Drug Safety 2006; 29 (7): 641-642
0114-5916/06/0007-0641/$39.95/0

A Survey of the Knowledge, Attitude and Practice of Adverse Drug Reaction Reporting by Clinicians in Eastern India

Adverse drug reactions (ADRs) are a not-so-silent threat to the health of a nation. For a country such as India, with a population of well over a billion people and a plethora of new drugs invading the market every day, the reporting of ADRs should be on a war-footing. The bandwidth of ADRs is very wide, ranging from common and innocuous to life threatening and rare. Hence, there is no denying that the implications of some ADRs are nothing short of lethal. The current status of pharmacovigilance-related activities in India either by the medical community or the pharmaceutical industry as postmarketing surveillance is far from satisfactory. Although efforts were initiated in 1982 by the Drugs Controller General of India and subsequently in the 1990s by the Indian Council of Medical Research, it did not take up the desired pace, thereby re-emphasising a real need for effective monitoring of ADRs. This provided the backdrop for launching the National Pharmacovigilance Programme (NPP) by the Government of India under the aegis of the Central Drugs Standard Control Organisation in November 2004 to provide a structured platform for nationwide ADR reporting.[1]

Under this programme, the Institute of Postgraduate Medical Education & Research in Kolkata has been identified as a surveillance centre in eastern India. Hence, the current survey was conducted to gauge the knowledge, attitude and practice quotients of the clinicians of this centre towards ADR reporting prior to the implementation of the NPP.

The study was a questionnaire-based survey conducted amongst all categories of clinicians attached to the clinical departments of the institute, including medical and surgical specialists, resident medical officers, postgraduate/postdoctoral trainees and general duty medical officers. The structured questionnaire was designed giving nearly equal weight to assess all three quotients, i.e. knowledge, attitude and practice of the clinicians towards ADR reporting. There were 21 questions that required a mixture of open-ended and closed responses. The questionnaire was distributed to the study population.

A total of 215 forms were distributed; of which, only 138 (64.2%) completed forms were returned. The median age of the respondents was 38 years and 48.2% of the respondents were female. The response rate amongst physicians from medical departments, such as general medicine, paediatrics, cardiology, nephrology, gastroenterology and respiratory medicine, was better than those in surgical units, such as general surgery, orthopaedics, ophthalmology, otolaryngology and gynaecology.

Assessment of the knowledge and practice quotients revealed that all respondents had knowledge of the perceived risks that ADRs impose but only 82.1% felt the need to report them. In total, 87.7% had encountered an ADR in their clinical practice; however, only 4.4% (6 of 138) had reported it either to the pharmaceutical company or had published it in a medical journal, and none had contacted the regulatory authorities. The reasons for under-reporting/not reporting were (i) not sure about causality, 87.7%; (ii) too trivial and common, 84.8%; (iii) not aware of the procedure to report, 87.7%; and (iv) not aware of whom to report to, 85.5%.

The survey revealed that 54% of clinicians had a practice of enquiring about ADRs of a product while reading medical literature or when meeting medical representatives. A total of 79.7% opined that only serious ADRs, unlabelled ADRs and those of newly launched drugs should be reported. According to them, inadequate knowledge about drug interactions was the major physician-related factor contributing to ADRs.

Important suggestions to improve reporting standards were the introduction of some short forms with regular collection and making provision for online and telereporting. One of 138 respondents suggested that the introduction of some incentives could improve ADR reporting. A total of 71.0% of

the clinicians were interested to know about the causality assessment of their reports.

Studies of the knowledge, attitude and practice of ADR reporting amongst healthcare professionals have been carried out worldwide. Under-reporting has been a matter of grave concern even in the most developed countries that have very structured reporting frameworks in place. Earlier attitudinal surveys of clinicians towards ADR reporting in different countries[2-6] have revealed information that is in tune with the observations of this knowledge, attitude and practice study. A MEDLINE search for similar studies carried out in India shows that there is only one such published survey, which was conducted amongst students and junior residents.[7]

The level of knowledge pertaining to basic ADR terminology and the criteria for reporting is comparatively less than that of similar studies carried out in some developed countries.[3,4] This lacuna in knowledge could be attributed to the fact that developed countries have already had a very structured reporting system in place for over 3 decades; hence, the healthcare professionals are more familiar with it.

It is indeed not very encouraging to note that although knowledge about ADR reporting is existent, the attitude and practice quotients are still grey zones amongst clinicians. A very important step in this direction would be to spread awareness about drug safety and pharmacovigilance issues by incorporating it in the medical teaching and training curriculum. In addition, regular communication with clinicians explaining reporting procedures may improve the reporting standards. With the NPP in place, it is intended that this scenario can be changed. Insight into the reasons for under-reporting should enable regulatory authorities to take appropriate measures to improve the ADR-reporting rates. Since all stakeholders of the health sector are aware of the baggage of healthcare costs that ADRs carry and were looking forward to a watchdog of sorts, the NPP could well be an answer to that – provided we all make optimum use of it.

Suparna Chatterjee, *Nazmun Lyle* and *Souvik Ghosh*
Department of Pharmacology, Institute of Postgraduate Medical Education & Research, Kolkata, India

Acknowledgements

The authors would like to thank: (i) Central Drugs Standard Control Organisation, New Delhi, under the Ministry of Health and Family Welfare, Government of India, for information about the National Pharmacovigilance Programme; and (ii) all postgraduate students from the department of Pharmacology who helped in the survey.

The authors have no conflicts of interest that are directly relevant to the content of this letter.

References

1. National Pharmacovigilance Protocol, Ministry of Health and Family Welfare, Government of India [online]. Available from URL: http://www.cdsco.nic.in/html/pharmaco.html [Accessed 2006 Jan 12]
2. Cosentino M, Leoni O, Oria C, et al. Hospital-based survey of doctors' attitudes to adverse drug reactions and perception of drug-related risk for adverse reaction occurrence. Pharmacoepidemiol Drug Saf 1999; 8 (1 Suppl.): S27-35
3. Eland IA, Belton KJ, van Grootheest AC, et al. Attitudinal survey of voluntary reporting of adverse drug reactions. Br J Clin Pharmacol 1999; 48 (4): 623-7
4. Perlik F, Slanar O, Smid M, et al. Attitude of Czech physicians to adverse drug reaction reporting. Eur J Clin Pharmacol 2002; 58 (5): 367-9
5. Li Q, Zhang SM, Chen HT, et al. Study on the knowledge and attitude to adverse drug reactions reporting among healthcare professionals in Wuhan city [in Chinese]. Zhonghua Liu Xing Bing Xue Za Zhi 2004; 25: 894-7
6. Herdeiro MT, Figueiras A, Polónia J, et al. Physicians' attitudes and adverse drug reaction reporting: a case-control study in Portugal. Drug Saf 2005; 28: 825-33
7. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: knowledge, attitude and practices of medical students and prescribers. Natl Med J India 2002; 15 (1): 24-6