

Disparities in Awareness and Prescribing Behaviour Related to Fixed-Dose Combinations among Practicing Physicians in Eastern India

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ABSTRACT

Background: Fixed-dose combinations (FDCs) offer various therapeutic benefits due to the combination of active components in a single dose. The irrational formulations resulted in negative impacts, high cost, and antimicrobial resistance. A lack of awareness and inconsistencies in prescribing behaviour highlighted the need to evaluate attitudes, knowledge, and practice regarding the rational use of FDCs.

Methods: This cross-sectional study aimed to evaluate behavioural patterns regarding fixed-dose combinations (FDCs) among physicians across various hospital departments. Conducted in a tertiary care hospital in India from November 2023 to November 2024, it included 202 physicians who provided verbal and written consent. Data collection involved a questionnaire assessing knowledge, attitudes, and practices (KAP) regarding FDCs. Statistical analysis used descriptive statistics, Chi-square tests, and a p-value of <0.05 for significance.

Results: The most prescribed fixed-dose combinations (FDCs) were Montelukast with Levocetirizine (52%), followed by Iron with Folic Acid (40.2%) and Co-Amoxiclav (38.5%). Regarding knowledge, 78.2% of participants were familiar with FDCs, and 70% recognised their potential harm. A majority (80.7%) agreed that prescriptions are necessary for FDCs. However, there were variations in prescribing practices, particularly in counseling, generic name usage, and dosage verification, highlighting areas for improvement.

Conclusion: The study concludes that better regulatory awareness and prescribing patterns are necessary for the safe and potential application of fixed-dose combinations.

Key-words: Fixed-dose combinations, Prescribing practices, Knowledge-Attitude-Practice, Rational drug use

INTRODUCTION

The therapeutically complementary, data-supported pharmaceutical formulations that combine two or more active medicines in a single dosage form can provide benefits.

The components and dosage of fixed-dose combinations can be optimized. However, reasonable formulation, acceptable indications, and regulatory oversight are the advantages of FDCs; without these protections, FDCs can increase the risk of improper therapy, unnecessary medical expenses, adverse drug reactions, and antimicrobial resistance ^[1].

India has been a global anomaly when it comes to the use and proliferation of oral FDC medications. Several FDCs have been promoted across a wide range of therapeutic classes, with some having unclear regulatory approval status or fixed combinations, and a percentage of them having limited evidence. Due to business and

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regulatory factors, rational and irrational FDCs are widely used in clinical practice. This circumstance makes prescribers' knowledge, attitudes, and prescription practices even more serious^[2].

Empirical studies in India found that prescribers have inconsistent attitudes regarding FDCs. The doctors and resident physicians are unaware of which FDCs are considered illogical, as several observational and questionnaire-based studies have shown that a considerable portion of those permitted are meant for clinical prescription. The current medication information at the point of care contributes to this knowledge and is influenced by commercial marketing, regional prescription practices, and inconsistent access to prescribing behaviour^[3].

In addition to determining immediate patient care, it maintains market demand for certain FDCs. Practising physicians play a serious role in prescription decisions. Effortlessness, patient adherence, cost, pharmaceutical effect, and perceived regulatory support are views of Physicians that can all serve as motivators for the continued use of FDCs, even when objective evidence of combination benefit is limited, according to qualitative and mixed-methods assessments. Therefore, an understanding of these behavioural developing treatments that improve rational usage requires determinants^[4].

Even though a few are seriously broken regionally, statistics. Geographical heterogeneity in awareness and prescribing habits is likely to result from India's heterogeneous medical education, healthcare delivery infrastructure, access to continuing medical education, and local pharmacies. A mainly related situation for analysing discrepancies is Eastern India, where doctors may encounter different information environments, varying experience with promotional methods, and inconsistent state-level regulatory submission. There is currently a lack of knowledge and educational responses, as little research has explicitly examined practising physicians in Eastern India to develop focused policy^[5].

A detailed assessment of practising doctors in Eastern India, which ranges from pharmaceutical safety to differences in FDC understanding and prescription practices, to antimicrobial stewardship and cost-effective prescribing, is necessary, given the public health implications. Such a study can measure knowledge factors that contribute to irrational prescription, and

direct personalised interventions that promote sensible FDC usage. Therefore, the purpose of the current study is to assess the extent and distribution of FDC-related knowledge, attitudes, and prescribing habits among Eastern Indian physicians, and to investigate the major variables associated with variation in those practices.

MATERIALS AND METHODS

Research design- This is a cross-sectional study to evaluate the behavioural patterns of fixed-dose combinations (FDCs). The study promotes the collection of data to capture knowledge, attitudes, and various practices as prescribed. The study was conducted among physicians from outpatient and inpatient wards across a broad range of departments, including Medicine, Surgery, Gynaecology & Obstetrics, Paediatrics, Dermatology, Psychiatry, Chest Medicine, Orthopaedics, ENT, and Emergency Medicine. The study was conducted in a tertiary care hospital in India. The study was conducted for 1 year, from November 2023 to November 2024, and data were collected during this period. Convenience sampling was used to select 202 patients. Both verbal and written consent were obtained from the participants.

Inclusion criteria

- Physicians working and practising in the outpatient and inpatient wards were included.
- Physicians of all departments, like Medicine, Surgery, Gynaecology & Obstetrics, Paediatrics, Dermatology, Psychiatry, Chest Medicine, Orthopaedics, ENT, and Emergency, were included in the study.
- Well-informed and written consent was taken for the participation.
- Patients selected for the study included faculty members, postgraduate trainers, senior residents, and staff.

Exclusion criteria

- Physicians who were not working or practising were excluded from the study.
- Unwilling participants were excluded.
- Without the authority to prescribe, any interns or medical students were not selected for the study.

Procedure- The study's procedure involved the development of a strategic questionnaire based on a literature review of fixed-dose combinations (FDCs). A

draft copy of the questionnaire was followed by a detailed review by the expert faculty of the tertiary care hospital. The review was conducted to evaluate the appropriateness of the content. The evaluation was done using a 4-point Likert scale, ranging from 1 (irrelevant) to 4 (highly relevant). Also, Content Validity Index (CVI) was used to ensure the scientific clarity of the study. To ensure validity, the KAP questionnaire was administered to all study participants. Different demographic parameters were recorded, including age, sex, experience, designation, and different department. Proper evaluation of knowledge, attitudes, and practices for prescribing was conducted. Participants reported mentioning the commonly recommended FDCs for clinical assessment. All the responses were recorded.

Statistical analysis- Collected data was analysed using IBM SPSS Statistics version 28. Descriptive statistics were used to summarise the findings. Different categorical variables have been used, like gender, department, designation, knowledge responses, and attitude. Data were represented as frequencies and percentages.

Different categorical variables, such as age and experience, were summarized using mean and standard deviation. The Chi-square test (χ^2) was used to determine the association between different categorical variables. P-value of <0.05 was maintained for statistical significance.

RESULTS

Table 1 shows the patient distribution across different medical disciplines, with the highest proportion in orthopaedics at 13.2%. Medicine, paediatrics and psychiatry follow this. A total of 11.2% have been observed in Gynaecology & Obstetrics. Medium strength of participation has been observed in the chest medicine, emergency, and dermatology departments, with estimates of about 9.9%, 9.2%, and 7.9%, respectively. About 5.3% of participants have undergone surgery, and 0.7% have received care in the neuro-medicine discipline. The table highlighted that participation across many medical disciplines, based on knowledge, attitude, and recommended prescription patterns, is based on fixed doses.

Table 1: Distribution of patient and their corresponding percentages for different medical disciplines

Disciplines	Number Participants (n= 202)	Percentage from Chart (%)
Medicine	24	11.80
Surgery	10	5.30
Gynaecology & Obstetrics	23	11.20
ENT	15	7.20
Orthopaedics	27	13.20
Neuromedicine	1	0.70
Psychiatry	24	11.80
Chest Medicine	20	9.90
Dermatology	16	7.90
Emergency	18	9.20
Paediatrics	24	11.80

Table 2 highlights the pattern for prescribing the distribution of fixed-dose combinations (FDCs). The most common prescribed pattern for FDC was Montelukast with levocetirizine, observed in 52% of participants. This highlights the maximum preference for respiratory and allergy-associated complications. 81 participants were prescribed iron with folic acid, and 78 were prescribed

co-amoxiclav. 72 participants were prescribed Pantoprazole with domperidone, highlighting a common gastrointestinal disorder. 45 participants were prescribed aspirin with atorvastatin. Frequently, 37 patients were prescribed a combination of ofloxacin with ornidazole for the recommended usage of the FDCs.

Table 2: Commonly Prescribed FDCs among participants and their corresponding percentages

Fixed-Dose Combination (FDC)	Participants (Updated %)	Number of Participants (n)
Pantoprazole + Domperidone	35.60	72
Ofloxacin + Ornidazole	18.10	37
Aspirin + Atorvastatin	22.30	45
Iron + Folic Acid	40.20	81
Montelukast + Levocetirizine	52	105
Co-Amoxiclav	38.50	78

Table 3 highlights different levels of knowledge, attitude, and prescribing practices among participants regarding fixed-dose combinations (FDCs). Most participants have a higher level of awareness of FDCs, with 78.2% reporting familiarity and 70% recognising the potential harm. 9.4% have known the initial number of FDCs listed in the 2022 National Essential Medicines. Positive

responses to attitude and a high rate of prescription requirements were observed. Also, healthcare providers should be aware of the guidelines for the medicine. More variations have been revealed in association with practice, with many participants highlighting counselling patterns, naming them generically and verifying them.

Table 3: Distribution of attitude, response to practice and knowledge level for the combination of fixed dose among different participants

Category	Question	Positive Responses (n)	Percentage (%)
Knowledge	Do you know about fixed-dose combinations?	158	78.20
	Do you know that FDCs may be harmful when all ingredients are not required for certain patients?	142	70.30
	Do you know that all FDCs available in the market are rational?	129	63.90
	Do you know that in case of ADRs, FDCs make it difficult to determine the culprit drug?	97	48
	Do you know FDCs can control antimicrobial resistance?	112	55.40
	Do you know 'Essential Medicine List'?	147	72.70
	Do you know the 2022 National List of Essential Medicines contains 384 medicines, of which only 22 are FDCs?	19	9.40%
Attitude	Do you agree that prescription is necessary to obtain FDCs from the pharmacy?	163	80.70
	Do you prefer prescribing FDCs rather than individual drugs?	134	66.30
	Do you agree that FDC use can help control antimicrobial resistance?	127	62.90

	Do you agree healthcare professionals should be aware of the National Essential Medicines List?	179	88.60
	Do you believe FDCs help reduce patients' pill burden?	168	83.20
Practice	Do you counsel patients properly before prescribing FDCs?	Always: 61 (30.2%)	Sometimes: 102 (50.5%)
	Do you write generic names of FDCs in prescriptions?	Always: 55 (27.2%)	Sometimes: 114 (56.4%)
	Do you mention the dosage of FDCs in the prescription?	Always: 49 (24.3%)	Sometimes: 118 (58.4%)
	Do you prescribe FDCs from the current National List of Essential Medicines?	Always: 66 (32.7%)	Sometimes: 99 (49.0%)
	Do you check the rationality of FDCs before prescribing?	Always: 57 (28.2%)	Sometimes: 115 (56.9%)

DISCUSSION

This study shows differences in the knowledge and prescribing practices of Eastern Indian practising physicians regarding fixed-dose combinations. Overall, we saw a mixed picture: while many doctors supported the theoretical benefits of FDCs, or were approved by regulations, prescription practices did not always align with national procedures or knowledge, and a considerable portion lacked current knowledge about which FDCs are evidence-based. These findings mirror those frequently reported for FDCs and extend previous investigations from India on attitudes, knowledge, and real-world prescribing practice ^[6].

In line with previous KAP investigations that established greater access to medication knowledge and continuing medical education in tertiary institutions, we found that doctors in tertiary/urban centres tend to have greater factual awareness than their peers in semi-urban or rural settings. According to Goswami *et al.* and the surveys that followed, resident physicians and physicians at teaching hospitals showed varying, but frequently insufficient, knowledge of FDC rationality, with both formal guidance and habit, and perceived convenience in clinical practice, being influenced ^[7].

This institutional and geographic gradient needs to improve the transmission of independent treatment guidance and regulatory decisions beyond large teaching institutions. The prescribing of potentially illogical FDCs and attitudes toward rational use were recurring elements in our investigation into the difference between determination.

Similar discrepancies were observed in Singh *et al.* and other cross-sectional studies, which showed that doctors who adhered to rational prescribing principles nevertheless continued to employ problematic combinations ^[8]. Despite qualitative investigation, market dynamics and supply-side promotion, independent of regulatory changes, commercial influence, and perceived patient adherence advantages, appeared as proximal determinants of FDC selection in our sample ^[9].

Despite regulatory involvement, the observed continuation of irrational or borderline FDC use is consistent with national assessments that highlight inconsistent enforcement across states and a market withdrawal. Bans decrease, but do not completely eradicate, irrational FDC availability and prescription, according to Miranda and colleagues and other policy evaluations ^[10]. This is in part because many drugs are either re-marketed with negligible reformulation or stay on the shelf. Our findings suggest that to modify prescriptions at scale, concurrent initiatives' knowledge is required to improve stewardship, update institutional formularies, and increase physician ^[11].

Our results from the regional prescribing-pattern study also show variations across therapeutic classes. Like previous prescribing audits that showed illogical FDCs in psychotropics, antimicrobials, and gastroenterology, our analysis discovered that some classes are still prone to improper fixed combinations in everyday practice ^[12]. This therapeutic variability calls for a one-size-fits-all method in favour of a customised engagement ^[13].

The current study's strengths include its combined assessment of knowledge and actual prescribing behaviour, as well as its focus on Eastern India. This region was less examined in previous KAP and prescribing audits. However, the self-reported knowledge and attitudes may be subject to social-desirability bias; it is cross-sectional, making it impossible to confirm causal determinants of prescribing; and sampling focused on specific hospitals may limit generalizability to all primary-care prescribers in the area. These warnings are similar to those made by earlier researchers and require combining survey data with qualitative interviews and prescription checks ^[14].

These comparisons for practice and policy have immediate consequences. To properly understand the regulatory position of extensively circulating FDCs, educational initiatives must be expanded to other tertiary centres. To minimise unintentional prescribing, institutional formularies should identify illogical or unauthorised FDCs at the point of care, and computerised prescribing systems should do the same. To avoid the gradual removal of prohibited combinations, market monitoring and active distribution should be combined with regulatory restrictions. The most immediate clinical and public health impact may come from class-specific stewardship initiatives, particularly for antibacterial and psychotropic FDCs ^[15].

In our findings, a consistent national pattern emerges, while physicians frequently appreciate in practice the concept of rational FDC use; knowledge, local prescribing norms, and market pressures sustain heterogeneity. These multifactorial drivers, combined with educational, institutional, and regulatory approaches, will be essential to confirm that FDCs fulfil their promise of safer, simpler, and more effective therapy.

CONCLUSIONS

The study has concluded that most participants reported greater awareness of fixed-dose combinations, gaps in understanding, and prescribing patterns. Most participants have recognised the benefits of FDCs, including reduced challenges associated with pills, improved compliance, and a positive attitude toward clinical benefit. Also, minimum awareness of the regulation of essential medicines requires more education and policies. Different responses related to policies revealed inconsistencies, to verify the rationality and ensure the accuracy of the documents regarding

names and doses. Outcome significantly stimulated the training and has updated various clinical recommendations to improve awareness of strategic regulation to promote the proper application of FDCs. These improved areas can contribute to patients' safety profiles and reduce antimicrobial resistance, thereby improving therapeutic response.

CONTRIBUTION OF AUTHORS

Research concept- Sreyanwita Mukherjee

Research design- Ratul Banerjee

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Materials- Ratul Banerjee

Data collection- Sreyanwita Mukherjee, Purnendu Mandal

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