Under-reporting of adverse drug reactions: A challenge for pharmacovigilance in India

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Introduction

Under reporting (UR) of adverse drug reactions (ADRs) is widespread and a daunting challenge in pharmacovigilance (PV).[1,3] This is because primarily most countries, including India follow the spontaneous or voluntary system of ADR reporting. There are patient-related reasons for UR like failure to recognize ADR or inability to link the ADR with a drug. The commonest doctor related reasons are the feeling of guilt, fear of litigation, ignorance, lethargy, inadequate risk perception about newly marketed drugs, diffidence, insufficient training to identify ADRs, and lack of awareness about PV program.[4]

Similarly, ADRs often go unnoticed due to failed ability of medical teams to recognize ADR or correlate precisely with biochemical, pathological or radiological abnormality.[5] However, the intensive monitoring in PV amplifies the detection

ABSTRACT

Aim: The aim was to evaluate the extent and factors responsible for underreporting (UR) of adverse drug reactions (ADRs) in India.

Materials and Methods: A retrospective observational, cross-sectional prospective questionnaire-based analysis was undertaken to evaluate the extent and factors for UR of ADRs in pharmacovigilance.

Results: At the time, this report was prepared, 90 ADR Monitoring Centers (AMC) were operational in India. Indian AMC functional rate was 56.45%. The average number of Individual Case Safety Reports reported by our center via VigiFlow per month was 48.038. In a period of the 3 years total number of ADRs reported was 3024. The average number of reports per month was 80.08. Active surveillance versus spontaneous reporting contributed 66.13% versus 33.86% of the total ADRs (P < 0.0001). Outpatient Department (OPD) contribution was 76.05% and indoor contribution was 23.94% of total reports (P < 0.0001). Department of Medicine (33%), followed by oncology (19.27%) and chest disease (13.49%) contributed maximally. The contribution of Pharmacology ADR monitoring OPD was 16.20%. Eye, ear, nose and throat and surgery, private Medical Colleges, hospitals in periphery, sub-district and district contributed no ADRs. ADR detection rates by clinical presentation, biochemical investigation and diagnostic tools were 84.33%, 14.57%, and 1.09% respectively (P < 0.0001). Reporting by postgraduate, registrars, consultants and nurses were 72.65%, 6.58%, 16.56% and 4.19% respectively (P < 0.0001). PG students in Pharmacology contributed an average number of 5.61 ADR reports/month. The lack of knowledge and awareness about Pharmacovigilance Programme of India (PvPI), lethargy, indifference, insecurity, complacency, workload, lack of training were the common factors responsible for UR. Major academic activity, exams, thesis and synopsis submission time influenced reporting of ADRs by postgraduate students.

Conclusion: UR is a matter of concern PvPI. Multiple interventions are needed to improve ADR reporting.

KEYWORDS: Adverse drug reaction, pharmacovigilance, spontaneous reporting, under reporting
Materials and Methods

A retrospective observational, prospective cross-sectional questionnaire-based analysis was undertaken to evaluate the extent and reasons of UR of ADRs in the ADR monitoring (ADR M) center, working under the PvPI, in a teaching tertiary care hospital in India. The suspected drug reactions monitoring data collection form was used, and the study was conducted with prior permission by the Institutional Ethics Committee.

The ADRs were reported, defined and categorized as per the defined standard operating procedures of PvPI. The severity and seriousness of the reaction, the outcome of reaction and onset time was recorded for every suspected ADR.

Adverse drug reactions reported from Outpatient Department (OPD) or indoor patients of any severity, duration and type were included. Any ADR due to poisoning, medication error, over dosage, over or noncompliance, natural products/alternate medicines and unidentified drugs were excluded in the analysis.

Detailed subgroup analysis of trends of ADR reporting in ADRM center of the tertiary care teaching hospital and in comparison to country wise ADRs reporting trends were undertaken. Working performance of ADRM center as indicated by ADR reports collected and reported by through the VigiFlow software 5.0 were taken as the basis to analyze extent of UR. Countrywide functional rate of ADR monitoring centers (AMC) was worked out. Average Individual Case Safety Reports (ICSRs) per month was compared among the AMC started in the first phase. The Central Drugs Standard Control Organization and Indian Pharmacopoeia Commission (IPC) monthly work report was also the basis of the current analysis.

Further, a questionnaire and face to face enquiry based prospective study was undertaken at our center to analyze the reasons of UR among various stakeholders likely to contribute to PvPI, namely doctors, which included residents, registrars and consultants (n = 100), nurses (n = 100) and pharmacists (n = 100). They were identified with a code number, and privacy and confidentiality was maintained regarding data throughout the study. A 10% of total strength of the total staff was selected from various Clinical Departments of the hospitals within the jurisdiction of ADRM center.

Verbal consent was obtained from all the participants as the study involved minimal risk and fell in category-C as per ICMR guidelines. Predesigned and pretested questionnaire based on the study objectives, taking guidance from the previous study[6] was subjected to a thorough peer review and subsequently modified as per the suggestions and used. Each participant was allotted 20 min to answer the options. The questionnaire constituted 20 questions and consisted three parts, that is, demographic profile, knowledge, attitude and practice and the common reasons for UR.

The focus was to evaluate the knowledge and awareness about PvPI, ADRs and PV, ignorance, if any e.g., only severe ADRs need to be reported, diffidence (fear of appearing ridiculous for reporting merely suspected ADRs), lethargy (an amalgam of procrastination, lack of interest or time and other excuses), indifference (the one case could not contribute to medical knowledge), insecurity (it is nearly impossible to determine whether or not a drug is responsible for a particular ADR) and complacency (only safe drugs are allowed in the market) as the factors for UR.

Statistical Analysis

Descriptive statistical analysis was carried out with the help of computer software SPSS Version 15 for Windows, released 2006. The data were expressed in n (%). Chi-square test was applied for some of the parameters to prove their statistical significance, \( P < 0.05 \) was considered as significant.

Results

At the time of study 90 AMC were operational in India and with 25 in South Zone, 28 in North Zone, 20 in West Zone and 17 in the East Zone. There are 20 non-government institutions, and the rest are Government Medical Colleges and Hospitals with operational PvPI.

The current study suggests that national mean AMC functional rate was 56.45%. Maximal AMC functional rate was 70% in the month of November, 2012. It was minimum in the month of July 2011 as 26.83%. The data of August 2011 was not available [Figure 1]. While comparing average number of ICSRs reported by VigiFlow per month from the earliest AMC started post-sustainable PvPI, JSS Medical College and Hospital, Karnataka contributed at rate of 212.46 followed by Institute of Pharmacology, Madras Medical College as 204.29. The leaders from North India are Postgraduate Institute of Medical Education and Research (PGIMER) Chandigarh contributing at the average rate of 170.63 followed by Lady Hardinge Medical College and All India Institutes of Medical Sciences (AIIMS) New Delhi. Whereas, the total number of ADRs reported through VigiFlow contributed by our center were 1249, the average number of ICSRs reported by VigiFlow per month by our center was 48.038 [Figure 2].

In a period of the 3 years total number of ADRs reported was 3024. The average number of reports per month reported by the center was 80.08 [Figure 3]. Active surveillance versus spontaneous reporting contributed 66.13% versus 33.86% (\( P < 0.0001 \)) of the total ADRs. OPD based reports comprised 76.05% and ADR reported from indoor patients was 23.94% of total ADR reports (\( P < 0.0001 \)). Department of Medicine (33%), followed by oncology (19.27%), chest disease (13.49%) contributed maximally in the current study. Total number of ADRs contributed by OPD of ADRM of Pharmacology was 490 (16.20%). However, few departments like eye, ENT, surgery did not contribute any ADR. Total number of ADRs contributed by private Medical Colleges in the adjoining region and by hospitals in periphery, sub-district and district hospitals was nil. ADR detection rates based on clinical presentation, biochemical investigation and diagnostic tools were 84.33%, 14.57% and 1.09% respectively, that is detection based on clinical presentation was significantly high.
as compared to laboratory and diagnostic tools ($P < 0.0001$). Total reporting by postgraduate students, registrars, consultants and nurses were 72.65%, 6.58%, 16.56% and 4.19%, respectively ($P < 0.0001$). The average number of ADR reports contributed per month by Pharmacology postgraduates was 5.61. Pharmacology postgraduate (66.13%) in comparison to other postgraduates (6.61%) contributed most ADRs ($P < 0.0001$). Number of thesis related to ADR were five during the period; three carried by Department of Pharmacology and one each by Dermatology and HIV medicine. Total four retrospective research analyses related to ADRs were carried out. Various measures to enhance the ADR reporting are depicted in Table 1. An analysis of the reasons of UR in the PV suggested lack of awareness and knowledge about PvPI, lethargy, indifference, insecurity, complacency, overwork, and lack of proper training in PV as commonly cited factors for UR by doctors, nurses and pharmacists of the hospital [Table 2].

**Discussion**

The results suggest that UR of ADR exists in India too. In India after the initiation of sustainable PvPI, AMC functional rate is recorded to be 56.45%. This indicates that nearly 43 centers yet remain nonfunctional even after being operational most of
Figure 3: Number of adverse drug reactions (ADR) reports submitted by ADR monitoring centre, Government Medical College Jammu to National Pharmacovigilance Centre, New Delhi

Table 1:
Performance of ADRM centre, GMC Jammu, India

| Parameters                                                                 | Values                                                                 |
|---------------------------------------------------------------------------|------------------------------------------------------------------------|
| Performance of the study ADRM center                                       |                                                                        |
| Total study period                                                        | 3 years                                                               |
| Total number of ADRs reported                                              | 3024                                                                  |
| Total number of ADRs reported in vigi flow                                | 1249                                                                  |
| Average number of reports per month                                       | 80.08                                                                 |
| Average number of ICSRs per month                                         | 48.038                                                                |
| Active surveillance versus spontaneous reporting                           | 66.13% versus 33.86% \( \pi^2 = 19.54, df=1, P<0.0001 \)               |
| OPD versus inward contribution                                             | 76.05% versus 23.94% \( \pi^2 = 52.22, df=1, P<0.0001 \)               |
| Total number of ADRs contributed by ADRM OPD                              | 490 (16.20%)                                                          |
| Total number of ADRs contributed by private medical colleges in the region| Nil                                                                   |
| Total number of ADRs contributed by periphery, sub-district and district hospitals| Nil                                                                       |
| Clinical presentation, biochemical investigation, diagnostic tools detection rate | 84.3%, 14.57%, 1.09% \( \pi^2 = 180, df=2, P<0.0001 \)               |
| Total reporting by postgraduate, registrars, doctors, nurses              | 72.65, 6.58, 16.56, 4.19% \( \pi^2 = 165.95, df=3, P<0.0001 \)        |
| Average number of ADR reports contributed by pharmacology postgraduates   | 5.61                                                                  |
| Pharmacist postgraduate versus other department postgraduates             | 66.13 versus 6.61% \( \pi^2 = 74.54, df=1, P<0.0001 \)                |
| Number of ADR contributed by postgraduates sitting in various medical OPDs | 2.28%                                                                 |
| Specialty wise contribution of ADR reports                                |                                                                        |
| Medicine/oncology/chest diseases/ADRM OPD/dermatology/psychiatry/pediatrics/orthopedics/gynecology/HIV medicine/rheumatology/ENT/surgery/eye | 998 (33.00%)/583 (19.27%)/408 (13.49%)/490 (16.20%)/92 (3.04%)/90 (2.97%)/90 (2.97%)/50 (1.65%)/40 (1.32%)/90 (2.97%)/93 (3.07%)/0 (0%)/0 (0%)/0 (0%) |
| ADR related activities in ADRM centre GMC Jammu                           |                                                                        |
| Number of thesis related to ADR-pharmacology, dermatology, HIV medicine   | 3, 1, 1; Total-5                                                       |
| Number of ADR related research in form of retrospective and prospective analysis | 4, 0                                                                  |
| Number of conference during said period-3rd national conference of ISRPT   | 1                                                                    |
| Number of CME during said period                                          | 2                                                                    |
| Total number of lectures for undergraduate                                 | 12                                                                   |
| Total number of practical sessions                                        | 8                                                                    |
| Number of awareness lectures doctors                                      | 4                                                                    |
| Number of awareness lectures for nursing staff                            | 4                                                                    |
| Number of public awareness camp for ADR reporting                         | 6                                                                    |
| Number of reminder to doctors                                             | 56; 10; 56                                                           |
| Total number of financial grants to conduct workshop by CDSCO/IPC          | Nil                                                                  |
| Number ADRs report published during study period from GMC                  | 1                                                                    |
| Number of rare ADRs published                                             | 2                                                                    |
| Number of rare ADRs under consideration by scholarly journals             | 6                                                                    |

Contd...
the time. This fact seriously needs to be addressed by IPC. AMC functional rate has been recorded in the range of 26.83–70%. While comparing average number of ICSRs reported to Vigiflow per month from the earliest AMC started after sustainable PvPI, JSS Medical College and Hospital, Karnataka contributed maximally, followed by Institute of Pharmacology, Madras Medical College. At the time this study was conducted, PGIMER leads in ADR reporting in North India followed by Lady Harding Medical College and AIIMS, New Delhi. Whereas, number of ADRs reported through Vigiflow and the average number of ICSRs reported by Vigiflow per month by our center was substantial. However, it remains less in comparison to these premier institutes. The probable reason for this is that our Institute is a tertiary care teaching institute catering to less number of patients in comparison to these apex institutes. Further, some of these institutes had an infrastructural setup for PV even before the sustainable PvPI was initiated, unlike our institute. The results of this study are in accordance to a recent study by World Health Organization (WHO), where it has been shown that high-income countries had the highest ADR reporting rates. There is, therefore, a need to strengthen ADR reporting, especially in low-income countries by suitably modifying the organizational structure, training and economic resources of national PV centers. Active surveillance contributed to the majority of the total pool of ADRs, suggesting UR of ADR. Passive surveillance system is limited by gross UR (<10% reporting rate), latency, and inconsistent reporting.

Making ADR reporting compulsory in the institution to address UR is a matter of debate. Some experts suggest it should be made need based. The Medical Council of India or accrediting bodies can take the lead in this direction. However, there is a concern that such a compulsion can lead to false reporting thus compromising the quality of reports. Regulators in United Kingdom, France, European Union, the United States and Canada are developing suitable approaches to enhance passive ADR reporting systems. In the current study, the reports received from OPD were higher than ADRs among inpatients. The lower reporting from indoor patients can be overcome by monitoring computerized medical records or by developing a system of active screening of all medical records of inpatients for ADRs.

Departments in private Medical Colleges in the adjoining region, hospitals in periphery, sub-district and district which failed to contribute in ADR reporting need to be involved in a collaborative approach, through training and awareness programs, to widen the reporting base.

In this study, the number of ADRs contributed by Pharmacology ADRM OPD was substantial thereby indicating that patient participation directly in ADR reporting can help intensify ADR reporting in India. Similar studies like ours suggest positive complementary contribution of patients to PV and drug safety. These studies have shown that direct reporting of ADRs by patients have prove useful in intensifying ADR reporting.

Adverse drug reactions often go unnoticed due to failure of medical teams to recognize adverse drug events or to correlate precisely with biochemical, pathological or radiological abnormality. Thus, biochemical investigations and diagnostic tools can pick up substantial number of ADRs and can play an important role in PV.

The present study suggests that the human resource, that is, Pharmacology residents can be utilized effectively to strengthen reporting and for educating the health professionals, providing feedback and personal communications with prescribers. Postgraduate exams, synopsis and thesis submission, summer and major festivals grossly affect the performance of this human resource with respect to ADR reporting, due to obvious reasons. As our study suggests, these periods and activities corresponded with low reporting. These factors must be anticipated, and timely measures need to be adopted to maintain the consistency in ADR monitoring and reporting.

Doctors (Interns, House officers), nurses, pharmacist and residents also need to be more actively involved in reporting ADRs, to widen the reporter base.

Intensive monitoring approach in PV can improve

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### Table 2: Factors responsible for UR from ADRM Centre GMC Jammu, India

| Factors for UR | Doctors | Nurse | Pharmacist | P |
|---------------|---------|-------|------------|---|
| Unawareness of PvPI | 68 | 80 | 81 | \( \chi^2=5.79, df=2, P=0.055 \) |
| Lack of knowledge | 22 | 91 | 79 | \( \chi^2=117.97, df=2, P<0.0001 \) |
| Ignorance | 56 | 98 | 92 | \( \chi^2=69.92, df=2, P<0.0001 \) |
| Diffidence | 81 | 88 | 86 | \( \chi^2=2.04, df=2, P=0.3606 \) |
| Lethargy | 78 | 82 | 71 | \( \chi^2=3.5, df=2, P=0.1738 \) |
| Indifference | 76 | 91 | 96 | \( \chi^2=20.04, df=2, P<0.0001 \) |
| Insecurity | 72 | 84 | 81 | \( \chi^2=4.7, df=2, P=0.095 \) |
| Complacency | 68 | 82 | 88 | \( \chi^2=12.85, df=2, P=0.0016 \) |
| Overworked | 92 | 90 | 89 | \( \chi^2=10.53, df=2, P=0.07672 \) |
| Lack of training | 68 | 93 | 93 | \( \chi^2=32.1, df=2, P<0.0001 \) |

Chi-square test. \( P<0.05 \) was considered significant. ADRM=Adverse drug reaction monitoring, ICSRs=Individual Case Safety Reports, OPDs=Out-patient department, GMC=Government Medical College, IPC=Indian Pharmacopeia Commission, CDSCO=Central Drugs Standard Control Organization.
the detection of ADRs.[6] Various approaches have been recommended to intensify reporting,[7-13] like, forming ADR reporting network within hospital,[7] encouraging and educating patients to report[8,9] and making ADR reporting compulsory for nurses.[10] Studies have reported a felt need to improve knowledge and attitude for ADR reporting by healthcare professionals.[11,12] Even telephonic intervention may help intensity ADR reporting.[13] The periodic E-mail, SMS alerts represent an effective and inexpensive way to raise the awareness of doctors about the importance of spontaneous ADR reporting.

However, the impact of interventions have been reported to decrease after the intervention is stopped as also noticed in the current study, hence the efforts must be ongoing, dynamic and continuous.[14] Integration of information obtained from primary care electronic medical records,[15] cohort event monitoring and targeted spontaneous reporting, being implemented by the WHO, in its public health programs, have shown to complement spontaneous reporting.[22] The impact of such strategies is yet to be evaluated in PvPI.

Human behavior, knowledge beliefs, and motivation play an important role in ADR reporting. UR might be improved through activities focused on modifying such factors.[23] UR is strongly associated with certain attitudes, that possibly could be modified through educational interventions.[24]

The results of the study suggest that lack of knowledge and awareness about PvPI, lethargy, indifference, insecurity, complacency, workload, and lack of proper training in PV were some factors responsible for UR. Ignorance in 95%; difference in 72%; lethargy in 77%; indifference and insecurity in 67%; and complacency in 47% of subjects were held responsible for UR in a similar study.[24]

Factors which promote ADR reporting like years of work experience, participation in educational activities related to the detection and resolution of drug-related problems, have not been evaluated in the current study. Factors that discourage reporting include uncertainty about the causal relationship between the ADR and the drug, forgetfulness, difference in reporting known ADRs and lack of time.[2]

The amount of time dedicated to teaching of PV in undergraduate and postgraduate courses in Pharmacology is low.[25] Similar finding is observed in the current study too. Thus, appropriate interventions to include ADR reporting and PV in an appropriate format should be mandated in the curriculum by the Medical Council of India and respective stakeholders in nursing and pharmacy education.

Only two rare case reports were published from the center during study period. Publication of rare and unusual ADRs and various research papers from the field of ADRs can serve as positive incentives for clinicians to report PV. However, clinicians tend to conceal fatal and serious ADRs in the recommended time frame, and some of these ADRs thus remain unreported. Clinicians need to be reassured that reporting ADRs has no legal implications. Seeking ADRM number or ID generated in the VigiBase, of case reports submitted for publication to journals is recommended to verify the authenticity of the reports, and also ensures that these reports are included in the VigiBase, as a part of the data submitted from India.

Conclusion

Under-reporting is observed in spontaneous ADR reporting. A multipronged approach in necessary to overcome UR, taking in to cognizance the factors that affect spontaneous reporting.

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