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an Observational Study to Determine the Factors Responsible for Underreporting of Adverse Drug Reactions Among the Resident Doctors of a Tertiary Care Center.

KEYWORDS: Pharmacovigilance, Adverse Drug Reactions (ADRs), Underreporting of ADRs, Causality factors of underreporting.

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ABSTRACT *Spontaneous adverse drug reaction (ADR) reporting is the backbone of pharmacovigilance. However, underreporting is a huge problem due to lack of reporting practices amongst healthcare professionals. This cross-sectional, questionnaire based study was conducted to find out the factor responsible for under-reporting of adverse drug reaction reporting amongst resident doctors. Majority of the respondents felt that ADR reporting is necessary and is a professional obligation, but should be voluntary. Majority of the respondents suggested that lack of awareness was the major factor. Other factors responsible for underreporting of ADRs were lake of monitoring system in the Hospital, lack of time, concern that the reporter may be blamed, lack of confidence, laziness and fear of legal action. Unawareness for the pharmacovigilance needs attention on priority basis, not only for the success of the pharmacovigilance programme, but also better clinical management of the patients in general.*

Background

Adverse drug reactions (ADRs) are a major cause for morbidity and mortality globally (Davies, 2007& Lazarou, Pomeranz, Corey, 1998). The World Health Organization (WHO) defines an ADR as "a response to a drug which is harmful and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of body functions" (WHO, 1975). ADRs can be a big threat to public health. In India, large number of Allopathic, Ayurvedic, Homoeopathic, Unani and Siddha medicines are available and being practiced in combinations. Hence, reporting of ADRs should be a priority area (WHR, 2009).

The National Pharmacovigilance Programme of India is founded on the recommendations formulated in the WHO and modified according to health care needs of our country. The Programme aims to raise the culture of adverse drug event notification and aims to generate broad based adverse drug reaction database on the Indian population and share the information with others. Despite the efforts of establishing adverse drug reaction monitoring centres in many health care centres of India and the presence of a large number of tertiary care facilities, pharmacovigilance is still in its infancy in India (Bhati et al, 2015).

Underreporting of ADRs remains a major obstacle for the pharmacovigilance programme not only in India but also throughout the world (Bateman et al, 1992). A systematic review published in 2006, which mentioned that only 5–10 per cent of ADRs are reported. This review had examined studies estimating underreporting of ADRs (Hazell & Shaki, 2006). The underreporting rate of ADRs by general practitioners ranged from 36 % to more than 99 %, while underreporting rates in the hospital setting ranged from 59 % to 100 %. Many factors contribute to underreporting by healthcare professionals; however, unawareness towards ADR and ADR reporting is an important factor (Biagic et al, 2013; Lopez-Gonzalez et al, 2009).

Method and Material

The present study was a questionnaire based cross-sectional and observational type. Study was carried out in July 2015 at AIIMS Bhopal of central India. The questionnaire was structured to find out factor responsible for underreporting of adverse drug reactions among resident doctors. It is a closed-ended questionnaire. The investigating team member has visited available doctors. The participants were requested to give their opinion regarding the research question. The respondents were allowed to choose multiple options. We kept many options for the participant's opinion like lack of an ADR monitoring system in the hospital, lack of awareness about how to report ADR, lack of time to fill an ADR form, concern that the reporter may be blamed, lack of confidence when an unknown ADR is encountered, laziness, and fear of legal action. All the data obtained was kept confidential. Data was compiled and analysed using online website, http://www.graphpad.com. The data was analysed with 95% confidence interval.

Result

In present study, we found that there was mixed opinion of participants. The most common factor responsible for underreporting of ADRs was found to be lack of awareness about pharmacovigilance programme. Sixty four (71%) participants opted lack of awareness as a most common reason for underreporting. The frequency of other opinions as a factor of underreporting of ADRs are lack of an ADR monitoring system in the hospital by 60 (67%) participants, lack of time by 32 (36%) participants, while concern that the reporter may be blamed by 20 (22%) participants. Moreover, other factors for underreporting were lack of confidence when an unknown ADR is encountered opted by 23 (26%) participants, laziness as a reason expressed by 16 (18%) participants, while fear of legal action revealed by 24 (27%) out of 90 participants.

Discussion

Other studies conducted in India had revealed that various factors responsible for underreporting were at different proportion. Desai and co-workers in their study used knowledge, attitude and practices questionnaire. The study exposed that physicians were aware of the adverse drug reactions and the importance of ADR reporting. However, under reporting and lack of knowledge about the reporting system were clearly evident (Desa et al., 2011). Ger-

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ritsen and co-workers compared the lecture based pharmacovigilance training methods with the practice based method by analysing the number and quality of reports sent in by graduate general practitioners who had been offered one of both approaches during their vocational training. The practice based methods resulted in significantly more and better documented reports and more often concerned unlabelled events than the lecture-based method (Gerritsen et al, 2011).

The most common practical problem which was faced by the doctors in the reporting of ADRs was that a majority of them (60.6%) did not know how and where the ADRs had to be reported. Hence, majority of them suggested that pharmacovigilance awareness programs should be organized as seminars or workshops (Hardeep, 2013). Discouraging factors for the ADRs reporting are concern that the report may be wrong by 80.9%, do not know how to report where to report and when to report by 95.2%, lack of time to fill-in a report by 72.9%, non-remuneration for reporting by 16.2%, concern that reporting may generate extra work by 41.1%, level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred by 81.8%, lack of confidence to discuss the ADRs with other colleagues by23.2% of participants (Gupta et. al, 2011).

According to Bhati et al, the factors responsible for underreporting of ADRs were, non-availability of forms (97%), absence of stringent laws pertaining to adverse drug events reporting (89%), lack of awareness of adverse drug reaction reporting form of Central Drug Safety Control Organisation (CDSCO) (68%), non-communication about adverse drug reactions of a new product by medical representatives (78%), lack of training as well as paucity of time (73%) (Bhati et al, 2015). In a study conducted by Muraraiah S et al, majority of the teaching faculty (80%), interns (59%) and nurses (54%) felt that there are no facilities in the hospital to report ADRs (Muraraias et al, 2011).

The study conducted by Chakrabarty et al found that ensuring proper education and frequent updating of health care professionals by training them in data collection, filtration, verification, interpretation and coding of adverse drug reactions, medicines coding, causality assessment, signal detection, risk management, and action in case of serious/fatal adverse drug events had enhanced reporting of adverse drug reactions (Chakrabarty, 2011).

And in our study we had found the similar results as previous studies. The most common reason responsible for underreporting was found to be unawareness about ADR reporting system and pharmacovigilance program. Majority of resident doctors are unaware about the existence of ADR monitoring centre.

Conclusion

Unawareness of the Pharmacovigilance and Pharmacovigilance Programme of India (PvPI) is the major factor responsible for underreporting of adverse drug reactions. So in order to increase ADR reporting rate, increasing awareness among the health care professionals is most effective way. Pharmacovigilance awareness can be increased by training, workshops and continuous medical education.

Figure 1: Graphical presentation of factors responsible for underreporting of ADRs.

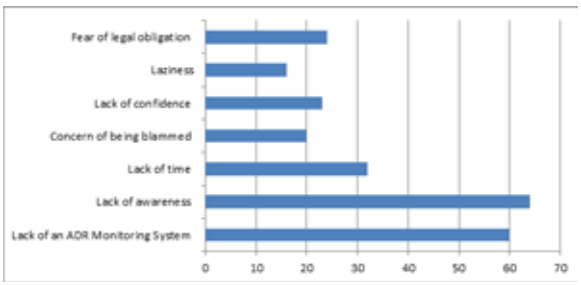

Table 1: Various factor responsible for underreporting with 95% confidence interval

Factors responsible for underreporting	No. of participants out of 90	Percentage	95% confidence interval
Lack of an ADR Monitoring System	60	67%	0.5640 to 0.7557
Lack of awareness	64	71%	0.6100 to 0.7950
Lack of time	32	36%	0.2643 to 0.4587
Concern of being blamed	20	22%	0.1480 to 0.3192
Lack of confidence	23	26%	0.1480 to 0.3192
Laziness	16	18%	0.1114 to 0.2705
Fear of legal obligation	24	27%	0.1858 to 0.3667

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