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Adverse Drug Reaction Reporting and Pharmacovigilance: Knowledge, Attitudes and Perceptions amongst Resident Doctors

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Abstract

Spontaneous adverse drug reaction (ADR) reporting is the cornerstone of pharmacovigilance. However, underreporting is a huge problem due to lack of reporting culture amongst healthcare professionals. This cross sectional, questionnaire based study was conducted to assess the knowledge, attitudes and practices regarding adverse drug reaction reporting amongst resident (trainee) doctors. It involved 407 post graduate resident doctors who could be contacted in 2 visits on consecutive days in the resident doctor's hostels, all the clinical wards, operation theatres and departments (convenience sampling). It was conducted in two Government teaching hospitals - B.J. Medical College, Pune and Seth G.S. Medical College, Mumbai. The knowledge of the resident doctors regarding reporting responsibilities, type of event and product to be reported and the reporting mechanisms, was found to be deficient. Majority of the respondents felt that ADR reporting is necessary and is a professional obligation but should be voluntary and remunerated. Perception of reporting process being tedious, lack of time, poor knowledge of reporting mechanism and inadequate expertise were the main reasons cited for underreporting. Majority of the respondents suggested regular training sessions and a closer working relationship with the pharmacovigilance department as a possible motivating factor to improve spontaneous ADR reporting rates. The deficiencies in knowledge, attitudes and practices of resident doctors regarding ADR reporting needs urgent attention on priority basis, not only for the success of the pharmacovigilance program, but for better clinical management of the patients in general.

INTRODUCTION:

Safety and efficacy are the two major concerns about a drug. While efficacy of a drug can be quantified with relative ease, the same cannot be said about safety. This is because, the adverse effect of a drug may be uncommon (but very serious) and many patients may be affected or subjected to a potential risk before the relationship with the drug is established. Adverse Drug Reactions (ADRs) are associated with a significant morbidity and mortality [1, 2]. Recent estimates suggest ADRs to be the fourth major cause of death in the Unites States of America (USA) [1]. This gave birth to the branch of pharmacovigilance. By definition, pharmacovigilance is, "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems". [3]

Spontaneous reporting has contributed significantly to successful pharmacovigilance. The contribution of health professionals, in this regard, to ADRs databases is enormously significant and has encouraged ongoing ascertainment of the benefit-risk ratio of some drugs [4, 5], as well as contributed to signal detection of unsuspected and unusual ADRs previously undetected during the initial evaluation of a drug [6, 7]. The Uppsala Monitoring centre (UMC, WHO), Sweden is maintaining the international database of adverse drug reaction reports (currently about 4.7 million case reports) received from several national centres (96 member countries). However, still, it is estimated that only 6-10% of all ADRs are reported [8]. Although, India is participating in the program, its contribution to UMC database is very little. This is essentially due to the absence of a vibrant ADR monitoring system and also lack of a reporting culture among health care workers.

Many factors are associated with ADRs under-reporting among health professionals. These factors have been broadly classified as personal and professional characteristics of health carers, and their knowledge and attitudes to reporting. Inman has summarized these factors as the 'seven deadly sins'. His description of the 'sins' include: attitudes relating to professional activities (*financial incentives*: rewards for reporting; *legal aspects*: fear of litigation or

enquiry into prescribing costs; and ambition to compile or publish a personal case series) and problems associated with ADR-related knowledge and attitudes (*complacency*: the belief that very serious ADRs are well documented by the time a drug is marketed; *diffidence*: the belief that reporting an ADR would only be done if there was certainty that it was related to the use of a particular drug; *indifference*: the belief that the single case an individual doctor might observe could not contribute to medical knowledge; and *ignorance*: the believe that it is only necessary to report serious or unexpected ADRs), and excuses made by professionals (*lethargy*: the procrastination and disinterestedness in reporting or lack of time to find a report card and other excuses) [9]. Lopez-Gonzalez et al., in their review of determinants of ADRs under-reporting from the global perspective, have shown that three of the seven 'sins' proposed by Inman that are associated with professional activity (financial incentives, fear and ambition to publish) seem to contribute less significantly to under-reporting [10]. Insecurity (the belief that it is nearly impossible to determine whether or not a medicine is responsible for a particular ADR) is another factor associated with under-reporting but was not proposed by Inman.

In order to improve the reporting rate, it is important to improve the knowledge, attitude and practices (KAP) of the healthcare professionals regarding ADR reporting and Pharmacovigilance. The best time to do it is probably during the under graduate and post graduate education of the doctors. This study is a step in that direction and endeavours to evaluate the baseline KAP of the post graduate resident doctors at two teaching hospitals in Maharashtra, regarding ADR monitoring and Pharmacovigilance. This would help us in planning interventions amongst this group of budding doctors.

MATERIALS AND METHODS:

Study design:

It is a cross sectional, questionnaire based survey.

Study setting:

Two government teaching, tertiary care hospitals in the state of Maharashtra (India) – Seth G. S. Medical College, Mumbai and B. J. Medical College, Pune.

Study population:

Study was planned in the resident doctors, who are pursuing their post graduation in any of the medical, surgical, paraclinical or preclinical fields. Resident doctors of super speciality disciplines (DM/ MCh) were excluded from the study

Study instrument:

The study instrument was a pre designed questionnaire which was structured to obtain the demographics of the doctors, information about their knowledge of ADR reporting, attitudes to reporting, and the factors that they perceived may influence reporting. Provision was also made for suggestions on possible ways to improve ADR reporting

Study conduct:

It was decided to administer the questionnaire to all the resident doctors who could be contacted in 5 visits on consecutive days in the resident doctor's hostels, all the clinical wards, out patient departments, operation theatres and departments (convenience sampling). A total of 407 (BJMC – 191, GSMC – 216) resident doctors could be contacted, and the questionnaire was handed to them after explaining them the purpose of the study. The doctors were requested to complete the questionnaire and hand it back immediately, to maximize the response rate. Those who were busy at that moment, were requested to return back the duly filled questionnaires within 1 day, in their respective department offices or the sister in-charge of their clinical wards (who were informed about the nature of the study). The mobile phone numbers of all the respondents who did not respond immediately was noted down. Those who did not respond by the next day were called up and the questionnaire was readministered, if the reason of non response was loss of the questionnaire. If the reason for non response was busy schedule, the doctors were requested to suggest a suitable time when they would

want to be contacted to return the duly filled questionnaire. Such doctors were contacted at the pre decided time and if they were free, the questionnaire was collected from them. Data was analysed using SPSS software (version 17).

RESULTS:

Out of the 407 administered questionnaires, 326 were received back. 12 were inadequately filled and hence were excluded from the analysis.314 were duly filled, giving a response rate of 77.2%. Response rate from BJMC and GSMC was 79.6% (152/ 191) and 75.7% (162/ 216) respectively.

Table 1: Demographic profile of the sample

Median age	26 years
Male: Female ratio	181:133
Year of residency	
First year	119
Second year	103
Third year	92
Department	
Surgical (General Surgery, Obstetrics and Gynaecology, ENT, Ophthalmology, Orthopaedics)	91
Medical (Internal medicine, Pediatrics, Skin, Psychiatry, Anaesthesia)	123
Paraclinical (Microbiology, Pathology, PSM, Pharmacology, Forensic, Radiology)	74
Preclinical (Anatomy, Physiology, Biochemistry)	26

Table 2: Knowledge about adverse event reporting among the resident doctors

Professionals qualified to report an adverse event	***Response (each out of 314)***
Doctors	96.5% (303)
Dentists	93.9% (295)
Nurses	70.7% (222)
Pharmacists	36.9% (116)
Physiotherapist	32.8% (103)
Whether event related to this be reported	***Response (each out of 314)***
Allopathic drugs	100.0% (314)
Herbals	29.6% (93)
Traditional and complementary medicines	27.7% (87)
Blood products	10.5% (33)
Biological	4.1% (13)
Medical devices	15.6% (49)
Vaccines.	97.78% (307)
Events which can be reported	***Response (each out of 314)***
Adverse events suspected to have been caused by new drugs	98.7% (310)
Any reaction that appears like an ADR but the cause of which is not certain	68.2% (214)
Any suspected drug interaction	38.9% (122)
Death of patient due to a suspected interaction	51.9% (163)
Congenital anomaly	6.6% (21)

Table 3: Practices regarding reporting mechanism:

	Questions	**Response (each out of 314)**
1.	Awareness regarding adverse drug reactions (ADRs) reporting and monitoring system (National Pharmacovigilance Centre) in India	43% (135/ 314) aware
2.	Have you reported any suspected adverse drug reactions to any of the ADR reporting and monitoring centres?	2.9% (9/ 314) have reported
3.	Awareness of existence of adverse drug reactions (ADRs) reporting and monitoring system at your hospital	49.5% (155/ 314) aware
4.	Did you report any suspected adverse drug reactions to ADR reporting and monitoring system existing at your hospital?	22.6% (71/ 314) have reported

Table 4: Attitudes regarding adverse event reporting:

ADR reporting is necessary?	**Frequency (each out of 314)**
Yes	89.5% (281)
No	10.5% (33)
ADR reporting is a professional obligation?	**Frequency (each out of 314)**
Yes	80.9% (254)
No	19.1% (60)
ADR reporting should be	**Response (each out of 314)**
Voluntary	86.9% (271)
Compulsory	13.7% (43)
Remunerated	73.6% (231)
Inclination to report an event	**Response (each out of 314)**
Reaction to a new drug	93% (292)
Serious event	88.9% (279)
Unusual event	82.8% (260)
Well recognized adverse reaction of a drug	22.9% (72)
Discouraging factors	**Response (each out of 314)**
Concern that the report may be wrong	80.9% (254)
Do not know how to report, where to report and when to report	95.2% (299)
Lack of time to fill-in a report and a single unreported case may not affect ADR database	72.9% (229)
Non-remuneration for reporting	16.2% (51)
Concern that reporting may generate extra work	41.1% (129)
Lack of time to actively look for ADRs while at work	77.1% (242)
Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred	81.8% (257)
Lack of confidence to discuss the ADR with other colleagues	23.2% (73)

DISCUSSION:

The study points out that the awareness about ADR reporting system, amongst resident doctors, in the country (43%) and even in their own hospitals (49.5%) is very low. More alarming, however, is the fact that very few resident doctors have ever reported an adverse event to any of the national centres (2.9%) or the ADR monitoring system of their own hospitals (22.6%) which is similar to the result obtained by Li Qing et al [11]. From these results we hypothesize that the management and propaganda of ADR monitoring is not perfect and need serious rethinking. Lack of knowledge of where ADRs should be reported would automatically affect reporting, therefore, awareness programmes; through publicity, would appear necessary to improve ADR reporting. Perhaps, the undergraduate training in pharmacovigilance and medicine risk perceptions may be either insufficient or improperly delivered to prepare the doctors for the task of ADR monitoring and reporting in their future career.

Though it is known to the doctors that the medical professionals like doctors and dentists can report an ADR, the awareness that even a nurse (70.7%), pharmacist (36.9%) or a physiotherapist (32.8%) can do so is very low. Active involvement of the paramedical staff in spontaneous reporting of ADR will go a long way in improving the reporting rates, since they are in closer contact with the patients for a longer duration, than the doctors. Also, it is a general perception that ADR reporting is only for allopathic drugs and vaccines. The knowledge that it encompasses other products like herbals, traditional medicines, and blood products, biological and medical devices is comparatively quite low.

It is also evident that the resident doctors perceive reporting an adverse event related to a new drug (98.7%) as the most important aspect of pharmacovigilance. The awareness that even suspected drug interactions and their consequences, congenital anomalies, and adverse events of which cause is not evident, require equal vigilance and prompt reporting. This is contrasting to the study by Li Qing et al in which 65.6% doctors were aware and willing to report suspected ADRs [11].

Although an overwhelming majority of the doctors (89.5 %, 281/ 314) felt that ADR reporting is necessary and also that it is a professional obligation (80.9%, 254/ 314). But they would be more inclined to do it, if the reaction is to a new drug (93%, 292/ 314), is serious (88.9%, 279/ 314) or unusual (82.8%, 260/ 314), which is similar to the results obtained by Li Qing et al and Karen J Belton et al, but contrasting to that obtained by Bateman et al [11, 12, 13]. Only 22.9% (72/ 314) doctors would want to

report an event if it was an already well recognised adverse reaction as opposed to 62% doctors who wanted to report a similar event in the study by Li Qing et al [11].

The factors dissuading the resident doctors from spontaneous reporting were mostly related to lack of understanding of the reporting procedure (95.2%), lack of adequate clinical knowledge (81.8%) and lack of time to actively look for and report the ADRs. The doctors also had a lot of misperceptions about the entire procedure and were apprehensive that it would increase their workload (41.1%) or they might be wrong in identification of ADRs (80.9%). These factors have also been pointed out in other studies. Anxiety of respondents not to appear incompetent or become subject of ridicule may cause them to want to report only ADRs that they consider certainly were caused by a drug. The need to allay this fear, through sensitization and pharmacovigilance education, cannot be over-emphasized.

While a majority of the doctors opined that ADR reporting should be voluntary (86.9%, 271/314) and remunerated (73.6%, 231/ 314), some (13.7%, 43/ 314) felt that it should be made compulsory. Interestingly, 57% (179/ 314) wanted that the identity of the reporter be kept confidential, which is contrasting to the result of DN Bateman et al [13]. This finding might be correlated with a high prevalence of anxiety among the resident doctors regarding the correctness of identification of an ADR as found in our study.

To improve spontaneous reporting rates, the resident doctors suggested organising training programmes, an uncomplicated reporting system with quick feedback regarding their specific report and also all other reports received by the pharmacovigilance system. Gestures like acknowledgment of the receipt of the report and an appreciation note would also help, motivating them to continue the pharmacovigilance activities. The result of the study by Manuela Tabali et al., demonstrates that an educational intervention can increase physician awareness of ADRs, and that physicians were able to incorporate the knowledge they gained from face-to-face training into their everyday clinical practice [14]. The effects of the educational intervention, however, were temporary and hence regular retraining is essential.

The study had a few limitations. It would have been more scientific to use qualitative research methodology (in depth interviews, focus group discussions) for such a study, which may be useful to gain better understanding of the knowledge, opinions and attitudes of the doctors and also help in the identification of elements that might be improved in the system of spontaneous notification. In order to generalise our findings, it is imperative that similar studies be done on a national basis in all the teaching hospitals of the country. Though the response rate was fairly good, with a higher response rate it would have been possible to draw more certain conclusions. The study findings cannot not be applied to the wider medical community as the study is restricted to physicians (only resident doctors), practicing in a hospital setup, where already a formal ADR reporting system exists.

In conclusion, our study strongly suggests that there is a great need to create awareness and to promote the reporting of ADR amongst resident doctors, which will lay a solid foundation for these budding healthcare professionals to be diligently involved in quality pharmacovigilance in their future practices. Training sessions to clarify the role of various healthcare professionals in pharmacovigilance, the events to be looked for and reported and to address the various perceived obstacles to spontaneous reporting, will hopefully fill the observed lacunae in knowledge and practices. A closer relationship between doctors and the pharmacovigilance centre and the feedback of the pharmacovigilance activities in the hospital are also suggested. Attitudinal and cultural changes, whereby ADR reporting is seen as an integral part of the clinical activities of the doctors, are very necessary for a long term improvement of ADR reporting.

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