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LETTER TO EDITOR

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# Development and evaluation of a voluntary education module on medicine safety for basic science medical students in Nepal

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Dear Editor,

Although medicines are beneficial, sometimes they can be harmful and can lead to potentially life threatening conditions and even lead to death. Medicines can cause Adverse Drug Reactions (ADRs), which has been defined by the World Health Organization (WHO) as 'a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function'.[1] Data suggests ADRs to be a major cause of morbidity and mortality worldwide.[2] Evidence suggests knowledge, attitude and practice towards ADR reporting and prevention among health professionals including medical doctors are poor.[3] Often health professionals do not report ADRs to concerned authorities and have a poor understanding regarding the existing ADR monitoring program in their countries.[4] A possible reason may be because medicine safety issues are inadequately addressed in the medical and health sciences curricula which emphasizes the beneficial effects of medicines and puts relatively less emphasis on their rational and safe use. In developing countries, pharmacovigilance is not adequately addressed in the curricula of health professions schools. ADRs are only included as a topic during didactic lectures and the practical aspects of reporting and preventing ADRs are inadequately addressed.[5] Educating medical students about the safe use of medicines and about existing ADR monitoring programs in their countries is important to address the current gap in knowledge.

This study evaluated basic science/preclinical undergraduate medical students' knowledge, attitude and practice (KAP) about medicine safety and pharmacovigilance both before and after an educational intervention, and students' feedback about the module using both qualitative and quantitative methods. The quantitative part included a pre-post interventional study evaluating respondents' KAP towards ADRs and pharmacovigilance, and survey of respondents' feedback on the module. The qualitative part consisted of a focus group discussion (FGD) conducted on completion of the module.

The study subjects were first and second year basic science undergraduate medical students of the College of Medical Sciences at Bharatpur, Nepal. Thirty-one students were selected considering their motivation and willingness to participate in the module and the study. KAP questionnaire (19 points) and feedback questionnaire (20 point Likert-type questions) were used.

The baseline KAP of the students regarding ADRs and pharmacovigilance were evaluated using the questionnaire before starting the module. Six one hour sessions spread over 3 months from November 2011 to January 2012 were conducted. The sessions were themed as 'Sensitization of the medical students to drug use problems and an overview of the module', 'Magnitude of harmful effects caused by medicines and historical aspects of Pharmacovigilance', 'Various causes of ADRs', 'Strategies to minimize the occurrence of ADRs', 'Medicine safety monitoring systems available in Nepal, South Asia and globally', and 'Politics

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of medicines with special emphasis on medicine safety'. The sessions were conducted using small group learning methods with 7 or 8 students in each group and the learning modalities used included group discussions, role-plays, elicitation sessions, and presentations.

The completed KAP questionnaires were evaluated giving a score of '1' for a correct answer or a positive response and '0' for a wrong or negative response. The total KAP scores at baseline were compared among various subgroups of respondents using 'Mann Whitney U test'. Wilcoxon signed ranks test was used to compare the pre and post intervention median total scores. A p value less than 0.05 was considered statistically significant. Similarly, the completed feedback questionnaires were analyzed. The FGDs were video recorded and analyzed manually.

Of the 31 respondents, 15 (48.3%) were male and 16 (51.6%) were female. The median (interquartile range (IQR)) baseline total score was 10 (8-11) (maximum possible score 19). The scores were not significantly different among respondents of various age groups, gender, method of financing of study, year of study, and nationality. The median (IQR) scores significantly improved immediately post-intervention (n=27) to 12 (11-14) ($p<0.001$). The feedback of the respondents regarding the module (n=29) was positive and the total median (IQR) score was 81 (73-86), maximum possible score being 100. The major feedback obtained during the FGD was related to the venue of the sessions, seating arrangements and logistics. The authors were successful in designing a module which improved participants' KAP regarding ADR reporting and pharmacovigilance, and was 'liked' by the students.

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