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## Original Article

### Community pharmacy staff's barriers and factors motivating to report adverse drug reactions: A prospective, cross-sectional study in Tamil Nadu

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## ABSTRACT

**Background:** The goal of this study is to assess community pharmacy staffs' barriers and motivating factors towards ADR reporting system in Tamil Nadu, India.

**Methods:** A cross-sectional study was conducted among the community pharmacy staffs. A questionnaire was distributed to all consented pharmacy staffs after ethics approval. The statistical significance of nominal and ordinal items was determined using the Chi square test and the relative important index (RII).

**Results:** The study received a total response rate of 70.09% (n=214). The top three barriers to ADR reporting were found to be "Reporting forms are too complicated" (RII=0.900), "Not clear how to report ADR" (RII=0.982), and "Not confident whether it is an ADR" (RII=0.913). "Reporting should be made as mandatory" as a high priority among the various factors encouraging community pharmacy staffs to report ADR.

**Conclusion:** The study concludes that ADR reporting form should be simplified for community pharmacy staffs in Tamil Nadu.

**Keywords:** Retail pharmacy, Pharmacovigilance, Drug monitoring, Knowledge, Practice

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## INTRODUCTION

Adverse drug reactions (ADRs) are an important subset of adverse drug events and are a major source of in-hospital morbidity and mortality, posing a large financial burden on patients and society as a whole.<sup>1</sup> Pharmacovigilance is a

highly specialised discipline of medicine concerned with the detection, assessment, comprehension, prevention, and control of adverse drug reaction. Drugs of poor quality can be removed from the market by identifying and reporting ADRs. ADR monitoring ensures that patients receive medications that are both safe and effective.<sup>2</sup> Through Pharmacovigilance Program of India (PvPI), all the healthcare professionals (HCPs) and patients are encouraged to report suspected ADRs to their preferred

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ADRs monitoring centre using the suspected ADRs reporting form (for HCPs).<sup>3</sup>

A community pharmacy is a retail store that deals directly with residents in the neighbourhood. Compounding, counselling, checking, and dispensing of prescription and over-the-counter medications and other products to patients with care, accuracy, and legality are among its tasks. Community pharmacy staffs work for the community pharmacy. They either supply drugs based on a prescription or, when legally authorised, sell them without one.<sup>4,5</sup>

Access to drugs is very easy in a large, densely populated country like India. For many conditions, most individuals buy medication from local community pharmacies instead of contacting a physician because it is easier, takes less time, and cost nothing.<sup>5-7</sup> As community pharmacy staffs have direct contact with the patients, they can play a tremendous role in ADR monitoring and reporting.

Despite the Government's efforts to incorporate all HCPs in ADR reporting, community pharmacy staffs participation in Tamil Nadu has remained awfully low, in contrast to trends in other Indian states and developed countries. There is insufficient information on the barriers that community pharmacy staffs in Tamil Nadu face when it comes to ADR monitoring and reporting. The present study aimed to identify the barriers and the factors that motivate the community pharmacy staffs in Tamil Nadu in reporting ADRs. This will assist the stakeholders to intervene and facilitate the reporting of ADRs by community pharmacy staffs.

## MATERIAL & METHODS

### Ethical statement and study site

A cross-sectional survey was conducted at community pharmacies in Tiruvallur district, an administrative district in the Indian state of Tamil Nadu for a period of 6 months. The study was approved by the Institutional Ethics Committee of the Sri Ramachandra Institute of Higher Education and Research, Deemed to be University, Porur, Chennai - 600 116, Tamil Nadu, India (Approval No. CSP/21/JAN/89/38).

### Development of study questionnaire

An extensive literature review was carried out by the research team to retrieve already published instruments and to identify the common domains. The rationale of questionnaire was reviewed by a panel of internal and external experts, namely pharmacologists, pharmacists, clinical psychologist and public health experts. Pharmacologists and pharmacists provided their comments on the lucidity and comprehensiveness of the items. External experts were asked to score each item's relevance on a scale of "not relevant" to "extremely relevant." For each item, a content validity ratio was determined, and a value greater than 0.78 was regarded satisfactory. The content valid item in the instrument was changed to a question format.

### Data collection

Staffs working in private pharmacies, either pharmacist or non-pharmacist was included in the survey. Staffs unwilling to consent were excluded. On reaching a community pharmacy, the purpose of the study was explained to the staff and he/she was invited to participate in the study. Written informed consent of the staffs was obtained from those who were willing. Study questionnaire was administered to the staffs to capture their knowledge regarding ADR, the existing practice of monitoring and reporting of ADR and their barriers in such monitoring and reporting. Factors motivating to report ADR were also noted from the respondents.

### Statistical analysis

The data was input into an excel spreadsheet. An independent researcher double-checked the data entry for quality assurance. The data was analysed using descriptive statistics. The chi square test was used on ordinal items. Due to the unequal distribution of responses, the chi square test yielded insignificant results. As a result, the key causes of poor ADR reporting among community pharmacy personnel in Tamil Nadu were determined using a relative important index (RII). The RII values were used to rank the items, with the item with the closest RII value to one being ranked as the most important element affecting the ADR reporting procedure. A significant value of 0.05 was assigned for analysis.

## RESULT & DISCUSSION

It took an average of 10 minutes to complete the survey for each participant. With a Cronbach's alpha of 0.81, almost all the items had satisfactory to exceptional consistency. A total of 214 pharmacy employees from community pharmacies were contacted. A total of 150 community pharmacy employees agreed to participate in the study. Pharmacists made up 75% of the responders, while other employees were assigned to work as health assistants. The socio-demographic characteristics of the respondents are summarised in Table 1. Male staffs were more numerous (71.9%), the majority of them were between the ages of 31 and 50, and 23.5% held a bachelor's degree in pharmacy. The majority of the employees (51.33%) had more than 11 years of working experience in a community pharmacy.

**Table 1: Baseline characteristics of Community pharmacy staffs**

| Socio-demographic variables | N   | %        |
|-----------------------------|-----|----------|
| Age in years                |     |          |
| 20-30                       | 34  | (22.66%) |
| 31-40                       | 54  | (36.00%) |
| 41-50                       | 41  | (27.33%) |
| >50                         | 21  | (14.00%) |
| Gender                      |     |          |
| Male                        | 110 | (71.9%)  |
| Female                      | 40  | (26.1%)  |
| Qualification               |     |          |
| Diploma in Pharmacy         | 73  | (43.7%)  |
| Bachelor of Pharmacy        | 36  | (23.5%)  |



|                     |    |          |
|---------------------|----|----------|
| Master of Pharmacy  | 4  | (2.6%)   |
| Others              | 37 | (24.2%)  |
| Experience in years |    |          |
| 1-5                 | 40 | (26.66%) |
| 6-10                | 33 | (22.00%) |
| ≥11                 | 77 | (51.33%) |

Table 2 shows the pharmacy staff's knowledge of ADRs and how to report them. In terms of familiarity with the term "pharmacovigilance," there is a lack of knowledge ( $p<0.01$ ). Despite vigilant PvPI, the majority of community pharmacy staffs in Tamil Nadu are unaware of the ADR reporting system. However, the majority of pharmacy employees (82%) believe that reporting ADR is critical for patient care.

**Table-2. Community pharmacy staffs knowledge about ADR and its reporting**

| Statements   | Yes (%)     | No (%)       | <i>p</i> -value |
|--|-------------|--------------|-----------------|
| Do you know the definition of ADR?   | 61 (40.6%)  | 89 (59.3%)   | 0.002           |
| Are you familiar with the term "Pharmacovigilance"?                        | 36 (24.0%)  | 114 (76.0%)  | 0.01*           |
| Are you aware of the existence of the ADR reporting system in India?       | 42 (28%)    | 108 (72.0%)  | 0.09            |
| Do you think reporting ADR is important for patient care?                  | 123 (82%)   | 27 (18%)     | 0.37            |
| Has any patient come to your pharmacy with complaints of ADR?              | 82 (54.66%) | 68 (45.33%)  | 0.55            |
| Is reporting ADR mandatory for community pharmacists?                      | 76 (50.6%)  | 74 (49.33%)  | 0.32            |
| Are you aware of an official and standard form available for ADR in India? | 32 (21.33%) | 118 (78.66%) | 0.49            |

Note: \* indicates statistical significance in  $\chi^2$  test, qualification was used as grouping variable

Table 3 shows community pharmacy staffs' current ADR reporting practises. In the previous 12 months, 62.66% of community pharmacy staffs did not record any ADR, while 99.33% of employees never reported any ADR. However, the majority of staff counselled their patients who came to them for ADR management in the previous year ( $p>0.04$ ).

**Table-3: Community pharmacy staffs practice regarding ADR and its reporting**

| Statement  | Yes         | No           | <i>p</i> -value |
|--|-------------|--------------|-----------------|
| Have you noticed any ADR within the last 12 months?                        | 56 (37.33%) | 94 (62.66%)  | 0.58            |
| Have you ever reported any ADR in the last 12 months?                      | 1 (2.7%)    | 149 (99.33%) | 0.45            |
| Have you ever counseled a patient for his / her ADR in the last 12 months? | 19 (12.66%) | 131 (87.33%) | 0.04*           |

Note: \* indicates statistical significance in  $\chi^2$  test, work experience was used as grouping variable

The barriers that community pharmacy staffs have in identifying and reporting ADR were noted from the perspectives of pharmacy staffs (Table 4). Reporting forms are too complicated ( $p=0.05$ ) and lack of time ( $p=0.01$ ) were the statistically significant factors hindering the reporting of ADRs. RII analysis revealed that "Reporting forms are too complicated" (RII=0.900), "Not clear how to report ADR" (RII=0.982), and "Not confident whether it is an ADR" (RII=0.913) were the top three barriers to ADR reporting. In addition, the majority of pharmacy staffs (73.33%) stated that reporting forms are not available in the pharmacy, and they were not confident about the classification of ADRs (83.3%). Furthermore, many staffs told that ADR reporting neither their responsibility (74%) nor their priority (78.6%).

**Table: 4 Barriers of community pharmacy staffs in reporting ADR**

| Barriers   | Agree, n (%) | Neutral, n (%) | Disagree, n (%) | RII   | Rank | <i>p</i> -value |
|--|--------------|----------------|-----------------|-------|------|-----------------|
| Reporting forms are not available                  | 110 (73.33%) | 32 (21.33%)    | 8 (5.34%)       | 0.893 | 5    | 0.75            |
| Reporting forms are too complicated                | 106 (71.33%) | 43 (28.66%)    | 1 (2.5%)        | 0.900 | 3    | 0.05*           |
| Reporting is time consuming                        | 105 (70%)    | 34 (22.66%)    | 11 (7.33%)      | 0.875 | 6    | 0.28            |
| Reporting may lead to any legal liability          | 81 (54%)     | 22 (14.66%)    | 47 (31.33%)     | 0.742 | 14   | 0.49            |
| Not clear how to report ADR                        | 142 (94.66%) | -              | 8 (5.33%)       | 0.982 | 1    | 0.74            |
| ADR reporting is not my duty                       | 111 (74%)    | 19 (12.66%)    | 20 (13.33%)     | 0.868 | 7    | 0.79            |
| Not clear what ADR is                              | 91 (60.66%)  | 27 (18%)       | 32 (21.33%)     | 0.797 | 11   | 0.27            |
| ADR reporting is not my priority                   | 118 (78.66%) | 17 (11.33%)    | 15 (10%)        | 0.895 | 4    | 0.14            |
| Lack of professional set up to discuss about ADR   | 99 (66%)     | 33 (22%)       | 18 (12%)        | 0.846 | 9    | 0.12            |
| Only safe drugs are marketed                       | 25 (16.66%)  | 26 (17.33%)    | 99 (66%)        | 0.502 | 17   | 0.32            |
| Not sure which drugs were responsible to cause ADR | 90 (60%)     | 37 (24.66%)    | 23 (15.33%)     | 0.815 | 10   | 0.94            |
| ADR was not serious enough to report               | 57 (38%)     | 17 (11.33%)    | 76 (50.66%)     | 0.624 | 15   | 0.91            |
| Did not have complete information to report        | 111 (74%)    | 18 (12%)       | 21 (14%)        | 0.866 | 8    | 0.51            |
| Not confident about the type of ADR                | 125 (83.3%)  | 11 (7.33%)     | 14 (9.33%)      | 0.913 | 2    | 0.24            |
| Lack of access to internet                         | 10 (6%)      | 25 (16.66%)    | 115 (76.66%)    | 0.495 | 18   | 0.71            |
| Lack of time                                       | 82 (54.66%)  | 28 (18.6%)     | 40 (26.66%)     | 0.760 | 12   | 0.01*           |
| Insufficient subject knowledge to detect ADR       | 76 (50.66%)  | 36 (24%)       | 38 (25.33%)     | 0.751 | 13   | 0.78            |
| No motivation                                      | 29 (19.33%)  | 23 (15.33%)    | 98 (65.33%)     | 0.513 | 16   | 0.82            |



| to report                                    |              |                |              |       |    |      |
|--|--------------|----------------|--------------|-------|----|------|
| No actions are taken based on the ADR report | 5<br>(3.33%) | 31<br>(20.66%) | 114<br>(76%) | 0.424 | 19 | 0.11 |

Note: \* indicates statistical significance in  $\chi^2$  test, work experience was used as grouping variable

Though none of the 6 items were statistically significant, with a RII of 0.986, "Reporting should be made as mandatory" as a high priority among the various factors encouraging community pharmacy staffs to report ADR, thus emphasising the need for a more robust ADR reporting system in Tamil Nadu (Table 5).

**Table: 5 Factors encouraging community pharmacy staffs to report ADR**

| Statement                                      | Agree (%)     | Disagree (%)  | RII   | Rank | p- value |
|--|---------------|---------------|-------|------|----------|
| Reporting should be made as mandatory          | 148 (98.66%)  | 2 (1.34%)     | 0.986 | 1    | 0.558    |
| Reporting form should be a simple one          | 131 (87.33%)  | 19 (12.66%)   | 0.873 | 2    | 0.97     |
| Reporting through pharmacy dispensary software | 64 (42.66%)   | 86 (57.33%)   | 0.426 | 7    | 0.05     |
| More clarity on which reactions to report      | 110 (73.33%)  | 40 (26.66%)   | 0.733 | 4    | 0.78     |
| Remuneration for reporting                     | 62 (41.33%)   | 88 (58.66%)   | 0.413 | 8    | 0.08     |
| Regular alerts to remind about reporting       | 51<br>-34.00% | 99<br>-66.00% | 0.34  | 9    | 0.81     |

Note:  $\chi^2$  test, age was used as grouping variable

When compared to earlier studies conducted in the UK<sup>1</sup>, Saudi Arabia<sup>2</sup>, and India<sup>8</sup>, the knowledge of community pharmacy staff regarding the ADR reporting system in the current study is poor. When compared to other studies, the practice of reporting an ADR in the present study is also low. For example, in the current study, 40% of community pharmacy staff had observed ADR in their customers over the previous year, while only 2.7 % of them reported ADR. A study conducted in Saudi Arabia stated that 52% of their staffs had noticed ADR in their customers during 1 year and out of that at least 36% had reported the ADR.<sup>2</sup> In another study performed in Australia, about 35% of respondents said they had reported ADR in the previous 12 months.<sup>9</sup>

The biggest barriers to reporting ADR in this study were "I do not know how to report" and "I'm not confident whether it is an ADR". These barriers are consistent with those found in earlier investigations.<sup>4,6</sup> In addition, when it came to the factors that encourage ADR reporting, the majority of the respondents in our study agreed that there should be any obligation to do so, and that guidelines on reporting and bulletins on Adverse Drug Reactions should be provided on a regular basis. They also stressed the need for a more simple method of reporting. In a study undertaken in Bangladesh and Australia, the same conclusion was reached.<sup>4,9</sup>

## CONCLUSION

In conclusion, the ADR reporting in community pharmacies in Tamil Nadu is not yet fully established. The existing training program may not be sufficient to sensitize all the community pharmacy staffs. Community pharmacy staffs have come out to declare that reporting will not be done unless it is made mandatory. Pharmacovigilance Program of India should use the findings of this study to improve and simplify the ADR reporting form for community pharmacy employees in Tamil Nadu.

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## Conflict of interest

The authors have no conflicts of interest to declare.

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