

Hospital-Based Adverse Drug Reaction Bulletin

An Indian Experience

Bulletins that focus on drugs and therapeutic aspects in general are often distributed by many hospitals and professional bodies involved with drug use.^[1-3] Bulletins with the specific aim of disseminating information on drug safety aspects are also published, most often by the national or regional pharmacovigilance centres of a country.^[4,5] The major aim of these bulletins is to provide feedback information to potential reporters and additionally educate healthcare professionals on drug safety issues for promoting safer prescribing.^[4] Although many hospitals with a functioning adverse drug reaction (ADR) reporting programme do have explicit bulletins for drug safety issues, the amount of published literature regarding the experiences with such supportive approaches at a hospital level is lacking.

The reporting of ADRs is still in its infancy in India and it is only recently that a national pharmacovigilance programme was initiated in this developing country.^[6] Only a handful of hospitals have a system for ADR reporting, and pharmacists have been instrumental in initiating and coordinating such systems in many of these hospitals as part of their clinical pharmacy activities. One of these hospitals, Kasturba Hospital (KH), in Manipal, South India, is a 1400-bed tertiary-care teaching hospital, where a spontaneous ADR reporting programme was initiated in July 2001. The ADR unit has received >1700 ADR reports since its inception.

As part of a multifaceted approach to strengthen and improve the utility of the ADR reporting programme of the hospital, a drug safety bulletin was developed and published in the year 2006 as a half-yearly publication. The aim of this bulletin is to facilitate the dissemination of information on ADRs reported in the hospital as well as to be a tool for educational intervention in promoting safer drug use. Drug safety issues used to be discussed as part of the regular clinical pharmacy bulletin, which has been published by the department since 2002. How-

ever, it was felt that there was a need to have an explicit bulletin on drug safety considering the quantum of information on this aspect sought by the healthcare professionals; 24.7% of the total queries received in the drug information (DI) centre attached to the department of clinical pharmacy were related to drug safety.^[7] Furthermore, interest was expressed by the healthcare professionals in having an exclusive drug safety bulletin based on the feedback (115 of the 144 respondents [80.5%] expressed an interest) obtained on the ADR reporting programme in 2005.

A simple and attractive graphic design was chosen for the bulletin, which is published as a 6-page bulletin. Copies (150) of the published bulletins are distributed to the healthcare professionals of KH and Dr. T.M.A. Pai Hospital, which is a 250-bed multispeciality hospital associated with KH, where the department of clinical pharmacy also provides its services. Additionally, copies were sent to the national and regional pharmacovigilance centres and a few other hospitals in South India with an ADR reporting unit. The purpose of sending the bulletins outside the hospitals was to create awareness and encourage others working in this field to initiate similar activities that will contribute to the pharmacovigilance programme in India, which is in its development stage. Along with the second issue, the bulletin is made available in a read-only portable document format (PDF) on the hospital's intranet to ensure easier and wider access. Furthermore, we plan to send PDF copies to the healthcare professionals of the hospitals as an email attachment, as well to include interested healthcare professionals outside the hospital in the emailing list. All these measures of modern information technology will ensure that the bulletin will have a wider reach, with not much additional expenditure.^[1]

The distributed ADR bulletin has different sections, which will be more or less constant, although it will allow for change based on the needs and feedback from the readers. The following sections are included:

- Data on ADRs reported in the unit, which include quantitative data on ADRs reported during the last 6 months, i.e. during the period of publica-

tion from the last issue. Five to six selected reports (uncommon reactions, common reactions with an unusual presentation, severe reactions, reactions to newer as well as less frequently used drugs), which were notified during the period of publication from the last issue, are presented along with some additional background information. Furthermore, the pattern of any ADRs of interest will be discussed in brief in this section (e.g. the pattern of ADRs to fluoroquinolones reported in the ADR unit was evaluated and presented along with the second issue).

- Case report: any interesting drug reaction will be presented in detail with a brief review of the literature with regard to incidence, pattern, management, predisposing factors and preventive measures if any.
- Drug safety article: the topic is chosen considering the information needs of the clinicians (e.g. the second issue included an article on peripheral neuropathy and nucleoside analogue antiretrovirals, which was selected considering the high number of queries related to ADRs of antiretrovirals [6% of ADR-related queries received in the DI centre]), including queries on peripheral neuropathy with antiretrovirals received in the DI centre.
- Drug reaction overview: the topic is chosen considering the pattern of ADRs noticed and where a need for educational intervention is required (e.g. among the reports of isoniazid-induced psychosis received in the ADR unit, upon evaluation it was observed that the dose of pyridoxine prescribed to the patients was low in spite of the fact the patients were predisposed to the central nervous effect of isoniazid). Hence, a write-up on isoniazid-induced psychosis was included in the first issue of the bulletin.
- Drug safety news: findings from any latest publication related to drug safety will be briefed or any information on drug withdrawal or labeling changes will be included. In addition to the dissemination of technical information on drug safety issues, the drug safety bulletin is utilised as a medium for increasing the awareness of the ADR

reporting programme in the hospital, how it functions and to educate readers regarding the importance of ADR reporting. The contribution of reporters in the functioning of the reporting programme is acknowledged. These are additional inputs that could be incorporated in possibly strengthening the reporting programme in a hospital.

A simple evaluation form was designed to obtain feedback from the readers of the bulletin and the same was distributed to the healthcare professionals of the hospital along with the second issue of the bulletin. A total of 54 responses (61.6% response rate) were received and evaluated. With respect to the overall impression regarding the bulletin, 30 respondents (55.5%) opined the bulletin as a 'useful' source of information followed by those who opined it as a 'very useful' source (40.7%). Seventy-five percent of the respondents rated the bulletin as 'good', followed by 22.2% who gave a rating as 'very good'. With respect to the frequency of the bulletin, a quarterly publication was suggested by many (44.4%) of the respondents. Evaluating the reader's opinion on the ultimate benefit of the bulletin majority (77.7%) of them opined that it helps in sharing of information on ADRs observed in the hospital, followed by those who opined that it helps in providing specific and detailed information on ADRs. General suggestions from the readers included the suggestion to provide more information on methods to prevent ADR, include sections on policy decisions based on the ADR reported in the hospital, establish a causality relationship and to provide updates on banned drug and ADR profile of new drugs. We intend to consider all these suggestions in upcoming issues.

Studies have shown that drug safety bulletins elicit a temporal increase in ADR reporting.^[4] We could not evaluate the isolated impact of the drug safety bulletin on the reporting rate as this was part of a multifaceted approach in improving the ADR reporting programme. We intend to evaluate the isolated impact of the bulletin on reporting rates at a later stage as well as the impact of topics discussed in the bulletin on drug prescribing behaviours.

Drug safety bulletins may be useful as a multifaceted tool to improve the utility of the ADR reporting programme by providing educational interventions depending on drug use pattern, meeting the information demands of the healthcare professionals, increasing the awareness and possibly the reporting rate, credibility and sensation of the utility of the reporting programmes and in-house sharing of drug safety issues. Drug safety bulletins could be beneficial in both set ups with well established ADR reporting in improving or maintaining the utility of the ADR monitoring unit or those in the initial stages in generating interest in the clinicians of the hospital in the utility of such programmes.

The drug safety bulletin was well accepted by the healthcare professionals of the KH hospital, and they find it quite useful and a good medium for sharing of information on drug safety issues observed in the hospital. Such bulletins will be a welcome addition in strengthening the ADR reporting programme in hospitals, especially those that are in their initial stages.

Jimmy Jose, Padma G.M. Rao and Beena Jimmy

Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka, India

Acknowledgements

We would like to acknowledge the staff and students of the Department of Pharmacy Practice and other health care professionals of Kasturba Hospital for their support in publishing the bulletin and their active contribution to the adverse drug reaction monitoring and reporting programme. The authors have no conflicts of interest that are directly relevant to the content of this letter.

References

1. Alderman CP. Development and evaluation of an electronic drug and therapeutics bulletin. *Ann Pharmacother* 2002; 36: 1637-41
2. Weekes LM, Brooks C. Drug and Therapeutics committees in Australia: expected and actual performance. *Br J Clin Pharmacol* 1996; 42: 551-7
3. Denig P, Haaijer-Ruskamp FM, Zijlsing DJ. Impact of a drug bulletin on the knowledge, perception of drug utility, and prescribing behavior of physicians. *Ann Pharmacother* 1990; 24: 87-93
4. Castel JM, Figueras A, Pedros C, et al. Stimulating adverse drug reaction reporting. Effect of a drug safety bulletin and of including yellow cards in prescription pads. *Drug safety* 2003; 26 (14): 1049-55
5. Boyd IW. The role of the Australian Adverse Drug Reactions Advisory Committee (ADRAC) in monitoring drug safety. *Toxicology* 2002; 181-182: 99-102
6. Adithan C. National pharmacovigilance program. *Indian J Pharmacol* 2005; 37: 347
7. George B, Rao PGM. Assessment and evaluation of drug information services provided in a South Indian teaching hospital. *Indian J Pharmacol* 2005; 37: 315-8