



Healthcare Professionals' Attitudes towards Adverse Drug Reactions Reporting in Primary Healthcare Settings: A Cross-sectional Survey

Cindra Tri Yuniar^{1*}, Rizka Zu Fadhilah¹, Kusnandar Anggadiredja¹, Lia Amalia¹

¹ Department of Pharmacology and Clinical Pharmacy, School of Pharmacy, Bandung Institute of Technology, Jl. Ganesha 10, Bandung, West Java, Indonesia

ARTICLE INFO

Submitted : 20-07-2023

Revised : 02-01-2024

Accepted : 18-01-2024

Published : 31-03-2024

Corresponding Author:

Cindra Tri Yuniar

Corresponding Author Email:

cindra@itb.ac.id/cindra.itb@gmail.com

ABSTRACT

Background: Spontaneous Adverse Drug Reactions (ADRs) reporting is a key to improving the post-marketing safety of medicines. The important factor of under-reporting is lack of awareness for the purpose of ADRs monitoring and reporting. Spontaneous reporting is performed by the patients or consumer to the healthcare professionals and/or industry, then the healthcare facilities and industry should report the suspected ADRs to the National Agency of Drugs and Food Control (NADFC). To date, there is a lack information and study about attitudes on ADRs reporting by healthcare professionals (HCPs), especially in primary healthcare settings.

Objectives: The aim of this study was to identify the attitudes towards ADRs reporting by healthcare professionals (HCP).

Methods: This research was survey study with cross-sectional design, from November 2022-March 2023. The questionnaire, that have been validated and reliable, was distributed to 3 primary healthcare facilities. demographic data questions (6 items), experiences (3 items), knowledge (4 items), and motives for reporting (1 item).

Results: Total 39 HCPs completed the survey, including 14 nurses, 9 midwives, 3 general physicians, 3 pharmacists, and 10 other professions. Most of respondents were women (84.6%), and mostly the HCPs have been working for ≥ 5 years (74.3%). Among 39 respondents, only 1 pharmacist have a good attitude about ADRs reporting. The other HCPs had a lack of knowledge and safety awareness. The dominant motives for reporting the ADRs was serious or severe ADRs (39.4%) and the assurance of causality assessment by suspected drugs (15.4%).

Conclusion: In conclusion, the HCPs in primary healthcare settings had poor attitudes towards ADRs reporting.

Keywords: ADRs reporting; attitude; healthcare professionals; primary healthcare

INTRODUCTION

Adverse drug reactions are defined as a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function, based on WHO definition term.¹ The adverse drug reactions (ADRs) are natural of all drug therapy and inflected by several factors, including dose and frequency of administration, genotype, and pharmacokinetic characteristics of special populations, such as paediatric and geriatric patients and those with hepatic or renal impairment. ADRs would lead to hospital admission, prolonged-hospitalization, and emergency department visits.² In 2016, the ADRs report involving older adults (>65 years old) is 5367 reports in Germany, which the highest report in age groups 76–84 and 70–79.³

The early detection of signals, rare, or serious ADRs will be obtained from spontaneous reporting.⁴ Spontaneous ADRs reporting is key to improving the post-marketing safety of medicines.⁵ One systematic review across 12 countries showed that the median under-reporting rate was 94%.⁶ The important factor of under-reporting is lack of awareness for the purpose of ADRs monitoring and reporting.⁵

In Indonesia, the ADRs report (paper based/website) voluntarily reported by healthcare professionals (HCPs) to the National Agency of Drug and Food Control (NADFC) using special form, called yellow form (paper based) or the digital form in the government website.⁷ Along with that, healthcare professionals have an important role to monitor and report the ADRs. Spontaneous reportings are performed by the patients or consumer to the healthcare professionals and/or industry, then the healthcare facilities and industry should report the suspected ADRs to the NADFC. Study from Musdar et al. showed that pharmacists in Indonesia had a good knowledge about the objective of ADRs reporting but only 46.9% pharmacists known about how to report the suspected ADRs to the NADFC.⁸

Primary healthcare facilities or locally called Puskesmas have an important role to serve the first healthcare services in national healthcare coverage program. To date, there was a lack information and study about ADRs reporting in primary healthcare facilities, especially about the attitude of HCPs. The aim of this study was to identify the attitudes of healthcare professionals on ADRs monitoring and reporting.

METHODS

Study settings

The study was a cross-sectional design using questionnaire, from November 2022 – March 2023. The questionnaire distributed online using Zoho[®] form in Puskesmas Ibrahim Adjie, Puskesmas Padasuka, and Puskesmas Garuda in Bandung area, Indonesia.

Population and Sample

The purposive sampling technique was applied to this study through population in three Puskesmas. The general physician, specialist physician, dentist, pharmacist, nurse, midwife, and other HCPs such as nutritionist or radiologist, were eligible to participate in the study. Inclusive criteria were men or women with age ≥ 18 years old and have been practiced for at least six months. The uncomplete data in questionnaire would lead to exclusion.

Study Instrument

The data was collected using a self-administered questionnaire, consists of demographic data questions (6 items), experiences (3 items), knowledge (4 items), and motives for reporting (1 item). The outcome measure of this study was responders' attitudes for ADRs reporting. The item surveys were discussed between researcher after study literature using Indonesian version and validated to 30 HCP respondents before study. The validity and reliability test were conducted using Pearson Product Moment, Kuder Richardson-20 (KR-20) and Cronbach's Alpha test. All the questions were valid ($r > 0.553$), acceptable (KR-20 score = 0.803), and reliable ($\alpha = 0.718$).

Data Analysis

The data collected through Zoho[®] form were recorded and retrieved in .xlsx format. Descriptive data and chi-square statistical analysis have been completed by IBM SPSS v.26.

RESULTS AND DISCUSSION

Demographic data

A total of 56 valid questionnaire were distributed and only 39 respondents (69.6%) agreed to filled out that completely. More than half of respondents were women (85%) and nurse (36%). As shown in Table I, about 33% respondents have been working for more than 20 years.

Experiences on ADRs handling

Overall, 17 respondents (43.6%) claimed to have experience on handling ADRs reported spontaneously by patient. Only 1 general physician had an experience on handling ADRs, but almost the ADRs case received by nurse (29.4%) and midwife (35.3%) in primary healthcare facilities. These results similar with the study in Pakistan that showed the ADRs reporting usually sent by patients to nurse.⁹ The characteristics of healthcare professionals in this study slightly different with other study about ADRs reporting, because of different clinical settings.^{10,11,12}

Table I. Demographic data

Characteristics	N (%)
Gender	
Male	6 (15.4)
Female	33 (84.6)
Profession	
Nurse	14 (35.9)
Pharmacist	3 (8)
General physician	3 (8)
Midwife	9 (23.1)
Other medical staff	10 (25.6)
Working experiences (years)	
<5	10 (25.6)
5 – 10	10 (25.6)
10 – 20	6 (15.4)
>20	13 (33.3)
Experiences on ADRs handling	
Yes	17 (43.6)
No	22 (56.4)

The ADRs monitoring and reporting more familiar in hospital setting than primary healthcare. A scoping review in Australia showed the ADRs mostly reported by hospital pharmacist compared with physician. Community pharmacists also received the ADRs report by the patients but only 40% of patients satisfied with the warning card in community pharmacists.¹³ Study in Sri Lanka showed although most HCP selected the correct definitions of ADRs and pharmacovigilance, the majority of HCP did not aware of the types of ADRs, banned drugs due to ADRs and ADRs reporting centers.¹⁴

Attitudes on ADRs reporting

The HCPs attitudes on ADRs reporting assessed by five item questions about reporting system applied in Indonesia by NADFC. The questions were a 2-point scale (yes/no), and the positive attitude expressed by the total score more than two. Among 39 respondents, only one pharmacist showed a positive attitude on ADRs reporting (Table II). The pharmacist usually had a good knowledge and attitude about ADRs.^{10,11} Different result showed in study held in Thailand that the physician had the highest score of attitudes, followed by pharmacist and nurse. But the overall mean attitude scores were not significantly different between physician, pharmacist, and nurse.¹⁵

Most respondents had a poor attitude towards ADRs monitoring or reporting. Study in Thailand showed that around 40% of all HCPs have a positive attitude towards severe ADRs monitoring, which is a lower proportion than the previous studies.^{11,16–18} The HCPs agreed that the management of severe ADRs could improve patient compliance, confirming a previous study that found that ADRs influence medication adherence.¹⁵ In the current study, the HCP respondents agreed that it can be difficult to differentiate between severe ADRs and adverse events with other causes, as found in the previous studies.^{17,18} Underreporting has been a global problem even in countries with more organized pharmacovigilance systems. The most common reasons for underreporting were being lack of time, uncertainty about ADRs diagnosis, what and where to report, difficulty in handling report forms, and lack of awareness of the reporting system requirements.¹⁹

Awareness among healthcare professionals, collaboration among other healthcare professionals and training for healthcare professionals were the highly suggested ways to improve ADRs reporting. Healthcare professionals believed that making ADRs reporting, a professional obligation and involved pharmacists for ADRs reporting can also improve ADRs reporting.²⁰

The healthcare professionals in Indonesia more familiar with the paper reporting method using yellow form than website or mobile app for ADRs reporting. This method is preferable because of the easier access to report the incidence immediately without electronic devices, such as handphone or computer, and internet connection. In the other hand, the paper method was applied as preliminary data before the clinical judgement and causality assessment in the facilities.

Most of the physicians and pharmacists were more concerned about ADRs, which are serious, including hospitalization, causing death or disability or reactions to newly marketed products, while nurses were even concerned about the reporting of both the minor and major types of reactions to drugs.²¹ This perception could be due to the reason that usual or minor ADRs are inevitable and do not cause much harm. However, serious, or life-threatening reactions may endanger the life of patient, and thus should be reported.

Table II. Attitudes on ADRs reporting by HCPs

Statement (Attitude on...)	N				
	Physician	Pharmacist	Nurse	Midwife	Other
Using yellow form for ADRs reporting	2	1	9	5	4
Using E-Meso website for ADRs reporting	0	0	0	0	0
Using Mobile app e-Meso for ADRs reporting	0	0	0	0	0
Reporting ADRs to quality committee in healthcare facility	1	2	5	4	6

The current study has some limitations. It was conducted only in the northeastern region of Bandung area. Hence, our findings may not be generalized to all HCPs in Bandung or Indonesia. Moreover, the gathered findings were obtained from self-administered questionnaire, which may be subject to recall and social desirability biases.

CONCLUSION

The HCPs in primary healthcare settings had poor attitudes towards ADRs reporting. The paper method using yellow form were more familiar for HCPs than website and mobile app for ADRs reporting. The intervention to increase ADRs reporting by healthcare professionals is needed.

ACKNOWLEDGEMENT

Authors thanks to Ikatan Apoteker Indonesia (IAI) West Java region for the support and the hospitality to all staffs in Puskesmas Ibrahim Adjie, Sukarasa, and Garuda during the research.

CONFLICT OF INTEREST

None to declare.

STATEMENT OF ETHICS

Approval for the study was obtained from Institutional Review Board, Fakultas Kedokteran, Universitas Padjadjaran, Bandung, No. 912/UN6.KEP/EC/2022 on September 16, 2022. Each respondent was informed about the study on the first page of the forms and continued to fill in the questions if they agreed to participate in the study.

REFERENCES

1. Edwards. I Ralph, Aronson JK. ADR definition. *The Lancet*. 2000;356:1255-1259. doi:[https://doi.org/10.1016/S0140-6736\(00\)02799-9](https://doi.org/10.1016/S0140-6736(00)02799-9)
2. Sultana J, Cutroneo P, Trifirò G. Clinical and economic burden of adverse drug reactions. *J Pharmacol Pharmacother*. 2013;4(SUPPL.1). doi:10.4103/0976-500X.120957
3. Dubrall D, Just KS, Schmid M, Stingl JC, Sachs B. Adverse drug reactions in older adults: A retrospective comparative analysis of spontaneous reports to the German Federal Institute for Drugs and Medical Devices. *BMC Pharmacol Toxicol*. 2020;21(1). doi:10.1186/s40360-020-0392-9
4. Kennedy D, Goldman S, Lillie R. Spontaneous reporting in the United States. In: *Pharmacoepidemiology*. 3rd ed. John Wiley&Sons; 2000:151-174.
5. Paudyal V, Al-Hamid A, Bowen M, et al. Interventions to improve spontaneous adverse drug reaction reporting by healthcare professionals and patients: systematic review and meta-analysis. *Expert Opin Drug Saf*. 2020;19(9):1173-1191. doi:10.1080/14740338.2020.1807003
6. Hazell L, Shakir SAW. *Under-Reporting of Adverse Drug Reactions A Systematic Review*. Vol 29.; 2006.
7. BPOM RI. *Pedoman Monitoring Efek Samping Obat (Meso) Bagi Tenaga Kesehatan*.; 2012.

8. Musdar TA, Nadhafi MT, Lestiono L, Lichijati L, Athiyah U, Nita Y. Faktor yang Mempengaruhi Praktik Pelaporan Adverse Drug Reactions (ADRs) oleh Apoteker di Beberapa Rumah Sakit di Surabaya. *JPSCR: Journal of Pharmaceutical Science and Clinical Research*. 2021;6(2):96. doi:10.20961/jpscr.v6i2.49794
9. Hussain R, Akram T, Hassali MA, et al. Barriers and facilitators to pharmacovigilance activities in Pakistan: A healthcare professionals-based survey. *PLoS One*. 2022;17(7 July). doi:10.1371/journal.pone.0271587
10. Hussain R, Hassali MA, Hashmi F, Akram T. Exploring healthcare professionals' knowledge, attitude, and practices towards pharmacovigilance: a cross-sectional survey. *J Pharm Policy Pract*. 2021;14(1). doi:10.1186/s40545-020-00287-3
11. Gidey K, Seifu M, Hailu BY, Asgedom SW, Niriayo YL. Healthcare professionals knowledge, attitude and practice of adverse drug reactions reporting in Ethiopia: A cross-sectional study. *BMJ Open*. 2020;10(2). doi:10.1136/bmjopen-2019-034553
12. Sendekie AK, Netere AK, Tesfaye S, Dagne EM, Belachew EA. Incidence and patterns of adverse drug reactions among adult patients hospitalized in the University of Gondar comprehensive specialized hospital: A prospective observational follow-up study. *PLoS One*. 2023;18(2 February). doi:10.1371/journal.pone.0282096
13. Tagne JF, Yakob RA, Dang TH, McDonald R, Wickramasinghe N. Reporting, Monitoring, and Handling of Adverse Drug Reactions in Australia: Scoping Review. *JMIR Public Health Surveill*. 2023;9. doi:10.2196/40080
14. Thilini Madhushika M, Jayasinghe SS, Liyanage PGC, Dilan Malinda WA, Abeykoon P. Knowledge, Attitudes, and Practices of Adverse Drug Reaction Reporting Among Healthcare Professionals in Sri Lanka- A Cross Sectional Study. *Hosp Pharm*. Published online 2023. doi:10.1177/00185787231194988
15. Srisuriyachanchai W, Cox AR, Jarernsiripornkul N. Exploring Healthcare Professionals' Practices and Attitudes towards Monitoring and Reporting of Severe Adverse Drug Reactions. *Healthcare (Switzerland)*. 2022;10(6). doi:10.3390/healthcare10061077
16. John LJ, Arifulla M, Cheriathu JJ, Sreedharan J. Reporting of adverse drug reactions: An exploratory study among nurses in a teaching hospital, Ajman, United Arab Emirates. *DARU, Journal of Pharmaceutical Sciences*. 2012;20(1). doi:10.1186/2008-2231-20-44
17. Adisa R, Omitogun TI. Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in Ibadan, southwestern Nigeria. *BMC Health Serv Res*. 2019;19(1). doi:10.1186/s12913-019-4775-9
18. Al-worafi YM. Knowledge, Attitude and Practice of Yemeni Physicians Toward Pharmacovigilance: A Mixed Method Study. *Int J Pharm Pharm Sci*. 2018;10(10):74. doi:10.22159/ijpps.2018v10i10.27407
19. Güner MD, Ekmekci PE. Healthcare professionals' pharmacovigilance knowledge and adverse drug reaction reporting behavior and factors determining the reporting rates. *J Drug Assess*. 2019;8(1):13-20. doi:10.1080/21556660.2019.1566137
20. Kc S, Tragulpiankit P, Gorsanan S, Edwards IR. Attitudes among healthcare professionals to the reporting of adverse drug reactions in Nepal. *BMC Pharmacol Toxicol*. 2013;14. doi:10.1186/2050-6511-14-16
21. Almandil NB. Healthcare professionals' awareness and knowledge of adverse drug reactions and pharmacovigilance. *Saudi Med J*. 2016;37(12):1350-1355. doi:10.15537/smj.2016.12.17059