# ATTITUDES AND KNOWLEDGE OF MEDICAL PRACTITIONERS AT SALEM TOWARDS PHARMACOVIGILANCE REPORTING SYSTEM

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**ABSTRACT**

Background and Objective: Spontaneous reporting of adverse drug reaction is essential for the success of pharmacovigilance program. But under-reporting of adverse drug reaction is common among medical practitioners. In order to improve the reporting rate, it's important to know the attitudes and knowledge of practitioners towards pharmacovigilance reporting. Hence, this study was designed with the above objective.

Methods: It is a cross sectional questionnaire based survey involving 300 medical practitioners working in government and private hospitals in and around Salem, Tamilnadu, India. It was predesigned to obtain the demographic detail, encountered adverse drug reaction, knowledge [awareness on existence of adverse drug reaction (ADR) reporting form, awareness on existence of pharmacovigilance centre, ADR on which disciplines to be reported, type of ADR to be reported, eligible person to report ADR] and attitudes of practitioners on pharmacovigilance reporting system. Collected data were entered in Microsoft excel spread sheet. Questions were analyzed individually and the descriptive statistical analysis was done using STATA 11 software. The relationship between experience of medical practitioners to encountering ADR and awareness of ADR reporting form were determined using Pearson chi-square test at $p<0.05$

Results: The response rate for the administered questionnaire was 83%. Majority of respondents were in the age group of 20-30 years. Male: female ratio was 152: 97. The mean duration of total experience of practitioners was 7.54 years. Knowledge and attitudes of practitioners towards pharmacovigilance reporting system was very low.

Conclusion: Proper educational and managerial intervention should be implemented to improve the reporting rate among the practitioners.

**KEY WORDS:** Adverse drug reaction, Pharmacovigilance, underreporting

## INTRODUCTION

Adverse drug reaction is defined by World Health Organization as "a reaction which is noxious and unintended and which occurs at doses of drug normally used in humans for prevention, diagnosis or therapy of disease, or for the modification of physiological function. [1] Adverse drug reactions to drugs are major global problem, many of which are preventable. A meta-analysis conducted in United States indicates ADR were the 4th major cause of death in 1997. [2] A study published from JSS hospital, Mysore, India shows 0.7% of hospital admissions were due to ADR and a total of 3.7% of the hospitalized patients experienced an ADR of which 1.8% had a fatal ADR. [3] Arulmani R et al.,(2007) showed that the overall incidence of ADR was 9.8% [4] and Desai CK et al.,(2011) showed the incidence of ADR in a tertiary care hospital (India) was 6.7%. [5] Above studies confirms that the drug related adverse reactions are common among Indians affecting both children and adults and causes morbidity and mortality. It imposes a major socioeconomic burden on the society. [6, 7] Hence, early detection and prevention of ADR is necessary. Drugs are marketed after completion of preclinical and clinical trial followed by approval by FDA. Clinical trial (Phase I-III) will identify the more common and predictable side effects of medicine. The rare adverse effect will be seen only when the drug is used in large number of patients under the conditions of everyday use. So, post marketing surveillance (clinical trial Phase-IV) of licensed medicines is very important to detect the less common, but sometimes very serious ADRs. This is done by pharmacovigilance program.

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Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems.

The main function of Pharmacovigilance is to

(i) Identify, quantify and document drug related problems.

(ii) To contribute to reduce the risk of drug related problems in health care systems

(iii) To increase knowledge and understanding of factors and mechanism which are responsible for drug related injuries. [8]

As there are variation in drug response among individuals in different countries, variation in prescribing habits, availability of drugs and drug regulatory system, WHO recommends every country to have their own pharmacovigilance program. [1] Pharmacovigilance program have played a major role in detection of ADR and had banned several drugs from the market, had improved the safety labeling of pharmaceutical products. [1] Spontaneous reporting of ADR by health care professionals is very important for the success of pharmacovigilance. It helps in assessing the benefit – risk ratio of marketed drugs and contributes to unsuspected and unusual ADR previously undetected in clinical trial. [9] But underreporting is very common, with a median underreporting rate (defined as percentage of ADRs detected from intensive data collection that were not reported to relevant spontaneous reporting systems) of 94% [10] and occurs frequently for serious and unlabeled reaction. [11, 12] Studies conducted in Northern Italy [13] and India [14] had also shown underreporting of ADR among health care professionals. In order to improve the reporting rate, it's important to know the attitudes and knowledge of practitioners towards pharmacovigilance reporting. The reasons for low reporting rate can be identified, so that suitable intervention may be planned in the future to improve ADR reporting. Hence, the present study was conducted with the following objectives.

- To study the demographic profile of the health care professionals under the study
- To know the knowledge of medical practitioners towards pharmacovigilance reporting system.
- To know the attitudes of medical practitioners to report adverse drug reactions.

**MATERIALS AND METHODS**

The study is a cross sectional questionnaire based survey involving 300 medical practitioners working in government and private hospitals in and around Salem, Tamilnadu, India. The study was conducted after obtaining Institutional Ethical Clearance for a period of 3months (July 2012-september 2012). The study was conducted with a predesigned questionnaire which had 10 questions (Annexure – 1). It was validated by Pharmacovigilance committee and Psychology professor. It was designed to obtain the demographic detail of practitioners, details on encountered adverse drug reaction and its category (Quest 1A, 1B, 1C), awareness about the existence of ADR reporting form (Quest 2), Pharmacovigilance centre (Quest 3), attitudes (Quest 4 – 6, 10) and knowledge (Quest 7 – 9) of medical practitioners about adverse drug reaction reporting. The participants were contacted individually and were explained about the purpose of the study. After obtaining their informed consent for participation in the study, they were given 30 minutes to fill the questionnaire. In case of doubts in understanding the questionnaire, clarifications were given. Collected data were analyzed individually and the descriptive statistical analysis was done using STATA 11 software. The relationship between experience of medical practitioners to encountering ADR and awareness of ADR reporting form were determined using Pearson chi-square test at $p<0.05$

**RESULTS**

The questionnaire was administered to 300 medical practitioners. Only 249 practitioners (83%) responded by completely filling the questionnaire. Table 1 shows the demographic profile of participated Medical practitioners.

A total of 192 (77.11%) respondents stated that they had encountered adverse drug reaction during their practice. Table 2 shows the type and severity of ADR encountered by the practitioners. Table 3 shows the relationship

between experience of medical practitioners and encountering adverse drug reaction. There was a statistically significant relation between experience and encountered ADR. With increase in experience the number of practitioners who had encountered ADR was high.

Awareness of ADR reporting form and pharmacovigilance centre:

Only 67(26.91%) practitioners were aware of existence of ADR reporting form. While the remaining 182 (73.09%) were not aware of existence of such form. 61(24.50%) practitioners were aware of existence of pharmacovigilance centre; others (188(75.50%)) were not aware of the existence of pharmacovigilance centre. Out of 67 practitioners who knew the existence of ADR reporting form only 24(35.82%) had reported encountered ADR. Table 4 displays ADR reporting by the practitioners. 43(64.18%) practitioners who had not reported ADR stated the following reasons for not reporting the ADR (Table 5). Chi-square test (Table 6) was used to find out the relationship between experience of practitioners and awareness of ADR reporting form. There was no statistically significant relationship between experience and awareness of ADR reporting form.

Attitudes towards ADR reporting:

- 214 (85.94%) practitioners opined that ADR reporting is a professional obligation and 35(14.06%) practitioners opined that ADR reporting is not a professional obligation.
- 110(44.18%) respondents stated that, it should be voluntary. 132(53.01%) respondents stated that it should be compulsory and 7(2.81%) respondents stated it should be remunerated.
- 200 (80.32%) doctors opined that the identity should be kept confidential and 49(19.68%) doctors opined it can be revealed.

Knowledge on ADR reporting:

- 8 practitioners (3.21%) gave the correct response to the disciplines in which ADR to be reported (i.e.) ADR to allopathic medicine, others (Homeopathy, Ayurveda, Siddha and traditional medicines), vaccines and biomedical devices.
- 39(15.66%) practitioners gave the correct response on type of ADR to be reported. (mild, moderate, severe reaction, reaction to new drug, death of a patient due to ADR, congenital anomaly, drug interaction, already known ADR to a drug, appears like ADR cause is unknown). 26(10.44%) practitioners opined only severe ADR should be reported.
- 28(11.25%) clinicians opined that doctors, nurses, pharmacist, physiotherapist and dentist were the eligible persons to report ADR and that was the correct response. Other practitioners gave different erroneous opinion.

**Table 1: Demographic profile of the Medical practitioners**

| Character | | No (%) |
|---|---|---|
| Age in years | 20-30 years | 146 (58.63%) |
| | 31-40 years | 60 (24.09%) |
| | > 41 years | 43 (17.27%) |
| Male : Female ratio | | 152:97 |
| Qualification | M.B.B.S | 95(38.15%) |
| | Specialty | 144(57.85%) |
| | Super specialty | 10(4%) |
| Experience | < 1 year | 77(30.94%) |
| | 1-5 years | 86(34.58%) |
| | 6-15 years | 48(19.26%) |
| | > 15 years | 38(15.22%) |
| Mean duration of total experience | | 7.54 years |

**Table 2: Type and severity of encountered ADR**

| **Encountered ADR** | | ***No (%)** |
|---|---|---|
| Type of ADR | Type A reaction | 78(40.63%) |
| | Type B reaction | 85(44.27%) |
| | Type A & B reaction | 29(15.10%) |
| Severity of ADR | Minor | 66 (34.38%) |
| | Moderate | 79 (41.15%) |
| | Severe | 23(11.98%) |
| | Lethal | 21 (10.93%) |

* - No of practitioners who encountered ADR = 192

| Table 3: Relationship between experience and encountering ADR | | | |
|---|---|---|---|
| Total Experience | Have you encountered any ADR | | Total No (%) |
| | Yes (No (%)) | No (No (%)) | |
| 0 – 1 years | 46(23.96) | 31(54.39) | 77(30.92) |
| 1 – 5 years | 68(35.42) | 18(31.58) | 86(34.54) |
| > 5 years | 78(40.63) | 8(14.04) | 86(34.54) |
| **Total** | **192(100)** | **57(100)** | **249(100)** |

Pearson Chi-square test = 22.34, P = 0.001, statistically significant

| Table 4: ADR reporting by the practitioners | | |
|---|---|---|
| **Whom did you report?** | **No** | **Percentage** |
| To the HOD | 13 | 54.17 |
| To the Head of the Institute | 4 | 16.67 |
| To the pharmaceutical company | 3 | 12.5 |
| To the pharmacovigilance centre | 4 | 16.66 |
| **Total** | **24** | **100** |

| Table 5: Reasons for not reporting the ADR | | |
|---|---|---|
| **Reason for not reporting ADR** | **No** | **Percentage** |
| No Need to report already known ADR(Complacency) | 14 | 32.56 |
| Reporting of encountered ADR may not contribute to the enhancement of medical knowledge (indifference) | 2 | 4.65 |
| Fear of litigation or enquiry(apprehension) | 4 | 9.30 |
| Lack of time(lethargy) | 1 | 2.33 |
| Multiple reasons | 2 | 4.65 |
| No response | 20 | 46.51 |
| **Total** | **43** | **100** |

| Table 6: Relationship of experience to awareness of ADR reporting form | | | |
|---|---|---|---|
| Total Experience | Are you aware of existence of ADR reporting form | | Total No (%) |
| | Yes ( No (%)) | No ( No (%)) | |
| 0 – 1 years | 19(28.36) | 58(31.87) | 77(30.92) |
| 1 – 5 years | 21(31.34) | 65(35.71) | 86(34.54) |
| > 5 years | 27(40.30) | 59(32.42) | 86(34.54) |
| **Total** | **67(100)** | **182(100)** | **249(100)** |

Pearson Chi-square test = 1.3466, P = 0.510, statistically not significant

**Annexure – 1**

**Attitudes and Knowledge of Medical practitioners at Salem towards**
**Pharmacovigilance reporting system**

1. Male ☐ Female ☐
2. Age 20-30 yrs ☐ 30-40 yrs ☐ 40-50 yrs ☐ 50-60 yrs ☐ 60-70 yrs ☐
3. Degree - M.B.B.S ☐ P.G. Diploma ☐ P.G. Degree ☐ Super specialty ☐ Internship ☐
4. Specialty –
5. Total Experience –

Questions:

1. A. During your practice, have you encountered any adverse drug reaction?

   Yes ☐ No ☐

   B. If encountered, mention the type of reaction

   a. Type A (Related to the dose, pharmacological properties of the drug, includes side effect, toxic effect, consequences of drug withdrawal) ☐

   b. Type B (Depends on patient immunological system. Includes allergy and idiosyncrasy) ☐

   C. Mention the severity of the reaction.

   a. Minor (No therapy/No antidote/No prolongation of hospitalization required) ☐

   b. Moderate (Requires change in drug therapy/ specific treatment/ prolongation of hospital stay) ☐

   c. Severe (Life threatening, causes permanent damage/requires intensive medical treatment) ☐

   d. Lethal (Directly or indirectly contributes to the death of the patient) ☐

2. Are you aware of existence of the ADR reporting form? -

   Yes ☐ No ☐

3. Are you aware of existence of any pharmacovigilance centers? - Yes ☐ No ☐

4. A. Have you reported any ADR till date? –

   Yes ☐ No ☐

   B. If yes, whom did you report to?

   a. To the HOD ☐

   b. To the head of the institute ☐

   c. To the pharmaceutical company ☐

   d. To the pharmacovigilance centre ☐

   C. Mention the reason for not reporting the ADR

   a. No need to report already known ADR to a drug ☐

b. Reporting of encountered ADR may not contribute to the enhancement of Medical knowledge ☐
c. Fear of litigation or enquiry ☐
d. Lack of time ☐
e. Lack of interest ☐

5. According to you, ADR reporting is a
   a. Professional obligation ☐
   b. Not a professional obligation ☐
6. ADR reporting should be
   a. Voluntary ☐
   b. Compulsory ☐
   c. Remunerated ☐
7. In your opinion, the adverse drug reactions due to the following disciplines / products needs to be reported or not?
   a. Allopathic medicine Yes ☐ No ☐
   b. Others (Homeopathy, Ayurveda, Siddha, Traditional medicines) Yes ☐ No ☐
   c. Vaccines Yes ☐ No ☐
   d. Blood products Yes ☐ No ☐
   e. Biomedical Devices Yes ☐ No ☐
8. According to you, which of the following type of reaction should be reported?
   a. Mild ☐
   b. Moderate ☐
   c. Severe ☐
   d. Reaction to new drug ☐
   e. Death of a patient due to the ADR ☐
   f. Congenital anomaly due to drug ☐
   g. Drug interactions ☐
   h. Already known ADR to a drug ☐
   I. Appears like an ADR, cause is unknown ☐
9. Who are eligible to report ADR?
   a. Doctors ☐
   b. Nurses ☐
   c. Pharmacist ☐
   d. Lay person ☐
   e. Physiotherapist ☐
   f. Dentist ☐
10. According to you, the identity of the reporting doctor should be kept
    a. Confidential ☐
    b. Revealed ☐

**DISCUSSION**

Adverse drug reaction reporting system with participation from all the health care professionals is well established in countries like Australia and Brazil. [15] In India it is still in the nascent stage. [16] This questionnaire survey helps in knowing the demographic profile, attitudes and knowledge of medical practitioners at Salem (Tamil Nadu, India) towards pharmacovigilance reporting system. The overall response rate was 83% and it was higher than 62% response rate reported by Amirta P et al.,(2011) in their study. [17] Majority of surveyed practitioners were in the age group of 20-30 years (58.63%) and the male: female ratio of responded practitioners was 152:97. Physician's knowledge of noticing ADR was good (77.11% of practitioners encountered ADR) and there was a statistically significant relation between experience and encountering ADR. With increase in clinical experience, the number of physician who admitted to have encountered ADR was high. This shows a positive reflection on the clinical skills and awareness about ADRs.

Studies done at Mumbai [18] and Muzzafarnagar [19] have shown better knowledge of ADR reporting but poor practice of ADR reporting among practitioners. But in our study, the knowledge regarding the existence of pharmacovigilance centre, ADR reporting form, type of reactions to be reported, ADR on which disciplines to be reported and persons who are eligible to report ADR is very low. 26.91% of respondents alone were aware of existence of ADR reporting form and 24.50% of respondents were aware of existence of pharmacovigilance centre. More educational programs on pharmacovigilance should be done to educate the practitioners. Among the 67 who knew the existence of ADR reporting form only 24 of them had reported encountered ADR. Others gave multiple reasons (lack of time, lack of interest etc) for not reporting ADR. The ADR reporting rate (9.63%) was very low in the present study and it was similar to other studies done at Mumbai [18] and Ahmedabad. [5] The reasons for under reporting were narrated by Inman as “Seven deadly sins”. [20] In our study we found the major reason for not reporting is lack of awareness of ADR reporting form and pharmacovigilance

centre. The other reasons are lethargy, lack of interest, apprehension, complacency and indifference.

85.94% of practitioners opined that ADR reporting is a professional obligation, the rate was little higher than that (80.9%) reported by Pankaj G et al.(2011) [21] Since the attitudes towards ADR reporting is good, targeted educational strategies on available ADR reporting pathway can improve ADR reporting. In the present scenario, ADR reporting by physician is a voluntary activity and 44.18% responded the same. 53.01% responded that it should be compulsory. It is less than the rate (84%) reported by Rishi et al. [22] Compulsory reporting if implemented, it will increase the quantum of reporting and also develops a culture of ADR reporting among physicians. 2.81% stated ADR reporting can be remunerated. Backstrom et al (2006) suggested a small economic inducement to stimulate ADR reporting. [23] But, economic inducement may create problem of over reporting or false reporting. ADR reporting is the responsibility of physicians to enhance patient safety and hence remuneration for ADR reporting should not be supported. Interestingly 80.32% of the respondents wanted the identity of reporting doctor should be kept confidential. This is contrasting (57%) the result done by Gupta P et al.(2011) [18] It may be due to fear of litigation among the practitioners, in case the identity becomes public knowledge. Necessary awareness measures are needed to overcome this hurdle.

The study finding shows that the awareness on ADR reporting pathway and knowledge on ADR reporting was very poor among the study group practitioners. The ultimate goal of pharmacovigilance is the prevention of patients being unnecessarily affected by negative consequence of drug therapy. [24] The goal can be achieved only with the proper reporting of adverse drug reaction by health care professionals. Here are some suggestions to improve ADR reporting among health care professionals.

- Adequate importance should be given to ADR reporting and pharmacovigilance in hospitals
- Each hospital should have their own pharmacovigilance unit for collection of ADR in that hospital and forwarding it to regional pharmacovigilance centre.
- ADR reporting can be made as an integral part of clinical activities.
- A closer relationship between doctors and pharmacovigilance unit in the hospital and acknowledgement of submitted reports by the pharmacovigilance unit
- Educating the health care professional by conducting Continuous medical education, workshops, conference, regular training and retraining session on ADR reporting system and its importance.
- ADR reporting forms should be made available easily and ADR drop boxes can be kept at suitable places in the hospital as a reminder to health care professionals.
- Incorporation of pharmacovigilance in the U.G and P.G syllabus and train the students in reporting techniques.
- Government of India can pass a law making ADR reporting by physicians compulsory

The study was confined only to the medical practitioners in our locality. Future studies can be targeted towards all health care professionals to know the real scenario of reporting system in our locality.

## CONCLUSION

Our study strongly suggests that there is a greater need to create awareness about pharmacovigilance reporting system among medical practitioners. It is the professional responsibility of all health care professionals to report ADR. If possible mandatory reporting by health care professionals can be implemented for better reporting of ADR. Information technology like E-mail or online reporting can be used for reporting ADR which helps to reduce time and cost.

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