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Knowledge, attitude and practice of adverse drug reaction reporting and affecting factors among health care providers working in ART clinics of public health facilities in Addis Ababa city, Ethiopia.

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ACRONYMS AND ABBREVIATIONS

ADE-adverse drug event

ADR- adverse drug reaction

AIDS- acquired immune deficiency syndrome

AOR- adjusted odds ratio

ART- anti retroviral therapy

ARV- anti retroviral

CI- confidence interval

COR- crude odds ratio

DACA- Drug Administration and Control Authority

FMHACA- Food, Medicine and Health administration Control Authority

HAART- highly active anti-retroviral therapy

HIV- human immune deficiency virus

KAP- Knowledge, attitude and practice

NGO- Non-Governmental organization

OR- odds ratio

PI- principal Investigator

PLWHA-people living with HIV/AIDS

SRS- simple random sampling

UMC – Uppsala monitoring center

WHO- World Health Organization

Abstract

New adverse events and toxicities are identified as people live longer on ART and the availability of numerous new drugs and drug combinations make systematic monitoring of ADR critical in the HIV program. The contribution of health professionals to adverse drug reaction databases is enormously significant, but under-reporting remains a major draw-back of spontaneous reporting and the level of adverse drug reaction reporting in Ethiopia is alarmingly low. Thus, a facility based cross sectional study was conducted in ART clinics of public health facilities of Addis Ababa city to assess the health care providers' knowledge, attitude & practice on adverse drug reaction reporting.

A total of 250 health care providers were included in the study by considering a 10% non-response rate. Using proportional allocation to type of facilities; 9 facilities from Public hospitals and 27 from health center based ART clinics were selected. Data was collected through a self-administered questionnaire from health professionals selected by simple random sampling methods. Observation was also used to verify existence of reporting forms in the facilities. After the data collection was completed, data was entered and processed using EPI-info software and exported to SPSS for analysis.

The response rate was 93.22%. Among respondents (108)46.2% were aware of the existence of a national Pharmacovigilance center in Ethiopia and only 92(39.3%) of them knew where it is located. Among the respondents only 134(57.3 %) of them were aware of the yellow card reporting scheme for reporting ADRs. Most respondents 208 (88.9%) agree the fact that ADR should be reported spontaneously at a regular basis. 212(92.7%) of them also agree that reporting ADR is part of their duty as health professionals & 197(84.2%) of the respondents believe that reporting ADR should be mandatory. 101 (43. 2%) of the respondents encountered at least one patient on ADR in their clinical practice in the past one year and 96(41%) of the respondents encountered at least one ADR on PLWHAs taking ART. But only 31(30.7%) of the respondents reported that they noted the ADR they encountered on patient clinical or pharmacy record and only 34(14.5%) of the respondents had ever reported ADRs.

The present study revealed the health care professionals have positive attitudes towards ADR monitoring and reporting. But there are gaps in knowledge and practice of ADR reporting. The major reasons for under reporting are found to be concern that the report may be wrong, lack of confidence on diagnosis of ADR and unavailability of reporting forms.

1. Introduction

1.1. Back ground

The safety of medicines is an essential part of patient safety. Global drug safety depends on strong national systems that monitor the development and quality of medicines, report their harmful effects, and provide accurate information for their safe use. The World Health Organization defines adverse drug reactions as «any harmful or undesired response to a medication, occurring at doses used for prophylaxis, diagnosis, and treatment in humans». (1)

Adverse drug reactions are global problems of major concern. They affect both children and adults with varying magnitudes, causing both morbidity and mortality. In addition to the human costs, ADRs have a major impact on public health by imposing a considerable economic burden on the society and the already stretched health-care systems.(2) Post marketing surveillance of drugs is very important in analysing and managing the risks associated with drugs once they are available for the use of the general population.(3)

People in every country of the world are affected by ADRs. In some countries ADR-related costs, such as hospitalization, surgery and lost productivity, exceed the cost of the medications.(4) Many studies have reported the huge impact that adverse drug reactions have on health care in general and on patients' health in particular, but because most cases go undetected, estimating the actual scale of this burden is almost impossible. It has been estimated that around +2.9-5.6% of all hospital admissions are due to ADRs and as many as 35% of hospitalized patients experience an ADR during their hospitalization. (5-7)

Much of the documented evidence available on medicine quality and ADRs comes from industrialized countries; for example, in its seminal report of 1999, the U.S. institute of Medicine estimated that up to 98,000 people die each year from medication errors in U.S. hospitals at a

cost of up to USD 29 billion per year (5). Authors of a meta-analysis estimated that ADRs alone excluding medication errors killed over 100,000 people in 1994 and were the fourth to sixth leading cause of death in the United States. (8)

Data is not readily available on the burden of ADRs in resource-limited settings like Ethiopia. It is however anticipated that the burden may even be more due to several factors including; High prevalence of HIV/AIDS, TB, Malaria and other co-morbid conditions; wide spread poor labeling and off-label use; use of traditional medicines and associated adverse events and interactions; genetic makeup; nutrition status; difference in risk-benefit profile and lack of regular monitoring for early signs of toxicity. (9)

Introduction of newer medicines like anti-retrovirals has changed the way in which diseases are treated. However, it is not without risks. ADRs are encountered commonly in daily practice, many of which are preventable.(10) It is known that different classes of adverse events might be displayed when drugs are exposed to different environmental conditions and genetic influences. (11)

Fee based ART program begun in Ethiopia in July 2003. By March 2005, through the support of Global Fund free ART service has been started at least at one site in all regions. Currently, 868 sites are providing ART services. Up to end of EFY 2005(2012/13), a total of 744,339 PLWHA were enrolled for HIV/care out of which 439,301 had been started on ART and 308,860 were currently on ART(12, 13)

Unfortunately, up to 25% of patients discontinue their initial HAART regimen because of toxic effects, noncompliance or treatment failure within the first 8 months of therapy. (14) A commonly cited cause of poor adherence to HAART is an adverse drug reaction. Short-term adverse effects are potential threats to successful introduction and maintenance of HAART. Although many factors may interfere with adherence to ARV therapy, adverse reactions to the

medications are among the most important. Continuous evaluation of the benefit and harm of ART will help to achieve the ultimate goal of making safer and more effective treatment available to patients. (15)

The contribution of health professionals, in this regard, to ADRs databases is enormously significant and has encouraged ongoing ascertainment of the benefit-risk ratio of some drugs as well as contributed to signal detection of unsuspected and unusual ADRs previously undetected during the initial evaluation of a drug (3). In spite of these benefits, under-reporting remains a major draw-back of spontaneous reporting. It is estimated that only 6–10% of all ADRs are reported globally. This high rate of under-reporting can delay signal detection and consequently impart negatively on the public health. (16)

The Uppsala monitoring center (UMC, WHO), Sweden is maintaining the international database of ADR reports (currently about 4.7 million case reports) received from several national centers (96 member countries). (17) Although, Ethiopia is participating in the program, its contribution to UMC database is very low. This is essentially due to the absence of a vibrant ADR monitoring system and also lack of a reporting culture among health care professionals.(11)

A department for monitoring ADRs in Ethiopia was launched in 2002. However, a total of only 249 ADR cases were reported between the years 2002 and 2007. Antiretroviral drugs were implicated in 70% of the cases reported. (11) And in the year 2003e.c (2010/2011) a total of 114 adverse drug reactions were reported. ARV drugs were implicated in more than 77% of cases reported.(18) Therefore, Information on the type and severity of ADRs to ART is inadequate and the safety profile of ART drug regimens that are currently on use in our setup are unknown.(19)

Thus, understanding the knowledge, attitude and practice (KAP) of adverse drug reaction reporting among health care providers in ART clinics is critical for countries like Ethiopia for reducing drug related problems. This study will show the status in general awareness and attitude

of health professionals, and the information gathered from this study will provide data to assist different governmental and non-governmental organizations to promote adverse drug reaction detection and reporting.

1.2. Statement of the problem

New adverse events and toxicities are identified as people live longer on ART and the availability of numerous new drugs and drug combinations make systematic monitoring of ADR critical in the HIV program. Adverse reactions are among the most important factors that interfere with adherence to anti-retroviral therapy. Continuous evaluation of the benefit and harm of ART will help to achieve the ultimate goal of making safer and more effective treatment available to patients.(12, 15, 20)

ARV drugs have low safety profile and given the facts, they need to be taken on chronic basis; they are consumed by patients who are immuno-deficient, and they are more prone to develop adverse reaction to any drug. Hence, monitoring and reporting of ADRs in HIV/AIDS patients receiving ART assumes a paramount importance. (21)

Health care providers are in a position to play a major key role in pharmacovigilance programs. Even though, voluntary ADR reporting has been effective as of 2002 in Ethiopia; the level of ADR reporting is alarmingly low. Thus, understanding the knowledge, attitude and practice (KAP) of adverse drug reaction reporting among health care providers is critical for improving existing pharmacovigilance system & to reduce drug related problems in our country.(11)

2. Literature review

At the point new medicines are registered for use in humans not much is known about those medicines beyond data obtained from clinical trials in controlled settings. Clinical trials for the evaluation of safety, efficacy and quality of new medicines are conducted in patients that may not necessarily represent all type of patients that will use the medicines when they are approved. Limited number of patients are exposed to the medicine during clinical trials and research settings differ from the conditions of use when the drug is marketed.(22)

Lack of complete understanding of the effects of long-term exposure, co-morbid conditions, and use in elderly, racial groups, children and pregnant women are other limitations of preapproval clinical trials. Currently, there has been a spate of increasing fast-track approval so as to make life-saving drugs available to patients that need them. An example is the fast-track approvals of antiretroviral (ARV) medicines. (23, 24)

Post-marketing surveillance and pharmacovigilance activities can help in obtaining real-life information of safety and effectiveness of medicines when they are being used in the population. These activities can be through spontaneous reporting systems and pharmaco-epidemiology studies for the validation of safety signals. (5, 22)

Post-marketing surveillance activities have resulted in the reappraisal of indications (extension or restrictions), identification of risk factors and characterization of users, identification of long-term toxicities, quality problems, etc. Safety monitoring is critical for public health programs. This is because significant harm to few patients can destroy the credibility, adherence to and success of a program. Rumors and myths about the adverse effects of medicines can spread rapidly and are difficult to refute in the absence of good data. Pharmacovigilance can provide these data. (22)

The devastation caused by the HIV/AIDS pandemic helped draw attention to the lack of access to medicines in resource-constrained areas especially sub-Saharan Africa. In response, new funding sources have made unprecedented sums of money available to procure essential medicines, including new products such as antiretroviral (ARV) medicines. With increased access to essential medicines comes a greater need to monitor and promote the safety and effectiveness of these medicines. Few developing countries, however, have the structures, systems, or resources in place to support medicine safety activities, and countries often lack unbiased, evidence-based information to help guide treatment decisions and promote rational—that is, safe, effective, and cost-effective use of medicines. (5)

Spontaneous reporting of ADRs has remained the cornerstone of pharmacovigilance and is important in maintaining patient safety. However, reporting of serious ADRs rarely exceeds 10%. Under reporting of ADRs is a common problem in pharmacovigilance programs.(25)Underreporting is very common, with an estimated median underreporting rate (defined as percentage of ADRs detected from intensive data collection that were not reported to relevant spontaneous reporting systems) of 94%, and occurs frequently for serious and unlabeled reactions. This can delay detection of important ADRs. Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare professionals as well as attitudes that are associated with a high degree of underreporting. (6, 26, 27)

The initiative of an international reporting system for ADRs came in the wake of the thalidomide tragedy in the early 1960s. This disaster was the catalyst for the initiation of a systematic collection of data on ADRs primarily through the hospital reporting program. Voluntary ADR reporting schemes have operated since the early 1960s in many western countries, first one started in the United Kingdom in 1964. (25)

The Ethiopian Pharmacovigilance Center (EPC) was established in 2002. According to the World Health Organization standards, countries with the best reporting rates generate over 200 reports per 1,000,000 inhabitants per year. Therefore, in Ethiopia with a population over 80 million, it is expected to receive at least 16,000 reports per year. Unfortunately, only 114 reports per year were sent to the IPC in the year 2010/11. (6, 18, 25)

Pharmacovigilance is very imperative in the HIV program since new adverse events and toxicities are identified, as people live longer on ART. The availability of numerous new drugs and drug combinations makes it critical to monitor more systematically adverse events linked to ARVs and OI medicines. Studies on the incidence of ADR from developing and developed countries have reported incidence of ADR among patients on ARVs to range between 11%-35.9% with incidence as high as 54% (28)in the presence of opportunistic infection. Incidence of severe ADR has been reported to be as high as 10% with a study observing an incidence rate of 8 per 100 person years. (29)

A study in UK that assessed practice of ADR reporting among physicians revealed a positive attitude about the yellow card reporting scheme and 63% of respondents claimed to have reported an ADR at least once in their carrier. The survey also showed factor for under reporting as lack of confidence in iatrogenic diagnosis. (30)

A study that assessed KAP of nurses in Theran showed the knowledge and practice of participants were not satisfying. However, their attitude towards pharmacovigillance was at a high level. The main cause of under reporting was reported as unawareness about the existence of such a national center. (31)

A study that assessed KAP of ADR reporting among medical practitioners in India showed that practitioners are aware of ADR reporting; their perception toward ADR reporting is right but it is

not reflected when it comes to the act of reporting of ADRs. Only 18.5 % of respondents had ever reported ADRs. (32)

A KAP study on ADR reporting among physicians in tertiary care hospital in Nigeria revealed that 85% of respondents encountered up to 5 ADRs/week and ADR reporting was considered important by 97% of respondents but only 15% of them had reported ADR's previously. (33)

A study in Sudan that assessed knowledge of health care providers(physicians, nurses & pharmacists) towards ADRs indicated statistically significant discrepancies in health care providers basic knowledge about adverse drug reactions. (34)

A study in 4 public health facilities of south west Ethiopia revealed that only 23% of the health professionals knew the existence of a national reporting system and more than half of the respondents agreed ADR reporting as part of their professional duty. (25)

Many factors are associated with ADRs under-reporting among health professionals. These factors have been broadly classified as personal and professional characteristics of health careers, and their knowledge and attitudes to reporting. (35) Inman has summarized these factors as the 'seven deadly sins'. His description of the 'sins' include: attitudes relating to professional activities (financial incentives: rewards for reporting; legal aspects: fear of litigation or enquiry into prescribing costs; and ambition to compile or publish a personal case series) and problems associated with ADR-related knowledge and attitudes (complacency: the belief that very serious ADRs are well documented by the time a drug is marketed; diffidence: the belief that reporting an ADR would only be done if there was certainty that it was related to the use of a particular drug; indifference: the belief that the single case an individual doctor might observe could not contribute to medical knowledge; and ignorance: the believe that it is only necessary to report serious or unexpected ADRs), and excuses made by professionals (lethargy: the procrastination

and disinterestedness in reporting or lack of time to find a report card and other excuses). (12, 36)

Lopez-Gonzalez et al , in their review of determinants of ADRs under-reporting from the global perspective, Insecurity (the belief that it is nearly impossible to determine whether or not a medicine is responsible for a particular ADR) is a factor associated with under-reporting. (35)

A study by A vallano etal in spain identified four types of obstacles to spontaneous reporting as important: (i) problems with the ADRs diagnosis; (ii) problems with the usual workload and lack of time; (iii) problems related to the organization and activities of the pharmacovigilance system; (iv) and problems related to potential conflicts. It therefore appears that factors that promote under-reporting may vary from one country to another. The determinants of ADRs under-reporting have not been extensively studied in Africa. (37)

3. Objective

3.1 General objective-

To assess the knowledge, attitude & practice of adverse drug reaction reporting and factors affecting reporting among health care providers working in ART clinics of public health facilities of Addis Ababa city, Ethiopia

3.2 Specific objectives-

- To assess knowledge, attitude & practice of health care providers towards ADR reporting
- To identify factors influencing adverse drug reaction reporting
- To assess availability of adverse reaction reporting tools in health facilities

4. Methodology

4.1. Study design:

A facility based cross sectional study design was used. The study was conducted by using primary data from health professionals in the ART clinics of health facilities. Observation was also used to verify existence of reporting forms.

4.2. Study area and period

The study was conducted in selected public health facility based ART Clinics of Addis Ababa city; which is the capital and largest city of Ethiopia as well as the seat of the African Union. The city covers 174.4 square kms, ten sub cities and 116 administrative woredas and has an estimated population of 3,146,999.

The health care delivery system consisted of 53 hospitals (of which 15 are public, 36 private hospitals and 2 NGO hospitals) and 52 health centers (of which 45 are public and 7 are NGO health centers). ART service is provided by governmental, NGO and private health institutions. There were 56 public health facilities and 23 non-governmental health facilities that deliver ART service in Addis Ababa at the time of the study. The study was conducted from September to October 2013.

4.3. Source population

The source population included health care providers working in ART clinics of public health facilities of Addis Ababa, Ethiopia.

4.4. Study population

The study population included health care providers (physicians, pharmacists, health officers and nurses) working in ART clinics of selected public health facilities of Addis Ababa, Since these professionals are responsible for ADR reporting in health facilities as per the ADR monitoring guideline of the country(20).

Inclusion criteria

Health care providers working in the ART clinics of the selected public health facilities with 6 and more months of experience and having the following qualifications were included;

Physicians- who are general practitioners and above;

Pharmacy personnel'- who have diploma in pharmacy and above;

Nurses' –who have diploma in nursing and above and

Health officers' – who have degree and above in public health practicing in the ART clinics were included.

Exclusion criteria-

Health care providers in the ART clinics who were on leave at the time of the study were excluded.

4.5. Sample Size

The required sample size is determined Using EPI INFO version7 for single population proportion for finite population (N=560);

N= (56*10)=560

n=n_0 / (1+n_0/N), where $n = \frac{(z\,\alpha/2)^2\ p(1-p)}{(d)2}$

Where;

n=sample size from finite population

$n_{0=}$sample size from infinite population

N= size of source population=560

Z=the standard score (critical value) corresponding to 95% confidence level = 1.96

d=the proportion of sampling error between the sample and the population = 5 %(0.05)

p= the estimated proportion of KAP of ADR reporting among health professionals = 50 %(0.5)

$n_{0=} (1.96)^2 0.5(0.5)/ (0.05)^2 = 384$

n=384/ (1+384/560) =227.9

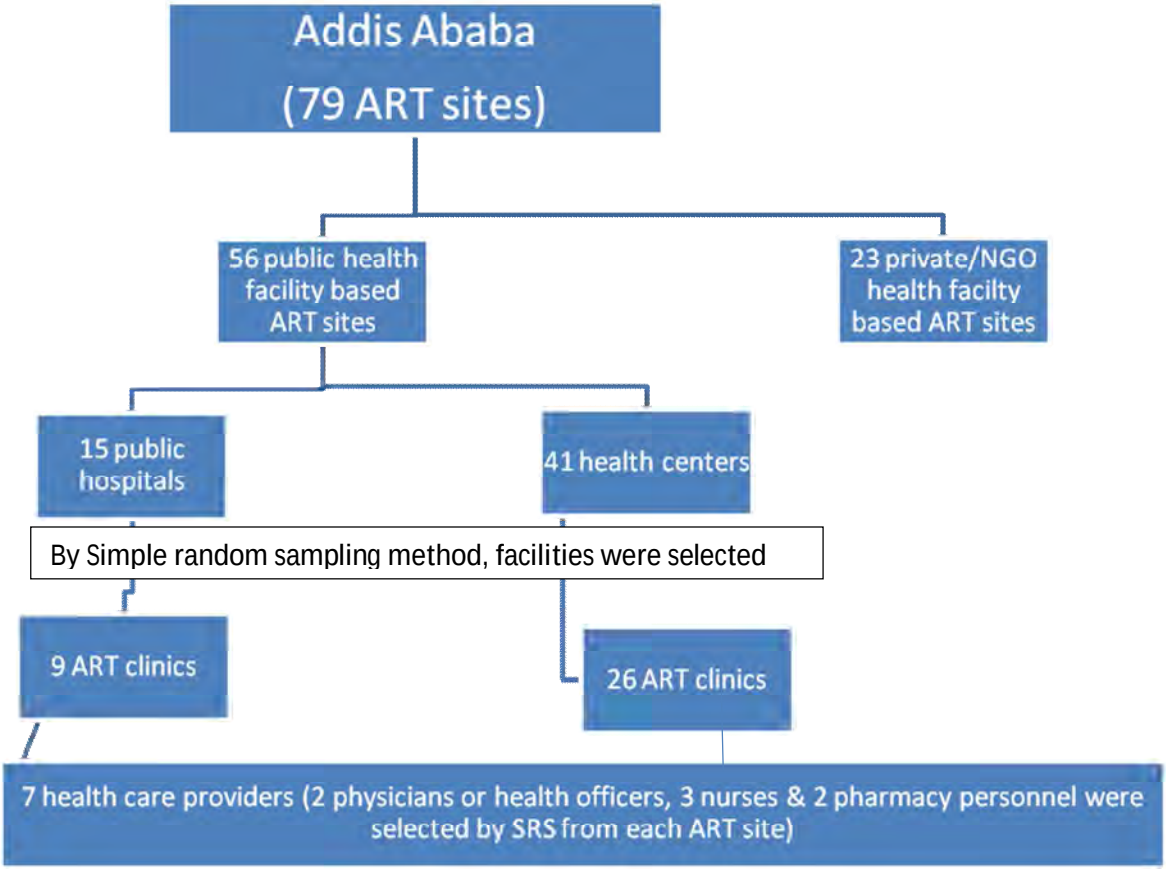
Adding 10 % for non-response, the final sample size is 251.

4.6 sampling procedure

This study was conducted in 36 public health facilities that give ART service in Addis Ababa. The 56 public health facilities currently giving ART service were first stratified as per the type of facility (level of care) and the number of facilities to be selected was allocated proportionally. Thus, from the available 15 public hospitals and 41 health centers that deliver ART service; 9 & 27 facilities were allocated respectively. Then, the allocated numbers of health facilities were selected from each type of health facility by SRS methods.

After identifying the health facilities, the second sampling procedure was sampling of health professionals, where 7 health professionals (2 physicians or health officers, 2 pharmacy personnel and 3 nurses) were selected from each ART clinic by SRS methods from the list of health professionals working in the ART clinics of the selected health facilities. Therefore, a total of 251 health professionals were included in the study.

Figure – 1 sampling procedure flow chart



4.7. Data collection procedure

A self-administered questionnaire was used for data collection. The questionnaire consisted of questions related to back ground variables, and questions that assess the knowledge, attitude and practice of ADR reporting by health professionals. The questionnaire was based on one used previously in a survey in Nigeria(38) but modified to take into account the national basis of the current investigation and simplified to exclude irrelevant and non-contributory questions. The modified questionnaire was pre-tested in 2 health facilities that were not included in the survey and subjected to further minor alterations before use.

Observation was also used to verify existence of ADR reporting forms in the selected health facilities. Four data collectors and two supervisors including the principal investigator were

involved in the data collection. The data collectors selected were health professionals, who have a diploma qualification in nursing or pharmacy and the supervisors were pharmacists.

Both the data collectors and supervisors were trained for half a day on the objective and methodology of the research, data recording and ethics to be followed during field work. Data was collected in the afternoon, since the patient load usually decreases at this time of the day. Data collected from the survey was properly handled after being checked for accuracy, consistency, omissions and irregularities. Questionnaires were numbered and stored properly.

4.8 Operational and standard definitions

Adverse drug reaction: A response to a medicine which is noxious and unintended, and which occurs at doses normally used in humans.

Adverse drug event: Any untoward medical occurrence that may present during treatment with a pharmaceutical product, but which does not necessarily have a causal relationship with this treatment

Pharmacovigillance: It is defined as the science and activities relating to the detection, assessment, understanding and prevention of ADR or any other possible drug related problems

Post marketing surveillance: is the practice of monitoring the safety of a pharmaceutical drug or device after it has been released on the market and is an important part of the science of pharmacovigilance.

Spontaneous reporting: reporting of adverse drug reaction as it occurs, arising from inclination rather than from planning or in response to others suggestions

4.9 Data analysis procedure

After the data collection was completed; first the data was checked for completeness and consistency, then the data was categorized, coded and entered using computer based software. EPI-info Version 7 was used to enter the data. Then, the data was exported to SPSS program for analysis; descriptive summary using frequencies, proportions, graphs and cross tabs were used to present study results. P-values less than 0.05 were considered as statistically significant.

We determined knowledge on ADR reporting using 6 yes/no questions. Each correct question corresponded to 1 point, and there was a total of 6 points for the 6 Questions. Respondents were considered to have adequate knowledge if they score 5 and above. And they were considered to have inadequate knowledge if they scored below 5 out of 6. The respondents attitudes were measured a using 13 items rated on a three point likert scale as agree, neutral and disagree. Favorable responses were given a score of 1 and we decided a high score more than 50% were indicative of a positive attitude and a score below and equal to 50% would be indicative of negative attitude. Health professionals practice was measured by identifying whether they encountered, documented & reported the ADRs or not.

Study variables

Dependent variables

Knowledge of ADR reporting

Atittude on ADR reorting

Practice of ADR reporting.

Independent variables

Demographic factors (Age & sex)

Difference in profession

Year of service

Training on pharmacovigillance

Knowledge about Reporting.

Attitude towards ADR reporting.

4.10. Data Quality Management

Self-administered Questionnaire was pre-tested before actual data collection and from the obtained feedback the self- administered questionnaire was adjusted accordingly.

The data collectors and supervisors were trained in data collection, sampling methods, purpose of the study and research ethics. On receiving of filled questionnaires data was checked for completeness and accuracy. Omissions and errors were communicated with the health professionals for correction immediately on receiving. Epi-info version 7 software was used to flag out of range values or errors while data processing.

4.11. Ethical Considerations

To conduct this research, project ethical approval was requested & secured from Addis Ababa University, School of Public health ethical clearance committee. Ethical clearance was also obtained from Addis Ababa Health Bureau Ethical review committee and permission was obtained from heads of health facilities where data collection was carried out.

During data collection process the data collectors informed each study participant about the purpose and anticipated benefits of the research project and the study participants were also informed on their full right to refuse to the study. The data collectors ensured privacy and confidentiality and informed participants that names will not be written on the questionnaires and provided the self-administered questionnaire to the participant.

5. Result

5.1. Socio demographic characteristics

The study was conducted in selected public health facilities of Addis Ababa city administration that deliver ART service to the public. 251 health care providers working in ART clinics of the selected health facilities were included in the study to assess Knowledge, attitude and practice of ADR reporting. Only 234 out of 251 respondents filled and returned their questionnaires within the stipulated timeframe giving a response rate of 93.22%.

36 Public health facilities were included in the study. Among these 27 (75.0%) were health centers, five (13.9%) & four (11.1%) were regional and referral hospitals respectively. From 234 health care professionals included in the study 15 (6.4%) of them were physicians, 59(25.2%) were health officers, 74(31.6%) were nurses and 86(36.8%) were pharmacy personnel. Among the respondents 71(30.34%) of them were diploma holders and the rest 163(69.66%) of them were degree graduates and above.

Respondents were in the age range of 20-45 with a median age of 28yrs. Most of the respondents 105 (44.9%) were in the age range of 26 to 30 years. 127(54.3%) of the respondents were males. Majority of the respondents 152 (65%) are having a clinical experience of 2 to 7 years and 108 (46.2%) of the respondents have worked from 13 to 36 months in ART clinics. The average number of clients seen per day by the health care providers ranged from 5 to 170 with a mean of 45 clients per day and with a standard deviation 27.56.

Table 1, Socio demographic profile of respondents in selected public health facility based ART cl2inics of Addis Ababa, Ethiopia Sep-Oct 2013

Variables	Labels	N=234	(%)		Variables	Labels	N=234	(%)
Age	< 20	4	1.71		Months of ART experience	<12	62	26.5
	21-25	53	22.65			13-36	108	46.2
	26-30	105	44.87			37-60	59	25.2
	31-35	42	17.95			61-84	5	2.1
	36-40	22	9.40			Sum	234	100
	≥41	8	3.42			Mean	27.82	
	Total	234	100		Average number of patients/clients seen per day	< 20	27	11.54
	Median	28				21-40	99	42.31
Sex	Male	127	54.27			41-60	87	37.18
	Female	107	43.73			61-80	9	3.85
	Total	234	100			≥81	12	5.12
Professional category	Nurse	74	31.62			Sum	234	100
	Physician	15	6.41			Mean	45.45	
	Health officer	59	25.21		level of training of respondents	Specialist/ Resident	1	0.43
	Pharmacy personnel	86	36.75			General practitioner	14	5.98
	Total	234	100			Degree in nursing	37	15.81
Months of clinical experience	< 24	37	15.81			Diploma in nursing	40	17.09
	25-84	152	64.96					
	85-144	29	12.39			Degree in Pharmacy	53	22.65
	145-204	10	4.28			Diploma in pharmacy	31	13.25
	≥205	6	2.56			Degree in public health	55	23.51
	Total	234	100			Others	3	1.28
	Mean	66.53				Sum	234	100

5.2. Knowledge on ADR reporting

From the 234 health care professionals, only 108(46.2%) were aware of the existence of a national pharmacovigillance center in Ethiopia and only 92(39.3%) of them knew where it is located. Among the respondents only 134(57.3 %) of them were aware of the yellow card reporting scheme for reporting ADRs.

134(68.8%) of the respondents recognized the need to report all adverse drug reactions for newly marketed drugs and 184 (78.6%) of respondents recognized the need to report serious reactions to established products.

Among the respondents, 134(57.3%) of them replied that ADRs are well documented at the time a drug is marketed and 82(35%) of the respondents did not know the difference between ADRs and side effects.

Analysis of the variables on knowledge revealed that 81(34.6%) of the respondents have adequate knowledge on ADR reporting. Whereas the remaining 153(65.4%) did not have adequate knowledge.

Table 2, Knowledge of health care professionals on ADR reporting in selected public health facility based ART clinics of Addis Ababa, Ethiopia, Sep-Oct 2013

Variables	Label	N=234	%
Awareness about existence of a national pharmacovigillance center	Yes	108	46.2
	No	126	53.8
	Sum	234	100
Knew where NPC is located	Yes	92	39.3
	No	142	60.7
	Sum	234	100
Knew the yellow card reporting scheme for reporting ADRs	Yes	134	57.3
	No	100	42.7
	Sum	234	100
All ADRs should be reported for established products	Yes	134	68.8
	No	100	31.2
	Sum	234	100
Serious reaction should be reported for established products	Yes	184	78.6
	No	50	21.4
	Sum	234	100
ADRs are well documented at a time a drug is marketed	Yes	134	57.3
	No	100	42.7
	Sum	234	100
ADR is the same as with a side effect	Yes	82	35
	No	152	65
	Sum	234	100

The study assessed the knowledge of respondents in relationship with their professional back ground. 62(72.1%) of Pharmacy personnel knew about the yellow card reporting scheme. Whereas only 30(40.5%) of nurses knew about it. (P=0.001). The difference between ADR and side effect were not known by 37(50%) and (21)35.6% of health officers and nurses respectively. But the difference was better known by 13(86.7%) of physicians and 64(74.4%) of pharmacy personnel. (p=0.003)

Table 3, Healthcare professionals' knowledge of ADR reporting by professional category in selected public health facility based ART clinics of Addis Ababa, Sep-Oct 2013

Variables		Physicians n=15	Pharmacy Personnel n=86	Nurses n=74	Health officers n=59	Stat' sign	X^2
Awareness of existence of a national pharmacovigillance center	yes= n(%)	8(53.3%)	45(52.3%)	33(44.6%)	22(37.3%)	0.312	3.568
	No= n(%)	7(46.7%)	41(47.7%)	41(54.1%)	37(66.7%)		
Know the yellow card reporting scheme for reporting ADRs	yes= n(%)	8(53.3%)	62(72.1%)	30(40.5%)	34(57.6%)	**0.001**	**16.282**
	No= n(%)	7(46.7%)	24(27.9%)	44(59.5%)	25(42.4%)		
All ADRs should be reported for newly marketed drugs	yes= n(%)	13(86.7%)	63(73.3%)	47(63.5%)	38(64.4%)	0.21	4.520
	No= n(%)	2(13.3%)	23(23.7%)	27(36.5%)	21(35.6%)		
Serious reactions should be reported for established products	yes= n(%)	14(93.3%)	68(79.1%)	55(74.3%)	47(79.7%)	0.425	2.794
	No= n(%)	1(6.7%)	18(20.9%)	19(25.7%)	12(20.3%)		
ADRs are well documented at a time a drug is marketed	yes= n(%)	8(53.3%)	48(55.8%)	45(60.8)	33(55.9%)	0.898	0.592
	No= n(%)	7(46.7%)	38(44.2%)	29(39.2)	26(44.1%)		
ADR is the same as with a side effect	yes= n(%)	2(13.3%)	22(25.6%)	37(50%)	21(35.6%)	**0.003**	**13.769**
	No= n(%)	13(86.7%)	64(74.4%)	37(50%)	38(64.4%)		

Regarding respondents' knowledge on where to report ADRs, majority 136(58.1%) replied as FMHACA, followed by pharmacy department 28(12%) and pharmaceutical manufacturers 25(10.7%). The study also revealed that majority of respondents were using national drug formulary & STG 94(39.1%) and standard text books 36(27%) as a source of information about ADR.

157(67.1%) of the health care professionals reported that they have not been introduced to ADR monitoring or Pharmacovigilance in their pre-service training and 146 (62.4%) of them responded that they have not attended any pre-service training on ADR monitoring and reporting in their clinical practice.

Table 4, General information about ADR reporting in selected public health facility based ART clinics of Addis Ababa city, Ethiopia, Sep-Oct 2013

Variable		N=234	%
Introduced to ADR monitoring in pre-service training	Yes	77	32.9
	No	157	67.1
	Total	234	100
Attended an in-service training on ADR monitoring & reporting in clinical practice	Yes	88	37.6
	No	146	62.4
	Total	234	100
Response on where to report ADRs	Manufacturers	25	107
	EPA	15	6.4
	FMHACA	136	58.1
	Ministry of health	20	8.5
	DTC of the facility	10	4.3
	Pharmacy department	28	12
	Total	234	100
Primary source of information about ADR	NDF & STG	94	40.2
	Standard text books	62	26.5
	Notes from training	21	9
	Drug sales man	19	8.1
	Others	38	16.2

5.3. Attitude of the respondents towards ADR reporting

Respondents were asked to indicate their agreement or disagreements on a three point likert scale 'agree', 'neutral' & 'disagree'. It was found out from the result that most respondents 208 (88.9%) agree the fact that ADR should be reported spontaneously at a regular basis. 212(92.7%) of them also agree that reporting ADR is part of their duty as health professionals & 197(84.2%) of the respondents believe that reporting ADR should be mandatory.

Most of them also agree on the idea that monitoring an ADR is important for the Public 219(93.6%) & for the health care system 222(94.9%) and improves quality of patient care 194(84.6%). 180(76.9%) of respondents think that there is a need to be sure that ADR is related to the drug before reporting. Some of the responders 87(37.2%) believe only ADR of prescription drugs need to be reported where as 126(53.8%) of them did not agree.

The statement of "one report of ADR makes no difference" was not agreed by the majority 170(72.6%) of the respondents. Only 52(22.2%) of the respondents agreed that reporting creates additional workload. Whereas, 162(62.92%) of them did not agree. The statement that "even if unknown, non-serious reactions should not be reported" was disagreed by 156(66.7%) of respondents. And also the statement that states ADR that cause persistent disability or incapacity should be only reported was not agreed by the majority 166(70.9%) of the respondents.

Analysis of the variables on attitude revealed that majority 217(92.7%) of the respondents have positive attitude towards ADR reporting.

Table 5, Attitude of health care professionals towards ADR reporting in selected public health facility based ART clinics of Addis Ababa, Ethiopia, Sep-Oct 2013

Variables	Agree N (%)	Neutral N (%)	Disagree N (%)
ADRs should be reported spontaneously at a regular basis	208(88.9%)	8(3.4%)	18(7.7%)
Reporting ADR is part of duty of health professionals	217(92.7%)	11(4.7%)	6(2.6%)
Reporting ADR should be mandatory	197(84.2%)	17(7.3%)	20(8.5%)
Reporting ADR is important for the public	219(93.6%)	8(3.4%)	7(3%)
Reporting ADR is important for the health care system	222(94.9%)	6(2.5%)	6(2.5%)
There is a need to be sure that ADR is related to the drug before reporting	180(76.9%)	22(9.4%)	32(13.7%)
Only ADR of prescription drugs need to be reported	87(37.2%)	21(9%)	126(53.8%)
Reporting ADRs improves quality of patient care	19(8.1%)	10(4.3%)	205(87.6%)
One report of ADR makes no difference	46(19.7%)	18(7.7%)	170(72.6%)
Reporting is not useful to the patient	19(8.1%)	10(4.3%)	205(87.6%)
Reporting creates additional work load	52(22.2%)	20(8.5%)	162(69.2%)
Even if they are not known, non-serious ADRs should not be Reported	47(20.1%)	31(13.2%)	156(66.7%)
Only ADRs that cause persistent disability or incapacity should be reported	45(19.2%)	23(9.8%)	166(70.9%)

5.4. Practice involving ADR encounter and its reporting

This assessment revealed that 101 (43. 2%) of the respondents encountered at least one patient on ADR in their clinical practice in the last one year and 96(41%) of the respondents encountered at least one ADR on PLWHAs taking ART. But only 31(30.7%) of the respondents reported that they noted the ADR they encountered on patient clinical or pharmacy record and only 34(14.5%) of the respondents had ever reported ADRs.

65(27.8%) of respondents claimed that they always give advice to their patients on possible ADRs of drugs. Whereas 70(29.9%) and 82(35.5%) respondents reported how often they give advice to patients on ADR as "usually" and "sometimes" respectively. And 65(27.8%) of respondents reported that they never give advice on potential ADRs of drugs that they give to their patients.

Table 6, Practice of ADR encounter and reporting by respondents in selected public health facility based ART clinics of Addis Ababa, Sep-Oct 2013

Variable		N = 234	(%)
Encountered ADR in last 12months	Yes	101	43.2
	No	133	56.8
	Total	234	100
Encountered ADR in clients on HAART in last 12months	Yes	96	41
	No	138	59
	Total	234	100
Recording observed ADR in patient clinical or pharmacy record	Yes	31	13.24
	No	75	32.05
	Not encountered	128	54.7
	Total	234	100
Giving advice for patients on possible ADRs of drugs	Always	70	29.9
	Usually	82	35
	Sometimes	17	7.3
	Never	65	27.8
	Total	234	100

Among the respondents 16(21.6%) of nurses, 11(12.8% of pharmacy personnel, 6(10.2%) of health officers and 1(6.7%) of respondents claimed to have reported an ADR. No statistically significant relationship was observed between professional categories and reporting of an ADR.

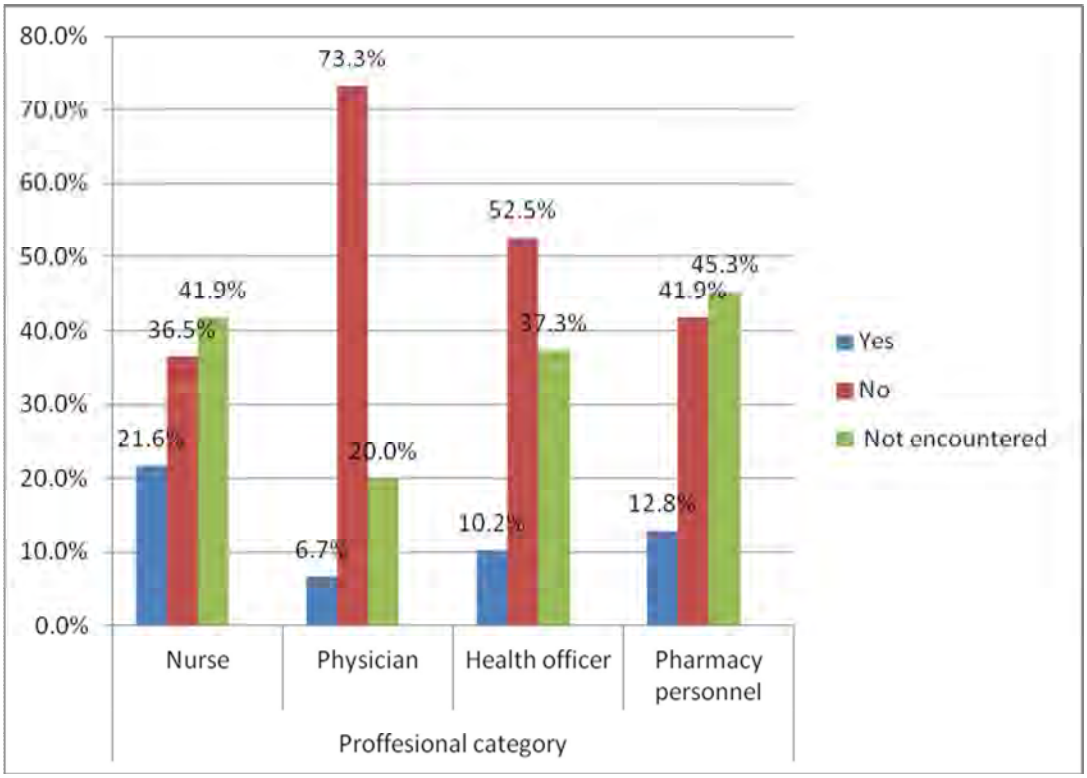


Figure 2, Reporting of ADRs by different professional category in selected public health facility based ART clinics of Addis Ababa; Ethiopia, Sep-Oct 2013

Number of ADR encounters

Among the respondents, 44(19%) of them had encountered at least one ADR within the past 1 year. 32(14%), 8(3%) and 6(2%) of respondents reported that they encountered 2, 3 and 4 ADR cases respectively. And 11(5%) of them encountered more than 4 ADR cases with in the past 1year.

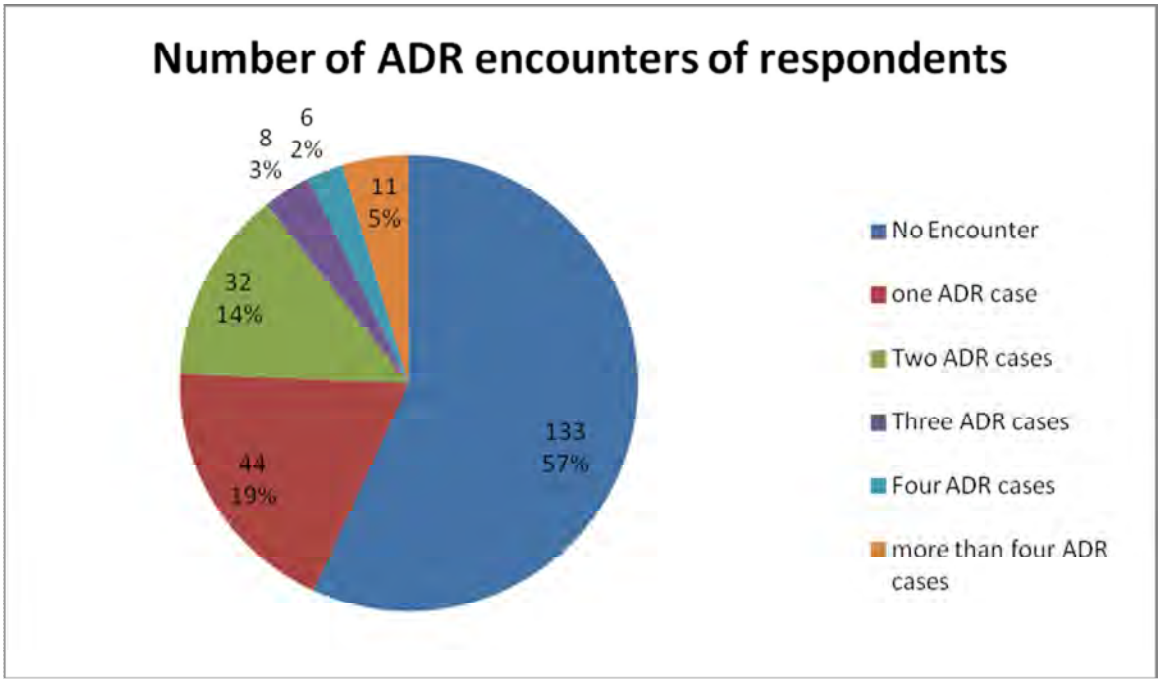


Figure 3, Number of ADR encounters by respondents in selected public health facility based ART clinics of Addis Ababa, Sep-Oct 2013

5.5. Factors affecting reporting of ADRs

Reasons for not reporting ADRs

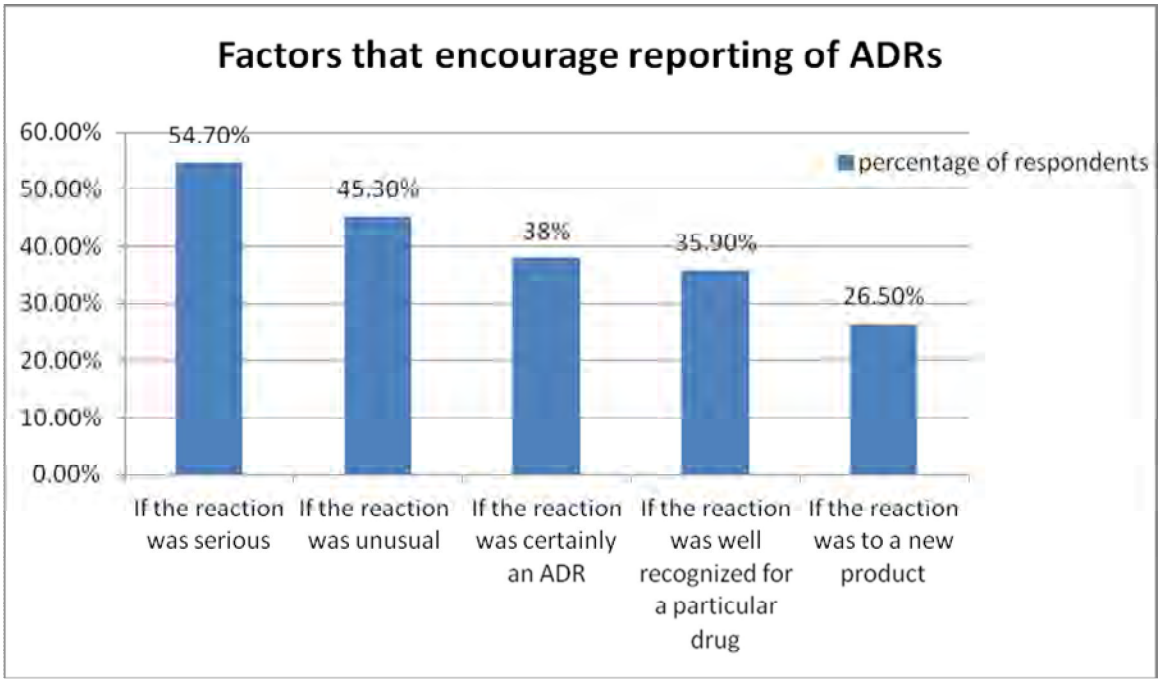
Respondents were asked to state their agreement or disagreement on the reasons for not reporting ADRs. The concern that the report may be wrong was the most agreed reason by 100(42.7%) respondents for not reporting ADRs followed by 'Level of clinical knowledge makes it difficult to decide whether an ADR occurred or not' by 99(42.3%) of the respondents. Unavailability of reporting forms and lack of confidence in discussing ADR with colleagues were also agreed as a reason for not reporting ADRs by 95(40.6%) & 84(35.9%) of respondents respectively.

Table 7, Reasons for not reporting ADRs by respondents in selected public health facility based ART clinics of Addis Ababa, Ethiopia; Sep-Oct 2013

Variable	Agree N (%)	Disagree N (%)	Neutral N (%)
Concern that the report may be wrong	100(42.7%)	102(43.6%)	32(13.7%)
ADRs are well documented by the time a drug is marketed	80(34.2%)	115(49.1%)	39(16.7%)
Reporting form is too complicated	55(23.5%)	150(64.1%)	29(12.3%)
Reporting is time consuming	67(28.6%)	157(67.1%)	10(4.3%)
Reporting ADR is a violation of patient confidentiality	56(23.9%)	161(68.8%)	17(7.3%)
One report makes no difference	57(24.4%)	160(68.4%)	17(7.3%)
Reporting form is not available adequately	95(40.6%)	112(47.9%)	27(11.7%)
There is no national ADR reporting system	84(35.9%)	139(59.4%)	11(4.7%)
Reporting is not useful to the patient	39(16.7%)	183(78.2%)	12(5.1%)
Reporting creates an additional workload	61(26.1%)	160(68.4%)	13(5.6%)
Lack of confidence in discussing the ADR with other colleagues	84(35.9%)	119(50.9%)	131(13.2%)
Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred	99(42.3%)	112(47.9%)	23(9.8%)

Factors that may encourage reporting of ADRs

The results of the study revealed that most respondents are encouraged to report an ADR; when the reaction was serious 128 (54.7%), when the reaction was unusual 106 (45.3%) and when the reaction was certainly an ADR 89 (38%).



- Multiple responses from respondents

Figure 4, Factors that encourage reporting of ADRs in selected public health facility based ART clinics of Addis Ababa, Sep-Oct 2013

Suggestions to improve ADR reporting

Respondents were asked open ended question to suggest possible ways to improve existing ADR reporting system and the following were the frequently mentioned responses; giving sensitization trainings to health care professionals, introduction of online reporting schemes, ensuring availability of forms, devising incentive system for reporters, promotion of ADR reporting by patients, devising access to patient records for pharmacists and making reporting obligatory.

5.6. Availability of ADR monitoring & reporting tools

Observation was used to verify existence of ADR reporting and monitoring tools. Standard ADR reporting forms were available in 23 (63.89%) of the facilities surveyed. Patient allergy cards were available in 19(52.7%) of the public health facilities surveyed and ADR monitoring and reporting guidelines were not available in most facilities 28(80%).

Table 8, Availability of ADR reporting and monitoring tools in selected public health facility based ART clinics of Addis Ababa, Ethiopia, Sep-Oct 2013

Variable	Label	N=36	%
Availability of ADR reporting forms	Yes	23	63.89
	No	13	36.11
	Sum	36	100
Availability of patient allergy cards	Yes	19	52.78
	No	17	47.22
	Sum	36	100
Availability of ADR reporting & monitoring guideline	Yes	28	77.78
	No	8	22.22
	Sum	36	100

6. Discussion

Adverse drug reactions contribute to excessive health care costs through increased patient morbidity and mortality. Several studies identify ADRs as important factors leading to hospital admissions. Therefore, monitoring of ADRs is an integral component of patient care. (39)Spontaneous reporting is the cornerstone for post marketing surveillance and is a method to generate signals of unrecognized ADRs. ADR reporting with Yellow Cards has tremendously improved pharmacovigilance of drugs in many developed countries and its use is advocated by the World Health Organization. Monitoring and reporting of ADRs is very imperative for public health programs like ART. And with the fact that ARVs are implicated in 70% of ADRs reported in the country, this study aimed to assess the knowledge, attitude and practice of health care professionals working in ART clinics of public health facilities on ADR reporting.(40)

Response rate obtained in the present study is close to a study in south India (41)and better than reports from several similar studies elsewhere(6, 30, 38, 40). This can be partly due to the convenience of time of data collection which was carried out in the afternoon. Where client load in the ART clinics usually decrease and collection of the filled questionnaires on the same date of administration has raised the response rate of respondents.

This study has shown inadequate knowledge of health care professionals about ADR reporting similar to previous studies in Ethiopia(25) and other African countries.(34, 38). The general lack of awareness is reflected on less than half of the respondents knew the existence of a national pharmacovigillance center in the country and only 39.3% were able to correctly identify Addis Ababa as the office. Lack of knowledge where ADRs should be reported would automatically affect reporting. A significant number of respondents 42.7% did not know about the existence of the yellow card reporting scheme. This is a relatively better figure from a previous study in south

west Ethiopia that reported 74% did not know about the yellow reporting form(25). But this proportion is rather very low when compared to a similar reporting scheme in the United Kingdom (30), Sweden(40) and India(39). The lack of awareness might be due to inadequate promotion of reporting form and reporting system to the health professionals.

The awareness of nurses about the yellow card reporting scheme was relatively lower compared with other professionals. But due to nurses' primary importance in the care of patients, especially patients on hospital admission, it is most likely that any acute adverse drug reaction will first be observed by them, hence it is important that they participate in the spontaneous reporting scheme. In countries where nurses are already participating in the ADR reporting scheme, studies have shown that they indeed contribute positively towards the promotion of ADR reporting. (42)

Most of the respondents recognized the need to report reactions to newly marketed drugs and serious reactions to established products but there was a misconception among respondents 134(57.3%) of them perceived that ADRs are well documented before a drug is marketed and 82(35.7%) replied that ADR is the same as a side effect. While WHO recommended to retain the term side effect for minor effects which are related to the pharmacological properties of the drug in order to avoid inflating the figures of drug induced diseases. (4) Perhaps, the undergraduate training on ADR monitoring and reporting may be either insufficient or improperly delivered to prepare the health care professionals for the task of ADR monitoring and reporting in their career.

It is a well acknowledged fact that information regarding ADRs changes continually and hence there is a need to constantly update health care professionals in this area. Most respondents in this study obtained information on ADRs from drug formularies and text books. Lack of, or inadequate, access to the internet can be a major limiting factor for obtaining current reports on

ADRs as most information from drug formulary and textbooks may be outdated and may not reflect the current situation of information on ADRs

Results of this study indicated a positive attitude by majority of respondents. Where 92.7% of respondents agreed ADR reporting as part of their duty and 84% of them agree reporting ADR to be mandatory. More than 90% of respondents also agree that reporting ADRs is important for the public and health care system. Such positive attitudes were also reported in similar surveys in Iran, India & Nigeria. (31-33)

Majority of respondents 76.9% misperceived that there is a need to be sure that ADR is related to the drug before reporting and 37% of them believed that only ADR of prescription drugs need to be reported. A similar finding was also obtained in a study in south west Ethiopia where 85.37% reported that there is a need to be sure that ADR is related to the drug before reporting. (25) A relatively lower proportion of respondents 24.4% reported they need to be certain that the reaction is really due to an ADR before reporting in a study among physicians in Sweden. (40) Also a study in India among physicians reported 32.5% of them indicated that they recommend only proven ADRs to be reported. (43)

From the 243 respondents, 101(43.2%) of them had encountered at least one ADR case in the past 12 months and 96(41%) of them encountered at least one ADR case on clients on HAART. But only 72(30.8%) of them claimed to record the encounter on patient records. And also only 14.5% of them had ever reported an ADR. A study in south west Ethiopia revealed all the respondents (n=82) had never recorded ADRs on clinical records nor reported ADR to the concerned body. (25) Whereas a study on ADR reporting among physicians in India reported that majority (64%) of them reported the suspected ADRs. (41) Another similar study in Sweden also reported 59 % of the respondents had reported at least one ADR in their carrier.(40)

ADRs have the potential to cause significant harm in patients. There is increasing awareness of the significant global and local impact of ADRs on patient care and public health. Local factors such as the high prevalence of HIV/AIDS, tuberculosis, health systems failures and illiteracy among patients contribute to the burden of drug related morbidity and mortality in Ethiopia. So it is imperative for health care professionals to know how & where to report an ADR. If they do not know these two things, it will affect spontaneous reporting. Poor spontaneous reporting is an indicator of poor management and dissemination of ADR monitoring.

The relatively higher proportion of nurses who claimed to have sent ADR reports to the national pharmacovigillance center in this study when compared with the other professionals is not concordant with reports from FMHACA. Where 75.5% of reports came from Physicians followed by 18.3% of reports coming from pharmacy personnel.(6) This result is partly due to the relatively few number of physicians working in ART clinics that participated in the study.

This study revealed that majority of respondents (>60%) were not introduced about ADR reporting in their pre-service training and did not attend any in-service training on ADR reporting as well. These trainings have also shown statistically significant associations with ADR reporting. ADR reporting should be intensively taught during undergraduate study, and this should be reinforced periodically through continuous education programs. (44)

Under reporting of ADRs is a common phenomenon in Africa and this has been established from previous studies in Malawi, Sudan & Nigeria.(34, 45, 46) The reasons for under-reporting, from our study were similar with those reported by Lopez-Gonzalez et al (35), include concern that the report may be wrong, lack of confidence in the level of clinical knowledge to decide an ADR occurred and unavailability of reporting forms were mentioned to a larger extent. These results are in congruence with studies in Nigeria & Nepal.(46, 47) But the reporting scheme operates on the basis of reporting all ADRs despite uncertainty about a causal relationship. (15)

In this survey, vast Majority of the respondents are encouraged to report an ADR when the reaction was serious and unusual and when the reaction was certainly an ADR. Our results are in line with another similar study in India which reported that physicians are more likely to report suspected ADRs for serious, unknown ADRs for new drugs (81%); serious, unknown reactions for established drugs (73%); and serious, known reactions for established drugs (65%) (43).

The findings from our observational study indicated unavailability of ADR reporting tools in some health facilities. Unavailability of reporting forms apparently limits reporting by health care professionals. This has been mentioned by different studies as a factor for not reporting ADRs.(30, 35, 48)

Strength and limitation of the study

Strength of the study

- The questionnaire was adopted from a previous study and pre-tested on similar setting and necessary modifications were made to minimize the difficulty during data collection.
- There was also a good response rate which strengthens the representativeness of the result of the study.

Limitation of the study

- The study might introduce recall bias.
- The study might introduce social desirability bias even though a lot has been done to minimize it.
- Qualitative way of data collection was not exhaustively used and this might have not enabled the study to exhaust all the possible responses.
- Like any other cross sectional study design, it shows exposure and outcome at same point in time. Thus, we cannot formulate cause and effect relationship from this study design.
- The study was conducted only in public health facilities of Addis Ababa, so it will not show overall picture of the problem

7. Conclusion

The present study identified that the health care professionals have positive attitudes towards ADR monitoring and reporting. But there are gaps in knowledge and practice of ADR reporting among health care professionals working in the ART clinics of public health facilities of Addis Ababa. Ethiopia.

The major reasons for under reporting are found to be concern that the report may be wrong, lack of confidence on diagnosis of ADR and unavailability of reporting forms. The results from observational study also indicated that reporting forms were not available in one third of the health facilities.

8. Recommendation

- Our study strongly suggests that there is greater need to create awareness and to promote the reporting of ADR among healthcare professionals by conducting pre-service and in-service trainings & trainings on ART should also give immense emphasis on ADR monitoring and reporting
- Integration of ADR reporting with routine clinical practice in the country is recommended. Only such approach can greatly influence in bringing reporting culture among healthcare professionals and may improve the reporting rates of ADR in our country.
- Ensuring the availability of reporting forms and introducing other reporting channels like internet & toll free numbers are recommended.
- Encouraging the involvement of all health care professionals in ADR reporting and providing feedbacks on ADR case reports are recommended.
- Direct reporting by the patients and mandatory reporting by health care professionals should be implemented in the pharmacovigillance system of Ethiopia as it can speed up the acquisition of knowledge about ADRs
- Further studies are recommended at a national level to exhaustively determine determinants of ADR reporting.

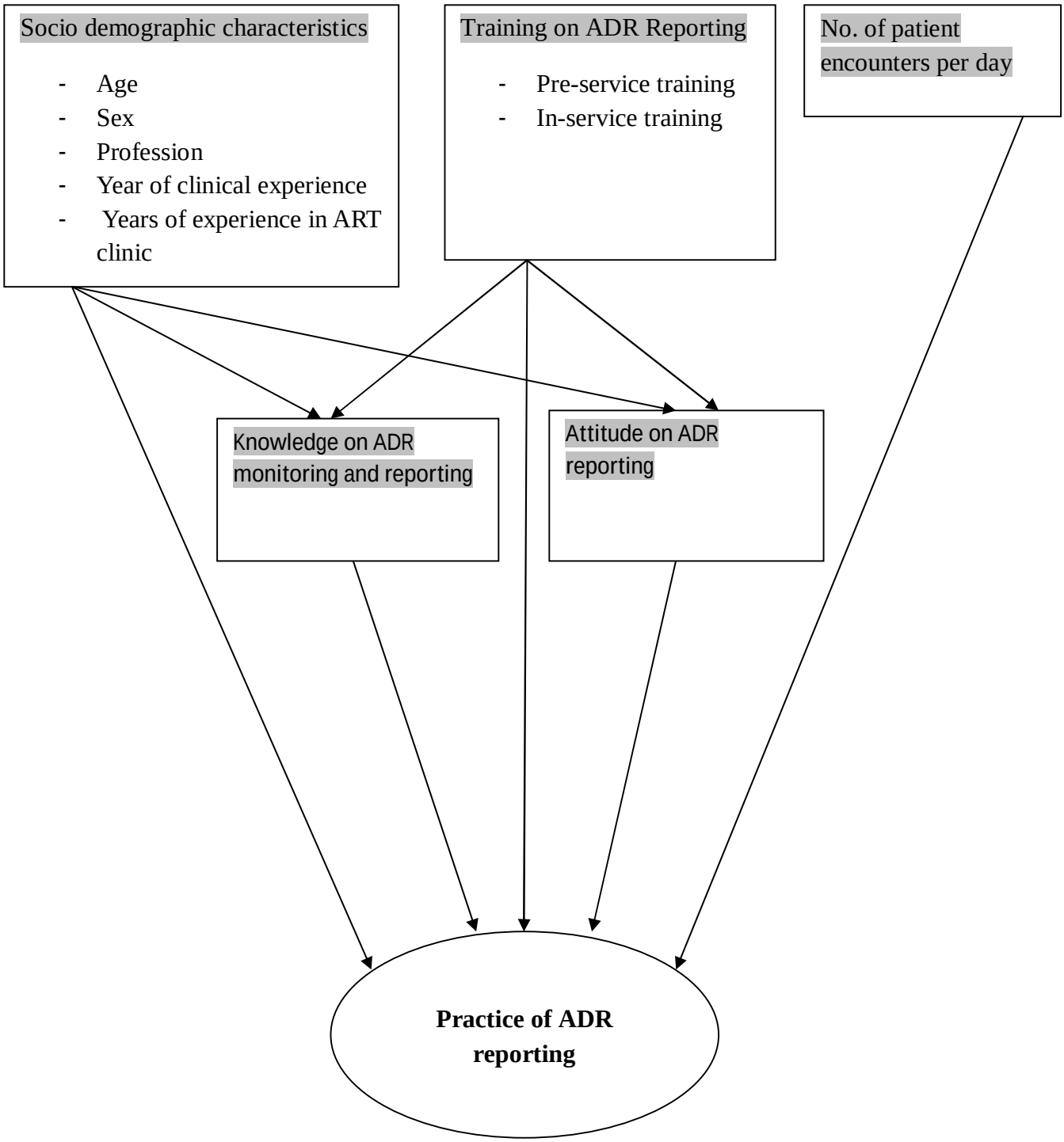
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Annex- 1 conceptual frame work for KAP study on ADR reporting among health professionals working in ART clinics of public health facilities of Addis Ababa, Ethiopia.



Annex 2: questionnaire

A study on assessment of knowledge, attitude and practice of ADR reporting among health care providers working in ART clinics of public health facilities in Addis Ababa, Ethiopia

A Self-administered Questionnaire

Introduction

Hello, my name is _____. I am collecting data for a study by Addis Ababa University, School of public health. The purpose of this study is to assess Knowledge, attitude and practice related to adverse drug reaction reporting among health care professionals. This is a self-administered questionnaire. It will take you about 15 minutes to complete the questionnaire.

Consent

Your answers are completely confidential. Your name or other identifier will not be written on this form, and other facts that might point to you will not appear when we present the survey. However, your honest answers to these questions will help us better understand status of ADR reporting and to recommend appropriate strategies to improve safety of medicines and patient care. We would greatly appreciate your help in responding to this survey.

Are you willing to participate? Yes/No.(if No, circle "No" and return questionnaire to data collector).

Note.

You can circle more than one choice where you think possible options are there.

Part 1.A General information about your health facility

101	What is the name of the health facility in which you are working?	_____
102	What is the type of your health facility?	1- Health center 4- General hospital 2- Regional hospital 5- Clinic 3- Referral hospital 6-Other _____
Part 1.B General information about you		
111	Your Sex	1-Male 2- female
112	Your age in years	_____ years
113	Professional category	1- Nurse 3- Health officer 2- Physician 4- Pharmacy personnel

114	Your level of training	1- General practitioner 5- Pharmacist 2- Specialist 6- Druggist 3- Nurse degree 7- Degree health officer 4- Nurse diploma 8-Other_____
115	How many years of clinical experience do you have?	_____years and _____months
116	How many years of experience do you have in ART clinic?	_____years and _____months
117	What is the average number of patients/clients that you see per day?	_____ patients
Part II- Knowledge related questions		
201	Are you aware of the existence of a national Pharmacovigilance center in Ethiopia? 1- Yes 2- No	
202	If the above is yes, where is it located? _____	
203	Are you aware of the yellow card reporting scheme for reporting of ADR? 1- Yes 2- No	
204	All ADRs should be reported for newly marketed drugs. 1- Yes 2- No	
205	Serious reactions should be reported for established products. 1- Yes 2- No	
206	Do you think that ADRs are well documented at the time a drug is marketed? 1- Yes 2-No	
207	Do you think that adverse drug reaction is the same as with side effect 1- Yes 2-No	
208	To whom do you think that ADRs should be reported? 01- Manufacturers 04- Ministry of health of the country 02- Ethiopian pharmaceutical association 05-DTC of respective health facility 03- DACA/FMHACA 06-Pharmacy department	
209	Have you been introduced to ADR monitoring or Pharmacovigilance in your pre-service (formal) training? 1- Yes 2-No	
210	Have you attended an In-service training on ADR monitoring & reporting in your clinical practice? 1- Yes 2- No	
211	What is your primary source of information about ADR? 1- National drug formulary and STG 3-Notes from the training 5-other_____ 2- Standard text books 4-Drug sales man	

Part III Attitude related questions				
To what extent do you agree with the following statements		**Agree**	**neutral**	**Disagree**
301	ADRs should be reported spontaneously at a regular basis			
302	Reporting ADR is part of duty of health professionals			
303	Reporting ADR should be mandatory			
304	Reporting ADR is important for the public			
305	Reporting ADR is important for the health care system			
306	There is a need to be sure that ADR is related to the drug before reporting			
307	Only ADR of prescription drugs need to be reported			
308	Reporting ADRs improves quality of patient care			
309	One report of ADR makes no difference			
310	Reporting is not useful to the patient			
311	Reporting creates additional work load			
312	Even if they are not known, non-serious ADRs should not be Reported			
313	Only ADRs that cause persistent disability or incapacity should be reported			
Part IV				
	To what extent do you agree with the following reasons for not reporting adverse drug reaction	**Agree**	**neutral**	**Disagree**
401	Concern that the report may be wrong			
402	ADRs are well documented by the time a drug is marketed			
403	Reporting form is too complicated			
404	Reporting is time consuming			
405	Reporting ADR is a violation of patient confidentiality			
406	One report makes no difference			
407	Reporting form is not available adequately			
408	There is no national ADR reporting system			
409	Reporting is not useful to the patient			
410	Reporting creates an additional workload			
411	Lack of confidence in discussing the ADR with other colleagues			
412	Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred			

413- Which are the Factors that may encourage you to report an ADR 1- if the reaction was serious 2- if the reaction was unusual 3- if the reaction was to a new product 4- if the reaction was certainly an ADR 5-if the reaction was well recognized for a particular drug 6-other_____	
Part V practice related questions	
501	Have you ever encountered a patient with ADR in your clinical practice, in the last 12 months? 01- yes 02- No
502	Have you ever encountered a patient on ART with ADR in your clinical practice, in the last 12 months? 01-yes 02-No
502	If the above is yes, how many patients with ADR did you see within the last 12 months? 01- One 03- Three 05- more than four 02- Two 04- Four 06- None
503	Have you noted the ADR you encountered on the patient clinical record/patient pharmacy record? 1yes 2- No 3-I have not encountered one
504	Have you ever reported the ADRs? 1- yes 2- No 3 I have not encountered one
505	How often do you give advice to your patients on possible adverse effects of drugs you prescribed, dispensed or administered? 1- usually 3- Never 2- Sometimes 4- Always
	Suggest possible ways of improving ADR reporting in Ethiopia. (Please list as many points as possible? _____ _____ _____ _____

Thanks a lot for your time