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Evaluation of Prescription Patterns, Adverse Drug Reactions, Antibiotic Usage, Cost in India for 2 Years

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ABSTRACT

Background: Drug safety is considered as an integral and important part of drug therapy where antibiotics are utilized and reports on drug safety components-Adverse Drug Reactions (ADR), adverse events both in premarketing and post marketing phase are taken into consideration to analyze drug cost leading to prolonged hospitalization.

Material and Methods: To evaluate ADR profile of antimicrobials over a period of 24 months (October 2010 to September 2012) in a tertiary care hospital of two different regions in India with an objective to assess social costs (cost analysis) of drugs.

Results: In 950 prescriptions an average of 1.7 Antimicrobial Agents (AMAs) were prescribed per patient and duration of stay was 6.8 days. The most common AMAs prescribed were combination of beta lactams followed by aminoglycosides in North India and combination of beta lactams followed by quinolones in South India. The parenteral route was preferred over oral and other routes of administration in both the regions. The percentage of drugs prescribed by generic name was 82% with 46% in North India and 36% in South India, respectively.

Conclusion: The current study suggests that ADRs due to antimicrobials is a significant health problem leading to increase in cost of hospitalization. Antibiotic prescription pattern, generic name usage, cost effective analysis data also presented in the study.

Keywords: Adverse drug reactions; Antimicrobial agents; Pharmacoeconomics; Cost analysis.

INTRODUCTION

Antibiotics are the most commonly prescribed drugs in developing as well as developed countries due to high prevalence of bacterial infectious diseases. Though the data on Adverse Drug Reactions (ADRs) related to antimicrobials exist in volumes, no study exists from the Indian hospitals exclusively analyzing the trends and patterns of ADR's related to antibiotics.

Moreover, variations in ADRs are likely to exist worldwide because of varied prescribing practices; and genetic and epidemiological variations of the population. Thus, undertaking such studies shall definitely prove useful in reframing hospital and national antibiotic policy in the interest of patient care and safety. Thus, an attempt was made to analyze a regional data existing in tertiary care teaching hospitals retrospectively to study profile of ADRs due to antimicrobials [1].

The ADRs are one of the major causes of extended hospitalization and added cost for the stakeholders. The cost of hospitalization is however, only a part of the total costs as most adverse reactions never come to clinical attention. There are two main costs associated with ADRs namely cost of treating illnesses due to ADRs and cost of avoiding them. The main objective of this study was to discuss costs of ADRs. Adverse drug reactions overburden healthcare system and this can be explained with some of their consequences: Morbidity, death-rate and additional unforeseen costs [2]. It is accepted that adverse drug reactions are a reason for about 5% of the cases to necessitate hospitalization. These factors lay the objective necessity of rationalization of the expenditure for healthcare and in particular for drugs. This study tried to establish prescription patterns, adverse drug reactions, antibiotic usage and cost in India for duration of two years 2 years [3]

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MATERIALS AND METHODS

Study design

This was a retrospective observational study conducted over a period of 24 months (from October 2010 to September 2012).The costs of illness and hospital stay in two different regions were taken into consideration [4].

Study sites

Rajendra Institute of Medical Science (RIMS), Ranchi, Jharkhand, India and Axon hospital, Hyderabad, Telangana, India were chosen for collection of data [5].

Patient enrolment

The patients were enrolled for the study after obtaining Informed Consent Form (ICF) either from patients or through legally acceptable representative for documentation of any suspected ADRs [6].

Inclusion criteria

Both male and female patients aged 20 to 80 years who were prescribed or treated with Antimicrobial Agents (AMA) were included in the study [7].

Exclusion criteria

Patient's with any cases of poisoning, medication error, over dosage, over/non-compliance and patients treated with natural products/alternate medicines and unidentified drugs were excluded from the study [8].

Patient data collection form

The relevant details such as clinical presentation, start and stop date of adverse event, relevant laboratory investigations, other relevant history including pre-existing diseases, suspected medication (including dose, frequency, route of administration, dates and duration of administration and indications for use) and concomitant medicines (including self-medication and herbal remedies) of inpatients were recorded on a patient data collection form [9].

Plan of work

The data were collected from patients admitted to general ward, Critical Care Unit (CCU), Intensive Care Unit (ICU) and Intensive Critical Care

Unit (ICCU) over a period of two years. The general wards, CCU, ICU and ICCU were visited every day and about patient, suspected ADR, suspected medication, reporter, date of reaction, date of recovery and presentation of problem were recorded. The details pertaining to suspected medication, name of drug, brand of manufacturer, generic name of manufacturer (if known), expiry date, dose used, route, frequency and therapy dates as well as reason for prescribing suspected drug were also assessed [10]. The information about de-challenge and re-challenge, concomitant medications, the relevant laboratory test results were recorded separately. Other relevant history including pre-existing medical conditions like allergy, pregnancy, smoking and alcohol usage and any organ dysfunction were also noted. The ADRs were defined and categorized as per the definition of Edwards and Arsonson, 2000. The severity and seriousness of reaction, mode of onset, nature of ADRs, type of reaction, the outcome

of reaction and onset time was recorded for every suspected ADR. Severity of reaction was classified as mild (bothersome but requires no change in therapy); moderate (requires change in therapy, additional treatment, hospitalization); severe (disabling or life-threatening). Onset of event was categorized as acute (within 60 minutes); sub-acute (1 to 24 hours) and latent (>2 days). Whereas nature and type of reaction was classified as type A (augmented); type B (bizarre); type C (continues use); type D (delayed) and type E (end of use). Outcome was described as fatal, recovering, recovered, unknown, continuing or other) as per recommended Standard Operative Procedure (SOP) of Pharmacovigilance Program of India (PvPI).

Detail sub-group analysis of ADRs detected and various socio-epidemiological, drug-related parameters like combination antibiotics, route of drug administration, rational/irrational antibiotics and other risk factors were also analyzed in the current study [11]. The four most frequently used pharmacoeconomic methods which evaluate the costs and benefits of various alternatives and indicate the best profit of the money invested and the way to redirect resources were used in this study, namely cost minimization analysis, cost benefit analysis, cost utility analysis and cost effective analysis. All techniques have similar purposes and measure the costs of the health interventions, but it is the benefits that distinguish among different healthcare programs. On the other hand costs incurred by the patients were calculated as direct costs and indirect costs. Data was inferred in percentile values. To study drugs, it is essential that we have a system for classifying them. Presently the most useful drug classification scheme is that developed by the WHO, it is known as ATC system, the letters standing for anatomic, therapeutic and chemical, which represents the three axes along which drugs are classified [12]. The first axis, anatomic is categorized according to the body system that is affected, within this classification drugs are next categorized by their main therapeutic use. The final sub-classification is by the chemical class of the drug. Each drug is assigned a unique identifying number, in order of appearance in the market, as illustrated in Table 7. The details of these patients were collected by an independent observer with consultation of doctors which was finally validated and confirmed by the in-charge ADRM centre, as an expert. The identity of reporter was kept confidential [13].

Data analysis

- Assessment of prescription pattern as per WHO drug use indicator.
- The prescribed drugs were classified according to the Anatomical Therapeutic Classification (ATC)-Defined Daily Dose (DDD) classification.
- The Prescribed Daily Dose (PDD) was calculated by taking the average of the daily doses of AMA's as the PDD. The PDD to DDD ratio was then calculated.

Statistical analysis

The data collected was expressed in n (%). P value at <0.05 was applied to prove statistical significance considering chi-square value was carried out with open epi: A web based epidemiological and statistical calculator [14].

Cost calculation

The Cost-Effectiveness Analysis (CEA) allows assessment of the economical expediency for application of the medical intervention by comparing the relative costs and outcomes (effects) of two or more courses of action. In the context of pharmacoeconomics, the cost-effectiveness of a therapeutic or preventive intervention is the ratio of the cost of the intervention to a relevant measure of its effect.

We calculated a Cost-Effectiveness Ratio (CER) by the standard formula [15].
CER=(DC+IC)/Ef, where DC-direct cost, IC-indirect costs, Ef-efficiency of treatment (number of the cured patients).

Cost analysis

The quantification of these cost categories requires, first, the basic costs of consumables, labor, transport and incineration of waste and secondly, knowledge of consumables used and time spent by the various grades of staff on each of the procedures involved [16]. The basic costs within these eight categories were obtained as follows: Antibiotic costs were obtained from the Monthly Index of Medical Specialties (MIMS), contract costs of other consumables were obtained from the hospital purchasing department and the pharmacy, costs of standard haematological and biochemical tests (tests performed to assess the adverse effects of the antibiotic used, for example serum urea and electrolyte measurement for nephrotoxic antibiotics such as gentamicin and vancomycin) were obtained from their respective departments, costs of labor (Table 1).

S.no	Cost category	Summarized costs
1	Antibiotic	The drug itself
2	Maintenance of IV Access	Insertion of IV cannula and maintenance of its patency
3	Drug delivery	Administration of drug to the patient
4	Drug monitoring	Measurement of serum antibiotic to ensure therapeutic and to avoid toxic levels
5	Drug readjustment	Modification of the dose of antibiotic following serum antibiotic measurement
6	General monitoring	Hematological and biochemical indices relatingto the use of the drug. For example, urea andelectrolytes are measured during a course of anephrotoxic antibiotic
7	Sharps disposal	Sharps are packed in plastic sharps boxes; theseboxes are then packed in clinical waste bags,delivered to the place of incineration andincinerated
8	Adverse effects	A substantial cost: the costing of these has notbeen attempted in this study5728

Table 1: Eight cost categories making up the cost of any antibiotic course.

Different costs were calculated during the stay of patients as follows

- Costs of antibiotics=(Cost of antibiotic unit × (Frequency\No. of days)).
- Costs of other medications=(Cost of medication × (Frequency\No. of days)).
- Costs of laboratory tests=(Cost of lab tests × (Frequency\No. of days)).

- Costs of other diagnostic tests=(Cost of other diagnostic tests × (Frequency\No. of days)).
- Total costs of antibiotics, other medications, laboratorytests and other diagnostic tests per hospital stay=(Cost of antibiotics+cost of other medications+cost of laboratory tests+costs of other diagnostic tests).

RESULTS

A total of 1008 patients were screened; of which 950 patients were enrolled into the study. A total of 58 patients were excluded as 46 of them were not prescribed with AMAs and 12 of them refused to give consent to participate in the study. Majority of the patients enrolled in North India belong to 60-70 years age group (n=98); while majority of patients enrolled in South India belong to 70-80 years age group (n=109), most of the enrolled patients were female (51%) and (34.5%) were male patients, 189 (39.0%) female patients reported ADRs. Majority of the enrolled patients were <65 years (58.2%). A total of 135 patients (24.4%) with age>65 years and 215 patients (54.2%) with age<65 years reported ADRs (Table 2).

Variables	No. of patients N=950	Patients with ADR's[a]
Gender		
Male (n (%))	466 (49.0)	161 (34.5)
Female (n (%))	484 (51.0)	189 (39.0)
Age		
≥ 65 (v (%))	553 (58.2)	135 (24.4)
<65 (n (%))	397 (41.8)	215 (54.2)
Region		
North India (n (%))	447 (47.1)	164 (36.7)
South India (n (%))	503 (52.9)	186 (37.0)
Number of co-morbid conditions		
<2 conditions (v (%))	501 (52.7)	143 (28.5)
≥ 2 conditions (v (%))	449 (47.3)	207 (46.1)
Note: ADR=Adverse Drug Reactions; N=Total Number of Patients; n=Number of patients meeting the criteria; [a] percentage was calculated with numerator as number of ADRs and denominator as number of patients in each category		

Table 2: Incidence of adverse drug reactions based on gender, age, region and co-morbid conditions.

Majority of the patients enrolled belong to South Indian hospital (52.9%). A total of 164 patients (36.7%) enrolled in North India and 186 patients (37.0%) enrolled in South India reported ADRs. Out of the enrolled patients were with <2 co-morbid conditions. A total of 143 patients (28.5%) with >2 co-morbid conditions and 207 patients (46.1%) with <2 co-morbid conditions reported ADRs as illustrated in Table 2 whereas Table 3 represents different types of antibiotics that were prescribed across different regions with beta lactams being the major AMA prescribed in both regions and Table 4 presents the costs incurred due to these prescriptions. Table 5 depicts the ATC codes of AMA's, PDD values and PDD/DDD ratio of drugs. Table 6 presents the cost effective analysis of the data collected from both the regions with a total amount of 3,25,896 INR being spent on AMAs with an average duration of stay of 6.8 days in hospitals.

Antibiotics	No. of prescriptions inNorth India	No. of prescriptions inSouth India
Beta lactams		
Penicillins (cloaxacillin, methicillin, penicillin V, penicillin G, Ampicillin,amoxycillin, piperarcilin)	187	130
Cephalosporins (cephalexin, cefuroxime, cefixime, cefpodoxime, ceftriaxone, cefaperazone, cefuroxime axetil, cefotaxime)	186	162
Carbapenems (imipenem, meropenem)	53	52
Combinations with beta lactamase inhibitors (ampicillin+salbactum, amoxicillin+clavulanic acid, piperacillin+tazobactum)	224	440
Aminoglycosides		
Amikacin	174	98
Tobramycin	103	50
Neomycin	22	23
Framycetin	46	21
Gentamicin	101	180
Tetracyclines		
Tetracycline	74	52
Doxycycline	96	89
Minocycline	63	32
Macrolides		
Azithromycin	105	203
Erythromycin	4	6
Roxithromycin	98	144
Clarithromycin	66	83
Lincosamides		
Clindamycin	139	118
Lincomycin	35	33
Oxazolidione		
Linezolid	46	52
Sulphonamides		
Sulfadiazine	35	34
Sulfamethoxazole	28	29
Combination with trimethoprim (cotrimoxazole)	132	146
Quinolones		
Norfloxacin	114	94
Ciprofloxacin	168	174
Ofloxacin	78	76
Levofloxacin	45	60
Gatifloxacin	35	37
Miscellaneous		
Metronidazole	55	68

Rifampicin/Rifampin	35	34
Chloramphenicol	58	46
Sulfasalazine	43	38
Anti-tubercular drugs	158	137

Table 3: Distribution of antibiotics in North Indian and South Indian patients.

Antibiotics class	No. of prescriptions in North India	Cost (INR)	No. of prescriptions in South India	Cost (INR)	Total no. of prescriptions	Cost (INR)
Beta lactams	650	60982	784	58946	1434	119928
Aminoglycosides	446	26430	372	17499	818	43929
Tetracyclines	233	14989	173	5440	233	20429
Macrolides	273	16542	436	19495	406	36037
Lincosamides	174	9845	151	6980	325	16825
Oxazolidiones	46	5690	52	4979	98	10669
Sulphoamides	195	10243	209	8985	404	19228
Quinolones	440	20491	441	16183	881	36674
Miscellaneous	349	13241	323	8926	672	22167
Note: INR=Indian rupees; no=number						

Table 4: Total number of antibiotics prescribed to patients in North India and South India grouped into class with cost.

DISCUSSION

This study is first of its kind in India to assess the use of antibiotics in a hospital setting involving inpatients as the study group. An ADR not only affects the quality of life but also increases the length of hospital stay leading to an increase in healthcare costs. Gender plays an important role in susceptibility for ADRs. Studies have shown that females are prone for ADRs. However, in our study even though higher number of females in both regions reported ADRs due to antibiotic use but this difference was not statistically significant. Though, ADRs are commonly observed in pediatric and geriatric patients, no data was calculated for pediatric population in this study as the information regarding pediatric population was incomplete from the hospital in South India. However, in both the regions more number of patients among age group ≥ 65 years compared to age group <65 years presented ADRs, but this difference was not statistically significant. Majority of the patients enrolled in North India belong to 60-70 years age group (n=98); while majority of patients enrolled in South India belong to 70-80 years age group (n=109).

The previous studies have shown advancing age, pediatric age, female gender, multiple drug usage, smoking, alcohol usage and irrational drug combination as important risk factors for ADRs. These results are in accordance to the study of Dharnidharkar who reported AMAs to be maximally responsible for ADRs and skin rash to be the dominant symptom in their study. Similarly, antimicrobials have been reported as the largest contributing to ADRs in the study of Palalian et al. and Singh H et al. Parenteral drugs constituted 88% of the total number of AMAs prescribed. On analyzing the route of administration of drugs 82.18% were given parenterally, 6.48% were given through oral route, 5.88% were given intramuscularly and 2.61% was given intraocularly 2.85% and topically. The major complaints reported by patients were fever and other symptoms related to respiratory, urinary, skin disorders, gastrointestinal and common road injuries for which they were prescribed antibiotics.

The most common AMAs prescribed were combination of beta lactams followed by aminoglycosides in North India and combination of beta lactams followed by quinolones in South India. The preferred route of administration was injectable. The percentage of drugs prescribed by generic name was 82% being 46% and 36% in North and South India respectively as illustrated in Table 3 of which *chi-square* value was calculated and was found to be 63.8123. The p value is <0.00001 significant at p<0.5. The present study provides us with an overall pattern of antibiotic use in

patients admitted in a tertiary care hospital along with their pharmacoeconomicity. Majority of the patients were males, the prevalence of gender inequality as a result of which males are preferentially taken to tertiary care institutes for treatment as compared to females with a similar severity of illness. Another observation was about the majority of the patients were prescribed at least one antibiotic and sometimes 2-3 antibiotics were also noticed based on the severity of illness. The average number of antibiotics being prescribed per patient is 1.7, as already mentioned, total antibiotic usage included both intravenous and oral antibiotics, of which beta-lactams (combinations the most) were maximally prescribed in both North and South India. Third generation cephalosporins were prescribed more frequently, which may be because the sites are a tertiary care hospitals and patients would have already been administered and probably developed resistance to lower generation antibiotics like co-trimoxazole, chloramphenicol, penicillinase resistant penicillins (methicillin, oxacillin, cloxacillin) etc. Culture sensitivity was done in most of the patients but due to prior exposure to antibiotics (before reaching the hospital), the cultures are negative most of the times. Majority of the drugs were given by intravenous route followed by the oral route. This mainly indicates that patients in wards or ICUs necessarily require the IV route for urgent control of infections and to minimize morbidity as compared to oral route. According to our study, there were a fairly good percentage of prescriptions by generic names but there is still a long way to go before we thoroughly inculcate this habit which will again help in reducing the cost, as was reported in. Most of the patients reach tertiary care hospital in advanced stage with prior appropriate/inappropriate exposure to antibiotics and it becomes an absolute necessity to use higher generations of antibiotics.

The most commonly noticed symptoms were respiratory infections, fever, severe diarrhea, injuries and patients in ICU were mainly requiring palliative care due to renal failure, UTI's due to long hospital stay and infections due to catheter etc. Beta lactams (Combinations with beta lactamase inhibitors (ampicillin+salbactum,amoxicillin+clavulanic acid, piperacillin+tazobactum) in both North and South India were prescribed more common; amikacinin North India and gentamicin in South India among aminoglycosides were prescribed frequently; azithromycin in both North and South India among macrolides were commonly prescribed, ciprofloxacin among quinolones was commonly prescribed in both North and South India and anti-tubercular drugs among miscellaneous agents were prescribed most commonly in both North and South India. The average duration of stay of patients was found to be 6.8 days. The overall rate of single drug prescription was 44% and that of fixed drug combinations was 46%. And out of the total number of AMAs prescribed, generic prescription rate was 2%. Overall, 82% of the total drugs were from the WHO list of essential medicine, 2010.This leads to increased cost of therapy. The antibiotics are gradually de-escalated based upon the patient response and protocol of treatment, the antibiotics prescribed with the difference in cost and the combined cost incurred on medications in both the regions is depicted in Table 5.

Drugs	ATC CODE	DDD	PDD	DDD/PDD
Beta lactamase	JO1CR	17	25.66	0.66
Penicillins	-	-	-	-
Cephalosporins				
First generation cephalosporins	JO1DB	2.3	0.77	2.98
Second generation cephalosporins	JO1DC	23	2.54	9.05
Third generation cephalosporins	JO1DD	19.8	13.83	1.43
Carbapenems	JO1DH	2.1	0.23	9.13
Aminoglycosides	JO1GB	0.8	0.68	1.17
Quinolones	JO1MA	3.1	2.87	1.08
Sulphonamides	JO1EC	3	1.27	2.36
Tetracyclines	JO1AA	1.3	0.55	2.36
Macrolides	JO1FA	2.1	1.55	1.35
Note: ATC=Anatomical Threrapeutic Classification; DDD=Defined Daily Dose; PDD: Prescribed Daily Dose				

Table 5: ATC codes of AMA's, PDD values and PDD/DDD ratio of drugs.

The efficiency of a drug as a possibility for improvement of health which ultimately resulted in ideal conditions, such as clinical trials and its effectiveness-the ensuing improvement of health in real conditions contributed to the increased pharmacoecomomicity in patients in North India compared to the patients of South India. In this study, the total amount spent on these prescriptions was 22,896.The average cost per prescription was 24.10. Average hospital pharmacy cost per prescription was 16.08. Average outside pharmacy cost per prescription was 8.02. Antibiotics accounted for 69% of the total cost followed by analgesics (15%) and multivitamins (9%). The frequency and the quantity of the individual drug prescribed were written in all prescriptions as notified by Ram Krishna Prasad et al in his two previous studies.

To study drugs, it is essential that we have a system for classifying them. Presently the most useful drug classification scheme is that developed by the WHO, it is known as ATC system, the letters standing for anatomic, therapeutic and chemical, which represents the three axes along which drugs are classified. The first axis, anatomic is categorized according to the body system that is affected, within this classification drugs are next categorized by their main therapeutic use. The final sub-classification is by the chemical class of the drug. Each drug is assigned a unique identifying number, in order of appearance in the market, as showed in Table 5 along with the calculations of Defined Daily Dose (DDD), Prescribed Daily Dose (PDD) and the ratio of it (DDD/PDD) (Table 6).

S NO.	Attributes	Dose
1	Total no. of prescriptions	950
2	Total no. of antibiotics prescribed	600
3	The average number of antibiotics being prescribed per patients	1.7
4	The total amount spent on these prescriptions (INR)	3, 25,896
5	The total amount spent by north Indian population (INR)	1, 78, 453
6	The total amount spent by south Indian population (INR)	1, 47,443
7	The average cost per prescription (INR)	343
8	Average hospital pharmacy cost per prescription (INR)	56.08
9	Average outside pharmacy cost per prescription (INR)	78.02
10	The average duration of stay of patients (days)	6.8

Table 6: Cost Effective Analysis (CEA) data.

A prescription by a doctoris a reflection of physicians attitude towards the disease and the role of drug in its treatment. The ultimate outcome of the dental prescription analysis gives a message to the prescribing physician to achieve rational and cost effective medical care. It also provides an insight into the nature of health care at that facility. Pharmaco economic evaluation is an analytical tool used with increasing frequency to assist decision making in the financing and management of pharmaceutical products in the health care system or national health insurance programs of an individual country. The Cost Benefit Analysis (CBA) is based on the economic standard of efficiency. CBA requires the measuring of all benefits and costs which are either directly or indirectly attributable to the outcome under investigation. CBA is important to healthcare economists and policy makers because it identifies inefficiency, and inefficiency equates to welfare loss (ideally, the aim is to minimize welfare loss). CBA has become the standard of modern welfare economics. The Cost Effectiveness Analysis (CEA) ratio can be a more practical tool for decision making than CBA in that it involves the comparison of the costs of achieving a particular non-monetary objectives; such as lives saved, health improvement, or quality of life. CEA ratios can be applied when the costs are expressed in money (*i.e.,* INR) and the benefits are in specific health outcomes. The pharmaco economic data of prescriptions drawn after CEA from our study is tabulated in Table 4 and 6 respectively. The field of pharmaco economics has been increasingly used to enhance the population's Quality of Life (QoL). However, to successfully impact a patient's life many factors such as the cost to the patient of purchasing multiple pharmaceuticals and the impact of those costs to society need to be addressed.

CONCLUSION

Drugs are a useful tool in the prevention of and treatment of symptoms and diseases, but if not used properly, they may be harmful and cause adverse effects or produce sub optimal effect. The prescription should be rational and hospital guidelines should be followed in consideration of patient's financial status. This study has shown to analyze the drug utilization pattern in patients along with the pharmacoeconomic evaluation based on the results obtained every patient was exposed to drugs. Most of the prescriptions were rational. Antibiotics form the cornerstone of therapy in practice. Both mono therapy and poly pharmacy were practiced. Safer drugs with less adverse effect profile were considered. The problems relating to the adverse drug reactions seriously encumber the health services in every country.

Based on pharmacoepidemological aspect/pharmacoeconomic grounds the cost of treatment differed vastly from region to region, as patients in North India were shown with increase percentile in their cost of illness and hospital stay due to the continuity in increasing medical costs, including the tremendous expenditure connected with the treatment of chronic illnesses, requiring assessment of the quality, efficiency and safety of new drugs, but also application of methods and criteria allowing systematic assessment and interpretation of the real contributions of new medicinal products.

We have not found any other population based studies that relate infectious symptoms in a cohort of patients to reported use of antibiotics. Regional variations in antibiotic consumption may be explained by a variety of factors. Several authors have suggested that doctors decision to prescribe and patients use of antibiotics are explained not only by clinical factors but also by differences in bacterial infections across regions. Difference in bacterial infection can hardly explain variation in morbidity as large as four fold among industrialized countries. The literature has suggested the lack of education, physicians and patients expectations, uncertainty, cultural and social behavior and differences in regulatory practice, among other factors. The results of the current study emphasizes the need for a hospital based team constituting of pharmacologists, dermatologists, physicians and consultants from emergency medicine to diagnose, correlate and manage ADRs promptly in the interest of patient safety. The results further stresses the need to improvise antibiotic prescription practices and reframing hospital antibiotic policy to minimize ADRs events related to antibiotics which will ultimately minimize the hospital stay and costs incurring from hospitalization. Further studies from time to time are required in drug utilization pattern and standard treatment guidelines to be circulated among practicing physicians.

ETHICAL COMMITTEE APPROVAL

The study was approved by the S2J independent ethics committee for Rajendra Institute of Medical Science (RIMS) situated in Ranchi, Jharkhand (North India), India and Axon hospital situated in Hyderabad, Telangana (South India), India. The study was conducted as per the declaration of Helsinki, 2000 version on ethical standards for medical research involving human subjects.

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LIMITATIONS OF CURRENT STUDY

The current study did not represent the true prevalence due to voluntary/spontaneous nature of reporting. Risk factor correlation was not studied in the current study.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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