

# Knowledge and perception regarding adverse drug reactions among undergraduate medical students of Bihar, Eastern India

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## ABSTRACT

**Background:** Adverse drug reactions (ADRs) have national and international monitoring and are part of teaching-learning of undergraduate medical course and curriculum. **Objectives:** To find the knowledge and perception of ADRs among undergraduate medical students in a tertiary care teaching institute in eastern India. **Materials and Methods:** This was an observational cross-sectional study conducted among the MBBS medical students by administration of pre-designed, pre-tested, semi-structured questionnaires. The data on their knowledge and candid reflections on ADRs were analyzed using software and compared with peers. **Results:** The responses from the participants on knowledge and perception of ADRs varied widely. Final-year students had the most precise response on classification, filing an ADR report, national reporting centers, and the first step in monitoring ADRs; the majority accepted their first-hand experience and legal and professional responsibilities on ADRs. Third-year students responded well on objectives, methods, and scope of patients on direct reporting or drug overdose and monitoring; respect patient confidentiality while reporting; and expect feedback from monitoring centers, with special training on ADR. Second-year students responded well on definitions, pharmacovigilance programs in India, alertness of banned drugs because of ADR, and related capacity building. **Conclusions:** The awareness and insight on ADRs of the undergraduate medical students were quite reasonable. However, further reinforcement is needed in future to be updated to relevant issues to their practice as primary care physicians.

**Keywords:** Adverse drug reactions, knowledge, perception, undergraduate medical students

## Introduction

Adverse drug reactions (ADRs) are the noxious and unintended responses to drugs at doses normally used in humans for prophylaxis, diagnosis or therapy, or modification of physiological functions.<sup>[1]</sup> ADRs lead to death, life-threatening

ailments, hospitalization, substantial and persistent disability or permanent change, psychosomatic disruptions, and compromised quality of life.<sup>[2]</sup> ADRs now include reactions occurring as a result of error, misuse or abuse, and suspected reactions to drugs that are unlicensed or being used off-label in addition to the authorized use of a medicinal product in doses prevalent in standard clinical use.<sup>[3]</sup> Safety and efficacy are the two main pillars of drugs as the effectiveness cannot be assessed easily and safely as any drug may have uncommon ADRs and care-seekers might be harmed unintentionally.<sup>[4]</sup> The importance of the knowledge and treatment procedures of ADRs among all

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levels of health care personnel becomes increasingly important for reported abnormal findings in the era of mass vaccination to assess these reactions and respond to them promptly.<sup>[5]</sup> Children are commonly prone to ADR, and extrapolation from adult dosages should be avoided as the volume of distribution and protein binding capacity differ widely.<sup>[6]</sup> ADRs are common in elderly citizens by changes in drug disposition, pharmacodynamic responses, and co-morbidities causing ADR even at lower doses.<sup>[7]</sup> People with renal and hepatic diseases are prone to ADRs as most drugs are metabolized by liver and excreted by kidneys.<sup>[8,9]</sup> Research groups from India recommended that the knowledge and competencies on ADRs and pharmacovigilance are relevant to the updating for the general primary care providers and family physicians and need reinforcement at regular intervals by continuing education.<sup>[10-13]</sup>

In the above scenario, the researchers explored knowledge and perception on ADR among the undergraduate medical students in a tertiary care rural hospital.

## Materials and Methods

### Study design

Institute-based observational cross-sectional study.

### Place of study

The study was conducted at the Mata Gujri Medical College and LSK Hospital, Kishanganj, Bihar, with prior approval from the competent authority.

### Duration of study

September 2021 to March 2023. STUDY POPULATION:

Undergraduate medical students of Mata Gujri Medical College and LSK Hospital, Kishanganj.

### Sampling technique

The census population of undergraduate medical students was recruited in the study.

#### INCLUSION CRITERIA.

MBBS undergraduates who are willing by informed consent.

#### EXCLUSION CRITERIA

- MBBS undergraduates who are unwilling to execute the informed consent process.
- MBBS undergraduates who do not agree to participate and follow up.
- Seriously ill undergraduates.
- First-year MBBS undergraduate students.

#### PRIMARY OUTCOME MEASURES.

The primary outcomes were knowledge and perceptions of ADRs of the undergraduate medical students.

### Study tools

The study tool was a pre-designed, pre-tested, semi-structured questionnaire (data collection tool) that included socio-demographic profiles (age, gender, school language medium), details of postings, and precise objective and subjective internalization on ADR.

### Data collection procedure

After approval from the Institute Ethics Committee (IEC), the study was initiated. Each participant was individually counseled prior to the study, where no potential risk is involved, and she/he would have full autonomy to leave the study at any point of time. Each participant was ensured that the data would only be used for research purpose and would not hamper her/his teaching-learning or evaluation, irrespective of the participation in the study or not. Following this, written informed consent was obtained from each participant. Ethical principles were strictly adhered to during data collection with strict confidentiality. All the collected data were kept confidential with the investigators and not disclosed for any type of assessment, management, or intervention. The principal investigator and co-principal investigators strictly adhered to GOI CoVID-19 guidelines during data collection.

### Data analysis

All the collected data were collated. Missing data were dealt with, and data were entered into MS Excel spreadsheets. Analysis was carried out using IBM SPSS-19, and Pearson Chi-square test was performed at an alpha level of 5%. After cross-checking with the individual responses to ensure consistency, reliability, and accuracy, observations were compared with publications on comparable variables to find similarity/disparity. Unique observations, if any found in the present work, were attempted to be explained, whenever possible, and conclusions were drawn carefully avoiding the biases and considering reliability and validity.

## Results

Altogether, 212 MBBS students (male 93, female 119) participated from second (80), third (74), and final (58) years, wherein responses on knowledge and perception on ADRs varied widely.

Final-year students had the best responses on 'Classification of ADR' [55 (94.8%)], 'Medical Representative cannot file ADR report' [13 (22.41%)], 'ADR reporting centers in India' [15 (25.86%)], 'First step to monitor ADR' [32 (55.17%)], and 'Simultaneous administration of multiple drugs increases risk of ADR' [48 (82.75%)]. Third-year students responded well on 'Objectives of ADR' [45 (60.81%)], 'ADR reporting methods' [49 (66.21%)], 'ADR be reported if causes both inconvenience and death' [66 (89.18%)], and 'patient can directly report ADR' [26 (35.13%)]. Second-year students had the best response on 'Definition of ADR' [61 (76.5%); 73 (91.25%)].

were well versed with pharmacovigilance programs in India. On 'Drug overdose as an ADR,' the responses were miserable, namely, final [21 (36.20%)], third [23 (31.08%)], and second years [24 (30.00%)] [Table 1].

Most of the final-year students responded 'Experienced ADR during practice training' [32 (55.17%)], 'Legal liabilities while reporting ADR' [43 (74.13%)], and 'ADR reporting is a time-consuming activity' [8 (13.79%)]. Most of the second-year students responded 'Aware of banned drugs or in limited use due to ADRs' [66 (82.50%)], had the highest response on 'Adequately trained in ADR reporting' [34 (42.50%)], and responded 'ADR reporting to be compulsory, voluntary or remunerated' [52 (65.00%)] (compulsory). Most of third-year MBBS students felt that 'patient confidentiality should be maintained while reporting ADR' [63 (85.13%)], had the highest response on 'expectation of feedback from monitoring centers' [69 (93.24%)], and felt the 'Need of special ADR training program' [69 (93.24%)]. On 'ADR reporting as a professional responsibility,' the responses were good, namely, final [57 (98.26%)], third [70 (94.59%)], and second years [71 (88.75%)] [Table 2].

In crosstab Pearson Chi-square test, all the variables showed highly significant (<0.01) products.

## Discussion

Drugs and ADRs are inherent to basic health care amid varied populations in the world. In the light of the increasing complexity of diagnosis and interventions, the primary care providers and family physicians need updating to manage colossal load of co-morbidities. Developed countries are also reporting ADRs routinely as growing menace amid unforeseen clinical scenarios.<sup>[3]</sup> To help identify ADRs globally, the World Health Organization uses Uppsala Monitoring Centre in Sweden via a database called Vigibase; other tools are used to determine ADR causality, namely, WHO-UMC tool, Naranjo ADR probability scale, and the Liverpool ADR causality tool.<sup>[14]</sup>

### Definition of ADR

In our study, the majority of the responders correctly defined ADR; final-year [35 (60.34%)], third-year [46 (62.16%)], and second-year [61 (76.25%)] students opted noxious and unintended response at normal dose, which is the most correct selection. The knowledge regarding ADR was declining from MBBS second year to final year, correlated with teaching of ADRs in Pharmacology in MBBS second year. A comparable observation was second (50%), third (44%), and final (46%) year,<sup>[1]</sup> with an overall response of 27.27%,<sup>[4]</sup> Final-year MBBS students defined ADR correctly (86.3%).<sup>[15]</sup>

### Classification of ADR

In our study, 94.8% from final-year MBBS students have agreed with the classification of ADR as mild, moderate, and severe. In a

similar study, 40.90% students classified the ADRs correctly.<sup>[4]</sup> In Goa, one-fourths of students were aware of the most common ADRs and 80% correctly identified which ADRs to be reported and poor classification of ADRs (18%).<sup>[15]</sup>

### Objectives of ADR reporting

In our study, 45 (60.81%) third-year students had the most correct option; 46 (57.50%) and 28 (48.27%) from the second year and final year opted the same. In a similar study, 54.5% students felt to quickly identify ADR as important and serious for early warning to concerned authorities and value for early establishment of cause-effect relationship between drug and reaction (22.72%); ADR monitoring was done to find out the incidence of particular reaction (13.63%).<sup>[2]</sup> Rehan HS *et al.* reported that objectives of ADR monitoring were known to 26.2% UG students.<sup>[3]</sup>

### Monitoring methods of ADR reporting

In our study, 49 (66.21%) students from the MBBS third year had chosen the most correct option of ADR reporting compared to 38 (65.51%) and 50 (62.25%) from MBBS final and second years. In a study by peers, 31.81% students noted that the spontaneous reporting system is used for ADR monitoring; half of them mentioned intensive monitoring for a particular drug.<sup>[4]</sup>

### Time to report ADR

In our study, 15 (25.86%) students from the final year had chosen the most correct option when to report ADR; third-year (21.62%) and second-year (20.00%) students had chosen the same. Another study reported that 10% students answered that ADR should be reported if it causes inconvenience to the patient; 6.67% felt to report after death of the patient; 83.33% answered ADRs should be reported if they cause both inconvenience and death of the patient.<sup>[4]</sup>

### Pharmacovigilance program of India

Among our participants, 73 (91.25%) of the second year correctly spelt on pharmacovigilance programs of India (PV) compared to the final year (89.65%) and third year (82.43%). In another study, only 10% were unaware of the PV program.<sup>[4]</sup> In a comparable study, 77 second-year MBBS students (40%), 58 third-year students (32%), and 48 final-year MBBS students (28%) were aware of PV programs;<sup>[3]</sup> second (46%), third (81.25%), and final (56.25%) year MBBS students were aware of PV programs.<sup>[5]</sup> In Goa, 66% knew Indian regulatory body for PV; 30.5% were aware of the National Pharmacovigilance Programme.<sup>[15]</sup> The PV awareness levels among undergraduates in Telengana<sup>[16]</sup> and Rajouri Jammu and Kashmir<sup>[17]</sup> were comparable; in Maharashtra, awareness on PV among medical interns was low (31.1%).<sup>[18]</sup>

### First step in monitoring of ADRs

This was responded well in our study, namely, final year (55.17%), third year (36.48%), and second year (36.25%). In Goa, 65.3% correctly knew who can report ADRs; 45.3% knew steps of ADR reporting; 54.5% correctly answered the questions related to knowledge.<sup>[15]</sup>

Table 1: Knowledge of ADR among our study participants

Parameters	MBBS final year	MBBS third year	MBBS second year
1. Definition of ADR			
a. Any undesirable or unintended consequence of drug administration	18 (31.03%)	00 (0.00%)	00 (0.00%)
b. Noxious and unintended response at excessive dose	3 (5.17%)	5 (6.75%)	5 (6.25%)
c. Noxious and unintended response at normal dose	35 (60.34%)	46 (62.16%)	61 (76.25%)
d. Potential Harmful event related to drug	2 (3.44%)	3 (4.05%)	1 (1.25%)
e. Unintended response to drug administration	00 (0.00%)	20 (27.02%)	13 (16.25%)
2. Classification of ADR			
a. Subclinical, Clinical, Lethal	3 (5.17%)	18 (24.32%)	22 (27.50%)
b. Mild, Moderate, Severe	55 (94.82%)	47 (63.51%)	50 (62.50%)
c. Subclinical, Clinical-	0 (0.00%)	3 (4.05%)	4 (5.00%)
d. Scale does not apply to ADR	0 (0.00%)	6 (8.10%)	4 (5.00%)
3. Objectives of ADR			
a. I and II	28 (48.27%)	45 (60.81%)	50 (62.25%)
b. III only	5 (8.62%)	8 (10.81%)	11 (13.75%)
c. II and III	21 (36.20%)	14 (18.91%)	6 (7.50%)
d. Don't Know	4 (6.89%)	7 (9.45%)	13 (16.25%)
4. Methods: I. Identify quickly important or serious ADRs and give early warning to concerned authority;; II. Attempt to establish a cause-effect relationship between drug and reaction; III. Find out the incidence of particular reaction			
a. I and II	38 (65.51%)	49 (66.21%)	50 (62.25%)
b. III only	11 (18.96%)	12 (16.21%)	11 (13.75%)
c. II and III	5 (8.62%)	0 (0.00%)	6 (7.50%)
d. Don't know	4 (6.89%)	13 (17.56%)	13 (16.25%)
5. Can you file an ADR report via a Medical Representative			
a. Don't Know	9 (15.51%)	13 (17.56%)	13 (16.25%)
b. No	13 (22.41%)	7 (9.45%)	17 (21.25%)
c. Yes	36 (62.06%)	54 (72.97%)	50 (62.50%)
6. ADR should be reported if it causes Inconvenience, Death, or Both			
a. Both	49 (84.48%)	66 (89.18%)	71 (88.75%)
b. Death	5 (8.62%)	3 (4.05%)	3 (3.75%)
c. Inconvenience	3 (5.17%)	5 (6.75%)	6 (7.50%)
d. None	1 (1.72%)	0 (0.00%)	0 (0.00%)
7. How many ADR reporting centers are there in India			
a. Correct	15 (25.86%)	16 (21.62%)	16 (20.00%)
b. Incorrect	43 (74.13%)	56 (75.67%)	62 (77.50)
c. No response	00 (00.00%)	02 (2.70%)	00 (00.00%)
8. Are you aware of the Pharmacovigilance Program of India PV			
a. No	6 (10.34%)	12 (16.21%)	7 (8.75%)
b. No response	0 (0.00%)	1 (1.35%)	0 (0.00%)
c. Yes	52 (89.65%)	61 (82.43%)	73 (91.25%)
9. Can patients directly report ADR			
a. Don't Know	7 (12.06%)	18 (24.32%)	13 (16.25%)
b. No	12 (20.68%)	26 (35.13%)	17 (21.25%)
c. Yes	39 (67.24%)	30 (40.54%)	50 (62.50%)
10. What is the first step in monitoring of ADRs			
a. Assess	12 (20.68%)	0 (0.00%)	1 (1.25%)
b. Document ADR	7 (12.06%)	22 (29.72%)	8 (10.00%)
c. Don't know	2 (3.44%)	3 (4.05%)	30 (37.50%)
d. Identify ADR	32 (55.17%)	27 (36.48%)	29 (36.25%)
e. Report ADR	5 (8.62%)	8 (10.81%)	12 (15.00%)
f. Treat ADR	0 (0.00%)	14 (18.91%)	0 (0.00%)
11. Is drug overdosing an ADR?			
a. No	3 (5.17%)	7 (9.45%)	10 (12.50%)
b. Don't Know	34 (58.62%)	44 (59.45%)	46 (57.50%)
c. Yes	21 (36.20%)	23 (31.08%)	24 (30.00%)

Contd...



Table 1: Contd...

Parameters	MBBS final year	MBBS third year	MBBS second year
12. Do you feel that simultaneous administration of multiple drugs increases risk of ADR			
a. Don't Know	1 (1.72%)	4 (5.40%)	7 (8.75%)
b. No	9 (15.51%)	20 (27.02%)	13 (16.25%)
c. Yes	48 (82.75%)	50 (67.56%)	60 (75.00%)

### Can patients directly report ADR?

In our study, the majority felt that patients can directly report ADRs, namely, final (67.24%), third (40.54%), and second year (62.50%); Goa<sup>[13]</sup> and Puduchery<sup>[19]</sup> studies reported comparable results. In Tamil Nadu, 98% undergraduate dental students felt that ADRs can be reported by health professionals other than doctors.<sup>[20]</sup>

### ADR reporting centers in India

In our study, knowledge on ADR reporting centers was quite low, namely, final year (25.86%), third year (21.62%), and second year (20.00%). In Rajouri study, knowledge among MBBS students in ADR reporting centers was quite high (94%).<sup>[17]</sup> In Indore, the majority knew the international adverse event monitoring center (78.57%) and regulatory body on ADRs in India (86.13%).<sup>[21]</sup>

### Experience of ADR during practice training

In our study, 55.17% final-year MBBS students experienced ADRs, concurrent with their better clinical exposure; 76.25% of second-year MBBS students responded negatively, may be due to a lack of adequate clinical exposure. In a similar study, 23, 34, and 48% of second-, third-, and final-year MBBS students experienced ADR.<sup>[3]</sup> In Goa, 38.9% identified ADRs, while only 6.3% reported to superiors.<sup>[15]</sup> In Indore, 25.21% had first-hand experience during ward posting; 60.08% had seen reporting forms, and 57.56% can fill ADR forms alone.<sup>[21]</sup>

### Awareness of drugs that are banned or in limited use due to ADRs

In our study, major students were aware of ADR-related banned drugs: second (82.50%), third (79.72%), and final year (77.58%). In comparable studies, MBBS second-year (70%), third-year (65%), and final-year (68%) students knew of ADRs associated with banned/limited use.<sup>[1]</sup> A Tamil Nadu study reported that responders knew that National centers can ban drugs in extreme cases.<sup>[20]</sup>

### Patient confidentiality during reporting of ADR

It was observed in our study that 12.5% of second-year MBBS students picked the correct option, and final-year MBBS students were marginally behind (12.1%). In a similar study, conducted in the year 2017, 80.00% of the respondents felt that patient confidentiality should be adhered to during reporting of ADR, while 15.67% disagreed, and 4.33% were unsure.<sup>[1]</sup>

### ADR reporting should be compulsory, voluntary, or remunerated (paid)

Among the respondents, the majority of final (60.34%), third (64.86%), and second-year (65.00%) MBBS students opted that ADR reporting should be compulsory; 12 (20.68%), 7 (9.45%), and 4 (5.00%) of final-year, third-year, and second-year students, respectively, felt that ADR reporting should be remunerated to add incentives to reporting; the remaining thought it should be voluntary. In a similar study, 26.60% of respondents said that a lack of incentives may have contributed to under-reporting of ADRs.<sup>[13]</sup> A study from West Bengal reported varied responses; second (34.11%), third (39.02%), and final-year (52.5%) MBBS students felt that ADR reporting is professional obligation and be mandated.<sup>[5]</sup> In an alike study, second (75%), third (68%), and final-year (65%) MBBS students wanted ADR reporting to be mandatory.<sup>[1]</sup> In an Indore study, 89.5% students were willing to implement ADR reporting in future clinical practice.<sup>[21]</sup>

### ADR Reporting is a time-consuming activity

It was observed in our study that 13.79% third-year MBBS students felt that ADR reporting was a time-consuming activity, the highest number to share that sentiment, while 89.18% final-year MBBS respondents disagreed, the highest percentage among the three groups doing so. In a similar study, responders asserted that under-reporting of ADR may stem from a busy professional schedule (29.60%) and lack of incentives (26.60%).<sup>[13]</sup>

### Capacity building

On the issues of competency on ADR reporting, the majority felt negative, namely, final year (86.20%), third year (79.72%), and second year (57.50%), while they were positive regarding requirements of special ADR training, namely, final year (93.10%), third year 93.24%, and second year (88.75%). In Goa, the majority of students (86.3%) also felt that pharmacovigilance and ADR monitoring should be taught in detail in the medical curriculum, although only 17.9% were interested in self-directed learning on these issues.<sup>[15]</sup> In the Indore study, the majority of participants (76.89%) were aware that ADR reporting is the responsibility of all health-care professionals; 94.96% opined that ADR should be part of curriculum; 35.71% attended workshops to report ADR under pharmacovigilance programs and attended the workshop conducted by the department within the institute.<sup>[21]</sup> In a study at Tamil Nadu, 99% dental undergraduates consented that pharmacovigilance is essential for the curriculum of all health-care courses.<sup>[20]</sup>

**Table 2: Response on perception and intended practice of ADR among our study participants**

Parameters	MBBS final year	MBBS third year	MBBS second year
14. Have you seen any case of ADR during practice training			
a. Don't Know	2 (3.44%)	4 (5.40%)	2 (2.50%)
b. No	24 (41.37%)	52 (70.27%)	61 (76.25%)
c. Yes	32 (55.17%)	18 (24.32%)	17 (21.25%)
15. Are you aware of drugs that are banned or in limited use due to ADRs			
a. Don't Know	6 (10.34%)	4 (5.40%)	2 (2.50%)
b. No	7 (12.06%)	11 (14.86%)	12 (15.00%)
c. Yes	45 (77.58%)	59 (79.72%)	66 (82.50%)
16. Do you consider legal liabilities while reporting ADR			
a. Don't Know	9 (15.51%)	14 (18.91%)	16 (20.00%)
b. No	6 (10.34%)	8 (10.81%)	18 (22.50%)
c. Yes	43 (74.13%)	52 (70.27%)	46 (57.50%)
17. Do you feel patient confidentiality should be maintained while reporting ADR			
a. Don't Know	2 (3.44%)	4 (5.40%)	9 (11.25%)
b. No	7 (12.06%)	6 (8.10%)	10 (12.50%)
c. No Response	0 (0.00%)	1 (1.35%)	0 (0.00%)
d. Yes	49 (84.48%)	63 (85.13%)	61 (76.25%)
18. Do you expect feedback from monitoring centers			
a. Don't Know	1 (1.72%)	2 (2.70%)	16 (20.00%)
b. No	4 (6.89%)	3 (4.05%)	18 (22.50%)
c. Yes	53 (91.37%)	69 (93.24%)	46 (57.50%)
19. Do you consider ADR reporting to be a professional responsibility			
a. Don't Know	1 (1.72%)	3 (4.05%)	2 (2.50%)
b. No	0 (0.00%)	1 (1.72%)	3 (4.05%)
c. Yes	57 (98.26%)	70 (94.59%)	71 (88.75%)
20. Are you adequately trained in ADR reporting			
a. No	50 (86.20%)	59 (79.72%)	46 (57.50%)
b. Yes	8 (13.80%)	15 (20.27%)	34 (42.50%)
21. Do you think special training programs should be provided			
a. Don't Know	0 (0.00%)	5 (6.75%)	5 (6.25%)
b. No	4 (6.89%)	0 (0.00%)	4 (5.00%)
c. Yes	54 (93.10%)	69 (93.24%)	71 (88.75%)
22. ADR reporting should be			
a. Compulsory	35 (60.34%)	48 (64.86%)	52 (65.00%)
b. Remunerated (Paid)	12 (20.68%)	7 (9.45%)	4 (5.00%)
c. Voluntary	11 (18.96%)	19 (25.67%)	24 (30.00%)
23. Do you feel ADR reporting is a time-consuming activity			
a. Don't Know	3 (5.17%)	5 (6.76%)	3 (3.25%)
b. No	47 (81.03%)	66 (89.18%)	70 (87.50%)
c. Yes	8 (13.79%)	3 (4.05%)	7 (8.75%)

### Legal liabilities while reporting ADR

On the legal liabilities while reporting ADR, our students responded well, namely, final (74.13%), third (70.27%), and second (57.50%). In a study from Goa, 11% opined that fear of legal consequences might be the reason for under-reporting of ADR.<sup>[15]</sup> In a study reported from Islamabad, Pakistan, legal liability issues were the key factors to discourage respondents to report ADR.<sup>[21]</sup>

### Simultaneous administration of multiple drugs increases risk of ADR

In our study, MBBS students responded well, namely, final year 48 (82.75%), third 50 (67.56%), and second 60 (75.00%). Multiple

drug exposure was noted by others as an independent risk of ADRs and needs monitoring in the light of benefit/risk ratio to improve the safety of patients.<sup>[22-24]</sup>

### Drug overdosing is an ADR or not

In our study, the responses on 'Drug overdose as an ADR' were miserable from MBBS students, namely, final 21 (36.20%), third 23 (31.08%), and second years 24 (30.00%), which were alarming for the investigators. Chen YC *et al.* in their robust study on proportion, seriousness, and prevention in Taiwan concluded that the drug administration in normal doses or overdoses has been reported with ADRs.<sup>[25]</sup>

## ADR reporting as a professional responsibility

The majority of students in our study felt that ADR reporting is their professional responsibility, namely, final 57 (98.26%), third 70 (94.59%), and second years 71 (88.75%). Health-care personnel should consider ADR reporting as professional obligation as an effective system of ADR reporting is vital to improve patient care and safety.<sup>[26]</sup> Under-reporting of ADRs is an apprehension for the PV systems and a major obstacle for well-timed reporting in India. We need robust ADR reporting infrastructure in health-care settings with improved cognition, perception, pro-activity, and capacity building on ADRs.<sup>[27,28]</sup> With updated competencies of national and international monitoring and patient counseling using all health-care professionals, the burden on ADR will be reduced.<sup>[29]</sup>

## Expectation of feedback from monitoring centers

In our study, in this issue, third-year students had the highest response (93.24%). The research group working on quality of ADR reporting in the 7-year surveillance study at the monitoring center in Central India suggested continuous training programs for health-care providers, collaboration of health-care facilities, and most importantly providing feedback. This will build confidence, alertness, and awareness on drugs causing ADRs for more reporting of ADRs.<sup>[30]</sup>

## Strengths of the study

In our study, we have recruited a census population to cancel out sampling bias and explored the reason for not reporting suspected or observed ADRs from the ground level of teaching-learning. As a novel study conducted in our institute, it was observed that undergraduate medical students demonstrated optimum knowledge and perception that are very important for their professional life to improve timely ADR reporting to competent authorities as future physicians.

## Limitations of the study

We had several limitations. First, this was a single-center study with a small sample size that has limited external validity of observation. Second, we could have involved interns and postgraduate students. Last, in a questionnaire-based study, participant bias is inevitable from novice undergraduate students who participated in such a study for the first time.

## Future directions of the study

ADR under-reporting is a great challenge to pharmacovigilance in the new millennium for the primary care physicians. In future, we hope to involve undergraduate and postgraduate students and interns of medical, pharmacy, and nursing courses in the our university campus.

## Conclusions

MBBS student participants demonstrated reasonable competencies in sensible cognitive and affective domains on

ADRs, internalized professional responsibility, and ardor to upgrade lifelong. The investigators felt that there is a need of dedicated capacity building on ADRs in pedagogy and andragogy for all health-care professional courses to help limit ADRs among care-seekers.

## Key take-home message

The novelty of the knowledge emerging from this original research is relevant to the interest of the journal readers who are in general primary care providers and family physicians.

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## Conflicts of interest

There are no conflicts of interest.

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