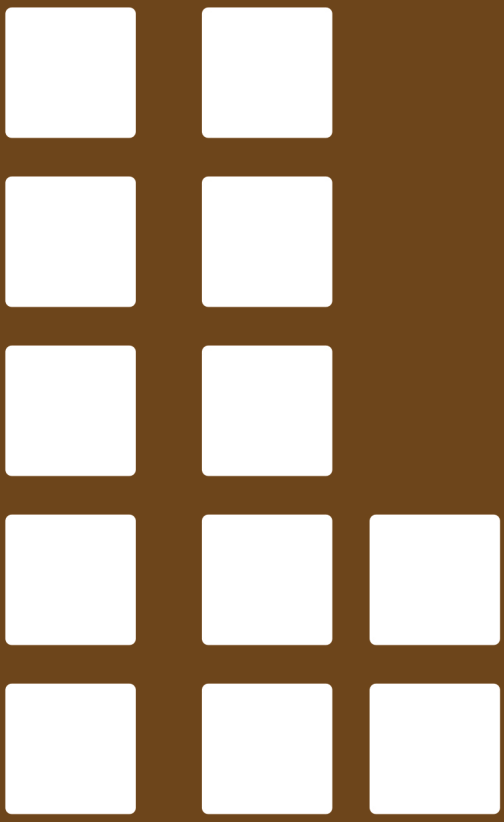
Report on the assessment of health care providers' knowledge, attitude and practice on Adverse Drug Reaction (ADR) reporting and its monitoring

Drug Administration and Control Authority of Ethiopia in collaboration with MSH/RPM plus/SPS



August 2009, Addis Ababa

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Acknowledgment

The Drug Administration and Control Authority would like to extend its gratitude to wards Management Science for Health/Strengthen the Pharmaceutical Services (MSH/SPS) for meeting all the financial expenses and also to the regional DACA Officials and regional pharmaceutical management associates of MSH/SPS for their valuable contribution throughout the entire process especially for the data collection.

Acknowledgment also goes to all health professionals in the health facilities who spend their precious time in filling the required data.

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Acronyms

AAU	Addis Ababa University
ADR	Adverse Drug Reaction
ASHP	American Society of Hospital Pharmacists
DACA	Drug Administration and Control Authority
EHNRI	Ethiopian Health and Nutrition Research Institute
EPA	Ethiopian pharmaceutical Association
MOH	Ministry Of Health
WHO	World Health Organization

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Summary

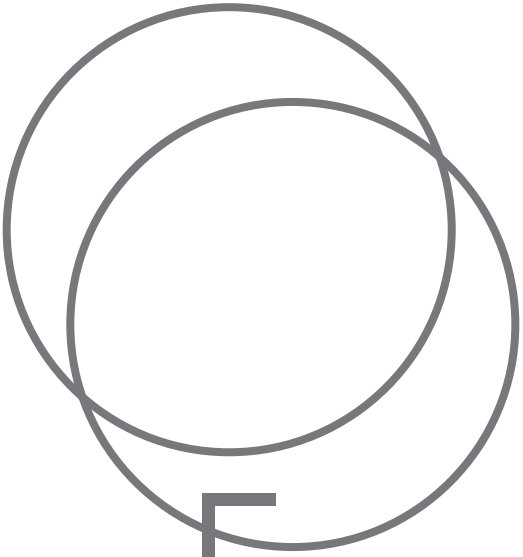
Introduction: Spontaneous reporting is the voluntary reporting of an adverse reaction by a physician, pharmacist and other health professionals or a patient with the main objective being able to provide signals about potentially serious, previously unknown safety problems with marketed drugs. In Ethiopia voluntary reporting has been effective as of 2002 through the rigorous activities performed by the adverse drug reaction monitoring division of the Drug Administration and Control Authority. But the level of awareness of health providers towards ADR monitoring was not satisfactory and hence the number of ADR reports received was low in amount. Hence, an assessment needs to be performed so that it can serve as a base for an intervention.

Objectives:

1. To measure the Knowledg, attitude and practice of physicians and pharmacists
2. To identify contributing factors that affect ADR reporting.
3. To come out with possible recommendation that improves ADR monitoring.
4. To generate baseline data for further studies and strategy for action.

Methods: A descriptive cross sectional assessment was conducted in 81 governmental hospitals. 500 self administered questionnaire were distributed to 103 pharmacists and 397 general practitioners and specialist. Results: 406 were returned and 400 were included in the study making the response rate 80%. Most of the providers use standard text books (179, 44.75%) as a source of information about adverse drug reactions. The majority of them (296, 74%) had never participated in any seminar on adverse drug reaction monitoring or pharmacovigilance. As far as knowledge was concerned it was observed that the terms adverse drug reaction (202,50.6%) and side effect (245,61.3%) are answered at least by half of the responders to a satisfactory level whereas differentiating between the above two (159,39.8%) and factors predisposing to adverse drug reaction (187,46.3%) seem to be found a little bit difficult. Similar result (181, 45.3%) was found for the understanding of the term pharmacovigillance and (53, 13.3%) of the respondents answered saying "I DON'T KNOW WHAT IT MEANS". Participants response as to whether they were introduced to adverse drug reaction monitoring or pharmacovigillance in their under graduate study showed that some (176, 44%) of them were introduced to but the majority (215, 53.8%) were not. Practice with ADR showed that (225, 56.25%), (134, 33.5%) and 54,13.5%) of the participants had encounter with an ADR in their practice during the last 12 months,3 months and 2 weeks in their day today activities respectively but only (34, 14.6%) had reported their encounter. Out of the total of ADRs encountered the total reported to DACA was only 5%. Names of the drugs which caused the last ADR they encountered were ranked as cotrimoxazole (40, 18.8%), Neviapine (38, 17.8%), ART drugs unspecified (10.4.7%) and TB drugs (10, 4.7%).The major organ system that was affected was the dermatological system (94, 42%). Most of the ADRs encountered by the respondents were found to be the moderate type (102, 45.1%) Some of them were severe enough to require hospital admission (79,35%) and the rest were mild (28,12.4%). Fatality or death of the patient with the ADR was observed in (8, 3.5%) of the cases. Responders attitude towards ADR monitoring was assessed using likert scale with the level of agreement extending from strongly disagree to strongly agree and almost all health

providers agree towards the fact that an ADR should be reported(96%) and it is part of the professional duty of a health professional(95%). Agreement was also observed on the fact that monitoring an ADR is important for the public(96%),for the patient(95%),and for the health care system(96%).Some of the responders (24%) believe that only ADR of prescription drugs need to be reported whereas most of them don't think so(69%). Among the reasons that affect reporting of an ADR, Some of the respondents (30.3%) believe that ADRs are well documented by the time a drug is marketed but this idea was not agreed upon by the majority (59.1%).Problems concerning the report form; reporting form is too complicated, reporting form is not available adequately were agreed upon to be true by (22.9%) and (68.8%) of the respondents respectively. Reporting is time consuming, reporting creates an additional workload were agreed upon by some (28.1%), (34.7%) respectively. conclusion: it is clear that vast amount of work needs to be done in the awareness creation aspect both at the preservice and inservice categories of the professionals based on the points of intervention observed so that the longterm goal of monitoring drug safety is fulfilled.



INTRODUCTION

1. Introduction

Drugs have become one of the most essential components of health care systems worldwide. Drugs save lives .This indisputable fact makes rational selection, procurement, distribution and use of drugs of paramount importance in health care.

Unfortunately there are often shortcomings in the prescribing and taking of drugs. One important concern is that of safety. Drugs are produced synthetically or from natural substances and most will exhibit some form of side effect or adverse reaction. This side effects or adverse reactions could be relatively mild or, in rare cases Serious and life threatening.

The World Health organization defines an adverse drug reaction as. "Any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases, or for the modification of physiological function. "An unexpected adverse drug reaction refers to a reaction, the nature or severity of which is not consistent with domestic labeling or market authorization, or expected from characteristics of the drug.

The American Society of Health system pharmacists provide another definition of ADR. It describes an ADR as an unexpected, undesirable, or excessive response to a drug that requires; discontinuing the drug, Changing the drug, modifying the dose, necessitates admission to a hospital, prolongs stay in a health facility, necessitates supportive treatments, significantly complicates diagnosis, negatively affects prognosis and results in temporary or permanent harm, disability, or death.
(Source: ASHP Technical Bulletins)

Marketing a new drug requires many clinical trials to establish efficacy, safety and quality. Pre-marketing clinical trials will determine the most common adverse events, those with an occurrence of one percent or more during the development of a new drug because of the limited size and controlled nature of these studies. Those reactions that are less common may not be identified in these pre-marketing studies and will rely on post marketing surveillance. Post marketing surveillance, is critical in that it decides whether the benefit of a drug outweigh its risks (1).In this important phase ,the science and activity that deals with the detection, assessment, understanding and prevention of adverse drug reactions and other drug related problems is pharmacovigilance.

Pharmacovigilance plays a crucial role in the study of safety and, by extension, in the overall pharmacotherapeutic decision making. Spontaneous reporting of adverse drug reactions is considered to be the cornerstone of any pharmacovigilance system (2).

Spontaneous reporting is the voluntary reporting of an adverse reaction by a physician, pharmacist and other health professionals or a patient with the main objective being able to provide signals about potentially serious, previously unknown safety problems with marketed drugs. Most countries have therefore established formal spontaneous programs to detect serious adverse reactions as efficiently and inexpensively as possible (3).

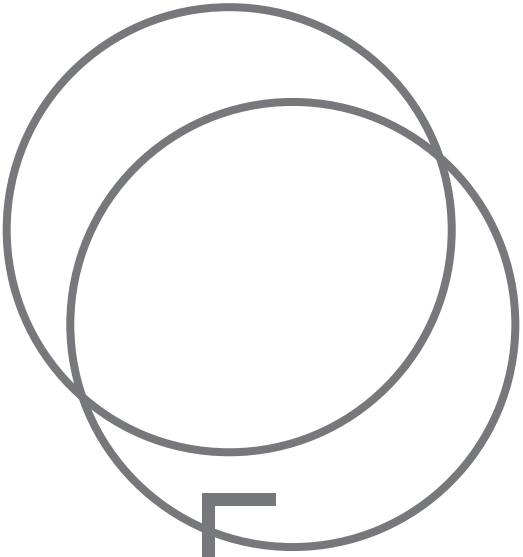
These reports have the advantage of being available immediately as new products are released and throughout the market life of a drug. The greatest limitation of spontaneous reports is that there is a significant underreporting of adverse reactions. It is estimated that reported adverse reactions rarely exceed 10%(4-7).A similar estimate is that the FDA receives by direct report less than 1% of suspected serious ADRs. This implies that cases spontaneously reported to any surveillance programme, generally represent only a small portion of the number that actually occurred (8).

Various studies have been performed in different countries to assess the reasons for under reporting of ADRs by physicians (9-15) and also by pharmacists (16-19).The most frequently mentioned reasons for not reporting ADRs were the ADR was not serious, the ADR was already Known, uncertainty concerning the causal relationship between the ADR and the drug, forgetting to report the ADR and lack of time.

STATEMENT OF THE PROBLEM

2. Statement of the problem

In Ethiopia voluntary reporting has been effective as of 2002 through the rigorous activities performed by the adverse drug reaction monitoring division of the Drug Administration and Control Authority. A simple reporting form was developed and is made available throughout all the health facilities. Various trainings were given and face to face discussions about adverse reaction monitoring were also performed. As for the reporting form; what to report, when to report and to whom to report were explained on different occasions. In spite of all this activities, still there remains some work to be done to improve the level of awareness of health providers towards ADR monitoring and thereby increase the number of ADR reports received .In order to do this, an assessment needs to be performed so that it can serve as a base for an intervention.



OBJECTIVE

3. Objective

3.1. General objective-

To assess the knowledge, attitude and practice of health care providers on adverse drug reporting and monitoring in the public health sector.

3.2. Specific Objectives

1. To measure Knowledge, attitude and practice of physicians and pharmacists.
2. To identify contributing factors that affect ADR reporting.
3. To come out with possible recommendation that improves ADR monitoring.
4. To generate baseline data for further studies and strategy for action.

METHODOLOGY

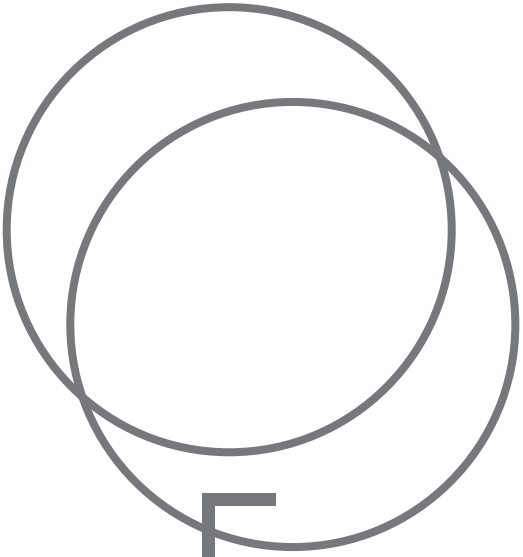
4. Methodology

4.1. Survey sites

Governmental hospitals in the 11 regions and city administrations of the country that are 81 in numbers were taken as the study sites to serve as a sampling frame (Annex 1). The reason why public sectors were only chosen is that most of the trainings and face to face discussions on adverse drug reaction reporting and monitoring were performed on this type of facilities hence measurement of the activities based on this performance is thought to be reasonable. Hospitals in which the pretest of the data collecting tool was performed were not included in the survey.

4.2. Survey design

A descriptive cross sectional survey using primary data from health professionals in the public sector was conducted from January –July, 2008.



SAMPLING

5. Sampling

5.1. Sample size

Taking the prevalence of under reporting of adverse drug reactions to be 50% (p=0.5) the sample size to be used in the survey was calculated as follows with 95% confidence level (z=1.96) and 5% standard of error(δ=0.05).

$$N=\frac{z^2p(1-p)}{\delta^2}$$

$$N=\frac{(1.96)^2\ 0.5(1-0.5)}{0.05^2}=\frac{3.8416 \times 0.25}{0.0025}=384.16$$

Adding 30% contingency for non response and design effect the total sample size will be rounded to 500. According to the 1999 health indicator (20), there are 973 physicians and 148 pharmacists in service in the public sector. From this total there are 186 specialists, 343 general practitioners and 103 pharmacists giving service in hospital settings.

All the 103 pharmacists in the hospitals were included in the survey and the rest 397 were divided between the general practitioners and specialists in proportion to their total number at hospitals.

Breaking down this sample size to Proportion of the sample size by the no of specialists (186) and General practitioners (343) available in the hospitals-

$$\frac{186\ X397}{529}=140 \qquad \frac{343\ X397}{529}=257$$

5.2. Sampling procedure

Sampling for Specialists

Table 1 Number of Questionnaires to be distributed to the specialists based on their number in the selected hospitals

No of specialists available	Total no of hospitals with this no of specialists	Questionnaires to be distributed to each hospital	Total no of questionnaires
≥8	8	6	48
7-5	14	3	42
4-2	16	2	32
1	14	1	14
		Total	136

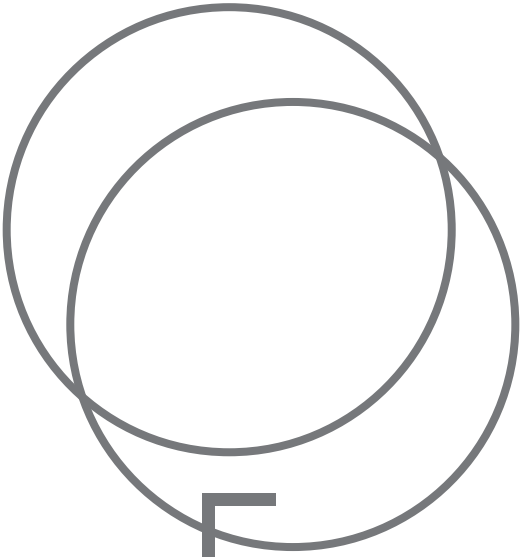
As table 1 indicates, for the 8 hospitals that have 8 or more specialists 6 questionnaires were sent for each hospital to be delivered to the specialists to be filled making the total 48 in number. This procedure continued as the table indicates for all the other hospitals accordingly. The rest 4 questionnaires were added to 4 referral hospitals with their no of specialists much higher .The remaining 29 hospitals do not have specialists in their service.

Sampling for the general practitioners

Table 2 Number of Questionnaires to be distributed to the general practitioners based on their number in the selected hospitals

No of general practitioners available	Total no of hospitals with this no of GPs	Questionnaires to be distributed to each hospital	Total no of questionnaires
≥8	22	6	132
7-5	9	5	45
4-2	31	2	62
1	15	1	15
		Total	**254**

As table 2 indicates there are 22 hospitals that have 8 or more general hospitals and each were given 6 questionnaires to be distributed among the general practitioners making the total to be filled 132.The remaining 3 questionnaires were given to hospitals with higher no of GPs .This continued for other hospitals in proportion to their number of general practitioners accordingly.



DATA COLLECTION & MANAGEMENT

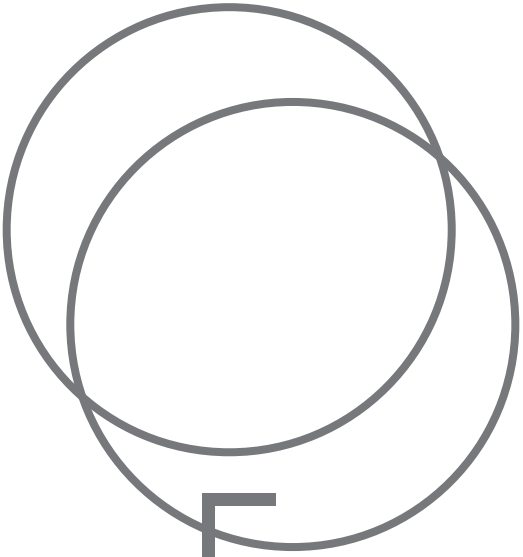
6. Data collection and management

6.1 Data collection

A Self administered questionnaire was developed and given for comment. This data collecting tool is composed of 53 relevant questions that could identify the demographics, assess the knowledge attitude and practice of the health professionals, identify references used and seminars taken by the health professionals on adverse drug reaction and its reporting system. The health providers were also asked to indicate some reasons for not reporting adverse drug reactions and were also allowed to indicate their agreement or disagreement on a 4 point likert scale from 'strongly agree' to 'strongly disagree'. A final open ended question invited the respondents to give comments on possible ways to increase knowledge attitude and practice towards adverse drug reaction monitoring system as a whole (Annex 2) The data collecting tool was pre-tested in 5 health facilities that were not included in the survey .The time of data collection was for 15 days .Data collected from the survey was properly handled after being checked for accuracy, consistency, omissions and irregularities. Questionnaires were numbered and stored properly.

6.2. Data entry and analysis

Data was entered into EPIINFO 2002 version and all the required analysis consisting of descriptive statistics was performed. Results were summarized in the form of tables. As for the qualitative open end questions that were answered by narration, an agreement based on relevant documents was prepared by the team that gives a score to each question hence each answer was judged fairly and accordingly by it (Annex 3).Advanced statistics using linear regression was tested to understand better the statistical significant of the relationship between the independent and dependent variables of the study.



STUDY VARIABLES

7. Study variables

7.1. Dependent variables

Knowledge about adverse drug reaction
Knowledge about Side effect.
Knowledge about the difference between the two.
Knowledge about Pharmacovigillance.
Knowledge about reporting system.
Attitude towards ADR reporting.
Practice of reporting ADR.

7.2. Independent variables

Demographic factors
Level of specialization
Difference in profession
Year of service
Training on pharmacovigillance

BENEFICIARIES' OF THE STUDY

8. Beneficiaries' of the study

The public in general and the policy makers in particular will be the beneficiaries of this study as areas of possible interventions will be obtained from to improve the ADR monitoring .

RESULTS & DISCUSSION

9. Results and discussion

Four hundred and six health providers completed the questionnaire,6 were omitted for discrepancy and the final total number of responses became 400(response rate 80%). Breaking down the response rate to physicians and pharmacists showed that 77% of the submitted questionnaires for the physicians and 91.2% of the pharmacists were filled and returned.

9.1. Demographic information

Out of this total, 82(20.7%) of the health providers who filled the data were from district hospitals, 139(35.1%) {95%CI=30.4%-40.1%} from zonal hospitals, 141(35.6%) {95% CI=30.9%-40.6%} from referral hospitals and 29(7.3%) were from central referral hospitals. The rest 5(1.3%) of questionnaire were left unanswered. The participant's Demographic information is summarized in Table 3.

Table 3. Demographic information of the health providers in the assessment (N=400).

Variable	Number	Percentage
Age		
20-30	238	59.50%
31-40	89	22.25%
41-50	51	12.75%
>51	8	2.00%
NA*	14	3.50%
Total	**400**	**100%**
Sex		
Male	337	84.30%
Female	63	15.70%
Total	**400**	**100%**
Profession		
Physician	306	76.50%
Pharmacist	94	23.50%
Total	**400**	**100%**
Level of Training/ Specialization		
General practitioner	198	49.50%
Internist	15	3.80%
Gynecologist	25	6.30%
Pediatrician	20	5.00%
Dentist	1	0.30%
Orthophaedist	2	0.50%
ENT specialist	_	_
Surgeon	26	6.50%
Pharmacist bachelor	94	23.50%
Pharmacist Masters	_	_
Others*	19	4.75%
Total	**400**	**100%**
Total months of service		
01-24	191	47.75%
25-49	52	13.00%
50-74	21	5.25%
75-99	11	2.75%
100-124	31	7.75%
125-149	13	3.25%
150-199	32	8.00%
200-360	42	10.5%
NA*	7	1.75%
Total	**400**	**100%**

NA*=Data was not filled
Others include = ophthalmologist, Dermatologist, Psychiatrist, Radiologist

Most of the responders, (59.5%) {95%CI=56.6%-66.5%} fell in the age group (20-30) and are male (84.3%).The result also indicates that most of the participants, (47.75%) {95%CI=43.6%-53.7%} in the assessment have a service year of 2 years and less.

The providers response as to who they think is responsible to remind patients about side effects of the drug they are given in the assessment shows that (61, 15.3%){95%CI=12%-19.3%} believe that it is the responsibility of the pharmacist/druggist and (66, 16.5%) {95%CI=13.1%-20.6%} said it is the treating physician who is responsible. The majority of them, (268, 67.2%) {95%CI=62.3%-71.7%} thought it is the responsibility of the physician and the pharmacist / druggist. Sources of information about adverse drug reactions used by the providers were summarized in table 4.

Table 4. Source of information of the participants about adverse drug reactions.

Source of information	Number	Percentage
1.Standard text books	179	44.75%
2.MIMS Africa	8	2%
3.British drug formulary	11	2.75%
4.Notes from the university training	52	13%
5. Drug sales man	2	0.5%
6. 1 and 4 together	53	13.25%
7. 1 and 3 together with different guidelines in the country	16	4%
8. 1 and 3 together	11	2.75%
9. 1 ,3,4 together	8	2%
10. 1,2,3,4,5	5	1.25%
11. 1,4 and different trainings	6	1.5%
12. 1,4 together with different guidelines in the country	6	1.5%
12.1,2,3 together	4	1%
13.1,2 together	2	0.5%
14.1 and leaflet	2	0.5%
15.1,3,5 together	2	0.5%
16.NA*	17	4.25%
16.Others*	16	4%
Total	**400**	**100%**

NA*=Data was not filled
Others include=leaflets, workshop materials, Internet, Australian prescriber

As observed from the result most of the providers use standard text books (179, 44.75%) {95%CI=40.6%-50.6%} as a source of information about adverse drug reactions .Some of them use their notes from university training (52, 13%) {10.1%-17.1%} or standard text books together with their notes from the university training (53, 13.25%) {95%CI=10.3%-17.4%}.

The respondents answer as to whether they have ever participated in any seminar which includes topic on adverse drug reaction monitoring or pharmacovigilance indicates that the majority of them (296, 74%) {95%CI=69.4%-78.2%} had never participated in any seminar whereas (93, 23.3%) {95%CI=19.3%-27.8%} of them had participated in the topic relevant to this assessment.

The participants' were asked to give the average number of patients they encounter in a day. Their response shows that the majority (275, 83.3%) {95%CI=78.9%-87.2%} of them encounter an average of 10-50 patients per day. Some of them (40, 12.1%) {95%CI=8.9%- 16.3%} put their average patient load as to fall between 51-100.Respondents with the highest patient encounter (101-200) amount to (13, 3.9%) {95%CI=2.2%-6.8%}.

As to the monitoring of adverse drug reactions, the response of the health providers as to who should monitor ADR the result shows that (282, 70.9%) {95%CI=66.1%-75.2%} of them think DACA should be responsible and the rest are given in the table below.

Table 5.Responsibility for monitoring ADR as the respondents answered

Responsibility	Number	Percentage
Ministry of Health	31	7.75%
DACA	282	70.5%
EHNRI	8	2%
EPA	4	1%
MOH and DACA	44	11%
MOH,DACA,EPA	9	2.25%
DACA and EPA	3	0.75%
AAU	1	0.25%
NA	9	2.25%
Others*	10	2.5%
Total	**400**	**100%**

NA*=Data is not filled
Others*include=MOH and EPA, All the above, DTC

2. Knowledge about adverse drug reaction

The assessment of the knowledge of the health providers about adverse drug reaction and other related terms by the open ended questions was scored based on the agreed upon points as to whether the answer to the given inquiry was fully answered adequately, inadequately and incorrectly. The results were summarized as follows.

Table 6 Results on the knowledge of adverse drug reaction of the respondents

Knowledge	Fully answered		Adequately answered		Inadequate answered		Incorrectly answered		Not Available*	
Term Adverse drug reaction	64	16%	138	34.6%	166	41.6%	26	6.5%	5	1.3%
Term Side effect	52	13%	193	48.3%	137	34.3%	16	4%	2	0.5%
Difference between the two above	44	11%	115	28.8%	159	39.8%	45	11.3%	37	9.3%
Predisposing factors to ADR	17	4.3%	170	42.5%	182	45.5%	18	4.5%	13	3.3%
Term Pharma-covigilance	32	8%	149	37.3%	41	10.3%	37	9.3%	87	21.8%

Not Available*=Data was not filled

As observed from the table the terms adverse drug reaction (202,50.6%)and side effect (245,61.3%) are answered at least by half of the responders to a satisfactory level whereas differentiating between the two(159,39.8%) and factors predisposing to adverse drug reaction(187,46.3%) seem to be found a little bit difficult. Same result was found for the understanding of the term pharmacovigillance (181, 45.3%) and (53, 13.3%) of the respondents answered saying “I DON’T KNOW WHAT IT MEANS”.

Participants response as to whether they were introduced to adverse drug reaction monitoring or pharmacovigillance in their under graduate study showed that some (176, 44%) {95%CI=39.1%-49%} of them were introduced to but the majority (215, 53.8%) {95%CI=48.7%-58.7%} were not.

3. Practice involving adverse drug reaction encounter and its reporting

This assessment tried to look into the health providers' practice of adverse drug reaction by asking about their encounter and their actions towards it. The summary is given in the table below.

Table 7 Results of participants encounter with ADR

ADR encounters	Number	Frequency
Encounter in the last 12 months		
YES	225	56.25%
NO	164	41.%
NA*	11	2.75%
Encounter in the last 3 months		
YES	134	33.5%
NO	251	62.75%
NA*	8	3.75%
Encounter in the last 2 weeks		
YES	54	13.5%
NO	329	82.25%
NA*	6	4.25%

As seen from the result (Table 7) ;(225, 56.25%), (134, 33.5%) and 54,13.5%) of the participants had encounter with an ADR in their practice during the last 12 months,3 months and 2 weeks in their day today activities respectively.

As to the number of patients they had encountered in the last 3 months, (62, and 27.1%) {95%CI=21.4%-33.3%} admitted that they had met with one patient with an ADR and (38, 16.6%) {95%CI=12%-22.1%} with 2 patients. Still some (41, 17.9%) {95%CI=13.2%-23.5%} said they have 3 or more encounters in the last 3 months.

Some of the participants, (205) gave the names of the drugs which caused the last ADR they encountered and it was summarized as follows in the table (Table 8).

Table 8 Names of the drugs that caused ADR during the last encounter

Name of the drug	Number	Frequency
Cotrimoxazol	40	18.8%
Nevirapine	38	17.8%
ART drugs	10	4.7%
TB drugs	10	4.7%
Zidovudine	6	2.8%
Ciprofloxacin	4	1.9%
Norfloxacin	4	1.9%
AntiTB+ART+Cotrimoxazol	4	1.9%
ART+Cotrimoxazol	4	1.9%
Phenobarbitone	4	1.9%
Nevirapine+Zidivudine	4	1.9%
AntiTB+ART	4	1.9%
Efavirenz	3	1.4%
Amoxicillin	3	1.4%
Procain Penicillin	3	1.4%
Nevirapine+Cotrimoxazole	3	1.4%
Doxycycline	2	0.9%
Rifampicine+INH	2	0.9%
Name Forgotten	2	0.9%
Fansidar	2	0.9%
Clarithromycin	2	0.9%
Nevirapine +INH	2	0.9%
Nevirapine+Rifampicine	2	0.9%
Ampicilline+Cotrimoxazol	2	0.9%
Antipsychotic	2	0.9%
Metoclopromide	2	0.9%
Cotrimoxazol+Fluconazole	2	0.9%
Antineoplastics	2	0.9%
Others*	40	18.7%

Others* include=Ampicilline, Ethambutol, Cimetidine, Traditional medicine, Erythromycin,Captopril,Azithromycin,Carbamazepine,Diazepam,Metotrexate,Isotretinon,Lidocaine,Diclophenac,Propylthiouracil,Contrast(IVP&HSG),Ibuprofen, Quinine, Halop(IVP&HSG),ibuprofen, Quinine, Haloperidol, Amiodarone, Combination of the listed drugs.

There were a total of 64 names of drugs listed by the health providers that caused ADR and the rest of them were also the combination of 2 or more drugs in the list (Table 8) that were taken together.

224 respondents gave the organ systems that were affected by the ADR observed. The major organ system that was affected was the dermatological system (94,42%) {95%CI=35.4%-48.7%}.The rest are given as follows (Table 9).

Table 9 Organ systems affected by the ADR as encountered by the responders

Organ system	Number	Frequency
Dermatological system	94	42%
Dermatology Hepatic system	23	10.3%
Hepatic system	12	5.4%
Dermatological +Gastrointestinal	10	4.5%
Dermato+Gastro+Hepatic system	10	4.5%
Dermatological+Ear &Eye	10	4.5%
Gastrointestinal system	9	4%
Dermato+Central nervous system	9	4%
Dermato+Hepatic +Central NS	8	3.6%
Central Nervous system	7	3.1%
Cardiovascular system	3	1.3%
Dermatologic+Metabolic System	2	0.9%
Others*	27	11.9%

Others*= Metabolic system, Ear &Eye, Respiratory system ,Immune system Hematologic system and a combination of the above listed Systems

As obtained in the result, most of the ADRs encountered by the respondents were found to be the moderate type (102, 45.1%) {95%CI=38.5%-51.9%} those that require only the discontinuation of the drug. Some of them were severe enough to require hospital admission (79,35%) and the rest were mild (28,12.4%)that do not necessitate the discontinuation of the drug. Fatality or death of the patient with the ADR was observed in (8, 3.5%) of the cases.

The participants' response as to whether they have noted the observed ADR in the patient clinical record indicated that of all the 229 respondents; (167,72.9%) {95%CI= 66.7%-78.6%} said they have recorded the ADR whereas the rest (62, 27.1%) said they have not.

Respondents practice towards adverse drug reaction reporting was asked in the assessment and the answer was that only (34, 14.6%) {95%CI=10.3%-19.8%} had reported and the rest (197, 84.5%) {95%CI=79.3%-88.9%} had never reported the ADR they encountered. This data of not reporting an ADR seemed to be higher than some studies performed for the same purpose. In a survey done at England, out of 280 participants 39% of the hospital pharmacists did not report the encountered ADR (21)

As to the question that asks the participants to whom did they report the ADR encountered, the following response was obtained.

Table 10 Participants response as to whom they reported the encountered ADR

To whom did you report	Number	Frequency
To Manufacturers	1	2.9%
To DACA	22	64.7%
To the pharmacy department	5	14.7%
To DTC	3	8.8%
Others*	3	8.8%

Others*=to the physicians, to ITECH, to ICAP

It is clearly seen that from this result that out of the total of ADRs encountered (413) only 22 is reported to DACA making the total reported to 5% only.

The responders were asked as to the frequency that which they give advice to their patients concerning the possible occurrence of adverse effects and only (129, 32.7%) {95%CI=28.2%-37.7%} of them answered they usually give advice (for >75% of the patients) and similar number also stated that they sometimes (for 50% of the patients) give advice. Some significant number (104, 26.4%) indicated that they rarely (<25%) gave advice to their patients.

Reasons of the health providers for not giving advice indicated that (120, 33.9%) of them don't regularly advise their patients because they are busy or have no time and (75, 21.2%) said they just don't give it enough attention for unknown reasons. Some (23, 6.5%) thought it to be the primary duty of the dispenser to give advice.

Other reasons for not giving advice as given are the patient will be worried and may stop the drug and compliance will be under question, language barrier, only few patients and few drugs have ADR, it is difficult to know the ADR, the ADR are too many to memorize and tell the patient, most drugs are safe, the job is left to the physician or nurse, the patient should not be loaded with information.

As to the contents of the advice concerning the possible ADRs to the patient, most of the participants gave adequate answers (218, 54.9%) mentioning some of the known ADRs and if the patient encounter something different to contact the health provider immediately and some of the respondents gave inadequate answers (77,19.4%).

Related to the above topic the participants were also asked if they ask history of pregnancy in women before giving a drug. Their response was that they usually (239, 61%), sometimes (67, 17.1%) and rarely (30, 7.7%) ask the history before.

4. Attitude of the responders towards ADR monitoring.

The participants were asked to indicate their agreement or disagreement on a 4-point Likert scale from 'strongly agree' to 'strongly disagree' and their response was summarized as follows in table 11.

Table 11 Participants attitude towards ADR monitoring(percentage)

Statements	**Level of agreement**				
	Strongly Agree	Strongly disagree	Agree	Disagree	NA
ADR Should be reported regularly	77.1%%	19.1%	0.3%	-	3.5%
Reporting is part of the professional duty of a health professional	66.8%	28.1%	0.5%	0.3%	4.3%
Monitoring drug safety Is important for the public	80.8%	16.3%	-	-	3%
Monitoring drug safety Is important for the patient	80.7%	14.8%	0.8%	-	3.8%
Monitoring drug safety Is important for the health care system	77.4%	18.8%	-	-	3.5%
There is a need to be sure that an ADR is related to the drug before reporting	50.8%	29.5%	10.3%	2.8%	6.8%
Only ADRs of prescription drug need to be reported	5.5%	18.8%	49%	20.1%	6.5%
Even if they are not known, non serious ADRs should not be reported	6%	19.3%	48.3%	19.8%	6.8%
Only ADRs that cause persistent disability or incapacity should be reported	2.5%	6.8%	44.8%	41.8%	4.3%
Reporting an ADR is part of the patient care	60%	33.3%	1.8%	1.3%	3.5%
Monitoring ADR improves quality of patient care in health facility	70.5%	24.3%	0.5%	0.8%	4%

It was found out from the result that almost all health providers agree towards the fact that an ADR should be reported(96%) and it is part of the professional duty of a health professional(95%).Most of them also agree on the idea that monitoring an ADR is important for the public(96%),for the patient(95%),and for the health care system(96%). Some of the responders (24%) believe that only ADR of prescription drugs need to be reported whereas most of them don't think so(69%). The statement that said "Only ADRs that cause persistent disability or incapacity should be reported" was not agreed upon by the majority of the participants(86%).The fact that monitoring ADR improves the quality of patient care in health facility was also agreed upon almost by all the participants(95%).

This attitudes towards underreporting as shown in the agreed statements; that there is a need to be sure that an ADR is related to the drug before reporting , non serious ADRs should not be reported are also shared by other countries health professionals as can be seen from some similar studies(16).

5. Participants reason for not reporting an ADR

The Participants were asked for their reason in not reporting an ADR encountered and it was stretched on a 4 level of agreement. The result was found to be as follows (Table12).

Table 12 Participants reason for not reporting an ADR

	Level of agreement					
	Strongly Agree	Agree	Disagree	Strongly disagree	I Don't Know	NA
Need to be certain of the association between the drug and ADR	27%	45.5%	15.8%	3.8%	-	NA
ADRs are well documented by the time a drug is marketed	8.5%	21.8%	46.6%	12.5%	0.5%	9.8%
Reporting form is too complicated	4.8%	18.1%	47.5%	9.8%	4.5%	15.3%
Reporting is time consuming	5.3%	22.8%	49.5%	10.8%	1.8%	10%
Reporting ADR is breach of patient confidentiality	4.5%	9.5%	52.5%	23.1%	0.3%	10.3%
One report makes no difference	3%	8.5%	54.5%	25.8%	0.3%	8%
Reporting form is not available adequately	30.8%	38%	14.8%	5%	4.3%	7.3%
There is no national ADR reporting system	19.6%	25.9%	31.3%	8.9%	4.8%	9.6%
Reporting is not useful to the patient	2%	2.55	46.2%	42.3%	0.5%	6.5%
Reporting creates an additional workload	6.3%	28.4%	40.5%	17.8%	0.3%	6.8%

Among some of the reasons that affect reporting of an ADR, Some of the respondents (30.3%) believe that ADRs are well documented by the time a drug is marketed but this idea was not agreed upon by the majority (59.1%).Problems concerning the report form; reporting form is too complicated, reporting form is not available adequately were shared upon to be true by (22.9%) and (68.8%) of the respondents respectively.

The reason reporting form is not available adequately is found to be common in some countries findings too. In a survey done by the European Pharmacovigilance Research Group on members of the European Union, it was mentioned as one of the reasons that discourage reporting and this same fact was found to be a reason in 60.4% of health professionals enrolled in a survey in China (13).

Further concerns and factors that affect reporting showed that reporting is time consuming (28.1%), reporting creates an additional workload (34.7%). Reporting ADR is breach of patient confidentiality (75.6%) and one report makes no difference (80.3%) were not considered as reasons for not reporting.

The result surprisingly shows the responders belief that there is no ADR reporting system in the country by a significant amount (45.5%). This belief is also shared by other countries physicians. In a study done in Malaysia, Germany and China, respectively about 40%, 20%and 52.2%of the respondents were not aware of the existence of their national ADR reporting system (9, 10, 13).

6. Differences and similarities between the two professions with respect to Knowledge attitude and practice towards ADR.

The knowledge between the two professions concerning adverse drug reaction, pharmacovigilance, and the difference between ADR and side effect was compared and the observed result was summarized as follows in the table.

Table 13 Differences and similarities in the knowledge about ADR and similar terms between the two professions (Percentage).

Knowledge	Fully answered		Adequately Answered		Inadequate answered		Incorrectly answered	
	Phys	Pharm	Phys	Pharm	Phys	Pharm	Phys	Pharm
Term Adverse drug reaction	9.5	38	35.1	32.6	46.6	25	7.5	3.3
Difference between ADR and Side effect	6.5	26.1	24.2	43.5	44.1	26.1	13.7	2.2
Factors predisposing to an ADR Difference	3.9	5.4	38.9	54.3	48.7	34.8	4.2	5.4
Term Pharmacovigilance	6.2	14.1	33.4	51.1	9.8	12	9.2	9.8

The result shows that there is a some difference between the two professions .The first two terms were answered by 44.6%and 30.7% of the physicians and by 70.6% and 69.6% of the pharmacists respectively.

The two professions also differ in being introduced towards ADR monitoring during their undergraduate studies. Only 33% of physicians were introduced about ADR but the percentage goes to 81.5% in case of the pharmacists.

Another interesting fact is that the majority of both professions had not taken any seminar towards ADR (78.1% physicians and 60.9% for pharmacists).

As to the encounter of ADR; 61.5% of physicians and 40% of pharmacists had experience in their professional practice in the past 12 months.

As indicated in the assessment both of the professions have similar practice towards ADR reporting with only 15.1% of physicians and 12.5% of pharmacists actually reporting an ADR. This data of not reporting an ADR seemed to be larger than some studies performed for the same purpose. In a survey done at England, out of 280 participants 39% of the hospital pharmacists did not report the ADRs they encountered (21).Also in a similar study done at Malaysia and China to identify factors that predict physicians failure to send ADR reports, a high proportion of the respondents (81.4% and 61.7%) indicated that they have suspected an ADR but haven't reported it (9,13).

The participants' attitude towards ADR monitoring and reporting and the difference and similarity observed between the two professions were summarized as follows in the given table (Table14).

Table 14 Attitude difference /Similarity towards ADR monitoring and reporting between the two professions (Percentage)

Statements	Level of agreement							
	Strongly Agree		Agree		Disagree		Strongly disagree	
	Phys	Pharma	Phys	Pharma	Phys	Pharma	Phys	Pharma
ADR Should be reported regularly	74	84.8	20.7	14.1	0.3	-	-	-
Monitoring drug safety is important for the patient	77	90.2	17.7	5.4	0.3	2.2	-	-
Monitoring drug safety is important for the health care system	75.1	84.8	20.3	14.1	4.3	1.1	-	-
There is a need to be sure that an ADR is related to the drug before reporting	51.6	46.7	28.1	34.8	9.5	12	2.6	3.3
Only ADRs of prescription drug need to be reported	6.3	3.3	21.1	12	49.7	47.8	15.5	34.8

Both of them agree mostly on the statement that ADR Should be reported regularly (Phys 94.7%, Pharm 98.9%), Monitoring drug safety is important for the patient (94.7%, 95.6%) and Monitoring drug safety is important for the health care system (95.4%, 98.9%).

Physicians have a little difference in their agreement towards the statement that only ADRs of prescription drug need to be reported (27.4%) than pharmacists (15.3%).

There was observed difference and similarity between the two professions with respect to reasons for not reporting an encountered ADR (Table 15).

Table 15 The two professions and their reasons for not reporting an ADR

	Level of agreement							
	Strongly Agree		Agree		Disagree		Strongly disagree	
	Phys	Pharm	Phys	Pharm	Phys	Pharm	Phys	Pharm
ADRs are well documented by the time a drug is marketed	8.8	7.7	22.9	17.6	47.1	45.1	9.8	22
Reporting form is too complicated	5.3	3.3	19.7	13	44.1	57.6	6.9	19.6
Reporting is time consuming	5.2	5.4	25.5	14.1	47.7	54.3	8.2	18.5
Reporting ADR is breach of patient confidentiality	4.2	5.4	9.8	8.7	52	54.3	23.5	20.7
One report makes no difference	2.9	3.3	7.5	12	54.9	53.3	24.8	28.3
There is no national ADR reporting system	23.4	7.7	27	20.9	25.3	50.5	6.3	16.5
Reporting creates an additional workload	6.3	6.5	29.9	22.8	38.8	46.7	16.8	20.7

The two professions show little difference in their reasons for not reporting as shown by their disagreement in the statements. ADRs are well documented by the time a drug is marketed (Phys 56.9%, Pharm 67.1%), reporting form is too complicated (Phys 51%, Pharm 77.2%), and their agreement on reporting is time consuming (Phys 30.7%, Pharm 19.5%) and there is no national ADR reporting system(Phys 50.4%, Pharm 28.6%).

There is a finding in a similar study in Germany that shows that 75.6% of the physicians in the survey also believe that ADRs are well known (10).Another study done in Dublin also concluded that uncertainty that the ADR was definitely caused by the drug, that the ADR was to trivial to report or it was too well known to report were some of the reasons for not reporting (11).The fact that reporting ADR is breach of patient confidentiality is also not agreed upon by the majority of participants in a study done by the European union(12).

7. Differences and similarities in the different age groups of the participants with respect to Knowledge attitude and practice towards ADR.

The participants response was analyzed in different age groups as to their Knowledge attitude and practice towards ADR and the result was described as follows (Table 16).

Table 16 The different age groups and their difference/ similarity in their knowledge towards ADR(Percentage.

Knowledge	Fully answered	Adequately answered	Inadequately answered	Incorrectly answered
Term Adverse drug reaction				
20-30	20.2	36.1	36.1	6.7
31-40	6.8	33	53.4	5.7
41-50	13.7	29.4	51	5.9
>51	-	50(?)	25	12.5
Difference b/n ADR &Side effect				
20-30	13.9	31.5	39.1	8.4
31-40	4.5	29.2	42.7	12.4
41-50	7.8	21.6	37.3	21.6
>51	12.5	12.5	50	12.5
Term Pharma-covigilance				
20-30	10.1	40.8	10.5	9.2
31-40	3.4	31.8	14.8	6.8
41-50	7.8	29.4	5.9	11.8
>51	-	50(?)	-	-

The result indicated that knowledge about the terms given is by far better in the first age group than the next ones .Term ADR is answered by 56.3% of the first age group and by 39.8% and 43.1% of the next two groups and this result goes similar for the rest terms given.

As for the practice of reporting, age group that reported the majority of the observed ADRs (47%) was the one from (20-30) to be followed by the third group (26%) and the second (20.5%).

The attitude difference observed between the age groups in the following table (table 17) shows that most of the statements were strongly agreed upon by the younger generation and this seems to decrease as the age of the provider increases.

Table 17 Attitude difference/Similarity between the different age groups towards ADR monitoring

Statements	Level of agreement			
	Strongly Agree	**Agree**	**Disagree**	**Strongly Disagree**
ADR Should be reported regularly				
20-30	78.8	17.8	0.4	-
31-40	77.5	18	-	-
41-50	70.6	23.5	-	-
>51	62.5	25	-	-
Monitoring drug safety is important for the patient				
20-30	81.1	14.3	1.3	-
31-40	84.3	13.5	-	-
41-50	74	14	-	-
>51	62.5	25	-	-
Monitoring drug safety Is important for the health care system				
20-30	78.6	18.1	-	-
31-40	79.5	18.2	-	-
41-50	72.5	17.6	-	-
>51	62.5	37.5	-	-
Only ADRs of prescription drug need to be reported				
20-30	5	19.3	48.7	21.4
31-40	5.7	21.8	47.1	21.8
41-50	7.8	15.7	51	11.8
>51	-	-	50(?)	25

Reasons for not reporting an ADR were assessed in the different age groups and their level of agreement was seen (Table 18).

Table18 Reasons for not reporting as observed in different age groups

Statements	Level of agreement			
	Strongly Agree	Agree	Disagree	Strongly Disagree
Need to be certain of the association between the drug and ADR				
20-30	28.6	48.3	13.9	2.5
31-40	25.8	48.3	15.7	5.6
41-50	21.6	31.4	23.5	5.9
>51	12.5	25	37.5	-
ADRs are well documented by the time a drug is marketed				
20-30	8	23.2	48.9	13.1
31-40	9	19.1	44.9	14.6
41-50	11.8	19.6	37.3	9.8
>51	12.5	12.5	62.5	-
Reporting form is too complicated				
20-30	3.8	16.9	51.5	11
31-40	5.7	27.3	35.2	8
41-50	7.8	11.8	49	9.8
>51	12.5	-	50	12.5
Reporting is time consuming				
20-30	5.9	18.9	52.9	11.8
31-40	2.2	38.2	40.4	6.7
41-50	5.9	15.7	45.1	15.7
>51	12.5	12.5	62.5	-
There is no				
national ADR reporting system				
20-30	15.2	27	37.1	8.9
31-40	28.1	23.6	24.7	7.9
41-50	22.4	24.5	20.4	12.2
>51	25	37.5	-	-
Reporting creates an additional workload				
20-30	7.6	26.5	42	18.5
31-40	5.7	36.4	34.1	18.2
41-50	3.9	21.6	41.2	17.6
>51	-	28.6	42.9	14.3

It shows clearly here that the first group agrees mostly (77%) on the statement that there is a need to be certain of association between the drug and the ADR before reporting than the third group (53%).

There is strong agreement with an increase in amount on the statements like Reporting form is too complicated ,reporting is time consuming and there is no national ADR reporting system as we go from the first group of participants to the last.

8. Differences and similarities of the participants with respect to Knowledge attitude and practice towards ADR in their different service years.

Table19 Differences and similarities between the participants service year and their Knowledge about ADR.

Knowledge	Fully answered	Adequately answered	Inadequate answered	Incorrectly answered
Difference b/n ADR & Side effect				
Months of service				
01-24	16.8	33.5	35.6	7.9
25-49	11.5	19.2	55.8	5.8
50-74	9.5	23.8	42.9	23.8
75-99	-	18.2	36.4	9.1
100-124	-	29	41.9	9.7
125-149	-	38.5	46.2	15.2
150-199	-	40.6	37.5	12.5
200-360	9.5	14.3	35.7	26.2
Predisposing factors to ADR				
Months of service				
01-24	3.7	49.7	41.4	4.7
25-49	5.8	42.3	42.3	3.8
50-74	4.8	33.3	57.1	4.8
75-99	-	36.4	54.5	-
100-124	9.7	35.5	41.9	9.7
125-149	-	46.2	53.8	-
150-199	3.1	37.5	50	-
200-360	4.8	31	50	7.1

Knowledge	Fully answered	Adequately answered	Inadequate answered	Incorrectly answered
Term Pharmacovigilance				
Months of service				
01-24	11.5	44	7.3	8.4
25-49	3.8	34.6	19.2	13.5
50-74	9.5	28.6	4.8	9.5
75-99	-	9.1	18.2	27.3
100-124	3.2	38.7	6.5	3.2
125-149	8.3	25	25	8.3
150-199	9.4	28.1	12.5	6.3
200-360	2.4	35.7	7.1	9.5

As observed from the above table, there seems to be a decrease in knowledge as service year increases. In the first group; all the three terms were answered by (50.3%, 53.4% and55.5%) of the participants whereas in the third group only by (33.3%, 38.6%and 38.1%) of them.

When the participants practice towards reporting was observed, in the first service year group (1-24 months-participants who have joined the health practice recently),it was found that only 12.6% had reported an ADR observed. Similarly in the second and third group reporting was performed by 15.4% and 8.3% of them. No one reported an ADR in the fourth group and 13.6%, 10 % and 11.8% of the responders reported in the next three groups. The last group (Providers who have served for about16-21 years in the health care) reporting was 36%.

Attitude towards ADR monitoring between each service year group has shown similarities as obtained from the result and it is described in the following table.

Table 20 Attitude towards ADR monitoring as seen in each service year group

Statements	Level of agreement			
	Strongly Agree	Agree	Disagree	Strongly Disagree
ADR Should be reported regularly				
Months of service				
01-24	80.4	15.9	0.5	-
25-49	80.8	17.3	-	-
50-74	71.4	23.8	-	-
75-99	72.7	18.2	-	-
100-124	77.4	22.6	-	-
125-149	84.6	7.7	-	-
150-199	68.8	25	-	-
200-360	69	23.8	-	-
Monitoring drug safety is important for the health care system				
Months of service				
01-24	79.6	17.3	-	-
25-49	82.7	15.4	-	-
50-74	85.7	14.3	-	-
75-99	60	30	-	-
100-124	80.6	16.1	-	-
125-149	69.2	23.1	-	-
150-199	68.8	21.9	-	-
200-360	73.8	23.8	-	-
Only ADRs of prescription drugs need to be reported				
Months of service				
01-24	5.8	16.8	49.2	23.6
25-49	3.8	23.1	50	15.4
50-74	20	20	30	30
75-99	9.1	27.3	45.5	9.1
100-124	9.7	6.5	51.6	29
125-149	-	38.5	46.2	7.7
150-199	-	29	51.6	9.7
200-360	2.4	19	47.6	16.7

Statement that ADR Should be reported regularly was strongly agreed upon more by the respondents early in the service than the ones who have stayed longer.

As for reasons of not reporting observed in each group of service year the following result was found (Table 21).

Table 21 Reasons for not reporting as observed in each group of service year

Statements	Level of agreement			
	Strongly Agree	**Agree**	**Disagree**	**Strongly Disagree**
ADRs are well documented by the time a drug is marketed				
Months of service				
01-24	7.4	21.6	50.5	13.2
25-49	13.5	26.9	40.4	13.5
50-74	4.8	19	47.6	28.6
75-99	9.1	27.3	36.4	-
100-124	3.2	22.6	48.4	9.7
125-149	7.7	23.1	46.2	-
150-199	9.4	21.9	34.4	15.6
200-360	14.3	16.7	47.6	7.1
Reporting form is too complicated				
Months of service				
01-24	4.2	15.8	52.1	11.6
25-49	1.9	17.3	51.9	9.6
50-74	5	20	35	15
75-99	-	27.3	54.5	-
100-124	9.7	19.4	35.5	9.7
125-149	-	46.2	23.1	69.2
150-199	12.5	21.9	40.6	3.1
200-360	4.8	16.7	45.2	11.9
Reporting is time consuming				

Statements	Level of agreement			
	Strongly Agree	**Agree**	**Disagree**	**Strongly Disagree**
Months of service				
01-24	5.8	17.3	54.5	12
25-49	5.8	23.1	50	11.5
50-74	9.5	28.6	52.4	4.8
75-99	-	36.4	36.4	9.1
100-124	3.2	29	48.4	6.5
125-149	-	69.2	7.7	-
150-199	6.3	18.8	50	6.3
200-360	4.8	23.8	42.9	16.7
There is no National ADR reporting system				
Months of service				
01-24	14.8	25.4	37	10.6
25-49	21.2	28.8	30.8	9.6
50-74	19	28.6	33.3	4.8
75-99	9.1	18.2	54.5	-
100-124	25.8	22.6	25.8	6.5
125-149	38.5	30.8	15.4	7.7
150-199	28.1	21.9	12.5	3.1
200-360	26.8	31.7	19.5	9.8

It was observed that respondents who have served in the healthcare delivery for about 10-12 years agreed that reporting form is too complicated (46.2%), reporting is time consuming (69.2%), there is no National ADR reporting system (69.3%) more than any other group.

9. Relationship between the respondent's patient load per day and their Knowledge attitude and practice.

Another relationship observed in this assessment was the Difference/ Similarity between the respondent's patient load per day and their Knowledge attitude and practice towards ADR monitoring and reasons for not reporting (Table 22).

Table 22 Relationship between the respondent's patient load per day and their Knowledge

Knowledge	Fully answered	Adequately answered	Inadequate answered	Incorrectly answered
Term Adverse drug reaction				
Patients/day				
10-50	12	32.1	46.7	8
51-100	22.5	45	25	5
101-200	38.5	30.8	23.1	7.7
201-300	-	50(?)	50(?)	-
Difference b/n ADR & Side effect				
Patients/day				
10-50	7.6	26.2	44.7	11.6
51-100	22.5	35	30	7.5
101-200	15.4	53.8	15.4	7.7
201-300	-	-	50(?)	50(?)
Predisposing factors to ADR				
Patients/day				
10-50	3.3	42.5	47.3	3.6
51-100	5	35	50	7.5
101-200	-	69.2	23.1	7.7
201-300	-	100(?)	-	-
Term Pharmacovigilance				
Patients/day				
10-50	6.2	37.2	10.6	10.2
51-100	15	47.5	7.5	5
101-200	15.4	38.5	15.4	-
201-300	-	100(?)	-	-

Participant's patient load per day and their practice towards ADR reporting indicates in the study that of those health providers with (10-50) patient encounters per day 13 % had reported an observed ADR and of those with (51-100) patients per day only 4.2% had reported an ADR .The rest participants with (101-200) patients in a day had a reporting experience of 20%.

As observed in the result relationship between the participant's attitude towards ADR monitoring and their daily patient load looks as follows (Table 23).

Table 23 Relationship between the participant's attitude and their daily patient load

Statements	Level of agreement			
	Strongly Agree	**Agree**	**Disagree**	**Strongly Disagree**
ADR Should be reported regularly				
Patients/day				
10-50	77.7	18.3	0.4	-
51-100	72.5	20	-	-
101-200	76.9	23.1	-	-
201-300	100(?)	-	-	-
Monitoring drug safety is important for the health care system				
Patients/day				
10-50	78.1	18.2	3.3	-
51-100	75	20	-	-
101-200	69.2	30.8	-	-
201-300	100(?)	-	-	-
Only ADRs of prescription drugs need to be reported				
Patients/day				
10-50	5.9	18.7	49.5	20.1
51-100	7.5	15	45	22.5
101-200	7.7	15.4	38.5	38.5
201-300	-	50(?)	50(?)	-

It is found that in all the selected statements the participants with different level of patient load seem to agree in a similar way.

Relationship between the participant's patient load and their reason for not reporting as observed in the result are given as follows (Table 24).

Table 24 Participant's patient load and their reason for not reporting

Statements	Level of agreement			
	Strongly Agree	Agree	Disagree	Strongly Disagree
Reporting form is too complicated				
Patients/day				
10-50	5.8	19	45.6	7.7
51-100	5	12.5	47.5	15
101-200	7.7	7.7	46.2	38.5
201-300	-	-	-	-
Reporting is time consuming				
Patients/day				
10-50	5.5	24.7	48	10.2
51-100	7.5	17.5	50	10
101-200	7.7	7.7	53.8	23.1
201-300	-	-	50(?)	50(?)
Reporting creates an additional workload				
Patients/day				
10-50	5.9	31.1	38.5	17.9
51-100	15	25	37.5	12.5
101-200	-	30.8	38.5	23.1
201-300	50(?)	-	50(?)	-

As observed, all the participants with different patient load seem to have the same level of agreement on the selected statements.

In order to see the statistical significance of the results correlation tests were performed and linear regression tests were carried out. The influence of independent variables on the dependent variables was observed .The result at 95% confidence limit and p-values showed that there is no evidence to suggest that there is a statistically significant relationship between the variables.

Some of the comments forwarded by the participants are given below-

- For good health care, reporting to responsible body is needed.
- DACA has started reporting system but continuous and updating systems are needed.
- Focal person per facility is needed to coordinate this activity.
- Reporting formats should be available at each health facility.
- Concerned bodies have to equip us with knowledge about ADR.
- There is no ADR reporting system and health professionals don't know about it.
- We don't know who to report it to.
- I don't know where and how to report.
- Every health professional should update himself by reading about ADR
- Never saw an ADR reporting form.
- Create awareness to the health professional on the system and the public.
- Strong central attention should be given to design a system.
- Sensitization of health professionals and support through DIC is needed.
- We have no format, would you please send us?.
- Recommendation from this survey should be applicable to all.
- DACA need to motivate DTC in some way.
- Create an effective communication channel between physicians and pharmacists as a whole.
- Decentralize the ADR monitoring system.
- ADR reporting should have incentives like measles and polio reporting.

- My first encounter about a concern on drug safety.
- Introducing Pharmacovigilance is important DACA has to make efforts to introduce it.
- I need feedback from the survey.
- I am lucky that I have never faced cases with ADR.
- Give training to graduating students.
- The pharmacy department should be responsible for collecting ADR reports.
- The health facility, DACA and MSH should work hard to facilitate this reporting system.
- Reporting should be obligatory.
- Pharmacists need to have access to patient record as to practice good pharmaceutical care
- Try to implement the system soon and plan it in a sustainable way.

CONCLUSION AND RECOMMENDATIONS

10. Conclusion and recommendations

The result shows that most of the providers use standard text books as an information about adverse drug reactions and some of them use their notes from university trainings .So it would be advantageous to have a curriculum in the training that could cover both the theoretical knowledge and practical training about ADR monitoring. The majority of the participants had never participated in any seminar .Most of them also think DACA should be responsible for monitoring an ADR even though some of them think MOH should be included too.

The terms adverse drug reaction and side effect are answered at least by half of the responders to a satisfactory level whereas differentiating between the two, factors predisposing to adverse drug reaction and pharmacovigilance seem to be found a little bit difficult. But it is also seen that most of the participants were not introduced about ADR monitoring in their under graduate study .This result could have been different and realistic if the questions on the knowledge of terms were not presented in the form of a structured questionnaire.

As to the encounter of an ADR, most of the participants had encounter with in their practice during the last 12 months,3 months or 2 weeks time before this survey. It can also be concluded here that from the participant's response on the drugs causing the ADR and the organ systems affected by it, the observed ADRs and or Side effects are the common and documented types of reactions. As observed in the ADR reports sent to DACA by health professionals the first two drugs indicted here are Cotrimoxazol and Nevirapine and their moderate type dermatological reactions.

The most needed result in this survey was the practice towards adverse drug reaction reporting and the answer was as expected and as observed in the in the reality (DACA has only249 reports in the 6 years since it had started its ADR monitoring system). Only 22 are reported to DACA out of the total encounters making the total reported to 5% only.

To get some insight into the preventive aspects of ADR from ocurring the participants were asked if the give advice to their patients concerning the possible occurrence of adverse effects and only (32.7%) of them answered they usually give advice. Most of them don't give advice.

As to the attitude tests most of them agree towards the fact that an ADR should be reported and it is part of the professional duty of a health professional. Most of them also agree on the idea that monitoring an ADR is important for the public, the patient and the healthcare system. But an agreement was also observed on the well known determinant of underreporting that is everywhere ; the need to be sure that an ADR is related to the drug before reporting and Only ADRs that cause persistent disability or incapacity should be reported.

Among reasons for not reporting; Problems concerning the report form, that it is not available adequately were shared upon to be true by most of the respondents. This has gone far more as to be believed that there is no ADR reporting system in the country by most of the health professionals.

It can also be concluded that the result shows that there is a difference between the two professions in answering the basic terms about adverse drug reactions and others related. Though this simple exercise are not enough to judge individuals knowledge it could also indicate the amount of attention given to the overall idea and when taken further to drug safety. This could also be the reflection of the type of undergraduate training given concerning ADR monitoring which as found in the result.

Both of the professions have similar minimum practice towards ADR reporting with only 15.1% of physicians and 12.5% of pharmacists actually reporting an ADR.

There was no observed difference on the attitude tests between the two professions but the two professions show little differences in their attitude as shown by their disagreement in the following statements. ADRs are well documented by the time a drug is marketed (Phys 56.9%, Pharm 67.1%), reporting form is too complicated (Phys 51%, Pharm 77.2%), and their agreement on reporting is time consuming (Phys 30.7%, Pharm 19.5%) and there is no national ADR reporting system(Phys 50.4%, Pharm 28.6%).

As to the different age groups response towards the knowledge attitude and practice of ADR monitoring, Knowledge and practice of reporting an ADR seems to be better in the first age groups than the next ones probably because they have graduated recently and may have the ambition not to be far from reading and also being involved in the practice. Most of the statements in the attitude test were also strongly agreed upon by the first age group.

In the reasons for not reporting there is strong agreement with an increase in amount on the statements like Reporting form is too complicated ,reporting is time consuming and there is no national ADR reporting system as we go from the first group of participants to the last.

In the relationship between knowledge and service year there seems to be a decrease in knowledge as service year increases. The fact that an ADR Should be reported regularly was strongly agreed upon more by the respondents early in the service than the ones who have stayed longer. Respondents who have served in the healthcare delivery for about 10-12 years agreed that reporting form is too complicated (46.2%) ,reporting is time consuming (69.2%), There is no National ADR reporting system(69.35) more than any other group. Participants with minimal (10-50) patient load per day had reported an observed ADR better than the others.

Possible areas of interventions and recommendations that can be forwarded from the observations could be as follows:

1. To begin with trainings given in undergraduate studies should be prepared in such away that at the end of the programme the trainee should have all the basic knowledge about concerns of drug safety and the detection, assessment, understanding and Prevention of an ADR and the national ADR monitoring system so that he/she could be equipped and be better involved during practice.

2. Successive continuous educations, seminars and consultative meetings with the health provider should be given in order to sensitize whatever knowledge and practice there is.

3. Educational programmes should be focused on altering the attitudes and reasons for not reporting obtained from this survey so that reporting is increased.

4. A system should be organized and strengthened so that health providers in the private practice should be involved in the ADR monitoring system.

5. Awareness creation on the existence and purpose of the ADR monitoring system in the country should be thoroughly done by DACA.
6. Reporting forms should be made available.

7. DTC should be strengthened in such a way that it could formulate polices regarding the management of adverse drug reactions in the facility.

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Annexes

Annexes

Annex 1 Name of hospitals included in the survey

No	Name of the Hospital
1	Adwa Hospital
2	St. Mary (Axum) Hospital
3	Midregenet (Shire) Hospital
4	Maereg (Dansha) Hospital
5	Dubti Hospital
6	Dil Chora Hospital
7	Hiwot Fana Hospital
8	Jegol Hospital
9	Harar Tb-Center Hospital
10	Karamara Hospital
11	Kebridehar Hospital
12	Mekelle Hospital
13	Quiha Hospital
14	Wukro Hospital
15	Adigrat Hospital
16	Lemlem Karl Hospital (Maichew)
17	Alamata Hospital
18	Abi Adi Hospital
19	Jimma Univ. Sp. Hospital
20	Mizan teferi Hospital
21	Bonga Hospital
22	Limugenet Hospital
23	Metu Hospital
24	Ambo Hospital
25	Shambu Hospital
26	Gindeberet Hospital
27	Fitche Hospital
28	Arba Minch Hospital
29	Chencha Hospital
30	Soddo Hospital
31	Dubbo Hospital
32	Hossana Hospital
33	Jinka Hospital
34	Tercha Hospital

No	Name of the Hospital
35	Gidole Hospital
36	Yirgalem Hospital
37	Dilla Hospital
38	Butajira Hospital
39	Durame Hospital
40	HawassaRefferalhospital
41	Debretabor Hospital
42	Gondar University Hospital
43	Debark Hospital
44	Metema Hospital
45	Tefera hailu Hospital
46	Woldia Hospital
47	Mekela gegnoch metasebia Hospital
48	Dessie referal Hospital
49	Boru meda Hospital
50	Hidar 11 Hospital
51	Debreberhan Hospital
52	Enat Hospital
53	Mehalmeda Hospital
54	Nekemte Hospital
55	Gimbi Hospital
56	Nejo Hospital
57	Aira Hospital
58	Dembi Dolo Hospital
59	Deder Hospital
60	Chiro Hospital
61	Bisidimo Hospital
62	Gelemso Hospital
63	Felegehiwot Hospital
64	Finoteselam Hospital
65	Mota Hospital
66	Debremarkos Hospital
67	Pawi Hospital
68	Bishoftu Hospital
69	Adama Hospital.
70	Metahara Hospital
71	Wonji Hospital
72	Black Line Hospital

No	Name of the Hospital
73	Ras desta Hospital
74	Zewditu Hospital
75	Ghandi Hospital
76	Yekatit 12 Hospital
77	Menelik Hospital
78	Paulos Hospital
79	Petros Hospital
80	Alert Hospital
81	Amanuel Hospital

Annex 2 Questionnaire

Identification number: _____

Questionnaire for the assessment of knowledge, attitude and practice of physicians and pharmacists in the public services towards adverse drug reaction monitoring in Ethiopia

Please answer the following questions on the space provided.

1. Level of your Health facility:

☐.01 District hospital ☐.02. Zonal hospital
☐.03. Referral hospital
☐.04. Central Referral hospital

2. Age (years): _____ Years

3. Sex: ☐. 01. Male ☐. 02. Female

4. Profession ☐. 01. Physician ☐. 02. Pharmacist

5. Level of training/ specialization

☐. 01. General practitioner ☐ . 06. Orthophaedist
☐. 02. Internist ☐ . 07. ENT specialist
☐. 03. Gynecologist ☐ . 08. Surgeon
☐. 04. Pediatrician ☐ . 09. Pharmacist bachelor
☐. 05. Dentist ☐ . 10. pharmacist Masters
☐. 11. Other, Specify----------

6. Total year of service as a physician or pharmacist:_____Years

Please answer the following questions genuinely.

7. What do you understand by the term adverse drug reaction?

_____

_____

8. What do you understand by the term side effect?

_____

_____

9. How do you differentiate adverse drug reaction from side effect?

_____

_____

10. What possible factors do you think predispose a patient to an adverse drug reaction?

_____

_____

11. What do you understand by the term pharmacovigilance?

_____

12. Have you been introduced to the ADR monitoring or pharmacovigilance in your under graduate study?

☐. 01.Yes ☐. 02. No

13. What is the average number of patient that you encounter per day?_____

14. Have you ever encountered patients with ADRs in your clinical practice in the last 12 months?

☐. 01.Yes ☐. 02. No

15. Have you ever encountered patients with ADRs in your clinical practice in the last 3 months?

☐. 01. Yes ☐. 02. No

16. Have you ever encountered patients with ADRs in your clinical practice in the last 2 weeks?

☐ . 01. Yes ☐ . 02. No

If your answer to # 14 is yes, answer question no. 17- 22. If your answer to # 14 is No, go to question 24.

17. How many patients with ADRs did you see during the last 3 months?

☐ . 01. Zero ☐ . 02. One ☐ .03. Two ☐ . 04. Three or more

☐ .05. Other, Specify _____

18. What was the drug which caused that last ADR you encountered?

_____

19. What was the organ system affected in the last ADR you encountered?

☐ .01. Dermatological system.
☐ .02. Gastrointestinal system.
☐ .03. Hepatic system.
☐ .04. Metabolic system
☐ .05. Central nervous system
☐ .06. Cardiovascular system
☐ .07. Ear &Eye
☐ .08. Pulmonary system
☐ .09. Renal system
☐ .10. Immune system
☐ .11. Others. Specify

20. How serious was that last adverse drug reaction you encountered?

☐ . 01. Fatal
☐ . 02. Severe (required hospital admission)
☐ . 03. Moderate (severe enough to discontinue the offending drug))
☐ . 04. Mild (does not necessitate discontinuing the drug)

21. Have you noted the ADR you encountered on the patient clinical record?

☐ .01.Yes ☐ . 02. No

22. Have you ever reported the adverse drug reaction?

☐ .01.Yes ☐ . 02. No

23. To whom did you report?
☐ 01. Manufacturers' ☐ 02 .DACA ☐ 03. Pharmacy department
☐ 04. DTC ☐ 05. MOH ☐ 06. Others,

24. How often do you give advice to your patients on possible adverse effects of the drugs you prescribe?
☐ . 01. Usually (for > 75% of my patients)
☐ . 02. Some times (50 % of my patients) of my patients)
☐ . 03. Rarely (<25 %)
☐ . 04. Never
☐ . 05. Other, Specify_____.

25. If you don't give regular advise, which of the following reasons describes your case best?
☐ . 01. Because you are too busy, no time
☐ . 02. Because you think that this is the primary duty of a dispenser (pharmacist/ Druggist)
☐ . 03. Because you don't give it enough attention for unknown reasons
☐ . 04. Other, Specify_____.

26. What advice do you give to your patients concerning any possible adverse drug reactions? _____
_____

27. In a female patient in child bearing age, how often do you ask history of pregnancy before prescribing any drug?
☐ . 01. Usually (for > 75% of my patients)
☐ . 02. Some times (50 % of my patients) of my patients)
☐ . 03. Rarely (<25 %)
☐ . 04. Never
☐ . 05. Other, Specify_____.

28. Who do you think is primary responsible to remind patients about side effects of the drugs they are given?
☐ . 01. Pharmacist/Druggist ☐ . 02. Treating physician
☐ . 03. Both
☐ . 04. Other, Specify_____.

29. What is your source of information about adverse drug reactions?
☐ . 01. Standard textbooks
☐ . 02. MIMS Africa
☐ . 03. British drug formulary
☐ . 04. Notes from the university training
☐ . 05. Drug sales-man
☐ . 06. Other, Specify_____.

30. Have you ever participated in any seminar which includes topic on ADR monitoring or Pharmacovigilance?
☐ 01.Yes ☐ 02. No

31. Who do you think is responsible for monitoring an ADR in Ethiopia?
☐ 01 MOH ☐ 02 DACA ☐ 03 AAU ☐ 04 EHNRI
☐ 05 EPA

Please mark on your level of agreements concerning the following statements

	Statements	Strongly agree	Agree	Disagree	Strongly disagree
32	ADR should be reported regularly				
33	Reporting is part of a duty of health professional				
34	Monitoring drug safety (Pharmacovigilance) is important for the public				
35	Monitoring drug safety (Pharmacovigilance) is important for the patient				
36	Monitoring drug safety Pharmacovigilance) is important for the health care system				
37	There is a need to be sure that an ADR is related to the drug before reporting				
38	Only ADRs of prescription drugs need to be reported				
39	Even if they are not known, non serious ADRs should not be reported				

	Statements	Strongly agree	Agree	Disagree	Strongly disagree
40	Only ADRs that cause persistent disability or incapacity should be reported				
41	Reporting an ADR is part of the patient care				
42	Monitoring ADR improve quality of patient care in health facility				
	Reasons for not reporting ADR				
43	Need to be certain of the association between the drug and ADR				
44	ADRs are well documented by the time a drug is marketed				
45	Reporting form is too complicated				
46	Reporting is time consuming				
47	Reporting ADR is breach of patient confidentiality				
48	One report makes no difference				
49	Reporting form is not available adequately				
50	There is no national ADR reporting system				
51	Reporting is not useful to the patient				
52	Reporting creates an additional workload				

53. Any additional comments? _____
_____
_____

Annex 3. Agreements for open ended questions

	Fully answered	Adequately answered	Inadequately answered	Incorrect answered
ADR ***noxious*** and ***unwanted*** reaction normal ***dose used in human***	ALL	2	1	Out of this
Side- effects minor effects(tolerable) Known Related to the pharmacological properties of the drug. normal ***dose used in human***	ALL	3	1	
Difference **See the two definitions**				
Pharmacovigilance Detection assessment understanding Prevention ADR	ALL	2	1	
Predisposing factor Patient factor Age, Wt, genetics Pregnancy, sex Previous allergy, Patient clinical condition (Liver, Renal etc.) Drug factor Interaction Nature of the drug Environmental factor Nutrition,pollution, Alcohol,cigarette	ALL	2	1	

	Fully answered	Adequately answered	Inadequately answered	Incorrect answered
Advice Known facts Discontinue drug/Don't Consult Health professional (Visit Health Facility)	ALL	2	1	

Annex 4 Instructions for data collection supervisors on how to distribute the questionnaires

Thank you very much for your willingness to coordinate and supervise the data collection of this adverse drug reaction survey

1. Please count all the questionnaires given to you and ask if you have any questions.

2. Explain to the health care provider the purpose and importance of the data collection and that their utmost cooperation will have significant impact towards the success of the survey and the overall adverse drug reaction monitoring system of the country.

3. Try as much as possible to give the questionnaire and make the healthcare provider fill it while you are sitting /standing with him/her or with in the next 10-20 minutes so as to avoid delay and increase the response rate as much as possible.

4. The first step should be to make sure that the hospital medical director gets the first questionnaire (This is a must!) Whether he is a specialist or a general practitioner

5. For the specialists/general practitioners, if the number of questionnaires given to you matches that of the number of specialists general practitioners in the setting give each questionnaire to each person .If the two numbers don't correspond select the person to give by lottery method.

6. Give one questionnaire to the pharmacy head if he is a pharmacist. If the head is not a pharmacist but his working partner is, give the questionnaire to the partner pharmacist.

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