Community-based participatory research and drug utilization research to improve childhood diarrhea case management in Ujjain, India: A cross sectional survey

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Abstract: Childhood diarrhea continues to be a major cause of under-five (U-5) mortality globally and in India. In this study, 1571 U-5 children residing in nine rural villages and four urban slums in Ujjain, India were included with the objective to use community participation and drug utilization research to improve diarrheal case management. The mean age was 2.08 years, with 297 (19%), children living in high diarrheal index households. Most mothers (70%) considered stale food, teething (62%) and hot weather (55%) as causes of diarrhea. Water, sanitation, and hygiene (WASH)-related characteristics revealed that most (93%) households had toilets, but only 23% children used them. The study identified ineffective household water treatment by filtration through cloth by most (93%) households and dumping of household waste on streets (89%). The results revealed low community awareness of correct causes of diarrhea (poor hand hygiene, 21%; littering around the household, 15%) and of correct diarrhea treatment (oral rehydration solution [ORS] and zinc use, 29% and 11%, respectively) and a high antibiotic prescription rate by health care providers (83%). Based on the results of the present study, context-specific house-to-house interventions will be designed and implemented.

Keywords: Child; diarrhea; water sanitation and hygiene; rehydration solution; zinc; case management; antibacterial agents; drug utilization; community participation; India

1. Introduction

Globally, diarrhea continues to be one of the major causes of mortality among children aged less than 5 years [1,2]. India as country has the highest number of childhood deaths due to diarrhea with 400,000 deaths annually [2]. Three states of India, including Madhya Pradesh (MP), account for nearly half of India's childhood diarrhea burden [3,4]. The majority of childhood diarrhea deaths (80%) occur in rural areas, where informal health care providers (IHCPs) are the predominant providers [5]. Oral rehydration solution (ORS) and zinc use can prevent 69% of the mortality associated with diarrhea among children aged less than 5 years [2,5]. Despite this, treatment according to the relevant

43   guidelines (i.e., ORS and zinc use) is provided only to 39% of children with diarrhea, but antibiotics
44   are prescribed to 72% of these children [6]. Studies have suggested that improved case management
45   including increasing ORS and zinc prescribing and reducing antibiotic prescribing, addressing social
46   determinants of health and research to identify cost effective intervention and promoting equitable
47   access to interventions is needed [7,8]. Some studies have examined health care workforces'
48   knowledge, attitude, and practice toward diarrhea [9-11]. Studies performed in India have shown
49   that parents' awareness of ORS is high (89%, 86.7%, and 90.7%), but the practice of using ORS for
50   diarrhea episodes is lower (51%, 54.8%, and 60%) in comparison to awareness among parents; these
51   results indicate a wide "know-do" gap [9-11].

52   The aims of this paper are to present data on community perceptions for causes of diarrhea,
53   perceptions for diarrhea treatment, treatment given at home and health-seeking behavior for
54   diarrhea, and the pattern of drug prescription by health care providers for diarrhea in the community.
55   Based on this study interventions would be planned to increase the ORS and Zinc prescription rates
56   in the community.

2. Materials and Methods

2.1 Study design and Setting

59   This cross-sectional community-based study was conducted between June to August 2017. This
60   survey was conducted in Ujjain district. Ujjain district is one of the 51 administrative districts in MP.
61   Ujjain district has a population of 1.9 million within an area of 6091 sq.km; 61% of the district is rural
62   [12]. A list of villages in Ujjain district and slums in Ujjain city (the district headquarters) was made,
63   and nine villages and four slums were randomly selected for the study.

2.2 Sample size calculation

65   For the sample size calculation, the ORS prescription rate was considered the primary outcome. It
66   was assumed that each intervention would increase the ORS prescription rate by 15% at least.
67   National Family Health Survey-4 (NFHS-4) data showed that the ORS prescription rate was 57% in
68   Ujjain district [13]. Thus, assuming 0.57 as the proportion of health care providers prescribing ORS
69   and assuming a 95% confidence interval for this proportion with a width not higher than 15%, the
70   minimum sample size needed was calculated to be 172 children with diarrhea. Since, the study was
71   planned in nine villages and four slums a conservative estimate of design effect of 4 was considered
72   appropriate [14]; this gave a minimum sample size needed of 688 children (172×4).

2.3 Sampling frame and data collection tools and methods

74   All households in each of the selected nine villages and four slums were manually listed to obtain a
75   sampling frame of households. A total of 2830 households were surveyed to list households having
76   children up-to 5 years of age. A total of 1181 households were identified to have children up-to 5
77   years of age. These households were further surveyed, and 1571 children were included in the study
78   after obtaining informed consent from the family head.

79   All households in the sampling frame were visited. Mothers or caregivers (maternal or paternal
80   grandmother/grandfather/aunt/uncle) were interviewed by trained data collectors and a predesigned
81   questionnaire was filled-in to obtain information on their perceptions of the causes of diarrhea. Other
82   questions explored their perceptions of treatment; number of diarrhea episodes experienced by their
83   child in the last 3 months and treatment given for the last diarrhea episode at home. Questions
84   assessed their awareness of ORS and zinc use; availability of ORS and zinc; feeding practices during
85   diarrhea and details of health-seeking behavior for the last diarrhea episode. The questionnaire
86   collected information on household factors including education status of the mother, caste, religion,

87 type of house, number of household members, and socioeconomic status. Information on water,
88 sanitation, and hygiene (WASH)-related variables was also collected from each household.

89 The questionnaire was first prepared in English, then translated to Hindi, and back translated by
90 subject and Hindi language experts [15]. Any discrepancy was resolved by reaching a consensus. For
91 assessing content and construct validity [15], the questionnaire was pilot tested on 50 respondents.
92 Changes were made to three questions related to household WASH characteristics and health-
93 seeking behavior for diarrhea, which had an intra-class correlation coefficient of less than 0.65.

94 The proportion of children prescribed ORS and zinc, timing of ORS and zinc initiation post diarrhea,
95 and duration of ORS and zinc use was calculated through house-to-house surveys. The antibiotic
96 prescribed for each diarrhea episode for a given child was also noted. To get an accurate account of
97 antibiotic use in the previous episode of diarrhea mothers/caregivers were asked to show the original
98 prescriptions, package inserts and partly used packages of all drugs consumed. Further, the mothers
99 were shown a picture of commonly marketed 20 antibiotic syrups. Injectable antibiotic use was
100 ascertained by interviewing the formal and informal health care providers catering to the study
101 population. If the mothers/caregivers could not identify the specific antibiotic using the above three
102 methods, then such an incident was classified as "non-use" of antibiotic.

103 The diarrhea index was calculated by summing the number of diarrhea episodes in the previous 3
104 months among all children aged less than 5 years residing in a given household divided by the total
105 number of children aged less than 5 years and multiplied by 100, as shown in the formula below:-

106 Diarrhea index = $\frac{\sum a_n + b_n + c_n + d_n}{y} \times 100$

107 Where,

108 *1.* a_n= Number of episodes of diarrhea in past 3 months in 1st child living in same household

109 *2.* b_n = Number of episodes of diarrhea in past 3 months in 2nd child living in the same household as a

110 *3.* c_n = Number of episodes of diarrhea in past 3 months in 3rd child living in the same household as a and b

111 *4.* d_n = Number of episodes of diarrhea in past 3 months in 4th child living in the same household as a, b and
112 c

113 *5.*   y = Number of children aged less than 5 year living in the same household

114 Households with a diarrhea index of 200 or more were considered to be households with a high diarrhea index
115 (HDI). The cut of HDI was decided post-hoc based-on results of study. All HDI households will be the targets
116 of community-based interventions to improve diarrhea case management in future.
117

118 *2.4 Data management and data analysis*

119 The data was collected on paper-based questionnaire. A database was created using Epidata 3.1 (The
120 EpiData Association, Denmark). Data entry was performed by trained research assistants and was
121 supervised by senior researchers. All data entered were double checked for quality assurance. All
122 continuous variables that follow a normal Gaussian distribution were presented as mean ± standard
123 deviation. All categorical variables were summarized and expressed as proportions. Data analyses
124 was performed using Stata (Version 13.0, Statacorp., Texas, USA).

125 *2.5 Ethical consideration*

126 This study was approved by the Institutional Ethics Committee (IEC) of R.D. Gardi Medical College,
127 Ujjain, India (Approval number: IEC/RDGMC/493). Informed consent was obtained from
128 participants before the interview. Participants had the right to withdraw from the study at any time.

3. Results

A total of 2830 households were approached and 1181 households, which had children below five year of age, were included in the study. From the 1181 households, 1571 children were included, with 815 boys and 756 girls. A total of 858 children belonged to rural areas and 713 were from urban slums. The selection of study participants and their distribution according to low and high diarrheal index households is depicted in Figure 1. In the study area 17 formal and 43 informal health care providers are present, which are often the first point of contact for healthcare seeking for the community. Mothers were the main caregivers in majority (99.6%) of households.

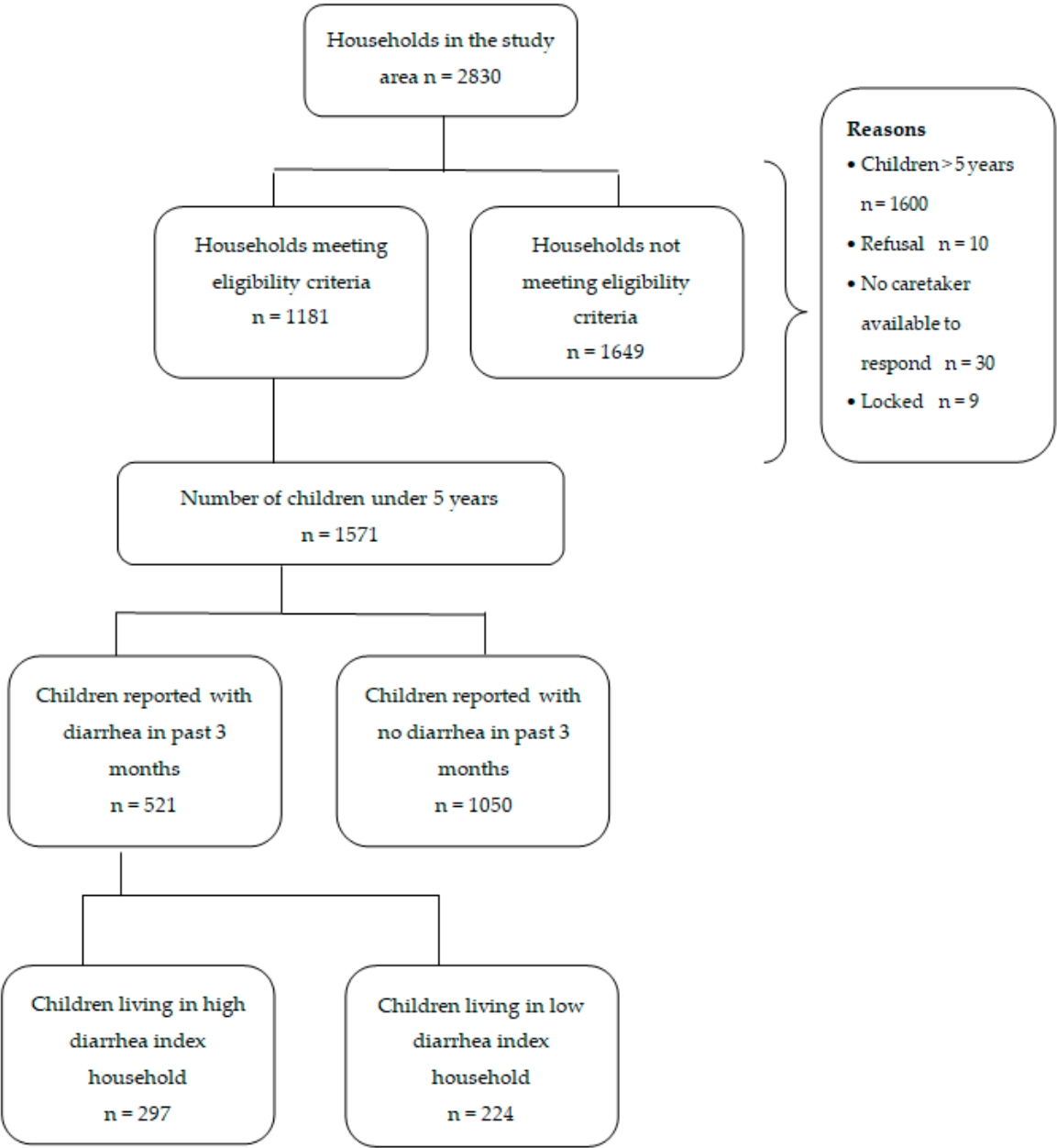



Figure 1 Process of selection of study participants and their distribution according to low and high diarrheal index households in the study

Table 1 provides the socio-demographic characteristics of the study participants.

142 **T**able 1 Socio-demographic characteristics of 1181 households having 1571 children included in the
143 survey

Socio-demographic characteristics		
Continuous variables	**Mean**	**SD**
Age of the children (years)	2.08	1.18
Family size (number)	7.20	3.24
Age of mother (years)	25.11	4.67
Categorical variables	**n = 1181 households**	**%**
Location		
Rural	660	56
Urban	521	44
Education status of mother		
Uneducated	240	20
Primary	629	53
Secondary or more	312	27
Caste		
General	151	13
Scheduled castes*	166	14
Scheduled tribes*	815	69
Other backward class*	49	4
Religion		
Hindu	695	59
Muslim	460	39
Others	26	2
Type of home		
Self-owned	1091	92
Rented	90	8
Number of household members		
≤ 4	254	21
5-8	586	50
≥9	341	29

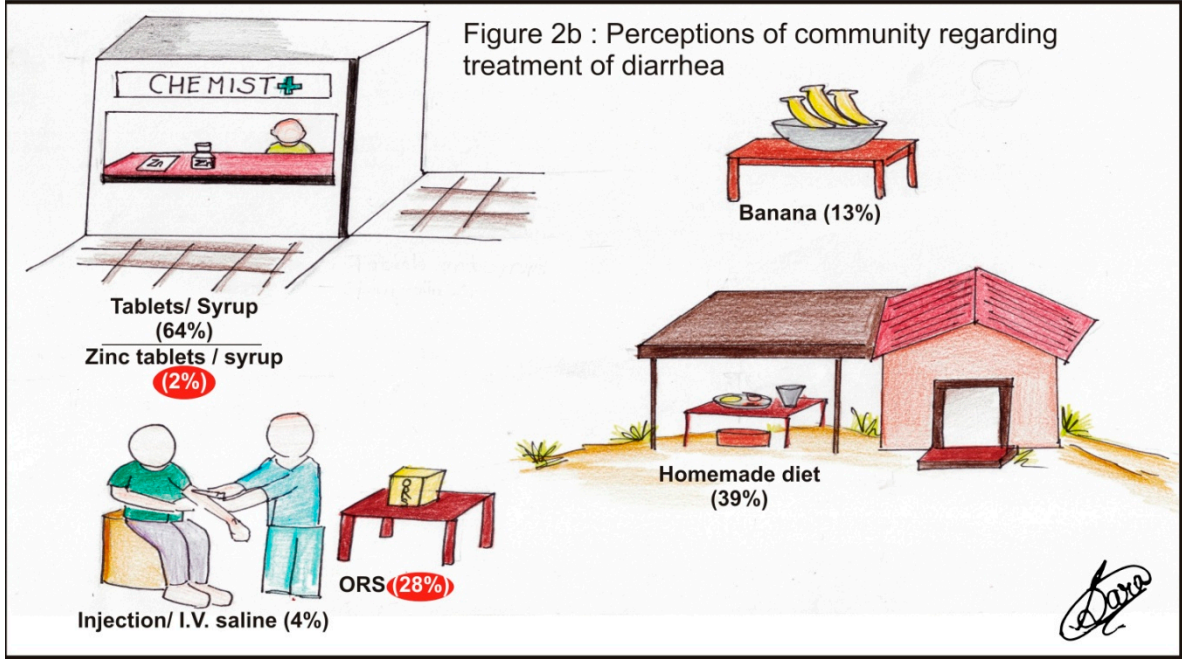
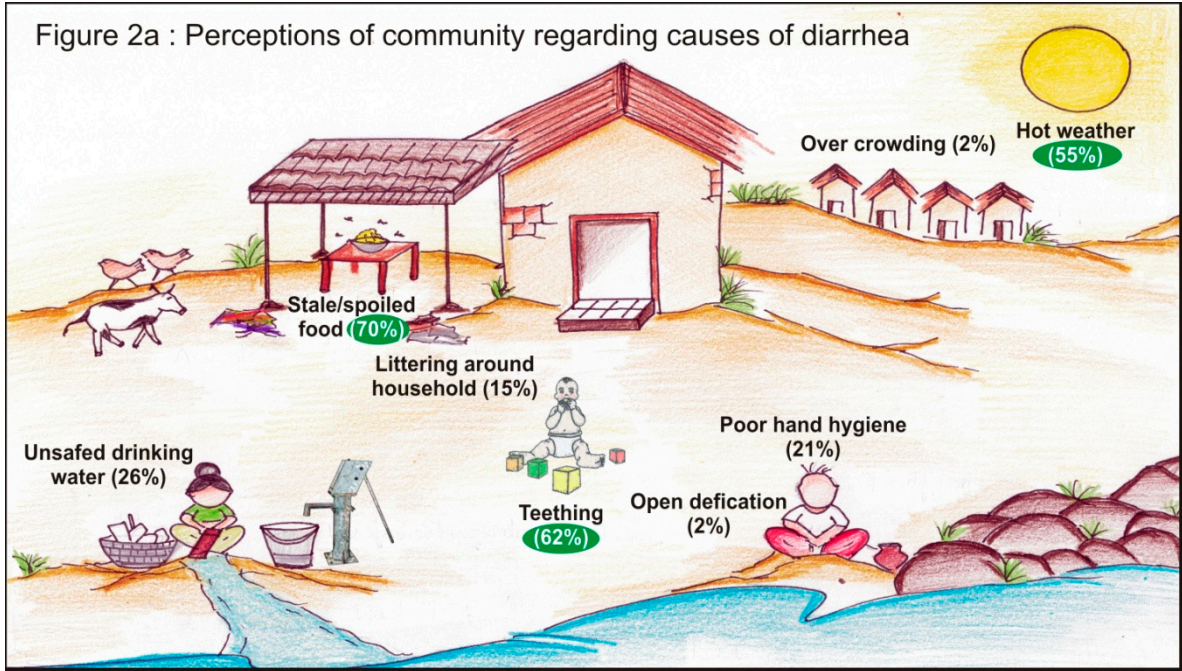
144 *For details see page 10-11 of reference 12

145 Table 2 provides the WASH characteristics of the households included in the study. Figure 2a depicts
146 the community perceptions of causes of diarrhea and Figure 2b depicts the community perceptions
147 of various effective treatments (supplement table S1).

148

149   Table 2 Water sanitation and hygiene related characteristics of 1181 the households.

Water sanitation and hygiene related characteristics	n = 1181	%
Water treatment		
Drinking water source*		
Hand-pump	709	60
Bore well	683	58
Tap (municipal supply)	294	25
Storage practices*		
Roof-top storage	242	20
Ground storage	1181	100
Drinking water storage containers*		
Earthenware pot (*Matka/Ghada*)	1181	100
Buckets	557	47
Plastic cans	298	25
Frequency of cleaning ground water containers		
Daily	779	66
Every 2nd-3rd day	250	21
Weekly or more	154	13
Do you treat water before drinking?		
No	283	24
Yes	898	76
Filtration using cloth	839	71
Coagulation, flocculation and sedimentation (by alum)	43	4.4
Boiling for 20 minutes	16	1.6
Sanitation		
Toilet constructed in household		
Yes	1100	93
Toilet used by adults	1080	91
Toilet used by children	276	23
Household waste		
Thrown on streets	1050	89
Burnt	83	7
Collected and disposed (municipal facility)	48	4
Hand washing done by mothers/caregivers		
After cleaning child's faeces	1155	98
After toilet	1153	98
After cooking	960	81
After cleaning child's urine	675	77
Before feeding child	603	51
To clean visible dirt	558	47
Before cooking	352	30
After cleaning nose/mouth	319	27

150   * Numbers and percentages totaling more than 1181 and 100%, respectively due to multiple responses

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152   Figure 2 Perceptions of 1571 mothers regarding cause (figure 2 a) and treatment of diarrhea (Figure
153   2 b) (Table S1 provides details in tabular form)

154

155　　　　　　Table 3 Feeding practice and treatment received by 521 (33%) children out of the total 1571 children
156　　　　　　　　　　　　　　　　during last episode of diarrhea

Categorical variables	n = 521	%
Feeding Practices*		
Continued breastfeeding	249	48
Top milk	270	52
Tea	230	44
Homemade diet	314	60
Mashed food/fruit	224	43
Heard about ORS	173	33
Where to get ORS?		
Health care workers	388	74
Pharmacy store	29	6
Don't know	104	20
Heard about zinc	62	12
Where to get zinc?		
Health care workers	177	34
Pharmacy store	29	6
Don't know	315	60
Treatment practices		
No treatment	11	2
Self-treatment only	155	30
Self-treatment with ORS	28	18
Self-treatment with left over medicines	123	79
Zinc tablet/ syrup	6	4
Homemade solutions	34	22
Treatment at healthcare facility	485	93
Government setting	83	17
Private setting	339	70
Formal health care provider	106	31
Informal healthcare provider	233	69
Medical store	63	13
Both self and healthcare facility	130	25
Received any treatment	510	98
Received an antibiotic	423	83
Received ORS	150	29
Received zinc tablets/syrups	54	11

157　* Numbers and percentages totaling more than 521 and 100%, respectively due to multiple responses

158　**Treatment given to children for the last episode of diarrhea**

159　　　Out of total 1571 children, 521(33%) children reported to have acute diarrhea. Among the 521

160　children having diarrhea a total of 510 (98%) children received some treatment (Table 3). Different

161　antibiotics prescribed to children during the last episode of diarrhea are shown in figure 3. The

162 most common antibiotic prescribed was ofloxacin (n = 104; 23%), followed by metronidazole (n = 72;

163 16%), and the most commonly prescribed combination of antibiotics was ofloxacin with ornidazole

164 (n = 175; 39%), followed by norfloxacin with ornidazole (n = 28; 6%). Overall antibiotic combinations

165 were prescribed to 54% children (n = 227). Among children who received treatment, (n = 423) 83%,

166 received antibiotics, 29% received ORS, and only 10% received zinc. Other drugs prescribed were

167 probiotics 25%, paracetamol 18%, loperamide to 16%, dicyclomine 7%, and ondansetron to 5%.

168 Figure 3 provides the details of antibiotics used for children with diarrhea.

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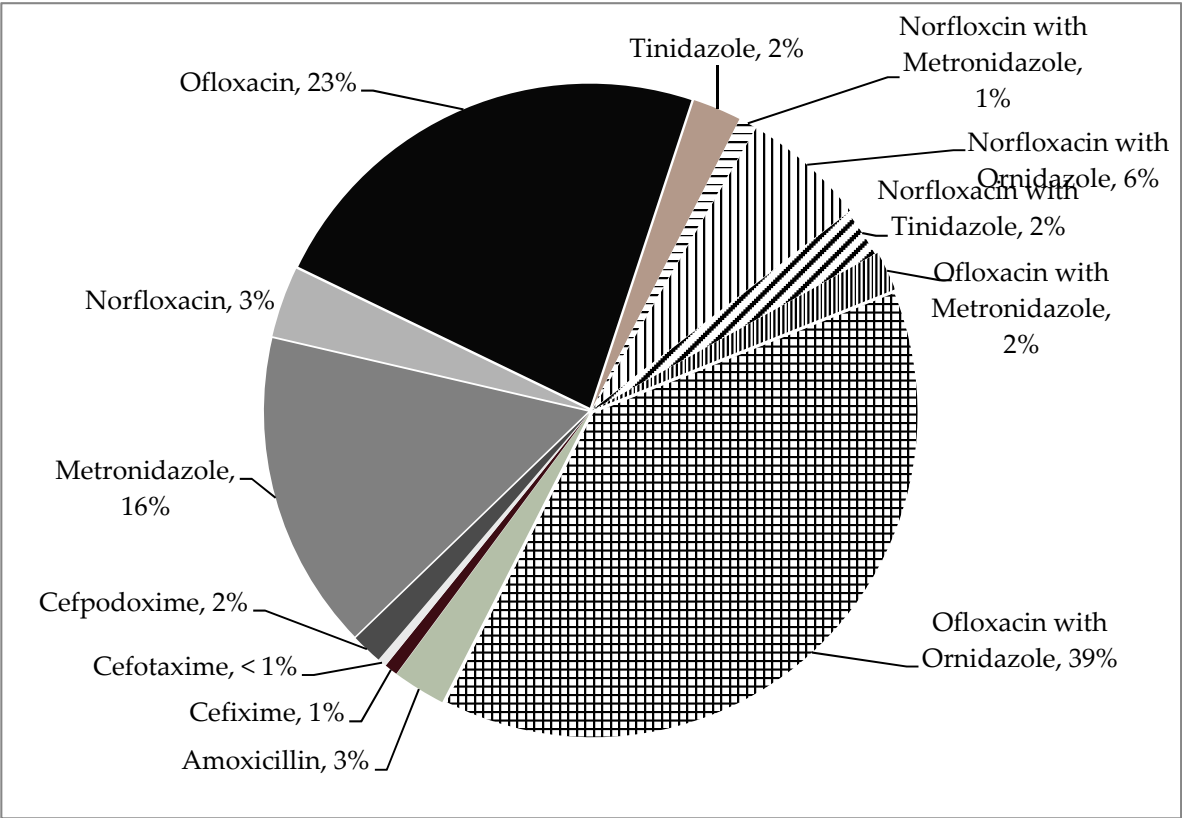
170 Figure 3 Antibiotics prescribed to children with diarrhea during last episode of diarrhea

171 **4. Discussion**

172 The study included a total of 1571 children residing in 1181 households located in both rural and
173 urban areas of Ujjian. The mean age of children include in the study was 2.08 years. The WASH
174 related characteristics revealed that most (60%) households used hand-pump as drinking water
175 source, and most (71%) households filtered water before storage using simple cloth. Many (93%)
176 households had a toilet built in household, but only 23% children used them. Most (89%) households
177 dumped their household waste on streets. Almost all (98%) mothers claimed to wash hands after
178 toilet use, but only 30% did so before cooking. Most (70%) mother perceived that stale or spoiled food
179 followed by teething (62%) and hot weather (55%) were most common causes of diarrhea. For
180 treatment of diarrhea the perception was that some form of tablets/syrups be prescribed (64%),
181 children given homemade diet (35%), and bannans were perceived to be beneficial by 13% mothers.
182 Nearly half mothers continued breast feeding during diarrheal episode however, only 33% and 12%,
183 of the mothers had heard about ORS and zinc, respectively. Of the children that received treatment
184 antibiotics were prescribed in 83% and ORS and zinc, in 29% and 11%, respectively.

185   In the present study, the major cause of diarrhea perceived by the community was stale food,
186   followed by teething and hot weather. Studies conducted in Eastern Sudan [16], Saudi Arabia [17],
187   and Nepal [18] have also reported stale food and teething as the major risk factors for diarrhea, as
188   identified by the community. In the three aforementioned studies, hygiene and sanitation-related
189   risk factors including, poor hand washing practices, open-air defecation, and littering around the
190   household were perceived as less important causes of childhood diarrhea by the community [16-
191   18], which is similar to the present study.

192   In India, diarrhea seasonality is well known [3,19]. Rotavirus infections present two seasonal
193   peaks in India, one in winter and the other in summer; the increase in temperature reduces the
194   transmission of rotavirus infections [20]. In summer, the limited potable water supply poses potential
195   public health risks for diarrhea [3]. The scarcity of portable water during hot Indian summers and
196   peaking of diarrhea during summers probably shapes the community perception that hot weather is
197   an important risk factor for diarrhea.

198   The community perceived unsafe drinking water as an important cause of diarrhea (26%). The
199   majority of households that reported household water treatment used simple filtration of drinking
200   water through cloth. According to WHO/UNICEF's core questions on drinking water and sanitation
201   for household surveys [21], simple filtration is classified as an inadequate method; however, it has
202   been shown to be effective in protecting against *Vibrio cholerae* infections in 65 villages in Bangladesh,
203   in which simple "sari" cloth was used for water filtration [22]. Most households in the study area had
204   access to safe drinking water sources. Fecal contamination of drinking water remains the most
205   important cause of diarrhea globally, although this was not specifically tested in the present study
206   [23]. Contamination of drinking water usually occurs not at the source but mostly at the household
207   level [24]. Littering around the household can play a major role, as perceived by the community. The
208   nonuse of toilets, even when available within households, is a problem that can be addressed through
209   behavior change communication (BCC) and has been reported in rural areas of Odisha, India [25]
210   and urban areas of Bhopal in MP [26]. Other resource-poor countries, such as Bangladesh [27],
211   Zambia [28], and Ethiopia [29], also show low utilization rates of latrines.

212   In this study, the majority (64%) of mothers/caregivers (Figure 2b) perceived that syrups and
213   tablets provided by health care providers are effective treatment for diarrhea. Knowledge on ORS
214   and its benefits for childhood diarrhea was poor in our settings (28%, Figure 2b), which is in contrast
215   to the findings of other studies conducted in India [9-11]. In our setting, the zinc use rate of 2% was
216   much lower than the national average rate of approximately 30% [3]. Moreover, there is a severe lack
217   of knowledge on zinc use among mothers in India and other resource-poor countries [30-32]. This
218   lack of knowledge and low acceptance for ORS and zinc use among community members/mothers
219   are prevalent despite the fact that ORS and zinc tablets are offered free of cost by the government
220   health sector and are offered at the doorstep by front-line health care workers in India. However, the
221   increased use of homemade fluids and banana is encouraging and should be promoted [33]. High
222   proportion of antibiotic prescribing, especially irrational combination of antibiotics, (most commonly
223   ofloxacin with ornidazole) for diarrhea has been documented and is major public health problem in
224   India [34]. High use of antibiotics for diarrhea in the study settings warrants specific interventions
225   for health care workers.

Methodological considerations

227   In the present study we attempted to retrospectively ascertain drug use mainly ORS and zinc
228   and antibiotics through interviews, which may be subject to bias due to differential recall. ORS and
229   zinc use recall were better than antibiotic recall as participants could recognize ORS and zinc easily.
230   This kind of recall bias would under estimate antibiotic use more compared to ORS and zinc use.

231

232 **5. Conclusions**

233   Childhood diarrhea is a major public health concern globally and in India. Effective
234 interventions are known but are rarely implemented in resource-limited settings and in settings with
235 fragmented health care systems, similar to the settings in this study. The results of this study
236 provided insights into community awareness of causes of diarrhea, its treatment, and other WASH-
237 related variables. The results of the present study will help us to design content-specific interventions
238 at the community level for the mothers, children and for health care workers.
239

240 **Availability of data and materials**
241 Due to ethical and legal restrictions, all inquiries should be made to The Chairman, Ethics Committee,
242 R.D. Gardi Medical College, Agar Road, Ujjain, India 456006 (E-mails: iecrdgmc@yahoo.in,
243 uctharc@sancharnet.in), giving full details of the intended use. Upon verification of genuineness of
244 the inquiry, the data that will be generated from various studies of this protocol will be made
245 available. For reference, please quote ethical permission number: 2016/01/18-493.
246

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256 **Conflicts of Interest:** The authors declare no conflict of interest.

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