

Original Article

## Treatment of pediatric diarrhea: a simulated client study at private pharmacies of Ujjain, Madhya Pradesh, India

Vishal Diwan<sup>1,2,3</sup>, Yogesh D Sabde<sup>4</sup>, Emma Byström<sup>3</sup>, Ayesha De Costa<sup>3</sup>

<sup>1</sup> Department of Public Health and Environment, R.D. Gardi Medical College, Ujjain, Madhya Pradesh, India

<sup>2</sup> International Centre for Health Research, R.D. Gardi Medical College, Ujjain, Madhya Pradesh, India

<sup>3</sup> Department of Public Health Sciences, Karolinska Institutet, Stockholm, Sweden

<sup>4</sup> Department of Community Medicine, R.D. Gardi Medical College, Ujjain, Madhya Pradesh, India

### Abstract

**Introduction:** In low- and middle-income countries such as India, private pharmacies play an important role in medical treatments, offering advice for common illnesses such as diarrhea and respiratory tract infections. There is a need to explore the details of the dispensing practices at the private pharmacies in low- and middle-income countries.

**Methodology:** The present study used simulated client methodology to assess the actual dispensing practices for patients with pediatric diarrhea at private pharmacies in an urban setting of an Indian province.

**Results:** This study identified 164 private pharmacies (84.10%) in the study setting that engaged in the practice of dispensing prescription drugs without prescriptions. Only about 40% asked clients if they had a prescription from a doctor. The average duration of consultations at the pharmacies was 1.3 minutes (range, 0.5–6 minutes). The dispensing of drugs was not in compliance with the recommended guidelines and regulations. The most commonly dispensed drugs were antibiotics (40.24%); of these, quinolones either alone or in combination with imidazoles were the most frequently dispensed. The other commonly dispensed drugs were antimotility drugs (31.10%) and *Lactobacillus acidophilus* (probiotics; 23.17%). The drugs were dispensed in inappropriate doses due to the absence of indications.

**Conclusions:** Overuse and misuse of all these prescription drugs dispensed by pharmacies pose significant issues, such as resistance, dangerous side effects, and high costs. At the same time, the pharmacies did not dispense recommended drugs such as oral rehydration solution and zinc, which they are authorized to dispense without a prescription.

**Key words:** diarrhea; simulated client; pharmacies; antibiotics; India.

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### Introduction

Diarrhea is the second-most common cause of death among children under five years of age globally. More than 80% of childhood deaths due to diarrhea occur in Africa and South Asia. India is the home for the highest number of childhood deaths due to diarrhea (386,600) [1]. Point prevalence surveys (over a two-week period) conducted in India revealed that 9%–19.8% of children under the age of five had suffered from diarrhea [2].

Diarrhea is easily treatable with an oral rehydration solution (ORS). Indeed, the government of India provides this treatment free of cost through the public sector [3]. However, most caregivers in Southeast Asia, and especially in India, turn to the powerful and diverse private sector that claims 78% of the total healthcare expenditure [4]. The private sector has a large variety of providers, which includes

qualified practitioners as well as many who do not have any formal qualifications [5]. A previous survey in India revealed that the majority of caregivers (58%) sought care from the private sector when their children suffered from a bout of diarrhea. Only 16% turned to the public sector; 13% received treatment in the home, and 13% of the children did not receive any treatment at all [6,7].

In low- and middle-income countries, pharmacies play an important role as first points of contact for the management of common illnesses. Patients seek symptom-based primary care and advice from these pharmacies [8-9]. In Nepal, as many as 80% of patients and caregivers turned to pharmacies for advice and medications for diarrhea (without having any prescription from a doctor) [9]. Caregivers and patients turn to pharmacies rather than physicians as the first point of contact because pharmacies are easier

to access, less expensive, and require less time [8,10]. In India, the vast majority of pharmacies are in the private sector, in which such consultations and treatments occur [10,11].

Simulated client (SC) is a versatile tool that has been widely used in both low- and high-income settings to assess the actual practices of pharmacies and drugstores [12]. Childhood diarrhea is one of several illnesses that have been assessed in pharmacies by using SC [9,13,14]. There is limited information on how children are actually treated for diarrhea in private pharmacies, which are often the first point of contact and where such symptom-based consultations and treatments often take place. Considering that diarrhea is a major killer of children under five years of age in India, it is vital to understand how children are treated in private pharmacies, where such care is frequently sought. This study aimed to assess the treatment of childhood diarrhea in private pharmacies in central India using SC.

## Methodology

### Study setting

This study was carried out in Ujjain, a city in the western part of one of India’s largest provinces, Madhya Pradesh. Ujjain has a population of half a million inhabitants. It is the headquarter town of a district of the same name. The district has a population of 1.9 million, of which 61% live in a rural setting [15]. The district has relatively better health indicators than the rest of the province. It has an infant mortality rate of 56 per 1,000 live births, and the under-five mortality rate is 74 per 1,000 live births [16].

### Private pharmacies

A 2012 census of private pharmacies in the Ujjain district identified 475 pharmacies, of which 387 were urban [17]. The inclusion criteria for this study, urban pharmacies with more than 30 clients per day, were identified from the previous census.

### Study design

This cross-sectional study used simulated clients.

### Data collection

Data was collected between May and July 2012, using simulated clients in Ujjain. Four male rural village health workers (30–35 years of age) connected to the medical school where the study was conducted were trained to serve as clients. They were trained to present themselves at pharmacies seeking care for a child who had a complaint of diarrhea (Table 1). The trained simulated clients (SC) divided the pharmacies between themselves, so that each pharmacy was visited by one of the SCs. Each of the SCs was provided with 40–50 Indian Rupees and instructed to purchase medicine if advised by the pharmacist to do so. After the visit, the SCs filled out a questionnaire within 15 minutes of leaving the pharmacy. The questionnaire elicited information regarding questions asked by the pharmacist, medicines dispensed, and advice offered. Each pharmacy was visited once, unless it was closed, and then a second visit was made before it was excluded. Ethical approval was obtained from the ethics committee of R.D. Gardi Medical College, Ujjain, India. Informed consent could not be

**Table 1.** Instructions to the simulated clients for the trained scenario at the pharmacy

Your child (male, 4 years of age) has had loose stools for two days. You go to the pharmacy and ask for treatment for this: <b>“My child has loose stools since two days. Please give me some medicine.”</b>	
If the pharmacist asks you any questions, the following are your responses:	
How old is the child?	4 years
What sex?	Male
How long since the child had the loose motion?	2 days
How many stools a day?	5-6 times a day
Any fever?	I haven’t measured
Any vomiting?	No
Any pain in abdomen or colic?	Mild
What did the child eat?	Simple household food
Child eating/drinking/loss of appetite?	Child a bit listless, not eating so much because he feels unwell.
Any weakness?	Little
Consistency of stool?	Loose
Colour of stool?	Yellow
Blood / mucus in stool?	Not noticed
Do you have a prescription?	No
Have you seen a doctor?	I do not have so much time. Also don’t want to spend.

obtained from the participating pharmacies, as it would have revealed the study; revealing the study would have compromised the study design and its results.

*Data analysis*

Data from the field instruments were coded and entered into EpiData version 3. The data was then exported to Stata version 12 for further analysis. The characteristics of pharmacies were described in proportions and ranges. Questions asked by pharmacists and drugs prescribed were presented as simple proportions.

**Results**

Two hundred private pharmacies qualified for this study, but only 164 pharmacies (84.10%) participated. Thirty-six pharmacies were excluded for the following reasons: 5 were closed despite repeated visits, 26 required clients to have a prescription in order to assist them, 1 advised hospitalization, and 4 did not sell medications for children. Table 2 shows the characteristics of the participating pharmacies.

When simulated clients visited the pharmacies, the average duration for consultation at the pharmacies was 1.3 minutes (ranging from 0.5–6 minutes). The

questions asked by the pharmacists as part of the consultation (and the proportion that asked the respective questions) are shown in Table 3. Most pharmacists asked about the age of the child and the duration and frequency of stools. However, only a quarter inquired about symptoms of dehydration or infection or other more severe symptoms. Only 15 pharmacies (9.1%) asked about the history of any blood or mucus in the stool. About 40% inquired if the client had a prescription or had visited a doctor.

Table 4 shows the treatments and drugs prescribed for pediatric diarrhea at the pharmacies. In the 39 pharmacies with at least one qualified staff member, antibiotics, antimotility drugs, and *Lactobacillus acidophilus* were dispensed at 41.03%, 25.64%, and 17.95% of pharmacies, respectively. The most commonly dispensed antibiotics were quinolones. Three-quarters of all antibiotics (50/66, 75.75%) were prescribed as a combination of a quinolone (ciprofloxacin, norfloxacin, or ofloxacin) and a nitroimidazole (metronidazole, ornidazole, or tinidazole). The pharmacists recommended antibiotic treatment for a median duration of three days (interquartile range, 2–3 days). Thirty-nine pharmacies (23.78%) dispensed antimotility drugs without antibiotics. ORS was dispensed by only 4 pharmacies

**Table 2.** Characteristic of the participating pharmacies

Characteristic	Count (n = 164)
Hours open	12 hours (range, 6–24 hours)
Number of customers/day	107 (range, 35–1,000)
Power cuts	3.85 hours/day (range, 2–6 hours/day)
Computerized	28 (17%)
System of medicine	
Modern	159 (97%)
Indian	5 (3%)
At least one qualified staff	39 (23.78%)

Source: Primary data of 2012 census of private pharmacies in the Ujjain district [17].

**Table 3.** Overview of pharmacist responses to simulated cases of pediatric diarrhea

Question asked by pharmacists (n = 164)	Responses	
	No.	%
Age of child?	161	98.2
How long has child had loose stools?	143	87.2
How many stools a day?	117	71.3
Any fever?	48	29.3
Any vomiting?	42	25.6
Any pain in abdomen or colic?	31	18.9
Child eating/drinking/loss of appetite?	31	18.9
Any weakness?	38	23.2
Blood/mucus in stool?	15	9.1
Do you have a prescription?	69	42.1
Have you seen a doctor?	66	40.2

**Table 4.** Treatments and drugs prescribed at pharmacies

Drugs prescribed (n = 164)	No. (%)
Antibiotic	66 (40.24)
Antimotility drugs	51 (31.10)
<i>Lactobacillus acidophilus</i>	38 (23.17)
Unlabeled drug*	36 (21.95)
ORS (oral rehydration solution)	4 (2.44)
Lactulose	4 (2.44)

\*Unlabeled drugs included loose tablets dispensed in small polythene bags.

(2.44%), and no pharmacies dispensed zinc preparations. Administration of home remedies to the ill children was advised by 26 pharmacies (15.9%), but none of them explained how to prepare, store, or administer the home remedies. None of the pharmacies advised only non-pharmacological management, *i.e.*, fluids commonly available at home. Forty-nine pharmacies (29.9%) advised simulated clients to visit a doctor.

## Discussion

### *Treatment practices*

This study reports on the dispensing practices of private pharmacies in central India when they are contacted as the first point of treatment for pediatric diarrhea. Out of 195 pharmacies visited, 164 pharmacies (84.10%) dispensed drugs without a prescription. Antibiotics (40.24%) and antimotility drugs (31.10%) were the most commonly dispensed drugs at these pharmacies, followed by *Lactobacillus acidophilus* (a probiotic), at 38 pharmacies (23.17%). Our study revealed extremely low levels of dispensation of ORS compared to earlier studies conducted in India. Pathak *et al.* reported that 71% of prescriptions were for antibiotics, which is higher than the 56% found in our study. Probiotics were also frequently prescribed in Pathak *et al.*'s study, at a rate of 68%, compared with the 42% rate in our study. They did not report on antimotility agents, which were prescribed often by our pharmacies [18].

### *Adherence to treatment guidelines*

To decrease diarrhea deaths among children, the Indian Academy of Pediatrics adopted the treatment guidelines recommended by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF), which focus primarily on the use of low-osmolarity ORS along with zinc for 14 days as an adjunct therapy [19-20]. Several studies in low- and middle-income countries have reported a lack of adherence to treatment guidelines for diarrhea as well as an overuse of antibiotics and antimotility

drugs among qualified practitioners [9,13,18]. In these settings, it is possible that pharmacy staff is not even aware of such guidelines, given that 88% of staff manning pharmacies on a day-to-day basis is unqualified [17].

### *Consultation on history of the illness*

The average duration for consultation at the pharmacies of 1.3 minutes is considerably lower compared to that reported in other studies. In Vietnam, an average duration of 2.4–2.6 minutes for consultations regarding childhood diarrhea was reported by pharmacists. The study concluded that the time spent for consultation was insufficient to assess the condition of childhood diarrhea [13]. The number of questions asked regarding the condition of the child by the pharmacists was low. The most frequently asked questions concerned the age of the child, the duration of loose stools in the child, and the number of stools the child had per day. Less than a third of the pharmacy staff asked questions regarding fever, vomiting, loss of appetite, and weakness – symptoms that would indicate if the child was suffering from a significant degree of dehydration. Antibiotics are recommended by the WHO in cases of dysentery (blood in stool); however, only 9.1% of the pharmacists asked whether there was any blood present in the stool. The routine use of antibiotics for infectious diarrhea in children is to be avoided, because it brings little benefit in most cases (as diarrhea is of viral etiology) and is associated with the risk of increasing antimicrobial resistance. Despite this, our study indicated that over half of all encounters resulted in antibiotics being dispensed.

### *Antibiotic use*

A considerably high proportion, 40%, of encounters received antibiotics, though none of the SC cases portrayed any symptoms of dysentery. The most commonly prescribed antibiotics in the present study were quinolones. In Thailand, the most commonly prescribed antibiotics were nifuroxazide,

cotrimoxazole, norfloxacin, erythromycin, and amoxicillin [14]. A study in Nepal revealed that metronidazole alone (43.4%), metronidazole with diloxanide furoate (24.5%), and norfloxacin (18.2%) were the most common antibiotics prescribed for diarrhea treatment [9]. The high number of antibiotic prescriptions reported indicates an overuse of antibiotics in the treatment of diarrhea. Eighty percent of India's health financing is out of pocket, including medicines [21]; hence, an overuse in antibiotics leads not only to an increased risk of drug resistance, but also to increased costs and side effects for individuals and their families [9]. Resistance to antibiotics is also a growing public health issue. A study in Ujjain revealed that 72% of children have *Escherichia coli* resistant to at least one antibiotic [22]. Additionally, in this same study, multidrug resistance was identified in 33% of the samples.

#### *Antimotility and probiotic drugs use*

Antimotility drugs and *Lactobacillus acidophilus* were dispensed in 31.10% and 23.17% of the cases, respectively, though neither is included in India's treatment guidelines. Additionally, antimotility drugs without antibiotics were dispensed at 39 pharmacies (23.78%). Adsorbents and antimotility drugs are known to be dangerous for children under the age of five, and the WHO restricts the use of antimotility drugs for children, since fatalities have been reported [9,23]. Probiotics are expensive to purchase, and there is limited evidence of their effectiveness in treating childhood diarrhea [24]. A recent study in Kenya and India reported that healthcare workers and pharmacy staff prescribe antibiotics (which they perceive to be stronger medicines) due to parents' expectations that these drugs will reduce the duration of diarrhea [25]. A similar rationale could explain the high proportion of antibiotics and antimotility agents dispensed in the study setting.

#### *ORS and zinc use*

ORS was only prescribed to 2.44% of the cases, which is a very low percentage. None of the pharmacies dispensed zinc preparations. Other studies in low- and middle-income settings have reported a low number of ORS-only treatments. In Thailand, only 5.2% pharmacies dispensed ORS alone for children suffering from viral diarrhea [14]. Aside from client expectations, private pharmacy staff are also likely to be driven by pecuniary incentives to make decisions on which drugs to dispense. Most clients pay for drugs at pharmacies as an out-of-pocket expense; thus, the

pharmacy staff are likely to dispense those drugs that create the best financial incentives [26].

#### *Role of education and legislation in dispensing antibiotics and antimotility drugs*

The high rate of antibiotics, antimotility drugs, and *Lactobacillus* dispensed in this study also indicates a lack of rational use of medications. The dispensing pattern did not vary much in pharmacies with qualified staff. This irrational use of medicines is driven possibly by a lack of knowledge, a pressure to fulfil client expectations, and a need to maximize financial incentives [26]. Education as well as stricter regulations for pharmacies are needed to improve the proper dispensing of medicines. The management of childhood diarrhea in private pharmacies was improved in Vietnam through an educational intervention [13]. Though the intervention had some positive outcomes in Vietnam, such interventions are difficult to implement in an unregulated private sector environment, in which staff who man pharmacies are not necessarily qualified or constant. Thus, it is uncertain whether education alone is enough to change the irrational dispensation of drugs in such a context. Financial incentives and high profit are also motivations to continue to dispense more medications than necessary. Therefore, regulations also need to be strengthened in order to improve dispensing practices at private pharmacies.

#### *Recommended approach for the dispensing of antibiotics and antimotility drugs*

In India, antibiotics and antimotility drugs are included in schedule H of Drugs and Cosmetics (2nd Amendment) Rules, 2013. Drugs listed in Schedule H cannot be sold without a prescription of a registered medical practitioner [27]. The retail supply of any drug dispensed on prescription from a registered medical practitioner is required to be supervised by a registered pharmacist. Our study revealed that the compliance to these rules was weak in the study setting, as only 23.78% of pharmacies had at least one qualified staff member. The proportion of pharmacies dispensing antibiotics was similar at pharmacies with and without qualified staff. The high percentage of untrained pharmacists in pharmacies is a barrier for the rational use of medications.

The strength of this study lies in the use of SC as a means to study the dispensing of drugs. This is a more valid method than using questionnaires, which can result in biases in the reported dispensation.

We did not elicit staff qualification at the time of the SC encounter, (the reported figures in table 2 are from 2012 census data) and thus are unable to comment on the actual proportion of staff who were qualified pharmacists. However, this proportion is expected to be low; our previous study [17] indicated the rate to be 12%. The studied pharmacies in a single city may have common dispensing patterns. The SC visited each pharmacy only once. The pharmacy staff could behave differently at different times.

## Conclusions

The dispensing of treatments for childhood diarrhea in the pharmacies that were visited was inappropriate. There was a severe under-dispensing of ORS and zinc, important elements in the management of pediatric diarrhea. Furthermore, antibiotics and antimotility agents were widely dispensed. Prescribing these medications is possibly driven by a lack of knowledge, a need to fulfil client expectations, and pecuniary incentives. Education alone is unlikely to influence this. Enhanced regulation of the private sector is necessary.

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## Authors' contributions

VD, YS, and AD conceived and designed the study. VD and YS performed the study. VD, YS, AD, and EB analyzed and interpreted data. VD, YS, EB, and AD wrote the paper. All authors read and approved the final manuscript.

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#### Corresponding author

Vishal Diwan  
Department of Public Health and Environment  
R.D. Gardi Medical College  
Ujjain, Madhya Pradesh, India  
Phone: +91 7368 262231  
Email: vishaldiwan@hotmail.com

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