Original Article

A prospective study to evaluate antimicrobial prescribing pattern among admitted patients in hilly Himalayan region of northern India

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Abstract

Background and Aim: Global scenario of antimicrobial (AM) utilization depicts 20–50% inappropriateness. Majority of the hospital admissions are due to unwanted effects because of non-judicial usage of these drugs. The present study focuses on utilization pattern of antimicrobials (AMs) in a tertiary care hospital in northern India. **Materials and Methods:** A prospective observational study was conducted over a period of one year in seven departments of a tertiary care hospital in hilly Himalayan region. Aim of the study was to analyze the AM utilization pattern using World Health Organization (WHO) indicators and instruments. **Results:** A total 700 prescriptions were analyzed in the present study. Injectable antibiotics (71%) followed by oral (29%) were most commonly prescribed. Beta lactams (79%) were the most frequently used antibiotic class. Most commonly prescribed AM was Ceftriaxone (30%). Majority of the time AMs were given empirically (44.8%), where most common indication was respiratory infections (42%). Culture and sensitivity tests were done for guiding curative therapy in 34.71% cases. The average duration of patient hospital stay was 8.81 days in the study population. The mean duration of prescribed antimicrobial treatment was 5.12 days. On an average 1.93 AMs were prescribed per patient. AMs were prescribed by International nonproprietary name (INN) in 62.19% of the admissions. The most common AM related adverse drug reaction was gastritis (96%) and skin rash (4%) with Amoxicillin + clavulanic acid being the most common causative agent. Total antimicrobial consumption was 148.24 DDD/100 bed days with Medicine department showing the highest consumption (36.25/100 bed days). **Conclusion:** The present study is the first and largest antimicrobial utilization study in the hilly Himalayan region of northern India. Our study found an urgent need for improvement of prescribing patterns, patient care indicators and strict adherence to standard guidelines.

Keywords: ADR profiling, antimicrobial/antibiotic, consumption, W.H.O indicators

Introduction

Antimicrobial drugs are one of the most widely utilized drug classes globally. Evidence shows that approximately one-third of the hospital admissions are being managed with antibiotic prescription during the course of treatment in the hospitals.[1,2]

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Infectious diseases are one of the entities causing significant morbidity and mortality worldwide. Resistant microorganisms are becoming more prevalent in the recent past and standing out to be a major threat in health care settings. Poverty, increasing infectious disease burden, accessibility to antibiotics with ease and injudicious use of antimicrobials are a few of the contributing factors for the increasing incidence of resistant microorganisms in India.[3] With negligible amount of newer antibiotics being developed, appropriate use of already available antibiotics has become the most crucial aspect to prevent the emergence of drug-resistant organisms.[4] Evidence has shown that resistant

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microorganisms have significant impact on health care system in terms of patient burden by increasing both mortality and morbidity and causing economic burden to a significant level.[5] Over usage of AMs and emergence of resistant organisms had shown proportionate relationship with each other and the regions with higher rate of antibiotic usage have shown the higher rate of antibiotic resistance compared to the regions with the lower rate of antibiotic usage.[6] There is a need for improving the antimicrobial prescription practice by giving feedback on the antimicrobial usage to the prescribers to improve the patient care, to reduce the financial burden on the hospitals and to combat the spread of resistant microorganisms through multidisciplinary approach. Utilization of antimicrobials is a double-edged sword, where rationale use will ensure cure of disease but irrational utilization may add to patient's health and financial miseries. Inappropriate prescription of AMs causes both increased expenditure on medical management along with increased morbidity and mortality by contributing to increased adverse drug reactions (ADRs) and the emergence of drug resistance to the available drugs.[6,7] Many studies in the recent past have also reported inappropriate use of the AMs and shown the importance of evaluating antimicrobial utilization and its impact on improving prescription patterns in healthcare settings.[8-10] Hence, there is a need for the health care settings to carefully observe the pattern of antibiotic usage and to do the necessary interventions in order to improve the quality of care while avoiding the harmful effects of irrational antibiotic treatment.[11] The literature available on prescription patterns seeks to observe, assess, and recommend improvement in treating physician's prescribing practices.[12]

The present study was designed to observe the AM usage pattern amongst the patients admitted in the selected wards of a tertiary care teaching hospital in northern India.

Methodology

It was a prospective observational study conducted for twelve months from April 2018 to April 2019. Approval of Institutional Ethics Committee (IEC) was taken before conducting the study. Written informed consent was taken from all patients. Patients on antibiotics admitted to General Medicine, General Surgery, Obstetrics and Gynecology (OBG), Pediatrics, Orthopedics, Oto- Rhino-laryngology (ENT) and Pulmonary Medicine departments were included in the study. Patients taking anti-tubercular therapy and/or anti-retroviral therapy were excluded as these patients were taking multiple antibiotics interfering with the calculation of the indicators. All the selected departments were visited and patients were selected randomly during the course of the study. All necessary information regarding the patients was noted in a pretested case report form (CRF). Information about antimicrobials prescribed such as name, dose, frequency, dosage form, duration of treatment, information about the culture sensitivity report were collected. They were followed up till they got discharged from the hospital. Data regarding ADRs reported due to AM usage were recorded with the help of a pre-formulated ADR checklist. W.H.O instruments and outcome indicators (i.e., Hospital, Prescribing, Patient care, and Supplemental indicators) were calculated.[13] Antimicrobial consumption (AMC) tool version 1.9.0, the anatomical therapeutic chemical-defined daily dose (ATC-DDD) classification system was used to determine and to quantify the consumption of antimicrobials. Descriptive statistics were applied to analyze data and results were expressed as mean, proportions, and standard deviations. The following equations were used to calculate antimicrobial consumption and results were expressed as DDD/100 bed days.

$$\frac{\text{DDD}}{\text{100 bed days}} = \frac{\text{Number of units administered in a given period} \times 100}{\text{DDD} \times \text{number of days} \times \text{number of beds} \times \text{occupancy index}}$$

$$\text{Occupancy Index} = \frac{\text{Total in patient service days for a period} \times 100}{\text{Total in-patient bed counts} \times \text{No.of days in the study period}}$$

Results

Total 700 patients from the seven selected departments were analyzed. Injectable formulations (71%) followed by oral forms (29%) were prescribed most commonly. Beta lactams (79%) followed by Aminoglycosides (16%) and Fluoroquinolones (5%) were most commonly used. Ceftriaxone (30%) was the most frequently used antibiotic, followed by Amoxycillin + clavulanic acid (27%) and Metronidazole (21%). Antibiotics were given empirically in 44.80%, curatively in 34.7%, and prophylactically in 20.4% of the patients. The commonest indication for empirical AM therapy was respiratory infections (42%) followed by GIT infections (36%), Renal diseases (12%), and CNS infections (10%). The remaining baseline characteristics of the included patients are depicted in Table 1.

Calculation of W.H.O indicators

Hospital indicators

All the essential or key antibiotics were found to be available in the wards on the day of visit, i.e., 100% availability and all the essential AMs were available in the hospital stores throughout the month. The cost of antibiotic treatment as a percentage of the total hospital medication expenditure was 29.87%. [Table 2]

Prescribing indicators

Average duration of prescribed antimicrobial treatment as a cumulative representation of all the selected departments was 5.12 days. Pulmonary medicine had shown a longer duration of antibiotic usage (7.79 days), followed by General

Table 1: Baseline characteristics of the study population

Distribution of cases among the selected departments (*n*=700)	Mean age (range)	Sex distribution	Co-morbidities[#]	Reason for AM prescription-Patient distribution	System involved in empirical therapy*
Medicine-104;	38.59 years	Males-321	Malignancy- 4.20%	Prophylactic- 20.40%	R/S- 42%
Surgery-105;	(1-70 years)	Females-379	Coronary artery disease-0.70%	Empirical- 44.80%	GIT- 36%
OBG-100;			CKD- 1.10%	Definitive- 34.70%	Renal- 12%
Pediatrics-97;			CLD- 1.10%		CNS- 10%
Orthopedics-97;			COPD- 4.40%		
ENT-94;			DM - 3.70%		
Pulmonary medicine. -103			HTN- 1.40%		

[#]CKD: Chronic kidney disease; CLD: Chronic liver disease; COPD: Chronic obstructive pulmonary disease; DM: Diabetes mellitus; HTN: Hypertension. *R/S: Respiratory system; GIT: Gastro intestinal tract; CNS: Central nervous system

Table 2: Results of Hospital Indicators

Parameter	Result
Presence of drugs and therapeutics committee (DTC)	Yes
Availability of STGs to treat infections	No
Availability of Essential medicines list	Yes
Number of antibiotics on the EML	82 generics
Percentage of medications denoted by generic name (INN)	100%
Availability of a set of key antimicrobials in the wards at the time of visit	100%
Average number of days that a set of key antibiotics found unavailable	Zero days/ month
Amount spent on antibiotics as a percentage of the total hospital medicine expenditure	29.87%

Medicine (5.41 days). The average number of AMs prescribed per patient was 1.93. Obstetrics and Gynecology (OBG) (2.29) followed by pulmonary medicine (2.05) had the highest average number of AM usage among the selected departments. All the antimicrobials were prescribed from the essential medicine list (National List of Essential Medicines-NLEM). Average cost of AM therapy per patient was 3450.20 Indian Rupees (INR) with Pulmonary Medicine having the highest cost of 402.41 INR. Average number of prophylactic antibiotic doses for cesarean section procedures was 17.03 per patient. None of them received antibiotic prophylaxis in accordance with Standard Treatment Guidelines (STGs). Seventeen Pneumonia cases were reported, most of which were from Pediatrics (8; 47%). It was seen that 88.23% of patients of Pneumonia received treatment according to clinical guidelines. Percentage of AMs prescribed by INN was 62.19%. Orthopedics (95.02%) followed by Pediatrics (74.85%) department had shown the highest percentage of prescription by generic name. [Tables 3 and 4]

Patient-care and supplemental indicators

The average length of stay in the hospital was found to be 8.81 days for each patient receiving the AMs, with Pulmonary Medicine showing longer duration of patient stay (11.67 days) followed by Orthopedics (10.37 days). Least duration of patient stay was seen in the department of ENT (3.3 days). Percentage of prescribed doses actually administered to the patient was 98.68%. The practice of getting culture and sensitivity tests for guiding curative therapy was observed in 34.71% patients. Department of Pulmonary Medicine had shown the highest percentage of culture and sensitivity tests (24%), followed by Pediatrics (14%) [Table 5]

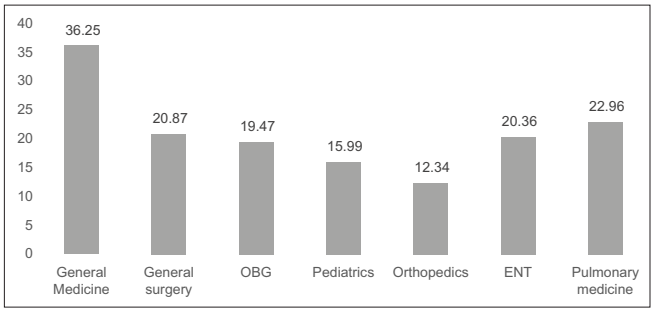

Figure 1: Antimicrobial consumption in individual departments (expressed in DDD/100 bed days)

Antimicrobial consumption

Total AM consumption was 148.24 DDD/100 bed days with Medicine department showing the highest consumption (36.25/100 bed days) followed by Pulmonary Medicine (22.96/100 bed days). Fluoroquinolone group was highly consumed class of AMs (18.86 DDD/100 bed days) followed by Aminoglycosides (15.04 DDD/100 bed days). [Figures 1 and 2]

Adverse drug reaction profiling

Most common ADRs reported due to AMs were gastritis (70; 96%) and skin rash (3; 4%). Amoxycillin + clavulanic acid combination was the most common agent causing gastritis (36.36%), followed by Piperacillin + tazobactam (20%). Majority of ADRs were of "possible" category according to the W.H.O-UMC classification system, followed by "probable" (20%) and 'certain' (5.45%). [Table 6]

Discussion

Appropriate monitoring of antibiotic usage pattern in clinical scenarios is essential for a developing health care facility. This could be achieved by active surveillance of antimicrobial use or by conducting antimicrobial utilization studies at regular intervals. This will provide important inputs in forming or reforming the hospital antimicrobial use policies. Information on antimicrobial utilization pattern will give a snap shot on their usage and is important for the health care setting to understand the magnitude of use and time trends of usage patterns.[14] In our study we have included total of 700 patients on antimicrobials from seven major departments of a tertiary care hospital in northern hilly region of India.

Table 3: Prescribing indicators results (Indicators 6-10, 13, 14)

Indicator	Department						
	General medicine	General surgery	Pediatrics	OBG	ENT	Pulmonary medicine	Orthopedics
% of hospitalizations with one or more AMs	100	100	100	100	100	100	100
Average number of AMs per hospitalization in which AMs are prescribed (SD)	1.93 (0.87)	1.91 (0.96)	1.75 (1.09)	2.29 (0.84)	1.26 (0.60)	2.05 (1.08)	1.82 (0.58)
% of AMs prescribed from FL/EML	100	100	100	100	100	100	100
Average cost of AMs prescribed per hospitalization in which AMs were prescribed	299.11	270.35	129.27	102.08	145.74	402.41	198.75
Average duration of prescribed AMs treatment days (SD)	5.41 (2.83)	5.05 (3.49)	6.16 (3.52)	3.51 (1.77)	3.30 (1.71)	7.79 (4.57)	3.95 (2.02)
% of Pneumonia patients who received AMs	100	0	100	0	0	100	0
% of patients who received treatment for pneumonia as per STGs*	100	-	100	-	-	71.4	-
% of AMs prescribed by INN	74.1	57.1	73	54.4	8.8	49.3	95

*National Treatment Guidelines for Antimicrobial Use in Infectious Diseases. Version 1.0 (2016)

Table 4: Results of Surgical antimicrobial prophylaxis indicators (Indicators 11, 12)

Parameter	Results
Number of patients underwent lower segment cesarean section (LSCS)	57
Number of patients receiving prophylactic antibiotics	57
Total number of prophylactic antibiotic doses prescribed for LSCS procedures	971
Average number of prophylactic doses prescribed for LSCS procedures	17.03
Percentage of patients receiving prophylactic AMs for LSCS according to the clinical guidelines*	None

*All Wales Medicines Strategy Group, All Wales Antimicrobial Guidance Group. Guidance on Antimicrobial Prophylaxis Related to Caesarean Section. September 2015

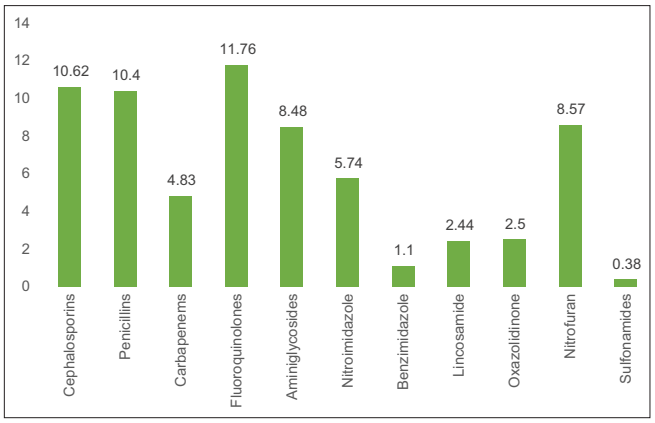

Figure 2: Overall antimicrobial consumption (expressed in DDD/100 bed days)

Prescribing pattern of antimicrobials

In our study major formulations used were injectable forms (71%), which was lesser than a study published by Atif *et al.*[15] (98%). Beta-lactam like Cephalosporins, especially Ceftriaxone (30%) were most commonly used followed by Penicillins (Amoxicillin + Clavulanic Acid) (27%). Similar findings were reported by Gopala Krishnan *et al.*[16] using the W.H.O indicators, which showed injectable forms of antibiotics and Beta-lactams being most commonly prescribed AMs. In our study, most of the AMs were given empirically (44.80%) followed by curatively (34.70%) and prophylactically (20.40%). The most common indication for empirical antibiotic prescription in our study was respiratory tract infections (42%) followed by GIT (36%) infections similar to findings reported by Khan *et al.*[17] and Gandra *et al.*[18]

Calculation of W.H.O indicators

1. Hospital indicators

The evidence supports that having a shortlist of essential medicines for any healthcare setting increases the quality of drug utilization patterns and thereby improving patient care. Our institute is found to have the drugs and therapeutics committee (DTC) and has been using the National List of Essential Medicines (NLEM) as a reference for procuring all the essential medicines. All AMs were prescribed from NLEM. Total 82 AMs were found to be in the NLEM and all of them were identified by the International nonproprietary name (INN). Indicators like the availability of key antibiotics in the hospital wards on the day of visit and time duration for which these agents are out of stock shows the hospital's commitment to management of hospital pharmacy medicine supply in order to provide the drug of choice for the infection.[13] Our study found that all the necessary AMs were available throughout the month and no AM was found to be out of stock on the day of study. As antibiotics contribute to more than 30% of the total hospital expenditure on medicine purchases, they tend to cause significant amount of financial burden on the health care setting if not used judiciously.[19] In our study it was found that amount spent on antibiotics as a percentage of the total hospital medication costs was 29.87% which was found to be much lower than a study from Nigeria by Akande *et al.* (72%).[20] Our finding was similar to W.H.O recommendation of 30%.[10]

2. Prescribing indicators

Percentage of patients with at least one antibiotic prescribed was 100% as we have included only the patients who are on antimicrobials. The average number of AMs prescribed per patient was 1.93. This value was higher than the values reported by Amaha *et al.*[21] and Atif *et al.*[15] which showed 1.29 and 1.4 (SD = 0.6) antibiotics per patient respectively. It was lower than the studies

Table 5: Results of Patient-care and supplemental indicators (Indicators 15-17)

Parameter	Departments						
	General medicine	General surgery	Pediatrics	OBG	E.N. T	Pulmonary medicine	Orthopedics
Number of AM doses prescribed Sum (mean±SD)	2185 (10.97±6.68)	2459 (11.33±8.92)	2244 (13.12±9.98)	1769 (7.41±4.66)	1189 (9±5.66)	3747 (17.42±13.05)	1295 (7.19±4.13)
Percent of doses of prescribed AM actually administered	97.71	99.3	98.30	99.37	98.99	98.74	98.37
Average duration of hospital stay of patients who received AM (SD)	9.14 (4.78)	8.96 (5.46)	8.39 (4.9)	7.68 (4.85)	3.30 (1.71)	11.67 (5.58)	10.37 (7.91)
Number of AM drug sensitivity tests reported per hospital admission with curative AM prescribed	53	28	56	35	3	59	8

OBG: Obstetrics and gynecology; ENT: Ear Nose Throat (Oto-rhino -laryngology); AM: Antimicrobial; SD: Standard Deviation

Table 6: ADRs associated with AMs

Antibiotic	ADR	Percentage	WHO-UMC* Classification
Amoxicillin + clavulanic acid	Gastritis	36.36	Possible
Vancomycin	Skin Rash	5.45	Certain
Piperacillin + Tazobactam	Gastritis	20	Possible
Ceftriaxone	Gastritis	9.09	Possible
Doxycycline	Gastritis	3.63	Possible
Levofloxacin	Gastritis	5.45	Possible
Azithromycin	Gastritis	3.63	Possible
Ciprofloxacin	Gastritis	9.09	Possible
Cefoperazone + Sulbactam	Gastritis	5.45	Possible
Ampicillin + sulbactam	Gastritis	1.81	Possible

*W.H. O-UMC: World health organization- Uppsala Monitoring Centre

reported by Gutema *et al.*[22] and Palikhe[23] which showed 2.1 and 2.41 (SD = 1.02) antibiotics per patient respectively.

In terms of cost burden on the institute contributed by AMs, average cost of AM therapy per admission was 3450.20 INR with Pulmonary Medicine showing the highest cost (402.41 INR). This finding was higher than a study reported by Shankar *et al.*[24] which showed average cost of AM therapy per patient as 1958.5 ± 1267.8 Nepalese Rupees. Mahindra *et al.*[25] had reported INR 1363.92 (95% CI: 1056.3 − 1671.6) which was lesser than the finding in our study. Antimicrobials use is associated with many unwanted, harmful events leading to toxicities, immunologic reactions, development of antimicrobial resistance. Prolonged use is associated with Clostridium difficile infections. Increased utilization leads to greater chances of these unwanted harmful events. Therefore, it is very important to have proper knowledge of these aspects while prescribing especially in terms of duration of administration.[26] In our study, the average duration of prescribed antibiotic treatment as a cumulative representation of all the selected departments was 5.12 days and the results were comparable to the studies reported by Atif *et al.* (5.4 days, SD = 3.2) and Mali *et al* (5.94 days, SD = 5.35).[27] Prophylactic usage of antibiotics for cesarean section (LSCS or C- section) is a very common practice for pre, intra – and post-operative period as this surgical procedure are considered to be important predisposing factors for postpartum infection than normal vaginal delivery.[28] In our study all the patients undergoing lower segment caesarean section have received antimicrobial prophylaxis with average number of doses of 17 per patient but none of them adhered to the standard treatment Guidelines (STG) which suggest Cefuroxime and Metronidazole as the preferred combination for LSCS procedures. In our study most commonly prescribed prophylactic antibiotics for C-section was a combination of Ceftriaxone, Metronidazole, and Gentamicin. Out of all the Pneumonia cases reported during the study period, 88.23% of the patients were given AM treatment according to the clinical guidelines.[29] WHO makes a strong emphasis on using INN while prescribing any AM agent.[15] Using the brand names instead of generic names while writing the prescription orders may have a negative impact on the health care settings such as increase in the risk of morbidity, mortality, and financial burden.[30] In our study, the percentage of AMs prescribed by INN was 62.19%, which was better than the finding reported by Shrestha *et al.* (16.94%).[31]

3. Patient care indicators

The duration of hospital stay is one of the indicators to determine the efficacy of hospital administration. Decrease in the duration of hospital stay has a significant impact in reducing the risk of infection and adverse reactions induced by medications along with betterment in the quality of patient care and decreased financial burden both on the institutes and on the patients.[32] In our study average duration of hospital stay for each patient receiving an antimicrobial was found to be 8.81 days which was lower than the finding reported by Aravani *et al.* (10 days).[33]

4. Supplemental indicators

It is very important to perform the culture and sensitivity tests before prescribing any antimicrobial agent, as this practice guides prescribers to select curative antibiotics for treating the infections thereby reducing many adverse events. Antibiograms must be performed as a routine practice through standardized methods which allows to correlate both inter and intra-hospital antimicrobial sensitivity patterns.[34] In our study the practice of getting culture and sensitivity tests done was found to be 34.71% (243/700), and was much better than the study reported by Atif *et al.* showing only 0.24% in terms of performing culture and sensitivity testing for antimicrobial prescription.

Antimicrobial consumption

WHO suggests the use of ATC classification and DDD/100 bed-days to quantify AM consumption, as it acts as a global standard both for analyzing and comparing results of antibiotics

usage and helps to form antimicrobial policy thereby formulating intervention strategies. And this knowledge is very much useful for proper understanding and interpretation of trends in antibiotic usage.[35] Our study had found that total antimicrobial consumption was 148.24 DDD/100 bed days with Medicine department showing the highest consumption (36.30/100 bed days) followed by pulmonary medicine (22.96/100 bed days). These findings were comparable to the studies reported by Sharma *et al.*,[36] Shankar *et al.*[37] and Peto *et al.*[38]

Adverse drug reaction profiling

Adverse drug reactions (ADRs) due to medications are considered to be one of the reasons for admissions into the hospitals most frequently with considerable morbidity and mortality. These unwanted events can be harmful causing a significant amount of impact on health care settings in terms of economic burden, prolonged hospital stay affecting the clinical outcomes adversely.[39,40] In our study the most common ADRs reported due to AMs were gastritis (70; 96%) and skin rash (3; 4%). Amoxicillin + clavulanic acid combination was the most common agent causing gastritis (36.36%), followed by Piperacillin + tazobactam (20%). These findings were found to be different from the study reported by Jung *et al.*[41] in which skin reactions (45.1%) followed by GIT reactions (32.6%) were most commonly reported. Findings were similar in terms of Penicillin group of antimicrobials causing most common ADRs (16.0%), followed by third-generation Cephalosporins (14.9%) to the studies reported by Shamna *et al.* and Lee *et al.*[42,43]

To summarize the findings among 700 prescriptions studied, Beta lactams were most commonly used antibiotic group. The most common indication for antimicrobial therapy was respiratory infections. Average duration of patient hospital stay and prescribed antimicrobial treatment was 8.81 and 5.12 days respectively. Average number of AMs prescribed for each patient was 1.93. Expenditure on antimicrobials as a percentage of the total hospital medicine costs was 29.87%. Antibiogram guided curative therapy was 34.71% among the patients studied. Gastritis and skin rash were most frequently reported ADRs. Total antimicrobial consumption was 149.43 DDD/100 bed days. Our study is the largest drug utilization study ever conducted in the northern part of India covering the hilly Himalayan region.

Conclusions and recommendations

Antimicrobial prescription pattern was found to be appropriate in terms of hospital and supplemental indicators. But there is a need for improvement in the area of prescribing and patient care indicators and the use of guidelines, educational initiatives, surveillance, and antibiotic restriction policies at all levels of health care. Results of this study may help the primary healthcare providers to rationalize the antibiotic utilization for better patient care in the hilly Himalayan regions.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient (s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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