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ทัศนคติของผู้ป่วยต่อการรายงานอาการไม่พึงประสงค์จากยาด้วยตนเอง

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Patients' Attitude Towards Self-Reporting of Adverse Drug Reactions

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หลักการและวัตถุประสงค์ : ปัจจุบันในหลายๆ ประเทศ ผู้ป่วยได้มีส่วนร่วมมากขึ้นในการรายงานอาการไม่พึงประสงค์จากยาไปที่ศูนย์เฝ้าระวังความปลอดภัยทางยา แต่ความเห็นของผู้ป่วยต่อระบบการรายงานนี้ยังมีการศึกษาในจำนวนที่จำกัด ดังนั้นการศึกษานี้จึงมีวัตถุประสงค์เพื่อสำรวจทัศนคติของผู้ป่วยที่มีต่อระบบการรายงานอาการไม่พึงประสงค์จากยาด้วยตนเองและยังศึกษาปัจจัยที่เกี่ยวข้องอื่นๆ ด้วย

วิธีการศึกษา : การศึกษาเชิงพรรณนานี้จัดทำขึ้นที่โรงพยาบาลมหาวิทยาลัยคือโรงพยาบาลศรีนครินทร์และศูนย์หัวใจสิริกิติ์ภาคตะวันออกเฉียงเหนือ โดยผู้ป่วยนอกที่อายุมากกว่า 18 ปี ซึ่งมีการใช้ยากลุ่มสแตติน (statins) อย่างน้อย 1 เดือน ได้รับแบบสอบถามชนิดตอบเอง โดยวัตถุประสงค์ของการศึกษาคือเพื่อประเมินทัศนคติของผู้ป่วยที่มีต่อการรายงานอาการไม่พึงประสงค์จากยาด้วยตนเอง คำถามเกี่ยวกับทัศนคติจำนวน 12 ข้อ ประกอบด้วยข้อความเชิงบวกและข้อความเชิงลบในจำนวนที่เท่ากัน และถูกประเมินโดยใช้ 5-point Likert scales ที่เรียงจากไม่เห็นด้วยอย่างยิ่ง (1) จนถึงเห็นด้วยอย่างยิ่ง (5) โดยคะแนนในข้อความเชิงลบจะถูกแปลงในทิศทางตรงกันข้ามก่อนแล้ว จึงคำนวณคะแนนทัศนคติโดยรวม (คะแนนต่ำสุด-สูงสุด=10-60)

ผลการศึกษา : อัตราการตอบกลับของแบบสอบถามที่สามารถนำมาวิเคราะห์ได้คือ ร้อยละ 51.7 ผู้ป่วยจำนวน 645-661 ราย ให้คำตอบในแต่ละข้อ แต่มีผู้ป่วยจำนวน 615 ราย ที่ให้คำตอบครบทั้ง 12 ข้อ โดยส่วนใหญ่ผู้ป่วยมีคะแนนทัศนคติต่อการรายงานอาการไม่พึงประสงค์จากยาด้วยตนเองในระดับปานกลางและสูง (คะแนนรวมเฉลี่ย±ส่วนเบี่ยงเบนมาตรฐาน =42.37±5.54) สำหรับข้อความเชิงบวก ผู้ป่วย

Background and objective : Nowadays, many countries over the world, patients increasingly involve in self-reporting of Adverse Drug Reactions (ADRs) to pharmacovigilance centre. There were limited studies relating to how patients view on this reporting system. Therefore, this study aimed to explore their attitude towards ADR self-reporting system by themselves and other related factors.

Method : This descriptive study was conducted at university hospitals, Srinagarind hospital and Queen Sirikit Heart Center of the Northeast. The out-patients, aged over 18 years old, had taken statins at least 1 month, received self-administered questionnaires to rate attitude towards patient self-reporting of ADRs. A total of 12 attitudinal questions, consisted of equal numbers of positive and negative statements, were rated on 5-point Likert scale ranging from strongly disagree (1) to strongly agree (5). Scores were conversely assigned for negative statements before summarizing total score (Min-Max=10-60).

Results : The response rate of valid questionnaire was 51.7%. There were 645-661 patients who gave responses in each statement but 615 patients responded to all 12 statements. Patients mostly had moderate to high scores of attitude towards self-reporting of ADRs (Mean total score±S.D.=42.37±5.54). In positive statement, most patients (89.2%) agreed or strongly

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ส่วนใหญ่ (ร้อยละ 89.2) เห็นด้วยหรือเห็นด้วยอย่างยิ่งกับข้อความที่ว่า "ผู้ป่วยมีความพร้อมในการรายงานอาการไม่พึงประสงค์จากยาโดยการสังเกตตนเองอย่างสม่ำเสมอ" สำหรับข้อความเชิงลบ ผู้ป่วยมักจะไม่เห็นด้วยหรือไม่เห็นด้วยอย่างยิ่งกับข้อความที่ว่า "การมีส่วนร่วมในการรายงานอาการไม่พึงประสงค์จากยาทำให้เสียเวลา" (ร้อยละ 86.0) และพบว่าทัศนคติต่อระบบการรายงานได้รับผลกระทบอย่างมีนัยสำคัญทางสถิติ ($p<0.05$) จากจำนวนโรคประจำตัวที่เป็น ($p=0.030$) และจำนวนประสบการณ์ของอาการไม่พึงประสงค์จากยา ($p=0.022$)

สรุป : โดยทั่วไป ผู้ป่วยมีทัศนคติในทางบวกต่อการรายงานอาการไม่พึงประสงค์จากยาด้วยตนเอง แม้ว่าผู้ป่วยรับรู้ถึงศักยภาพตนเองในการรายงานอาการ การให้ข้อมูลเกี่ยวกับโรคและยาควรมีการปรับปรุงด้วย

agreed that they were prepared for ADR reporting by regularly monitoring themselves. In negative statement, patients frequently disagreed or strongly disagreed that participation in ADR reporting was wasting their time (86.0%). Attitude towards this reporting system was significantly affected by number of comorbid diseases ($p=0.030$) and experienced ADRs ($p=0.022$).

Conclusions : Generally, patients had positive attitude towards self-reporting of ADRs. Although they perceived their potentials in making ADR reports, provision of information about comorbid diseases and drugs should also be improved.

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Introduction

The post-marketing surveillance system is principally based on voluntary reporting by healthcare professionals to identify new reactions, evaluate factors that may increase the risk of Adverse Drug Reactions (ADRs), and provide medication safety information to public[1]. In addition to the current reporting system, many countries; for example, the United Kingdom, the United States of America, Denmark, the Netherland, Canada, Australia, and New Zealand, allowed patients to directly submit ADR reports to their monitoring centres[2, 3]. The patient reporting system was mainly used for signal generation[3-5], furthermore, it provided some other different types of serious ADRs, drugs, and affected body systems to the existing pharmacovigilance system[6]. In Thailand, the Health Product Vigilance Centre (HPVC) is the mandatory authority responsible for medication safety. It has established the system for patients to submit online report of any problems of health products via its website, however, no published data on this operation is available yet[7]. Previous studies of patient self-reporting of ADRs in a tertiary-care teaching hospital in northeast of Thailand had found that patients were able to use symptom checklist questionnaires to report their experiences of adverse drug effects, most of which (60%-76%) were probable/possible ADRs[8-11]. The results also supported the willingness of patients in order to participate this system, however, their attitude towards this reporting method should be investigated in more details. Therefore, this study aimed to explore the patients' attitude towards ADR self-reporting system and other related factors. Statins, a class of lipid-lowering drugs, was chosen as the index drug in this study because it was widely used in Thai patients[12], whose common ADRs could be subjectively detected by any changes from their normal conditions.

Methods

This study was conducted at Srinagarind hospital and Queen Sirikit Heart Centre of the Northeast province of Thailand between 1 September 2011 and 31 March 2012. The study protocol was approved by the Ethics Committee for Human Research, Khon Kaen University [HE 541023].

Study design

This was a descriptive study which used self-administered questionnaires to explore patients' attitude towards self-reporting ADRs. Eligible patients were those

who aged 18 years or over and had taken statins, including simvastatin, rosuvastatin, or atorvastatin, for at least one month. Sample size calculation was principally based on the main study hypothesis for patients reporting at least 1 ADR, thus, this required at least 235 patients per each statin. Convenience sampling was performed to user of all study statins at out-patient department. In addition, mailed questionnaire was also used for data collection in atorvastatin- and rosuvastatin-treated patients to increase number of patients of both statins.

After patients had used symptom checklist questionnaires to report ADR experiences related to their statins, they received additional questionnaire about attitude towards self-reporting ADRs by themselves. The questionnaire contained 12 Likert scale questions which were adapted from the studies of motivations for reporting ADRs by patients[13, 14]. These questions included six positive statements (1, 4, 6, 7, 11, and 12) and six negative statements (2, 3, 5, 8, 9, and 10). Each statement was measured on 5-point Likert Scale ranging from 1 to 5. The scores given for positive statements were ranged from 1 to 5, e.g. strongly disagree to strongly agree, while the scores of negative statements were given in the opposite way. The total score was calculated by summing of scores from all attitudinal statements, in which the possible total score could range from 12 to 60. The range of total score (60-12= 48) was divided into three equal parts, and categorized as low level (12-27), moderate (28-43), and high (44-60) level of attitude towards ADR reporting. The questionnaire was tested for content validity by four healthcare professionals and it was also used for pilot study in 30 patients. Cronbach's a coefficient for internal consistency was unacceptable (0.617). After revision of the questionnaire according to comments from healthcare professionals and patients, the second pilot test in 15 patients resulted in 0.734 of Cronbach's alpha. The revised questionnaire was then used in main study.

Data analysis

Descriptive statistics were demographic data, medical profiles, patients' history, response rates, and attitudes towards ADR reporting system. The results were presented as frequency, percentage, mean±standard deviation (Mean±S.D.) for data with normal distribution, or median (Interquartile range: IQR) for non-normally distributed data. Statistical analysis in each attitudinal question was performed for all respondents who completed in that particular question but the total score was analyzed in respondents who completed all 12 attitudinal questions.

Independent variables were examined for associations with patients' attitude towards self-reporting ADRs. These included sex, age, education, comorbid diseases and drugs, type of statin, indication and duration of statin treatment, severity of the most bothersome symptom, and total number of reported symptoms. Pearson chi-square test was used to identify association of categorical data between independent and dependent variables. Multiple logistic regression analysis using Backward LR method was also performed to assess effects of a number of independent variables on the predicted variable. Results were presented as frequency, percentage, Odd Ratio (OR), p-value, and 95% Confident Interval (95% CI). The 95% confidence interval or p-value at 0.05 was chosen to accept or reject the null hypothesis.

Results

Demographic data

Total of 1,388 questionnaires were sent to the patients by pharmacist (337; 24.3%) and by mail (1,051; 75.7%). A 718 valid questionnaires (51.7%) came from 235 simvastatin-treated patients, 240 atorvastatin-treated patients, and 243 rosuvastatin-treated patients. Generally, most patients were male (55.0%) and aged between 51 and 70 years (Mean±S.D. 62.44±9.61). Almost half of them (47.5%) had graduated at least bachelor degree. Majority of patients had 1-2 comorbid diseases (54.5%) and had taken at least 5 concomitant drugs and over (38.6%). Primary prevention was most common indication for statin treatment (57.5%) and most patients had taken it longer than a year (82.5%). Most patients had taken statins as single treatment of lipid-lowering drug (92.2%), others had combination therapy. Of the total 718 patients, 546 patients (76.0%) had previously reported at least one adverse symptom in the checklist questionnaires (Table 1).

Table 1 Demographic data of respondents classified by methods of questionnaire distribution

Characteristics	Number of Patients (% by method of distribution)		
	By Pharmacist (n= 320)	By Mail (n= 398)	Total (n= 718)
Sex			
Male	183 (57.2)	212 (53.3)	395 (55.0)
Female	137 (42.8)	186 (46.7)	323 (45.0)
Age (years)			
≤ 50	38 (11.8)	33 (8.3)	71 (9.9)
51-70	220 (68.8)	276 (69.3)	496 (69.1)
>70	62 (19.4)	89 (22.4)	151 (21.0)
Mean±S.D.	61.69±9.76	63.05±9.45	62.44±9.61
Educational level			
Primary school or lower	100 (31.2)	77 (19.3)	177 (24.7)
Secondary school or Diploma	95 (29.7)	105 (26.4)	200 (27.9)
Bachelor degree or higher	125 (39.1)	216 (54.3)	341 (47.5)
Number of comorbid disease			
None	7 (2.2)	16 (4.0)	23 (3.2)
1-2	155 (48.4)	236 (59.3)	391 (54.5)
e”3	158 (49.4)	146 (36.7)	304 (42.3)
Median (IQR range)	2 (2-3)	2 (1-3)	2 (2-3)
Number of concomitant drug			
None	4 (1.2)	23 (5.8)	27 (3.8)
1-2	53 (16.6)	106 (26.6)	159 (22.1)
3-4	122 (38.1)	133 (33.4)	255 (35.5)
e”5	141 (44.1)	136 (34.2)	277 (38,6)
Median (IQR range)	4 (3-6)	4 (2-5)	4 (2-5)
Indication of statins			
Primary prevention	146 (45.6)	267 (67.1)	413 (57.5)
Secondary prevention	174 (54.4)	131 (32.9)	305 (42.5)
Combination therapy with other Lipid-lowering drugs			
No	294 (91.9)	368 (92.5)	662 (92.2)
Yes	26 (8.1)	30 (7.5)	56 (7.8)
Duration of statin treatment			
1-90 days	7 (2.2)	15 (3.8)	22 (3.1)
91-180 days	15 (4.7)	20 (5.0)	35 (4.9)
181-365 days	32 (10.0)	37 (9.3)	69 (9.6)
>365 days	266 (83.1)	326 (81.9)	592 (82.5)
MeanฑS.D.	1373.50±1014.03	1129.91±870.19	1238.47±944.15
Reporting potential Adverse Drug Reactions			
Not report	80 (25.0)	92 (23.1)	172 (24.0)
Reported at least 1 symptom	240 (75.0)	306 (76.9)	546 (76.0)

[a]Pearson chi-square test, [b]One-way ANOVA, [c]Median test

Attitude towards self-reporting ADRs

There were 645-661 patients who rated their attitude in each statement but 615 of them completed all 12 attitudinal statements. In general, patients had good or very good attitude towards self-reporting ADRs (Mean attitudinal score±S.D. ranged from 3.40±1.25 to 4.21±0.80). The highest and lowest mean attitudinal scores were found in statement 7 (4.21±0.80) and 8 (1.91±0.99), respectively. Most of them presented as agreed or strongly agreed that they were ready for self-reporting ADRs by always monitoring themselves (52.0% and 37.2%, respectively); they paid attention to ADRs because it affected quality of life (31.2% and 36.5%, respectively); they could provide complete ADR information to health professionals (44.8% and 25.0%, respectively); they were confident in self-reporting ADRs (43.3% and 21.7%, respectively); they were responsible to report ADRs (39.7% and 28.2%, respectively); and they could accurately report ADRs (30.7% and 20.0%, respectively) (Table 2).

Patients disagreed and strongly disagreed with most of the negative statements, excepts for statement 8 and 9. Most patients agreed or strongly agreed that they need health professionals to support ADR monitoring (47.3% and 37.7%, respectively) and that they could not differentiate between symptoms relating to drugs or diseases (32.2% and 19.7%, respectively). On the other hands, most patients disagreed or strongly disagreed that participation in self-reporting ADRs was wasting their time (43.3% and 43.6%, respectively); only health professionals could prevent and reduce seriousness of ADRs (35.7% and 28.6%); patients did not have to report non-serious ADRs to health professionals (34.9% and 26.0%); and self-reporting ADRs was difficult (40.3% and 19.2%, respectively) (Table 2).

Total attitudinal score could be calculated in 615 patients, whose average score was 42.37±5.54. The majority of patients (99.3%) had moderate or high level of attitudinal score and only four patients were classified as having low attitude towards self-reporting ADRs.

Table 2 Patients' attitude towards self- reporting of ADRs

Statements[a]	Number of patients responded in each scale[a] (%)					Total N	Mean[b]	S.D.
	1	2	3	4	5			
1. You pay attention to Adverse Drug Reactions (ADRs) because it affected your quality of life.	27 (4.1)	54 (8.2)	132 (20.1)	205 (31.2)	240 (36.5)	658	3.88	1.12
2. You think that your ADRs are not serious, therefore you didn't have to report to healthcare professionals (HCPs).	171 (26.0)	**229** (34.9)	75 (11.4)	154 (23.4)	28 (4.3)	657	3.55	1.22
3. You believe that only HCPs who could prevent ADRs and reduce the severity of your ADRs.	187 (28.6)	233 (35.7)	47 (7.2)	153 (23.4)	33 (5.1)	653	3.59	1.26
4. You can provide complete ADR information to HCPs.	13 (2.0)	21 (3.2)	165 (25.0)	295 (44.8)	165 (25.0)	659	3.88	0.89
5. Your participation in the reporting of ADRs to HCPs is wasting your time.	285 (43.6)	283 (43.3)	34 (5.2)	35 (5.4)	16 (2.5)	653	4.20	0.94
6. The prevention of ADRs is your direct responsibility.	35 (5.4)	72 (11.0)	103 (15.8)	259 (39.7)	184 (28.2)	653	3.74	1.14
7. You prepared for reporting of ADRs by self-monitoring regularly.	11 (1.7)	16 (2.4)	44 (6.7)	344 (52.0)	246 (37.2)	661	4.21	0.80
8. You need HCP to support the ADR reporting.	20 (3.1)	48 (7.3)	30 (4.6)	310 (47.3)	247 (37.7)	655	1.91	0.99
9. You do not know that the adverse reactions were caused by statins or other causes. (other drugs or diseases)	46 (7.1)	70 (10.8)	197 (30.3)	209 (32.2)	128 (19.7)	650	2.53	1.13
10. You think that reporting ADRs by yourself is difficult.	124 (19.2)	260 (40.3)	67 (10.4)	141 (21.9)	53 (8.2)	645	3.40	1.25
11. You are confident in reporting of ADRs.	18 (2.8)	27 (4.2)	181 (28.1)	279 (43.3)	140 (21.7)	645	3.77	0.93
12. You can report your ADRs accurately.	12 (1.9)	23 (3.6)	**284 (44.0)**	198 (30.7)	129 (20.0)	646	3.63	0.90

[a]Scales on table: 1= strongly disagree, 2= disagree, 3= not sure, 4= agree, and 5= strongly agree.

[b]Scores on negative statements (2,3,5,8,9, and 10) were translated before entering data in SPSS program

Table 3 Frequency, Mean, S.D., and Levels of total attitudinal scores

Level	Mean	S.D.	Median	IQR range	No. of patients(%)
Low	26.25	1.70	26.5	24.5-27.75	4 (0.7)
Moderate	39.38	3.28	40	37-42	401 (65.2)
High	48.40	3.31	47	46-51	210 (34.1)
Total	42.37	5.54	42	39-46	615 (100.0)

Level of overall attitudes: low (12-28), moderate (29-44), and high (45-60)

Factors associated with attitude towards self-reporting ADRs

Univariate analysis showed that attitudinal level was associated with age (p=0.044), number of comorbid diseases (p=0.005), number of concomitant drugs (p=0.017), and total number of reported symptoms (p<0.001) (Table 4).

Multivariate analysis was performed in 469 patients by multiple logistic regression analysis and adjusted for sex, age, education, number of comorbid diseases, number of concomitant drugs, and total number of reported symptoms. Increasing at least 1 comorbid disease (adjusted OR 0.830; 95%CI 0.701,0.982; p=0.030) and reporting more than 5 adverse symptoms (adjusted OR 0.624; 95%CI 0.417,0.934; p=0.022) were significantly associated with having low to moderate level of attitudinal score. (Table 5).

Discussion

Generally, patients had positive attitude towards this ADR self-reporting system. Although the present study was conducted in hospital settings, patients shared similar views to the study based on national surveillance in the Netherlands that they felt responsible for making ADR reports to the authority [14].

The majority of patients perceived that ADRs had effects on their quality of life (67.7%) and understood that they have to inform health professionals about it, even though symptoms were not serious (60.9%). These was confirmed by the previous study which found that ADR reported by patients provided more insight into impact on daily life [15]. Therefore, this patient-reporting method might enhance the detection of non-serious ADRs that are disturbing their well-being in general population. Unlike to the studies in the Netherlands that serious ADRs was the reason that patients submitted

Table 4 Univariate analysis of factors associated with patients' attitude towards self-reporting ADRs

Factors	Number of patients (%)			p-value
	Low and moderate (n= 405)	High (n= 210)	Total (n= 615)	
Sex				
Male	220 (54.3)	121 (57.6)	341 (55.4)	0.435[a]
Female	185 (45.7)	89 (42.4)	274 (44.6)	
Age				
<50 years	40 (9.9)	27 (12.9)	67 (10.9)	0.044[a]
51-70 years	279 (68.9)	155 (73.8)	434 (70.6)	
>70 years	86 (21.2)	28 (13.3)	114 (18.5)	
Educational level				
- Secondary school and lower	208 (51.4)	93 (44.3)	301 (48.9)	0.096[a]
- Bachelor degree and higher	197 (48.6)	117 (55.7)	314 (51.1)	
Number of Comorbid diseases				
None	9 (2.2)	13 (6.2)	22 (3.6)	0.005[a]
1-2	215 (53.1)	125 (59.5)	340 (55.3)	
>2	181 (44.7)	72 (34.3)	253 (41.1)	
Number of concomitant drugs				
No	14 (3.4)	10 (4.8)	24 (3.9)	0.017[a]
1-3	142 (35.1)	96 (45.7)	238 (38.7)	
>3	249 (61.5)	104 (49.5)	353 (57.4)	
Types of statins				
simvastatin	141 (34.8)	63 (30.0)	204 (33.2)	0.435[a]
atorvastatin	132 (32.6)	70 (33.3)	202 (32.8)	
rosuvastatin	132 (32.6)	77 (36.7)	209 (34.0)	
Indication of statin treatment[b]				
Primary prevention	240 (59.3)	121 (57.6)	361 (58.7)	0.695[a]
Secondary prevention	165 (40.7)	89 (42.4)	254 (41.3)	
Duration of statin treatment				
1-90 days	13 (3.2)	9 (4.3)	22 (3.6)	0.323[a]
91-180 days	18 (4.4)	9 (4.3)	27 (4.4)	
181-365 days	33 (8.2)	26 (12.4)	59 (9.6)	
>365 days	341 (84.2)	166 (79.0)	507 (82.4)	
Total number of reported symptoms				
1- 5 symptoms	158 (48.0)	84 (60.0)	242 (51.6)	<0.001[a]
6- 10 symptoms	92 (28.0)	27 (19.3)	119 (25.4)	
> 10 symptoms	79 (24.0)	29 (20.7)	108 (23.0)	

[a]Pearson chi-square test

[b]Indication of statin treatment: Primary prevention (Patients at high risk of cardiovascular events but do not have clinical features of vascular diseases); Secondary prevention (Patients with evidences of Cardiovascular diseases)

Table 5 Multiple logistic regression analysis of factors associated with attitudes towards self-reporting ADRs (Backward LR Method, N=469 patients)

Factors	Crude OR	95% CI	Adjusted OR[a]	95% CI	p-value
Number of comorbid diseases	0.819	0.711,0.945	0.830	0.701,0.982	0.030
Number of total reported symptoms					
1-5 symptoms	1		1		
> 5 symptoms	0.616	0.412,0.920	0.624	0.417,0.934	**0.022**

Factors that significantly affected attitude towards self-reporting of ADRs included number of comorbid diseases and number of symptom reported. Patients who had more disease conditions or experienced more numbers of unusual symptoms might had difficulties in making decision whether symptoms were caused by statins or other causes, therefore, this may discourage them in using this self-reporting questionnaire. It was found that when no other drugs were being used or no other changes had occurred, this would confirm the probability of the suspected ADRs[19].

There were limitations of the present study. Firstly, samples included patients who were diagnosed with chronic diseases in which medications were chronically used. Their views on ADR reporting may differ from patients experiencing ADRs to short-term medications. Secondly, self-administered questionnaire was the only method for ADR reporting in this study. Patients may have limited perspectives on other reporting method. Nonetheless, many attitudes were similar to previous studies that recruited patients taking medications in various classes and provided more reporting methods (i.e. paper form, telephone, website) to patients[13, 14, 17].

Conclusion

Patients were generally appreciated the ADR self-reported method by using symptom checklist questionnaire. However, they still required some essential information including side effects of drugs and comorbid diseases which drastically affected their ability to identify true ADRs. Initiating this ADR reporting system to Thai patients may be promising approach to cooperate the current pharmacovigilance system.

their reports to the centre[13, 14]. The use of symptom checklists in the present study may influence patients in reporting all experienced symptoms including non-serious symptoms in their perspectives. In contrast, patients reporting ADRs to the national pharmacovigilance centre had used the reporting form that may focus them to report what constitutes a serious problems[16]. Patients in the present study also recognized their roles in the prevention of ADRs (67.9%) and did not think that it would be a waste of time to make such reports (86.9%). These views may imply the willingness of patients' involvement in ADR reporting since it was found that the idea of making ADR reports was originally based on most reporters of the Yellow Card Scheme in the UK[17].

Although patients in the present study were confident for reporting and believed that their reports were accurate and complete in details, many of them still needed healthcare professionals to assist in reporting process. Patient reporting of ADRs, however, was the method that healthcare professionals could confirm if patients really had potential ADRs to the suspected drugs[13]. In addition, they expected information about the reactions and medicines from the reporting centre for what they had reported[17]. Patients in the present study also had difficulties when distinguishing symptoms between statins and other causes. In order to cope with these problems, essential approach should be given to patients in two steps; (1) preparing them for self-monitoring and (2) supporting them for ADR assessment. Healthcare professionals should inform patients about potential ADRs[18] and management if any adverse symptoms occur, especially when patients are prescribed drugs for the first time. In addition, when symptoms occur, healthcare professionals should pay attention to patients' complains and provide information to clarify their suspicious.

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