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Original Research Article

Evaluation of Antibiotic Prescribing Patterns among Pregnant Women in a Tertiary Care Teaching Hospital

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Abstract

Background: Pregnancy is a physiological state in which drug therapy carries a dual obligation to treat the mother effectively while avoiding harm to the developing fetus. Antibiotics are among the most frequently prescribed drug classes in pregnancy, yet prescribing is often empirical, and both under-treatment of genuine infection and unnecessary exposure to broad-spectrum agents carry consequences. Periodic audit of antibiotic prescribing in antenatal care is therefore essential to rational drug use and antimicrobial stewardship.

Objectives: To evaluate the pattern of antibiotic prescribing among pregnant women attending a tertiary care teaching hospital, to assess prescriptions against the WHO core prescribing indicators and the WHO classification, and to determine the fetal risk profile of the antibiotics prescribed.

Methods: A cross-sectional study was conducted over 12 months in the Department of Obstetrics and Gynaecology of Vanivilas hospital, Bangalore medical college research institute (BMCRI) tertiary care teaching hospital after institutional ethics committee approval. Pregnant women of any gestational age attending the outpatient department or admitted to the antenatal ward were enrolled after written informed consent. Prescriptions were transcribed into a pre-designed proforma. Antibiotics were classified using the WHO core prescribing indicators, classification (Access, Watch, Reserve), and by the former US-FDA pregnancy risk categories.

Results: Of 400 pregnant women, 248 (62.0%) received at least one antibiotic, accounting for 386 antibiotic prescriptions (mean 1.56 per exposed woman). The average number of drugs per prescription was 5.47, 68.9% of drugs were prescribed by generic name, and 79.4% were from the National List of Essential Medicines. Urinary tract infection (31.5%) and surgical/caesarean prophylaxis (25.0%) were the commonest indications. Beta-lactams were the most prescribed class (55.4%), led by amoxicillin–clavulanate (19.2%), and followed by nitrofurantoin (15.0%) and metronidazole (13.5%). By, 228 (59.1%) prescriptions were Access, 158 (40.9%) were Watch and none were Reserve. By the former USFDA categories, 92.7% were category B, 1.6% category C and 5.7% category D. A culture and sensitivity report was available before initiation in only 96 (38.7%) exposed women. Antibiotic exposure was significantly higher among inpatients than outpatients (88.1% vs 43.1%, $p < 0.001$).

Conclusions: Antibiotic prescribing in this antenatal population was broadly consistent with fetal safety, with a strong predominance of beta-lactams and category B agents. However, the proportion of Access-group antibiotics fell marginally short of the WHO 60% target, fixed-dose combinations and third-generation cephalosporins were used liberally, culture-guided prescribing was infrequent, and a small but avoidable proportion of category C and D agents was prescribed. Strengthening culture-based de-escalation, restricting empirical Watch-group use and embedding antenatal prescribing within the hospital antimicrobial stewardship programme are the priority interventions.

Keywords: Antibiotics, Pregnancy, Drug utilization, Prescribing pattern, classification, Rational drug use, Antimicrobial stewardship.

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Introduction

Pregnancy is a unique therapeutic setting in which every prescribing decision is made for two lives simultaneously. Infections during pregnancy are common and, if untreated, are associated with substantial maternal and perinatal morbidity, including chorioamnionitis, pyelonephritis, preterm labour, low birth weight and spontaneous abortion. [1] Antibiotics are consequently among the most frequently prescribed medicines in pregnancy. A recent systematic review and meta-analysis of 116 observational studies estimated that approximately one in four women worldwide consumes at least one antibiotic at some point during pregnancy, with wide regional variation. [2] A parallel systematic review reported prevalence estimates ranging from 2.0% to 64.3% across 79 studies, and noted that more than 90% of the available evidence originates from high-income countries, leaving prescribing practice in low- and middle-income settings poorly characterized. [3]

Prescribing for the pregnant woman is complicated by both pharmacokinetic and toxicological considerations. Gestation increases plasma volume, glomerular filtration rate and hepatic enzyme activity while lowering plasma albumin, so that the disposition of many antibiotics is altered and standard adult doses may yield subtherapeutic concentrations. [4] At the same time, the placenta permits transfer of most small, lipid-soluble antimicrobials to the fetus. The clinical calculus is therefore neither "avoid antibiotics" nor "treat freely". Treating asymptomatic bacteriuria in pregnancy, for example, clearly reduces the incidence of pyelonephritis and low birth weight and is firmly evidence-based. [5] Conversely, population-based cohort data have linked first-trimester exposure to certain agents, including clindamycin, quinolones and macrolides, with an increased risk of specific congenital malformations, [6] and prenatal antibiotic exposure has been implicated in disruption of the developing infant microbiome with possible longer-term immunological and metabolic consequences. [7]

Historically, prescribers have leaned on the USFDA five-letter pregnancy risk categories (A, B, C, D, X). These were withdrawn in 2015 under the Pregnancy and Lactation Labeling Rule, which replaced them with narrative risk summaries because the letter system was widely misread as a graded scale of safety. [8,9] Despite this, the letter categories remain in everyday clinical use in much of the world and continue to appear in prescribing audits, making them a pragmatic — if imperfect — audit tool.

A second and increasingly urgent dimension is antimicrobial resistance. The WHO (Access, Watch, Reserve) classification was introduced to steer prescribing towards narrow-spectrum agents with low resistance potential, and sets a country-level target of at least 60% of total antibiotic consumption from the Access group.10 Together with the WHO core prescribing indicators, [11] provides a reproducible framework for auditing antenatal antibiotic use.

Indian data on drug utilization in pregnancy exist, [12,13] but studies focusing specifically on the antibiotic component — indication, class, group, route, duration and culture linkage — remain limited, and antibiotic-prescribing audits from Indian tertiary hospitals have generally been conducted outside obstetric settings. [14] Given that empirical prescribing predominates in busy antenatal clinics, a focused audit is needed to identify where practice diverges from guideline recommendations. The present study was therefore undertaken to characterise antibiotic prescribing among pregnant women at a tertiary care teaching hospital and to benchmark it against the WHO prescribing indicators, the framework and accepted fetal safety classifications.

Materials and Methods

This was a cross-sectional drug utilization study conducted in the Department of Obstetrics and Gynaecology, Vanivilas hospital, BMCRI, Bengaluru. The study covered both the antenatal outpatient department (OPD) and the antenatal inpatient wards.

Ethical Considerations: The study protocol was reviewed and approved by the Institutional Ethics Committee (approval number [BMCRI/PS/82/201920]) before commencement. Written informed consent was obtained from every participant in a language she understood. Participation was voluntary, refusal carried no effect on care, and no intervention or change to prescribed therapy was made by the investigators. Participant identity was replaced by a study code, and data were stored in a password-protected file accessible only to the investigators.

Inclusion Criteria: Pregnant women of any age and any gestational age attending the antenatal OPD or admitted to the antenatal ward during the study period, who consented to participate.

Exclusion Criteria: Women who declined consent; those with incomplete or illegible prescription records; women attending only for antenatal registration or routine supplementation without a clinical encounter; and repeat visits of the same woman for the same episode (to avoid duplication of data, only the index prescription for each episode was analysed).

Sample size. Assuming an expected prevalence of antibiotic use in pregnancy of approximately 50% (chosen as the most conservative estimate given the wide range reported in the literature 2,3), with an absolute precision of 5% and a 95% confidence level, the required sample size was $n = Z^2p(1-p)/d^2 = (1.96)^2 \times 0.5 \times 0.5 / (0.05)^2 = 384$. Rounded up and allowing for incomplete records, 400 prescriptions were analysed.

Data Collection: Data were collected in a pre-designed, pre-tested proforma from the patient's case record and prescription, supplemented where necessary by patient interview. Variables recorded were: age, weight, educational and socioeconomic status, residence, gravidity and parity, gestational age and trimester, diagnosis, relevant comorbidities (anaemia, gestational diabetes, hypertensive disorders), all drugs prescribed (name, dose, route, frequency, duration), whether prescribed by generic or brand name, whether a fixed-dose combination (FDC), whether listed in the National List of Essential Medicines (NLEM),20 and, for antibiotics, the indication and whether a culture and sensitivity report was available before initiation.

Classification of Antibiotics: Antibiotics were classified in two ways: i) by the WHO classification 2023 into Access, Watch and Reserve groups;10 and (iii) by the former US-FDA pregnancy risk categories (A, B, C, D, X), retained for comparability with earlier published audits despite their formal withdrawal.8,9 Appropriateness of choice, dose and duration was assessed against the National Treatment Guidelines for Antimicrobial Use in Infectious Diseases16 and the ICMR treatment guidelines for antimicrobial use.17

WHO Core Prescribing Indicators: The following were computed as per the WHO manual How to investigate drug use in health facilities:11 average number of drugs per prescription; percentage of drugs prescribed by generic name; percentage of encounters with an antibiotic prescribed; percentage of encounters with an injection prescribed; and percentage of drugs prescribed from the essential medicines list.

Statistical Analysis: Data were entered into Microsoft Excel and analysed using SPSS version [IBM SPSS Statistics version 31.0 (IBM Corp., Armonk, NY, USA)]. Categorical variables are expressed as frequencies and percentages, and continuous variables as mean ± standard deviation. The chi-square test was used to compare categorical variables between groups (for example, inpatient versus outpatient antibiotic exposure and exposure across trimesters). A p-value < 0.05 was considered statistically significant.

Results

A total of 400 pregnant women were enrolled and their prescriptions analysed. Of these, 248 (62.0%) received at least one antibiotic, together accounting for 386 antibiotic prescriptions, a mean of 1.56 antibiotics per exposed woman.

Table 1: Demographic and obstetric profile of the study population (n = 400)

Variable	Category	Number (n)	Percentage (%)
Age (years)	< 20	34	8.5
	20–24	156	39.0
	25–29	142	35.5
	30–34	52	13.0
	≥ 35	16	4.0
	Mean ± SD	*25.4 ± 4.3*	—
Gravidity	Primigravida	178	44.5
	Gravida 2	132	33.0
	Gravida ≥ 3	90	22.5
Trimester at encounter	First	46	11.5
	Second	118	29.5
	Third	236	59.0
Setting	Outpatient (OPD)	232	58.0
	Inpatient (IPD)	168	42.0
Residence	Urban	214	53.5
	Rural	186	46.5
Education	Up to primary	122	30.5
	Secondary	178	44.5
	Graduate and above	100	25.0

Explanation: The study population was young, with 74.5% of women aged between 20 and 29 years and a mean age of 25.4 ± 4.3 years. Primigravidae formed the largest group (44.5%). The majority of encounters (59.0%) occurred in the third trimester, reflecting the frequency of antenatal

visits in late pregnancy and the concentration of admissions around delivery. Urban and rural representation was approximately balanced, and 42.0% of encounters were inpatient.

Table 2: WHO core prescribing indicators (400 prescriptions, 2,186 drugs)

Indicator	Observed value	WHO reference/optimal value
Average number of drugs per prescription	5.47	1.6–1.8
Percentage of drugs prescribed by generic name	68.9% (1,506/2,186)	100%
Percentage of encounters with an antibiotic prescribed	62.0% (248/400)	20.0–26.8%
Percentage of encounters with an injection prescribed	41.3% (165/400)	13.4–24.1%
Percentage of drugs prescribed from NLEM	79.4% (1,736/2,186)	100%
Percentage of antibiotics prescribed by generic name	71.2% (275/386)	100%
Percentage of antibiotic prescriptions that were FDCs	24.6% (95/386)	As low as possible

Polypharmacy was evident, with an average of 5.47 drugs per prescription against the WHO optimal range of 1.6–1.8; this is partly explained by the routine co-prescription of haematinics, calcium and folic acid supplements in antenatal care. Both the antibiotic encounter rate (62.0%) and the injection encounter rate (41.3%) substantially exceeded WHO reference values, though these figures are inflated by the inclusion of inpatient and peripartum encounters. Generic prescribing (68.9%) and NLEM adherence (79.4%) were reasonable but short of the ideal.

Table 3: Indications for antibiotic prescription (n = 248 women receiving antibiotics)

Indication	Number (n)	Percentage (%)
Urinary tract infection / asymptomatic bacteriuria	78	31.5
Surgical prophylaxis (caesarean section, episiotomy repair)	62	25.0
Premature/prolonged rupture of membranes (PROM/PPROM)	34	13.7
Respiratory tract infection	26	10.5
Genital tract infection / bacterial vaginosis	18	7.3
Skin and soft tissue infection	12	4.8
Intrapartum / puerperal pyrexia	10	4.0
Gastroenteritis / enteric fever	8	3.2
Total	**248**	**100.0**

Urinary tract infection, including asymptomatic bacteriuria detected on routine antenatal screening, was the single commonest indication (31.5%), followed by surgical prophylaxis (25.0%). Together, these two indications accounted for more than half of all antibiotic exposure. Genuinely therapeutic (as opposed to prophylactic) prescribing therefore constituted approximately 75% of use.

Table 4: Class-Wise and Drug-Wise Distribution of Antibiotics Prescribed (N = 386 Prescriptions)

Class	Individual antibiotic	Number (n)	Percentage of total (%)
Beta-lactams (214; 55.4%)	Amoxicillin + clavulanic acid	74	19.2
	Cefixime	46	11.9
	Ceftriaxone	42	10.9
	Cefotaxime	22	5.7
	Ampicillin	18	4.7
	Piperacillin + tazobactam	12	3.1
Nitrofuran (58; 15.0%)	Nitrofurantoin	58	15.0
Nitroimidazoles (52; 13.5%)	Metronidazole	52	13.5
Macrolides (30; 7.8%)	Azithromycin	22	5.7
	Erythromycin	8	2.1
Aminoglycosides (22; 5.7%)	Gentamicin	16	4.1
	Amikacin	6	1.6
Fluoroquinolones (6; 1.6%)	Ciprofloxacin / ofloxacin	6	1.6
Others (4; 1.0%)	Fosfomycin	2	0.5
	Clindamycin	2	0.5
Total		**386**	**100.0**

Beta-lactams dominated, accounting for 55.4% of all antibiotic prescriptions, with amoxicillin–clavulanate the single most frequently prescribed agent (19.2%). Third-generation cephalosporins (cefixime, ceftriaxone, cefotaxime) together accounted for 28.5% of prescriptions — a substantial share for a first- or second-line antenatal setting. Nitrofurantoin (15.0%) reflects the

predominance of urinary tract infection, and metronidazole (13.5%) the burden of bacterial vaginosis and its use in intra-abdominal and surgical prophylaxis regimens.

Table 5: Distribution of antibiotics by WHO classification (n = 386)

Group	Antibiotics included	Number (n)	Percentage (%)
Access	Amoxicillin–clavulanate, ampicillin, nitrofurantoin, metronidazole, gentamicin, amikacin, clindamycin, fosfomycin	228	59.1
Watch	Cefixime, ceftriaxone, cefotaxime, piperacillin–tazobactam, azithromycin, erythromycin, fluoroquinolones	158	40.9
Reserve	—	0	0.0
Total		**386**	**100.0**

Access-group antibiotics constituted 59.1% of prescriptions, marginally below the WHO country-level target of at least 60%.10 No Reserve-group antibiotic was prescribed, which is reassuring. The 40.9% Watch-group share was driven almost entirely by third-generation cephalosporins and azithromycin, indicating that empirical broad-spectrum prescribing is the principal target for stewardship intervention in this setting.

Table 6: Route of administration and duration of antibiotic therapy (n = 386)

Variable	Category	Number (n)	Percentage (%)
Route	Oral	236	61.1
	Intravenous	138	35.8
	Intramuscular	12	3.1
Duration	Single dose (prophylaxis)	58	15.0
	≤ 3 days	96	24.9
	4–7 days	186	48.2
	> 7 days	46	11.9

Oral therapy predominated (61.1%), consistent with the outpatient majority. Nearly half of all courses (48.2%) were of 4–7 days' duration. Courses exceeding seven days were prescribed in 11.9% of cases, largely in complicated pyelonephritis and PPROM. Single-dose prophylaxis accounted for 15.0%, aligning with recommended practice for caesarean prophylaxis.

Table 7: Distribution of antibiotics by former US-FDA pregnancy risk category (n = 386)

FDA category	Representative antibiotics prescribed	Number (n)	Percentage (%)
A	—	0	0.0
B	Penicillins, cephalosporins, piperacillin–tazobactam, nitrofurantoin, metronidazole, azithromycin, erythromycin, clindamycin, fosfomycin	358	92.7
C	Fluoroquinolones	6	1.6
D	Gentamicin, amikacin	22	5.7
X	—	0	0.0
Total		**386**	**100.0**

The overwhelming majority of antibiotics (92.7%) fell into former category B, indicating that fetal safety was, in general, appropriately prioritised. Category D aminoglycosides accounted for 5.7% of prescriptions and were confined to inpatients with severe or complicated infection, where the maternal benefit plausibly outweighs the risk. However, fluoroquinolones (category C, 1.6%) were prescribed in six instances of uncomplicated urinary tract infection where a safer alternative was available; this represents avoidable exposure.

Table 8: Microbiological support for antibiotic prescribing

Variable	Number (n)	Percentage (%)
Culture and sensitivity sent before initiating antibiotic (of 248 exposed women)	96	38.7
Culture positive (of 96 sent)	54	56.3
Escherichia coli	32	59.3 (of 54)
Klebsiella species	8	14.8
Enterococcus species	6	11.1
Staphylococcus aureus	5	9.3
Others	3	5.6
Therapy modified/de-escalated after report (of 54 positive)	28	51.9

Culture and sensitivity testing preceded antibiotic initiation in only 38.7% of exposed women; the remaining 61.3% received purely empirical therapy. *Escherichia coli* was the predominant isolate (59.3% of positive cultures), consistent with the urinary tract being the commonest site of infection. Where a positive report was available, therapy was modified or de-escalated in only about half of cases, indicating that culture results were under-utilised even when obtained.

Table 9: Comparison of antibiotic exposure across subgroups (n = 400)

Variable	Category	Received antibiotic, n (%)	Did not receive antibiotic, n (%)	p-value
Setting	Inpatient (n = 168)	148 (88.1)	20 (11.9)	**< 0.001**
	Outpatient (n = 232)	100 (43.1)	132 (56.9)	
Trimester	First (n = 46)	18 (39.1)	28 (60.9)	**0.002**
	Second (n = 118)	62 (52.5)	56 (47.5)	
	Third (n = 236)	168 (71.2)	68 (28.8)	
Gravidity	Primigravida (n = 178)	116 (65.2)	62 (34.8)	0.31
	Multigravida (n = 222)	132 (59.5)	90 (40.5)	

Antibiotic exposure was significantly higher among inpatients than outpatients (88.1% vs 43.1%, $p < 0.001$), reflecting the greater severity of infection and the routine use of peripartum surgical prophylaxis in admitted women. Exposure also rose significantly across trimesters, being lowest in the first trimester (39.1%) and highest in the third (71.2%, $p = 0.002$) — a pattern consistent with deliberate prescriber caution during organogenesis. Gravidity showed no significant association with antibiotic exposure ($p = 0.31$).

Discussion

This audit of 400 antenatal prescriptions found that 62.0% of pregnant women received at least one antibiotic. This is considerably higher than the pooled global prevalence of 23.6% reported by Orwa and colleagues in their meta-analysis of 116 studies, [2] and above the 37% reported from the unselected Danish COPSAC birth cohort. [18] Two methodological differences largely explain the gap. First, the present study is hospital-based and includes inpatient and peripartum encounters, whereas most population-based cohorts capture only community-dispensed prescriptions; excluding surgical prophylaxis would reduce our figure to approximately 46.5%. Second, tertiary referral centres concentrate complicated pregnancies. Even allowing for this, the magnitude of exposure is notable, and is consistent with the wide inter-study variability (2.0% to 64.3%) documented in the systematic review by Guimarães et al. [3]

The class distribution was reassuring. Beta-lactams accounted for 55.4% of prescriptions and 92.7% of all antibiotics belonged to former US-FDA category B, mirroring the pattern described in the review by Bookstaver et al., in which penicillins and cephalosporins are the recommended backbone of therapy for the great majority of infections in pregnancy. [1] Nitrofurantoin (15.0%) and metronidazole (13.5%) featured prominently, appropriately reflecting the predominance of urinary and genital tract infection. The evidence base for treating asymptomatic bacteriuria is robust, [5] and the fact that urinary tract infection was our commonest indication (31.5%) suggests that antenatal screening is functioning as intended.

Three findings warrant corrective action. First, Access-group antibiotics constituted 59.1% of prescriptions, marginally short of the WHO 60% target, [10] with third-generation cephalosporins alone accounting for 28.5%. Comparable Indian audits using the tool in non-obstetric departments have reported similar or greater reliance on Watch-group agents, [14] and Demoz et al. documented the same phenomenon among Ethiopian inpatients, concluding that empirical broad-spectrum prescribing is the dominant driver of stewardship failure. [15] Substituting narrow-spectrum agents where the likely pathogen is *E. coli* would shift this ratio materially.

Second, culture and sensitivity testing preceded therapy in only 38.7% of exposed women, and even where a positive report was available, therapy was de-escalated in only 51.9%. Given documented rising resistance among urinary isolates from antenatal populations, [19] empirical prescribing without subsequent review is both a clinical and an ecological risk.

Third, although category D aminoglycosides (5.7%) were restricted to severe inpatient infection, fluoroquinolones were prescribed in six cases of uncomplicated urinary tract infection where nitrofurantoin or a beta-lactam would have sufficed. Muanda et al. reported associations between first-trimester quinolone exposure and specific malformations, [6] and prenatal antibiotic exposure more broadly has been implicated in disruption of the neonatal microbiome. [7] Continued reliance on the withdrawn letter categories [8,9] may itself contribute to imprecise risk assessment, and prescriber education should move towards narrative, agent-specific risk

summaries. The polypharmacy observed (5.47 drugs per prescription) and generic prescribing rate of 68.9% are consistent with previous Indian drug utilization studies in pregnancy, [12,13] where routine supplementation inflates drug counts. Adherence to national antimicrobial guidelines [16,17] and to the NLEM20 was moderate and could be improved through a hospital antibiotic policy with a restricted formulary for the antenatal ward.

Conclusion

Antibiotics were prescribed to nearly two-thirds of pregnant women in this tertiary care setting, most commonly for urinary tract infection and surgical prophylaxis. The choice of agent was largely consistent with fetal safety: beta-lactams predominated, more than nine in ten prescriptions belonged to the former US-FDA category B, and no Reserve-group antibiotic was used. However, the audit identified clear and actionable gaps — Access-group use fell just short of the WHO 60% benchmark, third-generation cephalosporins were prescribed liberally as empirical first-line therapy, nearly a quarter of antibiotic prescriptions were fixed-dose combinations, culture and sensitivity testing preceded therapy in fewer than two in five women, and a small proportion of category C and D agents was prescribed where safer alternatives existed.

Strengthening antenatal antibiotic prescribing therefore requires three parallel measures: a hospital antibiotic policy specific to the obstetric unit that designates narrow-spectrum Access agents as first-line for uncomplicated urinary and genital tract infection; mandatory culture and sensitivity testing before initiating therapy in non-emergency situations, with a structured 48–72 hour review for de-escalation; and periodic prescriber education incorporating the framework and contemporary, narrative fetal-risk information rather than the withdrawn letter categories.

Regular prescription audit of this kind, embedded within the institutional antimicrobial stewardship programme, offers a practical route to safer and more rational antibiotic use in pregnancy.

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