

Knowledge, attitudes and practice of pharmacovigilance among health care professionals in Indonesia

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Abstrak

Latar belakang: Organisasi Kesehatan Sedunia (WHO) mendefinisikan Farmakovigilansi (PV) sebagai ilmu dan kegiatan yang berhubungan dengan deteksi, evaluasi, analisa dan pencegahan terjadinya efek samping yang berhubungan dengan obat. Tujuan PV adalah untuk meningkatkan pelayanan dan keamanan pasien yang mendapatkan obat. Indonesia telah bergabung bersama gerakan pengawasan obat internasional yang digagas WHO sejak tahun 1970, namun pelaksanaan kegiatan ini masih sangat minim. Peran serta tenaga kesehatan pada kegiatan ini juga masih sangat rendah. Survei ini bertujuan untuk menganalisis tingkat pengetahuan, sikap dan perilaku tenaga kesehatan (NAKES) di Indonesia terhadap PV.

Metode: Penelitian ini adalah survei menggunakan kuesioner yang disebarakan secara tertulis dalam seminar kesehatan dan menggunakan media daring. Kuesioner terdiri dari 6 pertanyaan/pernyataan mengenai pengetahuan, 6 pernyataan mengenai sikap, dan apakah NAKES yang menjumpai efek samping telah menanganai dan melaporkan efek samping tersebut dengan baik. Jika responden menjawab benar 80 % dari total pertanyaan pada bagian pengetahuan dan sikap, mereka digolongkan sebagai berpengetahuan atau bersikap baik.

Hasil: Kami menganalisis 109 dari 118 kuesioner yang dibagikan. Sebagian besar responden adalah perempuan (82,6%), dokter (91,7%), dan bekerja di level pelayanan primer. Pengetahuan yang baik tentang PV ditemukan pada 25,7% responden, sementara sikap terhadap PV yang baik 20% responden. Hanya 4 (3,%) dari total responden dapat dikategorikan sebagai pelaku PV yang baik. Kami tidak menemukan hubungan signifikan antara tingkat pengetahuan, sikap dan faktor lain dengan praktik PV yang buruk di antara HCP di Indonesia.

Kesimpulan: Pengetahuan, sikap dan perilaku tenaga kesehatan di Indonesia tentang PV masih rendah. Diperlukan sosialisasi berkelanjutan mengenai PV bagi para tenaga kesehatan di berbagai level. (*Health Science Journal of Indonesia 2016;7:59-63*)

Kata kunci: farmakovigilansi, tenaga kesehatan, keselamatan pasien.

Abstract

Background: World Health Organization (WHO) defines pharmacovigilance (PV) as a science and activities relating to detection, assessment, understanding and prevention of adverse effect or any other drug related problem. It aims to enhance patient care and patient safety in drug use. Although Indonesia has joined WHO international drug safety monitoring program since 1970s, the implementation is not applied effectively especially in developing country and there are poor contribution of health care professionals (HCPs) as an agent of the program. In this study, we assessed current knowledge, activities and practice of PV among HCPs in Indonesia.

Methods: This is a preliminary survey using a questionnaire distributed among HCPs through health seminar and internet. The questionnaire consists of statement/question about knowledge(6), activities(6) and whether HCPs who encounter ADRs handle and report it correctly. If the respondents gave 80 % suitable answers in the knowledge or attitude sections, they were categorized as having "good" knowledge or attitude. We analyzed whether knowledge, attitude and other characteristic had any influence on the respondents PV practice.

Results: We included 109 questionnaires from 118 distributed questionnaires. Most of the respondents were females (90 respondents, 82.6%), medical doctors (100 respondents, 91.7%), and were working in primary health care level. Good knowledge was found in 28 (25.7 %) of respondents, while good attitude towards PV were found in less than 20 % (18) of the respondents. Only 4 (3.7 %) of total respondents did a good pharmacovigilance practice. We found no significant association between level of knowledge, attitude and other factors to the poor practice of PV.

Conclusion: The knowledge, activities and practices of pharmacovigilance among HCPs in Indonesia were poor and requires a continuous socialization among HCPs in different level of care. (*Health Science Journal of Indonesia 2016;7:59-63*)

Keywords: pharmacovigilance, health care professionals, patient safety

World Health Organization (WHO) defines pharmacovigilance as a science and activities relating to detection, assessment, understanding and prevention of adverse effect or any other drug related problem.¹ It aims to enhance patient care and patient safety in drug use. Although WHO has established this program since 1961, the implementation is not applied effectively especially in developing country and there are poor contribution of healthcare professions as an agent of the program.¹

Since 1975, Indonesia has joined the WHO program for international drug monitoring. First it was introduced as MESO (*Monitoring efek samping obat* – Drug adverse events monitoring program) at 6 hospitals in Indonesia. However, Indonesia was just officially joined the WHO program for the International drug monitoring at 1990s.²

Pharmacovigilance activities and training in Indonesia are coordinated by the National Center for Pharmacovigilance under the Indonesian Regulatory Body (Badan Pengawasan Obat dan Makanan–BPOM). There are two ways to report adverse drug reactions (ADRs) in Indonesia, the first one using paper form (known as the "yellow form" and via online at <http://e-meso.pom.go.id/>). The activities depend on voluntary report from health care professionals (HCPs) and obligatory reporting from the pharmaceutical industries. In addition, the ministry of health coordinate a structured PV program for three specific drugs : HIV-AIDS, anti tuberculosis and anti-Malarial.²

Indonesia also joined the WHO-UMC collaborating centre for international drug monitoring. This, all report received by the national centre for pharmacovigilance were forwarded to the international centre in Upsala, Sweden through the Vigimed.^{2,3}

Until now, there is no data yet on practice of PV in Indonesia, especially among HCPs. Thus this preliminary survey aims to describe the level of knowledge, attitude and practice of pharmacovigilance among HCPs in Indonesia.

METHODS

A survey was conducted between February to November 2015 using our self-generated questionnaire. There are two version of questionnaires: paper and online. The paper questionnaires were distributed in three continuing medical education (CME) programs, conducted at February, March and November 2015. Respondents of online questionnaire were openly invited using social media (Facebook and Twitter) at early February and early March 2015.

Questionnaires development

An original questionnaire in Bahasa Indonesia were developed by the investigators. An independent external reviewer was asked to evaluate the questionnaire. A final draft paper version of the questionnaire was then tested among eight health care practitioners (testing respondents). After independently filled in the questionnaire, each testing respondents were asked whether they have any difficulty in understanding the questions and we noted the time needed to fill in the questionnaire.

The test within testing respondents showed that the questionnaire was easy to understand, and took in average 10-15 minutes to complete. Minor language changes was made in the final version of the questionnaire to enhance comprehension. Responses from the testing respondents were not included in the final analysis. Subsequently, an Online version of the final version of the questionnaire was made using Google Docs.

Type of questions

The questionnaires consists of four different sections. In the first section, respondents were asked for their demographic data and health care practice experiences. The second until fourth sections discusses the knowledge, attitude and practice of the health care practitioners towards adverse drug reactions, pharmacovigilance policies and activities.

There are six questions on knowledge and six questions on attitudes. Questions on knowledge include knowledge on definition of ADRs, reporting procedure of ADRs, reason for ADRs reporting and methods to send ADRs reports to the regulatory authority. For attitudes, we asked the respondents agreement on different statements: whether an ADRs need to be reported to the regulatory authority, determination of ADRs causality in the reports and their agreement on obligatory reporting for pharmaceutical industry.

In terms of practice, respondents were asked to recall their experience in handling adverse drug reactions in the last 6 months using structured questions. In addition we asked whether they ever received any information on drug safety in the last 6 months.

Ratings and data analysis

All sections were analyzed descriptively. Scoring was done for sections on knowledge and attitude. Each correct answer on knowledge and preferable answers on attitude towards pharmacovigilance was scored "1". Respondents who responded correctly or preferably for more than 80 % of the questions in

those section were categorized as “good”. Good PV practice was defined as when a HCP encounter adverse event, they will treat, record the event in medical reports and report the event to regulatory authorities. Data analysis were conducted using SPSS version 20.

RESULTS

In the final analysis, we included 109 questionnaires from 118 distributed questionnaires. Nine questionnaires were excluded from the analysis due to incomplete responses. Most of the respondents (87, 79.8 %) filled in the paper questionnaire, while the others filled in the online questionnaire. Most of the respondents were females (90 respondents, 82.6%), medical doctors (100 respondents, 91.7%), and were working in primary health care level. Most of them (66, 60.6 %) had less than 30 patients per day and 78 % of respondents regularly prescribes chronic medications for their patients (Table 1).

Good pharmacovigilance knowledge was found in 28 (25.7 %) of respondents, while good attitude towards PV were found in less than 20 % (18) of the respondents. Sixty-two respondents (56.9 %) of participants have encounter patients with a drug’s adverse drug events in the past 6 months. However, only 4 of them (3.7% of total respondents, 6.4 % of HCP who ever encounter adverse events in their practice) did a good pharmacovigilance practice. Interestingly, all of the HCP with good PV practice were female medical doctors work in primary health care.

Table 1. Characteristic of the respondents (n=109)

Characteristics	n (%)
Female	90 (82.6)
Type of health care profession :	
- Medical doctor	100 (91.7)
- Nurse	3 (2.8)
- Pharmacist	1 (0.9)
- Others (midwives, etc)	5 (4.6)
Level of health care :	
- Primary	92 (84.4)
- Secondary	11 (10.1)
- Tertiary	6 (5.5)
Average number of patients in a day	
- Less than 10	33 (30.3)
- 11 – 29	33 (30.3)
- 30 – 50	21 (19.3)
- More than 50	22 (20.2)
Treat chronic patients with chronic medications	85 (78.0)
Have a good knowledge on pharmacovigilance	28 (25.7)
Have a good attitude towards pharmacovigilance	18 (16.5)
Ever suspected or received complaints of an adverse event	62 (56.9)
Conduct a good pharmacovigilance practice	4 (3.7)

The most common symptoms suspected by HCP as an ADRs were mild to moderate ADRs including skin allergic reactions, gastrointestinal discomfort or oedema of the palpebra. Only one HCP reported a serious event of Steven Johnson. The most common suspected ADRs complained by their patient were pruritus and nausea.

Most of the HCPs that ever encounter adverse event in their practice (29 out of 62) treated the adverse event and stop the suspected drugs, without recorded it in the medical record or reported the event to the regulatory authorities. Most of the respondents said that they never receive any update safety information of a drug in last six month (77 respondents, 70.6 %). Among respondents that had received update safety information of a drug, half of them (16 out of 32 respondents) got the information from the pharmaceutical industries.

In table 2, we describe the knowledge and attitudes items in details. More than half of the respondents (56 respondents, 53.3 %) of respondents answered the definition of pharmacovigilance correctly. Most of the respondents aware that they were expected to voluntarily report the side effect of a drug (65 respondents, 59.6 %). Only 21 (19.3 %) of the respondents aware of the “yellow form” and only 10 (9.2%) of respondents knew about PV website from BPOM.

Almost all of the respondents (104 respondents, 95.4 % of respondents agree that an adverse event should be reported to the BPOM. More than 95 % of the respondents expects a reply from the BPOM if they do the adverse event reporting. Interestingly, 67.9 % (74) respondents did not agree if the requirement for adverse event reporting is only obligatory for the pharmaceutical industry and 66.1 % (72) did not mind if the industry contacting them to obtain more information on certain adverse event.

In table 3 we describe the influence of knowledge, attitude and other demographic factors towards practice of pharmacovigilance. Although being a female HCP and saw more than 30 patients per day seems to be resulted in a good pharmacovigilance practice, the relationship were not statistically significant. There are no relationship between good knowledge and good attitude with practice of PV among HCP.

Table 2. Knowledge and attitudes of respondents towards PV (N=109)

	Knowledge		Attitudes	
		n (%)		n (%)
Correct definition of ADRs and unintended drug effect	56 (53.3)		ADRs should be reported to BPOM	104(95.4)
Voluntary ADRs reporting	65(59.6)		Regulatory agency need to give feedback of ADRs reports	104 (95.4)
Report the ADRs to regulatory agency	49 (47.6)		Causality of ADRs need to be determined before the report can be submitted	23 (21.1)
Reason why ADRs need to be reported	79 (72.5)		Any HCPs who report ADRs should determine the causality	6 (5.5)
Aware about “Yellow form”	21 (19.3)		Not only pharmaceutical industry need to report ADRs	74 (67.9)
Regulatory agency website for PV	10 (9.2)		The pharmaceutical industry may contact the doctor for more information in the light of ADRs reporting	72 (66.1)

Note: ADRs =adverse events, PV = Pharmacovigilance, BPOM = Badan Pengawasan Obat dan Makanan – Indonesian regulatory agency.

Table 3. Comparison of respondents knowledge, attitude and demographic factors with their pharmacovigilance practice (n=62)

	Practice of Pharmacovigilance			
	Good (%)	Poor (%)	Relative risk (95 % CI)	p*
Good knowledge	1(10.0)	9(90.0)	0.95 (0.16 – 5.7)	0.46
Good attitudes	1(25.0)	3(75.0)	0.32 (0.04 – 2.4)	0.32
Female	3 (8.8)	31(91.2)	1.12 (0.62- 2.00)	0.67
Medical doctor	4 (9.8)	37 (90.2)	0.97 (0.92 – 1.02)	0.84
Work in primary clinics	4 (10.3)	35 (89.7)	0.92 (0.84 – 1.01)	0.72
Saw more than 30 patients in a day	2 (9.1)	20 (90.9)	1.05(0.38 – 2.93)	0.92
Treat chronic patients with chronic medications	4 (10.8)	33(89.2)	0.87 (0.77 – 1.00)	0.64

* Cox-regression with a dummy time variable of 40

DISCUSSION

In this survey we found that knowledge and attitudes of PV among health care professionals in Indonesia were very low. Thus, it is not suprisingly, the practice of PV among health care profesional were also very poor, where less than 4 % of our respondents had a good PV practice.

The low level of knowledge, attitude and practice found in this study was similar with findings in other countries. A systematic review of studies on PV activities in India showed that 55.6% of HCPs were not aware of the existence of the national PV programme. In addition, 28.7% of HCPs were not interested in reporting ADRs and 74.5% admitted that they never reported any ADRs to PV centers.⁴

In our survey we only found that less than one tenth of HCPs that ever encounter any ADRs in their practice reported it corectly to the regulatory authorities. This

number is slightly low compared to HCPs in India where 25 % of them has made the report. However, the respondents in our survey show a better attitude towards PV reporting with more than 90 % agree that ADRs should be reported to the regulatory bodies, while in India only 67 % of HCPs were interested to report ADRs to the PV centres.⁴

The clinical symptoms recognized by our respondents as ADRs were usually mild skin allergic reactions and gastrointestinal discomfort. This should not be suprising as more than 75 % of our respondents work in primary health care level. More severe adverse events were found in similar studies with HCPs working in hospitals as their respondents.⁵⁻⁷

Results from our survey has shown that although efforts to train HCP on PV voluntary reports had been conducted in the past, a low level of knowledge, attitude and practice of PV still found among Indonesian HCPs. New innovative efforts to train

HCPs in practice of PV need to be done continuously. A study in the Netherlands has shown that by a practice based training showed a better retainer of PV knowledge and practice among general practitioners compared to lecture-based training.⁸

We observed that female primary-care doctors with more than 30 patients per day seems to perform better in terms of PV reporting. However, we did not find any statistically significance association between sex, work-settings, type of HCPs and number of patients per day with the practice of PV. Previous studies in various population settings had pointed out that in general, knowledge, attitude and practice of any HCPs towards PV reporting were low.^{9–11} Similar low rate good PV practice were also found in tertiary hospital.¹² Thus, education efforts on PV should be targeted to all type of HCPs regardless of their work background.

The education efforts need also be accompanied with a constant reminders on the PV system itself. In our survey, we found that the PV practice were not associated with good knowledge and awareness on requirement for voluntary PV reporting. A similar study among doctors and nurses found that although they had good knowledge and awareness on ADRs and PV reporting, their practices need to be improved.¹³

This survey had limitations. First, we only analyzed data from 109 HCPs from thousands of health care professionals in Indonesia, thus our results might not be representative. Second, respondents were recruited via social media, thus the reason for non-participation and rate of response could not be recorded. However, our survey includes mostly primary care doctors, thus may give description on PV situation in non-hospital settings.

Drug safety monitoring should be conducted continuously to evaluate the consistency of risk-benefit ratio profile of a drug. The monitoring relies heavily on voluntary information collected by HCPs. It also needs close collaborations of all its key players: the regulatory bodies, ministry of health, HCPs, academia and pharmaceutical industries. All stakeholders have their own roles in PV with the main goal of maintaining patient safety.

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