SHORT REPORT

Involving the patient in reporting adverse drug reactions

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SUMMARY. A method is described for increasing the level of reporting of adverse drug reactions. Patients prescribed a black triangle drug (one being monitored by the Committee on Safety of Medicines) were given a leaflet by the dispensing chemists in one town, encouraging them to report any adverse reaction to their doctor. Over two two-month periods, reports of adverse reactions rose from six out of 576 in the control period (10 per 1000) to 11 out of 481 (23 per 1000) in the study period but only one 'yellow card' was submitted to the Committee on Safety of Medicines.

Introduction

THE black triangle symbol is used to identify drugs being monitored by the Committee on Safety of Medicines. Although doctors are encouraged to report adverse drug reactions the rate of reporting is low.[1] For black triangle drugs it is particularly important to stimulate reporting, and it has been suggested that doctors could give patients an advice leaflet when the prescription is issued to inform them that the drug is new and that any possible side effect should be reported to the doctor.[2] This approach was evaluated by monitoring prescriptions within an easily defined community. The chemist rather than the prescribing doctor was asked to issue the advice leaflet as it was felt that this would be more reliable and would reduce potential bias in the evaluation.

Method

There are 29 general practitioners in Livingston, a new town in West Lothian with a population of around 40 000. Most patients take their presentations to one of six chemists. With the consent of all doctors these six chemists agreed to monitor prescriptions issued over two periods of two months for 77 black triangle drugs.

During the first two-month period black triangle prescriptions were dispensed in the normal way but in the second period the patient was given a leaflet with the following instructions when a black triangle prescription was dispensed:

> 'This medicine is new. It is effective but has not yet been used in a very large number of patients. This means that there may be side effects which are still unrecognized. You could help to uncover such effects if you report to your doctor any new symptom or any unexpected effect that develops while you are taking the drug, or within a month or so of stopping it.'

Each prescriber was given a list of all the black triangle prescriptions he had issued and was asked to review the case notes to see whether any adverse reaction that could conceivably be attributed to the drug had been recorded within a month of the prescription date.

To overcome bias the doctors were not told when the data were being collected, and several months elapsed between obtaining their consent and the start of data collection by the chemists.

Results

Over the two periods details of 1057 prescriptions for black triangle drugs were recorded — 576 during the two-month control period and 481 during the two-month intervention period. These 1057 prescriptions were received by 896 patients, with 117 patients receiving more than one prescription for the same item. In the second period one patient was alarmed by the advice leaflet and refused to take his prescribed medication. This led to the withdrawal of one practice from the study and contributed to the smaller number of presciptions recorded during the second period. No other doctor or chemist reported any negative comments from patients.

In total, 17 possible adverse reactions were noted, with six in the control period (10 per 1000) and 11 in the intervention period (23 per 1000). Surprisingly only one 'yellow card' was submitted to the Committee on Safety of Medicines, during the intervention period, as a result of these reports.

The odds of an adverse reaction being reported to the doctor were increased by a factor of 2.2 when patients are given an advice leaflet (95% confidence limits 0.8–6.8), which is not significant at the 5% level using Fisher's exact test.

Discussion

The discovery of adverse drug reactions depends on anecdotal reporting or post-marketing research.[3] Many major post-marketing studies fail to find any adverse reactions attributable to the drug being studied, whereas adverse reactions are reported spontaneously for two-thirds of all new drugs.[4] In order to detect unusual reactions the sample required for realistic studies may be too large, for example in order to detect an incidence of one to two in 10 000 two groups of 306 000 patients would be needed.[5] Thus, there is little hope of detecting unusual adverse reactions with formal studies.

Spontaneous reporting is the least sophisticated and scientifically rigorous method, but the least expensive. However, while spontaneous reporting may be best for discovering minor reactions, it has often missed major adverse reactions, and journal reports have provided the first lead for many of these.[6,7] There can be problems with case reports in journals — one case may legitimately be reported more than once leading to numerator difficulties, and important information about causal association may be omitted.[8] Prescription event monitoring managed to generate as many 'green forms' in two years as 'yellow cards' collected by the Committee on Safety of Medicines in 20 years,[9] and yet has been criticized for failing to detect serious reactions.[10]

The Committee on Safety of Medicines was set up in 1963, and under the 1968 Medicines Act one of its functions is the

surveillance of each drug after marketing.[11] The Committee introduced the yellow card system in 1964, and the use of yellow cards has increased from 4500 per year to over 15 500 in 1986.[12] The provision of forms in prescription pads and the *British national formulary* appears to be helping.[12] However, less than 20% of doctors use the yellow card system,[13] and 80% of reports are sent in by only 7% of doctors.[3] An average of one card per doctor is submitted every four years.[14]

The administration of adverse drug reaction monitoring varies in different countries.[15-17] However, in the UK the opportunity for drug monitoring is enhanced by one general practitioner having a complete record for each individual, and by the existence of general practice lists which provide a defined population for studies.[18]

In this study patients were involved in adverse drug reaction reporting. Although one of the patients was made anxious, the method was generally well received by patients, doctors and chemists. The results suggest that patients can be stimulated to report adverse reactions to their doctor, but that any potential benefit is lost if these reports are not relayed to the Committee on Safety of Medicines by the doctor.

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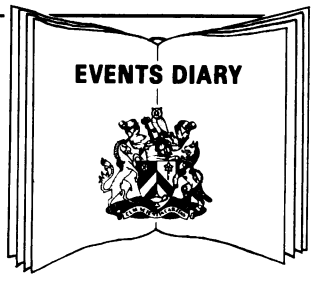

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