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Evaluation of Knowledge, Attitudes, and Perceptions of Pharmacovigilance (PV) amongst Health Professionals and Students

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ABSTRACT

Pharmacovigilance (PV) and drug safety remain important areas of study worldwide. Unfortunately, medical professionals and students generally do not understand the reporting of PVs and adverse drug reactions (ADRs). This study compares student knowledge, attitudes, and perspectives with those of healthcare professionals in the pharmacy, medical, dental, and nursing fields. A questionnaire study was conducted to determine the level of understanding and attitudes toward PV and ADR reporting among 82 healthcare professionals (52 pharmacists, 15 physicians, 10 dentists, and 5 nurses) and 100 undergraduate healthcare students (45 pharmacies, 12 physicians, 35 dentists, and 8 nurses). According to the survey, among medical professionals and students, pharmacists are better educated about pharmacovigilance and adverse drug reactions than physicians, dentists, and nurses. The study found that pharmacists had a more favorable attitude toward pharmacovigilance and ADR reporting than other healthcare professionals. Doctors and medical students ranked second in terms of understanding of pharmacovigilance and the ADR reporting system, followed by dentists and dental students, and nurses and nursing students ranked last. In conclusion, pharmacists and pharmacy students exhibited superior knowledge, attitudes, and views of PV and ADR reporting compared to other healthcare professionals and students. The paper underlines the necessity of integrating pharmacovigilance education into the Libyan healthcare system and school curricula to train staff and educate students for real-world practices and workplaces.

INTRODUCTION

The research and practices related to the identification, evaluation, understanding, and mitigation of side effects and other drug safety issues are referred to as pharmacovigilance. One of the core purposes of pharmacovigilance, which is related to this broad definition, is to prevent harm from adverse reactions in humans that arise from the use of health products inside or outside the parameters of the marketing authorization and in relation to their life cycle (Sabrina Nour, Gilles, 2018). Thus, pharmacovigilance's main goal is to promote the safe and effective use of medical products, especially by rapidly notifying patients, medical professionals, and the general public about the safety of medical products. Thus, pharmacovigilance is an activity that contributes to patient safety and public health protection. Only a few issues that are pertinent to pharmacovigilance-related activities include the assessment of drug-related mortality, medication errors, lack of efficacy reports, off-label usage, acute and chronic poisoning, abuse and misuse of health products,

adverse drug interactions with chemicals, and other issues.

Pharmacovigilance (e.g., imputable methodologies) might use clinical, epidemiological, experimental, or diagnostic approaches (to duplicate a detrimental impact in animals to better understand the mechanism involved for human protection). Pharmacovigilance's ultimate objective is to appropriately assess and maximize a health product's benefit/risk ratio over the course of its entire life cycle. (Gilles and Sabrina Nour. 2018). Following the thalidomide crisis in the early 1960s, which resulted in the deaths of tens of thousands of people and a significant number of disabilities (congenital) in those who used it (Neil et al., 2015), Dr. William McBride developed the idea of PV and the reporting of adverse reactions. Despite the fact that safety and the prevention of potential drug harm have historically been important objectives in drug development, the destruction brought on by such a catastrophe prompted calls from health authorities for a more rigorous approach to the evaluation of potential medication danger. As a result, the World Health Organization (WHO) launched the Programme for International Drug Monitoring (PIDM) in 1968 in Uppsala, Sweden, with the goal of assisting nations all over the world in setting up and maintaining their vigilance systems. Over the years, the PIDM membership has grown, and in 2019 there will be 166 countries participating (136 full members and 30 associate members). Among the 54 African member countries, Morocco and South Africa were the first two to join the IPMD in 1992. Since that time, 24 years ago, the number of African members has increased to 41, made up of 34 full-member countries and seven associate members.

When a medicine or other medical product has been officially approved and put on the market, it is subject to post-marketing surveillance. It is a part of the science of pharmacovigilance, which is concerned with the study, detection, assessment, and prevention of drug-related problems such as side effects, negative consequences, and the absence of positive benefits. The FDA (Food and Drug Administration) issues initial approval for a new drug once phase I, phase II, and phase III investigations are finished. Phase IV studies are therefore frequently used to describe post-marketing monitoring. This is incorrect technically because phase 4 trials can also be well-controlled, randomized experiments, unlike post-marketing surveillance, which is only observational and non-experimental (Vlahovic-Palcevski, 2018). Phase IV clinical trials, also known as post-marketing clinical (PMC) research studies, are carried out after the regulatory body has approved a product for marketing. Before a medicine is put on the market, its safety and effectiveness are evaluated using the data from the Phase IV study. In the pharmaceutical industry, phase IV research is currently a key stage in the product life cycle. If pharmaceutical companies are to respond and offer support in areas like client approvals, business expansion, and marketing, this new area of clinical research is crucial. The capacity to influence a practicable advantage is assessed by analyzing the conclusions for product marketing, expansion, and a cost-benefit advantage post-marketing activities (Viraj Suvarna, 2010).

The term Adverse Drug Reaction (ADR) is widely used in medical literature to refer to a variety of events that are superficially identical but inherently different, including side effects, undesirable reactions and occurrences, medication errors, and adverse drug effects. On the other hand, ADR is hard to define because it has evolved through time. ADRs are defined as "Any response to a medicine that is noxious and undesired and that occurs at levels typically used in humans for prophylaxis, diagnosis, or therapy of disease, or for the alteration of physiological function" (WHO, 1973), which is an outdated definition. ADRs were initially split into two main groups in the 1970s based on the drug's known pharmacology: type A and type B for amplified (dose-related) and inexplicable (non-dose-related), respectively (Luis Carlos López, 2010). In contrast to prevalence, which attempts to evaluate the total population of patients who have been impacted by an ADR occurrence represented as a proportion of the population, the incidence of ADR is primarily concerned with the frequency of occurrence or the number of new instances over a certain time. Due to the variety of research that has looked at the prevalence of reported ADRs and ADEs, it is difficult to report the breadth of ADRs accurately; prevalence has ranged from 0.2% to 54.5% when using hospital admissions as the denominator (Angamo et al., 2016).

The Pharmacovigilance Department was established inside the Pharmacy Department of the Libyan Ministry of Health following approval by the Minister of Health of Resolution No. 448 of 2015. By Resolution No. 418 of 2019, the Pharmacovigilance Department, which established Pharmacovigilance Departments at Hospitals, was established as part of the Global Program for Drug Safety. The Pharmacovigilance Center was given associate membership by Monitoring in 2018. The pharmacovigilance center was ranked 146 internationally and 14 in the Arab world when it received full membership in 2021. The study's objectives include evaluating the knowledge, attitudes, and perspectives of healthcare professionals and students (including pharmacists, doctors, dentists, and nurses) with regard to PV and ADR as well as their practices and experiences in relation to reporting suspected ADRs. Additionally, it attempts to gauge their awareness of PV and ADR as well as their attitudes toward reporting suspected ADRs.

METHODS

Study Sample and Design

The goals of the study include assessing the practices and experiences of healthcare professionals and students with regard to reporting suspected ADRs, as well as their knowledge, attitudes, and perspectives with regard to PV and ADR (including pharmacists, doctors, dentists, and nurses). It also makes an effort to determine their knowledge of PV and ADR as well as their attitudes toward informing others about suspected ADRs.

Questionnaire Development

The questionnaire was developed following a careful review of the literature to look for instruments that already existed. The first version of the questionnaire covered demographics, PV and ADR knowledge, attitude, and reporting perception, as well as PV and ADR actual practice in healthcare colleges.

Data Collection

Through interviews, conversations, and people-watching, data from several private and public colleges was acquired. Using a unique questionnaire, information on PV and ADRs, drug safety, and study-related specifics was acquired.

RESULTS AND DISCUSSION

Healthcare Professionals, Demographic information

82 healthcare professionals in total participated; of these, 63.4% were pharmacists, 18.3% were doctors, 12.2% were dentists, and 0.06% were nurses. Of all healthcare professionals, men made up the majority (54.9%). Table 1 displays a summary of the demographic details.

Table 1. Description of the study sample

Total	Total (%)	Pharmacist (%)	Physicians (%)	Dentists (%)	Nurses (%)
	100	63.4	18.3	12.2	0.06
Gender					
Male	54.9	36.6	11	7.3	0.0
Female	45.1	26.8	7.3	4.9	6.1
Age					
21-30	31.7	19.5	3.7	7.3	1.2
31-40	29.3	15.9	4.9	4.9	3.6
41-50	15.9	11	3.7	0.0	1.2
>50	23.1	17	6.1	0.0	0.0
Educational Qualification					
Bachelors	57.3	32.9	8.5	9.8	6.1
Master	19.5	15.9	3.6	0.0	0.0
PhD	23.2	14.6	6.1	2.4	0.0

Knowledge about Pharmacovigilance and ADRs Reporting

According to the report, only roughly 29% and 48% of medical experts can define PV and its purpose, respectively. Physicians (9.8%), dentists (7.3%), and nurses (1.2%) had the lowest awareness of PV among healthcare professionals, whereas pharmacists (17%) had the highest understanding. Also, compared to other healthcare professionals, a much larger proportion of pharmacists correctly identified Libya's state monitoring organization and vigilance system. Table 2 provides more information about the comparability of healthcare professionals' PV knowledge. Similar to how a higher percentage of pharmacists than other healthcare professionals agreed to have an ADR reporting system in Libya with the recommendation on the availability of a unique form to report the ADR to the PV Center.

Table 2. Health professional knowledge of pharmacovigilance and ADR notification.

No	Q No	% Correct answers				
		Total	Pharmacist	Physicians	Dentists	Nurses
1	Definition of PV	35.4	17	9.8	7.3	1.2
2	The functions of PV	58.5	37.8	11	3.7	6.1
3	PV includes	58.5	37.8	12.2	4.9	3.7
4	Libya vigilance system	50	35.4	9.8	4.9	0
5	Are there legal provisions in the Libyan law that is to PV acts	57.3	30.5	9.8	11	6.1
6	Drugs banned due to ADR	59.8	42.7	11	6.1	0
7	ADR reporting system in Libya	45.1	21.9	9.8	8.5	4.9
8	ADR form	42.7	29.3	9.8	3.7	0
9	Reporting ADR to the PV center	37.8	30.5	3.7	3.7	0
10	keeping records of ADRs	51.2	34.1	9.8	6.1	1.2

Attitude towards Pharmacovigilance and Reporting of DDRs

The majority of healthcare professionals had a positive attitude; 42.7% of them believed it was their responsibility to report adverse drug reactions (ADRs) in hospitals, and 78% of them advocated for the establishment of an ADR monitoring center in each hospital. The majority of medical professionals—82.9%—agree that it is crucial for all doctors to disclose side effects from medications. In comparison to other healthcare professions, pharmacists reported much higher positive sentiments toward PV (Table 3). For instance, 23.2% of pharmacists felt that they had a duty to report adverse drug reactions, compared to 7.3% of physicians, 6% of dentists, and 4.9% of nurses. According to 51.2% of pharmacists, ADR reporting is also necessary for all healthcare professionals, as opposed to 15.9% of doctors, 11% of dentists, and 4.9% of physicians.

Table 3. Healthcare professionals' attitudes toward pharmacovigilance and ADR reporting

No	Q No	% Correct answers				
		Total	Pharmacist	Physicians	Dentists	Nurses
1	The medical staff are in charge of informing hospitals of ADRs	42.7	23.2	7.3	7.3	4.9
2	Should every hospital establish an ADR monitoring center?	78	51.2	12.2	11	3.7
3	Is reporting of ADR necessary	82.9	51.2	15.9	11	4.9

Awareness of Pharmacovigilance and ADR Reporting

The study indicated that 91.5% of healthcare professionals agreed to teach PV in detail to all healthcare professionals and that 95.1% of healthcare professionals thought that undergraduate studies should include instruction on the PV system. According to Table 4, a higher proportion of pharmacists had more favorable opinions about the

value of PV training for both undergraduate students and healthcare professionals.

Table 4. Health practitioners' perceptions of PV and ADR

No	Q No	% Correct answers				
		Total	Pharmacist	Physicians	Dentists	Nurses
1	Including PV in the undergraduate curriculum to create awareness	95.1	58.5	18.3	12.2	6.1
2	The detailed teaching of PV to healthcare practitioners is necessary.	91.5	56.1	17.1	12.2	6.1

Medical Students, Demographics

100 students studying healthcare in total took part; 45% of them were pharmacy students, 12% were medical students, 35% were dentists, and 8% were nurses. Around 16% were enrolled in the fifth semester, 23% in the sixth, 24% in the seventh, 21% in the eighth, and 16% in the ninth. Most were female students (62%). Demographics are summarized in Table 5.

Table 5. Survey sample description.

	Total	Pharmacy	Medicine	Dentistry	Nursing
	%	%	%	%	%
Total	100	45	12	35	8
Gender					
Male	38	17	3	14	4
Female	62	28	9	21	4
Semester study					
5th semester	16	7	3	4	2
6th semester	23	7	4	7	5
7th semester	24	8	3	10	3
8th semester	21	5	1	12	3
9th semester	16	13	1	2	0
Type of College					
Private	60	43	17	0	0
Governmental	40	5	17	10	8

Knowledge about Pharmacovigilance and ADRs Reporting

It was discovered that 29 and 90% of healthcare students, respectively, properly defined PV and ADRs. Around 45% of students supported having a formal form for reporting ADRs. In addition, more pharmacy students than other healthcare workers correctly characterized the PV and ADRs and were aware that an official form for reporting ADRs was available (Table 6).

Table 6. Health student awareness of pharmacovigilance and ADR reporting

No		Total	Pharmacy	Medicine	Dentistry	Nursing
1	have you ever heard of PV	36	22	5	7	2
2	Definition of PV	29	19	5	3	2
3	Definition of ADR	90	46	10	28	6
4	Is there a legal provision in the Medicines Act that talks about photovoltaic activity?	11	2	3	6	0
5	Is there any official ADR declaration form?	45	34	3	8	0

Perception of Pharmacovigilance and ADR Notification

19% of healthcare students, according to the survey, think they are prepared to report negative drug responses. 79% of students said they would be interested in participating in such instruction, and nearly 93% of students stated that knowing about PV and ADR reporting systems is essential for their

studies. Table 7 shows that a significantly higher percentage of pharmacy students think PV education is important and are willing to participate in it.

Table 7. Views on PV and ADR Practice among Medical Students

No		Total	Pharmacy	Medicine	Dentistry	Nursing
1	being sufficiently ready to submit ADRs in your future practice	19	11	1	6	1
2	Education regarding PV and the ADRs reporting system is necessary for medical students.	93	45	8	32	8
3	If given the chance, would you be willing to further instruction in PV and the ADRs reporting system?	79	33	9	31	6

Only 30% of students majoring in healthcare reported they had gotten any kind of PV education, and only 21% believed PV was sufficiently covered in their school's curriculum (Table 8). Current PV and ADRs practice. Only 15% of participants claimed that their college Offered ADR recording training, and only 15% claimed that students could record ADRs while working as clerks. Pharmacy students have more experience reporting adverse drug reactions (ADRs) and have done so in their schools compared to other healthcare students.

Table 8. Current PV and ADR usage by healthcare students

No		Total	Pharmacy	Medicine	Dentistry	Nursing
1	Our faculty curriculum devotes a lot of time to pharmacovigilance.	21	13	6	2	0
2	Students at your college receive training in patient counseling and possible adverse medication reactions	15	8	3	4	0
3	During their clerkship, students in your faculty can complete ADR reporting.	15	8	2	5	
4	Have you already gotten PV education in any way?	30	19	3	7	1

This study was conducted to assess and compare knowledge, attitudes, and perceptions among healthcare professionals and also among healthcare students in the Tripoli region of Libya because it was anticipated that students would receive training and education about PV and ADRs during their final years of study. This survey found that a third of students and nearly half of healthcare professionals are familiar with PV. However, a higher percentage of students (90%) correctly defined ADRS. The hospital's ADR monitoring center advised.

All healthcare providers are required to report adverse drug reactions, and the majority of medical professionals had positive sentiments about the importance of doing so. ADR and PV reporting systems should be included in undergraduate programs, and healthcare professionals should have access to practice programs, according to the majority of healthcare experts. In comparison to other healthcare professionals and students, pharmacists and pharmacy students were shown to have higher knowledge, attitudes, and views related to pharmacovigilance and ADR reporting (medical, dentistry, and nursing students). As was to be expected, as pharmacy students received more instruction and training during their undergraduate degrees, the concept of PV and ADR reporting became increasingly familiar to them. In contrast to Rajiah ET alstudies of pharmacy students in Kuala Lumpur (55.6%) and Alwhaibi ET alstudies of pharmacy students in Saudi Arabia (23.8%), respectively, only 13% of pharmacy students in the current study said their curriculum adequately covered PV. In 2020, Alwhaibi et al. These findings from the current study show that students' understanding of pharmacovigilance is deficient,

and it needs to be included in future college curriculum.

CONCLUSIONS

The study discovered that pharmacists and pharmacy students have a higher comprehension, a more upbeat mood, and a better opinion of PV and ADR reporting when compared to other healthcare professionals and students. To improve PV and ADR reporting, which would raise the standard of healthcare for society, the study strongly advises the inclusion of pharmacovigilance education in undergraduate medical curriculum as well as workplace training for healthcare staff.

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