Reporting of adverse drug reactions by hospital doctors and the response to intervention

P. McGettigan, J. Golden, R. M. Conroy,¹ N. Arthur² & J. Feely

Department of Pharmacology and Therapeutics, Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8, ¹Department of Epidemiology and Preventive Medicine, Royal College of Surgeons in Ireland, Dublin 2, ²Irish Medicines Board, Earlsfort Terrace, Dublin 2, Ireland

Aims In Ireland there are relatively fewer adverse drug reaction (ADR/yellow card) reports from doctors in hospital than in general practice. The aim of this study was to review the attitudes to reporting of ADRs of hospital doctors and to determine the effect of making yellow cards freely available.

Methods A postal survey of actively practising doctors with follow-up of non-responders was undertaken. We addressed the single most frequently claimed deterrent to reporting, unavailability of yellow cards, by making cards prominently available and placing one in patient's chart upon admission. In addition, doctors were regularly reminded that ADRs should be reported.

Results Of 118 hospital based doctors, only 45% had ever reported an ADR. Fewer than 5% of pre-registration house officers had reported an ADR and the likelihood of reporting increased with seniority and was greater among physicians than surgeons. We found no evidence that doctors had published case reports in place of submitting ADR reports. Over 3 months, the greater availability of yellow cards and reminders about reporting ADRs led to an approximate five-fold increase in reports but reporting declined rapidly thereafter when verbal reminders were withdrawn, despite continued ready availability of cards suggesting that making cards available alone does not significantly increase reporting.

Conclusions This study indicates there may be more fundamental constraints to reporting than attitudinal surveys would suggest and we need to explore additional avenues to ensure a 'reporting culture'.

Keywords: adverse drug reactions, hospital doctors, intervention

Introduction

The spontaneous reporting of adverse drug reactions (ADRs) is fundamental to the safety surveillance of marketed medicines. A number of studies [1, 2] have suggested that fewer than 10% of ADRs are reported. Recently the European Pharmacovigilance Research Group conducted a series of surveys in European Union countries to assess the attitudes of doctors towards ADR reporting and identify reasons for under-reporting [3]. A primary objective of such research is to identify what steps might be effective at increasing the level of reporting. Studies in the United Kingdom [3] and in Ireland [4] which use almost identical ADR reporting systems (the yellow card system) have shown that hospital doctors are less likely than General Practitioners to report adverse drug reactions.

As there is a greater use of new and more toxic agents and polypharmacy within the hospital environment, we felt that a more detailed review of the attitudes of hospital based doctors was warranted. Furthermore, as earlier studies [3, 4] had suggested that unavailability of yellow cards was the most important single deterrent to reporting, we were

interested to determine the effect of making cards freely available in a group that held such a view.

Methods

We surveyed 45% of 430 actively prescribing doctors representing all grades and specialties, working in three Dublin Teaching Hospitals. With an initial 30% response rate following the first 100 questionnaires sent through the internal hospital mail, we became aware that the majority had not received the questionnaire. Therefore, the remainder (90) were contacted by phone or directly. Doctors were asked to indicate whether or not they had ever reported an adverse drug reaction, the number of reports made within the last year, 1–5 years previously or more than 5 years previously. Factors from previous studies [3, 4] that had been found to be important in the decision to report an ADR and those that had been noted to discourage reporting were included in the questionnaire and respondents were asked to rate these as important, unimportant or not sure. In the 2 years following this survey we reviewed the three Irish Medical Journals, British Medical Journal and Lancet including correspondence section, the Science Citation Corporate Index and the institutional annual reports for publication of ADR reports from the hospitals.

Following the survey, in the largest hospital we placed

Correspondence Professor John Feely, Department of Pharmacology and Therapeutics, Trinity Centre for Health Sciences, St James's Hospital, Dublin 8.

yellow cards (similar to those in the United Kingdom) in each patient's chart upon admission. Cards were also sent to each prescriber and made prominently available in each ward, doctors offices, clinics and any area where patients were treated. Prescribers were reminded both by circular and by direct contact of the availability and use of the yellow cards. We subsequently observed the number of reports returned to the National Regulatory Agency. After 3 months we ceased reminding prescribers to use the yellow card system.

Statistical analysis was by Chi-squared test and Fisher's exact test.

Results

The overall response rate was 65% and 118 questionnaires were completed by 23 Consultants, 48 Registrars, 25 Senior House Officers (SHOs) and 22 pre-registration House Officers (Interns). Only 45% of the respondents had ever reported an ADR and of this group 32% had done so within the previous year, 59% within 1–5 years previously and 9% more than 5 years previously. When asked about the number of ADRs reported approximately half (51%) had reported only one, while 28% had reported two, 11% had reported three and 8% more than three with 2% not being certain. The likelihood of having reported an ADR increased ($P < 0.05$) with seniority of position Consultants (83%), Registrars (50%), SHOs (36%), Interns (4.5%). Doctors in medical specialties made more reports (50%) than those in surgical specialties (36%).

Most respondents (93%) could identify a single most important reason for their reporting ADRs—seriousness of reaction, reaction to a new product, and a need to build drug safety profiles (Table 1). When asked to rate a series of recognised reasons for reporting as either important or unimportant a majority considered unusual reactions, reactions to a new product and the need to build a drug safety profile as 'important' for reporting (Table 1). Only 48% of respondents felt they could identify a single most important deterrent to reporting and unavailability of yellow cards, being too busy and unsure of how to report were the most frequently cited (Table 1). Overall, putative possible deterrents were more likely to be considered 'unimportant' than 'important' by respondents (Table 1). Comparing doctors who had reported an ADR with those who had not, the latter rated seriousness of the reaction more frequently ($P < 0.05$) as important. Similarly non-reporters cited 'unsure how to report' more frequently ($P < 0.01$) as a deterrent than did reporters of ADR.

During the initial 3 months, the Regulatory Agency received 24 ADRs compared with an average of 4 to 6 per quarter over the previous 2 years. The proportion, approximately 40%, of serious (fatal, disabling or resulting in or prolonging hospitalisation) ADRs reported and range of reactions was similar to that seen in the previous year but none involved new drugs. With the cessation of verbal and written reminders to doctors but continued availability of cards, the number of ADR reports in the subsequent 3 months fell to fourteen (three involved new drugs, a similar proportion as in previous years). Serious reactions included

Table 1 Factors considered important by doctors ($n = 118$) in (a) their decision to report an ADR and (b) issues that act as a deterrent to reporting.

a) <i>Reasons for reporting</i>			
(i) <i>The single most important reason (identified by 93% of respondents)</i>			
Seriousness of reaction			55%
Reaction to new product			19%
Need for safety profile			14%
Others (include unusual reaction, confidence in diagnosis)			12%
(ii) <i>Relative importance of reasons</i>			
		<i>Important</i>	<i>Unimportant</i>
Unusual reaction		68%	4%
Reaction to new product		68%	1%
Need to build drug safety profile		55%	7%
Seriousness of reaction		38%	3%
Degree of confidence in ADR diagnosis		27%	23%
b) <i>Deterrents to reporting</i>			
(i) <i>The single most important deterrent (identified by 48% of respondents)</i>			
Unavailability of cards			48%
Too busy			21%
Unsure how to report			20%
Others (include only safe drugs marketed, appear foolish)			11%
(ii) <i>Relative importance of deterrents</i>			
		<i>Important</i>	<i>Unimportant</i>
Unavailability of yellow cards		33%	28%
Too busy		24%	33%
Unsure of how to report		17%	52%
Only safe drugs are marketed		8%	68%
Risk of legal liability		4%	73%
The information if confidential		3%	68%
Risk of appearing foolish		3%	64%

anaphylaxis (mefenamic acid), ototoxicity (azithromycin), hepatitis (flucloxacillin), malignant neuroleptic syndrome (risperidone) and pulmonary embolism (norethisterone and oestrogen). In the 6 months following discontinuation of yellow card insertion into patients' charts upon admission, the level of ADR reporting from the hospital was similar to that prior to the intervention. In our search of medical journals we did not find any ADR report published by staff members of the hospitals under study.

Discussion

In three teaching hospitals, less than 50% of doctors have ever reported an ADR. This low level is similar in the United Kingdom [3] where only 55% of hospital based doctors had ever made an ADR report. As reported previously [5] increasing seniority and working in medical specialties increases the likelihood of reporting ADRs presumably reflecting the opportunity to report. The finding that less than one in twenty of interns mid-way through their pre-registration year had reported an ADR is of particular concern when one reflects that the purpose of internship is training and developing high professional standards. With the welcome development of a core curriculum, we suggest that reporting a certain number of ADR should be a mandatory core educational experience for pre-registration doctors. We have found previously [2], using financial incentives, that hospital prescribers once introduced to the ADR scheme, and having overcome the problems of unfamiliarity and lack of confidence, are likely to continue to use it after the incentive has been withdrawn.

We found that the issues that prescribers claim encourage and discourage ADR reporting were similar to those identified in the recent surveys [3, 4]. In contrast to the relative certainty (93%) that prescribers had in identifying a single most important reason for reporting relatively fewer (48%) could identify a single most important deterrent to reporting. Similarly more prescribers ranked the commonly cited deterrents as unimportant suggesting that other unexpressed deterrents may be important. We believe that the impediments to reporting ADRs go deeper than the reasons commonly cited by prescribers and each of these should be assessed objectively. For example Inman [6] has again recently drawn attention to the possibility that younger doctors, early in their career, may publish case reports rather than report an ADR to Drug Regulatory Agencies. This issue was not, however, a feature in the recent attitudinal surveys [3, 4]. As we [7] had noted a marked discrepancy between what our doctors believe to be important and what happens in practice, we examined Inman's hypothesis. A 2 year review of Irish and international medical journals did not reveal a single case report of adverse reactions from those hospitals, leading us to believe that this is not an important deterrent.

We were also able to look at the effect of addressing the most frequently cited deterrent, unavailability of yellow cards by distributing over 8000. Whereas this did have a significant short term impact (an approximate five-fold increase and 40% serious reactions), unless supported by frequent verbal or written reminders the availability of cards *per se* had only a lesser temporary effect on the reporting rate. We appreciate that making yellow cards available within the BNF and through national centres [8] has increased the reporting rate but the extent of the increase and recent report from Oxford [1] that only 6.3% of ADRs are reported and of these only 6.5% involved newer drugs points to ongoing major obstacles. It is obvious from this study that repeated and regular interventions are required to maintain prescribers' interest in the system. We believe that there is a need to develop 'a reporting culture' and within hospitals this should incorporate other healthcare professionals [9] as well as becoming a practical part of the curriculum for doctors in training.

This work was supported by the Health Research Board of Ireland. The co-operation of the staff of the Adelaide, Meath and St James's Hospitals is acknowledged.

References

- 1 Smith CC, Bennett PM, Pearce HM, *et al.* Adverse drug reaction in a hospital general medical unit meriting notification to the Committee on Safety of Medicines. *Br J Clin Pharmacol* 1996; **42**: 423–429.
- 2 Feely J, Moriarty S, O'Connor P. Stimulating reporting of adverse drug reaction by using a fee. *Br Med J* 1990; **300**: 22–23.
- 3 Belton KJ, Lewis SC, Payne S, Rawlins MD, Wood SM. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. *Br J Clin Pharmacol* 1995; **39**: 223–226.
- 4 McGettigan P, Feely J. Adverse drug reactions reporting: opinions and attitudes of medical practitioners in Ireland. *Pharmacoepid. & Drug Safety* 1995; **4**: 335–358.
- 5 Bateman DN, Sanders GLS, Rawlins MD. Attitudes to adverse drug reaction reporting in the Northern region. *Br J Clin Pharmacol* 1992; **34**: 421–426.
- 6 Inman WHW. Attitudes to adverse drug reaction reporting. *Br J Clin Pharmacol* 1996; **41**: 434.
- 7 McGettigan P, Chan R, McManus J, O'Shea B, Feely J. Sources of drug information in prescribing in general practice. *Br J Clin Pharmacol* 1994; **37**: 521P.
- 8 Rawlins MD. Reporting of adverse reactions. *Br J Clin Pharmacol* 1988; **26**: 1–5.
- 9 Hall M, McCormack P, Arthur N, Feely J. The spontaneous reporting of adverse drug reactions by nurses. *Br J Clin Pharmacol* 1995; **40**: 173–175.

(Received 4 September 1996,
accepted 4 March 1997)