



Healthcare Professionals' Knowledge, Attitudes and Practices Towards Pharmacovigilance and Adverse Drug Reaction Reporting in Public Hospitals in Lesotho

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Abstract

Background: The success of the global National Pharmacovigilance to monitor adverse drug reactions relies on the health professionals' voluntary reporting of adverse drug reactions. Underreporting of adverse drug reactions by healthcare professionals in public hospitals in Lesotho remains a serious challenge. The study assessed the knowledge, attitudes and practices of healthcare professionals towards pharmacovigilance (PV) and adverse drug reaction reporting (ADRs) in government hospitals in Lesotho.

Methods: A cross-sectional descriptive study was conducted across six government hospitals in the lowlands of Lesotho. Using stratified sampling, 106 KAP questionnaires were distributed between August and November 2023 and January 2024 among available healthcare professionals who were conveniently accessible. Data were analysed descriptively with the inferential statistics performed with the Chi-square test performed to assess the association between categorical data (nominal data) and statistical significance was set at $p < 0.05$. The analysis was conducted using IBM SPSS version 20.

Results: There were 63 healthcare professionals who responded (59.4 % response rate). Participants were predominantly females (58.7%), while males were 41.3%. The predominant age group was 30-39 years (69.8 %). The majority of the HCPs (39.7 %) had more than 10 years of practical experience, and 90.5 % demonstrated awareness about pharmacovigilance (PV). Despite the HCPs showed a generally positive attitude towards adverse drug reaction, 69.8 % ($n = 44$, $p = 0.009$) did not received basic training in ADR reporting, and 46.0% ($n = 29$, $p = 0.514$) encountered an ADR and did not report it. Half of HCPs (52.4%, $n = 33$, $p = 0.048$) did not submitted sufficient ADR reports Moreover, 84.1 % ($n = 53$, $p = 0.038$) expressed willingness to receive more training on ADR reporting.

Conclusion: ADR reporting in six public hospitals in Lesotho remains inadequate despite a higher awareness and positive attitude. Lack of access to ADR reporting forms and training on PV and ADR reporting significantly hinders ADR reporting practices. The findings highlighted significant gap between knowledge and practices which requires intervention to promote ADR reporting.

Recommendation: PV and ADR reporting awareness campaigns and continuous training may address these challenges. Strengthen the dissemination of the ADR reporting tools among the within the health care facilities.

Keywords: *Pharmacovigilance, Adverse Drug reaction, Spontaneous reporting*

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Introduction

The primary concerns for any medication are its safety and efficacy, as these directly influence adherence and patient care [1]. Consequently, Adverse drug reactions (ADRs) and pharmacovigilance (PV) studies

have become prominent and the most important aspects of patient care [1]. The Global Burden of Disease (GBD) data from 1990 to 2021 showed 12.5 million incidence cases of global Adverse Effects of Medical Treatment (AEMT) [2]. In Eastern Sub-Saharan Africa, there were



57.2 per 100,000 cases of AEMT reported between 1990 and 2021 [2]. According to the World Health Organisation (WHO), Pharmacovigilance (PV) is the science and the activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems [3]. Research in hospitals plays a key role in ensuring drug safety and improving patient care [4]; however, healthcare professionals usually have limited knowledge of ADRs or the voluntary reporting system, leading to underreporting [5].

In Lesotho, the pharmacovigilance program is still in its infancy, having been established in 2018, and only a limited number of reports have since been submitted to the national pharmacovigilance centre [6]. Therefore, there is a need to assess the knowledge, attitudes, and practices of health professionals towards pharmacovigilance and ADR reporting in Lesotho public hospitals [6].

Assessment of the knowledge, attitudes, and practices before an educational intervention could help in the development of health policies and strategies to improve reporting of adverse drug reactions in the public sector. This study aimed to assess health professionals' knowledge, attitudes, and practices towards pharmacovigilance and adverse drug reaction reporting in the public sector in Lesotho.

Methodology

The Lesotho Public Health Sector Expenditure Review (PER) 2017 showed that the government has 110 primary healthcare centres and 9 district public hospitals, that is, a public hospital per district, with an average of 288 bed capacity, employing an average of 5 doctors, 12 professional nurses, and 7 pharmacy personnel [7]

Study design and study site

This study was a cross-sectional study conducted in six government hospitals in the lowlands and foothills of Lesotho. These included: Butha-Buthe Hospital, Motebang Hospital, Berea Hospital, Queen Elizabeth II Hospital, Mafeteng Hospital and Ntsekhe

Hospitals, which serve the country's most densely populated districts [7].

Sample size determination

The study population comprised approximately 144 eligible health professionals working in six public hospitals: 30 doctors, 72 professional nurses, and 42 pharmacy personnel (pharmacists and pharmacy technicians). The required sample size was calculated using the calculator.net sample size calculator, with a Type I error of 5%, a 95% confidence level, and a 50% response distribution [8]. This yielded a final sample size of 106 participants. The sample size was allocated proportionately for doctors, professional nurses and pharmacy personnel (pharmacists and pharmacy technicians) in a 5:12:7 ratios.

Sampling criteria

A stratified sampling approach was applied, dividing participants into three strata: doctors, nurses, and pharmacy personnel, in proportion to their representation within the hospitals. Although the intention was stratified random sampling, in practice, questionnaires were distributed conveniently to those present and available during the study period. Of the 106 healthcare professionals approached (22 doctors, 53 nurses, and 31 pharmacy personnel), 15 doctors, 25 nurses, and 23 pharmacy personnel completed the questionnaires, yielding a total of 63 respondents and a response rate of 59.4%.

The survey was conducted between August and November 2023 and in January 2024. All the healthcare professionals working in the selected hospitals who consented to participate were included in the study. Quantitative data were collected using a structured questionnaire adapted from similar studies [9-11]. These ensured that validated questionnaires and methodologies were used to measure the study's objectives, thus ensuring face validity and reliability.

The structured self-administered questionnaire comprised 23 items: Five on demographics, six on knowledge towards PV and ADR reporting, six on attitudes towards PV and ADR reporting and six items on practice towards PV and ADR reporting.



Inclusion and exclusion criteria

All qualified and registered doctors, nurses, pharmacy personnel practising in the selected hospitals and who signed the informed consent to participate in the study were included, while other healthcare professionals, interns and registered doctors, nurses and pharmacy personnel who did not consent to participate were excluded.

Data analysis

The data was collected in the form of a hard copy questionnaire and captured on spreadsheets in Microsoft 365 Excel®. The data were analysed using IBM Statistical Package for Social Sciences (SPSS) version 20 with descriptive statistics and presented as percentages and frequency in tables, while graphs and charts were created with Microsoft 365 Excel®. For the inferential statistics, the Chi-square test was performed on the SPSS version 20 to assess the association between categorical data (nominal data) and statistical significance was set at $p < 0.05$.

Ethical consideration

The study received ethical clearance from the National University of Lesotho Institutional Research Board (IRB) and

Research Ethics Committee in the Ministry of Health, Lesotho (MOH-REC ID 50-2023). Additionally, permission was obtained from the six hospitals. Each participant provided informed consent. Anonymity and confidentiality were preserved using serial numbers.

Results

Based on the sample size, 106 questionnaires were distributed to healthcare professionals (HCPs), and the return rate of questionnaires was 59.4 % ($n = 63$). Physicians contributed 23.8 % ($n = 15$), pharmacy personnel contributed 36.5 % ($n = 23$), and nurses contributed 39.7 % ($n = 25$). There were more females, 58.7% ($n = 37$) than males, 41.3 % ($n = 26$). Additionally, the majority, 69.8 % ($n = 44$) of the HCPs were aged between 30-39, 15.9% ($n = 10$) belonged to the 18-29 age group, 7.9 % ($n = 5$) belonged to the 40-59 age group, and 50 or above years were 6.3 % ($n = 4$). About 39.7 % ($n = 25$) of the HCPs had worked for more than 10 years, 30.2 % ($n = 19$) had worked between 5 and 9 years, and only 6.3% ($n = 4$) had less than 1 year of work experience. (Table 1).

Table 1:
Demographics of the Participants (N = 63)

Category	Sub-category	Frequency N (%)
Healthcare professional type	Physicians	15 (23.8)
	Pharmacy personnel	23 (36.5)
	Nurses	25 (39.7)
Gender	Male	26 (41.3)
	Female	37 (58.7)
Age (years)	18-29	10 (15.9)
	30-39	44 (69.8)
	40-49	5 (7.9)
	50 or above	4 (6.3)
Qualification	MBChB	15 (23.8)
	B-Pharm degree (Honours)	7 (11.1)
	Diploma in Pharmacy Technology	16 (25.4)
	BSc-Nursing degree	10 (15.9)
	Diploma in General Nursing & Midwifery	13 (20.6)
	Others (i.e., Certificates in Nursing)	2 (3.2)
Experience in practice (years)	Less than 1	4 (6.3)
	1-4	15 (23.0)
	5-9	19 (30.2)
	10 or longer	25 (39.7)
Experience in private practice (years)	No	34 (54.0)
	1-2	12 (19.0)
	3-4	10 (15.5)
	5 or more	7 (11.1)

The knowledge of HCPs on pharmacovigilance and adverse drug reaction reporting in six public hospitals in Lesotho is reported in Figure 1. Most HCPs (90.5%, n = 57, p = 0.513) could define PV and the majority of the HCPs (82.3 %, n = 52, p = 0.758) were knowledgeable that PV activities aim to ensure patient safety while 54.0 % (n = 34, p = 0.161) of HCPs did not know that pharmacovigilance also improved public health and safety with the use of medicines. Although the majority of HCPs knew where the pharmacovigilance centre is located in Lesotho (77.8%, n = 49, p = 0.406), the majority (82.5 %, n = 52, p = 0.041) were not aware of when it was established. Furthermore, most HCPs (88.9 %, n = 56, p = 0.391) knew who was responsible for reporting ADRs. Table 2 shows the attitudes of the HCPs towards PV and ADR reporting in the

participating hospitals. The majority of the HCPs highlighted some challenges that discourage ADR reporting. Meanwhile, 61.9 % (n = 39, p = 0.097) of the HCPs did not know how to report ADRs. Furthermore, the majority of the HCPs (60.3 %, n = 38, p = 0.473) did not know where to report ADRs. Conversely, most HCPs (65.1 %, n = 41, p = 0.113) complained about the lack of access to the ADR reporting form in public hospitals. While a few HCPs (27% %, n = 17, p = 0.04) complained that the ADR report form was too long, a few HCPs (31.7 %, n = 20, p = 0.418) still found it difficult to decide whether an ADR had occurred or not. Few HCPs (p = 0.545) believed that reporting ADR would breach the patient's confidentiality, which could lead to litigation. (Table 2).

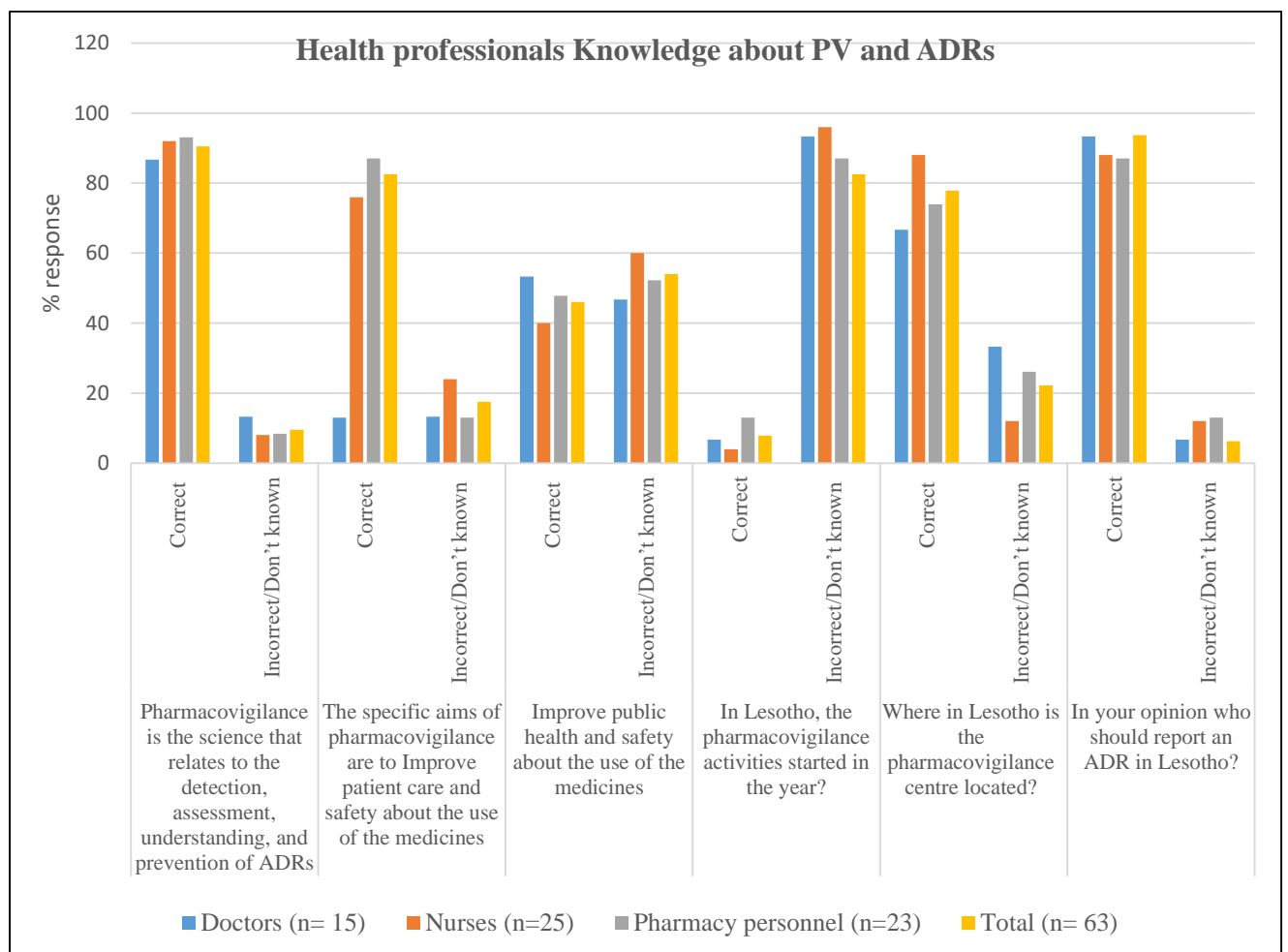


Figure 1: Knowledge of HCPs about Pharmacovigilance and Adverse Drug Reaction Reporting



The attitudes of the HCPs about PV and ADR reporting in six public hospitals are reported in Figure 2. Regarding suggestions to improve the reporting of ADR in public hospitals in Lesotho, 77.8 % (n = 49, p = 0.546) of HCPs believed that Pharmacovigilance should be taught in detail to undergraduates, interns, and postgraduates. The majority of the HCPs (84.1%, n = 53, p = 0.038) recommended workshops and seminars for HCPs as another method of improving the reporting of ADRs,

while some HCPs suggested PV and ADR reporting awareness campaigns could improve ADR reporting in public hospitals in Lesotho (66.7 %, n = 42, p = 0.137). Moreover, some HCPs (66.7 %, n = 42, p = 0.001) thought that monthly meetings discussing common ADRs encountered could improve the reporting of ADRs, while few (23.8 %, n = 15, p = 0.013) also believed that bulletins on ADRs could improve the reporting of ADR in public hospitals.

Table 2:

Shows Some of the Factors Affecting Healthcare Professionals' Reporting of ADR

What are the factors that might discourage you from reporting ADRs?	Physicians N= 15	Pharmacy personnel N= 23	Nurses N= 25	Total N = 63	p- value
Do not know how to report ADRs	10 (66.7)	12 (52.2)	17 (68)	39 (61.9)	0.097
Do not know where to report ADRs	9 (60)	10 (43.5)	19 (76)	38 (60.3)	0.128
Managing patients is more important than reporting ADRs	1(6.7)	2 (8.7)	1 (4)	4 (6.3)	0.473
Patient confidentiality may be breached	2 (13.3)	1 (4.3)	1 (4)	4 (6.3)	0.545
Lack of access to ADR reporting forms	7 (46.7)	17 (73.9)	17 (68)	41 (65.1)	0.113
The form is too long	8 (53.3)	3 (13)	6 (24)	17 (27.0)	= 0.04
Difficult to decide whether ADR has occurred or not	5 (33.3)	6 (26.1)	9 (36)	20 (31.7)	0.418
Fear of litigation	3 (20)	1 (4.3)	2 (8)	6 (9.5)	0.309

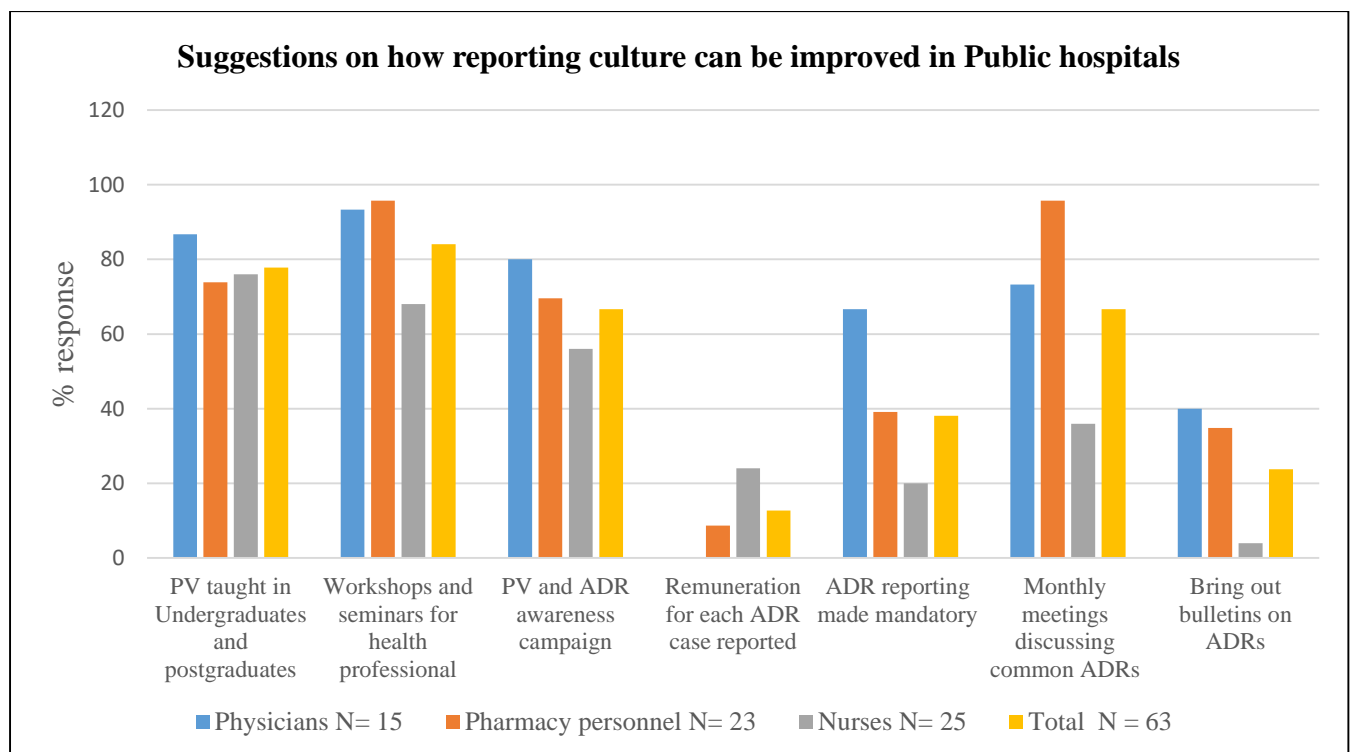


Figure 2:
Attitude of HCPs towards Pharmacovigilance and Adverse Drug Reaction Reporting

In Fig. 3, most healthcare professionals (HCPs) (88.9%, n = 56, p = 0.677) indicated that adverse drug reaction (ADR) reporting was useful for identifying new ADRs and establishing the safety of new drugs. Similarly, the majority (84.1%, n = 53, p = 0.060) reported that ADR reporting facilitates the sharing of information with colleagues. In addition, 93.7% (n = 59, p = 0.032) emphasised that ADR reporting was very important because it contributed to improving patient safety. Most of the HCPs (82.5 %, n = 52, p = 0.894) felt that reporting ADRs was very important, as it helps in measuring the incidence and frequency of ADRs. Half of the HCPs (p = 0.046) thought it was very important to report ADR because it is a legal requirement. Most importantly, 98.7% of healthcare professionals (HCPs) (n = 62, p = 0.448) expressed a positive attitude,

emphasising that reporting adverse drug reactions (ADRs) in public hospitals is very important.

Table 3 shows the HCPs' practice of pharmacovigilance and adverse drug reaction reporting. Most of the HCPs (69.8 %, n = 44, p = 0.009) had never received PV and ADRs reporting training throughout their clinical practice. Additionally, about less than half of the HCPs (46 %, n = 29, p = 0.154) had reported ADRs once in their clinical practice. Conversely, the majority of the HCPs (p = 0.541) indicated that they had come across an ADR and not reported it. Half of the HCPs (52.4 %, n = 33, p = 0.048) stated that their hospitals did not submit sufficient and appropriate ADR reports. It is worth noting that half of the HCPs (49.2 %, n = 31, p = 0.423) had difficulty in reporting ADRs.

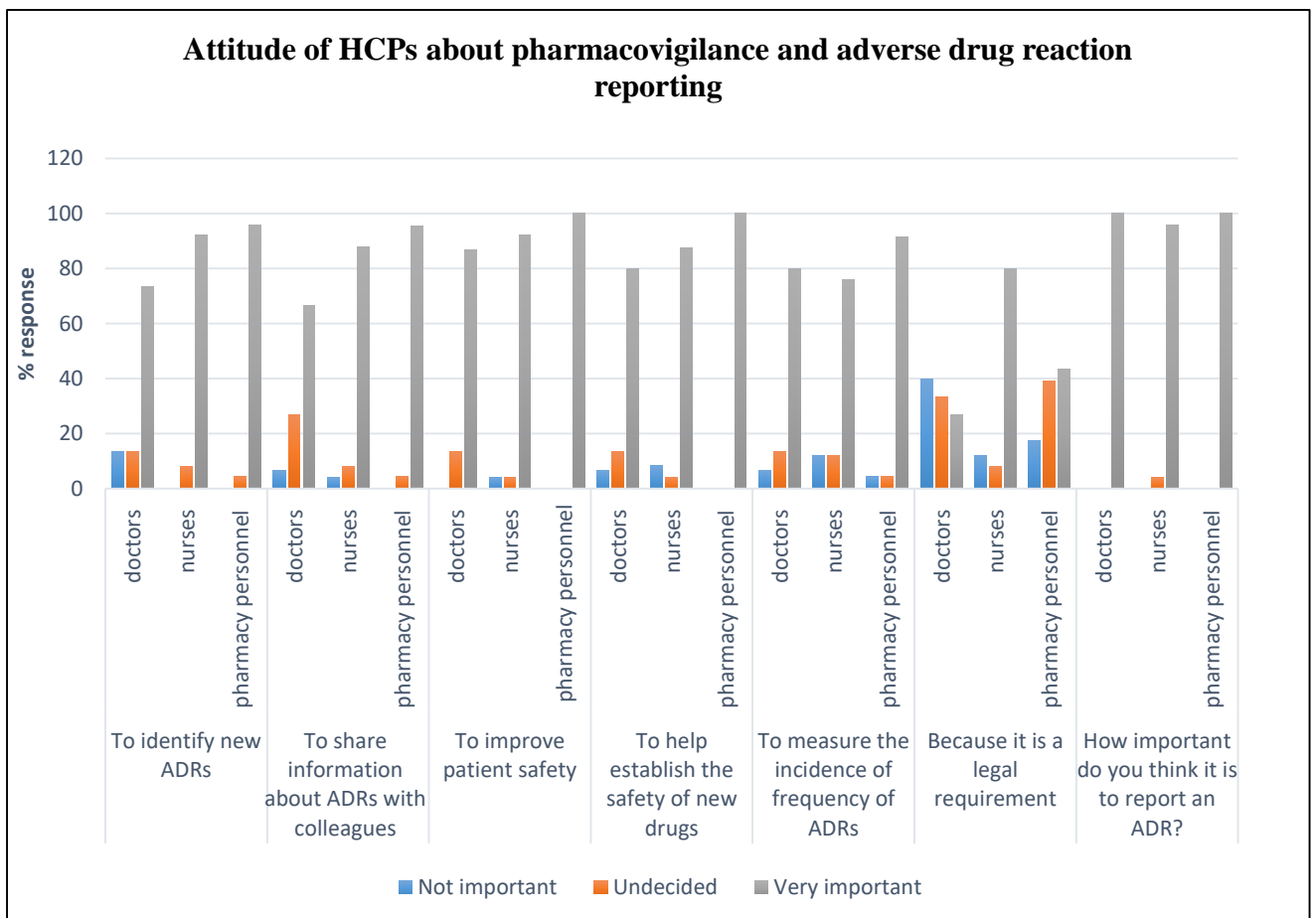


Figure 3:
Rating of the Attitude of HCPs about Pharmacovigilance and Adverse Drug Reaction Reporting



Discussion

Demographics of the HCPs

In the current study, about 63 questionnaires were returned, resulting in a 59.4 % response rate, which was similar to the study conducted in Northern Nigeria [12]. The response rate of our survey was moderate (59.4%), although low compared to other KAP studies [13-16]. This might be due to a limited number of healthcare professionals, as indicated in the Lesotho Annual Joint Public Expenditure Review (PER) 2017 [7]. The majority of the HCPs who participated in this survey were female. This is in line with previous KAP studies that reported more females in the cross-sectional survey studies [17-18]. Regarding age, qualifications, and job experience in practice, the majority of the HCPs who participated in the survey were young HCPs with a Diploma qualification and had more than 10 years of working experience. A similar study in Ethiopia also indicated that the participants were young HCP graduates, although their experience was less than 10 years in their survey [13].

Knowledge of the healthcare professionals on PV and ADR reporting

The majority of healthcare professionals have basic knowledge of Pharmacovigilance and adverse drug reaction reporting. These include the ability to define pharmacovigilance, state the aims of the pharmacovigilance, and identify personnel responsible for reporting ADR. This has been seen in similar studies conducted in various developing countries [9,11,16]. A large portion of the HCPs were aware of the existence of the national pharmacovigilance centre in Lesotho, but did not know when PV activities were initiated in Lesotho. The findings are in line with a recent study conducted in Pakistan reporting that healthcare professionals were aware of the existence of the National Pharmacovigilance Centre [16].

Although the HCPs were aware of the national PV centre, the majority were not aware of the ADR reporting forms in public hospitals. Similarly, a study conducted in Saudi Arabia indicated that health professionals did not know about the ADRs reporting tool [17].

Table 3:

Practice of HCPs about Pharmacovigilance and Adverse Drug Reaction Reporting

Practice-based questions		Doctors (n =15)	Pharmacy personnel (n = 23)	Nurses (n = 25)	Total N =63	p-value
Have you ever received any pharmacovigilance or ADR reporting training?	Yes	4 (26.7%)	11 (47.8%)	4 (16%)	19 (30.2%)	
	No	11 (73.3%)	12 (52.2%)	21(84%)	44 (69.8%)	= 0.009
Have you ever reported an ADR?	Yes	6 (40%)	14 (60.9)	9 (36%)	29 (46.0%)	= 0.154
	No	9 (60%)	9 (39.1%)	16 (64%)	34 (54%)	
Have you ever come across an ADR and not reported it?	Yes	7 (46.7%)	9 (39.1%)	13 (52%)	29 (46.0%)	= 0.541
	No	7 (46.7%)	10 (43.5%)	5 (20%)	22 (34.9%)	
	Don't know	1 (6.7%)	4 (17.4%)	7 (28%)	12 (19.0%)	
Do you think that your hospital submits sufficient and appropriate ADR reports?	Yes	0	3 (13.0%)	1 (4%)	4 (6.3%)	
	No	11 (73.3%)	12 (52.2%)	10 (40%)	33 (52.4%)	= 0.048
	Don't know	4 (26.7%)	8 (34.8%)	14 (56%)	26 (41.2%)	
Do you find any difficulty in reporting adverse drug reactions?	Yes	8 (53.3%)	10 (43.5%)	14 (56%)	32 (50.8%)	0.423
	No	7 (46.7%)	13 (56.5%)	11 (44%)	31 (49.2%)	



A study conducted in Nepal indicated that health professionals were unaware of a pharmacovigilance centre at the hospital, which could be a reason for underreporting of adverse drug reactions [18].

Attitudes of the healthcare professionals towards PV and ADR

Attitudes in the current study were measured by assessing the factors or challenges that may discourage or encourage the HCPs towards ADR reporting, as well as the recommendations for the interventions to improve ADR reporting. The majority of healthcare professionals (HCPs) demonstrated positive attitudes, emphasising that ADR reporting is very important and should be considered a mandatory responsibility for all HCPs, and this was mirrored in other studies [9,13,14,16]. It is noteworthy that although the HCPs showed positive attitudes towards ADR reporting, multiple factors discouraged them from reporting ADRs.

The majority of the HCPs lacked knowledge on how to report ADR and where to report ADR, which is consistent with previous similar studies [9,11,16]. Most HCPs cited that the lack of access to the ADR reporting form, coupled with a long ADR form, discouraged them from reporting ADR, leading to underreporting. A similar study in Pakistan showed underreporting due to unavailable ADR reporting forms in health facilities [19]. Moreover, Other factors that discouraged ADR reporting include the belief that managing patients was more important than reporting ADR, and that reporting breached patient confidentiality, which could lead to litigation. Additionally, the difficulty faced in deciding whether ADR had occurred deterred ADR reporting, in line with previous studies [9,11,16,20].

Most importantly, healthcare professionals suggested several interventions to strengthen ADR reporting in public hospitals. These included incorporating detailed pharmacovigilance training into undergraduate programs, as well as organising workshops and

seminars for practising healthcare professionals. A similar approach has been implemented in Turkey, where the Ministry of Health and the Higher Education Council integrated pharmacovigilance (PV) and ADR reporting into health professional curricula to promote reporting and increase awareness [20]. Workshops and seminars for healthcare professionals on PV and ADR reporting have been shown to improve ADR reporting in health facilities [21].

The majority of the healthcare professionals also believed that PV and ADR reporting awareness campaigns, bulletins on ADRs, monthly meetings to discuss common ADRs encountered in practice, and making ADR reporting mandatory for all healthcare professionals could improve ADR reporting in public hospitals. A large number of evidence from the International Coalition of Medicines Regulatory Authorities (ICMRA) survey reports on Increasing Adverse Event Reporting (IAER), revealed that awareness campaigns on PV and ADR reporting conducted via e-learning platforms, the use of bulletins on ADR, high-quality ADR training on reporting as well as making ADR reporting mandatory in health facilities increased the total number of ADR reported cases submitted to the authority [22].

Practice of the healthcare professionals towards PV and ADR

The majority of the HCPs had never received any PV or ADR reporting training throughout their practice, which might have led to the infrequent reporting of ADRs in public hospitals despite numerous encounters with the ADRs during their practice. Similar studies have reported low levels of ADR reporting among healthcare professionals, with only a small proportion having received training in pharmacovigilance (PV) or ADR reporting [11,23].

The healthcare professionals believed that their hospitals did not submit enough ADR reports to the Lesotho National PV Centre, and that they did not make much effort to report ADRs, despite the majority showing ease in



reporting ADRs. This may be attributed to healthcare professionals' lack of awareness regarding when pharmacovigilance (PV) activities were initiated in Lesotho and the location of the Lesotho National PV Centre. Moreover, a study in Northern Cyprus revealed that HCPs who lacked awareness of the location and PV activities within their country inadequately reported ADRs [23]. In India (Raipur), a similar study found a low level of practice by HCPs in reporting ADRs in the hospitals [24]. The majority of the HCPs above raised the issue of the lack of availability of ADR reporting forms and not knowing where to submit the ADR reports as the major challenges that led to them not reporting ADRs.

Limitations of the Study

The study was conducted in six public hospitals, and the conclusions were generated based on the smaller sample size calculated from the population due to limited resources and a small percentage of healthcare professionals. However, similar national PV studies can be done to get the overall outcomes of Pharmacovigilance in Public hospitals. During data collection, the study was divided into two phases (August 2023 to November 2023) for nurses and pharmacists and February 2024 for physicians, due to the doctors' strike, which adversely affected the data collection process. It is important to note that the results of this study cannot be generalised to the entire population of healthcare professionals in public hospitals.

Conclusion

The healthcare professionals working in six hospitals in Lesotho had a high level of awareness and a general positive attitude towards PV and ADRs reporting. However, ADR reporting in these hospitals remained suboptimal. Lack of training and limited access to the ADR reporting forms significantly hindered reporting ADR within the hospitals. Consequently, there is a need for continuous education and sensitisation of the HCPs regarding pharmacovigilance and ADR reporting in public hospitals in Lesotho.

Recommendations

The PV office at Ministry of Health Lesotho should implement regular training on PV and ADR for all the HCPs at the facility levels. The PV office should disseminate ADR reporting forms within the hospitals structures through use of digital platforms and hard copies. The facilities should strengthen the awareness programmes within the hospitals to promote reporting of ADRs.

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