

REVIEW

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

**Short Title: Healthcare Professional's Knowledge, Attitude and Practice**

Zelalem Gebretsadik Anbeo, Nurettin Abacioglu  
Department of Pharmacology, Near East University, Nicosia, T.R.N.C. via Mersin-10, TURKEY

## Corresponding Author Information

Zelalem Gebretsadik Anbeo  
zelalemgebretsadik@yahoo.com  
+251912387870  
<https://orcid.org/0000-0002-9957-114X>  
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## Abstract

ADRs (Adverse drug reactions) are a prominent cause of morbidity and mortality, as well as higher healthcare expenditures. Healthcare professionals (HCPs) play a crucial role in ADRs reporting through spontaneous reporting system, but under-reporting is its 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. Methods* 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 ADR reporting in Ethiopia. A standard procedure of systematic review protocol (PRISMA) was used to conduct this review. Demographic factors, sample size, response rate, survey delivery, HCPs working setting, encouraging and discouraging factors of ADR reporting were extracted information from articles. *Results* A total of 17 articles 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%. The majority 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 (PV) and ADRs are frequently recommended considerations. *Conclusion:* 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, it is suggested that specific educational interventions based on existing gaps in ADR reporting be developed and integrated into the health education curriculum or provided as in-service training after graduation.

**Keywords:** Adverse drug reactions; knowledge; attitudes; practice; healthcare professionals; reporting, pharmacovigilance

## 1. INTRODUCTION

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.<sup>1</sup> ADRs raise the risk of hospitalization, emergency department visits<sup>2</sup> and hospitalization lengthening everywhere over the world.<sup>3</sup> 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 PV system.<sup>3</sup> The reporting of suspected ADRs determines whether a PV system succeeds or fails.<sup>4</sup>

In the ADR reporting and PV system, healthcare practitioners play a critical role.<sup>5</sup> ADRs can be reported directly to national PV systems or to pharmaceutical manufacturers by both HCPs and patients.<sup>6</sup> The early detection of signals and dangers related to drug usage is improved by reporting ADRs to the appropriate regulatory body<sup>7</sup>

Despite widespread worries about medication safety, healthcare workers still lack understanding of PV and ADRs reporting.<sup>8,9</sup> Furthermore, according to recent studies, ADRs are underreported by healthcare workers, particularly in poorer nations. Only 2-4% of all adverse events and 10% of significant ADRs are reported globally, according to reports.<sup>10</sup> Any suspected adverse reaction, specifically those suspected reactions to newly authorized drugs and significant occurrences, should be reported by HCPs such as physicians, pharmacists, and nurses.<sup>11</sup> As a result, medicine safety evaluation must be considered an integral element of HCPs' daily clinical practice.<sup>5</sup>

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 under-reporting 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 aims to evaluate healthcare workers' knowledge, attitudes, and practices and identifying characteristics that encourage or discourage them from reporting ADRs.

## **2. METHODS**

### **2.1 literature search strategy**

To identify papers 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 taken into account. The PRISMA procedures were followed for conducting this literature review.<sup>10</sup> "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 "toxicity, drug" OR "Ethiopia" were combined search terms to identify eligible articles.

The search was performed in April 2020, with no restrictions on study design or publication year. (Figure 1). Publication year of article was not imposed on the search. The papers 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. In the literature search in electronic scientific databases, the same terms were employed.

### **2.2 Study selection and data abstraction**

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

### **2.3 Inclusion criteria**

Studies were chosen if they focused on HCPs' knowledge, attitudes, and practices regarding ADR reporting and PV, and they were done in Ethiopia. Both electronic grey literature articles search and published articles in scientific peer-reviewed journal articles were included in systemic review

## 2.4 Exclusion criteria

Studies on ADR data analysis, patients or consumers report, medication errors, general adverse drug events, prevalence and nature of ADRs in hospitals were excluded.

## 2.5 extraction and assessment of Data

A standardized data collection tool was used to perform for data abstraction. Author, year of publication, study objective, study period, study population, HCPs work setting, number of respondents and percent response rate, survey/study delivery (mail, face-to-face, self-administrative, e-mail/web), scale or type of questions used [yes or no questions, multiple-choice questions (MCQS), Likert scale, and open-ended questions], encouraging and discouraging factors of ADR are all characteristics extracted from each eligible study. In the tables, we've included factors that were statistically significant in the research.

## 3. RESULTS

### 3.1 Description of eligible study articles included in review

Totally 387 articles were 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 systemic review.

A total of 17 articles included in the systematic review were studies using self-administered questionnaires conducted among HCPs in Ethiopia and published between years 2012 to 2020 (February). Only one of these was a mixed-methods study, in which key informants completed a semi-structured questionnaire and self-administered questionnaires were used.<sup>12</sup> The rest of studies conducted cross-sectional design. 6 studies were conducted in Amhara region<sup>14-19</sup> 4 in the Oromia region,<sup>20-23</sup> 4 studies in the capital city Addis Ababa<sup>12,23,24</sup> and one study each was conducted in Tigray region,<sup>25,26</sup> Harare region.<sup>28</sup> The sample size for the comprised studies ranged from 62<sup>14</sup> to 708<sup>17</sup> HCPs from across databases searched for this study.

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

### 3.2 Demographic factors that impact of ADRs reporting by HCPs

According to one study, gender has a strong relationship with ADR reporting practice, with female physicians being 3.5 times more likely to report ADRs than male physicians.<sup>12</sup> However, another study found no link between different age groups and the likelihood of HCPs reporting ADR.<sup>17</sup> The practice of reporting ADRs is strongly linked to one's educational level. When compared to general practitioners, specialists are five times more likely to disclose ADR cases.<sup>12</sup> In two research, it was discovered that having more job experience as a health care worker increased the number of reports.<sup>12,27</sup> 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.<sup>12</sup> 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 the ADR reporting form's accessibility.<sup>27</sup> In addition, one study found that HCPs with less experience were more likely to record ADRs incorrectly.<sup>26</sup> Other research, on the other hand, revealed no statistically significant link between years of service and ADR reporting.<sup>17</sup>

According to a studies, having ADR reporting training has a statistically significant relationship with knowledge,<sup>14</sup> and having a high degree of knowledge is associated with ADR reporting.<sup>17</sup> 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 practice<sup>26</sup> and knowledge.<sup>15</sup>

### 3.3 Comparing ADRs reporting among different professions

A large number of studies show that all healthcare workers have inadequate understanding and habits when it comes to ADR reporting. Some research, on the other hand, demonstrate statistically significant differences amongst healthcare professions.<sup>29</sup> 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.<sup>20,30</sup> Physicians see much more patients with ADR than pharmacists and nurses, according to similar findings.<sup>19</sup>

Gurmesa and Dedefo,<sup>21</sup> evaluated the knowledge of HCPs among themselves, finding that physicians (84.2%) and pharmacists (84.2%) were more educated of 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 adequate knowledge of ADR reporting.<sup>14</sup> Nurses and health officers had an insufficient degree of understanding of ADR reporting when compared to pharmacists, according to another findings.<sup>15</sup> According to a survey conducted in Addis Ababa, 72.1% of pharmacists were aware of the yellow card reporting mechanism, while just 40.5 percent of nurses were<sup>11</sup>. According to a study in South West Ethiopia, pharmacists have significantly more knowledge than other health care professionals about the difference between adverse drug reactions and side effects, the term pharmacovigilance, the accessibility of a national reporting system, and the availability of an ADR reporting form.<sup>19,27</sup> Two studies comparing the attitudes of HCPs revealed that pharmacists (89.5 percent) 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.<sup>21,27</sup> However, when compared to 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.<sup>32</sup> Other study, on the other hand, showed no link between respondents' profession and their knowledge and attitudes about ADR reporting.<sup>30</sup>

### **3.4 HCPs' knowledge of ADR reporting**

Several studies found that HCPs' awareness of ADR reporting is low, despite the fact that few respondents were aware of or could define ADR and PV. According to a survey conducted in the Tigray region, 29.3 percent of respondents did not know the accurate definition of adverse reactions, and only 36.8% knew what to report.<sup>26</sup> According to a research conducted in Nekemte, 80%, 66.1%, 45.2%, and 48.7% of health professionals, respectively, do not understand the difference between ADR and side effect, the word Pharmacovigilance, the national ADR reporting system, or the existence of an ADR reporting form.<sup>22</sup> In a similar survey conducted in South West Ethiopia, 79% and 80% of professionals, respectively, did not comprehend the difference between ADR and side effect, nor the phrase PV.<sup>19</sup>

The term pharmacovigilance and its purpose were grasped by 20.2 % of HCPs in a survey conducted in North East Ethiopia.<sup>14</sup> Similar finding 36.8% knew the term pharmacovigilance<sup>30</sup>. Another survey of health centers in Gondar town found that only 12.7 % recognized what the term PV meant and could appropriately define it.<sup>15</sup> In contrast, the majority of HCPs 76.9%<sup>16</sup>, 70.2%<sup>31</sup> were able to 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.<sup>12</sup> According to a 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 percent knew where it was located.<sup>25</sup>

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

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

When it comes to the types of ADRs that should be reported, 69.2% of HCPs believe that all suspected ADRs should be reported, whereas 15% (12.8%) believe that only major ADRs should be reported.<sup>12</sup> Similar findings were obtained in North East Ethiopia 80.7% life threatening and 84.2% disability causing ADRs should be reported.<sup>30</sup>

### **3.5 HCPs' attitudes toward ADR reporting**

Studies revealed that the attitude of HCPs towards 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.<sup>11</sup> Other studies in North East Ethiopia 87.7%<sup>14</sup>, 93.0%<sup>30</sup>, in Tigray

region 67.4%<sup>26</sup>, in Southwest Ethiopia 57.31%<sup>19</sup>, in Addis Ababa 84%<sup>21</sup> in East Shoa zone 85.4%<sup>20</sup>, in Harar 60.68%<sup>26</sup> in Addis Ababa 92.7%<sup>23</sup>, in Nekemte 97.43%.<sup>22</sup>

Based on survey from Northeast Ethiopia majority of the health care professionals strongly agreed ADR reporting is compulsory 76.3%<sup>14</sup>, Similar findings in Nekemte town 57.9%<sup>21</sup>, 70.1%<sup>30</sup>, 37.8%<sup>26</sup>, in Gondar 82%.<sup>32</sup>

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

The majority of studies also agree that monitoring an ADR is vital for the public (93.6%), the health-care system (94.9%), and enhances patient care quality (84.6%).<sup>23</sup> 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.<sup>25</sup> A survey in east Shoa zone 94.7% and 88.6% agreed that reporting ADR is important for the public and improves quality of patient care, respectively.<sup>20</sup> Similar result was found in south west Ethiopia, where 71.95 %, 70.73 %, and 73.17 % agreed that reporting ADR is important for the public, the health care system, and patient care, respectively.<sup>19</sup> According to a survey conducted in Harare, 83.4% of HCPs believe reporting medication safety is critical for the public, and 73.2 % believe that reporting ADR is critical for the health care system.<sup>27</sup> According to a survey done in Gondar, 96.7% of respondents believe that ADR reporting is beneficial to public health.<sup>32</sup> 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.<sup>22</sup>

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.<sup>27</sup> Also studies with similar findings are conducted in Jimma 85.4%<sup>19</sup>, in Addis Ababa 76.9%,<sup>23</sup> East shoa Zone 76.3%,<sup>20</sup> in Gondar 83.3%,<sup>15</sup> in Easter Ethiopia, Harare 67.8%.<sup>27</sup> 73.7 % stated that one ADR report makes a difference.<sup>14</sup> One ADR report can make a difference, according to 82.0% of respondents.<sup>32</sup> On the other hand, 57.31 % and 56.10 % disagreed that one ADR report made no impact and that reporting is not relevant for the specific patient.<sup>19</sup> About 62.4 % disagreed that ADR reporting adds to burdens, while 39.3% were opposed to reporting just ADR if it causes permanent handicap.<sup>27</sup> ADR reporting is a time-consuming job that produces no results according to 10.5 % of health professionals.<sup>30</sup> According to a survey conducted in the Tigray, 64.8 %<sup>26</sup> believed that reporting adds to their burden, which is more than the 32.4 % found in the Amhara region.<sup>15</sup>

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

### **3.6 HCPs' reporting practices for ADRs**

According to the 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 the Amhara region, only 38.1% had experience marking ADRs on their clinical records.<sup>17</sup> 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,<sup>14</sup> only 27% of HCPs in Nekemte Town have dealt with ADR patients,<sup>21</sup> only 21.1 % of doctors in North East Ethiopia seen patients with ADR in the previous 12 months,<sup>30</sup> Only 15.85 % of clinicians in south-west Ethiopia had to deal with ADR throughout their work,<sup>19</sup> in Eastern Ethiopia 49.2% encountered ADR in the past 12 months of their clinical practice<sup>27</sup> "in Gondar only 28.6% claim to have reported an ADR to a reporting center at least once".<sup>32</sup> In two studies conducted in Addis Ababa, 43.2%<sup>22</sup> and 38.5%<sup>27</sup> 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<sup>26</sup>, survey conducted in Gondar, 55.9% of respondents had encountered at least one patient with ADRs during their job experience,<sup>15</sup> 64.6% of those in the East Shoa Zone said they had encountered ADR in their clinical practice.<sup>20</sup> 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.<sup>12</sup>

In most of studies HCPs who have encountered ADRs from their clients a small number of ADRs are ever reported. According to a survey conducted in Addis Ababa, only 27.4% of them have ever reported ADR situations to authorized agencies during their professional careers.<sup>12</sup> Similar result was found in Amhara

region 27.7%,<sup>17</sup> in Tigray region 32.1%,<sup>26</sup> in Gondar 49.1%<sup>26</sup>, a survey in South West Ethiopia among interviewed HCPs none of them reported via yellow card to responsible body,<sup>31</sup> in Addis Ababa 10.8%,<sup>27</sup> in East Shoa Zone 29.2%,<sup>20</sup> in North west Ethiopia 28.6%.<sup>32</sup> In contrast few studies reported that large number of respondents ever reported ADR. Based on study in North East Ethiopia 50% respondents reported ADRs,<sup>14</sup> another study in North East Ethiopia 83.3%,<sup>30</sup> in Harar 60.68%.<sup>27</sup>

On the other hand, 27.7% of HCPs who reported ADR did so to (Food, Medicine and Healthcare Administration and control Authority) FMHACA, the government agency in charge of monitoring and analyzing ADR in the country.<sup>17</sup> Similar result was found in Addis Ababa 39.36%,<sup>12</sup> in North east Ethiopia 29.41%,<sup>14</sup> in Nekemte 14.3%.<sup>21</sup>

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,<sup>20</sup> similar findings in North West Ethiopia 46% of respondents who had never reported any ADRs to any reporting centers.<sup>32</sup>

### **3.7 Encouraging and discouraging factors that influence ADR reporting**

#### **Encouraging factors**

Accessibility of ADR information sheets at (Outpatient Department) OPD 80.7 %, encouraging all health professionals to report 75.4 %, training to report ADR 72.8 %, encouraging patients to report 66.7%, drug information center assistance 66.7 %, and easy accessibility to ADR forms 59.6 % were all suggested by Alemu and Biru as ways to improve ADR reporting<sup>14</sup>. 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 %.<sup>21</sup>

#### **Discouraging factors**

In a survey conducted in north-eastern Ethiopia, respondents agreed that there is a lack of feedback 58.8%, reporting forms are not available when needed 46.4 %, not knowing where to report 46.4 %, not knowing how to fill and report the report form 41.2 %, other colleagues are not reporting ADR cases 37.7% and it is unclear whether there is a causal link between the drug and ADR 35.9%.<sup>19</sup> 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%).<sup>26</sup> 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 %).<sup>21,22</sup> Another survey found that 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.<sup>15</sup> 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 %).<sup>32</sup>

## **4. DISCUSSION**

A spontaneous ADR reporting system is essential for effectively discovering new adverse drug reactions, but it has one main drawback: under-reporting.<sup>8</sup> HCPs are accountable for identifying, recording and reporting of ADR. Their assistance in detecting and reporting ADR at an early stage is crucial.<sup>33</sup> Many factors, including a 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.<sup>34,35</sup> ADR reporting is strongly linked to healthcare workers' knowledge and attitudes.<sup>36</sup> To improve reporting processes, it is critical to examine healthcare practitioners' knowledge, attitude, and practice in relation to ADR reporting.<sup>37</sup>

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 the ADR reporting process. The 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 and HCPs reporting ADR. Few studies described sex and level of education have significant association with ADR reporting practice. Female physicians were 3.5 times more likely to report ADRs as compared

to male physicians.<sup>12</sup> This could be because females are more likely than their male counterparts to report adverse drug reactions.<sup>38</sup> Furthermore, females may be more aware of PV and ADRs reporting.<sup>39</sup> With regard to level of education similar with a study done in Ghana<sup>40</sup> and Egypt.<sup>40</sup> It is indeed possible that this is due to specialists receiving ADR training and having more expertise 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.<sup>40</sup>

HCPs with more work experience are more likely to practice, have higher expertise, and have a good attitude toward ADR reporting.<sup>26,12</sup> Similarly, HCPs with Less working experience have poor ADR reporting practices.<sup>26</sup> Increased years of experience are linked to a greater awareness of the national ADR reporting system's existence.<sup>26</sup> This finding is similar to one found in a Ugandan study, in which more experienced HCPs were four times more likely than less experienced professionals to have ever reported.<sup>41</sup> This could be due to increased exposure to numerous classes of drugs and a 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.<sup>41</sup> Only 23% of intern pharmacists and physicians in South Africa recognized how to report ADRs, according to a recent survey, yet % were familiar with the reporting form, having seen it before.<sup>38</sup> Van Eekeren et al.<sup>46</sup> discovered that there is no standard for teaching PV at universities, which could be one cause for this. Attending ADR reporting training was found to have a strong relationship with knowledge, and level of knowledge<sup>14</sup> was found to be linked to ADR reporting<sup>17,24</sup>. 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. HCPs who had not undergone ADRs reporting training, on the other hand, were more likely to have poor practice<sup>26</sup> and knowledge.<sup>15</sup> ‘‘This finding is consistent with the study by Lewis *et al.*, which included providing training to physician under reporting rate was 36%’.<sup>4</sup>

Physicians were provided personalized training on how and why to report suspected ADRs in the study's spontaneous component. However, despite the majority of 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.<sup>39</sup> This could be due to the impact of training to increase health professionals' grasp of 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.<sup>20,30</sup> similar finding physicians see more patients with ADR than pharmacy professionals and nurses.<sup>31</sup> 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.<sup>40</sup>

When compared between pharmacists with other HCPs professionals (physicians, nurses and health officers) they are more knowledge.<sup>31, 21, 14, 15, 27</sup> This disparity in knowledge could be due to the nature of pharmacist training, which places a strong emphasis on drugs and their safety.<sup>45</sup> 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.<sup>42</sup> 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 adverse drug reaction reporting, according to De Angelis et al., and Hanafi et al. 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.<sup>46</sup>

The outcomes of this review article revealed in Ethiopian lack of understanding about PV and drug safety. The findings of the several papers revealed that HCPs' awareness of ADR reporting is minimal, despite the fact that 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 the majority of trials, and was identified as a major obstacle to reporting ADRs. Numerous studies<sup>31,22,26,30,14,15</sup> showed that large number respondents have limited knowledge on the definition of ADR, the difference between ADR and side effect, the term PV, the national ADR reporting system and availability of ADR reporting form. It was clearly indicated that the portion of health care professionals have limited information or even not ever heard the existence national ADR reporting system, national guidelines, did not know about PV system and how to report ADR cases to responsible body.<sup>24,12,26,27</sup> Several HCPs are untrained, which can lead to inadequate knowledge of the ADRs 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 numbers of 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, 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 with a study in Nigeria where lack of knowledge of the forms and procedures for reporting cited as a determinant factor for reporting.<sup>43</sup> Moreover, a systematic review on 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.<sup>44</sup> Similar study in Spain also indicated that having the basic knowledge needed to report ADR as a determinant factor for ADR reporting.<sup>39</sup> This implied 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 that in turn encouraged 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. The majority of 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.<sup>14,28,12,31,22,30,24,16</sup> This is the same as a study in Sweden where the majority (80.9%) of the HCPs were in opinion that ADR reporting is the duty of physicians, nurses and pharmacists.<sup>46</sup> This implied that health professionals had appropriately recognized ADR reporting as a professional obligation.

Similarly, HCPs have stated that before reporting an ADR, it is necessary to confirm that the ADR is linked to the drug.<sup>26,31,23,20,15,27</sup> In research, a bigger number of respondents were 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. Only a few studies found that respondents agreed that reporting increases to their workload.<sup>27,30,26,15</sup> 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 as 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.<sup>14,21</sup> Many HCPs stated that they have encountered ADR in the course of their practice, however a sizable percentage do not report it to the appropriate authorities (regulatory authority, manufactures etc.).

Different articles, on the other hand, have looked into the reasons for underreporting ADRs. Common reasons indicated were lack of knowledge<sup>14,25,21</sup>, lack of feedback<sup>14,25,15,32</sup> reporting forms are not available when needed 46.4%,<sup>14,25,15,32</sup> other colleagues are not reporting ADR cases<sup>14</sup>, uncertain that causal association between the drug and ADR<sup>14,15,32</sup>, did not report because the ADR was well known (17.3%).<sup>32</sup> This is identical with similar review conducted in Europe.<sup>8</sup> Similar reasons for under ADR reporting were also mentioned in the qualitative section of this study. This implied that if relevant organizations worked to reduce these barriers, the reporting rate may 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.<sup>47</sup> Furthermore, this finding suggested 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 who reported an ADR was alarming.<sup>26,12,17,15,23,20,32</sup> Few of the health professionals who reported ADR did so to Ethiopia's

PV center, which is in charge of monitoring and analyzing ADR.<sup>21,14, 12,17</sup> Low reporting is a big concern among health professionals, according to this article. The fact that the majority of 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 Soyalan<sup>47</sup> observed a low level of practice by healthcare providers. According to Fadare et al.,<sup>48</sup> 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.<sup>8,41, 43</sup> Furthermore, health workers who did not obtain ADRs reporting training were more likely to practice poorly. A study conducted in Spain backs this up.<sup>39</sup> Similarly in study conducted in Uganda, HCPs also showed poor training in areas of ADR and reporting.<sup>37</sup> 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 a systematic evaluation of efforts to enhance ADRs reporting.<sup>44</sup> 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.<sup>49-51</sup> 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. In a study conducted in Nigeria and Italy, similar strategies were suggested as a solution to enhance reporting.<sup>52,53</sup> Other studies have found that offering incentives to health practitioners improves ADR reporting.<sup>54,55</sup> 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.<sup>55</sup> Improved reporting rates were achieved by increasing the accessibility of yellow cards on wards and encouraging the use of web-based reporting.<sup>56</sup> As a result, empowering HCPs in detecting and reporting suspicious drug reactions, as well as employing evidence-based tactics, is critical to improve Ethiopia's 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 as data were extracted based on self-reported information, the possibility of reporting errors and recall biases could not be ruled out in studies. The cross-sectional design used in articles may not be able to prove a causal link between ADR reporting and explanatory variables. Inconsistencies in the study's 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.

## **5. CONCLUSION**

Knowledge, attitudes, and practice of HCPs toward PV were found to be associated to 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. The 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 the existed gaps in knowledge and attitudes that can be integrated within the health education curriculum or in-service training after graduation.

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## **ABBREVIATIONS**

**ADRs:** Adverse Drug Reactions; **HCPs:** Health care professionals; **PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses; **MCQS:** Multiple-choice questions; **PV:** Pharmacovigilance. **FMHACA:** Food, Medicine and health care administration and control authority; **ART:** antiretroviral therapy, **OPD:** Outpatient Department

#### Author contributions

Corresponding author, XX, did a database searches to locate studies that meet the objectives of this systematic review. Extraction of data from each studies done. Editing and formatting done by Professor XXX.

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**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    | HCPs work settings          | Town/region                 |
|-----|----------------------------------|-----------------------|---|--|-----------------|-----------------------------|-----------------------------|
| 1   | Adimasu <sup>13</sup>            | March-April, 2013     | to evaluate indicators of Nurses knowledge related to ADR reporting at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital         | Nurses   | cross sectional | Hospital                    | Gondar/ Amhara              |
| 2   | Angamo et al., <sup>19</sup>     | January 2010          | To survey the knowledge, attitude and practices of ADR reporting among HCPs in selected health facilities in South West Ethiopia.                       | physicians, pharmacy , nurses                            | cross sectional | Hospital and health centers | Jimma Zone/ Oromia          |
| 3   | Alemu and Biru, <sup>14</sup>    | May 1-30, 2019        | To evaluate knowledge, attitude, and practice of HCPs about ADR reporting and the associated factors at selected public hospitals in Northeast Ethiopia | nurses, doctors, pharmacy, midwives, and health officers | cross sectional | Hospital                    | Amhara                      |
| 4   | Shanko and Abdela, <sup>27</sup> | 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., <sup>25</sup>    | March 3-25, 2016      | To analyze knowledge, attitude, and practice of HCPs towards ADRs reporting at inpatient wards  | HCPs at the inpatient wards of TASH                      | cross sectional | Hospital                    | Addis Ababa                 |
| 6   | Bule et al., <sup>19</sup>       | March - June 2014     | evaluated the knowledge, attitude and practices of ADR reporting among HCPs in Adama Hospital Medical College   | nurses, doctors, & pharmacists                           | cross sectional | Hospital                    | Adama/ Oromia               |
| 7   | Belete et al, <sup>29</sup>      | March -June 2014.     | to measure the knowledge, attitude, and practice of HCPs towards ADR reporting in Boru Meda Hospital  | Nurses, Doctors, Pharmacy, Midwifery and Health Officers | cross sectional | Hospital                    | North East Ethiopia/ Amhara |

|    |                                   |                         |  |  |   |   |                 |
|----|-----------------------------------|-------------------------|--|--|---|---|-----------------|
| 8  | Seid et al., <sup>14</sup>        | March - May 2017        | to evaluate the knowledge, attitudes, and practices of HCPs towards ADR reporting  | Nurses, health officers, pharmacy.                                 | cross sectional                             | health centers                          | Gondar/ Amhara  |
| 9  | Hailu et al., <sup>31</sup>       | March 2013 - July 2013  | to determine 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., <sup>11</sup>       | October-December, 2017  | To evaluate ADR reporting practices and associated factors among doctors in government hospitals in Addis Ababa.   | doctors working in the selected governmental hospitals             | Cross sectional mixed-methods study design. | hospitals                               | Addis Ababa     |
| 11 | Denekew, <sup>22</sup>            | September-October 2013. | To evaluate the knowledge, attitude & practice of ADR reporting and factors affecting reporting among HCPs working in ART clinics of public health facilities of Addis Ababa | health care providers working in ART clinics                       | cross sectional                             | ART clinics of public health facilities | Addis Ababa     |
| 12 | Gidey, et al., <sup>27</sup>      | January - March 2019    | to evaluate the knowledge, attitude and practice ADRs reporting and identify associated factors with ADRs reporting among HCPs   | Nurses, pharmacists, physicians.                                   | cross sectional                             | hospital                                | Tigray region   |
| 13 | Gurmesa and Dedefo, <sup>20</sup> | January - June 2015     | To evaluate the knowledge, attitude, and practice of HCPs working in Nekemte town towards ADR reporting  | Doctors, nurses , HO, pharmacists                                  | cross sectional                             | Health service centers                  | Nekemte/ oromia |
| 14 | Necho and Mulatu <sup>16</sup>    | May - November, 2012    | to evaluate the knowledge, attitude and practice of HCPs towards an ADR reporting and associated factors with reporting  | Doctors, nurses , pharmacy   | cross sectional                             | hospitals                               | Amhara          |
| 15 | Goshime, <sup>23</sup>            |                         | 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 et al., <sup>21</sup>      | Jan 24-Feb 7, 2014      | To define status of Knowledge, practices and attitudes towards ADR reporting among HCPs in Nekemte Hospital.   | physicians, pharmacy, health officers, nurses and anesthesiologist | cross sectional                             | hospital                                | Nekemte/ oromia |

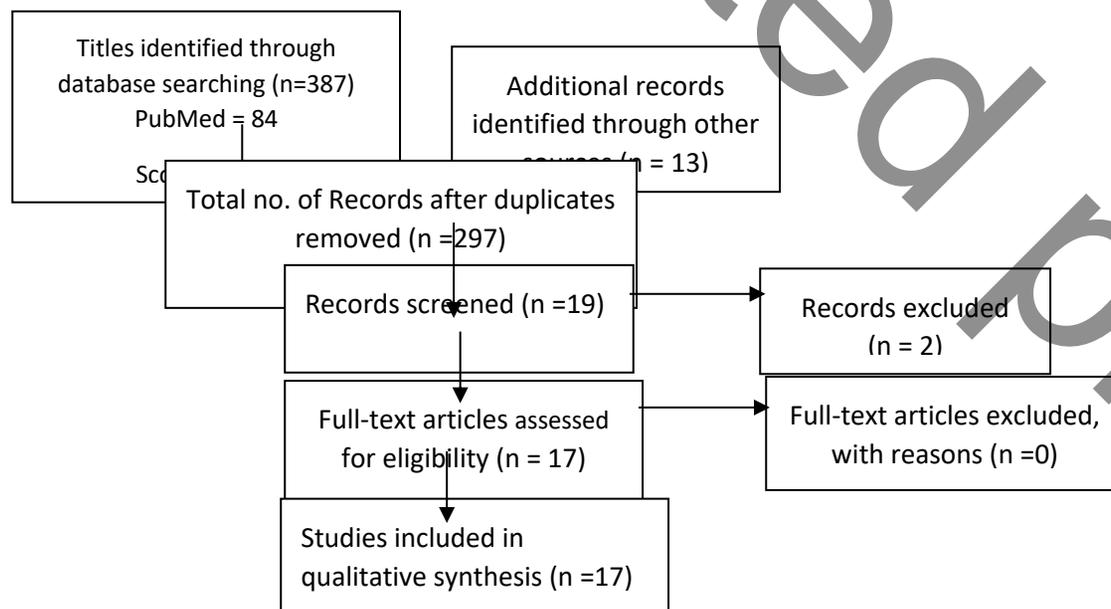
|    |                              |          |   |                                 |                 |          |               |
|----|------------------------------|----------|---|---------------------------------|-----------------|----------|---------------|
| 17 | Abay and Dires <sup>17</sup> | May 2007 | To assess the practice of ADR reporting and obstacles of reporting in Gondar University teaching and Bahirdar Felegehiwot referral hospitals. | physicians, nurses and pharmacy | cross sectional | Hospital | Gondar/Amhara |
|----|------------------------------|----------|---|---------------------------------|-----------------|----------|---------------|

**Table 2 shows the characteristics of studies that were considered in the systemic 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 persons 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 and March of 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) | Jan 24-Feb 7, 2014   | self-administered questionnaire | 150 (76.6%) | Yes/no, MCQs and Likert scale | knowledge, Attitude, practice |
| 17 | (13) | May-2007             | self-administered questionnaire | 141 (60.8%) | open and close end questions  | knowledge, Attitude, practice |

Identification  
 Eligibility  
 Included



**Figure 1:-**The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) procedures were followed for conducting this literature review

Un-corrected proof