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RESEARCH ARTICLE

Assessment of knowledge, attitude, and practice towards adverse drug reaction reporting among healthcare students of Namakkal District, Tamil Nadu

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Abstract

Background: Adverse drug reactions (ADRs) are recognised causes of increased mortality, morbidity, and high healthcare costs. The contribution of healthcare students to ADR databases is essential and has enabled continued drug detection to such an extent that it has led to identifying unsuspected and rare ADR signals. **Objective:** The study aims to evaluate healthcare students' knowledge, attitude, and practice (KAP) toward ADR reporting. **Methods:** This descriptive, cross-sectional study was conducted among 265 healthcare students of Namakkal district, Tamil Nadu, from various departments. A three-section questionnaire was developed in English and distributed online from July to October 2020. Each participant received a score for each KAP section. **Results:** Of the 265 healthcare students included in the study, 56.98% were female. The majority were pharmacy students 132 (49.81%), followed by medical 74 (27.92%) and nursing 59 (22.26%) students. There was a significant difference in ADR reporting among healthcare students. KAP of ADR reporting was higher among pharmacy students (88.68%) compared to the medical (19.25%) and nursing students (29.63%), with a *p*-value of 0.05. **Conclusion:** This study showed that pharmacy students had more awareness of ADR reporting than other healthcare students due to pharmacovigilance courses in their curriculum and adequate training during clerkships and internships. Hence, it is necessary to include pharmacovigilance and ADR reporting in other healthcare curriculum to reduce ADR underreporting in the future. Periodic educational interventions can improve these parameters of pharmacovigilance.

Introduction

Pharmacovigilance is a practice that monitors drug safety in real-world settings and records adverse drug events even during the post-marketing phase of a drug's life cycle (Abdel-Latif & Abdel-Wahab, 2015). The World Health Organisation (WHO) defines it as "the science and practices relating to the detection, evaluation, understanding, and prevention of adverse responses to medications or any other medicine-related problems" (WHO, 2002b). The Uppsala Monitoring Centre (UMC) is the field name for the WHO Collaborating Centre for International Drug Monitoring, which is based in Uppsala, Sweden. The UMC's mission is to review, collect, and disseminate information about pharmacological benefits, effectiveness, damage, and hazards from member countries' national programmes. (Abdel-Latif & Abdel-Wahab, 2015).

UMC-WHO is primarily responsible for maintaining a global database of adverse drug reaction reports obtained from various national centres around the world. Nonetheless, it is estimated that only 6-10% of all ADRs are reported globally (Feely, Moriarty & O'Connor, 1990).

An adverse drug reaction (ADR) is linked to a significantly longer duration of stay, increased financial burden, and a nearly two-fold increased risk of death. An ADR raises overall healthcare costs by increasing morbidity and, in extreme situations, mortality (Classen *et al*., 1997). They have varying degrees of impact on both children and adults, resulting in morbidity and mortality (Lazarou, Pomeranz & Corey, 1998; Pirmohamed *et al.,* 2004).

Although one of the fundamental goals of pharmacovigilance (PV) is to detect, assess, understand, and prevent adverse reactions to protect the public, patient self-reporting of ADRs was historically underestimated (Sales *et al.,* 2017). Around 5% of hospital admissions are due to ADRs, and as many as 35% of hospitalised patients experience an ADR during their hospitalisation (Baniasadi, Fahimi & Shalviri, 2008). Quality, safety, and efficacy-assured medicines are essential for patient health. Even before marketing, clinical and preclinical studies are done to validate its safety and efficacy. It has been found that severe and unexpected ADRs are less likely to be reported (FMHACA, 2014). The frequency of ADRs varies, with research showing incidences ranging from 0.15% to 30%. It is documented that elderly and hospitalised patients are more vulnerable than the adult population to ADRs (16.6% vs 4.1%) (Beijer & Blaey, 2002; Jose & Rao, 2006; Lazarou, Pomeranz & Corey, 1998).

India is among the participants in the UMC initiative, but its contribution to the database is limited, mainly because India lacks an active ADR monitoring system and a reporting culture among healthcare professionals (Feely, Moriarty & O'Connor, 1990).

Increasing the knowledge, attitude, and practices (KAP) of healthcare workers towards ADR reporting and PV is critical to improving reporting rates and the efficacy of the PV programme, thus preventing ADR underreporting. The ideal time to increase awareness is probably during undergraduate and postgraduate education training. However, it is the responsibility of healthcare providers to continue this activity throughout actual practice (Vora & Barvaliya, 2014).

A cross-sectional survey among 80 health workers and 360 patients assessed the knowledge, attitude, and practice towards adverse drug reaction reporting using semi-structured questionnaires consisting of open-ended and closed-ended questions. It showed that health workers were largely aware of pharmacovigilance but showed a low knowledge level of ADRs and PV concepts, with a moderately positive attitude towards ADR reporting. It also revealed that patients demonstrated lower awareness of PV and ADR reporting (Adisa & Omitogun, 2019).

Therefore, the primary goal of this study was to assess knowledge, attitudes, and practices towards pharmacovigilance and adverse drug reaction reporting among healthcare students of the Namakkal district, Tamil Nadu, India. The second objective was to explore the key roadblocks to healthcare personnel's spontaneous reporting of ADRs.

Methods

Study participants and survey

A cross-sectional web-based survey was conducted from July to October 2020 to evaluate the knowledge, attitudes, and practices toward ADR reporting among healthcare students of Namakkal District, Tamil Nadu, from various departments. A questionnaire consisting of a sociodemographic section and 22 KAP items (Appendix 1) was designed based on similar studies (Gupta *et al.,* 2015; Umair *et al.,* 2015; Nisa, Zafa & Sher, 2018).

The study was carried out online using Google Forms, and respondents were recruited by sharing the survey through the staff handling online classes and various online platforms (e.g., Facebook, Messenger, Telegram, WhatsApp). Students who refused to give consent and were busy with work were excluded from the study. Respondents were enrolled using age, sex, and region-based proportional and stratified sampling. More than 265 responded randomly, among the institutions having both health science and non-health science courses and the subset of health science individuals were chosen randomly. The sample size calculated by the Rao software was 265 students, taking a 95% confidence interval and a 5% margin of error.

The questionnaire consisted of sociodemographic details (e.g., name, age, and sex) and 19 KAP questions, where knowledge (12 items), attitude (4 items), and practice (3 items) were categorised into a low level (0) and good level (1). The filled-out questionnaires were assessed for their completeness and the type of responses regarding ADR reporting. The total response gotten from the departments includes 104 prefinal and intern Pharm.D. students; 74 intern students of MBBS, BHMS, and BDS; 59 final-year nursing and 28 final-year B. Pharm. Students.

Ethical clearance

This study was approved by the J.K.K. Nattraja ethics committee (J.K.K Nattraja College of Pharmacy). Ethical reference number: JKKNCP/ETHICS_PRACTICE/020PDS06.

Statistical analysis

Statistical analysis were done using Graph Pad PRISM software version 9.1.12. All the categorical variables

were presented as frequencies and percentages. Scatter plots, skewness, and kurtosis were examined to determine the normality of the data distribution. A two-way ANOVA test was performed to determine if there was a difference in the mean KAP score between factors (medical students, nurses, and pharmacists) and between independent variables. It was followed by post hoc Tukey's multiple comparison tests. A *p*-value of less than 0.05 was considered to be statistically significant.

Results

A total of 265 students were randomly selected from the three different healthcare fields with 132 (49.81%) pharmacy students, followed by 74 (27.92%) medical students and 59 (22.26%) nursing students. The majority of the respondents (56.98%) were female.

A cumulative analysis of all knowledge-based questions (n:12 questions) revealed that an average of 54.05% of students from all three categories answered correctly (Table I), with 48.53% of medical students, 66.85% of nursing students, and 46.75% of pharmacy students. Among the three professional categories, pharmacy students had good knowledge.

The results of a cumulative analysis of four attitude-based questions indicated that on average, 68.03% of students across all three categories answered correctly. Medical students had a correct answer rate of 71.96%, nursing students 60.17%, and pharmacy students 71.97%.

A cumulative analysis of three practice-based questions showed that an average of 45.01% of students from all three categories answered correctly. Pharmacy students had the highest percentage of correct answers at 62.12%, followed by nursing students at 50.82% and medical students at 22.07% (as shown in Table III).

The total KAP score calculated by cumulative average percentage of all the three dimensions was 55.69% (i.e., 54.05% of knowledge-based questions, 68.03% of attitude-based questions, 45.01% of practice-based questions) of students across all three categories answered correctly. Among the answers, when analyzed with the average of all three dimensions of different professionals, the average percentage response of pharmacists was 66.98% (i.e., 66.85% of knowledge-based questions, 71.97% of attitude-based questions, 62.12% of practice-based questions), which is higher than other professionals. Thus, pharmacists scored better than the other two professionals, which was further clarified using the ANOVA and statistical significance below.

Table I: Knowledge based questions

Questions	Medical		Pharmacy		Nursing	
	Number	%	Number	%	Number	%
Define pharmacovigilance	25	33.78	81	61.36	18	30.50
Define ADR	47	63.51	82	62.12	24	40.67
Are you aware of any formal reporting system available in our country?	31	41.89	90	68.18	26	44.06
Are you aware of any banned drugs due to adverse drug reactions?	48	64.86	88	66.66	36	61.01
Have you ever shared information about ADR with anyone?	43	58.10	109	82.57	39	66.10
Where is an international centre for adverse effect reaction monitoring located?	35	47.29	77	58.33	33	55.93
Which of the following is a major risk factor for the occurrence of maximum adverse drug reactions?	38	51.35	80	60.60	29	49.15
In case a serious adverse event in India is observed where it should be reported?	28	37.83	74	56.06	23	38.98
Which is the correct way for ADR Classification?	24	32.43	63	47.72	15	25.42
Which one of the following is the WHO online database for reporting ADRs?	42	56.75	108	81.81	36	61.01
From which of the sources do you gather information about ADR?	31	41.89	99	75.00	19	32.20
Side effects like headache fever and vomiting should not be reported.	39	52.70	108	81.81	33	55.93
Total	431	48.53	1059	66.85	331	46.75

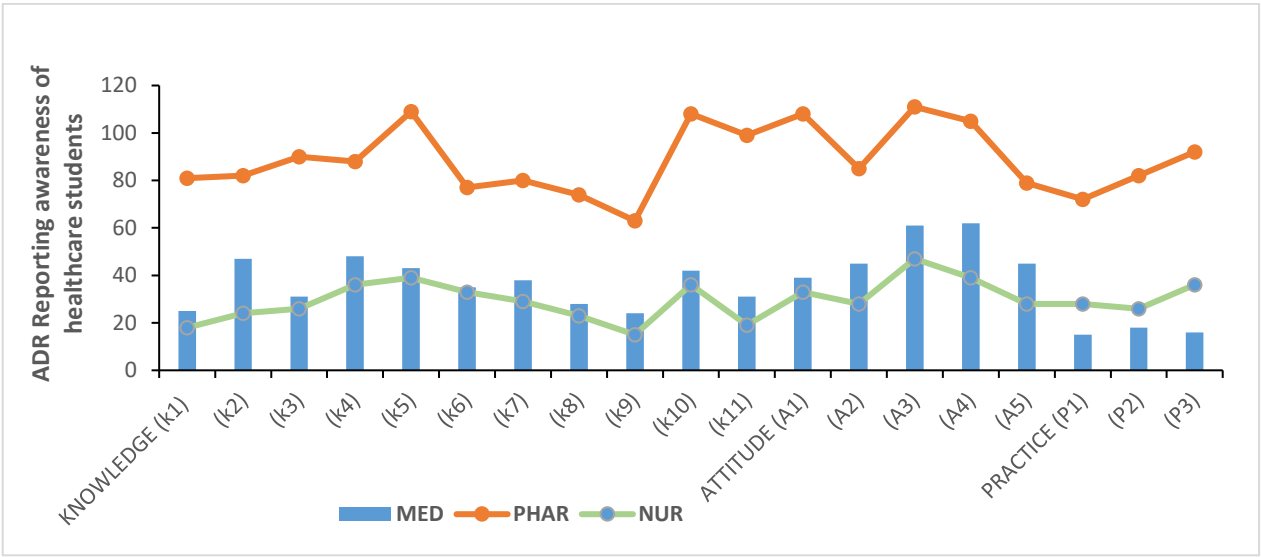
Table II: Attitude based questions

Questions	Medical		Pharmacy		Nursing	
	Number	%	Number	%	Number	%
Is ADR Reporting a mandatory process	45	60.81	85	64.39	28	47.45
Whether ADR reporting increases patient safety	61	82.43	111	84.09	47	79.66
Is ADR reporting a time-consuming process?	62	83.78	105	79.54	39	66.10
Healthcare worker's role	45	60.81	79	59.84	28	47.45
Total	213	71.96	380	71.97	142	60.17

Table III: Practice based questions

Questions	Medical		Pharmacy		Nursing	
	Number	%	Number	%	Number	%
Have you ever reported any suspected ADR?	15	20.27	72	54.54	28	47.45
Have you received Training on ADR reporting	18	24.32	82	62.12	26	44.00
Do you have the adverse reporting form available in your practising/ training hospital?	16	21.62	92	69.69	36	61.01
Total	49	22.07	246	62.12	90	50.82

From the overall mean score, the two-way ANOVA test yielded significant differences in KAP scores of students from different healthcare fields, with medical (35.92; 53.25; 16.33) and pharmacy (88.25; 95.00; 82.00) having significantly higher scores than nursing (27.58; 35.5; 82.00). The results of the ANOVA of awareness of ADR reporting depending on students of different healthcare fields (medical, pharmacy, nursing) are shown in Figure 1. The factor interaction of students of the different healthcare fields and KAP scores were significant ($F(1.153, 27.67) = 33.97$, $p < 0.0001$, $\eta 2 = 0.5765$).



Med: Medical; Phar: Pharmacy; Nur: nursing

Figure 1: Comparison of ADR reporting awareness of healthcare students

Figure 2 shows the results of the post hoc Tukey test applied for intergroup comparison of healthcare students from different fields. Significant differences in ADR awareness were found between medical students ($p<0.0001$), pharmacy students ($p<0.0001$), and nursing students ($p=0.0448$). The mean KAP score of pharmacy students (88.68) was significantly higher than that of medical (19.25) and nursing students (29.63), with p-value=0.05. (Table IV; Figure 2).

Table IV: Tukey's multiple comparisons tests

Relationship between	Mean difference	95.00% CI of diff.	Adjusted *p*-value
Medical *vs* Pharmacy	-69.43	-80.73 to -58.14	<0.0001
Medical *vs* Nursing	-10.38	-21.07 to 0.3072	0.0578
Pharmacy *vs* Nursing	59.05	52.98 to 65.13	<0.0001

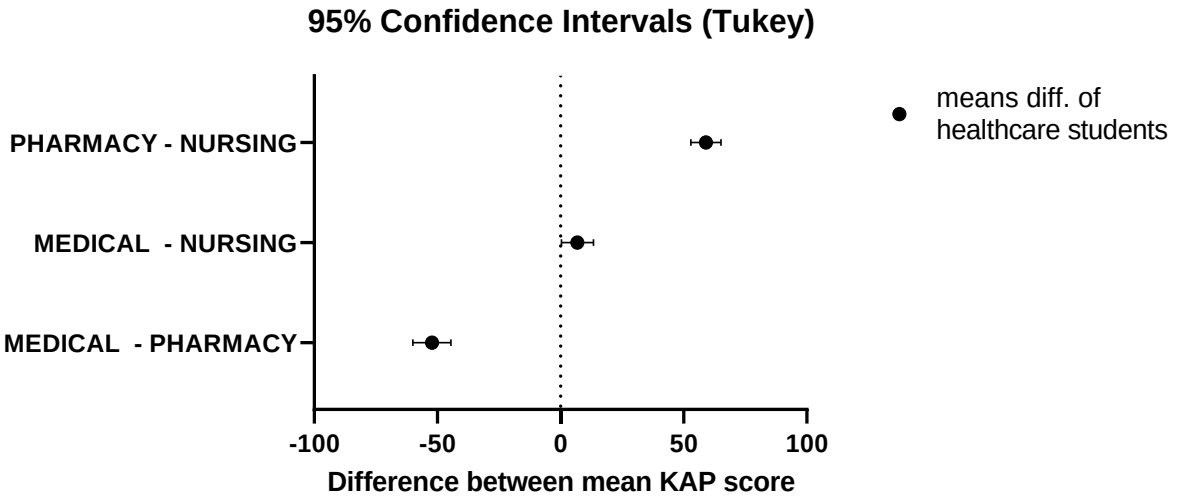


Figure 2: Turkey's multiple comparison tests

Discussion

The primary requirement of PV is the reporting of suspected ADRs. The post-marketing safety studies are critical in recognising possible risk factors correlated with the use of new drugs in the general population, and the participation of health professionals is essential in reporting suspected ADRs to strengthen signal detection (Bhagavathula *et al.,* 2016). Numerous factors are linked to ADR underreporting among healthcare professionals. Moreover, to increase the rate of reporting, healthcare professionals must be adequately educated about ADR reporting (Tandon *et al.,* 2015).

Students were aware of the basic terminologies of PV, which is consistent with other studies, but this theoretical understanding of ADRs and PV does not appear to have transferred into practical knowledge and so is unlikely to be adopted in practice. This result is consistent with findings from previous investigations (Rehan, Vasudev & Tripathi, 2002; Upadhyaya *et al.,* 2012; Gupta *et al.,* 2015). It could be due to discrepancies in defining PV terms and the lack of a specific, harmonised pharmacovigilance core curriculum in universities. In this study, 72.07% of students reported sharing information about ADRs with others, and 27.92% never had. Sharing information on ADR may help increase knowledge about it. A study revealed that lack of information about the patient is the key factor that discourages doctors from disclosing ADRs, like other studies carried out in developed countries (Scott *et al.,* 1990).

The mean attitude score of the pharmacy, nursing, and medical students was satisfactory, as 60% of the participants agreed that ADR reporting is mandatory. A vast majority of the participants agreed that ADR reporting increases patient safety, consistent with previous findings where the majority of medical students agreed that ADR reporting increases patient safety (Akshay & Hemanth Kumar, 2018). Among the participants, 59.62% disagreed that side effects like headache, fever, and vomiting should not be reported, while only 38.48% disagreed with this statement, similar to previous findings (Niza *et al*., 2021), where the majority of the healthcare professional disagreed that common side effects should be reported as they could indicate underlying causes (Adisa & Omitogun, 2019). Even with well-established drugs, reporting of ADRs, whether known, unknown, common, uncommon, dangerous, or moderate, is urged. (British Medical Association Board of Sciences, 2006; Li *et al*., 2018). Even though these ADRs do not pose a direct threat to life, they can induce secondary injuries in older individuals, such as falls and fractures, and can

have substantial mobility, cognition, and psychosocial ramifications (Monteiro, Dias & Vaz-Patto, 2021).

ADR reporting was decreased among healthcare students. In general, less than half of healthcare employees have a favourable attitude toward ADR reporting. Although healthcare providers play a critical role in ensuring a robust pharmacovigilance system, spontaneous ADR reporting by healthcare professionals is extremely low (6–10%) in many countries, which may be due in part to the fact that spontaneous ADR reporting is not a legal requirement in most countries (Okezie & Olufunmilayo, 2008; Oshikoya & Awobusuyi, 2009; Osakwe *et al.,* 2013). Among the responding samples, only 43.39% of ADR has been reported. Even half of its percentage did not achieve that with the sample (i.e., healthcare students). This result is similar to findings in India, where only 2.9% of students have ever reported an ADR (Gupta & Udupa, 2011).

In this study, the level of practice was poor, with only 45% of respondents having correct answers regarding PV practice. Our results contradict those in Brazil (Rabelo *et al.,* 2020), showing that pharmacists scored good and nurses low in PV-related practice. The knowledge score of medical students and nurses (48.53% and 46.75%) was lower than that of pharmacists (54.05%). Another study (Umair Khan *et al*., 2015) found considerable variations in knowledge, attitude, and practice between pharmacy and medical students, as measured by different knowledge questions. This disparity could be because pharmacy students spend two to four terms studying pharmacology and clinical pharmacy, while medical students study pharmacology only for one to two terms during their medical education. This fact implies that pharmacy students receive extensive instruction in pharmacology and clinical pharmacy, which is likely why they demonstrated more understanding in this domain than medical students. Pharmacovigilance courses should be incorporated into the curricula of both pharmacy and medical students to improve their understanding. Clinical sessions and clinical/research initiatives should also be implemented, and ADR monitoring should be regarded as an essential element of patient care. The UMC, likewise, supports these guidelines. Pharmacovigilance courses, along with the rational use of medication, should be taught to healthcare professional students at the undergraduate level, according to UMC (Mann *et al.,* 2007).

While comparing the mean ANOVA score of various healthcare students, pharmacy and medical students had a higher KAP score than nursing students, consistent with previous findings, where pharmacy students showed statistically significantly higher knowledge and practice than other healthcare professionals (Bepari *et al.,* 2020).

Limitations

The limitation of our study was the relatively small number of respondents and the fact it relied on the unequal distribution of participants from only one district. Hence, these findings cannot be generalised to the whole country. But it is believed that the study findings would be helpful for a large-scale study in the future.

Clinical implications

As a result of the study observations, several steps must be taken to ensure that doctors, nurses, and pharmacists report ADRs frequently. Seminars and conferences should be conducted to promote the culture of reporting and create awareness, thus reducing ADR underreporting, as one of the reasons for underreporting ADRs is the belief that only major ADRs should be reported (Kamtane & Jayawardhani, 2012; Ahmad *et al.,* 2013).

Another option is to make ADR reporting mandatory during undergraduate education, internship, and postgraduate training. According to a cross-sectional, questionnaire-based, metacentric study conducted in six different medical colleges in Riyadh, Saudi Arabia, the general awareness of PV in undergraduate medical students was poor (Sales *et al.,* 2017). Research presented at a paediatric tertiary care centre in Iran found that educational interventions and facility enhancement might help improve reporting rates (Baniasadi, Fahimi & Shalviri, 2008).

Conclusion

Pharmacists had relatively better knowledge and attitude towards ADR reporting. This survey on ADR reporting among healthcare students of Namakkal district suggests a lack of in-depth knowledge of the pharmacovigilance programme in the country. Consequently, there is a prominent need to create awareness and promote ADR reporting. Expanding the scope and content of pharmacovigilance training and linking pharmacovigilance services and universities are strategic initiatives that could have a good impact on this setting. In addition, ADR reporting must be an integral part of the clinical training of all healthcare professionals.

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Conflict of interest

There are no conflicts of interest to declare.

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Appendix A

ASSESSING THE AWARENESS OF ADR REPORTING AMONG HEALTHCARE STUDENTS IN NAMMAKAL DISTRICT, TAMIL NADU

DATA ENTRY FORM

PART1: SOCIODEMOGRAPHIC DETAILS

1. Name :
2. Age :
3. Gender : □ Male □ Female □ others
4. Course of study: □ Pharm. D □ MBBS □ Dental □ Nursing □ B.H.M.S

PART 2: KNOWLEDGE

1. Define pharmacovigilance
   a) The science of monitoring ADR's happening in a hospital

b) The process of improving the safety of drugs
c) The detection, assessment, understanding and prevention of adverse effects
d) The science detecting the type and incidence of ADR after the drug is marketed
e) Do not know

2. Define ADR?
   a) Noxious and unintended response to drug and occurs at doses normally used in man or animal for prophylaxis, diagnosis or therapy of disease
   b) Noxious and unintended response to drug and occurs at doses normally used in man for prophylaxis, diagnosis and therapy of disease.
   c) Any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment
   d) Any adverse reaction identified in regulatory documents such as investigators brochures or product monograph occurring within the expected frequency
   e) Do not know

3. Are you aware of any formal reporting system available in our country?
   a) Yes
   b) No
   c) Do not know

4. Are you aware of any banned drugs due to adverse drug reaction?
   a) Yes
   b) No
   c) Do not know

5. Have you ever shared information about ADR with anyone?
   a) Yes
   b) No

6. Where an international centre for adverse effect reaction monitoring is located?
   a) Sweden
   b) Germany
   c) United States
   d) Do not know

7. Which of the following is a major risk factor for the occurrence of maximum adverse drug reactions?
   a) Arthritis
   b) Renal failure
   c) Visual impairment
   d) All of these
   e) Do not know

8. In case a serious adverse event in India is observed where it should be reported?
   a) CDSCO
   b) Pharmacovigilance
   c) NCC or AMCs
   d) Indian Pharmacopoeia Commission
   e) Do not know

9. Which is the correct way for ADR Classification?
   a) Type A, B, C, D, E, F, and G
   b) Type 1, 2, 3, 4, 5, 6 and 7
   c) Known, unknown and common, uncommon
   d) Reversible and irreversible
   e) Do not know

10. Which one of the following is the WHO online database for reporting ADRs?
    a) ADR advisory committee
    b) Med safe
    c) Vigibase
    d) Med watch
    e) Do not know

11. From which of the sources do you gather information about ADR?
    a) Textbooks
    b) Journals
    c) Internet
    d) Medical representatives
    e) Seminars/conferences
    f) Direct mail brochures
    g) All of the above

12. Healthcare worker's role
    a) Preventing ADRs
    b) Detecting ADRs
    c) Managing ADRs
    d) Reporting ADR
    e) All of the above

PART 2: ATTITUDE

13. Side effects like headache fever and vomiting should not be reported.
    a) Strongly agree
    b) Agree
    c) Disagree
    d) Strongly disagree

14. Is ADR reporting a mandatory process?
    (a) Strongly agree
    (b) Agree
    (c) Strongly agree (d) Disagree

15. Whether ADR reporting increases patient safety
    (a) Strongly agree
    (b) Agree
    (c) Strongly agree
    (d) Disagree

16. Is ADR reporting a time-consuming process?
    (a) Preventing ADRs
    (b) Detecting ADRs
    (c) Managing ADRs
    (d) Reporting ADRs
    (e) All the above

PART 3: PRACTICE

17. Have you ever reported any suspected ADR?
    a) Yes
    b) No

18. Have you received Training on ADR Reporting?
    a) Yes
    b) No

19. Do you have the adverse reporting form available in your Practicing/training hospital?
    a) Yes
    b) No