

Identifying barriers to report adverse drug reactions using the Delphi method: Experience from an institute of national importance of India

INTRODUCTION

Adverse drug reaction (ADR) is a cause of concern as it increases the duration of hospitalization, health expenditure, morbidity, and mortality in patients.^[1,2] Government of India launched the nationwide pharmacovigilance program of India in 2010 to promote the safe use of medicines among its citizens.^[3] The inclusion of principles of pharmacovigilance in the new competency-based curriculum for Indian Medical graduates has re-emphasized its role in public health.^[4] The voluntary reporting system of ADRs is widely followed in many countries including India, and underreporting is a major drawback of it.^[5] Medical professionals cite many impediments such as fear of legal liability and lack of knowledge, but there is a lack of unanimity regarding the common factors which act as hindrances for reporting ADR.^[6,7] Moreover, most of these studies did not focus on resident doctors who are the first line of contact with patients. Therefore, this study aimed to explore the barriers of ADR reporting among resident doctors.

MATERIALS AND METHODS

A two-round Delphi agreement study was conducted to seek consensus on barriers of ADR reporting among resident doctors of a tertiary care institute of national importance using a 25-item survey tool. Forty-five resident doctors from various clinical specialties were included in this study as there is not any strict standard for the sample size of the Delphi panel.^[8] In the first round, all participants were provided the survey tool after explaining the purpose of the study. They were then asked to evaluate every question of the questionnaire, which they perceived as a barrier for the ADR reporting in their setting. Responses were obtained on a five-point Likert scale. All those questions which received score 4 (agree) or 5 (strongly agree) combinedly by more than 80% of the participants in the first round were considered as important and accepted. The questions for which 50%–80% of respondents combinedly awarded 4 or 5 were sent to the

second round for reassessment. Questions which scored 4 or 5 by <50% of participants were regarded as unimportant barrier and discarded from further evaluation. The second round had a similar setup as the first round, and only items meeting the above criteria were included in the evaluation. For each question, the average score of Round 1 (1–5) was provided to the participant along with his first-round rating. Participants were then asked to re-evaluate the items considering the average score of the other participants. The survey questions which received a rating of 4 or 5 by combinedly more than 80% of all respondents were added to the final list of questionnaires.

RESULTS

Out of 45 participants, 45 (100%) and 40 (90%) participated in round 1 and 2 consecutively. Consensus was obtained for statements such as “unavailability of reporting form” (combine total of agree and strongly agree was 89%), “complex reporting procedure” (93%), and “fear of legal problem” (84%) as barriers for ADR reporting in round 1 (total 7 statements) and for further two statements such as “Lack of motivation to report” (85%) and “Lack of time” (86%) in round 2. Following two rounds, consensus could not be obtained for 16 statements such as “I am NOT clear how to report an ADR” (21%), “I am unaware of the existing national reporting system for ADR” (12%), “I am NOT clear what the ADR is” (15%), and “I believe that ADR reporting is not important” (27%).

DISCUSSION

The study showed that participants knew what constitutes an ADR, how to report it, and what is the ongoing national program for ADR monitoring and did not consider these as barriers for ADR reporting. It differed with the observation of a study done a few years ago among undergraduate students in South India.^[9] This reflects the positive impact of teaching and training programs initiated on pharmacovigilance by different stakeholders. In this study,

participants indicated lack of time, lack of motivation, convoluted reporting form, and complex filling procedure as constraints for reporting which resonates with the finding of studies done among health professionals.^[6,7] These can be addressed by simplifying the existing reporting procedure and making the ADR reporting form easily accessible. Innovative steps such as installation of drop box at the crucial places of hospitals, regular publication of hospital bulletin comprising important ADR reported from the hospital might motivate, and foster reporting culture among resident doctors. As this was a single-center study, it might lack pan-Indian perspective. However, it was the first Delphi study to explore consensus among the resident doctors for ADR reporting. Moreover, the finding of this study might have future implications on the pharmacovigilance program of India as the participants of the current study will carry the mantle of spontaneous reporting.

CONCLUSION

To conclude, the impediments like unavailability of ADR reporting form, complex reporting procedure can be sorted out by simplifying the current reporting procedures and easy accessibility of resources. Other perceived barriers like fear of legal problems, lack of motivation, lack of professional environment can be addressed by a periodical sensitization program, words of assurance, and a conducive professional environment for ADR reporting.

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Conflicts of interest

There are no conflicts of interest.

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