Spontaneous Adverse Drug Reaction Reporting and the Obstacle in Amhara Region Referral Hospitals, Ethiopia

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Summary

In Ethiopia, to our knowledge, there is no study that shows the practice of ADR reporting and measuring the pitfall to report. The aim of the study is to assess the practice of ADR reporting and its obstacles to report in Gondar University teaching and Bahirdar Felegehiwot referral hospitals. Cross sectional study with semi structured questioner was used. Health professionals, who had encountered patients developing adverse reaction, accounted 60.3% (n=141). The study showed that about 52.9% (n=68) of health professional had encountered severe ADR, yet not reported them to anybody. Healthcare providers reported severe ADR for the ward physician (32.4%, n=68), pharmacy department of the respective hospitals (8.8%, n=68) and to National Drug Administration and Control Authority (DACA) (7.4%, n=68). The major obstacles to report were: (i) lack of information (97.2%, n=36); (ii) no training (83.3%, n=36); (iii) no knowledge of the program (77.8%, n=36); and (iv) no form, phone or fax number for reporting (66.7%, n=36). Few healthcare professionals, who encountered patients with severe ADR, reported to the national authority. Spontaneous ADR reporting has got many obstacles. The regulatory authority needs to advocate the role of ADR report and further training on ADR reporting for healthcare professionals is required.

Key word: Spontaneous report, Amhara region, drug

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Introduction

Decisions on treatment are guided, not only by the potential for benefit, but also by the nature and severity of ADR (1). Any drug may produce unwanted or unexpected adverse reactions (2). Adverse drug reaction is a response to a drug which is noxious, unintended and occurs at doses normally used for prophylaxis, diagnosis, or therapy (3, 4). Medication-related problems are the third leading cause of death after heart disease and cancer in the United States (4). Adverse drug reactions have been shown to result in a significant number of hospital admissions (5). The Quality in Australian Health Care Study estimated that 43% of adverse drug events were potentially preventable; however, the rise in ADR is not inevitable (6).

Adverse drug reaction reporting and monitoring system is important to collect, collate and analyze data as a means of establishing new knowledge and generating early signals of possible drug complications not reported through clinical trails. Output from such adverse drug reaction-reporting systems compliments the information appearing in the published literature (7). Adverse experience reports have been a vital aspect of postmarketing surveillance for all drug products (8) as Post-market assessments rely on information received through adverse reaction reports.

The proportion of cases reported may vary for a number of reasons. In addition to a lack of training in recognizing ADR, these factors include i) a lack of awareness of the existence and benefits of a reporting program, ii) the time and effort required to complete the reports, which competes with other work of a busy health professional, and iii) a reluctance to report by physicians who may view ADR reporting as opening their prescribing practices to outside scrutiny (9).

In Ethiopia, to our knowledge, there is no study that shows the practice of ADR reporting by health professionals and measuring the pitfall to report. The current study is, therefore, aimed to assess the picture of ADR reporting system and to pin point the problems associated with reporting in the stated area.

Methods

The study areas are Amhara region referral hospitals. In this region there are two referral hospitals- namely Gondar University Teaching Hospital and Felegehiwot Hospital. Gondar University teaching hospital is the attachment area of different health profession students-medical students, pharmacy students, nursing students, midwifery nursing students and other paramedic students. In this teaching hospital there are 51 physicians, 85 nurses, and 10 pharmacy professionals (druggist and pharmacist) who have direct patient relation. Felegehiwot hospital is found in Bahirdar, the capital city of Amhara region. Data from this hospital showed that 22 physicians, 52 nurses and 12 pharmacy professionals are involved in the health service of the hospital. . Only referral hospitals were selected for the study because they had fair distribution of health professionals-physicians, pharmacy professionals and nurses.

Cross sectional study using self-administered questionnaires with open and close end questions was used to collect data in May 2007. The questionnaire was pretested in field other than the study area. The following questions were forwarded to the respondents. Did you encounter patients developing adverse reaction to drugs; was it severe; did you report these ADR? To which organization or departments did you report the ADR Ministry of Health, Drug Administration and Control Authority, Regional Health Bureau, Pharmacy department of hospital or other? If you fail to report what are your obstacles not to report ADR?

Cross sectional study using self-administered questionnaires with open and close end questions was used to collect data in May 2007. The questionnaire was pretested in field other than the study area.

The study subject includes those physicians, nurses and pharmacy professionals working in Felegehiwot Referral Hospital and University of Gondar Referral Teaching Hospitals.

All physicians, nurses and pharmacy professionals were included in the study. These sum accounts to 73 physicians, 137 nurses and 22 pharmacy professionals. Data was handled using Epi info 6.04 and a simple descriptive statistics was used to present the results in the form of tables.

Permission was requested from Gondar University Hospital and Felegehiwot Referral Hospital director. The study subjects were also informed that the information collected would be anonymous; and participation would be totally voluntary.

Results

From the hospitals 141 usable questionnaires (response rate 60.8%) were received. Study showed that youngsters covered major proportion of the referral hospitals in Amhara region and the male to female ratio was 1.31:1. Nurses occupied a great portion in the hospitals followed by physicians and pharmacy professionals. The demographic data are shown in Table 1.

Health professionals, who ever encountered patients developing adverse reaction accounted 60.3%, out of this 80% (n=85) encountered patients with severe type of ADR (Table 2).

Of the total 141 health professionals 39.7 % did not encountered patients with ADR and the major reason they gave was failurity of patients to report ADR complains to health professionals (67.9%, n=56), followed by failure to diagnose ADR (26.8%, N=56) and respondents thought that drugs are safe (8.9%, n=56) (Table 2).

Staff tried to report severe type of ADR to various concerned body. The report was done highly for the ward physician (32.4%, n=68), next to this for pharmacy department of the respective hospitals (8.8%, n=68) and to Drug Administration and Control Authority (7.4%, n=68). They also reported to Regional Health Bureau (1.5%, n=68) and Kenya Medical Research Institute (1.5%, n=68) (Table 2).

Our result revealed that the health professionals out of the suggested method of ADR reporting did the major portion of the report, which is not recommended by the national authority (DACA).

Table 1 Demography of respondents on practice of adverse drug reaction reporting and its barrier in Amhara region referral hospitals; May 2007 N= 141

Demography		**No**	**Percentage**
Age	Below 25 years	56	39.72
	26-30 years	50	35.46
	31-40 years	26	18.44
	41-55 years	9	6.38
Sex	Male	80	56.74
	Female	61	43.26
Profession	Nurse	83	58.86
	Pharmacy professional	20	14.18
	Physician	38	26.95
Year of practice	0-5 years	86	60.99
	6-10 years	24	17.02
	11-15 years	12	8.51
	16-25 years	19	13.47

Table 2 Practice of ADR reporting in Amhara region referral hospitals; May 2007; n=141

Respondents ever encountered patients with ADR (n=141)		
	Yes	85 (60.3%)
	No	56 (39.7%)
Respondents ever encountered severe type of ADR (n=85)		
	Yes	68 (80%)
	No	17 (20%)
Respondents report ADR (n=68)		
	Yes	32 (47.1%)
	No	36 (52.9%)
ADR reported to (n=68)		
	Drug Administration & Control Authority	5 (7.4%)
	Pharmacy department of hospital	6 (8.8%)
	Regional Health Bureau	1 (1.5%)
	Ward Physician	22 (32.4%)
	Kenyan Medical Research Institute	1 (1.5%)
Reason why did not ever encountered patients with ADR (n=56)		
	Thinking that drugs are safe	5 (8.9%)
	Failure to diagnose ADR	15 (26.8%)
	Patients fail to revisit/report respondents for ADR complains	38 (67.9%)

Table 2 also showed that about 52.9% (n=85) of respondents did not ever try to report the suspected severe ADR. The major barriers to report were: (i) lack of information on how to report (97.2%, n=36); (ii) no training in recognizing/reporting ADR (83.3%, n=36); (iii) No knowledge of the program (77.8%, n=36); (iv) no form, phone or fax number for reporting (66.7%, n=36); (v) concern about legal liability (63.9%, n=36); and (vi) heavy work load (50%, n=36) (Table 3).

Discussion

Any suspected ADR is reported to responsible agencies within a country for instance in Ethiopia it is DACA. From the present study, only 47.1% of the individuals, who ever encountered patients with ADR, reported the ADR to various sectors- within and outside their working organizations. For the sake of taking action and further investigation, Ethiopian DACA is the executive body for collection of the countries ADR reports.

It is believed that adverse reaction reports received by responsible organization in different countries represent only a small percentage of adverse reactions that have occurred.[9] Some international studies estimate reporting rates to be as low as 1 - 10 % (10, 11, 12). The present study revealed that (7.4%, n=68) of individuals, who ever encountered patients with severe ADR, reported to DACA. Others report to ward physician (32.4%, n=68), pharmacy department of hospital (8.8%, n=68), regional health bureau (1.5%, n=68) and Kenyan Medical Research Institute (1.5%, n=68). These reports might only be vital for the patients, whom the health professionals encountered. But such type of report might not be important for further investigation by drug regulatory body, and this information may be obscured for other professionals who did not encountered such a condition.

The present study also showed that about 52.9% (n=68) of health professional had encountered severe ADRs, yet not reported them to anybody. This result is inline with a study in china, which reaches to 62.1%. And the major barriers to report in the current study were: (i) lack of information on how to report (97.2%, n=36); (ii) no training in recognizing/reporting ADR (83.3%, n=36); (iii) No knowledge of the program (77.8%, n=36); (iv) no form, phone or fax number for reporting (66.7%, n=36); (v) concern about legal liability (63.9%, n=36); and (vi) heavy work load (50%, n=36). A study in china revealed the major reasons for not reporting including: ignorant about the requirement and the reporting process of ADR (71.4%); address of the reporting agency and Forms unavailable 67.9%, 60.4%, respectively; unaware of the existence of a national ADR reporting system (52.2%); needless to report as the ADR being too well known (44.1%) (13).

The effectiveness of the drug safety monitoring system and signal detection is compromised by low reporting rates: under-reporting may cause an underestimation of a safety problem (9). Lack of reporting of life-threatening ADR can compromise population safety. There is a need to increase awareness of ADR reporting program (14).

Limitations to this study

The response rate was low. This might be due to the time of the collection (i.e. a cross-sectional study, which might not be suitable to include staff in annual leave, on-job training and others). We also get non-responders that felt enthusiastic about ADR reporting. If the non-responders were more, our result may overestimate the percent not to report ADR and barriers to reporting.

Table 3 Obstacles of spontaneous adverse drug reaction (ADR) reporting in Amhara region referral hospitals; May 2007; N= 36

Barriers		Frequency			
		Nurse	Physician	Pharmacy professional	Total (n=36) n (%)
Perception	Heavy workload	8	10	-	18 (50)
	Apathy	7	3	2	12 (33.3)
	Considered to be an 'additional' duty	5	3	-	8 (22.2)
	Negative attitude toward form-filling	1	-	1	2 (5.6)
Convenience and awareness	No form, phone or fax number for reporting	12	11	1	24 (66.7)
	Lack of information on how to report	20	11	3	34 (97.2)
	No knowledge of the program	16	11	1	28 (77.8)
Confidence	Lack of confidence in recognizing ADRs	-	-	2	2 (5.6)
	Tendency to report only *proven* ADRs	3	2	1	6 (16.7)
	No training in recognizing or reporting ADRs	17	11	2	30 (83.3)
	Fear of 'appearing foolish' for suggesting an event is a suspected ADRs	3	3	1	7 (19.4)
Motivation	Inadequate feedback	7	9	-	16 (44.4)
	Misconceptions about the purpose and usefulness of reporting	14	2	-	16 (44.4)
	No financial incentive	9	5	1	15 (41.7)
Legal	Concern about legal liability	19	2	2	23 (63.9)
	Fear of breaching patient confidentiality	4	3	1	8 (22.2)
Personal	Ambition to collect and publish a personal series of cases	6	3	1	10 (27.8)

NB. One respondent selects more than one obstacle

Conclusions

Health professionals tried to report severe type of ADR to various concerned body, which is not suggested in the national ADR reporting guideline. Only 7.4% of health professionals who encountered severe ADR reported to the national authority. i.e. the major portion of the report was done by the health professionals out of the suggested method of ADR reporting, which is not recommended by DACA. The present study also showed that about 52.9% (n=68) of health professional had encountered severe ADRs, yet not reported them to anybody. The major obstacles to report in the current study were: (i) lack of information on how to report; (ii) no training in recognizing/reporting ADR; (iii) No knowledge of the program; (iv) no form, phone or fax number for reporting; (v) concern about legal liability; and (vi) heavy work load. The piece of work recommends the regulatory authority to advocate the role of ADR report and further training on ADR reporting for healthcare professionals is required.

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