Reporting of adverse drug reactions by hospital pharmacists: pilot scheme

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Spontaneous reporting of suspected adverse drug reactions is an important element of pharmacovigilance.¹ The yellow card scheme of the Committee on Safety of Medicines and the Medicines Control Agency registers reports from doctors, dentists, and coroners but not pharmacists. The value of including pharmacists has previously been proposed,²⁻⁴ and we assessed the contributions of hospital pharmacists in a pilot scheme.

Subjects, methods, and results

The pilot scheme was established with the agreement of the Committee on Safety of Medicines and the Medicines Control Agency. During 1992 and 1993 any report of a suspected adverse drug reaction signed by a fully registered hospital pharmacist working in the Northern region was sent to the Northern Regional Monitoring Centre and entered on to the database. Hospital pharmacists were given special report forms that included space for the name of the patient's consultant and the reporting pharmacist. In all other respects the form was similar to the yellow card. Pharmacists assessed suspected adverse drug reactions using the current criteria.⁵ They were specifically asked not to file a report before obtaining the agreement of a member of the medical staff responsible for the patient's care. The patient's consultant was contacted if further information was required.

Table 1 shows the numbers of reported suspected adverse drug reactions during the scheme and in the preceding three years and succeeding two years. During the pilot scheme 72% (206/287) of reports from hospital pharmacists described serious drug reactions and 14% (40/287) concerned new drugs, compared with 48% (306/639) and 22% (140/639) of reports from medical staff ($\chi^2 = 35.7$, $P < 0.0005$; $\chi^2 = 7.4$, $P < 0.01$ respectively).

We assessed the completeness of reports for 17 key elements and the degree of causality on a scale of 1-4 (1, highly probable; 2, probable; 3, possible; 4, unlikely). For both medical staff and pharmacists, reports were on average 84% complete and the mean score for causality was 2.4.

At the end of the first and second years of the study we sent a questionnaire to all hospital pharmacists in the region and to all consultants whose patients had been the subject of a report, with response rates of 61% (258/414) and 82% (142/174) respectively. Ninety six per cent of consultants (136) had experienced no problems with the scheme and 97% (138) supported its continuation. Many thought it important that a pharmacist should discuss their patient with them before completing a report. Replies from hospital pharmacists showed no apparent problems with the study.

Table 1 Numbers of reports of adverse drug reactions from hospitals in Northern region, 1989-95

Year	From medical staff	From pharmacists	Total
1989	364	0	364
1990	360	0	360
1991	319	3	322
1992	337	145	482
1993	302	142	444
1994	300	77	377
1995	266	80	346

Comment

During the pilot scheme the reporting of adverse drug reactions in the region increased overall by 45%, with a 54% increase in the reporting of serious drug reactions. Reports from hospital pharmacists were comparable with and complementary to those from hospital medical staff and included significantly more suspected serious reactions. Although reporting by hospital medical staff was slightly less during the two years of the pilot scheme than in the preceding three years, reporting rates continued to fall over the two succeeding years (table 1). We do not believe that this downward trend is attributable to pharmacists' reporting.

Our results suggest that direct reporting of suspected adverse drug reactions by hospital pharmacists would enhance the yellow card scheme and improve pharmacovigilance within the United Kingdom. Since the pilot scheme finished, direct reports from hospital pharmacists in the former Northern region have continued to be registered, but without any encouragement to continue reporting the numbers have decreased. Nevertheless we believe that reporting by hospital pharmacists nationally would be useful if reporting was with the consent of the patient's consultant, as in our study, and if hospital pharmacists were trained appropriately with the support of hospital pharmacy managers.

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