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ORIGINAL ARTICLE

Knowledge, Attitudes, Practices and Barriers regarding pharmaco-vigilance among Healthcare Professionals: a cross-sectional study at EHU Oran, Algeria

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ABSTRACT

Objective: Adverse drug reactions (ADR) are a major public health issue, emphasizing the need for effective pharmacovigilance practices. This study aims to assess healthcare professionals' knowledge, attitudes, and practices (KAP) regarding ADR reporting and to identify barriers to effective reporting. **Methods**: This cross-sectional study was conducted at the University Hospital of Oran, Algeria, involving healthcare professionals with direct contact. A validated questionnaire was used to collect data on socio-professional characteristics, KAP and barriers related to ADR reporting. Statistical analysis was performed with a 5% significance level. **Results**: A total of 139 healthcare professionals participated (34.75% response rate). While 90% claimed to know the ADR definition, only 68% were correct, and 58% identified pharmacovigilance correctly, despite 81% claiming knowledge. Pharmacists demonstrated higher knowledge compared to doctors and paramedics ($p < 0.05$). Only 29.5% found their pharmacovigilance training sufficient, although 78.4% expressed interest in further training. Although 88.9% recognized the pharmacovigilance service, only 14.4% were aware of reporting documents. Electronic reporting was preferred by 56.8%. The main barrier was uncertainty about drug-ADR causality (56.8%). **Conclusion**: The study highlights gaps in KAP related to pharmacovigilance. Enhancing awareness, addressing barriers, and providing targeted training can improve ADR reporting and strengthen pharmacovigilance systems.

Keywords: Pharmacovigilance; adverse drug reactions; healthcare professionals, hospital.

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1. INTRODUCTION

Drug therapy is a key component of medical management, offering many benefits alongside significant disadvantages like adverse drug reactions (ADRs). The World Health Organization defines ADRs as harmful, unintended reactions to medicines that occur at doses normally used for treatment. These reactions can result from factors such as medication errors and off-label prescribing, posing a serious public health concern due to their association with increased morbidity and mortality [1,2]. Despite extensive research on ADRs, the exact incidence remains uncertain, with studies indicating rates ranging from 6% to 80%, influenced by factors such as population demographics, study settings, and hospital types [3,4]. In Algeria, research on ADR incidence is limited, with only one study addressing hepatotoxicity [5]. Nevertheless, ADRs represent a significant issue, highlighting the need for effective pharmacovigilance (PV) systems to monitor and enhance therapeutic safety [6]. Current PV practices rely heavily on spontaneous ADR reporting, which is the primary source of data. However, underreporting remains a critical concern across all countries, with median underreporting

rates reported as high as 94% [7]. Factors contributing to this underreporting include socio-professional influences, knowledge levels regarding PV, and healthcare professionals' attitudes [8,9]. In Algeria, the extent of underreporting and associated factors is largely unknown. Therefore, this study aims to identify the facilitators and barriers to ADR reporting, ultimately contributing to the development of strategies to improve PV responsiveness and enhance patient safety.

2. MATERIALS AND METHODS

Study design and settings

A cross-sectional, questionnaire-based study was carried out at the Hospital and University Establishment of Oran (HUEO), Algeria. The study was conducted over a two-month period, from January to February 2021.

Study Population

This study included healthcare personnel working across various medical, surgical, and technical departments at HUEO who provided informed consent and were employed at the hospital during the study period. Eligible participants were physicians, pharmacists, and paramedical staff with direct patient contact.

The following groups were excluded: non-medical and non-paramedical staff, such as administrative secretaries, security personnel, and cleaning staff; students and hospital trainees; administrative staff.

Questionnaire development

For data collection, a structured and predefined, anonymous Knowledge, Attitudes, Practices (KAP) paper questionnaire was used. The questionnaire was created by pharmacologists and was validated by epidemiologists at HUEO.

The questionnaire, organized into four main sections, included items covering the following areas: socio-professional characteristics of survey participants, including age, gender, professional status, job positions, departments, and years of practice; assessment of participants' knowledge level, measured by assigning one point for each correct response, which included two yes/no questions and six multiple-choice questions; evaluation of participants' attitudes and actual practices related to reporting ADRs through 11 related questions; investigation of potential barriers to ADR reporting and participants' expectations for improving the reporting process, assessed through six practice-related questions.

The feasibility, relevance, and clarity of the questionnaire were pre-tested on a sample of 10 randomly selected health professionals of the institute, and the final version was adjusted based on pre-test feedback. The questionnaire was distributed directly to healthcare professionals and collected the following day.

A knowledge score was prepared as a guiding tool to assess knowledge, one point for the correct answer and zero for the wrong answer. The sum of all items gives a maximum score of 6. Healthcare professionals were categorized based on their overall knowledge scores using the modified Bloom’s cutoff points as “good knowledge” if a score ranges 80–100% (5–6 points), “moderate knowledge” if a score ranges 50–79% (3–4point), and “poor knowledge” if a score ranges <50% (<3 points) of the maximum score.

Data Analysis

The collected data were entered and analyzed using IBM SPSS Statistics version 23. Quantitative variables were presented as mean ± standard deviation, while qualitative variables were summarized as frequencies and percentages. The Chi-square test was used to evaluate associations between qualitative variables. For quantitative variables, a one-way analysis of variance (ANOVA) was employed to compare means across multiple groups, assuming normal distribution and homogeneity of variances. A significance level of 5% ($p < 0.05$) was used to determine statistical relationships between variables.

3. RESULTS

Sociodemographic characteristics

The demographic details of the healthcare professionals are summarized in Table 1. 400 questionnaires were distributed among the healthcare professionals and 139 responded, achieving a response rate of 34.75%.

Table 1. Socio-professional details of the healthcare professionals (n=139)

		n (%)
Gender	Female	103 (74,1)
	Male	36 (25,9)
Mean age (in years)		33,35 ± 8,79
Age distribution (in years)	20 - 29	51 (36,7)
	30 – 39	44 (31,7)
	40 – 49	12 (8,6)
	50 - 59	7 (5,0)
	60 - 69	3 (2,2)
	NK	22 (15,8)
Professional status	Doctors	63 (45,3)
	Paramedical	61 (43.9)
	Pharmacist	15 (10.8)
Job Positions	General practitioners	5 (3,6)
	Residents	58 (41,7)
	Assistants	6 (4,3)
	Assistant Professors	7 (5)
	Associate Professors or Professors	2 (1,4)
	Registered Nurses	49 (35,3)
	Medical supervisors	7 (5)
	Pharmacy technicians	2 (1,4)
	Others	3 (2,2)
Work experience (in years)	⩽10	89 (64,0)
	11–20	23 (16,5)
	⩾21	7 (5)
	NK	20 (14,4)
Departments	Medical	90 (64,7)
	Surgical	30 (21,6)
	Technical	13 (13,7)

n: number, NK: not known

Knowledge levels about PV and ADR Reporting

In this study, 90% of the sample claimed to know the definition of ADRs; only 68% provided an accurate definition. Similarly, among the 81% of staff who claimed to know the definition of PV, only 58% selected the correct definition. The details on knowledge about PV and ADRs are provided in Table 2.

Table 2. Knowledge related questions and percentage of correct responses

	Knowledge Question	**Correct response [n (%)]**
Q1	What is an adverse effect	95 (68.3)
Q2	What is pharmacovigilance	80 (57.6)
Q3	Which medications should be monitored	86 (61.9)
Q4	Is reporting adverse effects mandatory for healthcare professionals	104 (74.8)
Q5	Who can report adverse effects	17 (12.2)
Q6	What type of adverse effect should be reported	71(51.1)

n: number

Regarding awareness of monitoring obligations, 61.9% of healthcare professionals recognized that all medications require monitoring for ADRs. Additionally, 74.8% understood their duty to report any suspected ADRs. However, only 50.4% of healthcare personnel knew that reporting should include all types of ADRs.

Interestingly, 83% of healthcare personnel were unaware that ADRs could be reported by any individual, regardless of medical background. In contrast, while 89.2% were aware that physicians are responsible for ADR reporting, only 28.1% knew that patients could do so.

Pharmacists exhibited a higher level of knowledge compared to doctors and paramedics. Correlation analysis between healthcare professionals' knowledge and their socio-professional characteristics revealed that only professional status (p = 0.00) and job position (p = 0.021) were significantly associated.

Attitudes towards PV and ADR Reporting

The majority of participants (84.9%) believed that reporting ADRs was necessary, with 82.7% agreeing that it would enhance patient safety. From the perspective of healthcare professionals, only 29.5% considered their PV training during their curriculum to be sufficient. There was also a significant relationship between healthcare professionals' perception of their training and their knowledge level in PV (p = 0.01). The majority of participants (78.4%) expressed a desire to participate in training on PV. There was a link between the desire to participate and factors such as age (p = 0,016), overall knowledge score in PV (p = 0,00), and their opinion on their training in this specialty (p = 0,01). The information on attitudes toward PV and ADR reporting is available in Table 3.Practice towards PV and ADR Reporting.

Table 3. Knowledge score based on professional status.

Knowledge score	Doctors [n (%)]	Paramedical [n (%)]	Pharmacist [n (%)]	Total [n (%)]
Good	23 (36,5)	5 (8,2)	11 (73,3)	39 (28.1)
Moderate	26 (41,3)	21 (34,4)	4 (26,7)	51 (36.7)
Poor	14 (22,2)	35 (57,4)	0	49 (35.2)

n: number

While 17.3% of respondents reported never encountering ADR during their duties, most participants (79.1%, n = 110) observed ADR with varying frequency. The frequency of ADR reported was significantly associated with the healthcare department in which the personnel worked (p = 0.000). The most frequently encountered ADR included drug-induced skin reactions (68%) and gastric disorders (56.3%).

Among the 110 participants who encountered ADRs in their practice, 102 proceeded to report them. Of these, 21 recorded ADRs in the patient's medical file, 24 formally reported them, and 57 did both. When the reporting frequency was below 1.2%, it was considered low.

The results showed that only 18.6% of respondents reported all ADRs they encountered, while 71.6% reported only some, with 51.8% of these ADRs being classified as severe. However, the correlation between the type of ADR reported and knowledge of which ADRs to report was not significant (p = 0.532).

Regarding awareness of PV resources, 73.6% of respondents knew that a PV department existed at HUEO, but only 14.4% were aware that reporting-related documents were available within their department. In 88.9% of cases, the PV Service at HUEO was recognized as the primary contact for ADR reporting (table 4). A significant association was found between awareness of the PV service and actual reporting to it (p = 0.023).

Table 4. Attitude towards PV and ADRs reporting.

Questions		Yes [n (%)]	No [n (%)]	IDK [n (%)]
Q1	Do you think reporting an adverse drug reaction is necessary?	118 (84,9)	2(1,4)	19 (13,7)
Q2	Do you think reporting adverse effects increases patient safety?	115 (82,7)	1(0,7)	23 (16,6)
Q3	Do you think your training on reporting adverse effects was sufficient?	41 (29,5)	49 (35,3)	49 (35,2)
Q4	Would you be interested in participating in a training day on pharmacovigilance?	109 (78,4)	6(4,3)	24 (17,3)

IDK: I don’t know. n: number. The percentage exceeded 100% for the multiple-choice questions.

Barriers to ADR reporting and pathways for improvement

The primary reason for not reporting ADRs was uncertainty about the link between the ADR and the specific drug, cited by 56.8% of respondents. The second most common reason, identified by 41.7% of participants, was a lack of knowledge about reporting procedures. Figure 1 offers a detailed visual representation of these barriers to reporting.

More than half of respondents (56.8%) expressed a preference for electronic reporting methods. However, cross-analysis revealed no significant association between the preference for electronic tools and the gender (p = 0.779), age (p = 0.181), professional role (p = 0.158), or rank (p = 0.105) of healthcare professionals. An overview of expectations and feedback for improvement in PV can be found in Table 5.

Figure 1. Reasons for Non-Reporting by Healthcare Professionals (n=139).

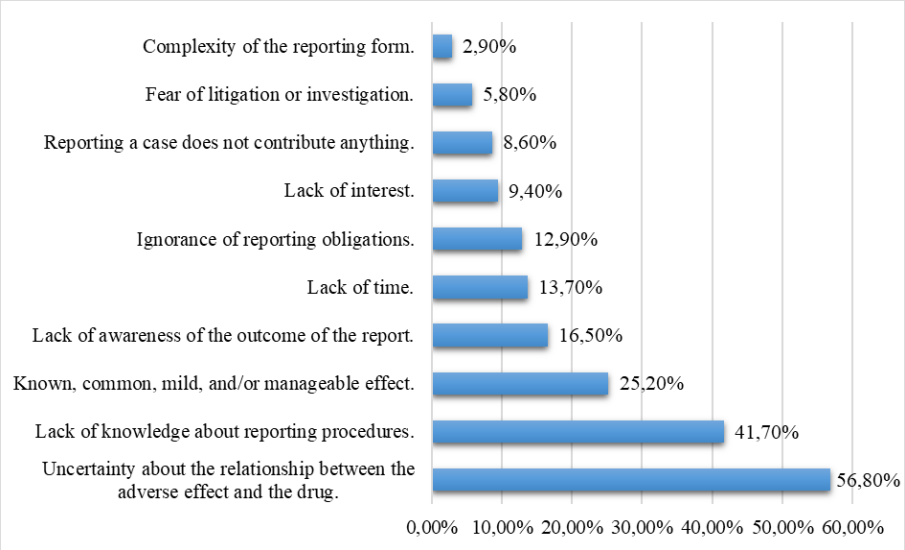

Table 5. Expectations and Feedback for Improvement in Pharmacovigilance.

		n (%)
Preferred reporting methods	Electronic Reporting (software, application)	79 (56,80)
	Reporting by Telephone	44 (31,70)
	Reporting via Simplified Forms	29 (20,90)
	Sending a Representative from the Pharmacovigilance Service	32(23)
Expectations of healthcare professionals after reporting ADRs	Identification of the Drug Involved.	87 (62,60)
	Management of the Adverse Effect.	89 (42,40)
	Withdrawal/Substitution of the Product.	39 (28,10)
	Information on the Adverse Effect.	59 (42,40)
	Health Alert.	35 (25,20)
Evaluation of the Pharmacovigilance Service of EHUO	Meets All Your Expectations.	12(8,6)
	Sufficient.	19 (13,7)
	Insufficient.	8(5,8)
	Unclear.	0
	You Did Not Receive a Response.	0
Response time	Quick.	11(7,9)
	Satisfactory.	24 (17,3)
	Long.	5(3,6)

After reporting ADRs, 62.6% of healthcare professionals surveyed hoped for the identification of the drug involved. Among those who reported ADRs, 12 individuals found that the feedback from the PV Service met their expectations, while 11 reported that the response time was quick. The cross-analysis of reporting practices with socio-professional characteristics, knowledge, attitudes toward ADR reporting, and the frequency of ADRs revealed a significant relationship only between reporting practices and the age of participants (p = 0.044).

4. DISCUSSION

ADRs are extremely common, with significant clinical, social, and economic impacts that deserve particular attention. Insufficient mobilization of healthcare professionals in spontaneous ADR reporting is the primary obstacle to an effective PV system. Gupta SK et al. highlighted that healthcare professionals' knowledge and attitudes are key factors influencing ADR reporting practices [10].

Sociodemographic characteristics

Despite the significance of ADR reporting, our study encountered challenges in achieving higher participation rates. With a 34.75% response rate, our study's participation was lower than that of studies such as Adisa R and al. (100%) and Wangge G and al. (92.3%) [11,12], but it was similar to the rate observed in Nahar N and al. (35%) [13] and higher than that in Alshakka M and al. (18%) [14]. In terms of sample size, our study (n=139) had a larger participant than that of some studies, such as those by Adisa R and al. (80 participants) [11], but it was smaller than that in the study by AlShammari TM and al. (336 participants) [15]. This suggests that, although our sample size is modest compared to large-scale studies, it still surpasses several others, providing a reasonable basis for our findings.

The demographic profile of our participants revealed a female predominance (74%), which is consistent with findings from several studies where women showed greater interest in participating in drug safety surveys [16–18]. A large proportion of our participants (68.4%) were young, aged between 20 and 39, a trend that aligns with similar studies conducted by Srinivasan V and al. (2017) [19], and AlShammari TM and al. [15]. Additionally, over half of the participants (64%) had less than ten years of professional experience, which is in line with studies by Alshammari TM and al. (2018), and Alsaleh FM and al. (2017), where early-career healthcare professionals constituted the majority [15,20]. This trend could be attributed to the high number of residents in our study, who made up 41.7% of our participants. Moreover, paramedical staff, primarily nurses (35.3%), represented a significant portion of the sample, which is consistent with findings from Palaian S and al. (51.7%) and Santosh KC and al. (40.5%) [21, 22]. Pharmacists, who have fewer opportunities for direct patient interaction, comprised only 10.8% of our sample, reflecting the findings of Thomas D and Zachariah S in their meta-analysis, which showed that nurses and doctors were the most involved healthcare professionals in ADR detection [9].

Knowledge in Pharmacovigilance

The knowledge of healthcare professionals regarding PV was moderate. This finding aligns with studies conducted in Turkey, Egypt, Ethiopia, and Nepal [23-26]. However, our results did not match those found in studies conducted in Kuwait, Jordan, and Malaysia, where adequate knowledge of PV was observed [20, 27, 28]. This discrepancy could be due to sociodemographic, interprofessional, and cultural variations among healthcare professionals.

According to our findings, pharmacists had the best knowledge of PV, followed by doctors, with paramedical staff showing the lowest level of knowledge. Similar results were observed in studies conducted in Bhutan, Saudi Arabia, Ethiopia, and Niger, where doctors and nurses were found to be less familiar with reporting ADRs compared to pharmacists [29–32]. Pharmacists receive university education and professional training focused on medications [33]. The low level of knowledge on ADRs and PV among paramedical staff was also highlighted in a meta-analysis by Salehi T and al. on nurses' KAP [34]. This may be due to the fact that PV or ADR-related topics are not included in their training programs [11].

In a study conducted by Albadawi TE and al., individuals with a short experience (less than two years) had better knowledge due to the recent completion of their studies [35]. In our case, aside from professional profile, there was no significant correlation between general knowledge and the socio-professional characteristics of participants. The level of knowledge among respondents observed in our study was consistent with findings reported by Datta S and Sengupta S [36].

Most of our participants (89.2%) were aware that doctors are involved in ADR reporting. This finding aligns with the study by Gordhon Y and Padayachee N, where 92% of respondents believed that physicians should be responsible for reporting [18]. In contrast, De Angelis and al. concluded that nurses were not fully aware of their role in ADR reporting [37], a conclusion also supported by Hanafi S and colleagues [38]. Currently, several countries have encouraged ADR reporting by patients. However, only 28.1% of our respondents knew that patients could do so. In this regard, the role of healthcare professionals remains significant and has been the focus of several publications [8].

Attitudes and Practices in PV

Despite modest knowledge, most of our healthcare professionals held a favorable attitude toward ADR reporting, consistent with the majority of healthcare professionals worldwide [39–43]. In this study, 82.7% of respondents believed that ADR reporting would increase patient safety. A similar finding was reported in the Netherlands (90%), India (97.3%), and Pakistan (92%) [44-46]. The importance of PV in medical practice was recognized by 84.9% of our respondents, similar to the majority of participants in the studies by Gupta P and al. and Katakheye VM and al. [47,48].

In evaluating ADR frequency at HUEO, 17.3% of our participants had never encountered an ADR. This aligns with findings from a German study, based on a telephone survey, which reported a similar rate (10.8%) [49]. This could be attributed to the fact that some of our participating departments were biological laboratories or surgical units, where medication use is limited. According to our respondents, common ADRs were typically cutaneous allergic reactions and gastrointestinal discomfort. This is not surprising, as 64.7% of our respondents worked in medical departments, a similar study reported the same results [12].

In our survey, more than two-thirds of healthcare professionals stated having reported ADRs encountered in their practice. This figure was higher than those reported in Nepal, Indonesia, India, and Saudi Arabia, where, respectively, 20.1%, 25%, 10%, and 21.7% claimed to report observed ADRs [22, 12, 50, 51]. However, the reporting frequency among our participants was low (1 to 6 times) relative to their professional experience.

In terms of the nature of ADRs reported, 18.6% of respondents indicated that they reported all ADRs, while 51.8% reported only those deemed serious. Reporting all ADRs remains an ideal in many PV systems. Special attention should be given to ADRs from new drugs, serious adverse reactions, unexpected reactions, and drug interactions that are potentially severe or clinically significant [31].

During the survey, we observed inappropriate reporting, with notifications sent to recipients other than those designated by national regulations (59.2% to colleagues). This finding, consistent with a study conducted among physicians in Bulgaria, could partially explain the underreporting of ADRs [52].

Among our survey participants, 73.6% were aware of the PV service at HUEO. This rate was similar to those reported in studies by Gurmesa LT and Defefo MG (91%) in 2016 and Katekheye VM and al. (92%) in 2017 [25, 48]. In contrast, the rate of unawareness of this system exceeded 60% in other studies [15, 20, 21, 40, 42, 50]. These findings show that knowledge of the PV center varied globally despite its different activities and could have a significant impact on ADR reporting rates, representing a major barrier to reporting. In our case, the existence of a significant relationship between awareness of the service and reporting to it ($p=0.023$) was not sufficient to overcome underreporting.

A study in China concluded that the absence of hospital reporting procedures and the lack of reporting forms discouraged hospital healthcare workers from reporting ADRs [53]. In our case, only 14.4% of participants were aware of the presence of reporting-related documents in their department.

Among the reasons for non-reporting of ADRs, the options “uncertainty of the ADR-drug relationship” (56.8%), “lack of knowledge about reporting procedures” (41.7%), and “manageable, known, mild, or frequent effect” (25.2%) were most commonly selected in our study. This attitude has been noted in the literature, with similar reasons cited, including lack of time, trivialization of the detected effect, complexity of the reporting process, lack of knowledge on what, when, and to whom to report, absence of remuneration, and the belief that ADR reporting was not part of the hospital medical staff’s duties [10, 20-22, 25, 39, 40, 54]. In their study, Alsaleh FM and al. suggested that participants might have felt uncomfortable answering questions due to limited knowledge of PV [20]. All of these factors, if addressed, could contribute to effectively initiating spontaneous reporting.

The practice of reporting can be influenced by various factors, as for socio-professional characteristics, our study revealed a significant relationship only between reporting practice and age. In a systematic literature review, it was indicated that ADR reporting practice was common across all categories of healthcare professionals [55].

Several of our participants claimed to have knowledge of the topic, but their responses were not necessarily accurate or complete. As suggested by Salehi T and colleagues, this may unfortunately impact their practice and lead to underreporting of ADRs. Therefore, it seems necessary to enhance healthcare professionals’ knowledge of the PV system [34].

Assessing healthcare professionals' attitudes toward ADR reporting was important, as attitudes can directly influence ADR reporting practices. In our study, although there was no relationship between healthcare professionals' interest in reporting and their reporting habits, their attitude was encouraging. According to Un Nisa Z and al., healthcare professionals’ positive attitudes should help them overcome obstacles to ADR reporting and view it as a professional duty [46].

Notably, only 29.5% of healthcare workers considered their PV training during their studies sufficient, while 78.4% expressed interest in additional training. These findings highlight the need for increased emphasis on PV in university curricula and suggest implementing a nationwide continuous training program for all healthcare professionals [56,57].

A significant relationship was found between the desire to participate in training, age, general PV knowledge, and opinions on prior training. This may be attributed to the enthusiasm younger professionals have for ADR reporting systems [15].

Participants' opinions and expectations

When asked about the most suitable reporting method, just over half of the participants (56.8%) preferred electronic reporting with a simplified reporting form. This strategy was also the most frequently cited by healthcare professionals in several studies conducted worldwide [10, 20, 25, 40, 50]. In our study, the preference for an electronic tool showed no significant relationship with gender (p=0.779), age (p=0.181), occupation (p=0.158), or rank (p=0.105) among healthcare professionals. These results align with a study from Kuwait, which also showed support for online reporting methods [20].

Regarding expectations following potential ADR reports, 62.6% of the surveyed healthcare professionals hoped for identification of the drug responsible. This can be facilitated with appropriate evaluation tools [36]. Among our participants, 42.4% wanted further information on the reported ADRs, a pursuit that could be beneficial for patients [48].

To assess the PV service's effectiveness, we examined participants' views on feedback received from their reports. Of 39 respondents, 12 felt that the feedback met their expectations, and 11 out of 40 found the response time satisfactory. Low feedback rates in the Iranian pharmacovigilance system may discourage ADR reporting by healthcare professionals. Whereas general feedback to ADR reporters and a positive, active relationship between the healthcare professionals and PV center could stimulate ADR reporting by the healthcare professionals. Sending feedback to healthcare professionals could also improve knowledge and awareness of ADR reporting [58].

Study limitations

The study was limited to a single hospital and involved a small sample size, which may introduce a selection bias. Due to anonymity, it was impossible to follow up with respondents in cases of missing answers. The study is limited to a single hospital (EHU Oran), which restricts the generalizability of the results to the entire Algerian healthcare system. The study relies mainly on bivariate analyses, whereas a multivariate analysis could have better identified independent predictors of adverse event reporting.

5. CONCLUSION

This study highlights significant gaps in PV knowledge and ADR reporting practices among healthcare professionals. While most participants recognized the importance of ADR reporting, many lacked accurate understanding of key concepts, and reporting rates remained low. The primary barriers to reporting included uncertainty about the link between ADRs and specific drugs, as well as insufficient knowledge of reporting procedures. A clear need for more comprehensive PV education was identified, particularly regarding the inclusion of relevant training in healthcare curricula. Furthermore, healthcare professionals expressed a strong interest in additional training, and there was a notable lack of awareness about available PV resources. Addressing these gaps is crucial for improving ADR reporting practices, enhancing patient safety, and ensuring better PV outcomes.

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