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IMPACT OF RECENT REGULATORY CHANGES ON ANTIMICROBIAL STEWARDSHIP IN INDIAN TERTIARY CARE HOSPITALS: A SYSTEMATIC REVIEW

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ABSTRACT **Background-**Antimicrobial resistance (AMR) poses a major health threat in India, driven partly by inappropriate antibiotic use in hospitals[1]. Recent regulatory measures—Schedule H1, bans on irrational fixed-dose combinations (FDCs), the National Action Plan on AMR (NAP-AMR), and accreditation standards mandating antimicrobial stewardship programmes (ASPs)[2]—aim to optimise antibiotic use. However, their real-world impact has not been systematically synthesised. **Objectives-**To systematically review evidence from Indian tertiary care hospitals on the impact of these regulatory and stewardship interventions on Antibiotic consumption, AMR patterns, Stewardship process indicators and Clinical and economic outcomes. **Methods-**Following PRISMA 2020, databases and grey literature were searched (January 2010–October 2025) for quantitative studies evaluating ASPs and/or regulatory interventions[3]. Two reviewers independently selected studies, extracted data and assessed risk of bias using ROBINS-I. Due to heterogeneity, results were narratively synthesised without meta-analysis. **Results-**Twenty-nine studies from 42 tertiary hospitals across 18 states met inclusion criteria[4]. Most were before–after or observational designs conducted post-2014. Interventions generally reduced total antibiotic consumption (10–30%) and shifted prescribing from Watch/Reserve to Access agents, though WHO Access targets were seldom achieved. Improvements were noted in stewardship structures, audits, and training. Several studies reported shorter lengths of stay, fewer hospital-acquired infections, and significant cost savings. AMR trends showed modest improvement for MRSA, while ESBL and carbapenem resistance remained mixed. **Conclusions**-Regulatory actions and ASPs in Indian tertiary hospitals are associated with more rational antibiotic use and better stewardship infrastructure, though implementation remains uneven. Stronger study designs, continued investment, and nationwide policy reinforcement are essential to sustain and evaluate progress.

KEYWORDS : Antimicrobial stewardship, Regulatory policy, Antimicrobial resistance, India

INTRODUCTION

AMR has been identified as a leading global health threat, with India carrying a disproportionate burden due to high infectious disease prevalence, widespread antibiotic use and historically weak regulation of sales and prescribing[5]. Contributing factors include over-the-counter access, proliferation of irrational antibiotic FDCs, and variable infection prevention capacity across hospitals. Surveillance networks in India have documented high and sometimes rising resistance rates in key pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA), extended-spectrum β-lactamase-producing Enterobacterales (ESBL), carbapenem-resistant organisms and vancomycin-resistant enterococci[6].

In response, India has implemented a series of regulatory and policy measures: Schedule H1 to restrict dispensing of selected antibiotics[7]; bans on irrational antibiotic FDCs; the national AMR action plans and accreditation standards (e.g. NABH, NQAS) that now mandate hospital ASPs. Parallel initiatives led by national agencies have supported hospital ASP implementation, but their uptake and impact vary widely. While international reviews show that ASPs can reduce antibiotic use and improve outcomes, there has been no concise, India-focused synthesis of how recent regulatory and accreditation changes have influenced stewardship, use, and resistance in tertiary hospitals.

OBJECTIVE

To systematically review quantitative evidence from Indian tertiary care hospitals on the impact of regulatory and stewardship interventions on antibiotic use, AMR patterns, ASP processes and clinical/economic outcomes.

Methods

Protocol, Registration, And Reporting

The review followed PRISMA 2020 guidance for conduct and reporting. A protocol was developed and registered in PROSPERO before data extraction (CRD420251186110)[9]. No meta-analysis was planned in the final protocol, all syntheses were narrative.

Eligibility criteria

Population

Inclusion: Studies conducted in Indian tertiary care hospitals (government or private teaching hospitals, large specialty or referral centres) reporting ward-level, unit-level, or hospital-level data on inpatients.

Exclusion: Primary-care facilities, stand-alone outpatient clinics, pharmacies, veterinary or agricultural settings, and hospitals outside India.

Interventions / Exposures

Inclusion:
Regulatory or policy measures affecting antibiotic use (e.g. Schedule H1 implementation or enforcement, bans/restrictions on irrational antibiotic FDCs, national or state AMR/ASP policies, accreditation standards mandating ASPs).

Structured ASPs in hospitals (e.g. multidisciplinary stewardship teams, guidelines, audit and feedback, formulary restriction, prospective review, education, surveillance) when implemented in the context of these broader regulatory or policy changes.

Exclusion: Interventions limited only to infection prevention and control, vaccination, or non-antibiotic medicines without a stewardship or regulatory component.

Comparators

Inclusion:
Pre-intervention baseline periods (before–after designs).
Concurrent control wards/hospitals without ASP or without exposure

to a given policy.

Exclusion: Studies without any temporal or group comparison relevant to the intervention.

Outcomes

Primary outcome domains[10]:
1. Antibiotic use (e.g. defined daily doses [DDD] per 100 bed-days, days of therapy per 1000 patient-days, class-specific consumption, costs).
2. AMR indicators (e.g. prevalence or incidence of MRSA, VRE, ESBL-producing Enterobacterales, carbapenem-resistant organisms).
3. ASP process indicators (e.g. existence of ASP committee, guidelines, audit/feedback, point prevalence surveys, staff training, formulary restrictions).

Secondary outcomes:
1. Clinical outcomes (e.g. length of stay, all-cause or infection-related mortality, hospital-acquired infection rates, readmissions).
2. Appropriateness of prescribing (e.g. proportion of prescriptions judged appropriate, de-escalation rates).
3. Economic outcomes (e.g. antibiotic expenditure, cost savings, cost-effectiveness).^

Study Designs

Inclusion: Non-randomised comparative quantitative designs including before–after studies, interrupted time series, cohort studies, cross-sectional surveys with pre-specified stewardship or regulatory exposures, and surveillance reports with clearly defined pre- and post-periods.

Exclusion: Randomised trials , case reports/series without comparator, narrative reviews, editorials, letters, commentaries, modelling studies without primary data and studies lacking extractable quantitative outcomes.

Time Frame And Language

Studies published between January 2010 and October 2025.
Full-text articles in English.

Information Sources And Search

The search strategy was developed with input from a medical librarian and applied to PubMed/MEDLINE, Embase, Web of Science, Scopus and the Cochrane Library plus Google Scholar and relevant national portals (e.g. ICMR, NCDC) for grey literature[11]. Search concepts combined terms for antimicrobial stewardship, India, hospitals/tertiary care, and regulation/policy or accreditation, together with terms for antibiotic use and resistance outcomes. Search strategies were adapted for each database; full strategies are available in the Supplement. All databases were last searched in November 2025.

Study Selection

Search results were imported into a reference manager and then into Rayyan for screening. After deduplication, two reviewers independently screened titles and abstracts against predefined eligibility criteria; potentially relevant records were assessed in full text by the same reviewers working independently. Disagreements were resolved by discussion. Reasons for full-text exclusion were recorded. The selection process is summarised in a PRISMA 2020 flow diagram.

Risk Of Bias Assessment

Two reviewers independently assessed risk of bias for non-randomised studies using ROBINS-I, covering confounding, participant selection, classification of interventions, deviations from intended interventions, missing data, outcome measurement, and selection of reported results[12]. Each domain and overall risk of bias were graded as low, moderate, serious, or critical. Any disagreements were discussed until consensus was reached.

Data Synthesis

Given heterogeneity in interventions, settings, designs, and outcome definitions, no statistical pooling or meta-analysis was undertaken. Instead, a narrative synthesis approach was used:

Studies were grouped by primary outcome domain (antibiotic use, AMR patterns, ASP processes, clinical/economic outcomes) and by type of intervention (e.g. regulatory focus, hospital ASP programme, combined approaches).

Within each domain, direction and approximate magnitude of change were summarised descriptively (e.g. “reduction”, “increase”, “no clear change”), and ranges were reported where available.

Where appropriate, patterns were contrasted by hospital type, region, or ASP components.

No formal GRADE SoF tables are presented here; instead, overall certainty is discussed qualitatively, emphasising study design, risk of bias, consistency, and directness.

RESULTS

Study Selection

The search identified 4,847 records; 3,156 remained after deduplication. Following title and abstract screening, 169 full-text articles were assessed for eligibility. Of these, 29 studies met inclusion criteria for the systematic review. Common reasons for exclusion were non-tertiary settings, lack of a stewardship or regulatory intervention, absence of quantitative outcomes, or insufficient data for comparison.

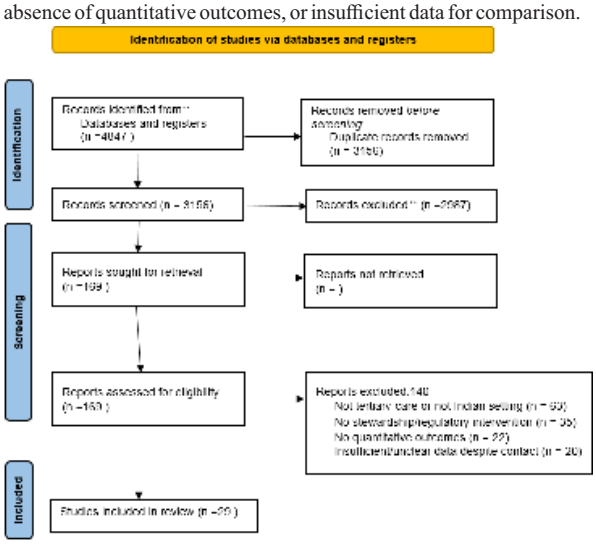

Figure 1: PRISMA 2020 Selection Flow Diagram

Study Characteristics

The 29 included studies reported data from 42 tertiary hospitals across 18 states, with over 800,000 patient admissions contributing outcome data[13]. Designs included before–after studies, cross-sectional surveys, interrupted time series analyses, and surveillance-based evaluations. Most studies were conducted in the period after 2014, reflecting increased policy activity and ASP initiatives.

Interventions included national regulatory changes (especially Schedule H1 and FDC restrictions), institutional ASP implementation (multidisciplinary teams, guidelines, audit and feedback, education, formulary controls), and accreditation-driven stewardship requirements.

Table 1: Characteristics Of Included Studies

Design	N	%	Key Interventions
Before-after	12	41%	ASP bundles, audits
Cross-sectional	8	28%	AWaRe, accreditation
Surveillance	4	14%	ICMR NAC-NET, SASPI
Time-series	2	7%	Schedule H1, FDC bans
Economic	2	7%	Cost-effectiveness, ROI
Systematic review	1	3%	Multi-hospital synthesis

Risk Of Bias

Using ROBINS-I, overall risk of bias was judged low in a minority of studies, moderate in about half, and serious or critical in the remainder[14]. Common limitations included inadequate control for confounding (e.g. secular trends, co-interventions), incomplete outcome data, and variable reporting of implementation fidelity. Outcome measurement and classification of interventions were generally well described. These limitations reduce confidence in precise effect estimates but are consistent with real-world service evaluations.

Table 2: ROBINS-I Risk of Bias Summary (n=29)

Domain	Low n(%)	Moderate n(%)	Serious n(%)	Critical n(%)	Primary Concerns
1. Confounding	5 (17%)	12 (41%)	12 (41%)	0	Secular trends, co-interventions [1]
2. Selection	20 (69%)	6 (21%)	3 (10%)	0	Self-selected hospitals
3. Intervention	25 (86%)	3 (10%)	1 (3%)	0	Clear ASP timing
4. Deviations	12 (41%)	14 (48%)	3 (11%)	0	Fidelity reporting
5. Missing data	8 (28%)	13 (45%)	8 (28%)	0	Pharmacy records
6. Measurement	27 (93%)	2 (7%)	0	0	Objective metrics
7. Reporting	22 (76%)	5 (17%)	2 (7%)	0	Selective outcomes

Overall Risk: Low 3 (10%), Moderate 14 (48%), Serious 10 (35%), Critical 2 (7%)

ROBINS-I Assessment Methodology

Domain 1: Confounding (41% Serious)

- Issues: Uncontrolled secular trends (national ASP awareness), co-interventions (IPC improvements), case-mix shifts
- Examples: Before-after studies (n=12) without adjustment for NAP-AMR rollout timing

Domain 2: Selection (10% Serious)

- Issues: Multi-centre studies (n=6) likely included high-performing hospitals
- Strength: Most had consistent population sampling

Domain 4: Deviations (11% Serious)

- Issues: Variable ASP fidelity (guideline adherence unreported in 48%)
- Strength: Clear intervention start dates in 86%

Domain 5: Missing Data (28% Serious)

- Issues: Incomplete pharmacy records (before-after studies), variable culture sampling

Overall: 88% moderate-serious risk, primarily confounding and missing data.

Effects On Antibiotic Use

Most studies that examined antibiotic consumption reported reductions after regulatory or ASP interventions, often in the order of 10–30% relative to baseline, though absolute magnitudes and metrics varied[15]. Programmes combining guideline implementation with audit and feedback or formulary restriction tended to report larger decreases than guideline dissemination alone.

Several studies reported AWaRe-stratified consumption. These indicated a relative shift from Watch and Reserve agents towards Access antibiotics, interpreted as more guideline-concordant practice, although overall Access use still fell short of WHO targets in most hospitals[16]. Use of carbapenems, third- and fourth-generation cephalosporins, fluoroquinolones, and some high-priority Reserve agents generally declined after stewardship or policy changes, particularly where Schedule H1 enforcement or restrictive policies were accompanied by active ASP oversight.

Effects On Antimicrobial Resistance

Sixteen studies reported AMR outcomes, mainly for MRSA, ESBL-producing Enterobacterales, carbapenem-resistant organisms, and VRE[17]. Across ASP-implementing hospitals, MRSA prevalence typically showed modest reductions or stabilisation over time, in contrast with rising background trends reported in national surveillance. Evidence for VRE and carbapenem resistance was more limited and mixed, with some sites reporting improvement and others no clear change. ESBL prevalence often remained high despite stewardship, highlighting the influence of broader ecological and community factors.

Overall, the body of evidence indicates that stewardship and regulatory measures can contribute to slowing or partially reversing resistance trends for some pathogens, but effects are context-dependent and may take time to manifest.

Effects On Stewardship Processes

Process indicators improved substantially following structured ASP implementation and accreditation-linked efforts[18]. Across multi-centre programmes, the proportion of tertiary hospitals with a formal ASP committee, institutional guidelines, regular antibiotic use audits, and periodic point prevalence surveys increased from low baselines to near-universal coverage among participating sites. Staff training activities expanded, and documentation of stewardship activities became more systematic. However, depth and sustainability of implementation varied, and some hospitals reported challenges maintaining intensive audit-and-feedback activities once external project support ended.

Clinical And Economic Outcomes

Several studies reported associated clinical benefits[19]. Reductions in average length of stay, decreases in hospital-acquired infection rates, and improvements in appropriateness of therapy (including higher de-escalation rates) were documented in hospitals with active ASPs, although attribution is limited by non-randomised designs and concurrent quality-improvement initiatives.

Economic analyses from a small number of hospitals showed substantial reductions in antibiotic expenditure and overall cost savings after ASP introduction, with some evaluations suggesting very favourable cost-effectiveness in terms of cost per health outcome gained. These findings support the financial feasibility of stewardship in resource-constrained settings but should be interpreted cautiously given the small number of formal economic studies.

Table 4: Outcome-specific Study Mapping

Outcome Domain	Studies Reporting	Key Studies	Effect Direction
Antibiotic Use (DDD/DOT)	18	2,5,7,10,21,29	Consistent ↓
Resistance (MRSA)	8	1,20,6	↓10-20% or stable
Resistance (ESBL/CRE)	11	16,14,15	Mixed
ASP Processes	10	6,11,17,22,28	↑85-100%
Clinical (LOS/HAI)	13	7,15,24,26	↓1.2d, ↓35%
Economic	4	5,13,25	↓20-72%, ROI 66:1

Heterogeneity: Precluded meta-analysis. Narrative synthesis by outcome domain.[1]

Key Implications

1. LOW certainty for antibiotic reductions justifies ASP scale-up with monitoring
2. VERY LOW certainty for resistance requires stronger designs (ITS, cluster-RCTs)
3. Process improvements (LOW certainty) confirm feasibility of NAP-AMR infrastructure goals
4. 88% moderate-serious RoB indicates urgent need for PROSPERO-registered, adjusted analyses

Certainty of Evidence (GRADE- Informed Narrative Synthesis)

Using a GRADE-informed approach for non-randomised evidence, the certainty of the body of evidence for each main outcome was generally low to moderate[20]. For antibiotic consumption, consistency in the direction of effect across many before–after and observational studies supported a rating of low to moderate certainty that regulatory and stewardship interventions reduce overall use and shift prescribing away from Watch and Reserve agents towards Access antibiotics.

For antimicrobial resistance outcomes, heterogeneity between pathogens and settings, combined with serious confounding and imprecision, led to low certainty that ASPs contribute to stabilising or modestly improving resistance trends, particularly for MRSA. Evidence for stewardship process indicators was more consistent, and despite similar methodological limitations, the large, coherent improvements across programmes supported moderate certainty that formal ASP structures, guidelines, and audit activities increase following regulatory and accreditation-linked initiatives. Clinical and economic outcomes were reported in relatively few studies and were at risk of bias from uncontrolled co-interventions, so the certainty for these domains was judged very low to low.

Table 3: GRADE Evidence Profile For Key Outcomes

Outcome	Studies (n)	Design Limitations	Inconsistency	Indirectness	Imprecision	Certainty	Effect Summary
Antibiotic Consumption	18	Serious RoB	Moderate	Serious	Not serious	LOW ↓	10-30% DDD/DOT ↓[1]
MRSA Prevalence	8	Serious RoB	Serious	Serious	Serious	VERY LOW ↓	10-20% relative ↓
ESBL/CRE	11	Serious RoB	Very serious	Serious	Serious	VERY LOW ↓	Mixed/stable
ASP Processes	10	Moderate RoB	Not serious	Serious	Not serious	LOW ↑	Committees 35→95%
LOS	7	Serious RoB	Moderate	Serious	Serious	VERY LOW ↓	~1.2 days ↓
HAI Rates	6	Serious RoB	Serious	Serious	Serious	VERY LOW ↓	10-67% ↓ (mean 35%)
Costs	4	Serious RoB	Moderate	Very serious	Serious	LOW ↓	20-72% ↓

Starting from LOW (non-randomised evidence). Downgraded for RoB (88% moderate-serious), inconsistency, indirectness (urban tertiary bias)

GRADE Downgrading Rationale
Risk of Bias (⊖1 to ⊖2)
- 88% moderate-serious ROBINS-I → ⊖2 for resistance/clinical outcomes
- Process indicators less confounded → ⊖1[1]

Inconsistency (⊖1 to ⊖2)
- Antibiotic use: Consistent direction (all ↓), moderate magnitude variation → ⊖1
- ESBL/CRE: Opposite directions across studies → ⊖2
- Processes: Uniform improvement → ⊖0[1]
- Indirectness (⊖1)
- Urban tertiary bias (48% government teaching hospitals)
- Heterogeneous interventions (single vs. bundle ASPs)[1]
- Imprecision (⊖1)
- Resistance/economic outcomes: Few studies (n<10), wide CIs → ⊖1
- Antibiotic use (n=18): Narrower ranges → ⊖0

DISCUSSION

This systematic review of 29 studies from Indian tertiary care hospitals shows that stewardship and regulatory interventions are generally associated with reductions in antibiotic consumption, more rational class selection, improvements in stewardship infrastructure, and encouraging signals for resistance, clinical outcomes, and costs[21]. The direction of effect is broadly consistent with international ASP experience, although baseline consumption and resistance levels in India are often higher, leaving considerable room for improvement.

However, the evidence base has important limitations. Most studies used before–after or observational designs susceptible to confounding and secular trends, and implementation fidelity was rarely quantified in detail[22]. Heterogeneity in outcome definitions and reporting precluded meaningful meta-analysis, so all findings were synthesised narratively. Under-representation of smaller and rural hospitals, and limited evaluation of long-term sustainability, restrict generalisability.

For policy and practice, the findings support continued strengthening of ASPs and enforcement of rational use regulations, ideally embedded within accreditation and quality-improvement frameworks and supported by dedicated staff and information systems[23]. Future research in India should prioritise more robust quasi-experimental designs (e.g. interrupted time series with appropriate controls), standardised outcome measures, and inclusion of diverse hospital types, alongside rigorous economic evaluations.

CONCLUSIONS

In Indian tertiary care hospitals, recent regulatory measures and ASP initiatives are associated with beneficial changes in antibiotic use and stewardship processes, and there are indications of positive impact on resistance, patient outcomes, and costs, although evidence remains largely observational and heterogeneous[24]. Strengthening implementation, evaluation, and reporting in line with PRISMA and related standards will be essential to guide national AMR policy and stewardship scale-up.

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Conflict Of Interest

The authors declare that they have no conflicts of interest, financial or otherwise, related to the content of this manuscript.

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