Pattern of Prescription Practices in Acute Respiratory Infection and Diarrhoea Cases in Out Patient Department of Tertiary Care Hospitals in West Bengal, India; A Cross Sectional Analysis through Rational Use of Medicine Consensus Approach

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Research Article

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Abstract

Background: Evaluation of prescription patterns would determine the drug utilization with main emphasis on rational use of medicine. The problem of irrational use of drugs is rampant particularly in developing nations. The present study was undertaken for evaluating the prevailed prescription patterns in tertiary hospitals with diarrhoea and/or Acute Respiratory Infection (ARI) to address specific areas of deficiencies and deviation from the available guidelines.

Method: We conducted this observational cross-sectional study from August 2019 to December 2020 in Medicine & Paediatrics outpatient departments and Urban Health Training Centre in two Government teaching hospitals in West Bengal, India. We included 630 prescriptions (511 – ARI, 119- diarrhoea) and evaluated in terms of disease and medicine prescribed including antibiotic related indicators. We compared prescription patterns across different age groups, different strata of prescribers and compared against WHO standards. A Rational Use of Medicine Consensus (RUMC) committee was formed and the prescriptions were assessed for appropriateness independently by a pharmacologist and clinician. Deviations, if any, were ascertained from the available guidelines and the acceptability of the deviations were determined by consensus

Result: Age and sex were mentioned in all prescriptions however signs & symptoms, provisional diagnosis and follow up visit were mentioned in 90.3%, 4.9% and 67.9% prescriptions respectively. Body weight was mentioned in 88.5% of prescription of children (< 18 years). Higher rates of Fixed Dose Combination (51%), lower proportion of generic drug (23.3%) and adherence to hospital formulatory (36.5%) were some the major concerns identified. Antibiotics prescription rate (APR) and multiple antibiotic prescription rate (MPR) were respectively 57% and 10%; both found significantly higher for diarrhoea than ARI. Deviations from Standard Treatment Guidelines were found in 98.9% prescriptions and 90.4% of which were unacceptable. Agreement between clinician and pharmacologist was observed in 90% prescriptions (Kappa -0.114). Deviations were most commonly observed with prescriptions by interns and house-staff (99.6%), whereas acceptable deviations were more frequent among the residents (15%).

Conclusion: We conclude that in light of identified irrational prescription patterns, development of level specific treatment protocol coupled with periodic training of physician including junior doctors is required to ensure rational medicine practice.

Background

Evaluation of prescription patterns comprises of studies mentioning drug utilization with main emphasis on rational use of medicine. The drugs are said to have been used rationally when medicines are prescribed to the patients aptly according to their clinical requirement, in doses appropriate to their clinical needs, for the requisite duration with minimum expenditure for both the patients and the community (1,2.) The problem of irrational use of drugs especially antibiotics is prevailing worldwide

(3,4). Absence of access to essential medicines have been found in one-third people whereas more than half of the medicines are either incorrectly prescribed or inappropriately dispensed or sold. Also absence of drug adherence was found in 50% patients. (5). The problem is further complex in developing countries (6). In developing countries, respiratory illnesses and diarrhoeal diseases remain the main causes of morbidity and mortality particularly in children, accounting for one in five deaths and resulting in 1.5 million annual fatalities (9). Majority of diarrhoea cases in children, especially under the age of five years are caused by viruses whereas both bacterial and viral diarrhoeas are found in adults. Motility disorders, lactose intolerance, irritable bowel syndrome, bile salt enteritis, inflammatory bowel disease are some of the non-infective causes leading to diarrhoea which are also more frequent among the adult population. Though it has been estimated that antibiotics are required in 5% of diarrhoea cases, use of antibiotics in practice are rampant (10). According to WHO, in developing countries half of all viral respiratory tract infections and viral diarrhoea were treated with antibiotics. Also, antibiotics were not found to be prescribed in 70% of pneumonia cases where the use was an absolute necessity (11). However, Overuse or underuse of Medicines ,prescribing wrong or ineffective medicines, polypharmacy practices, use of expensive fixed dose combination products and misuse of antibiotics are the common forms of irrational prescription. (7,8). Irrational prescription continues in practice despite presence of treatment guidelines. Since both Diarrhoea and Acute Respiratory Infections are major public health problem particularly in children, specific management guidelines are available from WHO, Ministry of Health Family Welfare, Govt of India and in different State Government Health Departments as well. (9, 12, 13)

However, the major challenge in implementing these guideline is lack of optimization between general practitioners and specialists. Guidelines prepared by WHO, Ministry of Health etc are actually tailormade for public health practitioners practising at low resource peripheral health settings. However, implementation of such guideline at tertiary care teaching hospital gets influenced by scientific knowledge and experience of different prescribers. Major concerns to prescribers remained: encroachment on professional autonomy and applying the same standards at all levels. (14). Selection of one guideline to follow in presence of many is also a matter of choice. Even in England, there is no predominance of adhering to NICE guideline over those formulated by Guidelines and Audit Implementation Network (GAIN) or the Royal Colleges. (15). The World Health Organization (WHO) has advocated for developing and practising Standard Treatment Guidelines (STGs) and National List of Essential Medicines Lists customised to the country. (16). Adaptation and customization of international & national guidelines to the local guideline, is a pragmatic approach as variation is likely to be expected between disease risk & population profile and health system determinants. A locally or regionally oriented guideline also build local ownership and acceptance. (17–24)

The Rational Use of Medicine Consensus (RUMC) is a national task force study being conducted by Indian Council of Medical Research (ICMR) in India with the aim to formulate a national standard guideline and training modules for different level of practitioners (intern, private practitioners, practitioners at public health settings etc) based on context specific evidence evolved from the study. Hence under the ambit of RUMC, the present study was undertaken for evaluating the prescription

patterns for acute onset diarrhoea and/or Acute Respiratory Infection mapping the specific areas of deficiencies and deviation from the available guidelines.

Methods

a) Aim, design and setting:

The primary objectives of this multicentric study were to assess prescribing patterns using the WHO criteria for prescription evaluation and to determine appropriateness of the prescription and acceptability of the deviations from standard guidelines through a consensus committee approach.

We used specific indicators expressed in terms of proportion (%) in disease related and medicine related domains. Within medicine related domains separate indicators are also used in case of Antibiotics as follows:

Disease Related	Medicine Related	Antibiotic Related
1) Prescription without at least a provisional diagnosis 2) Prescription without body weight	1)Average number of drugs per prescription: 2) Patients receiving monotherapy, polytherapy or no therapy 3) Prescriptions with all drugs from the hospital schedule list 4) Prescriptions with all drugs prescribed by generic name. 5) Prescriptions with fixed drug combinations (FDC) 6) Prescriptions with injectables. 7) Prescription with Probiotics among Diarrhoea cases 8) Prescription with Oral Rehydration Solution (ORS) among Diarrhoea cases	1)Antibiotic prescribing rate (APR%) = number of prescriptions that included at least one antibiotic/total number of prescriptions × 100%. 2)Multiple antibiotics prescribing rate (MPR %) = number of prescriptions that included at least two antibiotics of different groups /total number of prescriptions that included at least one antibiotic × 100%. 3)Parenteral antibiotics prescribing rate (PAPR%) = number of prescriptions that included at one injectable antibiotic /total number of prescriptions that included at least one antibiotic × 100%.

Study design & setting:

This cross-sectional study was conducted from August 2019 to December 2020 in the OPDs of Medicine and Pediatrics and the Urban Health Training Centre (UHTC) clinic of two Government teaching hospitals of West Bengal, an eastern state of India. Both are tertiary care hospitals. Former is located in the city whereas the later is at the peripheral district, however both these hospitals usually serves large segments of population.

b) Characteristic of participants

Inclusion & Exclusion criteria:

The study participants included prescription of patients fulfilling the following inclusion and exclusion criteria.

Inclusion criteria:

Prescriptions of patients mentioning the following details:

1. Signs & symptoms and/or diagnosis (provisional or final)

2. Prescriptions for the disease (any medication)

3. Patients /legally authorized person of the patient have to provide verbal consent/written

consent to capture/ copy the prescription for review

Exclusion criteria:

1. If critically ill, or consent not taken/cannot be given

2. Prescription without a single medication

3. Prescription not available from the patient.

Sample size calculation

For prescription evaluation studies, according to WHO a minimum of 600 prescriptions (25) are required to be studied. We assessed 630 prescriptions during the study period. Prescriptions were assessed after the physician have examined the respective patients and prescribed the medications.

c) Clear Description of Processes:

Data collection:

Patients coming to the OPD was approached after consultation while exiting from the OPD with the prescription or at hospital dispensary, through consecutive sampling. Prescriptions were screened for eligibility following consenting and those fulfilling the inclusion criteria were included in the study with capturing a photograph of the prescription. From the photographed prescription, demographic details, relevant clinical information, diagnosis and medication details, were abstracted in the Case Record Forms.

Ethical Statement:

After obtaining approval from the Institutional Ethics Committees of ICMR-NICED and participating institutes, written informed consent was taken from the patients returning from OPDs.

Data Management and analysis plan:

The data management system comprised of data entry, cleaning, back-up, and generation of regular reports. Built-in quality control mechanisms will be developed to ensure data quality and confidentiality. Prescriptions were analysed using the mentioned WHO indicators.

All above proportions were compared across age group (Pediatric and adults) and different categories of prescribers viz. Interns and House staffs, Post Graduate Residents and Faculties (RMO/Demonstrator/Clinical Tutor, Assistant Professor, Associate Professor and Professor.)

Assessment of prescription through Consensus Committee approach:

A Rational Use of Medicine Consensus Committee was formed with the objective to develop the assessment framework for diarrhoea and ARI prescription towards determining appropriateness and acceptability of the deviations. Both clinician and pharmacologist evaluated the prescriptions independently for appropriateness and identification of deviation from standard treatment guidelines. Following treatment guidelines were consulted as standard: (9,12,13,26)

1. WHO. The treatment of diarrhoea: a manual for physicians and other senior health workers. Geneva: World Health Organization; 2005.

2. Standard treatment guidelines. Management of Management of common Respiratory Infections in Children in India. July 2016, Ministry of Health & Family Welfare, Government of India.

3. Treatment Guidelines for Antimicrobial use in Common Syndromes, ICMR, 2019.

4. Standard Treatment Guideline, Institute of Health & Family Welfare, Govt. of West Bengal, 2011.

Since all the guidelines are mostly targeted to general practitioners in public health settings, they do not cover many additional drugs such as probiotics, antihistamines, leukotriene receptor antagonist, bronchodialators, mucolytics etc which are commonly prescribed in medical colleges setting. In such cases both pharmacologist and clinician performed the assessment based on the scientific rationale and their clinical expertise.

Further the pharmacologist judged the prescriptions as appropriate/inappropriate on the basis of signs and symptoms prescribed, adverse effects of drugs, route of administration, dose (appropriate as per age/ body weight, individualization, maximum dose/day mentioned for acute drug), duration being

correct, as per documented indication, possibility of drug interaction, prescription of generic names. The clinician judged the prescriptions independently as appropriate/inappropriate according to above criteria as well as their clinical judgement particularly optimizing symptom remission and tolerable adverse effects. Acceptability of Deviation was determined using the following matrix:

		Clinician	
		Appropriate	Inappropriate
Pharmacologist	Appropriate	Acceptable/No deviation	Consensus
	Inappropriate	Consensus	Unacceptable

In case of a disagreement between pharmacologist and clinician, acceptability of the prescription was discussed in the RUMC committee and case to case decision was taken based on the understanding of significant harm over benefit.

Results

Descriptive details of the assessed prescriptions

We abstracted total 630 prescriptions, of which 37.3%, 47.5% and 15.2% were respectively from medicine OPDs, Paediatric OPDs and UHTC OPD. Prescriber pattern thus obtained showed majority of prescriptions (42.9%) by faculties (RMO/Demonstrator/Clinical Tutor, Assistant Professor, Associate Professor and Professor.) followed by 39.7% by interns and house staffs and 17.5% by post graduate residents.

511(81.1%) prescriptions were for ARI and 119(18.9%) prescriptions were for diarrhoea. It was found that majority of the patients (63.2% - ARI and 64.7% - diarrhoea) were below 18 years age group. Around 56% and 49.6% patients suffering from ARI and diarrhoea respectively were females. Majority of ARI prescriptions were by faculties (43.8%) while maximum diarrhoea prescriptions were by interns and housestaffs (42.9%).

Assessment of prescribing patterns using the WHO criteria

Component wise analysis showed that age and sex were mentioned in all prescriptions. Body weight was mentioned in only 56.2% prescriptions. Signs and symptoms, provisional diagnosis and follow up visit were mentioned in 90.3%, 4.9% and 48.0% prescriptions respectively. None of the prescriptions had instructions in patient's vernacular language. Formulation, frequency and duration were not mentioned in 0.6%, 7.2% and 15.3% prescriptions respectively. Average number of drugs prescribed was 4.2 ±1.9 (median – 4). Proportion of prescriptions with generic names, adherent to hospital schedule, with Fixed Dose Combinations were respectively 23.3% ,36.5% and 51.0%. Prescriptions of all drugs with generic names and prescriptions with all drugs from the hospital schedule was much lower than the WHO standard of 100% for both the indicators. Antibiotics prescription rate (APR) was 57%. Multiple antibiotic prescription rate (MPR) was 10%. All the prescriptions for diarrhoea did not contain ORS (81.5%) whereas

probiotic was prescribed in 85% of diarrhoea irrespective of specific indication i.e. Antibiotic induced diarrhoea. None of the prescriptions had any injectable formulation hence PAPR was 0% [**Table 1**]

APR was observed to be higher for diarrhoea (65.5%) than ARI (55.2%). MPR is also high in case of diarrhoea (30%) as compared to ARI (3.9%). Among the diarrhoea cases, antibiotics were prescribed in 64.4% of acute watery diarrhoea and 66.7% in dysentery. Antibiotics of nitroimidazole class followed by quinolones, cephalosporins were mostly prescribed. Fixed Dose Combination of ciprofloxacin, tinidazole/ofloxacin, ornidazole and ofloxacin, metronidazole was also used. The antibiotics most commonly used in ARI was a combination of Amoxycillin and Clavulinic acid (Beta lactamase inhibitor) followed by Azithromycin, Cephalexin, Cefixime, Co- trimoxazole and Amoxycillin alone.

Appropriateness of the prescription and acceptability of the deviations through a consensus committee approach.

Deviation from standard guideline as evaluated by the RUMC and were present in 623 (98.9%) prescriptions. Among them only 60 (9.5%) were found acceptable. Out of 563 unacceptable deviations, 357(63.4%) suffered possibility of Adverse Drug Reactions(ADR), whereas, 421(74.8%) prescriptions had inconsistent/irrational indications. [**Figure 1**] Majority of the unacceptable deviations were due to antibiotics, followed by bronchodilators , antihistaminics, Proton Pump Inhibitor/H 2 receptor blocker/Antacids, Probiotics. [**Table 2**] Some of the frequently observed unacceptable deviations were as follows:

1. Prescription of bronchodilator in children through systemic route
2. Prescription of antibiotic in Upper Respiratory Tract Infection (URTI) without or with fever < 3 days, in absence of patch/ hemorrhage/shortness of breath.
3. Prescription of Probiotic without specific indication of Antibiotic induced diarrhoea.
4. Prescription of antibiotics (Ciprofloxacin, Metronidazole, Ofloxacin and others) in absence of documented bloody diarrhoea or dysentery.
5. Prescription of Montelukast in acute ARI
6. For acute disease, prescription of repeatedly used drug such as paracetamol (for fever), without mentioning maximum dose / day
7. Prescription of drugs like Pantoprazole, Ranitidine, Famotidine, Vitamin without specified indication.

Appropriateness of prescriptions as per clinician and pharmacologist revealed that only 1.1% of total prescriptions were appropriate according to both clinician and pharmacologist. There were 9.6 % prescriptions which were inappropriate as per pharmacologist but appropriate as per clinician. Agreement between pharmacologist and clinician were observed in 90.4% prescriptions (Kappa – 0.14) [**Table -3**]. These disagreements were resolved in RUMC meeting on case to case basis with following clarification:

1. Prescription of antihistaminic in ARI in children though identified as inappropriate by pharmacologist however a 2nd generation antihistaminic (cetirizine) may be considered as acceptable deviation but

1st generation (Chlorpheniramine) is unacceptable due to excessive sedation.

2. Prescription of Azithromycin in URTI identified as inappropriate by pharmacologist, as Azithromycin is not a 1st line antibiotic, but considered acceptable deviation by the clinician as standard practice.
3. Drugs prescribed by brand names are considered inappropriate by the pharmacologist but it was considered as an acceptable deviation.
4. Prescription of albendazole in children or Vitamin D in infants less than 6 months of age though considered inappropriate by pharmacologist when there is no indication, it is considered as acceptable deviation by consensus it adheres to national programme guideline
5. ORS prescribed without specific indication is also an acceptable deviation as it cause no apparent harm.

Completeness of prescriptions as per different criteria in various age groups

Body weight was mentioned in 88.5% of prescriptions of patients below 18 years age group. Of them, body weight was found in 93.4% patients upto 5 years of age, 88.9% of patients aged 5 -< 12 years, and 14.3% patients of 12- <18 years. None of the adult prescriptions had body weight mentioned in them. Signs and symptoms, provisional diagnosis were more commonly mentioned in adult patients whereas follow up visit was more commonly mentioned in <18 years age group. Higher proportion of prescriptions with generic name (27% vs 17%), and from hospital schedule list (41% vs 29%) and lower FDC (44% vs 63%) were observed in prescriptions of < 18 years as compared to adults. APR was also lower for children than adults (48 % vs 71 %).

Prescriptions with deviations were slightly lower in children (98.5% vs 99.5%). However, proportion of acceptable deviations were more in <18 years age group (12% vs 6%). [Data not presented]

Completeness of prescriptions as per different criteria across types ofprescriber

Body weight, signs and symptoms, follow up visit was mentioned most commonly by residents while provisional diagnosis was commonly mentioned by faculties. Prescriptions of all drugs with generic names and from hospital schedule list was mostly prescribed by residents while fixed dose combinations and antibiotics were mostly prescribed by faculties. Deviations were most commonly observed in the prescriptions of interns and housestaffs (99.6%), whereas acceptable deviations were more common among the residents (15%).Out of the unacceptable deviations, chances of ADR was most common among interns and housestaffs whereas prescriptions with inconsistent/irrational indication was most common among the faculties.[**Table 4**]

Discussion

In this study, polypharmacy emerged as a major concern as the average number of drugs prescribed per patient was 4.2 ± 1.9 which is much higher than WHO standard of ≤ 2 (27). However, few studies have also mentioned higher average number of drug prescription (28, 29) per patient, whereas, much lower

estimates (1.5) were also observed among under five children with acute diarrhoea in Bangladesh (30). Several others studies also reported an average ranging 2.8–3.2 drugs per patient (31–35). Mostly Prescribers are unaware of availability of Standard Treatment Guidelines and further lack of point of care rapid diagnostic facilities contributes to higher number of drugs prescription per patient. The higher number of drugs may enhance the chance of adverse drug reactions, antimicrobial resistance, healthcare expenditure and also interfere with prescription adherence. The high number of drugs per prescription may also account for the higher number of (51.0%) fixed dose combinations prescribed in this study.

Only 23.3% drugs were prescribed by generic names in this study. This is much lower than the standard cut off of 100% (27). Higher proportions of generic names were found in studies by Viswanath et. Al (36) (62.3%) and Shankar PR et al (29) (58.1%). Also in various other studies proportion of generic names in the prescriptions were found to be 46.2%-100% (31,32,37). Use of generic names is recommended by Government to reduce the healthcare costs. However, prescription patterns by different categories of prescribers may be influenced by promotions of particular brands of drugs accounting for such discrepancies. It was observed that 53.6% residents prescribed generic names as compared to only 18% for interns and faculties. However, drugs with Fixed Dose Combinations (FDC) were prescribed in little more than half of the prescriptions and similar findings had been reported by others also (37).

Injectable drugs were not prescribed in any of the prescriptions in this study as patients were first time OPD attendees. The standard value of proportion of prescriptions where injectables can be prescribed lies between 13.4–24.1% (27). The WHO also recommends lesser use of injectable medications as it increases the cost as well as morbidity and mortality like infections viz. HIV, Hepatitis B and C, air embolism etc. (38)

Overall 57.0% prescriptions have at least one antibiotic prescribed. Considering the higher magnitude of infectious diseases in the developing countries, WHO has limited the use of antibiotics in < 30% prescriptions in case of all infectious diseases (27, 39). Thus we observed a very high APR and significantly higher in case of diarrhoea and adult patients compared to their counterparts in the study ($p < 0.05$). In India, irrational antibiotic prescription is a serious concern as reflected by rates (20–72.8%) reported by different studies. (31,32,33,34,37). Antibiotic prescriptions without a provisional diagnosis in a first time patients supports the notion of physician to cover for immediate medical catastrophes than to consider back up antibiotics for future implication in the era of rapidly emerging antimicrobial resistance. We reported a MPR of 10% which is much lower than studies by Ashraf et.al (40) and Panchal et al (28) however, much lower usage of antibiotics of 1 per prescription i.e. 0% MPR was also reported by Bordoloi et al. (41) Disease wise variation shows that any antibiotic has been prescribed in 55.2% of ARI and 65.5% prescriptions with diarrhoea. In most of the prescriptions antibiotics have been prescribed as an empirical therapy without mentioning any provisional diagnosis. A study by Hekster et al also reported similar findings where diagnosis was not the deciding factor for prescribing antibiotics in half of the prescriptions (42.) Most episodes of watery diarrhoea in children and sometimes in adults supposed to be of viral aetiology where use of antibiotics is inappropriate, even, Acute Respiratory Infection may also sometimes be of viral origin having no indication for antibiotic prescription. This will ultimately contribute

to irrational use of drugs and ultimately antimicrobial resistance (43,44,45,46). Also according to ICMR guidelines, antibiotics should not be used for viral respiratory infections and watery diarrhoea and their use should be limited to Streptococcal pharyngitis, bacterial sinusitis and diarrhoea caused due to cholera, amoebiosis, Giarrdiasis, Shigellosis and those caused by Campylobacter or Aeromonas (26). The Guidelines issued by State of West Bengal in 2011 also inhibits inadvertent empirical use of antibiotics (13). However, our observations are not in adherence with those guidelines.

The most commonly used antibiotic for respiratory infection was a combination of Amoxycillin and Clavulinic Acid which was corroborated by other studies (47, 48). The most commonly used antibiotics for diarrhoea was Metronidazole alone or with Ciprofloxacin. However, studies by Panchal et al (28) and Maniar M et al (49) reported 3rd generation cephalosporin to be the most common antibiotic used in diarrhoea whereas Sharma S et al (22) reported fluroquinolones such as Norfloxacin alone or in combination with a nitroimidiazole to be the most frequent therapeutic choice. The easy availability of metronidazole and ciprofloxacin combined with prescriber`s inclination towards a broad spectrum to eliminate the possibility of mixed infection may drive such type of prescriptions. Azithromycin has been recommended by ICMR for patients with penicillin allergy whereas cephalosporins have been used as alternatives to penicillin (26). The state guideline also recommends use of Cotrimoxazole in paediatric population (13).

Deviations from the available treatment guidelines were found in 98.9% prescriptions, with 90.3% being unacceptable deviations. The unacceptable deviations were in the form of preventable ADR, documentation error or drugs prescribed for which rationality could not be explained. Some of these deviations are known to cause serious side effects, while the others, though not cause any significant harm, do not follow the standard prescription guidelines as a result of which the treatment may be ineffective or irrational. A study done at outpatient clinics of Saudi Arabia reported omissions of various components of the treatment regimen, with some even up to 91% incompleteness (50). Higher adherence to guidelines will actually lead to treatment regimen completion possibly because of the institutional culture of emphasizing on the treatment regimen prescription writing. (51)

In conclusion, the pattern of prescriptions revealed inappropriate practices in the form of multiple drugs, use of brand names, prescribing fixed dose combinations and overuse of antibiotics without any rationale and not adhering to the available guidelines (ICMR, State, WHO). Though the guidelines have overlaps, they are not all the same and also do not include all the possible treatment options creating a scope for physician to depend on his/her experience/expertise. The available guidelines are more suitable to the resource constrain primary care settings where simpler cases are expected to be managed, our study reflected the need of having level of healthcare specific treatment guidelines for curtailing the subjective approach. Apart from this, adequate training of various categories of physician is also required to ensure rationality of drug usage as well as quality of care. The evidence generated from this study will help to assess the practice of physicians in rational use of drugs and gap identified thus may be adequately addressed through structured capacity building, robust documentation and monitoring system and finally strengthening the antimicrobial stewardship programme.

Limitation:

We could not analyse the outcome of irrational prescriptions such as cure rate, adverse event as we do not have follow up component in our study. Since this was a quantitative analysis, prescription behaviour and the driving constructs towards the same cannot be explored further. A resource intensive qualitative study may substantiate the findings in future.

Abbreviations

ADR: Adverse Drug Reaction; WHO: World Health Organization; FDC: Fixed Dose Combination; OPD: Out Patient Department; ARI: Acute Respiratory Infection; NLEM: National List of Essential Medicine; ICMR: Indian Council of Medical Research; NICED: National Institute of Cholera and Enteric Disease ; IEC: Institution Ethics Committee ; CRF: Case Record Form; ORS: Oral Rehydration Solution; RUMC-C: Rational Use of Medicine Consensus- Committee; APR –Antibiotic Prescription Rate, MPR- Multiple Antibiotic Prescription Rate, PAPR- Parenteral Antibiotic Prescription Rate.

Declarations

Ethics approval and Consent to participate:

The Study was approved by the Institution Ethics Committee of ICMR-NICED (No. A-1/2019-IEC dated 18.10.2019), R.G.Kar Medical College and Hospital and College of Medicine (RGK/20 dated 21.08.2019) and Sagore Dutta Hospital (dated 21.09.219). Informed consent/assent was obtained from the patients themselves or the guardian in case the patient is less than 18 years of age. We hereby confirm that all methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable

Availability of Data and Materials

The data will be available from the corresponding author on request.

Competing Interests

The authors declare that they have no competing interests.

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Authors' contributions

DC, FD, SK, NC, SD- Protocol Design, literature review, data collection, data analysis, manuscript writing. DC, NC, RB, PD, – data collection and manuscript review, DC, FD, SK, NC, KD, SG, PB, SD- Data analysis, Data interpretation, manuscript review. All the authors have read and approved the final manuscript

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Tables

Table 1
Completeness of prescriptions as per different criteria according to disease and comparison with WHO core indicators

Criteria mentioned in prescription	Total(n = 630)	WHO Core Indicators
	n(%)	(%)
Body weight	354(56.2)	
Signs and symptoms	569(90.3)	
Provisional diagnosis	31(4.9)	
Follow up	302(48.0)	
Prescription having all Drugs with generic name	147(23.3)	100
Prescription of all Drugs from Hospital schedule list	230(36.5)	100
Prescription of all drugs having FDC	321(51.0)	
Antibiotic Prescription Rate	359(57.0)	< 30
Drug formulation not mentioned	4(0.6)	
Drug frequency not mentioned	45(7.2)	
Drug duration not mentioned	96(15.3)	
Prescriptions with injectables	0(0.0)	13.4–21.1
Average no.of drugs prescribed	4.2 ± 1.9	≤ 2

Table 2
Distribution of Drug responsible for unacceptable prescription. (n = 563 prescriptions, proportions are not mutually exclusive.)

Drug Category	No.	%
Bronchodilator	238	42.2
Antihistaminic	128	22.7
Antibiotic	246	43.7
Probiotic	87	13.8
Vitamins/Iron/Calcium/other supplements	56	9.9
Paracetamol/NSAIDS	28	5
PPI/H2 blocker/antacids	116	20.6
LT receptor antagonist	49	8.7
ORS	44	7.8
Enzymes	6	1
Antispasmodic	15	2.7
Antiemetic	12	2.1
Zinc	4	0.7
Steroids	7	1.2
Ear drop	1	0.2
Local applicant	8	1.4
Deriphylline	2	0.3
Racecodotril	1	0.2
Nasal drop	4	0.7
Mucolytic agent	2	0.3

Table 3

Appropriateness of prescriptions according to clinician and pharmacologist

Pharmacologist	Clinician		Total	Kappa
	Appropriate	Inappropriate		
Appropriate	7(1.1)	0(0.0)	7(1.1)	0.14
Inappropriate	60(9.5)	563(89.4)	623(98.9)	
Total	67(10.6)	563(89.4)	630(100.0)	

Table 4

Completeness of prescriptions as per different criteria across types of prescriber.

Criteria mentioned in prescription	Intern & Housestaff (n = 250)	Residents (n = 110)	Faculty (n = 270)
	n(%)	n(%)	n(%)
Body weight	106(42.4)	89(80.9)	159(58.9)
Signs and symptoms	247(98.8)	109(99.0)	213(78.8)
Provisional diagnosis	5(2.0)	1(0.9)	25(9.2)
Follow up	146(58.4)	92(83.6)	64(23.7)
Prescription having all Drugs with generic name	41(16.4)	59(53.6)	47(17.4)
Prescription of all Drugs from Hospital schedule list	81(32.4)	61(55.5)	88(32.6)
Prescription of all drugs having FDC	132(52.8)	29(26.4)	160(59.2)
Prescription with antibiotics	133(45.2)	29(26.4)	197(73.0)
Drug formulation not mentioned	1(0.4)	1(0.9)	2(0.7)
Drug frequency not mentioned	20(8.0)	3(2.7)	22(8.2)
Drug duration not mentioned	45(18.0)	14(12.8)	37(13.7)
Prescription With ORS*	n = 51	n = 22	n = 46
	43(84.3)	19(86.3)	35(76.0)
Prescriptions with deviations	249(99.6)	106(96.3)	268(99.2)
Prescriptions with acceptable deviations**	n = 249 11(4.4)	n = 106 16(15.0)	n = 268 33(12.3)
Prescriptions with chance of ADR***	n = 238 156(65.5)	n = 90 66(73.3)	n = 235 131(55.7)
Prescriptions with inconsistent/irrational indication***	n = 238 163(68.4)	n = 90 45(50.0)	n = 235 213(90.6)

*Proportion of prescriptions with ORS has been computed for diarrhoea cases only

**Proportion of acceptable deviations have been computed out of total deviations in each category

***Proportion of prescriptions with chances of ADR and inconsistent/irrationsl indication have been computed out of Unacceptable deviations in each category

Figures

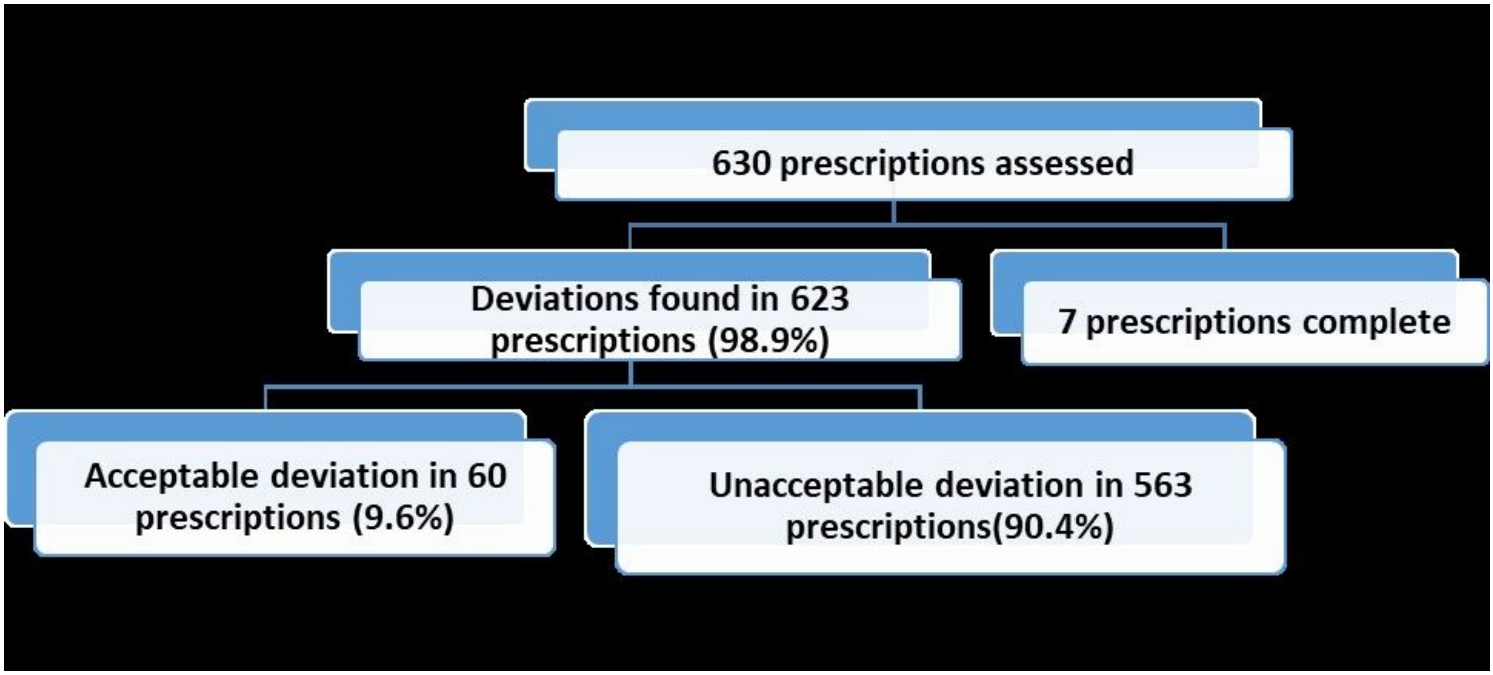

Figure 1

Acceptability of the deviations in assessed prescriptions through a consensus committee approach