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Knowledge, Attitude, Practice, and Barriers of Adverse Drug Reaction Reporting Among Healthcare Professionals in Timor-Leste: A Cross-Sectional Survey

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ABSTRACT

The Timor-Leste Pharmacovigilance (PV) became an associate member of the WHO Programme for International Drug Monitoring in 2019; however, the adverse drug reaction (ADR) reporting rate remains low, with only nine reports per 1342 million inhabitants over 5 years. This study aimed to evaluate the knowledge, attitude, practice, and barriers related to ADRs, pharmacovigilance, and ADR reporting among healthcare professionals (HCPs) in Timor-Leste. A cross-sectional survey with a validated, self-administered questionnaire was conducted among 600 HCPs, including clinical doctors, nurses, and pharmacy employees from one national referral and five referral hospitals. Of the 461 HCPs who responded (76.8% response rate), 98 were clinical doctors (21.3%), 311 nurses (67.4%), and 52 pharmacy employees (11.3%). The knowledge score on ADRs was 3.81 ± 0.36 out of 8, with clinical doctors, nurses, and pharmacy employees scoring 4.49 ± 0.51, 3.47 ± 0.24, and 4.56 ± 0.26, respectively. On pharmacovigilance and ADR reporting, the score was 3.00 ± 0.16 out of 8, with clinical doctors, nurses, and pharmacy employees scoring 3.36 ± 0.26, 2.81 ± 0.08, and 3.50 ± 0.24, respectively. All scores referred to the number of correctly answered questions. Positive attitudes were observed, with 53.4% agreeing that ADR reporting is crucial for drug safety, although only 22.0% reported observed ADRs. Key barriers included unavailability of reporting forms (81.0%), insufficient financial support (71.9%), and lack of reporting by colleagues (71.4%). These findings highlight the need for increased awareness, training, and resources to improve ADR reporting in Timor-Leste.

1 | Introduction

Timor-Leste is a small country in Southeast Asia located in the middle of Australia and Indonesia with a total population of 1342 million in 2022 and an approximate area of 14,950 km^2 [1, 2]. The government provides free public healthcare services for all Timorese people, including medicines [3]. The Ministry of Health established the Drug Act in May 26, 2010, which includes a thorough set of drug regulations. In 2018, the National Directorate of Pharmacy and Medicines (NDPM) updated the new Drug Act. However, this has not yet been passed in parliament, and it is currently awaiting approval by the Ministry of Health. Nevertheless, it needs the full implementation of the Drug Regulatory Authority [4]. The NDPM is equivalent to the national regulation authority; it is divided into three departments: Pharmaceutical Planning and Management of Acquisitions, Marketing Authorization, and Pharmacovigilance and Medicine Control [5, 6].

Summary

- What is the current knowledge on the topic?
  - ADR reporting is a critical component of pharmacovigilance, which ensures the safety and efficacy of medications.
  - However, there is often a gap between the importance of ADR reporting and the actual practices of HCPs, and inadequate knowledge leads to underreporting.
- What question did this study address?
  - Conclusive data on healthcare professionals' (HCPs) knowledge, attitudes, practices (KAP), and barriers remain limited. This study aimed to assess the current KAP and barriers to address and resolve them.
- What does this study add to our knowledge?
  - The study provides a comprehensive assessment of the current level of knowledge among HCPs in Timor-Leste regarding ADR reporting and valuable insights into the attitudes and practices of HCPs in Timor-Leste concerning ADR reporting.
  - Identifying gaps in knowledge and awareness offers valuable insights that can inform the development of targeted strategies to improve ADR reporting practices and enhance the overall pharmacovigilance system in the region.
  - Key strategies such as enhancing training programs, establishing a continuous feedback loop, incentivizing reporting behavior, and collaborating with professional associations would more effectively bridge the gap in ADR reporting practices.
- How might this change clinical pharmacology or translational science?
  - Our findings lead to more effective monitoring of drug safety, improved patient outcomes, and the advancement of pharmacovigilance practices, thereby bridging the gap between clinical research and practical healthcare applications.

Pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem" [7]. Timor-Leste adopted the practice of pharmacovigilance in 2016, mainly governed by the NDPM. Afterward, in 2018, the Pharmacovigilance Department sent three pharmacists for basic pharmacovigilance and adverse drug reaction (ADR) monitoring and reporting training [6, 8]. In 2019, the Timor-Leste pharmacovigilance became an associate member of the World Health Organization (WHO) Program for International Drug Monitoring at the Uppsala Monitoring Center [6]. From 2019 to 2023, the total number of individual case safety reports available at the pharmacovigilance department was 9: 4 cases were reported in 2019 during September–November, followed by 4 cases in 2020 during October, and the last case was reported in April 2023 [9].

According to the WHO, an ADR is "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" [10]. The spontaneous reporting system (SRS) of ADRs is important in the monitoring of unexpected events and uncommon ADRs, and it acts as a safeguard for medication safety. However, underreporting is a significant limitation of the SRS; only nine ADR reports have been sent to the pharmacovigilance center. The knowledge, attitude, practice (KAP), and barriers of healthcare professionals (HCPs) regarding ADRs and ADR reporting greatly contribute to the practice of pharmacovigilance. On the basis of the National Health Sector Strategic Plan (NHSSP) 2020, the total number of HCPs is 3688. They are composed of 35 specialist doctors, 889 general doctors, 1499 nurse and auxiliary nurses, 618 midwives, and 647 allied hospital package services (HPS) [11].

Background data regarding the KAP and barriers of HCPs can help develop strategies to improve ADR reporting and the pharmacovigilance system, but these have not been determined in previous literature. This study aimed to evaluate the current KAP and barriers of HCPs in Timor-Leste regarding pharmacovigilance and ADR reporting.

2 | Methods

2.1 | Study Design and Data Collection

A cross-sectional study using a survey-based questionnaire was administered in one national referral hospital (National Referral Hospital Guido Valadares) and five referral hospitals in Timor-Leste (referral hospitals Baucau, Maubessi, Suai, Maliana, and Oecussi). The survey was conducted among specialist doctors, general doctors, dentists, nurses, midwives, pharmacists, and pharmacy technicians from February 2024 to April 2024. HCPs were categorized into three groups: physicians and dentists (Group 1: clinical doctors), nurses and midwifes (Group 2: nurses), and pharmacists and pharmacy technicians (Group 3: pharmacy employees). Overall, 600 questionnaires were distributed, of which 320 were distributed to National Referral Hospital Guido Valadares, whereas 75, 55, 50, 50, and 50 were distributed to Referral Hospitals Baucau, Maubessi, Suai, Maliana, and Oecussi. In total, these hospitals had 163 clinical doctors, 374 nurses, and 63 pharmacy employees.

2.2 | Data Collection Tools and Methods

A self-structured, and validity- and reliability-tested questionnaire was used as a data collection tool. This questionnaire included a cover letter that provided information about the aim and purpose of the study, the expected number of participants, procedures for responding to the questionnaire, and the participants' right to withdraw. Reminders were sent to participants every 2 weeks; after 3 months, the researcher collected all the questionnaires from the pharmacy departments of each hospital. The questionnaire consisted of two sections. Section A was designed to obtain demographic information on the participants, whereas Section B consisted of 33 questions. There were 16 multiple-choice questions investigating HCPs' level of knowledge on ADRs, pharmacovigilance, and ADR reporting. Questions 1–8, 9–11, and 12–16 were related to knowledge on ADRs, pharmacovigilance, and ADR reporting, respectively. "Good, fair, and poor knowledge were defined as correct

answering ≥6, 3–5, and ≤2 out of 8 questions." The remaining 17 questions were related to attitude, practice, and barriers. The questions related to attitude were composed of four statements using a Likert scale in which 1 was *strongly disagreeing* and 5 was *strongly agreeing*; the questions related to practice contained five closed-ended questions and eight questions on barriers (supplement file for the questionnaire).

2.3 | Questionnaire Development

The questionnaire was tested for content validity and objectivity through the consensus of a panel of experts comprising Associate Professor Pramote Tragulpiankit (Mahidol University, Bangkok, Thailand), Dr. Watcharee Rungapiromman (Health Product Vigilance Center, Food and Drug Administration, Ministry of Public Health, Nonthaburi, Thailand), Agatha E. Santos (National Referral Hospital Guido Valadares, Timor-Leste), and Agil Bredly Musa (Dr. Cipto Mangunkusumo Hospital, Indonesia). The questionnaire was modified based on their comments. A pilot study for reliability testing was carried out at National Referral Hospital Guido Valadares. The questionnaire was evaluated by calculating the Cronbach's alpha of the filled questionnaires using SPSS software (version 18.0). Following the rule of George and Mallery (2003) [12] to interpret the output, the Cronbach's alpha of 0.857 for 33 questions was classified as good. Afterward, the questionnaires were translated into Tetum, the mother tongue of Timor-Leste, by a pharmacist with experience in ADR monitoring and fluent in English. After translation, another Timorese pharmacist who works as the antimicrobial steward at all the hospitals included in this study retranslated the questionnaire from Tetum to English. The questionnaires were distributed after final approval from both the Institutional Review Board (MU-DT/PY-IRB) of Mahidol University, Faculty of Dentistry/Faculty of Pharmacy, and the Unit of Ethical Research and Development of Timor-Leste (UERD-TL). (See supplement file for the informed consent and ethics approval).

2.4 | Statistical Analysis

The SPSS statistical program for Windows version 18.0 was used for data analysis. Descriptive statistics were used to analyze the demographic data and the level of KAP and barriers. Results were presented as the mean ± standard deviation (SD) for quantitative variables and a number with a percentage for categorical variables. There were eight questions used to assess knowledge on ADR and eight questions used to assess knowledge on pharmacovigilance with ADR reporting in the form of multiple-choice questions. Each correct answer was given a score of 1, with a maximum score of 8 for each domain. Depending on the score, the level of knowledge in each domain was classified as either "good" (≥6 points), "fair" (3–5 points), or "poor" (≤2 points). Attitude, practice, and barriers were described with numbers and percentages. Chi-squared analysis or Fisher's exact test analysis was performed as appropriate to determine the association between the responses to the question in each domain, with $p < 0.05$ indicating a significant difference.

3 | Results

3.1 | Demographics

Out of 600 questionnaires distributed, 461 (76.8%) HCPs responded. There were 169 males (36.7%) and 262 females (56.8%); 30 (6.5%) HCPs did not specify their sex. Respondents were 23 to 61 years old, with a mean ± SD of 37.60 ± 8.125 years; around half (50.1%) fell within the age range of 31–40 years. Their work experience ranged from 1 to 36 years, with most respondents having a work experience of 5–10 years (32.6%), followed by 11–19 years (26.7%) and 1–4 years (24.2%) (Supplementary for characteristics of the respondents). In the group of clinical doctors, there were 81 general practitioners and 17 specialists, composed of 4 anesthesiologists, 4 cardiologists, 1 nephrologist, 1 dermatologist, 1 oncologist, 2 internists, 2 surgeons, and 2 dentists. In the group of nurses, there were 259 general nurses, 1 anesthetic nurse, 2 dentist nurses, and 49 midwives. In the group of pharmacy employees, there were 10 pharmacists and 42 pharmacy technicians.

3.1.1 | HCPs Knowledge on ADRs (Q1–8)

The knowledge of HCPs on ADRs was evaluated using eight multiple-choice questions, as shown in Table 1. Most HCPs had varied responses in all items, with p-values below 0.05, and there was a significant difference in responses among HCPs, except for question 7 ("How is an adverse drug reaction diagnosed?") with the p-value above 0.05 and no significant difference in responses among HCPs.

3.1.2 | Mean Score of Knowledge on ADR

Overall, the mean ± SD score for this domain was 3.81 ± 0.36 points. Specifically, the groups of clinical doctors, nurses, and pharmacy employees had mean scores of 4.49 ± 0.51, 3.47 ± 0.24, and 4.56 ± 0.26 points, respectively, with the highest scores noted in the pharmacy employee group.

3.1.3 | Assessment of Knowledge on ADR

Out of the 104 respondents, 30.6% of clinical doctors, 16.0% of nurses, and 46.2% of pharmacy employees had good knowledge on ADR. On the basis of their scores, the pharmacy employee group was assessed to have a good level of knowledge regarding ADR. The specific details regarding their assessment are shown in Table 2.

3.2 | Knowledge on Pharmacovigilance With ADR Reporting Among HCPs (Q9–16)

3.2.1 | Knowledge on Pharmacovigilance With ADR Reporting

The knowledge of HCPs on pharmacovigilance and ADR reporting was evaluated using eight multiple-choice questions, as shown in Table 3. The answers to questions regarding the definition and purpose of pharmacovigilance and the availability of ADR reporting forms at their workplace were significantly different across

TABLE 1 | Knowledge of ADRs among healthcare professionals.

Questions	Profession (number of response)	Number of response (%)			*p*
		Correct	Incorrect	Don't know	
Q1. What is the appropriate definition of an ADR according to WHO?	Clinical doctors (98)	72 (73.5)	21 (21.4)	5 (5.1)	$p < 0.027$*
Unintended responses to a drug at high doses					
A response to a drug that is noxious and unintended and occurs at doses normally used	Nurses (311)	176 (56.6)	90 (28.9)	45 (14.5)	
The intended outcome of the medication at any dose					
The intended outcome of the medication at any dose	Pharmacy employees (52)	31 (59.62)	15 (28.84)	6 (11.54)	
Don't know					
Q2. What does "type A adverse drug reaction" mean?	Clinical doctors (98)	65 (66.33)	17 (17.34)	16 (16.33)	$p < 0.017$*
Adverse drug reactions that are not related to dose					
Adverse drug reactions that are related to the drug's pharmacological characteristics	Nurses (311)	174 (55.9)	96 (30.9)	41 (13.2)	
Uncommon adverse drug reactions					
The reaction is very harmful	Pharmacy employees (52)	35 (67.3)	11 (21.2)	6 (11.5)	
Don't know.					
Q3. What does a type B adverse drug reaction mean?	Clinical doctors (98)	49 (50.0)	32 (32.7)	17 (17.3)	$p < 0.001$*
Adverse drug reactions related to dose.					
Adverse drug reaction due to overdose	Nurses (311)	108 (34.7)	154 (49.5)	49 (15.8)	
ADR cannot be predicted and is not related to the drug's pharmacological characteristics					
The reactions that are not serious	Pharmacy employees (52)	32 (61.5)	14 (27.0)	6 (11.5)	
Don't know					
Q4. What can lead to adverse drug reactions?	Clinical doctors (98)	69 (70.0)	28 (29.0)	1 (1.0)	$p < 0.001$*
Drugs					
Vaccine	Nurses (311)	148 (47.6)	163 (52.4)	0 (0.0)	
Traditional medicine					
All the above	Pharmacy employees (52)	36 (69.2)	16 (30.8)	0 (0.0)	
Don't know.					
Q5. What is the seriousness of ADR?	Clinical doctors (98)	59 (60.2)	38 (38.8)	1 (1.0)	$p < 0.010$*
Death					
Life-threatening	Nurses (311)	153 (49.2)	158 (50.8)	0 (0.0)	
Requires prolonged hospitalization					
All the above	Pharmacy employees (52)	35 (67.3)	17 (32.7)	0 (0.0)	
Don't know					

(Continues)

TABLE 1 | (Continued)

Questions	Profession (number of response)	Number of response (%)			*p*
		Correct	Incorrect	Don't know	
Q6. What incidents led to the establishment of drug monitoring systems in many nations by 1960?	Clinical doctors (98)	35 (36.0)	48 (49.0)	15 (15.0)	$p < 0.001$*
Diethylene glycol-related death					
Thalidomide tragedy	Nurses (311)	58 (18.6)	204 (65.6)	49 (15.8)	
Chloroform-related death					
All the above	Pharmacy employees (52)	24 (46.2)	21 (40.3)	7 (13.5)	
Don't know					
Q7. How is an adverse drug reaction diagnosed?	Clinical doctors (98)	44 (45.0)	51 (52.0)	3 (3.0)	$p > 0.081$
By evaluating the time frame between an ADR and the use of the drug					
By observing and recognizing the pattern of reaction	Nurses (311)	126 (40.5)	184 (59.2)	1 (0.3)	
By withdrawing the drug in question					
All the above	Pharmacy employees (52)	25 (48.0)	26 (50.0)	1 (2.0)	
Don't know.					
Q8. How are adverse drug reactions managed?	Clinical doctors (98)	57 (58.0)	33 (34.0)	8 (8.0)	$p < 0.016$*
By evaluating the time frame between an adverse drug reaction and the use of the drug					
By symptomatic treatment	Nurses (311)	136 (44.0)	159 (51.0)	16 (5.0)	
By changing to an alternative drug					
All the above	Pharmacy employees (52)	19 (36.5)	29 (55.8)	4 (7.7)	
Don't know					

Abbreviation: ADR, adverse drug reaction.
Note: p-value*, Chi-squared test or Fisher's exact test when at least one of the cells was less than 5.

TABLE 2 | Assessment of the knowledge on adverse drug reactions.

Score scale—knowledge on ADR (0–8)	Number of all responses (%) ($N = 461$)	Number of professional responses (%)		
		Clinical doctors ($N = 98$)	Nurses ($N = 311$)	Pharmacy employees ($N = 52$)
Good (≥ 6)	104 (22.6)	30 (30.6)	50 (16.0)	24 (46.2)
Fair (3–5)	235 (50.9)	57 (58.2)	161 (51.8)	17 (32.7)
Poor (≤ 2)	122 (26.5)	11 (11.2)	100 (32.2)	11 (21.1)

the HCPs. This indicates that HCPs had differing views or levels of knowledge on these three aspects. However, for the remaining five questions, the responses from HCPs were fairly consistent, with no statistically significant differences observed among them.

3.2.2 | Mean Score of Knowledge on Pharmacovigilance With ADR Reporting

Overall, the mean ± SD score for this domain was 3.00 ± 0.16 points. Specifically, the groups of clinical doctors, nurses, and pharmacy employees had mean scores of 3.36 ± 0.26, 2.81 ± 0.08, and 3.50 ± 0.24 points, respectively, with the highest scores noted in the pharmacy employee group.

3.2.3 | Assessment of Knowledge on Pharmacovigilance With ADR Reporting

Among the 14 respondents, 4.0% of clinical doctors, 2.3% of nurses, and 5.8% of pharmacy employees had achieved the correct answer of ≥ 6. Based on their scores, the pharmacy employee group was assessed to have a good level of knowledge regarding pharmacovigilance with ADR reporting; this was the

TABLE 3 | Knowledge of pharmacovigilance with ADR reporting among healthcare professionals.

Questions	Profession (number of response)	Number of response (%)			*p*
		Correct	Incorrect	Don't know	
Q9. What is the most accurate definition of pharmacovigilance?	Clinical doctors (98)	68 (69.4)	9 (9.2)	21 (21.4)	$p < 0.001$*
Science and activities related to the detection, assessment, understanding, and prevention of adverse drug effects					
Detection of the type and frequency of ADRs after a drug has been marketed	Nurses (311)	145 (46.6)	66 (21.2)	100 (32.2)	
The process of enhancing drug safety					
All the above	Pharmacy employees (52)	22 (42.3)	3 (5.8)	27 (51.9)	
Don't know					
Q10. What is the purpose of pharmacovigilance?	Clinical doctors (98)	66 (67.3)	29 (29.6)	3 (3.1)	$p < 0.001$*
Address patients' safety					
Monitoring drug safety and efficacy profiles	Nurses (311)	153 (49.2)	135 (43.4)	23 (7.4)	
Minimize the risk related to drug use					
All the above	Pharmacy employees (52)	41 (79.0)	9 (17.0)	2 (4.0)	
Don't know					
Q11. Where is the National Pharmacovigilance Center located in Timor-Leste?	Clinical doctors (98)	65 (66.3)	29 (29.6)	4 (4.1)	$p > 0.213$
Department of Public Health					
National Directorate of Pharmacy and Medicines, Minister of Health	Nurses (311)	187 (60.0)	113 (36.0)	11 (4.0)	
National Hospital, Guido Valadares					
All the above	Pharmacy employees (52)	39 (75.0)	11 (21.2)	2 (3.8)	
Don't know					
Q12. Where would you report any ADR cases you saw in your practice?	Clinical doctors (98)	35 (35.7)	43 (43.9)	20 (20.4)	$p > 0.766$
National Directorate of Pharmacy and Medicine					
Pharmacovigilance center in your hospital	Nurses (311)	91 (29.3)	151 (48.6)	69 (22.1)	
Medical department.					
Dermatology department	Pharmacy employees (52)	14 (26.9)	27 (51.9)	11 (21.2)	
Don't know					
Q13. Is the ADR reporting form available at your workplace?	Clinical doctors (98)	11 (11.0)	85 (87.0)	2 (2.0)	$p < 0.001$*
Yes	Nurses (311)	75 (24.1)	235 (75.6)	1 (0.3)	
No	Pharmacy employees (52)	20 (38.5)	32 (61.5)	0 (0.0)	
Don't know.					

(Continues)

TABLE 3 | (Continued)

Questions	Profession (number of response)	Number of response (%)			*p*
		Correct	Incorrect	Don't know	
Q14. Which of the following scales is used to determine that an ADR was caused by a particular drug?	Clinical doctors (98)	24 (24.5)	63 (64.3)	11 (11.2)	$p > 0.488$
Naranjo algorithm					
Hartwig scale	Nurses (311)	57 (18.33)	206 (66.24)	48 (15.43)	
Schumock and Thornton scale					
All the above	Pharmacy employees (52)	9 (17.3)	38 (73.1)	5 (9.6)	
Don't know					
Q15. Why is it important to report adverse drug reactions?	Clinical doctors (98)	45 (45.9)	45 (45.9)	8 (8.2)	$p > 0.191$
Marketed drugs have limited data on drug safety					
Marketed drugs have limited data on rare or very rare adverse drug reactions	Nurses (311)	141 (45.3)	156 (50.2)	14 (4.5)	
Marketed drugs have limited data on new serious adverse drug reactions					
All the above	Pharmacy employees (98)	31 (59.6)	20 (38.5)	1 (1.9)	
Don't know					
Q16. Which of the following methods is most frequently used to report ADR?	Clinical doctors (98)	15 (15.3)	77 (78.6)	6 (6.1)	$p > 0.147$
Prescription event monitoring					
Spontaneous reporting	Nurses (311)	24 (7.7)	265 (85.2)	22 (7.1)	
Patient registry					
All the above	Pharmacy employees (52)	6 (11.5)	45 (86.5)	1 (2.0)	
Don't know					

Abbreviation: ADR, adverse drug reaction.
Note: p-value*, Chi-squared test or Fisher's exact test when at least one of the cells was less than 5.

highest among the three groups. The specific details regarding their assessment are shown in Table 4.

3.3 | Attitude Toward Pharmacovigilance Activities and ADR Reporting Among HCPs

All HCP respondents were ranked on their attitudes about five Likert scale questions, as shown in Table 5. All questions regarding attitude were significantly different among respondent HCPs. The overall attitude, expressed as a percentage for each question, is demonstrated in Figure 1A. Around 53.4% and 48.0% of all respondents strongly agreed that ADR reporting is an important activity and that HCPs have a responsibility for ADR reporting, respectively.

3.4 | Practice of HCPs on ADR Reporting

Practice of the HCPs on ADR reporting was surveyed from five questions. Their possible choice consisted of "Yes", "No", "Don't know", and "Not sure." The distribution and percentages among HCPs are shown in Table 6. All questions about practice of ADR reporting were significantly different among respondent HCPs. Overall responses to the practice of the ADR reporting are demonstrated by Figure 1B.

3.5 | Barriers to Pharmacovigilance Activities and ADR Reporting

The barriers to pharmacovigilance activities and ADR reporting were assessed by eight questions among HCPs, and their responses are shown in Table 7. Except for question 6, that is, "Do you think that a single ADR report has no impact?", the other responses were not significantly different among HCPs for barriers to pharmacovigilance and ADR reporting. Overall, HCPs provided their responses to the barriers to pharmacovigilance and ADR Reporting as shown in Figure 1C.

4 | Discussion

This is the first study that explores the KAP and barriers of HCPs in Timor-Leste on ADR and pharmacovigilance with ADR

TABLE 4 | Assessment of the knowledge on pharmacovigilance with ADR reporting.

Assessment of the knowledge on PV with ADR reporting				
Score scale—Knowledge of PV and ADR reporting (0–8)	**Number of all (%) responses (*N* = 461)**	**Number of professions (%)**		
		Clinical doctors (*N* = 98)	**Nurses (*N* = 311)**	**Pharmacy employees (*N* = 52)**
Good (> 6)	14 (3.0)	4 (4.0)	7 (2.3)	3 (5.8)
Fair (3–5)	268 (58.0)	62 (63.3)	169 (54.3)	37 (71.2)
Poor (< 2)	179 (39.0)	32 (32.7)	135 (43.4)	12 (23.0)

Abbreviations: ADR, adverse drug reaction; PV, pharmacovigilance.

TABLE 5 | Healthcare professionals' attitudes toward pharmacovigilance activities and ADR reporting.

Likert scale questions	All respondents**	Clinical doctors	Nurses	Pharmacy employees	*p*
Q1. Reporting adverse drug reactions is an important activity to improve the safety of medicine?	457	96	309	52	$p < 0.001$*
Strongly disagree	13 (2.8)	2 (2.1)	10 (3.2)	1 (2.0)	
Disagree	15 (3.3)	0 (0.0)	15 (4.9)	0 (0.0)	
Neutral	47 (10.3)	5 (5.2)	41 (13.3)	1 (2.0)	
Agree	138 (30.2)	22 (22.9)	102 (33.0)	14 (27.0)	
Strongly agree	244 (53.4)	67 (69.8)	141 (45.6)	36 (69.0)	
Q2. Health professionals have a responsibility for ADR reporting?	456	96	308	52	$p < 0.001$*
Strongly disagree	11 (2.4)	2 (2.1)	9 (3.0)	0 (0.0)	
Disagree	23 (5.0)	1 (1.0)	21 (7.0)	2 (4.0)	
Neutral	48 (11.0)	4 (4.2)	41 (13.0)	2 (4.0)	
Agree	157 (34.0)	22 (22.9)	119 (39.0)	16 (31.0)	
Strongly agree	217 (48.0)	67 (69.8)	118 (38.0)	32 (61.0)	
Q3. Pharmacovigilance should be included as a core topic in medical education?	457	96	309	52	$p < 0.001$*
Strongly disagree	18 (4.0)	2 (2.0)	16 (5.2)	0 (0.0)	
Disagree	15 (3.0)	0 (0.0)	15 (4.9)	0 (0.0)	
Neutral	49 (11.0)	4 (4.2)	41 (13.3)	4 (7.7)	
Agree	169 (37.0)	24 (25.0)	125 (40.4)	20 (38.5)	
Strongly agree	206 (45.0)	66 (68.8)	112 (36.2)	28 (53.8)	
Q4. Monitoring serious ADRs is complicated?	457	96	309	52	$p < 0.002$*
Strongly disagree	20 (4.3)	4 (4.2)	14 (4.5)	2 (3.8)	
Disagree	35 (7.7)	4 (4.2)	28 (9.1)	3 (5.8)	
Neutral	75 (16.4)	9 (9.4)	62 (20.1)	4 (7.7)	
Agree	184 (40.3)	33 (34.3)	128 (41.4)	23 (44.2)	
Strongly agree	143 (31.3)	46 (47.9)	77 (24.9)	20 (38.5)	

Abbreviations: ADR, adverse drug reaction; HCP; healthcare professional.
Note: all respondents **, the number of respondents without missing answers in each question; *p*-value*, Chi-squared test or Fisher's exact test when at least one cell was less than 5.

reporting. Assessing this KAP is important for the improvement of the pharmacovigilance system. The study included various HCPs (i.e., clinical doctors, nurses, and pharmacy employees) who play essential roles in medication usage across five referral hospitals and one national referral hospital in Timor-Leste. The overall response rate was 76.8% (461/600). Similar studies focusing on the KAP of HCPs in different countries reported response rates varying from 53.6% to 94.7% [13–17]. Most of the respondents were nurses (67.5%). In this study, 76.5% of the HCPs graduated from Timor-Leste, whereas the remainder graduated abroad. Most HCPs in the survey also received the highest qualification (a diploma) in their respective fields.

HCPs play various roles in ADR reporting and pharmacovigilance systems. In general, HCPs are more likely to recognize and report significant ADRs if they feel confident in their capacity to diagnose, manage, and prevent reactions caused by medicines. Previous studies have found that ADRs are not reported due to a lack of knowledge about pharmacovigilance and ADRs themselves [18, 19]. Thus, some ADRs occur, yet remain unreported by the HCPs.

This study found that a considerable number of HCPs understood the definition of an ADR (61.0%), type A (59.4%) and type B (41.0%) ADRs, and the causes of an ADR (54.9%). Around 46.2% of the HCPs did not know about serious adverse events, and only 25.4% knew about events that lead to the establishment of drug monitoring. Furthermore, 48.0% of pharmacy employees, 45.0% of clinical doctors, and 40.5% of nurses understood the procedure involved in diagnosing ADR. There was no significant difference between HCPs in terms of knowledge about diagnosing an ADR ($p > 0.081$). Notably, only 58.0% of clinical doctors had knowledge about the management of an ADR. Overall, only 42% and 46% of respondents knew about diagnosing and managing ADR. The overall mean score ± SD of the knowledge among HCPs for ADR was 3.81 ± 0.36 points, whereas clinical doctors, nurses, and pharmacy employees, respectively, scored 4.49 ± 0.51, 3.47 ± 0.24, and 4.56 ± 0.26 points. Most HCPs (50.9%) were evaluated to have a fair level of knowledge on ADRs. Specifically, pharmacy employees (46.2%) and clinical doctors (30.6%) had more knowledge on ADR than nurses (16.0%). Similarly, a study in Bhutan found a good level of knowledge in 44.7%, 36.5%, and 35.4% of clinical doctors, pharmacy employees, and nurses, respectively [14]. However, another study from Turkey found that about 51.9% of participants lacked knowledge regarding ADRs [15]. The different results from these studies may be due to discrepancies in the criteria, cutoff points, number of questions, number of participants, and study setting.

ADR reporting is one main activity of pharmacovigilance. The expected process for HCPs to report an ADR compose of awareness about medication safety, early detection, assessment and feedback on ADR reporting in order to improve medication use process. Therefore, HCPs should understand the definition of pharmacovigilance, its purpose, and the location of the pharmacovigilance center in order to report an ADR, but only 51.0%, 56.0%, and 63.1% of HCPs, respectively, understood these items according to our survey. The pharmacovigilance of Timor-Leste has only established one pharmacovigilance center located in the NDPM. The PV information was shared in a series of orientation seminars, and the pharmacy department in each hospital distributed the ADR forms to HCPs. Even though the national referral hospital has not yet established the pharmacovigilance center, nine reports have been reported by national hospital HCPs. The ADR reporting process involves HCPs identifying potential signals, completing the ADR form, and sending it to the pharmacy department. The pharmacy department initiates the assessment and notifies the PV center staff, who then collect the reported cases. Among the respondents, only 30.4% knew where to report ADR cases. Interestingly, 76.4% of respondents did not know about the ADR form available in their workplace. HCPs access ADR forms manually, and because this consumes a lot of time, the reports may be misplaced. The pharmacovigilance center has never performed a causality assessment on reported ADRs. More than 60% of HCPs did not know that the Naranjo scale was helpful for causality assessment. In terms of the importance of ADR reporting, only 47.0% of respondents knew about the importance of reporting an ADR. The spontaneous method is used for reporting ADRs as it is of low cost and straightforward. However, the study found that more than 80% of HCPs did not select the spontaneous reporting method. Notably, the mean ± SD score of HCPs regarding pharmacovigilance and ADR reporting was 3.00 ± 0.16 points, whereas clinical doctors, nurses, and pharmacy employees, respectively, had scores of 3.36 ± 0.26, 2.81 ± 0.08, and 3.50 ± 0.24, respectively. Overall, 58.0% of HCPs lacked knowledge on pharmacovigilance and ADR reporting; specifically, this included 63.3%, 54.3%, and 71.2% of clinical doctors, nurses, and pharmacy employees, respectively. Comparatively, the average knowledge of pharmacy employees and clinical doctors on pharmacovigilance and ADR reporting was higher than that of the nurses. This may be because pharmacovigilance is included in the curriculum of pharmacy employees, whereas clinical doctors are involved in pharmacovigilance activities. The findings of this study were consistent with studies in Bhutan, Nigeria, Turkey, Ghana, and Nepal [14, 15, 17, 20, 21]. Although various HCPs were recruited in these countries, all of these surveys revealed that HCPs generally had inadequate knowledge on pharmacovigilance and ADR reporting. For instance, the study in Bhutan found a good level of knowledge regarding pharmacovigilance and ADR reporting in only 40.4%, 49.4%, and 28.8% of clinical doctors, pharmacy employees, and nurses, respectively. Another survey in Turkey found that 51.9% of HCPs lacked knowledge about pharmacovigilance and ADR reporting [15]. The highest rate was found in the survey in Nigeria (85%) [20].

The attitude of HCPs toward ADR, PV, and ADR reporting is poised to change as more HCPs become aware of drug safety. In this study, all HCPs have a positive attitude toward the four statements on the Likert scale. Around 53.4% and 48.0% of the respondents strongly agree that reporting ADR is an important activity to improve medication safety, and it is their responsibility to report. These results were consistent with the Nepal and Saudi Arabia studies. Around 96.6% and 80.9% agreed that reporting an ADR was an important activity and it was their responsibility (Nepal study), [21] whereas around 93.2% and 61% agreed to the same statements (Saudi Arabia study) [13]. Moreover, 68.8% of clinical doctors and 53.8% of pharmacy employees strongly agreed that PV should be added as a core topic in medical education. This result consisted of a Turkey study. Around 78.2% of

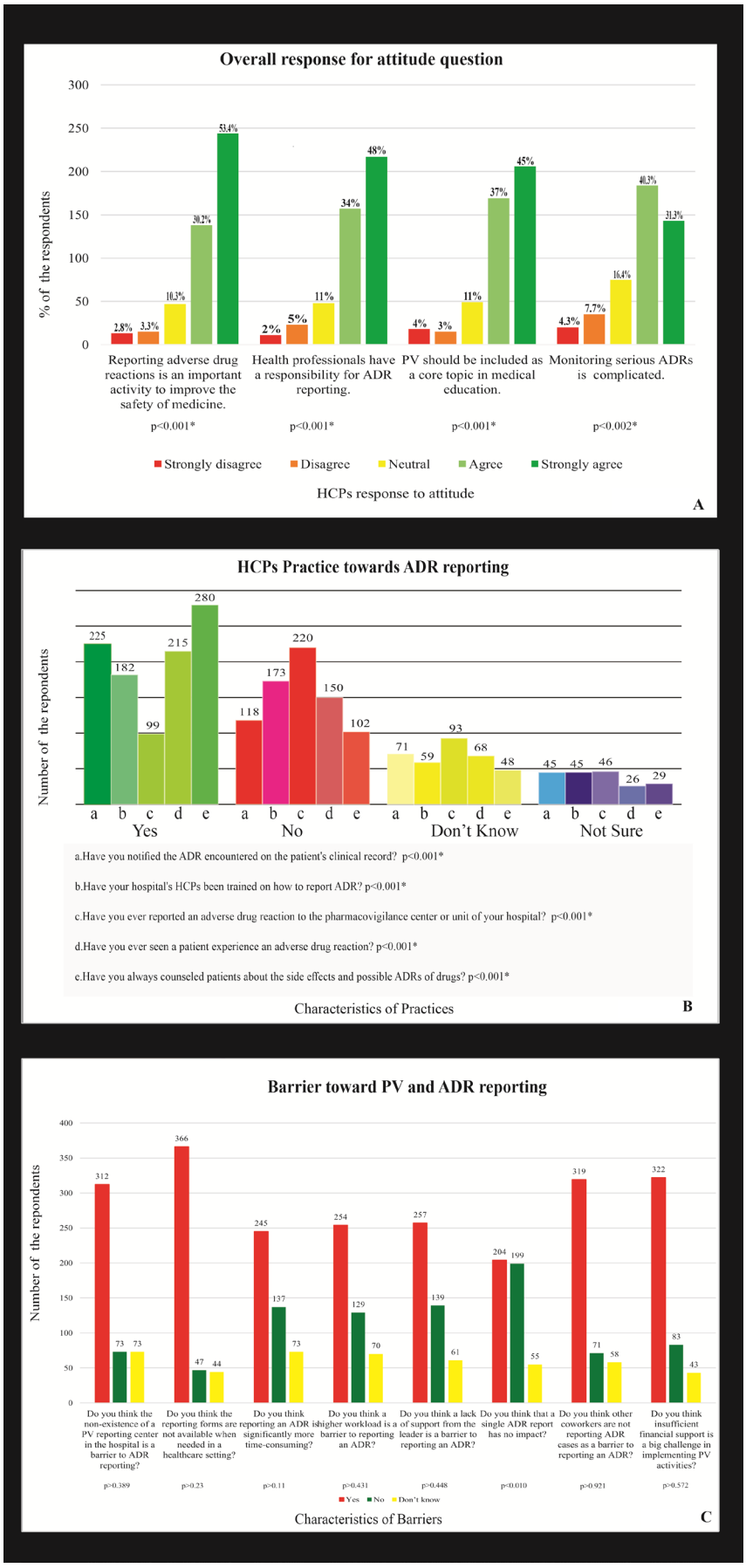

FIGURE 1 | Legend on next page.

FIGURE 1 | (A) Healthcare professionals' (HCPs') responses to the attitude statements. (B) Healthcare professionals' (HCPs') practice on adverse drug reaction (ADR) reporting. (C) Healthcare professionals' (HCPs') responses to the barriers questions regarding pharmacovigilance (PV) to ADR reporting.

TABLE 6 | HCPs' practice of ADR reporting.

Practice (number of response without missing answer)	Profession (number of response)	Response (%)				*p*
		Yes	No	Don't know	Not sure	
Q1. Have you notified the ADR encountered on the patient's clinical record? (459)	Clinical doctors (96)	67 (69.8)	16 (16.7)	7 (7.3)	6 (6.2)	$p < 0.001$*
	Nurses (311)	147 (47.3)	79 (25.4)	52 (16.7)	33 (10.6)	
	Pharmacy employees (52)	11 (21.2)	23 (44.2)	12 (23.1)	6 (11.5)	
Q2. Have your hospital's HCPs been trained on how to report ADR? (459)	Clinical doctors (96)	27 (28.1)	35 (36.5)	12 (12.5)	22 (22.9)	$p < 0.001$*
	Nurses (311)	139 (45.0)	113 (36.0)	39 (13.0)	20 (6.0)	
	Pharmacy employees (52)	16 (30.8)	25 (48.0)	8 (15.4)	3 (5.8)	
Q3. Have you ever reported an ADR to the PC or unit of your hospital? (458)	Clinical doctors (95)	13 (13.7)	39 (41.1)	18 (18.9)	25 (26.3)	$p < 0.001$*
	Nurses (311)	71 (22.8)	154 (49.5)	69 (22.2)	17 (5.5)	
	Pharmacy employees (52)	15 (29.0)	27 (51.9)	6 (11.5)	4 (7.6)	
Q4. Have you ever seen a patient experience an ADR? (459)	Clinical doctors (96)	59 (61.5)	17 (17.7)	13 (13.5)	7 (7.3)	$p < 0.001$*
	Nurses (311)	143 (46.0)	104 (33.0)	50 (16.0)	14 (5.0)	
	Pharmacy employees (52)	13 (25.0)	29 (55.8)	5 (9.6)	5 (9.6)	
Q5. Have you always counseled patients about the side effects and possible ADRs of drugs? (459)	Clinical doctors (96)	78 (81.2)	9 (9.4)	4 (4.2)	5 (5.2)	$p < 0.001$*
	Nurses (311)	178 (57.2)	73 (23.5)	39 (12.5)	21 (6.8)	
	Pharmacy employees (52)	24 (46.2)	20 (38.5)	5 (9.6)	3 (5.7)	

Abbreviations: ADR: adverse drug reaction, HCP: healthcare professional, PC: pharmacovigilance center.
Note: p-value*: Chi-square test or Fisher's exact test when at least one of the cells was less than 5.

clinical doctors agreed that PV should be added to the medical education curriculum [15]. Of all the respondents, only 4.3% did not agree that monitoring a serious ADR was complicated. The present study revealed that most HCPs had a positive attitude toward ADR, PV, and ADR reporting, which is similar to previous studies reported from Nigeria, Turkey, Saudi Arabia, Nepal, and Ghana [13, 15, 17, 20, 21] where all HCPs had a positive attitude toward PV and ADR reporting. Recently, a Turkey study found that 71.1% of HCPs had a positive attitude about ADR, PV, and ADR reporting [15]. In addition, there was a significant difference among HCPs regarding the importance of reporting ADR, HCPs are responsible for ADR reporting, PV should be added to the medical education curriculum, and monitoring a serious ADR was complicated ($p < 0.002$*).

This study revealed that all HCPs were aware of patient safety. More than 48.0% of the respondents notified the ADR encountered in the patient's medical history, and 37.7% did not receive any training on reporting an ADR. Similarly, it was found that 37.1% did not train from the Ghana study [17], and the highest percentage of HCPs who did not receive any training were 82.6% and 66.0% from Nigeria and Turkey studies, respectively [15, 20]. Among the respondents, only 22.0% were experienced with reporting any ADRs. The present finding was consistent with the study from Indonesia: although all 22 respondents had encountered ADR cases in their practice site, only 9.09% of them reported ADRs [22]. Additionally, 46.8% of HCPs had seen patients with experience of ADRs before and more than 60.0% of the respondents always provided patients counseling on the possible ADRs of drugs. This finding is similar to the other studies from Saudi Arabia and Ethiopia. The study from Saudi Arabia reported that 84.3% of HCPs had seen patients experience ADR and 56.7% had counseled the patients about the adverse effects of drugs, [13] whereas in Ethiopia, 30.4% of HCPs had seen patients experience ADR and 27.4% had counseled the patients regarding the side effect that might occur [19]. In Timor-Leste, pharmacists have started engaging in direct patient interactions, and hospital pharmacists are also working to establish and expand clinical pharmacy activities, such as patient counseling and medication management [23].

TABLE 7 | Barriers among HCPs to pharmacovigilance activities and ADR reporting.

Barriers (number of response without missing answer)	Profession (number of response)	Response (%)			*p*
		Yes	No	Don't know	
Q1. Do you think the nonexistence of a PV reporting center in the hospital is a barrier to ADR reporting? (458)	Clinical doctors (96)	71 (74.0)	13 (13.5)	12 (12.5)	$p > 0.389$
	Nurses (310)	203 (65.5)	51 (16.5)	56 (18.0)	
	Pharmacy employees (52)	38 (73.1)	9 (17.3)	5 (9.6)	
Q2. Do you think the reporting forms are not available when needed in a healthcare setting? (457)	Clinical doctors (96)	84 (87.5)	5 (5.2)	7 (7.3)	$p > 0.233$
	Nurses (309)	240 (77.7)	38 (12.3)	31 (10.0)	
	Pharmacy employees (52)	42 (80.8)	4 (7.7)	6 (11.5)	
Q3. Do you think reporting an ADR is significantly more time consuming? (455)	Clinical doctors (94)	43 (45.7)	37 (39.4)	14 (14.9)	$p > 0.118$
	Nurses (309)	178 (57.6)	82 (26.5)	49 (15.9)	
	Pharmacy employees (52)	24 (46.2)	18 (34.6)	10 (19.2)	
Q4. Do you think a higher workload is a barrier to reporting an ADR? (453)	Clinical doctors (96)	49 (51.0)	34 (35.0)	13 (14.0)	$p > 0.431$
	Nurses (307)	179 (58.0)	79 (26.0)	49 (16.0)	
	Pharmacy employees	26 (52.0)	16 (32.0)	8 (16.0)	
Q5. Do you think a lack of support from the leader is a barrier to reporting an ADR? (457)	Clinical doctors (96)	55 (57.3)	26 (27.1)	15 (15.6)	$p > 0.448$
	Nurses (309)	178 (57.6)	92 (29.8)	39 (12.6)	
	Pharmacy employees (52)	24 (46.2)	21 (40.3)	7 (13.5)	
Q6. Do you think that a single ADR report has no impact? (458)	Clinical doctors (96)	32 (33.3)	53 (55.2)	11 (11.5)	$p < 0.010$*
	Nurses (310)	155 (50.0)	118 (38.0)	37 (12.0)	
	Pharmacy employees (52)	17 (32.7)	28 (53.8)	7 (13.5)	
Q7. Do you think other coworkers are not reporting ADR cases as a barrier to reporting an ADR? (447)	Clinical doctors (95)	69 (72.6)	13 (13.7)	13 (13.7)	$p > 0.921$
	Nurses (300)	210 (70.0)	50 (16.7)	40 (13.3)	
	Pharmacy employees (52)	39 (75.0)	8 (15.4)	5 (9.6)	
Q8. Do you think insufficient financial support is a big challenge in implementing PV activities? (448)	Clinical doctors (94)	65 (69.0)	16 (17.0)	13 (14.0)	$p > 0.572$
	Nurses (302)	217 (71.9)	58 (19.2)	27 (8.9)	
	Pharmacy employees (52)	40 (76.9)	9 (17.3)	3 (5.8)	

Abbreviations: ADR, adverse drug reaction; HCPs, healthcare professionals; PV, pharmacovigilance.
Note: p-value*, Chi-squared test or Fisher's exact test when at least one of the cells was less than 5.

Underreporting is one of the limitations of the spontaneous reporting method. Worldwide, it has been mentioned that intrinsic and extrinsic factors also contribute to underreporting [24]. This study found that more than 80% of the respondents confirmed that the ADR form was not available in their workplace when needed as a major reason for underreporting. Similar results were reported from Nigeria, Ethiopia, Turkey, and Albania: 78.8%, 79.7%, 41.7%, and 44.3% of respondents, respectively, stated the ADR form was not available when needed [15, 16, 19, 20]. Among the respondents, 71.9% stated that insufficient budget was a big barrier to implementing PV activities. This rate was higher than the study conducted in Turkey (51.9%) [15]. It may be due to the budget number. The pharmacovigilance department had an annual budget for ADR monitoring of about $7000 per year. This budget was only for training and was not included in the advertisement. If the PV department had additional financial support, a key initiative would be to enhance awareness among HCPs and patients about the importance of ADR reporting. The study found that more than 67% of HCPs stated that the non-existence of PV centers in their region was one of the barriers to underreporting. Other barriers were also identified in this study: coworkers did not report the ADR, lack of support from a leader, time consuming, higher workload, and a single ADR has no impact on patient safety (69.2%, 55.7%, 53.1%, 55.1%, and 44.5%, respectively). The finding was consistent with previous studies [15–17, 25, 26]. Recently, a study from Ghana found that 94.7% of HCPs mentioned that the higher workload was a barrier to reporting an ADR [17]. In addition, the study from Turkey found that 32.8% stated reporting an ADR was more time consuming, 63.8% reported a higher workload, 43.2% mentioned no pharmacovigilance center in their institution, 63.6% thought that a single ADR has no impact, and 21.8% highlighted that other coworkers did not report that the ADR was a barrier to reporting an ADR [15]. On the basis of the study results, the most concerning gaps were lack of knowledge, reporting infrastructure, limited financial support for

pharmacovigilance activities, lack of reporting culture among HCPs, and low reporting practice despite positive attitudes. To improve knowledge, practices, patient safety, and pharmacovigilance activities among HCPs, it is recommended to implement frequent training programs and educational initiatives, and foster interprofessional relationships among all HCPs.

One limitation of this study is that all the questionnaires were translated into the local language. Nevertheless, an overall response rate of more than 70% was garnered from the national hospital and five referral hospitals. One referral hospital, however, had a response rate of only 11%, likely due to respondents having difficulty in understanding the questions.

5 | Conclusion

The surveyed HCPs in Timor-Leste had a moderate level of knowledge regarding ADRs, pharmacovigilance, and ADR reporting. Pharmacy employees and clinical doctors had more knowledge about ADRs than nurses. However, all three groups of HCPs had inadequate knowledge on pharmacovigilance and ADR reporting. In addition, HCPs working at six referral hospitals in Timor-Leste have positive attitudes toward pharmacovigilance activities and ADR reporting; however, the reporting culture is not well developed, as reflected by the huge gap between the ADRs encountered and the ADR reporting trend among HCPs. The unavailability of ADR reporting forms and colleagues' negative reporting nature are significantly discouraging them from reporting ADRs.

Author Contributions

J.D., P.T., and W.R. wrote the manuscript; J.D., P.T., and W.N. designed the research; J.D., W.N., W.R., and P.T. performed the research; and J.D., W.N., W.R., and P.T. analyzed the data.

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Conflicts of Interest

The authors declare no conflicts of interest.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.