Public confidence in ADR identification and their views on ADR reporting: mixed methods study

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Abstract

Purpose: The value of patients as potential reporters into pharmacovigilance systems is acknowledged worldwide and allowed in Thailand. However, nothing is known about the Thai public's awareness of direct patient reporting facility or their views concerning it. This study aimed to determine confidence among members of the public in identifying suspected ADRs, information sources they use and their views towards direct ADR reporting.

Methods: Mixed methods study consisting of self-administered questionnaires (phase 1) and semi-structured, face-to-face interviews (phase 2) with members of the public, recruited in primary care centres, pharmacies and public places during October 2013 to February 2015. All questionnaire respondents reporting an ADR were invited to participate in Phase 2. Written informed consent was made before the start of the interview.

Results: There were 414 (17.2%) of 2400 questionnaire respondents who had experienced an ADR, almost half (46%) of whom used their own experience to identify ADRs. Having a degree, having a severe ADR and consulting a physician increased respondent confidence in the association between medicine and suspected ADR. The majority (27) of the 30 interviewees indicated general agreement with patient reporting to regulatory authorities. Four main themes emerged covering reasons for reporting ADRs including expectations of health authorities, healthcare professionals and manufacturers, and helping other people. Awareness of direct reporting was low with a desire for a range of reporting methods.

Conclusion: Results indicate support among the Thai general public of direct ADR reporting. Greater promotion of direct reporting by all healthcare professionals is required.

Keywords: Adverse drug reactions; ADR identification; ADR reporting; Mixed methods; Public's confidence

1 Introduction

Spontaneous reporting is a fundamental drug safety monitoring process, the effectiveness of which is dependent on voluntary reporting, mainly by healthcare professionals, but which is limited by under-reporting and report quality [1-2]. The potential value of patients as potential reporters into pharmacovigilance systems is increasingly acknowledged worldwide. Direct patient reporting to regulatory authorities is viewed as important and a large numbers of countries now permit and encourage patients to report ADRs [3-4]. Patient reporting may enable earlier detection of unexpected ADRs and increase the overall rate of spontaneous reporting. Previous studies have shown that healthcare professionals and patients report a similar proportion of ADR in term of seriousness and that the quality of information reported by patients was good. Moreover, many studies suggested that patient reporting provides a range of benefits and their reports tend to provide more detailed descriptions of their experiences than those of healthcare professionals [5-7].

In Thailand, the Health Product Vigilance Centre (HPVC) is the authority responsible for drug safety, to which patients have been allowed to submit online reports of suspected ADRs since 2010 but the number of reports received is very limited. However, nothing is known about the public's awareness of this reporting facility or their views concerning it. Several studies elsewhere have shown the need for greater publicity regarding direct patient reporting and a need for multiple reporting methods to be available [5, 8-9]. Patients use a variety of means to help them identify suspected ADRs. In countries where patient information leaflets are widespread, such as the UK, these play an important role in ADR identification, which then facilitates direct reporting [5]. However in Thailand, these leaflets are not routinely available with medicines and a previous qualitative study found that Thai patients rely more on health professionals to identify suspected ADRs [10]. Greater understanding is needed about the methods by which Thai patients identify suspected ADRs, plus their views on reporting these. Such understanding could help to improve both the rate and the quality of patient ADR reporting. Our previous study focused on the frequency and characteristic of ADRs, views of Thai people towards ADR information and ADR knowledge [14]. This study subsequently aimed to determine experiences of members of the public who had had a suspected ADR on the information sources and other means used to help identify the suspected ADR, factors affecting their confidence in the association and their views towards direct ADR reporting.

2 Methods

2.1 Study design and study sample

The study was approved by the Khon Kaen University Ethics Committee for Human Research in accordance with the Declaration of Helsinki and the International Conference on Harmonization for Good Clinical Practice (Institutional Review Board Number: IRB00001189). It was a two phase, mixed methods study and was conducted in Khon Kaen province, the second-largest of the north-eastern provinces of Thailand, during October 2013 to February 2015.

2.1.1 Phase 1

This phase involved a self-administered questionnaire designed to determine experiences of the general public with regard to ADRs, which was developed using previous literature [5, 11-13]. Full details of the questionnaire are described elsewhere, together with overall results [14].

Here we present data from study respondents who indicated they had experienced a suspected ADR. In addition to questions relating to the ADR experience itself, the questionnaire included three further questions: (i) information sources used to help determine the association between a symptom and suspect drug; (ii) other factors which helped them to make the association, using options derived from previous work [10]; and (iii) confidence about the association, using five levels (lowest, low, medium, high, highest).

The final questionnaires were directly distributed by hand to participants who were aged over 18 years, by convenience sampling at three main types of locations: four primary care units (PCU), four community pharmacies and three public areas, with a total target sample size of 2400. After distribution, the researchers left the area to give recipients time to decide to participate and allow sufficient time to complete the questionnaires themselves before they were collected. Further details are published elsewhere [14]. Once completed questionnaires were returned, all Phase 1 respondents who reported they had experienced an ADR and completed all relevant sections of the questionnaire, were verbally invited to participate in Phase 2 and to provide their contact details. All respondents who were willing to participate in the interview and gave contact information were included.

2.1.2 Phase 2

This phase consisted of a semi-structured, face-to-face interview to explore further how participants identified their unexpected symptoms as an ADR and their views towards ADR reporting. Phase 1 respondents were telephoned to make an appointment for interview. Written informed consent was obtained from all participants before the start of the interview. During interviews, which were all performed by AP aiming for a duration of between 30 to 45 minutes, open questions were asked based on the interview schedule as a standard guideline, and all were audio-recorded. The interview guideline was developed by the research team, based on previous literature [10] and covered: identification and evaluation of the suspected ADR (sources used, factors considered) and their attitudes towards reporting ADRs (experiences and expectations about reporting to health professionals and authorities).

2.2 Data analysis

2.2.1 Phase 1

All valid data retrieved from the returned questionnaires were analyzed using IBM SPSS for Windows version 19.0 (IBM Corp., Armonk, N.Y.). Respondents' confidence in ADR identification was reported using descriptive statistics, then confidence was dichotomized into medium/low/lowest and high/highest. Relationships between variables were analyzed using Pearson Chi-square ($\chi 2$) test. Logistic regression was used to determine factors associated with degrees of certainty. Differences with p-values less than 0.05 were regarded as statistically significant.

2.2.2 Phase 2

All interviews were transcribed into Thai. The transcripts were translated into English by AP and all were checked independently by NJ, for accuracy. Interview data were analyzed using thematic analysis. The interview transcripts were first read and coded manually by AP and the analysis was checked and reviewed by

NJ. Discussions took place between these two researchers which enabled codes to be categorized into major themes and for new codes to emerge. The codes and themes from the second analysis were discussed and reviewed again by all researchers and final themes agreed.

3 Results

There were 2935 people invited to participate, of these 2450 accepted a questionnaire and 2400 returned a valid questionnaire. Demographic details of the study participants are shown in Table 1. of the 2400 respondents, 414 (17.2%) indicated they had experienced an ADR. The majority of these respondents were female (66.4%; n=275) and the average age was 38.1± 15.6 years (range from 18 to 79 years). A half were graduates with a bachelor degree or higher (50.2%; n=208). There were 170 (41.1%) of respondents who claimed to have an underlying chronic disease.

[Insert Table 1 here]

3.1 Phase 1 Questionnaire findings

Two-thirds (276; 66.7%) of questionnaire respondents had experienced mild symptoms, 105 (25.4%) moderate and 33 (8.0%) severe symptoms. Over half (230; 55.0%) indicated their experience was within the last year. The information sources used by respondents to help in identifying ADRs are shown in Table 2, with personal experiences and health professionals being the most commonly cited. Table 3 shows the individual means by which respondents made the association between the symptoms and suspected drugs. The reason most frequently selected was that the ADRs occurred after the drugs were taken (350; 53.4%), with other frequently cited reasons being: no co-medication being taken concurrently (90; 13.7%), ADRs occurred after the drugs were taken again (89; 13.6%), and they had experienced ADRs from this drug before (48; 7.3%).

[Insert Table 2 here]

[Insert Table 3 here]

In response to question (iii), over half the respondents felt that their level of confidence in the experience being an ADR was high (120; 29.0%) or highest (90; 22.9%). A further 124 (30.0%) had a moderate level of confidence and less than a fifth had little confidence in the association between suspected ADR and medicine: n=39 (9.4%) low level and n=36 (8.7%) lowest level.

Factors potentially related to respondents' confidence in the association between the symptom and the drug were initially analyzed by Pearson chi-square. Univariate analysis showed that respondents with higher education level ($p=0.001$), working for the state or in business ($p=0.006$), having higher income (0.011), increasing severity of ADR ($p<0.001$) and whether or not they had consulted a physician ($p<0.003$) were significantly associated with higher confidence in ADR identification (Table 4). Table 5 shows the results of logistic regression analysis, which indicates that higher educational level was the most significant factor in increasing confidence in the association (OR 2.412; 95%CI 1.589, 3.662; $p<0.001$). In addition, a clear trends was visible in confidence level with increasing ADR severity and consulting a physician was also associated with high confidence.

[Insert Table 4 here]

[Insert Table 5 here]

3.2 Phase 2 Semi-structured interviews

A total of 64 Phase 1 participants (15.5%) provided contact details and indicated a willingness to participate in semi-structured interviews, and 30 (47%) interviews were conducted. Of the remaining 34 people, 20 subsequently refused to be interviewed and 14 could not be contacted by phone. The mean duration of the interviews was 27.8±7.6 minutes. Interviewees differed slightly from Phase 1 respondents in that more were female, they were older, more were graduates with a bachelor degree and more had underlying chronic disease (Table 1). However they were similar in terms of the severity of their ADR experiences.

3.2.1 How ADRs were identified

All interviewees provided at least one explanation regarding the processes that they used to identify their unusual symptom as an ADR. Two main themes emerged, covering factors related to medicine use and information sources.

Factors related to medicines use

The identification process mentioned most frequently, indeed by all participants, was the timing relationship, most of whom indicated that symptoms occurred after they took the suspected medicines. Others mentioned that symptoms had never occurred before and that symptoms disappeared after they discontinued the suspected medicines. Some could relate their unusual symptoms to suspected medicines because it was their first time of taking these medicines.

> *"I did not discontinue medicine immediately. I continually took it for 5 to 7 days because I did not believe that symptoms were caused from this medicine that I took, until I stopped taking the suspected medicine and symptoms disappeared."* (Female, 39, Doctoral Degree, no U/D)

Interview data provided more detail about how people supported the identification of ADRs through other means, such as consideration of the possibility of alternative causes, changes in the symptom relating to the dose taken and previous experiences with similar drugs. For example:

> *"It did not relate to chronic underlying disease because I experienced the disease for many years and the symptoms had never occurred before. If the symptoms were related to the disease, the symptoms would be occurring since many years ago."* (Female, 27, Bachelor degree, no U/D)

> *"I had increased and decreased the dose of my suspected medicine. Symptom was decreased when I reduced the dose, and the symptom was getting worse when I increased the dose."*(Female, 53, Diploma, U/D)

Interestingly, there were nine participants took the suspected medicine again after the symptom was disappeared. Three of these were re-challenged with the suspected medicine because either they or healthcare professionals were not aware of the previous ADR and thus unable to prevent recurrence. *"I forgot to tell physician that I had history of drug allergy. Surprisingly, I was prescribed Penicillin again and I took it. So, the symptoms occurred and then I hurried to take anti-histamine and the symptoms were relieved."* (Male, 71, Bachelor degree, U/D)

Some subjected themselves to re-challenge with the suspected medicine in order to confirm their suspicion of the ADR.

"*I was not sure that whether I was allergic to Biocalm or not. So I tried to take it again for muscle relaxation. The symptoms occurred as I had previously experienced after I took it. Then, I took anti-histamine and the symptoms were relieved within an hour."* (Male, 62, Master degree, U/D)

Information sources

Other ways in which participants assessed unusual symptom as an ADR involved their use of information sources, together with their personal beliefs about their medicine. Over half the participants said they used information sources to confirm their identification. The information was directly provided by healthcare professionals in 11 participants, but six obtained information from non-healthcare professionals, including friends and the internet, as well as using their own knowledge.

"I did not think that my symptoms related to other medicines because physician told me that you were allergic to Sulfa drug. So, I was confident that I was allergic to Sulfa drug." (Male, 70, Master degree, U/D)

Personal beliefs related to perceptions about the strength of medicines, administration and their body's ability to accept medicines.

"I thought that unusual symptoms occurred because I was prescribed too high a dose of medicine and I [only] took a little bit of water. Therefore, I would receive a concentrated dose of medicine." (Female, 25, Bachelor degree, U/D)

3.2.2 Attitudes towards direct reporting of ADRs

Two main themes emerged concerning attitudes towards patient reporting to regulatory authorities, with the majority indicating general agreement with this, as well as providing opinions on methods of ADR reporting.

"It is good because it would reduce workload of medical staff. Furthermore, patients are best understanding of their health status than other person. Hence, to allow patients to report ADRs by themselves is good." (Case 030, Male, 25, Bachelor degree, U/D)

Only a few disagreed with patient reporting, with reasons given being because they perceived that reporting ADRs was unimportant, the reported data may be incorrect and the difficulty of reporting. The majority considered it was appropriate for patients to report directly themselves, but some considered that reporting should go through health professionals.

Regarding the method of ADR reporting, preferred methods were varied, including internet, email, Facebook, telephone, call center and post.

"Report ADRs via internet is the best because nowadays everybody has own smart phone and they could access through the internet by themselves." (Female, 22, Bachelor degree, no U/D)

Several commented that they would need feedback after reporting or felt they should be able to discuss the suspected ADR with someone, which influenced their suggestions for the ideal reporting method.

"They should set up telephone or internet and have available staff to answer any questions immediately, because the person who experienced unusual symptoms would feel anxiety with their symptoms." (Female, 27, Bachelor degree, no U/D)

3.2.3 Expectations about reporting of ADRs

Four themes were evident from the interviews covering reasons why people may want to report ADRs and their expectations regarding reporting. These were: expectations of health authorities, healthcare professionals and manufacturers, and helping other people.

Expectations of health authorities

More than half the participants expressed views concerning health authorities, some of which included their need for more information, as well as responses when they reported an ADR. Most participants felt that they lacked knowledge and desired more. Others mentioned that the authorities needed to affirm safety and quality of marketed and prescribed drugs after they reported an ADR.

"I would want to receive information about how to manage ADRs after I reported an ADR. Moreover the authorities should affirm manufacturing processes of medicine if there are many people experienced an ADR." (, Female, 22, Bachelor degree, no U/D)

Some participants stated that no one knew about patient reporting via Thai HPVC. They viewed it as a task of health authorities to promote how this worked and how to access this system, illustrated by the following statement:

"The Thai FDA should advertise about direct reporting to the public such as this website (Thai HPVC) because nobody knew about this method and they did not know the way to report their symptoms." (Female, 22, Bachelor degree, no U/D)

Expectations of manufacturers

Most participants expressed the hope that medicines should be improved, and that leaflets or brochures may be more widely available and the reported ADRs should be added into these leaflets. *"The drug company should create short leaflet for patients when their medicines are dispensed."* (Female, 20, Bachelor degree, no U/D)

Expectations of healthcare professionals

Some participants expressed views that they wanted to inform healthcare professionals about ADRs because they desired healthcare professionals to monitor and manage their unusual symptoms.

"I would need home visit and close monitoring from healthcare professionals to prevent recurrent of unusual symptoms." (Male, 71, Bachelor degree, U/D)

To help other people

Many interviews described altruistic views, demonstrating the desire to share their experiences and to make other people aware of ADRs.

"I would not require any acknowledgement ... only the word "thank you" from the authorities. I think that it could be useful to other person. If there were many people allergic to this medicine, Thai FDA should be concerned about safety information of medicines or withdraw the suspected medicine if possible." (Female, 37, Doctoral degree, U/D)

4 Discussion

4.1 Main findings

This study showed that among Thai people who had experienced a suspected ADR, those with higher educational levels, more severe symptoms and those who had discussed their experience with a health professional had greater confidence in the association. All questionnaire respondents were able to provide at least one reason that they suspected a causal relationship between the suspected ADR and a drug. Almost half drew on personal experiences, with over a third confirming their causality assessment with healthcare professionals. The latter figure is higher than was found in studies from both the UK [15] and Japan [16]. Other information sources, such as medicine leaflets and the Internet, were used relatively infrequently, similar to these other studies [15-16].

Timing relationships was the most common basis on which suspected ADRs were identified, which is also in line with other studies [10, 15-17]. The qualitative data confirmed that people tended to try to eliminate other potentially causative factors and many used their experiences of re-challenge to evaluate their symptoms. Studies in both the UK and the US have proposed that patients could identify their ADRs related to the suspected medicines based on both timing issues and their own knowledge [18-19]. Our study also confirmed this, with some being aware of individual drugs' potential for causing ADRs, However beliefs about medicines also influenced some individuals' views on the association.

While the Thai HPVC has allowed the public to directly report unexpected symptoms related to medicine and health products since 2010, this is the first study to explore public views on and awareness of this system. It found that most of the interview participants were in favour of direct reporting as contributing to pharmacovigilance in Thailand. However a minority felt that in order to confirm causality assessment of their ADRs, patients should report ADR to healthcare professionals first. A similar view was expressed by some patients in a qualitative UK study [20] who considered that ADR reporting was a task for health professionals and not their responsibility, whereas the prevailing concern in our study was the quality of reports and certainty of the association. Altruistic reasons were mentioned by most interviewees, with only a minority expressing the view that it was an opportunity for personal gain, which is in line with other studies in UK and the Netherlands [13, 21-23]. Patient reporters in the UK considered that reporting was important for both manufacturers and authorities, leading to potential improvements in medicines, as well as amendments to information leaflets and withdrawal of medicines if necessary [13], which was also found in the present study. The personal benefits sought were more information about medicines, confirmation about suspected ADRs and management of their ADR, which again is in line with previous work [22]. Other participants were not desirous of receiving feedback.

These previous studies have involved people who had reported suspected ADRs to regulatory authorities, in countries where provision of a patient information leaflet with all supplied medicines is a legal

requirement. Our study involved members of the public, none of whom had reported, in a country where patient information leaflets are scarce [24]. It is therefore interesting that some interview participants had an understanding of the potential implications of reporting ADRs for medicines leaflets. Indeed some suggested that such leaflets should be provided with all medicines and include the ADRs reported by the public. There was however a lack of awareness of the reporting process, and suggestions for greater publicity and alternative reporting options were offered.

4.2 Strengths and limitations

This mixed method study targeted the community-dwelling public with experiences of suspected ADRs, as potential contributors to direct reporting in Thailand. The study was conducted in only one area of Thailand, but involved multiple recruitment methods in order to reach a diverse population. Studies elsewhere have used street survey or telephone survey to obtain views and experiences of the public on direct ADR reporting, while many studies exploring how people identify ADRs have involved people who have already reported their experience to regulatory authorities. Self-completed questionnaires were used to determine confidence in identifying ADRs, enabling factors affecting confidence in this to be studied. Interviews then enabled participants to explain their experiences and provide opinions on direct reporting individually in their own words.

5 Conclusion

The findings suggest that the general public in Thailand use mainly their own experience and information from health professionals to identify suspected ADRs. They are not aware of the facility to report ADRs directly, but are willing to share their experiences of suspected ADRs with the Thai regulatory authority, to improve medicines safety. Greater promotion is required of direct reporting, by all stakeholders, including the Thai FDA, as well as individual physicians, pharmacists and nurses.

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Contributions of Authors

All authors contributed to the design of the study, plan for the work and interpretation of the results. NJ and AP analyzed the data and wrote the first manuscript; NJ and JK were involved in revising the manuscript. All authors approved the final submission version.

Compliance with Ethical Standards

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Conflicts of interest

Narumol Jarernsiripornkul, Arunrot Patsuree and Janet Krska declare that they have no conflict of interest.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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Table 1 Demographic details of study participants

Characteristic	Phase 1 (N=414)	Phase 2 (N=30)
Gender		
▪ Male	139 (33.6)	8 (26.7)
▪ Female	275 (66.4)	22(73.3)
Age (year)		
▪ <45	266 (64.3)	13 (43.3)
▪ ≥45	148 (35.7)	17 (56.7)
Mean ± SD	38.1±15.6	45.2±18.7
Median (Range)	36 (18-79)	50 (19-71)
Education Level		
▪ Secondary school and lower	206 (49.8)	9 (30.0)
▪ Bachelors Degree and higher	208 (50.2)	21 (70.0)
Major career		
▪ Not working	46 (11.1)	6 (20.0)
▪ Student	95 (22.9)	6 (20.0)
▪ Farmer / manual worker	51 (12.3)	1 (3.3)
▪ Government official and state enterprise employee	128 (30.9)	14 (46.7)
▪ Own business	94 (22.7)	3 (10.0)
Income (Baht)		
▪ ≤ 20,000	314 (75.8)	18 (60.0)
▪ More than 20,000	100 (24.2)	12 (40.0)
Underlying Disease		
▪ Yes	170 (41.1)	19 (63.3)
▪ No	244 (58.9)	11 (36.7)
Levels of ADR severity		
▪ Mild	276 (66.7)	19 (63.3)
▪ Moderate	105 (25.4)	7 (23.3)
▪ Severe	33 (8.0)	4 (13.3)

Table 2 Information sources used to identify ADRs (N=414)

Sources of information	Total N (%)
Own experiences	191 (46.1)
Healthcare professionals	158 (35.8)
Information leaflets	64 (15.5)
Relatives	63 (15.2)
Internet	45 (10.9)
Books	5 (1.2)

Table 3 Factors involved in ADR identification

Reasons	Total N (%)
▪ ADRs occurred after the drugs were taken	350 (84.5)
▪ No co-medication was taken when ADRs experienced	90 (21.7)
▪ ADRs occurred after the drugs were taken again	89 (21.5)
▪ Had experienced ADRs from this drug before	48 (11.6)
▪ Symptoms of an underlying disease were not similar to the ADR symptoms	34 (8.2)
▪ Other people who took similar drugs have experienced the same ADRs	29 (7.0)
▪ Physical and/or blood examination were abnormal after the drugs were taken	11 (2.7)
▪ Other reasons	4 (1.0)

Table 4 Univariate analysis of factors related to levels of ADR identification (N=414)

Characteristic / Levels of confidence	No. of individuals (%)		Total N	p-value[a]
	Low to moderate (N=199)	High (N=215)		
Gender				
▪ Male	67 (33.7)	72 (33.5)	139 (33.6)	0.969
▪ Female	132 (66.3)	143 (66.5)	275 (66.4)	
Age (year)				
▪ Less than 45	130 (65.3)	136 (63.3)	266 (64.3)	0.660
▪ ≥ 45	69 (34.7)	79 (36.7)	148 (35.7)	
Education Level				
▪ Secondary school and lower	116 (58.3)	90 (41.9)	206 (49.8)	0.001
▪ Bachelors Degree and higher	83 (41.7)	125 (58.1)	208 (50.2)	
Major career				
▪ Not working/student	61 (30.7)	80 (37.2)	141 (34.1)	0.006
▪ Farmer/manual worker	35 (17.6)	16 (7.4)	51 (12.3)	
▪ State employee/own business	103 (51.8)	119 (55.3)	222 (53.6)	
Income (Baht)				
▪ ≤ 20,000	162 (81.4)	152 (70.7)	314 (75.8)	0.011
▪ More than 20,000	37 (18.6)	63 (29.3)	100 (24.2)	
Underlying chronic disease				
▪ Yes	82 (41.2)	88 (40.9)	170 (41.1)	0.955
▪ No	117 (58.8)	127 (59.1)	244 (58.9)	
Concomitant medication use				
▪ Yes	46 (23.1)	50 (23.3)	96 (23.2)	0.973
▪ No	153 (76.9)	165 (76.7)	318 (76.8)	
When ADRs occurred				
▪ Within 1 month ago	45 (22.6)	37 (17.2)	82 (19.8)	0.386
▪ Within 6 months to 1 year ago	69 (34.7)	79 (36.7)	148 (35.7)	
▪ More than a year ago	85 (42.7)	99 (46.0)	184 (44.4)	
ADR duration				
▪ 1 - 3 days	109 (54.8)	120 (55.8)	229 (55.3)	
▪ 4 - 6 days	46 (23.1)	39 (18.1)	85 (20.5)	0.660
▪ 1 - 4 weeks	21 (10.6)	28 (13.0)	49 (11.8)	
▪ 1 - 3 months	11 (5.5)	16 (7.4)	27 (6.5)	
▪ More than 3 months	12 (6.0)	12 (5.6)	24 (5.8)	
ADR severity				
▪ Mild	153 (76.9)	123 (57.2)	276 (66.7)	<0.001
▪ Moderate	39 (19.6)	66 (30.7)	105 (25.4)	
▪ Severe	7 (3.5)	26 (12.1)	33 (8.0)	
Consulted with physician				
▪ Yes	77 (38.7)	115 (53.5)	192 (46.4)	0.003
▪ No	1222 (61.3)	100 (46.5)	222 (53.6)	
Dechallenge				
▪ Yes	167 (83.9)	179 (83.3)	346 (83.6)	0.855
▪ No	32 (16.1)	36 (16.7)	68 (16.4)	

[a] Pearson Chi-Square test

Table 5 Logistic regression analysis of factors associated to levels of certainty in ADR identification

Variables	No. of individual (%)		Adjusted OR	95% C.I.		p-value[a]
	Low to moderate	High		Lower	Upper	
Education Level						
▪ Secondary school and lower	130 (65.3)	136 (63.3)	1			
▪ Bachelors Degree and higher	69 (34.7)	79 (36.7)	2.412	1.589	3.662	<0.001
ADR severity						
▪ Mild	153 (76.9)	123 (57.2)	1			
▪ Moderate	39 (19.6)	66 (30.7)	2.082	1.284	3.378	0.003
▪ Severe	7 (3.5)	26 (12.1)	5.251	2.134	12.920	<0.001
Consulted with physician						
▪ No	1222 (61.3)	100 (46.5)	1			
▪ Yes	77 (38.7)	115 (53.5)	1.666	1.097	2.530	0.017

[a] The association between variables was analyzed by Logistic regression