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Knowledge, Attitude, and Practice of Adverse Drug Reaction Reporting Among Community Pharmacies in Addis Ababa, Ethiopia

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Abstract

Background

Adverse drug reactions (ADRs) are a significant cause of morbidity, mortality, and increased healthcare costs despite the benefits of drugs. In Ethiopia, ADR reporting remains low, indicating underreporting and weak pharmacovigilance. Therefore, this study aimed to assess the knowledge, attitude, and practice of community pharmacists toward ADR reporting in Addis Ababa, Ethiopia.

Methodology

A community-based cross-sectional study was conducted in December 2025 among community pharmacists in Kolfe Keranio Sub-city, Addis Ababa, Ethiopia. Community pharmacies were selected using a survey sampling method, and data were collected from pharmacists through a structured, self-administered questionnaire assessing knowledge, attitude, and practice of ADR reporting. The collected data were checked for completeness, coded, and entered into Microsoft Excel, where descriptive statistics were used for analysis and results were presented in tables and percentages.

Results

A total of 103 community pharmacies participated. Among respondents, 73 (70.9%) could differentiate ADRs from side effects, while only 37 (35.9%) felt adequately trained in ADR reporting. Most respondents, 90 (87.4%) and 87 (84.5%), were aware of the national ADR reporting system and reporting forms, respectively. Overall, about 70% demonstrated good knowledge and 90% showed a positive attitude, though reporting practice was low.

Conclusion

A clear gap exists between pharmacists' knowledge and positive attitudes toward ADR reporting and their actual practice, with low reporting and counseling rates. Key barriers especially causality uncertainty, workload, and low motivation contribute to under-reporting, indicating the need for practical training, clear guidelines, and improved reporting systems.

Trial registration

'Not applicable'

Contributions to the Literature

- Adds context-specific evidence on pharmacovigilance challenges in Ethiopian community pharmacies, where data are scarce.
- Shows that improving knowledge alone is insufficient, emphasizing the need to address behavioral and system-level drivers of ADR reporting.

- Highlights key operational barriers, including uncertainty in causality assessment and workload pressures, affecting routine reporting.
- Informs public health strategies by identifying practical interventions to strengthen ADR reporting and improve medication safety in low-resource settings.

BACKGROUND

Drugs play a crucial role in the prevention, diagnosis, and treatment of diseases, as well as in reducing symptoms and improving patients' health and quality of life. However, their use is not without risk, as medications can produce unintended and sometimes harmful effects. These harmful outcomes are referred to as adverse drug reactions (ADRs) (1). The World Health Organization (WHO) defines an ADR as "any noxious, unintended, and undesired effect of a drug that occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy" (2). ADRs are a major global health concern and are among the leading causes of morbidity, mortality, and poor therapeutic outcomes (3).

ADRs can also be described as harmful or unpleasant reactions that may require prevention, specific treatment, dose adjustment, or withdrawal of the drug (4). It is important to distinguish ADRs from related terms such as side effects and toxic effects. Side effects may or may not be dose-related and can occur through mechanisms different from the intended therapeutic action, whereas toxic effects are usually dose-dependent and represent an exaggerated pharmacological response. Although the terms "adverse effect" and "adverse reaction" are often used interchangeably, they differ slightly in perspective, with adverse effects viewed from the drug's perspective and adverse reactions from the patient's perspective (5). Regardless of terminology, these effects pose serious challenges to patient safety and healthcare systems.

Globally, ADRs contribute significantly to hospital admissions, prolonged hospital stays, increased healthcare costs, and preventable deaths. A study conducted in the United States reported that approximately 108,000 patients died due to ADRs and 2.2 million experienced adverse reactions to properly prescribed drugs (6). Studies from China, Northern India, and Italy have shown that healthcare professionals often have inadequate knowledge regarding ADR reporting, contributing to underreporting (7–9). In contrast, countries with strong pharmacovigilance systems, such as Sweden, report approximately 500 ADR cases per million population annually (10). Namibia reported 126 cases per million population (11), whereas Ethiopia reported only 249 cases between 2002 and 2007 and 307 cases between 2007 and 2012, indicating significant underreporting (12).

In Ethiopia, ADR reporting is guided by national pharmacovigilance regulations, which require all healthcare professionals including physicians, pharmacists, nurses, and others—to report ADRs. This responsibility also extends to private health institutions, non-governmental organizations, and charitable facilities. Timely reporting is essential to ensure data accuracy and reliability; therefore, suspected ADRs should ideally be reported while the patient is still in the healthcare facility to allow clarification through further assessment (12,13). Despite these guidelines, ADR reporting remains low. Studies indicate that

although healthcare professionals encounter ADRs in practice, reporting rates are minimal. For example, one study found that none of the professionals who encountered ADRs reported them to the responsible authority (1,14). Common reasons for underreporting include the perception that the reaction is not serious, belief that it is already known, uncertainty about causality, lack of time, forgetfulness, and inadequate knowledge of reporting procedures (2,15).

The burden of ADRs in Ethiopia is likely substantial due to widespread irrational drug use, misuse of antibiotics, preference for injectable medications, use of traditional and herbal medicines, and extensive self-medication. Additionally, genetic and environmental factors may influence drug responses, and studies suggest that the Ethiopian population may have distinct genetic characteristics that could increase susceptibility to ADRs (3,16).

Healthcare professionals' knowledge, attitudes, and practices (KAP) play a critical role in ADR reporting. Knowledge levels vary across countries, with studies from China, Northern India, and Italy reporting low levels, while higher levels have been observed in countries such as the United Kingdom, Nigeria, and Australia (17–19). In Ethiopia, knowledge of ADR reporting among healthcare professionals has been reported to be moderate, with approximately 50.6% demonstrating satisfactory knowledge (20).

Attitudes toward ADR reporting also differ. Some healthcare professionals demonstrate positive attitudes, recognizing the importance of reporting in improving patient safety, while others show negative attitudes. Studies from Hong Kong and the United Kingdom indicate generally positive attitudes among pharmacists, although actual reporting rates remain low (21). Conversely, negative attitudes have been observed among physicians in Nigeria, Germany, and Canada (22).

In terms of practice, many healthcare professionals are able to identify ADRs but fail to report them. Studies indicate that although a majority have encountered ADRs, reporting is limited due to lack of knowledge on reporting procedures or where to submit reports (23). For instance, research in China found that 62% of doctors had encountered ADRs that were not reported, while studies in India showed that only 43% of participants were aware of reporting systems (24).

Several factors contribute to underreporting, including lack of access to reporting forms, insufficient knowledge on how to report, lack of motivation due to poor feedback systems, and logistical challenges such as absence of reporting contacts. Pharmacists often assume that ADRs are already known, while nurses commonly cite lack of time as a barrier (25). To address these challenges, strategies such as regular training, improving access to reporting tools, strengthening feedback mechanisms, centralizing reporting systems, and increasing awareness through drug safety information have been recommended.

Community pharmacy professionals play a vital role in ADR detection and reporting, as they are often the first point of contact for patients. Assessing their knowledge, attitudes, and practices is essential for identifying gaps and strengthening pharmacovigilance systems. Therefore, this study aims to assess the knowledge, attitude, and practice of community pharmacists toward ADR reporting in Addis Ababa,

Ethiopia. The findings are expected to support policy development, enhance professional training, improve ADR reporting rates, and ultimately contribute to better patient safety and healthcare quality.

METHODS AND MATERIALS

Study Area and Period

This study was conducted among community pharmacies in Kolfe Keraniyo, one of the 11 sub-cities in Addis Ababa. The sub-city covers an area of 61.25 square kilometers and has a total of 150 pharmacies and 78 drug stores. The study period extended from August 2025 to January 2026.

Study Design

A community-based cross-sectional study design was employed to assess the knowledge, attitude, and practice (KAP) of community pharmacy professionals regarding adverse drug reaction (ADR) reporting. This design involves collecting data at a single point in time, making it suitable for determining the current status and prevalence of KAP among participants. It is cost-effective, time-efficient, and appropriate for studies conducted under limited resources. However, it does not establish cause-and-effect relationships.

Study Population

The source population for this study included pharmacy personnel working in selected community pharmacies of Kolfe Keraniyo sub-city. The study population consisted of pharmacy professionals who were available at the selected community pharmacies during the data collection period and were willing to participate in the study.

Sample Size and Sampling Technique

The study was conducted among community pharmacies located in Kolfe Keraniyo sub-city, Addis Ababa, Ethiopia. The sample size was determined using the single population proportion formula, where n_0 represents the initial sample size, Z is the standard normal value at a 95% confidence level (1.96), P is the estimated proportion of the study variable, and d is the margin of error set at 5% (0.05). In the absence of prior similar studies, the value of P was assumed to be 0.5 to obtain the maximum sample size. Using this formula, the initial sample size was calculated to be 384.

After applying the correction formula, the sample size was reduced to 114 pharmacies. However, due to limitations related to time, financial resources, and logistical feasibility, it was not possible to include all 114 pharmacies. Therefore, a total of 103 community pharmacies were included in the study. During the data collection period, all 103 selected pharmacies participated, resulting in a response rate of 91.2%.

According to available records, there were 114 registered community pharmacies operating in the sub-city during the study period, and the inclusion of 103 pharmacies was considered adequate to provide a representative assessment of knowledge, attitude, and practice (KAP) regarding adverse drug reactions (ADRs) among community pharmacy professionals while remaining feasible within resource constraints.

A simple random sampling technique was employed to ensure that each community pharmacy had an equal chance of being selected. This approach minimized selection bias and improved the representativeness of the sample, thereby enhancing the generalizability of the study findings to community pharmacies in Addis Ababa. In each selected pharmacy, one pharmacy professional (either a pharmacist or druggist) who was present at the time of data collection and consented to participate was included in the study.

Inclusion and Exclusion Criteria

All pharmacy professionals working in community pharmacies within Kolfe Keraniyo sub-city were included in the study. However, those who were not willing to participate or who were on leave during the data collection period were excluded.

Study Variables

The dependent variables in this study were knowledge about ADR reporting, practice of ADR reporting, and attitude towards ADR reporting. The independent variables included age and sex of the participants.

Operational Definitions

Adverse drug reactions (ADRs) are harmful and unintended effects occurring at normal drug doses. Community pharmacies are retail drug outlets operated by pharmacy professionals, and pharmacy personnel are diploma- or degree-holding professionals working as dispensers in these settings. Knowledge refers to understanding of ADRs, with scores ≥ 75% classified as good and < 75% as poor. Attitude is the disposition toward ADR reporting, with scores ≥ 75% considered positive and < 75% negative. Practice refers to the application of knowledge, with scores ≥ 50% indicating good practice and < 50% poor practice.

Data Collection Methods and Materials

Data were collected using a self-administered questionnaire developed specifically for this study based on relevant literature and prepared in English to address the study objectives; the questionnaire is included as a supplementary file. It comprised sections designed to assess socio-demographic characteristics as well as the knowledge, attitude, and practice of community pharmacy professionals regarding Adverse Drug Reaction (ADR) reporting in Kolfe Keraniyo.

Three pharmacy students were recruited to assist with data collection and supervision, and data were collected at times deemed convenient to reach participants at their workplaces. Only individuals who voluntarily agreed to participate were included in the study, and clear instructions regarding the purpose and objectives of the study were provided by the data collectors. Participants were advised not to consult or share information with others while completing the questionnaire to ensure the integrity of the responses. The questionnaires were distributed and subsequently collected upon completion.

Data Processing and Analysis

The collected data were checked for completeness, accuracy, and consistency during and after data collection. Data analysis was performed using Microsoft Excel. Descriptive statistical methods, including frequencies and percentages, were used to summarize the data, and the results were presented in tables.

Data Quality Management

Pre-testing was conducted on 5% of the study population before the actual data collection. Based on the results of the pre-test, appropriate adjustments were made to the questionnaire. During data collection, all completed questionnaires were carefully checked to ensure completeness and consistency of the information provided.

RESULTS

Socio-demographic characteristics of respondents

Most participants were female (59.2%), under 35 years (≈ 89.3%), and held a diploma (33.9%) or bachelor's degree (62.1%). The majority were pharmacists (72.8%) with 1–10 years of experience (91.26%), seeing 10–30 patients daily (70.87%) within 5–10 minutes per consultation (64.08%) and working ≥ 8 hours (65.1%). Although 89.3% were introduced to ADR reporting during undergraduate study, only 35.9% received further training, indicating gaps in ongoing professional development. High workload and limited resources may contribute to under-reporting, highlighting the need for regular training and improved access to reporting tools (Table 1).

Table 1
Socio-demographics of pharmacy personnel working at community pharmacies

	Variables	values	Total	percentage
1	Type	Private	103	100%
2	Sex	Male	42	40.8%
		Female	61	59.2%
3	Age	< 25	45	43.7%
		26–35	47	45.6%
		36–45	9	8.7%
		> 45	2	1.9%
4	Profession	Pharmacist	75	72.8%
		Druggist	28	27.2%
5	Highest level of education	Diploma	35	33.9%
		Bachelor	64	62.1%
		Other	4	3.8%
6	Year of experience	< 1yr	6	5.8%
		1–5	68	66.02%
		6–10	26	25.24%
		> 10	3	2.91%
7	Minutes to attend a patient	< 5	22	21.36%
		5–10	66	64.08%
		11–15	5	4.85%
8	Patients per day	< 10	5	4.85%
		10–30	73	70.87%
		31–60	23	22.33%
		61–90	1	0.97%
		> 90	1	0.97%
9	Working hour per day	< 8	36	34.9%
		≥ 8	67	65.1%
10	Do you introduced to ADR in your undergraduate study	Yes	92	89.3%

		No	11	10.7%
11	Do you get seminar/training on ADRs reporting	Yes	37	35.9%
		No	66	64.1%

Knowledge on ADRs Reporting

Overall, respondents demonstrated generally good knowledge of ADR reporting, with about 72–75% showing adequate understanding. Most were familiar with pharmacovigilance (79.6%), the national reporting system (87.4%), and the ADR reporting form (84.5%). The majority correctly identified Ethiopian Food and Drug Authority (EFDA) as responsible for receiving (73.8%) and monitoring (94.1%) ADR reports, and recognized pharmacists as key reporters (86.4%) and conventional medicines as reportable (81.5%). However, notable gaps remained, including poor differentiation between ADRs and side effects (29.1%), limited awareness of ADR documentation at marketing (44.6%), and low recognition of reporting for vaccines/blood products (13.6%) and herbal medicines (3.9%). These findings indicate the need for continuous training to strengthen pharmacovigilance knowledge and practice (Table 2).

Table 2
Knowledge of respondents about ADR reporting

	Variables	Value	Total	percentage
1	Do you think that an adverse drug reaction is the same as side effect	Yes	30	29.1
		No	73	70.9
2	Do you know the term pharmacovigilance (ADR)	Yes	82	79.6
		No	21	20.4
3	Do you know the existence of a national ADR reporting system?	Yes	90	87.4
		No	13	12.6
4	Do you know the ADR reporting form?	Yes	87	84.5
		No	16	15.5
5	Do you think that ADRs are well documented at the time a drug is marketed?	Yes	46	44.6
		No	57	55.4
6	Where are the reports for ADRs supposed to be sent?	MOH	1	0.97
		EFDA	76	73.8
		PFSA	2	1.9
		KOLFE-FDA	22	21.3
		EPA	2	1.9
		Others	0	0
7	Which profession is required to report suspected cases of ADRs?	Doctors	10	9.7
		pharmacist	89	86.4
		Nurses	2	1.9
		Traditionalists	0	0
		others	2	1.9
8	What reactions should be reported?	Those due to conventional medicines	84	81.5
		Those due to vaccines and blood products	14	13.6
		Those due to herbal medicines	4	3.9

		Those due to medical devices	1	0.97
9	Who do you think is primarily responsible to remind and follow up with patients about the side effects of drugs they are given?	Pharmacists	76	73.7
		Physicians	25	24.2
		Nurses	1	0.97
		Others	1	0.97
10	Whom do you think is responsible for monitoring ADR in Ethiopia	MOH	2	1.9
		EFDA	97	94.1
		EPA	4	3.8
		others	0	0

Attitudes on ADRs reporting

The attitude of community pharmacy professionals toward ADR reporting was found to be positive. Approximately, 90% (93) of respondents showed a positive attitude toward ADR reporting. Among this study pharmacists demonstrated strong positive attitudes toward ADR reporting. The majority recognized it as a professional duty (94.2% agreed) and agreed it should be done regularly (97%). They also valued its importance for patients (67.9%), the public (64.1%), and the healthcare system (66.9%). However, a significant barrier was a misconception about causality, with 88.3% believing a reaction must be confirmed as drug-related before reporting. This highlights a need for targeted education and clearer guidelines to convert their supportive attitudes into consistent reporting practices (Table 3).

Table 3
Attitudes of respondents about ADR reporting

	Statement	Categories	Frequency
1	ADR should be reported regularly	Strongly Agree	70(67.9%)
		Agree	30(29.1%)
		Neither	3(2.9%)
		Disagree	0
		Strongly disagree	0
2	ADR reporting is part of the duty of health professionals	Strongly agree	65(63.1%)
		Agree	32(31.1%)
		Neither	5(4.8%)
		Disagree	1(0.97%)
		Strongly disagree	0
3	Reporting drug safety is important for the public	Strongly disagree	66(64.1%)
		Agree	23(22.3%)
		Neither	9(8.73%)
		Disagree	3(2.9%)
		Strongly disagree	2(1.94%)
4	Reporting drug safety is important for the patient	Strongly agree	70(67.9%)
		Agree	23(22.3%)
		Neither	6(5.82%)
		Disagree	2(1.9%)
		Strongly disagree	2(1.9%)
5	Reporting drug safety is important for the healthcare system	Strongly agree	69(66.9%)
		Agree	23(22.3%)
		Neither	4(3.9%)
		Disagree	3(2.9%)

		Strongly disagree	4(3.9%)
6	There is a need to be sure that an ADR is related to the drug before reporting	Strongly agree	51(49.5%)
		Agree	40(38.8%)
		Neither	6(5.8%)
		Disagree	4(3.9%)
		Strongly disagree	2(1.9%)
7	Only ADRs of prescription drugs need to be reported	Strongly agree	11(10.67%)
		Agree	14(13.6%)
		Neither	16(15.5%)
		Disagree	52(50.5%)
		Strongly disagree	10(9.7%)
8	Only ADRs that cause persistent disability or incapacity should be reported	Strongly agree	10(9.7%)
		Agree	16(15.5%)
		Neither	13(12.6%)
		Disagree	39(37.9%)
		Strongly disagree	24(23.3%)
9	Reporting of ADR should be voluntary	Strongly agree	34(33%)
		Agree	28(27.2%)
		Neither	14(13.6%)
		Disagree	15(14.5%)
		Strongly disagree	12(11.6%)
10	Community pharmacists can contribute to the detection and reporting of ADRs	Strongly agree	45(43.9%)
		Agree	36(34.9%)
		Neither	12(11.6%)
		Disagree	6(5.8%)
		Strongly disagree	4(3.9%)

Reasons for not reporting ADR

The main barriers to ADR reporting were uncertainty about the drug–reaction relationship (Strongly Agree 33.9% + Agree 49.5%), concerns about patient confidentiality, lack of motivation, and perceived workload. Although most respondents recognized the importance of ADR reporting and were aware of the national system, these factors continued to limit consistent reporting, indicating the need for targeted training and supportive pharmacovigilance strategies (Table 4).

Table 4
Reason of respondents for not reporting ADR

	Statement	Categories	Frequency
1	Need to be certain of the association between the drug and ADR	Strongly agree	35(33.9%)
		Agree	51(49.5%)
		Neither	6(5.9%)
		Disagree	7(6.8%)
		Strongly disagree	4(3.9%)
2	Reporting ADR is a breach of patient confidentiality	Strongly agree	10(9.7%)
		Agree	36(34.5%)
		Neither	17(16.5%)
		Disagree	27(26.2%)
		Strongly disagree	13(12.6%)
3	One report makes no difference	Strongly agree	1(0.97%)
		Agree	17(16.5%)
		Neither	22(21.3%)
		Disagree	45(43.7%)
		Strongly disagree	18(14.5%)
4	The reporting form is not available adequately	Strongly agree	8(7.8%)
		Agree	34(33%)
		Neither	30(29.1%)
		Disagree	26(25.2%)
		Strongly disagree	5(4.8%)
5	There is no national ADR reporting system	Strongly agree	5(4.8%)
		Agree	17(16.5%)
		Neither	20(19.4%)
		Disagree	41(39.8%)

		Strongly disagree	20(19.4%)
6	Reporting is not useful to the patient	Strongly agree	5(4.9%)
		Agree	8(7.8%)
		Neither	9(8.7%)
		Disagree	41(39.8%)
		Strongly disagree	40(38.8%)
7	Reporting creates an additional workload	Strongly agree	10(9.7%)
		Agree	23(22.3%)
		Neither	25(24.3%)
		Disagree	29(28.1%)
		Strongly disagree	16(15.5%)
8	Lack of motivation for reporting	Strongly agree	12(11.6%)
		Agree	42(40.8%)
		Neither	20(19.4%)
		Disagree	21(20.3%)
		Strongly disagree	8(7.8%)

Practices on ADRs reporting

The practice of ADR reporting among community pharmacy professionals was low. Only 32.1% encountered ADR cases in the past 12 months, and just 26.2% had ever reported an ADR, indicating substantial under-reporting. Reports were mainly directed to pharmacy heads (25.2%), with fewer sent to the Ethiopian Food and Drug Authority (18.4%) or the Ministry of Health Ethiopia (14.5%), and none to manufacturers. Patient counseling was inconsistent, with 31.1% never advising patients and only 21.3% doing so regularly. Overall, despite reasonable awareness, poor reporting and counseling practices highlight the need for targeted training, improved reporting access, and strengthened pharmacovigilance systems (Table 5).

Table 5
Respondents state of practice on ADR reporting

	Variables	Categories	Frequency
1	Have you ever encountered patients with ADRs in your pharmacy practice, in the last 12 months?	Yes	33(32.1%)
		No	70(67.9%)
2	How many patients with ADR did you see during the last 12 months?	1	25(24.3%)
		2	15(14.5%)
		3	9(8.7%)
		4	4(3.8%)
		> 4	4(3.8%)
		No	46(44.6%)
3	Have you ever reported adverse drug reactions?	Yes	27(26.2%)
		No	76(73.8%)
4	To whom did you report?	Pharmacy head	26(25.2%)
		Manufacturers	0
		KOLFE-FDA	7(6.8%)
		EFDA	19(18.4%)
		MOH	15(14.5%)
		Others	36(34.9%)
5	How often do you advise your patients on possible adverse effects of drugs you dispensed?	Usually	22(21.3%)
		Sometimes	37(35.9%)
		Rarely	12(11.6%)
		Never	32(31.1%)

Comparison of Knowledge and Practice of ADR Reporting

This bar graph illustrates the discrepancy between knowledge and practice of ADR reporting among community pharmacy professionals. While a high proportion of respondents demonstrated good knowledge particularly regarding pharmacovigilance (79.6%), the national reporting system (87.4%), and ADR reporting forms (84.5%) the actual practice of ADR reporting was considerably low. Only 32.1% had encountered ADR cases and just 26.2% had ever reported them, with regular patient counseling also limited (21.3%). This highlights a significant knowledge–practice gap in ADR reporting (Fig. 1).

Barriers to ADR Reporting

This pie chart presents the major barriers influencing ADR reporting among respondents. The most prominent barrier was the need for certainty about the causal relationship between the drug and the reaction (83.4%), followed by lack of motivation (52.4%), concerns about patient confidentiality (~ 44%), and perceived workload (~ 32%). These barriers persist despite generally positive attitudes toward ADR reporting, contributing to the observed under-reporting in practice (Fig. 2).

DISCUSSION

This study examined the socio-demographic characteristics, knowledge, attitudes, barriers, and practices related to adverse drug reaction (ADR) reporting among community pharmacy personnel in Kolfe Keranio Sub-City. The findings provide a comprehensive picture of pharmacovigilance activities at the community pharmacy level and reveal a consistent pattern: while awareness and attitudes toward ADR reporting are generally favorable, actual reporting practices remain suboptimal. This gap has important implications for patient safety and the effectiveness of the national pharmacovigilance system.

The socio-demographic profile of respondents indicates that the community pharmacy workforce is predominantly young and relatively early in their professional careers, with most holding diploma or bachelor's degree qualifications. A large proportion were pharmacists with fewer than ten years of experience. This composition suggests that the workforce is academically prepared and potentially adaptable to new practices. However, structural challenges within the work environment appear to limit their performance in pharmacovigilance activities. High patient flow, extended working hours, and short consultation times reduce opportunities for thorough patient assessment, medication review, and detection of potential ADRs. In such busy settings, priority is often given to dispensing efficiency rather than clinical monitoring, which may lead to missed or unrecognized adverse reactions, as reported in similar settings (1,4).

Although most participants were introduced to ADR reporting during their undergraduate education, only a minority had received additional in-service or continuing professional training. This highlights a gap in continuous professional development, which is essential for reinforcing knowledge and translating theory into practice. Previous studies have similarly shown that limited practical training contributes to weak pharmacovigilance engagement (4).

In terms of knowledge, respondents demonstrated generally good awareness of pharmacovigilance, the national ADR reporting system, and reporting tools. Most correctly identified the Ethiopian Food and Drug Authority (EFDA) as the authority responsible for receiving and monitoring ADR reports, and recognized pharmacists as key reporters. This aligns with findings from studies conducted in Ethiopia and other developing countries (11,12).

However, important knowledge gaps remain. A notable proportion of respondents could not clearly distinguish ADRs from side effects, and awareness of reporting requirements for vaccines, blood

products, and herbal medicines was limited. These findings suggest that knowledge is often superficial rather than comprehensive, which may result in selective reporting and missed ADRs (12).

Attitudinal assessment revealed generally positive perceptions toward ADR reporting, with most participants recognizing it as a professional responsibility and an essential component of patient safety. This is consistent with findings from studies conducted in Hong Kong and the United Kingdom (18).

Nevertheless, a key misconception was identified: many respondents believed that ADRs should only be reported when causality is certain. This misunderstanding of spontaneous reporting principles may discourage reporting of suspected ADRs and contribute to under-reporting, a challenge also highlighted in previous research (19).

Several barriers to ADR reporting were identified, including uncertainty about causality, concerns about patient confidentiality, workload pressures, limited motivation, and inconsistent access to reporting tools. These barriers reflect both practical and perceptual challenges that reduce participation in pharmacovigilance systems. Similar constraints have been widely reported in the literature (20,21).

Workload and time limitations appear particularly influential, as busy pharmacy environments often prioritize dispensing over documentation. In addition, lack of confidence in identifying ADRs and fear of incorrect reporting further contribute to low reporting rates (21).

In practice, ADR reporting was notably low. Only a small proportion of respondents had ever reported an ADR, and most reports were made internally rather than to regulatory authorities such as the Ethiopian Food and Drug Authority. Patient counseling was also inconsistent, with many professionals rarely advising patients about potential adverse effects. This limits early detection and further contributes to under-reporting (19).

The gap between knowledge, attitude, and practice observed in this study is consistent with findings from Ethiopia and other developing countries, where awareness does not necessarily translate into action (20). This highlights the need for interventions that focus on practical implementation rather than knowledge alone.

Overall, while community pharmacy professionals demonstrated acceptable awareness and positive attitudes toward ADR reporting, pharmacovigilance practice remains inadequate, highlighting the need for a multifaceted approach to strengthen reporting. Key strategies include continuous, practice-oriented professional training, improved access to reporting tools, enhanced collaboration with the EFDA, and the introduction of simplified or electronic reporting systems. Encouraging direct reporting to regulatory authorities, integrating routine patient counseling into daily pharmacy practice, and providing supportive supervision with feedback mechanisms are also critical to improving reporting behavior. Addressing these gaps through targeted educational and system-level interventions is essential to enhance pharmacovigilance, ultimately improving medication safety and healthcare outcomes in community pharmacy settings.

CONCLUSION

The study reveals a critical gap between pharmacy professionals' awareness of ADR reporting and their actual practice. Although most participants demonstrated good knowledge of pharmacovigilance systems and held positive attitudes toward ADR reporting, actual reporting and patient counseling practices were notably low. This gap is further compounded by deficiencies in key concepts and major barriers particularly uncertainty about causality, workload, lack of motivation, and confidentiality concerns which contribute to persistent under-reporting. Therefore, moving beyond awareness requires targeted interventions, including regular practical training, clear guidelines, user-friendly reporting tools, and stronger regulatory collaboration to effectively translate knowledge into consistent reporting and improved patient safety.

This study has limitations, including its focus on community pharmacies in Kolfe Keranio Sub-City, limiting generalizability; a small sample and cross-sectional design, restricting causal inferences; reliance on self-administered, self-reported data, which may introduce recall and social desirability bias; and lack of verification of actual ADR reports, with limited depth due to time and resource constraints.

To strengthen ADR reporting, it is recommended that the EFDA provide clear guidelines and reporting tools, oversee compliance, and support training initiatives; community pharmacy personnel actively identify, report, and counsel patients on ADRs; pharmacy owners and managers facilitate reporting by managing workloads and providing feedback; patients engage in reporting ADR experiences; and researchers conduct studies to identify barriers and inform improvements to the national pharmacovigilance system.

List of Abbreviations

- ADRs…..Adverse Drug Reactions
- EFDA….Ethiopian Food and Drug Authority
- KAP…..Knowledge, Attitude, and Practice
- WHO…..World Health Organization

Declarations

Ethical approval and consent to participate

This study was approved by the Ethics Committee of the Africa Medical College Research and Community Service Office (AMC/11/00413/18). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. All participants were informed about the purpose of the study and their selection process, assured of confidentiality, and provided written informed consent prior to participation. Participation was voluntary, and respondents were informed of their right to decline any

question or withdraw from the study at any time without consequence. No personal identifiers were collected, and anonymity was strictly maintained.

Clinical trial number

‘Not applicable’

Consent for publication

‘Not applicable’

Availability of data and materials

The datasets generated and analyzed during the current study are not publicly available due to privacy and ethical concerns but are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

‘Not applicable’

Authors' contributions

N.S., A.S., H.Y., and B.Z. drafted the proposal work, synthesized the appropriate methodology, conducted the data analysis, generated the results, and forwarded the relevant conclusions. H.S. provided the analysis, limitation, discussion section, recommendation and write up of the study. K.T. contributed relevant discussion and recommendations for the study. All authors read and approved the final manuscript.

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References

1. Ahmad A, Patel I, Balkrishnan R, Mohanta G, Manna P. An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: a pilot study. Perspect Clin Res. 2013;4(4):204-8.

2. Alsaleh FM, Alzaid SW, Abahussain EA, Bayoud T, Lemay J. Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait. Saudi Pharm J. 2017;25(6):830-7.
3. Atsbeha BW, Suleyman SA. Medication knowledge, attitude and practice (KAP) among University of Gondar freshman students, northwestern Ethiopia. Pharmacol Online. 2008;1:4-12.
4. Ahmad A, Khan MU, Srikanth AB, Kumar B, Singh NK, Trivedi N, et al. Evaluation of knowledge, attitude and practice about self-medication among rural and urban north Indian population. Int J Pharm Clin Res. 2015;7(5):326-32.
5. Alaynesh G. Assessment of Knowledge, Attitude and Practices on Adverse Drug Reaction Reporting Among Pharmacy Personnel Working at Community Pharmacy, Addis Ababa, Ethiopia. Addis Ababa University; 2015.
6. Practices of health-care providers toward pharmacovigilance and adverse drug reaction reporting at a comprehensive cancer center in Jordan. Perspect Clin Res. 2019;10(3):115-20.
7. Adisa R, Omitogun TI. Awareness, knowledge, attitude, and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centers in Ibadan, southwestern Nigeria. BMC Health Serv Res. 2019;19:1-14.
8. Afifi S, Maharloui N, Peyman P, Namazi S, Gharaei AG, Jahani P, et al. Adverse drug reactions reporting: pharmacists' knowledge, attitude, and practice in Shiraz, Iran. Int J Risk Saf Med. 2014;26(3):139-45.
9. Pirmohamed M, Atuah KN, Dodoo AN, Winstanley P. Pharmacovigilance in developing countries. BMJ. 2007;335(7618):462-5.
10. Kassa BA, Biru TT. Health care professionals' knowledge, attitude, and practice towards adverse drug reaction reporting and associated factors at selected public hospitals in Northeast Ethiopia: a cross-sectional study. Biomed Res Int. 2019;2019:1-10.
11. Gidey K, Seifu M, Hailu BY, Asgedom SW, Niriayo YL. Healthcare professionals knowledge, attitude and practice of adverse drug reactions reporting in Ethiopia: a cross-sectional study. BMJ Open. 2020;10(2):e034553.
12. Shanko H, Abdela J. Knowledge, attitudes, and practices of health care professionals toward adverse drug reaction reporting in Hiwot Fana Specialized University Hospital, Harar, Eastern Ethiopia: a cross-sectional study. Hosp Pharm. 2018;53(3):177-87.
13. Li Q, Zhang SM, Chen HT, Fang SP, Yu X, Liu D, et al. Awareness and attitudes of healthcare professionals in Wuhan, China to the reporting of adverse drug reactions. Chin Med J (Engl). 2004;117(6):856-61.
14. Kuemmerle A, Olsson S, Van Erps J, Burri C, Lalvani PS. Assessment of global reporting of adverse drug reactions for anti-malarials, including artemisinin-based combination therapy, to the WHO Programme for International Drug Monitoring. Malar J. 2013;10:57.
15. Pal DS. Africa pharmacovigilance meeting. Kenya: WHO; 2013.

16. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: knowledge, attitude and practices of medical students and prescribers. Natl Med J India. 2002;15(1):24-7.
17. Cosentino M, Leoni O, Banfi F, Lecchini S, Frigo G. Attitudes to adverse drug reaction reporting by medical practitioners in a Northern Italian district. Pharmacol Res. 1997;35(2):85-8.
18. Oshikoya KA, Awobusuyi JO. Perceptions of ADR reporting among healthcare workers. [Details missing].
19. Ayalew MB. Self-reported ADR reporting practice among health professionals in Ethiopia. PLoS ONE. 2017;12(6):e0178993.
20. Ethiopian Food and Drug Authority (EFDA). National Pharmacovigilance Guideline. Addis Ababa: EFDA; 2019.
21. Lopez-Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions. Drug Saf. 2009;32(1):19-3.

Figures

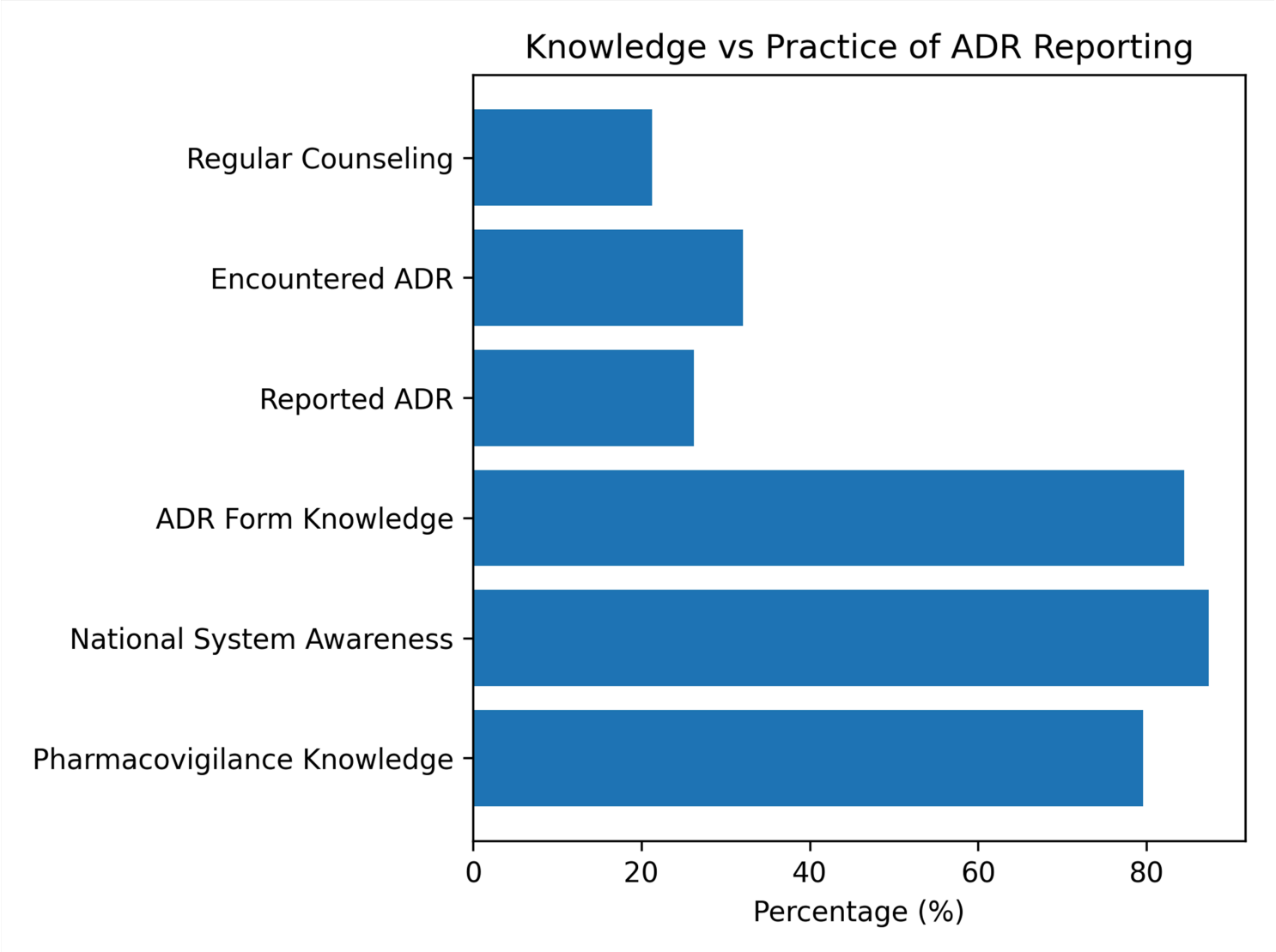


Figure 1

Knowledge versus Practice of ADR Reporting

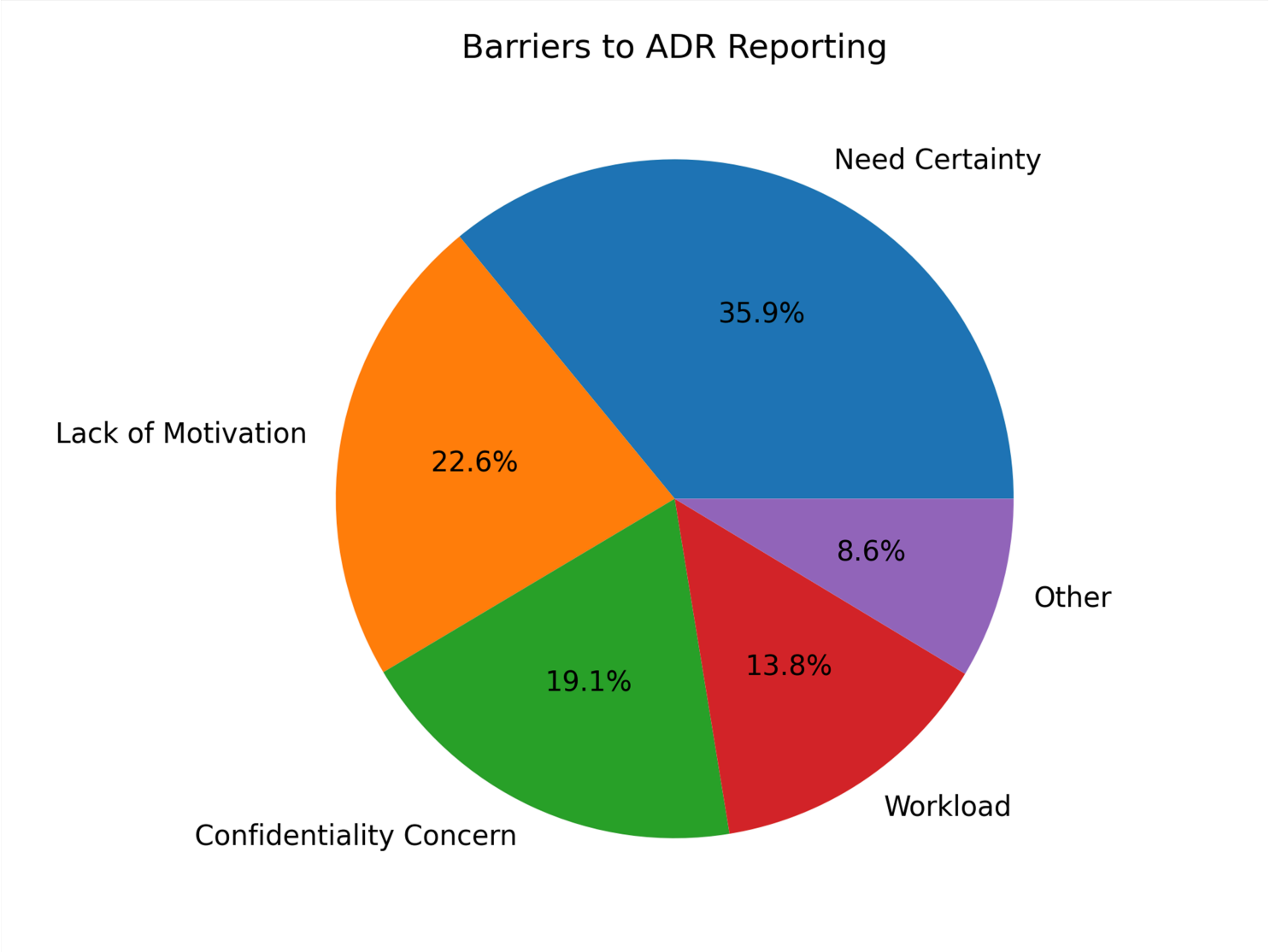


Figure 2

Barriers to ADR Reporting

Supplementary Files

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- ADRQuestionerEnglish.docx