AWARENESS ABOUT THE REPORTING OF THE ADVERSE DRUG REACTIONS (ADRs) AMONG THE NURSING STAFF IN A TERTIARY CARE GOVERNMENT HOSPITAL

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ABSTRACT:

Background: For assessment of awareness in nurses about reporting of ADR, this study was conducted among the nursing staff of Rural Tertiary care teaching hospital in western Maharashtra. **Methods:** This is a cross-sectional observational study conducted for a period of 3 months. Pre-validated questionnaire consisting of 20 questions was distributed among the nursing staff to assess their awareness attitude, knowledge regarding reporting of ADR. **Results:** 96% agreed that reporting of ADR is necessary. 90% thought that Pharmacovigilance should be taught to them. 88% felt that ADR Monitoring Centre should be established in every hospital & 66% believed that only serious ADRs need to be reported. 68% have experienced ADR during their working hours in hospital. Only 46% have ever reported ADR. 30% have ever seen the ADR reporting form. 50% have been trained on reporting of ADR. None of them knew that SAE should be reported within 24 hrs. **Conclusion:** This study revealed adequate knowledge and positive attitude but poor practice of ADR reporting among the nurses in a tertiary care teaching hospital.

KEYWORDS: ADR Questionnaire, Pharmacovigilance, Nurses.

INTRODUCTION:

Adverse Drug Reaction (ADR) as defined by the World Health Organization (WHO) is "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function". These are an imperative public health crisis striking a substantial fiscal burden on the society and health care systems. It is one of the major reasons of hospitalization (5% -20%) in India. Uppsala Monitoring Centre (UMC), Sweden; which maintains the international database of the ADR reports has observed that, only 6% -10% of all the ADRs are reported. Hence, the detection and reporting of ADR becomes vital and

should be done appropriately by the health experts to ensure safer usage of drugs in patients and to serve the purpose of Pharmacovigilance.[42]

WHO defines pharmacovigilance as "The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine- related problems". In 2010, the Pharmacovigilance Programme of India (PvPI) was initiated for monitoring ADRs in our country and to safeguard public health by assuring the safety of medicinal products. Doctors, nurses and pharmacists are key healthcare professionals involved in prescribing, dispensing, administering, storage and disposal of medicines. Under reporting of ADRs is a common problem in the implementation of PvPI in our country. Various studies have revealed that ADR reporting by health care providers is directly related to their knowledge, attitude and practice (KAP) about Pharmacovigilance.[1]

ADR reporting rate in India is below 1% compared to worldwide rate of 5%, because ADR reporting is not considered as a part of routine professional practice. It might be due to lack of knowledge & sensitization about ADR reporting. Health Care Professionals (HCPs) are the pillars of health care system. From the studies conducted in several countries to assess the knowledge, attitude and practices of HCPs, in can be concluded that nurses had marginally less KAP than the doctors. Since, nurses spend more time in patient care and tend to see ADR earlier, compared with other health care team members. Therefore, it can be hypothesized that, the nurses can play significant role in monitoring, detection and reporting of adverse event. [32]

ADR reporting rate can be increased by improving the knowledge and practice of the nursing staff. Our study would be a step in the same direction to evaluate the basic knowledge, attitude and the practices of the nursing staff towards ADR reporting.

AIM:

To assess the awareness about the reporting of the adverse drug reactions (ADRs) among the nursing staff.

OBJECTIVE:

To assess the awareness about the reporting of the adverse drug reactions (ADRs) among the nursing staff.

METHODOLOGY:

MATERIALS AND METHODS:

Type of Study: A prospective, cross sectional, observational, close ended questionnaire-based study

Place of Study: Study was conducted among the nursing staff of Rural Tertiary care teaching hospital, Ambajogai, Maharashtra, India.

Period of Study: 3 months (January 2020 – March 2020)

Sample Size: Nurses from all specialties working in the hospital were enrolled in the study.

Inclusion criteria: Nursing staff of the hospital from all specialties were included in the study

Exclusion criteria: i) Those who were not willing to participate in the study

ii) Those who did not return the questionnaire within the stipulated time

Study Design: The study instrument was a questionnaire consisting of 20 questions (items), designed to assess the knowledge, attitude and practices regarding pharmacovigilance. This questionnaire was pre-validated by five Senior Pharmacologists from different institutes, prior to the study.

Prior approval was taken from the Institutional Ethics Committee to conduct the study.

Written consent was taken from all the participants prior the data collection.

Structured, pre-validated questionnaire containing 20 questions was used for this study. The details of the questionnaire are as follows: (APPENDIX-1)

1) Knowledge related questions: The assessment of participant's knowledge of Pharmacovigilance included seven questions (items) on definition and purpose of Pharmacovigilance, knowledge of ADR related to medicines from other sources,

responsibility of reporting ADR, knowledge of National Pharmacovigilance Programme, Regulatory body responsible for monitoring ADRs, Long term benefits of ADR reporting.

2) Attitude related questions: The assessment of participant's attitude towards Pharmacovigilance included six questions (items) on necessity of reporting ADRs, teaching of Pharmacovigilance, prevention of ADR and opinion about ADR Monitoring Centre.
3) Practices related questions; The assessment of participant's practice on ADR reporting included six questions (items) on experience of ADR, report to Pharmacovigilance Centre, ADR reporting form, training to report ADRs, reporting of serious adverse events, reporting of unexpected ADRs, presence of Pharmacovigilance Committee in institute
4) One question was asked for the reason of underreporting i.e. factors discouraging from reporting ADR.

   The participants (50 nurses) were personally briefed about the study questionnaire and were requested to complete and return the questionnaire immediately.

   The information was recorded and analyzed using suitable statistical methods using Microsoft excel worksheet (Microsoft office 2016)

All 50 nurses completed and returned questionnaire within the stipulated time. Thus, response rate was 100%.

For questionnaire refer Appendix 'A'

OBSERVATION TABLE:

Table 1. Questions related to knowledge

Q. No	Correct Response (%)	Incorrect Response (%)
1.	**30 (60%)**	**20 (40%)**
2.	**28 (56%)**	**22 (44%)**
3.	**26 (52%)**	**24 (48%)**
4	**47 (94%)**	**03 (6%)**
5.	**32 (64%)**	**18 (36%)**
6.	**30 (60%)**	**20 (40%)**
7.	**44 (88%)**	**06 (12%)**

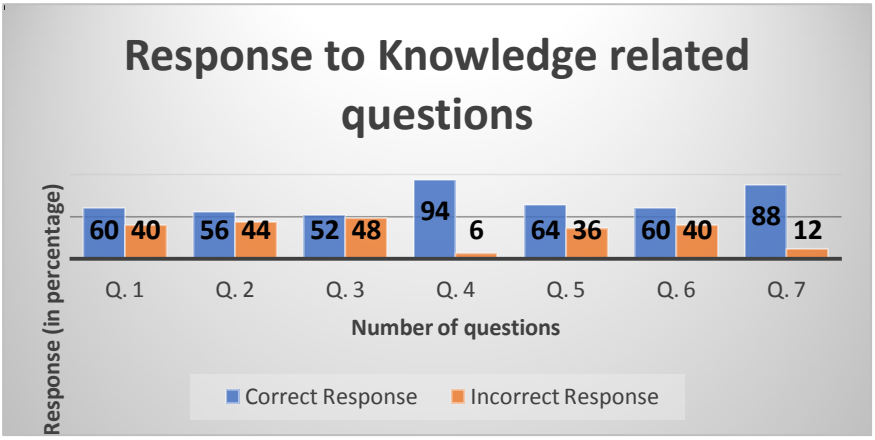
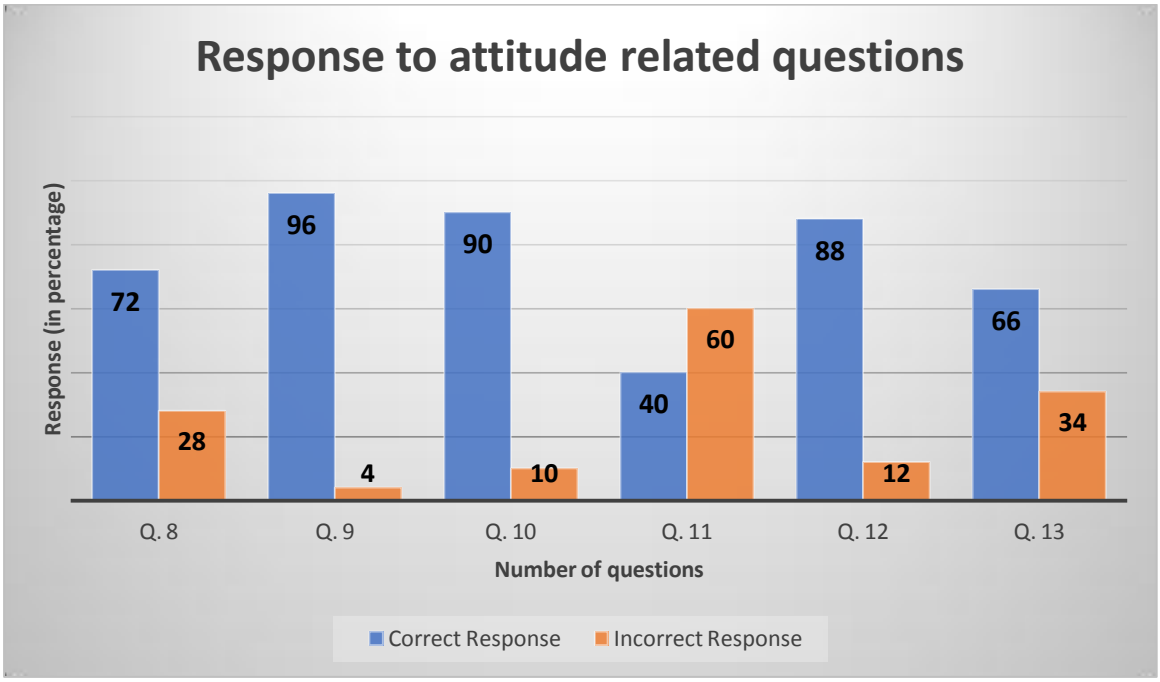


Table 2. Questions related to Attitude

Q. No	Correct Response (%)	Incorrect Response (%)
8.	36 (72%)	14 (28%)
9.	48 (96%)	02 (4%)
10.	45 (90%)	05 (10%)
11.	20 (40%)	30 (60%)
12.	44 (88%)	06 (12%)
13.	33 (66%)	17 (34%)



Q. No	Correct Response (%)	Incorrect Response (%)
14.	**34 (68%)**	**16 (32%)**
15.	**23 (46%)**	**27 (54%)**
16.	**15 (30%)**	**35 (70%)**
17.	**25 (50%)**	**25 (50%)**
18.	**00 (0%)**	**50 (100%)**
19.	**23 (46%)**	**27 (54%)**

Table 3. Questions related to Practice

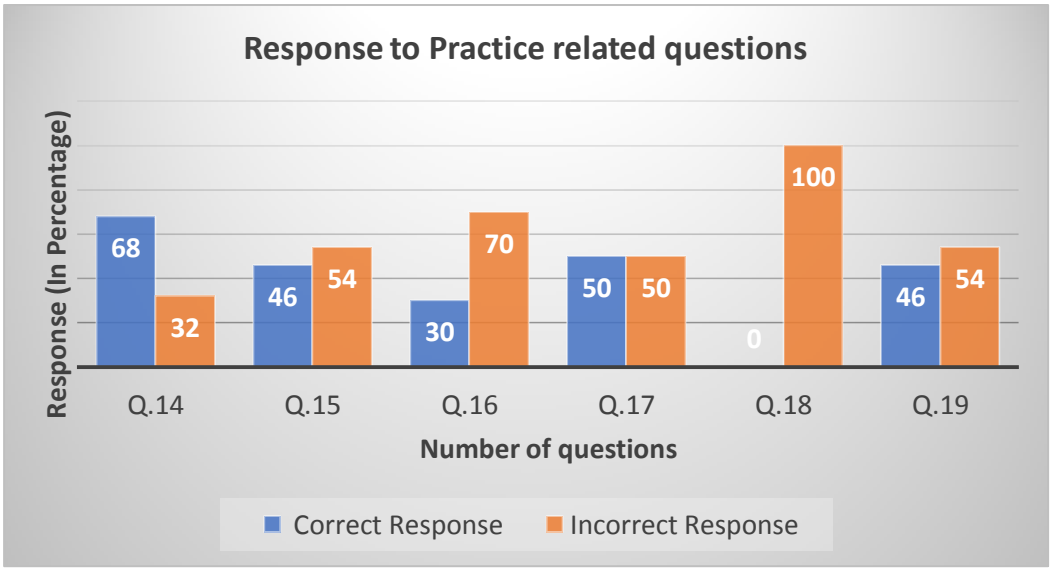
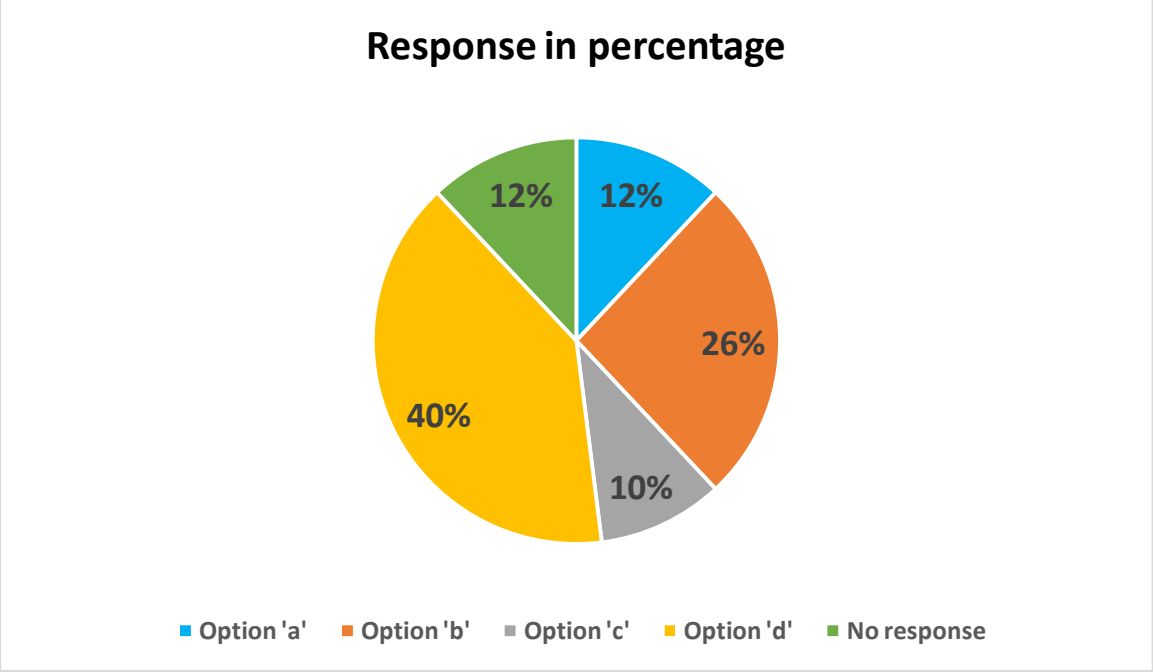


Table 4: Reason for Underreporting of reporting ADR

Q. NO	Option 'a'	Option 'b'	Option 'c'	Option 'd'	No response
20	06 (12%)	13 (26%)	05 (10%)	20 (40%)	06 (12%)



STATISTICAL ANALYSIS

The data was represented by mean of numbers (N) and percentages (%) and graphs of correct and incorrect responses depending on their appropriateness to the variable in question.

RESULTS

Total 50 questionnaires were distributed among 50 nurses irrespective of their age and sex. All of them completed and returned the questionnaire within the stipulated time period. Thus, the response rate was 100%.

ASSESSMENT OF PHARMACOVIGILANCE RELATED TO KNOWLEDGE:

Total seven questions were asked to the nurses to judge their knowledge about Pharmacovigilance.

While assessing the knowledge of the nurses about Pharmacovigilance, it was found that total of 60% , (N= 30) respondents out of 50, were knowing the correct meaning and definition of the term Pharmacovigilance and gave the correct response which is nothing but “the detection, assessment, understanding and prevention of (Adverse Drug Reactions) ADRs” according to the World Health Organization.

According to 56% (N=28) nurses, the most important purpose of Pharmacovigilance is to identify the safety of the drug.

Only 52% (N=26) of the nurses were aware that Pharmacovigilance is not only related to the ADR due to the drugs and vaccines but, it also includes herbal products, medical devices, etc.

About 94% (N=47) of the nurses were aware that ADR reporting is the responsibility of all health care professionals such as doctors, pharmacists, etc.

64% (N=32) of the nursing staff were aware regarding the existence of PvPI i.e. National Pharmacovigilance Programme.

About 60% (N= 30) nurses were aware that the regulatory body responsible for monitoring ADRs in India is CDSCO.

88% (N= 44) nurses believed that, ADRs reporting would help in patient safety in a long term.

ASSESSMENT OF PHARMACOVIGILANCE RELATED TO ATTITUDE:

Six questions were asked to assess the attitude of the nursing staff for ADR reporting.

While assessing the Pharmacovigilance related attitude of the nursing professionals, it was found that a total of 72% (N= 36) believed that ADR reporting is a professional obligation for them.

96% (N=48) agreed that reporting of ADR is necessary.

Overall, 90% (N= 45) nursing staff were of the view that Pharmacovigilance should be taught in detail to all health care professionals.

Surprisingly only 40% (N=20) of the nursing staff read article on prevention of ADRs.

Most of the nursing staff (88%, N= 44) felt that ADR Monitoring Centre should be established in every hospital.

About 66% (N= 33) of the nurses believed that only serious/ unexpected ADRs need to be reported.

ASSESSMENT OF PHARMACOVIGILANCE RELATED TO PRACTICE:

On assessing the Pharmacovigilance related practices, it was found that only 68% (N= 34) of nurses have experienced ADRs in patients during their working hours in a hospital.

Only 46% (N= 23) have ever reported ADR to Pharmacovigilance Centre.

Furthermore, only 30% (N= 15) of the nurses have ever seen the ADR reporting form.

In accordance with this, it was found that only 50% (N= 25) have been trained on reporting an ADR.

None of the nursing staff (0%, N=0) knew that the SAE (Serious Adverse Event) should be reported to the regulatory body within 14 days.

DISCUSSION

Nurses are often the sources in alerting the physicians about possible ADRs of the drugs. [19] Hence, this study was performed with the intention of assessing the knowledge, attitude and practices of the nurses towards Pharmacovigilance and ADRs. The response rate was highest (100%). In this questionnaire- based study, we included the nursing staff of rural tertiary care hospital in Marathwada region of Western Maharashtra.

This study showed that, the nurses had knowledge and supportive attitude towards Pharmacovigilance. However, actual practice of reporting was low (only 40%) among the participants. [1,8]

In this study, 67.71% and 60.65% nurses had the knowledge about Pharmacovigilance and existence of National Pharmacovigilance Program (PvPI) and regulatory body i.e. CDSCO is responsible for ADR monitoring in India respectively. 94% nurses knew that all HCPs are equally responsible for reporting of ADRs. About 88% nurses felt that ADR reporting by them would help in long term patient's safety. [8,19]

Only 52% nurses were aware that Pharmacovigilance also includes problems related to other systems of medicines existing in India that use medicines from herbs, animal & blood products, vaccines, medical devices etc. [1]

Majority of nurses (90%) considered that ADR reporting is important and should be made mandatory. This finding is similar to the finding of Agarwal et al. [1,8,19]

Moreover, about 72% nurses thought that ADR reporting is their professional obligation, which is similar in the studies done in Nagpur and Tamil Nadu.[1]

Only 40% nurses, ever read an article on prevention of ADR. This reflects low level attitude towards gaining knowledge about ADR. This finding is contradictory to the finding of the study done by Hanafi et al.

Majority of the nurses (88%) felt the necessity of establishing ADR Monitoring Centre in every hospital. [9]

66% nurses were aware that any ADR should be reported regardless of its seriousness and unexpected occurrence. Our findings are similar to John et al, Ekman et al (2012) [4]

Overall, 68% nurses had experienced ADRs in their patients, but only 46% had reported them to Pharmacovigilance Centre.

LIMITATIONS AND RECOMMENDATIONS

Since, this study was conducted in only one setting (hospital/ institution), the finding may not be generated to other contexts. Results inherent to questionnaire-based studies such as subjective response and recall bias. Being a cross sectional study, it cannot provide definite relationships between nurse's characteristics, knowledge variable, attitudinal variable and practice variables collected. Although this study does provide evidence to facilitate further research in similar settings. It would be logical to extend this study to other teaching hospitals, private practitioners, members of allied fields, doctors and students of medical and associated streams to generalize the finding of this study. Hence, further study is required to investigate temporal relationships and strength of association between these variables.

CONCLUSION

This study revealed adequate knowledge and positive attitude but the poor practices of ADR reporting among the nurses in a tertiary care teaching hospital in Western Maharashtra. They displayed an acceptance of professional responsibility towards ADR reporting. Lack of clinical knowledge, fear that the report may be wrong and lack of time to report are the key factors that discourage them from ADR reporting. ADR training would be a useful step in improving ADR reporting among nurses. Ensuring constant availability of ADR reporting forms in all wards are the ways to improve ADR reporting among nursing staff..

Therefore, an educational intervention of Pharmacovigilance should be incorporated during their nursing courses. It is necessary to conduct CMEs, ADR related training programs until we reach the point that voluntary reporting of ADRs becomes a routine and habitual among the nursing staff.

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APPENDIX-A

Pharmacovigilance Questionnaire:

Specialty: Age: Sex:

Please tick on the most appropriate option.

1. Definition of Pharmacovigilance.
   (a) The science detecting the type and incidence of ADR after drug is marketed.
   (b) The science of monitoring ADR's occurring in a hospital.
   (c) The process of improving the safety of the drug.
   (d) The detection, assessment, understanding and prevention of ADRs.
2. The most important purpose of Pharmacovigilance is
   (a) To identify safety of the drug
   (b) To calculate incidence of ADRs
   (c) To identify predisposing factors to ADRs
   (d) To identify previously unrecognized ADRs
3. Pharmacovigilance includes problems related to-
   (a) Drugs and Vaccines
   (b) Herbals
   (c) Medical devices
   (d) All of the above
4. The health-care professionals responsible for reporting ADRs in a hospital are
   (a) Doctors
   (b) Nurses
   (c) Pharmacists
   (d) All of the above
5. Does our country have National Pharmacovigilance Programme?
   (a) Yes
   (b) No
   (c) Can't say
   (d) May be
6. In India which regulatory body is responsible for monitoring ADRs?
   (a) Central Drugs Standard Control Organization (CDSCO).
   (b) Indian Council of Medical Research (ICMR).

(c) Indian Clinical Research Institute (ICRI).

(d) Medical Council of India (MCI).

7. Do you know reporting of ADR would help patient safety in the long term?
   (a) Yes
   (b) No
   (c) Don't know
   (d) May be
8. Do you know ADR reporting is professional obligation for you?
   (a) Yes
   (b) No
   (c) Can't say
   (d) May be
9. Do you think reporting of ADR is necessary?
   (a) Yes
   (b) No
   (c) Can't say
   (d) May be
10. Do you think Pharmacovigilance should be taught in detail to health-care professionals?
   (a) Yes
   (b) No
   (c) Can't say
   (d) May be
11. Have you ever read any article on prevention of ADRs?
   (a) Yes
   (b) No
12. What is your opinion about establishing ADR Monitoring Centre in every hospital?
   (a) Should be in every hospital
   (b) Not necessary in every hospital
   (c) One in a city is sufficient
   (d) Depends on number of bed size in the hospitals
13. Do you think only serious or unexpected ADRs need to be reported?
   (a) Yes

(b) No

(c) Don't know

(d) Can't say

14. Have you ever experienced ADRs in your patients during your clinical practice?

(a) Yes

(b) No

15. Have you ever reported ADR to the Pharmacovigilance Centre?

(a) Yes

(b) No

(c) Don't know where to report

(d) Don't know how to report

16. Have you seen the ADR reporting form?

(a) Yes

(b) No

17. Have you been trained on how to report ADR?

(a) Yes

(b) No

18. A serious adverse event in India should be reported to the regulatory body within?

(a) One day

(b) Seven calendar days

(c) Fourteen calendar days

(d) Fifteen calendar days

19. Is there any Pharmacovigilance Committee in your institute?

(a) Yes

(b) No

(c) In the process of forming

(d) Don't know

20. Which of the following factors discourage you from reporting ADRs?

(a) No remuneration

(b) Lack of time to report ADR

(c) A single unreported case may not affect ADR database

(d) Difficult to decide whether ADR has occurred or not