

PRACTICE OBSERVED

Practice Research

Adverse drug reaction cards carried by patients

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Abstract

Five hundred patients were asked whether they were allergic to any medicines. The description given of any stated reaction was assessed to see whether an important adverse drug reaction was likely to have occurred. The patients' records were also examined for corroborative evidence. Poor documentation often made it difficult to confirm the patient's claim of drug sensitivity. A total of 89 patients may have suffered from important adverse reactions to 113 drugs. Full documentation of adverse reactions is important, but only eight patients carried any information to warn others of their sensitivities. Patients should be asked about drug sensitivities and, if appropriate, given written confirmation of them. A quick, simple method of doing this would be to provide patients with a plastic card, similar to a credit card, with instructions and details of the reaction written on it with an indelible pen.

Introduction

People are often unable to state whether they have suffered an adverse reaction to a medicine. Furthermore, they seldom seem to carry any information that would warn others of their reactions. In certain circumstances this could have serious consequences—for instance, when a patient is brought unconscious into a casualty department. The Royal College of General Practitioners recommends the practice of tagging records with coloured markers to warn the clinician that there is a history that could affect current or

future diagnoses or treatment. The system consists of different coloured stickers, which are put either on the right edge of the front of the patient's envelope or along the top edge of a projecting insert card. "Sensitivities"—drug sensitivities, severe toxic drug idiosyncrasies, and major allergies—are indicated by a red marker. In this study a similar system was used; a warning was written on the top right-hand corner of the front of the notes and a red flag inserted into the notes. Obviously, this system is useful only if the notes are available at the time of consultation; it might be more useful if the patients themselves carried the relevant information.

Before introducing such a system several questions need to be answered.

- (1) Is such a system necessary? How many patients can state any drug sensitivity and, of these, how many already carry confirmatory evidence on them?
- (2) Is the present warning system accurate? Is it a sound basis from which we could start issuing warning cards to patients?
- (3) Can a system be introduced that issues cards to patients quickly with the minimum of disruption to the practice?

Method

The study took place in Sheffield in an urban practice of roughly 4200 patients served by one full time partner, one part time partner, and a trainee. A short questionnaire was constructed (fig 1). Part I was completed at the start of each consultation, when the patient was asked if he or she was allergic to anything (question 1). If the reply was No the doctor progressed no further and the consultation could proceed. If the reply was Yes the doctor continued through the remainder of part I. Question 2 was structured so that the patient was unable to name the offending drug but was progressively positive of an important adverse reaction: anaemia (three); post-operative analgesic (one); local reaction to injection (one); no improvement made (one); brother allergic (one); went bad with penicillin (one). Facial or limb swelling, mouth ulceration, loss of consciousness, oculogyric crises, and methemoglobinemia would, however, probably be considered to be serious adverse reactions by most doctors. From our own descriptions 23 patients probably suffered from such serious adverse reactions. Unfortunately, only

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patient could not describe the reaction. (3) Those who were unlikely to have experienced any adverse reaction (41) patients. The description given (if at all) was poor, and there was no documentary evidence of a reaction in the notes.

TABLE I—Grouping of patients whose history of sensitivity and documented evidence in notes were combined

Patient's description	Evidence in notes		All patients
	Present	Absent	
Good	31	48	79
Poor	10	60	70
Could not describe or demand sensitivity	10	40	50
Total	41	410	500

If group (3) is excluded then 89 patients may have reacted adversely to 113 drugs or medicines, and these are classified in table II. Antibiotics were the commonest offending drugs (penicillin 41 patients, co-trimoxazole 18, ampicillin eight), and other antibiotics seven. Even then documentation of evidence was present (41 of 89 possible cases (46%); this was often vague or incomplete, so it is impossible to say from this study how many patients had suffered from serious life-threatening reactions. Development of a skin eruption was the most frequently described reaction (table III). Table III

TABLE II—Types of drugs causing adverse reactions

Drug	Adverse reaction tagged on notes	Adverse reaction not tagged on notes	All patients
Antibiotics	60	14	74
Analgesics	2	1	3
Barbiturates	2	1	3
Diuretics	1	1	2
Mucolytics	4	1	5
Urethral dilators	1	1	2
Serotonin	6	0	6
Total	87	26	113

*Some patients suffered more than one adverse reaction.

TABLE III—Description given by patients, probably indicative of important adverse reaction

Description	No.
Rashes or blanches	57
Swelling of face or limb/water or water in mouth	15
Serious gastrointestinal upset*	11
Blurred or waxy vision	7
Mouth ulcers or blisters	7
Loss of consciousness	5
Mucous spasm oculogyric crisis	1
Swollen	1
Urethral spasm rash	1
Total	100†

*The patient with reported gastrointestinal upset in fact suffered from barbiturate anaemia.
†Some patients suffered more than one adverse reaction.

sets out the descriptions that were probably indicative of an important adverse reaction. Eight patients gave descriptions that were probably not indicative of an important adverse reaction: anaemia (three); post-operative analgesic (one); local reaction to injection (one); no improvement made (one); brother allergic (one); went bad with penicillin (one). Facial or limb swelling, mouth ulceration, loss of consciousness, oculogyric crises, and methemoglobinemia would, however, probably be considered to be serious adverse reactions by most doctors. From our own descriptions 23 patients probably suffered from such serious adverse reactions. Unfortunately, only

one of these patients had evidence of the reaction documented in their notes.

Patients claiming sensitivity to a drug were asked who had told them about it (76) and that a doctor had told them was the most common answer for 48 of the eight patients who gave a poor description of their reaction. Only eight patients said that they carried warning information, such as a bracelet or SOS tins. Furthermore, only four of these patients were able to produce it at the time of consultation.

Part I of the questionnaire took approximately 30 seconds of consultation time to complete, even if all five questions were to be asked. Completion of part II took about one minute, although this obviously depended on the size of the patient's notes.

Discussion

The incidence of adverse drug reactions is unknown. Many factors contribute to this lack of knowledge. Patients developing a reaction may not report it to the prescribing doctor, and sometimes patients confuse side effects with true allergic reaction. Certain viral illnesses themselves produce a rash, which may be confused with a hypersensitivity reaction to medicines concurrently prescribed. Some illnesses predispose people taking certain drugs to develop a rash or, for instance, almost 95% of patients with glandular fever develop a rash if they take ampicillin. Some patients or doctors mistakenly believe that sensitivity to one group of drugs indicates a similar sensitivity to another group of drugs. Finally, in developing a maculopopular rash with ampicillin are rarely also allergic to penicillin, which produces an urticarial eruption. Indeed, the ampicillin maculopopular rash may not have an immunological basis and, by itself, may not be a contraindication to subsequent treatment with ampicillin. Many patients, however, are often denied subsequent treatment with penicillin as well as ampicillin because of fears of cross sensitivity or failure to distinguish between the two antibiotics.

The definition of an important adverse reaction is difficult. In this study important adverse reactions were taken to be all hypersensitivity reactions and severe drug intolerances. Although rarely life threatening, these reactions cause a lot of distress and discomfort so it is important to try to avoid prescribing the offending drugs again. Unfortunately, the diagnosis usually has to be based on clinical suspicions alone as skin and blood tests do not help. Using this method, these reactions cause a lot of distress and discomfort so it is important to try to avoid prescribing the offending drugs again.

In total, 89 (18%) patients may have suffered from an important adverse reaction, although there will always be an element of doubt as to whether this is the true position. Indeed, this study illustrates some of the problems found when trying to confirm possible adverse reactions. A description of the reaction was absent from many patients' notes. Perhaps the doctor tagged the notes without recording the reaction in the notes or perhaps the patient's ideas about drug sensitivity were wrong. When the reaction was documented they were often incomplete or vague. This made an assessment of the reaction's severity difficult. In this study no attempt was made to see how many patients had inadvertently been re-exposed to the offending medicines. Oswald found that 28 (36%) of 78 patients who had a recorded penicillin allergy had been re-exposed to penicillin, with further reactions in only four patients. When an adverse reaction occurs it is, therefore, important to document carefully in the patient's notes the indication for treatment, the drug prescribed, and details of the suspected reaction to it. This may help doctors in the future to assess whether the reaction warrants continued avoidance of the suspected drug.

The records of 75 patients were tagged and a surprisingly high proportion of patients (68%) could accurately name the offending drug, although only eight patients claimed to carry warning information on them. There is, therefore, a need to issue patients with documented warning information. The information should be on a plastic card, probably of credit card size, with instructions printed on it and the reaction details (name of offending drug, date, and description of reaction) written with an indelible pen. I do not believe that these cards exist at present, but perhaps the pharma-

The following classification was used for reported adverse reactions

(A) Symptoms suggestive of a hypersensitivity reaction—for example, urticaria, pruritus, oedema, facial swelling, loss of consciousness, collapse, difficulty in breathing.

(B) Symptoms suggestive of important drug intolerance—for example, gastrointestinal upset (but not nausea), unsteady, dizziness, oculogyric crisis.

(C) Symptoms not accepted as indicating drug hypersensitivity or intolerance—for example, nausea with vomiting, poor response to analgesics, or failure to improve despite treatment.

Finally, to indicate that a questionnaire had been completed (so that the patient was not asked again) the letter Q was pencilled on to the front of the notes. Some assessment was made of the time taken to complete the questionnaire.

Results

Over three weeks in May 1985, 500 consecutive patients (316 women (63% and 184 men (37%)) were questioned. One hundred and twenty five patients stated that they were allergic to something, although 39 qualified this by saying that they were not allergic to any drugs or medicines (fig 2).

The records of 75 patients were tagged to warn of previous adverse reactions. Of these patients, 51 were able to name accurately the drugs written on their records, 11 could name some but not all of the drugs, and three named drugs different from those written on their records—for example, one named penicillin but the tag warned of allergy to Seprin (co-trimoxazole). Ten patients were not aware that their notes were tagged as denoting any allergy and four claimed an allergy to substances such as pollen or fur but not to any drug.

Twenty one patients claimed a sensitivity to some medicines, although their notes were not tagged. Further six patients claimed sensitivity to substances that they recognised as not being medicines but that might be important in future medical care (stacking paper (four), Steriprin (one), and tartrazine (one)). Twenty seven patients, therefore, seemed to have suffered from reactions that might lead to the tagging of notes. Certainly, 24 (86%) of these patients gave a good description of their reactions, which compared well with the proportion of patients with tagged records who gave a good description of their reaction (55.73%). All the patients' records were examined to see if there was any documentary evidence of an adverse reaction. Six (25%) of the 27 patients with possible newly discovered reactions had evidence of the problem contained in their notes. Conversely, 40 (15%) of the 75 tagged records had no evidence to support the warning. This detailed examination of all 500 medical records showed two reactions that were not mentioned either on the cover of the notes or by the patient.

FIG 1—Questionnaire completed at each consultation

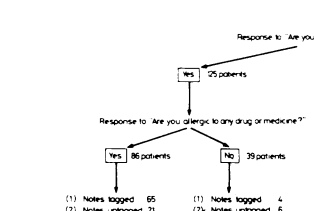


FIG 2—Patients' responses to questionnaire (500 questionnaires were completed)

written on the cover of the patient's notes. The record cards made were then examined to see if there was any evidence of an adverse drug reaction. If no such record was found but the patient had claimed some drug sensitivity the letters were examined in case the reaction had occurred in hospital. Any mention in the records of an actual or suspected reaction, even if the entry was incomplete or vague—such as "rash, possible Seprin allergy"—was taken as documentary evidence. Evidence was looked for solely to see if the records contained any descriptions that might help the doctor to assess whether an important drug reaction had occurred. This did not imply any proof of the existence of a drug sensitivity.

One had occurred in someone known to be sensitive to another drug and the other in someone thought not to be sensitive to any drugs.

- (1) Those who probably had experienced an adverse reaction (31 patients). A good description of the reaction was given and documentary evidence was present in the notes. (2) Those who possibly had experienced an adverse reaction (58 patients) if a good description of the reaction was given but no documentary evidence existed. (3) Documentary evidence existed but no

could be persuaded to produce them as a service to patients. Forgetful patients might then be protected from exposure to offending drugs if their records were not available; unconscious patients would also be protected. This, of course, implies that patients will carry this information, which may not be the case. Doctors would need to emphasise the continued use of the cards so that patients thought that they were worth carrying.

As almost 70% of patients consult their general practitioner in any one year, most patients at risk could be issued with cards in a short space of time. Unfortunately, the present tagging system is not sufficiently accurate to be desirable if wearing cards for an adverse reaction has any drug reactions, and part I of the questionnaire could facilitate this. An assessment of whether any important drug reaction has occurred (based on the patient's description and any evidence in the notes) could be made and, where appropriate, warning cards issued. Detailed examination of 500 patients' records showed only two reactions not mentioned by the patient and not marked on the cover of the notes. Detecting these two reactions took a lot of time. Scrutiny of all patients' records could not, therefore, be justified, although this might mean that a few adverse reactions

100 YEARS AGO

The subject of hats as things of beauty—or ugliness—has been made the theme for eulogy or condemnation, and their influence from a sanitary point of view has not been altogether overlooked. There is, however, much to be said in defence of the most maligned salt hat, the analogy of which in shape and shade to certain common objects has caused it to be compared, in England, to a "chumney-pot"; in America, to a "stove-pipe"; and in France, to a "tuva de poêle." The hat, be it shape, colour, and dimensions what they may, is a part of our attire, and has, therefore, with our other garments, certain duties to perform, as intervening between ourselves and the ambient atmosphere. The degree to which any particular form of hat complies with the requirements laid down for clothing generally may be accepted as the criterion of its eligibility as a "title"—an expression which, by the way, is etymologically irreproachable, although, like the hat in question, it may be open to criticism as a matter of taste. A hat ought, of course, to be as comfortable as possible, but obvious as this is, it is a point in which many, probably the majority of hats, contravene the laws of comfort and sanitary health. The interference with the circulation which results from compression of the blood vessels between the hard sharp rim of a hat and the underlying skull, together with the maintenance of an abnormal and undesirable temperature confined to a particular area, may reasonably be charged with contributing largely to the calumny of people of the better class, whose obstinate attention to rules of fashion and etiquette obliges them to wear the hat in fashion, irrespective of considerations of ease or suitability. Next to being light, it is essential that the material of which a hat is constructed should be such as to interpose a non-conducting barrier to shelter the head from the frivolous changes of an inclement climate, and this object is admirably attained by hats in which a thick layer of air affords the protection of its poor conductivity against cold or heat. Here, as elsewhere, ventilation should be provided for, and hatters have introduced various modifications, all more or less inefficient, for this purpose. The importation of the French habit of doffing the hat on every conceivable occasion has unfortunately done much to minimise the evils which might have been superadded from this source. So far, then, the orthodox salt hat complies with these conditions to an extent which varies according to the maker. But even its most ardent admirer would spare it all a "thing of beauty," and the mutability of its fabric precludes it, alas! from ever being a "joy for ever." All the advantages pertaining to the use of the "salt hat" may be secured both better and cheaper in the form of its straw analogue which, at any rate for summer wear, is, from its convenience and comfort, a standing protest against the arbitrary caprice of fashion, which condems urban residents to wear it in any position at all to wear a structure which is ruined by rain, carried away by wind, and cumbersome anywhere. Part of the bias attending exile from town is the history of unfettered freedom in the matter of head-covering. So far we have spoken of the male headgear, and it may be confidently anticipated that if reports of health and comfort are ignored by men, the ladies are not likely to make their observance a speciality. Indeed, the headgear of the average female in any rank of society, as less a protection against the elements than a means of self-decoration, and a potent

agent in that struggle of "natural selection," described by Darwin as influencing the females of many animals. In the case of a show or a tennis, willingly would the lady remove her headgear, and bear on her unprotected head the blows of the elements, on the principle of the negro who took such particular care of his new hat on the ground that his hat was his own, while his head was his master's. The female is already handicapped by the legitimate arrangement of her hair, which she trusts to grow in exactly the opposite direction to that suggested by nature, and places it in a bundle on the head, so as to interfere with growth and nutrition to an extent that the wiser of men's hats could not rival. It is, probably, idle to hope for any reform in this direction, and the hygienist may "en vau" in the wilderness of indifference with which society fenes him round, with the main concern now for his only reward. (British Medical Journal 1886: 1114.)

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A good deal has been written on the pernicious influence of certain classes of literature on the mental development of rising generations, and some sanitary checks have been placed, of late years, on the indiscriminate publication of works belonging to the class of "romance," and the "novel." There are, however, other departments of literary depravity, as the indications of which are probably quite as injurious, in different degrees, as the indications of this category belonging to the Dick Turpin type, where a highway robbery with violence is raised to the level of a fine art. Somewhat allied to this class of literature, but superior to it in point of style and sentiment, are the novels in which the incidents of a life and scalp with the utmost gusto and enthusiasm. The proceedings at a recent assize court in France demonstrate the fact that these exciting and blood-thirsty tales cannot be told with impunity to some very weak-minded youth with a criminal bent of mind. After a course of this literature, translated into their own language, two young countrymen, sons of rich farmers, one already a *breve de notaire*, took to themselves the names of "Bismarck" and "Napoleon," and proceeded to murder to maturity a plan of abduction, rape and murder, to be followed by suicide, which they first worked out in the form of a narrative, and finally proceeded to carry into execution. The victim was a girl of fifteen, the daughter of a neighbouring farmer. The allowed herself to be taken into a lonely place, where the young heroes carried out their plans, and finally left the girl with five shillings, from the effect of which she speedily died. There was a hitch in the arrangements, and the youthful assassins were arrested the next day; among their papers being found the "plan of attack." "Notwithstanding an able and eloquent defence by their advocates, they were each sentenced to different terms of imprisonment. In addition, their parents were condemned to pay £1000 damages to the father of the victim. This ghastly history shows to what an extent certain classes of literature are capable of being injurious to the mind. But these are the naturalness of feeble mental stamina may fairly be assumed, but it is nevertheless quite possible that but for this fortuitous occasion, they might have grown up into very tolerable citizens. (British Medical Journal 1886; 1: 733.)