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Original Research Article

Preferential mode of zinc and adherence to treatment: zinc syrup or zinc tablet

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ABSTRACT

Background: Diarrhoea has evident itself among the leading causes of under-five childhood mortality globally as well as in India. Although the benefits of zinc supplementation in diarrhoea management have been established, there remain many barriers to the widespread implementation of this treatment strategy. In India, a very small proportion of children in need, 20 per cent in urban and merely 5 per cent in rural, have access to zinc supplementation. The study aimed to assess zinc adherence in the community and find out the preferential mode of zinc as tablet or syrup, to stick to the scheduled adherence.
Methods: The proposed method of study is a simple household survey complimented by secondary research around the preference and usage of zinc and ORS among under five children, suffered from diarrhoea in the last 14 days preceding the survey date.
Results: The study revealed that 95 per cent of the respondents preferred zinc syrup over zinc tablet for treatment of diarrhoea due to its ease to administer and palatable taste to children. Eighty nine per cent of the total urban and 62 per cent of total rural respondents received zinc in syrup form, indicating the preferred mode of zinc by service providers over tablets.
Conclusions: It has been observed that the caregivers tend to give the complete dosage of zinc if it is available in the syrup form. However, it is important to generate evidence to understand the preferential mode of zinc; tablet or syrup in terms of administration of drug, its usage and its cost.

Keywords: Adherence, Diarrhoea, Preferential, SDI, Syrup, Zinc

INTRODUCTION

Diarrhoea has evident itself among the leading causes of under-five childhood mortality globally as well as in India. More than 5 lakhs under five children worldwide and over one lakh under five children in India die due to diarrhoea. Approximately 321 children per day aged under-five die due to diarrhoeal diseases and around 70 per cent of these children are below two years.[1] However, proof of evidence suggests that almost all the deaths due to diarrhoea can be averted by preventing and treating dehydration by the use of ORS (oral rehydration solution) and administration of zinc along with adequate nutritional intake by the child during diarrhoea. Other proved vital approaches to prevent diarrhoea are use of safe drinking water, hand-washing, sanitation, immunization and exclusive breastfeeding/appropriate nutrition.[2]

Many studies have shown that zinc supplementation results in a 25 per cent reduction in duration of acute diarrhoea and 40 per cent reduction in treatment failure or

death in persistent diarrhoea. These studies also revealed that children receiving zinc experience a decrease in the severity of their diarrhoea episodes. A 10-14 days course has proven to provide a prophylactic protection against future bouts of diarrhoea for two to three months after the episode.[3] Supplementary zinc benefits children with diarrhoea because it is a vital micronutrient essential for protein synthesis, cell growth and differentiation, immune function, and intestinal transport of water and electrolytes. Zinc is also important for normal growth and development of children both with and without diarrhoea. Zinc deficiency is associated with an increased risk of gastrointestinal infections, adverse effects on the structure and function of the gastrointestinal tract, and impaired immune function.[4]

Although the benefits of zinc supplementation in the management of diarrhoea have been established, there remain a number of barriers to the widespread implementation of this treatment strategy. Currently a very small proportion of children in need have access to zinc supplementation. It can be seen from national family health survey (2015-16) data, only 20.3 per cent of under five children in India, suffering from diarrhoea in last two weeks, received zinc. In urban areas of India, it is 23.7 per cent while in rural 19.1 per cent.[5] As per the mid-term evaluation under stop diarrhoea initiative (SDI) project, being implemented by save the children in 9 locations of 4 states viz. Delhi, Uttarakhand, Uttar Pradesh and West Bengal, usage of ORS and zinc collectively for treatment of diarrhoea is very less i.e. 7.8 per cent. In the intervention areas zinc was administered to 9.7 per cent and ORS was administered to 55.5 per cent only.

To understand the preference of dosage form of zinc and its adherence to 14 days of treatment, SDI conducted an assessment study in the intervention areas of project. The purpose of the study was to assess whether the availability of zinc in syrup form rather than the tablet form, will increase the utilization of zinc for the treatment of diarrhoea. The objective of the study is to assess zinc adherence in the community and find out the preferential mode of zinc either tablet or syrup to stick to the scheduled adherence.

METHODS

The proposed method of study is a simple household survey conducted from February 2018 to March 2018. It was complimented by some secondary research around the usage and preference of the uptake of zinc and ORS among children under five who have suffered from diarrhoea in the last fourteen days preceding the date of survey. The approaches for interviewing the households consist of using both primary and secondary research methods.

The secondary research consisted of undertaking rigorous literature reviews on the "incidence of diarrhoea and usage of zinc and ORS as treatment" on under five children undertaken in the country. Furthermore, we had a look through the current SDI project document. This was followed by undertaking a primary survey for the study. The primary research consists of undertaking face to face interviews with households having children below 5 years of age who had diarrhoea in the last fourteen days preceding the date of survey.

The survey questionnaires were administered by community health volunteers (CHVs), who were trained on using these questionnaires. Data collection work by CHVs was supervised by their supervisors. The supervisors revisited at least 10 per cent households to ensure adequate data quality for drawing inferences about the population.

Sampling design

The study sites comprised of four rural blocks of four districts viz. Bahraich, Balrampur, Pilibhit and Shravasti of Uttar Pradesh and one urban slum location of Kolkata, West Bengal. For the administration of the research tools, the entire block of the project was included.

The sample size was calculated using the following assumptions and norms:

- Eighteen per cent is the population of children under five years of age of the total population (this is the WHO standard formula for developing countries and gives only estimated population. Actual population may vary based on the total fertility rate (TFR) and the under-five mortality rate). The figures shown here in the table are calculated as 11 to 15 per cent of the total population.
- Margin of error or confidence interval which means positive and negative deviation from the actual survey result was fixed at ±5 per cent.
- The confidence level of 95 per cent was fixed which means how confident we are that the survey result represents the true but calculated values.

All the children below five years of age including neonatal children form the study population. Only those who have had diarrhoea in the past 2 weeks prior to the survey were considered for calculation of the sample size.

In each of the project sites, 15-20 PSUs (villages/clusters) were sampled by using probability proportional to size (PPS) method. The sample size calculated for a block was distributed in these 15-20 PSUs based on the ratio of population in the sampled villages. The project considered using a two-stage sampling approach.

A brief description of the proposed method of selection of villages and households has been presented here under:

Step 1: Selection of intervention villages/wards: at the onset, a sample of intervention villages covered under the survey was drawn. As explained above, a total of 15-20

villages have been selected from the catchment area of the program.

Step 2: Selection of respondents from intervention villages/wards: house listing was conducted in every selected village (children under five who had diarrhoea within 14 proceeding to survey). From the list, the specified numbers of children in each village, using simple random sampling were selected.

Data Processing

The data was processed and analysed using SPSS. The study data collected was cleaned for consistency and the accuracy and the validation was done through cross verification of the sample. The tabulation plan was prepared for the analysis of the collected data and the relevant comparative analysis of prescribed performance variables was done.

Limitations of the study

Assessment confined to stop diarrhoea initiative interventions areas.

RESULTS

The total sample size of the study stands at 4077 of which 83.5 per cent belongs to rural areas and remaining 16.5 per cent to urban area. More than 95 per cent of children were aged more than 2 years in both rural and urban area of study area. Fifty three per cent households with male child and 47 per cent with female child were studied. More than 3/4th of the respondents (mothers) age in rural area was between 21-30 years, 20 per cent between age of 31-40 years and 3 per cent less than 21 years of age in rural areas. Whereas, in urban areas, 69 per cent of mothers belonged to age group of 21-30 years, 22 per cent belonged to age group of less than 21 years and 9 per cent to the age group of 31-40 years. In rural area, more than one fourth of mothers had four or more children and in urban area more than 95 per cent mothers had three or less number of children (Table 1).

Table 1: Percentage of respondent mothers with respect to number of children.

Number of Children	Rural	Urban
1, 2 or 3 children	68.2	95.25
4, 5 or 6 children	27.1	4.45
7, 8 or 9 children	4.4	0.15
10, 11 or 12 children	0.25	0.15

In rural areas more than 60 per cent of mothers while in urban areas around 20 per cent of mothers were illiterate.

For the treatment of diarrhoea, more than 80 per cent of respondent in urban 63 per cent respondent in rural area consult a doctor and bought medicine from the medical store, whereas more than 90 per cent of rural respondents use electoral/ORS/glucose, approximately half of the respondents also use mixture of salt, lemon and sugar. In urban areas, one fourth of the respondents used mixture of salt, lemon and sugar and also electoral or ORS or glucose. Hardly six per cent of rural and three per cent of urban respondents use zinc syrup or tablet (Table 2).

Table 2: Treatment of diarrhoea at household level.

Treatment of diarrhoea at household level	Rural (%)	Urban (%)
Use of mixture of salt, lemon and sugar	49	25
Consult doctor and buy medicine from the medical store	63	81
Use of electrol/ORS/glucose	91	26
Use of homemade light recipes like porridge	8	10
Giving spices and condiments like fenugreek, nutmeg, clove, carom seeds	0	3
Massage with warm oil or foment with hot water	3	10
Zinc tablets or syrup	6	3
Give warm water to drink, black tea or sugar with tea leave	9	1
Other home remedies and homemade recipes	7	3
Incorrect answer	0	0
No answer	0	0

More than 95 per cent of mothers identified diarrhoea as three or more times watery stools. Fifty seven per cent in rural and 42 per cent of urban respondents also know diarrhoea as yellow or green stools. Fourteen per cent and 5 per cent of rural and urban mothers respectively associated diarrhoea with vomiting.

Only 11.4 per cent respondents had ORS packet available at home. In rural areas only 7.4 of respondents had ORS packet at home and in urban area 31.8 per cent of them had ORS packets available at home. More than 81 per cent respondents of the study area knew where the ORS packets are available. Knowledge on place of availability of ORS packets was slightly higher in rural areas (82 per cent) as compared to urban areas (76.4 per cent). Rural respondents obtained ORS packets from multiple sources - government health centres (52.5 per cent), private clinic (37.8 per cent), private pharmacies (43.9 per cent), ASHAs (33.3 per cent); whereas urban respondents obtained ORS packets from government health centres (86.5 per cent), private clinic (45.2 per cent), and private pharmacies (88.9 per cent).

Ten per cent of rural respondent and 29.6 per cent of urban respondent administered ORS only first day to child. Whereas, 29 per cent of rural and 40 per cent of

urban respondents administered ORS for only first two days. Fifteen per cent of urban and 30.30 per cent of rural respondent administered ORS for three days. Approximately 10 per cent of rural and 2.3 per cent of urban respondent did not administer ORS (Figure 1).

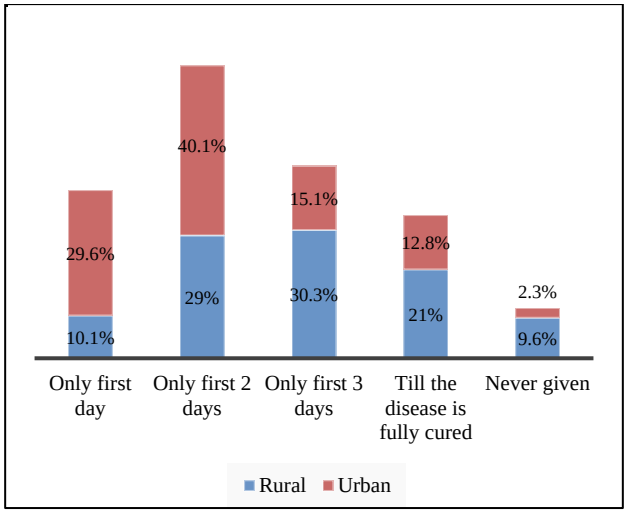

Figure 1: ORS administration to children in rural and urban locations.

Hardly 7.7 per cent of respondents received zinc for treatment of diarrhoea (n=4076). Of these merely 5 per cent were from rural and one fifth were from urban area. Of the 7.7 per cent who received zinc, 72 per cent of them received zinc in form of syrup and 26 per cent in form of tablet. Thirty eight per cent of respondents from rural and 11 per cent of urban respondents received zinc tablets, whereas 89 per cent of urban and 62 per cent of rural respondents received zinc syrup (Figure 2). Of these 25 per cent in rural and 30 per cent in urban received zinc from government health centres; Forty four per cent of rural and 65 per cent of urban respondents from private clinic; Twenty seven per cent of rural respondents from ASHA; eight per cent of respondents from rural and seventeen per cent of respondents from urban received from private pharmacies.

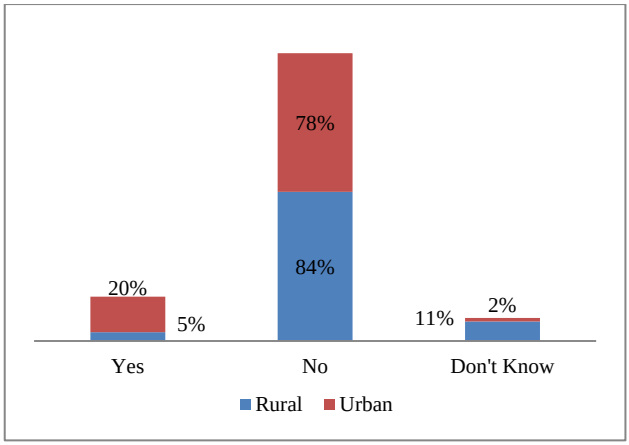

Figure 2: Respondents received zinc for treatment.

Sixty per cent of respondents received zinc from private sources and 40 per cent from government facilities. None of the respondents (67 in rural; 15 urban) received 14 zinc tablets and all the respondents across urban and rural gave zinc tablet to children for less than 7 days. Forty eight per cent of rural and 87 per cent of urban started giving zinc tablet from day first; whereas 44 per cent of rural respondent and 13 per cent of urban respondent started giving zinc tablet from second day and 6 per cent of rural respondent started zinc tablet from third day and two per cent of rural respondent did not respond. Fifty eight per cent of rural and 65 per cent of urban respondent started giving zinc syrup from first day.

Thirty two per cent of rural and 64 per cent of urban respondent stopped giving the syrup in between. Thirty eight per cent of rural and 25 per cent of urban respondent finished the entire bottle. Thirty per cent of rural and 11 per cent of urban continued the zinc syrup (Figure 3). All the respondents responded that the syrup bottle gets completed in 7 or less days. Ninety four per cent of respondents who received zinc during treatment of diarrhoea as well as 95.5 per cent of respondents who did not receive zinc during the last episode for treatment of diarrhoea preferred syrup over tablets.

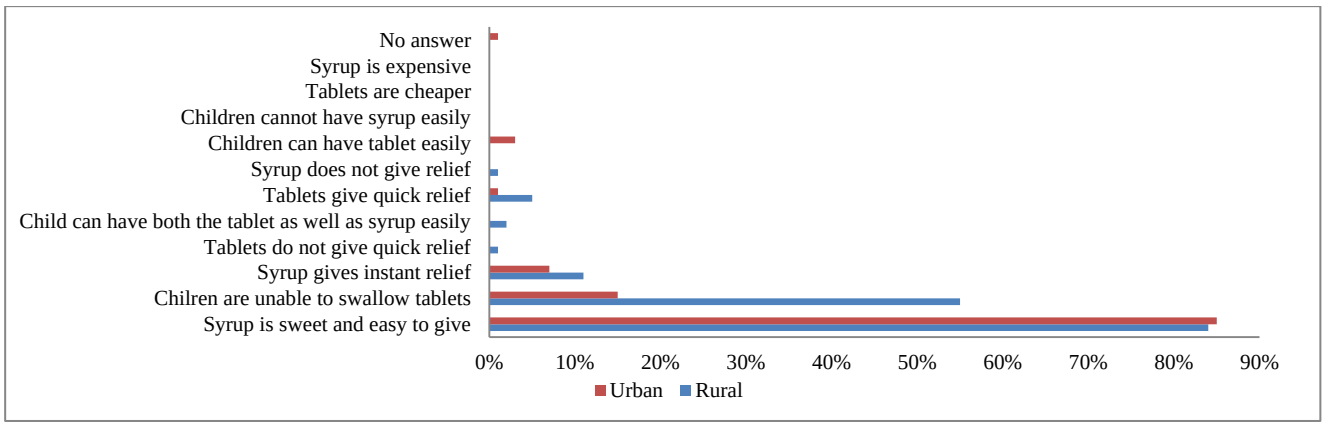

Figure 3: Preference of respondents for zinc syrup over zinc tablets.

DISCUSSION

Adherence to the treatment regimen for 10 to 14 days is essential to ensure the full effect of zinc for the prevention and treatment of diarrhoea. However, adherence to treatment can be obtained only if the zinc products promoted for use in the management of diarrhoea are acceptable to infants and young children. As a general guideline, a treatment may be considered to have good acceptability if 80 per cent of the prescribed treatment is taken by at least 70 per cent of the children.[6] Acceptance of the zinc (tablet or syrup) by mothers first is critical to adherence to treatment by children. The current study revealed that 95 per cent of the respondents preferred zinc syrup over zinc tablet for treatment of diarrhoea due to its ease to administer and palatable taste to children.

Zinc supplementation for the treatment of diarrhoea is a critical treatment intervention and since 2004, zinc has been recommended by WHO and UNICEF as the only treatment to be coupled with oral rehydration salts for the treatment of all diarrhoea episodes.[7] In view of the recommendations of UNICEF, WHO and the department of biotechnology and the proven effectiveness of the use of zinc in diarrheal disease management, on 2nd November 2006 the GoI issued a directive (Z 28020/06/2005/CH) stating that "it has now been decided to administer zinc in the national program as an adjunct to ORS in the management of diarrhea in children older than 3 months". The policy stressed the fact that zinc should be made "freely available and accessible round the year in every village, and all health personnel, including private practitioners and Anganwadi workers must be included in the network of zinc distribution." Data from recently conducted fourth round of National Family Health Survey revealed that hardly one fifth of children suffering of diarrhoea get zinc tablets (NFHS 4) and adding to it the adherence to the treatment with zinc tablets in not adequately documented in Indian context. This fact is supplemented by the current study findings of only 20 per cent in urban and merely 5 per cent in rural areas received zinc for treatment. The recommendation of freely available and accessible zinc round the year seems to posting immense challenges in front of policy makers and program managers in the country.

An expert committee constituted by the Ministry of Health and Family Welfare recommended that as zinc supplementation is an adjunct treatment to ORT, it should always be promoted together with ORS solution or other home available fluids recommended locally for the management of diarrhoea. It did not recommend use of zinc fortified ORS in the country. The recommendation regarding dosage was that: all cases of diarrhea should receive zinc in addition to ORS; 20 mg of zinc sulphate must be given daily in the form of dispersible tablets in childhood diarrhea control programme for (children under 6 months of age must receive 10 mg daily) 14 days continuously.[8] The current study reveals that 89 per cent of the total urban and 62 per cent of total rural respondents, who received zinc, received zinc Syrup indicating the preferred mode of zinc over tablets by service providers. The dispersible tablets due to its difficulty in administering to children and its pungent taste are not preferred over syrup. For than a decade, zinc has been incorporated as adjuvant to low osmolality ORS for treatment of diarrhoea. As per the recommendations of high level committee, Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) has approved zinc in form dispersible tablets (rather than syrup) for treatment of diarrhoea. It has been observed that for children, dosage form of syrup is preferred over tablet form due to its ease of administration and masking nature over the pungent taste of drugs. Moreover, as far as possible, the dosage form of drugs must be acceptable to beneficiaries.

USP monograph standards mention zinc sulphate tablets contain not less than 95.0 per cent and not more than 105.0 per cent of the labelled amount of zinc sulphate monohydrate ($ZnSO_4.H_2O$). It may contain one or more suitable flavours and sweeteners. Zinc sulphate oral solution contains not less than 90.0 per cent and not more than 110.0 per cent of the labelled amount of zinc sulphate monohydrate ($ZnSO_4.H_2O$). It may contain one or more suitable flavours and sweeteners.[9] Pharmacopeia mentions equal standards of zinc in tablet and syrup form. Further, short-term supplementation of zinc during diarrhoea results in a large increase in plasma Zn concentration, regardless of whether the additional Zn is provided as a dispersible tablet or solution.[10,11] Water-soluble zinc salts have a strong bitter metallic after-taste, and children will refuse to take the medicine if this metallic after-taste is not completely masked. The National List of Essential Medicines India (NLEMI) lists zinc sulphate syrup for diarrhoea which is different from the recommendation made in the GOI directive of 2006.[6]

CONCLUSION

Zinc has been available in both tablet form as well as syrup form. Apart from the supply/procurement issues with regards to zinc, a few behavioural issues have also been observed over a course of time.[11] For example; one of the reasons for not following the complete 14 day regiment of zinc tablets is the metallic taste of the tablet. Although zinc syrup has not been made available across the country but it has been observed that the mothers/ caregivers tend to give the complete dosage of zinc if it is in the syrup form. However there is lack of systematic evidence to substantiate this statement. Considering this it is important to generate evidence to understand which mode of zinc; tablet or syrup is preferential in terms of administration of drug, its usage and its cost. Understanding this preference from a number of stakeholders will help in designing the strategies that will contribute to improved usage of zinc for children affected with diarrhoea.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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