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Attitudes to adverse drug reaction reporting in the Northern Region

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1 The attitudes and knowledge of doctors in the Northern Region to reporting of adverse drug reactions were assessed using a postal questionnaire to all doctors in two, previously identified, high reporting and two low reporting health districts. Comparisons were made of the attitudes and knowledge within professional groups (GPs, Consultants and Junior Hospital Doctors), and between the amalgamated doctor groups.

2 1181 of 1600 doctors (74%) responded. Despite being selected on the basis of previous adverse drug reaction reporting patterns, GPs and consultants from high and low reporting districts perceived they had sent a similar number of ADR reports, and there were few differences in opinion and attitude within these two groups.

3 Most differences within doctor groups were found for junior doctors, with those from low reporting districts indicating they had sent significantly less yellow cards than those in high reporting districts. There were also significant differences in the estimates junior doctors made with a frequency of adverse drug reactions, the existing documentation on adverse drug reactions, and the purposes of the adverse reaction scheme.

4 General Practitioners in low reporting areas stated they wrote more prescriptions ($P < 0.02$), consultants spent more time in clinical contact ($P < 0.01$) and junior doctors did both ($P < 0.01$), all of which suggest different workloads may effect reporting of adverse drug reactions.

5 When given clinical examples, or asked about the CSMs black triangle scheme, all doctor groups performed poorly.

6 The number of reports stated as being sent increased with time from qualification for 10 years, then seemed to plateau. Some hospital specialties (e.g. surgery) indicated sending fewer reports than others. Differences seemed more marked between rather than within professional sub groups.

7 The knowledge about adverse drug reactions of doctors of all three professional subgroups studied could be improved. This survey has highlighted a number of areas, for example workload, responses of hospital doctors in certain specialties, and the numbers of reports sent with time from qualification, that could be addressed in future campaigns to increase reporting.

Keywords adverse drug reaction reporting

Introduction

Spontaneous reporting of adverse drug reactions to the Committee on Safety of Medicines via the 'Yellow Card' scheme is a fundamental part of the safety surveillance of marketed drugs. The yellow card reporting scheme has operated in the United Kingdom for over 25 years. During this time the annual reporting rate, as well as the number of reports related to prescription volume, have increased four-fold. Nevertheless the overall reporting rate is substantially less than that expected from intensive studies of the incidence of drug-induced morbidity and mortality (Davies, 1985). It is recognised, however, that the attitude of doctors to the reporting of adverse drug

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reactions (ADR) is of great importance in determining whether they actually make reports (Koch-Weser *et al.*, 1969; Rogers *et al.*, 1988).

The Northern Regional Monitoring Centre for the Committee on Safety of Medicines (CSM) receives adverse reaction reports originating within the Region. We have related these to clinical activity based on population size for general practice, and death and discharges for hospitals (Bateman *et al.*, 1991). When assessed in this way both hospital and general practice reporting rates vary widely. However, no correlation was observed between the rates of reporting from hospitals and general practitioners within the same Health District.

The present study was designed to determine, by questionnaire, the opinions of doctors within high and low reporting Districts in an attempt to assess whether there were differences in knowledge, or attitudes, that might explain observed differences.

Methods

A questionnaire was sent to all hospital doctors and to all principals in general practice in two high, and two low reporting districts in the early spring of 1991. In the absence of any correlation between hospital and general practice reporting rates (Bateman *et al.*, 1991) different districts were chosen for hospital doctors and GPs. The districts chosen for surveying general practitioners had reporting rates averaging 0.3 to 0.1 reports per 1000 population per annum: districts selected to study hospital doctors had average reporting rates of 1.3 and 0.2 per 1000 deaths or discharges per annum.

All participants were sent a personally addressed letter and a questionnaire, outline details of which are shown in Table 1. Full details can be obtained from the authors. One question (number 8) was based on that of Rogers and colleagues (1988) from a survey of physicians working in the United States. Non-responders were sent a reminder letter and a second copy of the questionnaire.

Statistical methods

Analysis of the responses to the questionnaire was carried out using the Statistical Package for the Social Sciences (SPSSX). Cross-tabulation of variables was examined using the chi-square test distribution. The observed significance level of the test was taken at the 5% level or less.

Results

1600 doctors were sent questionnaires and 1181 (74%) were returned completed. The response rates were lower (Table 2) from general practitioners and junior doctors in low reporting districts, but consultants's response rates were similar. The characteristics, knowledge and attitudes of these three professional groups are summarised in Tables 2, 3, 4, 5, 6, 7 and 8.

Table 1 Outline details of questionnaire on adverse drug reaction reporting

Question number	
1.	Estimated number of Yellow Card reports returned in career: Never: once: 2–4: 5 or more.
2.	Factors in decision to report: Severity: Unusual reaction: Awareness of similar reaction: New product: Other.
3.	Potential problems with Yellow Card: Availability: Complexity: Space: Identity self: Identity patient: Responsibility.
4.	Estimate of proportion of patients suffering any reaction: (9 bands ranging from < 0.1% to > 50%)
5.	Estimate of proportion of patient suffering serious reaction: (9 bands ranging from < 0.1% to > 50%)
6.	Purposes of Yellow Card: Identification of safe drugs: Incidence of reactions: To identify disease treated: Predisposing factors: Bizarre reactions: Unrecognised reaction: Comparison of toxicity in drug group.
7.	Meaning of symbol: Report all reactions: New product: Hospital only product.
8.	Attitudes to reporting: One case does not contribute to medical knowledge: Impossible to determine causality: ADRs well documented: Financial reimbursement required: Professional obligation to report: Increased liability to reporting doctor: CSM will badger reporter for more data: Time taken too much.
9.	Types of reaction where Yellow Card indicated: Established drugs; New drugs; Interactions: Teratogenicity: Vaccines.
10.	Clinical Examples: DVT with oral contraception: Agranulocytosis with sulphonamide: Jaundice with chlorpromazine: Rash with ampicillin: Cough with lisinopril.
11.	Suggestions for easier methods of reporting.
12–17	Demographic data: Work place: Speciality: Gender: Year of qualification: Time in patient care: Prescriptions per day.

General practitioners

GPs in high and low reporting districts had similar characteristics with respect to sex ratio, time since graduation, time in direct patient contact and understanding of the significance of the inverted black triangle symbol (Table 2). Perhaps surprisingly (since the high and low reporting districts were selected on their known reporting rates), GPs from the two categories of districts perceived that they sent in similar numbers of yellow cards. Knowledge about, and attitudes to, the yellow card system were generally similar amongst GPs from high and low reporting districts (Tables 3, 4, 5, 6 and 7). However, GPs in low reporting districts, estimated that they wrote significantly more prescriptions, and a higher proportion of this group expressed uncertainty as to

Table 2 Demograpic details, details of previous reporting, estimates of frequency of adverse reaction and meaning of black triangle symbol (percentages) in High (H) or Low (L) Districts for General Practitioners (GP), Consultants and Junior Hospital Doctors (JD)

		GP		*Consultant*		*JD*	
		H	L	H	L	H	L
Questionnaire returned		262	105**	256	74	432	52*
(% Responders)		(79)	(68)	(82)	(75)	(70)	(58)
Sex Ratio M:F		4:1	4:1	11:1	8:1	2:1	3:1
Median decade of qualification		70–79	70–79	60–69	60–69	80–89	80–89
> 75% Time in direct patient contact		63%	66%	44%	59%*	58%	78%**
Median for numbers of prescriptions/day		20–39	40–59*	1–9	1–9	1–9	10–19**
% indicating making a previous yellow card report							
	Never	12	14	24	25	42	73*
	> 5	35	28	21	25	8	0
Estimated % frequency of ADRs	< 1%	25	15	25	31	14	40*
Any	> 5%	40	52	42	42	54	34*
	< 0.1%	51	58	47	60	35	62*
Serious	> 1%	13	5	13	10	21	8*
% with correct meaning of inverted black triangle							
Report all ADRs		85	83	66	65	67	73
New product		58	60	48	44	64	72
Hospital only drug		84	81	63	52	64	59

* $P < 0.05$
** $P < 0.01$ – Statistical differences within professional groups. The chi-squared analysis examined the distribution of responses, but for clarity, results within particular bands have been shown.

Table 3 Factors perceived to be important in deciding whether to send a Yellow Card (% Responding 'yes') in High (H) or Low (L) Districts for General Practitioners (GP), Consultants and Junior Hospital Doctors (JD)

Reaction	*GP*		*Consultants*		*JD*	
	H (n = *262*)	*L* (n = *105*)	*H* (n = *256*)	*L* (n = *74*)	*H* (n = *432*)	*L* (n = *52*)
Severity	85	86	84	85	73	78
Unusual/unexpected	96	98	97	100	93	82
Awareness of similar reports	62	61	59	60	56	88*
New product	93	93	91	92	87	94

*$P < 0.05$ – The chi-squared analysis was based on categories 'yes', 'not sure' and 'no'.

whether their identity should be revealed to the CSM (19% *vs* 6%, $P < 0.01$).

Consultants

Consultants in high and low reporting districts were similar in relation to sex ratio, year of qualification, clinical specialty and perceived prescribing habits. More consultants in low reporting districts spent in excess of 75% of their time in direct clinical contact. As with GPs, consultants in high and low reporting districts believed they made similar numbers of yellow card reports.

Although the majority of responses from consultants revealed no differences in knowledge and understanding of the yellow card scheme, when the overall pattern of responses (strongly, slightly agree/disagree) were compared, there were some important discriminating responses. More consultants from low reporting districts (Low 14%, High 5% $P < 0.05$) indicated that reporting forms had insufficient space. A higher proportion from low reporting districts stated that the purpose of the scheme was to identify safe drugs (Table 4), an incorrect answer. The low reporting consultants also felt that reporting of single cases could not contribute to medical

Table 4 Purposes of the Yellow Card System: % giving the correct answer (Y/N) in High (H) or Low (L) Districts for General Practitioners (GP), Consultants or Junior Hospital Doctors (JD)

	GP		*Consultant*		*JD*	
	H (n = *262*)	*L* (n = *105*)	*H* (n = *256*)	*L* (n = *74*)	*H* (n = *432*)	*L* (n = *52*)
To measure the incidence of all adverse reactions to drugs (Y)	59	56	59	64	52	69
To identify the disease for which a particular drug is prescribed (N)	84	83	89	78	94	80
To identify factors which might predispose toxicity (e.g. dose, age) (Y)	86	86	80	83	85	88
To identify bizarre reactions to drugs (Y)	95	95	90	94	94	88
To identify previously unrecognised reactions to drugs (Y)	99	100	99	100	99	98
To enable toxicity of drugs in similar therapeutic classes to be compared (Y)	69	59	55	55	58	59
To enable safe drugs to be identified (N)	24	22	40	23	42	27

Table 5 Reasons for under reporting, (%) agreeing slightly and strongly, in High (H) or Low (L) Districts for General Practitioners (GP), Consultants or Junior Hospital Doctors (JD)

Statement	*GP*		*Consultant*		*JD*	
	H (n = *262*)	*L* (n = *105*)	*H* (n = *256*)	*L* (n = *74*)	*H* (n = *432*)	*L* (n = *52*)
One case cannot contribute to medical knowledge	16	10	19	27*	12	18
Impossible to determine responsible drug	41	41	43	46	38	41
Serious ADRs well known when drug is marketed	25	23	13	20	16	36**
Should be financially reimbursed	26	30	8	14*	8	23**
Professional obligation	91	93	95	91**	98	96
Reporting increases personal liability	12	19	9	17	9	20
Reporting results in badgering by CSM	32	36	28	33	24	46**
Takes too much time to report ADR	31	28	32	33	22	28
Would report if easier method	51	55	52	55	47	55

* $P < 0.05$
**$P < 0.01$ – The chi-squared analysis was based on responses in four categories 'strongly agree', 'slightly agree' and 'strongly disagree'. For clarity the 'strong' and 'slightly' categories have been amalgamated.

knowledge (Table 5), and that reporters should be financially reimbursed (Table 5). In addition, the strength of feeling that there was a professional obligation to report differed, with 80% strongly agreeing from high reporting, but only 60% from low reporting districts. Consultants from low reporting districts were also less likely to report a case of jaundice with chlorpromazine (Table 7).

Junior doctors

Junior doctors in low reporting districts appeared to spend more time with patients, issued more prescriptions, and more commonly admitted to never having sent in a yellow card (Table 2). They also had a more optimistic view of the safety of drugs than junior doctors in high reporting districts. Specialty mix also appeared to influence reporting, with a higher preponderance of surgical specialities amongst junior doctors in low reporting (47.1%) compared with high reporting districts (28.4%).

Overall, junior doctors in low reporting areas had a less clear view of the purpose of the yellow card scheme. In particular, a higher proportion believed that serious reactions are well-documented when a new drug is marketed (Table 5); that they should be financially rewarded for making reports (Table 5); that reporting results in badgering for further information by the CSM (Table 5); and that all suspected reactions to all drugs should be reported (Table 6). Responses to clinical examples (Table 7), however, were similar except for that about lisinopril and cough, where fewer doctors in low reporting areas would have made a report. Interestingly, junior doctors from low reporting districts

Table 6 Answers to question 'Which of the following types of adverse drug reaction do you think the CSM are hoping to receive information about?' % giving correct answer (N/Y) in High (H) or Low (L) Districts for General Practitioners (GP), Consultants and Junior Hospital Doctors (JD)

Statement	*GP*		*Consultants*		*JD*	
	H (n = *262*)	*L* (n = *105*)	*H* (n = *256*)	*L* (n = *74*)	*H* (n = *432*)	*L* (n = *52*)
All suspected ADRs to establish drugs (N)	45	50	38	32	45	28
Serious (a) suspected ADRs to establish drugs (Y)	95	92	93	91	94	96
All suspected ADRs to new drugs (Y)	94	93	91	85	95	96
Only serious (a) ADRs to new drugs (N)	80	80	79	66	86	79
Any serious (a) adverse interaction suspected (Y)	93	87	92	91	94	81**
Any teratogenicity (Y)	96	100	91	93	95	88**
Any suspected ADR to vaccine (Y)	75	74	74	69	81	88

(a) Serious means particularly dangerous, incapacitating or lethal.

* $P < 0.05$
** $P < 0{\cdot}01$ – The chi-squared analysis examined response in three categories, 'yes', 'not sure' and 'no'.

Table 7 Clinical examples of adverse reactions (% indicating correct responses) in High (H) or Low (L) Districts for General practitioners (GP), Consultants and Junior Hospital Doctors (JD). The correct response was 'Yes' for all but ampicillin rash

Reaction	*GP*		*Consultant*		*JD*	
	H (n = *262*)	*L* (n = *105*)	*H* (n = *256*)	*L* (n = *74*)	*H* (n = *432*)	*L* (n = *52*)
Deep venous thrombosis with oral contraceptives	56	49	37	28	29	43
Agranulocytosis with sulphonamide	81	84	68	64	75	74
Jaundice with chlorpromazine	40	37	35	21*	36	45
Rash with ampicillin	84	80	70	77	78	67
Cough with lisinopril	42	44	23	23	38	25**

* $P < 0.05$
**$P < 0.01$ – The chi-squared analysis examined responses in three categories, 'yes', 'not sure' and 'no'. The statistical differences reflect a high 'not sure' response.

also stated they would be more likely to send a report if they were already aware of a similar adverse reaction with the drug (Table 3).

Discussion

The purpose of the questionnaire was to attempt to identify factors which might underlie differences in the pattern of reporting of adverse reactions by doctors in the Northern Region. Several determinants emerge. Firstly the responses suggest that the amount of available time may be a significant determinant of ADR reporting, since in all three categories doctors in lower reporting areas appeared to be spending more time in direct clinical contact with patients, the GPs and junior hospital doctors indicated that they wrote more prescriptions. Secondly doctors in low reporting areas generally appear to lack appreciation of adverse drug reaction reporting and the purposes of the yellow card scheme. For example junior hospital doctors, in low reporting districts were more likely to underestimate the incidence of all adverse reactions when compared with those from high reporting districts, 40% considering any adverse reaction would occur in less than 1 in 100 patients and 62% considering that serious reactions occurred at an incidence of less than 1 in 1000. For some questions, although there is a statistically significant difference, the absolute magnitude of this difference may appear small. For example 88% junior doctors in low reporting districts said they would report teratogenicity, compared with 95% of high reporting districts. Bearing in mind the total number of practising doctors, however, a 7% change in reporting would be clinically useful. It was only amongst junior hospital doctors that there was concordance between perceived and actual reporting rates. This tends to suggest a degree of self deception in other groups, since this was the marker on which the doctors surveyed were selected.

Although this study was not primarily designed to examine differences between professional sub groups (GP, Consultant or junior hospital doctors) it suggests there are more differences between these categories of doctors in the three different professional sub groups, than within categories from low and high reporting districts. Thus GPs said they had made more reports

than consultants (despite being qualified less time), and junior hospital doctors said they had made least ($P < 0.001$) (Table 2). This is consistent with the pattern of reporting observed in the Regional Monitoring Centre over the past 5 years. Doctors in surgical specialities, had sent the least yellow cards, with 40% of consultants, and 47% of junior doctors admitting to never having submitted reports. It seems unlikely that they see no adverse drug reactions, but lack of familiarity with the wide availability of forms (e.g. in the British National Formulary) may be a factor, since 30% of all consultants stated that yellow cards were not readily to hand. 65% of consultants and 58% of junior doctors in medical specialities indicate they had sent more than five reports. 6% of consultants, as opposed to 21% GPs and junior doctors, felt it was not their responsibility to send in yellow card reports. 5% of GPs and 6% of consultants, but only 1% of junior doctors felt that the yellow card form was too complicated.

Overall most doctors understood the purposes of the yellow card scheme (Table 4), and were likely to be influenced by similar factors in making a report (Table 3). It is a matter for concern that a high proportion of all doctor groups were unaware that yellow card data is used extensively to compare the toxicity of drugs in a similar therapeutic class (Table 4). A surprisingly high proportion were unfamiliar with the purpose of the CSM's black triangle symbol however (Table 2) and this proportion was greatest amongst hospital doctors. Of equal importance, and concern, were the responses to clinical examples of adverse reactions. Clearly many doctors did not feel that reporting serious, though established reactions, was necessary. Similarly most doctors would not have reported a reaction to a new drug (lisinopril), despite the CSMs targetting of new drugs for particular attention (Table 7). GPs were more likely to provide correct responses to these clinical examples than other groups.

Attitudes to confidentiality of their own identity were similar in all groups, with 85–88% of doctors being happy to disclose their name. There was more caution about disclosing patients' identities with 23% of GPs expressing concern. All doctors tended to underestimate the true incidence of adverse reactions (Table 2). It is of interest that the opinions of doctors in our survey (Table 5) were similar to those previously reported from doctors in the USA (Rogers *et al.*, 1988).

In conclusion we have detected differences in opinions and attitudes amongst doctors working in health districts with low adverse reaction reporting compared with those with high reporting rates. These differences are greatest amongst junior hospital doctors and least amongst GPs. Doctors could have had these opinions before obtaining their positions, or acquired them while working in them. In either case they should be susceptible to education. The attitudes of GPs, consultants and junior hospital doctors to reporting adverse reactions suggests a broad awareness of, and support for this scheme but lack sufficient knowledge to contribute to it optimally.

The importance of the spontaneous reporting scheme needs to be highlighted to doctors in all walks of medicine, but targeting specific areas, especially amongst hospital staff, would appear to be worthy of further effort. Issues such as the impact of workloads and differences beween speciality groups on reporting rates need further study.

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