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Patient reporting of suspected adverse drug reactions: a review of published literature and international experience

A. Blenkinsopp,[1] P. Wilkie,[2] M. Wang[3] & P. A. Routledge[4]

[1]*Department of Medicines Management, Keele University, Keele, UK,* [2]*Chairman of Lay Committee, Academy of Medical Royal Colleges and Former Lay Member of Committee on Safety of Medicines (CSM) and Chair of the CSM Patient Reporting of ADR Working Group,* [3]*Lay Member of the Expert Advisory Group on Patient Information to the Medicines and Healthcare Products Regulatory Agency and* [4]*Professor of Clinical Pharmacology, Wales College of Medicine, Cardiff University, Cardiff, UK*

Correspondence
Alison Blenkinsopp, Professor of the Practice of Pharmacy, Department of Medicines Management, Keele University, Keele, Staffs ST5 5BG, UK.
Tel: +44(0) 1782 583474
Fax: +44(0) 1782 713586
E-mail: a.blenkinsopp@keele.ac.uk

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Aims
To synthesize data from published studies and international experience to identify evidence of potential benefits and drawbacks of direct patient reporting of suspected adverse drug reactions (ADRs) by patients.

Methods
Structured search of MEDLINE, CINAHL and PsycINFO supplemented by internet searches and requests for information to key contacts.

Results
Seven studies (eight papers) were included in the review. None of the studies concerned spontaneous reporting by patients. Information on patient reporting systems was obtained for six countries, with summary data reported by four. Patient reports identified possible new ADRs that had not previously been reported by health professionals. The quality of patient reports appears to be similar to that of health professional reports. There is some evidence that patients report an ADR when they consider their health professional has not paid attention to their concerns. Patient reports may, at least initially, be more time consuming to process.

Conclusions
Overall, the evidence indicates that patient reporting of suspected ADRs has more potential benefits than drawbacks. Evaluation of patient reporting systems is needed to provide further evidence.

Introduction

Research has long confirmed the extensive human and economic costs of adverse drug reactions (ADRs) to prescribed medicines. In the UK a major study of hospital patients found that up to 6.5% of admissions were due to ADRs, three-quarters of which were judged preventable. Of those patients admitted with an ADR, 2.3% died as a result [1]. An earlier systematic review found that ADRs were responsible for 7% of hospital admissions and an estimated one in 10 hospital bed days in the UK [2]. Pirmohamed *et al.* has estimated that the number and seriousness of ADRs in primary care might be equivalent to the hospital figures and in their study the estimated annual

cost to the National Health Service (NHS) was £466 million [1].

These figures do not take into account ADRs which do not result in admission to hospital or which occur when patients are already in hospital. In addition, these figures do not consider the cost to the patient and their family or to society in, for example, days lost from work. In a meta-analysis of 39 prospective studies of already hospitalized patients in US hospitals, the incidence of serious ADRs was 6.7% [confidence interval (CI) 5.2, 8.2] and of fatal ADRs 0.32% (CI 0.23, 0.41), making ADRs between the fourth and sixth leading cause of death in the USA [3].

Healthcare systems rely mainly on the detection and reporting of suspected ADRs to identify new reactions, record the frequency with which they are reported, evaluate factors that may increase risk and provide information to prescribers with a view to preventing future ADRs. Following the thalidomide tragedy the UK established the Yellow Card Scheme, a voluntary system for reporting of ADRs by doctors, dentists and coroners in 1964. Prescribers complete a hard copy or, more recently, an electronic Yellow Card and submit it to the Medicines and Healthcare Products Regulatory Agency (MHRA). Other healthcare professionals, including pharmacists and nurses, were included in this system during the last decade. While the UK Yellow Card system for spontaneous reporting of ADRs is highly regarded internationally, under-reporting of ADRs by health professionals is a well-recognized problem in the UK and worldwide. Indeed the World Health Organization issued a report which was effectively a plea to health professionals to report ADRs [4].

In addition to spontaneous reporting of suspected ADRs, some countries, notably England/Wales and New Zealand, use prescription event monitoring (PEM) to solicit all events that occur while patients are receiving selected monitored medicines. Data are analysed by the monitoring centre.

Patient reporting of suspected ADRs has the potential to increase knowledge about the possible harm of medicines. By patient reporting we mean a slightly adapted version of the van Grootheest definition: 'users of drugs (or their parents or carers) reporting suspected ADRs directly to a spontaneous reporting system' [5]. Patient reporting has been incorporated into the pharmacovigilance systems in several countries, including the USA, Canada, Australia, New Zealand, Denmark, Sweden and the Netherlands. Until very recently, however, patients in the UK were not able to report directly suspected ADRs to the MHRA, although some organizations had been proposing this for several years. In 2001, the UK Consumers' Association called for patient reporting to be introduced after highlighting the fact that doctors were often failing to pass on information about suspected adverse reactions to drugs to the MHRA [6].

Since the mid 1990s, the UK mental health charity MIND has called for attention to be paid to patients' reports of suspected ADRs. MIND operated its own patient reporting scheme in 1995 and 2001 to give users of psychiatric services an opportunity to report on the side-effects of their medication. The MIND reporting card was based on the official Yellow Card but also asked about how much information people received at the time their medicines were prescribed, the help they received from their doctors and the perceived efficacy of their drug treatment. Three years later, MIND published summaries of the patient reports they received and again called for the regulatory authorities to introduce patient reporting: 'The new MHRA should be more proactive in seeking adverse reaction reports, and establish further ways of using direct experience of medicines in its drug safety monitoring' [7].

Since January 2005 patients in the UK have been able to submit electronic reports directly to the MHRA and, since autumn 2005, paper and telephoned reports, although these are referred to as 'pilots'. Prior to 2005 there was one small pilot of formal patient reporting in the UK [8]. Patients made indirect reports through nurse telephone triage within a general NHS telephone advice service (NHS Direct). The details of how patients' calls were handled are unclear – e.g. how calls were classified as a potential ADR report, whether patient's comments were recorded verbatim and whether nurses forwarded all reports or made decisions about which would be formally reported. Only 39 reports were forwarded to the MHRA in the 1-year period over which it operated and the intended national roll out in autumn 2003 [9] did not occur. The report of the Independent Review of Access to the Yellow Card Scheme concluded that 'in general the pilot scheme has not been successful' and that 'it has been criticised by some stakeholders for not collecting the patient perspective directly from patients themselves' [10].

Positive and negative effects of patient reporting can be viewed from a number of different perspectives and we found only one previous review on this subject, published in 2003 [5]. We conducted a review of published literature and of reported international experience of patient reporting with the aim of informing the future development, implementation and evaluation of patient reporting.

Methods

Internet searching and key contacts were used to identify international reports of patient reporting. Search terms were 'patients', 'ADR reporting', 'adverse drug reaction reporting', 'side-effect reporting'. In addition, specific websites were identified through colleagues. The reference list of each report was checked to identify further relevant reports and research studies.

A structured literature search was conducted using MEDLINE, CINAHL and PsycInfo and using both MESH and text search terms 'adverse drug reaction reporting systems', 'side-effect reporting', 'patient', 'consumer', 'self report'. The search dates were 1 January 1980 to 31 October 2005. MEDLINE searches produced large numbers of abstracts, very few of which were relevant. CINAHL produced one relevant abstract (duplicating one already identified from MEDLINE) and PsychInfo none. Abstracts of the identified studies were then assessed for relevance to the scope of the review. Studies were included if they included empirical data concerning the reporting of suspected ADRs by patients. Studies which were concerned only with ADR reporting by healthcare professionals were excluded. The full paper was obtained for each study being considered for inclusion in the review. Study designs and methods varied considerably and a basic assessment of research quality was made. The reference list of each paper was checked to identify any further relevant studies. No studies were excluded on grounds of quality.

Results

International experience of patient reporting

We identified six countries with systems for patients to report suspected ADRs (Table 1), four of which (Denmark, the Netherlands, Sweden and Australia) had published summary data.

Denmark Patients can report ADRs to the Danish Medicines Agency (DMA) using the same reporting form used by doctors. The form can be printed from the DMA website, where there are guidelines on its completion. Analysis of the patient ADR reports received in the first year of Denmark's scheme showed that the 149 reports represented 7% of all reports received. One-third of the suspected ADRs described were new to the Agency, i.e. they had not previously been described in the medicine's Summary of Product Characteristics (SPCs). Isotretinoin, citalopram and rofecoxib were the medicines most frequently involved. The Agency said that patient reports took longer to process because they were more difficult to classify according to the existing international coding system. However, no data were presented on the time taken to process patient reports compared with health professional reports [11].

The Netherlands The Netherlands Pharmacovigilance Centre (Lareb) has accepted patient reports via its website since 2003. Patients' reports were more likely than health professional reports to be about serious ADRs [12]. The staff of Lareb reported that 'the first experi-

Table 1
Patient reporting systems

Country	Direct or indirect reporting to regulators	Reporting method/s	System commenced
Australia	Indirect	Telephone, to pharmacists	2003
Denmark	Direct	Hard copy and eform. Same reporting form used by doctors	2003
The Netherlands	Direct	Electronic	2003
	Indirect via DGV consumer group scheme	Electronic	2004
Sweden	Indirect, via KILEN	Electronic, telephone, e-mail, hard copy	1978
USA	Direct	Electronic, paper based and telephone	1993
Canada	Direct	Telephone	2003

DGV, Meldpunt Medicijnen; KILEN, a patients reporting system run by a consumer group.

ence with patient reports in the Netherlands shows that for patient reports, the documentation grade does not differ from physicians' reports' [12]. Half of patients making reports in the first 6 months of the service said their reason for doing so was that their health professional had not listened to their concerns. Many reports in the early months were of suspected ADRs that had occurred more than a year previously, suggesting that the period to reach steady state for contemporaneous reports might be at least 6 months [13]. The Netherlands also has a consumer group-run reporting system Meldpunt Medicijnen (DGV), which was set up in 2004 and received almost 2000 reports relating to 2500 incidents in its first year [14].

Sweden In Sweden KILEN, a patients reporting system run by a consumer group, has been receiving reports from patients since 1978. The data collected by KILEN showed that patients reported different things in different ways and sometimes in greater volume than did professionals. The importance of patient reporting in not only contributing to 'signal generation' but also providing data on 'adverse changes in the quality of life which can be very important, real and distressing to the medicine user yet are unlikely to be clear to a prescriber' was also highlighted [15]. KILEN conducted a comparison of patient and health professional reports on sertraline and this system appears to be the only one providing feedback to those submitting reports [16].

Australia An 18-month trial of consumer ADR reporting using the Adverse Medicine Events (AME) telephone hotline in Australia began in October 2003 [17]. The AME scheme involved indirect reporting by patients, in that reports are filtered by health professionals rather than directly by patients to the Australian Drug Reaction Advisory Committee (ADRAC). The Australian system therefore falls outside our definition of patient reporting.

In the first year 1909 calls were received and about half of these involved suspected ADRs. Overall 20% of calls resulted in a formal report to the ADRAC [18]. A further 30% did not result in an ADRAC report because 'reporting criteria were not satisfied or the caller needed to ring back with further detail'. The ADRAC criteria were: were serious or novel incidents; had a strong causal association, or were related to recently marketed drugs. Statins, antidepressants, analgesics, methotrexate and herbal medicines were the medicines most frequently involved. Some 20% of suspected adverse effects reported were not listed in existing product information [19]. More recent data from the AME have been analysed and further publications are forthcoming. However, the future status of patient reporting in Australia is uncertain as it has not yet been adopted as national policy and funding for the scheme was time-limited. The AME Line was, at the time of writing, being evaluated through a questionnaire to consumers, focusing on awareness, usage and perceived value.

USA The Food and Drug Administration's MedWatch scheme includes patient reporting and in 2004 these comprised 15% of the 24 553 reports received [20]. However, we were unable to find any summary of reports received or evaluation of their processing. Van Grootheest and colleagues stated in their review that most patient reports in the MedWatch system came through pharmaceutical companies [5]. There are no published data on the drugs featuring in reports made by patients to MedWatch.

Canada A nonprofit patient advocacy group established the PharmaWatch organization in 2001 for patients to report ADRs. Two years later in 2003 Health Canada, the regulatory body, established a toll-free consumer ADR reporting line. It has been stated by others that 'in Canada reports from patients are accepted but not encouraged' by the regulatory authority, Health Canada [21] and that awareness among consumers that they could report ADRs, or of the existence of the toll-free line, was low [22]. There are no published data on numbers or types of reports made by patients to Health Canada.

Review of published literature

The search for primary studies involving patient reporting of suspected ADRs identified eight papers from seven studies, all of which were included in the review.

A qualitative study in the USA explored the processes used by patients to decide possible causes of symptoms and potential attribution as a suspected ADR. The results indicated that 'people have knowledge about ADR symptoms that is substantially accurate' and that they may use a 'prototype' to facilitate identification of symptoms as an adverse effect [23].

In a study designed to develop a method for patients to report symptoms that they believed were caused by a prescribed medicine, a questionnaire was sent to 2300 patients [24, 25]. Patients were asked about specific medicines including four antidepressants, three anticonvulsants and two analgesics. The researchers also reviewed 310 of those patients' medical records to compare symptoms recorded by the general practitioner (GP). Patients' reports of suspected ADRs are said by

the researchers to 'have a high probability of being drug-related'. The results suggested that 'patients do not report all symptoms they suspect to be ADRs to their general practitioner (GPs) and GPs do not record all symptoms which may be reported to them' and the researchers concluded there was significant under-reporting of ADRs to regulatory authorities. The study did not explore patients' reasons for not discussing some suspected ADRs with their doctor.

Mitchell and colleagues investigated Australian patients' ability to provide written reports about ADRs to amoxicillin and trimethoprim-sulphamethoxazole. Patients also participated in a structured telephone interview about suspected ADRs. Data from these two sources were reviewed by an expert panel and the researchers concluded that sensitivity of reaction reporting was low but specificity of event reporting was high. The authors concluded that 'national centres monitoring adverse drug reactions should probably resist pressure to accept reports of reactions directly from the public, but a system based on large scale reporting of events might be valuable in aiding the early detection of symptomatic reactions to new drugs' [26].

Other researchers have attempted to compare the propensity of patients and health professionals to report ADRs and to compare the nature of the reports made. A Belgian study in which ADR reports were sourced from pharmacist interviews with 168 patients in hospital and compared with health professional reports over the same period found 32 patient reports and 12 professional reports. Only two ADRs reported by patients were reported by professionals. The authors state that while professionals' reports contained a higher percentage that were classified as 'serious', the patient interviews were more likely to detect ADRs that had caused their admission to hospital [27]. Although this is a small study, its findings suggest that the percentage of 'serious' reports, if used as an indicator of 'value', may not provide the full picture. However, as patients' reports were elicited by a health professional, it is not known how many spontaneous reports would have been made by the patients.

In another study which aimed to compare patient reports with those of health professionals, Aspinall and colleagues compared 198 outpatients' reports of suspected ADRs (obtained from structured telephone interviews) with those of health professionals (obtained from two face-to-face interviews) and spontaneous reports by health professionals to the ADR reporting system [28]. One-quarter of patients had one or more suspected ADR and the patients identified 83 suspected ADRs. During the first interviews with health professionals, 26 suspected ADRs were identified by them. The researchers then interviewed the patients, after which a second interview with the health professionals was conducted. The latter identified a further 19 suspected ADRs. Thus the health professionals identified 54% of the suspected ADRs described by patients. In the researchers' subsequent analysis of the patient reports, only one of the 83 suspected ADRs was classified as 'doubtful' using a commonly used causality assessment tool [29]. (The Naranjo method estimates the probability of an adverse drug reaction. It includes 10 questions and reaches one of three conclusions about a suspected ADR: Yes, No or Don't know.)

The studies reviewed so far have compared data on reports generated through research, but very few studies have systematically compared 'real life' reports made by patients and health professionals about the same medicine. Research in the UK compared doctors' and patients' reports of suspected reactions to selective serotonin reuptake inhibitors (SSRIs). The doctors' reports were those submitted through the Yellow Card scheme to the MHRA. The patient data included the content of 1374 e-mails sent to the 'Panorama' programme following its broadcast about paroxetine, and messages e-mailed to the international English-language website of Social Audit (established to investigate problems with antidepressants) during the preceding 3 years. The researchers concluded that 'reports from users and relatives – especially with respect to behavioural effects – communicated information that professional reporters can never be expected to provide. They were far richer, and described suicidality and withdrawal symptoms much more clearly and intelligibly than the Yellow Card reports' [20, 30, 31]. The findings of this research need to be considered in the context that the Social Audit website did not require completion of a highly structured minimum dataset, whereas the Yellow Card has a set of required data fields with more limited space. Nevertheless, the data indicate that patient reports which are unfiltered by professional interpretation can bring a new contribution to understanding ADRs, particularly those that have not previously been known. KILEN has conducted a study comparing professional and patient reports of ADRs for the SSRI antidepressant, sertraline, and a summary analysis on its website shows substantial differences between patient and professional reports.

Discussion

International experience

There seems to have been little formal evaluation (as opposed to monitoring) of existing patient reporting schemes. Some countries have reported on the numbers

and nature of reports received but none seems to have reported on patient experience.

There is evidence from several countries indicating that patient reports do identify possible new ADRs that are not included in existing SPCs. However, there are no data to show the percentage of these reports that are subsequently confirmed as new ADRs.

Where data were available on numbers of reports compared with those of professionals, patient reports comprised 7–15% of the total. During 2005, 950 patient reports were received by the MHRA [32]. None of the countries with patient reporting in place reported that the quantity of reports received had an adverse impact on existing pharmacovigilance work. Only one country (Denmark) made any comment on process issues in relation to incorporating patient reports into existing systems and their experience suggests there are issues, at least initially, in coding data from patient reports.

There is little evidence in the public domain about if and how patient reports have been integrated into wider pharmacovigilance. A recent conference (Health Action International 2005) resulted in a call for greater sharing of data and experience with a view to strengthening international systems of patient reporting.

Concerns have been expressed that patient reports might be inferior to those of professionals. The definition of what constitutes the 'quality' of ADR reports is open to interpretation. Van Grootheest and colleagues argue that 'the quality of the report concerns the information given in the report. Some minimum elements are needed to make a report useful'. Van Grootheest and colleagues have stated that patient and physician reports did not differ in this respect. Other countries with patient reporting systems did not comment explicitly on issues of completeness or quality of reports.

Published literature

The lack of research into patient reporting of suspected ADRs is noteworthy. Most published studies were small and none involved spontaneous reporting by patients. In most cases reports were requested from patients by health professionals or researchers. This is not to say that the findings offer no insights that might assist the development of patient reporting, but that transferability of findings will be limited.

Overall, the findings from published research to date suggest that patients are likely to identify and report more ADRs than health professionals. There is some evidence that patients are able to attribute correctly possible newly recognized ADRs. Not all suspected ADRs identified by patients are discussed with a health professional and, even when they are, many are not reported to regulators. While the published studies did not explore the reasons why patients did not report all symptoms that they suspected to their doctor, the findings may indicate that patients may accept or tolerate some ADRs in a trade-off for potential benefit as they perceive that benefit to be. The studies do not clarify how well publicised patient reporting has been, which seems an important issue in relation to the numbers of reports. Also, while patients may accept or tolerate some ADRs as a trade-off and not report because of that perceived trade-off, they may not report because they do not believe that the healthcare professional will do anything about it and may not take it seriously.

Strengths and limitations

A strength of our review is that it brings together, for the first time, reported experience from patient ADR reporting schemes with published evidence.

Conventional database searches were supplemented by a snowballing technique comprising follow-up of studies cited in papers and reports, discussion with colleagues, supplemented by general internet searches. It is possible that we may not have identified all relevant studies. None of the research studies was based on spontaneous patient reports. The designs of the reviewed studies were appropriate to meet their objectives and overall quality was good. Data from countries with patient reporting systems are spontaneous reports but none seems yet to have been subjected to analysis that could contribute to areas of the evidence base that are currently unpopulated.

Synthesis of evidence

In the past a number of potential benefits and drawbacks of patient reporting have been proposed without any supporting evidence being cited. In Table 2 we summarize these and identify where there was evidence from the review to support or refute them.

The data indicate that there is now sufficient evidence to re-examine the potential benefits and drawbacks of patient reporting of ADRs. In their 2003 review Van Grootheest and colleagues concluded that, at that time, the data were insufficient to establish whether patient reporting added value to existing pharmacovigilance systems. Our review has considered new evidence. It shows that evidence is emerging to reassure those who have expressed concerns about certain aspects of patient reporting. Our findings provide evidence that patient reporting does add value to professional reports of ADRs by identifying possible new reactions. The

Table 2
Potential benefits and drawbacks of patient reporting of suspected adverse drug reactions (ADRs)

Potential benefits	Potential drawbacks	Evidence from the review
Patients may be more likely to identify a symptom or sign as a suspected ADR than health professionals	Patients' reports may contain incorrect clinical attributions of symptoms to specific medicines	Insufficient evidence
	Quality of patient reports might be lower than reports made by health professionals	Some evidence that patient and healthcare professional reports are of similar quality [12]
Patients may report ADRs that are different from those reported by health professionals	Usefulness of reports that have not been medically validated might be less because patients may misattribute symptoms to an ADR	Some evidence that different ADRs are reported [11, 15, 19]
Patients may report new ADRs that do not feature in existing product information	Patients' reports, even where attribution is correct, might have a higher proportion of nonserious ADRs or of known reactions to medicines	Some evidence that new ADRs reported [11, 19]
Patients may report suspected ADRs that they would not wish to discuss with their healthcare professional	Patient reporting might adversely affect their relationship with the prescriber	No evidence found
A better understanding of the patients' experience of ADRs because that experience is received without filtering or 'interpretation' by a health professional	The system might be used by lobbying groups, for example, for organized reporting campaigns	Patients' descriptions of suspected ADRs to SSRIs identified some symptoms which health professionals were unable to describe correctly in their ADR reports [14, 19, 29, 30]
Patients may use vocabulary which is enlightening in understanding adverse drug reactions	Patients reports might be time consuming to process because the descriptions of ADRs that they contain are different from those of health professionals	Some evidence that patient reports are initially more time consuming to process [11]
Information from patients may challenge understanding of what is a 'tolerable' side-effect		No evidence found
Patients may be quicker to report ADRs than health professionals	Possible duplication of reports and potential for multiple reporting of the same ADR	Some evidence that patients may report ADRs more quickly [11, 19]
Patient reporting may result in increased reporting by health professionals	Health professionals might become less likely to make reports of suspected ADRs	No evidence found
Increased likelihood of receiving reports to fill 'blindspots' in the current system including over-the-counter medicines and complementary therapies		No evidence found
If the overall number of ADR reports increases as a result of patient reporting this could offset the known problems of under-reporting of ADRs by health professionals	Increased number of reports might create additional 'noise' that could distract from signal detection, and result in system overload	Evidence that patient reports comprise less than 10% of total reports [11]
		No evidence of patient reports resulting in distraction from signal detection
Introducing patient reporting indicates a change in attitude in which patient experience is valued		No evidence found
Patients' contribution to medicines suspected ADRs will be recognized		No evidence found

reported experience of those countries that have introduced patient reporting of ADRs has been positive to date. A recent editorial on improving the management of ADRs concluded that 'the newly established consumer reporting service will also facilitate better understanding of consumer perspectives. This must be incorporated into information sources and supported by clear instruction on management' [33]. The European Medicines Evaluation Agency/Committee on Proprietary Medicinal Products (EMEA/CPMP) Working

Group with Patient Organizations has called for those countries with patient reporting systems in place to share their experience in order for the group to make further recommendations on patient reporting [34]. It is now important that those countries with patient reporting systems publish data on the reports received and how that information has been used to improve the management of ADRs. In the UK a specification has recently been issued, with a budget of up to £200 000, for applications to evaluate patient ADR reporting [35].

Conclusions

The review has added to the evidence base on patient reporting of suspected ADRs and has identified where additional research could be focused. There is a paucity of published research to evaluate the spontaneous reporting of suspected ADRs by patients. However, there is now substantial experience, from several countries in which patient reporting is established, that patients have identified possible new ADRs. None of the countries with patient reporting systems has reported poor quality of patient reports to be an issue. Spontaneous reports from patients appear to contribute a relatively small percentage of total reports. Concerns about low quality and large numbers of irrelevant patient reports thus appear to be unfounded. Therefore, we conclude that the introduction of patient reporting should now be considered by other countries, together with robust evaluation of process and outcomes.

Conflict of interest

All of the authors have worked to develop and implement the UK system of patient ADR reporting. All were members of the UK Committee on Safety of Medicines working group on patient reporting of ADRs until it was disbanded in October 2005. This paper was developed from a brief rapid review conducted by the authors as part of the work of the UK Committee on Safety of Medicines working group on patient reporting of adverse drug reactions. This paper is an updated and extended version of that review, which was part of an internal proposal for evaluation of patient ADR reporting.

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