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DRUG SAFETY

Factors affecting patient reporting of adverse drug reactions: a systematic review

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Keywords adverse drug reaction reporting system, adverse drug reactions, barriers, motives, patient, pharmacovigilance

AIM

The aim of the present study was to determine the barriers and motives influencing consumer reporting of adverse drug reactions (ADRs).

METHODS

A systematic review, guided by the Cochrane Handbook, was conducted. Electronic searches included MEDLINE, EMBASE, PsycINFO, CINAHL, PubMed and the Cochrane Database of Systematic Reviews from 1964 to December 2014. Eligible studies addressed patients' perceptions and factors influencing ADR reporting. Studies about healthcare professional (HCP) reporting of ADRs were excluded. Studies were appraised for quality, and results were analysed descriptively.

RESULTS

Of 1435 citations identified, 21 studies were eligible. Studies were primarily conducted in the UK, the Netherlands and Australia. The identified barriers to patient reporting of ADRs (n = 15 studies) included poor awareness, confusion about who should report the ADR, difficulties with reporting procedures, lack of feedback on submitted reports, mailing costs, ADRs resolved and prior negative reporting experiences. The identified motives for patients reporting ADRs (n = 10 studies) were: preventing others from having similar ADRs, wanting personal feedback, improving medication safety, informing regulatory agencies, improving HCP practices, responding to HCPs not reporting their ADRs and having been asked to report ADRs by HCPs.

CONCLUSIONS

Most patients were not aware of reporting systems and others were confused about reporting. Patients were mainly motivated to make their ADRs known to prevent similar suffering in other patients. By increasing patient familiarity and providing clear reporting processes, reporting systems could better achieve patient reporting of ADRs.

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WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT

- Little is known about patients reporting of adverse drug reaction. Understanding the barriers and motives for reporting by patients could be of benefit in improving medication safety.

WHAT THIS STUDY ADDS

- Patient reporting of ADRs needs to be actively supported by increasing patient familiarity with available ADR reporting systems, HCPs encouraging them to report, providing clear guidance on using the reporting system as well as providing feedback.
- Reporting of ADR by patients is important because it will provide regulators with patients' perspective and because of the under-reporting by HCPs.

Introduction

Adverse drug reactions (ADRs) cause significant morbidity and mortality across diverse populations worldwide and have an economic impact upon the healthcare system [1]. The World Health Organization (WHO) monitors spontaneous ADR reporting in the majority of countries. A common problem is under-reporting [2]. It is estimated that only 5–10% of ADRs are reported [3]. Although there is no estimate of patient reporting, 95% of healthcare professionals (HCPs) do not report ADRs [4].

In 1976, a British physician, Inman, was the first to publish reasons for under-reporting by HCPs [5], including: (i) complacency (believing that serious ADRs are well documented when the drug is released on the market); (ii) fear of being involved in a lawsuit; (iii) guilt for having been responsible for damage observed in a patient; (iv) ambition to publish a case series or financial benefit; (v) lack of awareness of the notification process; (vi) insecurity about reporting suspicions of an ADR; and (vii) indifference. These factors were subsequently confirmed in two systematic reviews of barriers and motives to HCP reporting of ADRs [1, 2]. One systematic review concluded that direct reporting from patients may be one way of reducing under-reporting rates [4].

Patients are often knowledgeable about their health condition and treatments, and are therefore well positioned to participate in reporting ADRs and to improve drug safety [6]. However, to our knowledge, there has not been a systematic review reporting the factors influencing patient reporting of ADRs.

To determine strategies for improving voluntary reporting of ADRs by patients, it is important to identify influential factors. In this context, the objective of the present study was to identify the barriers and motives that influence the reporting of ADRs by patients.

Methods

A systematic review, guided by the Cochrane Handbook [7], was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria [8]. In accordance with PRISMA guidelines, our systematic review was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 4 December, 2014 and was last updated on 19 January, 2015 (registration number CRD42014015310) [8].

Search protocol

A health sciences librarian (E.W.) designed the search strategies. Literature search strategies relied on medical subject headings (MeSH) and text terminology related to patient reporting of ADRs. The following databases were searched without language restriction: MEDLINE, EMBASE and PsycINFO (all Ovid interface; CINAHL; PubMed; Cochrane Database of Systematic Reviews; and Grey Literature). The PROSPERO registry was also searched for ongoing or recently completed pertinent systematic reviews.

Search terms used for MEDLINE (see Figure 1) and other databases included: patients, consumers, public, adverse drug reactions, report, reporting, spontaneous, pharmacovigilance and surveillance. Reference lists of eligible studies were also scanned. Citations published from inception of spontaneous ADR reporting in 1964 up to 5 December 5, 2014 were searched.

Selection process

Studies were eligible for inclusion if they: (i) addressed patients' perceptions of ADR reporting and (ii) focused on factors influencing patient reporting of ADRs. No language requirements were imposed, although, owing to resource limitations, only non-English publications amenable to Google Translate conversion were included (see Table 1).

1 exp "Drug-Related Side Effects and Adverse Reactions"/ (91869)
2 (adverse adj2 (event* or effect* or reaction*) adj2 (drug* or medication*)).tw. (18310)
3 or/1-2 (105036)
4 Self Report/ (10502)
5 (underreport* or over report* or report*).tw. (2716324)
6 Product Surveillance, Post marketing/ (5926)
7 databases, factual/ or databases, pharmaceutical/ (47311)
8 (regulatory adj1 (agenc* or authorit*)).tw. (6439)
9 or/4-8 (2766445)
10 3 and 9 (20774)
11 adverse drug reaction reporting systems/ or pharmacovigilance/ (6281)
12 pharmacovigilan*.tw. (2370)
13 or/10-12 (25934)
14 Patients/ (16871)
15 attitude/ or attitude to health/ or health knowledge, attitudes, practice/ (186227)
16 Behavior/ (27521)
17 or/15-16 (211128)
18 14 and 17 (2422)
19 ((patient* or consumer*) adj2 (awareness or attitude* or perception* or perspective* or belief* or behavior* or participation).tw. (34287)
20 consumer participation/ or patient participation/ (33633)
21 report* behavior*.tw. (1831)
22 or/18-21 (69254)
23 13 and 22 (225)

Figure 1
Ovid MEDLINE database search strategy

Table 1

Study inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Study design	Regardless of methodology, qualifying studies that answered the question 'what factors influence the reporting of ADRs by the public?' were included	Letters, editorials and narrative reviews were excluded
Participants	All studies addressing patients' perceptions of ADR reporting were included	Studies addressing patient and HCP roles in pharmacovigilance; perception of HCPs on ADR reporting; studies comparing frequencies of reported ADRs by patients *vs.* HCPs; frequencies of ADRs reported by patients; and studies addressing the role of regulators on pharmacovigilance
Language	Studies reported in all languages, if we were able to translate them	Studies unable to translate

ADR, adverse drug reaction; HCP, healthcare professional

After the identification of studies, duplicates were removed using standard software (ENDNOTE 7). Two independent reviewers (R.D., R.S.) conducted three levels of screening. Level one screening, using citation titles only, determined study relevance to the overall objective of the systematic review. Only citations judged as 'excludable' by both reviewers were removed. Level two screening, using title and abstract, determined if the study met the inclusion criteria (see Table 1). Level three screening used the full text to determine eligibility.

The two reviewers independently extracted data, with disagreements resolved through discussion. To extract data from the included studies, reviewers used a modified form based on the Cochrane Effective Practice and Organization of Care Review Group (EPOC) data collection tool. The form was modified to extract data on factors influencing ADR reporting by health consumers, and barriers and motives for health consumers to report ADRs. The modified data collection form was piloted on five randomly selected included studies before its actual use. Using an extraction form ensured a systematic process for data extraction. The following data were extracted: (i) characteristics of studies (country, setting, design and number of participants); (ii) data collection procedures (self-administered structured questionnaire, focus group, and semi-structured telephone and face-to-face interviews); and (iii) barriers and motives influencing ADR reporting by health consumers. Quality appraisals were conducted by the two reviewers (R.D., R.S.) using the Critical Appraisal Skills Programme (CASP) criteria for the descriptive observational studies [9]. Disagreements about data extraction and quality appraisal results were resolved by discussion. Authors of included studies were contacted, as needed, to obtain further information.

For the quality appraisal, the two reviewers independently rated each study for: (i) a clear statement of aims; (ii) methodology; (iii) research design to address research aims; (iv) recruitment strategy; (v) data collected; (vi) whether the relationship between researcher and participants was considered; (vii) ethical issues; (viii) rigor of data analysis; (ix) clear statement of findings; and (x) research value. Disagreements were resolved by consensus. Studies were considered to be of high quality if scores were 80% or above on CASP criteria, medium quality for 60–79.9% and low quality for <60%.

Data analysis

Owing to heterogeneity across study outcomes, data were analysed descriptively. Study comparisons were grouped to answer the research questions. Findings were synthesized based on outcomes. The characteristics of included studies were presented in a narrative format, as recommended by PRISMA [8].

A MeaSurement Tool to Assess Review (AMSTAR) [10] was used to assess the methodological quality of the review. AMSTAR characterizes the quality of systematic reviews at three levels: 8–11 indicating high quality, 4–7 medium quality and 0–3 low quality [11].

Results

Of 1435 citations reviewed, 21 studies, published in 24 papers, were included (see Figure 2). These were published between 2008 and 2014 and used a range of methods. They were conducted in the UK (n = 5 studies), the Netherlands (n = 4), Australia (n = 3) and one each in Italy, Portugal, Romania, Bulgaria, Malaysia, Nepal, Pakistan, Uganda and Saudi Arabia (see Table 2). Overall, quality ratings were medium to high, with only two rated as low quality [9].

Barriers to patient ADR reporting

Of the 21 studies, 15 described barriers to the reporting of ADRs. These included: (i) poor awareness; (ii) confusion as to who reports ADRs, and to whom; (iii) difficulties with ADR reporting procedures and forms; (iv) ADR resolved; (v) lack of feedback on previous ADRs submitted; (vi) mailing costs; and (vii) prior negative experience (see Table 3).

Poor awareness. Of the 15 studies, 14 qualitative and quantitative studies cited poor public awareness of ADR reporting systems. Many participants did not know that there was a national regulatory agency. In seven quantitative studies, 75% (range 44.1–93.8%) of participants were not aware of available ADR reporting systems [12–18].

Confusion as to who reports ADRs, and to whom. Eight studies reported that patients were not sure who should report an ADR, and to whom. For example, in the UK, some participants considered it their duty to report ADRs,

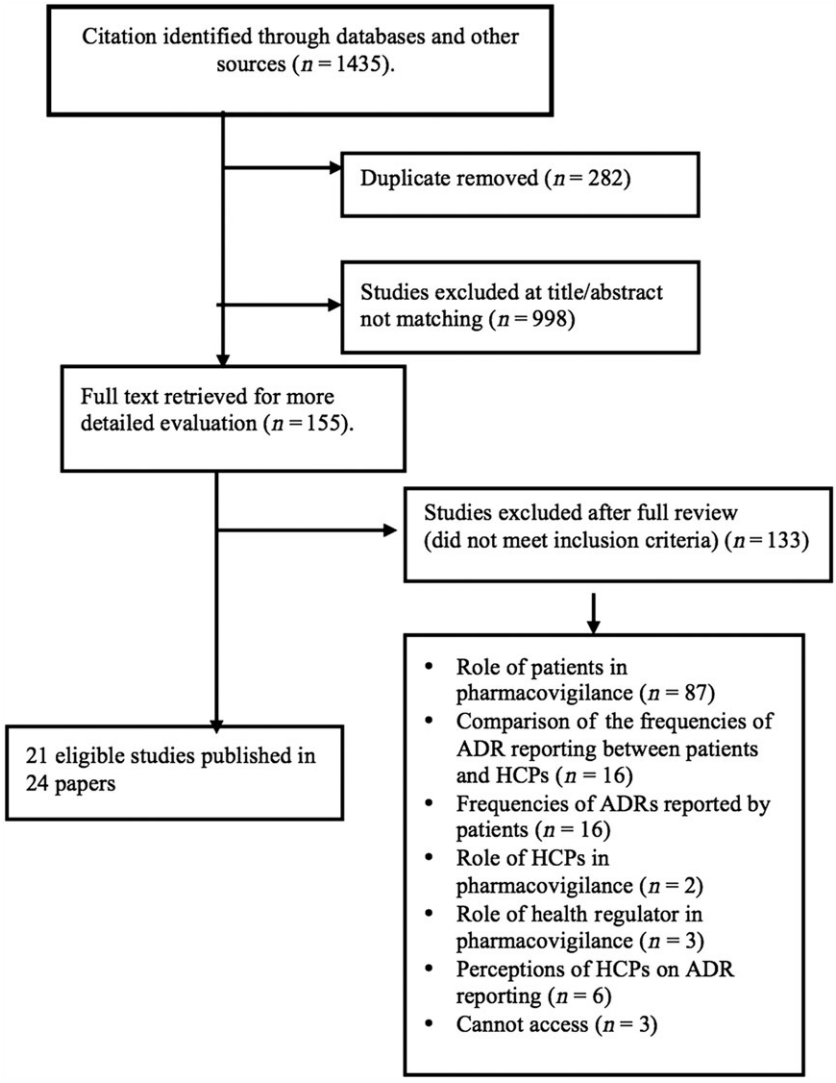

Figure 2
Flow of identified studies through the review process. ADR, adverse drug reaction; HCP, healthcare professional

whereas in other countries patients identified the HCPs as most responsible for reporting [13, 19, 20].

Difficulties with ADR reporting procedures and forms. Four quantitative and qualitative studies identified difficulties with procedures and reporting forms. The proportions describing difficulties ranged from 15.9% in the UK to 80% in Saudi Arabia [12, 13]. For example, in the UK study, participants described: (i) paper forms as tedious, lengthy, awkwardly constructed, inconsistent with online forms, and available only in English; (ii) telephone reporting being limited to working hours, which was inconvenient and time consuming; and (iii) technical problems with online reporting that often resulted in a loss of information [13].

Anticipating ADRs to resolve. Five qualitative studies reported that patients believed that ADRs would resolve after stopping or completing their treatment, and they did not think there was a benefit to reporting the ADR [13, 18, 19, 21, 22].

Lack of feedback on previously submitted ADRs. Two studies reported patients' concerns over the lack of feedback to submitted ADR reports. For example, in a UK study, 32% of participants expected feedback from the ADR report, and 1.9% felt that a lack of detailed feedback might discourage them from completing an ADR report in the future [13, 20]. This problem was not reported in the Netherlands, where the health authority provides customized feedback on each ADR report submitted [13].

Mailing costs. Two studies conducted in Uganda and Nepal identified patients' poor economic status as a barrier to reporting ADRs because they could not afford the cost of mailing their reports [22, 23].

Prior negative experience. One study in Uganda described prior negative experience as a barrier [5]. Patients feared that reporting ADRs would be met with disapproval by their HCPs.

Table 2

Characteristics of included studies

Author/Year	Location	Design	Participants	Data collection	Quality rating
Aljadhey and Albogami (2013) [12]	Saudi Arabia	Observational, cross-sectional study	204 adults	Self-administered structured questionnaire	Medium
Arnott *et al.* (2013) [20]	UK	Qualitative	17 parents without previous experience of submitting ADR report and 27 with this experience	Semi-structured telephone and face-to-face interviews	High
Avery *et al.* (2011) [13]	UK	Mixed-model approach combining qualitative and quantitative research methods	Patients reported ADRs (27 in telephone interviews, 40 in focus group, 1362 in evaluable questionnaire and 2028 in Omnibus survey)	Semi-structured telephone interviews, questionnaire, focus group, and Omnibus survey	High
Braun *et al.* (2010) [21]	Australia	Observational, cross-sectional study	620 patients at 60 community pharmacies and rural pharmacies in three Australian states	Self-administered structured questionnaire	Medium
Bukirwa *et al.* (2008) [22]	Uganda	Qualitative	16 adults	Focus group	High
Elkalmi *et al.* (2013) [14]	Malaysia	Qualitative, descriptive	334 adults	Face-to-face interview using a structured questionnaire	High
Farcas *et al.* (2010) [28]	Romania	Qualitative	50 patients taking antidepressant	Self-administered structured questionnaire	Medium
Gujral *et al.* (2010) [32]	UK	Cross-sectional	154 adults	Self-administered structured questionnaire	Medium
Harmark *et al.* (2013) [24]	Netherlands	Mixed-model approach combining qualitative and quantitative research methods	21 adults	Face-to-face interview using a structured questionnaire	High
Jha *et al.* (2014) [23]	Nepal	Cross-sectional study using qualitative and quantitative methods	23 adults	Face-to-face interview using a semi-structured questionnaire	High
Krska *et al.* (2011) [15]	UK	Quantitative	272 adults	Face-to-face interview using a semi-structured questionnaire	High
Lebanova and Getov (2014) [16]	Bulgaria	Cross-sectional study	211 adults	Self-administered questionnaire	High
Lorimer *et al.* (2012) [19]	UK	Qualitative	15 adults	Face-to-face interview using a semi-structured questionnaire	High
Matos *et al.* (2014) [17]	Portugal	A descriptive-correlational study	948 adults	Closed-answer questionnaire	Low
Parrella *et al.* (2014) [33]	South Australia	Cross-sectional	2002 adults	Face-to-face interview using a structured questionnaire	High
Qamar *et al.* (2014) [34]	Pakistan	Cross-sectional	1566 adults	Face-to-face interview using a structured questionnaire	Medium
Robertson and Newby (2013) [18]	Australia	Cross-sectional study	2484 adults	Structured telephone interview and online survey	High

(*continues*)

Table 2

(Continued)

Author/Year	Location	Design	Participants	Data collection	Quality rating
Rolfes *et al.* (2014) [25]	Netherlands	Qualitative	3 adults	Face-to-face interview using a semi-structured questionnaire	Low
Salvo *et al.* (2013) [35]	Italy	Cross-sectional study	744 adults	Structured questionnaire, telephone interview	Medium
van Hunsel *et al.* (2010) [26]	The Netherlands	Cross-sectional study	1005 adults	Web-based questionnaire	High
van Hunsel *et al.* (2010) [27]	The Netherlands	Qualitative	21 adults	Face-to-face interview using a structured questionnaire	Medium

ADR, adverse drug reaction

Table 3

Barriers for patient reporting of ADRs

Author (year), country	Poor awareness	Confusion as to who reports ADRs, and to whom	Difficulty with ADR reporting procedures and forms	ADRs resolved	Lack of feedback on submitted ADR	Mailing cost	Prior negative experience
Aljadhey and Albogami (2013) [12], **Saudi Arabia**	87%		80%				
Arnott *et al.* (2013) [20], **UK**	√	√			√		
Avery *et al.* (2011) [13], **UK**	74%	√	15.9%	√	√		
Braun *et al.* (2010) [21], **Australia**	√	√		√			
Bukirwa *et al.* (2008) [22], **Uganda**				√		√	√
Elkalmi *et al.* (2013) [14], **Malaysia**	65.6%						
Gujral and Cairns (2010) [32] **UK**	√	√					
Jha *et al.* (2014) [23] **Nepal**	√	√	√			√	
Krska *et al.* (2011) [15] **UK**	93.8%						
Lebanova *et al.* (2014) [16], **Bulgaria**	78.7%	√					
Lorimer *et al.* (2012) [19] **UK**	√	√	√	√			
Matos *et al.* (2014) [17], **Portugal**	44%	√					
Parrella *et al.* (2014) [33] **Australia**	√						
Robertson and Newby (2013) [18], **Australia**	89.7%			√			
Salvo *et al.* (2013) [35], **Italy**	√						
Total	14	8	4	5	2	2	1

ADR, adverse drug reaction

Table 4

Motives for patients to report ADRs (n = 10)

Author (year), country	Preventing similar ADRs in others	Improving drug safety	Seriousness of ADRs	Desire for personal feedback	Informing others	Improving HCPs practice	Responding to HCPs not reporting patient ADRs	Being asked to report ADR by HCPs
Avery *et al.* (2011) [13], **UK**	26%	12.7%	√	60.8%	7%	12.2%	7.8%	√
Arnott *et al.* (2013) [20], **UK**	√	√		√			√	
Farcas *et al.* (2010) [28], **Romania**	√							
Harmark *et al.* (2013) [24], **the Netherlands**	89%	√		√		84%		√
Krska *et al.* (2011) [15], **UK**			86%					
Lorimer *et al.* (2012) [19], **UK**			62.4%					
Matos *et al.* (2014) [17], **Portugal**			81.1%	√				
Rolfes *et al.* (2014) [25], **the Netherlands**	√							
van Hunsel *et al.* (2010) [26], **the Netherlands** [26]	√	√	√	√	√			
van Hunsel *et al.* (2010) [27], **the Netherlands**	√	√			√	√		
Total	7	5	5	5	3	3	2	2

ADR, adverse drug reaction; HCP, healthcare professional

Motives for patients to report ADRs

There were 10 qualitative and quantitative studies that identified motives for patients to report ADRs (see Table 4). Motives included: (i) preventing similar ADRs from occurring in others; (ii) improving drug safety; (iii) considering the seriousness of the ADR; (iv) desiring personal feedback; (v) raising awareness of specific ADRs; (vi) improving HCP practices; (vii) responding to HCPs not reporting ADRs; and (viii) having been asked to report ADRs by HCPs.

Preventing similar ADRs in others. Seven of 10 studies reported that patients wanted to prevent others from suffering similar problems, and perhaps help to find better treatments [13, 20, 24–28].

Improving drug safety. Patients in five studies believed that drug safety could be improved by reporting ADRs [13, 20, 24, 26, 27]. For example, in the Netherlands, patients specifically indicated their willingness to invest time in ADR reporting to enhance drug safety [24].

Considering the seriousness of the ADRs. Three quantitative and two qualitative studies indicated that judging the ADR as serious was the main motivation for patients to report [13, 15, 17, 19, 26]. For example, in two UK surveys, the majority of respondents (62% and 86%, respectively) declared that only serious ADRs requiring hospital admission or affecting daily life were worthy of reporting [15, 19, 26]. Similarly, in Portugal, participants agreed or strongly agreed that severity was the primary reason for reporting ADRs [17].

Desiring personal feedback. One quantitative and four qualitative studies discussed patients' desire for personal feedback. Participants wanted to learn and find others who shared the same experience, to acquire more details about the ADRs and to seek confirmation that the report was received [13, 17, 20, 24, 26].

Raising awareness of specific ADRs. In three quantitative studies, patients indicated that informing regulators, drug manufacturers, HCPs and the public about ADRs was the only way to create awareness of such incidents [13, 26, 27].

Improving HCP practices. In two quantitative studies and one qualitative study, patients raised the view that HCPs need to be informed about ADRs [13, 24, 26]. They felt that

reporting ADRs would inform HCPs about unknown ADRs, and that this would improve their knowledge and practices.

Responding to HCPs not reporting patients' ADRs. Two studies cited that failure of HCPs to report ADRs motivated patients to report these themselves. Patients emphasized how HCPs consulted about the ADRs had not taken their concerns seriously [20]. This motivated some patients in the UK to self-report [13]. Other patients were motivated to report because they did not think that HCPs would report their ADRs accurately, given that HCPs have limited time and may not be able to provide precise details [13].

Asked to report ADRs by HCPs. In two qualitative studies, patients indicated that HCPs asked them to self-report ADRs. In the Netherlands, patients were encouraged by pharmacy assistants to self-report ADRs [24], while in the UK patients were encouraged by pharmacists [13].

Discussion

The present study identified factors influencing patient ADR reporting, with the intention of using these findings to determine approaches that could be used to improve voluntary patient reporting, and ultimately improve patient safety. All of the 21 included studies had been published since 2008, suggesting a growing interest in this area. Fifteen of these studies indicated a range of barriers and 10 identified motives for patient reporting of ADRs. Our findings led us to make the following observations.

Common barriers to patient reporting of ADRs were similar to those previously identified for HCPs [2, 4]. Specific barriers both for patients and HCPs included poor awareness about available reporting systems, uncertainty about who should be responsible for submitting the ADR reports, and lack of feedback for submitted reports. Barriers that were unique to patient reporting were mailing costs, prior negative experiences and resolved ADRs. Postal mailing costs for patients to report ADRs was identified in two developing countries; this may not be an issue in other countries, where electronic and telephone reporting are available for patients.

Common motives for patients to report ADRs were altruistic or personal. Examples of altruistic motives were preventing harm to others, feeling responsible for reporting ADRs and reporting their experiences publicly to improve medication safety. Personal motives included the severity of reactions and patients' desire for feedback. The desire for feedback was also a motive for HCPs to report ADRs [2]. Another motive that encouraged patients to report ADRs was their concern about HCPs not having time to report ADRs, and this was consistent with the barriers identified by HCPs [2].

Strategies to enhance patient ADR reporting should focus on the most common and feasible barriers to address. If patients are unaware of available reporting systems, how they work and how they are accessed, their contributions will continue to decline. First, strategies are needed to increase patients' awareness of reporting systems, and HCPs' awareness that patients can report on their own. Interestingly, in the two studies in which HCPs encouraged patients to report, the HCPs were limited to those who worked in pharmacies [13, 24]. Second, national regulatory agencies could learn from the Netherlands, where responses are provided to patients who report ADRs [24] by letters of acknowledgment. Issuing a response has the potential to reassure patients that their information has been received and may in fact improve subsequent ADR reporting. Finally, increasing patient ADR reporting provides opportunities to promote educational interventions. For example, patients could be directed to websites that provide high-quality drug information, if the ADRs have already been acknowledged in drug information materials.

Interestingly, most included studies were conducted in the UK, the Netherlands and Australia, with none conducted in North America. Patient reporting of ADRs was established in the USA and Canada in 1960 and 1965, respectively [13], and it appears that use of these reporting systems there has not been evaluated to the same extent as in other countries.

Limitations and strengths

One limitation of the present review was that three full-text articles were not accessible to determine if they were eligible to be included [29–31]. The titles of these articles indicated that they included ADR reporting by patients but there were no authors listed. Although authors of the included studies used a variety of measures to determine factors influencing patient ADR reporting, our systematic review appropriately synthesized the diverse forms of evidence identified. When the methodological quality of our systematic review was appraised using the AMSTAR instrument, it was rated as meeting nine out of 11 criteria. For the two missing items, one was not applicable because there was no meta-analysis conducted (methods used to combine the findings of studies appropriate) and we did not assess for publication bias.

Conclusion

Several barriers and motives influencing patient reporting of ADRs were identified in 21 studies. Poor patient awareness of available reporting systems was the main barrier to patient reporting of ADRs, and this finding was consistent with studies conducted with HCPs. The main motive for patient reporting of ADRs was altruism, to prevent others from suffering from the same drug reaction. Patient reporting of ADRs should be actively supported by increasing patient familiarity with available ADR reporting systems, HCPs encouraging them to report, providing clear guidance on using the reporting system, as well as providing feedback. Initiating strategies that are informed by these factors has the potential to improve spontaneous patient ADR reporting.

Competing Interests

All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare no support from any organization for the submitted work, no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years, and

no other relationships or activities that could appear to have influenced the submitted work.

Dr Rana Shash and Erica Wright made important contributions to various stages of developing the systematic review.

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