

EVALUATION OF KNOWLEDGE AND ATTITUDE OF THE FUTURE PRESCRIBERS ABOUT PHARMACOVIGILANCE: EXPERIENCE OF FOUR MEDICAL COLLEGES OF CHITTAGONG

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Summary

The study was designed to evaluate knowledge, attitude and practice of future prescribers of four Medical Colleges of Chittagong, Bangladesh about Pharmacovigilance. The specific aim was to identify the reasons for underreporting and to determine the measure that could be adopted to increase reporting of ADRs (Adverse Drug Reactions). A cross-sectional, multicenter Questionnaire survey was conducted among the final year medical students and intern doctors to assess the knowledge and attitude regarding the importance of ADRs reporting and Pharmacovigilance of Chittagong Medical College (CMC) Chattagram Maa-O-Shishu Hospital Medical College (CMOSHMC) Cox's Bazar Medical College (CoxMC) Southern Medical College (SMC) during July, 2015. The questionnaires were provided to five hundred and eight participants of which two twenty four final year students and one hundred fifty six intern of four medical colleges responded completely to the survey. 65% responders were aware of the term Pharmacovigilance. Only one third of respondent correctly answer the location of international (35% intern and 25% final year) and national ADRs monitoring centre (24% intern and 35% final year). Almost all

participants (100%) had no training on ADRs reporting and did not see any ADRs reporting form in their study period. Majority (96%) of the respondent felt that study related to antimicrobials should be thought in details to all health care students during their undergraduate training period. The major cause of under reporting in their views is insufficient knowledge about how to report (89%) and difficult to diagnosis ADRs (50%). The study revealed a deficiency of knowledge, attitude and practice about ADR reporting and Pharmacovigilance. In order to have a successful Pharmacovigilance program, future prescribers need education, training and motivation about reporting of ADRs and Pharmacovigilance with an ultimate direction towards ensuring patient safety. Best intervention will be made by training of our future prescribers during their study period.

Key words

Pharmacovigilance; ADRs; Allergic reactions; Iatrogenic disease; Fatality.

Introduction

Adverse Drug Reactions (ADRs) are an important source of iatrogenic disease that result in different consequences ranging from allergic reactions to fatality, hospitalization for longer duration and increased treatment costs [1-10]. Thomas et al estimated that 9.7 percent of the ADEs result into permanent disability [11]. ADRs have become public health issue after the thalidomide catastrophe, which caused more than 10000 cases of phocomelia [12]. After that, countries started to establish their national Pharmacovigilance system for reporting ADRs. Later on, World Health Organization (WHO) established their Collaborating Centre in Uppsala University and named that as Uppsala Monitoring Centre [13]. Medicine enters into the market after clinical trial, which usually fail to identify rare ADRs because of small number of subjects included in the study. Striker and Psaty mentioned that very little is known about the safety of a medicine at the time of marketing, while much more might be known about efficacy [14].

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In general, prevalence rate of ADRs was 3.22%, 4.78% and 5.64% for England, Germany and USA respectively [15]. In Europe, approximately 3.6% of all hospital admissions are caused by ADRs and up to 10% of patients experience ADRs during their stay in hospitals. Besides, the percentage of hospitalizations that end in fatal ADRs is 0.5% [16]. Gyllensten et al conclude that approximately 10% of the total direct healthcare costs are caused by adverse drug events of which nearly half of them occurred in outpatient settings [17]. In the US, 106,000 hospital patients died from ADRs in 1994, which was fourth leading cause of death after heart disease, cancer and stroke [18]. Till today, spontaneous reporting is the most common system of detecting ADRs. Many medicines withdrawn from market due to safety concern identified during post marketing surveillance [19].

In Bangladesh, World Health Organization supported establishment of a cell in the Directorate General of Drug Administration (DGDA) in 1996. Later in 1997, a 10 member ADRs Advisory Committee (ADRAC) was formed by the Ministry of Health and Family Welfare. The ADRAC was assigned to evaluate, analyze and make recommendation for solving problems of medicinal hazards due to ADRs. Bangladesh has submitted their first batch of adverse reaction case reports to VigiBase through VigiFlow in December 2014 and became the 120th member country of WHO pharmacovigilance program [13].

From Bangladesh, very few reports of ADR were published in scientific journals. Among those, Islam and Rahman reported a case of fatal toxic epidermal necrolysis due to levofloxacin, Nahar et al studied on the adverse effects of two antitubercular drug regimen and another study conducted in Khulna Medical College revealed that ADRs caused 25% fatality [20-22]. Study at Dhaka Medical College conducted in Medicine and Skin Outpatient Department revealed incidence of ADRs as 11.9% [23]. Uzzal stated that in last 20 years, the DGDA authorities received only 50 ADRs reports, among which only 10 reports were completed properly [24].

Current voluntary reporting schemes are invariably accompanied by under-reporting of adverse-reaction, which can delay between marketing and detection of an adverse reaction. Almost 7 million patients were exposed to Fenfluramine before the association with valvular heart disease was adequately convincing to the regulators for its withdrawal from the market [25].

Inadequate knowledge and reluctant attitude of the doctors have been found to be associated with under-reporting [26,27,28]. There is no formal targeted teaching and training about detection and reporting of ADRs in the undergraduate curriculum. Situation become worse as there is no periodic reinforcement of ADRs monitoring in internship and postgraduate studies [28]. Undergraduate Curriculum of Bangladesh contains ADRs reporting and how to communicate risk-benefit issues to patients [29]. However, the mentioned contents are not adequately taught and evaluated during undergraduate study and examinations [30-31].

Considering the above described scenario, the present study was conducted to evaluate knowledge and attitude towards reporting of ADRs and Pharmacovigilance of the future prescribers of four Medical college Hospitals of Chittagong, Bangladesh. The study attempted to identify the reasons for underreporting and to determine the measures that could be adopted to increase reporting.

Materials and methods

A cross-sectional, multicenter questionnaire survey was conducted among the final year medical students and intern doctors of Chittagong Medical College (CMC) Chattagram Maa-O-Shishu Hospital Medical College (CMOSHMC) Southern Medical College (SMC) and Cox's Bazar Medical College (CoxMC) during July, 2015. The questionnaire was designed to assess the baseline knowledge about Pharmacovigilance with special emphasis on the importance of ADRs reporting. The questionnaire was provided to all students who attended the particular class of the studied medical colleges. Later on, the completed questionnaires were collected in the Department of Pharmacology & Therapeutics of the respective Medical Colleges.

Results

The questionnaires were provided to a total of five hundred and eight participants of which two eighty eight were final year MBBS students and two twenty were intern doctors of two government and two private medical colleges. Among them, two twenty four (224/288) final year students and one hundred fifty six (156/220) intern doctors of four medical colleges responded completely to the survey. Response rate by institutions in case of final year students were CMC (83%), CMOSHMC (69%), SMC (70%) and CoxMC (72%) respectively, which were 65%, 86%, 62% and 76% in case of intern doctors.

Table 1 showed details about Final year students and intern doctors' knowledge about pharmacovigilance. 60% of the final year students and 73% of interns were aware of the term 'Pharmacovigilance' in four Medical Colleges. 20% students and 25% intern can define Pharmacovigilance. For the question regarding regulatory body only 25% final year and 35% intern correctly answer the location of international ADRs monitoring centre. 35% students and 24% intern are aware about the location of regulatory body responsible for ADRs monitoring in Bangladesh. All of the respondent (could not answer correctly the WHO database for reporting ADRs. Significantly lowest percentage of students know how to report (4 % final year students and 3% intern doctors) where to report (2% final year students and 3% intern doctors) and what type of ADRs should be reported (43% final year students and 56% intern).

Attitude of the final year MBBS medical students and intern doctors towards reporting of ADRs are showed in table II. 94% respondents (90 % final year students and 94% intern doctors) of Four medical colleges strongly agreed reporting of ADRs are necessary and reporting is a professional obligation (76 % final year students and 73% intern doctors)).

65% Medical students and 75% intern think that major cause of under reporting in their views is insufficient knowledge about how to report (89%) and difficult to diagnosis ADRs (93%). reporting system of reporting is too methodological (92%), Doctors are too busy to send reports (88%).

Final year medical students training and practice towards ADRs Reporting showed in table III 45% students and 50% intern mentioned that they learned Pharmacovigilance related topics during their study period. Question regarding training on ADRs reporting, they did not take any training on ADRs reporting in their study period. 95% students and 97% intern think that Pharmacovigilance should be thought in details to all health care students during the study period. 92% respondent mentioned that they have never seen ADRs reporting form. Majority of students pointed out that to improve ADRs reporting IT have significant role (75% students and 85% intern).

Table I: Final year Medical Students' knowledge About Pharmacovigilance

Knowledge	All n=380	Final year Students n=224	Intern doctors n=156
Awareness on Pharmacovigilance	65% (247/380)	60% (133/224)	73% (114/156)
Location of international center for ADRs monitoring center	29% (110/380)	25% (56/224)	35% (54/156)
Regulatory body responsible for ADRs monitoring in Bangladesh.	30% (115/380)	35% (78/224)	24% (37/156)
WHO online database of ADRs Reporting	0% (0/380)	0% (0/224)	0% (0/156)
Know about reporting procedure and reporting form	4% (14/380)	4% (9/224)	3% (5/156)
Know about what type of ADRs should be reported	48% (183/380)	43% (96/224)	56% (87/156)
Who is responsible for report	70% (226/380)	68% (152/224)	73% (114/156)
Method commonly used to report	27% (103/380)	24% (53/224)	32% (50/156)

Table II: Attitude of the final year MBBS medical students and intern towards reporting of ADRs

Attitude	All n=380	Final year Students n=224	Intern doctors n=156
System of reporting is too methodological	92% (349/380)	90% (201/224)	94% (148/156)
Report form not available	76% (288/380)	73% (163/224)	80% (125/156)
ADRs reporting is professional obligation	74% (281/380)	76% (167/224)	73% (114/156)
Doctors feel that would be exposed to legal	64% (243/380)	65% (146/224)	62% (97/156)
Only safe drug are marketed	60% (228/380)	60% (134/224)	57% (90/156)

Unsure how to report an ADRs	89% (338/380)	85% (192/224)	93% (146/156)
Difficult to decide whether ADRs has occurred or not	50% (190/380)	47% (106/224)	53% (84/156)
Insufficient clinical knowledge	82% (313/380)	65% (145/224)	75% (168/156)
Too busy to send an report an ADRs test	88% (334/380)	85% (192/224)	91% (142/156)
Lack of awareness to report of ADRs	48% (182/380)	40% (90/224)	58% (92/156)

Table III: Undergraduate training and practice of ADRs Reporting

Undergraduate training and practice of ADRs reporting	All n=380	Final year Students n=224	Intern doctors n=156
Have you ever learnt about Pharmacovigilance related topics during your study period?	47% (178/380)	45% (100/224)	50% (78/156)
Have you ever trained on how to report ADRs?	0% (0/380)	0% (0/224)	0% (0/156)
Have you ever seen the ADRs reporting form?	8% (30/380)	8% (18/224)	7% (12/156)
Do you think that Pharmacovigilance should be thought in details to all health care students during the study period?	96% (363/380)	95% (212/224)	97% (151/156)
Do you think role of IT in facilitating ADRs reporting in your country	79% (300/380)	75% (168/224)	85% (132/156)

Discussion

In developed countries, ADRs reporting and monitoring has become a routine clinical practice concerning patient's safety. Never the less, in Bangladesh, the physicians, other health professionals and patients/consumers are not adequately aware about ADRs. There has been no multicenter study conducted in Bangladesh that evaluated knowledge, attitude and practice of medical students about reporting of ADRs. The present study revealed that medical students and intern doctors share similar perceptions toward reporting of ADRs and Pharmacovigilance across Medical Colleges.

The present study showed that, 60% of final year and 73% of intern aware of the term Pharmacovigilance in four Medical Colleges. 20% students and 25% intern can define Pharmacovigilance. For the question regarding regulatory body only 25% final year and 35% intern correctly answer the location of international ADRs monitoring centre. 35% students and 24% intern doctors are aware about the location of regulatory body responsible for ADRs monitoring in Bangladesh. Similar result showed conducted by Meher et al in south india revealed that 30% final year students can define Pharmacovigilance and 67% students know about International Pharmacovigilance Monitoring Centre [32].

A study conducted among medicine and pharmacy students, 91.7% students answered wrongly to the WHO database for reporting ADRs [33]. Similar result showed in the present study and all of the respondents (100%) could not answer correctly to the WHO database for reporting of ADRs.

Regarding reporting of ADRs, an attitudinal survey conducted among Dutch physician revealed that 72% doctors were uncertain whether the ADRs was caused by medicine, did not know how to report (22%), 18% were not aware about necessity to report and 36% mentioned the reporting system as too methodological [34]. Similar result showed in the present study, though in this study very low proportion of students and intern doctors know how to report (4% and 3%), where to report (2% and 3%) and what type of ADRs should be reported (43% and 56%). Participants mentioned system of reporting as too methodological (92%) and the doctors are too busy to send reports (88%).

Only 5.3% of doctors ever reported ADRs, a survey result conducted in Malaysia [35]. Similar result was found in other countries as well [33,36-37]. In our study, all students and intern doctors mentioned that they did not take any training on ADRs reporting in their study period and have not seen any reporting form. About 23 % of students strongly agree that only serious and unexpected ADRs must be reported. This finding is alike to that of previous survey involving healthcare professionals [38].

Major reason for under reporting is lack of knowledge about how to report (89%) and difficult to diagnosis ADRs (50%) which was reflected in our study. This finding is similar with a survey conducted in UAE (71%) [33]. Continuous Medical Education (CME), undergraduate practical, workshop on pharmacovigilance might be effective to overcome the situation [37-38].

Pharmacology Department of Medical Colleges should organize structured training program for the medical students about importance, detection, analysis, reporting and follow-up of adverse drug reactions [38-39]. In our study 90% students and 85% intern strongly recommended detail teaching and training needed to all health care professionals during their undergraduate study period. In some countries like UK, France, Sweden, the ADRs reporting rates are much higher ranging from 40 to 70% [34]. The main reason for this may be that in these countries ADRs monitoring system is well established and ADRs reporting is mandatory [39-40].

In our study, final year MBBS students (76%) and intern (73%) believed that ADRs reporting is a professional obligation which is alike with earlier studies [33,39-43]. Practice of ADRs reporting can be improved in future by generating awareness among the future prescribers on the importance of reporting, the reporting system and their obligation to report ADRs. Knowledge on ADRs reporting was not given much consideration during doctors training as majority of doctors interviewed had advocated for the need of training on ADRs reporting [44-47]. A latest program Med Watch Learn, Med Watch training program has been released by USFDA (United State Food and Drug Administration) which is intended to teach doctors, students, and patients to learn how to complete reporting form online to report any adverse drug reaction, medication error or product problem [48].

Most of the respondents (81% final year and 91% intern) opined that pharmacovigilance centre should be established in all the hospitals and reporting of ADRs should be compulsory. Doctors are wholehearted to learn and practice Pharmacovigilance if proper training given to them revealed in this study. This is the turn of the Pharmacologists of Bangladesh, who need to take initiative to incorporate this important issue into mainstream medical education in order to convert the existing education system to a transformational one [49-50].

The present study revealed the extreme need of immediate incorporation of teaching-learning activities directed towards generating awareness among future prescriber about detection and reporting of ADRs at undergraduate medical curricula, which may further be strengthened during internship period. Appropriate combination of these interventions could form a concrete basis for doctors to ensure Pharmacovigilance in Bangladesh.

Conclusions

Adverse drug reactions are discussed or mentioned in every text books of Pharmacology, though the approach is inappropriate to understand the importance of Pharmacovigilance as well as its relevance with safe use of medicine. By creating awareness and conducting training to our future prescribers about Pharmacovigilance at undergraduate medical course and providing continuous medical education to the prescribers may improve the existing status of underreporting of ADRs.

Disclosure

All the authors declared no competing interest.

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