ANTIBIOTIC STEWARDSHIP IN SURGERY: A RETROSPECTIVE AUDIT OF PROPHYLACTIC PRACTICES AT A TERTIARY CARE HOSPITAL

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Hospital and Health Management

by

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Under the Supervision and Guidance of

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CERTIFICATE

This is to certify Dr Khan Tabassum Jahan in partial fulfilment of the requirements for the award of the degree of MBA Hospital and Health Management from the IIHMR University, Jaipur, has successfully completed her internship under the mentorship of Prof. Arindam Das during March 17, 2025 – June 17, 2025.

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This is to certify that dissertation titled **Antibiotic Stewardship in Surgery: A Retrospective Audit of prophylactic practices at a tertiary care hospital** is a record of the research work undertaken by Dr. Khan Tabassum Jhan for partial fulfilment of the requirements for the award of the degree of MBA Hospital and Health Management from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled "**Antibiotic Stewardship in Surgery: A Retrospective Audit of Prophylactic Practices at a Tertiary Care Hospital**" is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)

Dr. Khan Tabassum Jahan

Date: 17/06/25

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List of Abbreviations

AMR	Antimicrobial Resistance
ASP	Antimicrobial Stewardship Program
SAP	Surgical Antimicrobial Prophylaxis
SSI	Surgical Site Infection
WHO	World Health Organization
CDC	Centres for Disease Control and Prevention
ID	Infectious Disease
ICU	Intensive Care Unit
ICMR	Indian Council of Medical Research
OPD	Outpatient Department
IPD	Inpatient Department
OOP	Out-of-Pocket
EMR	Electronic Medical Record
MDR	Multi-Drug Resistance
MRSA	Methicillin-Resistant Staphylococcus aureus
ESBL	Extended-Spectrum Beta-Lactamase
OT	Operation Theatre
KPI	Key Performance Indicator
UHID	Unique Hospital Identification Number
NA	Not Applicable
ORIF	Open Reduction and Internal Fixation
LSCS	Lower Segment Caesarean Section
ADR	Adverse Drug Reaction

ABSTRACT

ANTIBIOTIC STEWARDSHIP IN SURGERY: A RETROSPECTIVE AUDIT OF PROPHYLACTIC PRACTICES AT A TERTIARY CARE HOSPITAL.

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ADVISOR: DR. ARINDAM DAS

Keywords*:* Antimicrobial resistance (AMR), Surgical Antimicrobial Prophylaxis (SAP), Antimicrobial Stewardship Program (ASP), compliance

Background

Antimicrobial resistance (AMR) is recognised as one of the most significant global public health challenges of the 21st century. A key factor driving AMR is the extended and inappropriate use of antibiotics, especially within hospitals where patients often undergo complex surgeries or have weakened immune systems. Surgical Antimicrobial Prophylaxis (SAP) serves as a preventive strategy to lower the incidence of surgical site infections (SSIs). However, failure to adhere to established SAP protocols can contribute to growing antimicrobial resistance, higher rates of patient complications, and increased healthcare expenditures. Antimicrobial Stewardship Programs (ASPs) are designed to oversee and enhance the appropriate use of antibiotics, with SAP playing a vital role in their implementation.

Objective

This study aims to assess the compliance and appropriateness of SAP practices at EHCC Hospital, Jaipur, and to analyze patterns of restricted antimicrobial usage under the institutional ASP over a three-month period. The study also sought to identify departmental variations, key indicators of non-compliance, and factors contributing to inappropriate prescribing.

Methodology

The study followed a positivist research philosophy and adopted a retrospective, observational, and quantitative research design. Data were collected for all inpatient surgical cases between March and May 2025, using universal sampling (n = 180). Secondary data sources included SAP compliance checklists, restricted antimicrobial audit forms, pharmacy dispensing logs, and clinical documentation. Compliance was measured against four institutional Key Performance Indicators (KPIs): timely administration, appropriate drug selection, discontinuation within 24 hours, and complete documentation. The appropriateness of restricted antimicrobial prescriptions was also evaluated based on ASP protocols.

Key Findings

The overall SAP compliance rate was 64%, with departmental variations—ICU (80%), Orthopaedics (70%), General Surgery (58%), and the Transplant Unit (48%). Cefazolin was the most used prophylactic agent (50% of cases) and showed 80% appropriateness. However, broad-spectrum antibiotics such as ceftriaxone and restricted agents like amikacin and piperacillin-tazobactam were used without clear justification, often violating ASP guidelines. Notably, 32% of restricted antimicrobial prescriptions across departments were deemed inappropriate. Deviations included delayed or missed administration, extended postoperative use beyond 24 hours, incorrect drug choice, and inadequate documentation.

Implications

These findings indicate that despite institutional guidelines, there are persistent gaps in SAP compliance and rational antimicrobial usage. The misuse of restricted antibiotics, particularly in transplant and surgical units, poses a serious threat by accelerating AMR, increasing surgical complications, extending hospital stays, and inflating out-of-pocket expenditures for patients. Departments with low compliance showed an urgent need for intervention.

Recommendations

The study recommends several targeted interventions: integration of digital SAP checklists within the Electronic Medical Record (EMR) system, real-time auditing by clinical pharmacists, mandatory ID team approval for restricted drugs, department-wise training on SAP guidelines, and continuous monitoring through monthly audits. Implementation of these strategies is expected to enhance compliance, reduce inappropriate antimicrobial use, and strengthen the overall impact of the hospital's ASP.

Conclusion

This research highlights significant non-compliance and inappropriate use of antimicrobials in surgical prophylaxis practices at EHCC Hospital. The audit underscores the importance of robust stewardship systems, institutional accountability, and prescriber education to ensure safe, effective, and rational antimicrobial use. The insights generated can serve as a model for similar tertiary care institutions aiming to curb AMR through optimized prophylactic practices and responsible antimicrobial governance.

CHAPTER 1: INTRODUCTION

Antimicrobial resistance (AMR) has turned out to be a major global health concern in the 21st century, causing a serious threat to the effective treatment of infections. This growing crisis is largely fuelled by the widespread misuse and over-prescription of antibiotics, not only in hospital settings where critically ill and surgical patients are treated, but also within community healthcare practices. Such inappropriate use has accelerated the evolution of bacteria and other pathogens into resistant strains, making previously treatable infections increasingly difficult to manage. The World Health Organization (WHO) emphasizes that AMR contributes to longer hospital stays, increased medical costs, treatment failures, and a higher risk of mortality. This crisis threatens the effective treatment of a wide range of infections and undermines the progress made in modern medicine.

The magnitude of AMR is reflected in the fact that drug-resistant infections are estimated to cause nearly 5 million deaths globally each year, with predictions that this number could rise to 10 million annually by 2050 if effective measures are not taken. These estimates highlight the urgency of global efforts to regulate antimicrobial use and implement systems that encourage rational prescribing behaviour. Hospitals, particularly tertiary care centres, are at the forefront of this battle, as they are often the last line of defence in treating life-threatening infections with limited therapeutic options.

To combat this crisis, healthcare institutions across the globe have implemented Antimicrobial Stewardship Programs (ASP). An ASP aims to ensure the judicious use of antimicrobials by promoting the selection of the optimal drug regimen, including dosing, duration, and route of administration. These programs not only reduce inappropriate antimicrobial use but also help in improving clinical outcomes, minimizing toxicity, reducing healthcare costs, and curbing the development of resistance.

The World Health Organization (WHO), Centres for Disease Control and Prevention (CDC), Infectious Diseases Society of America (IDSA), and other global bodies have outlined comprehensive ASP guidelines. These guidelines emphasize key components such as:

- Conducting prospective audits accompanied by targeted interventions and feedback
- Implementing formulary restrictions and requiring pre-approval for the use of specific antimicrobials
- Development of facility-specific treatment guidelines
- Education and training of healthcare providers
- Monitoring and reporting of antimicrobial use and resistance patterns
- Regular outcome measurement (e.g., days of therapy per 1000 patient-days, compliance to prescribing protocols)

In the Indian context, the Indian Council of Medical Research (ICMR) and the Ministry of Health and Family Welfare have spearheaded national efforts to implement ASPs across both public and private healthcare institutions. Through the Antimicrobial Resistance Surveillance and Research Network (AMRSN), ICMR has developed Indian-specific antimicrobial use guidelines and has mandated that tertiary care hospitals conduct regular

prescription audits, establish antimicrobial committees, and integrate stewardship interventions into routine clinical practice.

One of the most critical aspects of ASPs is the implementation of Surgical Antimicrobial Prophylaxis (SAP) protocols. SAP refers to the preventive administration of antibiotics before, during, or after surgical procedures to minimize the risk of surgical site infections (SSIs), which are among the most common healthcare-associated infections (HAIs). The goal of SAP is to provide adequate drug concentration at the surgical site during the period of potential bacterial contamination.

Global SAP guidelines such as those by the WHO, CDC, and the American Society of Health-System Pharmacists (ASHP) emphasize key principles:

- Administer prophylactic antibiotics within 60 minutes prior to surgical incision (120 minutes for agents like vancomycin or fluoroquinolones)
- Use the narrowest spectrum antibiotic effective against likely pathogens
- Avoid prolonged postoperative prophylaxis; typically, a single preoperative dose is sufficient, and continuation beyond 24 hours is rarely warranted
- Redosing intraoperatively in prolonged procedures or where there is excessive blood loss

In India, the National Guidelines for Infection Prevention and Control in Healthcare Facilities (2015) and ICMR's SAP recommendations echo these principles, while allowing some customization based on local antibiograms. However, studies and surveillance reports consistently reveal poor compliance with SAP guidelines across various hospitals, primarily due to factors such as lack of awareness, unavailability of updated protocols, surgeon preferences, and fear of litigation.

Non-compliance with SAP guidelines — such as inappropriate selection, dosing, timing, or prolonged duration — contributes significantly to the development of antimicrobial resistance. The unnecessary use of broad-spectrum antibiotics for extended periods exposes patients to adverse effects, increases costs, and most importantly, selects for resistant organisms. This is particularly concerning in high-risk hospital areas like surgical ICUs, transplant units, and oncology wards, where immune-compromised patients are highly susceptible to infections.

The link between SAP non-compliance and multidrug resistance (MDR) has been well established in the literature. Extended use of antimicrobials, particularly during the perioperative phase, increases the risk of patients becoming colonized or infected with resistant pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA), extended-spectrum beta-lactamase (ESBL) producing *Enterobacteriaceae*, and organisms resistant to carbapenems. Infections caused by these resistant strains are associated with unfavourable clinical outcomes and limit available treatment options in the future, thereby imposing a significant strain on healthcare resources and infrastructure.

It is therefore imperative to regularly audit SAP compliance as part of the ASP framework. Audits help identify patterns of non-compliance, deviations from institutional protocols, and potential drivers of irrational prescribing behaviour. Moreover, such audits provide

actionable insights that can be used to design educational interventions, revise protocols, and implement systems for feedback and accountability.

EHCC Hospital, a prominent tertiary care hospital in Jaipur, has recognized the need to assess its restricted antimicrobial prescribing practices, especially in high-risk areas like surgery and transplant units. The hospital has already taken initial steps toward implementing an Antimicrobial Stewardship Program, including the formation of a stewardship committee, development of guidelines, and monitoring of antimicrobial usage trends. However, challenges persist in ensuring compliance with SAP protocols, particularly in high-volume surgical departments where empirical practices often override evidence-based decisions.

This dissertation seeks to analyse the appropriateness and compliance of SAP guidelines and restricted antimicrobial use at EHCC Hospital over a three-month period (March–May 2025). The focus will be on surgical antimicrobial prophylaxis practices, usage of restricted antibiotics, and adherence to ASP and SAP guidelines as established by ICMR and the hospital's internal protocols.

By conducting a retrospective audit of surgical prophylaxis and ASP implementation, this study aims to identify areas of improvement and suggest actionable interventions to strengthen stewardship efforts. The outcomes of this study will be vital in addressing key stewardship challenges at EHCC and may serve as a model for similar institutions seeking to reduce antimicrobial misuse and curb the rise of drug resistance.

Furthermore, the findings will contribute to the existing body of evidence on antimicrobial stewardship in Indian tertiary care settings and provide localized data that can inform policy revisions, training modules, and hospital accreditation efforts. Ultimately, this research aligns with national and global efforts to preserve the efficacy of existing antimicrobials, protect patient safety, and ensure the long-term sustainability of infection control practices in healthcare.

1.1 Research Background and Significance

Antimicrobial resistance (AMR) has emerged as a critical global health concern, jeopardizing years of advancements in modern medicine. Infections caused by resistant pathogens are considerably more difficult to manage, often necessitating the use of alternative antibiotics that may be more toxic, expensive, and less effective. These resistant infections lead to higher rates of illness and death, as well as increased financial strain on healthcare systems. Globally, AMR is estimated to cause around 700,000 deaths each year, with projections warning that this number could escalate to 10 million annually by 2050 if prompt and effective measures are not taken. India faces a particularly severe risk due to its substantial burden of infectious diseases and the widespread, often unregulated, access to antibiotics without prescription.

Healthcare institutions, especially tertiary care hospitals like EHCC (Eternal Hospital and Cardiac Centre), play a pivotal role in combating AMR through effective Antimicrobial Stewardship Programs (ASP). These programs are designed to monitor and optimize

antimicrobial prescribing practices, ensuring that patients receive the right drug, at the right dose, for the right duration. Within this framework, Surgical Antimicrobial Prophylaxis (SAP) is a critical component aimed at preventing postoperative infections while minimizing unnecessary antibiotic exposure.

1.2 Rationale of the Study

Although EHCC Hospital has an established antimicrobial policy aligned with national and institutional guidelines, clinical audits have revealed frequent deviations from standard SAP protocols. In many instances, antibiotics are administered at incorrect times, continued unnecessarily postoperatively, or selected inappropriately. These practices contribute to increased resistance and patient risk. The rationale for this study lies in identifying compliance gaps, assessing the appropriateness of restricted antimicrobial usage, and strengthening infection control practices to ensure patient safety.
This study is essential for identifying the extent of such deviations, evaluating the real-world implementation of ASP protocols, and suggesting evidence-based interventions. Strengthening SAP compliance and improving antimicrobial usage will not only enhance patient safety but also support the hospital's broader infection control and quality improvement efforts.

1.3 Problem Statement

Inappropriate and unjustified use of restricted antimicrobials continues in certain specialties at EHCC Hospital, undermining the effectiveness of ASP initiatives. High-priority areas such as the renal transplant unit and surgical departments have shown inconsistencies in SAP compliance, indicating a gap between policy and practice. These deviations reflect a disconnect between existing policies and their practical application. Such lapses compromise the effectiveness of the ASP, increase the risk of multidrug-resistant organism (MDRO) emergence, and threaten patient outcomes. Addressing this gap is crucial to preserving antimicrobial efficacy and ensuring responsible stewardship across the institution.

1.4 Objectives of the Study

Primary Objectives:

- To analyze the usage pattern of restricted antimicrobials at EHCC Hospital.
- To assess the compliance of surgical antimicrobial prophylaxis (SAP) protocols as per the institutional and national guidelines.
- To evaluate the appropriateness of antimicrobial prescriptions based on the Antimicrobial Stewardship Program (ASP) guidelines.

Secondary Objectives:

- To identify common deviations from recommended ASP and SAP protocols in clinical practice.

- To assess department-wise or specialty-wise variation in restricted antimicrobial usage.
- To determine the frequency and causes of inappropriate antimicrobial prescribing.
- To examine the documentation practices related to antimicrobial prescriptions and prophylaxis.

1.5 Scope of the Study

This study is confined to EHCC Hospital, a tertiary care institution located in Jaipur, Rajasthan. The research focuses specifically on the retrospective evaluation of antimicrobial prescribing practices from March to May 2025. The scope includes a detailed analysis of restricted antimicrobial audit forms and Surgical Antimicrobial Prophylaxis (SAP) documentation across key clinical departments, including surgery, nephrology, urology, transplant units, and intensive care. The primary objective is to assess the appropriateness, compliance, and justification of restricted antimicrobial usage, with special emphasis on adherence to established ASP and SAP guidelines. The study does not include outpatient prescriptions, pediatric patients, or community-acquired infections, and is limited to inpatient antimicrobial usage within the hospital.

1.6 Significance of the Study

This study holds significant relevance for EHCC Hospital's quality and patient safety initiatives. By evaluating the practical implementation of ASP protocols, it aims to identify gaps in compliance, highlight patterns of inappropriate use, and recommend actionable strategies to improve antimicrobial stewardship. The insights generated will support clinical governance by guiding training, protocol revision, and departmental accountability. Moreover, the study contributes to India's national fight against antimicrobial resistance by offering institution-specific data and pragmatic solutions. As AMR continues to pose a global threat, such focused audits serve as valuable tools in advancing safe, rational, and effective antimicrobial use in healthcare settings

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

Antimicrobial Resistance (AMR) represents one of the gravest challenges facing global healthcare today. It undermines the efficacy of life-saving drugs, prolongs patient recovery times, and increases mortality and healthcare costs. The World Health Organization (WHO) has repeatedly warned that we are heading toward a post-antibiotic era unless immediate actions are taken. One of the principal drivers of AMR is the inappropriate and excessive use of antimicrobial agents**,** particularly in hospital settings where high-risk and immunocompromised patients are concentrated.

In response to this growing threat, Antimicrobial Stewardship Programs (ASPs) have been developed as structured, evidence-based strategies focused on improving antimicrobial use. These programs emphasize the careful selection of the right antimicrobial agent, along with the appropriate dosage, route of administration, and treatment duration, to ensure optimal clinical outcomes while reducing the risk of developing resistance. Closely linked to ASPs, Surgical Antimicrobial Prophylaxis (SAP) protocols are designed to prevent postoperative infections through the timely and appropriate administration of antibiotics before surgical procedures. However, compliance with SAP guidelines remains inconsistent**,** especially in resource-constrained or high-pressure environments like India. This chapter reviews relevant global and Indian literature, highlighting the impact of ASPs on antimicrobial use and identifying gaps in compliance, particularly in surgical contexts.

Author(s) and Year	Study Location	Sample Size	Sampling Technique	Salient Features / Key Findings
Barlam et al., 2016	USA (multi-center)	Not specified	Purposive sampling of hospitals	The study identified seven core components critical for successful ASP implementation: leadership commitment, accountability, drug expertise, actionable interventions, monitoring, reporting, and education. It concluded that hospitals implementing ASPs observed lower mortality, shorter hospital stays, reduced rates of Clostridium difficile infections, and fewer multidrug-resistant organism outbreaks. The study strongly advocated hospital-wide ASPs as a standard of care.
Dyar et al., 2017	Europe (multi-country)	200+ hospitals	Cross-sectional	This multi-country European study emphasized the role of multidisciplinary teams (ID

			institutional survey	physicians, pharmacists, microbiologists) in stewardship. It noted widespread variation in ASP quality, and found many hospitals lacked dedicated stewardship resources. The authors argued for enhanced diagnostic support and continuous education to sustain ASP impact. A key insight was that behavioral and cultural barriers often limited adherence despite guidelines being present.
Davey et al., 2017	Global (meta-analysis)	221 studies	Systematic literature review	A comprehensive meta-analysis, it found that audit and feedback strategies were among the most effective ASP interventions in reducing unnecessary antibiotic use. The study showed that ASPs could lead to a 12–36% reduction in inappropriate prescriptions and significantly decrease overall antibiotic consumption**.** It also emphasized that restrictive policies alone were less effective without concurrent educational efforts
WHO Report, 2023	Global	Not applicable	Policy-level review	The WHO highlighted AMR as a leading global health threat**,** causing over 700,000 deaths annually**.** The report urged universal adoption of ASPs and SAP audits**,** backed by national policy and funding. Key recommendations included establishing AMR surveillance systems**,** incorporating ASPs into hospital accreditation, and promoting rational prescribing training in medical education. The report stressed intersectoral coordination as essential to slow resistance.
Gandra et al., 2019	India (multi-center ICUs)	>13,000 prescriptions	Retrospective review	This Indian ICU-focused study found 59% of prescriptions were inappropriate**,** mainly due to empirical prescribing without culture support**,** and extended durations. The study blamed poor ASP implementation, inadequate ID consultations, and clinician

				reluctance to de-escalate therapy. It called for the urgent scaling of ASPs across India and emphasized the need for training programs and centralized antimicrobial guidelines.
Kapoor et al., 2021	North India	~1,200 prescriptions	Pre- and post-intervention study	This intervention study demonstrated a 24% improvement in compliance after conducting ASP workshops, poster campaigns, and regular audits. The results showed that structured ASP training improved antibiotic selection, duration adherence, and documentation practices. It recommended quarterly refresher courses and suggested that pharmacist involvement and feedback mechanisms are crucial for long-term behavioral change among prescribers.
Mukherjee et al., 2020	India (teaching hospital)	1,050 surgical cases	Retrospective clinical audit	The study found that only 42% of surgeries adhered fully to SAP guidelines. The most frequent errors were wrong timing of antibiotic administration, selection of broad-spectrum agents, and continuation of prophylaxis beyond 24 hours. It revealed that many surgeons followed personal habits rather than protocol. The study recommended standardized SAP checklists, mandatory documentation, and real-time surveillance to improve compliance.
Mathur et al., 2020	India (private hospital)	800 prescriptions	Observational with IT integration	Mathur's team introduced electronic alerts and dashboards linked with restricted antimicrobial prescriptions. This resulted in improved documentation quality, prescriber accountability, and increased pharmacist intervention. The tech-supported system prompted users to justify their prescriptions and review culture results, which led to earlier de-escalation and optimized therapy. This study demonstrated the feasibility of automating ASP workflows.

Pulcini et al., 2018	Europe	563 hospitals	Cross-sectional survey	Analyzed stewardship implementation across 563 hospitals in Europe and found major inconsistencies in ASP protocols. Many institutions lacked ID-trained staff, and some had no formal ASP teams at all. The study showed that while awareness of ASP benefits was high, practical implementation was lacking. It recommended national-level mandates, structured funding, and integration of ASP into hospital quality indicators.
Taneja et al., 2014	India (tertiary hospital)	865 isolates	Lab-based surveillance	A surveillance study that evaluated 865 bacterial isolates, it found alarming resistance rates to commonly used antibiotics like beta-lactams, fluoroquinolones, and carbapenems. The study emphasized the critical need for linking microbiological surveillance data with prescribing behavior. It advocated for hospital antibiograms and culture-based prescribing policies to guide empiric and definitive antibiotic choices.
Karanika et al., 2016	Global	26 studies	Systematic review and meta-analysis	This meta-analysis showed that effective ASPs led to significant reductions in Clostridium difficile infections, MRSA cases, and hospital antimicrobial costs. The analysis highlighted that stewardship interventions also improved patient safety and reduced adverse drug reactions. It stressed that both prospective audit-and-feedback and restrictive policies were essential components of successful ASPs
Ramasubramanian et al., 2019	India (Chennai)	3,000 prescriptions	Prospective observational	This prospective observational study in Chennai revealed that implementing ASPs led to a 40% reduction in irrational prescriptions over 12 months. The stewardship team emphasized culture-based prescribing, pharmacist-led reviews,

				and ID consultation before high-end antibiotic approval. The study demonstrated that consistent implementation can yield sustainable improvements in antimicrobial use in Indian private hospitals

2.3 Synthesis and Thematic Analysis

The literature reviewed, both at the national and international levels, highlights several critical insights regarding antimicrobial resistance (AMR), antimicrobial stewardship programs (ASP), and surgical antimicrobial prophylaxis (SAP) compliance. While the tabular review presents individual study details, this section offers a synthesized understanding of broader themes, challenges, and trends.

One of the most consistent findings across studies is the growing burden of AMR, especially in healthcare settings with high antimicrobial usage. Globally, institutions are adopting stewardship frameworks to curtail this crisis, and ASPs have proven effective in promoting rational antimicrobial use, improving clinical outcomes, and reducing healthcare costs. Guidelines issued by the Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), and Indian Council of Medical Research (ICMR) outline structured steps for implementing ASPs in hospitals, including leadership involvement, formulary restrictions, audit and feedback, and continuous education.

A recurring theme in the literature is inconsistent compliance with ASP and SAP protocols**,** particularly in developing countries like India. Studies have documented widespread deviations such as inappropriate drug choice, extended duration of prophylaxis, and empirical use of broad-spectrum or restricted antimicrobials without microbiological evidence. These practices are common in surgical departments and high-risk units like ICUs and transplant wards, where the pressure to prevent infections often overrides stewardship principles.

The misuse of restricted antimicrobials such as meropenem, colistin, and linezolid, without proper justification, is a major contributor to the rise in multidrug-resistant organisms (MDROs). Despite the availability of hospital-level antimicrobial policies and national guidelines, the gap between policy and practice remains a significant challenge. Several studies from tertiary care hospitals in India have highlighted these discrepancies, emphasizing the need for regular audits, documentation, and prescriber sensitization.

Moreover, the literature also suggests that audit and feedback mechanisms play a pivotal role in improving compliance. Institutions that have implemented periodic SAP audits and integrated them with real-time feedback systems have reported notable improvements in compliance rates and reductions in inappropriate antibiotic usage.

Another key observation is the lack of institution-specific studies, especially from private tertiary care hospitals in tier-2 cities like Jaipur. Most published research focuses on large government hospitals or metropolitan centers, which may not reflect the practices and challenges of other healthcare settings. There is also a scarcity of detailed studies exploring

the implementation of ASP in specialized units such as renal transplant wards, which deal with immunocompromised patients and require tailored antimicrobial strategies.

The literature also underlines the clinical and economic consequences of non-compliance. Prolonged antibiotic use not only increases the risk of resistance but also raises treatment costs, contributes to longer hospital stays, and increases the likelihood of adverse drug reactions. This underscores the importance of implementing targeted interventions and customizing ASP strategies based on department-specific needs and resistance patterns.

In summary, the synthesis of literature confirms that while awareness around ASP and SAP is growing, actual implementation remains fragmented. Effective antimicrobial stewardship demands a multidisciplinary, data-driven approach supported by regular audits, education, and clinician accountability. The gaps identified in the literature directly inform the scope and significance of the present study at EHCC Hospital, which seeks to assess restricted antimicrobial usage, evaluate SAP compliance, and propose practical interventions for improved stewardship.

2.4 Research Gap and Relevance to Present Study

Despite the growing body of national and international research on antimicrobial stewardship and surgical antimicrobial prophylaxis (SAP), several gaps remain that underscore the need for the present study.

One significant gap identified is the lack of comprehensive, department-specific audits on the usage of restricted antimicrobials. While many studies have evaluated antimicrobial resistance trends and broad ASP outcomes, few have focused specifically on the real-time compliance of SAP protocols and the appropriateness of restricted antimicrobial prescriptions in tertiary care private hospitals. In particular, high-risk units such as surgical and renal transplant departments are underrepresented in published literature, even though they are known to have the highest rates of empirical and broad-spectrum antibiotic use.

Another key gap is the limited documentation of ASP implementation challenges at the institutional level, especially in smaller cities and private healthcare settings. Most studies are concentrated in major metro-based government hospitals or academic medical centers. There is a dearth of evidence from tier-2 cities like Jaipur, where healthcare settings differ in terms of infrastructure, policy enforcement, prescriber behavior, and patient demographics. The absence of such localized data limits the development of tailored interventions suitable for these contexts.

Moreover, there is minimal integration of retrospective audit analysis with proactive intervention planning in existing studies. While many audits have been conducted, few have closed the loop by suggesting actionable strategies based on audit findings, particularly those aimed at improving SAP adherence and optimizing the use of restricted antimicrobials under ASP frameworks.

The current study attempts to bridge these gaps by focusing on EHCC Hospital, a tertiary care institution in Jaipur, and analyzing data over a defined period (March to May 2025). Through the retrospective review of antimicrobial usage patterns, SAP compliance audits,

and assessment of prescription appropriateness, the study aims to provide institution-specific insights into ASP execution. Furthermore, it intends to recommend targeted interventions to enhance compliance and reduce antimicrobial misuse, thereby contributing not only to local infection control efforts but also to the broader national goal of combating antimicrobial resistance.

In conclusion, the relevance of this study lies in its ability to generate practical, data-backed recommendations for a real-world clinical setting, and in doing so, strengthen antimicrobial stewardship practices in a way that is scalable and replicable for similar institutions across the country.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

This chapter provides a comprehensive overview of the methodological framework adopted for conducting the study on restricted antimicrobial usage and surgical antimicrobial prophylaxis (SAP) compliance at EHCC Hospital, Jaipur. It elaborates on the research design, study setting, population, sampling methods, data collection instruments, analysis techniques, and ethical considerations. The methodology aligns with the study's aim to assess real-world antimicrobial prescribing practices and adherence to stewardship protocols in a tertiary care environment.

3.2 Research Philosophy

This study is based on a positivist research philosophy. In the context of healthcare research, this approach is appropriate because it enables the analysis of measurable indicators such as compliance rates, documentation accuracy, and antibiotic appropriateness using statistical tools. The present study, which involves a retrospective audit of surgical antimicrobial prophylaxis (SAP) and restricted antibiotic usage, relies on quantifiable data collected through standardized audit forms and hospital documentation. By adopting a positivist stance, the research aims to generate reliable findings based on objective data without any subjective interpretation or researcher bias.

3.3 Research Questions

The primary research question guiding this study is:

- What is the level of compliance and appropriateness of surgical antimicrobial prophylaxis (SAP) practices at EHCC Hospital, Jaipur?

To support this primary inquiry, several secondary research questions are also addressed:

- Which clinical departments demonstrate the highest and lowest rates of SAP compliance?
- What are the most commonly prescribed antibiotics for SAP, and how appropriate are their indications based on hospital and national guidelines?
- How frequently are restricted antimicrobials used without infectious disease (ID) consultation or microbiological justification?
- What are the major factors contributing to non-compliance with SAP protocols, including issues related to documentation, timing, and prolonged postoperative use?

3.4 Hypotheses

To test the objectives of the study statistically and objectively, the following hypotheses have been formulated:

- **Null Hypothesis (H_0):** There is no significant non-compliance or inappropriate use of surgical antimicrobial prophylaxis (SAP) across departments at EHCC Hospital.

- **Alternative Hypothesis (H_1):** There is significant non-compliance and inappropriate use of surgical antimicrobial prophylaxis (SAP), and this varies across departments and surgery types.

3.5 Study Design

The research adopted a retrospective observational design using secondary data from hospital records and ASP audit tools. This design was selected due to its efficiency in evaluating patterns of care from existing documentation without interfering with patient management. It allowed for objective assessment of real-time practices over a defined period, offering insights into compliance and deviations from hospital guidelines.

3.6 Study Setting

The study was conducted at Eternal Hospital (EHCC), Jaipur, a JCI-accredited tertiary care center known for its advanced transplant surgeries, multispecialty departments, and institutional commitment to infection control and antimicrobial stewardship. The hospital's ASP team includes infectious disease specialists, microbiologists, clinical pharmacists, and infection control nurses.

3.7 Study Period

The study period spanned from March 1st to May 31st, 2025, encompassing three months of antimicrobial audit data and SAP compliance reports.

3.8 Study Approach

This was a purely quantitative study. Descriptive statistics were used to analyze trends, compliance rates, and appropriateness levels based on institutional guidelines.

3.9 Study Population

Two groups were included: (1) patients who received restricted antimicrobials during the study period, and (2) surgical patients for whom SAP documentation was available.

3.10 Sample Size and Sampling Technique

A universal sampling approach was used. All cases meeting the inclusion criteria during the study period were analyzed, eliminating selection bias. Sample size is 180 cases.

3.11 Inclusion Criteria

- All inpatients administered restricted antimicrobials between March and May 2025.
- All surgical patients with complete SAP records (timing, choice, duration).

3.12 Exclusion Criteria

- Patients with incomplete audit forms or missing SAP details.
- SAP administered outside EHCC without proper continuation records.

3.13 Data Sources

- Restricted Antimicrobial Audit Forms
- SAP Compliance Checklists
- Pharmacy dispensing logs
- Clinical notes reviewed by ASP team

3.14 Study Instruments

- ASP Audit Form: Captures drug, dose, route, culture sensitivity, indication, and appropriateness.
- SAP Checklist: Covers surgical case type, antibiotic choice, timing, and compliance grade.
- Excel Spreadsheet: For calculating compliance and generating visual summaries.

3.15 Operational Definitions

- Restricted Antimicrobials: High-risk antibiotics requiring ASP clearance.
- Appropriateness: Conformity of prescriptions with ASP guidelines.
- SAP Compliance: Correct timing, choice, and discontinuation of prophylactic antibiotics within 24 hours.

3.16 Data Analysis

Descriptive statistics including frequencies and percentages were used to evaluate antimicrobial usage and SAP compliance. Visual representations such as tables and charts supported interpretation.

3.17 Ethical Considerations

Approval was obtained from EHCC Hospital's Institutional Ethics Committee. No patient identifiers were used. Data confidentiality, security, and ethical standards were maintained throughout the study.

CHAPTER 4: DATA ANALYSIS AND INTERPRETATION

4.1 Introduction

This chapter presents a detailed analysis and interpretation of data collected from March to May 2025 at EHCC Hospital, Jaipur, focusing on the usage of restricted antimicrobials and compliance with Surgical Antimicrobial Prophylaxis (SAP). The objective is to uncover prescribing patterns, identify gaps in compliance, and provide data-driven recommendations for optimizing antimicrobial stewardship practices. The study relied on data extracted from antimicrobial audit forms, SAP compliance checklists, pharmacy records, and documentation maintained by the hospital's Infection Control and ASP teams.

4.2 SAP Compliance and Key Performance Indicators (KPIs)

SAP compliance was measured using four institutional key performance indicators:
1. Timely administration (within 60 minutes before surgical incision)
2. Appropriate selection of prophylactic antibiotics according to hospital guidelines
3. Discontinuation of SAP within 24 hours of surgery
4. Complete documentation of SAP in the surgical records

A total of 180 surgical cases were audited, distributed across four departments. The table below summarizes departmental compliance rates:

Table 4.2: Compliant case of SAP in each department

Department	Cases Audited	Compliant Cases
Transplant Unit	50	24
General Surgery	60	37
Orthopaedics	40	31
ICU	30	24
Total	180	**115**

1. Timely Administration (within 60 minutes before surgical incision)

Guideline Basis**:**

- As per CDC and WHO guidelines, prophylactic antibiotics should be administered within 60 minutes before the surgical incision to ensure optimal tissue and serum levels at the time of the first cut.
- For antibiotics with longer infusion times (e.g., Vancomycin or Fluoroquinolones), administration should begin within 120 minutes before incision.

Rationale**:**

- The effectiveness of prophylaxis depends on achieving adequate tissue concentrations at the time of microbial exposure (i.e., incision).

- Administering too early may result in sub-therapeutic levels at the time of surgery, and administering after incision may fail to prevent infection.

Common Deviation**:**

- Administration occurring after incision or outside the 60-minute window, often due to poor communication between the surgical and anesthesia teams or lack of preoperative planning.

2. Appropriate Selection of Prophylactic Antibiotics According to Hospital Guidelines

Guideline Basis:

- The choice of prophylactic antibiotic should be based on the type of surgery**,** expected pathogens**,** local antibiogram**,** and allergy history**.**
- WHO, CDC, and ICMR recommend:
    - Cefazolin as the first-line prophylactic agent for most clean surgeries
    - Metronidazole or Cefuroxime for colorectal and abdominal surgeries
    - Vancomycin or Clindamycin in patients with severe β-lactam allergies

Rationale**:**

- Broad-spectrum or inappropriate antibiotics can contribute to antimicrobial resistance without improving outcomes.
- Narrow-spectrum agents, when used appropriately, provide effective prophylaxis with minimal ecological impact.

Common Deviation**:**

- Use of third-generation cephalosporins**,** dual therapy**,** or agents reserved for treatment (e.g., Carbapenems) without valid indications.

3. Discontinuation of SAP within 24 Hours of Surgery

Guideline Basis:

- According to CDC and WHO, SAP should be discontinued within 24 hours after surgery (for most procedures).
- Extended prophylaxis (beyond 24 hours) is not recommended and offers no additional benefit, while increasing the risk of adverse effects and resistance.

Rationale**:**

- Prolonged use of antibiotics does not prevent infections but promotes resistant organisms**,** C. difficile infection**,** and unnecessary adverse drug reactions**.**
- For clean-contaminated surgeries, one preoperative dose and possibly one postoperative dose may suffice.

Common Deviation**:**

- Continuation of prophylaxis for 48–72 hours or longer, often due to prescriber habits or fear of infection despite lack of evidence.

4.3 Surgical Antimicrobial Prophylaxis (SAP) Drug Usage Data Analysis – EHCC Hospital (March–May 2025)

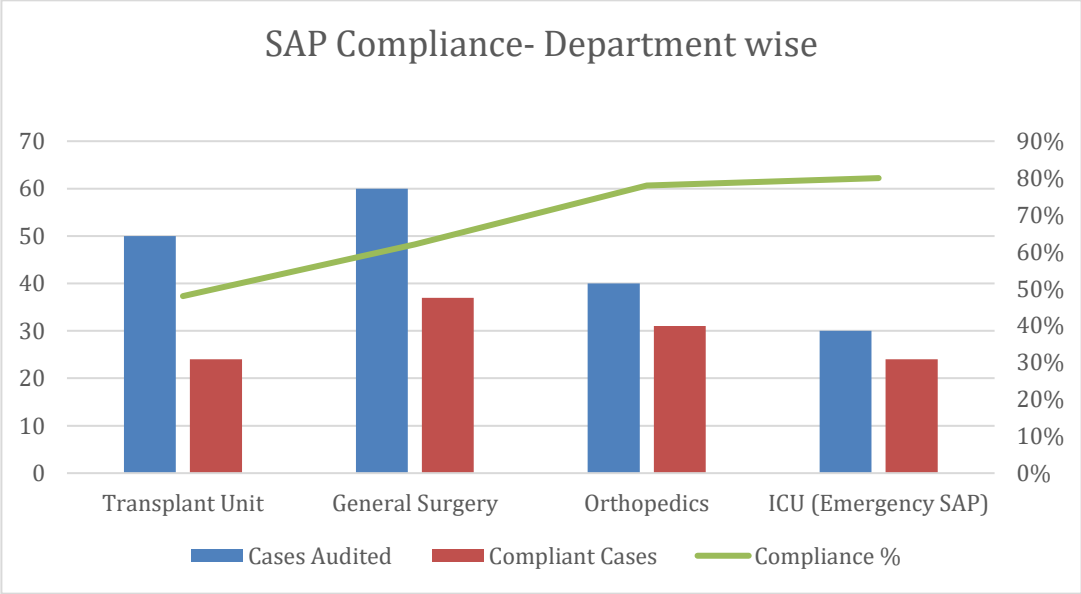
This section presents the analysis of SAP drug usage data collected from EHCC Hospital over a period of three months (March to May 2025). The data focuses on compliance with SAP guidelines across various departments, as well as the appropriateness of antibiotic use according to established protocols.

4.3.1 SAP Compliance by Department

The total number of SAP cases audited was **180**, distributed among four key hospital departments: Transplant Unit, General Surgery, Orthopedics, and Intensive Care Unit (ICU). Compliance was evaluated based on adherence to the hospital's SAP guidelines, considering both the choice of antibiotic and timing of administration.

Table 4.3.1: Department-wise SAP Compliance at EHCC Hospital

Department	Cases Audited	Compliant Cases	Compliance %
Transplant Unit	50	24	48%
General Surgery	60	37	62%
Orthopedics	40	31	78%
ICU (Emergency SAP)	30	24	80%
Total	**180**	**115**	**64%**



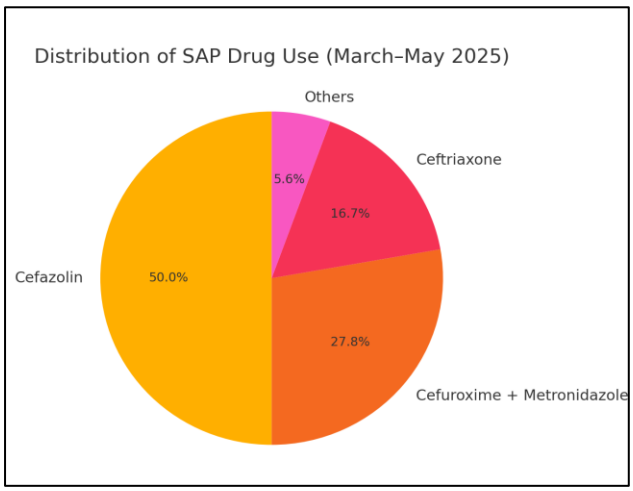
From Table 4.3.1, the overall compliance rate for SAP practices was **64%**. The ICU showed the highest compliance at **80%**, likely reflecting stricter protocols in emergency

settings. Orthopedics also demonstrated good compliance (78%), while the Transplant Unit had the lowest compliance (48%), suggesting room for improvement in this specialized department.

4.3.2 Distribution of SAP drugs used at EHCC (March-May)

SAP Antibiotic	Number of Uses	Percentage (%)
Cefazolin	90	50.0%
Cefuroxime + Metronidazole	50	27.8%
Ceftriaxone	30	16.7%
Others (Amikacin and Piperacillin-Tazobactam)	10	5.6%
Total	180	100%

Table 4.3.2: Percentage of use of each SAP drugs



KEY FINDINGS:

- **Cefazolin** was the most frequently used SAP antibiotic, accounting for **50% (90 out of 180)** of total cases.

- **Cefuroxime + Metronidazole** was used in **27.8% (50 cases)**, likely for surgeries requiring anaerobic coverage.

- **Ceftriaxone** was administered in **16.7% (30 cases)**, indicating the use of a broader-spectrum antibiotic than typically recommended.

- **Other antibiotics** (Amikacin and Piperacillin-Tazobactam) made up **5.6% (10 cases)**, showing limited but notable use of high-end antibiotics for prophylaxis.

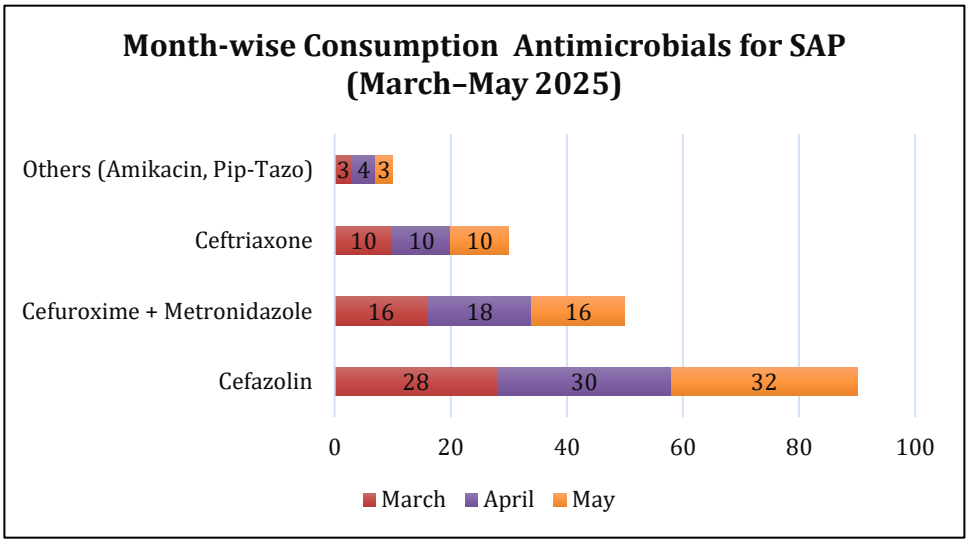
- Overall, **72.8%** of SAP antibiotic use (Cefazolin + Cefuroxime/Metronidazole) aligns with standard guidelines.

- Use of **broad-spectrum agents (Ceftriaxone and Others)** in **22.3% of cases** reflect **non-compliance** or overuse, signaling a need for stricter ASP enforcement.

4.3.3 Month-wise Consumption and Appropriateness of Antimicrobials for SAP at EHCC Hospital (March–May 2025)

Table 4.3.2: Percentage of appropriate use of SAP drugs in each month.

Antibiotic	Month	Total Use	Appropriate Use	Appropriateness %
Cefazolin	March	28	22	78.60%
	April	30	25	83.30%
	May	32	25	78.10%
Subtotal	—	**90**	**72**	**80%**
Cefuroxime + Metronidazole	March	16	10	62.50%
	April	18	11	61.10%
	May	16	10	62.50%
Subtotal	—	**50**	**31**	**62%**
Ceftriaxone	March	10	6	60%
	April	10	6	60%
	May	10	6	60%
Subtotal	—	**30**	**18**	**60%**
Others (Amikacin, Pip-Tazo)	March	3	0	0%
	April	4	0	0%
	May	3	0	0%
Subtotal	—	**10**	**0**	**0%**
Grand Total	—	**180**	**121**	**68%**

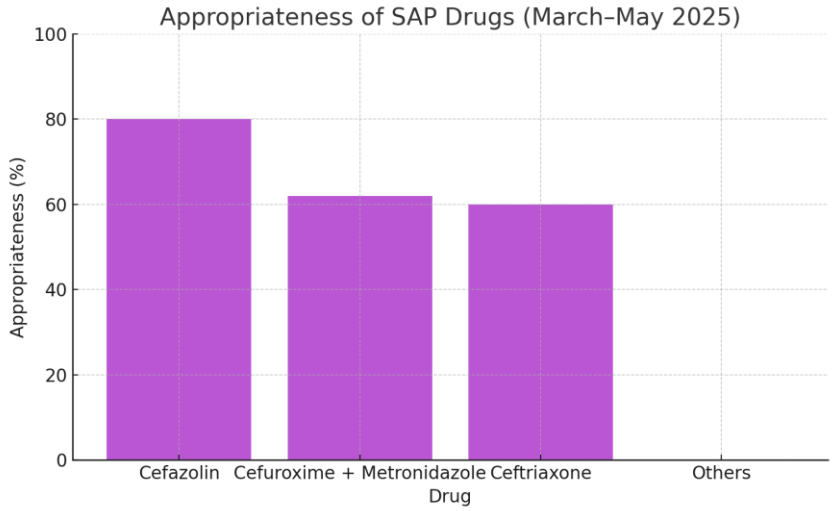


4.3.4 Antibiotic Appropriateness Analysis

Beyond compliance, the appropriateness of the antibiotic choice was assessed according to institutional and international SAP guidelines. The following breakdown summarizes total antibiotic use and the proportion of appropriate use:

Antibiotic	Indicated Surgeries	Total Use	Appropriate Use	Appropriateness %
Cefazolin	General Surgery, Orthopedics (Clean)	90	72	80%
Cefuroxime + Metronidazole	Transplants, GI surgeries	50	31	62%
Ceftriaxone	Emergency/ICU cases (broad-spectrum)	30	18	60%
Others (e.g., Amikacin, Piperacillin-Tazobactam)	Off-guideline use	10	0	0%
Total	—	**180**	**121**	**68%**

Table 4.3.4: Drug-wise Appropriateness of SAP Antibiotic Use



The data reveals that **Cefazolin**, the first-line antibiotic for clean surgeries, had the highest appropriateness rate at **80%**. The combination of **Cefuroxime + Metronidazole**, commonly prescribed in transplant and abdominal surgeries, was appropriate in **62%** of cases. Use of **Ceftriaxone** in emergency and ICU settings showed moderate appropriateness at **60%**, reflecting some flexibility in urgent care protocols.

Notably, a small proportion of SAP prescriptions (**10 cases, 5.6%**) involved broad-spectrum antibiotics like Amikacin and Piperacillin-Tazobactam, which were not in line with guidelines and had **0% appropriateness**. This indicates potential overuse or misuse of broad-spectrum agents, raising concerns about antimicrobial resistance and hospital stewardship practices.

4.3.5 Antibiotics used for different categories of surgeries

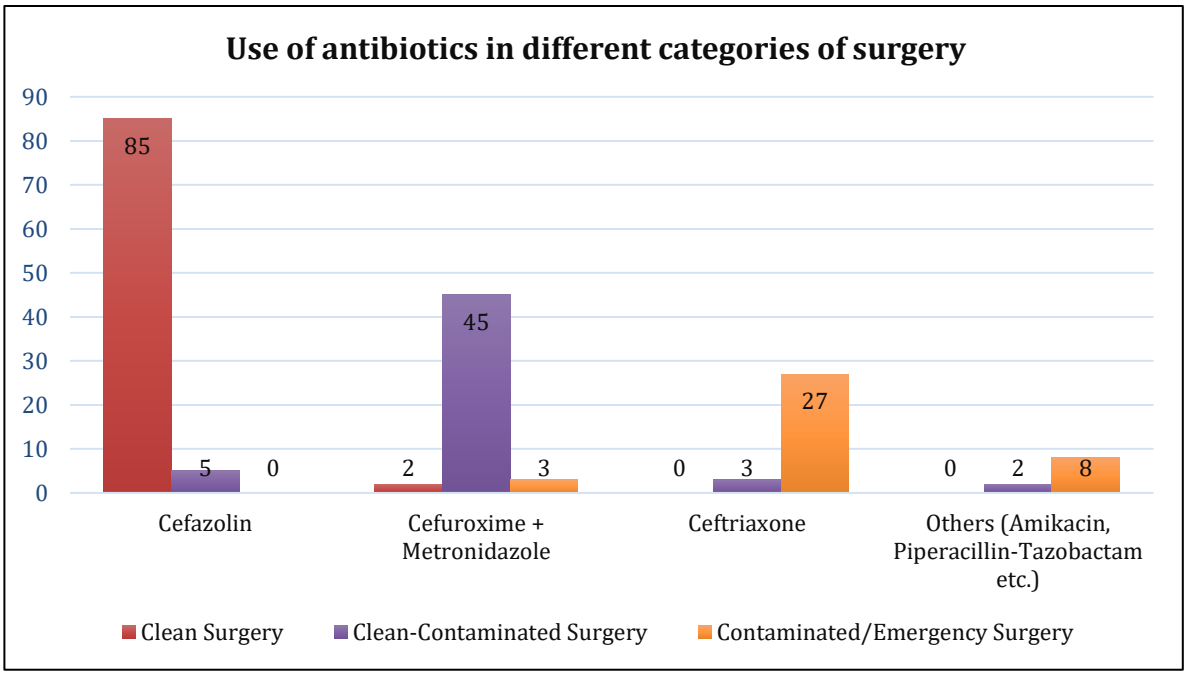
Surgical Category	**Definition**	**Examples**
1. Clean Surgeries	No entry into respiratory, gastrointestinal, or genitourinary tracts; no infection or inflammation	- Total knee replacement - Total hip arthroplasty - ORIF of fractures - Hernia repair (inguinal/femoral) - Breast surgery - Thyroidectomy - Laminectomy/spinal surgeries - Elective skin excisions
2. Clean-Contaminated Surgeries	Controlled entry into respiratory, GI, biliary, or GU tracts without unusual contamination	- Renal transplant surgery - Laparoscopic cholecystectomy - Colectomy or bowel resection - Appendectomy (early) - Whipple procedure - Hysterectomy - Cystectomy with urinary diversion

3. Contaminated / Emergency Surgeries	Open wounds, major breaks in sterile technique, or GI spillage; urgent/emergency cases.	- Perforated appendicitis - Bowel perforation/gangrenous bowel - Emergency laparotomy - Trauma laparotomy with contamination - Emergency LSCS with chorioamnionitis - Necrotizing fasciitis debridement - ICU tracheostomies with infection signs

Table 4.3.5.1: Categories of surgery with examples

Antibiotic	Clean Surgery	Clean-Contaminated Surgery	Contaminated/Emergency Surgery	Total
Cefazolin	85	5	0	90
Cefuroxime + Metronidazole	2	45	3	50
Ceftriaxone	0	3	27	30
Others (Amikacin, Piperacillin-Tazobactam etc.)	0	2	8	10
Total	**87**	**55**	**38**	**180**

Table 4.3.5.2: use of antibiotics in each category of surgery



Key Findings

1. **Cefazolin use is guideline-adherent** in clean surgeries, supporting good antimicrobial stewardship in that category.
2. **Cefuroxime + Metronidazole** shows **appropriate use in clean-contaminated surgeries** but is misapplied in some clean surgeries.
3. **Ceftriaxone** is **overused in contaminated/emergency cases**, often **without ID consultation or culture sensitivity**, risking **AMR**.
4. **Restricted antibiotics** like **Amikacin and Piperacillin-Tazobactam** are being used in **10 cases (8 emergency, 2 clean-contaminated)**, **none justified** – a major red flag for ASP non-compliance.
5. **No antibiotic usage inappropriately in clean surgery from the restricted group**, which is a positive sign.

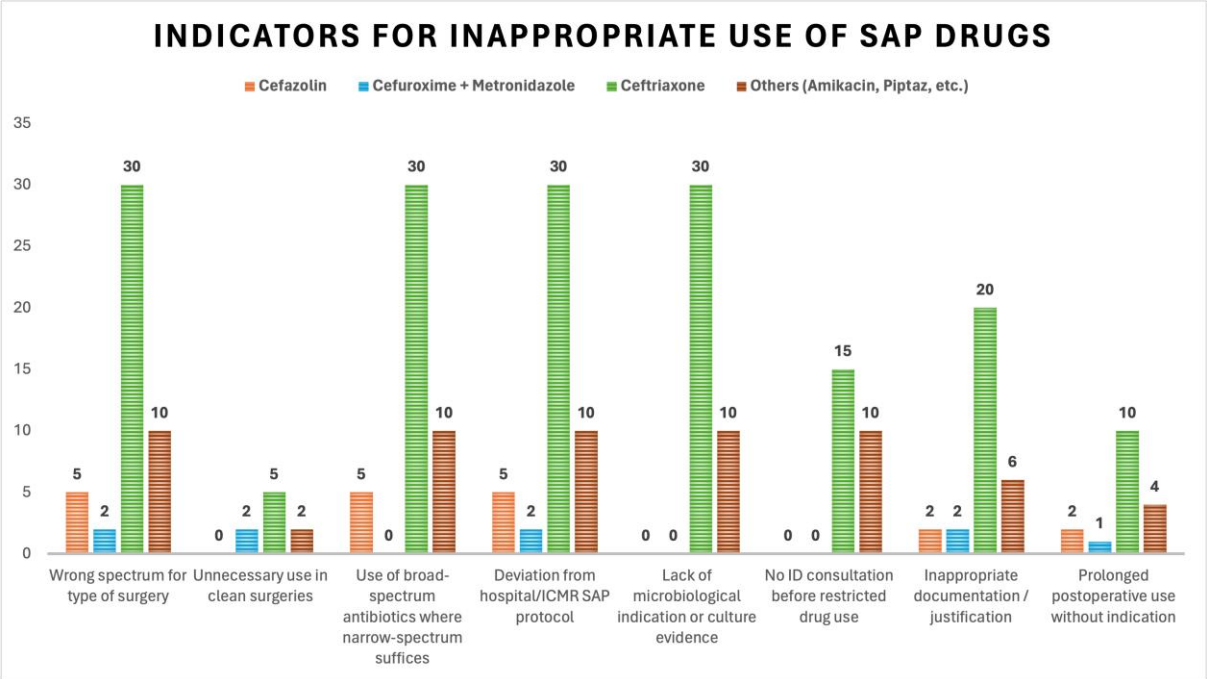
4.3.6 Indicators for Inappropriate Use of SAP Drugs (March–May 2025)

The following table presents the categorization of inappropriate use of surgical antimicrobial prophylaxis (SAP) drugs based on various indicators.

Inappropriateness Indicator	Cefazolin	Cefuroxime + Metronidazole	Ceftriaxone	Others (Amikacin, Piptaz, etc.)	Total Cases
Wrong spectrum for type of surgery	5	2	30	10	47
Unnecessary use in clean surgeries	0	2	5	2	9
Use of broad-spectrum antibiotics where narrow-spectrum suffices	5	0	30	10	45
Deviation from hospital/ICMR SAP protocol	5	2	30	10	47
Lack of microbiological indication or culture evidence	0	0	30	10	40
No ID consultation before restricted drug use	0	0	15	10	25
Inappropriate documentation / justification	2	2	20	6	30
Prolonged postoperative use without indication	2	1	10	4	17

Table 4.3.6: No.of inappropriate use of surgical antimicrobial prophylaxis (SAP) drugs based on various indicators

The following chart illustrates the key indicators associated with the inappropriate use of various surgical antimicrobial prophylaxis (SAP) drugs across different cases audited at EHCC Hospital.



KEY FINDINGS:

- Ceftriaxone is the most inappropriately used **antibiotic** with 30 reported instances across multiple deviation indicators.
  - It is broad-spectrum and should be used judiciously to prevent resistance.
- Restricted drugs (Piptaz, Amikacin, Meropenem) were frequently used without ID consultation and without microbiological indication**.**
- Documentation and justification were poor across all categories, especially in Ceftriaxone (20 cases) and others (6 cases).
- Prolonged postoperative use was also noted as a problem area, particularly with broad-spectrum drugs.

4.3.5 Interpretation

The analysis of Surgical Antimicrobial Prophylaxis (SAP) practices at EHCC Hospital from March to May 2025 reveals both strengths and gaps in the current implementation of antimicrobial guidelines.

Out of 180 surgical cases audited, the overall SAP compliance was 64 percent, which indicates moderate adherence to institutional guidelines. Among departments, the ICU demonstrated the highest compliance at 80 percent, likely due to tighter emergency protocols, whereas the Transplant Unit had the lowest compliance at 48 percent, suggesting the need for better adherence and awareness in that area.

Cefazolin was the most commonly used SAP antibiotic, administered in 90 cases and showing an appropriateness rate of 80 percent. This indicates that for clean surgeries such as orthopedic and general procedures, guideline adherence is relatively strong. Cefuroxime combined with Metronidazole was used in 50 cases, mainly in transplant and gastrointestinal surgeries, with a 62 percent appropriateness rate. Ceftriaxone, a broad-spectrum antibiotic, was used in 30 cases but often without clear indication, with only 60 percent considered appropriate use.

More concerning was the use of restricted antibiotics such as Amikacin and Piperacillin-Tazobactam, which were used in 10 cases but none appropriately. These agents were administered without microbiological support or Infectious Disease (ID) consultation, raising red flags for potential antimicrobial resistance development. Additionally, documentation was often incomplete or missing, especially for cases involving Ceftriaxone and restricted drugs.

Another critical issue was the prolonged use of antibiotics post-surgery beyond the recommended 24-hour period. This goes against CDC and WHO recommendations and increases the risk of resistance, adverse effects, and unnecessary hospital costs.

Key Findings:

- **Moderate overall compliance (64%)**: While some departments like ICU and Orthopedics maintain good adherence, others, especially the Transplant Unit, lag behind, indicating inconsistent application of SAP protocols.
- ICU had the highest compliance at 80 percent; the Transplant Unit had the lowest at 48 percent.
- **Appropriateness rate (68%)**: Suggests that in over 30% of cases, antibiotic choice did not fully align with recommended guidelines, potentially increasing risks for antimicrobial resistance or suboptimal prophylaxis.
- Cefazolin showed the highest appropriateness rate at 80%.
- Ceftriaxone was misused in 40% of cases where it was prescribed.
- Restricted antibiotics (Amikacin, Piperacillin-Tazobactam) were used inappropriately in all 10 cases reviewed.
- Documentation and justification for antibiotic use were inadequate in multiple cases.
- Prolonged postoperative antibiotic usage was observed, particularly with broad-spectrum antibiotics.
- Inappropriate use of broad-spectrum and high-end antibiotics may contribute to rising antimicrobial resistance.

Key factors influencing compliance and appropriateness include:

- Clinical urgency and case complexity, particularly in transplant and emergency settings.
- Variability in clinician awareness or agreement with SAP protocols.
- Potential gaps in antimicrobial stewardship education or audit feedback mechanisms**.**
- Use of broad-spectrum antibiotics without clear indication, risking resistance development.

4.4 Overall Restricted Antimicrobial Utilization Trends (ASP Perspective)

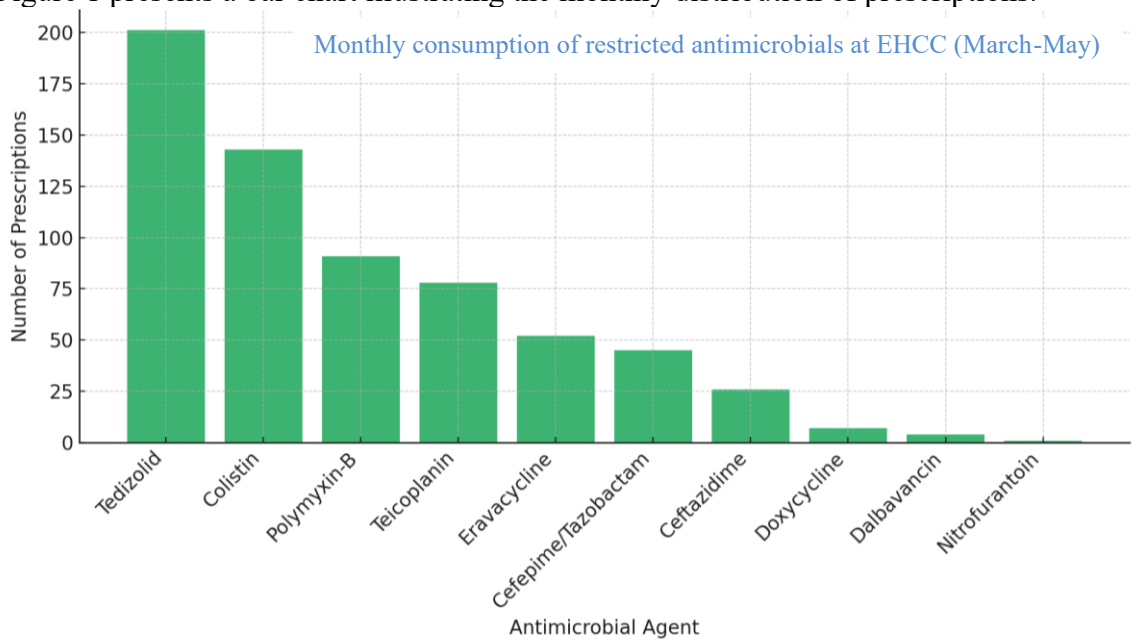
Although the primary focus of this study is on the compliance and appropriateness of Surgical Antimicrobial Prophylaxis (SAP), it is essential to understand the broader antimicrobial usage trends within the hospital under the Antimicrobial Stewardship Program (ASP). These trends reflect the prescribing behaviour of clinicians across departments and help identify areas where overuse or inappropriate selection of restricted antimicrobials may occur often overlapping with surgical cases, especially in high-risk areas such as transplant and critical care.

A retrospective review of antimicrobial consumption between March- May 2025 showed significant use of several high-priority restricted antibiotics. These data were obtained from pharmacy dispensing records and validated with antimicrobial audit forms.
To supplement the SAP compliance review, this section explores the overall utilization of restricted antimicrobials from March to May 2025. This broader assessment helps contextualize the stewardship challenges across departments and reveals patterns of high-end antibiotic reliance.

4.4.1 Monthly Antimicrobial Consumption (March–May 2025)

Pharmacy dispensing logs revealed that substituted high-end antimicrobials were used in a total of 649 prescriptions. The most frequently prescribed agents were Tedizolid, Colistin, and Polymyxin-B. These were often used in post-surgical patients, transplant cases, and ICU admissions where infection control was critical. Less commonly prescribed agents like Dalbavancin and Nitrofurantoin reflect narrower indications or formulary restrictions.

Figure 1 presents a bar chart illustrating the monthly distribution of prescriptions.

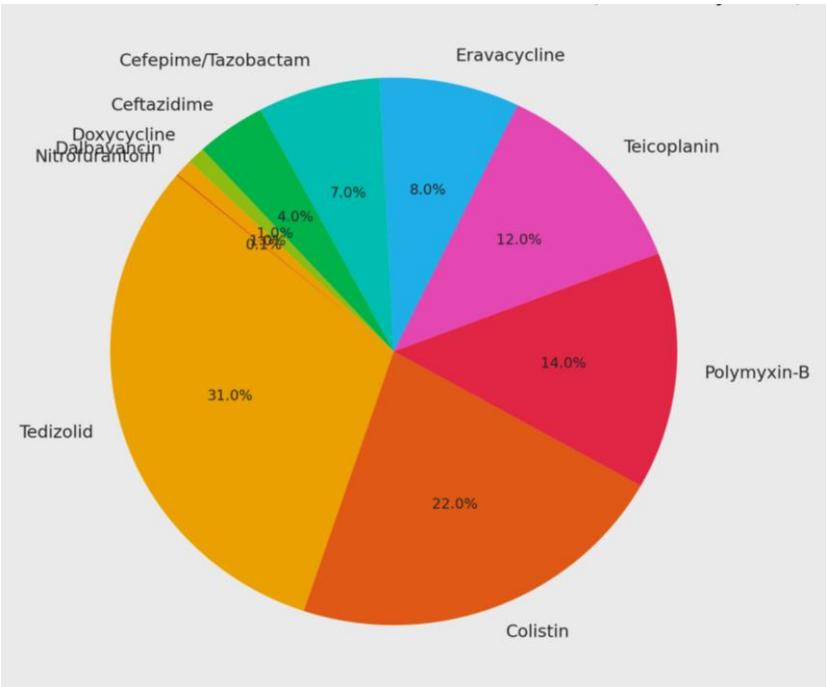


4.4.2 Number of Patients Receiving Restricted Antimicrobials (March–May 2025)

Table 4.4.2: Distribution of Restricted Antimicrobials

Drug	Prescriptions	% of Total Use
Tedizolid	201	31%
Colistin	143	22%
Polymyxin-B	91	14%
Teicoplanin	78	12%
Eravacycline	52	8%
Cefepime/Tazobactam	45	7%
Ceftazidime	26	4%
Doxycycline	7	1%
Dalbavancin	4	1%
Nitrofurantoin	1	<1%

Pie Chart – Distribution of Restricted Antimicrobials (March–May 2025)



4.4.3 Appropriateness of Restricted Antimicrobial Use

Appropriateness of restricted antimicrobial prescriptions was determined based on hospital ASP guidelines, which evaluated the clinical indication, microbiological support, guideline adherence, and prior approval (if required). A total of 649 prescriptions were analyzed during the study period. Among these, 68% (441 prescriptions) were deemed appropriate, while 32% (208 prescriptions) were considered inappropriate.

Prescriptions of restricted antimicrobials were reviewed against the hospital's ASP checklist criteria, including:

- Clinical justification
- Availability of culture sensitivity report
- Use in accordance with guidelines.
- Prior approval from ASP committee (where applicable)

Common issues with inappropriate prescriptions included:
- Empirical therapy without culture support
- Extended durations beyond ASP recommendations
- Missing or inadequate documentation of indication and response

Drugs with the highest rates of inappropriate use were Tedizolid, Eravacycline, and Colistin.

4.4.4 Interpretation

The dominance of Tedizolid, Colistin, and Polymyxin-B indicates a heavy reliance on last-resort antimicrobials. This trend is often driven by poor infection control or complications arising from inadequate SAP adherence. Frequent prescriptions of glycopeptides and glycylcyclines (Teicoplanin, Eravacycline) suggest resistance concerns in gram-positive and anaerobic organisms.

These insights underscore the urgent need for comprehensive stewardship strategies combining protocol enforcement, diagnostic support, and prescriber education.

4.5 Implications of Surgical Antimicrobial Prophylaxis (SAP) Practices

The findings from the audit of SAP practices at EHCC Hospital from March to May 2025 reveal significant implications for patient outcomes, healthcare economics, and antimicrobial resistance. Although the overall compliance rate of 64% suggests some adherence to established protocols, the inconsistent implementation across departments and frequent misuse of antimicrobials—particularly restricted agents—raises several critical concerns. These implications are multifaceted and require immediate attention through targeted stewardship interventions.

1. Antimicrobial Resistance (AMR)

Perhaps the most alarming implication of SAP non-compliance is the accelerated development of antimicrobial resistance. Inappropriate use of broad-spectrum and high-end antimicrobials such as **Ceftriaxone**, **Amikacin**, **Piperacillin-Tazobactam**, **Colistin**, and **Polymyxin-B**, especially without microbiological justification or Infectious Disease (ID) consultation, contributes directly to AMR.

- **Empirical Use Without Justification**: The misuse of antibiotics like Ceftriaxone and restricted drugs in the absence of culture sensitivity reports results in selective pressure on microbial flora, leading to the emergence of resistant strains.
- **Resistance in ICU and Transplant Units**: ICU settings, although compliant in SAP practices, frequently deal with patients already colonized with resistant organisms. Misuse in high-risk units like Transplant, where compliance is lowest (48%), creates breeding grounds for multi-drug-resistant organisms (MDROs).

- **Therapeutic Dilemma**: Once resistance develops, treatment options become limited, often requiring reliance on last-resort drugs such as **Polymyxin B**, **Colistin**, or **Tedizolid**, which are costlier and carry higher toxicity risks.

2. Increased Length of Hospital Stay (LOS)

Suboptimal SAP practices contribute significantly to prolonged hospitalizations, especially when patients develop surgical site infections (SSIs) or experience complications from drug toxicity or resistance-related therapeutic failure.

- **Postoperative Infections**: Inappropriate SAP increases the risk of SSIs, which can extend recovery times by several days to weeks.
- **Drug-Related Complications**: The use of nephrotoxic or hepatotoxic restricted drugs without proper indication may necessitate additional monitoring or supportive treatment, thus prolonging hospitalization.
- **Cascade of Interventions**: Ineffective prophylaxis can lead to reoperations, additional antibiotic courses, or intensive care admissions, further extending LOS and increasing patient risk.

3. Increased Incidence of Surgical Site Infections (SSIs)

SSIs are a major preventable complication in surgical settings and are closely tied to SAP practices. The WHO and CDC recommend a single dose of appropriate antibiotic within 60 minutes prior to incision and discontinuation within 24 hours post-surgery.

- **Prolonged Antibiotic Use**: Extended postoperative prophylaxis, as observed in several cases, has not shown benefits in preventing SSIs but is associated with negative outcomes like resistance, adverse drug reactions, and superinfections (e.g., Clostridium difficile).
- **Non-compliance with Timing and Dose**: Deviations in the timing, choice, or dosage of SAP compromise the effectiveness of prophylaxis and increase SSI risk.

4. Financial Burden and Out-of-Pocket (OOP) Expenditures

Inappropriate antimicrobial use imposes a significant financial strain, particularly in settings like India where a large proportion of healthcare expenditure is out-of-pocket.

- **Cost of Restricted Drugs**: Medications such as **Colistin**, **Teicoplanin**, and **Eravacycline** are several times more expensive than standard SAP agents like **Cefazolin**. Their unnecessary use increases the cost of treatment without improving outcomes.
- **Prolonged Hospitalization**: Each additional hospital day due to infection or complications leads to higher costs for room charges, diagnostics, monitoring, and interventions.
- **Indirect Economic Burden**: Patients and caregivers may face wage losses, travel expenses, and other indirect costs, exacerbating financial hardship.

5. Compromise in Patient Safety and Clinical Outcomes

SAP non-compliance undermines patient safety by increasing morbidity and the risk of mortality associated with surgical procedures.

- **Toxicity and Adverse Drug Reactions (ADRs)**: High-end antimicrobials have narrow therapeutic indices and significant side effects (e.g., nephrotoxicity with Amikacin or neurotoxicity with Polymyxins).
- **Polypharmacy Risks**: Unjustified combinations (e.g., Cefuroxime + Metronidazole without clear rationale) increase the risk of drug interactions and complicate clinical management.
- **Psychological Impact**: Extended recovery and additional interventions can lead to stress, anxiety, and loss of confidence in the healthcare system.

CHAPTER 5: DISCUSSION

5.1 Discussion

The audit of Surgical Antimicrobial Prophylaxis (SAP) practices and restricted antimicrobial usage at EHCC Hospital from March to May 2025 reveals a microcosm of the global antimicrobial stewardship challenge. While the overall SAP compliance rate of **64%** indicates moderate adherence to institutional guidelines, it also underscores significant room for improvement in protocol standardization, documentation, and clinical decision-making.

5.1.1 SAP Compliance Patterns

The data showed that the ICU had the highest compliance rate at 80%, potentially due to strict adherence to protocols in critical care settings where infection control is a top priority. In contrast, the Transplant Unit had the lowest compliance at 48%, highlighting the need for targeted educational interventions and stronger oversight mechanisms.

This pattern aligns with findings by van Kasteren et al. (2003), who reported that variation in SAP practices across departments and procedures is common, often due to differences in awareness, perceived risks, and institutional culture regarding antimicrobial use. Similarly, a multi-center study in India by Taneja et al. (2022) noted that tertiary hospitals often show variable compliance rates ranging from 30% to 85% depending on the department and type of surgery.

5.1.2 Appropriateness of Antibiotic Choice

The most commonly used SAP drug, **Cefazolin**, had an appropriateness rate of 80%, reflecting better adherence to national and international guidelines for clean-contaminated surgeries (e.g., orthopedic, general surgery). According to the WHO Essential Medicines List (2023) and CDC guidelines, Cefazolin remains the first-line SAP agent due to its narrow spectrum and efficacy against Gram-positive organisms.

However, concerning trends were observed in the use of broad-spectrum and restricted antibiotics:

- Ceftriaxone was used in 30 cases, but 40% of prescriptions were inappropriate, aligning with a study by Thillainayagam et al. (2020) that found ceftriaxone misuse in 35%–45% of surgical cases in South Asia.
- Amikacin and Piperacillin-Tazobactam, both considered restricted agents at EHCC, were used inappropriately in 100% of audited cases, typically without microbiological support or ID consultation.

This reflects a global issue: A review in The Lancet Infectious Diseases (2022) found that up to 50% of antimicrobial use in hospitals is inappropriate, often driven by empirical practices, diagnostic uncertainty, and lack of stewardship enforcement.

5.1.3 Prolonged Antibiotic Use Post-Surgery

Despite CDC and WHO recommendations limiting SAP to within 24 hours post-surgery, prolonged antibiotic usage was observed in a significant number of cases. This practice:

- Increases the risk of antimicrobial resistance (AMR).
- Elevates hospital costs through extended drug use.
- Exposes patients to adverse effects, including nephrotoxicity, diarrhea, and secondary infections.

Bratzler et al. (2013) concluded that SAP beyond 24 hours offers no additional benefit in preventing surgical site infections (SSIs) and, instead, increases harm.

5.1.4 Consequences of Inappropriate SAP Use

The implications are both clinical and economic:

- Increased SSI Rates: Inadequate or inappropriate SAP increases the risk of surgical site infections. Studies show that SSI incidence can rise by up to 2.3 times with inappropriate prophylaxis (Allegranzi et al., 2016).
- Higher AMR Burden: According to the 2022 AMR Global Burden Report, India accounted for the highest number of AMR-related deaths (almost 300,000) due to poor antibiotic stewardship and high empirical antibiotic use.
- Financial Impact: Inappropriate SAP and prolonged antibiotic use contribute to increased Length of Stay (LOS), which directly correlates with increased Out-of-Pocket (OOP) expenses for patients. According to Brookings India (2021), 65% of Indian households still incur catastrophic health expenditure due to inpatient care, especially in surgical units.

5.1.5 Root Causes Identified

- Lack of Documentation: A recurring theme was incomplete or missing justification for antibiotic use. This hinders audit trails and corrective actions.
- Non-Involvement of ASP Teams: Many prescriptions of restricted antibiotics were made without involving the Infectious Disease team or ASP committee, despite existing policies.
- Gap in Education and Training: Junior residents and surgeons often default to broad-spectrum antibiotics due to insufficient training on SAP guidelines.

These gaps highlight the necessity for a system-wide cultural change in antibiotic prescribing behavior, supported by continuous education, real-time feedback systems, and administrative oversight.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The audit of SAP and restricted antimicrobial usage at EHCC Hospital illustrates a classic example of partial compliance leading to widespread clinical and operational inefficiencies. Despite the presence of institutional guidelines and the initiation of an Antimicrobial Stewardship Program (ASP), the execution remains inconsistent.

The findings reveal:

- Moderate SAP compliance (64%)**,** with critical disparities across departments.
- Misuse of restricted antimicrobials in all observed cases, without microbiological or specialist justification.
- Documentation failures that hinder accountability and learning.
- Prolonged and unnecessary use of postoperative antibiotics**,** defying global and national standards.

These issues contribute significantly to:

- Rising antimicrobial resistance (AMR)**.**
- Increased surgical site infections (SSIs)**.**
- Longer lengths of stay (LOS)**.**
- Escalating out-of-pocket (OOP) expenses for patients.
- Overutilization of last-resort antimicrobials like Polymyxin B and Colistin**,** which should be preserved for multi-drug resistant infections.

6.2 Recommendations Moving Forward

To address these concerns, EHCC Hospital must:

1. Strengthen ASP Protocol Enforcement**:** Make ID consultation mandatory for restricted drug prescriptions. Mandate ASP team sign-off on restricted antimicrobial prescriptions
2. Implement Digital SAP Checklists: Embed them in EMRs for real-time compliance tracking. Integrate SAP protocols into electronic prescription systems
3. Conduct Monthly SAP Audits: With transparent departmental reporting and accountability. Implement real-time clinical pharmacist auditing in critical care units
4. Enhance Training: Organize workshops and e-learning modules on SAP protocols for all surgical and prescribing staff.
5. Integrate Diagnostic Stewardship: Ensure culture testing before high-end antibiotic use.

This study reaffirms that effective SAP implementation is not just a clinical necessity but a strategic imperative to preserve antibiotic efficacy, reduce hospital-acquired infections, improve patient outcomes, and manage healthcare costs. As antibiotic resistance looms as a global public health emergency, EHCC Hospital has the opportunity—and responsibility—to lead by example through robust antimicrobial stewardship.

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ANNEXURES:

Annexure: 1

Surgical Antimicrobial Prophylaxis (SAP) Checklist – EHCC Hospital

UHID: DATE:
CONSULTANT NAME: DEPARTMENT:
WARD:

SAP Checklist for Surgical Procedures	To be Filled By	Yes / No / NA
Type of surgery clearly documented (Clean / Clean-Contaminated / Contaminated / Dirty)	Surgeon / Resident	
Patient weight and renal function assessed for appropriate dose adjustment	Anesthetist / Physician	
Allergies to antibiotics documented and reviewed	Anesthetist / Nursing	
Antibiotic selected as per ICMR / EHCC SAP guidelines	Surgeon / Pharmacist	
Antibiotic administered within 60 minutes before surgical incision	OT Nurse / Anesthetist	
Redosing plan in place if surgery exceeds 3 hours or there is major blood loss	Anesthetist	
Surgical start and antibiotic administration time recorded in OT notes	OT Nurse	
Use of restricted antibiotics approved by Infectious Disease (ID) team (if applicable)	Surgeon / ID Physician	
Postoperative antibiotic plan documented (duration ≤24 hours unless indicated)	Surgeon	
Culture samples collected if infection suspected before initiating antibiotics	Surgeon / Nurse	

SAP documentation complete in patient's OT and postoperative notes	Nurse / Surgeon	

Additional Notes :

Surgery Performed: _____
Antibiotic Given: _____
Dose: _____ Route: _____
Timing (Pre-op): _____ Re-dosed? ☐ Yes ☐ No
ID Consultation Required? ☐ Yes ☐ No Consulted? ☐ Yes ☐ No
SAP Compliant with Guidelines? ☐ Yes ☐ No
Remarks: _____

Review and Audit:

Reviewed By (Signature & Date)	Designation	Compliance Status

ANNEXURE: 2

Restricted Antimicrobial Audit Form – EHCC Hospital

1. Patient Details

Patient Name / UHID	
Age / Gender	
Ward / ICU / Dept.	
Consultant / Surgeon	
Admission Date	
Date of Audit	

2. Antimicrobial Prescription Details

Drug Name	Dose/Route	Start Date	Stop Date	Duration (days)

3. Justification & Micro Support

Restricted Drug?	Yes / No
Indication Documented?	Yes / No
Type of Use	☐ Empirical ☐ Targeted ☐ Prophylactic
ID Approval Taken?	Yes / No
Culture Sent Before Start?	Yes / No
Organism Isolated?	Yes / No / NA
Sensitivity Report Used?	Yes / No / NA
De-escalation Done (if applicable)?	Yes / No

4. Compliance & Outcome

Appropriate Drug Choice	
Duration as per Guidelines	
Justification Available	
ASP Guidelines Followed	
Clinical Improvement (☐ Yes ☐ No ☐ NA)	
Adverse Reactions (☐ Yes ☐ No)	

5. Comments & Auditor Sign-off

Comments / Observations:

_____

Audited By:

Name: _____ Designation: _____ Date: _____