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A prospective observational study on prescription pattern and drug utilization pattern of fluoroquinolones in a tertiary care hospital.

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Abstract

Background:

Fluoroquinolones (FQs) are widely prescribed broad-spectrum antibiotics, yet their extensive use contributes to antimicrobial resistance (AMR) and raises important safety concerns. This study prospectively evaluated FQ prescribing and drug-utilization patterns in a tertiary care hospital to identify gaps requiring stewardship attention.

Methods:

This prospective observational study included 300 adult patients who received FQs across multiple clinical departments. Information was extracted from medical records using a structured form documenting demographics, clinical details, FQ type, dose, indication, duration, and outcomes, including adverse drug reactions (ADRs). Prescriptions were assessed for appropriateness against institutional guidelines, and data were analyzed descriptively.

Results:

A total of 300 adult patients receiving fluoroquinolone therapy were included. The mean age was 54.2 ± 12.5 years; 165 (55.0%) were males, and 135 (45.0%) were females. Diabetes mellitus was observed in 126 (42.0%) patients, hypertension in 114 (38.0%), and chronic kidney disease in 51 (17.0%). Ciprofloxacin was most frequently prescribed [144 (48.0%)], followed by levofloxacin [111 (37.0%)] and ofloxacin [45 (15.0%)]. Urinary tract and lower respiratory tract infections were the leading indications. Empirical therapy was used in 216 (72.0%) cases, while culture-guided therapy was documented in 84 (28.0%). Overall, 135 (45.0%) prescriptions were appropriate, whereas 165 (55.0%) were inappropriate, mainly due to non-bacterial indications or prolonged duration. Adverse drug reactions occurred in 36 (12.0%) patients, predominantly gastrointestinal symptoms. Culture reports showed high fluoroquinolone resistance in E. coli (65.0%) and Klebsiella species (55.0%).

Conclusion:

The study demonstrates substantial inappropriate FQ prescribing, primarily driven by empirical therapy and poor adherence to guidelines. Strengthening antimicrobial stewardship is essential to reduce resistance and enhance patient safety.

Recommendations:

Implement department-specific stewardship audits, restrict empirical FQ initiation, reinforce guideline-based prescribing through regular training, and integrate culture-guided therapy to optimize antibiotic use and curb resistance development.

Keywords: *Fluoroquinolones, Prescribing patterns, Drug utilization research, Antimicrobial resistance, Adverse drug reactions, Antimicrobial stewardship, Tertiary care hospital.*

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Introduction

Fluoroquinolones (FQs) are a critical class of synthetic broad-spectrum antibiotics widely used to treat various infections due to their potent bactericidal activity and favorable pharmacokinetic profiles, including good oral bioavailability and tissue penetration [1]. They have become a cornerstone in both community and hospital settings for managing respiratory, urinary tract, gastrointestinal, and skin infections, among others. In many healthcare settings, FQs such as ciprofloxacin and levofloxacin are among the most frequently prescribed antibiotics, often utilized as empiric therapy, which can lead to high rates of use[2].

The extensive use of FQs, while effective in many scenarios, is a major contributing factor to the escalating global health crisis of antimicrobial resistance (AMR), leading to the emergence of resistant pathogens like methicillin-resistant Staphylococcus aureus (MRSA) and Pseudomonas aeruginosa [3]. Studies in India have shown high resistance levels; for example, one report indicated ciprofloxacin and levofloxacin resistance rates in E. coli isolates at around 77% and 71%, respectively. The high prevalence of antibiotic use, often without adequate microbiological confirmation, further exacerbates the resistance problem.

The challenge is further compounded by concerns regarding the safety profile of FQs, as regulatory agencies like the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have mandated boxed warnings and restrictions due to associations with serious, potentially permanent, adverse effects [4, 5, 6]. These include tendinopathy (tendon rupture), peripheral neuropathy, and aortic aneurysm/dissection. The risk of these adverse events, though rare, necessitates a rigorous benefit-risk evaluation before prescribing, particularly for uncomplicated infections where alternatives exist.

Given these efficacy benefits and safety concerns, monitoring and evaluating how FQs are prescribed in clinical practice is essential to promote rational drug use, minimize resistance development, and ensure patient safety. Studies have consistently shown suboptimal adherence to guidelines, with a high percentage of unnecessary fluoroquinolone therapy, either for non-bacterial syndromes or for durations longer than recommended. Implementing robust antimicrobial stewardship programs (ASPs) has proven effective in reducing FQ consumption and subsequently increasing pathogen susceptibility, highlighting the importance of ongoing surveillance.

This prospective study aims to analyze the current prescribing patterns and drug utilization trends of fluoroquinolones within a specific tertiary care hospital setting. The findings will provide valuable insights into adherence to local and national clinical guidelines and help identify potential areas for targeted interventions to optimize antibiotic stewardship efforts.

Material and method

Study Design and Setting

This was a hospital-based prospective observational drug-utilization study with a cross-sectional analytical design, conducted over one year from August 2024 to July 2025. The study was carried out in the inpatient departments of Konaseema Institute of Medical Sciences and Research Foundation, Amalapuram, Andhra Pradesh, India.

Konaseema Institute of Medical Sciences and Research Foundation is a tertiary care teaching hospital that provides specialist and super-specialist healthcare services to patients from Amalapuram and the surrounding rural and semi-urban regions of Andhra Pradesh. The institution has multiple clinical departments, diagnostic laboratory support, pharmacy services, and medical record facilities, making it suitable for evaluating prescription patterns, antimicrobial utilization, and patient-related clinical outcomes. The study was conducted after obtaining approval from the Institutional Ethics Committee of Konaseema Institute of Medical Sciences and Research Foundation.

Participants and selection method

The study population consisted of adult inpatients who were prescribed at least one fluoroquinolone antibiotic during the study period. Participants were selected using a consecutive sampling method. All eligible patients admitted to the participating departments and receiving fluoroquinolone therapy during the defined study period were screened for inclusion.

Patients of either gender aged 18 years or above who received ciprofloxacin, levofloxacin, ofloxacin, or any other fluoroquinolone for therapeutic or prophylactic indication were included. Patients with incomplete medical records, missing prescription details, unclear diagnosis, or transfer out of the study department within 24 hours of admission were excluded. Written informed consent was obtained from all participants or their legally authorized representatives before data collection.

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Study size

A total of 300 adult patients were included in the study. The sample size was determined based on the expected proportion of inappropriate or non-guideline-based fluoroquinolone prescribing in hospital settings. Assuming an expected inappropriate prescribing proportion of 50%, which gives the maximum sample size, with 95% confidence level and 6% absolute precision, the minimum required sample size was approximately 267. After adding nearly 10% to compensate for incomplete records or exclusions, the required sample size was rounded to 300 patients. This sample size was also considered feasible within the one-year study duration and adequate to describe fluoroquinolone prescription patterns, indications, route of administration, duration of therapy, adverse drug reactions, and culture-sensitivity-based utilization.

Data collection procedure

Data were collected prospectively by reviewing prescription charts, case sheets, laboratory records, microbiology reports, and discharge summaries using a pre-designed structured data collection form. The collected variables included age, gender, diagnosis, comorbidities, indication for fluoroquinolone use, type of fluoroquinolone prescribed, dose, dosage form, route of administration, frequency, duration of therapy, empirical or definitive use, culture and sensitivity results, clinical outcome, and adverse drug reactions.

Fluoroquinolone prescriptions were assessed for appropriateness based on institutional antibiotic guidelines, indication, dose, duration, route of administration, and availability of microbiological evidence wherever applicable. Drug utilization was also evaluated using relevant prescribing indicators and descriptive measures such as frequency, percentage, mean, and standard deviation.

Drug Utilization Pattern Assessment

The FQ utilization patterns were assessed using the following methods:

World Health Organization (WHO) prescribing indicators: Parameters such as the average number of drugs per prescription, percentage of antibiotics prescribed by generic name, and percentage of antibiotics prescribed from the Essential Drugs List were evaluated.

Defined Daily Dose (DDD) methodology: The consumption of specific FQs was quantified using the WHO Anatomical Therapeutic Chemical (ATC) classification system and the DDD/100 bed-days metric to allow for standardized comparison of drug usage.

Bias

Several measures were taken to minimize potential sources of bias. Selection bias was reduced by using consecutive sampling of all eligible patients during the study period rather than selective enrolment. Information bias was minimized by using a standardized data collection form and extracting data from multiple hospital records, including prescription charts, case sheets, laboratory reports, and discharge summaries. To reduce observer bias, prescription appropriateness was assessed using predefined institutional antibiotic guidelines rather than subjective clinical judgment alone.

Misclassification bias was addressed by clearly defining empirical therapy, culture-guided therapy, appropriate prescription, inappropriate prescription, and adverse drug reactions before data analysis. Data entry errors were minimized through cross-checking of collected forms and verification of key variables. Since culture and sensitivity reports were not available for all patients, resistance-related findings were interpreted only among patients with available microbiological data. The single-center design and reliance on hospital documentation were recognized as potential limitations while interpreting the findings.

Data Analysis

All collected data were compiled and entered into a spreadsheet program (e.g., Microsoft Excel) and analyzed using appropriate statistical software (e.g., Statistical Package for the Social Sciences (SPSS) version [mention version]). Descriptive statistics, such as mean, standard deviation, and percentages, were used to summarize demographic data and prescribing patterns. Inferential statistical tests (e.g., Chi-square test, t-test) were used to determine associations between variables where appropriate. A P value of less than 0.05 was considered statistically significant.

Ethical Considerations

The study protocol was reviewed and approved by the Institutional Ethics Committee, Konaseema Institute of Medical Sciences, Amalapuram, Andhra Pradesh, India. Patient confidentiality was maintained throughout the study period by using anonymized identifiers. All procedures were performed in accordance with the ethical standards of the

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responsible committee on human experimentation and with the Helsinki Declaration.

Results

Participant flow

A total of 300 adult inpatients who received at least one fluoroquinolone antibiotic during the study period were screened for eligibility. All screened patients fulfilled the inclusion criteria, were enrolled after informed consent, and were included in the final analysis. No patient was excluded after enrolment because of incomplete prescription records, transfer within 24 hours, or withdrawal of consent. The participant flow is presented in Table 1.

Table 1. Participant flow of the study population

Study stage	Number of patients	Remarks
Adult patients receiving fluoroquinolone therapy screened	300	Identified from inpatient prescription records
Patients assessed for eligibility	300	Screened according to inclusion and exclusion criteria
Patients fulfilling inclusion criteria	300	Age >=18 years and prescribed at least one fluoroquinolone
Patients excluded	0	No exclusion after eligibility confirmation
Patients enrolled in the study	300	Written informed consent obtained
Patients included in final analysis	300	Complete prescription and clinical data available

Baseline demographic and clinical profile

The demographic and baseline clinical characteristics of the study participants are summarized in Table 2. The mean age of the participants was 54.2 +/- 12.5 years. Male patients constituted 165 (55.0%) of the study population, while female patients accounted for 135 (45.0%). Diabetes mellitus was the most common comorbidity, observed in 126 (42.0%) patients, followed by hypertension in 114 (38.0%) and chronic kidney disease in 51 (17.0%).

Patient names were recorded only in the source data collection form for internal verification and were replaced with anonymized study identification codes during analysis. Admission and discharge dates were reviewed from inpatient records for clinical documentation and assessment of hospital stay, but individual identifiers were not reported in the manuscript to maintain participant confidentiality.

Table 2. Baseline demographic and clinical profile of participants

Variable	Number (n=300)	Percentage (%)
Male	165	55.0
Female	135	45.0
Mean age, years	54.2 +/- 12.5	-
Diabetes mellitus	126	42.0
Hypertension	114	38.0
Chronic kidney disease	51	17.0

Clinical history and allergy profile

Relevant medical history was documented for all participants, and the major comorbidities are shown in Table 3. Surgical history was clinically relevant in patients treated for surgical-site infections or postoperative infectious indications. A documented history of fluoroquinolone allergy was not observed among the analyzed participants. Patients with known allergy to fluoroquinolones were not prescribed these agents and therefore did not form part of the final study cohort.

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Table 3. Medical, surgical, and drug-allergy history of participants

Clinical variable	Number (n=300)	Percentage (%)
Diabetes mellitus	126	42.0
Hypertension	114	38.0
Chronic kidney disease	51	17.0
Relevant surgical history/postoperative indication	45	15.0
Documented fluoroquinolone allergy	0	0.0

Fluoroquinolone prescribing pattern

The distribution of fluoroquinolones prescribed during the study period is presented in Table 4. Ciprofloxacin was the most frequently prescribed agent, accounting for 144 (48.0%) prescriptions, followed by levofloxacin in 111 (37.0%) and ofloxacin in 45 (15.0%). Moxifloxacin and norfloxacin were not prescribed in the study cohort.

Table 4. Fluoroquinolone utilization pattern

Fluoroquinolone prescribed	Number of prescriptions	Percentage (%)	Common indication
Ciprofloxacin	144	48.0	Urinary tract infections
Levofloxacin	111	37.0	Lower respiratory tract infections
Ofloxacin	45	15.0	Surgical-site infections
Moxifloxacin	0	0.0	Not prescribed
Norfloxacin	0	0.0	Not prescribed

Indications and treatment approach

Urinary tract infections and lower respiratory tract infections were the leading indications for fluoroquinolone therapy, as shown in Table 5. Empirical therapy was used in 216 (72.0%) patients, whereas culture-guided therapy was documented in 84 (28.0%) patients. The intravenous route was initially used in 180 (60.0%) patients, and 150 of these patients were subsequently shifted to oral therapy following clinical improvement. The mean duration of fluoroquinolone therapy was 8.5 +/- 3.2 days.

Table 5. Indication and treatment approach for fluoroquinolone therapy

Parameter	Number	Percentage (%)
Empirical therapy	216	72.0
Culture-guided therapy	84	28.0
Initial intravenous therapy	180	60.0
IV-to-oral switch among IV-treated patients	150/180	83.3
Mean duration of therapy, days	8.5 +/- 3.2	-

Appropriateness of prescriptions

Prescription appropriateness according to institutional antibiotic guidelines is shown in Table 6. Overall, 135 (45.0%) prescriptions were appropriate with respect to indication, dose, route, and duration, while 165 (55.0%) were inappropriate. The most common reasons for inappropriate use were treatment of non-bacterial infections or asymptomatic bacteriuria and prolonged duration of therapy.

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Table 6. Appropriateness of fluoroquinolone prescriptions

Prescription category/reason	Number	Percentage (%)
Appropriate prescriptions	135	45.0
Inappropriate prescriptions	165	55.0
Non-bacterial infection/asymptomatic bacteriuria among inappropriate prescriptions	80/165	48.5
Prolonged treatment duration among inappropriate prescriptions	60/165	36.4

Clinical outcomes, safety, and resistance pattern

The clinical outcomes, adverse drug reactions, and resistance findings are summarized in Table 7. A positive clinical response, defined as cure or significant improvement, was observed in 240 (80.0%) patients, while 60 (20.0%) patients required a change in antibiotic regimen or had treatment failure. Adverse drug reactions were recorded in 36 (12.0%) patients, with gastrointestinal symptoms being the most common. Among patients with available culture and sensitivity reports, high fluoroquinolone resistance was observed among E. coli (65.0%) and Klebsiella species (55.0%).

Table 7. Clinical outcomes, adverse drug reactions, and resistance findings

Parameter	Number	Percentage (%)
Clinical cure/significant improvement	240	80.0
Treatment failure/change in antibiotic regimen	60	20.0
Patients with adverse drug reactions	36	12.0
Total adverse drug reactions recorded	39	-
Gastrointestinal adverse reactions	21	-
Central nervous system adverse reactions	9	-
Musculoskeletal symptoms	6	-
E. coli resistance to fluoroquinolones	-	65.0
Klebsiella species resistance to fluoroquinolones	-	55.0

Discussion

The findings of this prospective observational study provide important evidence on the utilization pattern, appropriateness, safety profile, and resistance concerns associated with fluoroquinolone use in a tertiary care hospital. Fluoroquinolones were prescribed to 300 adult inpatients, indicating their frequent use in routine clinical practice. This prescribing pattern may be explained by their broad antimicrobial spectrum, good oral bioavailability, tissue penetration, and clinical usefulness in common infections such as urinary tract infections and lower respiratory tract infections [7]. Ciprofloxacin and levofloxacin accounted for most prescriptions, suggesting that these agents remain preferred choices for empirical treatment in hospital settings [8].

A major observation in this study was the high proportion of inappropriate fluoroquinolone prescriptions, which accounted for 55.0% of total use. This finding indicates a considerable gap between clinical prescribing practice and institutional antibiotic guidelines. The main reasons for inappropriate use were treatment of non-bacterial conditions, use in asymptomatic bacteriuria, and prolonged treatment duration. These findings suggest that fluoroquinolones may often be continued beyond the required period or initiated without sufficient microbiological confirmation. Such practice increases unnecessary antibiotic exposure and may contribute to avoidable adverse effects and antimicrobial resistance [9,10].

Empirical therapy was used in 72.0% of patients, while culture-guided therapy was documented in only 28.0%. This finding reflects a strong dependence on empirical antibiotic initiation in the inpatient setting. Although empirical therapy may be clinically justified in acutely ill patients, continued use without culture confirmation or early de-escalation can reduce the rationality of antimicrobial

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therapy. The low proportion of culture-guided treatment highlights the need for improved diagnostic stewardship, early specimen collection, timely microbiology reporting, and review of antibiotic therapy after 48–72 hours [10].

The high fluoroquinolone resistance observed among E. coli and Klebsiella species is clinically important. Resistance was documented in 65.0% of E. coli isolates and 55.0% of Klebsiella isolates. These findings suggest that routine empirical use of fluoroquinolones for infections commonly caused by these organisms may have reduced effectiveness in the study setting. This pattern may be related to repeated or inappropriate fluoroquinolone exposure, especially in urinary and respiratory infections. The findings support the need for local antibiogram-based prescribing rather than routine empirical selection of fluoroquinolones [11].

Adverse drug reactions were documented in 12.0% of patients. Most reactions were gastrointestinal symptoms, while central nervous system effects and musculoskeletal complaints were also observed. Although most adverse events were mild, the presence of tendinopathy-related symptoms is relevant because fluoroquinolones are known to be associated with rare but potentially serious adverse effects. This finding reinforces the need for careful patient selection, avoidance of unnecessary prescriptions, and close monitoring, particularly among elderly patients and those with comorbidities such as chronic kidney disease [12].

The findings of this study emphasize the need to strengthen antimicrobial stewardship activities within the institution. Regular prescription audits, clinician feedback, restriction of empirical fluoroquinolone use, and mandatory documentation of indication and planned duration may improve prescribing quality. Culture-based therapy should be encouraged wherever feasible, and empirical therapy should be reassessed once microbiological results become available. Training programs for prescribers on fluoroquinolone safety, resistance trends, and guideline-based duration of therapy may further reduce inappropriate use [8,13].

Overall, this study shows that fluoroquinolones continue to be widely used in tertiary care practice, but a substantial proportion of prescriptions are not fully aligned with guideline-based recommendations. The combination of high empirical use, inappropriate prescribing, documented adverse reactions, and significant resistance among common Gram-negative pathogens indicates the need for a more cautious and evidence-based approach. Strengthening antimicrobial stewardship and diagnostic support can improve patient safety, preserve fluoroquinolone effectiveness, and reduce the risk of further antimicrobial resistance [10,13].

Generalizability

The findings of this study are broadly applicable to similar tertiary care hospitals in India where fluoroquinolones remain widely used for empirical therapy. The demographic profile, prescribing habits, and microbial resistance patterns reflect routine clinical practice in resource-constrained settings. Although the results are most relevant to institutions with comparable patient loads and antibiotic policies, the insights can guide stewardship initiatives in other regions facing rising resistance trends. However, extrapolation to highly specialized centers should be undertaken cautiously.

Conclusion

This prospective evaluation of fluoroquinolone prescribing revealed substantial gaps in rational antibiotic use, with more than half of all prescriptions failing to meet established appropriateness criteria. Empirical therapy dominated clinical decision-making, and poor alignment with diagnostic evidence contributed to considerable antimicrobial resistance among common pathogens. Despite most patients showing clinical improvement, the incidence of adverse reactions and high resistance rates indicates the need for more judicious selection of these agents. Strengthening institutional antimicrobial stewardship, improving diagnostic support, and promoting guideline adherence are essential to curb unnecessary fluoroquinolone exposure, enhance therapeutic outcomes, and protect the long-term efficacy of this important drug class.

Limitations

This study was conducted in a single tertiary care hospital, which restricts wider applicability to diverse healthcare settings. Culture and sensitivity reports were available for only a subset of patients, limiting the precision of resistance analysis. Adverse drug reactions relied on documentation in medical records, which may have resulted in underreporting. The study did not assess prescriber knowledge or attitudes, which could have offered deeper insights into behavioral factors influencing inappropriate fluoroquinolone use.

Recommendations

Hospitals should strengthen antimicrobial stewardship programs through regular auditing of prescriptions, real-time feedback to clinicians, and mandatory documentation

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of indications for broad-spectrum antibiotics. Diagnostic stewardship must be enhanced by encouraging early culture sampling and promoting definitive therapy guided by sensitivity results. Prescribers should undergo periodic training focused on updated guidelines, optimal treatment duration, and safety considerations associated with fluoroquinolones. Introduction of clinical decision-support tools within electronic prescribing systems can further reduce unwarranted antibiotic use. Multidisciplinary review of empirical therapy after 48–72 hours is essential to ensure rational, evidence-based antibiotic selection and reduce resistance.

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Abbreviations
FQ – Fluoroquinolone
ADR – Adverse Drug Reaction
AMR – Antimicrobial Resistance
DDD – Defined Daily Dose
ATC – Anatomical Therapeutic Chemical Classification
C&S – Culture and Sensitivity
UTI – Urinary Tract Infection
LRI – Lower Respiratory Tract Infection

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Conflict of interest
The authors declare no conflict of interest.

Author contributions
AA-Concept and design of the study, results interpretation, review of literature, and preparation of the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript.**GL**-Concept and design of the study, results interpretation, review of literature, preparing the first draft of the manuscript, and revision of the manuscript.**NRK**-Review of literature and preparing the first draft of the manuscript. Statistical analysis and interpretation.

Data availability
Data available on request

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With more than 18 years of teaching and administrative experience, Dr. Acharya has held several leadership positions, including Vice Principal, Principal, Chief Warden, Member Secretary of Institutional Ethics and Animal Ethics Committees, and is an approved PhD Guide under Dr. NTR University of Health Sciences, Vijayawada. His visionary leadership has significantly enhanced the institution's academic quality, clinical exposure, research infrastructure, and postgraduate training standards.

He has completed prestigious national faculty development programs such as the Revised Basic Course Workshop (rBCW), Advanced Course in Medical Education (ACME), and National Teacher Training Course (NTTC, JIPMER, Puducherry). He also serves as Coordinator for Pharmacovigilance and Materiovigilance Programs under IPC–PvPI and MoHFW, Government of India, contributing actively to national drug safety and regulatory initiatives.

A prolific academician, Dr. Acharya has authored and co-authored more than 100 scientific publications in reputed national and international indexed journals. His wide-ranging research covers toxicology, pharmacovigilance, antimicrobial resistance, endocrinology, neuropharmacology, and clinical pharmacology. His recent studies include long-term analyses of pyrethroid, paraquat, and chlorpyrifos poisoning, investigations into antimicrobial resistance trends, and predictive models for treatment outcomes in dermatological and toxicological emergencies.

Dr. Acharya's professional interests include clinical pharmacology, toxicovigilance, rational drug use, pharmacovigilance systems, and innovations in medical education technologies. He continues to mentor numerous postgraduate and undergraduate researchers while playing an integral role in curriculum reform, ethics governance, and institutional academic advancement.**ORCID iD**: https://orcid.org/0009-0000-7967-9092

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