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A Comperative Study on Health Sector in South Asia and Middle East Countries (Pharmacovigilance Insights)

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ABSTRACT

The market mesmerized innumerable count of medicine especially in south Asian countries as well in middle east, irrationalities on drug promotional activities, lack of proper monitoring in existing system, failure on to promote individual patient care through proper advices, In simple words, pharmacovigilance insights needs to be elaborated, because the activities related purely on drugs, and no one free from adverse effects. Even in the existing pharmacovigilance system were found under reporting on ADR amongst the health care providers, it needs to develop new dimensional view, and to create public awareness programs on this regards. The illustrated data collected 463 experts in health care field from Middle East and South Asian region, specially emphasized on introspective view of participants' on reporting adverse drug reaction and indirectly asked general population views on this regards. It needs to address pharmacovigilance system have major role to play improve quality of life, It is concluded that on reporting adverse drug reaction most of the people hesitated in existing facilities due to complicacy in procedure, factors like time constraints, lack awareness about this programs, But almost welcomed if the patient going to report adverse drug reaction directly. Simplicity in procedure is the major concern.

Keywords: Pharmacovigilance, ADR, Quality of Life

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INTRODUCTION

The term coined by the WHO as science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems. Why the importance needs to be raised, when the drug molecule introduced in the market, rarely trial have been conducted thousands of people, excluded especially in geriatric as well as pediatric population, even completely avoided both in pregnant and lactating women, Scaffidi et al (2016) disclosed the facts based on this studies found meagerly pregnancy related research reported, and neglected therapeutic uses of medicines in pregnant ladies especially in emergency situation and even lack of clinical evidences, leads to complication in later practice (teratogenicity). But the drugs in clinical practices followed in masses at varied doses for longer time instead of fixed dose conducted just few weeks as in clinical trial system. Here noted facts that once drugs launched in the market, it take longer time to withdraw from the market due to adverse drug reaction,

It needs special concern in geriatric population, increased medical needs as they grow older who were switched on poly pharmacy, prone to drug interaction and adverse drug reactions, together hindered patient's adherence, finally periled quality of patient's life. The term adverse drug reaction is in itself great virtue, WHO coined the terms as any response to a drug which is noxious, un intended and occurs as does used in man for prophylaxis and diagnosis or therapy of disease or modification of physiological function. Here definition itself excluded over accidental or intentional, under this purview eliminated the facts such as drug abuse, therapeutic failure and drug administration error. Bertram G. Katzung et al (2013) explained importance of Adverse drug reaction that occurs in susceptible patients due to intolerance, idiosyncrasy, or it may be immunologically mediated, most of them screened out in IND or in phase 1 to 3 clinical trial, before launched in the market. Here all adverse drug reaction (it may be serious or life threatening, disabling, or reasonably drug related or unexpected) must be reported on concerned ministry of health. Recently FDA disclosed that adverse drug reaction is the one of the fourth

causes leading to death, which were found higher than pulmonary diseases, AIDS, accidents and automobile deaths.

WHO enumerated majority of people still depends on traditional forms of medicines especially both in undeveloped and developing countries. But the situation maneuvered by cooperate lobbies especially in Asian countries.Bchav SS (2015) reviewed 318 articles on utilization studies on drugs, counted on irrational prescription, enlightened needs for monitoring system, remedial solution to counteract this problem still in confused facts. R Purushotham Naidu (2013) peer reviewed studies highlighted on current market flooded with drugs, which day to day increasing, here aggressive marketing technology partially encouraged mass consumption of drugs and producing environmental wastages. Regulating authorities needs to take precautionary measures to curtail on disease mongering situation, and implement legislative policies.

Lisha J,J (2012) studies conducted in tertiary care hospitals in UAE revealed that meagerly reporting ADR, the clinician were found willing to participate on ADR monitoring system, however pharmacovigilance insights were found still in infancy. Similar studies found by Subramaniyan (2016) conducted in India, highlighted "the importance of pharmacovigilance system" well known things on part of nurses and doctors, however studies revealed that practically they were found hesitated to report ADR on existing system. Mohamed N Al-Narifi (2015) gives prominence to report adverse drug reaction based on his study, generally physician welcomed to report ADR, but averted because of legal consequences and dissuaded due to attitude of concerned staff (pharmacist). The fruitfulness can achieved through by ensuring inter professional coordination between different professional groups working in health care field. Prashansa Agarwal(2014) highlighted importance of pharmacovigilance system in Drug discovery and development process, the subjects involved scrutinizing submission reports on adverse drug events in new drug development process, and should establish independent drug safety monitoring boards, the concerning bodies responsible for onto present summaries on serious adverse events, periodic monitoring on drugs used for chronic disease and disorders, and overall activities related to beneficial effects of drugs, weighed on risks involved on this subject matter. It gives comprehensive view on risk management plan (RMP), Fatima Suleman (2010), illustrated view on importance of pharmacovigilance system especially concerned responsibility of drug manufactures, drug regulating authorities, and in public health programs, clinical institutions, academic researchers, health care providers, as well in media, and on part of large consumers. Based on this study, author postulated lack of understanding what should do on reporting ADR and other minor things like time constraints, and heavy works loads on paper, it also advocated that pharmacist have major role to play on monitoring existing pharmacovigilance system.

METHODOLGY

As the studies focus on health care providers, professional commitment, attitudes towards practicing, people concerned expectations as well as contributing factors on ethical dilemma, and also dialectical peculiarities were noticed. The research based on direct personal contact and also online reply by the respondents. For the justification, it used specific research tools, "questionnaire and interview guide" to study survey, point out that in qualitative and quantitative in nature, in fact questionnaire at large and interview guide at lesser extent to gather exhaustively bigger information in all 463 samples (physician – 179, Dentist 43, pharmacist 66, nurses 45, Researcher 52, professors-66) considered on this part of studies.

In the survey design, the most important facts to design standardized questionnaire, it free from personal bias, initially data collection done by observing on consumer's attitude, concerned general perception whole community in health care system, the researcher spend time in Dubai (UAE), Sohar, Muscat (Oman), in which large amount of international migrant met from the region of south Asia and middle east, and in south India, it takes four years and takes maximum efforts to reach in a conclusion. Here author not only closely inspected on attitude, and perception of people related on health promoting activities but also behavior of shoppers, and health care providers and other intermediate agencies (representatives, consultant agencies), systematic approach done throughout this studies to carry out functioning on this research studies which attributed in quantitative and in qualitative terms.

Sample techniques

For this study, simple stratified random sampling techniques as well as direct personal approach concerned through questionnaire, In this study researcher bottom out both primary and secondary data, the research survey limited only a few of the members distributed in wild geographic area. There are 463 respondents are chosen using random sample techniques, in which lottery method used for the selection of respondents.

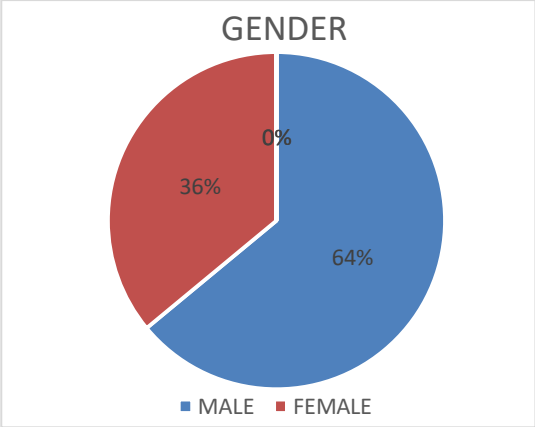
Here questionnaire designed closed one, here participants can mark any one of the option based on his/hers presumption, opinion on conventional practice of adverse drug reporting system, revealed introspective views and shared personal experiences based on his/hers clinical experiences, also dictated suggestive methods in counterpart on general population on reporting adverse drug reaction.

Time Dimension

The present studies were cross sectional one, as the nature of studies it have limitation on to conduct longitudinal research, repeated research articles relevant to topic published in different areas partially implicated failure on to implementation of health policy, without suggesting any remedial solution, data collection for this research studies carried over eleven months from expert members under this subject consideration in south Asia (India, Pakistan, Bangladesh and, Nepal) middle east countries (Egypt, turkey, Saudi, Oman, UAE, Iran, Iraq, Jordan).

DATA ANALYSIS:

Analysis classification of Data (Demographic Profiles)



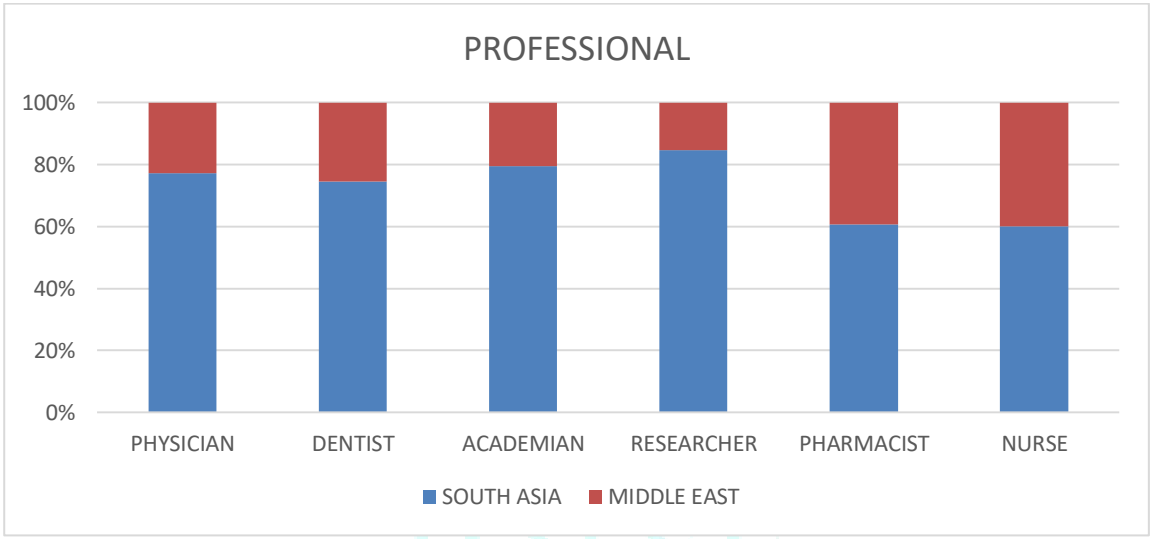
Demographic data profile in this research data interpreted, in certain extent it have crucial role to play based on subject studies, the analysis of diagram represented a total of 463 participant in which 296 participants were found male, and remaining 167 respondents were found female, the weightage given almost same for both sex (male/female)

Analysis classification of Data (Profession)

the subjects related on health care, almost all section of the societies who served in clinical field considered on this subjects, here priority given to the physician because of all role on this relevant field subjugated (accustomed in their clinical practice), by them. Even these studies under consideration education of participants, which reflected on this studies many factors like quality of participants, behavior of respondents, research competencies, and innovative capabilities.

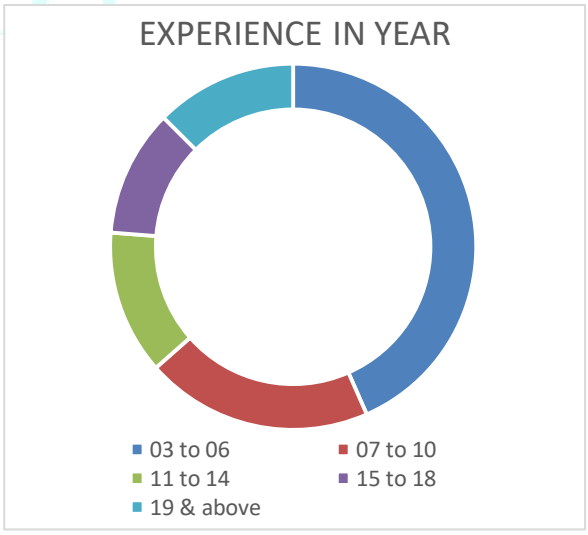
The analysis of above data represented different stake holders in health care field like physician, dentist, professors, researcher, pharmacist, nurses. In which overall 179 physician in the region of South Asia (138) and counterpart Middle East countries (41).Dentist being participated on this research studies a total of 43 from south Asian region (32), and one from Middle East found eleven participants.

And a total 78 highly experienced medical professors worked in familiar institutes around the globe, from the south Asian region (62), and one counterpart from Middle East countries (16), and a total of 62 well expert researches practicing in clinical field, from South Asian countries (44), from Middle East countries (8), and pharmacist who were well known things based on his clinical exposure, A total of 66 pharmacist participated on this studies from south Asian region (40) and one from Middle East (26), one of the major mediator in clinical field like 45 nurses participated on this studies from the region of south Asia (27), counterpart from Middle East countries (18).

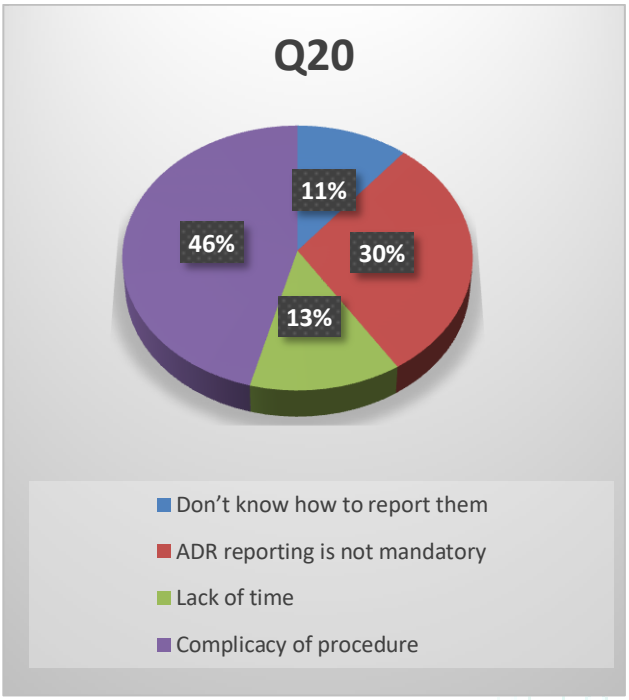


The above table illustrated on experience of health care providers in their clinical practices. Initially a total of 520 participants responded on this research studies, through online survey conducted by using Google forms (admaero2017@gmail.com, admaero2000@gmail.com, admaero2018@gmail.com,) and on by offline service through by personal approach. However 57 participants rejected due to incomplete data, and on by below three years experiences found. Based on subjects considered importance of experience in clinical fields' minimum of three years

Finally selected a total of 463 participants to those whom experience between 3 to 6 years found (201+43.19%), between 7 to 10 years (93+20.08%), between to 11 to 14 (59+12.74%), between 15 to 19(52+11.23%), between 20 and above (58+12.52%)

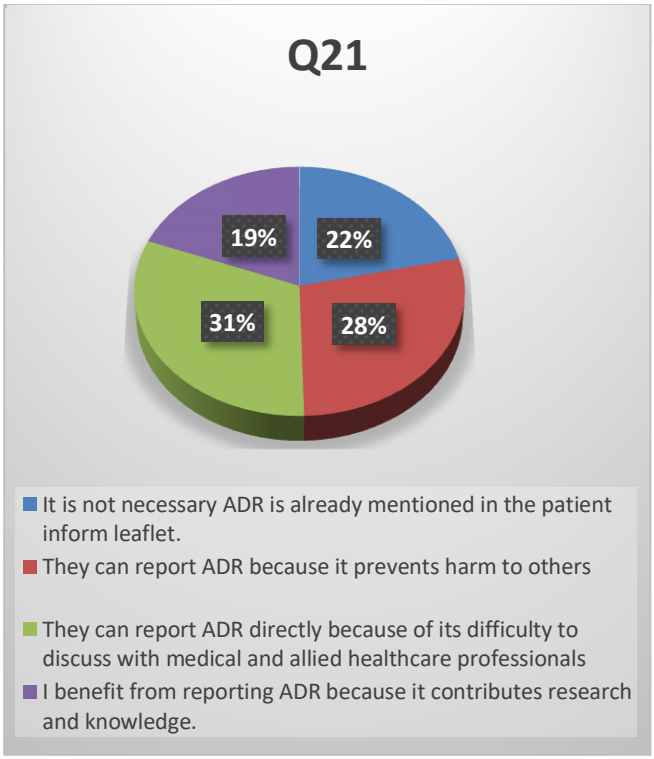


Analysis of classification of Data (HCP's Introspective view on ADR - Reporting) How do you know report adverse drug reaction?



The above picture show introspective view of health care professionals on reporting adverse drug reaction on their clinical findings such as don't know how to report them (50+10.9%), ADR reporting is not mandatory (137+29.9%), lack of time (61+13.3%), nearly half of the participants commented through this statement "complicacy of procedure (210+45.9%)" primarily needs to be addressed, and five participants withdrawn to comment on this statement.

Analysis of classification of Data (General view on ADR - Reporting), How is likely that you recommend to the patient, if he/she is going to report ADR directly?



The above picture depicted on (if once the ADR reporting system encouraged and implemented for the public) how can maintain true validity, and general view of health care providers on relevant question, the statement made "It is not necessary ADR is already mentioned in the patient inform leaflet" marked (99+21.4%), and one second statement "they can report ADR because it prevents harms to others" (130+28.1%), and one third statement almost one third of the population assured "They can report ADR directly because of its difficulty to discuss with medical and allied healthcare professionals" (145+31.4%) and one fourth option "I benefit from reporting ADR because it contributes research and knowledge" opted meagerly 88 participants found valid percentage 19, out of 463 participants, one person not made any comment on them.

RESULTS

The data shows significant difference whether health care professionals ideally placed, on to spot adverse drug reactions and to play an important role in the long term monitoring commonly prescribed drugs, final statement shows introspective view on adverse drug reaction monitoring system by the health care providers, the parameters selected based on literature reviews, Don't know how to report them, ADR reporting is not mandatory, lack of time, and complicacy of procedures, here nearly half of the participants agreed on terms of complicacy in procedure, and one third of participants agreed in terms of ADR reporting is not mandatory, and one sixth participants agreed due to lack of time, remaining ten percentages of participants statement made don't know how to report them.

Here under consideration on spontaneous reporting system, illustrated in the next statement "How is likely that you recommend to the patient, if he/she is going to report ADR directly?" responses were made like It is not necessary ADR is already mentioned in the patient inform leaflet, They can report ADR because it prevents harm to others, They can report ADR directly because of its difficulty to discuss with medical and allied healthcare professionals, I benefit from reporting ADR because it contributes research and knowledge. Here more than one third of participants opined "they can report ADR directly because of difficulty to discuss with medical and allied health care providers" it may be due to previous statement made due to lack of time, or here patient were direct victim, he/she can gives more accurate description, once they have suffered. Nearly one third of participants agreed on the second statement "patient can report ADR because it prevents harms to others" partially suggested, importance on encouraging ADR reporting system amongst the public. Nearly one fifth of the participants found dedicated personalities commented through this statement "I benefit from reporting ADR because it contributes research and knowledge."

DISCUSSION

The subjects under consideration on spontaneous reporting system, the similar statement made by Mireille (2010), needs for encouragement to report adverse drug reaction spontaneously, here statistical data monitored especially on long term used drugs, briefed on this statement "How is likely that you recommend to the patient, if he/she is going to report ADR directly?" responses were made like one "It is not necessary ADR is already mentioned in the patient inform leaflet, They can report ADR because it prevents harm to others, They can report ADR directly because of its difficulty to discuss with medical and allied healthcare professionals, I benefit from reporting ADR because it contributes research and knowledge". Here more than one third of participants opined "they can report ADR directly because, it is difficult to discuss with medical and allied health care providers" it may be due to lack of time on part

of physician found, who were engaged in busy schedule. Here patient were direct victim, he/she can gives more accurate description, once they have suffered. Nearly one third of participants agreed on the second statement "patient can report ADR because it prevents harms to others" partially suggested, importance on encouraging ADR reporting system amongst the public. N Shiva Krishna (2016) opined pragmatic methods to report ADR reporting system in hospital system, however spontaneous reporting system have wide concern, usually health care providers hesitated due to uncertainty about drug causing ADR, here this problem can solved by designing suitable software with help of statistical tool, it can verified on commonly encountered drug effects. It needs to awareness programs amongst the people, it benefited whole community as one recommended by Mangala S (2013), Kishor B. Rathod (2015) have conducted studies in rural areas in India. The above view also supported by the Mohammed Alshaka (2010), Khan MA (2014),proposed integration of technology through interconnectivity regionally as well as one with internationally (like MADRAC- in Malaysia), The studies focused in developing countries suggested that institutional level reporting ADR system should be changed because of enthusiasm on stakeholders increased, it should promoted consumer awareness programs in general population.

By these studies nearly one fifth of the participants found dedicated personalities commented through this statement "I benefit from reporting ADR because it contributes research and knowledge" Inez Rebeoro Vaz (2016) stated that out of 3865 articles reviewed in 29 different projects hinted that (from which 24 percentage ADR reported by the patient, three fourth reported by the health care professionals, here electronic media provides valuable information gives aggregated percentage on ADR. Christine M. Thorp (2008) in earlier publication inscribed role of health care professionals on to report adverse drug reaction especially commonly used one in long terms. As professionals, they should be able to advise patient and in needy cases refer to them on to other experts in health care field.

REFERENCES

1. Christine M. Thorp (2008), "Pharmacology and Health Care Professionals: Pharmacology for the Health Care Professions".*ISBN-13: 978-0470510179.*
2. Fatima Suleman (2010), Pharmacovigilance Who Is Responsible And Why Should We Care South African Pharmaceutical Journal 77(9), 56-58.
3. Mohammed Ahmed Alshakka (2010.) The Importance of the Consumer Pharmacovigilance System in Developing Countries: *A Case of Malaysia. Journal of Clinical and Diagnostic Research.* 4: 2929-2935.
4. Mireille Gony (2010), Improving Adverse Drug Reaction Reporting in Hospitals Drug Saf; 33 (5).
5. Lisha JJ, Mohammed A (2012).Reporting of Adverse Drug Reaction: An exploratory study among nurses in a teaching hospital in Ajman, UAE." *DARU Journal of Pharmaceutical Sciences: 20*(44).
6. Bertram G. Katzung, Susan B. Masters, Anthony J. Trevor Et Al (2013)."Introduction of Therapeutics "Basic & Clinical Pharmacology, 11th Edition
7. R Purushotham Naidu (2013). Causality Assessment: A Brief Insight In To Practices In Pharmaceutical Industry Volume Perspectives In Clinical Research 4(4):233-236.
8. Prashansa Agarwal (2014) Drug Discovery and Development: An Insight In To Pharmacovigilance Journal of Pharmacovigilance, 2(1)
9. Khan MA (2014), Pharmacovigilance in India: A Need Indeed, Journal of Pharmacovigilance J Pharmacovigilance, 2(2).
10. Khan MA (2014), Pharmacovigilance in India: A Need Indeed, Journal of Pharmacovigilance J Pharmacovigilance, 2(2).
11. Banchav Ss (2015) Systematic Review of Drug Utilization Studies & the Use of The Drug Classification System In The WHO-SEARO Region Indian Journal Of Medical Research: 120-129.
12. K. Lakshmi Surekha* , N. Shiva Krishna (2016) Monitoring of Adverse Drug Relations In Sai Srinivasa Hospital, Nalgonda Using Spontaneous Reporting Method, *World Journal Of Pharmacy And Pharmaceutical Sciences* 5(6): 1212-1223.
13. Scaffidi (2016), "The pregnant woman as a drug orphan: A Global Survey of Registered Clinical trials Pharmacological interventions in Pregnancy" *BJOG of International Journal of Obstetrics and Gynecology*: 124(1).
14. Inez Reberio Vaz (2016) How to promote adverse drug reaction reports using information system – a systematic review and Meta-analysis, *BMC Medical Informatics and Decision Making* 16(27).