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A distance-learning programme in pharmacovigilance linked to educational credits is associated with improved reporting of suspected adverse drug reactions via the UK yellow card scheme

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Aims
The effect of a distance-learning package linked to educational credits on the rate and quality of spontaneous adverse drug reaction (ADR) reporting by general practitioners (GPs) and pharmacists in Wales was investigated.

Methods
In April 2000, 477 GPs and 261 pharmacists enrolled in the 12 month programme.

Results
The number and quality of yellow card reports improved compared with those of a control region in England (Northern Region).

Conclusions
We conclude that an educational initiative in drug safety linked to incentives may be associated with a significant but perhaps short-lived improvement in the rate and quality of ADR reporting.

Introduction

Eighty percent of medicines are prescribed in the community. Consequently effective pharmacovigilance in the primary care setting is an essential aspect of drug safety surveillance [1]. Despite the obvious successes of spontaneous reporting schemes in detecting faint drug safety signals, reporting rates remain low [2]. We have previously shown that the reporting rate of ADRs by GPs in Wales varies markedly, and that only 63% had submitted at least one yellow card over a 4 year period between 1992 and 1995. Lack of awareness or understanding of the UK spontaneous reporting scheme (yellow card scheme) was a common explanation for failure by GPs to report suspected ADRs in that study [3]. In

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view of these findings we decided to investigate the effectiveness of education on reporting rates by linking an initiative involving education in drug safety systems with educational credits for reporting suspected ADRs.

Methods

A distance learning bulletin entitled 'Iatrogenic disease: who is responsible' was sent to 1745 general practitioners and 2039 pharmacists practising in Wales (population 2,937,000, prescriptions per head of population in 2000–01 (PPHP) = 14.7), inviting them to complete 20 multiple-choice questions (MCQs) based on the content of the bulletin. Those who satisfactorily completed the 20 question single best answer MCQ on issues covered in the bulletin were awarded two Postgraduate Education Allowance (PGEA) credits or Continuing Postgraduate Professional Education (CPPE) hours. A preliminary feedback document was sent to each participant. Those who then submitted up to three yellow cards that met with the CSM's guidelines of 'appropriateness' (i.e. all suspected reactions to black triangle drugs, herbal remedies, serious suspected reactions to established drugs and vaccines, and all adverse reactions in children) over the following 12 months received a further continuing education credit/hour to a maximum of three (i.e. five credits in total).

The number and appropriateness of reports submitted in the prestudy (control) period from 1st April 1999–31st March 2000 and the study period 1st April 2000–31st March 2001 were compared with those from the Northern Region (population 2,894,300, PPHP 12.05) where the educational programme was not introduced. Comparisons of reporting rate were performed using Chi-squared analysis.

Results

The MCQs were completed and returned by 477 (27%) of GPs, 99% of whom attained a mark of 70% or more. In the subsequent 12 months, 298 (62%) of these participants submitted 767 yellow cards, 669 (87%) of which were deemed appropriate. The MCQs were completed and returned by 261 (13%) pharmacists and 99% attained a mark of 70% or more. In the subsequent 12 months, 43 (17%) of these participants submitted 77 reports, 70 (90%) of which were deemed appropriate. The total number of yellow card reports and those classified as 'appropriate' in both health regions are shown in Table 1.

Although reporting rates increased both in Wales and the Northern Region over the study period, the increase in reporting by GPs and particularly pharmacists in Wales was significantly greater than that seen in the control (Northern) region (GPs $\chi^2 = 37$, $P < 0.001$, Pharmacists $\chi^2 = 15.6$, $P < 0.001$). This difference between regions was maintained when only those yellow cards classified as 'appropriate' by CSM criteria were considered. We are not aware of any other factors that may have contributed to the difference in the reporting rates.

To assess whether only established reporters were responding to this programme and whether the effects were sustained after the study year had ended we examined the rate of reporting by the 477 GPs taking part in the programme in the 12 month period before and after the initiative in Wales. In the 12 month period prior to the study 116 of the 477 individual doctors who completed the MCQ had submitted at least one yellow card (total 224). In the 12 month period following the study 129 doctors who had completed the MCQ during the study period submitted at least one yellow card (total 249). The year after the study 135 GPs who had entered the study completed a yellow card, and 69 of these GPs had sent in a report in the year prior to the study.

To assess if taking part in the MCQ improved the relevance of yellow card reports by GPs we examined the number of 'appropriate' reports submitted by those doctors who completed the MCQ in the 12 months prior

Table 1
The total number of yellow card reports and those classified as 'appropriate' in the two health regions studied

	Total number of ADRs reported				Total number of 'appropriate' ADRs reported			
	GPs (Nthn)	GPs (Wales)	Pharm (Nthn)	Pharm (Wales)	GPs (Nthn)	GPs (Wales)	Pharm (Nthn)	Pharm (Wales)
Control year	722	717	153	144	542	519	121	110
Study year	1123	1658	162	278	906	1460	127	253
% change	+56	+131	+5	+92	+67	+181	+4	+130
χ^2 test		36.9, $P < 0.001$		15.6, $P < 0.001$		49.1, $P < 0.001$		21.4, $P < 0.001$

to the study, the 12 month study period and the 12 months thereafter. Prior to the study 160 of the 224 (71.4%) yellow cards were deemed appropriate. During the year of the study 669 of the 767 (87%) yellow cards submitted were appropriate and in the year after the study 188 of the 249 yellow cards submitted (75.5%) were appropriate using CSM criteria.

Discussion

The significant increase in adverse drug reaction reports in Wales compared with the Northern region for the period of the study was associated temporarily with this educational initiative. Around 76% of the individuals who enrolled in this study had not sent in a yellow card in the previous year. Adverse drug reaction reporting by physicians has been shown to be increased by providing promotional interventions [4] and by providing a fee [5]. This study indicates that an educational bulletin linked to educational credits can influence both the rate and appropriateness of spontaneous card reporting in a UK geographical region amongst general practitioners and pharmacists. However if the effect is to be sustained, drug safety issues and the importance of yellow card reporting may need to be built into continuing medical education programmes and repeated regularly.

Competing interests: None declared.

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