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RESEARCH ARTICLE

Survey of patients' experiences and their certainty of suspected adverse drug reactions

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Abstract *Background* Patients are best placed to recognize and monitor their own experiences of adverse drug reactions (ADRs), however they may need medicines information to help them do so. In Thailand patients rarely receive information leaflets, but are permitted to report ADRs directly to the regulator. *Objectives* To determine frequency of ADRs reported by hospital out-patients, the information sources used to evaluate suspected ADRs and patients' confidence in ADR identification. *Setting* Srinagarind hospital in Khon Kaen, the second-largest province of North-eastern Thailand. *Methods* A questionnaire designed for self-completion and distributed to out-patients at this tertiary hospital using systematic random sampling over a 2-month period. *Main outcome measures* Frequency of reported ADRs, information sources confirming ADRs and degree of confidence in ADR identification. *Results* Of 1,195 questionnaires distributed, 1,044 usable responses were obtained (87.4 %). The majority of respondents were female (57.1 %) with average age 39.6 ± 13.6 years. Of 1,044 valid questionnaires, 257 (24.7 %) patients indicated they had experienced an ADR with high (56.0 %) and moderate (31.9 %) degree of confidence in ADR identification. The most frequent causative agent was an anti-infective (19.1 % of the patients). Major sources of information used for ADR assessment were healthcare professionals (35.5 %) and past ADR experience (25.5 %), with information leaflets being used infrequently (14.6 %). *Conclusions* This study showed high frequency of ADRs among Thai patients who were mostly confident about casual relationships with medicines. Patients mostly used healthcare professionals as confirmation source to evaluate suspected ADRs. Reliable medicines information sources such as information leaflets should be made more widely available.

Keywords Adverse drug reactions · Medicines information · Patients' experience · Patient reporting · Thailand

Impact of findings on practice

- Direct patient ADR reporting should be further promoted within routine practice to support the existing spontaneous ADR reporting system.
- Healthcare professionals should pay attention to ADRs reported by patients and could encourage direct reporting.
- As essential information on drug safety, the development of patient information leaflets (PIL) and more widespread distribution is needed for Thai patients.

Introduction

ADRs are defined as an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific

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treatment, or alteration of the dosage regimen, or withdrawal of the product [1]. It has been suggested that approximately one half of serious ADRs are not detectable without post marketing surveillance [2]. A meta-analysis has found the incidence of serious ADRs in hospitalized patients was 6.7 % and of fatal ADRs was 0.32 % [3]. More recently two large prospective studies in the UK found the incidence of serious ADRs in hospital in-patients was 4.7 % [4], that 6.5 % of patient admissions to hospital were related to ADRs, and that 2.3 % of ADR-related admissions were fatal [5]. Hospital admissions due to ADRs can affect patients in many ways such as increasing cost of treatment, prolonging hospital stay and increasing risk of hospital infection [6]. Most ADRs are identified through voluntary reporting by healthcare professionals via spontaneous reporting systems (SRS), but limitations still remain with these systems such as under-reporting, bias and poor quality of reports [7, 8].

Direct patient reporting, allowing patients to report suspected ADRs by themselves, is currently gaining interest worldwide. Many countries have permitted patient self-reporting to national pharmacovigilance systems such as United Kingdom, United States, Netherlands, Denmark and Sweden [9, 10]. Patients are best placed to understand and monitor their own illness and can explain their own experiences of ADRs better than healthcare professionals. Increasingly patients are taking greater interest in their own disease and treatment and desire information about ADRs [9, 11, 12]. A literature review in 2007 showed that patient reporting could identify novel ADRs and that the quality of reports was similar to those from healthcare professionals [13]. Studies have found that patient reports were equally likely to be serious compared to those of health professionals, that they reported different ADRs, some unlabelled (not in patient leaflet) and that they reported more detail of the symptoms and impact of the ADR than health professionals [14, 15]. Patient reporting also has the potential to speed up acquisition of new knowledge, and increase reporting rate and accuracy of ADR reporting [16, 17]. A more recent review suggest that patients report serious ADRs, which may differ from those of health professionals, and while patient reports can provide greater detail of the symptoms and their impact than reports from health professionals, they may give less objective information [18].

In Thailand, patient reporting of ADRs was initiated by the Heath Product Vigilance Center (HPVC) in 2010, but is little known due to lack of public promotion and therefore in practice direct patient reporting is limited. Previous studies have shown that Thai patients can identify suspected ADRs and that 63.3 % of suspected ADRs to antiepileptic drugs reported by patients were related to the drug studied [16, 19]. Thai patients may receive medicine information from health professionals at the point of prescribing or dispensing. However, in contrast to many other countries, written information is infrequently provided with medicines supply, hence the sources of information which patients use to identify ADRs in Thailand may differ from those used elsewhere.

Aim of the study

This study therefore was designed to determine frequency of ADRs reported by hospital out-patients, the information sources used to evaluate suspected ADRs and patients' confidence in ADR identification.

Ethical approval

The research design was a retrospective cross-sectional study. It was approved by the Khon Kaen University Ethics Committee for Human Research.

Methods

Setting

Questionnaires were distributed to out-patients at Srinagarind hospital, the main tertiary medical referral centre for Northeast of Thailand and the main teaching hospital for the Faculty of Medicine of Khon Kaen University.

Questionnaire development

A questionnaire designed for self-completion was developed by the research team using previously published literature [20, 21] following translation of relevant instruments by two experts in ADRs and English language. The questionnaire consisted of two sections as follows:

Section 1 Closed questions were used to obtain demographic data on gender, age, education level, career and income. An open question was used to obtain information on underlying chronic diseases.

Section 2 A definition of ADRs was provided and patients were instructed to read the definition before completing this section, which sought details of ADR experiences together with a list of possible sources of information used to confirm suspected ADR, modified from a previous study [20]. These were: past ADR experience; patient leaflet; healthcare professional such as physician, pharmacist, nurse; family, relatives or friends; internet; books and other sources. Patients were asked to provide the timeframe of their most recent ADR experience as being within the past 1 week, 1 month,

6 months, 1 year, 5 years or over 5 years ago. Details of the symptoms suspected to be an ADR, the medicines associated with the suspected ADR and its indication were determined using open questions. Closed questions were used to enable patients to report the perceived severity of their ADR (mild, moderate or severe) and their confidence in the experience being an ADR (uncertain, moderate or high degree of certainty). Suspected drugs that patients reported were classified using the anatomical therapeutic chemical classification system (ATC) and ADRs were classified by system organ class (SOC) according to MedDRA terminology.

Questionnaire testing

The complete questionnaire was evaluated by three healthcare professionals with expertise in ADR identification and reporting. The index of consistency (IOC) score retrieved from each expert was calculated to evaluate the consistency between each questions, ensure they met the study objectives and to check the appropriateness of wording in questionnaire (IOC = 0.94). Subsequently the questionnaire was adjusted according to expert opinions and then the questionnaire was piloted in 20 outpatients at Srinagarind hospital. These patients were also interviewed to assess their ability to complete the questionnaire fully and to make suggestions for amendments as needed.

Questionnaire distribution

The final self-administered questionnaires were distributed by researchers to the out-patients who were waiting for prescriptions at the out-patient Pharmacy Department, Srinagarind hospital by using a systematic random sampling process during September to October 2011 and October to November 2012. The process involved drawing lots from numbers 1 to 10 daily to select a random start, then the researchers distributed the questionnaires to patients by counting from the chair which they sat and using a sampling interval equal to ten. The questionnaires were collected by the researchers after the patients completed them at the pharmacy area.

Statistical analysis

Data retrieved from the questionnaire were analyzed by using SPSS for Windows version 19.0. Patient characteristics and ADR experiences were reported using descriptive statistics. Relationships between variables were analyzed by Pearson Chi square tests. A p value < 0.05 was chosen to show the significant difference between groups.

Results

Response rate

A total of 1,195 questionnaires were distributed, of these 1,044 were completed sufficiently to be analyzed which resulted in a response rate of 87.4 %. The remaining 151 patients approached refused to respond to the questionnaire; reasons for refusal were not sought and no demographic details were obtained from non-responders.

Demographic data

The majority of respondents were female (57.1 %) and the average age was 39.6 ± 13.6 years, with two-thirds of patients' being in the age groups 31–45 (37.2 %), and <31 years (29.5 %). Approximately three-fifths of the respondents were graduates with a bachelor/higher' degree (61.2 %). Other demographic characteristics are shown in Table 1. There were 426 (41.0 %) patients who indicated they had an underlying disease, of these the most frequent were diseases of circulatory system (n = 112; 20.9 %), followed by diseases of respiratory system (n = 104; 19.4 %) and endocrine, nutritional and metabolic disease (n = 85; 15.8 %).

ADR experiences reported

From the total of 1,044 valid questionnaire responses, 223 (21.4 %) patients indicated they had experienced an ADR and a further 34 (3.3 %) patients were not sure but had a recent experience which could have been an ADR. The remainder indicated they had never experienced an ADR (n = 787; 75.4 %). Of the 257, 139 (54.1 %) patients had experienced an ADR within past year and 85 (33.1 %) more than 1 year ago, while 33 (12.8 %) did not remember when the last ADR occurred (Table 2). Most respondents indicated the ADR experience was short-lived, lasting for between 1 and 3 days (n = 137; 53.3 %) or between 4 and 7 days (n = 49; 19.1 %). However 46 (17.9 %) indicated their experience lasted for more than 1 month. Equal proportions indicated the severity of the ADR identified was moderate or severe (38.5 % for both categories). Over half the respondents (n = 138; 53.7 %) claimed they always reported to their physician when a suspected ADR occurred but just over fifth (n = 54; 21.0 %) never did so (Table 2).

Classification of suspected drugs and ADR symptoms

Of the 257 patients who experienced a suspected ADR, the most frequent causative agent was an anti-infective (n = 49; 19.1 %), followed by musculoskeletal (8.9 %)

Table 1 Comparison of ADR experiences in relation to patients' characteristics

Demographic	Number of patients reporting ADRs n (%)		Total n (%)	*p* value
	Yes	No		
Gender (n = 1,044)				
Male	101 (22.5)	347 (77.5)	448 (42.9)	0.178[a]
Female	156 (26.2)	440 (73.8)	596 (57.1)	
Age (year; n = 1,039)				
≤30	58 (18.9)	249 (81.1)	307 (29.5)	<0.001[a]
31–45	83 (21.4)	304 (78.6)	387 (37.2)	
46–60	89 (32.6)	184 (67.4)	273 (26.3)	
>60	26 (24.6)	46 (75.4)	72 (6.9)	
Mean ± SD			39.6 ± 13.6	
Median (range)			39 (15–83)	
Education level (n = 1,031)				
Lower high school (grade 1–9)	37 (28.0)	95 (72.0)	291 (28.0)	0.307[a]
High school (grade 7–12)	56 (21.5)	205 (78.5)	101 (9.7)	
Bachelor degree and above	161 (25.2)	477 (74.8)	638 (61.2)	
Underlying chronic disease (n = 1,039)				
Yes[b]	98 (16.0)	515 (84.0)	613 (100.0)	<0.001[a]
No	158 (37.1)	268 (62.9)	426 (100.0)	

[a] Pearson Chi Square test

[b] Top five underlying disease including diseases of the circulatory system (n = 112, 20.9 %); respiratory system (n = 104, 19.4 %); endocrine, nutritional and metabolic diseases (n = 85, 15.8 %); digestive system (n = 47, 8.8 %) and musculoskeletal system and connective tissue (n = 47, 8.8 %), respectively

and central nervous system drugs (7.8 %), respectively (Table 3). The majority of patients reported only one symptom (n = 143; 59.1 %), but 99 patients reported more than one symptom (40.9 %), with a total of 377 different symptoms being reported. Of these 173 (45.9 %) involved the skin followed by nervous system disorders (18.0 %) and gastrointestinal disorders (16.4 %). The symptoms experienced most frequently were rash (25.2 %), itch (11.7 %) and edema (9.0 %). The most commonly reported suspected drugs and ADR symptoms are shown in Table 3.

Consequence of suspected ADRs

After their experiences about two-thirds (n = 198; 77.1 %) of patients claimed to have stopped the suspected medicine, of these 23 patients claimed to have stopped using the suspected medicine after completion of the course and the rest (n = 59; 23.0 %) of respondents never stopped. After stopping the medicine, most respondents (n = 119; 60.1 %) reported that the symptoms disappeared and 73 (36.9 %) respondents reported that the symptoms reduced. On the other hand some of respondents reported that the symptoms did not change (n = 3; 1.5 %) or increased (n = 3; 1.5 %). Of the respondents who stopped and restarted the suspected drugs (n = 77), 65 respondents (84.4 %) reported that the ADR symptoms reappeared but 12 (15.6 %) reported that the ADR symptoms did not reappear.

Identification of suspected ADRs

The degree of certainty respondents felt in relation to their suspected ADR was high, with more than half of respondents being certain about the association (n = 144; 56.0 %) followed by moderate (n = 82; 31.9 %) and only a small proportion being uncertain (n = 31; 12.1 %). In univariate analysis, educational level showed no clear association with confidence in identifying an ADR, with similar proportions of respondents with bachelor/higher degree indicating high levels of certainty compared to those with lower education (87.6 vs. 89.3 % respectively). More of those who indicated they always report a suspected ADR to their physician were confident (94.9 %) than those who did not/sometimes reported (79.8 %; $p < 0.001$). Seventy-seven respondents (30.0 %) were using concomitant medication whilst experiencing their ADR, but this did also not appear to affect confidence levels (87.0 vs. 88.3 % who did not use concomitant medication; $p > 0.05$). Table 4 shows the sources of information that patients used to confirm their ADR assessment. Only 51 (14.6 %) used a patient information leaflet for this purpose.

Discussion

Our study showed the frequency of ADR experiences among Thai hospital out-patients was 24.7 %, with over

Table 2 Characteristics of ADRs reported by patients (N = 257)

Experience of ADRs	No. of patients n (%)
Co-medication	
Yes	77 (30.0)
No	180 (70.0)
When was the most recent ADR event	
Within the past 1 week	35 (13.6)
Within the past 1 month	37 (14.4)
Within the past 6 months	38 (14.8)
Within the past 1 year	29 (11.3)
Within the past 5 years ago	38 (14.8)
More than 5 years ago	47 (18.3)
Cannot remember	33 (12.8)
How long did you experience the ADR	
1–3 days	137 (53.3)
4–7 days	49 (19.1)
1–4 weeks	25 (9.7)
>1 month	46 (17.9)
In your opinion, how severe was the ADR	
Severe	99 (38.5)
Moderate	99 (38.5)
Mild	59 (23.0)
Confidence about ADR self-assessment	
High	144 (56.0)
Moderate	82 (31.9)
Uncertain	31 (12.1)
Did you report to physician about the ADR	
No	54 (21.0)
Sometimes	65 (25.3)
Always	138 (53.7)

half of these occurring in the previous year. The frequency is lower than that found in other studies [7, 16, 22–24], possibly because we distributed questionnaires to randomized people waiting for prescriptions at pharmacy area, hence did not focus on a specific group of patients or medicines. Furthermore participants were given no prior explanation or knowledge about ADRs other than a simple definition before completing the questionnaire, as was the case in some other studies.

Most of the patients who had experienced ADRs identified only one symptom, similar to previous studies in Thailand, UK and Australia [16, 23, 25]. Most perceived the severity of their experiences to be moderate or severe as has also been found previously [16]. The drugs responsible for ADR experiences were also similar to those found in other studies [9, 22, 26]. The top four of the most frequently reported drug groups related to suspected ADRs were anti-infective, musculoskeletal, central nervous system and respiratory system drugs, and the most frequently reported body system affected was the skin all of which are consistent with spontaneous reports from health professionals in Thailand [27]. This suggests that, if direct reporting to the regulator were to be further encouraged, patient reports may be similar to those of health professionals and could usefully add to pharmacovigilance, as has been found elsewhere [9, 13, 18].

More of our respondents claimed to have informed physicians about their ADR experience than was found in other studies [28, 29], which could again have been due to different methodologies. It could also be due to a greater willingness of patients to discuss experiences in recent years or the high educational levels of our respondents. Confidence in identification of ADRs was generally high in this population, but was not related to educational level or concomitant medication use. Those who reported the experience to a physician were more likely to be confident in their assessment than those who did not, which may relate to the use of health professionals as the major source of information used to confirm ADRs.

Studies in the UK show that patient information leaflets supplied with medicines are the commonest sources of information which patients use to confirm their suspected ADRs, followed by healthcare professionals and the internet [23, 27]. In Thailand, patients infrequently receive a patient leaflet with their medication, therefore healthcare professionals are, unsurprisingly, ranked as the major information source. However they have limited time to provide information about ADRs [30], hence it is interesting that many respondents also used previous experiences to make an assessment of causality. Patients could be supported in more effectively identifying ADRs through wider availability of information sources which can be self-accessed such as patient information leaflets and internet sources. In Thailand, drug companies provide insufficient numbers of leaflets to pharmacies, there is no work to date on the development of appropriate leaflets for patients and, as in other countries, general internet information sources about medicine are not controlled by the Thai Food and Drug Administration, so accuracy cannot be guaranteed. Further development and wider availability of patient information leaflets plus reliable internet information, controlled by the regulator, could facilitate Thai patients in assessing suspected ADRs, without recourse to health professionals.

Strengths and limitations

The questionnaire was developed from previous studies in the literature which had been used in similar patients [20, 21]. The hospital setting used is the largest tertiary care hospital in northeast region of Thailand and provides

Table 3 Top five of most commonly reported suspect drugs according to ATC drug groups and ADRs classified by system organ class

Drug group (ATC code)	No. of patients n (%) (n = 257)	Drug[a] (No. of patients)
General Antiinfectives, systemic (J)	49 (19.1)	Penicillin (15), Tetracycline (5), Amoxicillin (4), Norfloxacin (4), Sulfamethoxazole (4), Ampicillin (3), Sulfa drug (2)
Musculo-skeletal system (M)	23 (8.9)	Aspirin (4), Ibuprofen (4), Diclofenac (2), Paracetamol combined with Orphenadrine (2), Celecoxib (1), Floctafenine (1), Tolperisone (1)
Central nervous system (V)	20 (7.8)	Paracetamol (3), Chlorpheniramine combined with Paracetamol (2), Amitriptyline (1), Clorazepate (1), Dimenhydrinate (1), Lithium carbonate (1), Pyridostigmine (1), Reboxetine (1), Sertraline (1), Tramadol (1)
Cardiovascular system (C)	12 (4.7)	Amlodipine (2), Atorvastatin (1), Digoxin (1), Enalapril (1), Rosuvastatin (1), Simvastatin (1)
Respiratory system (R)	11 (4.3)	Chlorpheniramine (3), Chlorpheniramine combined with Paracetamol (1), Paracetamol combined with Phenylephrine (1), Theophylline (1)
Adverse drug reactions (ADRs)	**No. of events n (%) (n = 377)**	**Drug[a] (No. of patients)**
Skin and subcutaneous tissue disorders	173 (45.9)	Penicillin (17), Tetracycline (9), Sulfamethoxazole (8), Aspirin (6), Amoxicillin (5)
Nervous system disorders	68 (18.0)	Chlorpheniramine (3), Herbal medicine (2), Acetazolamide (1), Chlorpheniramine combined with Paracetamol (1), Antacid (1), Clobetasol (1), Cyclophosphamide (1), Enalapril (1), Ganamycin (1), Latanoprost (1), Lithium carbonate (1), Moxifloxacin (1), Oral contraceptive (1), Pseudoephedrine (1), Streptomycin (1)
Gastrointestinal disorders	62 (16.4)	Cyclophosphamide (4), Moxifloxacin (2), Pyridostigmine (2), Theophylline (2), Tramadol (2) Antacid (1), Chlorpheniramine combined with Paracetamol and Pseudoephedrine (1), Ibuprofen (1), Penicillin (1), Tetracycline (1)
Musculoskeletal and connective tissue disorders	17 (4.5)	Prednisolone (2), Amitriptyline (1), Amoxicillin (1), Norfloxacin (1), Rosuvastatin (1), Tetracycline (1)
Respiratory, thoracic and mediastinal disorders	16 (4.2)	Amoxicillin (1), Chlorophyll (1), Diclofenac (1), Norfloxacin (1), Sulfa drug (1)

[a] Top five drugs within the top five drug groups and system organ classes

Table 4 Sources of information used by patients to evaluate suspected ADRs (n = 349)

Information	No. of patients (%)
Health care professionals	124 (35.5)
Past ADR experience	89 (25.5)
Patient leaflet	51 (14.6)
Family, relatives, friends	36 (10.3)
Internet	21 (6.0)
Books	3 (0.9)
Others	25 (7.2)

services to patients from a wide population base. Study participants were not selected based on any previous medication history or ADR history and a systematic random sampling method was used. The response rate was very high, but while most patients completed the questionnaire without help, some of them required assistance due to poor eyesight or lack of time. Generalizability of the results to the Thai population is limited, since the study was performed in only one hospital. In addition, the ADRs reported by patients on the questionnaire were not reviewed or further assessed by healthcare professionals, and no attempt was made to assess the actual causality. There is also a possibility of recall bias, particularly in those patients whose experience of ADRs was more than 1 year previously.

Conclusions

The study found a relatively high proportion of Thai hospital out-patients reported experiencing an ADR, many occurring in the last year and that most were confident in the causal association. The most commonly reported drugs and symptoms were similar to data from healthcare professional reports to the Thai regulatory authority. The majority confirmed their ADR assessment by discussion with a healthcare professional, or used previous similar experiences and only 14.6 % used a patient information

leaflet. Information leaflets and other objective sources of information about medicines for patients should be more widely available in Thailand.

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Conflicts of interest There are no conflicts of interests to declare.

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