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Evaluating the knowledge, attitudes and practices among nursing staff and nursing students towards adverse drug reaction reporting at a public tertiary hospital and college, Islampur Sangli

Madhura Shirishkumar Bhosale

Assistant Professor Department of pharmacology; Symbiosis Medical College for Women, Symbiosis International (Deemed University), Gram: Lavale, Tal: Mulshi, Dist: Pune, Maharashtra, India Pin: 412115

Shraddha Yadav

Associate Professor Department of pharmacology; Symbiosis Medical College for Women, Symbiosis International (Deemed University), Gram: Lavale, Tal: Mulshi, Dist: Pune, Maharashtra, India Pin: 412115

Sharvari Thorat

Tutor Department of forensic medicine; Symbiosis Medical College for Women, Symbiosis International (Deemed University), Gram: Lavale, Tal: Mulshi, Dist: Pune, Maharashtra, India Pin: 412115

Vijaya Rajmane

Department of microbiology Prakash Institute of Medical Sciences (PIMS) & Research, Urun Islampur

Leena Salunkhe

Department of Community Medicine Prakash Institute of Medical Sciences (PIMS) & Research, Urun Islampur

Shruti Vimal

Professor Department of Pathology; Symbiosis Medical College for Women, Symbiosis International (Deemed University), Gram: Lavale, Tal: Mulshi, Dist: Pune, Maharashtra, India Pin: 412115

Abstract---Voluntary or spontaneous reporting of adverse drug reactions is a process of monitoring the safety of drugs post-marketing, providing a way to discover new, occasional or unseen

adverse drug reactions. Even though its importance, there is overall underreporting of adverse drug reactions by nursing staff and nursing students in India. The study assessed the knowledge, attitudes and practices of nursing staff and nursing students on adverse drug reaction reporting at a tertiary public-sector hospital and college in Islampur, Sangli. A validated questionnaire based cross sectional study conducted among the nursing staff and nursing students in the tertiary public-sector hospital and college the data was then electronically captured on Microsoft excel spreadsheet & stata® (version 14) chi squared test was run in order to discover significant associations in the data 255 questionnaires sent out, 200 nursing staff & students responded to the questionnaire (78.43% response rate). The overall score on knowledge of ADR reporting was found to be average among nursing staff, nursing students half of the participants knew about reporting adverse drug reactions. 85.71% nursing staff feels ADR reporting in the hospital should be mandatory. Around 75% nursing students were of the opinion that ADR reporting by one person can make a significant difference to the community. Although, 39.5% of participants had encountered adverse drug reactions, only 10% had reported. Even with an awareness of adverse drug reactions, participants were unlikely to report adverse drug reactions due to lack of knowledge & practises. Adverse drug reaction reporting is necessary to make sure patient safety. The advantages of reporting should be emphasized by promoting continuous professional development in pharmacovigilance and, placing more priority on adverse drug reactions at an undergraduate level.

Keywords---adverse drug reaction reporting, India knowledge, medicine safety, nurse, pharmacovigilance.

Introduction

Adverse drug reactions (adrs) are the alarming health issues these days. These ADR's are defined as the "response to drug which is noxious & unintended, and which occurs at dose normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" (International drug monitoring: The role of national centres. World Health Organization report series. World Health Organization, Geneva, Switzerland. (available from American Public Health Association, 1015 18th st., N.W., Washington, DC 20036), 1972 47 pp. 16 × 24CM. Price \$1.00, 1973) .Detection of any new, any serious and even unknown reactions by health care professionals (hcp) or patients known as spontaneous reporting of adrs. Historically, many life-threatening adrs were discovered via spontaneous. In the 1950's, thalidomide was put on the market and prescribed to pregnant women resulted in thousands of expectant mothers devastatingly giving birth to babies with a congenital defect called phocomelia, in which babies are born with underdeveloped limbs.(Miller, 1969, McBride, 1961) Another study showed that adrs were responsible for 3.4% of the hospital admissions and 3.7% developed adrs during their hospital stay. (Arulmani, Rajendran and Suresh, 2008) The incidence of serious adrs are more than 6.5 %

in India. (Pharmacovigilance India Summit aims to build reporting culture, 2011) Along With morbidity and mortality caused by ADRS, adrs are also a financial stress on the healthcare system (Wasserfallen 2001; Goettler M, Schneeweiss S, Hasford J 1998) hence, their early detection and prevention is necessary. Spontaneous underreporting of adrs is a problem worldwide. Underreporting of ADR leads to incomplete data and can un-noticed the ADR. Healthcare professionals have an ethical responsibility to report adrs for the safety of their patients. Nurses are an important part of the health care system. They are known to have an important role in ADR reporting in hospitals. (Hall, McCormack, Arthurs and Feely, 1995) thus, their level of awareness of adrs, opinions and attitudes towards reporting is important. The difficulties of reporting of adrs that they face will have the main role in rate of reporting. Hence this study was conducted to assess the knowledge, attitude and practice patterns of nursing faculty and students towards ADR reporting.

Methods

Study design

It was cross sectional, questionnaire based study aimed to achieve background knowledge on the perceptions of nurses on ADR reporting. A literature review was conducted between Septembers to November 2019. A questionnaire was then compiled consisting of questions relating to knowledge, attitudes and practices of Nurses. A total of 20 questions were used based on 3 similar studies. (Bäckström, Mjörndal, Dahlqvist, 2002; Bigi and Bocci, 2017) In order to achieve the aim of the study, the questions were categorised. There were 20 questions in all (7 related to knowledge, 7 related to attitude and 6 to assess practice).

Sample size calculation

We used www.raosoft.com software to calculate the sample size. As 1 month total 300 (ipd) patients admits in hospital, so taking that in a consideration as population size, with margin of error 5% & confidence level 95% minimum sample size is 169.

Site selection

A total 255 nurses & nursing students working at Private medical college in Islampur, Maharashtra. The study was conducted for a period of one month i.e. December 2019 to January 2020. The Subsequent approval was taken by the hospital PTC (The Pharmacy and Therapeutic Committee). The study details were communicated to head nurses in the all wards. They were then responsible for announcing the study and requesting participation by nurses and nursing students. All interested participants collected and subsequently returned the questionnaires to an assigned study box that was located in all the wards.

Inclusion criteria

- All nurses and 3rd year Revised General Nursing & Midwifery (RGNM) students included in study.

Exclusion criteria

- Doctors and pharmacists were excluded from the study.
- Those who did not wish to participate were excluded from the study

Data collection

The questionnaires were distributed to head nurses in all the wards, who distributed and collected the questionnaires within their departments. For students the Student Repetitive were guided for distribution and collection of data. Reminders were sent to heads of all respective department beforehand to ensure that students and nurses were made aware of the study. Those who chose to respond were asked to complete the informed consent form. They were guaranteed anonymity with regards to their questionnaire responses, in that no personal or identifiable information was asked to be disclosed. Only the researchers involved had access to the questionnaires after they were completed.

Data analysis

Data was collected in the form of the hard copy from nurses (n = 140) and students (n=60). The data was then electronically captured on Microsoft Excel spreadsheet & Stata® (Version 14) Chi squared test was run in order to discover significant associations in the data.

Ethical considerations

The study was approved by the institutional ethics committee

Results and Discussion**Results****Assessment of Knowledge on ADR reporting**

Total nurses (140) & nursing students (120) working at Prakash Institute of Medical Science and Research centre. In that all the nurses (140) and 60 students participated in study. The overall level of knowledge on ADR reporting are summarized in Table 1. The composite score on knowledge of ADR reporting was found to be moderate among nursing staff, nursing students

Assessment of attitude on ADR reporting

There were 7 questions to assess the attitude towards reporting of ADRs as summarized in Table 2 77.14% of nursing staff and 43.33% nursing students are confident about ADR. More than 85% of all the respondents were of the opinion that ADR reporting by one person can make a significant difference to the community. Maximum of the nursing staff were in support of mandatory and voluntary ADR reporting in the hospital. Around 53% of the respondents disagreed on financial rewarding for ADR reporting. About 13 % of nursing students reported that ADR reporting in the hospital is not required

Assessment of Practices on ADR reporting

It shows that just 10% of the responders had ever reported any suspected ADR. A mere 16.5% of respondents had received previous pharmacovigilance training. More than 35% responders ever come across with an ADR it is summarized in Table 3

Discussion

The main target of pharmacovigilance is to ensure the patient's safety and rational use of medicines. The contribution of India to WHO global individual case safety reports is 3%. (Kalaiselvan, Thota and Singh, 2016) Underreporting of ADRs is a universal phenomenon that exists as the fragility of current voluntary reporting scheme. (Agrawal et al., 2017) Along with various other factors, the knowledge attitude and practice of healthcare professionals play a significant role in the spontaneous reporting of ADRs. (Khan, Goyal, Chandel and Rafi, 2013) Many times, nurses and nursing students are the first contact with patients throughout the day. Both can observe the effects and adverse reactions of medicines, therefore the present study was undertaken to assess the knowledge attitude and practice of nurses and nursing students on ADR reporting (Hall, McCormack, Arthurs and Feely, 1995) . From the analysis of data generated in our study, it was revealed that knowledge about ADR reporting exists among nurses in addition to the right perception towards ADR reporting (K, A., Maria and Pandit, 2017) which was encouraging. But it's not reflected when it involves the act of reporting of ADRs. This finding was in accordance to the study conducted by Survase P et al in 2017 (Survase et al., 2017) and Lohit K et al in 2017 (K, A., Maria and Pandit, 2017). The practice of ADR reporting is discouraging. Our study observed that despite the adequate knowledge and attitude, among 80% nurses only 10 % have ever reported any ADRs indicating the existence of poor ADR reporting. Among Nursing student's 43.33% nursing students are confident about ADR but still very poor ADR Reporting. This indicates the need for appropriate education regarding reporting of ADR's which might make a significant difference. The result of the study conducted by Vural et al. shows that only 8% of nurses report the ADR which is comparable to our study, as well as it is comparable with Zaveri et al (Vural, 2015,Zaveri and Chaudhari, 2019)Conducting regular Continuing Medical Education (CME), giving information regarding the correct filling of ADR forms and training nurses and nursing students regarding the reporting of ADRs is important to improve the reporting of ADRs. These measures could improve the quality and quantity of the reports. Refining ADR reporting, apart from minimizing the incidence of adverse drug reactions in clinical practice, will also motivate depletion in health care costs. Thus the overall result of the study indicates the need to extend the level of sensitization for health care workers to improve their ADR reporting It seems clear from the current evidence that ADRs have become a considerable worldwide public health problem that required to be addressed at all levels of health care.

Conclusion

Pharmacovigilance is the foundation to the safety and success of a drug. India is diverse in its population with numerous diseases like HIV, TB and diabetes which

provides an absolute landscape for possible ADRs. Further investigations into the gaps in the undergraduate pharmacovigilance curriculum should be conducted. Education, resources and support to healthcare professionals are key to the success of improving pharmacovigilance. Apart from this Pharmacology residents can be utilized effectively to strengthen reporting and for educating the health professionals, providing feedback and personal communications with prescribers. A multipronged approach is necessary to overcome the under reporting of ADR's.

Limitations of the Study

The data obtained and conclusions drawn were specific to this environment, however similar studies could be done in other hospitals in order to get a more complete picture of pharmacovigilance in India.

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Table 1: Knowledge responses regarding adverse drug reaction reporting

Knowledge about ADR reporting	Yes	Percentage of answering questions	NO	Percentage of answering questions
1.Do you know how to report an ADR?	102	51%	98	49%
2.Do you aware of suspected ADR reporting system in India?	123	61.5%	77	38.5%
3.Do you aware of Adverse reaction monitoring centre (AMC) in college?	110	55%	90	45%
4.Do you know of any drug that has been banned recently due to ADR?	123	61.5%	77	38.5%
5. Do you know which type of ADR should be reported?				
a) None 10(5%)				
b) All ADRs 130(65%)				
c) Others (all serious, to new drugs, unknown to old drugs) 60(30%)				
6. Do you know, to whom ADR should be reported?				
a) ADR reporting center 98(49%)				
b) Others (HOD of institute, nearby hospital, drug manufacturer)				

52(26%)
c) All of the above 50(25%)
7. Which of the following scales is used to establish the causality of an ADR?
a) No response 110(55%)
b) Hardwig and Siegel 31(11%)
c) WHO-UMC scale 31(11%)
d) Naranjo scale 36(18%)

Table 2: Attitude responses regarding adverse drug reaction reporting

No	Attitude questions	Responses	Nursing staff (n=140)	Nursing students(n=60)
1.	To feel confident about ADR due to particular drug	Agree	108	26
		Disagree	10	21
		Don't know	22	13
2.	One should know possible ADR during treatment	Agree	120	34
		Disagree	10	20
		Don't know	10	06
3.	ADR reporting by one person can make a huge difference	Agree	122	45
		Disagree	08	09
		Don't know	10	06
4.	ADR reporting in the hospital by health care professional should be voluntary	Agree	120	45
		Disagree	00	10
		Don't know	20	05
5.	ADR reporting in the hospital should be mandatory	Agree	120	28
		Disagree	00	21
		Don't know	20	11
6.	ADR reporting in the hospital should be financially rewarded	Agree	25	07
		Disagree	75	18
		Don't know	40	35
7.	ADR reporting in the hospital is not required	Agree	120	08
		Disagree	10	05
		Don't know	10	47

Table 3: Practice of ADRs reporting among nurses and nursing students

Practices of ADR reporting	YES		NO	
	N	%	N	%
Have you ever reported any suspected adverse drug reaction?	20	10%	178	89%
Have you attended	27	13.5%	173	86.5%

any CME on ADR reporting?				
Have you ever shared information about ADR with anyone?	77	38.5%	123	61.5%
Have you ever come across with an ADR?	79	39.5%	121	60.5%
Have you ever been trained on how to report ADRs?	33	16.5%	167	83.5%
Do you keep records of ADR?	43	21.5%	157	78.5%