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 collaborative 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 any 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.[1] 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 if the patient was unable to name the offending drug he was progressively prompted to see if he could recall it. This procedure is similar to normal clinical practice. When a patient said that he carried some warning information on him he was asked to produce it for examination by the doctor. If children were not old enough to give a reliable history their parents were questioned.

Part II of the questionnaire was completed after each surgery. The notes were first examined to see if the patient's reply correlated with any warnings written on the cover of the patient's notes. The record cards inside 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 Septrin 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.

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Part I

NAME: _____

(1) Are you allergic to anything? YES/NO (specify _____)
If YES are you allergic to any drug or medicine? _____

(2) What is the name of drug or medicine? _____
If above unanswered what type of drug or medicine is it? _____
If above unanswered is it Septrin, penicillin, or ampicillin? _____

(3) What reaction did you have? _____

4. Who said you were allergic? _____

(5) Do you carry anything to warn others of your allergy? YES/NO _____
If YES ask patients to show you (describe): _____

Part II

AGE _____ SEX _____

Are the notes marked?	YES/NO
Is the marking for sensitivity or drug intolerance?	YES/NO YES/NO
Is there evidence for the marking?	YES/NO (Specify _____)
Has a new sensitivity been discovered?	YES/NO
Is there any evidence for this?	YES/NO (Specify _____)
Is the patient aware of the allergy marked on notes?	YES/NO

FIG 1—Questionnaire completed at each consultation.

The following classification was used for reported adverse reactions.

(A) Symptoms suggestive of a hypersensitivity reaction—for example, rashes, 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), tinnitus, dizziness, oculogyric crisis.

(C) Symptoms not accepted as indicating drug hypersensitivity or intolerance—for example, nausea with antibiotics, 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 Septrin (co-trimoxazole). Ten patients were not aware that their notes were tagged: six denied 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. A further six patients claimed sensitivity to substances that they recognised as not being medicines but that might be important in future medical care (sticking plaster (four), Steristrip (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 (22%) of the 27 patients with possible newly discovered reactions had evidence of the problem contained in their notes. Conversely, 40 (53%) 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.

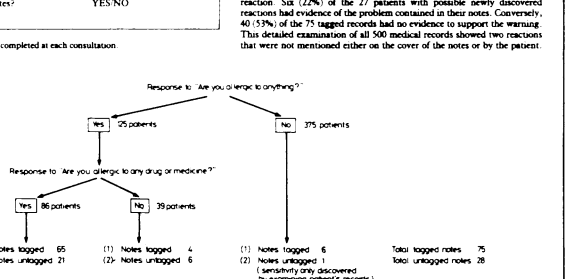

FIG 2—Patients' responses to questionnaire (500 questionnaires were completed).

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.

To try to clarify who was likely to have suffered from an adverse reaction the patient's history was combined with the evidence documented in the records (table I). The patients could thus be divided into three groups. (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): (*a*) a good description of the reaction was given but no documentary evidence existed; (*b*) documentary evidence existed but the patient could not describe the reaction. (3) Those who were unlikely to have experienced any adverse reaction (411 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 when history of sensitivity and documented evidence in notes were combined*

Patient's description	Evidence in notes: Present	Absent	All patients
Good	31	48	79
Poor	10	8	18
Could not describe or denied sensitivity	10	403	413
Total	41	459	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 when documentary 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 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: nausea (three); poor response to analgesic (one); local reaction to injection (one); no improvement made (one), brother allergic (one); went hot with penicillin (one). Facial or limb swelling, mouth ulceration, loss of consciousness, oculogyric crises, and haemolytic anaemia would, however, probably be considered to be serious adverse reactions by most doctors. From their own descriptions 23 patients probably suffered from such serious adverse reactions. Unfortunately, only nine of these patients had evidence of the reaction documented in their notes.

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	13	4	17
Barbiturates	2	1	3
Decongestants	2		2
Miscellaneous	4	1	5
Sticking plaster or Steristrips		6	6
Unknown	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 blotches	57
Swelling of face or limb with or without rash	15
Serious gastrointestinal upset*	13
Blisters at wound site	6
Mouth ulcers or blisters	3
Loss of consciousness	3
Muscular spasm: oculogyric crisis	1
Swollen joint	1
Overall severity plus rash	1
Total	100†

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

Patients claiming sensitivity to a drug were asked who had told them about it. Most (76) said that a doctor had told them. This was true even for six 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 talisman. 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 had 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 reactions. 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—for instance, almost 95% of patients with glandular fever develop a rash if they take ampicillin.[2] Sometimes patients or doctors mistakenly believe that sensitivity to one group of drugs indicates a similar sensitivity to another group of drugs. Patients developing a maculopapular rash with ampicillin are rarely also allergic to penicillin, which produces an urticarial eruption. Indeed, the ampicillin maculopapular rash may not have an immunological basis and, by itself, may not be a contraindication to subsequent treatment with ampicillin.[3] 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.[4] Using this rather pragmatic definition, five patients who were sensitive to dressings were included as these substances may be used in future medical care. Similarly, one patient had his notes tagged for possible sensitivity to tartrazine as medicines contain this substance.

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 patients' ideas about drug sensitivity were wrong. When details were 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.[6] 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. Ideally this should be 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 pharmaceutical industry could be persuaded to produce them as a service to patients. Forgetful patients might then be protected from re-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[7] most patients at risk could be issued with cards in a short space of time. Unfortunately, the present tagging system is not sufficiently accurate for it to be dependable if warning cards were issued, as six patients had an adverse reaction documented in their notes but their notes were not tagged. Patients should, therefore, be asked about 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 would be missed. There will often be an element of doubt when tagging notes, and doctors will need to decide for themselves how they wish to define important drug reactions. If the reaction is fully documented, however, other doctors could reassess the position at a future date.

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100 YEARS AGO

The subject of hats as things of beauty—or ugliness—has been oft 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 much maligned silk hat, the analogy of which in shape and shade to certain common objects has caused it to be compared, in England, to a "chimney-pot," in America, to a "stove-pipe," and in France, to a "tuyau de poêle." The hat, be its 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 "tile"—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 light as is compatible with stability, but, obvious as this is, it is a point in which many, probably the majority of hats, contravene the laws of comfort and capillary health. The interference with the circulation which results from compression of the blood-vessels between the hard sharp rim of a hat and the unyielding skull, together with the maintenance of an abnormal and undesirable temperature round a particular area, may reasonably be charged with contributing largely to the *calvinism* of people of the better class, whose obsequious 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 inconstant 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 unintentionally done much to minimise the evils which might have been superadded from this source. So far, then, the orthodox silk hat complies with these conditions to an extent which varies according to the maker. But even its most ardent admirer would hesitate to call it 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 "tall" 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 condemns urban residents of any position at all to wear a structure which is ruined by rain, carried away by wind, and cumbersome anywhere. Part of the bliss attending exile from town is the luxury of unfettered freedom in the matter of head-covering. So far we have spoken of the male headdress, and it may confidently be anticipated that if reasons of health and comfort are ignored by men, the ladies are not likely to make their observance a speciality. Indeed, the headdress of the average female, in any rank of society, is 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 shower or a tempest, 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 illegitimate arrangement of her hair, which she trains 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 vilest of men's hats could not rival. It is, probably, idle to hope for any reform in this direction, and the hygienist must e'en wait in the wilderness of indifference with which society fences him round, with the *mens conscia recti* for his only reward. (*British Medical Journal* 1886;ii:174.)

A good deal has been written on the pernicious influence of certain classes of literature on the mental development of rising generations, and some salutary checks have been placed, of late years, on the indiscriminate publication of works belonging to the section which is hurtful because obscene. There are, however, other departments of literary activity, the effects of which are probably quite as injurious, in different directions, as the indecent. To this category belong romances of the Dick Turpin type, where 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 red Indians tomahawk 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 youths 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 *clerc de notaire*, took unto themselves the names of the "Trailing Snake," and the "Red Bear," respectively, and proceeded to mature a plan of abduction, rape and murder, to be followed by suicide, which they first worked out in the form of a narrative, and then proceeded to carry into execution. The victim was a girl of fifteen, the daughter of a neighbouring farmer. She allowed herself to be taken into a lonely place, where the young heroes carried out their plans, and finally left the girl with fifteen stabs, from the effect of which she speedily died. There was a hitch in the suicidal 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 advocate, they were each sentenced to fifteen years' penal servitude. In addition, their parents were condemned to pay £800 damages to the father of the victim. This ghastly history shows to what an extent certain undeveloped minds are capable of being misled. That these lads were naturally of feeble mental stamina may fairly be assumed, but it is nevertheless quite possible that but for this fortuitous excitation, they might have grown up into very tolerable citizens. (*British Medical Journal* 1886;ii:733.)