

A Systematic Review of Knowledge, Attitude and Practice on Adverse Drug Reactions and Pharmacovigilance among Doctors

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ABSTRACT

Background: Adverse drug reactions (ADRs) have been making headlines because of life threatening issues. ADRs are always underreported and still the major public health problem. Spontaneous reporting system has remained the most significant method for safeguarding patients' lives.

Objectives: Is to examine and analyse the various pharmacovigilance (PV) studies conducted among doctors and to make recommendations for future research.

Study Selection: 32 studies covered from 2004 to 2014 were selected.

Data Sources: Four electronic data-bases including Science-Direct, Springer-Link, PubMed and MEDLINE were used to obtain 129 relevant publications using HotBot, FreeFullPDF, and Google Scholar as search engines.

Data Extraction: Studies conducted on doctors were selected covering research from ten countries.

Inclusion Criteria: Only studies done from 2004 to 2014 were included, KAP studies done on ADRs and pharmacovigilance among doctors were selected.

Exclusion criteria: All studies done before 2004 and studies done on general public KAP were excluded; similarly, studies conducted on healthcare professionals in general were excluded; also studies done on adverse drug event (ADE) reporting were excluded. The study was conducted from April to August, 2014.

Data Synthesis: Knowledge, attitude and practice (KAP) regarding ADRs reporting by doctors were poor. Longitudinal study involving educational intervention and training through workshops and seminars were found to be effective in improving doctors' knowledge and attitude.

Conclusion: There is urgent need to improve knowledge, awareness and practice of doctors on pharmacovigilance. It is imperative for WHO and national pharmacovigilance centres to take proactive measures to curb the menace of ADRs in order to safeguard the patients' lives. The curriculum of all health and health related schools should be restructured with respect to pharmacovigilance without any delay and hesitation.

INTRODUCTION

Worldwide there is increase in public attention on ADRs, this was evidenced by the bill passed by US senate requiring pharmaceutical companies to provide ADRs information to the public (Gray, 1996). Several highly publicized reports and policy makers have urged medical practitioners to put more effort to curtail the problem of ADRs (Kohn *et al.*, 2000; Kachhadiya *et al.*, 2009). The pharmacovigilance study was initiated following the disaster caused by thalidomide in pregnant

women in 1961 (WHO, 1969). Pharmacovigilance studies is becoming more important as new drugs are entering the market in jet speed and increase in number of drugs withdrawn because of ADRs (ISDB, 2005; Salam *et al.*, 2013).

It is imperative to acknowledge that currently trial drugs on Ebola virus are now used by West African countries for emergency treatment. Post-marketing safety studies of these drugs have become absolute necessary to avoid any disaster. The major concern is that majority of these drug were developed either in north America or Europe using people from these regions as small scale clinical trials. Hence, there are higher probabilities of ADRs from Ebola medicine due to genetic, cultural, environmental and social differences.

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Definition

ADRs is any noxious, unintended, and undesired effect of drug that occurs as a result of treatment with drug at a normal doses used in man for diagnosis, prophylaxis, and treatment (WHO, 1972). ADRs can be describe as “an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product (Edward and Aronson, 2000).

Generally drugs and any other substances that is capable of producing a therapeutic effect can also lead to unwanted or adverse effects, some drugs produce low risk (e.g. hydroxocobalamin or nystatin), whereas others produce high risk (e.g. antineoplastic and immunosuppressant drugs) (Edward and Aronson, 2000). The term “**adverse effect**” is preferable to other terms such as “side effect” or “toxic effect”, side effect occurs via different mechanism and may be dose-related or not. E.g. Sedation due to anti histamines is a side effect, since this action is not associated with the therapeutic effect; similarly anaphylaxis with cephalosporin which is non-dose related is a side effect. A toxic effect is an exaggeration of the desired therapeutic effect which is usually not common at normal doses. E.g. Hypotension due to thiazide diuretics is a toxic effect that occurs by the same mechanism as the therapeutic effect (diuresis). Drug toxicity occurs at a higher dose that is to say toxic effect is always dose-related (Edward and Aronson, 2000).

The terms “adverse reaction” and “adverse effect” are interchangeable, except that an adverse effect is seen from the point of view of the drug, whereas an adverse reaction is seen from the point of view of the patient. However, the terms “adverse effect” and “adverse reaction” must be distinguished from “**adverse event**”. An adverse effect is an adverse outcome that can be attributed to some action of a drug; an adverse event is an adverse outcome that occurs while a patient is taking a drug, but is not or not necessarily attributable to it (Edward and Aronson, 2000).

ADRs are classified into six types (with mnemonics): dose-related (Augmented), non-dose-related (Bizarre), dose-related and time-related (Chronic), time-related (Delayed), withdrawal (End of use), and failure of therapy (Failure) (Edward and Aronson, 2000).

Pharmacovigilance is a science and activities relating to the detection, assessment, understanding and prevention of adverse drug effects (WHO, 2002). Spontaneous reporting system is considered the main mechanism of pharmacovigilance study for gathering information about ADRs after drug is marketed for use by consumers (Edward and Aronson, 2000).

METHODS USED IN PHARMACOVIGILANCE

In safety study, signals can be generated through four different methods: spontaneous reporting published case reports, cohort studies and post-marketing clinical trials. Now the primary

method of collecting post marketing information on the safety of drugs is spontaneous reporting systems (SRS). The main function of SRS is the early detection of signals of new, rare and serious ADRs. A spontaneous reporting system enables physicians and increasingly more often, pharmacists and patients to report suspected ADRs to a pharmacovigilance center (van Grootheest *et al.*, 2004; van Grootheest and de Jong-van, 2004). The major task of the pharmacovigilance center is to collect and analyze the reports and to inform stakeholders of the potential risk when signals of new ADRs arise. Spontaneous reporting is also used by the pharmaceutical industry to collect information about their drugs. By means of a SRS it is possible to monitor all drugs on the market throughout their entire life cycle at a relatively low cost (Harmark and van Grootheest, 2008).

The Pharmacovigilance method used by regulatory authorities is the same with pharmaceutical industries. (1) The possibility of new ADRs is first identified by signal generation processes. This followed by period of signal strengthening and in the second step such signals is subjected to (2) hypothesis testing i.e. processes that determine whether the signal indicating new ADR, or whether it is wrong. The procedure of signal generation is relatively easy if the right systems are in place, the hypothesis testing process is challenging and often time consuming and may require variety of approaches (Talbot and Nilsson, 1998).

The specific objectives of Pharmacovigilance

- i. To improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions.
- ii. To improve public health and safety in relation to the use of medicines.
- iii. To contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more cost-effective use.
- iv. To promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public (Talbot and Nilsson, 1998).

AIM OF THE STUDY

- i. To investigate previous researches conducted on KAP of doctors on ADR reporting.
- ii. To relate the outcome obtained by various studies.
- iii. To find out the gaps identified by the various researchers and make recommendations for further research.

Operational Definitions

Knowledge: Means theoretical or practical understanding of the subject matter.

Attitude: A predisposition or a tendency to respond positively or negatively towards a certain idea, object, person, or situation.

Practice: Application of knowledge or practical approach to the subject matter.

Table 1: Summary of the Reviewed Articles.

S/N	Year	First Author	Study Design	Study Participants & Settings	Response Rate & Sample Size	Measured Outcomes	Conclusion	Suggestions
1	2005	Herdeiro, MT	Case-Control self-completed questionnaire	Random sample of physicians in Northern Region of Portugal	54.3%, Experiment(n=88), Control (n=771), Total (n= 859)	Knowledge and attitude	The study revealed that medical practitioners' attitude was strongly associated with under-reporting of ADRs	Under-reporting could be greatly reduced by changing the attitude of Medical practitioners
2	2006	Backstrom, M	Interventional Case-Control self-completed questionnaire	Random sample of physicians in Health Care Centres from Two Districts of Northern Sweden	66%, (n = 540)	Increase in attitude and practice with economic inducement	Economic inducement had increase the ADRs reporting rate	There is need to investigate the impact of incentives in ADRs monitoring
3	2006	Chatterjee, S	Cross Sectional self-completed questionnaire	Physicians from Eastern India	64.2%, (n = 215)	Knowledge, attitude and practice	The doctors had good knowledge but poor attitude and practice	There is need to include pharmacovigilance training in undergraduate curriculum
4	2008	Fracas, A	Cross Sectional self-completed questionnaire	Doctors from Hospitals in Cluj-Napoca, Romania	86%, (n = 200)	Knowledge, attitude and practice	Doctors had poor knowledge, attitude and practice	It is crucial to increase doctors awareness on ADR reporting
5	2009	Passier, A	Cross Sectional self-completed questionnaire	Random sample of General Medical Practitioners (GPs), Netherlands	47%, Activer-reporters(n=500), Non-reporters(1000), Total (n = 1500)	Knowledge and attitude	Active reporters had better knowledge and attitude than Nson-reporters	There is need to increase communication between GPs and both pharmacist and patients
6	2009	Ramesh, M	Cross Sectional self-completed questionnaire	Random sample of Doctors of Jagadguru, Basappa and Holdsworth Hospital Mysore, India	88%, (n = 110)	Attitude and perception	The doctors had good knowledge and attitude but their practice is in adequate.	Pharmacist should be included in ADRs reporting
7	2009	Oshikoya, KA	Cross Sectional self-completed questionnaire	Cluster sample of Doctors in Lagos State University Teaching Hospital, Nigeria	82.5%, (n = 99)	Perception	Doctors had inadequate knowledge and awareness on ADRs reporting	All doctors should undergo continuous education and training on ADRs reporting
8	2009	Tabali, M	Longitudinal study, Questionnaire and face to face interview	Random sample of Physicians from 12 states, Germany	100%, (n = 38)	Changes in ADRs reporting rate	Educational intervention had increase physicians awareness on ADR reporting	There is need to increase awareness and educational intervention in pharmacovigilance
9	2011	Awodele, O	Cross Sectional self-completed questionnaire	Doctors in private hospitals in Lagos West Senatorial District, Nigeria	93%, (n = 270)	Knowledge and practice	The doctors working in a private hospitals had good knowledge but poor practice	There is need for training for doctors working in a private hospitals
10	2011	Chopra, D	Cross Sectional self-completed questionnaire	Doctors of Lady Hardinge Medical College and associated Hospital	100%, (n = 100)	Knowledge, attitude and practice	The doctors had inadequate knowledge and poor practice	There is need for more awareness and educational intervention
11	2011	Bello, SO	Cross Sectional self-completed questionnaire	Convenient sample of Physicians from four government Hospitals in Sokoto, Nigeria	100%, (n = 61)	Knowledge and attitude	Doctors had poor knowledge, attitude and practice	There is need for awareness campaign for physicians and patients

12	2011	Gupta, P	Cross Sectional self-completed questionnaire	Convenient sample of Resident doctors of B.J and Seth G.S Medical Colleges Mumbai, India	77.2%, (n = 407)	Knowledge, attitude and perception	Knowledge, attitude and practice of doctors were deficient	There is need for more awareness and educational intervention
13	2011	Desai, CK	Cross Sectional self-completed questionnaire	Prescribers of Tertiary Care Hospital of B.J Medical College Ahmedabad, India	61%, (n = 436)	Knowledge, attitude and practice	The prescribers knowledge and practice were poor but had good attitude	The reporting procedure should be made easy and convenient for doctors
14	2012	Kharkar, M	Cross Sectional self-completed questionnaire	Medical practitioners from four different zones, India	73%, (n = 1200)	Knowledge, attitude and practice	The Medical practitioners had good knowledge and attitude but poor practice	There is need to include pharmacovigilance training in undergraduate curriculum
15	2012	Rishi, RK ¹	Cross Sectional self-completed questionnaire	Random sample of Medical practitioners from 15 India states	100%, (n = 100)	Opinion and attitude	The doctors had good attitude and opinion but poor practice	There is need for workshops and conferences with continuous medical education for physicians on ADRs reporting
16	2012	Rishi, RK ²	Cross Sectional self-completed questionnaire	Random sample of Medical practitioners from 15 India states	100%, (n = 100)	Knowledge, attitude and practice	The physicians had poor knowledge and attitude	There is need for introducing use of information technology in pharmacovigilance and direct patient reporting
17	2012	Pimpalkhute, SA	Cross Sectional self-completed questionnaire	Convenient sample of Resident doctors of Government Medical college, Nagpur, India	93.3%, (n = 90)	Knowledge and attitude	The doctors had poor knowledge, attitude and practice	There is need to increase doctors awareness on ADRs reporting
18	2012	John, L J	Cross Sectional self-completed questionnaire	Convenient sample of Doctors working in a Tertiary Care Hospital, United Arab Emirate	76%, (n = 55)	Knowledge and practice	The doctors had poor Knowledge, attitude and practice	There is need to initiate workshops and training programs on pharmacovigilance for doctors
19	2012	Upadhyaya, P	Cross Sectional self-completed questionnaire	Cluster sample of Postgraduate doctors working in a Tertiary Care Hospital, Mahatma Gandhi Medical College, Jaipur, India	100% (n = 50)	Knowledge and practice	Knowledge and practice was poor	There is need to maintain close relationship between physicians and pharmacovigilance center
20	2012	Kamtane, RA	Cross sectional-Observational Questionnaire based	Random sample of doctors working in different fields, Hyderabad India	78.3%, (n = 120)	Knowledge, attitude and perception	The physicians had poor knowledge but good attitude and perception	ADRs reporting by Pharmacist, Nurses and even Patients should be encouraged
21	2013	Shailesh, N	Longitudinal self-completed questionnaire	Convenient sample of Graduate doctors of Mahatma Gandhi Institute of Medical Sciences Maharashtra, India	100%, (n = 65)	Knowledge, attitude and practice	Medical graduates had poor knowledge and practice but good attitude. The knowledge improved after intervention	There is need for medical graduates to undergo continuous education and training on ADRs reporting
22	2013	Adhikary, J	Cross Sectional self-completed questionnaire	Cluster sample of Physicians of Rajajeswari Medical college and Hospital, Bangalore, India	70.9%, (n = 189)	Knowledge, attitude and practice	The physicians limited knowledge and practice but better attitude	It is desirable to initiate workshops and training programs on ADR reporting
23	2013	Paveliu, MS	Questionnaire and face to face interview	Random sample of Physician working in Southern Romania	100%, (n = 532)	Perception	The doctors had poor knowledge and practice but good attitude	Pharmacovigilance study should be included in the curriculum of training residents physicians
24	2013	Adedeji, WA	Cross Sectional self-completed questionnaire	Cluster sample Doctors Ladoke Akintola University of Technology, Oyo, Nigeria	100%, (n = 35)	Attitude and practice	The doctors had good knowledge but attitude and practice	There is need to establish pharmacovigilance committee in the hospital
25	2013	Agarwal, R	Cross Sectional self-completed questionnaire	Simple random sample of Private practitioners of Klang Valley, Malaysia	61%, (n = 238)	Knowledge, attitude and practice	Knowledge, attitude and practice of doctors was inadequate	There is need for teaching pharmacovigilance in detail in undergraduate curriculum
26	2013	Khan, SA	Cross sectional self-completed questionnaire	Cluster sample of Doctors in Teaching Hospital India	62.9%, (n = 108)	Knowledge and attitude	Knowledge, attitude and practice of doctors were poor	There is urgent need for knowledge intervention to improve pharmacovigilance and enhance patient safety

27	2013	Thomas, TM	Cross sectional self-completed questionnaire	Doctors of Tertiary Health Centers in Mangalore, Southern India	100%, (n = 60)	Knowledge, attitude and practice	The Knowledge and attitude of doctors were good but the practice level was poor	There is need for more awareness on ADRs reporting through continuous education and training
28	2013	Sanghavi, DR	Longitudinal- self-completed questionnaire	Cluster sampling of Doctors in Bharati Teaching Hospital, Pune, India	36.4%, (n = 220)	Knowledge, attitude and practice	The physician had good attitude but poor knowledge and practice	The quality of ADR reporting can be improved via education and training of the clinicians
29	2014	Iffat, W	Cross sectional self-completed questionnaire	Random sample of Doctors in public and private hospitals and clinics in Karachi, Pakistan.	40.9%, (n = 550)	Knowledge and attitude	The Doctors had good knowledge of ADRs reporting but poor attitude.	There is need for continuous education and training for physicians about pharmacovigilance
30	2014	Bisht, M	Case control self-completed questionnaire	Convenient sample of Doctors of Tertiary Care Teaching Hospital, Uttarakhand, India	80%, Doctors that attended lectures (n=125), Doctors that didn't attend (n=125)	Knowledge, attitude and practice	After the educational intervention, the doctors knowledge and attitude improved but poor practice	Strategies should be employed to increase doctors awareness and reporting culture
31	2014	Aithal, S	Cross sectional self-completed questionnaire	Convenient sample of Doctors of Tertiary Health care Hospital, Davangere, Karnataka, India	39%, (n = 42)	Knowledge and attitude	The doctors had poor knowledge but good attitude and practice	There is need to address factors discouraging doctors from reporting ADRs
32	2014	Kiran, L J	Cross sectional self-completed questionnaire	Cluster sample of Clinicians of Teaching Hospital, South Karnataka, India	80%, (n = 150)	Knowledge, attitude and practice	The clinicians had poor knowledge and practice but good attitude	There is need for more awareness and educational intervention

MATERIALS AND METHODS

This article focused on researches done on ADRs and PV, it was also based on WHO definition of ADRs excluding therapeutic failure, overdose, errors in drug administration, and noncompliance (Lazarou *et al.*, 1998; Patel and Ganguly, 2010). ADRs are caused by inherent properties of the drug (non-preventable); therefore, they are most relevant to this study (Phillips *et al.*, 2001).

Study Selection: Studies conducted from 2004 to 2014 were selected because they were considered most recent and will portray the current picture of what is obtainable in countries where the various researches was conducted.

Data Sources: Four electronic data bases including Science-Direct, Springer-Link, PubMed and MEDLINE were used to obtain 129 relevant publications on knowledge, attitude and practice on ADRs and PV among doctors using HotBot, FreeFullPDF and Google scholar as search engines. The search terms included: ADRs, PV, ADRs reporting, drug surveillance, PV study, survey on ADRs reporting, spontaneous reporting of ADRs, ADR signal detection combined with the following: doctors, medical practitioners, awareness, knowledge, attitude and practice.

Inclusion Criteria: Only studies done from 2004 to 2014 were included, KAP studies done on ADRs and PV among doctors were selected.

Exclusion criteria: All studies done before 2004 and studies done on general public KAP were excluded; studies conducted on healthcare professionals in general were excluded; also studies done on adverse drug event (ADE) reporting were excluded. The references of all the initial articles that met the inclusion criteria were cross-checked, and more relevant articles were retrieved and included.

Data Extraction: Researches from several countries were selected and about ten countries were covered in this article. Finally, 32 articles were chosen, examined and analysed; areas that require further investigation were also identified. The various research findings were correlated and based on the various outcome recommendations and conclusion was made. The article was reviewed by the first two authors.

RESULT

Description of the Articles Included

Total of 29 articles obtained from different countries that met the inclusion criteria was reviewed. Nineteen articles were published in India (Kiran *et al.*, 2014; Aithal *et al.*, 2014; Bisht *et al.*, 2014; Sabghavi *et al.*, 2013; Adhikary *et al.*, 2013; Shailesh *et al.*, 2013; Thomas *et al.*, 2013; Khan *et al.*, 2013; Kamtane and Jayawardhani, 2012; Upadhyaya *et al.*, 2012; Pimpalkhute *et al.*, 2012; Rishi *et al.*, 2012a; Rishi *et al.*, 2012b; Kharkar and Bowalekar, 2012; Desai *et al.*, 2011; Gupta and Udupa, 2011; Chopra *et al.*, 2011; Ramesh and Parthasarathi, 2009; Chatterjee *et al.*, 2006); four studies from Nigeria (Adedeji *et al.*, 2013; Bello

and Umar, 2011; Awodele *et al.*, 2011; Oshikoya and Awobusuyi, 2009); two from Romania (Paveliu *et al.*, 2013; Farcas *et al.*, 2008), one from Pakistan (Iffat *et al.*, 2014), one from Malaysia (Agarwal *et al.*, 2013), one UAE (John *et al.*, 2012), one Germany (Tabali *et al.*, 2009), one from Netherland (Passier *et al.*, 2009), one from Sweden (Backstrom and Mjorndal, 2006) and finally one from Portugal (Herdeiro *et al.*, 2005). Two surveys were longitudinal studies (Tabali *et al.*, 2009; Sanghavi *et al.*, 2013); two studies (Paveliu *et al.*, 2013; Tabali *et al.*, 2009) used face to face interview in addition to questionnaire as a research tool; the remaining surveys were cross-sectional questionnaire based studies. The topic ADR reporting or PV by doctors was discussed in all the articles reviewed. The terms 'physicians', 'medical practitioners', 'doctors' were used by all the authors and a times interchangeably because they were all considered to mean the same thing.

Doctors' Knowledge towards ADR Reporting

According to the various article reviewed, doctors' knowledge was assessed based on five main parameters, namely: Definition or awareness on ADR and PV; who is to report ADR and location of ADR reporting centre; purpose of reporting; as well as awareness on reporting procedure and reporting forms.

Definition or Awareness on ADR and PV

The result of the various researches indicated poor knowledge of ADR reporting by doctors even though many of them were aware of or could define ADR and PV. Study conducted in Pakistan reported that 88% of the medical practitioners were aware of ADR (Iffat *et al.*, 2014), also positive findings were obtained in a study from India 52.3% (Thomas *et al.*, 2013), 57% (Shailesh *et al.*, 2013) and 66% (Chopra *et al.*, 2011). In another survey carried out in Nigeria 82.9 % of doctors were aware of PV (Awodele *et al.*, 2011), also in India 58% (Kharkar and Bowalekar, 2012), 69.1% (Khan *et al.*, 2013), and 64.3% (Pimpalkhute, 2012). In contrast, study conducted in Romania revealed that only 22.6% of physicians were aware of PV (Paveliu *et al.*, 2013), similar findings was obtained in a study from Pakistan 31.5% (Iffat *et al.*, 2014); also in a study from India 54.4% of physicians were not aware of PV (Kantame and Jayawardhani, 2012).

Who is to Report ADR and Location of ADR Reporting Centre?

Doctors' in most cases gave less priority to the contribution of other health workers in ADR reporting, also their awareness on ADR reporting centre was generally low. Survey carried out in Nigeria reported that 89% of respondents felt that doctors are most qualified to report ADR (Oshikoya and Awobusuyi, 2009), 59% (Awodele *et al.*, 2011), similar outcome was obtained in India 95% (Sanghavi *et al.*, 2013), 95.7% (Kamtane and Jayawardhani, 2012), 97% (Khan *et al.*, 2013) and Pakistan 64% (Iffat *et al.*, 2014).

Regarding the ADR reporting centre, a research conducted in Pakistan showed that only 15.5% of physicians know the ADR reporting centre (Iffat *et al.*, 2014), similar findings were obtained from study in India 11.7% (Thomas *et al.*, 2013), 15% (Kiran *et al.*, 2014), 25% (Shailesh *et al.*, 2013), 30% (Chopra *et al.*, 2011), and 47.5% (Kharkar and Bowalekar, 2012), and in Nigeria 40.4% (Oshikoya and Awobusuyi, 2009). Another research conducted in Malaysia revealed that 57% of doctors do not know where to report ADRs (Agarwal *et al.*, 2013), similar result was found in India 43% (Sanghavi *et al.*, 2013). In contrast, study conducted in Nigeria indicated that 71.4% of medical practitioners were aware of PV centre (Adedeji *et al.*, 2013), similar result was obtained from India 80.9% (Khan *et al.*, 2013).

Purpose of Reporting

Majority of the doctors knew the purpose of ADR reporting. Based on survey results from Netherlands, 90% of medical practitioners believed that ADR reporting contribute to drug safety (Passier *et al.*, 2009), similar outcome was reported from India 97.3% (Desai, 2011). Another doctors from India stated that PV study will benefit patients 96% (Rishi *et al.*, 2012a), 98% (Ramesh and Parthasarathi, 2009), 93.6% (Kamtane and Jayawardhani, 2012). Also large population of medical practitioners (96%) from India stated that all the drugs available in the market are not safe (Rishi *et al.*, 2012) and 93.6% (Kamtane and Jayawardhani, 2012).

Awareness on reporting procedure and reporting form

Lack of awareness of the procedure and reporting form was common among the physicians interviewed. A survey from UAE revealed that 71% of the doctors do not how to report ADR (John *et al.*, 2012) which is similar to result obtained from India 92.5% (Sanghavi *et al.*, 2013), Malaysia 55.6% (Agarwal *et al.*, 2013), Nigeria 95.1% (Bello and Umar., 2011), Romania 68% (Farcas *et al.*, 2008). Also in another study from Pakistan only 9.7% are aware of the reporting system, similar results were obtained from India 6% (Aithal *et al.*, 2014), 44% (Pimpalkhute *et al.*, 2012), 43% (Gupta and Udupa, 2011), and 43% (Bisht *et al.*, 2014). In contrast, studies from India have shown that 73% of doctors know the reporting system in their country (Chopra *et al.*, 2011), 75% (Thomas *et al.*, 2013), 59.2% (Kharkar and Bowalekar, 2012). With respect to the reporting form, a research from Malaysia showed that 69% of doctors said the reporting form is not available while 60.9% said it is difficult to fill.

Doctors' attitude towards ADR reporting

Four themes were identified with respect to doctors' attitude towards ADR reporting including: Obligation to report, Nature of ADR to report, Factors that influence ADR reporting and ADR due to newly marketed drug.

Obligation to Report

There was strong agreement among the medical practitioners on the need to report ADR. Based on survey from

Romania, majority of the medical practitioners strongly agreed ADR reporting is mandatory 60.1% (Paveliu *et al.*, 2013), similar finding was obtained from UAE 66.7% (John *et al.*, 2012), Pakistan 80% (Iffat *et al.*, 2014), also from several studies from India 95% (Adhikary *et al.*, 2013), 81% (Sanghavi *et al.*, 2013), 85.1% (Kamtane and Jayawardhani, 2012), 84% (Rishi *et al.*, 2012b), 66.2% (Khan *et al.*, 2013), 51% (Bisht *et al.*, 2014), and 80.9% (Gupta and Udupa, 2011). In contrast, only one study from India had different finding where only 15.2% of the medical practitioners believed reporting ADR is compulsory (Pimpalkhute *et al.*, 2012).

Nature of ADR to Report

It was evident that majority of doctors do not know which type of ADR should be reported. Survey carried out in India has shown that only 10% of the doctors knew what type of ADR should be reported (Chopra *et al.*, 2011). In another study conducted in Sweden 94% of doctors stated that severity of an ADR is the determinant of reporting (Backstrom and Mjorndal, 2006), similar findings were reported from Nigeria 77.8% (Oshikoya and Awobusuyi, 2009), Romania 50% (Farcas *et al.*, 2008), also in India 81.3% (Rishi *et al.*, 2012b), 95.6% (Khan *et al.*, 2013), 83.8% (Pimpalkhute *et al.*, 2012), 56% (Desai *et al.*, 2011), and 79.7% (Chatterjee *et al.*, 2006). In several other studies doctors opined that only unusual ADR should be reported, in UAE 95% (John *et al.*, 2012), Nigeria 70.7% (Oshikoya and Awobusuyi, 2009), also in India 72.1% (Khan *et al.*, 2013), 95% (Thomas *et al.*, 2013), 94% (Bisht *et al.*, 2014), 74.4% (Chopra *et al.*, 2011). In contrast, only one study gave positive result as the doctors felt that all ADRs should be reported 92% (Sanghavi *et al.*, 2013).

Factors that Influence ADR Reporting

Based on survey findings doctors believed that many factors discourage reporting, only few felt that there some factors encourage ADR reporting.

Factors that Encourage Reporting

Research carried out in Northern Sweden indicated that certainty about ADR encourage reporting by 80% of physicians (Backstrom and Mjorndal, 2006). Survey from UAE also revealed that 96.4% of physicians said that patient safety encourage reporting (John *et al.*, 2012).

Factors that Discourage Reporting

In a survey conducted in UAE 71% of physicians suggested that lack knowledge of reporting procedure is major reason for under-reporting (John *et al.*, 2012). Similar findings was obtained in India 87.7% (Chatterjee *et al.*, 2006), 70% (Desai *et al.*, 2011), 95.2% (Gupta and Udupa, 2011), and Nigeria 48.6% (Adedeji *et al.*, 2013). In another surveys ADR reporting was considered as time consuming, India 81.8% (Gupta and Udupa, 2011), 45% (Sanghavi *et al.*, 2013) and Netherland 35% (Passier *et al.*, 2009). In a survey conducted in Malaysia doctors felt that

uncertainly about ADR discourage reporting 76.6% (Agarwal *et al.*, 2013), similar outcome was obtained in Sweden 75% (Backstrom and Mjorndal, 2006), Romania 40.2% (Paveliu *et al.*, 2013) and India 80.9% (Gupta and Udupa, 2012), 30.9% (Khan *et al.*, 2013). In a study conducted in Nigeria 68.6% of doctors revealed that lack of awareness of reporting form discourage reporting (Adedeji *et al.*, 2013), similar result was obtained from India 47% (Aithal *et al.*, 2014), and 49.2% (Desai *et al.*, 2011). In another survey carried out in Portugal 20% of physicians felt that ADR report will put their carrier at risk (Herdeiro *et al.*, 2005), also in India 46.5% (Kamtane and Jayawardhani, 2012).

ADR due to Newly Marketed Drug

Doctors opinion varied in terms of new drugs but majority said ADRs due to new drug should be reported, in Pakistan 85.7% (Iffat *et al.*, 2014), Malaysia 59.3% (Agarwal *et al.*, 2013), India 98.7% (Gupta and Udupa, 2011), 98.3% (Thomas *et al.*, 2013), 65% (Bisht *et al.*, 2014), 35.7% (Pimpalkhute *et al.*, 2012). In contrast, one survey from Romania reported that only 10% of the doctors said unexpected ADR could result from new drug (Paveliu *et al.*, 2013), similar negative finding was obtained from India where 77.9% of doctors felt that all serious ADR were known before the drug is marketed (Khan *et al.*, 2012).

Practice of Doctors towards ADR

Practice of doctors was based on four parameters in majority of surveys conducted. These includes: Encounter with ADRs, Number of ADRs ever reported, Training on ADR reporting and Source of information to the doctors.

Encounter with ADRs

Survey data indicated that doctors' practice on ADRs reporting is generally poor because many came across ADRs but did not take any action. In a study conducted in Nigeria 64.9% of medical practitioners said they have not come across ADR (Awodele *et al.*, 2011), similar finding was obtained in Pakistan 65.6% (Iffat *et al.*, 2014). However, another survey carried out in Nigeria 70.5% of physicians have encountered ADRs (Bello and Umar, 2011), 85.7% (Adedeji *et al.*, 2013), equivalent outcome was obtained from India 80% (Chopra *et al.*, 2011), 87.7% (Chatterjee *et al.*, 2006), 96% (Sanghavi *et al.*, 2013), 77% (Kiran *et al.*, 2014), 78.7% (Kamtane and Jayawardhani, 2012), 86% (Rishi *et al.*, 2012a), 68% (Bisht *et al.*, 2014), 67.9% (Pimpalkhute *et al.*, 2012), 56.8% (Adhikary *et al.*, 2013) and 50% (Upadhyaya *et al.*, 2012).

Number of ADRs Ever Reported

It is without any doubt that doctors report only small number of ADRs or not at all. Survey done in Malaysia have shown that only 5.3% of doctors ever reported ADRs (Agarwal *et al.*, 2013), similar result was found in UAE 11% (John *et al.*, 2012), Romania 15% (Fracas *et al.*, 2008), Nigeria 5.6% (Awodele *et al.*, 2011), 7% (Bello and Umar, 2011), 2% (Oshikoya and Awobusuyi, 2009), and 29% (Adedeji *et al.*, 2013), also from

India 4.4% (Chatterjee, 2006), 2.9% (Gupta and Udupa, 2011), 15% (Desai *et al.*, 2011), 15 % (Kiran *et al.*, 2014), 22.1% (Adhikary *et al.*, 2013), 25% (Thomas *et al.*, 2013), 25% (Pimpalkhute *et al.*, 2012), 30% (Chopra *et al.*, 2011), and 18.5% (Kharkar and Bowalekar, 2012). Similarly, survey from Romania revealed that 79.9% of doctors interviewed did not report any ADR (Paveliu *et al.*, 2013), comparable result was obtained in India 77% (Bisht *et al.*, 2014). In contrast, article from Sweden have positive finding with 62% that have ever reported an ADR (Backstrom and Mjorndal, 2006), also an encouraging result was obtained from two articles done in India with 41% (Ramesh and Parthasarathi, 2009) and 40% (Upadhyaya *et al.*, 2012) reporting rate.

Training on ADR Reporting

Doctors generally agreed that they have not received adequate training to report ADRs. Survey done in UAE have shown that only 5.5% were trained on how to report ADRs (John *et al.*, 2012), similar outcome was obtained in Nigeria where 89.6% of doctors said they need training on ADR reporting (Awodele *et al.*, 2011), India 100% (Sanghavi *et al.*, 2013), 95.9% (Adhikary *et al.*, 2013), 80.9% (Kamtane and Jayawardhani, 2012) and 45% (Bisht *et al.*, 2014). In contrast one study revealed that 50% of the respondents said were taught how to report ADR during their undergraduate studies (Upadhyaya *et al.*, 2012).

Source of Information to the Doctors

Many doctors could not identify the most appropriate source of information in PV, as majority of them did not refer to PV centre or pharmacist for information. Survey carried out in Pakistan have shown that 24% of doctors refer to internet, 33.6% seminar, 18.4% journal, 10.4% drug advert (Iffat *et al.*, 2014), similarly, in Nigeria 41.4% book/journals, 18.3% seminars/ training, 4.4% internet (Awodele *et al.*, 2011), also India 63% of doctors identified internet as source of information, 65% seminar, 69% journal, 40% medical books (Bisht *et al.*, 2014), other doctors (89%) emphasised on the role of information technology (Rishi *et al.*, 2012b), 93.6% (Kamtane and Jayawardhani, 2012), and 75% (Sanghavi *et al.*, 2013).

DISCUSSION AND CONCLUSION

ADRs and pharmacovigilance studies have become prominent and one of the most important aspect of patient care. Research in these areas in hospitals, medical and health related schools, pharmaceutical industries, and communities are of paramount importance. According to various researches reviewed KAPs of doctors were at the lowest level.

Doctors' knowledge towards ADR reporting

Knowledge is the first thing to consider when it comes to ADRs reporting. Based on the various articles reviewed, doctors' awareness on ADR reporting was inadequate. ADR reporting is a very wide concept and requires contributions of professionals from

different disciplines; vast majority of the doctors interviewed did not acknowledge the contribution of other health care professionals as potential ADRs reporters (Kamtane and Jayawardhani, 2012; Oshikoya and Awobusuyi, 2009; Khan *et al.*, 2013). It is important to note that awareness of the reporting centre is also crucial; large population of doctors were ignorant of the PV centre (Iffat *et al.*, 2014; Thomas *et al.*, 2013). Similarly, with regards to reporting procedure, majority of the doctors surveyed do not know how to report ADR nor they had access to the reporting card (John *et al.*, 2012; Sanghavi *et al.*, 2013; Bello and Umar, 2011; Agarwal *et al.*, 2013). It is essential for doctors to possess wide knowledge on ADRs and ADR reporting procedure, and also able to assess the causal relationship between the identified disorder and the suspected drug. It is clear that knowledge on ADR reporting was not given much consideration during doctors training as majority of them interviewed had advocated for the need of training on ADR reporting (Awodele *et al.*, 2011; Kamtane and Jayawardhani, 2012; Sanghavi *et al.*, 2013).

Doctors' attitude towards ADR reporting

Doctors' attitudes towards ADR reporting was quite discouraging, surveys carried out reported that large percentage of doctors believed that only serious ADRs should be considered more important or they don't even know what type of ADR to report (Backstrom and Mjorndal, 2006; Rishi *et al.*, 2012b; Oshikoya and Awobusuyi, 2009). It is important to acknowledge that less serious and unusual ADRs are also important because they might serve as a clue to the possibility of fatal ADR to occur in the future. The factors identified by doctors as obstacles in reporting ADR should be dealt with immediately; they include lack of knowledge of reporting procedure, time consumption, uncertainty about the ADR, availability of the reporting form, and legal problem (Chatterjee *et al.*, 2006; Gupta and Udupa, 2011; Agarwal *et al.*, 2013; Adedeji *et al.*, 2013; Kamtane and Jayawardhani, 2012). However, since most of the doctors considered ADR reporting as professional obligation they should be able to overcome most of the obstacles stated as no part of patient care seems to be friendly (Iffat *et al.*, 2014; Sanghavi *et al.*, 2013; Paveliu *et al.*, 2013). Based on this reason, it can be established that awareness lecture is urgently needed to improve the doctors' attitude towards ADR reporting. Further research should be conducted to evaluate doctors' opinions with respect to ADR monitoring.

Doctors' practice towards ADR reporting

According to various research outcomes, doctors' practice towards ADR reporting was far below expectation. Meanwhile, the rate at which ADRs were reported to the relevant regulatory authority was quite overwhelming; greater part of the doctors that came across ADR either sent few reports or did not reported at all (Chatterjee *et al.*, 2006; Agarwal *et al.*, 2013; Oshikoya and Awobusuyi, 2009; John *et al.*, 2012). It was evident that hospitals managements, pharmaceutical companies, drug

regulatory agencies did not made significant contribution towards educating doctors on ADR monitoring and reporting. Survey conducted in UAE revealed that only 5.5% of doctors received training on ADR reporting (John *et al.*, 2013). This have suggested the urgent need for all stake holders to come together to ensure proper implementation of PV program. It is imperative for doctors to identify hospital drug and therapeutic committee, PV centres and pharmacist as the major source of drug safety information. Further interventional studies should be carried out in order to improve doctors' practice which the major aim of PV. It is recommended that PV program can be improve by establishing more ADRs monitoring centres, including PVstudy in medical, pharmacy and nursing students curriculum, involvement of other health care workers like physiotherapist, medical laboratory scientist and medical health record in ADRs reporting. Providing legal backing for ADRs reporting and public awareness campaign are also very essential.

Several articles reviewed have established that the major challenge in health care delivery services especially medicine related issues are ADRs; doctors knowledge, attitudes and practices were generally poor. Drug regulatory authorities, pharmaceutical companies, healthcare professionals and academia must be proactive in ADRs detection, documentation and reporting. It has become unconditionally essential for WHO, national and hospital based pharmacovigilance centres to provide the necessary materials for ADRs reporting and to make the reporting procedure easy across the tertiary, secondary and primary health care centres worldwide.

Limitation of the Study

In the course of review several obstacles were encountered but the main limiting factor in this study is that the findings cannot be generalised to all doctors. This is because many countries were not represent in the review, also some articles full text were not accessible. Lack of funding as well played a role because few articles came across needed to be purchased online. Another limitation is heterogeneous nature of some few surveys that differs from others in terms of study design.

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