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RESEARCH ARTICLE

A study to assess the knowledge and attitude regarding Pharmacovigilance Programme of India among interns in a tertiary care hospital

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ABSTRACT

Background: The Pharmacovigilance Programme of India (PvPI) aims at sensitizing the health-care providers toward strengthening the spontaneous reporting of adverse drug reactions (ADRs) which are a significant cause of morbidity and mortality and to protect the lives of millions of people living in a vast country like India. **Aims and Objectives:** This study aims to analyze the knowledge and attitude regarding PvPI among interns in a tertiary care hospital. **Materials and Methods:** This cross-sectional model was approved by Scientific Research and Institutional Ethics Committee. All the 120 internees of Sri Venkateshwaraa Medical College Hospital and Research Centre were evaluated for their knowledge and attitude regarding PvPI with the help of pre-validated structured questionnaire. This study was conducted for a period of 3 months after obtaining written informed consent from each participant. The data were analyzed using descriptive statistics. **Results:** Findings of this study showed that 81% were aware of PvPI, whereas 75% had very good knowledge about Naranjo's causality assessment. 43% of the entrants were willing to report ADR. 65% of the participants agreed the mandatory reporting of ADR with 35% of uncertainty and 14% accepted that collection boxes at all departments are helpful for ADR reporting. **Conclusion:** This study has demonstrated that knowledge and attitude toward PvPI are gradually improving among interns. The ADR reporting could be made mandatory in a tertiary care hospital as an integral part of clinical activities, which is the only solution, wherein PvPI can be implemented effectively.

KEY WORDS: Pharmacovigilance; Knowledge; Attitude; Internees; Adverse Drug Reactions

INTRODUCTION

The word "Pharmacovigilance" in French means, a discipline involving detection, evaluation, and prevention of undesirable effects of medicines.[1] The World Health Organization (WHO) defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse drug effects or any other possible drug-related problems, particularly long-term and short-term adverse drug reactions (ADRs) of medicines."[2]

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Launch of Pharmacovigilance Programme of India (PvPI)

In 1986, a pilot ADR monitoring system was started in India with 12 regional centers.[3] Later in 1997, India became the member of the WHO Programme for International Drug Monitoring governed by the Uppsala Monitoring Centre (UMC), Sweden. A nationwide revised ADR monitoring program was launched by Health Ministry in July 2010 and was named as PvPI.

The specific aims of pharmacovigilance are to:

- Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions,

- Improve public health and safety in relation to the use of medicines,
- Contribute to the assessment of benefit, harm, effectiveness, and risk of medicines,
- Encouraging their safe, rational, and more effective (including cost-effective) use, and
- Promote understanding, education, and clinical training in pharmacovigilance and its effective communication to the public.[4,5]

The importance of pharmacovigilance (safety monitoring of medicinal products) is as follows:

1. Drug monitoring
2. Pharmaceutical preparations – adverse effects
3. ADR reporting
4. Product surveillance, post-marketing
5. Legislation of Drug Series (includes process involved from manufacturing, distribution till labeling and pricing).

During the past few years, the science of pharmacovigilance has evolved, to recognize the importance of safety use of medicines to enhance patient care.[4] At present, it's concerns have been widened to include herbals, traditional and complementary medicines, blood products, biological, medical devices, and vaccines.[6-8]

The Burden of ADRs on Public Health

It has become increasingly clear that the safety profile of medicines is directly linked with sociopolitical, economic, and cultural factors that, in turn, affect access to medicines, their utilization patterns, and public perceptions of them.[9] Generation of data's of ADRs helps in practicing evidence-based medicine and thus prevents significant cause of morbidity and mortality with a special impact on economic burden and welfare of the community.[10]

Indian Scenario of ADR Reporting

In our country, there is a huge divergence in the population with regard to genetic and cultural traditions. Hence, this kind of information would help the government to plan and design optimal health-care policies for the well-being of the community.

The UMC [Figure 1], Sweden, estimated that only 6–10% of all the ADRs are reported globally in which the contribution from India to UMC is very little (2%).[11] Nearly 20% of patients experience some adverse event during hospitalization, of that 2.37–4.01% attributed to admissions. It is estimated that only 6–10% of the ADRs are reported.[12]

Once a medicine is ready for marketing, a larger number of population is exposed for consumption; a post-marketing surveillance only can monitor the safety and effectiveness in real-life situations.[13] Many adverse effects of the drug, drug interactions, interactions with food, incidence of new ADRs, and some rare adverse effects (1:100,000) will be exhibited after being used by majority of the community, which can only be brought through effective pharmacovigilance program.[3]

Need for the Study

In a tertiary care hospital, the medical internees are the first level health-care providers under the guidance of the specialists.[14,15] Hence, there is a strong need to create awareness regarding PvPI and also to emphasize the importance of reporting ADR among medical residents so that it will be inculcated in their routine day-to-day practice.

Hence, a questionnaire-based study was planned with a primary objective to evaluate the knowledge and attitude of interns toward PvPI which will give a snapshot about the level of their awareness, thus helping us in designing the methods for better promotion of pharmacovigilance.

MATERIALS AND METHODS

The study was conducted after getting approval from Scientific Research and Institutional Ethics Committee. Written informed consent was obtained from all the candidates. This was a cross-sectional questionnaire-based model done among all the 120 compulsory rotational residential internship (CRRI) of Sri Venkateshwaraa Medical College Hospital and Research Centre, Puducherry, for a period of 3 months (November 2018–January 2019).[16]

Inclusion Criteria

We have included 120 interns of both genders.

Exclusion Criteria

Those who are not willing to participate, incomplete questionnaire form were excluded from the study. The nature and purpose of the study and the instructions for filling up the questionnaire were explained in detail to all the study subjects. The questionnaire was predesigned, validated on the basis of similar previous studies. All the 10 questions were answered in the stipulated time. The data obtained were analyzed using descriptive statistics.

RESULTS

The demographic profile of the 120 study subjects showed a considerable greater proportion of females participants (56%) over male (44%) CRRIs [Figure 2]. The knowledge of PvPI (questions 1–5) among the study subjects was analyzed by their correct and incorrect response [Table 1]. The attitude (questions 6–10) was tested, as agree, disagree, and uncertain [Figure 3].

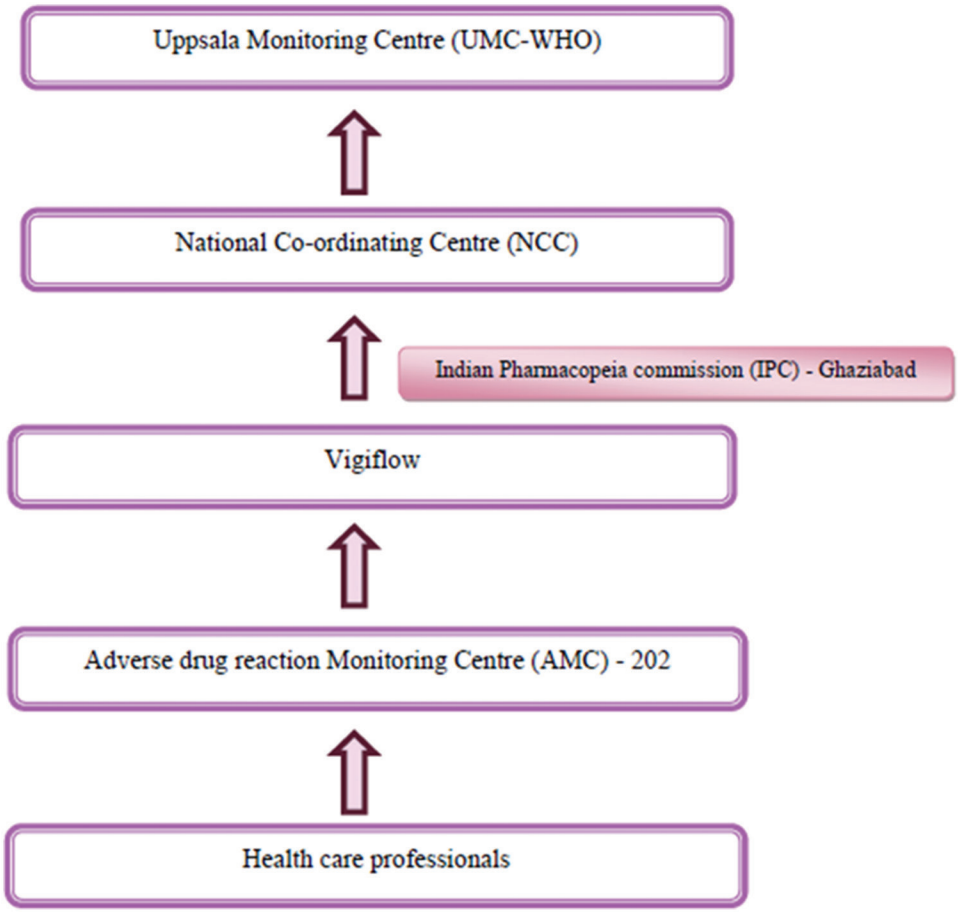

Figure 1: Steps in adverse drug reaction reporting

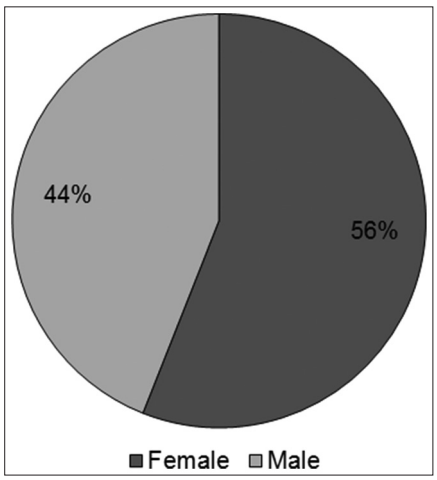

Figure 2: Gender percentage

Table 1 depicts knowledge toward existence of PvPI with adequate response 81% while 19% of the study subjects were ignorant. 60% of the participants know the definition of pharmacovigilance, whereas 40% of the study subjects were lacking. The knowledge regarding the regulatory body responsible for monitoring ADR was good among 50% of the candidates and 50% reported incorrect response. Majority (75%) of the entrants admitted the responsibility of doctors, nurses, and pharmacists in reporting ADR with very poor (25%) acknowledgment from the remaining. 75% of the CRRIs were well aware of Naranjo's causality assessment scale while 25% exhibited wrong perception.

About 57% of the study subjects had the positive attitude toward the drug safety as the primary goal of PvPI, whereas 34% showed uncertainty, while 9% disagreed. Of 120, a great interest was noticed among 69% of the participants toward reporting of all the suspected adverse events as per the National Pharmacovigilance Programme (NPP). The mandatory reporting of ADR was favored by 65% of the candidates, whereas 35% were with confused ideas. Among the study subjects, 43% were willing to report ADR while 12% disagreed and the remaining 45% of them had uncertainty toward willingness. The launching of collection boxes at all the departments was supported by only 14% of the respondents.

DISCUSSION

The CRRIs were assessed because they play a major role in interacting with patients in various clinical departments. In our country, majority of the studies were conducted only among doctors, particularly in tertiary care teaching hospitals. Hence, there is an urgent demand to create spontaneous

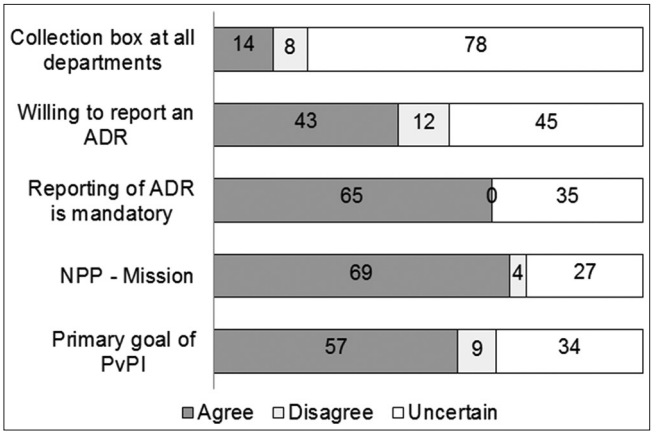

Figure 3: Attitude toward Pharmacovigilance Programme of India

Table 1: Knowledge regarding PvPI (parenthesis indicates percentage)

Questions 1–5	Correct response	Incorrect response
Awareness regarding the existence of PvPI	97 (81)	23 (19)
Pharmacovigilance definition	72 (60)	48 (40)
Regulatory body is responsible for monitoring ADRs	60 (50)	60 (50)
The health-care professionals responsible for reporting ADRs in a hospital	90 (75)	30 (25)
Causality assessment scale (Naranjo's)	90 (75)	30 (25)

PvPI: Pharmacovigilance Programme of India, ADRs: Adverse drug reactions

reporting habit among internees as they are also an invaluable source for collecting, analyzing, and reporting ADRs as a long-term goal to strengthen the PvPI. Hence, this study was conducted with an aim to explore the knowledge and attitude toward PvPI.

This study results revealed that 81% of the participants had very good knowledge about existence of PvPI which could be due to the teaching of basic principles of ADR reporting during undergraduate curriculum and 75% were well aware of Naranjo's causality assessment scale of ADR reporting. This could be due to effective hands-on training during their pharmacology practical sessions which are not in accordance with the study results of Kulmi.[11] The response to definition of pharmacovigilance showed that 60% of our study subjects gave correct response which is well in line with the findings of Komaram and Dhar study.[1] The remaining 40% perceived that pharmacovigilance deals only drug-related problems which can be clarified by effective medical education strategies such as academic detailing, feedback on individual cases, reminders, and soliciting the support of acknowledged experts (pharmacologists).

Of 120 participants, 75% of our study subjects agreed the moral responsibility of the doctor, pharmacist, and the nurses toward ADR reporting which was not comparable to a similar study done by Srinivasan *et al*. that might be due to low percentage of training imparted to the health-care professionals indicating that there is need to educate and sensitize about the knowledge and importance of ADR reporting.[4]

The findings of our study are not consistent with other study done by Sandeep *et al*. which showed that 50% of our participants were aware that the regulatory body responsible for ADR monitoring is CDSCO.[12] 57% of our interns agreed toward the drug safety as the primary goal of PvPI which was not comparable with Katekhaye *et al*. reports.[3] This potential obstacle could be achieved through reporting of ADR even if casualty is not established and provision of regular electronic communication updates on the safety of drugs to all health-care professionals.[12]

A previous study conducted by Dudhe and Bhore had shown a right attitude (66%) to report ADRs which is in accordance with our observations, wherein 69% of our CRRIs favored NPP mission and 4% unfavored with the discouraging factors such as forgot to report and afraid of the legal action against them while the remaining 27% were uncertain.[10]

Vakade *et al*. showed a surprisingly great response toward mandatory ADR reporting (88.63%) which is inconsistent with our study findings that 65% of our study subjects were in support while 35% were uncertain, which could be due to their assumption that a single unreported case may not affect ADR database and none of them disagreed in this regard. The major deterring factor may be "lack of time" among their busy schedule, lack of confidence, and inapt professional approach regarding the rules and procedures of ADR reporting.[13]

Katekhaye *et al.* has showed that 86% of their participants had agreed to report even a single ADR that can contribute to medical knowledge which was inconsistent with our study, wherein only 43% of our entrants had interest to report.[3] The launch of collection boxes at various departments was agreed only by 14% of the internees while 78% of the candidates were uncertain about the importance of collection boxes, which will favor immediate ADR reporting, time saving so that precised and effective practice of reporting ADR can be achieved. This unmet attitude toward collection boxes needs sensitization and awareness.

Suggestions

The various measures to improve the pharmacovigilance can be through

1. Establishing a separate pharmacovigilance outpatient department with ADR specialist in each and every clinical department
2. Multimodality interventions to prevent under-reporting, namely reassurance among doctors that reporting has no legal implications and making ADR reporting mandatory

in all tertiary care hospitals
3. Providing financial aid for voluntary ADR reporters (public), as it was done previously for smallpox surveillance and successful eradication
4. Facilitate ADR reporting by E-mail, fax, and through phone.[17]

CONCLUSION

The concluding remarks of this study showed that majority of the interns were well aware of the causality assessment scale and the moral responsibility of the health-care providers in reporting ADR. There was a moderate awareness regarding the regulatory authorities for monitoring ADR. Most of the participants had a positive attitude toward the drug safety as the primary goal of PvPI and mission of NPP. This study emphasizes the vital to strengthened ADR reporting through constant motivation by continuing medical education programs, frequent training, and various workshops. The ADR reporting could be made mandatory in a tertiary care hospital; an integral part of clinical activities is the only solution, wherein PvPI can be implemented effectively.

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