ASSESSMENT OF THE KNOWLEDGE, ATTITUDE AND PRACTICES (KAP) OF PATIENTS TOWARDS REPORTING ADVERSE DRUG REACTIONS (ADRS)

A Dissertation submitted to

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Submitted by

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MAY – 2019

EVALUATION CERTIFICATE

This is to certify that this dissertation work entitled **"ASSESSMENT OF THE KNOWLEDGE, ATTITUDE AND PRACTICES (KAP) OF PATIENTS TOWARDS REPORTING ADVERSE DRUG REACTIONS (ADRS)"** is the Bonafied work carried out by **RAMSARAN. M.R, Register No: 261640712** under the guidance of **Dr. G. GOPI, M Pharm Ph. D.,** Professor and head, Department of Pharmacy Practice, for the partial fulfilment of the requirement of award for **Master of Pharmacy** and this is forwarded to **The Tamilnadu Dr. M.G.R Medical University, Chennai** during the academic year **2018 – 2019** has been evaluated on_____

Evaluators:

1. 2.

CERTIFICATES

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DECLARATION

I Hereby I declare that this thesis work **"ASSESSMENT OF THE KNOWLEDGE, ATTITUDE AND PRACTICES (KAP) OF PATIENTS TOWARDS REPORTING ADVERSE DRUG REACTIONS (ADRS)"**is the Bonafied work has been originally carried out by myself under the guidance and supervision of **Dr. G. GOPI M. Pharm., Ph.D.,** Assistant Professor and Head, Department of Pharmacy Practice, Padmavathi College of Pharmacy and Research Institute, Periyanahalli, Dharmapuri, Tamilnadu. I also declare that the matter embodied in its original and the same has not previously formed the basis for the award of any degree, diploma, associateship or fellowship of any other university or institution.

Place : Dharmapuri **RAMSARAN .M.R.**

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RAMSARAN .M.R

Reg. No: 261640712

DEDICATED TO

MY BELOVED FAMILY,

TEACHERS AND FRIENDS

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LIST OF ABBREVIATIONS

ADR	Adverse Drug Reaction
ADRAC	Australian Drug Reaction Advisory Committee
AE	Adverse Events
AERS	Adverse Event Reporting System
AME	Adverse Medicines Events
CARM	Centre for Adverse Reaction Monitoring
CDSCO	Central Drug Standard Control Organization
CEM	Cohort Event Monitoring
DMA	Danish Medicines Agency
ENT	Ear Nose and Throat
FDA	Food and Drug Administration
GPs	General Practitioners
IEC	Institutional Ethics Committee
IPC	Indian Pharmacopoeia Commission
KAP	Knowledge Attitude and Practice
Lareb	Netherland Pharmacovigilance Programme
MADRAC	Malaysian Drug Advisory
MHRA	Medicines Healthcare Regulatory
MPA	Medical Product Agency
NCC	National Coordination Centre
OBG	Obstetrics and Gynecology
OPD	Out Patient Department

PvPI	Pharmacovigilance Programme of India
SOC	System Organ Class
SPCs	Summary of Product Characteristics
SPSS	Statistical Package for Social Science
SSRIs	Selective Serotonin Reuptake Inhibitors
STD	Sexually Transmitted Disease
TGAs	Therapeutic Goods Administration
TSR	Targeted Spontaneous Reporting
UK	United Kingdom
UMC	Uppsala Monitoring Centre
US	United States
WHO	World Health Organization
WHO-ART	World Health Organization-Adverse Reaction Terminology

INTRODUCTION

Adverse drug reactions are the inevitable risks associated with use of drugs. Adverse drug reactions can increase the unnecessary human sufferings, increase the cost of the treatment and increase the morbidity and mortality[1].Vigilant assessments on adverse drug reactions are very much essential for the early identification and the development of preventive strategies. Various studies have shown that most of the Adverse drug reactions are preventable with proper precautions and preventive strategies taken during the initiation of drug therapy,[2] in order to take these precautions and preventive strategies proper knowledge about the adverse drug reactions and its mechanisms , predisposing factors ,risk factors, risk populations are absolutely essential. This type of information are only accessible from the previous reports and therefore reporting of observed suspected adverse drug reactions by healthcare professionals to the national agencies is very much needed for the development of a drug safety data bank, in each country. The reporting culture of adverse drug reactions was initiated in 1960's.[3] Based upon the frequency of reports obtained from different parts of the world many drugs were withdrawn from the markets, new reactions were added to drug labels, use of particular drugs are restricted in particular populations and some precautionary warnings are advised in risk populations. Though the adverse drug reactions reporting system exist in the world since 50 years the complete safety profile of a drug molecules are very difficult to establish since some rare and long term adverse drug reactions are very difficult to detect[4].

Clinical trials are inadequate to establish the complete safety profiles of the drug since these trials are conducted in a selected number of patients for a small

period of time and also the special populations are generally excluded from the clinical trials[5].But once the drugs are approved for the marketing these drugs are widely used in all types of populations to treat their specific health problems[6].Even though different methods are available for reporting adverse drug reactions in the post marketing phase, spontaneous reporting systems, is the commonly used method because of its simplicity and is more economic.[7] In this method all the health care professionals are encouraged to report the suspected adverse drug reactions in their clinical practice. But under reporting is very high due to the lack of time, awareness about ADR reporting, and less importance on adverse drug reactions reporting culture[8, 9].

The world health organisation initiated an international drug monitoring programme to monitor the safety of drugs and safeguard the population in 1968 after the thalidomide disaster[3].This programme always encourages the health care professionals to report the adverse drug reactions to the respective national pharmacovigilance centres. Each country has its own national pharmacovigilance programmes to ensure the safe use of medicines in their populations. Various healthcare professionals like doctors, pharmacists and nurses are authorised to report adverse drug reactions to the national pharmacovigilance programmes[10] .Reporting of these adverse drug reactions always depends upon the knowledge attitude and practice of healthcare professionals toward adverse drug reactions reporting. In recent years in order to overcome the problem of under reporting, international drug monitoring programme and the national pharmacovigilance programmes have initiated the consumer reporting as patients directly experience the adverse events with their medications. The concept of consumer reporting was originated

inNetherland pharmacovigilance system and is well executed and functioning there[11, 12].There are some evidences published on usefulness of patients reporting ADRs. Observation in a study suggests that Patients' descriptions of suspected adverse drug reactions to SSRIs clearly identified some symptoms which health professionals were unable to describe correctly in their ADR reports [13,14,15,16].

Patient reports are recorded by The Netherlands Pharmacovigilance Centre (Lareb) via its website since 2003. Finding of a study conducted in Netherlands, suggests that compared to health professional reports,Patient reports were more likely to be about serious ADRs [11]. When it was reported to Lareb authorities about 'the first experience with patient reports in the Netherlands, shows that the completeness of patient reports does not differ from physicians' reports[12].This suggest the importance of patient reports which are no less compared to physician reports.

Evidence from Netherlands study suggest that more than half of patients who reported to lareb in the first 6 months of the service was mainly due to physician's negligence towards patients expected unpleasant experiences with their medicines[12].

Many countries have allowed Patients to report ADRs directly since the beginning of their pharmacovigilance programmes, such as US, Canada, Australia and New Zealand[17].

Spontaneous reporting of ADR's are achieved through electronic forms, Telephone and Paper forms, in New Zealand operated by Centre for Adverse Reactions Monitoring [CARM] pharmacovigilance centre (http://carm.otago.ac.nz/start.asp) [18].

In Canada patients report an adverse drug reaction to the Canadian Vigilance Program at Health Canada. Reports are submitted to Health Canada by post, telephone, or via the internet. The Canada Vigilance Program electronically records submitted information to detect medication safety alerts[17].

In Australia patient reports are collected to assist in the post market monitoring of the safety of therapeutic goods under the Therapeutic Goods Act 1989 (the Act). All reports are assessed and entered into the Therapeutic Goods Administration's (TGA's) Australian Adverse Drug Reactions System (the ADRS)[17].

In a Analysis of adverse drug reactions reports received in the first year of Denmark's patient reporting scheme by Danish Medicines Agency (DMA) in which it is showed that the One-third of the suspected ADRs described were new to the Agency, i.e. they had not previously been described in the medicine's Summary of Product Characteristics (SPCs)[19].

Even though patient reporting cannot substitute other methods of pharmacovigilance it can complement them. There are some published evidences that patients may report adverse drug reactions more quickly [19, 20],though the possible duplication of reports and potential for multiple reporting of the same ADR cannot be ruled out.

Under reporting of adverse drug reactions are a major limitation in spontaneous reporting method. Even though voluntary reporting of adverse drug reactions by health care professionals is so active, under reporting is more common due to lack of knowledge, lack of interest and lack of training to health care

professionals towards adverse drug reactions reporting Evidences show that patients do not report all symptoms they suspected to be adverse drug reactions to their general practitioner (GPs) and GPs do not record all symptoms which may be reported to them' and there was significant under-reporting of adverse drug reactions to regulatory authorities[21,22].Lack of knowledge, lack of motivation etc. may be the reasons for under reporting of ADR among patient population. In a study published in 2007 it has been stated that in Canada, awareness among consumers that they could report adverse drug reactions, or the existence of the toll-free line for this purpose, was low[20, 23]. This suggests that mere existence of pharmacovigilance setup is not enough, evaluation of patient's knowledge and attitude regarding ADR reporting and reporting systems are also important.

In India the National pharmacovigilance program (NPP) was launched by the Ministry of Health and Family Welfare in July 2010, coordinated by The Indian Pharmacopoeia Commission and conducted by the Central Drugs Standard Control Organization (CDSCO), New Delhi. ADR reports received from the affiliated medical colleges were systematically recorded and forwarded to the national coordinating centre and the data base is created. The primary activity of coordinating centre involves the causality assessment. There after the reports are uploaded to WHO database (VIGIBASE) maintained by Uppsala monitoring centre. These ADR reports are subjected to further analysis for the identification of signals by the respective authorities at national and international level. And the identified signals are communicated to the respective regulatory bodies for the implementation of regulatory decisions[24].

The concept of Patient reporting adverse drug reactions was initiated in India on 2013 by the pharmacovigilance programme of India. Toll free numbers were launched for the patients to report the unpleasant effects experienced by the patients with the use of medicines[24].Various factors have been found to be responsible for underreporting of adverse drug reactions. These factors are mainly related with the knowledge and attitudes, as described by a model known as the "seven deadly sins" developed by Inman to explain the reason for under-reporting of adverse drug reactions[25]. Studies reveal that the patient sensitization towards adverse drug reactions reporting will lead to an increase in the number of reports[26].Specific studies are to be conducted in order to formulate strategies to improve patient reporting adverse drug reactions like patient sensitisation programmes, advertisements etc. For that purpose and for the overall improvement of spontaneous patient adverse drug reactions reporting and pharmacovigilance programme as a whole; it is imperative to know the existing knowledge, attitude and practice of patient's adverse drug reactions reporting.

The reporting ofadverse drug reactions by consumers always depends on the knowledge of patients about the importance of adverse drug reactions reporting. In order to develop a patient reporting culture in the country awareness programmes on adverse drug reactions should be conducted at different regional levels. The effort made by the national pharmacovigilance programmes to improve the awareness on consumer reporting is minimal. Dissemination of basic information on the importance of adverse drug reactions reporting through the media is one of the best methods to improve the awareness of public about adverse drug reactions reporting. The national pharmacovigilance programme has initiated such type of information

disseminations through media recently but the extent of information grasped by the public on this particular matter is questionable[27]. In order to ascertain the knowledge of patients on adverse drug reactions reporting and for the development of suitable promotional activities to improve the patient reporting of adverse drug reactions based on current knowledge status, studieson knowledge, assessment and practiceare very much essential.

Since two years, efforts were made at the study site to sensitize the patients towards reporting of ADRs[26].The findings were corroborating the usefulness of patient reporting the ADRs. However there are limited studies explained about patient's attitudes and behaviours towards ADR reporting. Thus this study was designed to assess the Knowledge, Attitudes and Practices (KAP) of patients towards ADRs reporting.

AIM AND OBJECTIVES

To assess the Knowledge, Attitude and Practices (KAP) of patients towards reporting Adverse Drug Reactions (ADRs).

LITERATURE REVIEW

1. Akram Ahmad, Isha Patel, Rajesh Balkrishnan, G. P. Mohanta, and P. K. Manna conducted a cross-sectional survey to assess the knowledge, attitude and practice of Indian pharmacists with the aim of exploring the pharmacists participation in ADR reporting system, identifying the reasons of under reporting and determining the possible steps to increase reporting rates. The survey was carried out using a pretested questionnaire comprising 33 questions (10 questions on knowledge, 6 on attitude, 7 on practice, 7 on future of ADR reporting in India and 3 on benefits of reporting ADRs.).Four questions were included at the beginning of the survey to collect demographic data like age, gender, highest qualification achieved and profession.The study was conducted, over a period of 3 months from May 2012 to July 2012. The pretested questionnaire was distributed to a total of 400 participants at their work place by Email and via social networking sites.The data were analyzed using the Statistical Package for Social Sciences (SPSS). The response rate of the survey was 67%. 95% responders were knowledgeable about ADRs. 90% participants had a positive attitude towards making ADRs reporting mandatory for practicing pharmacists. 87.5% participants were interested in participating in the National Pharmacovigilance program, in India. 47.5% respondents had observed ADRs in their practice, and 37% had reported it to the national pharmacovigilance center. 92% pharmacists believed reporting ADRs immensely helped in providing quality care to patients butonly 59% responders knew which organization was responsible for collecting and monitoring ADRs in India (CDSCO). The study reveals that the Indian pharmacists have a relatively better attitude towards ADR

reporting. However, they have a limited knowledge and practice with regard to ADR reporting and pharmacovigilance. Even though, pharmacists felt ADR monitoring to be essential and were willing to report, they are unaware about the NPP.Also pharmacists with higher qualifications such as a Pharm D have better KAP.[39]

2. Chetna K. Desai, GeethaIyer, Jigar Panchal, Samidh Shah, and R. K. Dikshit conducted a observational cross sectional questionnaire based study to evaluate the knowledge, attitude, and practices (KAP) regarding ADR reporting among prescribers at the Civil Hospital, Ahmedabad, and also to determine the causes of under-reporting of ADRs. The study was carried out by administering a KAP questionnaire, comprised of 15 questions (knowledge 6, attitude 5, and practice 4) to a total of 436 prescribers. The study enrolled prescribers (faculty consultants and postgraduate students or residents) from all specialties working in the hospital after obtaining an informed consent.Four questions were open ended, while the others were close ended. The questionnaires were assessed for their completeness and the type of responses regarding ADR reporting. Microsoft Excel worksheet (Microsoft Office 2007) and Chi Square test were used for statistical analysis. A total of 260 (61%) prescribers completed the questionnaire. The response rate of resident doctors (70.7%) was better than consultants (34.5%). ADR reporting was considered important by 97.3% of the respondents; primarily for improving patient safety (28.8%) and identifying new ADRs (24.6%).A majority of the respondents suggested that they would like to report serious ADRs (56%). However, only15% of the prescribers had reported ADRs previously. The reasons cited for this were lack of information on where

and how to report and also the lack of access to reporting forms. About 26.2% of the respondents opined that patients should also be allowed to report ADRs. The respondents were tested for their awareness about the ADR reporting centre. Twenty five of them were aware that ADRs could be reported to the Peripheral Centre, National Pharmacovigilance Program. Also under reporting and lack of knowledge about the reporting system became clearly evident by this study.[40]

3. RituPahuja, BirendraShrivastava, Pankaj Kumar Sharma, Kamal Kishore, Sandeep Mahajan and Radhika Sood conducted a 4 month cross-sectional study among patients hospitalized at All India Institute of Medical Sciences, New Delhi, to determine level of consumer or patient awareness on adverse drug reaction reporting system in India. The main outcome measured were the knowledge on side effect or adverse effect of medicines, proportion of respondents experienced adverse drug reactions, whether participants reported adverse drug reactions, their perception towards reporting adverse drug reactions, awareness on existing system of Pharmacovigilance in India and their preferable mode of reporting adverse drug reactions in future. The data collected was consolidated in Microsoft Excel spread sheet (2007) and was rechecked for completeness and accuracy. The questionnaire was analysed and percentage of response was determined. All statistical calculations were performed using Statistical Package for Social Science (SPSS) Version 20.0. Of the 1000 questionnaires distributed, only 770 completed questionnaires were returned giving the overall response rate as 77%. A majority (74%) of respondents were aware of adverse drug reactions, of which only 29.4% had experienced adverse drug reaction. Only 8.9% of respondents thought of reporting adverse drug

reactions while 40.6% considered it is important to report adverse. A poor awareness was observed among consumers (4%) on the existence of National Pharmacovigilance Programme in India. Over 78.5% of respondents feel consumers should be involved in ADR reporting and 86% were willing to report ADRs if they were provided with the convenient method of ADR reporting.The survey of awareness among patients at All India Institute of Medical Sciences concludes that consumer awareness towards ADR reporting was found to be low and could be improved. Introduction of educational interventional programs in hospitals, clinics and social media will create awareness and encourage consumers to report ADRs.[42]

4. JyotirmoyAdhikary, BasavarajBhandare, Adarsh. E and Satyanarayana .V conducted a cross sectional, questionnaire based study to assess the knowledge, attitude and practice (KAP) of ADR reporting among all the physicians in a tertiary care hospital over a period of 1 months.A questionnaire composed of 25 questions was distributed among all the physicians. For every Physician 30 minutes was given to fill up the questionnaire. . First part of the questionnaire was designed to get the demographic information of the participant physician. The remaining questions were designed to evaluate knowledge (10 questions), Attitude towards ADR reporting (5 questions), practice of adverse drug reaction reporting (7 questions), two open ended questions to know the encouraging and discouraging factors for ADR reporting, and finally one open ended question to get suggestions from physicians for improvement of ADR reporting.The questionnaire was distributed to 189 physicians, but only 122 returned the completed questionnaire giving a response rate of 70.9%.This study revealed

inadequate knowledge and poor practice of ADR reporting. Though 56.8%physician felt that they encountered ADRs, only 22.1% had actually ever reported an ADR. The most common reasons of under reporting were lack of time (34.5%), followed by lack of knowledge of reporting procedure (30.4%). But the physicians showed relatively better attitude towards ADR reporting. 95.0% felt that that ADR reporting is necessary and79.5%supported for establishing ADR monitoring center in every hospital. Also out of 122 respondents, **77** (63.1%) were postgraduates and 45 (36.8%) were undergraduates. Most of the physicians (95.9%)suggested thatcontinuous medical education and training on ADR reporting is necessary for overcoming the problem of underreporting of ADRs. The study results revealed the existence of underreporting of ADRs, but also the willingness of clinicians to be trained in ADR reporting and contributing to the pharmacovigilance programme[41].

5. Manoj Goyal, Monika Bansal, Shailesh Yadav, Varnika Grover and Preetkanwal conducted a questionnaire based studyto assess the knowledge, attitude and practices of the medical professionals towards the ADRs and their reporting in a teaching hospital. A structured validated questionnaire consisting of both open and closed ended questions was distributed to a total of 150 participants to collect the information after approval from the Institutional Ethics Committee (IEC).The study participants comprised of the medicalteachers working in various preclinical, Para clinical and clinical specialties of the institute. The response rate was 85%. Eighty percent of the respondents identified ADR as one of the major causes for mortality and morbidity in patients. ADR reporting was considered important by 87.5% respondents. More than 85% wrote that they did

not have enough knowledge about how to report an ADR. One hundred percent of the participants believed that there should be a system of ADRs reporting and monitoring in the institute. Alsoall of them opined that this kind of system would be useful for their patients and for them to be better healthcare professionals. Interestingly, all the respondents believed that if the teachers from allied streams (dental, nursing, physiotherapy, pharmacy) are sensitized and trained, it will be useful. This study reveals thatthere are gaps between knowledge and ADRs reporting among doctors working in a teaching hospital. These gaps need to be filled by improved training and awareness in pharmacovigilance at various levels of healthcare system.[43]

6. Cristiano Matos, Florence van Hunsel andJoão Joaquim conducted a 6-monthdescriptive-correlational survey from June to November 2013 in general adult consumers from a community pharmacy in Coimbra, Portugal,. The study was performed looking for consumers' attitudes and knowledge regarding spontaneous reporting and the reasons and opinions that can influence consumers' ADR underreporting, who used prescribed medicines or over-the-counter (OTC) drugs.This study provides an adequate exploration about what motivates consumers to report an ADR and the reasons and opinions about reporting.Attitudes and opinions were surveyed by personal interview in a closedanswer questionnaire using a Likert scale. Questionnaires from healthcare professionals or incomplete ones were not considered. Data were analyzed using descriptive statistics, chi-square ($\chi 2$) tests, and Spearman's correlation coefficients. One thousand eighty-four questionnaires were collected (response rate of 81.1 %) and 948 completed were selected for analysis. Of the

respondents, 44.1 % never heard about SNF. Younger people and those with a higher education were significantly more likely to be aware of SNF. Only one consumer had previously reported directly an ADR. Reporting ADRs indirectly through a healthcare professional (HCP) was preferred by 62.4 %. The main reasons for consumers reporting spontaneous ADR would be the severity of reactions (81.1 % agreed or strongly agreed) and worries about their situation (73.4 % agreed or strongly agreed). Only weak and moderate correlations were found between studied statements. The study reveals that consumers are more likely to do spontaneous report about severe reactions or if they are worried about the symptoms. Tailored and proactive information on ADR reporting and educational interventions on consumers could increase the number of reports from consumers in Portugal.[44]

7. Ravinandan A.P, Achuta. V, Vikram. K. Ramani[2], Santhosh Uttangi and Sushil Kumar Lconducted a prospective questionnaire-based study, to assess the knowledge, attitude, and practice of pharmacists towards adverse drug reaction (ADR) reporting, for a period of 6 months in different pharmacies of Davangere city. Among 145 pharmacists approached, 70.34% pharmacists agreed to give the consent for study. Majority of them were male (90.2%). First, the purpose of the study was explained to pharmacists and questionnairecomprising 15 multiple choice questions, where five questions belong to knowledge, five belongs to attitude and five related to practice was given to the subjects under study.The data collected from the pharmacists was documented and entered into Microsoft excel sheet for further analysis. Out of these respondents, only 14.7% pharmacists knew the correct definition of ADR. Only 31% were aware of

Pharmacovigilance Programme of India. 93.1% were positive about beneficial outcomes of ADR reporting and monitoring system and75.4% agreed that pharmacists could be the right person to assist physician in ADR reporting.However80.4% thought that they are not adequately trained in ADR reporting.Only 22 pharmacists were known about the types of ADRs and 44 about the predisposing factors, which contributes to their poor knowledge toward ADR aspects. The study reveals that majority of pharmacists have poor knowledge towards Pharmacovigilance aspects, but positive attitude towards ADR reporting, whereas attitude has been reported good compared to knowledge and practice.Also incorporation of ADR reporting concepts in education curriculum, training of pharmacists and voluntary participation of pharmacists in ADR reporting is very vital in safe guarding the public health.[45]

8. Het B. Upadhyaya, Mukeshkumar B. Vora, Jatin G. Nagar, and Pruthvish B. Patel conducted a cross-sectional questionnaires based study to evaluate the knowledge, attitude and practices (KAP) toward pharmacovigilance and ADRs of postgraduate students of Tertiary Care Hospital in Gujarat. . Postgraduate residents from different clinical departments were enrolled in the study. All the participants were first explained about the purpose of the study and then the questionnaires comprising of 22 questions were administered to a total of 101 participants. They were given 30 min to fill them and hand it back. Any clarification needed in understanding the questionnaires and additional time to filled form was provided.The KAP survey questionnaire was analyzed, question-wise and their percentage value was calculated with the help of Microsoft excel spread sheet in MS Office 2007. . Average 34.83% correct and 64.08% incorrect

knowledge about ADRs and pharmacovigilance and an average 90.76% students were agreed to reporting ADRs is necessary, mandatory and increased patient's safety. About 86.14% of postgraduate students agreed that lack of training of ADR reporting is challenging factor for implementing pharmacovigilance program in India.Only 7.92% of postgraduate doctors were reported ADR at institute or ADR reporting centre. This study reveals that postgraduate students have a better attitude toward reporting ADRs, but have lack of knowledge and poor practices of ADRs. The majority of postgraduate students were felt ADR reporting and monitoring is very important, but few had ever reported ADRs because of lack of sensitization and knowledge of pharmacovigilance and ADR. The findings of the study suggest that there is need for continuous education and sensitization regarding pharmacovigilance and ADR reporting system for residents and improving the ongoing pharmacovigilance activities in the hospital.[46]

9. Nilesh Arjun Torwane, SudhirHongal, Abhishek Gouraha, EshaniSaxena and Kalpesh Chavanconducted a 2 months cross-sectional questionnaire survey with an aim of assessing the knowledge, attitude and practice (KAP) related to pharmacovigilance among the healthcare professionals in a teaching hospital located in Central India region. A total of 392 questionnaire comprising 18 close-ended questions along with questions to assess the demographic details of the subjects was distributed among the healthcare professionals. The questions were categorized into four categories as knowledge related questions containing five questions on definition and purpose of pharmacovigilance, responsibility of reporting ADRs, knowledge of National Pharmacovigilance Programme, and

regulatory body responsible for monitoring ADRs.There were four attitude-related questionson the necessity of reporting ADRs, teaching of pharmacovigilance, prevention of ADR, and opinion about ADR monitoring center and eight practice related questions onexperience of ADRs, report to pharmacovigilance center, ADR reporting form, training to report ADRs, reporting of serious adverse event, identification of rare ADRs, methods to monitor ADRs of new drug, presence of Pharmacovigilance Committee in Institute.. Finally the last question to determine the reasons for underreporting, ie, factors discouraging from reporting ADRs. It was found that only 38.01% healthcare professionals comprising medical, nursing and dental professionals were aware regarding the existence of pharmacovigilance program of India where as 75.51% health-care professionals agreed that reporting of ADR is necessary. While only 40.56% healthcare professionals felt that ADR monitoring centre should be established in every hospital. Similarly, very few healthcare professionals, that is, 6.12% have ever reported ADR to pharmacovigilance centre. The results of our study indicate that the majorityof the healthcare professionals had a poor knowledge and attitude about pharmacovigilance. There was a huge gap between the ADR experienced, and ADR reported by the healthcare professionals especially among dentist and nursing staff.[47]

10. WelelawNechoMulatu and AlemayehuWorkuconducted an Institutional based cross sectional study to assess the knowledge, attitude and practice of health professionals towards an adverse drug reaction reporting and factors associated with reporting in Amhara region. This study was conducted for a period of six months. 708 participants were selected for the study using a two stage cluster

sampling technique. That is a pretested self-administered questionnaire for data collection and an in-depth interview to collect qualitative data. The questioner comprised 35 items, eight on demographic characteristics and general information on the reporting system, 11 items on knowledge, 10 on attitude and 6 on practice towards ADR reporting. The subjects under study includes physicians (16.2 %), nurses (68.8%) and pharmacy personnel (15%).Multivariate binary logistic regression was used for the statistical analysis. It was found that none of the respondents mentioned the national ADR reporting guideline as their source of information on ADR reporting. Based on the overall knowledge score, about two thirds (65.8%) of the respondents had insufficient knowledge on the ADR reporting system. The majority of respondents (95.4%) strongly agreed or agreed that reporting ADR is the duty of health professionals. Whereas 87.2% of the respondents strongly agreed or agreed that reporting adverse drug reactions is important to identify relatively safe drugs. A very small proportion of respondents (16.2%) had ever reported ADR they encountered during their professional practice. Also less than half of the respondents (38.1%) had the experience of noting the ADR they encountered on their clinical records. This study revealed that even though majority of health professionals have positive attitude towards ADR reporting, reporting among health professionals is low. This could be due to low level of knowledge and awareness among health professionals towards ADR reporting.Another important finding of this study is that health professional who participated in any ADR related training are about 2 times more likely to report compared with none trained ones.[48]

11. G R Pullagura, R Adepu, Pranav V B Raju, P Rohith, U R Rakshith and Justin K conducted a 6 month prospective observational study to evaluate the efficacy of patient reporting of suspected ADRs with ambulatory patients in a South Indian tertiary care teaching hospital. Patients receiving medicines in outpatient Medicine department were explained about safe usage of their medication and were motivated to report telephonically to the investigators in case of any unpleasant experiences with their medicines. On receipt of the call, details about the event were collected and identified. All the identified ADRs were assessed for time temporal relation, causality (WHO causality assessment scale, Naranjo's scale, Karch&Lasgna's scale), Severity (modified Hartwig and Siegel's scale) and predictability & preventability(Schumock and Thornton scale). Further an investigation was also done to assess the quality of report and barriers in reporting ADRs by patients. Based on the information obtained, the ADR(s) were coded and groupedunder the System organ class (SOC) affected using the WHO Adverse Reactions Terminology (WHO-ART).Descriptive statistics, T-test and Chi-Square test were applied to analyze the data. Among the 1125 enrolled patients, 128 patients called back to report 95 ADRs [8.44%]. More number of reports were received from female patients (57%) compared to males (43%). Highest number of reports were received from patients in age group of 40-60 (40%) and from graduates (38.8%). Majority ADRs experienced were belonged to GI disorders (35.78%) and Skin & Appendages (23.10%). Quality of patient reporting was found to be similar with physicians [T-test (0.986)]. Among the patients who have reported the ADR□s, majority of them (65) reported to have recovered from the ADR, however outcomes were not known in 9 patients and ADRs found to be continuing at the time of follow up in 21

patients.The study reveals that the patient sensitization towards ADR reporting has shown an increased the number of reports[26].

12. Florence van Hunsel, Christine van der Welle, Anneke Passier, Eugène van PuijenbroekandKees van Grootheest conducted a study to quantify the reasons and opinions of patients who reported adverse drug reactions (ADRs) in the Netherlands to a pharmacovigilance centre.A web-based questionnaire developed from the data, from interviews investigating patients' motives for reporting ADRs, was sent to 1370patients who had previously reported an ADR to a pharmacovigilance centre. The questionnaire comprised of a list of all categories of quotes from an earlier study which were rephrased to statements. Thestatements were divided into 'Reasons' and 'Opinions'. The questionnaire also addressed a number of demographic aspects including age, gender, level of education etc. The web-based survey was first tested in a small group of testers and subsequent sent to the selected e-mail addresses. After two weeks a reminder was sent to all non-responders. The data were analysed using descriptive statistics, $\chi 2$ tests to detect significant differences in motives and opinion and Spearman's correlation coefficients to measure possible relationships between one or more statements. The response rate was 76.5% after one reminder.The main reasons for patients to report ADRs were to share their experiences (89% agreed or strongly agreed), the severity of the reaction (86% agreed or strongly agreed to the statement), worries about their own situation (63.2%agreed or strongly agreed) and the fact the ADR was not mentioned in the patient information leaflet (57.6% agreed or strongly agreed). Of the patient-responders, 93.8% shared the opinion that reporting an ADR can preventharm to other

people, 97.9% believed that reporting contributes to research and knowledge, 90.7% stated that they felt responsible for reporting an ADR and 92.5% stated that they will report a possible ADR once again in the future. The patients report ADRs for various reasons, of which the most important are a severe ADR, wanting to share experiences, worry about the ADR in a personal context and the ADR not being mentioned in the patient information leaflet. The highlevel of response to the questionnaire shows that patients are involved when it comes to ADRs and that they are also willing to share their motivations for and opinions mabout thereporting of ADRs with a pharmacovigilance centre.This study reveals that it is the attitude of the healthcare professionals which made them report the ADRs directly to the pharmacovigilance centre. Also the patients had multiple motives for reporting such as preventing harm to other patients, making the ADR publicly known, increasing medical knowledge and wanting to improve the patient information leaflet.[49]

13. V. Lokesh Reddy, S.K. Javeed Pasha, Dr.MohanrajRathinaveluandDr. Y. Padmanabha Reddy conducted aprospective knowledge attitude practice (KAP) questionnaire study of 6 month duration to assess the awareness of Pharmacovigilance and ADR reporting, and also to evaluate the impact of an educational intervention among Pharmacy students in South India. A validated self-administered (KAP) Knowledge, attitude, perception survey questionnaire was administered to a total of 225 participants.The study criteria included students of M.Pharm(Pharmaceutics, Pharmacology & Analysis Departments), Pharm.D, both regular(IV, V, and VI) and post baccalaureate (PB), and final year students of B.Pharm. An interactive educational intervention was designed

for all participants of pre-KAP questionnaire survey and the impact of effectiveness of educational intervention among the pharmacy students was evaluated by means of post-KAP questionnaire survey.The KAP questionnaire consisted of 30 questions out of which 20 questions related to basic knowledge and information about pharmacovigilance, 05 questions related to student's attitude, and remaining 05 questions related to perception regarding identification of ADR and reporting nature.The pairedt-test and chi-square test (to compare the difference in correctness for each question) in GraphPadInStat was used for statistical calculation. The overall response rates between pre intervention and post intervention was statistically significant (P< 0.001) shows effectiveness of educational intervention for improving awareness of pharmacovigilance and ADR reporting among the participants. The study among the pharmacy students (UG, PG and Pharm.D) showed an overall response rate of 90%. This study concluded that an educational intervention can increase awareness of pharmacovigilance among the participants and incorporate this gained knowledge of pharmacovigilance for opting career and routine clinical practice.[50]

14. WajihaIffat, Sadia Shakeeka, SaimaNaseem, Shehla Imam and Marvi Khan conducted a study to evaluate the knowledge, attitude and perception of adverse drug reaction reporting among the medical and dental students. This transversal study was conducted from March till Aug 2013 by adopting a pre validated questionnaire distributed to senior medical and dental students in different medical universities of Karachi. The pre validated questionnaire comprising of 31 questions (knowledge 15 and attitude 16) and also questions to acquire the

demographics of the students, information about their attitude and knowledge towards ADR reporting was distributed to a total of 530 students. Descriptive statistics were used to demonstrate students' demographic information and their response to the questionnaire items. Pearson's chi-squared test was executed to evaluate the association of gender, institution and professional year of students with their response.Out of 650 survey questionnaires, only 531 were returned back in useable form. The study showed that 88.13% of the students have the knowledge of ADRs and 82.67% considered that reporting of ADRs to pharmaceutical company and Ministry of Health is necessary. Majority of the students (70.80%) agreed that the ADR reporting system in Pakistan needs further improvement. Few respondents (27.49%) have information about the availability of DRAP form for reporting of ADR. Approximately, 59.88% of the students considered that ADR reporting should be included in course contents,53.29% considered ADR reporting is a professional obligation and 52.73% have the confidence to discuss ADR with their colleagues More than 55% of the students did not know the term pharmacovigilance. Only 9.79% and 8.85% of the students know where to report and how to report ADRs respectively.The survey based study greatly emphasized on creating awareness through regular training, re-enforcing of guide lines and promoting the reporting of ADRs amongst health care professionals ensuing in improving the quality of pharmacovigilance in their future practices.[51]

15. D N Bateman, G L Sanders, and M D Rawlins conducted a survey to assess the attitudes and knowledge of doctors in the Northern Region in reporting of adverse drug reactions using a postal questionnaire to all doctors in two,

previously identified, high reporting and two low reporting health districts. Comparisons were made of the attitudes and knowledge within professional groups (GPs, Consultants and Junior Hospital Doctors), and between the amalgamated doctor groups.1181 of 1600 doctors answered the questionnaire giving a respond rate of 74%. Despite being selected on the basis of previous adverse drug reaction reporting patterns, GPs and consultants from high and low reporting districts perceived they had sent a similar number of ADR reports, and there were few differences in opinion and attitude within these two groups. Most differences within doctor groups were found for junior doctors, with those from low reporting districts indicating they had sent significantly less yellow cards than those in high reporting districts. There were also significant differences in the estimates junior doctors made with a frequency of adverse drug reactions, the existing documentation on adverse drug reactions, and the purposes of the adverse reaction scheme. 4. General Practitioners in low reporting areas stated they wrote more prescriptions, consultants spent more time in clinical contact and junior doctors did both, all of which suggest different workloads may effect reporting of adverse drug reactions. When given clinical examples, or asked about the CSMs black triangle scheme, all the doctor groups performed poorly. The number of reports stated as being sent increased with time from qualification for 10 years, then seemed to plateau.[52]

16. ZeyanaS. Al Bimani, Shah Alam Khan, Pratap David conducted a study to assess the diabetes mellitus related knowledge attitude and practices (KAP) of Omani adult patients. Diabetic patients were recruited using the convenient sampling method from Outpatient diabetes clinic of various primary health care

centers and private hospitals in Muscat region of Sultanate of Oman. KAP of patients who agreed to participate in the study were assessed by administering a self designed questionnaire containing 15 close ended or multiple choice type questions. Face-to face interviews of the patients were conducted. The collected data were analyzed by SPSS software.106 patients with Type 2 Diabetes Mellitus participated in this study (42 men and 64 women). Majority of them were; married (83%), above 50 years (64.2%), on oral hypoglycemic (56.6%), having family history of diabetes (66%). The mean ± SD knowledge score of participants was found to be 4.92 ± 1.22 out of maximum possible score of 8. In conclusion Omani patients seemed aware and displayed satisfactory diabetes knowledge and good practices except adherence to regular exercise.[53]

17. Eland IA, Belton KJ, Van Grootheest AC, Meiners AP, Rawlins MD and Stricker BH conducted a survey to assess attitudes towards reporting of ADRs and to study which types of ADRs are mostly reported. A questionnaire seeking reasons for nonreporting was sent to a random sample of 10% of medical practitioners in The Netherlands in October 1997. After 6 weeks, a reminder was sent to those who had not responded. One thousand four hundred and forty two(73%) questionnaires were returned, of which 94% were complete. The percentage of GPs (51%) which had ever reported an ADR to the national reporting centre was significantly higher than the percentage of specialists (35%), who reported more often to the pharmaceutical industry (34% vs 48%). 86% of GPs, 72% of surgical specialists and 81% of medical specialists had ever diagnosed an ADR, which they had not reported. Uncertainty as to whether the reaction was caused by a drug (72%), the ADR being trivial (75%) or too well

known (93%) were the most important reasons for not reporting. 18% were not aware of the need to report ADRs, 22% did not know how to report ADRs, 38% did not have enough time, 36% thought that reporting was too bureaucratic and only 26% of Dutch physicians knew which ADRs to report. A serious ADR, an unlabelled ADR, an ADR to a new drug, history of reporting of one or more ADRs, and specialty were all independently associated with reporting of 16 hypothetical ADRs. Surgical and medical specialists tended to report less often than GPs. There is a considerable degree of underreporting, which might partly be explained by lack of knowledge and misconceptions about spontaneous reporting of adverse drug reactions.[54]

18. Al-Maskari F, El-Sadig M, Al-Kaabi JM, Afandi B, Nagelkerke.N conducted a study to evaluate the Knowledge, Attitude and Practices of Diabetic Patients in the United Arab Emirates. A random sample of 575 Diabetes Mellitus patients was selected from diabetes outpatient's clinics of Tawam and Al-Ain hospitals in Al-Ain city (UAE) during 2006–2007, and their knowledge attitude and practice were assessed using a validated questionnaire. The KAP contained socio-demographic data that include gender, age, occupation, marital status, educational level, income, family history of diabetes, duration of diabetes and medications. The questionnaire was translated into Arabic separately by two bilingual translators. There were 23 knowledge questions related to definitions, symptoms, causes and complications of DM. Attitudes were assessed using a series of questions on positive and/or negative attitudes towards having the disease. Patients' practices were assessed using questions on self-care, dietary modification, compliance with medications, weight control, self-monitoring of

blood sugar, and regular follow up. Data were analyzed using SPSS version. One-way ANOVA and Student t- test were used to compare groups. Correlation between variables was assessed using Pearson correlation coefficients. Thirty-one percent of patients had poor knowledge of diabetes. Seventy-two had negative attitudes towards having the disease and 57% had HbA1c levels reflecting poor glycemic control. Only 17% reported having adequate blood sugar control, while 10% admitted non-compliance with their medications. The study showed low levels of diabetes awareness but positive attitudes towards the importance of Diabetes Mellitus care and satisfactory diabetes practices in the UAE.[55]

19. Sandeep Kumar Gupta, Roopa. P.Nayak, R. Shivaranjani, and Surendra Kumar Vidyarthi conducted a study to evaluate the knowledge, attitude, and practices (KAP) of the healthcare professionals about pharmacovigilance in Dhanalakshmi Srinivasan Medical College and Hospital (DSMCH), Tamil Nadu. The study was a cross-sectional questionnaire-based study. The study participants consisted of all the healthcare professionals (doctors, nurses, and pharmacists) who gave their informed consent and who were working at the hospital during the study period. KAP questionnaire was designed to assess the demographic details of the healthcare professionals, their knowledge of pharmacovigilance, attitudes towards pharmacovigilance, and their practice on ADR reporting. There were 20 questions in all (seven related to knowledge, four related to attitude, and eight related to practice). One question was asked to determine the reasons for under reporting. Pretesting of questionnaire was done on 20 randomly selected health professionals of the institute. One hundred and fifty pretested questionnaires

were distributed among the healthcare professionals and 101 responded. 62.4% healthcare workers gave correct response regarding the definition of pharmacovigilance. 75.2% of healthcare workers were aware regarding the existence of a National Pharmacovigilance Program of India. 69.3% healthcare professional agreed that ADR reporting is a professional obligation for them. Among the participants, 64.4% have experienced ADRs in patients, but only 22.8% have ever reported ADR to pharmacovigilance centre. Only 53.5% healthcare workers have been trained for reporting adverse reactions. But, 97% healthcare professionals agreed that reporting of ADR is necessary and 92.1% were of the view that pharmacovigilance should be taught in detail to healthcare professional. This study demonstrated that knowledge and attitude towards pharmacovigilance is gradually improving among healthcare professionals, but unfortunately the actual practice of ADR reporting is still deficient among them.[57]

20. Sourav Das Choudhury, Somak Kumar Das, AvijitHazra, conducted a study to assess knowledge, attitude, and practice regarding insulin use among diabetic patients in a tertiary care hospitals. Type 1 and 2 diabetic patients, aged 18 years and above, attending the Medicine/Endocrinology out-patient department or admitted as in-patients in three hospitals in and around Kolkata were enrolled. A pretested structured questionnaire comprising of 51 items was administered through face-to-face interview. Responses from 385 subjects were analyzed. Both higher educational and higher economic standards were associated with better understanding of insulin use. Longer duration of diabetes and its treatment (oral anti-diabetic drugs and insulin) were associated with better knowledge of

some parameters. Female subjects were less aware of HbA1C as a monitoring tool. Among current insulin users, 70% had never used a glucometer, only 27.33% carried simple carbohydrates for use in hypoglycaemic attacks, and 32% failed to rotate sites for insulin injection. In conclusion the patients had sufficient knowledge and practice regarding insulin use.[58]

21. Bäckström M, Mjörndal T, Dahlqvist R and NordkvistOlssonTconducted a study to investigate attitudes of general practitioners (GPs) and hospital physicians in Sweden towards spontaneous reporting of adverse drug reactions(ADRs). Two areas in the northern region of Sweden were selected for the study. A knowledge and attitude questionnaire followed by a reminder letter 2 weeks later was addressed to all GPs and hospital physicians in the study areas. The total response rate from the study areas was 748 of the 1274 questionnaires sentout (58.7%). Of those who responded, 236 were GPs, 433 were hospital physicians and 79 had other positions. Of the responders, 252 stated that they had never reported any ADR and 488 that they had reported at least once in their career. Issues that came out as important in the decision to report or not to report were whether the reaction was considered well known or not, the severity of the reaction, hesitance to report only on suspicion, lack of knowledge of existing rules, giving priority to other matters and lack of time to report ADRs. Only minor differences in these regards were observed between male and female physicians. This investigation reveals that the physicians in northern Sweden have a fairly good knowledge about the existing rules for reporting ADRs in Sweden. However, the attitudes leave room for considerable underreporting due to matters related mainly to the medical impact of the reaction and of reporting

it, but also to the scientific "paradox" of reporting only on suspicion and of course due to lack of time in the health care setting.[59]

22. P Subish, M Izham and P Mishra conducted a study to evaluate the knowledge attitude and practices on adverse drug reactions and pharmacovigilance among healthcare professionals in a Nepalese hospital. The study was carried out at MTH, a 700 bedded tertiary care hospital located in Western region of Nepal. Healthcare professionals were randomized and included in the study.10 percentage of the study population were included. Altogether a total of 24 healthcare professionals including 7 consultants/ doctors with a post graduate degree, 12 nurses, 2 pharmacists and 3 medical officers were included in the study. KAP questionnaires were used in the study, consisting of 25 questions.15 knowledge, 5 attitude and 5 practice questions. The filled KAP questionnaires were collected and was analyzed using descriptive statistics using the Microsoft excel spread sheet. The SPSS (version 9) package was used to calculate the Cronbach alpha value. The study identified the Knowledge attitude and practices of the healthcare professionals in MTH regarding ADR monitoring and pharmacovigilance. Overall the KAP scores were low.[60]

23. Jarernsiripornkul N, Krska J, Richards RM and Capps PA conducted a questionnaire based study on ‘Patient reporting of adverse drug reactions: useful information for pain management? The study was designed to compare reports of perceived adverse drug reactions (ADRs) obtained directly from patients taking tramadol to those found in clinical trials and two methods of postmarketing surveillance.A postal questionnaire was distributed to 1048 patients who had a prescription for tramadol dispensed over a 3month

period.Most (84%) of the 344 respondents reported at least one symptom perceived as an ADR to tramadol. Dry mouth, lightheadedness and constipation were most commonly reported. Almost half (48%) rated their most bothersome symptom as at least moderate and 43% cloed to have reported symptoms to their doctor. Perceived problems had led 38 respondents to stop taking tramadol. The 10 most frequently reported symptoms were all previously reported ADRs to tramadol. Although relatively minor, all 10 also appeared in reports to the UK Committee on the Safety of Medicines (CSM) and in prescription event monitoring. For many symptoms, the estimated range of frequency was in line with published reports, but considerably higher than that of postmarketing surveillance methods. Symptoms were reported by the majority of respondents and for many symptoms the frequency was high. Many patients did not report symptoms they perceived to be adverse effects to their doctor. The results indicate that patient perceptions of potential ADRs are relevant and should be an integral part of a pain management strategy.[9]

24. Jarernsiripornkul N, Krska J, Capps PA, Richards RM and Lee A conducted a questionnaire based study on ‘patient reporting of potential adverse drug reactions: a methodological study’. The study was carried out to develop a systematic generic method of enabling patients to report symptoms which they believe to be due to a particular prescribed drug. A piloted body system based questionnaire was distributed to patients registered with 79 medical practices in Grampian prescribed one of nine recently marketed 'black triangle' drugs. These comprised four antidepressants, three anti epileptics and two analgesics. This requested respondents to identify any symptoms experienced over the previous

year which they thought could be due to the 'black triangle' drug they had used. A sample of medical records was examined to compare symptoms recorded with those reported by patients. A classification system was developed for the study to enable the assessment of symptoms reported for their potential relationship to patients' drug therapy. All symptoms reported were classified, taking into account information provided by patients on their concomitant drugs and diseases. A specialist pharmacist independently reclassified a sample of the symptoms to validate the process. A 36.3% response rate was obtained (837/2307) with 742 respondents (88.6%) reporting at least one symptom. The median per patient was 6.0, with almost half (48.5%) reporting fewer than five symptoms. Most symptoms (71.0%) were classified as being probably or possibly related to the drugs studied. Agreement between researcher and specialist on the classification of 75.3ethi% of 716 symptoms was obtained (Kappa=0.563). Responses from patients prescribed antidepressant drugs were more likely to include symptoms potentially caused by these drugs (74.5% of all symptoms reported) than those from patients prescribed analgesics (67.4%) or anti epileptics (65.1%). Patients reporting large numbers of symptoms were more likely to report some which were classed as unlikely to be an ADR or unattributable. Of the 742 reporting symptoms in questionnaires, 402 (54.2%) claimed to have reported some or all of these to their doctor. Only 162 (22.6%) of 716 patient reported symptoms were documented in the primary care medical records of 103 patients prescribed tramadol or venlafaxine. Repondents were clearly willing to report symptoms, the majority of which were classed as possibly/probably related to the drugs studied. The results suggest that patients do not report all symptoms they suspect to be ADRs to their GP and that GPs do

not record all symptoms which may be reported to them. The method could help to identify problems which patients perceive as being related to their drug therapy and contribute to increased ADR reporting.[8]

25. Joseph O Fadare, Okezie O Enwere, AO Afolabi, BAZ Chedi and A Musa conducted a cross-sectional and questionnaire-based study involving mainly medical doctors, nurses and pharmacists working in different departments of the Aminu Kano Teaching Hospital. A total of 110 questionnaires were distributed to the respondents (60 doctors, 40 nurses, 10 pharmacists). The completion of the questionnaire by respondents was taken as their consent to participate in the study. Only 65 respondents filled and returned the questionnaire within the stipulated time frame, giving a response rate of about 59.1 %. The standard yellow reporting form for adverse drug reactions was only known to 35.9 % of the participating health care workers. Only 42.7 % of the respondents had ever reported an adverse drug reaction and the report was verbal in over 75 % of cases. Ignorance of the rules and procedures of reporting, lack of knowledge of the forms for reporting and which ADRs to report were some of the factors responsible for non-reporting of adverse drug reactions among respondents in the study. The study reveals thatadverse drug reaction reporting using the yellow card reporting scheme is low among health care workers (doctors, nurses and pharmacists) in Kano, Nigeria.[56]

METHODOLOGY

Study site:

The study was conducted at Krishnagiri Government District Head Quarters Hospital, which is a 350 bedded hospital and has one of the biggest critical and emergency facilities and Trauma care. The hospital cater to the healthcare needs of more than 10,000 outpatients and 2,500 inpatients every month. It consists of various departments including general medicine, surgery, paediatrics, pulmonology, cardiology, obstetrics and gynaecology (OBG), gastroenterology, neurology, urology, ophthalmology, nephrology, Ear Nose and Throat (ENT), Sexually Transmitted Disease (STD) and Radiology.

Study design:

This was a prospective questionnaire based study.

Study period:

The study was carried out for a period ofSix months from August 2018 to January 2019.

Study Criteria

Inclusion criteria:

- Patients visiting the OPD and receiving prescriptions for medicine from the outpatient department ofKrishnagiri Government District Head Quarters Hospital

- Patients aged above 18 years.

Exclusion criteria:

- Patients who are mentally challenged.
- Patients who are unwilling to participate.

Sources of data:

- Interviewing the Patients.

Ethical Committee approval:

The study was approved by the Ethical Committee of the Department of Pharmacy practice, Padmavathi college of Pharmacy and research institute.

Designing of KAP Questionnaire:

A suitable KAP (Knowledge, Attitude, Practices) questionnaire was prepared in English and was validated with the support of experts (2 clinical pharmacists, anexpert from National Pharmacovigilance Programme of India and another expert from Netherland Pharmacovigilance Programme [Lareb]). The validated questionnaire was pretested in a small group of patients' population.

The questionnaire comprised of 21 questions of which 9 questions were related to knowledge, 5 questions to attitude and the remaining 6 questions to practice of patients towards ADR reporting.The multiple choice questionnaire allowed the patients to choose an appropriate response from provided list of options.

Patient demographics details such as name, age, sex, education, profession and contact number were also recorded.

Computerization of KAP Questionnaire:

The KAP questionnaire designed for use in this study was computerized using Microsoft Excel 2010,for easy accessibility, retrieval and analysis of collected data.

Study Procedure:

Patients who met the study criteria were enrolled into the study after obtaining the informed consent.

The KAP questionnaire was distributedto the patients under study. Before filling the questionnaire, the patients were briefed about the purpose of the study and importance of filling it.

The patients were given sufficient time to fill the form and the research pharmacist were available to clarify any doubts during filling. Then the completed questionnaire were collected from the subjects for further analyses.

Finally the collected questionnaires were evaluated to assess the KAP of the patients towards ADR reporting using logistic regression analysis.

Data analysis:

Descriptive statistical analysis method was used to analyse the findings. The study subjects were grouped gender wise into male and female and their respective percentage proportion was calculated. Patients were also categorized based on age

group, literacy as well as professional status and the percentage proportion was calculated for all the required parameters. Chi square test was used to determine significant differences regarding the knowledge, attitude and practice of study subjects among different sex and also those belonging to different educational groups.

RESULTS

Demographic details of the Study population.

A total of 1500 patients satisfying the inclusion criteria were enrolled into the study. Following is the demographic details of the patients responded to the study questionnaire.

Majority patients were in the age of 21-40years (55.7%) followed 41-60years (30.7%). The average age of all the respondents was 37.5 years. About 54% of the respondents (814) were males and 41% of the respondents with graduation and above qualification. The literacy rate of males was more when compared to females [P=0.16]. The professional status of the respondents reveals that 28% are with employment. The complete details are shown in Table-1

TABLE-1 Demographic details of the enrolled patients

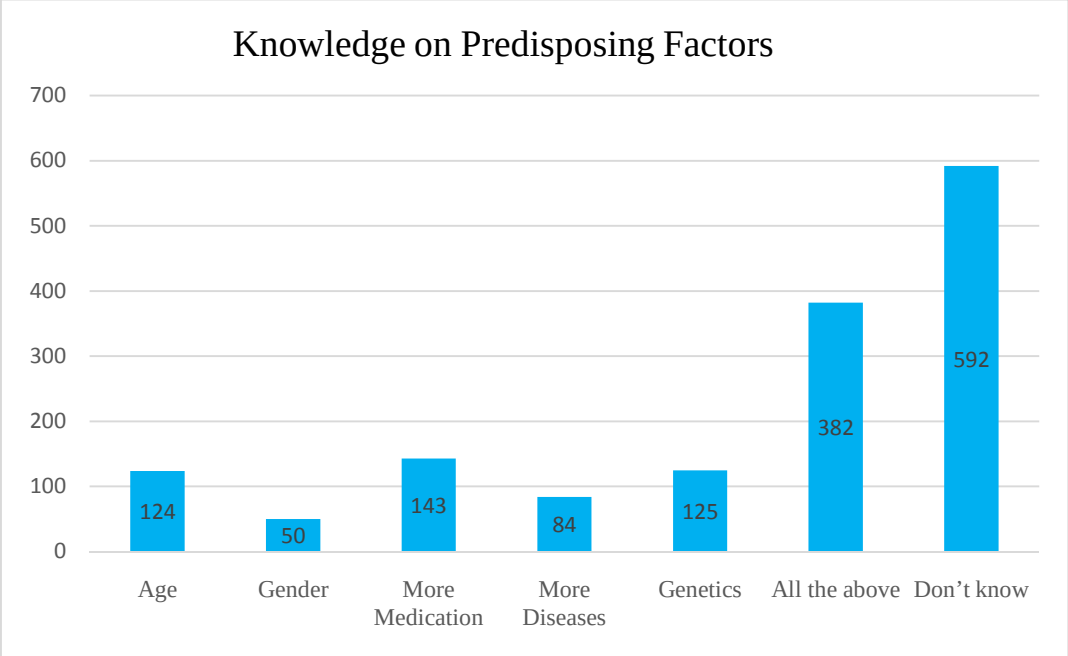
FEATURES	CATEGORY	NUMBER	PERCENTAGE (%)
AGE	**1-20**	**95**	**6.3**
	21 -40	**834**	**55.7**
	41-60	**461**	**30.7**
	61-80	**102**	**6.8**
	81-100	**8**	**0.5**
GENDER	**Male**	**814**	**54**
	Female	**686**	**46**
EDUCATION	**Primary School**	**153**	**10**
	Secondary school	**262**	**18**
	PUC	**469**	**31**
	Graduate and above	**616**	**41**
PROFESSION	**Employment**	**421**	**28**
	Business	**253**	**17**
	Profession	**220**	**14**
	Others	**606**	**41**

Assessment of Knowledge.

Among 1500 Patients responded to the interview,325(21.7%) patients told that they had experienced an unpleasant effect after using the medicines**.**Only 35(11%)patients has coined unpleasant effect as Adverse Drug reactions followed by 120 (37%) patients as side effects, 25(7.7%) as drug poisoning, 95(29%) as allergy reaction,40 (12.3%) as all the above and 10 (3%) patientsare unaware. Among the patients who termed the unpleasant event, as ADR, 24 patients were Graduates, and 8 patients were with PUC.

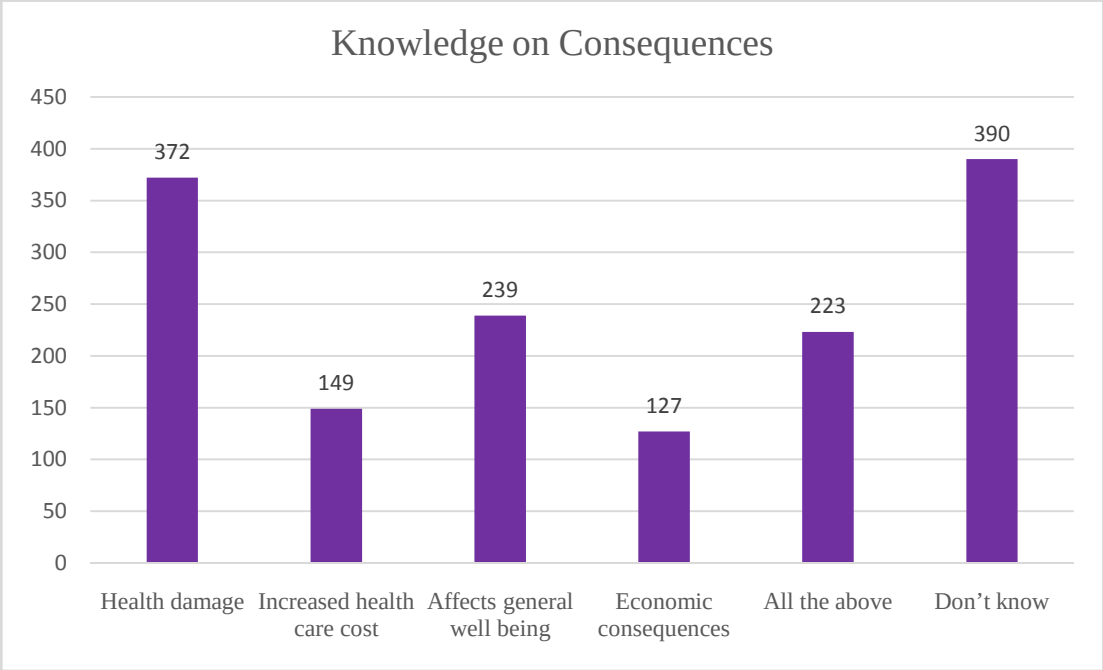
To the question of predisposing factors for the development of the unpleasant effects, 382 (25%) patients have given the correct answer.Among them 239 patients are with Graduation and above. 113 patients are with PUC pass, with Secondary school were 26, and with primary school were 4 patients. Details of patient's responses about predisposing factors were presented in Figure-1.

Figure-1 Knowledge of the patients about predisposing factors.



When the patients were asked regarding the consequences of the unpleasant effects 223 (15%) chose the correct answer and remaining 372 (25%) patientsmarked it ashealth damage, 149 (10%) increased costs, 239 (16%) affects general wellbeing, 127 (8%) Economic consequences and 390(26%) patients was not able to answer.

Figure-2 Knowledge of the patients about consequences of the unpleasant effects



Among these 223 patients, 117 are male and 106 are female patients. 146 patients are Graduates and above, 60 patients are with PUC pass, 12 secondary school and 5 patients' primary school. The details of the findings about knowledge on consequences are presented in figure-2. 1373 (91%) patients agreed that they would report to the doctors whenever they experience an unpleasant effects, followed by 25 (2%)patients said they report to nurse and 52(3.4%) patients said they report to pharmacists.

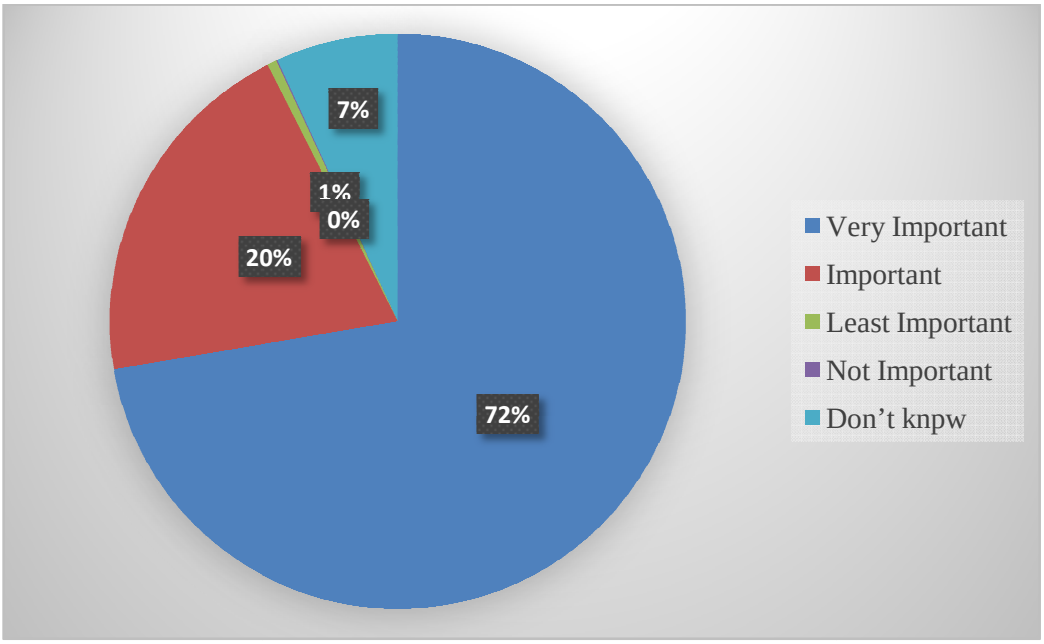
Only 148 (9.8%) of the responded patients told that they have heard about the agency that collects information about the unpleasant effects. Out of this 148 patients, 39% were correctly answered the agency as Pharmacovigilance Programme of India (PvPI). Among the patients who gave the correct answer, 45 were graduates and above, and 11 were PUC pass. Among them 90 were males and 58 were females.

Only 7.1% (107) of the patients were aware about the toll free number to report the unpleasant effects. Out of which 63 patients were graduate and above, 33 patients were PUC pass and 7 and 4 constitute secondary school and primary school pass respectively.

Assessment of Attitude.

Among the responded patients, 1390 (92.7%) patients said that they will report unpleasant effects that they have experienced. Out of which 771 were males and 619 were females. Out of these 1390 patients, 78%(1085) patients considered reporting is very important and it is their responsibility. About 21% of the patients responded that ADR reporting is important.

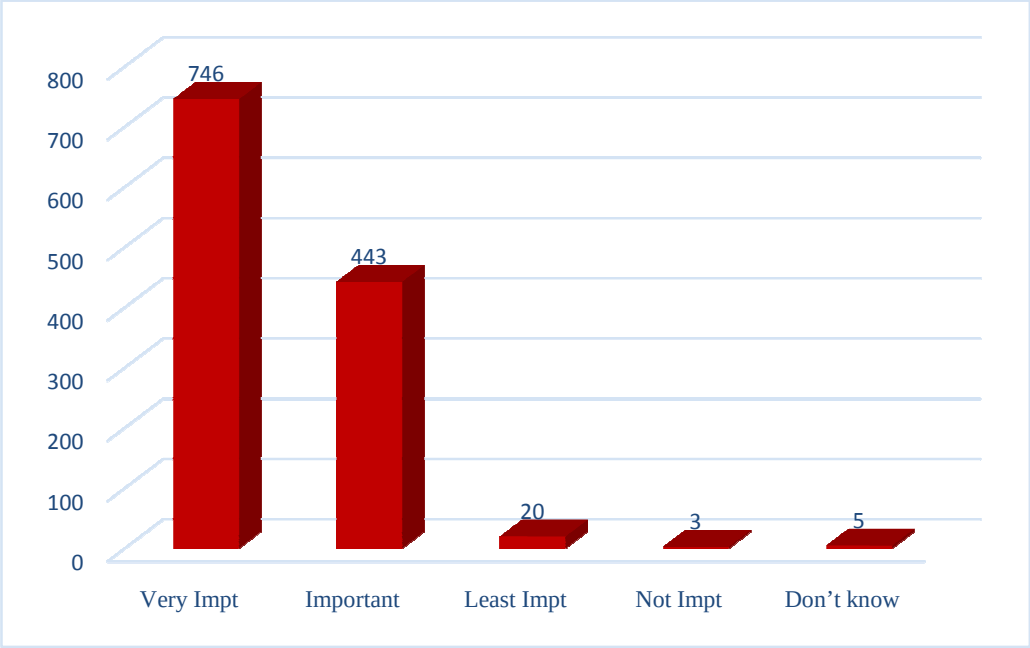
Figure-3 Attitude of the patient respondents towards ADR reporting.



Out of the 1085 patients who considered reporting is very important, 504 patients were with graduation and above. The findings are presented in figure-3.

When the patients were asked about any special knowledge required to report, 81% (1217) of the patients had agreed that they require special knowledge for reporting any unpleasant effects. Among them746 (61%) patients considered special knowledge is very important.Among 746 patients 376 are graduates and above 256 patients are with PUC qualification. The findings of patient's perception about ADR reporting are presented in figure-4.

Figure-4 Patient's perception about ADR reporting

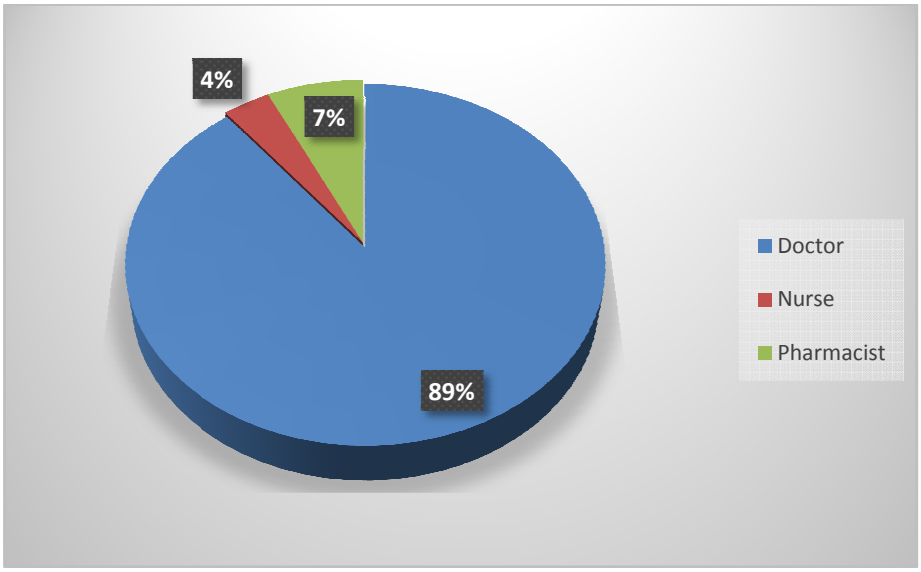


Among the respondedpatients,75% of patients haveagreed that reporting by patients is important whereas 752 (50%) patients strongly agreed and 39% (586)agreed about the patient's importance in reporting.

Assessment of Practice.

Among the 325 patients, who had experienced ADRs, 286 (88%) have saidthat they have reported them. Among the patients who reported ADRs, 171 were males and 115 were females.

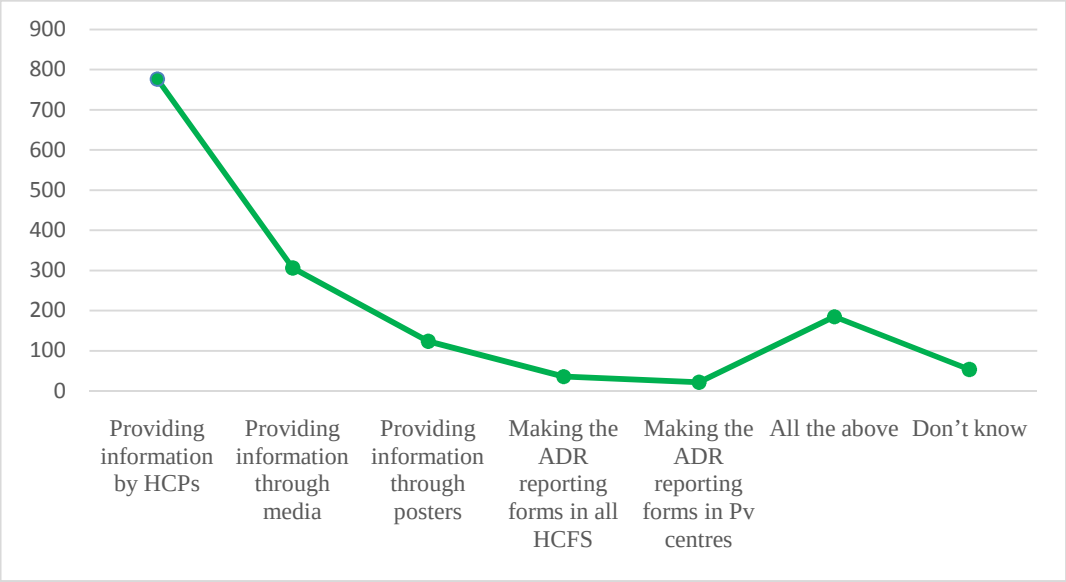
Figure-5 Assessment of ADR reporting practices.



When the patients were asked whether they would advise any of their family members experienced any unpleasant effects, for consulting the doctor, majority of the patients have agreed that they would. 830 patients expressed strongly agree and 33patients expressed agree.And when asked whether the patient would advise to stop the medications if his/her family members experienced any adverse effects, 33% persons have expressed strongly agree, 37% patients have expressed agree. The findings are presented in Figure-5.

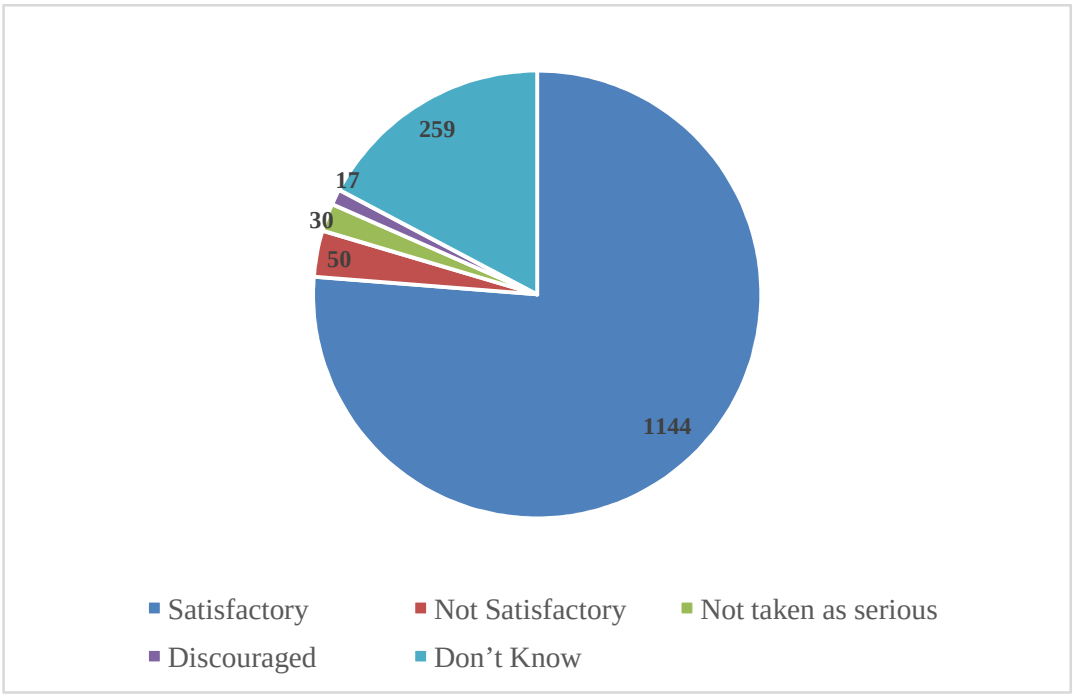
When asked about the preferred method that can help the patients to improve the reporting of unpleasant effects associated with the use of medications, majority of the patients have expressed that they prefer, the mode of information given by the health care professionals. The Findings are presented in figure-6.

Figure-6 Preferred Methods of ADR Reporting



When the patients were enquired about the feedback or reactions they got from Doctor/pharmacist when they reported abouttheir unpleasant effects , 76% described it as satisfactory, 3% not satisfactory, 2% not taken as serious and 1% discouraged in reporting. The findings are presented in figure-7.

Figure-7 Clinicians Feedback on patient's reporting.



DISCUSSION

Adverse drug reactions are an imperative public health crisis striking a substantial fiscal burden on the society and health-care systems[45]. In the beginning of Pharmacovigilance programme only the Health care professionals were authorized to report the suspected ADRs to the regulatory authorities. The new Pharmacovigilancelegislation allows even the consumers to report the unpleasant effects experienced by them with the drugs directly to the competent authorities in all European countries and in India. Consumer reporting is available in India since 1st august 2014 but the reports received by Pharmacovigilance programme of Indian (PvPI) is very less when compared to the consumers who experience the ADRs. Under reporting of ADR is very common among all the health care professionals. Consumer reporting could be anopportunity to reduce the under reporting. Patient contribution is still relatively a small percentage of total reports in India. Pharmacovigilance Programme of India has developed guidelines, reporting forms and toll free number for the consumers to report ADRs. The biggest concern on patient reporting of ADR is the quality of the reports. Studies from India and Netherland states that the reports made by the patients and health care professionals do not differ much; in terms of quality. Netherlands experience on patient reporting states that patient reports can be considered for the identification of new signals and rare ADRs. Hence patient reporting of ADRs play a major role in Pharmacovigilance to identify the new and rare ADRs.

In order to develop an efficient consumer reporting culture in each country, the awareness in ADRs reporting's and its importance should be improved among

the consumers. The extent and the quality of reports always depend on the basic knowledge and awareness on the importance of ADR reporting among the public. As per our knowledge there is no study to assess the knowledge, attitude and practice of consumers towards reporting of ADRs in India. Most of the Indian KAP studies on pharmacovigilance are focussed on health care professionals. Hence findings of the study are very important to further strengthening the consumer reporting culture in India in regional wise.

The study findings revealed that the patient's knowledge regarding the adverse drug reactions was found to be limited. The number of patients who knows about the consequences or predisposing factors of adverse drug reactions is found to be less. Patients with higher education are found to have more knowledge about the ADR reporting. And patients with better knowledge are found to be more willing to report. Shortcomings in the Indian pharmacovigilance programme strategies regarding patient reporting ADR was found as the number of people with knowledge of a dedicated toll free number for ADR reporting and even the existence of a pharmacovigilance agency was very less. Therefore better strategies have to be formulised by the pharmacovigilance programme of India, so as to equip the patients with adequate knowledge and exposure about ADR and ADR reporting mechanisms. Though the number of males correctly answering the knowledge related questions is more than females, gender wise there is no huge differences in knowledge level considering the total number of subjects enrolled.

In a study conducted in Netherlands it was found that patient wanted to have more information, as the information that patients receive from their physician or

pharmacist is not always sufficient and that in some cases, patient and health-care professional communication could be improved[1]. The same was found in our study also; as it was found that knowledge level in patients about ADRs were less. And it was also highlighted in our study that patient prefer more information from healthcare professionals.

In a study conducted in Portugal it was found that 55.9 % of respondents knows about the National Pharmacovigilance System (SNF) and 86.7% knows that it is possible to report an ADR, either to SNF directly or through a healthcare practitioner; these possibilities were learned mainly from practitioners and/or pharmacy.[43]But it was found that only less than 10 % of the subjects know about Pharmacovigilance Programme of India (PvPI), and toll free number for ADR reporting in our study.

In a study conducted on 1000 subjects representing general population (patients) vishing AIIMS hospital, New Delhi 74% of the respondents were aware what an ADR is, 73.3% considered only doctors are to be the right person among other HCPs to report ADRs, while very few 4% were aware on the existence of National Pharmacovigilance Programme in India. In a study conducted in UK ,awareness of the UK's Yellow Card Scheme for reporting was also found to be low as only 172 of 2028 respondents (8.5%) were aware of the scheme, and only three had used it[67].Whereas in our study it was found that of the 21.7% subjects who experienced unpleasant effects only 11% called it as ADR,and 91% considered doctor as the right person to report their ADRs to and of the 148 subjects (9.8%) who heard about an ADR collecting agency 39% has correctly named it as PvPI.The

findings could be attributed to the lack of knowledge among consumers on what ADRs to report, were to report and how to report.

The assessment of the attitude of patients towards adverse drug reactions reporting was found to be encouraging as an overwhelming majority of the enrolled subjects was willing to report any unpleasant effect experienced by them and not willing to take them for granted. And most of them considered the process of adverse drug reactions reporting as important too. ADR reporting is very important to protect the safety of Indian population. This suggest that with the right patient sensitisation and imparting knowledge regarding the ADR reporting process the patients ADR reporting programme can be a success as the patients have a largely positive attitude towards the same.

In a study conducted in Netherlands, it was shown that patients are very much involved when it comes to ADRs and that they are also willing to share their motivations for and opinions about the reporting of ADRs with a pharmacovigilance centre.It was also found in that study was90.7% stated that they felt responsible for reporting an ADR and 92.5% patients stated that they will report a possible ADR. Similar findings were found out in a study conducted in AIIMS New Delhi, as 40.6% of the study subjects considered it is important to report ADRs.[42]Our study also suggests the same as more than 90% patient consider ADR reporting as either important or very important and have a positive attitude towards ADR reporting.

During the course of the study, assessment of practice component of patent reporting ADR provided useful insights. It was found that in case of an adverse drug reaction experience, the number of patients who communicated the same with the

doctor is very high. Data of direct patient reports to PvPI agency is not available. This indicates that the patients are willing to report their unpleasant effects to doctors rather than to pharmacists or other healthcare professionals.Only a minimum number of subjects have ever reported their ADRs to a pharmacist or a nurse. Practice of reporting ADR to National Pharmacovigilance programme is not observed in the study population.

Improvements in this aspect, that is popularising the role of healthcare professionals other than doctor who is authorised to report ADRs to, among patients may be useful in making the patient ADR reporting all the more effective. Most of the patients demand that they require more information on ADRs reporting through healthcare professionals. This information will help them to improve the reporting culture. Other preferred source of information by the consumer includes posters, Medias and other healthcare facilities.

Study suggests the importance of healthcare professional's role in improving practice of patient reporting ADR. Encouragement from healthcare professionals is an important factor for improving patient reporting ADRs. Positive feedbacks from healthcare professionals always encourage the consumers to communicate ADRs to healthcare professionals. Most of the study population agreed that their healthcare professionals are encouraging them to communicate the ADRs during the consultation.

In a study conducted in Netherlands patients who reported non-serious ADRs were satisfied with a general acknowledgement letter as well as with a personalized feedback from healthcare professionals, sending a feedback to reporters is useful to

increase knowledge about ADRs, to build a relationship with the reporter and it may also influence the reporting rate positively[65].In our study also general satisfaction about the feedback from HCPs are positive.

In a study conducted in Portugal of the respondents, 57.6% had the perception that they had already suffered an ADR, although only one consumer had previously reported an ADR directly to National Pharmacovigilance System (SNF). Another two had reported through a healthcare practitioner[43].Whereas in our study more than 80% of the subjects have communicated their ADR experiences to the doctor, though the data of direct patient reporting to PvPI is not available.

In a study conducted ona sample of over 1000 subjects representing general population (patients) vishing AIIMS hospital, New Delhi,29.4% of the subjects experienced ADRs however, only few 8.9% thought of reporting it[42]. The study results were found to be lesser than with a similar UK study in which reporting rate of ADRs among consumers was found to be 23.5%[67]. In an another study conducted in Australia, among the respondents who had experienced a side effect, 84.6% reported the event to a health care professional, most often a general practitioner[66]. Whereas 21.7% of our study population has experienced ADRs and majority of them communicated the same to the doctors.

ADR reporting by patients can be improved by formulising new and innovative strategies. One of the methods is the educational intervention, which includes increasing the availability of ADR reporting cards on ward as well as encouraging to use web based reporting that can improve the reporting rate. Patient reporting can be increased by providing information about ADRs through

questionnaires, chart reviews and patient interviews[64]. Some studies suggest that Clinical Pharmacist intervention can increase reporting rates by improving the patients' knowledge regarding adverse drug reactions.

There are various strategies used to improve ADR reporting by the patients.

Spontaneous reporting

In all countries national PV systems rely heavily on spontaneous (or voluntary) reporting in which suspected adverse drug reactions (ADRs) are reported to a national coordinating centre by health professionals, manufacturers or directly by patients. Of all the sources of data for drug safety monitoring, the spontaneous reporting systems provide the highest volume of information at the lowest maintenance cost, and have proven their value in the early detection of patient safety issues related either to the products themselves or to their.

An important way to increase the reporting of ADRs is through the promotion of patient self-reporting. The benefits of this idea have been confirmed in different studies. Patient self-reporting has a complimentary role to play in increasing the level of ADR reporting in a developing country such as India. The most important function of spontaneous reporting systems is the early identification of signals and formulation of hypotheses, leading to further confirmatory investigations or sometimes regulatory warnings and changes of product information leaflets[7].

CONCLUSION

- At the end of the study the findings concludes that patients have a positive attitude towards ADR reporting, and the ADR reporting practices among the patient was also relatively high. Whereas shortcomings were found out in the knowledge levels of patient towards ADR and ADR reporting.

- The findings suggests that patients knowledge on ADRs and the practice of ADR reporting can be improved if the patients are adequately sensitised which will strengthen the ADR data to national pharmacovigilance programme.

LIMITATIONS

Limitations in verifying the authenticity of some of the claims made by the patients like whether reported the ADRs or not.

FUTURE DIRECTIONS

- To enhance the ADR reporting rate by the patients by increasing the awareness level of the patients through improved information dissipation by health care professionals, and through print and electronic media

- To encourage patient to directly report suspected ADRs to PvPI through toll-free number (1800-180-3024)

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DEPARTMENT OF PHARMACY PRACTICE

Knowledge, Attitude and Practises (KAP) of Patients towards Adverse Drug Reactions Reporting – A Study.

Demographic details of the patient

1. Name: ……..

2. Gender: Male/Female

3. Age: …….

4. Education: Primary school /Secondary school / PUC/ Graduate and above

5. Profession: Employment/ Business/ Profession

I am informed about the study by investigators and I fully understood about the study and wilfully I am participating in this study without any coercion.

Signature of the Patient

Date:

Place:

KAP Questionnaire

Note: Please answer all the questions with tick mark (√)

1) Have you used or are you using any medications?

☐ Yes ☐ No

2) If yes, did you experience any unpleasant effect with any of your medicines?

☐ Yes ☐ No

3) If yes, which of the following medical term is used for such unpleasant effects?

☐ Side effects
☐ Adverse Drug Reactions
☐ Drug Poisoning
☐ Allergy Reactions
☐ All the above

4) Have you ever been told by your health care professional that which of the following causes may contribute to the development of such unpleasant effects?

☐ Age
☐ Gender
☐ More number of medications
☐ More diseases
☐ Family predisposition (Genetics)
☐ All the above

5) What do you think are the consequences of medication related reactions could be?

☐ Health damages
☐ Increased health care costs
☐ Affects a person's general well being
☐ Economic consequences for instance by not being able to work
☐ All the above

6) When you suffer from a medication related side effect, whom do you consider to contact regarding
the problem .

- ☐ Doctor
- ☐ Nurse
- ☐ Pharmacists
- ☐ Anybody of the health care professionals

7) Have you ever heard about an agency which collects the information about medication related unpleasantness?

☐ Yes ☐ No

8) If yes, what is the name of such agency in India?

- ☐ Pharmacovigilance Programme of India (PvPI)
- ☐ Pharmacy council of India (PCI)
- ☐ Indian Pharmaceutical Association (IPA)
- ☐ Drug Control Department

9) Are you aware about any toll free number for reporting unpleasant effects caused by drugs in India?

☐ Yes ☐ No

10) If you experience a side effect, would you report it to your health care professional?

☐ Yes ☐ No

11) If yes, how important it is for you to report such experience?

- ☐ Very Important
- ☐ Important
- ☐ Least Important
- ☐ Not important

12) Do you think you need to have special knowledge and skills to report such unpleasant effects?

☐ Yes ☐ No

13) If yes, how important you consider to have the necessary knowledge and skills to report?

- ☐ Very Important
- ☐ Important
- ☐ Least Important
- ☐ Not Important

14) Do you feel that reporting of such unpleasant effects by patients is important?

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

15) Have you ever reported any such unpleasant effect to your doctor or pharmacists?

☐ Yes ☐ No

16) If yes, to whom did you report?

- ☐ Doctor
- ☐ Pharmacist
- ☐ Nurse
- ☐ None

17) Whenever any of my family members experience any unpleasant effect with medicine I, advise them to contact their Health Care Professionals, to discuss this issue.

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

18) Whenever any of my family members experience any unpleasant effect with medicine I, advise them to stop using the medicines.

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

19) Which of the following do you think can help the patients to improve the reporting of unpleasant effects associated with the use of medications?

☐ Providing information on reporting of adverse drug reaction by Health Care Professionals

☐ Providing information on reporting of adverse drug reactions through posters

☐ Providing information on reporting of adverse drug reactions through media like TV, radio, internet.

☐ Making the adverse drug reaction reporting form for consumers available in all health care facilities

☐ Making the Adverse drug reaction reporting forms available on the website of the Pharmacovigilance Centers

☐ All the above.

20) If you informed about your side effects to any doctor/pharmacists, what is there feeling/feedbacks?

☐ Satisfactory and encouraged for further reporting

☐ Not-satisfactory

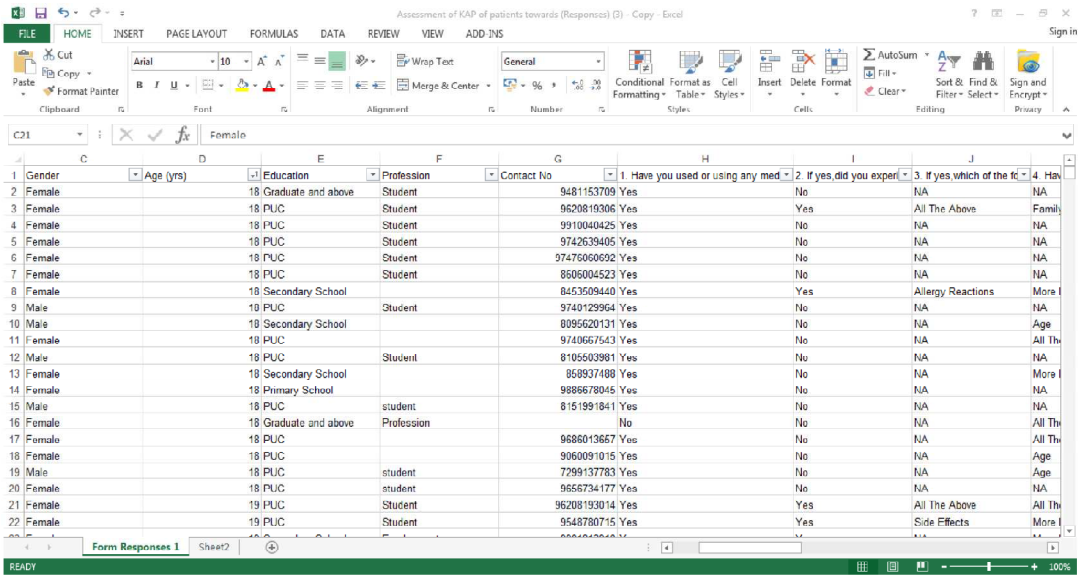
☐ Discouraged in reporting

☐ Not taken it as serious

21) Any specific suggestions:

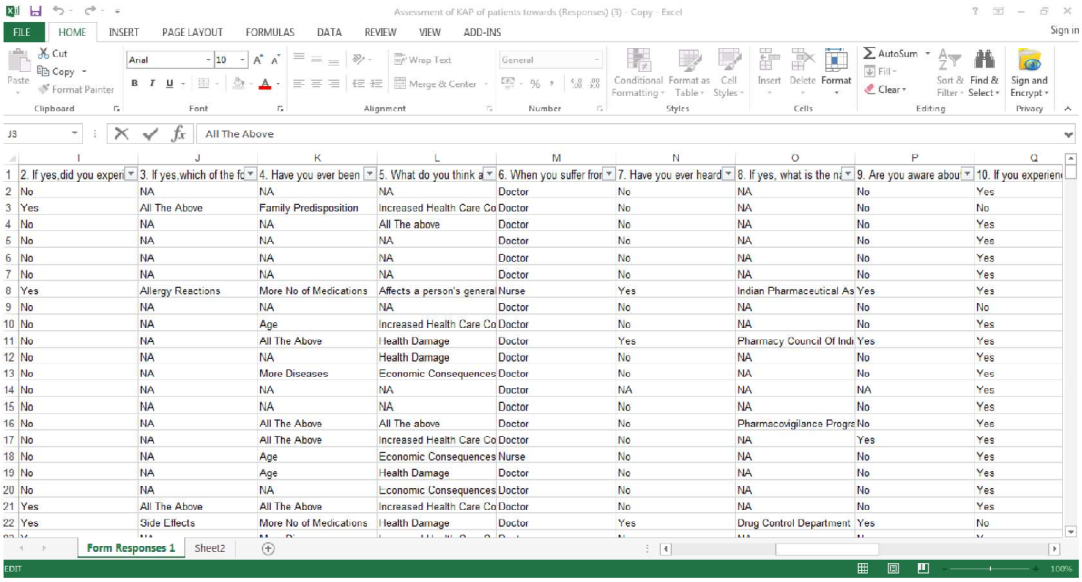
_____

_____



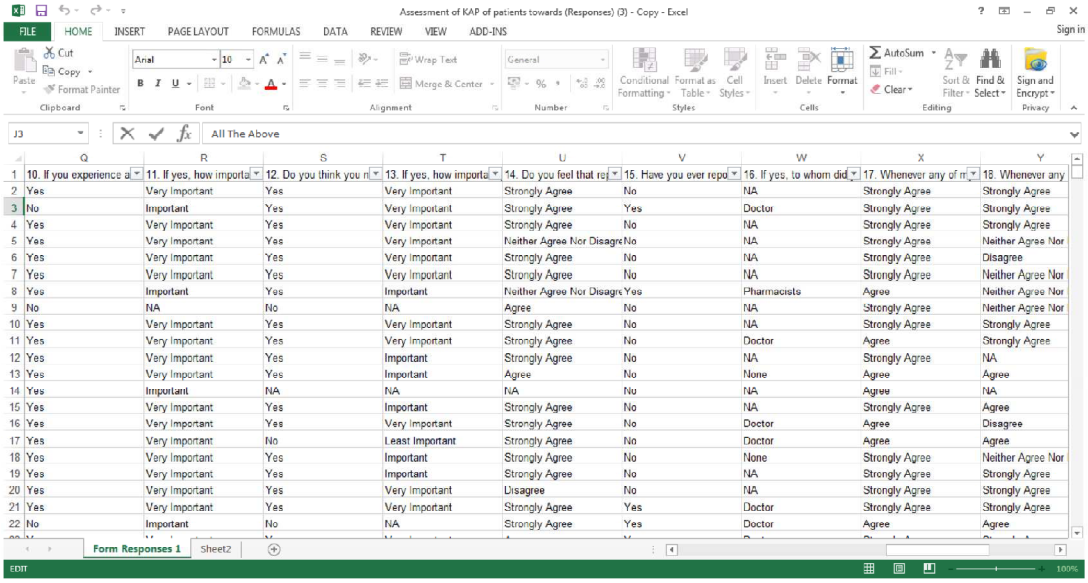
	C	D	E	F	G	H	I	J
1	Gender	Age (yrs)	Education	Profession	Contact No	1. Have you used or using any med	2. If yes,did you experi	3. If yes,which of the fc
2	Female	18	Graduate and above	Student	9481153709	Yes	No	NA
3	Female	18	PUC	Student	9620819306	Yes	Yes	All The Above
4	Female	18	PUC	Student	9910040425	Yes	No	NA
5	Female	18	PUC	Student	9742639405	Yes	No	NA
6	Female	18	PUC	Student	97476060692	Yes	No	NA
7	Female	18	PUC	Student	8606004523	Yes	No	NA
8	Female	18	Secondary School		8453509440	Yes	Yes	Allergy Reactions
9	Male	18	PUC	Student	9740129964	Yes	No	NA
10	Male	18	Secondary School		8095620131	Yes	No	NA
11	Female	18	PUC		9740667543	Yes	No	NA
12	Male	18	PUC	Student	8105603981	Yes	No	NA
13	Female	18	Secondary School		858937488	Yes	No	NA
14	Female	18	Primary School		9886678045	Yes	No	NA
15	Male	18	PUC	student	8151991841	Yes	No	NA
16	Female	18	Graduate and above	Profession		No	No	NA
17	Female	18	PUC		9686013667	Yes	No	NA
18	Female	18	PUC		9060091015	Yes	No	NA
19	Male	18	PUC	student	7299137783	Yes	No	NA
20	Female	18	PUC	student	9656734177	Yes	No	NA
21	Female	19	PUC	Student	96208193014	Yes	Yes	All The Above
22	Female	19	PUC	Student	9548780715	Yes	Yes	Side Effects

(1)



	I	J	K	L	M	N	O	P	Q
1	2. If yes,did you experi	3. If yes,which of the fc	4. Have you ever been	5. What do you think a	6. When you suffer fror	7. Have you ever heard	8. If yes, what is the na	9. Are you aware abou	10. If you experien
2	No	NA	NA	NA	Doctor	No	NA	No	Yes
3	Yes	All The Above	Family Predisposition	Increased Health Care Co	Doctor	No	NA	No	No
4	No	NA	NA	All The above	Doctor	No	NA	No	Yes
5	No	NA	NA	NA	Doctor	No	NA	No	Yes
6	No	NA	NA	NA	Doctor	No	NA	No	Yes
7	No	NA	NA	NA	Doctor	No	NA	No	Yes
8	Yes	Allergy Reactions	More No of Medications	Affects a person's general	Nurse	Yes	Indian Pharmaceutical As	Yes	Yes
9	No	NA	NA	NA	Doctor	No	NA	No	No
10	No	NA	Age	Increased Health Care Co	Doctor	No	NA	No	Yes
11	No	NA	All The Above	Health Damage	Doctor	Yes	Pharmacy Council Of Indi	Yes	Yes
12	No	NA	NA	Health Damage	Doctor	No	NA	No	Yes
13	No	NA	More Diseases	Economic Consequences	Doctor	No	NA	No	Yes
14	No	NA	NA	NA	Doctor	NA	NA	NA	Yes
15	No	NA	NA	NA	Doctor	No	NA	No	Yes
16	No	NA	All The Above	All The above	Doctor	No	Pharmacovigilance Progra	No	Yes
17	No	NA	All The Above	Increased Health Care Co	Doctor	No	NA	Yes	Yes
18	No	NA	Age	Economic Consequences	Nurse	No	NA	No	Yes
19	No	NA	Age	Health Damage	Doctor	No	NA	No	Yes
20	No	NA	NA	Economic Consequences	Doctor	No	NA	No	Yes
21	Yes	All The Above	All The Above	Increased Health Care Co	Doctor	No	NA	No	Yes
22	Yes	Side Effects	More No of Medications	Health Damage	Doctor	Yes	Drug Control Department	Yes	No

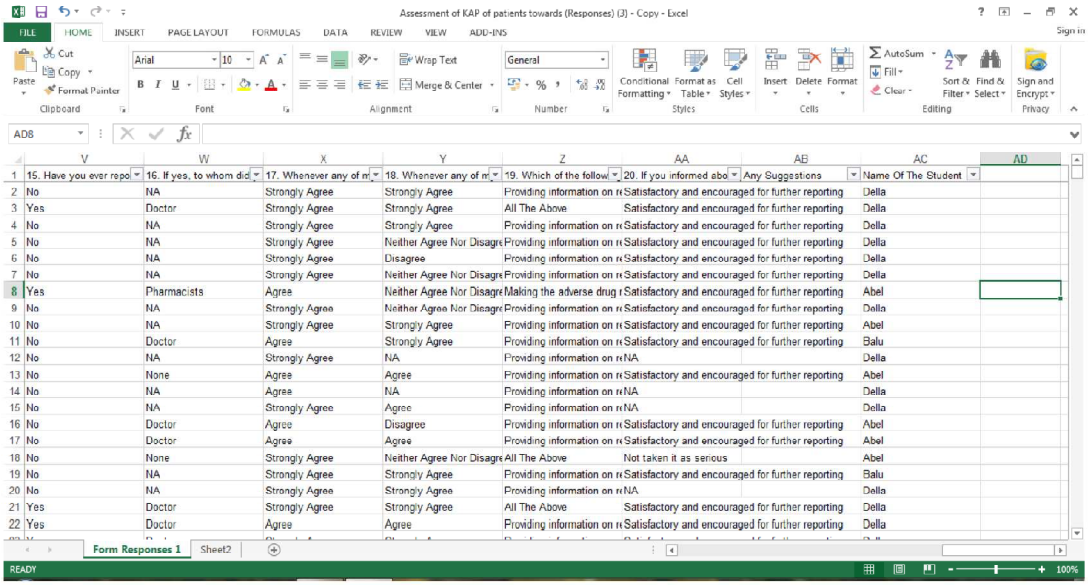
(2)



Assessment of KAP of patients towards (Responses) (3) - Copy - Excel

	Q	R	S	T	U	V	W	X	Y
1	10. If you experience a	11. If yes, how importa	12. Do you think you n	13. If yes, how importa	14. Do you feel that re	15. Have you ever repo	16. If yes, to whom did	17. Whenever any of m	18. Whenever any
2	Yes	Very Important	Yes	Very Important	Strongly Agree	No	NA	Strongly Agree	Strongly Agree
3	No	Important	Yes	Very Important	Strongly Agree	Yes	Doctor	Strongly Agree	Strongly Agree
4	Yes	Very Important	Yes	Very Important	Strongly Agree	No	NA	Strongly Agree	Strongly Agree
5	Yes	Very Important	Yes	Very Important	Neither Agree Nor Disagre	No	NA	Strongly Agree	Neither Agree Nor
6	Yes	Very Important	Yes	Very Important	Strongly Agree	No	NA	Strongly Agree	Disagree
7	Yes	Very Important	Yes	Very Important	Strongly Agree	No	NA	Strongly Agree	Neither Agree Nor
8	Yes	Important	Yes	Important	Neither Agree Nor Disagre	Yes	Pharmacists	Agree	Neither Agree Nor
9	No	NA	No	NA	Agree	No	NA	Strongly Agree	Neither Agree Nor
10	Yes	Very Important	Yes	Very Important	Strongly Agree	No	NA	Strongly Agree	Strongly Agree
11	Yes	Very Important	Yes	Very Important	Strongly Agree	No	Doctor	Agree	Strongly Agree
12	Yes	Very Important	Yes	Important	Strongly Agree	No	NA	Strongly Agree	NA
13	Yes	Very Important	Yes	Important	Agree	No	None	Agree	Agree
14	Yes	Important	NA	NA	NA	No	NA	Agree	NA
15	Yes	Very Important	Yes	Important	Strongly Agree	No	NA	Strongly Agree	Agree
16	Yes	Very Important	Yes	Very Important	Strongly Agree	No	Doctor	Agree	Disagree
17	Yes	Very Important	No	Least Important	Strongly Agree	No	Doctor	Agree	Agree
18	Yes	Very Important	Yes	Important	Strongly Agree	No	None	Strongly Agree	Neither Agree Nor
19	Yes	Very Important	Yes	Important	Strongly Agree	No	NA	Strongly Agree	Strongly Agree
20	Yes	Very Important	Yes	Very Important	Disagree	No	NA	Strongly Agree	Strongly Agree
21	Yes	Very Important	Yes	Very Important	Strongly Agree	Yes	Doctor	Strongly Agree	Strongly Agree
22	No	Important	No	NA	Strongly Agree	Yes	Doctor	Agree	Agree

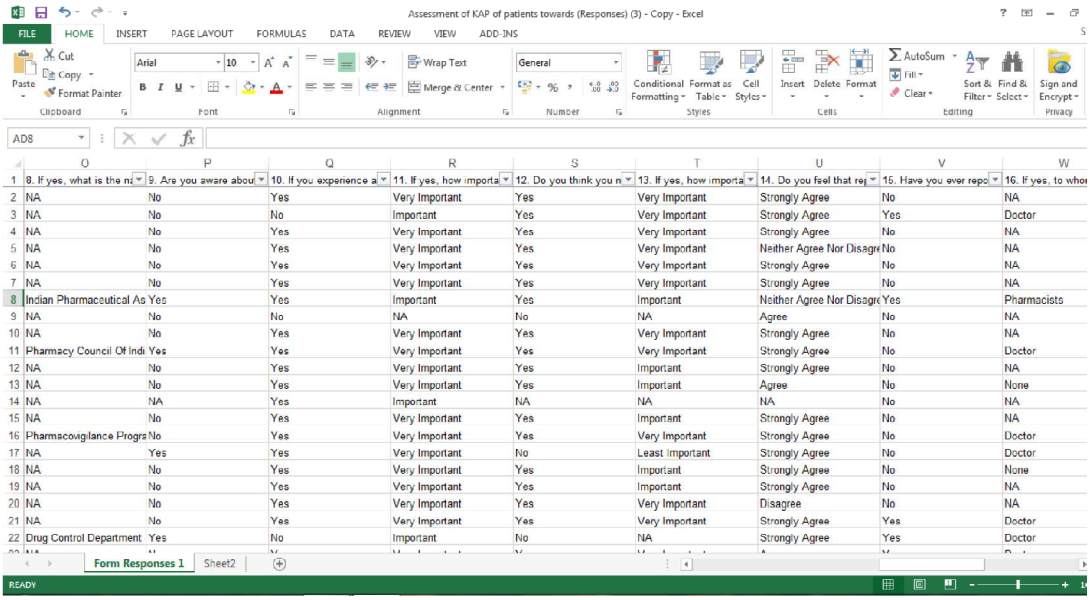
(3)



Assessment of KAP of patients towards (Responses) (3) - Copy - Excel

	V	W	X	Y	Z	AA	AB	AC	AD
1	15. Have you ever repo	16. If yes, to whom did	17. Whenever any of m	18. Whenever any of m	19. Which of the follow	20. If you informed abo	Any Suggestions	Name Of The Student	
2	No	NA	Strongly Agree	Strongly Agree	Providing information on n	Satisfactory and encouraged for further reporting		Della	
3	Yes	Doctor	Strongly Agree	Strongly Agree	All The Above	Satisfactory and encouraged for further reporting		Della	
4	No	NA	Strongly Agree	Strongly Agree	Providing information on n	Satisfactory and encouraged for further reporting		Della	
5	No	NA	Strongly Agree	Neither Agree Nor Disagre	Providing information on n	Satisfactory and encouraged for further reporting		Della	
6	No	NA	Strongly Agree	Disagree	Providing information on n	Satisfactory and encouraged for further reporting		Della	
7	No	NA	Strongly Agree	Neither Agree Nor Disagre	Providing information on n	Satisfactory and encouraged for further reporting		Della	
8	Yes	Pharmacists	Agree	Neither Agree Nor Disagre	Making the adverse drug r	Satisfactory and encouraged for further reporting		Abel	
9	No	NA	Strongly Agree	Neither Agree Nor Disagre	Providing information on n	Satisfactory and encouraged for further reporting		Della	
10	No	NA	Strongly Agree	Strongly Agree	Providing information on n	Satisfactory and encouraged for further reporting		Abel	
11	No	Doctor	Agree	Strongly Agree	Providing information on n	Satisfactory and encouraged for further reporting		Balu	
12	No	NA	Strongly Agree	NA	Providing information on n	NA		Della	
13	No	None	Agree	Agree	Providing information on n	Satisfactory and encouraged for further reporting		Abel	
14	No	NA	Agree	NA	Providing information on n	NA		Della	
15	No	NA	Strongly Agree	Agree	Providing information on n	NA		Della	
16	No	Doctor	Agree	Disagree	Providing information on n	Satisfactory and encouraged for further reporting		Abel	
17	No	Doctor	Agree	Agree	Providing information on n	Satisfactory and encouraged for further reporting		Abel	
18	No	None	Strongly Agree	Neither Agree Nor Disagre	All The Above	Not taken it as serious		Abel	
19	No	NA	Strongly Agree	Strongly Agree	Providing information on n	Satisfactory and encouraged for further reporting		Balu	
20	No	NA	Strongly Agree	Strongly Agree	Providing information on n	NA		Della	
21	Yes	Doctor	Strongly Agree	Strongly Agree	All The Above	Satisfactory and encouraged for further reporting		Della	
22	Yes	Doctor	Agree	Agree	Providing information on n	Satisfactory and encouraged for further reporting		Della	

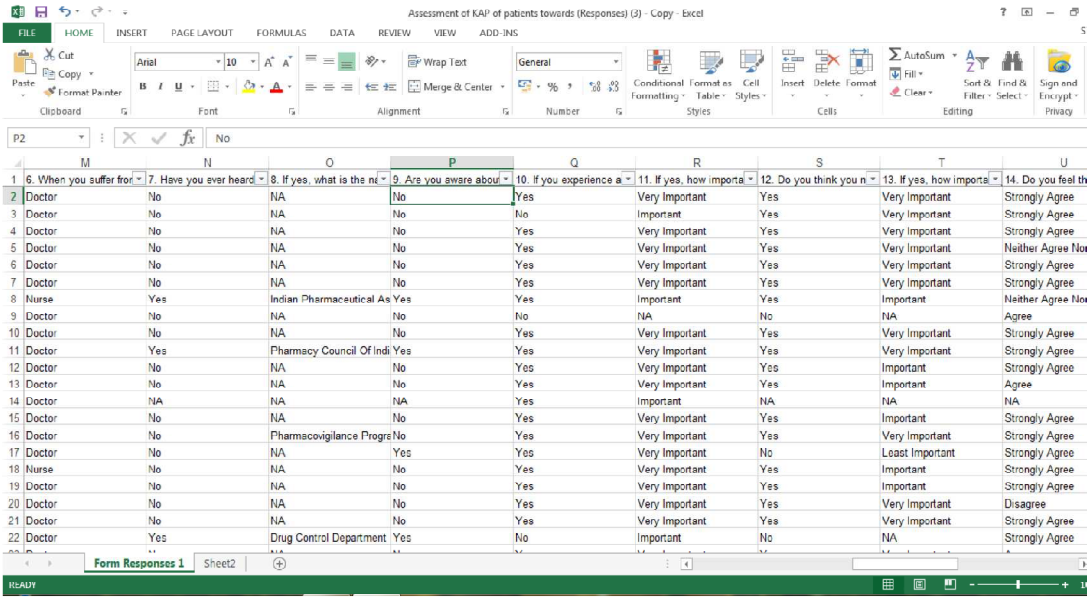
(4)



Assessment of KAP of patients towards (Responses) (3) - Copy - Excel

	O	P	Q	R	S	T	U	V	W
1	8. If yes, what is the na	9. Are you aware about	10. If you experience a	11. If yes, how importa	12. Do you think you n	13. If yes, how importa	14. Do you feel that rej	15. Have you ever repo	16. If yes, to whor
2	NA	No	Yes	Very Important	Yes	Very Important	Strongly Agree	No	NA
3	NA	No	No	Important	Yes	Very Important	Strongly Agree	Yes	Doctor
4	NA	No	Yes	Very Important	Yes	Very Important	Strongly Agree	No	NA
5	NA	No	Yes	Very Important	Yes	Very Important	Neither Agree Nor Disagre	No	NA
6	NA	No	Yes	Very Important	Yes	Very Important	Strongly Agree	No	NA
7	NA	No	Yes	Very Important	Yes	Very Important	Strongly Agree	No	NA
8	Indian Pharmaceutical As	Yes	Yes	Important	Yes	Important	Neither Agree Nor Disagre	Yes	Pharmacists
9	NA	No	No	NA	No	NA	Agree	No	NA
10	NA	No	Yes	Very Important	Yes	Very Important	Strongly Agree	No	NA
11	Pharmacy Council Of Indi	Yes	Yes	Very Important	Yes	Very Important	Strongly Agree	No	Doctor
12	NA	No	Yes	Very Important	Yes	Important	Strongly Agree	No	NA
13	NA	No	Yes	Very Important	Yes	Important	Agree	No	None
14	NA	NA	Yes	Important	NA	NA	NA	No	NA
15	NA	No	Yes	Very Important	Yes	Important	Strongly Agree	No	NA
16	Pharmacovigilance Progra	No	Yes	Very Important	Yes	Very Important	Strongly Agree	No	Doctor
17	NA	Yes	Yes	Very Important	No	Least Important	Strongly Agree	No	Doctor
18	NA	No	Yes	Very Important	Yes	Important	Strongly Agree	No	None
19	NA	No	Yes	Very Important	Yes	Important	Strongly Agree	No	NA
20	NA	No	Yes	Very Important	Yes	Very Important	Disagree	No	NA
21	NA	No	Yes	Very Important	Yes	Very Important	Strongly Agree	Yes	Doctor
22	Drug Control Department	Yes	No	Important	No	NA	Strongly Agree	Yes	Doctor

(5)



Assessment of KAP of patients towards (Responses) (3) - Copy - Excel

	M	N	O	P	Q	R	S	T	U
1	6. When you suffer fror	7. Have you ever heard	8. If yes, what is the na	9. Are you aware about	10. If you experience a	11. If yes, how importa	12. Do you think you n	13. If yes, how importa	14. Do you feel th
2	Doctor	No	NA	No	Yes	Very Important	Yes	Very Important	Strongly Agree
3	Doctor	No	NA	No	No	Important	Yes	Very Important	Strongly Agree
4	Doctor	No	NA	No	Yes	Very Important	Yes	Very Important	Strongly Agree
5	Doctor	No	NA	No	Yes	Very Important	Yes	Very Important	Neither Agree Nor
6	Doctor	No	NA	No	Yes	Very Important	Yes	Very Important	Strongly Agree
7	Doctor	No	NA	No	Yes	Very Important	Yes	Very Important	Strongly Agree
8	Nurse	Yes	Indian Pharmaceutical As	Yes	Yes	Important	Yes	Important	Neither Agree Nor
9	Doctor	No	NA	No	No	NA	No	NA	Agree
10	Doctor	No	NA	No	Yes	Very Important	Yes	Very Important	Strongly Agree
11	Doctor	Yes	Pharmacy Council Of Indi	Yes	Yes	Very Important	Yes	Very Important	Strongly Agree
12	Doctor	No	NA	No	Yes	Very Important	Yes	Important	Strongly Agree
13	Doctor	No	NA	No	Yes	Very Important	Yes	Important	Agree
14	Doctor	NA	NA	NA	Yes	Important	NA	NA	NA
15	Doctor	No	NA	No	Yes	Very Important	Yes	Important	Strongly Agree
16	Doctor	No	Pharmacovigilance Progra	No	Yes	Very Important	Yes	Very Important	Strongly Agree
17	Doctor	No	NA	Yes	Yes	Very Important	No	Least Important	Strongly Agree
18	Nurse	No	NA	No	Yes	Very Important	Yes	Important	Strongly Agree
19	Doctor	No	NA	No	Yes	Very Important	Yes	Important	Strongly Agree
20	Doctor	No	NA	No	Yes	Very Important	Yes	Very Important	Disagree
21	Doctor	No	NA	No	Yes	Very Important	Yes	Very Important	Strongly Agree
22	Doctor	Yes	Drug Control Department	Yes	No	Important	No	NA	Strongly Agree

(6)