ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AND ADVERSE DRUG REACTION REPORTING AMONG NURSING STAFF

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CERTIFICATES

EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled **"Assessment of knowledge, attitude and practice of pharmacovigilance and adverse drug reaction reporting among nursing staff"** submitted by the student bearing **Reg. No: 261640210** to **"The Tamil Nadu Dr. M.G.R. Medical University"**, Chennai, in partial fulfillment for the award of Degree of **Master of Pharmacy** in Pharmacy Practice was evaluated by us during the examination held on……

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I further declare that this work is original and this dissertation has not been submitted previously for the award of any other degree, diploma, associate ship and fellowship or any other similar title. The information furnished in this dissertation is genuine to the best of my knowledge.

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1. INTRODUCTION

WHO characterizes adverse drug reaction (ADR) as any reaction to a medication which is harmful and unintended, and which happens at measurements typically utilized as a part of man for prophylaxis, analysis or treatment of illness or for the alteration of physiological capacity.[1] Antagonistic medication responses are negative outcomes of medication treatment.[2] They are one of the main sources of grimness and mortality. It has been assessed that around 2.9-5.6% of all clinic affirmations are because of ADRs and upwards of 35% of hospitalized patients encounter an ADR amid their hospitalization.[3] An unconstrained revealing of ADRs has remained the foundation of pharmacovigilance and is imperative in keeping up tolerant wellbeing.[4] In India, all social insurance experts including specialists, medical caretakers, and drug specialists can report an ADR by filling an ADR type of the Central Drugs Standard Control Organization.[5] The dynamic interest of social insurance experts in the pharmacovigilance program can enhance the ADR revealing.[6]

The ADR revealing rate in India is underneath 1% contrasted with the overall rate of 5%.[7] One reason for low reporting rate in India might be an absence of learning and sharpening towards pharmacovigilance and ADR among health care professionals (HCPs). The examination likewise demonstrated that the normal cost associated with treating these ADRs was INR 900/ - per patient.[8]In India, Pharmacovigilance is still in early stage and there exists very limited knowledge about this discipline.[9]Inadequate funds, lack of trained staff, and lack of awareness about detection, communication, and spontaneous monitoring of ADRs may be the reason, gross underreporting of ADRs is a cause of concern.[10]

The market today is flooded with an enormous number of drugs for various ailments. The Pharmaceutical industries are busy innovating testing and manufacturing new drugs day in and day out, such that 45 drugs gained FDA

approval in 2015 and 41 new drugs were launched in 2014 every year on an average.[11] Before the drugs are marketed, they undergo stringent measures to assess their safety profile; still, certain unusual, rare, serious adverse drug reactions may go undetected at this level. This applies more to newer drugs which may lead to severe adverse drug reactions which may not have come to light yet owing to a short span of their use. ADRs (adverse drug reactions) are responsible for about 5 % to 20% of hospital admissions.[12]About 2.9% ADRs lead to hospitalization and approximately 6.3% ADRs develop while one is in the hospital.[13] One third of these ADRs are preventable.[14]

In India, National Pharmacovigilance Centre (NPC) has been formed which is an active participant in the on-going activities of UMC and in the past years, the PV programme has gained momentum such that the reporting rates from India have increased from 0.5% to 2%, still these figures are very low as compared to other countries.[15]All healthcare professionals can report an ADR by filling an ADR reporting form provided by CDSCO (Central Drug Standard Control Organization). Still, under reporting is highly prevalent. An important part in this under reporting is played by the lacunae in the knowledge (especially lack of knowledge of how and whom to report about ADRs) and attitude of various health care professionals towards monitoring and reporting of ADRs.[16] The success of a PV program depends upon the active involvement of the healthcare professionals such as doctors, pharmacists, nurses and can greatly reduce the burden on limited health care resources in developing countries like India.[17]

Increasing health professional and student participation in national medication reporting programs remains an important goal in promoting safe health care practices. Opportunities for improvement in pharmacy curricula and practice sites toward interactive experiences with reporting programs should be continually evaluated.[18] Thus, early identification of ADRs is extremely important for both government and non-government health care organizations.

Pharmacovigilance (PV)

Pharmacovigilance is concerned with only two outcomes: safety and efficacy. Does a drug work and is it safe? It touches on almost every aspect of the drug lifecycle - from preclinical development to post-market surveillance - making it one of the most fundamental functions within a life science company.

Pharmacovigilance – also known as drug safety - is a broad term that describes the collection, analysis, monitoring and prevention of adverse effects in drugs and therapies. It is a completely scientific and process-driven area within pharma.

The definition of an adverse event is any reaction within a patient's body caused by a drug/candidate molecule – a side effect. A serious adverse event is a life-threatening side effect that causes hospitalisation, incapacity, permanent damage or, in extreme cases, the death of a patient. Adverse event reporting is mandatory for all clinical research investigators, even if the side effects are only suspected.

The role of pharmacovigilance is to determine which adverse events cross the line of a drug's efficacy. In other words, analysing which side effects are worth the risk to patients compared with how effective they are at treating a disease. For instance, chemotherapy is known to cause some very serious side effects but when faced with life-threatening cancer, these side effects are considered acceptable given the potential to cure a patient. However, if a drug used to cure a headache caused similar side effects, the risk to the patient would be considered too great and the benefit not substantial enough to justify the potential damage.

Main areas of pharmacovigilance

Pharmacovigilance is a huge and encompassing discipline, but we can broadly divide pharmacovigilance into four main sub-specialisms:

Operations:

This sector is where many life science professionals interested in drug safety jobs will begin their career. Typical jobs within drug safety operations include case processor, drug safety officer/associate and drug safety manager, and of course team lead and directorships. These professionals will collect and record information during preclinical development and clinical trials, in addition to gathering real world evidence (RWE) of adverse events reported by doctors and patients post-market. Operations are also usually responsible for creating standard operating procedures (SOPs), individual case study reports, literature screening and regulatory expedited reporting.

Surveillance:

Professionals who focus more within surveillance tend to look towards risk management and signal detection jobs. This also involves performing analysis of the data collated by the wider division. Professionals in this area can hold an array of titles, the most common of which are pharmacovigilance scientist and drug safety physician, but like in all teams, there are many degrees of seniority and remit available. These professionals perform analysis on the drug safety information gathered by the wider department and assist with the creation and review of aggregate reports. They also create development safety update reports (DSURs) for drugs in clinical research, and periodic benefit risk evaluation reports (PBRER) for post-market drugs. These reports ultimately help the team to draw conclusions around the safety and efficacy of a drug or candidate molecule.

Systems

This division is concerned with the building and ongoing development of a fully robust and innovative system, charged with the responsibility for housing and allowing access (in various forms) to vast quantities of safety data. This safety data

is usually collated by those working in operationally focused roles, but is accessed by all. The systems division constantly has to improve, and stay in line with, changing regulations and requirements for the business/ health authorities, making this a very challenging and vital aspect of drug safety.

Qualified Person for Pharmacovigilance (QPPV)

QPPVs jobs are mainly concerned with marketed drugs and those about to be authorised, but as QPPVs are considered by many to be subject matter experts, their expertise is utilised across the discipline and wider business. These senior pharmacovigilance roles will only be held by very experienced professionals and their focus is to understand, plan for and advise upon the regulations and requirements that companies must adhere to across the EU. This is a highly strategic appointment and one of great importance.

Fortunately for drug safety professionals, there are several pharmacovigilance jobs available to them due to the different types of companies within life sciences, including global pharmas, small pharmas, generics companies, drug safety consultancies and health authorities. Each offers slightly different opportunities but in every case, there is plenty of scope for professionals to progress their pharmacovigilance career.

Importance of pharmacovigilance

Pharmacovigilance is arguably the most essential function within a life science company. To develop, manufacture and commercialise a drug a company must adhere to strict regulations. Many of these regulations will focus on the patient's safety and the added benefit to the patient derived from the drug. This, in a nutshell, is the mission of drug safety and highlights why this discipline plays such a central and important role within pharmaceuticals.

Patient safety and continuous vigilance

By definition, drug safety ensures that a patient's safety and wellbeing is safeguarded throughout the entire drug development lifecycle, including when the drug is readily available on the market. Indeed, drugs are continuously monitored for other side effects on patients, and any new data is collected and reported to health authorities on a regular basis. While other areas focus on improving patient lives in everything that they do, no other department has such a sharp focus on patient safety as an end-point.

Power and authority

This continuous vigilance does mean that, alongside others in the business, senior leaders within a drug safety team have the responsibility and authority to recommend that a development process is stopped, or that an approved drug is pulled from the market. EU QPPVs are especially important in this process, and again this goes to demonstrate the importance and central role of drug safety.

Keeping it moving

In many ways, drug safety helps to keep the wheels of a pharmaceutical company moving. The nature of drug safety means that it works on a very cross-functional basis. Therefore, the influence and value which the division can add to other aspects of the business is tremendous.[19]

Adverse event reporting

The activity that is most commonly associated with pharmacovigilance (PV), and which consumes a significant amount of resources for drug regulatory authorities (or similar government agencies) and drug safety departments in pharmaceutical companies, is that of adverse event reporting. Adverse event (AE) reporting involves the receipt, triage, data entering, assessment, distribution,

reporting (if appropriate), and archiving of AE data and documentation. The source of AE reports may include: spontaneous reports from healthcare professionals or patients (or other intermediaries); solicited reports from patient support programs; reports from clinical or post-marketing studies; reports from literature sources; reports from the media (including social media and websites); and reports reported to drug regulatory authorities themselves. For pharmaceutical companies, AE reporting is a regulatory requirement in most countries. AE reporting also provides data to these companies and drug regulatory authorities that play a key role in assessing the risk-benefit profile of a given drug. The following are several facets of AE reporting:

Individual Case Safety Report (ICSR)

One of the fundamental principles of adverse event reporting is the determination of what constitutes an Individual Case Safety Report (ICSR). During the triage phase of a potential adverse event report, it is important to determine if the "four elements" of a valid ICSR are present: an identifiable patient, an identifiable reporter, a suspect drug, and an adverse event.

If one or more of these four elements is missing, the case is not a valid ICSR. Although there are no exceptions to this rule there may be circumstances that may require a judgment call. For example, the term "identifiable" may not always be clear-cut. If a physician reports that he/she has a patient X taking drug Y who experienced Z (an AE), but refuses to provide any specifics about patient X, the report is still a valid case even though the patient is not specifically identified. This is because the reporter has first-hand information about the patient and is identifiable (i.e. a real person) to the physician. Identifiability is important so as not only to prevent duplicate reporting of the same case, but also to permit follow-up for additional information.

The concept of identifiability also applies to the other three elements. Although uncommon, it is not unheard of for fictitious adverse event "cases" to be reported to a company by an anonymous individual (or on behalf of an anonymous patient, disgruntled employee, or former employee) trying to damage the company's reputation or a company's product. In these and all other situations, the source of the report should be ascertained (if possible). But anonymous reporting is also important, as whistle blower protection is not granted in all countries. In general, the drug must also be specifically named. Note that in different countries and regions of the world, drugs are sold under various tradenames. In addition, there are a large number of generics which may be mistaken for the trade product. Finally, there is the problem of counterfeit drugs producing adverse events. If at all possible, it is best to try to obtain the sample which induced the adverse event, and send it to either the EMA, FDA or other government agency responsible for investigating AE reports.

If a reporter can't recall the name of the drug they were taking when they experienced an adverse event, this would not be a valid case. This concept also applies to adverse events. If a patient states that they experienced "symptoms", but cannot be more specific, such a report might technically be considered valid, but will be of very limited value to the pharmacovigilance department of the company or to drug regulatory authorities.[20]

Coding of adverse events

Adverse event coding is the process by which information from an AE reporter, called the "verbatim", is coded using standardized terminology from a medical coding dictionary, such as MedDRA (the most commonly used medical coding dictionary). The purpose of medical coding is to convert adverse event information into terminology that can be readily identified and analyzed. For instance, Patient 1 may report that they had experienced "a very bad headache that

felt like their head was being hit by a hammer" [Verbatim 1] when taking Drug X. Or, Patient 2 may report that they had experienced a "slight, throbbing headache that occurred daily at about two in the afternoon" [Verbatim 2] while taking Drug Y. Neither Verbatim 1 nor Verbatim 2 will exactly match a code in the MedDRA coding dictionary. However, both quotes describe different manifestations of a headache. As a result, in this example both quotes would be coded as PT Headache (PT = Preferred Term in MedDRA).

Seriousness determination

Although somewhat intuitive, there are a set of criteria within pharmacovigilance that are used to distinguish a serious adverse event from a non-serious one. An adverse event is considered serious if it meets one or more of the following criteria: results in death, or is life-threatening;requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability or incapacity;results in a congenital anomaly (birth defect); oris otherwise "medically significant" (i.e., that it does not meet preceding criteria, but is considered serious because treatment/intervention would be required to prevent one of the preceding criteria).[20]

Aside from death, each of these categories is subject to some interpretation. Life-threatening, as it used in the drug safety world, specifically refers to an adverse event that places the patient at an immediate risk of death, such as cardiac or respiratory arrest. By this definition, events such as myocardial infarction, which would be hypothetically life-threatening, would not be considered life-threatening unless the patient went into cardiac arrest following the MI. Defining what constitutes hospitalization can be problematic as well. Although typically straightforward, it's possible for a hospitalization to occur even if the events being treated are not serious. By the same token, serious events may be treated without hospitalization, such as the treatment of anaphylaxis may be successfully performed

with epinephrine. Significant disability and incapacity, as a concept, is also subject to debate. While permanent disability following a stroke would no doubt be serious, would "complete blindness for 30 seconds" be considered "significant disability"? For birth defects, the seriousness of the event is usually not in dispute so much as the attribution of the event to the drug. Finally, "medically significant events" is a category that includes events that may be always serious, or sometimes serious, but will not fulfill any of the other criteria. Events such as cancer might always be considered serious, whereas liver disease, depending on its CTCAE (Common Terminology Criteria for Adverse Events) grade—Grades 1 or 2 are generally considered non-serious and Grades 3-5 serious—may be considered non-serious.[21]

Expedited reporting

This refers to ICSRs (individual case safety reports) that involve a serious and unlisted event (an event not described in the drug's labeling) that is considered related to the use of the drug. (Spontaneous reports are typically considered to have a positive causality, whereas a clinical trial case will typically be assessed for causality by the clinical trial investigator and/or the license holder.) In most countries, the timeframe for reporting expedited cases is 7/15 calendar days from the time a drug company receives notification (referred to as "Day 0") of such a case. Within clinical trials such a case is referred to as a SUSAR (a Suspected Unexpected Serious Adverse Reaction). If the SUSAR involves an event that is life-threatening or fatal, it may be subject to a 7-day "clock". Cases that do not involve a serious, unlisted event may be subject to non-expedited or periodic reporting.

Clinical trial reporting

Also known as SAE (serious adverse event) reporting from clinical trials, safety information from clinical studies is used to establish a drug's safety profile in humans and is a key component that drug regulatory authorities consider in the decision-making as to whether to grant or deny market authorization (market

approval) for a drug. SAE reporting occurs as a result of study patients (subjects) who experience serious adverse events during the conducting of clinical trials. (Non-serious adverse events are also captured separately.) SAE information, which may also include relevant information from the patient's medical background, are reviewed and assessed for causality by the study investigator. This information is forwarded to a sponsoring entity (typically a pharmaceutical company) that is responsible for the reporting of this information, as appropriate, to drug regulatory authorities.

Spontaneous reporting

Spontaneous reports are termed spontaneous as they take place during the clinician's normal diagnostic appraisal of a patient, when the clinician is drawing the conclusion that the drug may be implicated in the causality of the event. Spontaneous reporting system relies on vigilant physicians and other healthcare professionals who not only generate a suspicion of an ADR, but also report it. It is an important source of regulatory actions such as taking a drug off the market or a label change due to safety problems. Spontaneous reporting is the core data-generating system of international pharmacovigilance, relying on healthcare professionals (and in some countries consumers) to identify and report any adverse events to their national pharmacovigilance center, health authority (such as EMA or FDA), or to the drug manufacturer itself.[22] Spontaneous reports are, by definition, submitted voluntarily although under certain circumstances these reports may be encouraged, or "stimulated", by media reports or articles published in medical or scientific publications, or by product lawsuits. In many parts of the world adverse event reports are submitted electronically using a defined message standard.[23]

One of the major weaknesses of spontaneous reporting is that of under-reporting, where, unlike in clinical trials, less than 100% of those adverse events occurring are reported. Further complicating the assessment of adverse events, AE

reporting behavior varies greatly between countries and in relation to the seriousness of the events, but in general probably less than 10% (some studies suggest less than 5%) of all adverse events that occur are actually reported. The rule-of-thumb is that on a scale of 0 to 10, with 0 being least likely to be reported and 10 being the most likely to be reported, an uncomplicated non-serious event such as a mild headache will be closer to a "0" on this scale, whereas a life-threatening or fatal event will be closer to a "10" in terms of its likelihood of being reported. In view of this, medical personnel may not always see AE reporting as a priority, especially if the symptoms are not serious. And even if the symptoms are serious, the symptoms may not be recognized as a possible side effect of a particular drug or combination thereof. In addition, medical personnel may not feel compelled to report events that are viewed as expected. This is why reports from patients themselves are of high value. The confirmation of these events by a healthcare professional is typically considered to increase the value of these reports. Hence it is important not only for the patient to report the AE to his health care provider (who may neglect to report the AE), but also report the AE to both the biopharmaceutical company and the FDA, EMA. This is especially important when one has obtained one's pharmaceutical from a compounding pharmacy.

As such, spontaneous reports are a crucial element in the worldwide enterprise of pharmacovigilance and form the core of the World Health Organization Database, which includes around 4.6 million reports (January 2009), growing annually by about 250,000.[22]

Aggregate reporting

Aggregate reporting, also known as periodic reporting, plays a key role in the safety assessment of drugs. Aggregate reporting involves the compilation of safety data for a drug over a prolonged period of time (months or years), as opposed to single-case reporting which, by definition, involves only individual AE reports. The

advantage of aggregate reporting is that it provides a broader view of the safety profile of a drug. Worldwide, the most important aggregate report is the Periodic Safety Update Report (PSUR) and Development Safety Update Report (DSUR). This is a document that is submitted to drug regulatory agencies in Europe, the US and Japan (ICH countries), as well as other countries around the world. The PSUR was updated in 2012 and is now referred to in many countries as the Periodic Benefit Risk Evaluation report (PBRER). As the title suggests, the PBRER's focus is on the benefit-risk profile of the drug, which includes a review of relevant safety data compiled for a drug product since its development.

Other reporting methods

Some countries legally oblige spontaneous reporting by physicians. In most countries, manufacturers are required to submit, through its Qualified Person for Pharmacovigilance (QPPV), all of the reports they receive from healthcare providers to the national authority. Others have intensive, focused programmes concentrating on new drugs, or on controversial drugs, or on the prescribing habits of groups of doctors, or involving pharmacists in reporting. All of these generate potentially useful information. Such intensive schemes, however, tend to be the exception.[23]

2. LITERATURE REVIEW

Nisa[24]*et al*., (2018)evaluated a study to assess the knowledge, attitude, practice and factors associated with ADR reporting by healthcare professionals (physicians and pharmacists) in secondary and tertiary hospitals of Islamabad. A pretested questionnaire comprising of 27 questions (knowledge 12, attitude 4, practice 9 and factors influencing ADR reporting 2) was administered to 384 physicians and pharmacists in public and private hospitals. Respondents were evaluated for their knowledge, attitude and practice related to ADR reporting. Additionally, the factors which encourage and discourage respondents to report ADRs were also determined. The data was analysed by using SPSS statistical software. Among 384 respondents, 367 provided responses to questionnaire, giving a response rate of 95.5%. The mean age was 28.3 (SD = 6.7). Most of the respondents indicated poor ADR reporting knowledge (83.1%). The majority of respondents (78.2%) presented a positive attitude towards ADR reporting and only a few (12.3%) hospitals have good ADR reporting practice. The seriousness of ADR, unusualness of reaction, new drug involvement and confidence in the diagnosis of ADR are the factors which encourage respondents to report ADR whereas lack of knowledge regarding where and how to report ADR, lack of access to ADR reporting form, managing patient is more important than reporting ADR legal liability issues were the major factors which discourage respondents to reportADR. The study reveals poor knowledge and practice regarding ADR reporting. However, most of the respondents have shown a positive attitude towards ADR reporting. There is a serious need for educational training as well as sincere and sustained efforts should be made by Government and Hospital Authorities to ensure proper implementation of ADR reporting system in all of the hospitals.

Farha[25]*et al*., (2018)conducted a study in Jordan University Hospital on various healthcare providers to assess their pre- and post-knowledge and perception towards pharmacovigilance and adverse drug reactions (ADRs) reporting via

questionnaire before and after an educational workshop. Among the 200 invited healthcare providers, 150 attended the educational workshop (response rate 75.0%). Pre-workshop, healthcare providers showed an overall low knowledge score (7.8/19), where only 8.7% could define pharmacovigilance correctly. On the other hand, they showed a favorable perception score (33.6/39). Following educational workshop, knowledge scores significantly improved by 67.9% (P-value <0.05). A similar finding was obtained for perception scores, where perception scores significantly improved by 10.1% following workshop (P-value <0.05). Continuous efforts are needed to implement different strategies including education modules and the provision of appropriate training programs to increase awareness and improve perception towards pharmacovigilance among healthcare providers. Future study is needed to evaluate the impact of improving knowledge and perception on ADRs reporting practice.

Alshammari[26]*et al*., (2018)conducted a cross-sectional survey between January and February of 2013 in nine tertiary care hospitals (governmental and private) that provide highly specialized medical services in Riyadh, Qassim, and the Eastern region of the Kingdom of Saudi Arabia. A validated questionnaire was used to assess the knowledge, attitudes, and practices of HCPs regarding the ADR reporting system. All statistical analyses were performed using SAS version 9.2. In total, 480 questionnaires were distributed, and the response rate was 70% (n = 336). Only 33% of the participants were aware of the National Pharmacovigilance Centre (NPC). Of those HCPs who were familiar with the NPC and their responsibility to report ADRs, most (50%) were pharmacists, followed by physicians (24%) and nurses (16%), and these differences were statistically significant ($p < 0.01$). Twentyseven percent of the participants were involved in reporting ADRs; among these HCPs, 62% were pharmacists, 26% were nurses, and 6% were physicians. Most participants (95%) favoured reporting ADRs caused by antibiotics and new/old drugs. The prominent factors discouraging ADR reporting included fear that the

report might be incorrect (46%) and lack of time (44%). A significant lack of knowledge, positive attitudes, and practices regarding ADRs and reporting was observed in hospital HCPs. This finding represents an international concern, and urgent action is needed to promote drug safety and pharmacovigilance in this region.

Keerthana[27]*et al*., (2017) undertaken a study to evaluate the knowledge, attitude, and practices (KAP) regarding ADR reporting among prescribers. Materials and methods: A pretested KAP questionnaire comprising of 17 questions was administered to 63 prescribers. The questionnaires were assessed for their completeness and the type of responses regarding ADR reporting. Result and discussion: A total of 63 prescribers completed the survey. ADR reporting was considered important by 51.9 % of the respondents; primarily to share Information about ADR with colleagues(37.3%). A majority of the respondents opined that they would like to report serious ADRs (31.1%). 93.3% of the prescribers had reported ADRs in their practise. Preferred methods for reporting were post(32.2%). The prescribers are aware of the ADRs and the importance of their reporting. However, under reporting and lack of knowledge about the reporting system are clearly evident. Creating awareness about ADR reporting and devising means to make it easy and convenient may aid in improving spontaneous reporting.

Sharrad[28]*et al*., (2017) evaluated the knowledge, attitude and practices (KAP) of the pharmacists towards ADRs and pharmacovigilance in Basra Hospitals. A cross-sectional analytical study was carried out in the province of Basra. All the pharmacists present in the Basra province during the study period were enrolled in the study and the convenience sampling technique was utilized for analysis. Hence, 530 pharmacists took part in the study. This questionnaire was tested and made error-free prior to using. This questionnaire contained 5 knowledge-based questions, 5-attitude related questions and tow questions which were related to the practices used towards the ADRs. The response rate was 24.9 %.The results of our study clearly point out that in spite of the pharmacists positive attitude there was a lack of

appropriate knowledge and practice to implement ADRs reporting successfully. The results emphasized the critical need for interventions to support ADRs reporting activity and to maintain Pharmacist's positive attitude. Our findings suggested that the need for positive evidence based on educational and managerial interventions regularly to improve ADR reporting. It would be more beneficial, if the Ministry of higher education would suggest some more measures to review and perhaps improve pharmacy colleges' curricula to guarantee the incorporation of PV and ADRs reporting system conception.

Sharrad[29]*et al.*, (2017)evaluated the knowledge, attitude and practice towards reporting of ADR and pharmacovigilance among final year students studying in the college of pharmacy at a public university in Basra. This questionnaire was tested and made error-free prior to using. This questionnaire contained ten knowledge-based questions, five attitude related questions and two questions which were related to the practices used towards the ADRs. The participants were interviewed and data was collected. A total of 83 respondents participated in the study. The mean knowledge score of pharmacovigilance and ADR reporting for the final year pharmacy students was 6.26 + 1.56.In general, the participants had a good attitude towards ADRs. Most of the participants of the survey, i.e., 96.3% (80), did not attend in any ADR workshop or training course. Most of the participants of the survey, i.e., 95.1% (79), did not have any idea about ADR reporting process. It was concluded from the results that the Pharmacovigilance plays an important role in safe and effective use of drugs in a situation which arises after the marketing and sales of drugs. Regarding the research, the pharmacy students displayed relatively modest knowledge and positive attitude but inadequate practice regarding ADRs and pharmacovigilance. There is a requirement for continuous learning strategy for the pharmacists.

Alsaleh[30]*et al.*, (2017) study documented the knowledge, attitude and practices (KAP) of pharmacists toward PV and ADR reporting and to explore the

barriers to implementing a fully functional PV program in Kuwait. Pharmacists working at governmental hospitals were asked to complete a paper-based 25-item questionnaire. A total of 414 pharmacists received the questionnaire and 342 agreed to participate, giving a response rate of 82.6%. Most pharmacists were knowledgeable about the concepts of PV (61.5%) and ADRs (72.6%) and the majority (88.6%) was willing to implement ADR reporting in their clinical practice. Despite this positive attitude, only 26.8% of participants had previously reported an ADR and the main reason for underreporting were stated as not knowing how to report (68.9%). Barriers that hinder the implementation of a PV center included lack of cooperation and communication by healthcare professionals and patients (n = 62), lack of time and proper management (n = 57), lack of awareness of staff and patients (n = 48) and no qualified person to report ADRs (n = 35). Overall this study shows that hospital pharmacists in Kuwait had good knowledge and positive attitude toward PV and ADRs reporting. However, the majority of them have never reported ADRs. These results suggest that targetededucational interventions and a well-defined policy for ADR reporting may help increase ADR reporting and support the implementation of a fully functional independent PV center in Kuwait

Tew[31]*et al*., (2016)study was aimedto investigate the KAP towards ADR reporting among HCPs working at primaryoutpatient care in Kuala Muda District Health Office, Kedah, Malaysia.A cross sectional study was done by survey using a self-administered structured questionnaire.The questionnaire was distributed to all healthcare professionals working at primary outpatient care.The overall response rate was 87.4%. The mean knowledge score was 66.9% ± 19.86for doctors and 76.9% ± 13.87 for pharmacists (p=0.03). 43.8% of the healthcare professionals did not aware of theblue card reporting system in Malaysia. Almost all of the respondents agreed that ADR reporting should be mademandatory and they recognized that it's their professional obligation to report any ADR. However, only 51.9% ofdoctors and 70.8 % of pharmacist had reported. Half of the respondents

professed that ADR forms are too complexto fill and almost all of the respondents (90.4% doctors and 87.5% pharmacists) declared that they are lacking oftime to fill in the report. 69.2% of doctors expressed that they have not been trained on ADR reporting which wascontradicting with the pharmacists (12.5%) ($p<0.001$). Almost all respondents (82.7 % doctors and 95.8pharmacists) concurred that ADR reporting should be taught in details to them.Respondents reflected inadequate knowledge on ADR reporting. The prevalence of unsatisfactorypractices and attitudes among these HCPs contributed to failure to report ADR even if the ADR was identified.Educational intervention strategies can be introduced in order to promote ADR reporting.

Sah[32]*et al*., (2017) study was planned to assess the knowledge, attitude and practices of PhV among community pharmacist in Delhi, India. Cross sectional, questionnaire based study was conducted to evaluate the knowledge, attitude and practice of PhV among 200 community pharmacists of Delhi (west Delhi) India. Majority (74%) of the respondents felt that ADR reporting is necessary but only 9% were aware of existing PhV Program of India. Only 5% of pharmacists knew about elements of PhV. Forty percent (40%) of pharmacists did not know where to report ADRs and 26% felt that there is no need to report ADRs. Significant number (77%) of pharmacists felt that ADRs reporting will damage their image. 96% never try to find ADRs and in case if they get ADRs from patients, majority (95%) of them never report to anybody. Almost all (96%) of respondents cited busy schedule as the main reason for non-reporting and 86% said that it will be very convenient if ADRs are collected by someone from them. Community pharmacists had positive attitude towards ADRs reporting but their knowledge and practice regarding PhV need to be improved. There is a need of regular training to increase their role in PhV.

Srinivasan[33]***et al*.,** **(2017)**conducted a study to identify the possible factors responsible for underreporting (UR) of adverse drug reactions (ADRs) and encourage the healthcare professionals to substantiate the Pharmacovigilance Programme of India (PvPI). The present study was a cross-sectional questionnaire-based study to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance among practicing healthcare professionals working in the Saveetha Medical College & Hospital, Thandalam, Chennai. The statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 23 software. The result shows difference in explicit knowledge and tacit knowledge among healthcare professionals. Attitude questions have identified the affective behaviour of the respondents and practice questions shows evidence of a paradigm shift towards an organized pharmacovigilance constructivism. KAP of the healthcare professionals highlights the under-reporting of ADR; Multimodality interventions are needed to improve spontaneous ADR reporting.

3. NEED OF THE STUDY

The most serious ADRs lead to hospitalization, and hospital stays can lead to further ADRs. Hence, HCPs and hospitals can play a significant role in minimizing ADR-related morbidity and mortality.[34] HCPs can play multiple roles by carefully reviewing the full patient history, particularly the drug allergy and drug-drug interaction history, to avoid any unwanted ADRs. In addition, reporting ADRs to the responsible office at their hospital or the regulatory authority is a pharmacovigilance approach that can be used to minimize ADRs because reporting ADRs can increase HCPs' awareness of reactions, which could result in the avoidance of particular drugs, thus reducing the harm associated with reactions to particular drugs.[35]

Several drugs have been withdrawn from the market as a result of HCPs reporting ADRs.[35] However, understanding the knowledge and practice of health care professionals regarding ADR reporting is very important for enhancing the reporting of ADRs.[36]

Therefore, the present study is undertaken to determine the current status of ADR reporting and also to investigate knowledge and attitude of particularly nursing staffs towards pharmacovigilance and ADR reporting.

4. AIM AND OBJECTIVES

AIM

- To assess the knowledge, attitude and practice of pharmacovigilance and adverse drug reaction reporting among nursing staffs.

OBJECTIVES

- To assess the knowledge of pharmacovigilance towards adverse drug reaction reporting
- To assess the attitude and practice towards adverse drug reaction reporting
- To determine the factors that encourages the study subjects to report adverse drug reaction
- To evaluate the factors that discourages the study subjects not to report adverse drug reaction

5. PLAN OF THE WORK

The entire study was conducted out for a period of 10 months. The study was designed as given below:

Phase I

- Conduct literature review
- Design questionnaire form and patient consent form.
- Obtain the approval from the institutional ethical committee and hospital authority

Phase II

- Collect participant's demographical information
- Collect KAP questionnaire towards pharmacovigilance and adverse drug reaction

Phase III

- Data analysis
- Submission of report

6. METHODOLOGY

Study site

- The study was conducted in 3 different multi-speciality hospitals, at Chennai.

Study design

- Cross sectional, questionnaire based study

Study setting

- This study was conducted from December 2017 to August 2018 for a period of 10 months.

Study sample

- The study sample size was 300.

Inclusion criteria

- Nurses
- Any age group

Exclusion criteria

- Other health care professionals
- Study participants with unwillingness are excluded

Study tools

The study questionnaire was prepared for incorporating participant's demographic details like age, gender and designation and working experiences. In KAP, Knowledge part of the questionnaire included sixteen questions that were used

to measure the knowledge of nurses related to ADR and pharmacovigilance such as definition, awareness, purpose of ADR, PV, reporting system, regulatory body etc. The attitude part comprised of eight questions about their thoughts and views related to ADR and reporting. Attitudes related questions were developed in 5-point likert scale. The practice part of questionnaire included three questions such as type, nature, methods for ADR reporting. Finally the fifth section was limited to two questions with the help of which factors encouraging and discouraging to nurses to report ADR were determined.

Data collection

A structured pretested questionnaire was prepared. After pilot-scale testing, the questionnaire was modified. After obtaining approval from IEC and hospital authority, a questionnaire was distributed to nursing staffs.Participants were explained about the purpose of the study. Those who showed interest to participate in the study were requested to fill the questionnaire in 30 min with ensured confidentiality. The responses to the questionnaire were analyzed, categorized and presented in percentages.

7. RESULTS

Table 1: Gender wise distribution of participants

Gender	Total no of participants n= 151(%)
Female	144(95.3%)
Male	7(4.63%)

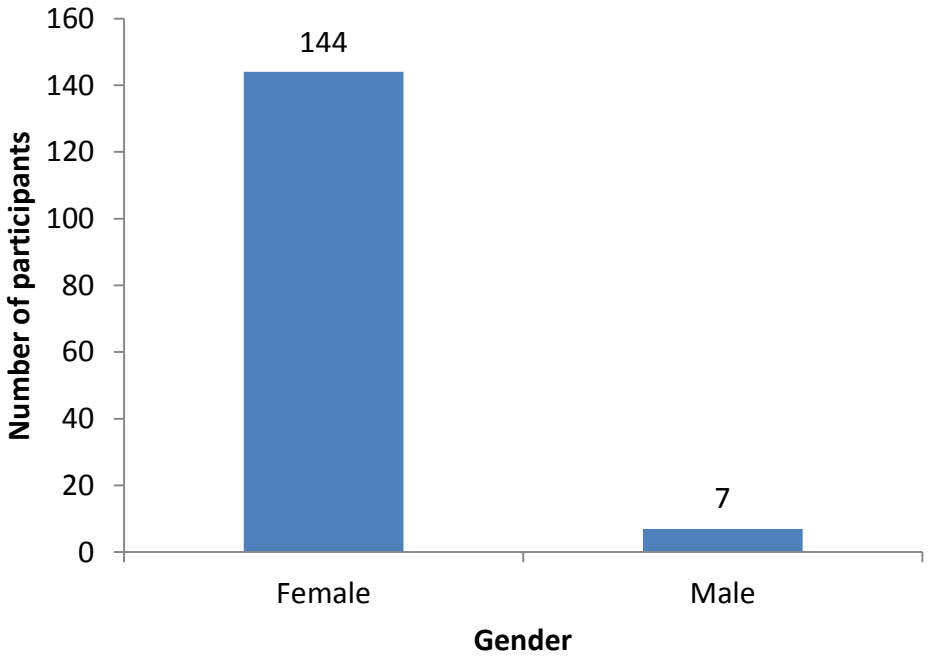

Figure 1: Gender wise distribution of participants

Table 2: Age wise distribution of participants

Age group in years	Total no of participants n= 151 (%)
16-20	0
21-25	112(74.1%)
26-30	26(17.2%)
31 and above	13(8.6%)

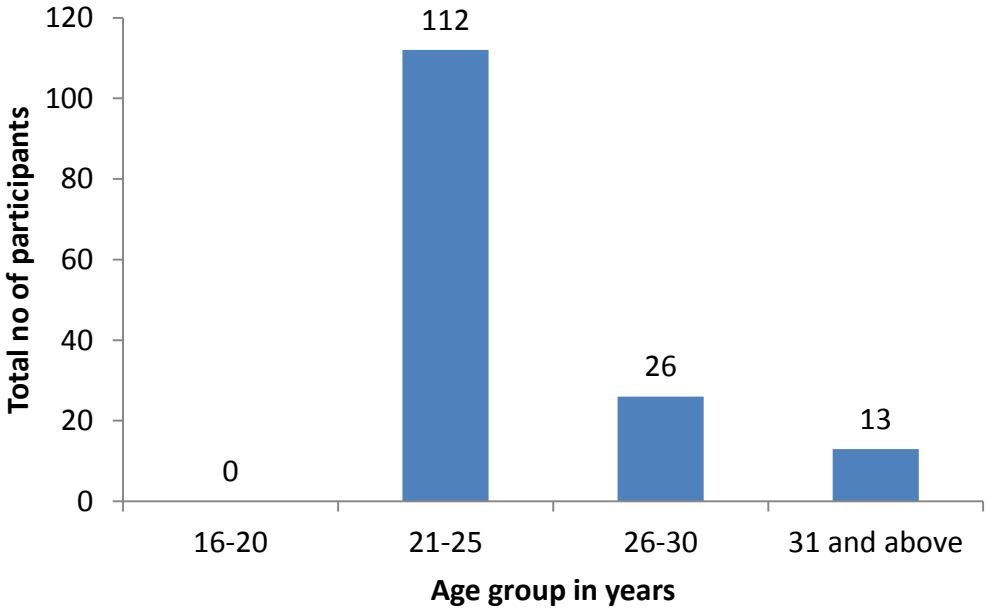

Figure 2: Age wise distribution of participants

Table 3: Experience wise distribution of participants

Working Experience in years	Total no of participants n=151 (%)
<1	2(1.3%)
1-5	132(87.4%)
6-10	10(6.6%)
11-15	0
16-20	0
>21	7(4.6%)

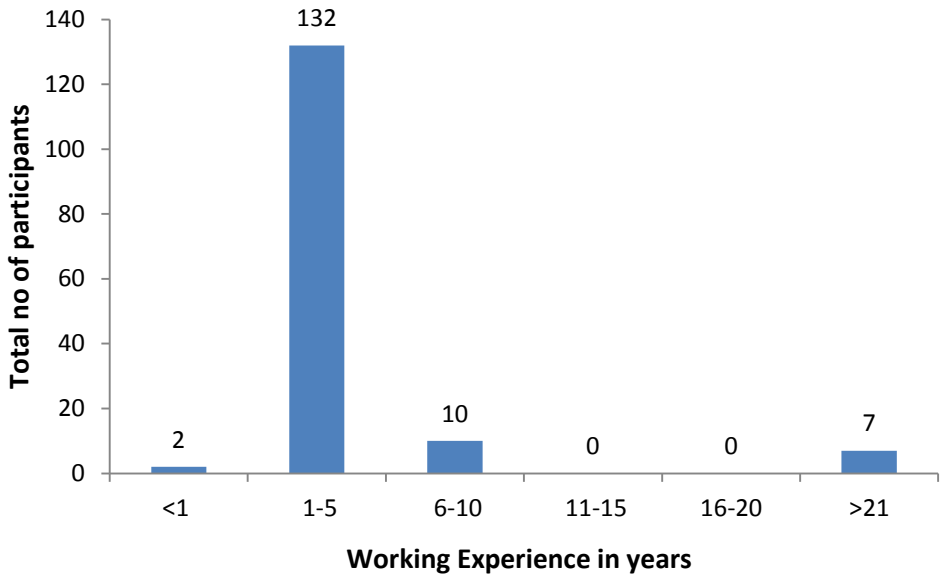

Figure 3:Experience wise distribution of participants

Table 4: Grade/Rank wise distribution of participants

Designation	Total no of participants n=151(%)
Beginner/junior	3(1.9%)
Nurse	139(92%)
Senior Nurse	1(0.6%)
Nurse specialist	5(0.3%)
Senior nurse specialist	2(0.1%)
Head of nurse	1(0.6%)

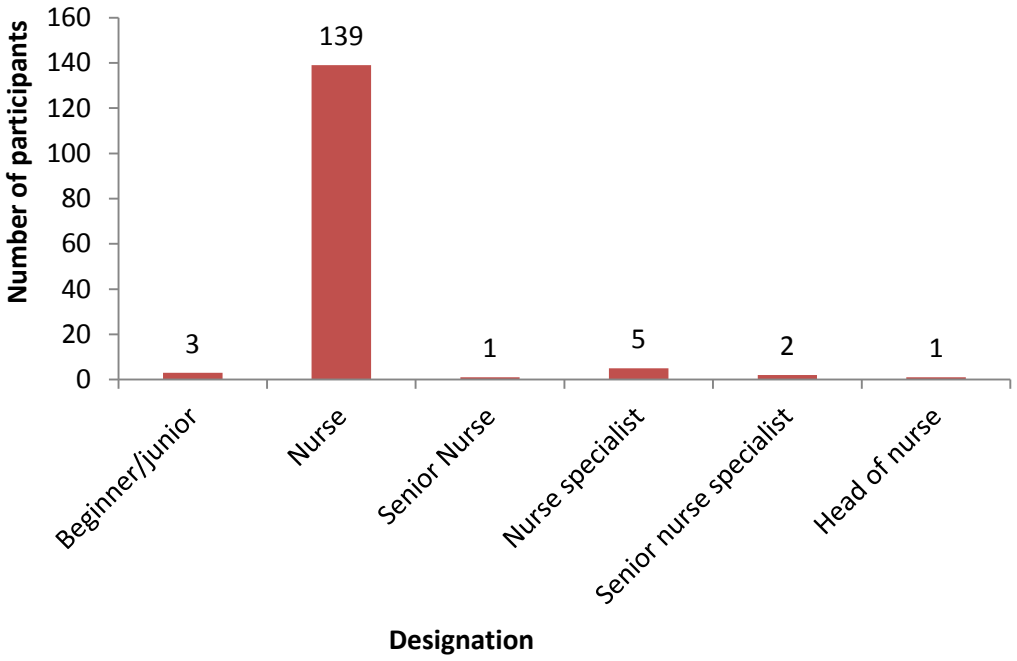

Figure 4: Grade/Rank wise distribution of participants

Table 5: Awareness status

Awareness status	**Total no of participants n=151(%)**
Have you attended any program/seminar relate to PV	
Yes	147(97.3%)
No	4(2.6%)

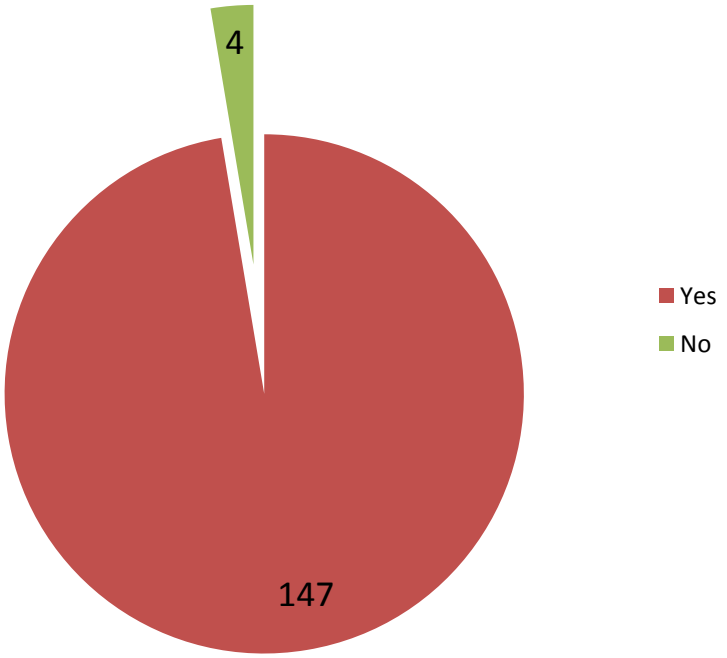

Figure 5: Knowledge towards ADR/PV

Table 6: Knowledge towards ADR/PV

S.No	Question regarding knowledge	Respondent response n= 151 (%)
1	Pharmacovigilance a) The science of monitoring ADR's happening in a hospital b) The process of improving the safety of drugs c) The detection, assessment, understanding and prevention of adverse effects d) The science detecting the type and incidence of ADR after the drug is marketed e) Do not know	94 (62.2%) 21(13.9%) 30(19.8%) 2(1.3%) 4(2.6%)
2	ADR a) Noxious and unintended response to drug and occurs at doses normally used in man or animal for prophylaxis, diagnosis or therapy of disease b) Noxious and unintended response to drug and occurs at doses normally used in man for prophylaxis, diagnosis and therapy of disease c) Any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment d) Any adverse reaction identified in regulatory documents such as investigators brochures or product monograph occurring within the expected frequency e) Do not know	64 (42.3%) 21 (13.9%) 46 (30.4%) 15 (9.9%) 5 (3.3%)

S.No	Question regarding knowledge	Respondent response n= 151 (%)
3	Are you aware of any formal reporting system available in other countries a) Yes b) No	 116(76.8%) 35(23.1%)
4	Are you aware of any drug that has been banned in the world due to ADR? a) Yes b) No c) Do not know	 18(11.9%) 23(15.2%) 110(72.8%)
5	Have you ever shared information about ADRs with anyone? a) Yes b) No	 8(5.3%) 143(94.7%)
6	Where is an international centre for adverse effect reaction monitoring located? a) Sweden b) Germany c) USA d) Do not know	 12(7.9%) 28(18.5%) 65(43%) 46(30.4%)
7	Which of the following is a major risk factor for the occurrence of maximum adverse drug reactions? a) Arthritis b) Renal failure c) Visual impairment d) All of these e) Do not know	 24(15.8%) 64(42.3%) 16(10.5%) 5(3.3%) 42(27.8%)

S.No	Question regarding knowledge	Respondent response n= 151 (%)
8	Are you aware of any of the below reporting centre or system in India where you can report ADR? a) Madras Medical College, Chennai b) Christian Medical College, Vellore c) PSG institute, Coimbatore d) Govt. Kilpauk Medical College, Chennai e) Ministry of health f) No centre for reporting g) Do not know	 43(28.4%) 5(3.3%) 0(%) 50(33%) 41(27.1%) 0(%) 12(7.9%)
9	Identify the types of ADR's? a) Type A, B, C, D, E, F and G b) Type 1, 2, 3, 4, 5, 6 and 7 c) Known, unknown and common, uncommon d) Reversible and irreversible e) Do not know	 0(%) 0(%) 0(%) 0(%) 151(100%)
10	Which one of the following is the WHO online database for reporting ADR's? a) ADR advisory committee b) Med safe c) Vigibase d) Med watch e) Do not know	 64(42.3%) 24(15.8%) 12(7.9%) 30(19.8%) 21(13.9%)
11	From which sources do you gather information about ADRs to new drugs? a) Textbooks b) Journals c) Internet d) Medical representatives e) Seminars/conferences	 15(9.9%) 2(1.3%) 23(15.2%) 3(1.9%) 78(51.6%)

S.No	Question regarding knowledge	Respondent response n= 151 (%)
	f) Direct mail brochures	0(%)
	g) All of the above	30(19.8%)
12	Side effects like headache, fever and vomiting should not be reported?	
	a) Strongly agree	21(13.9%)
	b) Agree	84(55.6%)
	c) Disagree	40(26.4%)
	d) Strongly disagree	6(3.9%)
13	What to report**:**	
	a) Serious adverse event (SAE)	12(7.9%)
	b) Adverse Event	8(5.2%)
	c) Adverse drug reaction (ADR)	32(21.1%)
	d) Side Effect	84(55.6%)
	e) All	9(5.9%)
	f) Not know	6(3.9%)
14	Which ADR should be reported	
	a) All serious ADRs	123(81.4%)
	b) ADRs to herbal and non-allopathic drugs	0(%)
	c) ADRs to new drugs	0(%)
	d) ADRs to vaccines	0(%)
	e) Unknown ADRs to odd drugs	14(9.2%)
	f) All of the above	14(9.2%)
15	In India which Regulatory body is responsible for monitoring of ADR's?	
	a) Central Drugs Standard Control Organization*	4(2.6%)
	b) Indian Institute of sciences	57(37.7%)
	c) Pharmacy Council of India	68(45%)
	d) Medical Council of India	22(14.5%)

S.No	Question regarding knowledge	Respondent response n= 151 (%)
16	Pharmacovigilance includes a) Drug related problems b) Blood related products c) Herbal products d) All of the above	 67(44.3%) 0(%) 23(15.2%) 61(40.3%)

Table 7: Attitude towards ADR reporting

Attitude towards ADR	Total no of participants n= 151 (%)			
	Strongly agree	**Agree**	**Disagree**	**Strongly disagree**
ADR reporting necessary	126(83.4%)	25(16.5%)	0(%)	0(%)
ADR reporting should be mandatory	136(90%)	15(9.9%)	0(%)	0(%)
ADR reporting increase patient safety	131(86.7%)	20(13.2%)	0(%)	0(%)
ADR is time consuming	110(72.8%)	25(16.5%)	8(5.2%)	8(5.2%)
Do you think it is necessary to confirm that an ADR is related to a particular drug before reporting it?	8(5.2%)	131(86.7%)	12(7.9%)	0(%)
Education programs have positive effect on ADRs reporting	148(98%)	3(1.9%)	0(%)	0(%)
Consulting the physician is important before report an ADR	63(41.7%)	53(35%)	35(23.1%)	0(%)
With my present knowledge, I am very well prepared to report any ADRs notice in my future practice.	8(5.2%)	84(55.6%)	10(6.6%)	49(32.4%)
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	151(100%)	0(%)	0(%)	0(%)

Table 8: Practice towards ADR reporting

Practice	Yes	No
Have you reported any ADR	89(59%)	62(41%)

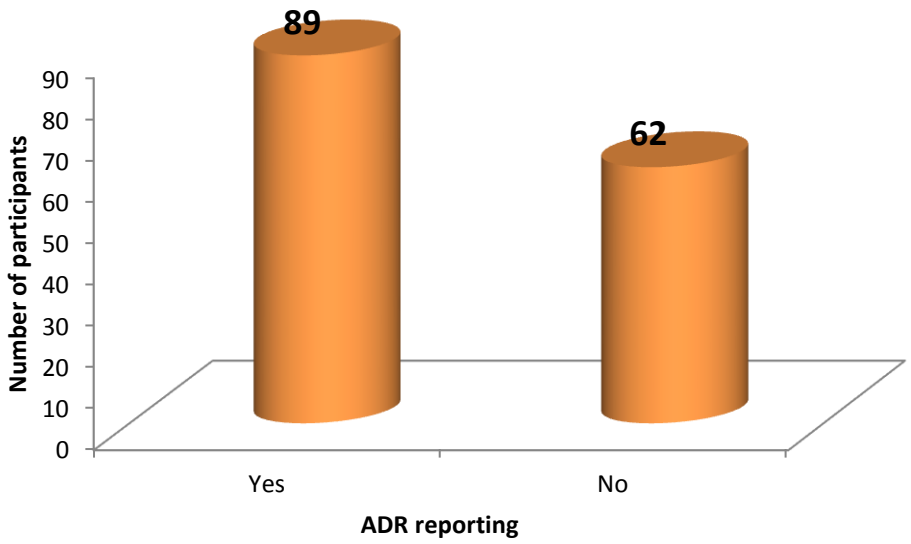

Figure 6: Practice towards ADR reporting

Table 9: Distribution of nature of ADR

Nature of ADR reported	Total no. of participants n= 89 (%)
Severe	84(94.3%)
Moderate	26(29.2%)
Mild	51(57.3%)
All of the above	0(%)

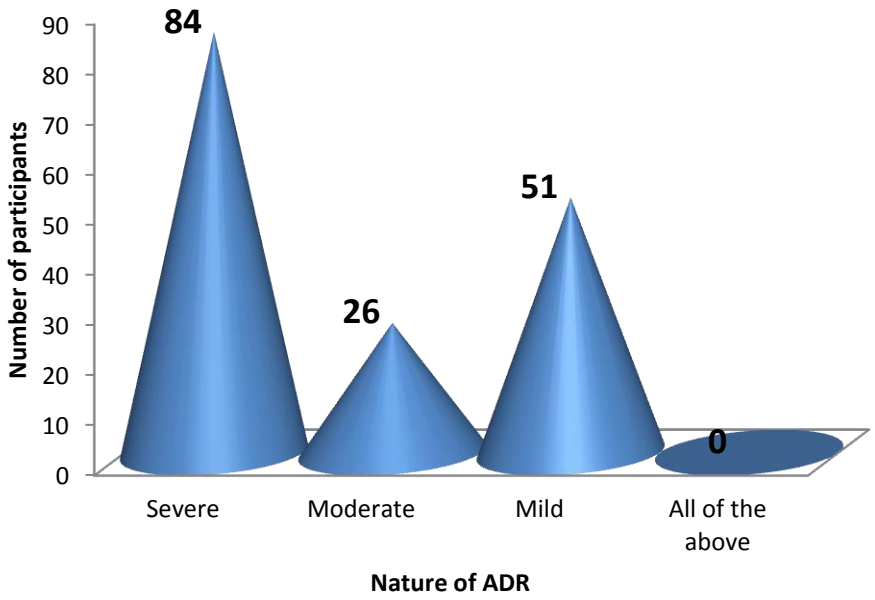

Figure 7: Distribution of nature of ADR

Table 10: Practice towards ADR prevention

Practice	Yes	No
Have you done any intervention to prevent ADRs	0(%)	89(58.9%)

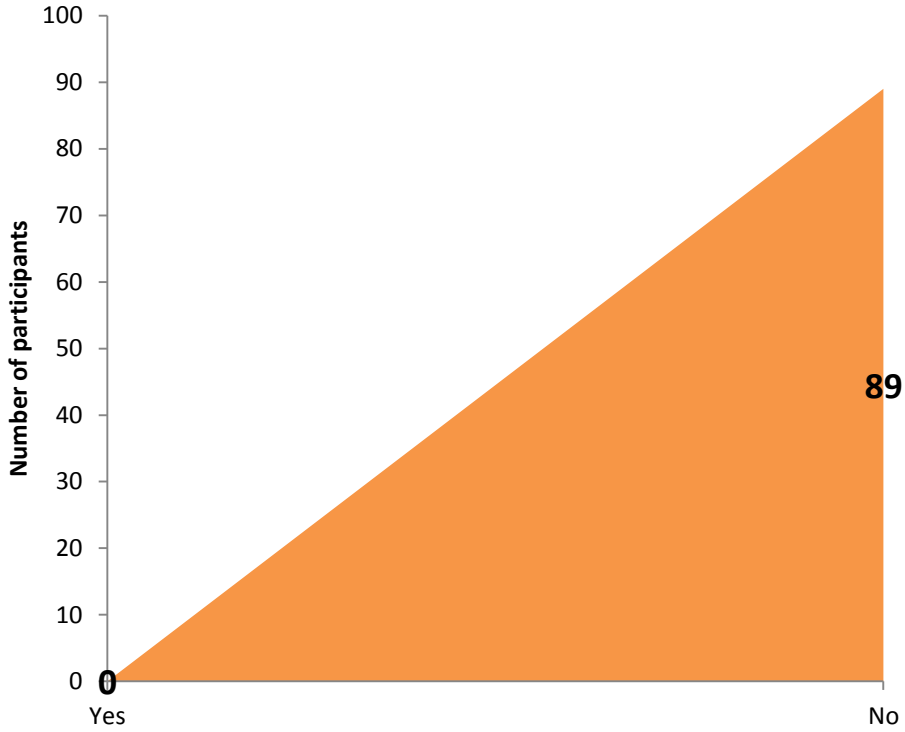

Figure 8: Practice towards ADR prevention

Table 11: Distribution of ADR reporting centre

ADR reporting centre by respondents	Total no. of participants n= 151(%)
Colleagues/ immediate reporting	119(78.8%)
Head of department	20(13.2%)
Ministry of health	0(%)
Do not know	12(7.9%)

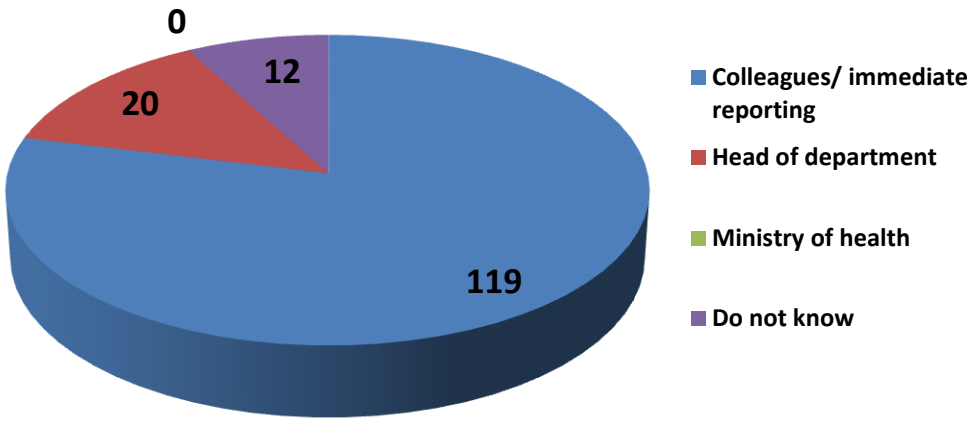

Figure 9: Distribution of ADR reporting centre

Table 12: Distribution of preferred methods of ADR reporting

Preferred methods to report ADR	Total no. of participants n=151(%)
Direct contact	139(92%)
Post	0(%)
Telephone	12(7.9%)
Mail/website	0(%)

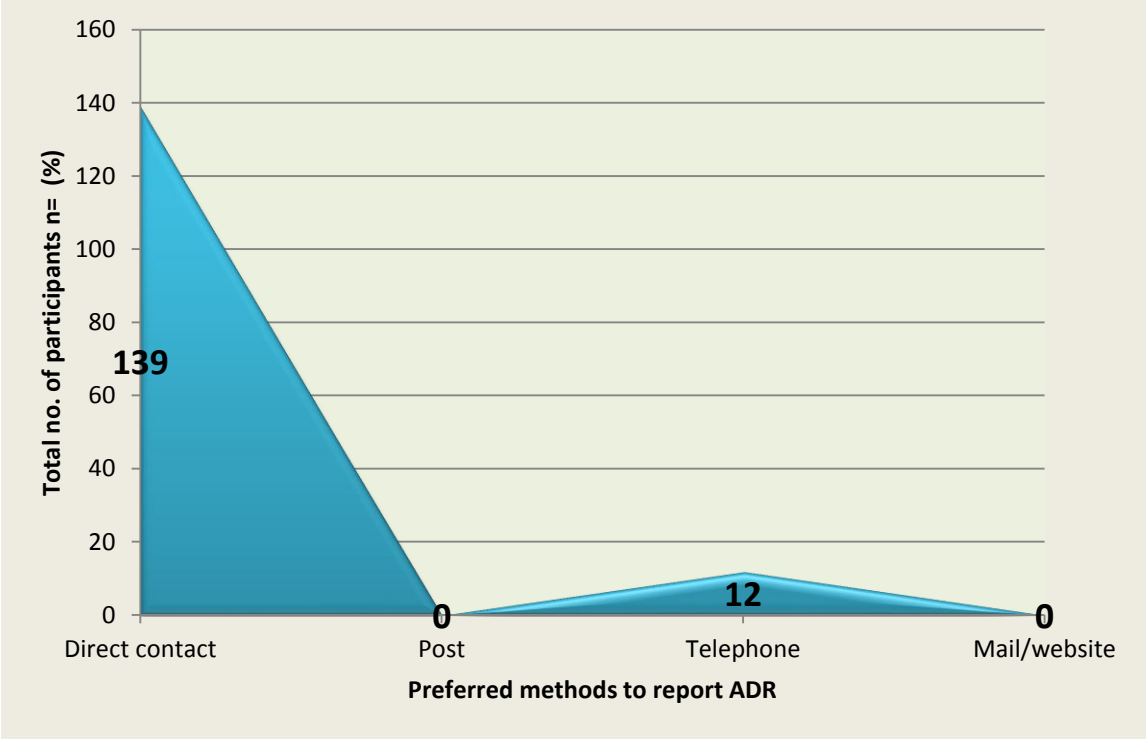

Figure 10: Distribution of preferred methods of ADR reporting

Table 13: Distribution of factors responsible for ADR reporting

Factors that encourage you to report ADRs	Total no. of participants n=151(%)
Seriousness of reaction	9(6%)
Unusualness of reaction	0(%)
Involvement of new drug	0(%)
Confidence in diagnosis of ADR	0(%)
All of above	142(94%)

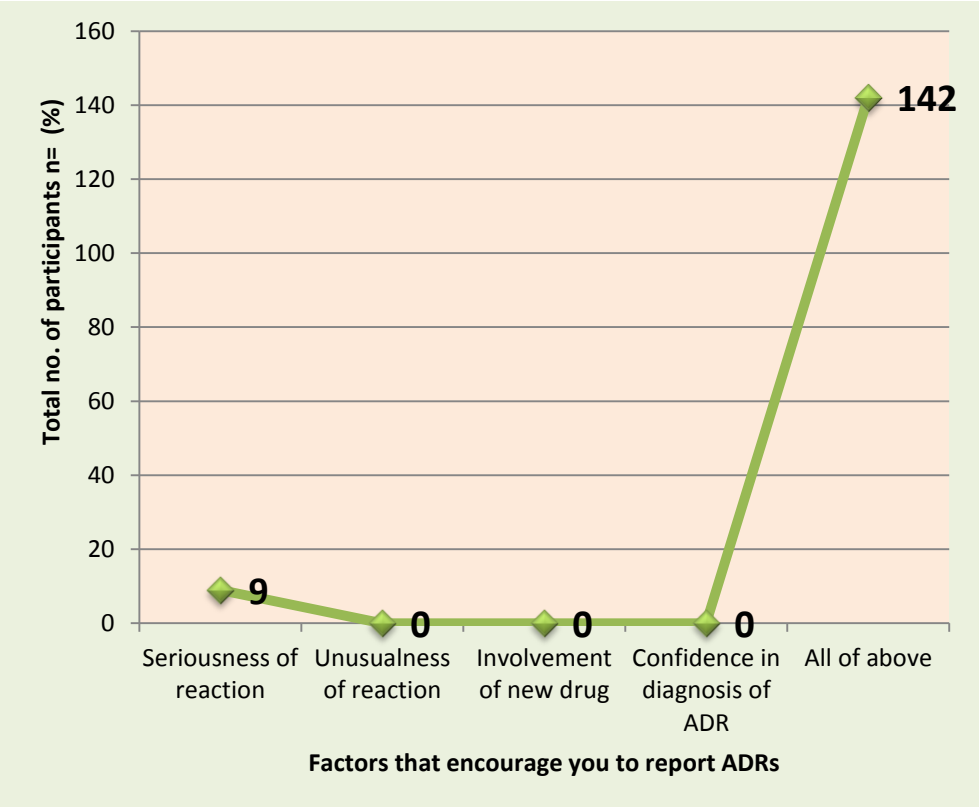

Figure 11: Distribution of factors responsible for ADR reporting

Table 14: Factors that hinder ADR Reporting

Factors that discourage you to report ADRs	**Total no. of participants n= 151 (%)**
Did not know how to report	14(9.2%)
Do not think it important	3(1.9%)
Managing patient was more important	30(19.8%)
Lack of access to ADR reporting form	23(15.2%)
Patient confidentiality issue	54(35.7%)
ADR reporting is physicians' duty	0(%)
Reporting is time consuming	13(8.6%)
Legal liability issue	2(1.3%)
All of above	12(7.9%)

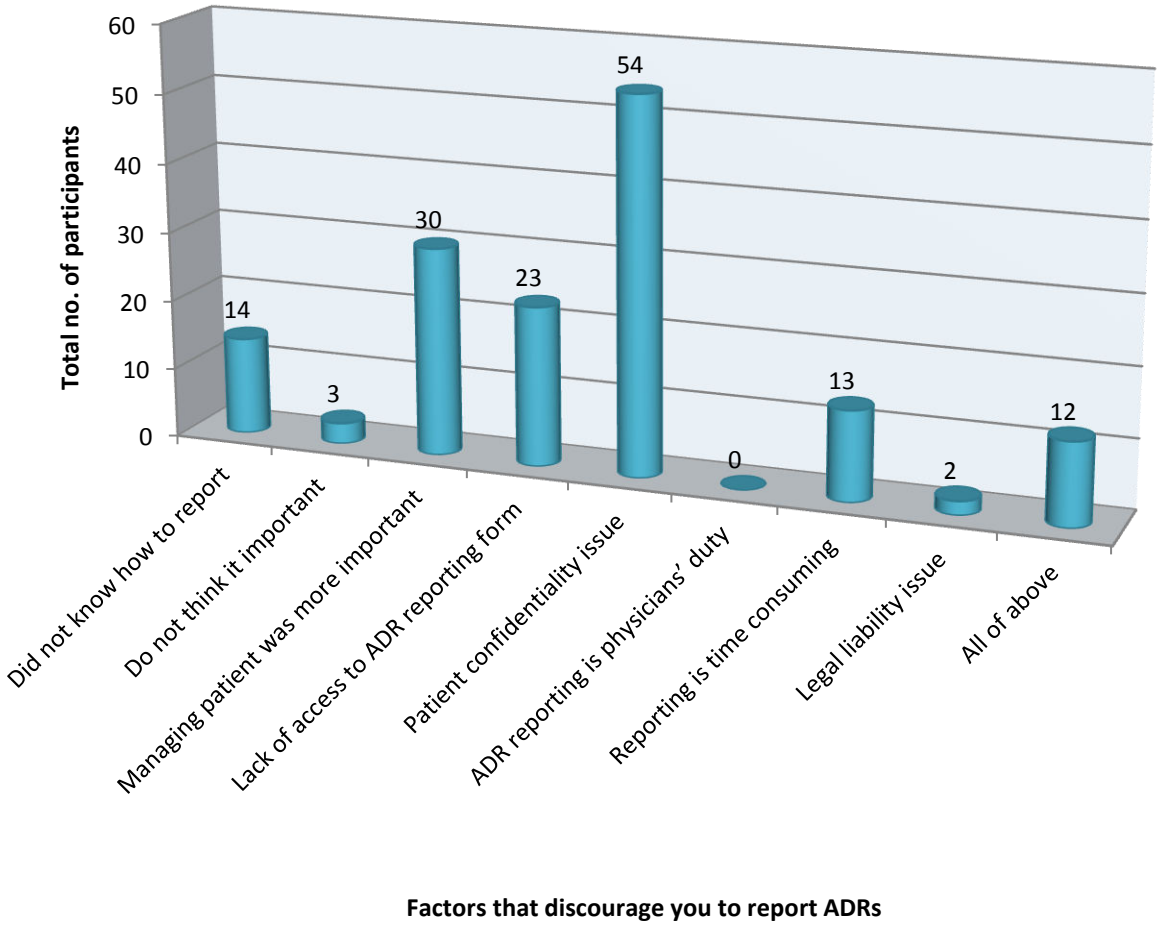

Figure 12: Factors that hinder ADR Reporting

8. DISCUSSION

The objective of the study was to assess the knowledge, attitude and practice of pharmacovigilance and adverse drug reaction reporting among nursing staffs. The study was conducted in the multi speciality hospitals at Chennai. 300 participants were randomly approached for collecting the data. Out of 300, 150 were responded.

In present study total 300 questionnaires were distributed among nursing staffs who were working in different private multi speciality hospitals at Chennai. Out of 300 questionnaires, 151 were filled and return back it. In table 1, majority of study participants were female nursing staffs 144(95.3%) than male 7(4.63%). Similarly, women were found to be more interested in participating in surveys investigating drug safety issues.[26]

Age wise distribution of study participants were presented in Table 2. 112 (74.1%) study participants were present in the age group of 21-25 years, 26 (17.2%) participants in 26-30 years and least participants were 13(8.6%) in age group of 31 and above. In previous study eighty-four percent of the participants were between20 and 40 years of age which is similar to our study report. Therefore, young HCPs are likely more enthusiastic about ADR reporting systems.[26]In previous study male health care professionals were higher than female which is inconsistent with our study report.[33]

In table 3, majority of study participants 132(87.4%) had working experience of 1-5 years than 10(6.6%) had 6-10 years. Only 7(4.6%) nursing staffs had greater than 21 years of experience and 2(1.3%) participants had less than 1 years of experience which mean fresher. None of the participants were present in between 11-15 and 16-20 years of experience. More than half (54%) of the study participants were at the early stages of their professional careers (up to five years of experience), which might explain the limited knowledge and awareness of the ADR reporting

system. However, many participants had more years of experience, and these participants had more knowledge regarding the ADR reporting system.[26,33]

In table 4, 139(92%) participants had designation as nurse, 5(0.3%) as nurse specialists, 3(1.9%) as beginners/juniors, 2(0.1%) as senior nurse specialists and each 1(0.6%) as head of nurse and senior nurse. In another study by Ahmad *et al*., among 151 nursing staffs, 147(97.3%) have attend seminars/programmes related to pharmacovigilance and others 4(2.6%) have didn't attend any programmes. Training professionals with prior exposure to pharmacovigilance practices could result in betteroutcomes.[37] Strengthening the regular education and training of HCPs about pharmacovigilance and ADR reporting is a very important step towards improving the safety and quality of life of patients Alshammari*et al*., (2015).[26]

There were 16 questions assessing knowledge regarding ADR. As shown in table 6, 30(19.8%) and 21 (13.9%) knew about the term pharmacovigilance and ADRs respectively, 151(100%)don't knew about the types of ADR. Among respondents, 12(7.9%) knew where the International Centre for adverse drug reaction monitoring is located. Only 18(11.9%) were aware of the drugs that are banned due to ADR whereas 64(42.3%) knew the major risk factor for the occurrence of ADR. A small proportion of respondent 41(27.1%) knew where to report ADR in India and only 116(76.8%) knew about the formal reporting system in other countries. The majority of respondents 143(94.7%) did not share information regarding ADR to anyone, whereas 78(51.6%) respondents gathered information about ADR through the seminars, 15(9.9%) from textbooks, journals 2(1.3%), medical representative 3(1.9%), internet 23(15.2%) and all of the above 30(19.8%) respectively. None had collected from direct mail brochures. Among respondents, 21(13.9%) believed that side effects like a headache, vomiting and fever should never be reported. Only a small proportion of the respondents were aware of WHO online database for reporting ADR 12(7.9%). In India, 4(2.6%)

knew about which Regulatory body is responsible for monitoring of ADR's. 67(44.3%) knew about pharmacovigilance which includes drug related problems.

Knowledge regarding ADR is very important when it comes to reporting ADR. It is very important for physicians as well as pharmacists to possess great knowledge of ADR and procedure of reporting ADR. The results showed that health care professionals have poor knowledge regarding ADR reporting which is in correspondence with studies conducted in other different cities of Pakistan which include Lahore, Abbottabad and Hyderabad, all these studies show poor knowledge of physicians and pharmacists regarding ADR reporting.[38,39] Similar studies carried out in India showed poor knowledge of physicians and pharmacists regarding ADR.[40]A study carried out inIndia reveals that 41.6% were aware of the International Centre for ADR monitoring.[41]On the other hand, the studies conducted in India by Ghosh*et al*., and Gupta *et al*., showed that the healthcare professionals have high knowledge regarding ADR reporting but still the poor practice of ADR.[42,43]

Many respondents could not identify the most appropriate source of information on ADR. According to the previous study, 31.9% physicians and pharmacists refer to the internet, 18.4% textbooks, 12.7% journals and 4.7% to seminars.[24]

Attitude towards ADR reporting were presented in table 7. Majority of participants had given response as strongly agree for the questions like ADR reporting necessary 126(83.4%), ADR reporting should be mandatory136(90%), ADR reporting increase patient safety 131(86.7%), ADR is time consuming 110(72.8%), Education programs have positive effect on ADRs reporting 148(98%), Do you think Pharmacovigilance should be taught in detail to healthcare professionals 151(100%) and least for Consulting the physician is important before report an ADR63(41.7%). Since most of the physicians and pharmacists consider

ADR reporting is necessary, they should overcome the obstacles in reporting ADR and report ADR voluntarily, whenever they encountered and should consider ADR reporting as their professional obligation.[24]

131(86.7%),84(55.6%) had given response as agree for the questions Do you think it is necessary to confirm that an ADR is related to a particular drug before reporting it and With my present knowledge, I am very well prepared to report any ADRs notice in my future practice. Meanwhile 49(32.4%) given response as strongly disagree for I am very well prepared to report any ADRs notice in my future practice. This clearly shows that most of the nursing staffs had very good attitude towards ADR reporting and pharmacovigilance. Study by Desai *et al*., showed that 97.3% in India believe that ADR reporting increase patient safety.[44]

59% of nursing staffs have reported ADR and 41% have never reported any ADR. Out of 89 ADR, 84(94.3%) were found to be severe, 51(57.3%) were mild and 26(29.2%) were moderate. None of the nursing staffs had ever done any interventions to prevent ADRs. The ADR reporting practice among physicians and pharmacists was far below than expectations. ADR has not been reporteddespite encountering ADR in their daily practice. One of the important findings of this study is the majority of respondents 88.3%never reported ADR. Only 11.7% reported ADR and those who have reported ADR did not report to the proper place, only 9.1% respondents report ADR to the Ministry of Health.[24]

Out of 151 participants, 119(78.8%) replied that ADR reporting center were colleagues/ immediate reporting, 20(13.2%) said head of department, 12(7.9%) said do not know. Itis evident from the study that physicians and pharmacists are not encouraged by their workplace to report ADR. The majority statedthat their workplace does not encourage them to report ADR and does not provide any information regarding ADR reporting. Alarge proportion of respondent stated that they have never been trained for reporting ADR.[24]Furthermore, different healthcare

professions were compared in this study, and pharmacists (77%) were found to be better informed regarding the NPC's location; most physicians and nurses thought the NPC existed within the Ministry of Health. Knowledge, awareness, and practice are interrelated but might not always bereciprocal. In our study, a quite encouraging percentage (73%) of HCPs were aware of the ADR reporting system at their workplace; however, only 27% of the HCPs were able to report ADRs.95% of the participants responded that they would report ADR reactions for both old and newly marketed agents.[26]

Among 151 nursing staffs, most of them 139(92%) had reported that direct contact as preferred method to report ADR and rest 12(7.9%) reported as telephone. Furthermore, only 22% of the participants were aware that the NPC was located at the SFDA. However, this lack of knowledge is not a major concern because HCPs can report ADRs online or viae-mail, postal mail, fax or phone, and all of these routes are accepted by the NPC as reporting methods.[45]

Distribution of factors responsible for ADR reporting is presented in table 12. 142(94%) reported as all of the above such as seriousness of reaction, unusualness of reaction, involvement of new drug, confidence in diagnosis of ADR. The remaining 9(6%) had reported as seriousness of reaction. Our study report is highly correlate with Nisha et al.[24]

Factors that discourage the respondents to report ADR include patient confidentiality issue 54(35.7%) and managing patient was more important 30(19.8%). Some stated that lack of access to ADR reporting form 23(15.2%), did not know how to report 14(9.2%), reporting is time consuming13(8.6%), all of above 12(7.9%), do not think it important 3(1.9%), legal liability issue 2(1.3%). One of the findings of previous study is that lack of knowledge on how, where and whom to report ADR is one of the main reasons which discourages physicians and pharmacists to report ADR.[24]Whereas studies carried out in India by Shah *et al*.,

revealed that lack of time is the main reason that discourages healthcare professionals to report ADR.[46]

Previous studies around the world by Adhikary*et al*., and Abubakar*et al*., emphasised great importance in providing awareness regarding ADR reporting and education interventions have a positive impact on increasing awareness regarding ADR reporting among healthcare professionals. Therefore it is very important to provide education and training to improve ADR reporting system.[47,48]

According to a study by Bisht*et al*., in India, the healthcare professionals who have received educational training regarding ADR reporting hadadequate knowledge of pharmacovigilance and improved awareness regarding ADR.[49] Proper education and training should be provided to healthcare professionals at regular interval to increase their knowledge regarding ADR reporting. Some other studies also confirmed that educational interventions lead to an increased awareness about ADR reporting (Li *et al*.,2004, Rajesh *et al*., 2011).[9,50] Knowledgeand awareness of ADR reporting alone is not sufficient, and anemphasis on the practical involvement of HCPs in ADR reporting isrequired.[51]

One of the main limitations, number of participants is very less. The findings should not be extrapolated to nursing staffs in other hospitals. It is necessary to extend this type of study to other hospitals in India to obtain more generalizable results. Knowledge and perception may vary on other locations. Therefore, its findings cannot be generalized to the whole country.

9. CONCLUSION

- The study discloses that nursing staffs have poor knowledge and poor practice but good in attitude towards ADR reporting. Even though they have reported more number of severe ADRs, they didn't perform any further interventions to prevent it. The major factor which discourages them from reporting ADR is a patient confidentiality issue and managing patient was more important. Seriousness of reaction, unusualness of reaction, involvement of new drug, confidence in diagnosis of ADR was the factors that encourage nursing staffs to report ADR.

- Based on the outcomes of the present study following recommendations are concluded. ADR reporting forms should be freely available in all hospitals as it can improve the reporting rates of ADR in the country. ADR reporting should be mandatory for all healthcare professionals. Each hospital should have a database on ADR which should be considered by healthcare professionals. The nursing syllabus curriculum needs to be revised to include ADR and pharmacovigilance. Continuous education programme and workshop want to be conducted regularly relate to how and where to report ADR.

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College of Pharmacy

J.K.K.NATTRAJA ETHICS COMMITTEE
J.K.K.NATTRAJA COLLEGE OF PHARMACY
(MANAGED BY J.K.K.RANGAMMAL CHARITABLE TRUST)
Natarajapuram, NH-544 (Salem to Coimbatore),
Komarapalayam -638 183. Namakkal District. Tamil Nadu.

Ref: JKKNCP/ETHICS_PRACTICE/018PDS02 ***Date: 17.01.2018***

To
Dr. N. Venkateswaramurthy, M.Pharm, PhD.,
Department of Pharmacy Practice,
J.K.K. Nattraja College of Pharmacy,
Kumarapalayam – 638183,
India.

DearVenkateswaramurthy,

The proposal entitled **"ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AND ADVERSE DRUG REACTION REPORTING AMONG NURSING STAFFS"** was reviewed by the ethics committee in its meeting held on 17.*01.2018*and permission is granted to you to carry out the study.

Thanking you,

Yours faithfully,

Dr. A. Sivakumar
Chairman of Ethics Committee

INFORMATION FOR PATIENT

Dear participant,

I am a post graduate student of 'JKK Nattraja College of Pharmacy' currently conducting a project entitled **"Assessment of knowledge, attitude and practice of pharmacovigilance and adverse drug reaction reporting among nursing staffs".**

For this, am requesting you to fill the structured questionnaire. No identifiable personal data's will be disclosed.

Thank you very much for your kind participation.

CONSENT FORM

I, have read and understand the above information. I have agreed to allow my data to be collected for the project work.

_____ _____

Signature of participant Date

QUESTIONNAIRE

Age: Gender: Male / Female

Name of the working hospital:

Are you aware of any pharmacovigilance program? Yes/no

I. Knowledge towards ADR

1. Define pharmacovigilance?
   a) The science of monitoring ADR's happening in a hospital
   b) The process of improving the safety of drugs
   c) The detection, assessment, understanding and prevention of adverse effects
   d) The science detecting the type and incidence of ADR after the drug is marketed
   e) Do not know

2. Define ADR?
   a) Noxious and unintended response to drug and occurs at doses normally used in man or animal for prophylaxis, diagnosis or therapy of disease
   b) Noxious and unintended response to drug and occurs at doses normally used in man for prophylaxis, diagnosis and therapy of disease
   c) Any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment
   d) Any adverse reaction identified in regulatory documents such as investigators brochures or product monograph occurring within the expected frequency
   e) Do not know

3. Are you aware of any formal reporting system available in other countries
   a) Yes
   b) NO

4. Are you aware of any drug that has been banned in the world due to ADR?
   a) Yes
   b) No
   c) Do not know

5. Have you ever shared information about ADRs with anyone?
   a) Yes
   b) No

6. Where is an international centre for adverse effect reaction monitoring located?
   a) Sweden
   b) Germany
   c) USA
   d) Do not know

7. Which of the following is a major risk factor for the occurrence of maximum adverse drug reactions?
   a) Arthritis
   b) Renal failure
   c) Visual impairment
   d) All of these
   e) Do not know

8. Are you aware of any of the below reporting centre or system in India where you can report ADR?
   a) Madras Medical College, Chennai
   b) Christian Medical College, Vellore
   c) PSG institute, Coimbatore
   d) Govt. Kilpauk Medical College, Chennai
   e) Ministry of health
   f) No centre for reporting
   g) Do not know

9. Identify the types of ADR's?
   a) Type A, B, C, D, E, F and G
   b) Type 1, 2, 3, 4, 5, 6 and 7
   c) Known, unknown and common, uncommon
   d) Reversible and irreversible
   e) Do not know

10. Which one of the following is the WHO online database for reporting ADR's?
   a) ADR advisory committee
   b) Med safe
   c) Vigibase
   d) Med watch
   e) Do not know

11. From which sources do you gather information about ADRs to new drugs?
   a) Textbooks
   b) Journals
   c) Internet
   d) Medical representatives
   e) Seminars/conferences
   f) Direct mail brochures
   g) All of the above

12. Side effects like headache fever and vomiting should not be reported?
   a) Strongly agree
   b) Agree
   c) Disagree
   d) Strongly disagree

13. What to report**:**
   a) Serious adverse event (SAE)
   b) Adverse Event
   c) Adverse drug reaction (ADR)
   d) Side Effect
   e) All

f) Not know

14.Which ADR should be reported

a) All serious ADRs
b) ADRs to herbal and non-allopathic drugs
c) ADRs to new drugs
d) ADRs to vaccines
e) Unknown ADRs to odd drugs
f) All of the above

15. In India which Regulatory body is responsible for monitoring of ADR's?

a) Central Drugs Standard Control Organization*
b) Indian Institute of sciences
c) Pharmacy Council of India
d) Medical Council of India

16. Pharmacovigilance includes

a) Drug related problems
b) Blood related products
c) Herbal products
d) All of the above*

II. Attitude towards ADR reporting

ADR reporting (Put tick)	**Strongly agree**	**Agree**	**Disagree**	**Strongly disagree**
ADR reporting necessary				
ADR reporting should be mandatory				
ADR reporting increase patient safety				
ADR is time consuming				
Do you think it isnecessary to confirmthat an ADR is related toa particular drug				

beforereporting it?				
Education programs have positive effect on ADRs reporting				
Consulting the physician is important before report an ADR				
With my presentknowledge, I am verywell prepared to reportany ADRs notice in myfuture practice.				
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?				

1. Why it is important to report ADR
   a) To identify and detect new ADR
   b) To share information about ADRs with colleagues
   c) To improve patient safety
   d) To identify relative safe drugs
   e) To measure the incidence of ADRs

2. What factors do you think are important whole deciding to report an ADR?
   a) Unusualness of the reaction
   b) Involvement of a new drug
   c) Confidence in diagnosing of an ADR

III. Practice towards ADR reporting

1. Have you reported an ADR? Yes/No

2. ADR reported per week
   a) 0-5/week
   b) 6-10/week
   c) More than 10/week

3. ADR reporting centre
   a) Concerned pharmaceutical company
   b) Head of department
   c) Ministry of health
   d) Don't know

4. Nature of ADR reported
   a) Severe
   b) Moderate
   c) Mild
   d) All of the above

5. Preferred method to report ADR
   a) Direct contact
   b) Post
   c) Telephone
   d) Mail/website

6. Professional responsible to report ADR
   a) Physicians
   b) Pharmacist
   c) Both physicians and pharmacists

7. List the common ADR that you have reported
8. Have you done any intervention to prevent ADRs? Yes/no

IV. Factors that encourage you to report ADRs

a) Seriousness of reaction
b) Unusualness of reaction
c) Involvement of new drug
d) Confidence in diagnosis of ADR
e) All of above

V. Factors that discourage you to report ADRs

a) Did not know how to report
b) Not knowing where to report
c) Do not think it important
d) Managing patient was more important
e) Lack of access to ADR reporting form
f) Patient confidentiality issue
g) ADR reporting is physicians' duty
h) Reporting is time consuming
i) Legal liability issue
j) All of above