Attitudes to adverse drug reactions and their reporting among medical practitioners

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Summary

The adverse drug reaction (ADR) reporting rate within the medical profession is exceptionally low, and doctors' approaches and attitudes to ADRs were explored through personal structured interviews. The total sample comprised 104 doctors in private practice, divided into three groups: 59 general practitioners, 26 medical specialists and 19 surgical specialists. Certain differences emerged between the groups. The surgical group observed far fewer ADRs than the other groups and not a single member had ever reported an ADR. A significantly larger number of medical specialists considered it necessary to report an ADR to an outside agency, while general practitioners tended to believe that only newly released medicines required ADR reporting. However, few doctors of any specialty regarded ADR reporting as part of the action they would take in their handling of ADRs in practice. The commonest explanation advanced for the marked underreporting of ADRs was that unusual or serious reactions were very infrequent and the common or trivial ones did not warrant reporting. Apathy and indifference were rated as the next most pertinent influence in non-compliance, while such factors as fear of personal consequences (e.g. criticism, medicolegal action) and uncertainty about what to report were deemed to be relatively unimportant.

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Post-marketing surveillance is essential for assessing the safety of medicines, and voluntary reporting by doctors is necessary for detecting adverse drug reactions (ADRs), especially when these are rare.

The Medicines Safety Centre (MSC) is an independent and neutral body attached to the Department of Pharmacology of the University of Cape Town and funded jointly by the University of Cape Town and Ciba-Geigy (Pty) Ltd. One of its principal functions is to monitor ADRs in the community. Every quarter since January 1981 the MSC has circulated a newsletter to all doctors, dentists and pharmacists in the Western Cape enclosed with which is an ADR report form and a business reply-paid envelope. Recipients are regularly encouraged to notify the MSC of any ADR (however mild or common) by means of the form. Those who return the form receive prompt feedback through a letter of thanks, coupled with brief comments on the case from one of the MSC's professional staff. Another ADR form with reply-paid envelope accompanies the acknowledgement letter. Confidentiality is guaranteed with regard to the names of doctors and patients.

The number of ADRs reported has remained fairly constant but extremely low. During 1984 and 1985, approximately 14 800 and 16 000 forms respectively were distributed to doctors, of which 144 and 149 respectively were returned — a response rate of about 1%. The actual number of reporting doctors was 106 for 1984 and 104 for 1985, of whom 38 and 45 respectively sent in more than one report. Therefore, between 2,5% and 3,0% of all doctors reported at least once during the course of a year and only 1% more than once.

The present survey set out to evaluate the attitudes of doctors to ADR reporting in an attempt to identify the factors responsible for the very low response rate. The study was conducted on random samples of doctors in private practice by means of a structured personal interview.

Subjects and methods

The study was restricted to doctors in private practice for two reasons. Firstly, we wanted to interview doctors who were individually responsible for the prescribing of medicines and who had the sole responsibility to report ADRs. This was more easily achieved in the private sector, because in hospitals doctors tend to decide on medication as a team, so that the onus to notify ADRs does not rest on a single person. Secondly, accurate lists of hospital doctors are not generally available and this made random sampling difficult. All private medical practitioners are listed in a special section of the telephone directory which, in the case of specialists registered with the South African Medical and Dental Council, also designates their respective specialties.

Groups selected

Using the current telephone directories for the Cape Town area and its environs (Stellenbosch, Strand and Somerset West), we alphabetically tabulated the names of and numbered every medical practitioner in terms of the following groups: (*i*) general practitioners (GPs); (*ii*) medical specialists (MSs), including paediatricians and psychiatrists; and (*iii*) surgical specialists (SSs), including ophthalmologists and obstetricians and gynaecologists. We excluded pathologists, radiologists and anaesthetists, who are not primarily concerned with the regular prescribing of medicines for the treatment and management of illness.

Having drawn up master lists of doctors for each group, we used random number tables to generate samples from the three groups so that each was represented numerically in the same proportions as existed within the total population of doctors in private practice.

Procedure

Each doctor was then approached telephonically and asked if he/she would kindly give up 15 minutes to discuss ADRs. The

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doctor was subsequently visited and interviewed in his/her rooms by one of us (M.W.). The various items in the interview questionnaire will be listed in the following section.

Results

The following indicates that 104 doctors were finally interviewed in the following groups:

	GP	*MS*	*SS*	*Total*
No. of names drawn	73	28	20	121
Not available (e.g. holiday, left practice)	12	2	0	14
Refused to co-operate	2	0	1	3
No. interviewed	59	26	19	104

Analysis of responses

The responses to the interview fell into two categories depending on the questionnaire item: (*i*) specific answers (e.g. 'yes/no'), which can easily be categorised and analysed; and (*ii*) descriptive answers, which cannot be categorised so easily; only the most common responses are presented in this article.

The results are given separately for the GP, MS and SS groups, and in the case of (*i*), the chi-square test was applied to detect significant differences between the three groups of doctors.

Questionnaire items

1. What do you understand by the term 'adverse drug reaction'? The three most common responses (in descending order) given by the three groups were as follows:

GP	*MS*	*SS*
1. Unexpected reaction	Unwanted reaction	Unexpected reaction
2. Harmful reaction	Unexpected reaction	Harmful reaction
3. Unwanted reaction	Harmful reaction	Unwanted reaction

The consensus was that an ADR is an unwanted and/or unexpected reaction to a medicine and one that is harmful to the patient.

2. Are ADRs a common or an unusual occurrence in your practice?

	GP	*MS**	*SS*	*Total*
Common	25 (42,5%)	9 (36%)	0 (0%)	34 (33%)
Unusual	34 (57,5%)	16 (64%)	19 (100%)	69 (67%)
	59	25	19	103

*One member of this group was unable to commit himself.
$\chi^2 = 11{,}79$; $P < 0{,}01$.

In general, ADRs were regarded as uncommon, but there was a significant difference between the groups in that none of the SSs claimed that ADRs were common.

3. What happens in your practice when you encounter an ADR? Of the doctors in the total sample, 72 (69%) answered that they would withdraw the drug and probably change to an alternative if that were possible. Only 13 (12,5%) — 6 GPs (10%), 6 MSs (23%) and 1 SS (5%) — spontaneously mentioned that, as part of their usual practice, they would either report the ADR to the MSC or telephone the MSC for advice.

4. Do you consider it necessary to advise any outside agency of an ADR and, if so, whom?

	GP	*MS*	*SS*	*Total*
Yes	31 (52,5%)	23 (88,5%)	13 (68,5%)	67 (64,5%)
No	28 (47,5%)	3 (11,5%)	6 (31,5%)	37 (35,5%)
	59	26	19	104

$\chi^2 = 10{,}32$; $P < 0{,}01$.

Significantly more of the MS group considered it necessary to advise another agency of an ADR. Only half the GPs were of this opinion.

The two most common agencies cited by those who answered in the affirmative were as follows:

	GP	*MS*	*SS*
MSC	17 (55%)	19 (83%)	6 (46%)
Medic Alert	5 (16%)	1 (4%)	3 (23%)

5. Do you tell the pharmaceutical representative about the ADR?

	GP	*MS*	*SS*	*Total*
Usually yes	40 (68%)	11 (42%)	6 (31,5%)	57 (55%)
Usually no	19 (32%)	15 (58%)	13 (68,5%)	47 (45%)
	59	26	19	104

$\chi^2 = 9{,}80$; $P < 0{,}01$.

Significantly more of the GP group favoured informing the pharmaceutical representative.

6. Do you take action if your diagnosis of an ADR is based on a strong suspicion rather than on certainty?

	GP	*MS*	*SS*	*Total*
Yes	56 (95%)	24 (92%)	18 (95%)	98 (94%)
No	3 (5%)	2 (8%)	1 (5%)	6 (6%)
	59	26	19	104

Not significant

Although over 90% said they would take action (e.g. withdrawing the drug or reducing the dose), only 7 (7%) would contact the MSC to report the reaction or ask advice.

7. Do you take action if the ADR is trivial?

	GP	*MS*	*SS*	*Total*
Yes	34 (58%)	15 (58%)	10 (53%)	59 (57%)
No	25 (42%)	11 (42%)	9 (47%)	45 (43%)
	59	26	19	104

Not significant

Just over half the doctors answered in the affirmative and said that the action they would take would depend on the seriousness of the patient's condition. They would usually withdraw the drug, reduce the dose or change to an alternative.

8. Do you consider a well-established and common side-effect to be an ADR?

	GP	*MS*	*SS*	*Total*
Yes	29 (49%)	13 (50%)	13 (68,5%)	55 (53%)
No	30 (51%)	13 (50%)	6 (31,5%)	49 (47%)
	59	26	19	104

In general, opinion on this question was almost equally divided. There were no significant differences between the three groups, although proportionately more members of the surgical group tended to regard a well-established side-effect as an ADR.

9. Do you think it is important to report an ADR involving an old medicine (i.e. one that has been available for years), or is it only necessary to report on newly released medicines?

	GP	*MS*	*SS*	*Total*
New only	45 (76%)	5 (19%)	3 (16%)	53 (51%)
New and old	14 (24%)	21 (81%)	16 (84%)	51 (49%)
	59	26	19	104

$\chi^2 = 35{,}00$; $P < 0{,}01$.

A large and significantly higher proportion of the GP group considered that it was important to report only on new medicines. In the case of MSs and SSs, the great majority regarded it as important to report on old as well as new medicines.

10. Do you take any action if the ADR is based solely on the patient's subjective report (e.g. dizziness, depression) and there are no objective signs?

	GP	*MS*	*SS*	*Total*
Yes	41 (69,5%)	18 (69%)	9 (47%)	68 (65%)
No	18 (30,5%)	8 (31%)	10 (53%)	36 (35%)
	59	26	19	104

Not significant

There were no significant differences between the three groups, although the surgical group was less likely to take action on the basis of a subjective report. Of the doctors who answered in the affirmative, 21% would only take action under certain circumstances, e.g. if the reaction was serious.

11. Are you aware of the MSC and the quarterly newsletter and ADR forms that it distributes?

	GP	*MS*	*SS*	*Total*
Yes	57 (97%)	24 (92%)	15 (79%)	96 (92%)
No	2 (3%)	2 (8%)	4 (21%)	8 (8%)
	59	26	19	104

Very few doctors were not aware of the MSC, and there were no significant differences between the three groups.

12. Have you ever used the services of the MSC or reported an ADR to the MSC?

	GP	*MS*	*SS*	*Total*
No	29 (47,5%)	10 (38,5%)	17 (89,5%)	55 (53%)
Yes	31 (52,5%)	16 (61,5%)	2 (10,5%)	49 (47%)
	59	26	19	104

$\chi^2 = 13{,}07$; $P < 0{,}01$.

More than half the doctors had never used the MSC either to seek advice or to report an ADR. A significantly greater percentage of SSs had not used the MSC and none of the SSs had ever reported an ADR. Of the 49 doctors who used the MSC, 26 (53%) had reported an ADR.

13. Do you have any comments or explanations as to why so few doctors report ADRs to the MSC? Most of the respondents gave more than one explanation. The factors listed below were cited by at least 10% of the respondents in each group.

GP (57 subjects)*	
Very few ADRs are seen, and those that are are minor, well-established and not worth reporting	31 (54%)
Apathy	26 (45,5%)
Too busy	17 (30%)
Uncertain about what to report	8 (14%)
ADR form is not readily available when needed	7 (12%)
MS (26)	
Very few unusual ADRs are seen	14 (54%)
Apathy	12 (46%)
ADR form is not readily available when needed	7 (27%)
Too busy	7 (27%)
Ignorance of the value of the MSC and ADR reporting	5 (19%)
Burdened by too much paperwork	4 (15%)
Would feel threatened or embarrassed	3 (11,5%)
SS (19)	
Very few ADRs are seen, and those that are are minor, well-established and not worth reporting	14 (74%)
Ignorance of the value of the MSC and ADR reporting	7 (37%)
Burdened by too much paperwork	4 (21%)
Too busy	4 (21%)
Apathy	3 (16%)
ADR form is not readily available when needed	2 (10,5%)
Unawareness of the existence of the MSC	2 (10,5%)

*The 2 doctors in the GP group who were not aware of the MSC and had never received the ADR forms refused to comment on this and subsequent questions, since they knew nothing about the ADR reporting procedure.

Out of the total sample of 102, at least 10% of respondents gave the following explanations for the poor reporting of ADRs:

1. Very few ADRs are seen, and when they are observed they are minor, well-established and not worth reporting — 59 (58%)
2. Apathy — 41 (40%)
3. Doctors are too busy to find time to complete the ADR form — 28 (27%)
4. Ignorance of the value of the MSC and ADR reporting — 20 (19,5%)
5. ADR form is not readily available when needed — 16 (16%)
6. Doctors are already burdened by too much paperwork — 11 (11%)

It is of interest to note that only 9 doctors (9%), 8 of whom were in the GP group, mentioned uncertainty about what to report. Furthermore, only 5 doctors (5%) suggested that doctors did not report ADRs because they feared personal criticism, embarrassment or humiliation.

14. Do you think a telephone service whereby a doctor could telephone in an ADR rather than filling in a form would help?

	GP	*MS*	*SS*	*Total*
Yes	45 (79%)	18 (69%)	13 (68,5%)	76 (74,5%)
No/ uncertain	12 (21%)	8 (31%)	6 (31,5%)	26 (25,5%)

Not significant

The great majority of doctors regarded a telephone service as a useful idea.

15. Which of the following factors do you think are important in explaining the low response rate of doctors to ADR reporting? (These do not necessarily apply to you but to doctors in general.) The following table lists the numbers and percentages of those who responded *in the affirmative*. There were no significant differences between the three groups in any of the items.

	GP (57)	*MS (26)*	*SS (19)*	*Total (102)*
When evidence for an ADR is insufficient, doctors are reluctant to commit themselves	45 (79%)	23 (88,5%)	16 (84%)	84 (82%)
When patients are on more than one drug, it is difficult to know which is responsible	49 (86%)	25 (96%)	18 (95%)	92 (90%)
Doctors do not want to give a drug a bad name	2 (3,5%)	4 (15%)	1 (5%)	7 (7%)
Doctors could not be bothered to report	46 (81%)	23 (88,5%)	12 (63%)	81 (79,5%)
Doctors are too busy, even if they want to report	29 (51%)	12 (46%)	10 (52,5%)	51 (50%)
The report form does not reach the doctor	8 (14%)	6 (23%)	7 (37%)	21 (20,5%)
The form is too complicated	15 (26%)	1 (4%)	3 (16%)	19 (18,5%)
Doctors have a negative attitude towards form-filling	52 (91%)	25 (96%)	14 (74%)	91 (89%)
Doctors are wary of reporting ADRs because of the consequences for themselves (e.g. medicolegal)	6 (10,5%)	4 (15%)	3 (16%)	13 (13%)
Would the concept of drug event rather than adverse drug reaction get a better response from doctors because it does not directly incriminate the drug?	8 (14%)	3 (11,5%)	0 (0%)	11 (11%)

Discussion

The participation of doctors in spontaneous reporting schemes is an efficient means of obtaining new ADR reports.[1] The present survey was prompted by the remarkably low ADR reporting rate in the Cape Town region despite persistent efforts of the MSC to promote such reporting and to provide feedback to those who co-operate. Only 2,5 - 3% of doctors report at least once in the course of a year and 1% more than once. A prospective study among GPs in the UK[2] found that over a 4-week period each practitioner recorded an average of

6,38 suspected ADRs, whereas the low number reported by our doctor population over 1 year shows massive resistance to ADR reporting. We therefore set out to explore doctors' attitudes and approaches to ADRs by means of a structured interview.

We confined our study to private practitioners for reasons outlined above, but during 1984 and 1985, 21% and 23% respectively of doctors reporting to the MSC were based in hospitals. The hospital situation requires special study, since many of the most serious ADRs are observed within a hospital setting. Of the ADR returns from the private sector in 1984 and 1985, 86% and 84% respectively emanated from general practitioners.

ADRs were regarded as common by about 40% of the GP and MS groups, while 100% of the SS group deemed them uncommon. Moreover, not a single SS interviewed had ever submitted an ADR report to the MSC, compared with 27% and 38,5% of the GP and MS groups respectively. These observations may reflect the fact that SSs use medicines less (especially on a long-term basis) than the other groups.

About two-thirds of all doctors — and significantly more of the MS group (88,5%) — considered it necessary to notify an outside agency (usually the MSC) of an ADR, but only 12,5% spontaneously indicated that it was part of their practice to involve the MSC if they encountered an ADR. This did not signify a lack of awareness of the MSC and its ADR monitoring function, since 92% of all doctors interviewed were familiar with the MSC and had received its mailings. On the other hand, it was of interest that two-thirds of the GP group would inform the pharmaceutical representative about an ADR, while approximately two-thirds of the MS and SS groups would not do so. Again, if doctors observed a reaction which they strongly suspected was an ADR, over 90% of them would take some action (e.g. withdrawing the drug or reducing the dose), but only 7% would actually notify or seek advice from the MSC.

Another area of difference between the doctors was that over 80% of the MS and SS groups thought it important to report ADRs on old as well as new medicines whereas 76% of the GP group would limit themselves to newly released medicines.

The critical issue is why doctors are so non-compliant about ADR reporting, and it appears that the concept of an ADR is central to this matter. The great majority of our respondents considered an ADR to be an unexpected or harmful reaction; in fact, on specific questioning, half of them excluded well-established side-effects as ADRs. Furthermore, by far the commonest explanation volunteered for the under-reporting of ADRs was that doctors observed very few unusual or severe ADRs in practice and did not feel justified in reporting well-known or minor reactions. Although unusual side-effects are indeed rarely encountered, the ability to make a distinction between common and uncommon effects presupposes a sound grasp of the side-effects profile of the various medicines. This certainly cannot be assumed, and the MSC has repeatedly urged that all ADRs should be reported. Although our sample of doctors considered serious ADRs to be worth reporting, studies from the UK[2] and Sweden[3] indicate that doctors are remiss about these too and fail even to report ADRs which are life-threatening or result in hospitalisation.

The four other main reasons spontaneously given were (in decreasing order) apathy, being too busy, not recognising the value of ADR reporting and not having the ADR form at hand when it is needed. All these factors represent a general attitude of unconcern. It is interesting that, contrary to an oft-held view, fear of personal consequences (e.g. medicolegal action or criticism by peers) was not identified as an important influence by our sample of respondents.

It has been suggested that the term *drug event* might be more acceptable than *adverse drug reaction* and encourage better reporting because it does not directly incriminate the medicine. We specifically asked this question, and very few (10%) of our respondents agreed — in fact, one doctor replied that to him a 'drug event' was a dinner hosted by a pharmaceutical company at a fashionable hotel!

Form-filling was regarded in a negative light by about 90% of doctors and so we enquired whether an ADR 'telephone-in' service might be more attractive than completing ADR forms. This was endorsed by the great majority of doctors, and it is a facility which might be developed further. However, as increasing numbers of doctors have access to desk-top computers, we are establishing a national computer-linked service similar to the British 'Prestel'. This will provide immediately accessible drug information to all practitioners who, in turn, will be able to key in their ADR reports and get rapid, individual feedback. It remains to be seen whether this will facilitate ADR reporting.

This survey explored why 97% of doctors in the Cape Town region never report an ADR in the course of a year despite repeated pressure to do so by the MSC. The task of reporting has fallen on a very small core of conscientious practitioners, a trend which is similar but less extreme in the UK, where 80% of ADR reports were submitted by 7,4% of doctors within the National Health Service.[4] Apathy is undoubtedly a major factor, especially against the backdrop of a busy practice. Although there is a widespread lack of appreciation of the importance of ADR reporting, we doubt whether further attempts to inculcate positive attitudes will substantially improve motivation. In France, Sweden and Norway ADR reporting is mandatory, and yet despite the force of legal decree the reporting rate remains low.[3] The prognosis is poor and it appears that, like all else which passes between doctors and their patients, ADRs will continue to remain largely outside the reach of an external agency.

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