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Assessment of Knowledge, Attitude and Practice of Healthcare Professionals towards Adverse Drug Reaction Monitoring and Reporting: A Cross-Sectional Study in Kerala

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ABSTRACT
The contribution of all healthcare professionals is vital to promote an efficient adverse drug reaction reporting system. In this context, healthcare professionals are important to observe patients' response regarding drug therapy and to report an Adverse Drug Reaction Pharmacovigilance is a practice aimed to monitor drug safety in life conditions and capture adverse drug events during post marketing phase of drugs life cycle. But under reporting of adverse reactions is a major cause of concern and threat to the pharmacovigilance systems. This thesis highlights importance of knowledge, attitude and practice of health care professional towards adverse drug reaction monitoring and reporting. Modern medicines have changed the way in which diseases are managed and controlled. However, despite all their benefits, evidence continues to mount that adverse drug reactions (ADRs) are common cause of illness, disability and even death. Knowledge, attitude and practices of health professionals towards ADRreporting are known to have crucial contribution in the detection and reporting of the reactions.A cross sectional questionnaire-based study was conducted on 216 health care professionals to assess their knowledge, attitude and practice towards ADR reporting. A pretested questionnaire comprising 27 questions was administered to healthcare professionals. Data was collected using Google forms. The statistical analysis was done using MS Excel, under the Micro-Soft XP operating system 2013.Majority of the respondents were Doctors (9.7%), Nurses (27.8%), Pharmacist (22.7%), Students (39.8%). Among the respondents 96.75% had good knowledge. 64(29.6%) participants encountered ADRs in the past 12 months. The majority of respondents (93.5%) had a positive attitude towards ADRs reporting. The study revealed that majority of the respondents had good knowledge, positive attitude and very limited practices towards ADR reporting.

Keywords: Adverse Drug Reaction (ADR), Pharmacovigilance, Knowledge, Attitude and Practice (KAP), Health Care Professionals (HCP), World Health Organization(WHO)

I. INTRODUCTION

Adverse Drug Reaction (ADR) is defined by World Health Organisation (WHO) as "Any reaction toa drugthatis noxious, unintended and occurs at doses used for prophylaxis, diagnosis and therapy excluding failure to accomplish the intendedresponse".[1]. Adverse drug reactions are classified into six typesdose-related (Augmented): which can be predicted from the known pharmacology of the drug (example Hypoglycaemia –Insulin), non-dose-related (Bizarre) : which is unpredictable, rare and fatal (example Anaphylaxis to penicillin) ,dose-related and time-related (Chronic):which occurs due to prolong treatment (example :Hypothalamic pituitary adrenal axis suppression by corticosteroids) , time-related (Delayed) :occurs after years of treatment(example : teratogenicity and carcinogenesis) ,withdrawal (End of use) : which occurs after the withdrawal(example : Tachyphylaxis) and failure of therapy (Failure) :often caused by drug interaction(example : failure of oral contraceptives in presence of an enzyme inducer).An adverse drug reaction is one which has an unknown etiology, causing an enormous burden on both the society and healthcare system and contributes to about 5% to 20% of hospitalization worldwide.[2]

The safety, efficacy and quality of medicines are essential components to the overall wellbeingof patients. When determining the safety of new pharmaceuticals, testing and clinical trials are conducted. These allow for a range of adverse drug reactions (ADRs) to be identified, some of which occur frequently and others that may be extremely rare. ADR is a major problem that

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occurs worldwide. Health professionals played a very vital role in reporting of ADR around the world which has led to the detection of serious and unusual ADR that were previously undetectable and many drugs like "Rofecoxib "were withdrawn in the past ,therefore enhancing the safety of patients, It has been noticed inthe past that ADR reporting has provided early warning signs and therefore increases patient safety.[3]Pharmacovigilance and report of adverse drug reaction were started after the thalidomide disaster in the mid-20th century .Thalidomide was the drug which was prescribed in many countries to alleviate morning sickness in pregnant women and this drug was teratogen and caused congenital disorder in newborns. After the disaster,Pharmacovigilance is the science and activity related to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems. [4]NationalPharmacovigilanceCentreswereestablish edinanumberofcountriesaroundtheworld.

The Pharmacovigilance Programme of India (PvPI) is under Indian Pharmacopoeia Commission which is a constant endeavor and it encourages the active participation of all healthcare professionals including doctors, nurses, pharmacist and medical students in reporting any suspected ADR to the Central Drug Standard Control Organisation (CDSCO) by filling a suspected ADR reporting form.Healthcare professionals (HCPs) reports ADRs to nearest ADR Monitoring Centres (AMCs) under PvPI and the same is collected and collated by the Indian Pharmacopoeia Commission (IPC), National Coordination Centre (NCC). The Uppsala Monitoring Centre (UMC), Sweden maintains the international database of ADR report received from different countries.[5]UMC works by collecting, assessing and communicating information from member countries' national pharmacovigilancecentres in regard to the benefits, harm, effectiveness and risks of drugs. The main aim of UMC is to achieve worldwide safety among young and old. They develop several tools for helping International Drug Monitoring Programme. They are Vigibase, Vigiflow, Vigilyze,Vigimine,Vigimed,Vigiaccess.[6]

All ADRs ranging from minor to severe reactions should be reported with particular concern to ADRs to new medicines, serious adverse drug reactions, unexpected reactions, and drug interactions which are potentially serious or clinically significant. Modern medicines have substantially changed the diseases treatment schemes that improve the treatment outcomes in many medical conditions. However, adverse reactions to medicines are a common cause of morbidity, hospital admissions, longer hospital stay, disability, and even mortality [7]. It is important for healthcare professionals in the pharmacovigilance program can improve the ADR reporting.

Reporting of ADR can result in detection of serious and unusual ADR which can reminded undetected during a clinical trial. Rational use of medicines not only decreases morbidity and mortality but also increases the quality of life , so in order to improve rational use of medicines the safety, efficacy and quality of medicines should be ensured , on the other hand irrational use of medicines can life threatening because it could be the reason for serious adverse drug reaction[8] .During postmarketing phase of approved drug, spontaneous adverse drug reaction reporting used for risk benefit evaluation and monitoringof new drugs. Spontaneous reportingof ADRs refers to the passive reporting of ADRs by healthcare professionals or patients as they witness them. Active reporting refers to activities used to "study the causal relationship betweenmedical interventions and harmful effects" through targeted surveillance[9].ADR results in temporary or permanent harm, disability, or death or that requires discontinuing the drug, changing the drug therapy, modifying the dose, necessitates admission to a hospital, prolongs stay in a health-care facility, necessitates supportive treatment, significantly complicates diagnosis, and negatively affects prognosis and became as global problem in both developingand developed countries with a significant number of morbidity and mortality hence,the detection , recording and reporting of ADR becomes vital in safe use of medicines. To improve participation of health-care professionals in spontaneous reporting, it might be necessary to design strategies that modify Knowledge, Attitude and Practice (KAP) about PV and ADR reporting. Studies Conducted in medical interns, nurses and hospital pharmacists suggested that continualawarenessprogrammesonADR reportingandPVmightimprovetheirpracticingskills and paves the way toward the quality of care.[10] Health care professionals responsible for identifying, documenting and ADRs reporting. Their contribution to early detection and reporting is essential. ADR reporting affects factors including lack of awareness, ambiguity about who should report, difficulties with reporting procedures, lack of feedback on submitted reports, rapid resolution of adverse events and so on.[11]

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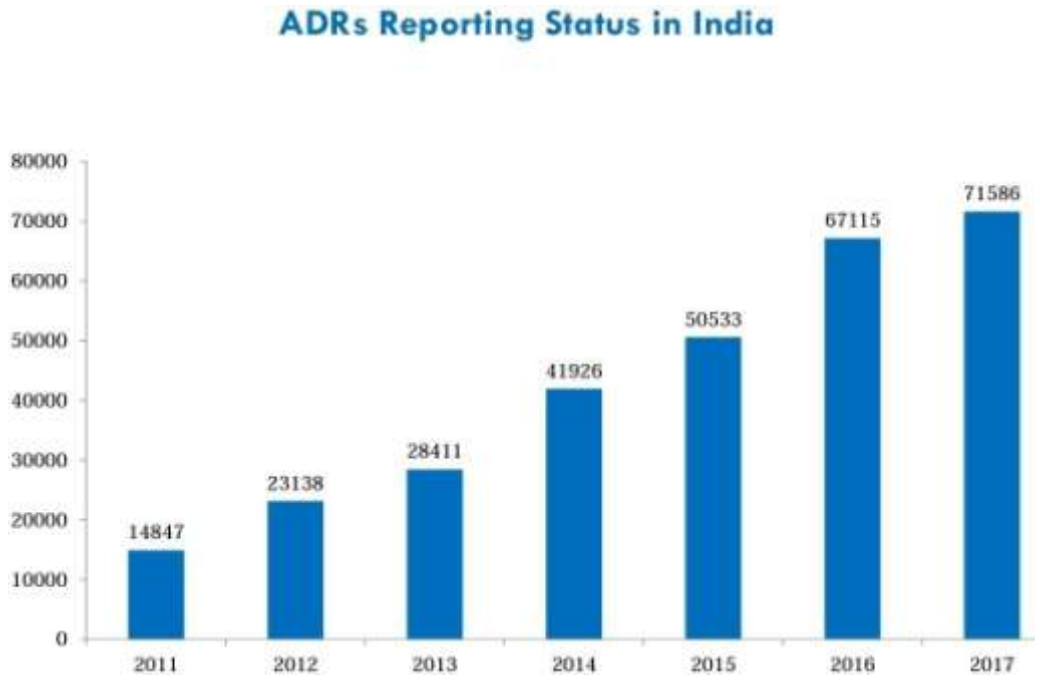

Fig.1ADRs Reporting Status in India

Pharmacovigilance plays an essential role in the reduction of ADRs; thus, the evolution and growth of this science are critical for effective and safe clinical practice. ADRs spontaneous reporting systems are the basic components for the comprehensive post-marketing surveillanceof drug-induced risks. These systems are inexpensive and simple to operate and they enable the generation of signals indicating potential problems, allowing the identification of new and rare ADRs, but also enable continuous monitoring of all drugs used in real life situations from the time they are first marketed. However, their strength is tightly connected to the actual reporting rate by health care professionals.[12]

Adverse drug reactions (ADRs) have been shown to constitute a significant health challenge in both developed and developing nations by being associated with increased morbidity and mortality, prolonged hospital stays, increased utilization of healthcare resources and increased cost of healthcare.[13]Globally,adversereactions tomedicationsarethefourthtothesixth leading cause of death. ADRs have become a major global public health concern that needs to be addressed at all levels of the health care system. In January 2000, the Institute of Medicine reported that medication related problems annually cause nearly 44,000 - 98,000 deaths. Inwhich an estimated 7,000 deaths are attributed to ADRs.[14] ADR spontaneous reporting iscurrently the basic method for collecting information about adverse post-marketing risks andevents. Spontaneous reporting systems are inexpensive and simple to operate, and form the coreof the global World Health Organization (WHO) database.[15]

Maintaining and monitoring drug's efficacy and safety is a critical point in clinical practice. Thus, pharmacovigilance is an essential clinical discipline to ensure the appropriate use of medicines and patient safety, worldwide.[16] The term "adverse effect" is preferable to otherterms such as "side effect" or "toxic effect", side effect occurs via a different mechanism and may be dose-related or not. A toxic effect is an exaggeration of the desired therapeutic effect which is usually not common at normal doses, and drug toxicity occurs at a higherdose thatis to say the toxic effect is always dose-related the terms "adverse reaction" and "adverse effect" are interchangeable,exceptthat anadverse effectis seen from the point of view ofthe drug, whereas an adverse reaction is seen from the point of view of the patient.[17]

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The main emphasis of a spontaneous reporting system is to identify serious unidentified ADR. Underreporting is a noteworthy disadvantage of spontaneous reporting. HCPs play an important role in spontaneous reporting of ADR and management of drug therapy. Widely used spontaneous reporting system by HCPs can be applied to all drugs and can cover the entire population with ease of practice and at low cost.[18] Many studies conducted among health professionals elsewhere showed lack of knowledge about pharmacovigilance and ADRs reporting, so there is a need to study the knowledge of health professionals regarding PV as they are responsible to report ADR during their practice. Attitude of health professionals towards pharmacovigilance will encourage them to report and follow ADRs[19].

The hypothesis of this study was that scarce pharmacovigilance knowledge of HCP is the main reason for underreporting. A survey was conducted to test this hypothesis and illuminate, from HCPs' point of view, the existing factors limiting the reporting rates of ADRs.[20]

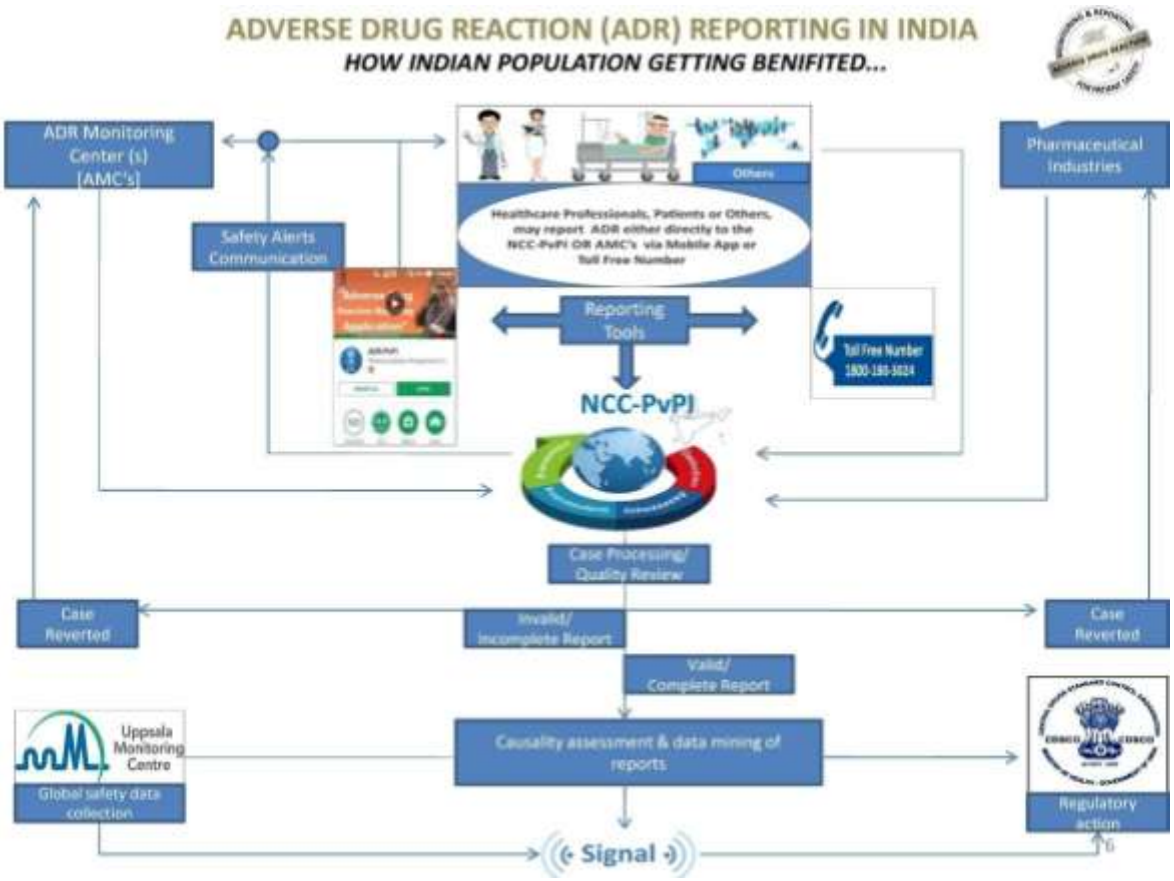

Fig.2:AdverseDrugReactionReportinginIndia[21]

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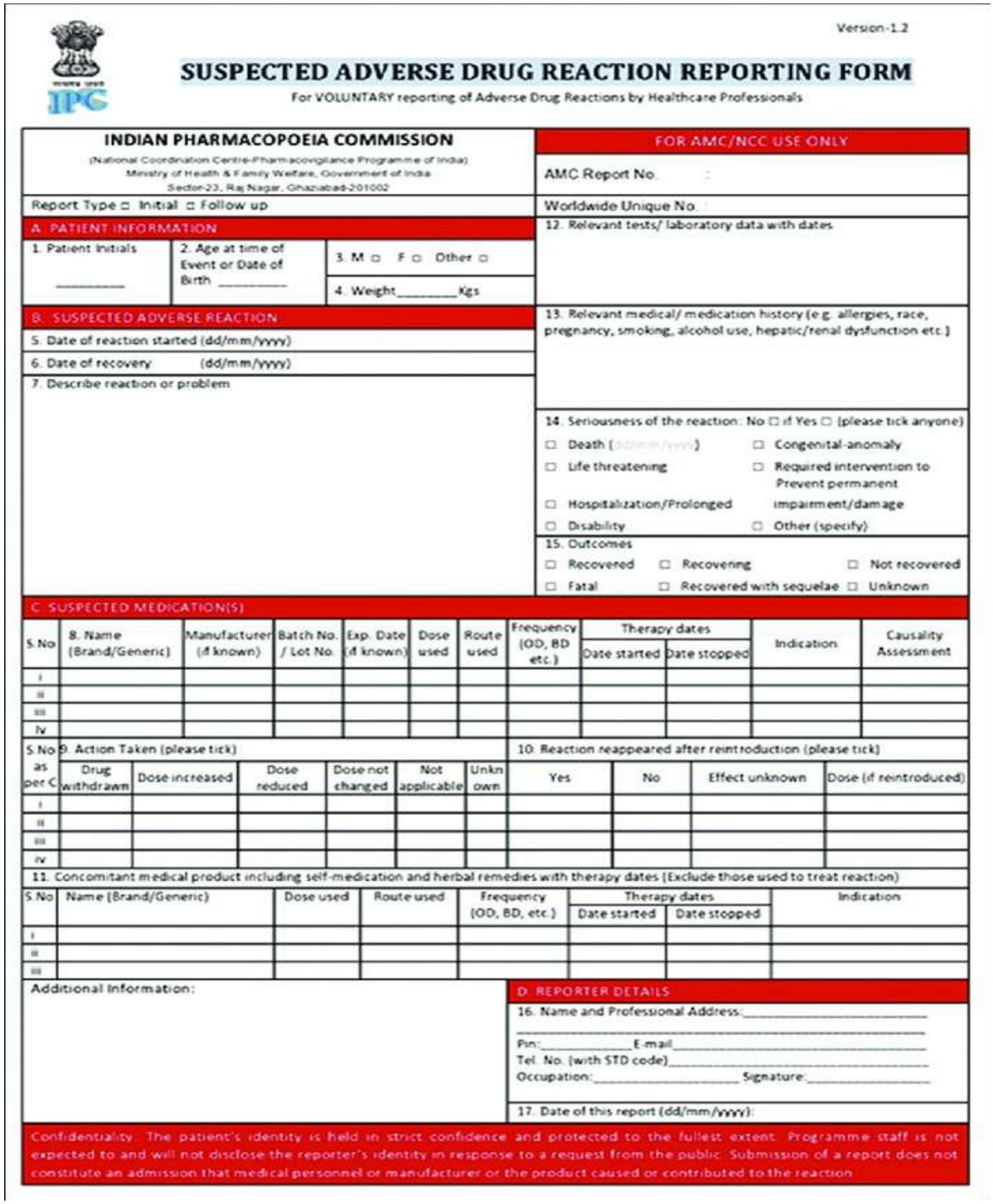

Version-1.2

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY
AMC Report No.
Worldwide Unique No.

Report Type □ Initial □ Follow up

A. PATIENT INFORMATION

1. Patient Initials _____
2. Age at time of Event or Date of Birth _____
3. M □ F □ Other □
4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No □ if Yes □ (please tick anyone)
□ Death (dd/mm/yyyy) □ Congenital-anomaly
□ Life threatening □ Required intervention to Prevent permanent impairment/damage
□ Hospitalization/Prolonged
□ Disability □ Other (specify)

15. Outcomes
□ Recovered □ Recovering □ Not recovered
□ Fatal □ Recovered with sequelae □ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i											
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____
_____
Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

Fig.3:Suspected ADR reporting form

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II. METHODOLOGY

STUDYDESIGN

The study was a cross-sectional questionnaire-based study. The study participants consisted ofall the healthcare professionals (doctors, nurses, and pharmacists) who gave their informed consent and who were working at the hospital during the study period. The study was conducted at the period of January 2021 to April 2021.

KAPQUESTIONNAIRE

Study instrument, that is KAP questionnaire was prepared using standard literature and self-knowledge and experience. It is designed for both the assessment and improving the knowledge and awareness among the participants. A total of 27 questions were related to knowledge,attitudeand practice ofADR reporting.All thequestions were developedinthe view of knowing their knowledge on ADRs to assess their perception towards ADR reporting.

DESIGNINGDATACOLLECTIONFORMAND VALIDATION

Priortousingthedatacollectionformofvalidatedforap propriatenessand understanding.

INCLUSIONCRITERIA

Healthcareprofessionalsworking inthe hospital duringthestudy periodand who were willingto participate in the study after providing the informed consent

EXCLUSIONCRITERIA

Healthcare professionals other than doctors, nurses and pharmacists were excluded from the study. Those who did not consent to participate were not included in the study.

STUDYDATACOLLECTION

A total of 216 healthcare professionals participated in this cross-sectional questionnaire-based study.A time period of one week was given for the participants to read, understand and answer the question. Online platform such as Google forms were used for conducting the survey.

STATISTICALANALYSIS

All data summarises and listings were generated using MS Excel, under the Micro –Soft XP operating system 2013. Descriptive statistics such as percentage, mean, SD were used to analyse the data.

III. OBSERVATIONS & RESULTS

In the current study, questionnaires were distributed among 216 health care professionals (Doctors-21, Nurses-60, Pharmacist-49, Students-86). Of these 216 were duly completed and returned.

❑ **Healthcareprofessionals'knowledgerega rdingADRreporting:**

Therewere7questionsassessingtheknowledgeofhealt hcareprofessionalstowardsADR.

TABLE:1Questionnaire based on Knowledge

Questions	**NumberofRespondents**				**Frequency (n) (n=156)**	**Percentageof Respondents (%)**
	Doctors (21)	Nurse (60)	Pharmacist (49)	Students (Pharmacy/ Nursing)(86)		
1.Define Pharmacovigilance?	19 (8.7%)	56 (25.9%)	48 (22.2%)	86 (39.8%)	209	96.75%

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2.DefineAdversedrug reaction?	19 (8.7%)	55 (25.48%)	49 (22.7%)	85 (39.3%)	208	96.29%
3.Do you think ADR reporting is a part of professional obligationof all related to health care? (yes)	21 (9.7%)	60 (27.8%)	49 (22.7%)	86 (39.8%)	216	100%
4.Which one of the following is the Indian online database for reporting ADR? (ADRPvPI)	14 (6.4%)	47 (21.7%)	38 (17.6%)	59 (27.3%)	158	73.14%

Among the respondents, 66.7% of the respondents reported antibiotics as the drug, 13% of respondents reported gastrointestinal drugs, 8.8% reported tuberculosis drugs and 11.6% of them reported antidiabetics as the drug.

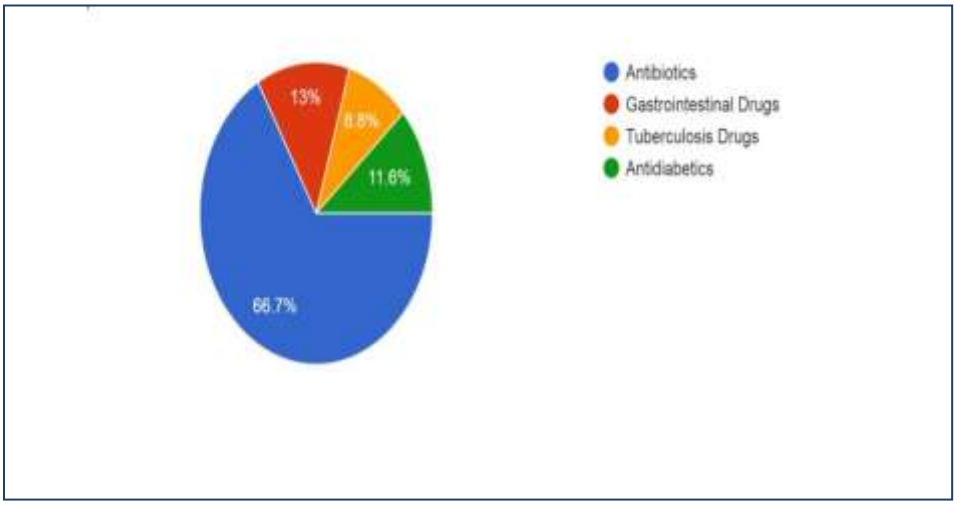

Fig.4:Drugs that frequently causes ADR

Among the respondents 57.9% of the respondents reported vomiting as the most adverse effect ever been reported, 10.2% respondents reported headache, 5.1% respondentsreported fever, 23.6% respondents reported itching and others (2%) includes rashes, drowsiness, GIT disturbances and Steven Johnson syndrome.

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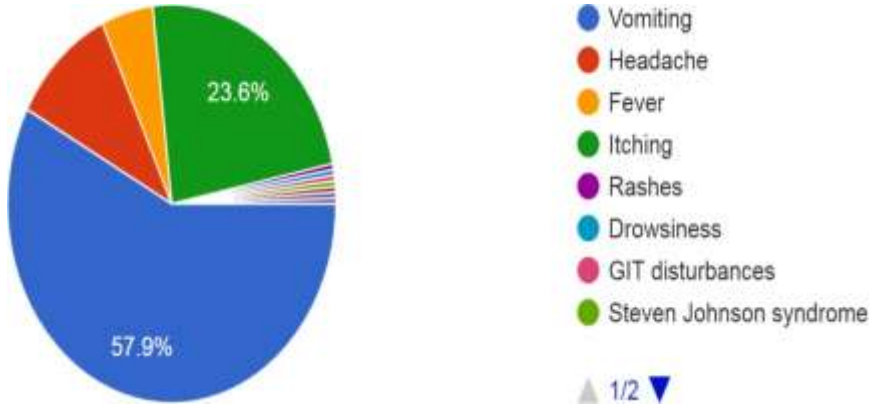

Fig.5:Adverse effect reported in patients

The results of the study revealed that age (6%) is the mostpossible risk factors for the occurrence of ADR, 1.9% of respondents reported gender as the risk factor, 19.9% respondents reported multiple drugs, 3.7% of respondents reported disease state and 68.5% of respondents reported all of the above factors are responsible for the occurrence of ADR.

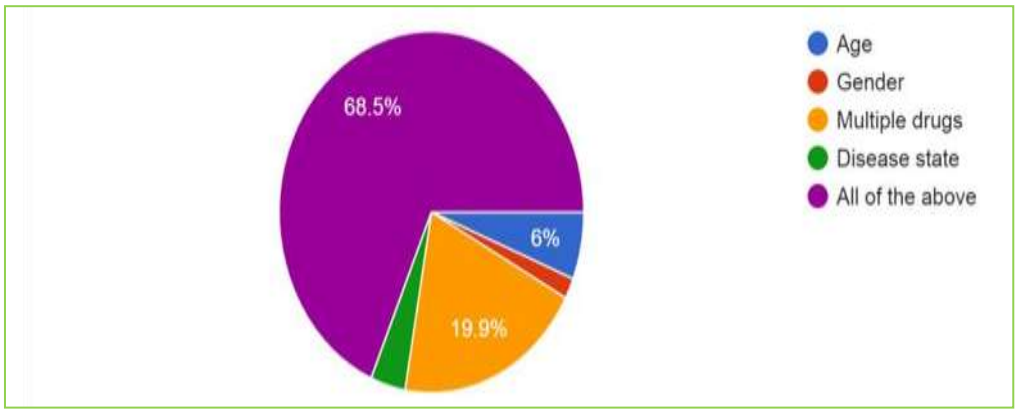

Fig.6:Factorsaffectingtheoccurrence ofADR

❑ **Healthcareprofessionals'attituderegardingADRreporting**:

Thereare5questionsassessingtheattitudeofhealthcareprofessionalstowardsADR.

TABLE:2QuestionnairebasedonAttitude

Questions	**NumberofRespondents**	**Frequency (n) n=216**	**Percentage of Respondents(%)**

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	Doctors (21)	Nurses (60)	Pharmacists (49)		
1.Do you think close monitoringisrequiredfor new drugs? (yes)	19 (8.7%)	56 (25.9%)	45 (20.8%)	199	92.12%
2.Do you think ADR reportingshouldbemade mandatory?(yes)	19 (8.7%)	55 (25.4%)	44 (20.38%)	84 (38.875%)	202	93.51%
3.Haveyoueverseenthe ADRreportingform?Are you willing for ADR reporting? (yes)	15 (6.4%)	39 (18.07%)	32 (13.8%)	45 (20.87%)	131	60.64%

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4.Have you ever been trainedonhowtoreport ADR? (yes)	14 (6.1%)	37 (17.4%)	27 (12.1%)	39 (18.04%)	117	87.03%
5.Do you think ADR reportingwillbenefithealt h caredeliverysystem?(yes)	19 (8.7%)	50 (32.1%)	47 (21.7%)	72 (33.3%)	188	87.03%

❑ **HealthcareprofessionalspracticeregardingADR reporting**:

Thereare4questionsassessingthepracticeofhealthcareprofessionalstowardsADR reporting.

TABLE:3QuestionnairebasedonPractice

Questions	**NumberofRespondents**				**Frequency (n) n=216**	**Percentageof Respondents (%)**
	Doctors (21)	Nurses (60)	Pharmacists (49)	Students (Pharmacy/ Nursing)(86)		
1.Doyoukeep recordofADR? (yes)	14 (6.4%)	48 (22.2%)	31 (14.3%)	38 (17.5%)	131	60.64%

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2.Did you ever counsel the patients regardingpossibility of ADR?(yes)	14 (6.04%)	49 (22.7%)	35 (16.25%)	37 (17.12%)	135	62.55%
3. Have you anytime read an article onthepreventionof ADR?(yes)	14 (6.04%)	34 (15.7%)	39 (17.6%)	57 (26.3%)	144	66.6%
4. Have you ever shared information aboutADRwithany one? (yes)	15 (6.9%)	47 (21.7%)	48 (22.2%)	55 (25.4%)	165	76.38%

IV. DISCUSSION

One of the main goals of this study was to investigate the knowledge of HCPs towards ADRs reporting. This issue is critical for research to identify the necessary interventions, as HCPs cannot effectively participate in the reporting without sufficient knowledge of the ADR and its reporting process. Since ADRs are an important cause of morbidity and mortality and increased health care costs, all HCPs should be alert and keen towards any unexpected or suspected reactions occurring in patients taking medicines, assessing, managing, and reporting the encountered adverse events, which are an integral part of the pharmaceutical care process.

In our study of an average 75% of the participants (21 Doctors ,60 Nurse, 49 Pharmacist and 86 Students) have the knowledge about the identification of ADR, its management, reporting process, preventive measures and PV importance. When compared to other studies participants (V.Meda et .al) the knowledge of our study participants is good.55.6% of the respondents knew the term ADR which are comparable with a study done in Saudi Arabia(39.6%). 63% of the respondentsknew the term pharmacovigilance which are comparable with a study done in Northeast Ethiopia (20.18%).

In our study of an average 95% of participants (9 Doctors (4.2%), 21 Nurses (9.7%), 26 Pharmacist (12%) and 160 (74.1%) of participants believed that reporting of ADR is the responsibility of all healthcare professionals. When compared to other study (V. Srinivasan, et.al), about 52.6% of healthcare professionals believed that reporting of ADR is the collective responsibility of Doctors, Nurses and Pharmacist too. Similarly in our study, 49.4% of participantsweretrainedonhowtoreportADR.Whencomparedtootherstudy(KiduGidey,et .al), more than half of the participants were untrained, which leads to insufficient knowledge of ADR reporting. In our study, the majority of Pharmacists showed a better knowledge towards ADR reporting as compared to physicians, nurses and students. This is similar to studies conducted by Rabia Hussain, et.al, where Pharmacists were able to define ADR more appropriately than physicians and nurses.

Our study reveals that 54.4% of physicians, pharmacist and nurses know about the International centre forreportingADR.Asimilarstudy(Zaka UnNisa, et.al),whichshowsthatonly15.5%of physicians,Pharmacistandnurseswereknow abouttheADRreportingcentre.This studyreveals

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poorknowledgeandpracticeregardingADRreporting. However,mostoftherespondentsshown a positive attitude towards ADR reporting. In our study reveals that healthcare professionals had good knowledge, practice and positive attitude towards ADR reporting.

V. SUMMARYANDCONCLUSION

Adverse drug reaction isa major problemthat occurs worldwide. Health care professionalsplays a vital role in reporting of ADR around the world. Our study identified that the health care professionals have good knowledge and positive attitudes towards ADR monitoring and reporting. The practice ofhealthcare professionalsishowevernot satisfactoryinADRreporting. This suggests that a lot needs to be done to improve the practice of ADR reporting. Majority of the dispensers did not know the ADR reporting form, the existence of the national ADR monitoringsystemandthetypeofreactionsto report.The majorreasonsforunderreportingmay be wrong, lack of confidence on diagnosis of ADR and unavailability of reporting forms. The results from observational study also indicated that reporting forms were not available in one third of the health facilities.

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ANNEXURES

QUESTIONNAIRE BASED ON ADR REPORTING AMONG HEALTH CARE PROFESSIONALS

1. DefinePharmacovigilance?

a. ThescienceofmonitoringandreportingADRshappeninginahospital
b. Theprocessofimprovingthesafetyofdrugs
c. Thedetection,assessment,understandingandpreventionofadverseeffects
d. ThesciencedetectingthetypeandincidenceofADRafterthedrugismarketed
e. TheprocessofdeterminingADR

2. DefineADR?

a. Noxiousandunintended response todrugandoccursat dosesnormally usedinman or animal for prophylaxis, diagnosis or therapy of disease
b. Noxious and unintended response to drug and occurs at doses normally used in manfor 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. Anyadversereactionidentifiedinregulatorydocumentssuchasinvestigators, brochures or product monograph occurring within the expected frequency
e. Adversedrugreactionofadrug

3. Do you think ADR reporting is a part of professional obligation of all related to health care?

a. Yes
b. No
c. Donotknow

4. HaveyoueverseenacaseofADRduringyourwardposting?

a. Yes

b. No

5. Ifyes,haveyoueverreportedonADRinthelast12months?

a. Yes
b. No
c. Maybe

6. WhichofthedrugsthatfrequentlycauseADR?

a. Antibiotics
b. GastrointestinalDrugs
c. TuberculosisDrugs
d. Antidiabetics

7. Whichisthemostadverseeffecteverbeenreported?

a. Vomiting
b. Headache
c. Fever
d. Itching e.Diarrhoea

8. Whatarethepossibleriskfactorsfortheoccurrence ofADRs?

a. Age
b. Gender

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c. Multipledrugs
d. Diseasestate
e. Alloftheabove

9. Whichfactordiscouragesyoufromreportingthe ADRs?

a. Difficultyin decision
b. Treatmentis important
c. Fearofnegative impact
d. Lackoftime
e. Lackofawareness

10. ThehealthcareprofessionalsresponsibleforreportingADRinahospitalis/are?

a. Doctor
b. Pharmacist
c. Nurses
d. Allofthe above

11. HaveyoueverbeentrainedonhowtoreportADR?

a. Yes
b. No

12. HaveyoueverseentheADRreportingform?AreyouwillingforADRreporting?

Ans:

13. DoyouthinkreportingADRisnecessary?

a. Yes
b. No

14. Doyouthinkthattheclose monitoringisrequiredfornewdrugs?

a.Yes b.No c.Maybe

15. DoyoukeeprecordofADR?

a.Yes b.No

16. DoyouagreethatPharmacovigilanceasasubjecttobetaughtinallthehealthcare professional programs?

a. Agree
b. Stronglyagree
c. Disagree
d. Stronglydisagree

17. Didyouevercounselthepatientsregardingthepossibilityofthe ADR?

a.Yes b.No

18. HaveyouanytimereadanarticleonthepreventionofADR?

a.Yes b.No

19. HaveyoueversharedinformationaboutADRs withanyone?

a.Yes b.No

20. AreyouawareofsuspectedADRreportingsysteminIndia (PvPI)?

a.Yes b.No

21. Doyouthinkherbalmedicinecancause ADR?

a.Yes b.No c.Maybe

22. DoyouthinkADRreportingwillbenefittheheal thcaredeliverysystem?

a.Yes b.No c.Maybe

23. DoyouthinkADRreportingshouldbemademandatory?

a.Yes b.No

24. AreyouawareofmobilesoftwareandapplicationforsuspectedADRreporting?

a.Yes b.No

25. WhichoneofthefollowingistheIndianonlinedatabaseforreportingADRs?

a. ADRadvisorycommittee
b. MEDsafe
c. ADRPvPI
d. Vigibase
e. Medwatch
f. Donotknow

26. FromwhichsourcesdoyougatherinformationaboutADRstonewdrugs?

a. Textbook b.Journals c.Internet
d. Medical representatives
e. Seminarsor conferences
f. Directmail brochures
g. Allofthe above

27. Areyouawareofanydrugthathas beenbanned inthe IndiaduetoADR? Ifyes,name any drug?

Ans: