

A Systematic Review of Healthcare Professionals' Knowledge, Attitudes, and Practices Regarding Adverse Drug Reaction Reporting in Ethiopia

D Zelalem Gebretsadik ANBEO*, D Nurettin ABACIOĞLU

Near East University, Faculty of Pharmacy, Department of Pharmacology, Nicosia, Cyprus

ABSTRACT

Adverse drug reactions (ADRs) are a prominent cause of morbidity and mortality and higher healthcare expenditures. Healthcare professionals (HCPs) play a crucial role in ADR reporting through spontaneous reporting systems, but under-reporting is their major limitation. The goal of this study is to evaluate HCPs' knowledge, attitude, and practice regarding ADR reporting as well as the factors that influence reporting using research papers that are currently available. A literature search was conducted using sources such as PubMed, Scopus, and Google Scholar to find studies that evaluated HCPs' knowledge, attitudes, and practices regarding ADRs reporting in Ethiopia. A standard procedure of systematic review protocol was used to conduct this review. Demographic factors, sample size, response rate, survey delivery, HCP working setting, and encouraging and discouraging factors of ADR reporting were extracted from articles. A total of 17 articles were included in the systematic review out of 384. The number of HCPs in the included studies ranged from 62 to 708. Response rate ranges from 76.1% to 100%. Most of the research included in this evaluation looked at HCPs, who worked in hospitals. When pharmacists were compared to other HCPs, they were more likely to report ADRs; because they had higher knowledge, attitude, and practice. Lack of understanding, unavailability of reporting forms, uncertainty about the causal relationship between the drug and ADR, and failure to report because the ADR was well known were among the common hurdles to ADR reporting identified in research. To improve reporting, educational initiatives and continued training in pharmacovigilance and ADRs are frequently recommended considerations. In Ethiopia, there is a pressing need to close the gap in HCP knowledge, attitudes, and practice regarding PV and ADR reporting. To address this point, specific educational interventions based on existing gaps in ADR reporting should be developed and integrated into the health education curriculum or provi

Key words: Adverse drug reactions, knowledge, attitudes, practice, healthcare professionals, reporting, pharmacovigilance

INTRODUCTION

Adverse drug reactions (ADRs) are one of the most common drug-related issues, and they are a considerable cause of illness and death as well as a significant economic burden.¹ ADRs increase the risk of hospitalization, emergency department visits,² and length of hospitalization³ ADRs are monitored using a variety of ways, the most prominent of which is voluntary or spontaneous reporting, which is considered the cornerstone of any pharmacovigilance (PV) system.³ Reporting of suspected ADRs determines, whether a PV system succeeds or fails.⁴

In the ADR reporting and PV systems, healthcare practitioners play a critical role.⁵ ADRs can be reported directly to national PV

systems or to pharmaceutical manufacturers by both healthcare professionals (HCPs) and patients.⁶ The early detection of signals and dangers related to drug usage is improved by reporting ADRs to the appropriate regulatory body.⁷

Despite widespread worries about drug safety, HCPs still lack understanding of PV and ADR reporting.^{8,9} Furthermore, according to recent studies, ADRs are underreported by HCPs, particularly in poorer nations. Only 2-4% of all adverse events and 10% of significant ADRs are reported globally according to reports.¹⁰ Any suspected adverse reaction, specifically those suspected reactions to newly authorized drugs and significant occurrences, should be reported by HCPs such as physicians,

^{*}Correspondence: zelalemgebretsadik@yahoo.com, Phone: +251912387870, ORCID-ID: orcid.org/0000-0002-9957-114X Received: 06.08.2021, Accepted: 06.10.2022



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pharmacists, and nurses.¹¹ As a result, medicine safety evaluation must be considered an integral element of HCPs' daily clinical practice.⁵

In Ethiopia, a variety of cross-sectional studies have been conducted to assess HCPs' knowledge, attitude, and practice regarding ADR reporting as well as the causes of underreporting by HCPs. To our knowledge, no comprehensive literature review has examined available studies that evaluated HCPs' knowledge, attitude, and practice of ADR reporting. This study evaluates HCPs' knowledge, attitudes, and practices and identifies characteristics that encourage or discourage them from reporting ADRs in Ethiopia.

METHODS

Literature search strategy

To identify published articles that meet the objectives of this systematic review, a literature search was conducted using the databases PubMed, Scopus, and Google Scholar. A review was conducted to verify that the literature was thoroughly covered and that current performance on HCP ADR reporting in Ethiopia was considered. The preferred reporting items for systematic reviews and meta-analyses (PRISMA) procedures were followed for conducting this literature review'.¹⁰ "Adverse reactions" and "drug-related side effects" OR "adverse drug event" OR "adverse drug reaction" OR "drug side effects" OR "drug toxicity" OR "side effects of drugs" OR "toxicity, drug" OR "medication side effect" OR "Ethiopia" were combined search terms to identify eligible articles.

The search was performed on April 2020 with no limitations on study design or publication year (Figure 1). The publication year of the article was not imposed on the search. The articles were chosen based on their titles and abstracts. A manual search was also carried out; significant article reference lists identified throughout the screening process were manually searched to find other qualified studies that had not been discovered previously. To complement the information, an internet search was undertaken using Google Scholar and the generic search engine Google. Through the literature search in electronic scientific databases, the same terms were employed.

Study selection and data abstraction

The literature search comprised all articles were conducted in Ethiopia until February 2020. The authors screened the titles and abstracts of the studies that were identified and evaluated them according to the inclusion and exclusion criteria. The whole text of the selected abstracts was then evaluated. The reviewers revised the all studies that were potentially eligible, and two of the authors agreed on the final inclusion.

Inclusion criteria

Studies were chosen, if they focused on HCPs' knowledge, attitudes, and practices regarding ADR reporting and PV, and they were conducted in Ethiopia. Both electronic grey literature articles searches and published articles in scientific peerreviewed journal articles were included in systematic review.

Exclusion criteria

Studies on ADR data analysis, patient or consumer reports, medication errors, general adverse drug events, and prevalence and nature of ADRs in hospitals were excluded.

Extraction and assessment of data

A standardized data collection tool was used to perform data abstraction. Author, year of publication, study objective, study period, study population, HCP work setting, number of respondents and percent response rate, survey/study delivery



Figure 1. The preferred reporting items for systematic reviews and meta-analyses procedures were followed for conducting this literature review

(mail, face-to-face, self-administrative, e-mail/web), scale or type of questions used (yes or no questions, multiple-choice questions, Likert scale, and open-ended questions), encouraging and discouraging factors of ADR are all characteristics extracted from each eligible study. In the tables, we have included factors that were statistically significant in the research.

RESULTS

Description of eligible study articles included in review

A total of 387 articles was collected from the scientific databases PubMed (n: 84), Scopus (n: 137), and Google Scholar (n: 166) for qualitative analysis. Following the removal of duplicate citations, 297 publications were subjected to title and abstract screening with 17 being chosen for full-text evaluation and eventual inclusion in the systematic review.

A total of 17 articles included in the systematic review was studies using self-administered questionnaires conducted among HCPs in Ethiopia and published between 2012 and 2020 (February). Only one of these was a mixed-method study, in which key informants completed a semi-structured questionnaire and self-administered questionnaires were used.¹² The rest of the studies conducted a cross-sectional design. Six studies were conducted in Amhara Region,¹³⁻¹⁹ 4 in the Oromia Region,²⁰⁻²³ 4 studies in the capital city Addis Ababa,^{12,23,24} and one study each was conducted in Tigray Region,^{25,26} Harare Region.^{27,28} The sample size for the comprised studies ranged from 62¹⁴ to 708¹⁷ HCPs from across databases searched for this study.

Response rate ranges from 76.1%²⁷ to 100%.^{20,21,29-31} Majority of the studies considered in this review surveyed hospital-based HCPs (physicians, pharmacy personnel, nurses, midwives, and health officers) working in public hospital settings. One study involved pharmacists, who worked in community settings.²⁵ Only nurses working in hospital settings were surveyed in one study.¹³ Figure 1 shows a PRISMA flowchart indicating the study selection at each stage. The study characteristics and outcomes are detailed in Tables 1 and 2.

Demographic factors that impact ADR reporting by HCPs

According to one study, gender has a strong relationship with ADR reporting practice, with female physicians are 3.5 times more likely to report ADRs than male physicians.¹² However, another study found no link between different age groups and the likelihood of HCPs reporting ADR.¹⁷ The practice of reporting ADRs is strongly linked to one's educational level. Compared to general practitioners, specialists are 5 times more likely to disclose ADR cases.¹²

In two previous reports, it was discovered that having more job experience as HCP increased the number of reports.^{12,27} When compared to physicians with one to three years of experience, those with more than six years of experience were 4.6 times more likely to report ADR instances.¹² HCPs with 10 to 14 years of experience (84.6%) substantially acknowledged that they are aware of the national ADR reporting system and that they are aware of ADR reporting form's accessibility.²⁷ In addition, one

study found that HCPs with less experience were more likely to record ADRs incorrectly.²⁶ Another research, on the other hand, revealed no statistically significant link between years of service and ADR reporting.¹⁷

According to studies, having ADR reporting training has a statistically significant relationship with knowledge,¹⁴ and having a high degree of knowledge is associated with ADR reporting.¹⁷ When compared to participants who had received ADR reporting training, professionals who had not received ADR reporting training were 0.722 times (72.2%) less likely to have adequate knowledge. Furthermore, healthcare personnel who had not been trained in ADR reporting were more likely to have poor practice²⁶ and knowledge.¹⁵

Comparing ADR reporting among different professions

Several studies indicated that all HCPs have inadequate understanding and habits regarding ADR reporting. Some research, on the other hand, demonstrated statistically significant differences among HCPs.²⁹ According to studies, physicians have a better likelihood of diagnosing ADRs than other health providers because they either lack confidence in diagnosis or play fewer responsibilities in the ward for intervention.^{20,30} Physicians see much more patients with ADR than pharmacists and nurses, according to similar findings.¹⁹

Gurmesa and Dedefo²³ evaluated the knowledge of HCPs among themselves, finding that physicians (84.2%) and pharmacists (84.2%) were more educated about ADR reporting than health officers (56%) and nurses (25.7%). According to another study, nurses, health officials, and physicians were 93.1% less likely than pharmacy professionals to have an adequate knowledge of ADR reporting.¹⁴ Nurses and health officers had an insufficient degree of understanding of ADR reporting, when compared with pharmacists, according to another finding.¹⁵ According to a survey conducted in Addis Ababa, 72.1% of pharmacists were aware of the yellow card reporting mechanism, while just 40.5% of nurses were.¹¹ According to a study in South West Ethiopia, pharmacists have significantly more knowledge than other HCPs about the difference between ADRs and side effects, the term PV, the accessibility of a national reporting system, and the availability of an ADR reporting form.^{19,27} Two studies comparing the attitudes of HCPs revealed that pharmacists (89.5%) have a positive attitude about ADR reporting, followed by medical doctors (89.5%, 73.6%). Nurses had the worst attitude with only 20% having a positive attitude.^{21,27}

However, when compared with physicians and nurses, pharmacists had the least awareness of ADR reporting, according to another study. It also revealed that pharmacists lacked knowledge of how to report ADRs and the types of ADRs that should be reported.³² Another study, on the other hand, reported no link between respondents' professions and their knowledge and attitudes about ADR reporting.³⁰

HCPs knowledge of ADR report

Several studies found that HCPs' awareness of ADR reporting is low, although few respondents were aware of or could define ADR and PV. According to a survey conducted in the

Table	Table 1. Summary of the articles used in this systematic review for data analysis and synthesis						
No	Author	Study period	Objective of study	Study population	Study design	HCP work settings	Town/region
1	Adimasu ¹²	March-April, 2013	To evaluate indicators of nurse knowledge related to ADR reporting at Felege Hiwot Referral Hospital and University of Gondar Teaching Hospital	Nurses	Cross- sectional	Hospital	Gondar/ Amhara
2	Angamo et al. ¹⁴	January, 2010	To survey the knowledge, attitude and practices of ADR reporting among HCPs in selected health facilities in southwest Ethiopia	Physicians, pharmacy, nurses	Cross- sectional	Hospital and health centers	Jimma zone/ Oromia
3	Kassa Alemu and Biru ¹⁹	May 1-30, 2019	To evaluate knowledge, attitude and practice of HCPs about ADR reporting and the associated factors at selected public hospitals in North East Ethiopia	Nurses, doctors, pharmacy, midwives, and health officers	Cross- sectional	Hospital	Amhara
4	Shanko and Abdela ¹⁸	February- March, 2015	Assessment of baseline knowledge, attitudes and practices of HCPs working in HFSUH	Nurses, physicians, pharmacists	Cross- sectional	Hospital	Harar/Harar Region
5	Teshome et al. ²¹	March 3-25, 2016	To analyze knowledge, attitude and practice of HCPs toward ADRs reporting at inpatient wards	HCPs at the inpatient wards of TASH	Cross- sectional	Hospital	Addis Ababa
6	Bule et al. ²²	March-June, 2014	To evaluated the knowledge, attitude and practices of ADR reporting among HCPs in Adama Hospital Medical College	Nurses, doctors, and pharmacists	Cross- sectional	Hospital	Adama/ Oromia
7	Belete et al. ²⁷	March-June, 2014	To measure the knowledge, attitude and practice of HCPs toward ADR reporting in Boru Meda Hospital	Nurses, doctors, pharmacy, midwifery, and health officers	Cross- sectional	Hospital	North East Ethiopia/ Amhara
8	Seid et al. ²⁶	March-May, 2017	To evaluate the knowledge, attitudes and practices of HCPs toward ADR reporting	Nurses, health officers, pharmacy	Cross- sectional	Health centers	Gondar/ Amhara
9	Hailu et al. ³⁰	March-July, 2013	To determine the knowledge, attitude and practices of HCPs regarding (ADR) reporting in Northwest Ethiopia	Doctors, nurses, and pharmacists	Cross- sectional	Hospital	Gondar/ Amhara
10	Nadew et al. ¹¹	October- December, 2017	To evaluate ADR reporting practices and associated factors among doctors in government hospitals in Addis Ababa	Doctors working in selected governmental hospitals	Cross- sectional mixed- methods study design	Hospitals	Addis Ababa
11	Denekew ¹⁶	September- October, 2013	To evaluate the knowledge, attitude, and practice of ADR reporting and factors affecting reporting among HCPs working in ART clinics of public health facilities of Addis Ababa	Healthcare providers working in ART clinics	Cross- sectional	ART clinics of public health facilities	Addis Ababa

Table	Table 1. Continued						
No	Author	Study period	Objective of study	Study population	Study design	HCP work settings	Town/region
12	Gidey et al. ²⁵	January- March, 2019	To evaluate the knowledge, attitude and practice of ADR reporting and identify associated factors with ADR reporting among HCPs	Nurses, pharmacists, physicians	Cross- sectional	Hospital	Tigray Region
13	Gurmesa and Dedefo ²³	January-June, 2015	To evaluate the knowledge, attitude and practice of HCPs working in Nekemte town toward ADR reporting	Doctors, nurses, health officers, pharmacists	Cross- sectional	Health service centers	Nekemte/ Oromia
14	Mulatu and Worku ²⁰	May- November, 2012	To evaluate the knowledge, attitude and practice of HCPs toward ADR reporting and associated factors with reporting	Doctors, nurses, pharmacists	Cross- sectional	Hospitals	Amhara
15	Goshime ¹⁷		To evaluate the knowledge, attitude, and practices on ADR reporting among community pharmacists in Addis Ababa	Community pharmacies	Cross- sectional	Community pharmacies	Adds Ababa
16	Tariku and Eshetu Mulisa⁵	January 24-February 7, 2014	To define the status of knowledge, practices, and attitudes toward ADR reporting among HCPs in Nekemte Hospital	Physicians, pharmacists, health officers, nurses, and anesthesiologist	Cross- sectional	Hospital	Nekemte/ Oromia
17	Abay and Dires ¹³	May, 2007	To assess the practice of ADR reporting and obstacles of reporting in Gondar University Teaching and Bahirdar Felege Hiwot Referral Hospitals	Physicians, nurses, and pharmacists	Cross- sectional	Hospital	Gondar/ Amhara

ADR: Adverse drug reactions, HCPs: Healthcare professionals, HFSUH: Hiwot Fana Specialized University Hospital, ART: Antiretroviral therapy, TASH: Tikur Anbessa Specilized Hospital

Tigrai Region, 29.3% of respondents did not know the accurate definition of adverse reactions and only 36.8% knew what to report.²⁶ According to a research conducted in Nekemte, 80%, 66.1%, 45.2%, and 48.7% of health professionals do not understand the difference between ADR and side effects, the word PV, the national ADR reporting system or the existence of an ADR reporting form.²² In a similar survey conducted in southwest Ethiopia, 79% and 80% of professionals, respectively, did not comprehend the difference between ADR and side effects, nor the phrase PV.¹⁹

The term PV and its purpose were grasped by 20.2% of HCPs in a survey conducted in North East Ethiopia.¹⁴ Similar findings were that 36.8% knew the term PV.³⁰ Another survey of health centers in Gondar town found that only 12.7% recognized what the term PV meant and could appropriately define it.¹⁵ In contrast, most HCPs (76.9%,¹⁶ 70.2%³¹) could tell the difference between ADR and side effects.

According to a study conducted on physicians in Addis Ababa, 30.2% had never heard of the ADR reporting system, 49.6% had never heard of national guidelines, and 71.3% had no idea how to submit ADR instances to the appropriate organization.¹²

According to research conducted in Addis Ababa's antiretroviral therapy (ART) clinics, 46.2% were aware of the presence of a national PV center, but only 39.3% knew, where it was located.²⁵

According to a research conducted by Teshome et al.,²¹ in Addis Ababa, 49.8% of respondents were aware of the responsible entity to whom ADR should be reported. Similar findings were found in Amhara region, 57.1%;¹⁷ in North East Ethiopia, 21.1%;¹⁴ in Gondar, 49%;¹⁵ in West Ethiopia, 24%;²¹ in South West Ethiopia, 46.34%;¹⁹ and in Eastern Ethiopia, 61.36%.²⁷ Regarding the yellow card approach for ADR reporting, 37.4% of HCPs were aware of its existence.²¹ 51.8% chose yellow card for ADR reporting, according to similar studies.¹⁴ The yellow card reporting mechanism for reporting ADRs was known to be 57.3%.²³

Other studies indicated 63.2% and 59.6%,³⁰ 58.5% and 47.7%²⁰ recognized the availability of national reporting system and ADR reporting form in Ethiopia, respectively. According to research conducted in the Tigray Region, 39.4% were aware of National Reporting Center and just 31.9% knew where to report.²⁶

When it comes to the types of ADRs that should be reported, 69.2% of HCPs believe that all suspected ADRs should be

Table 2. The characteristics of studies that were considered in the systematic review for ADR reporting knowledge, attitude, and practice among Ethiopian HCPs

No	Authors	Study period	Survey delivery method	Sample size (response rate)	Type of questions (scale) used	Measured outcomes (findings)
1	(11)	October-December, 2017	Self-administered questionnaire and key person interview	422 (96%)	MCQ for knowledge and Likert scales for attitude, open-ended interview questionnaire	Knowledge, attitude, practice
2	(17)	April-June, 2014	Self-administered questionnaire	422 (89.9%)	MCQ, likert scale questions	Knowledge, attitude, practice
3	(20)	May-November, 2012	Self-administered questionnaire	708 (88.3%)	Yes/no, Likert scale questions	Knowledge, attitude, practice
4	(23)	January-June, 2015	Self-administered questionnaire	133 (100%)	Yes/no, likert scale questions	Knowledge, attitude, practice
5	(19)	May, 2019	Self-administered questionnaire	120 (95%)	Yes/no, likert scale questions	Knowledge, attitude, practice
6	(19)	March-June, 2014	Self-administered questionnaire	62 (92%)	Yes/no, likert scale questions	Knowledge, attitude, practice
7	(25)	January-March, 2019	Self-administered questionnaire	362 (84.8%)	MCQ, likert scale questions, yes/no	Knowledge, attitude, practice
8	(26)	March-May 2017	Self-administered questionnaires	102 (100%)	Yes/no, MCQs and Likert scale	Knowledge, attitude, practice
9	(14)	January, 2010	Self-administered questionnaires	82 (100%)	Yes/no and Likert scale	Knowledge, attitude, practice
10	(16)	September-October, 2013	Self-administered questionnaires	251 (93.22%)	Yes/no, MCQs and Likert scale	Knowledge, attitude, practice
11	(21)	March, 2016	Self-administered questionnaire	280 (76.1%)	Yes/no and Likert scale	Knowledge, attitude, practice
12	(22)	March-June 2014	Self-administered questionnaire	130 (100%)	Yes/no, MCQs and Likert scale	Knowledge, attitude, practice
13	(18)	February to March, 2015	Self-administered questionnaire	325 (91.4%)	Yes/no, MCQs and Likert scale	Knowledge, attitude, practice
14	(30)	March to July, 2013	Self-administered questionnaire	156(96.1%)	Yes/no, MCQs and Likert scale	Knowledge, attitude, practice
15	(12)	March to April, 2013	Self-administered questionnaire	214 (100%)	Yes/no, MCQs and Likert scale	Knowledge, attitude, practice
16	(15)	January 24-February 7, 2014	Self-administered questionnaire	150 (76.6%)	Yes/no, MCQs and Likert scale	Knowledge, attitude, practice
17	(13)	Мау, 2007	Self-administered questionnaire	141 (60.8%)	Open and close end questions	Knowledge, attitude, practice

ADR: Adverse drug reactions, HCPs: Healthcare professionals, MCQ: Multiple-choice questions

reported, whereas 15% (12.8%) believe that only major ADRs should be reported.¹² Similar findings were obtained in North East Ethiopia 80.7% life-threatening and 84.2% disability-causing ADRs should be reported.³⁰

HCPs' attitudes toward ADR reporting

Studies revealed that the attitude of HCPs toward ADR reporting is positive. The participants agreed that ADR reporting benefits public health, that one report can make a difference and that filling out the ADR yellow form is helpful. They also agreed that ADR reporting should be mandatory. ADR reporting is the responsibility of all health practitioners, according to 95.3% of doctors in Addis Ababa.¹¹ Other studies in North East Ethiopia 87.7%,¹⁴ 93.0%,³⁰ in Tigray Region 67.4%,²⁶ in Southwest Ethiopia 57.31%,¹⁹ in Addis Ababa 84%²¹ in East Shoa zone 85.4%,²⁰ in Harar 60.68%²⁶ in Addis Ababa 92.7%,²³ and in Nekemte 97.43%.²²

Based on a survey from North East Ethiopia, majority of the health care professionals strongly agreed that ADR reporting is compulsory (76.3%).¹⁴ Similar findings obtained in Nekemte town (57.9%,²¹ 70.1%,³⁰ 37.8%,²⁶) and in Gondar (82%).³²

According to a survey conducted in the East Shoa zone, 93.8% of HCPs believed that ADRs should be reported on a frequent basis.²⁰ Similar findings in North East Ethiopia 77.2%,¹⁴ Tikur Anbessa Specialized Hospital 87.3%²³ in Addis Ababa 88.9%,²² reporting at health center level in Gondar 79.4%,¹⁵ Eastern Ethiopia, Harare 73.9%,²⁷ Nekemte 78.3%.²²

Majority of studies also agree that monitoring an ADR is vital for the public (93.6%), the health care system (94.9%), and patient care quality (84.6%).²³ According to a survey conducted in Addis Ababa, 90.1%, 85.5%, and 92.5% of HCPs agree that ADR reporting is beneficial for patients, the public, and the healthcare system, respectively.²⁵ In a survey in the east Shoa zone 94.7% and 88.6% of respondents agreed that reporting ADR is important for the public and improves the quality of patient care, respectively.²⁰ A similar result was found in southwest Ethiopia, where 71.95%, 70.73%, and 73.17% agreed that reporting ADR is important for the public, health care system, and patient care, respectively.¹⁹ According to a survey conducted in Harare, 83.4% of HCPs believe that reporting medication safety is critical for the public, and 73.2% believe that reporting ADR is critical for the health care system.²⁷ According to a survey conducted in Gondar, 96.7% of respondents believe that ADR reporting is beneficial to public health.³² A similar survey in Nekemte town found that 90.4%, 96.5%, and 98.2% of interviewees stated that ADR monitoring is important for the public, the patient, and the health care system, respectively.22

On the other hand, over 77% of HCPs believe that before reporting an ADR, it is necessary to confirm that it is related to the medicine.²⁷ Also studies with similar findings are conducted in Jimma (85.4%),¹⁹ in Addis Ababa (76.9%),²³ East Shoa zone (76.3%),²⁰ in Gondar (83.3%),¹⁵ and in Easter Ethiopia (67.8%).²⁷ 73.7% stated that one ADR report makes a difference.¹⁴ One ADR report can make a difference according to 82.0% of respondents.³² On the other hand, 57.31% and 56.10% disagreed that one ADR report had no impact and that reporting was irrelevant for the specific patient.¹⁹ About 62.4% disagreed that ADR reporting adds to burdens, while 39.3% were opposed to report only ADR if it causes permanent handicap.²⁷ ADR reporting is a time-consuming job that produces no results according to 10.5% of health professionals.³⁰ According to a survey conducted in Tigray, 64.8%²⁶ believed that reporting adds to their burden, which is more than 32.4% found in the Amhara Region.¹⁵

The majority of HCPs do not know which form of ADR should be reported regarding the nature of ADR to report, in a survey conducted in Addis Ababa, 35.4% of clinicians disagreed that all suspected ADR instances should be reported.¹² Another survey in Tigray Region found that 51.1% disagreed that only prescribed medications should be reported.²⁶ Similar results were found in Nekemte by 9.5%.²² Another survey in West Ethiopia found that 43.6% believe that reporting ADRs is encouraged, when the reaction is serious.²¹ Similar findings were obtained in Gondar (44.1%).¹⁵

HCPs reporting practices for ADRs

According to findings of the studies, HCPs' reporting of ADRs is often poor since many encountered ADRs but did nothing about them. According to a survey conducted in Amhara region, only 38.1% had experience marking ADRs on their clinical records.¹⁷ Similar findings were found in North East Ethiopia, where 29.82% of clinicians experienced at least one patient with ADR in the previous 12 months,¹⁴ only 27% of HCPs in Nekemte town have dealt with ADR patients,²¹ only 21.1% of doctors in North East Ethiopia seen patients with ADR in the previous 12 months.³⁰ Only 15.85% of clinicians in South West Ethiopia had to deal with ADR throughout their work,¹⁹ in Eastern Ethiopia 49.2% encountered ADR in the past 12 months of their clinical practice²⁷ "in Gondar only 28.6% claim to have reported an ADR to a reporting center at least once".32 In two studies conducted in Addis Ababa, 43.2%²² and 38.5%²⁷ of HCPs said they had seen at least one patient with ADR in the previous year.

In the Tigray Region, however, 74.9% of clinicians experienced ADR in the previous 12 months of practice,²⁶ survey conducted in Gondar, 55.9% of respondents had encountered at least one patient with ADRs during their job experience,¹⁵ 64.6% of those in the East Shoa zone said they had encountered ADR in their clinical practice.²⁰ A study of physicians in Addis Ababa found that 84.3% of physicians experienced ADR cases during their professional careers with 87.2% of physicians recording the cases in the patients' medical records.¹²

In most studies on HCPs who have encountered ADRs from their clients, a small number of ADRs have reported. According to a survey conducted in Addis Ababa, only 27.4% of them have reported ADR situations to authorized agencies during their professional careers.¹² Similar results were found in Amhara region 27.7%,¹⁷ in Tigray Region 32.1%,²⁶ in Gondar 49.1%,²⁶ a survey in South West Ethiopia among interviewed HCPs none of them reported *via* yellow card to responsible body,³¹ in Addis Ababa 10.8%,²⁷ in East Shoa zone 29.2%,²⁰ and in North west Ethiopia 28.6%.³² In contrast, few studies reported that a large number of respondents ever reported ADR. Based on a study in North East Ethiopia, 50% of respondents reported ADRs,¹⁴ another study in North East Ethiopia 83.3%,³⁰ in Harar 60.68%.²⁷

On the other hand, 27.7% of HCPs who reported ADR did so to Food, Medicine and Healthcare Administration and Control Authority, the government agency in charge of monitoring and analyzing ADR in the country.¹⁷ Similar results were found in Addis Ababa 39.36%,¹² in North East Ethiopia 29.41%,¹⁴ and Nekemte 14.3%.²¹

In contrast, a study in East Shoa zone indicated that 67.7% of respondents reported to have never reported ADRs to any of the responsible bodies,²⁰ similar findings were found in northwest Ethiopia; 46% of respondents who had never reported any ADRs to any reporting centers.³²

Encouraging and discouraging factors that influence ADR report

Encouraging factors

Accessibility of ADR information sheets at outpatient departments by 80.7%, encouraging all health professionals to report by 75.4%, training to report ADR by 72.8%, encouraging patients to report by 66.7%, drug information center assistance by 66.7%, and easy accessibility to ADR forms by 59.6% were all suggested by Kassa Alemu and Biru¹⁹ as ways to improve ADR reporting. In west Ethiopia, awareness creation on what, when, and to whom to report ADRs accounted for 42.1%, with in-service training accounting for 26.3%.²¹

Discouraging factors

In a survey conducted in North Eastern Ethiopia, respondents agreed that there is a lack of feedback by 58.8%, reporting forms are not available, when needed by 46.4%, not knowing where to report by 46.4%, not knowing how to fill and report the report form by 41.2%, other colleagues are not reporting ADR cases by 37.7%, and it is unclear whether there is a causal link between the drug and ADR by 35.9%.¹⁹ According to a study from eastern Ethiopia, the causes for under-reporting were inaccessibility of the reporting form (53.9%), ambiguity of how to report (51.9%), and lack of feedback from the responsible entity (41%).²⁶ In a research in West Ethiopia, under-reporting of ADRs was due to a lack of awareness and information about what, when, and to whom to report them (30.8%), and a lack of commitment from HCPs (25.5%).^{21,22} Another survey found that the reasons for not reporting were the need to be certain of how to report ADR (52.9%), the unavailability of ADR reporting forms (51%), and the lack of feedback (47.1%) were all factors for not reporting.¹⁵ According to a survey conducted in Gondar, respondents stated that they were unsure about reporting ADRs (23.2%), that they had not received feedback (18%), that they did not have access to reporting forms (15.3%), and that they did not report since the ADR was quite well (17.3%).32

DISCUSSION

A spontaneous ADR reporting system is essential for effectively discovering new ADRs, but it has one main drawback: underreporting.⁸ HCPs are accountable for identifying, recording, and reporting ADR. Their assistance in detecting and reporting ADR at an early stage is crucial.³³ Many factors including lack of awareness, uncertainty about who should report, challenges with reporting procedures, lack of feedback on submitted reports, and rapid resolution of adverse occurrences affect ADR reporting.^{34,35} ADR reporting is strongly linked to HCPs rs knowledge and attitudes.³⁶ To improve reporting processes, it is critical to examine healthcare practitioners' knowledge, attitude, and practice in relation to ADR reporting.³⁷

This systematic review focused on health care professionals' knowledge, attitude, and practice regarding ADR reporting as well as the many factors affecting ADR reporting in Ethiopia. The findings of this review study revealed that the primary hurdles to reporting by health care personnel were a lack of understanding of basic concepts linked to PV and ADR reporting process. Majority of research found that health professionals lacked knowledge and experience but had a positive attitude toward reporting ADRs. Most health care professionals suggested giving continuous education or special training courses relevant to PV and the ADR reporting process to improve ADR reporting.

According to studies, there is a link between demographic parameters and professional setting characteristics as well as HCPs reporting ADR. Few studies have described that sex and education have significant associations with ADR reporting practice. Female physicians were 3.5 times more likely to report ADRs than male physicians.¹² This could be because females are more likely than their male counterparts to report ADRs.³⁸ Furthermore, females may be more aware of PV and ADR reporting.³⁹ With regard to level of education, similar with a study done in Ghana and Egypt.⁴⁰ It is indeed possible that this is due to specialists receiving ADR training and having more expertize in the field. In addition, experts knew more about PV and ADR reporting than general practitioners. This put them in a better position to notify the national PV center about any ADRs they faced.⁴⁰

HCPs with more work experience are more likely to practice, have higher expertise, and have a good attitude toward ADR reporting.^{12,26} Similarly, HCPs with less working experience have poor ADR reporting practices.²⁶ Increased years of experience are linked to greater awareness of the national ADR reporting system's existence.²⁶ This finding is similar to one found in an Ugandan study, in which more experienced HCPs were four times more likely than less experienced professionals to have ever reported.⁴¹ This could be due to increased exposure to numerous classes of drugs and better understanding of their properties as a result of extensive work experience. Furthermore, experienced HCPs have the opportunity to participate in in-service trainings and other scientific conferences. Years of experience among physicians and other healthcare personnel were similarly linked to knowledge and attitudes concerning PV and ADR reporting according to the study.⁴¹ Only 23% of intern pharmacists and physicians in South Africa recognized how to report ADRs according to a recent survey, yet percentage was familiar with the reporting form having seen it before.³⁸ Van Hunsel et al.⁴⁶ discovered that there is no standard for teaching PV at universities, which could be one cause for this.⁴²⁻⁴⁵ Attending ADR reporting training was found to have a strong relationship with knowledge, and the level of knowledge¹⁴ was linked to ADR reporting.^{17,24} In comparison to participants who had received ADR reporting training, HCPs who had not received ADR reporting training were less likely to have adequate knowledge. On the other hand, HCPs who had not undergone ADR reporting training were more likely to have poor practice²⁶ and knowledge.¹⁵ This finding is consistent with the study by Lewis et al., which included providing training to physicians under reporting rate was 36%.⁴ Physicians were provided personalized training on how and why to report suspected ADRs in the study's spontaneous component. However, despite most events being mild to moderate in nature, this low underreporting rate may indicate, in addition to the

effect of training, a greater motivation to report ADRs in this patient. This is similar to a study conducted in Spain which found that participation in educational activities related to the detection and resolution of drug-related problems was linked to ADR reporting.³⁹ This could be due to the impact of training to increase the grasp of health professionals on the reporting process.

In this review, research revealed statistically significant disparities in knowledge, attitude, and practice regarding ADR reporting among healthcare workers. According to studies, physicians have a better likelihood of diagnosing ADRs than other healthcare providers because they either lack confidence in diagnosing or have less duties on the ward to intervene.^{20,30} Similar findings were found with physicians seeing more patients with ADR than pharmacy professionals and nurses.³¹ This could be because physicians were older and had more years of experience than pharmacists. Pharmacists, on the other hand, claimed to have a better understanding of PV and ADR than physicians.⁴⁰

When compared with other HCPs professionals (physicians, nurses, and health officers), pharmacists have more knowledge.^{14,15,21,27,31} This disparity in knowledge could be due to the nature of pharmacist training, which places a strong emphasis on drugs and their safety.45 Similar findings were found in a study from South Africa on various degrees of knowledge among different occupations with nurses having the least understanding on how to report.⁴² According to the study, an alarming 92% of respondents felt that physicians should be held accountable for reporting. "Who is accountable for adverse drug reporting?" is a question that has to be addressed. Nurses are not fully aware of their role in ADR reporting, according to Van Hunsel et al.⁴⁶ found a similar result with 89% of nurses preferring to refer the report to the physicians for completion. Workload, inattention, trust in reporting, and fear of litigation are all possible explanations for low nurse reporting rates according to other studies.46

The outcomes of this review article revealed an Ethiopian lack of understanding about PV and drug safety. The figs of the several papers revealed that HCPs' awareness of ADR reporting is minimal, even though a small proportion of them were aware of or could define ADR and PV. Insufficient awareness of PV ideas, methods, and functioning was found in most trials and was identified as a major obstacle to reporting ADRs. Numerous studies^{14,15,22,26,30,31} showed that a large number of respondents have limited knowledge on the definition of ADR, the difference between ADR and side effects, the term PV, the national ADR reporting system, and the availability of ADR reporting forms. It was clearly indicated that a portion of health care professionals have limited information or have never heard the existence of a national ADR reporting system, national guidelines and do not know about the PV system and how to report ADR cases to the responsible body.^{12,24,26,27} Several HCPs are untrained, which can lead to inadequate knowledge of ADR reporting. This represents an important issue that needs to be addressed; the PV center in Ethiopia should provide training for HCPs. This review showed that only a few HCPs

were aware of the existence of an ADR system in Ethiopia. This meant that most of the professionals did not have information about the center responsible for monitoring ADRs in Ethiopia. Similarly, a lack of knowledge about the national ADR reporting system was reported in different regions of the country. This is a critical observation, which is undoubtedly related to the current underreporting of ADRs. This finding is similar to a study in Nigeria, where lack of knowledge of the forms and procedures for reporting is cited as a determinant factor for reporting.⁴³ Moreover, a systematic review on the determinants of ADR reporting conducted in Spain confirmed that knowledge of health professionals appeared to be strongly related with reporting in a high proportion of studies.⁴⁴ A similar study in Spain also indicated that having the basic knowledge needed to report ADR was a determinant factor for ADR reporting.³⁹ This implied that a certain level of knowledge is required for a health professional to report ADR. Those health professionals with adequate knowledge have a higher chance of understanding the key procedures of reporting such as what to report, where to report, and when to report, which in turn encourages reporting. HCPs' positive attitudes regarding ADR reporting were discovered to be a critical factor in predicting ADR reporting. Positive attitudes such as the perception that reporting will benefit public health, increase patient safety, and contribute to a better understanding of drug risk, are essential characteristics to consider, when designing interventions aimed at increasing HCP reporting rates. Most study participants believed that reporting is vital for the public, improving patient safety and the health-care system; that one report can make a difference; that filling out the ADR yellow form is helpful; and that ADR reporting should be mandatory.^{12,14,16,22,24,28,30,31} This is the same as a study in Sweden, where majority (80.9%) of the HCPs were in opinion that ADR reporting is the duty of physicians, nurses,

Similarly, HCPs have stated that before reporting an ADR it is necessary to confirm that the ADR is linked to the drug.^{15,20,23,26,27,31} In research, a bigger number of respondents was concerned about legal liability during reporting. This indicated that the majority of health professionals working in hospitals across the country are unaware that any reported case cannot be utilized as a source document for legal difficulties as stated clearly in the ADR reporting guideline.

and pharmacists.⁴⁶ This implied that health professionals had

appropriately recognized ADR reporting as a professional

obligation.

Only a few studies found that respondents agreed that reporting increased their workload.^{15,26,27,30} Though it may take some time to fill out the report forms, the percentage of respondents who hold this belief, as revealed by this study, may influence motivation to report adverse responses. HCPs should consider ADR reporting a responsibility and be familiar with current PV systems.

Several surveys identified factors that facilitate ADR reporting to improve PV system training to report ADR, encouraging patients to report, availability of ADR information sheets, encouraging all health professionals to report, and drug information center assistance.^{14,21} Many HCPs stated that they have encountered ADR during their practice; however, a sizable percentage do not report it to the appropriate authorities (regulatory authorities, manufactures, *etc.*).

Different articles, on the other hand, have looked into the reasons for underreporting ADRs. Common reasons indicated were lack of knowledge,^{14,21,25} and lack of feedback.^{14,15,25,32} Besides reporting forms are not available, when needed 46.4%.^{14,15,25,32} Other reasons were that other colleagues are not reporting ADR cases,¹⁴ uncertain that causal association between drug and ADR,^{14,15,32} did not report because the ADR was well known (17.3%).³² This is identical to a similar review conducted in Europe.⁸ Similar reasons under ADR reporting were also mentioned in the gualitative section of this study. This implied that, if relevant organizations worked to reduce these barriers, the reporting rate might be improved. Lack of effective feedback mechanisms from the concerned organization through various channels may deter health professionals from reporting ADR. In a few of the studies included in this review, feedback from the PV center with information regarding the reported ADR was identified as a positive element that could improve reporting. Receiving personalized feedback from a PV center was thought to be a major motivator to report an ADR in the future in a study done in the Netherlands.⁴⁷ Furthermore, this finding suggests that health practitioners across the country have linked ADR reporting to legal and ethical concerns. This indicated that health professionals' perceptions of various impediments are essential in establishing the causes of underreporting and that removing these impediments could lead to an increase in spontaneous reporting. ADR reporting is hampered by the difficulty of reporting mere suspicions, health professionals, who are encouraged by one-sided drug advertising, and the idea that only safe pharmaceuticals are allowed on the market.

Based on the studies included in this review, HCPs' reporting of ADRs is often poor, as many encounter ADRs but do nothing about them. Responses based on encountered vs. reported ADRs were used to assess healthcare practitioners' practices. The disparity between the number of respondents, who encountered an ADR in practice and the proportion, and who reported an ADR was alarming.^{12,15,17,20,23,26,32} Few of the health professionals who reported ADR reported it to Ethiopia's PV center, which is in charge of monitoring and analyzing ADR.^{12,14,17,21} Low reporting is a big concern among health professionals, according to this article. The fact that most health professionals lacked fundamental comprehension of the reporting system could explain the low reporting rate. Poor feedback and limited reporting options may have an additional impact on reporting. Similarly, despite having strong understanding and awareness of ADRs, Toklu and Soyalan⁴⁷ observed a low level of practice by healthcare providers. According to Fadare et al.⁴⁸ despite the fact that 80% of respondents experienced an ADR, less than half of them (42.7%) chose not to report it.

Health practitioners with a low degree of knowledge were more likely to record adverse events incorrectly. Many previous studies have found a link between low levels of knowledge among health practitioners and bad ADR reporting practices.^{8,41,43} Furthermore, health workers who did not obtain ADR reporting training were more likely to practice poorly. A study conducted in Spain backs this up.³⁹ Similarly, in a study conducted in Uganda, HCPs also showed poor training in areas of ADR and reporting.³⁷ As a result, more training is required in terms of identifying ADR, the goal of ADR reporting, and the availability of resources for ADR reporting.

Findings from this review have important implications. Different measures should be developed to improve HCPs' limited knowledge of the ADR and its reporting. Multiple interventions appear to have had more impact than single interventions according to systematic evaluation of efforts to enhance ADRs reporting.⁴⁴ Several studies have found that educational interventions such as oral workshops, oral presentations, group discussions, developing ADR newsletters in hospitals, and ongoing training in PV and ADR reporting increased knowledge and attitude scores.⁴⁹⁻⁵¹ Incorporating PV-related activities into undergraduate and postgraduate training programs could help improve reporting. In a study conducted in Nigeria and Italy, similar strategies were suggested as a solution to enhance reporting.^{52,53}

Other studies have found that offering incentives to health practitioners improves ADR reporting.^{54,55} In a study conducted in Spanish that included both financial incentives and educational activities, the average number of ADRs reported increased by up to sixfold.⁵⁵ Improved reporting rates were achieved by increasing the accessibility of yellow cards on wards and encouraging the use of web-based reporting. As a result, empowering HCPs in detecting and reporting suspicious drug reactions and employing evidence-based tactics is critical to improve Ethiopian PV systems. This is particularly crucial for less experienced health workers and those, who have never had ADR reporting training. Nonetheless, more research is needed to determine the impact of these interventions on ADR reporting knowledge and practice in our setting.

The main limitation of this review was that data were extracted based on self-reported information and the possibility of reporting errors and recall biases could not be ruled out in studies. The cross-sectional design used in these articles may not be able to prove a causal link between ADR reporting and explanatory variables. Inconsistencies in the study were population of interest, data gathering scales, and methodology. Because some of the questions in the eligible studies were closed-ended and others were open-ended, the outcomes of this evaluation could be influenced by differences in how they were asked. The encouraging and discouraging variables that influence reporting are not necessarily worded exactly as they appear in the articles; slight edits were made to fit them into the final list of factors. These modifications are unlikely to influence the review's principal finding.

CONCLUSION

Knowledge, attitudes, and practice of HCPs toward PV were found to be associated with ADR reporting in this systematic review. Sex, level of education, years of experience, and profession appear to have an impact on reporting among personal and professional factors. When compared to other HCPs, pharmacists had more expertise, good attitudes, and a higher reporting rate. Involvement of HCPs in maintaining drug safety necessitates a thorough understanding of PV ideas, processes, and functions. ADR reporting is a vital component of ensuring drug safety at the individual and population levels, and HCP participation is critical. To improve ADR reporting by HCPs, it is recommended to design customized curricular interventions based on existing gaps in knowledge and attitudes that can be integrated within the health education curriculum or in-service training after graduation.

Ethics

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: Z.G.A., N.A., Design: Z.G.A., N.A., Data Collection or Processing: Z.G.A., N.A., Analysis or Interpretation: Z.G.A., N.A., Literature Search: Z.G.A., N.A., Writing: Z.G.A., N.A.

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