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Knowledge and Perception of the New Drug Approval Process among Medical Students

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Abstract

Background: Understanding the new drug approval process is essential for future physicians to ensure safe prescribing & evidence-based clinical practice.

Objective: To assess the knowledge & perception of medical students regarding the new drug approval & regulatory process.

Methods: A descriptive cross-sectional study was conducted among 100 medical students using a validated questionnaire assessing knowledge, awareness, & perceptions. Data were analyzed using descriptive statistics.

Results: Overall mean knowledge score was 56.4% ± 12.8. Only 32% correctly identified all phases of clinical trials. Awareness of national regulatory authorities was high (78%), but detailed understanding of pharmacovigilance systems was low (41%). Positive perception toward including regulatory science in curriculum was reported by 89%.

Conclusion: Medical students possess moderate awareness but inadequate in-depth knowledge of drug approval pathways. Integrating structured regulatory education into medical training is necessary.

Keywords: Knowledge, Perception, Drug & Medical Students.

Study Design: Cross sectional Study.

Introduction

The process for approving new drugs guarantees that medications available in the market are safe, effective, & backed by robust clinical evidence. Regulatory agencies like the FDA, EMA, & national drug enforcement organizations are essential for maintaining public safety[1].

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Future prescribers, medical students need to grasp these procedures to make sound therapeutic choices & accurately interpret evidence-based guidelines[2-3]. Nonetheless, research indicates that understanding in this field is frequently restricted.

This research seeks to assess the knowledge, awareness, & perceptions of medical students concerning the drug approval process, pinpoint gaps, & propose educational enhancements.

A highly effective health care system functions optimally when it emphasizes access, cost-effectiveness, & the rational use of medicines. Rational use of medicines means patients obtain medications that are suitable for their clinical needs, in the correct doses tailored to their individual requirements, for a sufficient duration, & at a cost-effective rate for both patients & the community[4-5]. Misconceptions, inadequate information among patients, pressures to prescribe, profit-driven attitudes of prescribers, enticing promotional tactics from pharmaceutical companies, & insufficient scrutiny by regulatory bodies will all contribute to irrational prescribing practices. This results in significant resource wastage, increased adverse drug reactions, the emergence of antibacterial resistance, & higher treatment costs, all of which could be significantly reduced by promoting the rational use of medicines among doctors & healthcare professionals[6].

To address the issue of irrational prescribing, it is essential to first measure it & hold the relevant healthcare professionals accountable. Creating a benchmark for its assessment is crucial for implementing focused, effective, & rational prescribing behaviors.

Material & Methods

A total of **100 undergraduate medical students** (3rd to final year) from a single medical college participated for 01 Year.

Data Collection Tool

A structured questionnaire with three components:

1. **Demographics**
2. **Knowledge (10 multiple-choice questions)**
3. **Perception (Likert scale)**

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Scoring

- Each correct response = 1 point
- Maximum score = 10
- Categorization:
  - **High knowledge:** ≥ 8
  - **Moderate:** 5–7
  - **Low:** ≤ 4

Statistical Analysis

Data were analyzed using descriptive statistics (means, percentages, SD). Results are presented in tables.

Result

Table 1: Demographic Characteristics of Participants (n = 100)

Variable	Category	n (%)
Age (years)	20–22	48 (48%)
	23–25	52 (52%)
Gender	Male	43 (43%)
	Female	57 (57%)
Academic year	3rd year	33 (33%)
	4th year	37 (37%)
	Final year	30 (30%)

Table 2: Distribution of Knowledge Scores

Knowledge Category	Score Range	n (%)
High knowledge	8–10	18 (18%)
Moderate knowledge	5–7	52 (52%)
Low knowledge	0–4	30 (30%)
Mean knowledge score	—	**56.4% ± 12.8**

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Table 3: Correct Responses to Individual Knowledge Questions

Knowledge Item	Correct n (%)
Identification of national drug regulatory authority	78 (78%)
Understanding of pre-clinical testing	64 (64%)
Knowledge of all clinical trial phases (I–IV)	32 (32%)
Awareness of accelerated approval pathways	29 (29%)
Understanding of generic drug approval	58 (58%)
Awareness of pharmacovigilance systems	41 (41%)
Knowledge of emergency use authorization (EUA)	46 (46%)
Role of ethics committees	74 (74%)
Requirements for new drug application	39 (39%)
Post-marketing surveillance understanding	44 (44%)

Table 4: Perception toward Drug Approval & Regulatory Education

Perception Statement (Likert 5-point)	Agree/Strongly Agree n (%)
Drug approval knowledge is essential for future practice	92 (92%)
Curriculum lacks sufficient regulatory science content	81 (81%)
Clinical trial processes should be taught in detail	87 (87%)
Pharmacovigilance training should be compulsory	84 (84%)
Interest in attending workshops on drug regulation	76 (76%)

Discussion

This research shows that while medical students grasp the fundamental structure of drug approval, noticeable knowledge deficiencies are present, particularly concerning clinical trial stages, expedited approval routes, & pharmacovigilance frameworks[7].

The significant number of students with moderate or low knowledge (82%) underscores the inadequate focus on regulatory education in medical programs. The strong positive attitude towards incorporating regulatory science emphasizes the necessity for educational reform[8].

The results correspond with international research showing comparable shortcomings among healthcare trainees. Enhancing regulatory science modules, engaging workshops, & case-oriented learning could address these shortcomings[9-10].

The supreme ability to prescribe medications results from the gradual buildup of knowledge regarding how drugs work & their interactions with the body. To excel in this skill, it is crucial to have a solid grasp of related fields like cell biology, biochemistry, physiology, & clinical medicine[11-12]. This renders P&PT a daunting topic in the medical curriculum. It also leaves students open to gaps in their understanding of this subject.

Conclusion

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Medical students show moderate overall knowledge but poor detailed understanding of the drug approval process. Given their future role in prescribing & evaluating medical evidence, integrating structured & practical training on drug regulation is essential.

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