a rate of 251 notifications per million inhabitants in a year. Likewise, in the period 2018 to 2020, 24 771 suspected adverse drug reactions (SADRs) were reported by health professionals, 62% of which were spontaneous, with pharmacists reporting the most (38.3%), followed by physicians (18.2%) and nurses (17.5%); 5% of all notifications were serious.[20] At the National Hospital of the National Police of Peru "*Luis N. Sáenz*," since 2004, physicians have been reporting ADRS through interconsultations to the Clinical Pharmacy Service and the clinical pharmacists perform pharmacotherapeutic follow-up (PF) by providing information on the drugs involved in order to achieve a good evolution of the condition. However, since under-notification was still observed, it was proposed to evaluate the inclusion of in-service training (IST) for physicians and nurses as part of the role of the clinical pharmacist, to increase reporting to improve drug safety for the benefit of the patient.

The objective of this study was to analyze the impact of the role of the clinical pharmacist in increasing the reporting of SADRs, reported through interconsultations by physicians after implementing IST, as well as to observe the characteristics of ADRs reported by the clinical pharmacist to DIGEMID before and after IST.

Methodology

The study design was longitudinal, reports of suspected SADRs notifications made by physicians through interconsultations were evaluated during 36 months (January 2017 to June 2018 and July 2018 to December 2019), before and after the in-service trainings (IST). These periods were compared considering that the training was delivered from July to September 2018 and replicated from April to June 2019. The IST were delivered in 2 stages due to the high turnover of professionals in this health facility.

Setting

The study was conducted at the National Hospital of the National Police in Peru *"Luís N. Sáenz*" (HNPNP) by the Clinical Pharmacy Service, a national reference, recognized by the DIGEMID as a clinical training center for pharmacists; it was also accredited as a teaching center for the Second Specialty Program in Clinical Pharmacy. The hospital is a third level care, with a capacity of 500 beds, located in the city of Lima-Peru. The Clinical Pharmacy Service—Pharmacy Department, is part of the health system according to technical standards approved by RM N°546-2011-MINSA and RM N°862-2015-MINSA. The HNPNP was selected because it was one of the health facilities with the highest number of ADR reports to DIGEMID within the Institutional Reference Center of the National Police of Perú (CRI-PNP), and the services of the Medicine Division for presenting the highest number of cases of SADRs.

It should be noted that at the time of the study, clinical pharmacists carried out PF, Drug Information and Pharmacovigilance (PV) activities; they were also responsible for identifying, monitoring, evaluating and reporting ADRs to DIGEMID.

Population

The sample size and type of sampling was by convenience. We studied the interconsultations registered in the clinical pharmacy service by physicians of the Division of Medicine services (inpatient or outpatient). In addition, the reports of ADRs related to interconsultations that were sent to DIGEMID were obtained from the file of the Clinical Pharmacy service. In both cases, data were obtained before and after the IST.

In-Service Training (IST)

It was coordinated with the heads of each department to schedule training sessions for medical professionals and nurses. Training was provided in 11 Medical Services: Internal Medicine, Pneumology, Endocrinology, Oncology, Neurology, Nephrology, Mental Health, Dermatology, Immunology and Allergy, Rheumatology, and Gastroenterology. These ISTs were scheduled as part of the mandatory academic meetings in service and were attended by all physicians, not including those absent for justified reasons; the nursing group was convened by its chief of staff.

As a previous activity to propose the IST, a diagnosis of attitudes and knowledge was made by applying a questionnaire to the physicians (n = 101) and nurses (n = 76) of the Department of Medicine, obtaining that the lack of notification of SADRs was due to: not knowing who to inform (15.3%), insufficient clinical knowledge (13.2%) and lack of certainty regarding the suspect drug (11.8%). These aspects were emphasized in the IST (Table 1).

The IST is comprised 5 topics: (I) Pharmacovigilance concepts and classification of ADR according to WHO-ART; (II) History of international and national PV; (III) Specific legal norms to the country; (IV) Safety alerts published by DIGEMID, mentioning high sanitary surveillance of the country and the importance of voluntary reports; (V) Topic V was individualized for physicians and nurses. The IST for each medical specialty contained the characterization of ADRs

Table 1. Reasons for Not Reporting SADRs.

	Total	Nurse	Physician	*P*-value
Question	n = 177(%)	n = 76(%)	n = 101(%)	
Reasons				
In your opinion, what is the reason for not reporting ADRs? (You may select more than one option)				
Don't know whom to report	44 (15.3)	9 (7.8)	35 (20.2)	.005
A busy schedule	43 (14.9)	20 (17.4)	23 (13.3)	
Insufficient clinical knowledge	38 (13.2)	20 (17.4)	18 (10.4)	
Difficult to identify the suspected drug substance	34 (11.8)	14 (12.2)	20 (11.6)	
The health care professional should collect data and publish them himself/herself	32 (11.1)	15 (13.0)	17 (9.8)	
Lack of incentives	21 (7.3)	3 (2.6)	18 (10.4)	
Difficult to admit harm to the patient	16 (5.6)	7 (6.1)	9 (5.2)	
Reporting has no influence on treatment regimens	14 (4.9)	2 (1.7)	12 (6.9)	
Only safe drug products are available on the market	13 (4.5)	7 (6.1)	6 (3.5)	
The ADR is well known	7 (2.4)	6 (5.2)	1 (0.6)	
Reporting may indicate ignorance	6 (2.1)	3 (2.6)	3 (1.7)	
Other	13 (4.5)	6 (5.2)	7 (4.1)	
Did not answer	7 (2.4)	3 (2.6)	4 (2.3)	

obtained from the Clinical Pharmacy data registry, which included the frequency of ADRs according to their severity, causality, organs and systems (eg,, for dermatology: skin and appendages disorders; for gastroenterology: gastrointestinal system disorders, among others), In addition, the drugs with the highest percentage of ADRs were described using Anatomical, Therapeutic and Chemical (ATC) classification and historical experiences of clinical cases of serious ADRs occurring in the hospital were added. The IST for nurses considered administration errors, incompatibilities, infusion speed, while promoting attitudes of responsibility and the need for reporting. The IST was developed by the principal investigator.

The Role of the Clinical Pharmacist in Pharmacovigilance

Attention of Interconsultations: After receiving an interconsultation to the Clinical Pharmacy service on SADR, prepared by the physicians of the hospitalization or outpatient services, the clinical pharmacist developed pharmacotherapeutic follow-up, constantly monitored the patient, maintained fluid communication with the health team in written form (clinical history, case analysis report) and verbally (interviews), and provided suggestions. Interconsultation to clinical pharmacy is defined as the consultation made by a health professional to the clinical pharmacist to provide complementary care related to the rational and safe use of medicines in hospitalized or ambulatory patients.

Pharmacotherapeutic Follow-up (PF): The clinical pharmacist, in order to achieve a complete analysis of the clinical case, performed PF to the patient: (I) Recorded health data, pharmacotherapy and other data useful for PF in appropriate formats; (II) Analyzed the case, supported by a search for evidence-based information in Dynamed, Micromedex, Drug.com, high surveillance regulatory agencies; in addition, to strengthen the pharmaceutical intervention, he performed searches under the PICO (Patient, Intervention, Comparison, Outcome) strategy to find articles related to the clinical case, using search engines: PubMed, Trip database, Scopus, Science Direct. (III) The pharmaceutical interventions were also recorded in the patient's clinical history under the SOAP (Subjective, Objective, Assessment, Plan) modality as a response to the interconsultations.

Reporting of ADR to DIGEMID: After performing PF, clinical pharmacists obtained data on the patient's clinical evolution (therapies, analytical, diagnostic tests) that allowed SADRs to be evaluated for reporting to the DIGEMID, in accordance with the provisions of NTS 123-MINSA/DIGEMID-V.01 "Technical health standard regulating pharmacovigilance and technovigilance activities for pharmaceuticals and medical devices" (RM N°539-2016-MINSA). The reports were made through e-Reporting, an On-line reporting medium of the World Health Organization-Uppsala Monitoring Center (WHO-UMC). To assess causality and severity they used the Karch and Lasagna algorithm, modified according to CENAFyT guidelines, while the type of ADR was classified according to Edwards and Aronson.[21]

The production of clinical pharmacists was recorded in the "Health Information Sheets," where all processes related to patient care were included: Interconsultations, PF, PV. The record was made using Current Procedural Terminology (CPT) codes, according to the health sector catalog.

https://www.gob.pe/institucion/minsa/normas-legales/188312-902-2017-minsa.

Figure 1 describes the functions of the Clinical Pharmacist in terms of his/her role in pharmacovigilance regarding to medical Interconsultations and includes the proposed IST with the objective of reducing underreporting.

Data Analysis

All data were tabulated and analyzed using the Stata v14 statistical package. Categorical variables were expressed as frequencies and percentages. The knowledge score was calculated as the sum of the correct answers, the absolute and relative frequencies were determined. Pearson's chi-square test was used to evaluate differences between groups for categorical variables. A *P*-value of significance less than .05 was considered statistically significant.

Ethical Considerations

The study was approved by the HNPNP Ethics Committee. The confidentiality of the participants' data was always maintained.

Results

During and after the IST, a total of 102 interconsultations were obtained from all the trained services, of which 75 were SADRs. Clinical pharmacists performed PF on 100% of the patients from the interconsultations, obtaining data on clinical evolution (therapies, analytical, diagnostic tests) useful for evaluating SADRs and reporting to DIGEMID through e-Reporting. Prior to IST only 38 interconsultations were received, of which 32 were SADRs to which PF were also performed. The reports of the SADRs were made in physical formats obtained from the DIGEMID web page.

Comparing the 38 versus 102 interconsultations before and after the IST, an increase of 168.4% was observed, 32 (84.2%) of the previous and 75 (73.5%) of the subsequent ones were SADRs (Figure 2).

The interconsultations made by Internal Medicine and Pneumology physicians remained in the same proportion before and after the IST, while other services that before the IST had not reported SADRs began to report SADRs: Endocrinology, Dermatology, Mental Health, Neurology and Allergy (Table 2).

Regarding causality, before the IST more than 50% were certain ADRs, after the IST there was a predominance of possible and probable ADRs (61.3%), with the highest increase (+25.7%) in possible ADRs; the distribution of the causality of ADRs was statistically significant ($P=.001$). Observing the severity, mild ADRs had the highest increase (+18.6%); the distribution of severity of ADRs was not statistically significant ($P=.067$). Regarding the type of ADRs, those in group C started to be reported after IST, being

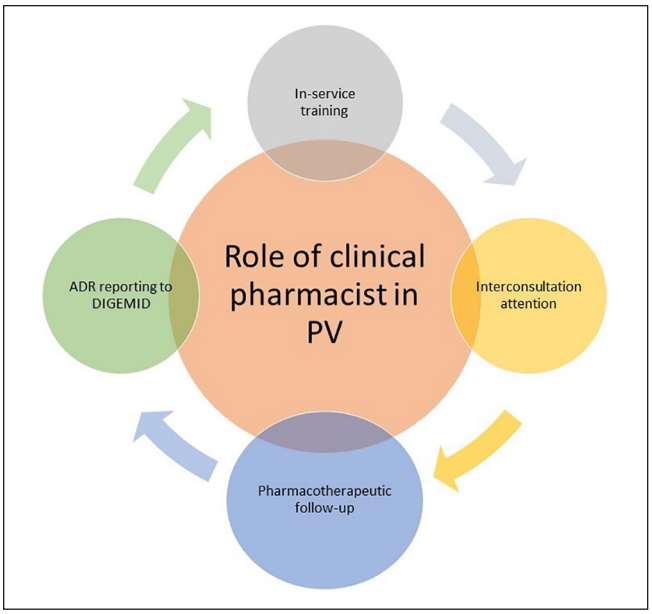

Figure 1. Role of the clinical pharmacist in pharmacovigilance including training of the health care team.

reported for mometasone (oral candidiasis), methotrexate (drug-induce dermatitis), pyrazinamide (erythema multiforme), bortezomib (neuropathic pain), tramadol (leukocytoclastic vasculitis), among others; in addition, a reduction was observed in the report of type B ADRs (−23.7%); the distribution of the type of ADR was statistically significant ($P=.009$) (Table 3).

Serious SADRs reported increased from 4 to 12. Among the most relevant were Neurological disorders (altered state of consciousness due to the use of Imipenem/cilastatin) and Application site disorders (gangrenous cellulitis due to the use of alteplase), the latter were reported by a physician during training; this was a patient who required 10 days of hospitalization including shock trauma and ICU (Table 4).

For the classification of ADRs according to organs and systems affected, World Health Organization-Adverse Reaction Terminology (WHO-ART) was used (Figure 3), and the SOC groups of ADRs reported before and after IST were compared. In general, reports regarding Skin and appendage disorders were the most frequent, although it was observed that after the IST there was an increase in ADRs related to the following groups:

Gastrointestinal system disorders, Neurological disorders and Hepatobiliary disorders, Musculoskeletal disorders, Platelet, bleeding, and clotting disorders, Metabolism and nutrition disorders.

According to the ATC classification, The drugs that caused the greatest number of ADRs were systemic ant infectives (J), including antibiotics. After the IST, the number of reports of reactions related to group A drugs increased and, in addition, ADRs associated with group B, C, D, and R

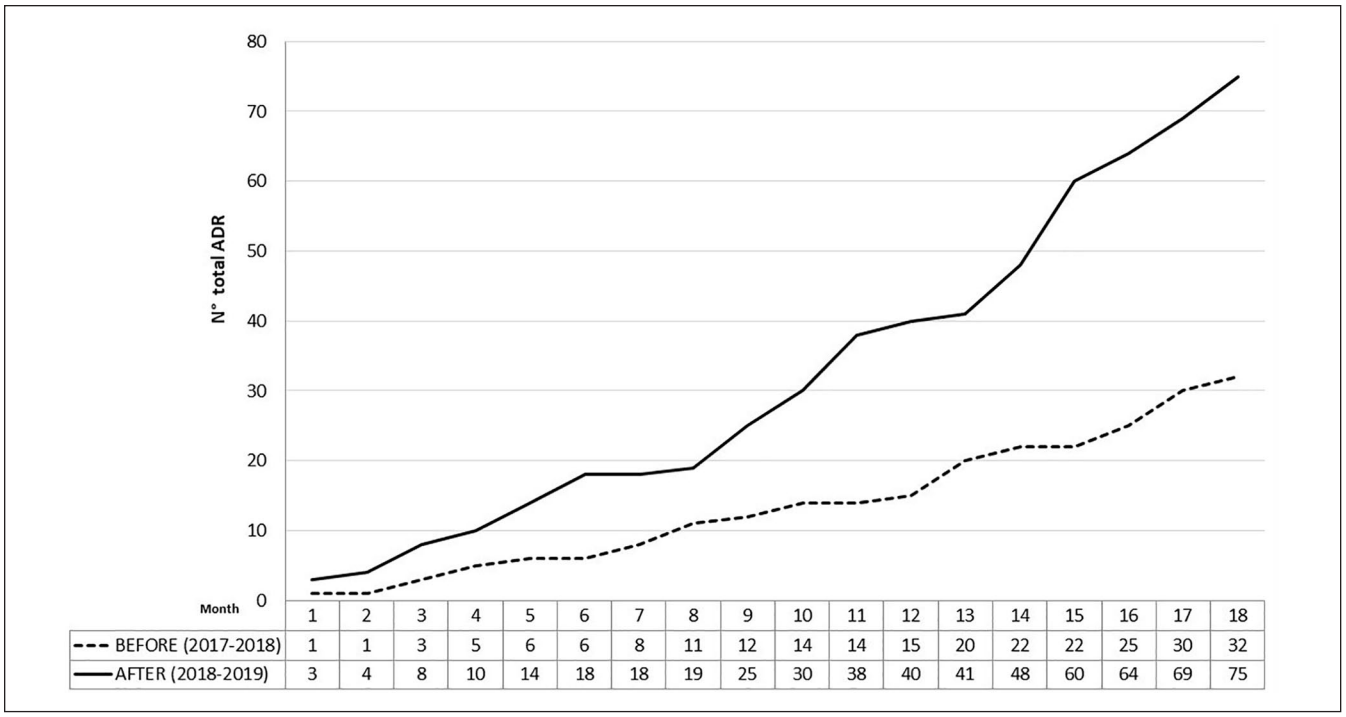

Figure 2. Interconsultations generated by physicians to clinical pharmacists of the clinical pharmacy service during the period 2017 to 2019 (+168, 4%).

Table 2. Medical Services that Reported SADR Before and After the Training to the Health Care Team.

	Before (n = 32)		After (n = 75)	
Service	n	100.0%	n	100.0%
Internal medicine	15	46.9	34	45.3
Pneumology	6	18.8	14	18.7
Endocrinology	0	0	10	13.3
Oncology	3	9.4	5	6.7
Neurology	0	0	2	2.7
Nephrology	2	6.3	2	2.7
Mental health	0	0	1	1.3
Dermatology	0	0	1	1.3
Immunology and allergies	0	0	1	1.3
Rheumatology	3	9.4	0	0
Others	3	9.4	5	6.7

Table 3. Characterization of ADRs from Interconsultations Before and After In-Service Training.

		Before	After	
Interconsultations related to ADR		n = 32	n = 75	*P*-value
Causality	Conditional	3 (9.3%)	14 (18.7%)	.001*
	Possible	2 (6.3%)	24 (32%)	
	Probable	10 (31.3%)	22 (29.3%)	
	Definite	17 (53.1%)	15 (20%)	
Severity	Mild	3 (9,4%)	21 (28%)	.067**
	Moderate	25 (78.1%)	42 (56%)	
	Severe	4 (12.5%)	12 (16%)	
Type of ADR	A	18 (56.3%)	50 (66.7%)	.009*
	B	14 (43.7%)	15 (20%)	
	C	0	10 (13.3%)	

Note. *P*-value: Chi-square.
*$P < .05$.
** $P < 0.1$.

drugs which previously went unnoticed, began to be reported (Figure 4).

Discussion

This study developed from a Clinical Pharmacy Service showed that after IST, medical interconsultations increased approximately 3 times; these were not only related to SADRs but also to drug-drug interactions, changes in therapy and dose adjustment. The growing concern about underreporting of SADRs, recognized in several studies,[22] calls for multidisciplinary management. The integration of clinical pharmacy services into the health care system has allowed its evolution worldwide.[10]

Table 4. Severe ADRs Observed Before and After In-Service Training.

Severe ADR			
Before		After	
Drug	ADR	Drug	ADR
Phenytoin	Steven Johnson Syndrome	Imipenem + cilastatin	Altered state of consciousness
Iopamidol	Acute renal failure	Alteplase	Gangrenous Cellulitis
Vancomycin	Allergic reaction	Cefazolin	Skin rash
Rifampicin	Dress	Ethambutol	Dress
		Pyrazinamide	Erythema multiforme
		Imipenem + cilastatin	Convulsions
		Isoniazid	Elevation de of hepatic enzymes
		Pyrazinamide	Elevation de of hepatic enzymes
		Vancomicyn	Decreased creatinine clearance
		Oxacillin	Skin rash
		Ertapenem	Neurotoxicity
		Gentamicin	Dress

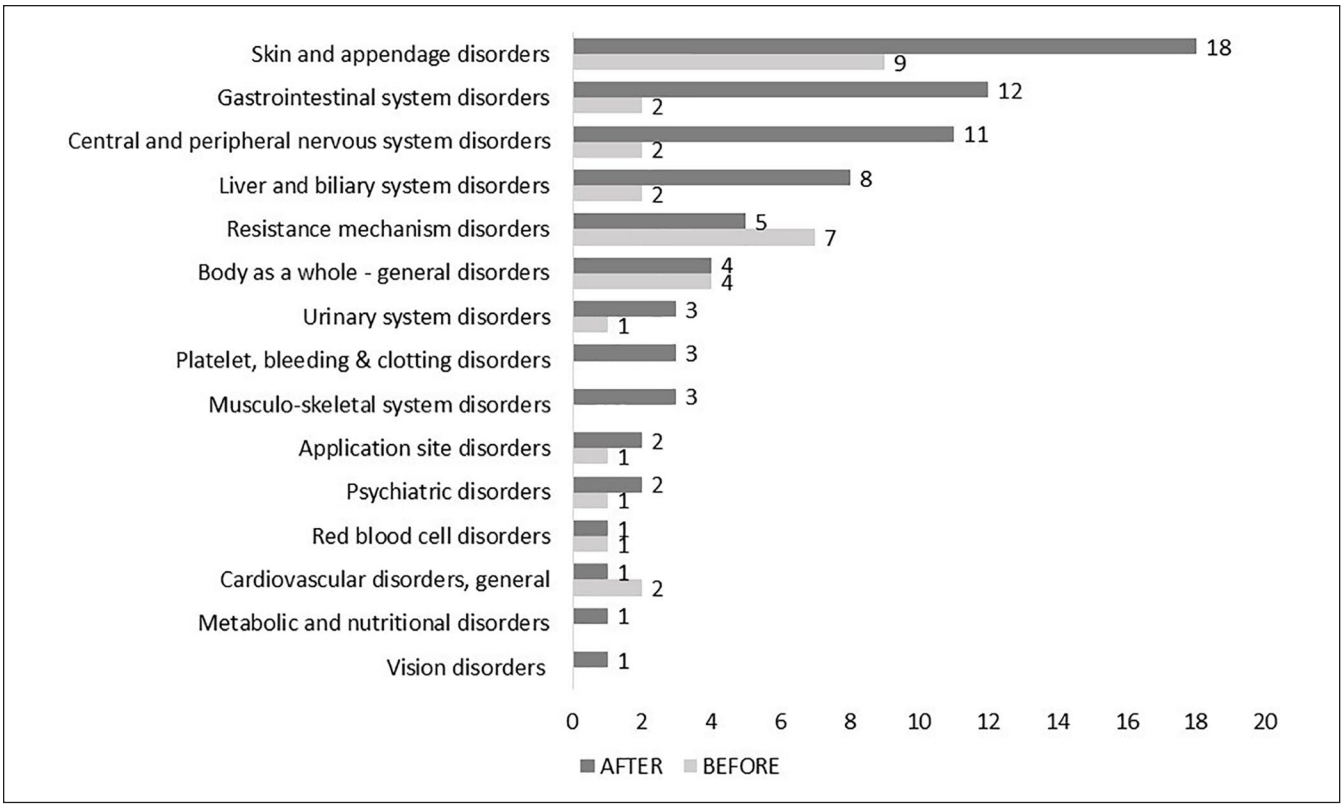

Figure 3. Reporting of ADR by organs and systems according to the WHO-ART classification before and after training of the health care team.

The results of our study showed that in all cases the clinical pharmacist was present for the absolution of interconsultations through the PF. A review study describes the same trend regarding pharmacist involvement in patient follow-up and prevention of ADRs,[17] and another study shows clinical pharmacist involvement in active follow-up and interaction with physicians, related to the treatment of ADRs to obtain complete information.[18] Previous studies report that pharmacists play an important role in drug safety, as experts in pharmacotherapy interacting in multidisciplinary healthcare teams.[19,23] The existence of an exclusive hospital pharmacovigilance service has been proposed.[24]

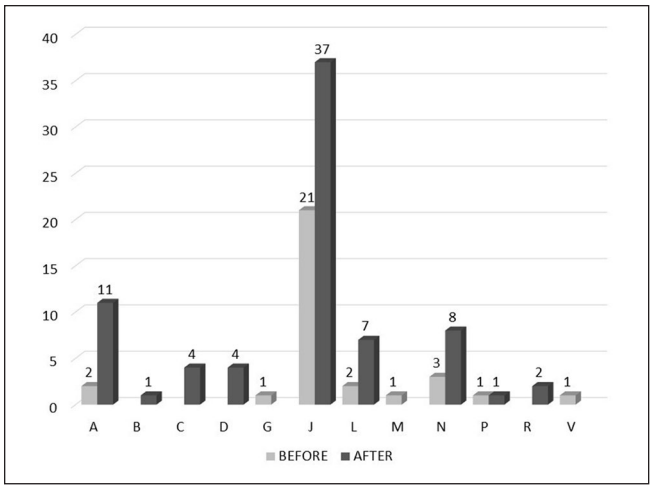

Figure 4. Distribution of drugs causing ADRs according to the anatomical, therapeutic, and chemical (ATC) classification system. A = alimentary tract and metabolism; B = blood and blood-forming organs; C = cardiovascular system; D = dermatological; G = genitourinary system and sex hormones; J = general anti-infectives for systemic use; L = antineoplastic and immunomodulating agents; M = musculo-skeletal system; N = nervous system; P = Antiparasitic products, insecticides, and repellents; R = respiratory system, and V = various.

Another important result was observed related to the medical interconsultations corresponding to SADRs, which represented more than double the number before IST (32 vs 75). This, added to the usual role of the clinical pharmacist in the PF and all the functions involved in this activity, has allowed physicians and nurses to understand the work carried out in the clinical pharmacy and, in turn, motivates them to report the SADRs observed in their patients. However, underreporting still persists, if we take as a reference a meta-analysis study, where they found that the frequency of ADRs in hospitalized patients reached 16%,[2] which implies that more than 300 ADRs should be reported per year. Another study shows that educational intervention increases ADR reporting by 65.4% in the 8 months following the intervention,[8] almost similar to our results.

For this study, SADR communications made through interconsultations represented a form of SADR notification, where the percentage of interconsultations made by Internal medicine physicians before and after the IST was maintained over time, this could be due to the close interrelation between this service and the clinical pharmacy service, since there were clinical pharmacy residents, which did not occur with other hospital services where the residents had sporadic rotations. In contrast, the percentage of interconsultations in Pneumology was maintained, this would be due to the fact that SADRs are due to the use of antituberculosis drugs that lead to hospitalization of the patient, in many severe cases, constant follow-up by the clinical pharmacist is required. Other services that had not yet reported SADRs: Endocrinology, Dermatology, Mental Health, Neurology and Allergy, made notifications after receiving the IST.

Our study also measured the characterization of ADRs reported by clinical pharmacists to DIGEMID by causality, severity and type. Regarding causality, we found that these improved ($P = .001$), since before it were more than half certain, while after the IST others such as possible and probable predominated, which means that before the IST physicians had to be sure of the causal relationship to make interconsultations. Likewise, in terms of severity before the IST, mild ADRs were reported in higher percentage, while after the training severe ADRs increased up to 3 times more than what was found before the IST, despite the belief of the supposed legal problem that reporting could entail. In relation to the type of ADR, our study observed an increase in the reporting of type A. These types of ADRs are predictable. That is, they are expected or common reactions, which makes there is a greater predisposition to report expected ADRs. Other studies also report that this reporting attitude improves after IST.[4,17] In an Iranian investigation of clinical pharmacist intervention, physicians and nurses had a more predisposed attitude to report SADRs, regardless of severity, frequency and previous documentation ($P < .005$).[25]

The most frequent ADRs according to the organs and affected systems, before and after IST, were Skin and appendage disorders, which could be attributed to anti-infectives of systemic use, with antibiotics being the most reported drugs, corroborating what was reported by Alsalimy et al[19] In the present study, this was due to the fact that most of the reports came from Internal medicine. Additionally, we observed other drug groups that were not previously reported such as groups B (Blood and blood-forming organs), C (Cardiovascular system), D (Dermatological), R (Respiratory system) of the Anatomical Therapeutic Chemical, ATC classification.

Implementing the IST to the functions of the clinical pharmacist who works within a clinical pharmacy service does not increase costs, does not require staff expenses, brings the benefit of reducing underreporting and, if included in multidisciplinary rounds, achieves significant interventions and opportune that propitiate a potential saving in resources.[11,26] It would also be convenient to consider the use of Clinical Decision Support Systems (CDSS) as an assistance resource already validated for this task. Pharmaceutical interventions by telephone with the help of CDSS were carried out in the Netherlands and were accepted by physicians, especially for clinically relevant problems and those related to treatments started during admission.[13] Clinical pharmacists in France optimized the standardized pharmacological treatment of the alerts reported by the CDSS.[14]

The results also showed that the IST should be personalized according to the medical specialty. The experience of several authors[7,8,27-29] indicate that the use of clinical cases that occurred in the center where the training is given is a valuable resource. In the present study, historical data from 2 recent years were included, which were of great support in showing the magnitude of the problem and raising staff awareness. The knowledge imparted, such as classification

of ADR according to WHO-ART, the country's own legal regulations, and alerts from high surveillance countries, have also been addressed in other studies.[7,30] In contrast to other studies that point out that professionals should be trained in the completion of ADR reporting forms.[7,27]

From the experience of other authors, it is considered that after IST, it may be necessary to implement a sustained strategy to reinforce the habit of reporting SADRs and ADRs. Biagi et al[31] resorted to e-mails to provide drug safety guidance and raise awareness of the importance of reporting but were only successful as long as messaging was maintained, while Potlog Shchory et al[29] during their multicenter intervention study increased reporting by 74-fold using posters, lectures, distance learning and reminders, however, this decreased over time.

It has been demonstrated that the implementation and maintenance of a continuous intervention program by a member of the pharmacovigilance specialist staff improves the rates of ADR reporting,[29] which is why the present study proposes to include IST in the role of the clinical pharmacist, so that its scope can be sustained over time and allow the problem to be successfully addressed. This would be in line with the new competency profile of the Peruvian pharmacist recently published by a Ministerial Resolution-316-2022-from the Ministry of Health. Finally, this study provides an alternative to increase the reporting of SADR by professionals and the development of pharmacovigilance through a multidisciplinary team in the interest of safety in the use of drugs in patients. These results led the clinical pharmacy service to include the IST in its procedure, once a year, to medical specialties. However, further studies will be necessary to demonstrate its sustainability over time.

Limitations

One of the limitations of the study was not knowing the change in the knowledge, attitudes, and perceptions of the professionals after the training, because there was no subsequent survey due to the high staff turnover in this hospital; only communications through interconsultations were considered.

Due to variability in the design, it was difficult to compare this research with other interventions that sought to decrease underreporting of SADRs by physicians. No studies have been found that report on communication of SADRs through consultations; we only had reference to those carried out by SADR notification sheets and perceptions on the notification practice through surveys.

Sustainability over time was not possible to measure due to the sudden change in the global health situation with the advent of the COVID-19 pandemic.

Conclusion

The reporting of SADRs augmented, significantly increasing the number of medical interconsultations to notify SADRs, by incorporating IST to the functions of the clinical pharmacist. This allowed for timely pharmacotherapeutic follow-up with added clinical value, aimed at evaluating the ADR and making the respective report to the DIGEMID. Also, a greater number of serious ADRs were reported. It is necessary to continue researching on preventable adverse effects with interventions by the clinical pharmacist that may arise when monitoring and pharmacotherapeutic follow-up are performed.

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