

Prescribing pattern and appropriateness of drug treatment of diarrhoea in hospitalised children at a tertiary care hospital in India

Abstract

Objectives: To analyze the prescribing pattern and appropriateness of drug treatment of diarrhoea in hospitalized children. The economic burden of the disease and adverse drug reactions (ADRs) occurring during the course of treatment was also studied. **Materials and Methods:** It was a prospective, observational, single center study undertaken in pediatric inpatients of diarrhea, aged one month to twelve years over a period of eighteen months at a tertiary care teaching hospital in western India. Modified Kunin's criteria along with the guidelines set by the Indian Academy of Pediatrics (IAP) and WHO were followed for assessing the appropriateness of the antimicrobials prescribed. The adverse drug reactions occurring during course of the treatment were noted and the economic burden of the disease was calculated as direct and indirect costs. **Results:** A total of 103 patients were enrolled, of whom 45% were in the age group of one month to one year. Diarrhoea with some dehydration was diagnosed in 50.5% patients followed by severe dehydration (34.9%) and no dehydration (14.6%). The number of drugs and antimicrobials prescribed per patient were 7.53 ± 1.87 and 1.92 ± 0.67 , respectively. Rehydration fluids (31.6%) and antimicrobials (25.5%) were the commonest drug groups prescribed. Among the antimicrobials, cefotaxime, cotrimoxazole and amoxicillin with clavulanic acid were frequently prescribed. Appropriate antibacterial therapy was given in only 13% of the cases. Only one ADR due to cotrimoxazole was observed. The economic burden of the disease was calculated to be Rs. 3164.81 per patient. **Conclusion:** Inappropriate use of antimicrobials was seen in the study. Emphasis on proper diagnosis and treatment, education and availability of locally effective guidelines may help in a better and judicious use of drugs in children.

Key words: Adverse drug reactions, Diarrhoea, drug utilization, modified Kunin's criteria, pediatric patients

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INTRODUCTION

Children represent about 40% of India's population. Most suffer from frequent, usually self-limiting illnesses. Drug use in children has not been as extensively researched as in adults. It has been observed that 18.2% of children take drugs that are not required.^[1] Respiratory tract and gastrointestinal tract are the common sites for infections in children. Diarrhoea or gastroenteritis is defined as "passage of loose, liquid or watery stools more than three times a day with/without bloody stools, vomiting or dehydration". Each year 12 million children in developing countries die before they reach their 5th birthday, many during the first year of life. Among these, 16% deaths are due to acute diarrhoeal disease. Among five children nearly one's death is due to diarrhoea, a loss of about 1.5 million lives each year. This toll is greater than that caused by AIDS, malaria and measles combined.^[2] In India, diarrhoeal disease accounts for 8.2% of total burden of disease, contributing 22 million Disability Adjusted Life Years (DALYs), the highest among communicable diseases.^[3] On an average, a child suffers from around 12 episodes of diarrhoea, 4 such episodes occurring in infancy.^[4] This has a negative impact on quality of life and can result in considerable healthcare costs.

The pathogens causing diarrhoea are mainly viruses in children below the age of five years, while both bacterial and viral pathogens are implicated in adults. Other causes of diarrhoea are disordered motility, lactose intolerance, irritable bowel disease, bile salt enteritis, inflammatory bowel disease etc. Rotaviruses are the most common organisms (15-25%) causing diarrhoea in children followed by bacterial pathogens like *Escherichia coli* (10-20%), shigella (5-10%), campylobacter (10-50%), *Vibrio cholerae* (5-10%) and salmonella species. The use of new low osmolarity ORS and zinc supplementation in all cases of diarrhoea in addition to breast feeding, continued feeding and selective use of antibiotics help in reducing morbidity and mortality due to diarrhoea. The WHO estimates that antibiotic treatment is necessary in only one in twenty cases of childhood diarrhoea. Yet huge resources are currently spent on anti-diarrhoeal drugs annually, most of which are useless or harmful. Therapeutic guidelines have been issued by the WHO and Indian Academic of Pediatrics (IAP), which aim at reducing the inappropriate use of antimicrobials and anti-diarrhoeal drugs in treatment of diarrhoea. The effectiveness of such guidelines can be evaluated by drug utilization research. This study was carried out to evaluate the utilization pattern of drugs prescribed for diarrhea in children admitted in a tertiary care hospital in a state of western India. The compliance with Standard Treatment Guidelines, cost and adverse reactions to drugs used in treatment of diarrhea in these patients were also evaluated.

MATERIALS AND METHODS

This was a prospective, observational, single center study, undertaken in pediatric inpatients of diarrhoea at Civil Hospital Ahmedabad (CHA), a tertiary care teaching hospital in western India. The study was carried out over a period of 18m. Permission from Medical Superintendent and the Head of the respective paediatric unit was obtained before conducting the study. Children aged between 1m to 12years, of either gender and diagnosed to be suffering from diarrhoea were included after consent from the parents/guardians. Demographic and clinical data obtained from these patients were recorded in pretested case record form (CRF) and analyzed to determine the utilization pattern of drugs used. The economic status of the caretakers of the patients was determined^[5] and the immunization status was determined in reference to the national immunization schedule.^[6] Modified Kunin's criteria^[7] and the guidelines of the Indian Academy of Pediatrics, India^[8] (IAP) were used to assess the appropriateness of drugs prescribed. The cases were categorized as per the following criteria:

- I. Agree with the use of antimicrobial therapy; the protocol (choice, route, duration, and dosage) is appropriate.
- II. Agree with the use of antimicrobial therapy; the protocol (choice, route, duration and dosage) is probably appropriate. Usually a microbiology report is missing to classify the protocol in another category.
- III. Agree with the use of antimicrobial therapy; but a different antimicrobial (less expensive, less toxic, narrower spectrum, other combination) is preferred.

IV. Agree with the use of antimicrobial therapy but a modified dose, interval, duration or route of administration is preferred.

V. Disagree with the use of antimicrobial therapy, administration is unjustified.

Categories I and II indicate "appropriate therapy", categories III and IV indicate that there was some major deficiency in the choice or use of antimicrobials and category V indicates unnecessary antimicrobial use. The economic burden of the disease was calculated as direct and indirect cost of therapy.^[9] The adverse reaction of these drugs were noted and analyzed for seriousness and causality assessment using standard assessment scales. The data was recorded and analyzed using Microsoft Excel spreadsheet 2007. Chi-square test was used for statistical analysis and $P < 0.05$ were considered to be statistically significant.

RESULTS

A total of 103 inpatients of diarrhoea were enrolled over the period of 18m. Out of these, 56 (54.4 %) were males and 47 (45.6%) were females (male to female ratio was 1.19: 1). The mean age of the patients was 2.77 ± 2.84 years with a range of 1m to 11years. Most patients (45%) were less than 1year of age. About 57% belonged to the lower income group (family income less than 40,000 per annum). A total of 78.8% patients were fully immunized as per the National Immunization Schedule. Pica was reported in 13 patients (12.6%). Protein Energy Malnutrition (PEM) was observed in 42 (40.8%) inpatients; among these 33 patients had mild to moderate malnutrition and 9 patients had severe malnutrition (Grade III and IV) [Table 1].

Out of 103 inpatients, 15 (14.6%), 52 (50.5%) and 36 (34.9%) were diagnosed with no, some and severe dehydration, respectively

Table 1: Demographic and Clinical characteristics of pediatric inpatients with diarrhoea (n = 103)

Patient characteristic	Number of patients (%)
Age	
>1 month to ≤ 1 year	45 (43.7)
>1 year to ≤ 3 years	26 (25.2)
>3 years to ≤ 5 years	12 (11.7)
>5 years	20 (19.4)
Gender	
Male	56 (54.4)
Female	47 (45.6)
Immunization status	
Complete	81 (78.6)
Partial	14 (13.6)
Nonimmunized	7 (6.8)
Unknown	1 (0.97)
Status of dehydration	
No dehydration	15 (14.6)
Some dehydration	52 (50.5)
Severe dehydration	36 (34.9)

[Table 1]. On stool examination, infection with *Vibrio cholerae* was detected in 5 patients and with *E.coli* in 4 patients while stool examination was negative for pathogens in the remaining patients. Anaemia, severe malnutrition and septicaemia were observed in 64, 9 and 5 patients respectively. The average duration of diarrhoea was 2.31 ± 1.63 days in inpatients with a frequency of 4 to 15 diarrhoeal episodes per day. Out of 103 inpatients, 99 patients were cured and discharged, while 2 patients died during course of therapy. The cause of death in these patients was septicaemia with severe dehydration. Two patients were lost to follow up. The patients were hospitalized and administered medicines for an average duration of 4.49 ± 2.09 days with a range of 1 day to 15 days.

A total 776 drugs were prescribed as 781 formulations in these inpatients. A switch from intravenous to oral formulation was observed in 5 cases during therapy. This was attributed to an improvement in the patients' condition. The mean number of drugs prescribed per patient was 7.53 ± 1.87 (range 3 to 15). Seven drugs were prescribed in 28% patients. Out of the various drugs prescribed, 245 (31.6%) were rehydration fluids like ORS (102), ringer lactate (71) and, isolyte-P (71), normal saline (1). Other frequently prescribed drugs were antimicrobials (198; 25.5%) followed by zinc (98; 12.6%) and nutritional supplements (69; 8.9%). Other drugs prescribed included anti-emetics (64), haematinics (48), antipyretics (24), anticonvulsants, bronchodilators, corticosteroids and other electrolytes like magnesium chloride, potassium chloride and calcium chloride [Figure 1].

A total of 257 (33.11%) fixed dose combinations (FDCs) were prescribed. Among these 183 (71.20 %) were rational FDCs like amoxicillin + clavulanic acid, ORS and cotrimoxazole, while 74 (28.79%) were irrational FDCs like nutritional supplements and ibuprofen with paracetamol. Out of the 781 drug formulations prescribed, 329 (42.1%) were prescribed by their brand names, while 57.9% were prescribed by their generic names. Zinc acetate was most frequently prescribed by its brand name. Among the brand formulations, 227 (69%) were dispensed by private pharmacies while 102 (31 %) were dispensed by the hospital pharmacy. Out of the 781 formulations prescribed, 481 (61.6%) were oral formulations and

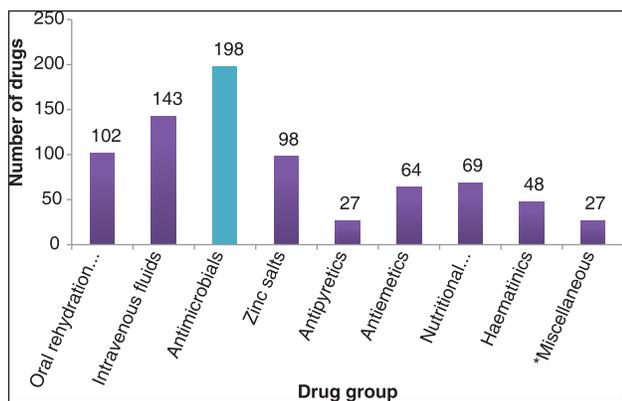


Figure 1: Drugs prescribed in pediatric inpatients of diarrhoea at CHA (n = 776)

298 (38.2%) were intravenous injections including vials (154; 51.9 %) and pints (143; 48.15%). Two drugs were administered as nebulisers. Syrup (307; 63.8%) followed by powders (107; 22.2%) and tablets (67; 13.9 %) were the common oral formulations prescribed.

Out of 103 inpatients, 71 patients received ringer lactate (RL) and normal saline, which was considered rational since intravenous rehydration fluids are considered the primary treatment of diarrhea with severe dehydration and in those with mild and moderate dehydration who are unable to take adequate ORS within 4h. Two patients suffering from severe dehydration were administered Isolyte P as primary rehydration fluid instead of RL, which was not appropriate. Isolyte P was additionally administered in 71 inpatients. The doses and frequency of all the intravenous rehydration fluids and oral rehydration fluids were appropriate and as per the IAP guidelines. A total of 102 formulations of ORS were administered in the right dose and duration soon after the severity of dehydration and diarrhea abated.

Antimicrobials were prescribed to all inpatients (100%). Most inpatients (60; 58.3%) received two antimicrobials during their hospital stay. The average number of antimicrobials prescribed per patient was 1.92 ± 0.67 (range 1 to 4). Twelve different antimicrobials were prescribed; among these cefotaxime (68) was the most prescribed followed by cotrimoxazole (55) and amoxicillin + clavulanic acid (25) [Figure 2]. The antimicrobials that accounted for more than 90 % of the total antimicrobials used (Drug Utilization (DU) 90%) are listed in Table 2.

The appropriateness of antimicrobial usage was evaluated using modified Kunin's criteria and IAP guidelines for treatment of

Table 2: DU 90% of antimicrobials in pediatric inpatients of diarrhoea (n = 103)

Antimicrobial	Number of prescriptions (%)
Cefotaxime	68 (34.34)
Cotrimoxazole	55 (27.78)
Amoxicillin+ clavulanic acid	25 (12.63)
Doxycycline	15 (7.57)
Ceftriaxone	12 (6.06)
Ofloxacin	6 (3.03)
Total	181 (91.41)

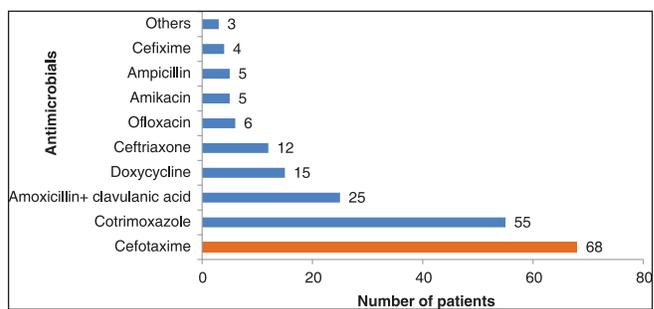


Figure 2: Antimicrobials used in pediatric inpatients of diarrhoea at CHA (n = 198)

diarrhea. Analysis of case records showed that antimicrobials were actually indicated in 40 (38.83%) patients (17 patients required one antimicrobial and 23 patients required two) as per the recommended guidelines. Among 40 (38.83%) inpatients who required antimicrobials, the use was appropriate only in 13 (12.62%) patients (category I and II), while it was inappropriate in 27 (26.21%) patients (category III and IV). The use of antimicrobials was not necessary in 63 (61.17%) patients (category V) [Table 3].

Ninety eight (12.63%) zinc preparations (zinc acetate) were prescribed in 95.15 % inpatients. All 98 prescriptions of zinc salts were considered as rational as per IAP and WHO guidelines.

The rationality of the prescriptions was also evaluated in reference to the WHO core indicators. It was observed that polypharmacy (7.53 ± 1.87 drugs per encounter) was widely practiced. Antimicrobials and parenteral drugs (injections) were prescribed to all the patients. Nearly 57.9% drugs were prescribed by their generic name. More than 65% of the drugs prescribed were included in the National Essential Medicines List (EML) 2011 and WHO EML 2010 [Table 4].

An analysis of the ADRs observed in the patients showed that maculopapular rash was reported in a 5m old male child due to cotrimoxazole use. The ADR was non-serious in nature. Patient recovered within a day after the drug was withdrawn. Causality assessment was carried out using WHO-UMC and Naranjo's causality assessment scales and cotrimoxazole was the probable drug causing this ADR. The ADR was not severe and not preventable. Total cost incurred to treat the ADR was Rs 28.30.

The average hospital expenditure incurred per patient per day was Rs 527.29. Considering the average duration of hospitalization of 4.49 days, the average hospital expenditure per inpatient was Rs 2367.53. The average cost of drugs prescribed per inpatient was Rs 212.46, while the average cost of medical supplies was Rs 20.55. Average cost of transportation per inpatient was Rs 94.17. Hence; the average total direct cost per inpatient amounted to Rs 2694.71. The average indirect cost per inpatient calculated as the loss of wages of parents/guardians per patient was Rs 470.10. Therefore

the economic impact of diarrhea was Rs 3164.81 per inpatient. The total economic impact of diarrhea in these patients calculated over a period of 18 months was Rs. 3,25,975.43 for 103 inpatients.

DISCUSSION

Each year, an estimated 2.5 billion cases of diarrhoea occur in children under five years of age and 12 million of them die in developing countries.^[10] The WHO and Indian Academy of Pediatrics have recommended guidelines for its treatment emphasizing early rehydration therapy and restrictions on use of drugs like antimicrobials and anti-diarrhoeals. In spite of guidelines, misuse of drugs like antimicrobials, anti-diarrhoeal etc. has been observed in various studies hence, the present study was undertaken.

It was observed that majority of the patients were males and below one year of age, which was also seen in a study conducted in Chennai,^[11] the Leeds study^[12] and the USA study.^[13] Usually most children are weaned from breast feeding at an age of 4 to 6 months. The possibility of infection by faeco-oral route is more likely during this period because of improper and unhygienic feeding practices. Further, while maternal antibodies are declining over this period, the child is yet to develop its own defenses against infections.^[14] While the predominance of diarrhoea in male children cannot be explained, it is assumed that the male children were likely to be brought to the hospital for treatment that the females. This is an unfortunate but common practice in India. A follow-up observational study in Kolkata,^[15] India found that boys with diarrhoea were more likely to be given oral rehydration fluids than girls, and were more likely to be taken to qualified health professionals for treatment. Most inpatients (78.84%) were fully immunized as per the National immunization schedule. This reflects a general awareness among the caregivers about immunization and a good functional immunization program for children by health care providers.

Severe malnutrition PEM Grade III and IV was observed among 5 (4.8 %) and 4 (3.8%) patients respectively in our study. A Chennai

Table 3: An assessment of appropriateness of antimicrobials used for pediatric patients of diarrhoea (n = 103)

Kunin's criteria	No of patients (%)	Justification
Criteria I - Agree with the use of antimicrobial therapy, the protocol is appropriate.	6 (5.8)	—
Criteria II - Agree with the use of antimicrobial therapy, the protocol is probably appropriate but a microbiology report is missing to classify the protocol in another category.	7 (6.8)	Microbiology testing was performed, but report was inconclusive. However the protocol was appropriate
Criteria III - Agree with the use of antimicrobial therapy, but a different antimicrobial is preferred.	27 (26.21)	Too many antimicrobials were prescribed concomitantly; the combination of antimicrobial was not synergistic or antimicrobial cover was inadequate in some cases
Criteria IV - Agree with the use of antimicrobial therapy but a modified dose, interval, duration or route of administration is preferred.	0 (0)	—
Criteria V - Disagree with the use of antimicrobial therapy, administration is unjustified.	63 (61.17)	Infections viral in origin, Antimicrobials not required

study^[11] found that 24 (1.4 %) patients suffered from PEM Grade IV. These findings reiterate that PEM and diarrhoea are interrelated and the management of diarrhoea in these patients should also take this fact into consideration.

The inpatients in this study were followed up till discharge from hospital. The average duration (4.49 ± 2.09 days) of hospital stay was similar to a study conducted in pediatric inpatients at a tertiary care hospital, Nepal.^[16] The average number of drugs/injections per encounter is an important index in prescribing practices.^[17] The values in our study are higher than the recommended limit of two drugs per encounter and the international average of 2.2 drugs per prescription.^[18] Polypharmacy was evident in the study as in 27% of inpatients; seven drugs were concomitantly prescribed. A cluster survey conducted in under five children of acute diarrhoea at Bangladesh found that the average number of drugs prescribed per patient was 1.5; a figure much lower than that found in our study^[19] while a Nepal study^[16] found that the average number of drugs per pediatric inpatient was 4.5 ± 3.7 . Hence, it is evident that the practice of polypharmacy is prevalent in our setup; thereby suggesting irrational prescribing practice in this regard. Polypharmacy practice is well known to be associated with drug related adverse drug reactions, medication errors, clinically significant drug interactions and an increased rate of admissions to hospital. The reasons for this practice could range from lack of accuracy/confidence in diagnosis or lack of awareness of the various treatment guidelines and needs further evaluation.

Table 4: An analysis of drug utilization as per WHO Core indicators in pediatric patients of diarrhoea

WHO Core indicators	Inpatients (n=103)
Number of drugs prescribed per encounter (mean + SD)	7.53±1.87
Percentage of drugs prescribed by generic name	57.87
Percentage of encounters resulting in the prescription of an antimicrobial	100
Percentage of encounters resulting in the prescription of an injection	100
Percentage of drugs prescribed from National Essential Medicines List (EML) 2003	66.97
Percentage of drugs prescribed from WHO EML 2010	65.3

A total 776 drugs were prescribed in 103 inpatients. Rehydration fluids and antimicrobials were the most commonly prescribed drug groups. No anti-diarrhoeals agents were prescribed to these patients. The average number of antimicrobials prescribed per inpatient in our study was 1.92 ± 0.67 with a range of 1 to 4 antimicrobials. Majority inpatients (58%) received two antimicrobials during their hospital stay. When compared with other studies conducted in central Thailand^[20] and Chennai,^[11] it was observed that antimicrobials were prescribed significantly more in our study ($P < 0.05$). Zinc salts were prescribed more often in our study as compared to that reported in the Chennai study ($P < 0.05$) [Table 5]. Ceftriaxone was the most commonly used antimicrobial followed by amikacin. The use of antimicrobials was significantly higher in our study than in other studies mentioned above.

While all patients in our study were prescribed antimicrobials, they were indicated only in 38.8% patients with cholera, severe malnutrition, a positive stool culture, septicemia, and in children less than 3 months. Only 12.6% patients in our study received antimicrobials appropriately. Inappropriate use of antimicrobials in children with diarrhea has been reported by other researchers as well. A cross-sectional study conducted in 424 patients of diarrhoea at central region province of Thailand observed that only 27.4% cases were appropriately managed with antimicrobials and 72.6% were inappropriately treated as per the guidelines.^[20] Injudicious use of antimicrobials observed in our study may be due to factors like doubtful diagnosis and underuse of laboratory investigations resulting in an empirical use of antimicrobials. While the exact reason needs further evaluation, this injudicious use of antimicrobials needs attention and appropriate interventions for rectification.

Appropriate use of ORS as well as intravenous rehydration fluids as per WHO and IAP guidelines was observed in most cases, except in two cases where Isolyte P was used as replacement fluid in severe dehydration rather than RL. Isolyte P is recommended in literature as a maintenance fluid in pediatric patients; however the WHO and IAP guidelines do not recommend this fluid for maintenance fluid therapy. A questionnaire based study conducted in emergency pediatric department at New Zealand and Australia found that 86% of physicians would use intravenous fluids in severe dehydration, most commonly half normal saline (with glucose) and normal saline.^[21] Zinc acetate was prescribed in 95.2% inpatients which was better than the Chennai study (65%). A questionnaire based national survey found that 16.9% of prescribers prescribe zinc supplements for treatment of diarrhoea.^[22] Zinc supplements

Table 5: Treatment of diarrhoea in pediatric inpatients - A comparison with published studies

Parameter	Our study (n=103) (%)	Howteerakul N <i>et al</i> (Central Thailand) ^[20] , 2004 (n=149) (%)	Balasubramanian S <i>et al</i> (Chennai, India) ^[11] , 2007 (n=1700) (%)
Age less than 1 year	43.68	45	49.88
Males	54.37	56	NA
Patients prescribed antimicrobial	100	92*	41.8*
Patients prescribed ORS	99.02	NA	NA
Patients prescribed zinc salts	95.15	NA	65*

* $p < 0.05$ considered significant using Chi-square test

are recommended in patients of diarrhoea because it reduces the severity and frequency of diarrhoea.

Certain good prescribing practices have been observed in our study. For example, more than 70% of FDCs like ORS, cotrimoxazole and amoxicillin + clavulanic acid etc. used in patients are included in EML (National and WHO). A study conducted in pediatric inpatients at a tertiary care hospital in Nepal found that FDCs constituted 6.9% of all drug used.^[16] Prescription of single drug formulations instead of FDCs may make better prescribing sense in terms of cost and safety. Generic prescribing and use of essential medicines are important parameters to evaluate the rational use of medicines (RUM). It was observed in this study that nearly half of the drugs in indoor patients were prescribed by their generic names. Our study fares similar or better than other studies, in this regard. This is attributed to the fact that most drugs supplied by hospital pharmacy are generic products, which are likely to be chosen by prescribers. Brand drugs were also prescribed in our study. In spite of availability of medicines from the hospital pharmacy, nearly 34 % of inpatients had purchased drugs from commercial pharmacies. This practice suggests a gap in communication between the hospital pharmacists and the prescribers regarding the list of available drugs. In the present study 65.3% of drugs prescribed to inpatients were from the WHO Essential Medicine List, while 67% of drugs were from National Essential Medicine List 2003. Essential drugs offer a cost-effective solution to many health problems in a developing country. Knowledge, availability and access to drugs in the EML promote rational therapeutics.

The higher cost of therapy incurred in our study as compared to previous studies^[23,24] may be attributed to increasing cost of drugs and health care facilities. A difference in the healthcare policies between our country and other countries (reimbursements, higher monetary value for productivity) and the prospective nature of this study may also account for this discrepancy. However, simple measures like curtailing polypharmacy, generic prescribing, appropriate selection of drugs and their formulations and definitive instead of empirical therapy can minimize the cost burden in these patients.

One ADR was reported to drugs prescribed for acute gastroenteritis with severe dehydration in our study. A review study of ADRs in pediatric patients estimated an overall incidence of ADRs in inpatients to be 9.53% and that in outpatients to be 1.46%.^[25] A rather low incidence of ADR (0.9%) in inpatients was reported in our study as compared to the above studies. Under-reporting of minor or non serious ADRs like nausea or vomiting which were either not detected or reported could contribute to low reporting.

The findings of this study suggested that a relatively rational approach to oral and parenteral rehydration therapy and zinc but inappropriate and overuse of antimicrobials, nutritional supplements and irrational FDCs in our study. However; further studies in this area are warranted before suggesting ways to reduce the economic impact of the disease. This is important for a centre like ours with a huge patient population, most of whom belong to the lower and lower middle socioeconomic groups. Some of the recommendations

that may be made based on this study include reducing polypharmacy and empirical prescribing, encouraging generic prescribing and appropriate choice of drugs and their formulations.

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