Pharmacovigilance Practice: The Current Challenges and the Gaps in the Medical Students' Curriculum

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ABSTRACT

Adverse drug reaction is defined by the WHO as a response to a medicinal product which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, therapy of disease or for the modification of physiologic function. The term Pharmacovigilance was coined by a French group of pharmacologist and toxicologist in the 1970s, which implied strategy promoting detection and assessment of side effects and adverse drug reaction. The first endeavor made to resolve the problem of drug safety was announced in 1961 promptly after the disaster caused by thalidomide treatment in pregnant women. The World Health Organization center for adverse drug reaction monitoring is known as the Uppsala Monitoring Centre. It is an International establishment with the responsibility of coordinating the program based on an agreement made in 1978. The major challenges of Pharmacovigilance program are underreporting, and the best solution is to resolve the problem from the grassroots. This claim could be justified as the outcome of previous knowledge, attitude and practice studies on adverse drug reactions and Pharmacovigilance among medical students was inadequate. Also, the curriculum of teaching and training of medical students was insufficient. The aim of this review was to discuss the current challenges facing adverse drug reactions reporting system and to highlight the gap left in the training of medical students.

INTRODUCTION

Medical students as the future healthcare authorities need to be professionally trained to be a rational and a holistic doctor (Islam *et al.,* 2014a; Salam *et al.* 2013a; Salam *et al.* 2013b; Salam *et al.* 2013c). Globally undergraduate medical education should be directed towards the rational use of medicine and medical graduates should able to prescribe safe and effective medicine. A medical doctor should also capable of recognizing, managing and report the adverse drug reactions (ADRs) and drug interactions. ADRs is an important health care threat in both developing and developing countries and eventually increases more morbidity and mortality (Khan *et al.,* 2013; Hanlon *et al.,* 2006; Pirmohamed *et al.,* 2004; Lazarou *et al.,* 1998). Irrational use of medicine primarily uphold more ADRs and causing more infirmity than the disease itself (Zhang *et al.,* 2001; Islam *et al.,* 2014b; Abubakar *et al.,* 2014; Salam *et al.,* 2013d). More

information on this objective will be generated by carrying out more studies with respect to medical students' knowledge, attitude and practice (KAP) on ADRs and Pharmacovigilance (PV) (Sivadasan *et al.,* 2014; Upadhyaya *et al.,* 2012). In Nigeria, many deaths occurred due to ADRs and continued for some period of the absence of alerting the regulatory authorities that could have prevented more damages (Awodele *et al.* 2011). ADRs have continued to cause injury to many patients, leading to an increased hospital admission ranging from 0.3% to 11% (Bisht *et al.,* 2014; WHO, 2002). It has become necessary to monitor ADRs as early as possible in order to save patients, to detect ADRs before they clinically manifest, and to ensure the safe and efficient use of medications (Sivadasan *et al.,* 2014). It was clearly evident that the main shortcoming of ADRs surveillance is a lack of awareness and poor practice among health professionals (Sivadasan *et al.,* 2014; Elkalmi *et al.,* 2011; Palaian *et al.,* 2011; Aziz *et al.,* 2007). A study conducted on ADRs surveillance among the healthcare workers in a teaching hospital in northern India revealed that more than 60% doctors did not know how and where to report the ADRs (Hardeep *et al.,* 2013). Medical students training on ADRs reporting should begin from undergraduate, and strengthened during internships (Sivadasan *et al.,* 2014; Hardeep *et al.,* 2013).

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Another research revealed that pharmacy students are more familiar than medical students with respect to ADRs reporting (Elkalmi *et al.*, 2011). This happened because pharmacy students were taught more about PV in their curriculum. Therefore, this has prompted the need for similar curriculum for medical students (Sivadasan *et al.*, 2014; UMC, 2013; Rajesh *et al.*, 2011; Elkalmi *et al.*, 2011).

Current Global Challenges

The existing educational and training curriculum on ADRs and PV used for medicine and pharmacy students was found to be insufficient in Malaysia and Nigeria (Lai *et al.*, 2015; Sivadasan *et al.*, 2014; Health System, 2012; Sim, 2004; Elkalmi *et al.*, 2011). This justifies the need for collaborative efforts to upgrade education and training on ADRs reporting within medical and pharmacy schools (Lai *et al.*, 2015; Sivadasan *et al.*, 2014; Bisht *et al.*, 2014; Kiran *et al.*, 2014; Vora *et al.*, 2012; Elkalmi *et al.*, 2011). Other studies concluded that reporting of ADRs is yet to become a routine practice among the population of health care workers studied in Pakistan, India, and Nigeria (Iffat *et al.*, 2014; Bisht *et al.*, 2014; Ogundele *et al.*, 2012; Vora *et al.*, 2012). Spontaneous reporting scheme using the yellow card system was found to be less among healthcare workers in Kano, Nigeria (Fadare *et al.*, 2011). Multiple studies indicated that participation of nurses in PV program is less, and incorporating them into the program will help tremendously in upgrading reporting of ADRs (Hanafi *et al.*, 2012; Palaian *et al.*, 2011). Imparting knowledge and awareness of PV among pharmacy and medical students through continuous educational intervention would update their knowledge and practice (Sivadasan *et al.*, 2014; Vora *et al.*, 2012; Elkalmi *et al.*, 2011). Convincingly, based on the previous research conducted, it was established that there are many gaps left with respect to educating and training of medical students on ADRs and PV which include teaching in class and practical demonstration during clinical ward round as well as regular seminars and workshops on how to report (Raza and Jamal, 2015; Arici *et al.*, 2015; Ponmari *et al.*, 2015; Bagewadi *et al.*, 2015; Ismail *et al.*, 2015; Khan *et al.*, 2015; Iffat *et al.*, 2014). Furthermore, there is also need for visitation of PV center in order to update their knowledge and become familiar with the system, also there is a need for an improvement in their curriculum of teaching (Raza and Jamal, 2015; Arici *et al.*, 2015; Ponmari *et al.*, 2015; Bagewadi *et al.*, 2015; Ismail *et al.*, 2015; Khan *et al.*, 2015; Iffat *et al.*, 2014).

Medical Students' Curriculum of Malaysia and Nigeria

The sample of medical students' pharmacology curriculum for Malaysia was obtained (Sim, 2004) and that of Nigeria (Health System, 2012). The Nigerian medical students' curriculum indicated that only 20 weeks were allocated to the teaching of Integrated Pathology and Pharmacology, meaning that only 10 weeks belongs to pharmacology out of 6 years duration which is not enough considering the comprehensive coverage of the course (Health System, 2012). Similarly, in Malaysia, the

majority of pharmacology lectures was delivered during preclinical years. Subsequently, during the clinical years, only 6 hours lecture given in Universiti Malaya, 0 hours lectures in Universiti Sains Malaysia and 0 hours lectures in Universiti Putra Malaysia (Sim, 2004). It was clear that during the preclinical years a lot of background courses that will boost the understanding of pharmacology are yet to be studied (Sim, 2004). Also, some percentage of pharmacological knowledge is likely to escape because of the more than two-year interval between the last lecture and beginning of practice after graduation (Sim, 2004). In a recent study, "medical students from both public and private universities in Malaysia felt that their medical programs did not provide sufficient teaching and learning of prescribing skills" (Lai *et al.*, 2015). "These findings indicate an insufficient emphasis on clinical pharmacology and prescribing skills training in the medical curriculum" (Lai *et al.*, 2015). The samples of the medical students' curriculum are shown in Table 1.

Table 1: Pharmacology curriculum of Malaysian medical students, 2003/2004 (Sim, 2004).

Medical school	UM	USM	UPM
Type of degree	**MBBS**	**MD**	**MD/BS (Med Sci)**
Preclinical training Period	Year I to Year III	Year I to Year III	Year I to Year III
Clinical exposure starts in	Yr II	Yr II	Yr I
Pharmacology Lectures			
Total hours in Year I	0	1.5	15
Total hours in Year II	51	25.5	29
Total hours in Year III	0	23.5	0
Total hours in Clinical Years	6	0	0
Pharmacology Practical			
Total hours in Year I	0	0	6
Total hours in Year II	27	0	0
Total hours in Year III	0	0	0
Pharmacology Tutorials			
Total hours in Year I	0	0	7
Total hours in Year II	4	0	6.5
Total hours in Year III	0	0	0
PBL Tutorials			
Total hours in Year I	16	0	0
Total hours in Year II	24	145.5	0
Total hours in Year III	8	152.5	0
Total hours in clinical Years	16	0	0

Table. 2: Nigerian medical students' curriculum, 2012 (Health System, 2012).

S/N	200-300 Levels	Total No of Weeks
1	GIP	4
2	Integrated CBS	36
3	Clinical Application of Basic Science	12
4	Introduction to Professionalism and Ethics	4
5	MHD	4
	Cumulative Total	60
	MBBS Part I Final (300 Level First Semester)	
	Basic Medical Science-200, 300,400,500 Levels	
6	**Integrated Pathology and Pharmacology**	**20**
	Cumulative total	80
	MBBS Part II Final (500 Level First Semester)	
	Clinical Science I-200, 300,400,500 Levels	
7	Clinical Introductory Posting	4
8	Pediatric	20
9	Obstetrics and Gynecology	20
	Cumulative total	124
	MBBS Part III Final (500 Level 2nd Semester)	

	Clinical Science II-200, 300,400,500 and 600 Levels	
10	Medicine	20
11	Surgery	20
12	Surgical Specialties	16
13	Preventive and Social Medicine	20
14	Family Medicine	8
15	Radio-Diagnostic Intervention and Therapy I	8
16	Psychiatry	8
17	Integrated Infectious Disease Posting	4
18	Elective Clinical Research Posting or Clerkship	4
	Cumulative Total	232
	MBBS Part IV Final (600 Level 2nd Semester)	

Previous Knowledge, Attitude, and Practice Studies of Medical Students Regarding PV

1- Pharmacy students had more knowledge of adverse drug reaction (ADRs) and PV compared to the medical students (Raza and Jamal, 2015). However, in general, both pharmacy and medical students, KAP score was not average. Interestingly, despite inadequate knowledge, both medical and pharmacy students showed the proper attitude towards ADR reporting. The majority of the medical students (95%) mentioned that reporting of ADR should be made mandatory (Raza and Jamal, 2015). It was recommended to conduct an educational intervention to improve knowledge of medical students. Also, there is a need to upgrade curriculum of both undergraduate pharmacy and medical students with respect to PV program (Raza and Jamal, 2015). In addition, the study concluded that the deficiency in the knowledge of ADRs and PV is due to non-inclusion of ADR reporting in the pharmacy and a medical students' curriculum which may translate to poor reporting by the healthcare professionals during their practice (Raza and Jamal, 2015).

2- Two-hour sessions (one-hour theory and one-hour practical) related to the basic definitions and regulations of PV was introduced among 5th-year medical students since 2005 in the school piloted (Arici *et al.,* 2015). After evaluation of the knowledge of 5th-year medical students about ADR reporting and Turkish PV program one year after undergoing the training, the overall knowledge of the students increased (Arici *et al.,* 2015). It was suggested that the medical students surveyed are more confident and ready to participate in the voluntary ADR reporting in their future professional career. The majority of the medical students studied were aware of the existence of a national PV center and regulations in Turkey (Arici *et al.,* 2015). This recommends the need for inclusion of PV in the medical students' curriculum and additional program during the internship. Although medical students can not report the ADR according to current regulations, they were ready to be involved in the program. Since several countries have recently approved direct reporting by patients, the inclusion of medical students in the list of reporters is also possible (Arici *et al.,* 2015).

3- Another study reported that the second year MBBS students have adequate knowledge and attitude of ADRs reporting when they were compared with resident doctors (Ponmari *et al.,* 2015). Inelegantly, despite having good knowledge and attitude their learning experience was miserable. This was attributed to their tight study schedule which made them not to concentrate only on one area (Ponmari *et al.,* 2015). The resident doctors had high scores compared to the final year MBBS students, which may be due to their clinical practice. It was suggested that teaching ADRs to undergraduate medical students will improve their awareness and increase the practice of PV in the future (Ponmari *et al.,* 2015).

4- A study involving medical students in which both Pre-KAP and Post-KAP was conducted on PV, it was evident that all the participants had very less information about ADRs reporting during Pre-KAP studies (Bagewadi *et al.,* 2015). However, there was a significant improvement in their knowledge and attitude after Post-KAP studies. The study involved educational session using lectures and PowerPoint presentations as teaching aids after Pre-KAP session (Bagewadi *et al.,* 2015). The outcomes of the study showed that didactic lectures, power point presentations and diagrams increased, the concept of ADRs reporting among the medical students. As a result, it was suggested that knowledge of medical students can be increased by including PV topics in the undergraduate curriculum and again during internship and residency (Bagewadi *et al.,* 2015).

5- The research on the medical and dental student revealed that more than 55% of the students did not know the term PV and only 13% were aware of the existence of ADR reporting system in any hospital of Karachi (Iffat *et al.,* 2014). The majority of the students, 71% suggested that the PV program in Pakistan needs more upgrading. It was established that there is a need for more awareness of ADR reporting system and to increase the good relationship between regulatory agencies and the healthcare professionals (Iffat *et al.,* 2014). In addition, about 60% of the medical students mentioned that ADR reporting should be made obligatory. The study advocated that PV program should be done as an essential component of the undergraduate, internship and postgraduate training program (Iffat *et al.,* 2014).

6- Another Malaysian study finding suggested inadequate KAP and the need for educational interventions with respect to the PV program in both undergraduate studies and during housemanship (Ismail *et al.,* 2015). Medical schools, regulatory authorities claimed that a lot of improvement was made in the undergraduate training, but yet there are an abundance of irrational prescribing throughout the world (Ismail *et al.,* 2015). It is important to note that without proper ADRs reporting, a lot of ADR will occur in the future. Necessary measures should be taken to improve the medical student curriculum with respect to PV program (Ismail *et al.,* 2015).

7- Another research carried out among final year pharmacy students, and medical student indicated that pharmacy student had better knowledge and attitudes on ADRs reporting than final year medical students (Khan *et al.,* 2015). Also, in general, both pharmacy and medical students' demonstrated inadequate

knowledge of ADRs and PV. This was associated with the lack of inclusion of PV training in undergraduate student' curriculum. In addition, male medical students had more knowledge than female medical students (Khan *et al.,* 2015). The difference in that exist between pharmacy, and medical students can be explained in that pharmacy students had two to four semesters of pharmacology and two to four semesters of clinical pharmacy in their Pharmacy curriculum (Khan *et al.,* 2015). Conversely, medical students studied pharmacology only within two semesters in their medical curriculum. This shows that Pharmacy students received the much better teaching of pharmacology and clinical pharmacy. The curriculum of teaching both medical students need to be improved in order to upgrade their knowledge (Khan *et al.,* 2015).

8- The overall knowledge of ADRs and PV is generally inadequate for the medical students surveyed. Although the students have demonstrated good attitudes, their practice was not acceptable (Abubakar *et al.,* 2015a). The present study indicated that PV program is still in infancy, especially in developing countries. The current academic curriculum should be restructured with respect to PV research to prevent atrocities of pharmaceutical products (Abubakar *et al.,* 2015a). The learning of PV should start as early as possible in medical school. Medical students who have real knowledge of PV are likely to provide more efficient health services in their future practices (Abubakar *et al.,* 2015a). This can be achieved by creating awareness about PV, implementing ADR reports as part of the undergraduate training, internship and postgraduate training, provision of the feedback on ADRs reports and the involvement of pharmacists and nurses in ADRs monitoring (Abubakar *et al.,* 2015a).

9- An additional study showed good knowledge and attitude with respect to ADRs and PV among the medical students. Unfortunately, the practice of medical students was found to be unsatisfactory (Abubakar *et al.,* 2015b). Among the 108 participants, 80% got the definition of ADRs correct; 63% of them knew the precise functions of PV. In addition, 82% strongly agreed that ADR reporting is the health care worker's responsibility; 82% also said PV should be taught in detail. In contrast, only 15% strongly agreed that they were adequately trained on PV; and only 4% have ever reported ADRs. Furthermore, only 8% mentioned they had access to the ADRs reporting form (Abubakar *et al.,* 2015b). It was recommended that adverse drug reaction monitoring should be included in detail in the medical students' curriculum. Likewise, there is a need to implement the use of information and communication technology in prescribing, dispensing, and drug administration, as well as the utilization of the automated system with ADRs monitoring (Abubakar *et al.,* 2015b).

Factors Affecting KAP Studies

Several factors affect the accuracy and the precision of KAP (KAP) studies. Here are some of them: **(1) Translating or transliterating the instrument:** once the questionnaire or oral interview was initially formulated in English transliterating it into a local language for the understanding of the respondents might pose a lot of challenges, and this may be necessary if the respondents could not understand English. Similarly, if the questionnaire was initially formulated in a local language translating it into English perfectly may be difficult (Launiala, 2009). **(2) Bias**: if the respondents are students, they may be compelled to participate in the study to please their lecturers; also, local people like giving only correct answers to the investigator; likewise, the researchers and assistants may have previous answers to research questions in their mind (Launiala, 2009). **(3) Confounding**: there certain factors in research that even if they are not directly related, one cannot conclude they are mutually exclusive. Example, in a particular study a researcher may not be interested in age, gender or economic status of the respondents, but it may be obvious the final result could be influenced by any of them. In other words, the outcome of the research depends on which age group was studied, gender, tribe or income. Confounding is defined as a situation in which the effects of two processes are not separated (Launiala, 2009). **(4) Methodology**: the method is the most important part of the research, the poor methodology may lead to all the KAP study-related problems and may ruin the validity and reliability of the final outcome (Charan and Biswas, 2013; Pourhoseingholi *et al.*, 2013; Launiala, 2009; Dahiru *et al.*, 2006). **(5) Sample size**: small sample may affect the accuracy and the reliability of the final result and the excessive sample may be difficult to analyze or unnecessarily increase the cost of the research (Charan and Biswas, 2013; Pourhoseingholi *et al.*, 2013; Launiala, 2009; Dahiru *et al.,* 2006).

DISCUSSION AND CONCLUSION

Generally, the knowledge of ADRs and PV among the medical students were found to be moderate. Although some of them have demonstrated good attitudes, their practice still remains low. The practice of the medical students largely needs to be upgraded in order to prepare them for future challenges. Recent studies reported a positive correlation between knowledge and attitude and between knowledge and practice on ADRs and PV, although the correlation found was poor (Abubakar *et al.,* 2015a; Abubakar *et al.,* 2015b; Abubakar *et al.,* 2015c). This is an indication that both medical students' attitude and practice can be improved possibly by upgrading knowledge through lectures, seminars and workshops with respect to ADRs and PV (Abubakar *et al.,* 2015a; Abubakar *et al.,* 2015b; Abubakar *et al.,* 2015c). Furthermore, the knowledge, attitude and practice of medical students can be enhanced possibly through the inclusion of PV subject in their curriculum of teaching in order to safeguard patients and advance the healthcare delivery services in the future. In order to ensure the safe use of medicines, PV studies must be strengthened from the grassroots (Raza and Jamal, 2015; Arici *et al.,* 2015; Ponmari *et al.,* 2015; Bagewadi *et al.,* 2015; Ismail *et al.,* 2015; Khan *et al.,* 2015; Iffat *et al.,* 2014). The learning of PV

should start early in the training of doctors. Medical students that have real knowledge of PV are likely to provide more adequate health services in their future practice. The reporting of ADRs using the relevant forms in each country should be demonstrated to students like prescription writing and other practical procedures. The urgent improvement needed in PV studies can be achieved through creating awareness about PV, implementing adverse drug reaction reporting as part of the undergraduate training, internship and post-graduate training, provision of the feedback on ADRs reports and the involvement of pharmacists, nurses and even patients in ADRs monitoring. Countries policy makers can adopt centralized national program in every medical school curriculum to teach PV to the Medical student to develop ADR reporting skill.

Limitations of the Study

1- The study did not cover many medical students KAP studies.
2- The outcome of this review cannot be generalized to all medical students; more studies need to be revised to enable generalization of these findings.

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CONFLICT of INTEREST

Authors possess no financial or any other conflict of interest.

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