WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
SJIF Impact Factor 7.632
Volume 10, Issue 1, 288-299 Research Article ISSN 2278 – 4357

A STUDY ON AWARENESS ABOUT "ADVERSE DRUG REACTION & PHARMACOVIGILANCE PRACTICES" AMONG MEDICAL STUDENTS

Mantasha Sultan, Divya Kukreja, Aditi Vyas, Shweta Thakur, Pooja Singh and Dr. Masheer A. Khan*

School of Pharmacy, Devi Ahilya Vishwavidyalaya, Takshshila Campus, Khandwa Road, Indore, India.

Article Received on
24 October 2020,

Revised on 14 Nov. 2020,
Accepted on 04 Dec. 2020

DOI: https://doi.org/10.17605/OSF.IO/QNUKM

***Corresponding Author**
Dr. Masheer A. Khan
School of Pharmacy, Devi Ahilya Vishwavidyalaya, Takshshila Campus, Khandwa Road, Indore, India.

ABSTRACT

The aim of our project is to Study awareness about Adverse Drug reaction reporting and Pharmacovigilance practices among Undergraduate interns and postgraduate medical students. The purpose of surveying among the UG and PG students is to check the practices regarding reporting of ADRs in the hospital and their knowledge about the field of pharmacovigilance. To check the points for the analysis we made a questionnaire consisting of general questions regarding the same which includes, the basic knowledge about pharmacovigilance, the ADR reporting system in India, whether they dealt with an ADR case ever, have they ever gone through the types of ADR reporting forms available for Doctors, patients, consumers etc., to know about the condition of ADR reporting in the hospitals. We have tried to get the knowledge about the conveniences they have and they need in reporting an Adverse Drug Reaction as there is low ADR reporting in India. We tried to know in which fields of Pharamacovigilance more attention should be given. Awareness about WHO's online database "Vigibase" has been checked. According to the survey's results we have elaborated and organized our project by underlying the methods of Pharamacovigilance, mandatory points of the field and measures which can increment the awareness of ADR and Pharamacovigilance.

KEYWORDS: Pharmacovigilance, Adverse Drug reaction, ADR reporting.

INTRODUCTION

WHO defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem."[1]

The goals of PV are to bolster patient safety concerning medicine use by providing a system to collect, assess, and distribute drug safety data. PV activities involve monitoring approved drugs and investigational medicinal products (IMPs) to:

- Identify previously unknown adverse effects
- Recognize changes in the frequency or severity of known adverse effects
- Assess a drugs risk/benefit to determine if action is required to improve safety
- Ensure the accuracy of information communicated to healthcare professionals and patients, and to ensure information contained in patient information leaflets (PILs) is up to date.[1]

Basic steps in pharmacovigilance include

- Safety Data Management
- Signal Detection
- Signal evaluation & making decision in regard to safety issue
- Actions, Including regulatory to public health
- Providing information to all concerned partied & stakeholders.[2]

WHO's definition of adverse drug reaction which has been in use for about 30years is "a response to a drug that is noxious and unintended and occur at doses normally used ina man for prophylaxis, diagnosis or therapy of a disease or for modification of physiologic function. Adverse drug reaction can be further classified into six categories.[3]

An adverse drug event is an injury resulting from medical intervention related to a drug. This includes medication errors, adverse drug reaction, allergic reaction & overdoses.[4]

The terms adverse drug reaction & adverse drug event are interchangeable, except that an adverse effect is seen from the point of view of the drug and adverse drug reaction is seen from point of view of patient.[3]

Objectives Pharmacovigilance are to:

- Improve patient care and safety in relation to the use of medicines and all medical & paramedical interventions;
- Improve public health and safety in relation to the use of medicines;
- Detect problems related to the use of medicines and communicate the findings in a timely manner;
- Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, leading to the prevention of harm and maximization of benefit;
- encourage the safe, rational and more effective (including cost-effective) use of medicines, and
- Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.[5]

Scope: - Pharmacovigilance involves activities related to understanding assessment, detection & prevention of adverse effects or any other drug related problems Pharmacovigilance is a continuous process accepted for safety evaluation accompanied by steps to improve safe usage of medicines. Pharmacovigilance is a science important to reverse most of the adverse effects by modifying the dose or omitting the offending drug. Pharmacovigilance knowledge on safety of drugs is obtained from clinical usage practiced daily involving patients, health professionals, regulatory authorities and pharmaceutical companies. Pharmacovigilance in companies is characterized in monitoring safety of the drug post launch.[6]

Pharmacovigilance Programme of India (PvPi): The Central Drugs Standard Control Organization (CDSCO), New Delhi under the aegis of Ministry of Health & Family Welfare, Government of India has initiated a nationwide pharmacovigilance programme in July 2010, with All India Institute Of Medical Sciences, New Delhi as National Coordination Center (NCC) for monitoring Adverse Drug Reaction in the country to safe guard public health. In the year 2010, 22 ADR monitoring centers (AMC) including AIIMS, New Delhi has been setup under this program. To ensure implementation of this program in a more effective way, the National Coordination Center was shifted from AIIMS New Delhi to Indian Pharmacopoeia Commission, Ghaziabad Uttar Pradesh on 15th April 2011.[2]

METHOD

The pharmacovigilance method can be categorized as Passive surveillance, Stimulated reporting, Active surveillance, Comparative observational studies, Targeted clinical investigation, Descriptive studies. Passive Surveillance is of two type Spontaneous Reporting & Case Series whereas Active Surveillance is of three types Sentinel Sites, Drug event Monitoring, Registries. Comparative Observational Studies can be further divided as Cross Sectional Studies & Cohort Study.[10-22]

Project Study

The survey was conducted with a prospective to know the awareness about adverse drug reporting & pharmacovigilance practices among undergraduate interns and postgraduate students. The study was conducted under the guidance of Dr. Masheer Ahmed Khan, Lecturer at School Of Pharmacy, Devi Ahilya Vishwavidyalaya Indore [M.P]. Participants were taken from various medical colleges across the country and their Identity was kept confidential.

Material

Study Centre

The study was conducted at Devi Ahilya Vishwavidyalaya, Indore, M.P. which is an educational Centre with comprehensive facilities for education, research and the institute provides full time postgraduate and doctoral courses in pharmacy.

Study design

A cohort study was carried out to determine awareness on ADR reporting system among medical students.

Study duration

This study was conducted for a period of 3 months (March 2020 - June 2020).

Study population

The survey questionnaire was distributed to 140 medical students.

Study tools

A questionnaire was developed after extensive review of literature, discussion with mentors and colleagues. The final questionnaire consisted of 15 questions.

The content validity and reliability of the questionnaire were measured prior to using the questionnaire. The survey questionnaire was analyzed and percentage of response was calculated.

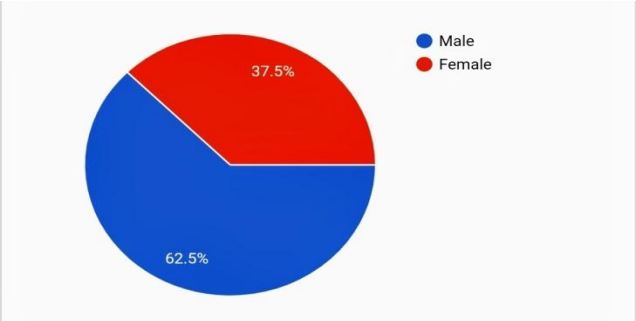
Distribution and collection of data

The questionnaire was distributed online using Google form. Before filling up the questionnaire, the objectives of the study and the contents of the questionnaire were briefed. The respondents were asked to answer and submit the questionnaire.

DISCUSSION

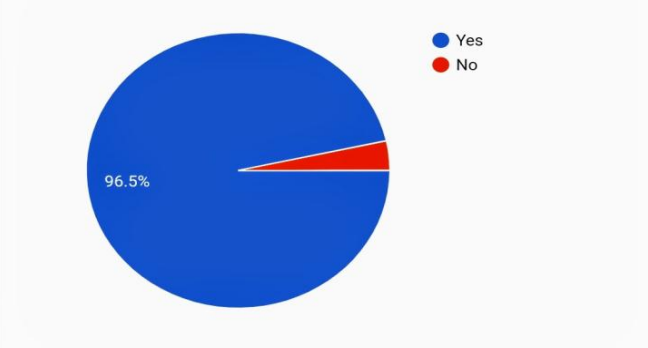
The study was conducted to know the awareness about Adverse Drug Reaction and Pharmacovigilance practices among medical interns and post graduate students.

In this study, there were a total of 140 participants out of which 67.4% were undergraduate interns and 32.6% were post graduate students. The survey was conducted online through the medium of Google Forms. Participants were taken from various medical colleges across the country. There were 62.5% male candidate and 37.5% female candidate.

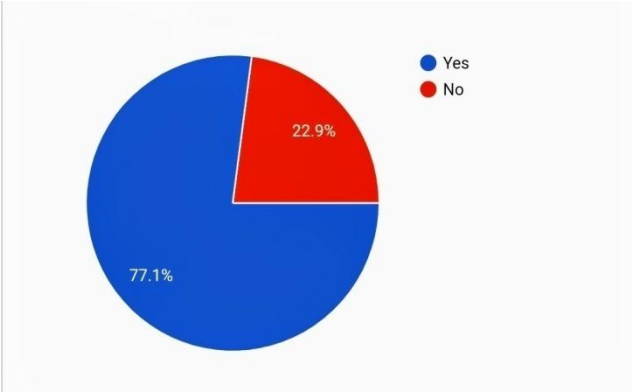


The findings from our study indicate that

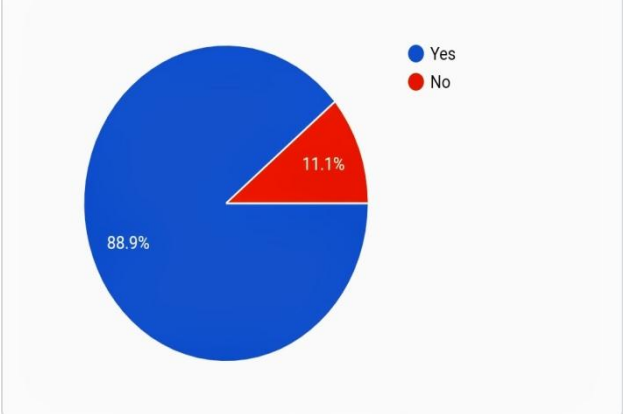
About 96.5% candidates were aware about the term Pharmacovigilance while the rest were not.



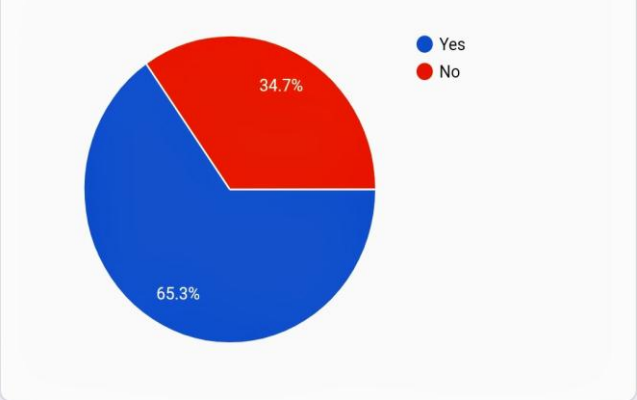
77.1% were aware about the National Pharmacovigilance Program of India and 22.9% candidates were not aware.



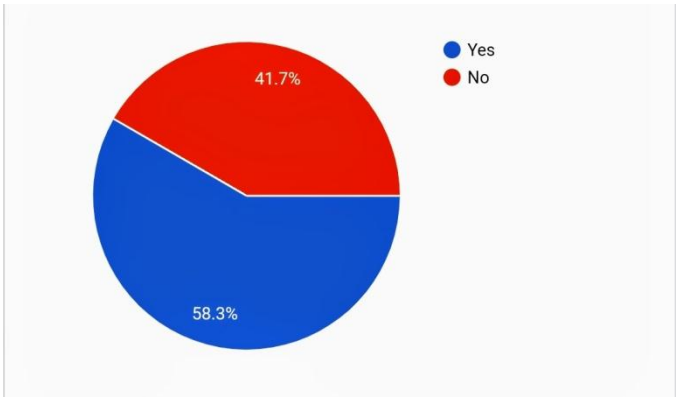
88.9% were aware about the Adverse Drug Reporting system and 11.1% were not aware.



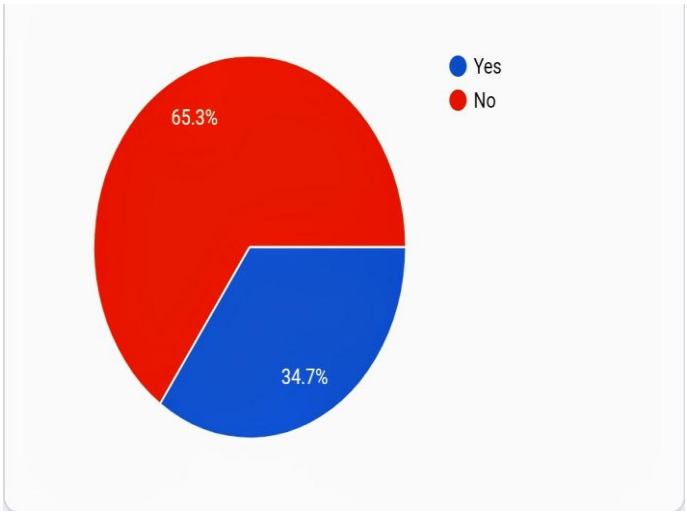
65.3% were aware about the WHO's online database for reporting adverse drug reaction (Vigibase) and 34.7% were not aware.



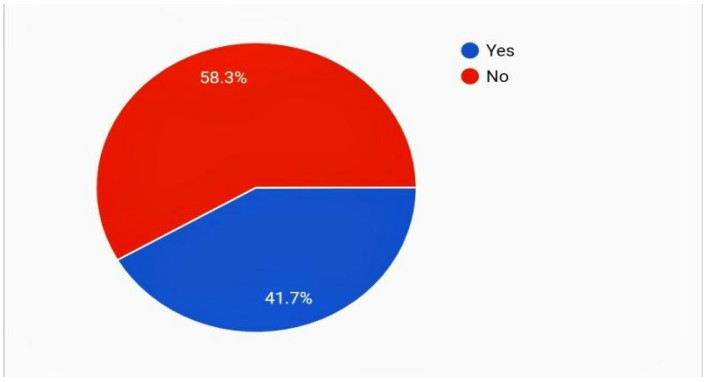
58.3% have experienced an Adverse Drug Reaction in their career while 41.7% have not.



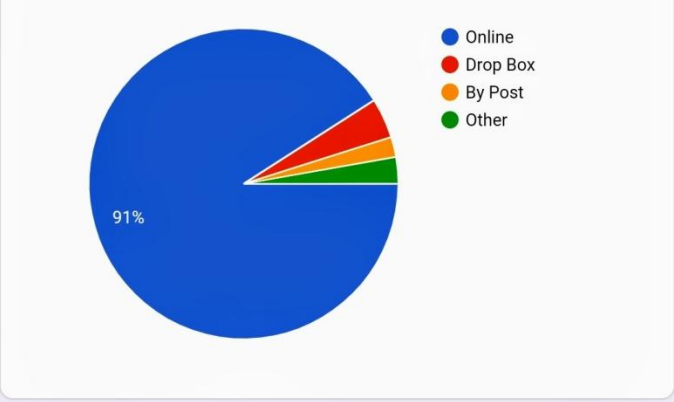
Among these 34.7% have reported an adverse drug reaction and 65.3% have not



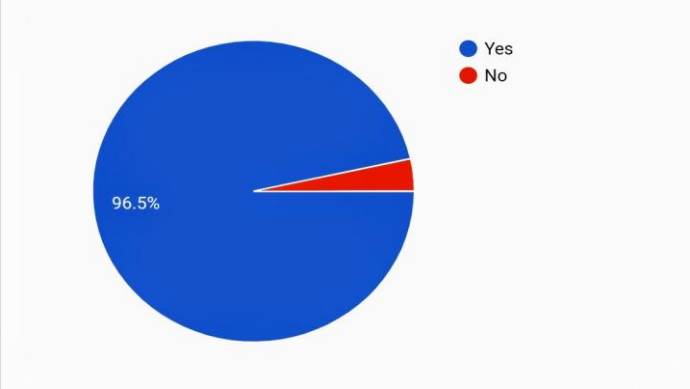
41.7% have seen an adverse drug reaction reporting form and 58.3% have not.



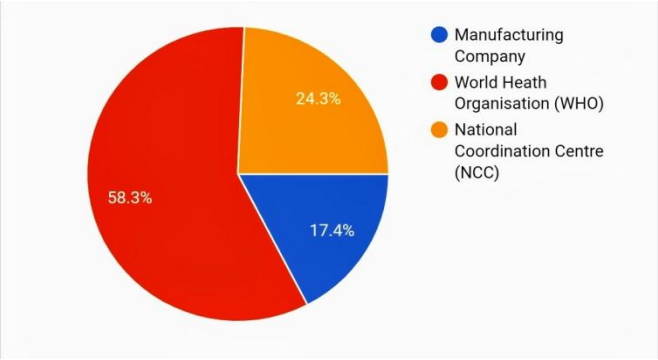
When asked about the convenient method to report an Adverse Drug Reaction over 91% agreed for the online option while the rest chose drop box, by post & others.



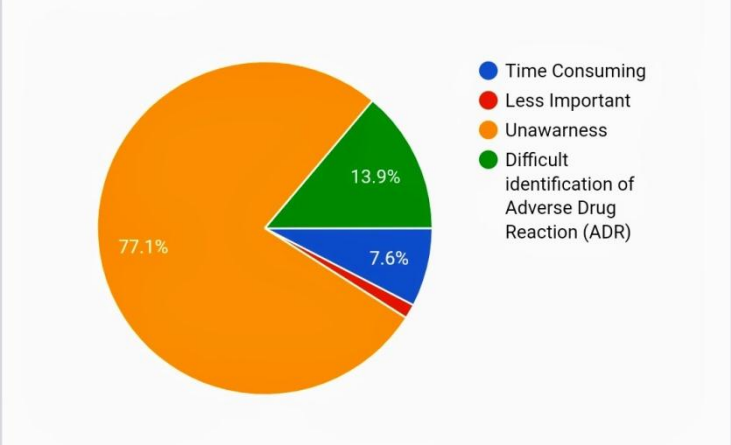
Over 96.5% candidate felt that there is a need to increase awareness about Adverse Drug Reaction reporting in India.



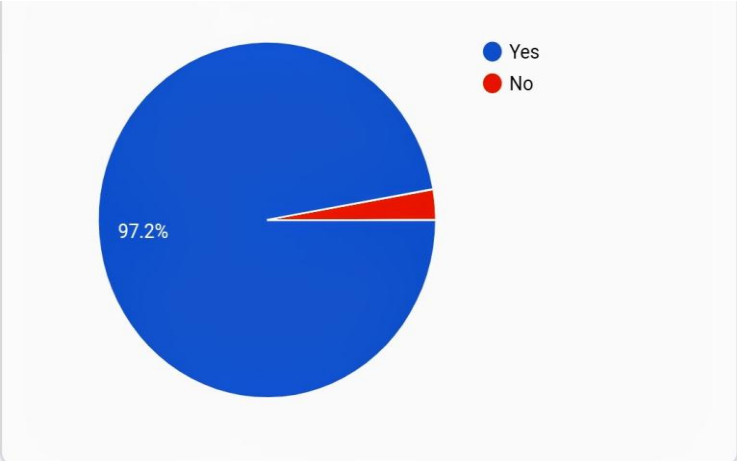
When asked about the concerned organization to report an adverse drug reaction 58.3% of the total believes it to be WHO, 24.3% say National Coordination Center & 17.4% say the Manufacturing Company.



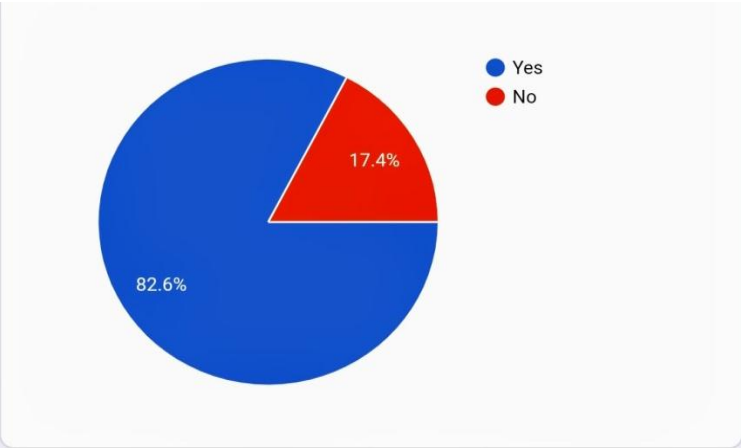
Over 77.1% think the reason behind low Adverse Drug Reaction reporting is unawareness, 13.95% say its difficult identification of an Adverse Drug Reaction & 7.6% find it time consuming.



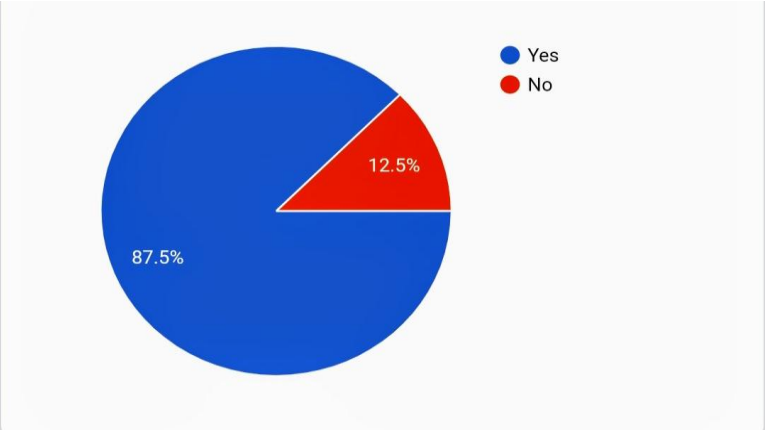
Among these 97.2% agreed to report an Adverse Drug Reaction if a convenient method was provided.



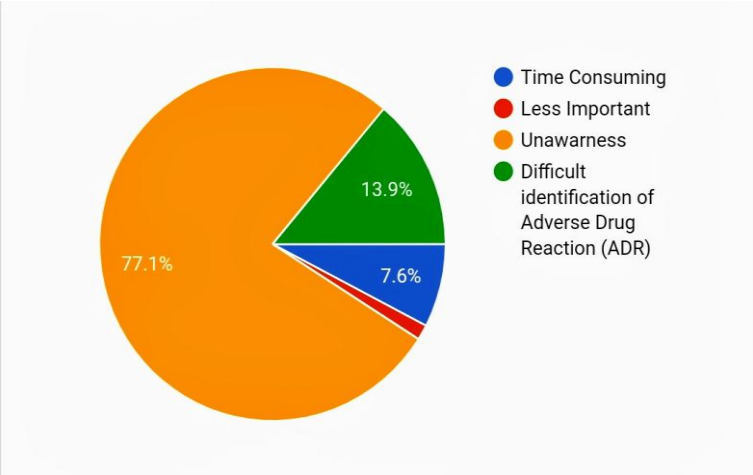
82.6% candidate have an Adverse Drug Reaction reporting system present at the hospital while 17.4% do not, which indicate the lack of proper hospital management and hence a low rate of reporting.



87.5% believe that pharmacist assistance is helpful in detection reporting and management of an Adverse Drug Reaction and 12.5% believe it to be not.



At last, about 60.4% think increasing awareness among heath care professionals would encourage Adverse Drug Reaction reporting, 31.3% think simplifying the method would & 8.3% think provision of feedback on reported Adverse Drug Reaction would.



SUMMARY

S.NO	QUESTION	% YES	% NO
1	Are you aware about the term pharmacovigilance?	96.5%	3.5%
2	Are you aware about the National Pharmacovigilance Programme of India?	77.1%	22.9%
3	Are you aware about the Adverse Drug Reaction (ADR) reporting system?	88.9%	11.1%
4	Are you aware about the WHO's online database for reporting Adverse Drug Reaction (ADR) i.e. Vigibase?	65.3%	34.7%
5	Have you ever experienced an Adverse Drug Reaction (ADR) in your professional practice?	58.3%	41.7%
6	Have you ever reported an Adverse Drug Reaction (ADR)?	34.7%	65.3%
7	Have you ever seen an Adverse Drug Reaction (ADR) reporting form?	41.7%	58.3%
8	Do you think there is a need to increase awareness about Adverse Drug	96.5%	3.5%

	Reaction (ADR) in India?		
9	Will you be interested in reporting, if convenient method is provided?	97.2%	2.8%
10	Is an Adverse Drug Reaction (ADR) reporting system present at your Institute / Hospital?	82.6%	17.4%
11	Do you think pharmacist assistance is helpful in detection, reporting and management of an Adverse Drug Reaction (ADR)?	87.5%	12.5%

GENDER

MALE	62.5%
FEMALE	37.5%

WORKING STATUS

UNDERGADUATE INTERN	67.4%
POST GRADUATE STUDENT	32.6%

CONCLUSION

This study provides a baseline idea about the knowledge and perception of pharmacovigilance in medical interns. The results of our study concludes, that there is low awareness about the reporting an adverse drug reaction and several methods can be adapted to improve ADR reporting (like by means of online reporting) and recognition of ADR. Introduction of educational interventional programs in hospitals, clinics and social media will create awareness and encourage ADR reporting. The survey is considered to be successful as it helped us to know the ground reality of pharmacovigilance among medical students.

REFERENCES

1. https://www.technologynetworks.com/drug-discovery/articles/amp/what-is-pharmacovigilance-328154.
2. https://www.researchgate.net/publication/285358673_PHARMACOVIGILANCE_NEED_FOR_INDIAN_PHARMA_INDUSTRY.
3. https://scholar.google.co.in/scholar?q=adverse+drug+reaction&hl=en&as_sdt=0&as_vis=1&oi=scholart#d=gs_qabs&u=%23p%3DbMAcQ2VF7RoJ.
4. https://health.gov/our-work/health-care-quality/adverse-drug-events#:~:text=An%20adverse%20drug%20event%20.
5. https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:df37e834-0c6a-4deb-b755-06f36e0797ca.
6. https://www.jli.edu.in/blog/pharmacovigilance-opportunities-india/#:~:text=Scope%20of%20Pharmacovigilance,improve%20safe%20usage%20of%20medicines.

7. https://www.researchgate.net/publication/285358673_PHARMACOVIGILANCE_NEED_FOR_INDIAN_PHARMA_INDUSTRY.
8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4576445/.
9. https://www.omicsonline.org/scholarly/pharmacovigilance-journals-articles-ppts-list.php.
10. Ankur Rohilla et al, Nishant Singh, Vipin Kumar, Mohit Kumar Sharma, Amarjeet Dahiya, Ashok Kushnoor, Pharmacovigilance : Need and Objectives, Department of Pharmaceutical Sciences, Shri Gopi Chand Group Of Institutions, Baghpat-250609, UP, India, Oct - Dec 2012.
11. Saurabh Nimesh, Anurag Chaudhary, Anjana Sharma, Kapil Dev Negi, Pharmacovigilance programme Of India: A Review , Department Of Pharmacology, Meerut Institute Of Engineering And Technology, Meerut (Uttar Pradesh), India.(3 : 9), 2019.
12. Krupa C.Thula et al, Bhargavi H.Jadav, Dilip. G. Maheshwari, Regulatory Requirements Of Pharacovigilance System And Its Comparison In India And USA, Department Of Quality Assurance, L. J. Institute of Pharmacy, Ahmedabad, Gujarat 382210, India, ISSN-2230-7346, 2015.
13. Post marketing surveillance, Gupta SK, Srivastava Sushma, textbook of pharmacovigilance safe use of medicine, 2nd edition 2019, JPB publication, pg no 55-70.
14. Introduction, Mann D Ronald, Andruise B Elizabeth, Mann's pharmacovigilance, 2nd edition, Jonhn Wiley & Sons Ltd, 2007; 105.
15. WHO Pharmacovigilance guidelines.
16. World Health Organization and Global Fund. Minimum requirements for a functional pharmacovigilance system. Geneva: World Health Organization; 2010(http://www.who.int/medicines/areas/quality_safety/safety_efficacy/PV_Minimum_Requirements_2010_2_en.pdf.
17. https://apps.who.int/medicinedocs/documents/s19612en/s19612en.pdf.
18. https://apps.who.int/medicinedocs/en/d/Jh2934e/2.html.
19. https://www.primevigilance.com/resources/what-is-pharmacovigilance/need-for-pharmacovigilance/.
20. https://www.technologynetworks.com/drug-discovery/articles/amp/what-is-pharmacovigilance-328154.
21. https://www.who.int/hiv/topics/pharmacovigilance/2a_why_pv.pdf?ua=1.