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UNDERSTANDING THE PATH FROM RESEARCH TO PATIENT CARE: KAP OF SECOND-YEAR MBBS STUDENTS ON DRUG DEVELOPMENT, CLINICAL TRIAL PHASES AND NDCT RULES 2019 BEFORE AND AFTER SENSITISATION

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ABSTRACT

Introduction: Drug development, phases of clinical trials, investigational new drugs and the NDCT Rules 2019 are now competencies in the CBME curriculum for MBBS students. We assessed the knowledge, attitude and practice (KAP) of second-year MBBS students on these topics before and after a sensitisation session. **Methods:** This cross-sectional, questionnaire-based study was done in the Department of Pharmacology, GSVM Medical College, Kanpur, among 252 second-year MBBS students in December 2025. A 15-item questionnaire (7 knowledge, 4 attitude and 4 practice questions) was given on Google Forms as a pre-test. After sensitisation, the same questionnaire was given as a post-test. Responses were compared using the Chi-square test ($p<0.05$). **Results:** The pre-test was answered by 191 students (75.79%) and the post-test by 186 (73.81%). Correct knowledge answers rose from 67.31% to 78.03% ($p<0.001$), and the mean knowledge score from 4.71 ± 1.96 to 5.46 ± 1.34 out of 7. The meaning of GCP (69.63% to 96.24%), the phase of post-marketing surveillance (69.11% to 89.78%) and the meaning of ICH (56.02% to 75.81%) improved most ($p<0.001$ each). Agreement that animal testing should come before testing in humans rose from 67.03% to 80.22% ($p=0.044$). Practice responses were favourable at baseline (67.38–82.89% "Yes") and did not change significantly. **Discussion:** A single session improved factual knowledge, but attitudes and intended practice changed little. Teaching on these topics should be repeated and interactive. The study was done at one

centre, and the pre- and post-test groups were analysed as independent samples although 149 students took both tests.

KEYWORDS: Ethics committees, research; Drugs, investigational; Drug approval; Product surveillance, postmarketing; Competency-based education; Education, medical, undergraduate; Pharmacology.

INTRODUCTION

Drug development covers everything that happens between a promising molecule in the laboratory and an approved medicine in clinical use. It is conventionally described in five steps: discovery and development, preclinical research, clinical research, regulatory review, and post-market safety monitoring.[1] Historically, many drugs, or their antecedents, were found by observing their effects on normal or diseased physiology. Over the last generation this phenotypic approach was largely replaced by target-based discovery, in which molecules are designed to modulate a specific molecular target. More recently, phenotypic drug discovery has re-emerged and contributed several first-in-class medicines, and the two strategies are now used together.[2]

Because every prescriber uses medicines that have passed through this process, the competency-based undergraduate curriculum for the Indian Medical Graduate requires students to describe an overview of drug development, the phases of clinical trials and Good Clinical Practice.[3]

Complications of drug development

Bringing a new drug to market is slow and expensive. It takes more than 10–15 years and, on average, over US$1–2 billion to bring one new drug to approval.[4] An independent analysis of 63 of the 355 new therapeutic agents approved by the US Food and Drug Administration (FDA) between 2009 and 2018 estimated a median capitalised research and development investment of US$985 million per drug and a mean of US$1.3 billion, after accounting for failed trials. The median was highest for antineoplastic and immunomodulating agents, at about US$2.8 billion.[5]

The situation in India is different. India is the third largest producer of medicines by volume, but it holds only about 1–2% of the global market by value, and its industry has grown mainly on generic drugs and active pharmaceutical ingredients. Saroglitazar, a dual PPAR-

α/γ agonist approved by the Drug Controller General of India in June 2013 for diabetic dyslipidaemia, was the first new chemical entity discovered and developed by an Indian pharmaceutical company.[6] A review of proprietary drug research by Indian companies between 1994 and mid-2016 identified more than 200 preclinical and clinical development compounds, of which only one had reached the market.[7]

Attrition is the main reason for this cost. Only 10–15% of candidates that enter clinical testing are eventually approved. Analyses of clinical trial data from 2010 to 2017 attribute the failures to four causes: lack of clinical efficacy (40–50%), unmanageable toxicity (30%), poor drug-like properties (10–15%), and lack of commercial need or poor strategic planning (10%).[4] Success rates also differ widely between therapeutic areas; in one large analysis of more than 21,000 compounds, oncology had an overall success rate of only 3.4%.[8]

Special provisions apply to drugs for rare diseases. The New Drugs and Clinical Trials (NDCT) Rules, 2019 define an orphan drug as a drug intended to treat a condition affecting not more than five lakh persons in India, and orphan drugs are among the categories eligible for waiver of local clinical trials.[9]

Clinical trials in drug development

Under the NDCT Rules, a clinical trial is any systematic study of a new drug or investigational new drug in human subjects to generate data on its clinical, pharmacological (pharmacodynamic or pharmacokinetic) or adverse effects, with the objective of determining its safety, efficacy or tolerance.[9] Clinical trials connect preclinical evidence to therapeutic use. ICH E8(R1) stresses that the design of each study should reflect the current state of knowledge about the drug, the condition being treated and the intended population, with clearly defined objectives, endpoints and control groups, and with randomisation used where internal controls are present.[10]

Good Clinical Practice (GCP) sets the ethical and scientific standard for trials. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) adopted the revised GCP guideline, E6(R3), on 6 January 2025. It restructures GCP around a set of principles and gives greater weight to quality by design and risk-proportionate trial conduct.[11] Its first principle states that the rights, safety and well-being of participants are the most important considerations and should prevail over the interests of science and society; another requires that everyone involved in a trial be qualified

by education, training and experience for their tasks.[11] In India, the NDCT Rules require trials to follow the GCP Guidelines formulated by the Central Drugs Standard Control Organisation (CDSCO), and research outside the scope of drug trials is governed by the national ethical guidelines of the Indian Council of Medical Research (ICMR).[9,12]

Types of clinical trials

By purpose, the National Institutes of Health (NIH) describes six types of clinical trials: prevention, screening, diagnostic, treatment, behavioural, and quality-of-life (supportive care) trials.[13] ICH E8(R1) instead classifies studies by their objective in the development programme: human pharmacology, exploratory, confirmatory and post-approval studies. Exploratory and confirmatory studies are usually referred to as phases 2 and 3, respectively.[10] The designs used include dose–response studies, randomised controlled trials, adaptive designs that combine exploratory and confirmatory objectives, and, after approval, comparative effectiveness studies and large simple randomised trials.[10]

Phases of clinical trials

Phase 0 (exploratory or microdosing studies): First-in-human studies that give sub-therapeutic doses to a few participants. A microdose is defined as less than one-hundredth of the dose expected to produce a pharmacological effect, up to a maximum of 100 µg (30 nmol for protein products).[14,15] These studies have no therapeutic or diagnostic intent. They provide early human data on pharmacokinetics and, increasingly, on mechanism of action and pharmacodynamics, which helps weed out unsuitable candidates before full-scale development.[14]

Phase I (human pharmacology): Usually conducted in 20–100 healthy volunteers or people with the disease or condition, most often 20–80, over several months.[16] The initial administration of a drug to humans is intended to determine the tolerability of the dose range and the nature of the adverse reactions to be expected, and pharmacokinetic studies are performed at this stage.[10]

Phase II (exploratory): Involves up to several hundred people with the disease or condition and lasts from several months to two years.[16] These studies explore efficacy, establish proof of concept and identify doses and regimens for subsequent confirmatory studies.[10]

Phase III (confirmatory): Pivotal studies in 300–3,000 participants with the disease or condition.[16] They are designed to confirm the preliminary evidence of efficacy and to establish the safety profile in larger, more representative patient populations, most often through randomised controlled trials. Their results form the basis of the application for marketing approval.[10]

Phase IV (post-approval studies): Carried out after approval, often in several thousand participants.[16] They extend understanding of the benefit–risk relationship in general or special populations, identify less common adverse reactions, refine dosing recommendations, and include comparative effectiveness, long-term follow-up and pharmacoepidemiology studies.[10] In India, periodic safety update reports must be submitted every six months for the first two years after approval and annually for the next two years.[9]

New chemical entity

Under the NDCT Rules [Rule 2(1)(v)], a new chemical entity (NCE) is a substance that no drug regulatory authority in any country has yet approved for marketing as a drug, and that is proposed to be developed as a new drug for the first time by establishing its safety and efficacy.[9] A related but broader term is 'new drug'. It covers a drug not yet approved as safe and efficacious by the Central Licencing Authority (CLA), and also an approved drug proposed with new claims such as a new indication, route of administration, dosage or dosage form. It further includes new fixed-dose combinations, modified-release or novel drug-delivery forms, and products such as vaccines, rDNA-derived products, monoclonal antibodies and gene therapies. Most new drugs remain 'new' for four years from the date of permission; modified-release and novel-delivery forms, and biological products such as vaccines, are always deemed new drugs.[9]

Investigational new drug

The NDCT Rules [Rule 2(1)(r)] define an investigational new drug as a new chemical or biological entity or substance that has not been approved for marketing as a drug in any country.[9] Unlike an NCE, the term covers biological as well as chemical entities, and it refers to the product while it is under clinical study; US regulations define it as a new drug or biological drug that is used in a clinical investigation.[18] In the United States, IND also refers to the application that a sponsor must file with the FDA before testing a new drug in humans. Federal law requires an approved marketing application before a drug can be shipped across state lines, and the IND is the means by which the sponsor obtains an exemption from that

requirement.[17] The application covers three broad areas: pharmacology and toxicology data, manufacturing information, and clinical protocols and investigator information. After submission, the sponsor must wait 30 calendar days before starting any clinical trial, during which the FDA reviews the IND to ensure that participants will not be exposed to unreasonable risk.[17]

The FDA describes three types of IND.[17]

Investigator IND: submitted by a physician who both initiates and conducts the investigation and under whose immediate direction the drug is given. It may be used to study an unapproved drug, or an approved drug for a new indication or in a new patient population.

Emergency Use IND: allows the FDA to authorise use of an experimental drug in an emergency that does not allow time for a standard IND submission. It is also used for patients who do not meet the criteria of an existing protocol, or when no approved protocol exists.

Treatment IND: submitted for experimental drugs that have shown promise in clinical testing for serious or immediately life-threatening conditions, while the final clinical work and FDA review are in progress.

INDs are also categorised as commercial or research (non-commercial).[17] In India, an application to conduct a clinical trial of a new drug or investigational new drug is made to the CLA in Form CT-04, and permission is granted in Form CT-06. The decision is due within 90 working days. This is reduced to 30 working days when the drug is discovered in India, or when its research and development is done in India and it is proposed to be manufactured and marketed in India. In both cases permission is deemed granted if the CLA does not respond in time. The trial must also be registered with the Clinical Trials Registry–India before the first participant is enrolled.[9]

New Drugs and Clinical Trials Rules, 2019

The NDCT Rules were notified by the Ministry of Health and Family Welfare, Government of India, on 19 March 2019 (G.S.R. 227(E)) under sections 12 and 33 of the Drugs and Cosmetics Act, 1940. They apply to all new drugs, investigational new drugs for human use, clinical trials, bioavailability and bioequivalence studies, and ethics committees, and they replaced Part XA and Schedule Y of the Drugs and Cosmetics Rules, 1945. The Drugs

Controller (India) is the CLA under the Rules. The Rules contain eight schedules (Table 1).[9,19]

Table 1: Schedules of the New Drugs and Clinical Trials Rules, 2019.

Schedule	Subject matter
First	General principles and practices for clinical trials
Second	Requirements and guidelines for permission to import or manufacture a new drug for sale or to undertake a clinical trial
Third	Conduct of clinical trials, including documents for Ethics Committee registration, protocol format and serious adverse event reporting formats
Fourth	Requirements and guidelines for bioavailability and bioequivalence studies
Fifth	Post-marketing assessment, including periodic safety update reports
Sixth	Fees payable for licences, permissions and registration certificates
Seventh	Formulae to determine the quantum of compensation for clinical trial-related injury or death
Eighth	Forms (applications, registrations and permissions, e.g. CT-01, CT-02, CT-04, CT-06)

Source: New Drugs and Clinical Trials Rules, 2019.[9]

Constitution of the Ethics Committee

An Ethics Committee (EC) for clinical trials must have at least seven members from medical, non-medical, scientific and non-scientific areas. These must include at least one lay person, one woman, one legal expert, and one independent member from a related field, such as a social scientist, a representative of a non-governmental voluntary agency, a philosopher, an ethicist or a theologian. At least 50% of members must be unaffiliated with the institution. The chairperson must be an unaffiliated member, and the member secretary an affiliated one.[9] Medical scientists and clinicians on the committee must hold at least a postgraduate qualification in their specialty, and all members must complete the training specified by the CLA. A member with a conflict of interest may not be involved in overseeing the protocol concerned.[9]

Registration and proceedings of the Ethics Committee

The EC applies to the CLA for registration in Form CT-01, and registration is granted in Form CT-02. The registration is valid for five years unless suspended or cancelled, and renewal must be sought 90 days before expiry.[9] A protocol can be reviewed only when at least five members are present: a medical scientist (preferably a pharmacologist), a clinician, a legal expert, a social scientist or equivalent member, and a lay person.[9]

Functions and records of the Ethics Committee

The EC reviews and approves trial protocols and related documents, oversees the trial to safeguard the rights, safety and well-being of participants, and carries out ongoing review of approved trials. It analyses serious adverse events and reports on them to the CLA, and it may suspend or discontinue a trial that is likely to compromise participants, informing the head of the institution and the CLA.[9,19] For trial-related death or injury, the EC gives its opinion on financial compensation, which is calculated using the formula in the Seventh Schedule. Separately, the sponsor must provide free medical management for as long as the investigator considers it necessary, or until the injury is shown to be unrelated to the trial.[9] The EC must keep its records for five years after each trial is completed. These include its constitution, members' curricula vitae, standard operating procedures, reviewed protocols, correspondence, minutes, decisions, and records of serious adverse events and compensation.[9]

Post-trial access to drugs under the NDCT Rules

Post-trial access means making a new drug or investigational new drug available to a participant after the trial if it was found beneficial to that participant, for as long as the investigator and the EC consider necessary.[9] When the investigator recommends it and the EC approves, the sponsor must provide it free of cost if two conditions are met. First, the trial was for an indication with no alternative therapy, and the investigator found the drug beneficial to the participant. Second, the participant or legal heir has consented in writing, the investigator has certified the need, and the participant or legal heir has declared in writing that the sponsor bears no liability for post-trial use.[9]

Academic clinical trials

An academic clinical trial is a trial of a drug already approved for a certain claim, initiated by an investigator or an academic or research institution, for a new indication, route of administration, dose or dosage form. Its results are intended only for academic or research purposes and not for seeking marketing approval from the CLA or any other regulatory authority.[9]

No CLA permission is needed if four conditions are met: the trial is solely for such academic purposes; it begins only after approval by the EC; its observations are not required to be submitted to the CLA; and they are not used for promotional purposes. If an academic trial may overlap with a regulatory trial, or its nature is in doubt, the EC must inform the CLA in writing within 30 working days. The CLA must clarify within 30 working days; if it does not,

no permission is presumed to be required. Academic trials must follow the approved protocol and the ICMR National Ethical Guidelines.[9,19]

MATERIALS AND METHODS

This cross-sectional, questionnaire-based study was conducted in the Department of Pharmacology, G.S.V.M. Medical College, Kanpur, Uttar Pradesh, among second-year MBBS students as a part of undergraduate teaching. All 252 students of the batch were eligible to participate.

First, a pre-test was conducted on 18 December 2025. A questionnaire of 15 questions on the knowledge, attitude and practice of Drug Development and Phases of Clinical Trial, Investigational New Drug and NDCT Rules 2019 was provided online through Google Forms (time allotted: ~10 minutes). Students also entered their name, roll number and e-mail address. The responses were recorded, and the students were then sensitised on the same topics.

After sensitisation, the same questionnaire was provided online through Google Forms as a post-test on 18 December 2025 (time allotted: ~10 minutes), and the answers were analysed. Students gave consent before answering the questionnaire.

Of the 15 questions, 7 were knowledge-based: 6 closed-ended multiple-choice questions and 1 true/false question. Four were attitude-based questions with five response options (strongly agree, agree, disagree, strongly disagree and not sure), and four were practice-based questions with three response options (yes, no and not sure). The knowledge questions were auto-graded by Google Forms, with one mark for each correct answer, giving a knowledge score out of 7.

A total of 192 responses were received in the pre-test and 188 in the post-test. One blank pre-test submission and two duplicate post-test submissions were excluded, so that only one complete response per student was retained. This left 191 pre-test and 186 post-test responses for analysis; 149 students responded in both tests.

Unanswered knowledge questions were counted as incorrect, as in the Google Forms auto-grading. For the attitude and practice sections, students who left any question in that section unanswered were excluded from the analysis of that section.

Statistical analysis was done using the Chi-square test, and a p value less than 0.05 was considered significant.

RESULTS

Out of 252 students, 191 (75.79%) responded in the pre-test and 186 (73.81%) in the post-test (Fig 1); 149 (59.13%) students responded in both tests.

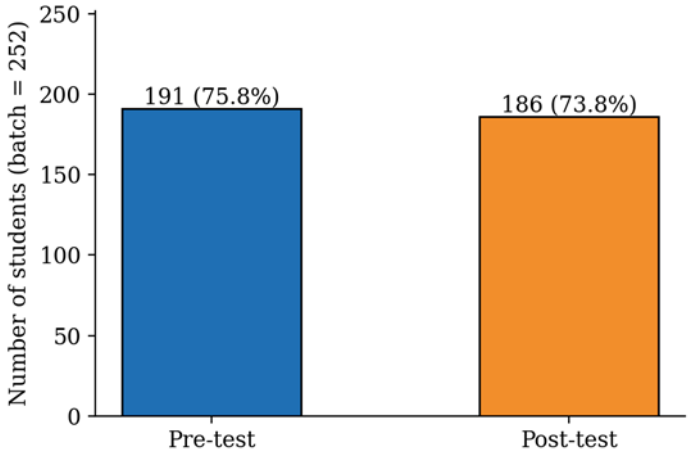


Fig 1: Student response in pre-test and post-test.

Knowledge: The proportion of correct answers to all knowledge questions taken together rose from 67.31% in the pre-test to 78.03% in the post-test ($\chi^2 = 38.10$, $p < 0.001$). The mean knowledge score increased from 4.71 ± 1.96 to 5.46 ± 1.34 out of 7 (median 5 and 6, respectively). A significant improvement was seen in three questions: the meaning of GCP (69.63% to 96.24%), the stage of post-marketing surveillance (69.11% to 89.78%) and the meaning of ICH (56.02% to 75.81%) ($p < 0.001$ for each). There was no significant change in the importance of Phase Zero ($p = 0.107$) or the GCP true/false statement ($p = 0.075$), both of which already had high pre-test scores. The number of stages in drug development (43.98% to 41.94%, $p = 0.689$) and the question on which statement is not a principle of GCP (61.26% to 60.75%, $p = 0.920$) showed no improvement (Table 2, Fig 2).

Table 2: Responses of students to knowledge-based questions in the pre-test and post-test.

Question	Pre-test correct (n = 191)	Post-test correct (n = 186)	χ^2 (df = 1)	p value
Q1. What does GCP stand for?	133 (69.63%)	179 (96.24%)	46.74	<0.001
Q2. How many stages are there in drug development?	84 (43.98%)	78 (41.94%)	0.16	0.689
Q3. Why is Phase Zero in clinical trial important?	150 (78.53%)	158 (84.95%)	2.59	0.107
Q4. Post-marketing surveillance is carried out in which stage of clinical trial?	132 (69.11%)	167 (89.78%)	24.55	<0.001
Q5. Which of the following is not a principle of GCP?	117 (61.26%)	113 (60.75%)	0.01	0.920
Q6. The principles of GCP assess safety, integrity and quality of clinical trials by addressing elements related to the design, conduct and reporting of clinical trials (True/False).	177 (92.67%)	180 (96.77%)	3.16	0.075
Q7. ICH stands for?	107 (56.02%)	141 (75.81%)	16.39	<0.001
All knowledge answers pooled	900/1337 (67.31%)	1016/1302 (78.03%)	38.10	<0.001

Unanswered questions were counted as incorrect.

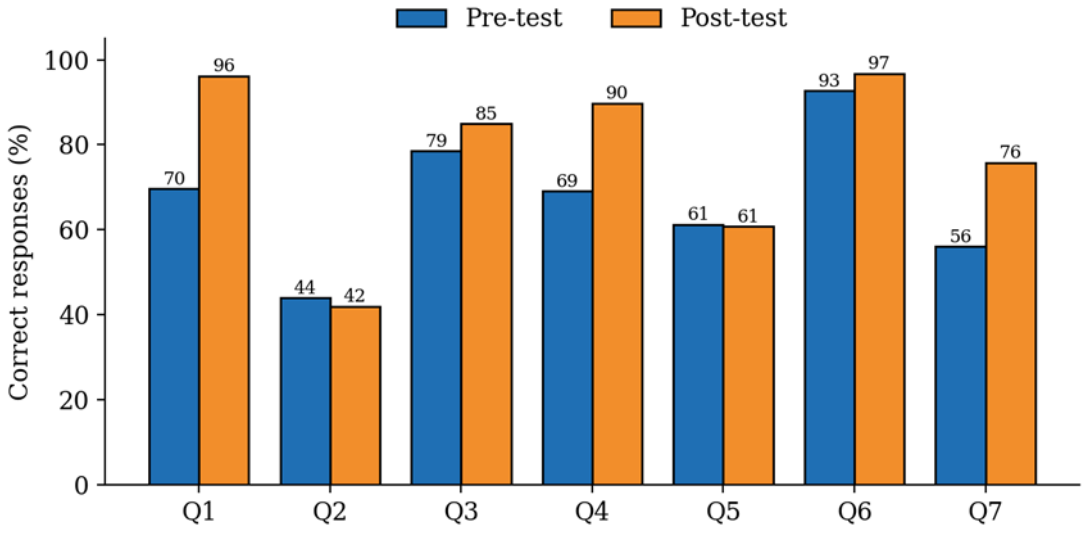


Fig 2: Correct responses (%) to knowledge-based questions Q1–Q7 in the pre-test and post-test.

Attitude: After sensitisation, the proportion of students who agreed or strongly agreed that laboratory and animal testing is necessary before testing drugs on humans increased from

67.03% to 80.22%, a significant change (p = 0.044). "Not Sure" responses fell in all four attitude questions, and agreement rose in each. For the other three questions, however, the change was not statistically significant (p = 0.080, 0.101 and 0.258, respectively) (Table 3).

Table 3: Responses of students to attitude-based questions in the pre-test and post-test.

Question	Test	SA	A	D	SD	NS	χ^2 (df)	p value
Q1. Do you feel laboratory and animal testing is necessary before testing drugs on humans?	Pre (n = 185)	64 (34.59%)	60 (32.43%)	12 (6.49%)	20 (10.81%)	29 (15.68%)	9.78 (4)	0.044
	Post (n = 182)	82 (45.05%)	64 (35.16%)	6 (3.30%)	9 (4.95%)	21 (11.54%)		
Q2. Do you feel results of clinical trial should be made public before the trial ends?	Pre (n = 185)	17 (9.19%)	45 (24.32%)	51 (27.57%)	16 (8.65%)	56 (30.27%)	8.34 (4)	0.080
	Post (n = 182)	21 (11.54%)	49 (26.92%)	52 (28.57%)	26 (14.29%)	34 (18.68%)		
Q3. Do you feel results of GCP laws are followed in India appropriately?	Pre (n = 185)	15 (8.11%)	50 (27.03%)	23 (12.43%)	7 (3.78%)	90 (48.65%)	7.76 (4)	0.101
	Post (n = 182)	21 (11.54%)	62 (34.07%)	10 (5.49%)	7 (3.85%)	82 (45.05%)		
Q4. Do you feel implementation of GCP before clinical trial is necessary?	Pre (n = 185)	53 (28.65%)	66 (35.68%)	11 (5.95%)	9 (4.86%)	46 (24.86%)	5.30 (4)	0.258
	Post (n = 182)	57 (31.32%)	79 (43.41%)	10 (5.49%)	6 (3.30%)	30 (16.48%)		

SA = Strongly Agree; A = Agree; D = Disagree; SD = Strongly Disagree; NS = Not Sure. Students with any unanswered attitude question were excluded from this table.

Practice: Most students gave favourable ('Yes') responses even in the pre-test (67.38% to 82.89%), and these increased slightly in the post-test (74.18% to 90.11%) while 'Not sure' responses fell. None of these changes was statistically significant (p = 0.357, 0.095, 0.391 and 0.190) (Table 4).

Table 4: Responses of students to practice-based questions in the pre-test and post-test.

Question	Test	Yes	No	Not sure	χ^2 (df)	p value
Q1. Will you participate in post-marketing surveillance when you are practising clinically?	Pre (n = 187)	126 (67.38%)	26 (13.90%)	35 (18.72%)	2.06 (2)	0.357
	Post (n = 182)	135 (74.18%)	20 (10.99%)	27 (14.84%)		
Q2. Will you apply knowledge of GCP while practising clinically?	Pre (n = 187)	154 (82.35%)	14 (7.49%)	19 (10.16%)	4.71 (2)	0.095
	Post (n = 182)	164 (90.11%)	7 (3.85%)	11 (6.04%)		
Q3. Will the knowledge of clinical trial stages of medications help you practise clinically?	Pre (n = 187)	155 (82.89%)	18 (9.63%)	14 (7.49%)	1.88 (2)	0.391
	Post (n = 182)	160 (87.91%)	12 (6.59%)	10 (5.49%)		
Q4. Will you encourage patients to participate in clinical trials?	Pre (n = 187)	145 (77.54%)	13 (6.95%)	29 (15.51%)	3.32 (2)	0.190
	Post (n = 182)	153 (84.07%)	12 (6.59%)	17 (9.34%)		

Students with any unanswered practice question were excluded from this table.

In short, the Chi-square test showed a significant improvement ($p < 0.05$) in overall knowledge, in three of the seven knowledge questions and in one of the four attitude questions. The practice questions did not change significantly.

DISCUSSION

Drug development, the phases of clinical trials, investigational new drugs and the NDCT Rules 2019 are now part of the competency-based undergraduate pharmacology curriculum.[3] In the present study, we assessed the knowledge, attitude and practice of second-year MBBS students on these topics before and after a sensitisation session. Of the 252 students in the batch, 75.79% took the pre-test and 73.81% the post-test.

In the pre-test, 67.31% of all knowledge answers were correct, and this rose to 78.03% after sensitisation ($p < 0.001$). The baseline in our study was considerably higher than in the earlier study from our department, in which only 31.80% of pre-test answers were correct, rising to about 66% after sensitisation.[20] One reason may be that the topic is now explicitly listed as a curricular competency. Our students also performed better than those in earlier Indian surveys. Sharma and Jindal found that only 20.2% of final-year medical students in Gujarat had good knowledge of the concept of clinical trials.[21] Malav et al. reported 28.2% in the

good category among 390 undergraduates in South Rajasthan.[22] These comparisons should be interpreted cautiously because the questionnaires were different.

The improvement was greatest for three questions: the meaning of GCP, the phase of post-marketing surveillance and the meaning of ICH. All three are factual items that were directly addressed during sensitisation. Questions on the importance of Phase 0 and on the GCP true/false statement had high pre-test scores (78.53% and 92.67%), leaving little room for improvement.

In the attitude section, agreement increased and 'Not Sure' responses decreased for all four questions after sensitisation. However, the change was significant only for the need for laboratory and animal testing before testing drugs on humans ($p = 0.044$). A similar pattern was reported by Anzai et al. In their study, medical students' knowledge of clinical trials improved significantly after a curricular intervention, but their attitudes towards clinical trials, though generally positive, did not change significantly.[23]

In the practice section, most students already intended to participate in post-marketing surveillance, apply GCP, use their knowledge of trial phases and encourage patients to join clinical trials (67.38% to 82.89% 'Yes'). This proportion increased further after sensitisation (74.18% to 90.11%), but the change was not significant. The high baseline leaves limited room for measurable change, and these questions measure intentions rather than actual behaviour. Educational interventions are known to improve medical students' awareness of clinical trials,[24] but a single sensitisation session may be insufficient to change attitudes and professional intentions. Repeated, hands-on exposure may work better, for example case-based discussions, sitting in on an Ethics Committee meeting, or taking part in pharmacovigilance work.

Limitations

This was a single-centre study, so the findings may not apply to students at other institutions. Gender and age were not recorded. The pre-test and post-test groups overlapped (149 students answered both) but were analysed as independent groups with the Chi-square test. A paired analysis of matched students would have been more appropriate. Using the same questionnaire twice may also have produced a testing effect.

CONCLUSION

Second-year MBBS students had moderate baseline knowledge of drug development, phases of clinical trials, GCP and related regulations, and a single sensitisation session significantly improved their factual knowledge. Their attitudes and intended practices were largely positive even before sensitisation and changed little afterwards. The NMC has already placed these topics in the undergraduate CBME curriculum. Our results suggest that one session is enough to raise factual knowledge but not to shift attitudes, so the teaching should be repeated and interactive (CMEs, symposia, workshops), with more time on the NDCT Rules 2019, the Ethics Committee and pharmacovigilance.

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