The impact of pre-emptive home delivery of ORS + zinc on treatment for child diarrhea: a randomized controlled trial in Bauchi, Nigeria

Study Protocol

Version 5

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Abbreviations:

- LMIC: Low-and-middle income countries
- ORS: Oral Rehydration Salts
- WHO: World Health Organization
- cRCT: cluster Randomized Controlled Trial
- CHAI: Clinton Health Access Initiative
- DHS: Demographic and Health Survey
- DMMA: Drug & Medical Consumables Management Agency
- DRF: Drug Revolving Fund
- MNCH: Maternal and Child Health
- LGA: Local Government Areas
- EA: Enumeration Areas
- CHIPS: Community Health Influencers, Promoters, and Services
- NGN: Nigerian Nairas
- GPS: Geographic Positioning System
- DHIS2: District Health Information Software 2
- ITT: Intent-to-treat
- ICC: Intra-Class Coefficient
- MDE: Minimum Detectable Effect
- p.p.: Percentage points

I. Background

Diarrhea[1] is the second leading cause of death for children in low- and middle-income countries (LMICs) with nearly half a million children under five years old dying each year.(1) This is true even though nearly all such deaths could be prevented with a simple and inexpensive medicine: oral rehydration salts (ORS). ORS has been lauded as one of the most important medical advances of the 20th century,(2) yet it has been underutilized for decades.(3) Nearly half of diarrhea cases around the world do not currently receive ORS.(4) Millions of young lives could be saved if we can find ways to increase ORS use.

One promising approach for increasing ORS use is delivering the product directly to the home for free prior to a child having a case of diarrhea. This has the benefit of overcoming two key barriers to ORS use:

1) It makes it free to household. Although ORS is relatively inexpensive, price is still a barrier to use in low-income settings.(5)
2) It makes it more convenient. Although ORS is generally accessible at health facilities, children in sub-Saharan Africa get diarrhea many times throughout the year, and leaving the house to retrieve ORS is an ordeal. Delivering the product directly to the home makes it so ORS is readily available for use immediately when the child comes down with diarrhea.(5)

This pre-emptive home delivery intervention was tested with a randomized controlled trial (RCT) in Uganda in 2017 and results were promising; the intervention increased the share of cases treated with ORS over the subsequent month by 19 percentage points (37% increase; $p < 0.001$).(5)

Before this intervention can be broadly scaled up, it is important to replicate it in other settings and measure effects over a longer period of time to make sure results are generalizable. In this study, we will use a cluster-randomized controlled trial to evaluate the effect of the pre-emptive home delivery intervention implemented at much broader scale in Bauchi, Nigeria. We will also estimate how the intervention effects evolve over the 12-months following the deliveries to help inform how frequently the deliveries should be made.

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[1] According to the World Health Organization, diarrhea is defined as "the passage of three or more loose or liquid stools per day (or more frequent passage than is normal for the individual)."

II.   Research questions & hypotheses

II.I. Primary research question & hypothesis

Through this study, we will answer the following primary research questions:

RQ1a: Does pre-emptive home delivery with free distribution of ORS and zinc coupled with information about the importance of proper treatment (henceforth referred to as "the intervention") result in greater use of ORS to treat child diarrhea (for children under the age of 5) over the 6 months following the deliveries, relative to the status quo (i.e., in the absence of such an intervention)?

RQ1b: Does the intervention result in greater use of ORS to treat child diarrhea (for children under the age of 5) over the 12 months following the deliveries, relative to the status quo?

Consequently, the primary hypothesis for the study is that:

Pre-emptive distribution of free ORS + zinc packets and the information about the importance of proper treatment increases ORS usage for children under 5 years of age during diarrhea incidents over the intervention period (6 months and/or 12 months).

Rationale: Using ORS to treat diarrhea reduces the probability of death from diarrhea by 93%.(6) Zinc results in additional health benefits but these benefits are much smaller than the benefits from ORS, which is why the primary research question is related to ORS use. We will assess our outcomes using a six-month intervention timeline as well as a twelve-month intervention timeline to help inform the effectiveness of bi-annual campaign (average effect over 6 months) and an annual campaign (average effect over 12 months).

Relatedly, an additional objective of this study is to assess how the intervention effects change over time, as more time passes between the ORS + zinc deliveries and diarrhea episode initiation.

RQ1.1: How much does the effect of the intervention on use of ORS to treat child diarrhea (for children under the age of 5) change over time?

Rationale: As more time passes, households might be less likely to have ORS + zinc stored in their homes when the child comes down with diarrhea (e.g. if they used it for a previous case, gave it away, or lost it).

II.II. Secondary research questions

We will additionally aim to answer the following secondary research questions:

RQ2: Does the intervention result in <u>greater use of ORS combined with zinc</u> to treat child diarrhea (for children under the age of 5) relative to status quo?

Rationale: ORS combined with zinc is the WHO recommended standard of care.

RQ3: Does the intervention result in a <u>lower use of antibiotics</u> to treat child diarrhea (for children under the age of 5) relative to status quo?

Rationale: Antibiotics are frequently used but are inappropriate for most cases of child diarrhea (a large majority of cases are viral).(7,8) Overuse of antibiotics contributes to antibiotic resistance and can harm the child. Although we will not be able to distinguish between appropriate and inappropriate use, understanding the extent to which ORS + zinc use is a substitute for antibiotic use is important for designing policies to reduce antibiotics overuse.

RQ4: Does the intervention result in <u>increased use of zinc</u> to treat child diarrhea (for children under the age of 5) relative to status quo?

Rationale: Zinc should be supplemented with ORS, per the WHO guidelines.

RQ5: Does the intervention result in <u>decreased time to initiation of ORS use</u> (for children under the age of 5) relative to status quo?

Rationale: ORS use should start as soon as possible after the child starts having diarrhea.

RQ6: Does the intervention result in <u>increased exposure to unsafe water for exclusively breastfed children (< 6 months of age)</u> relative to status quo?

Rationale: ORS needs to be mixed with water to be consumed. Babies that are exclusively breast feeding would not drink any water in absence of ORS use. Thus, if the water used to mix the ORS not clean, increasing ORS use among this group could lead to increased exposure to unsafe water.

RQ7: Does the intervention result in <u>decreased willingness to purchase new ORS packets among caregivers,</u> relative to status quo?

Rationale: Households that receive free ORS could be less likely to purchase ORS in the future due to an anchoring effect,(9) or because they are waiting for more free packets in the future.

RQ8: Does the intervention result in <u>decreased child mortality (all cause, and diarrhea-related) in children under the age of 5</u> relative to status quo?

Rationale: The ultimate objective of increasing ORS use is to reduce child mortality. However, the effects of ORS on mortality are not well documented, and existing estimates are outdated. While this study is not designed to be powered to detect mortality effects, we will nevertheless analyze this outcome. The results will potentially be useful for future meta-analyses even if imprecise.(10)

RQ9: Does the intervention result in decreased hospitalizations due to diarrhea in children under the age of 5 relative to status quo?

Rationale: Similar to mortality, we did not design the study to be powered to estimate changes in hospitalization. But this is an important outcome and worth collecting and analyzing even though we might be under-powered.

RQ10: Does the intervention result in fewer diarrhea episodes in children under the age of 5 in the months following the intervention relative to status quo?

Rationale: Evidence suggests that supplementing ORS with zinc for treating child diarrhea lowers the incidence of diarrhea.(11)

RQ11: Does the intervention reduce care-seeking outside the home for diarrheal episodes in children under the age of 5 relative to status quo?

Rationale: ORS and Zinc are the WHO recommended treatments for child diarrhea. If households have these available at home when the episode starts, there is less need to seek care outside the home. Reducing care seeking outside the home has potential benefits such as saving caretaker time and lost wages, reducing out of pocket health costs, and reducing use of unnecessary treatments.

RQ12: What share of ORS and Zinc co-packs delivered were wasted (used for other purposes besides treating diarrhea)?

Rationale: Since families will receive free packets of ORS and zinc, it is possible that packets are used up by other family members, given away to others who need it, or lost.

RQ13: What share of eligible households received an ORS/zinc delivery?

Rationale: Tracking the number of households that receive the intervention will allow us to a) more accurately assess the effect of the intervention, and b) evaluate feasibility of the program.

RQ14: What is the cost per child reached with the intervention?

Rationale: We expect this intervention to be highly cost-effective; this measure would be a pre-cursor to the evaluation of this expectation.

RQ15: Does having ORS <u>stored in the home</u> when a child comes down with diarrhea result in <u>greater use of ORS to treat child diarrhea</u> (for children under 5) compared to not having ORS stored at home?

Rationale: The main mechanism through which we expect the intervention to work is by increasing pre-emptive home storage, so it is important to know what the effect of pre-emptive home storage is on diarrhea treatment outcomes. Better fidelity or management of the intervention could improve home storage.

RQ16: Does the intervention change the likelihood that children under-5 misses days of pre-school?

Rationale: If the intervention reduces diarrhea prevalence or the severity of illness we would expect children to be more able to attend school.

RQ17: Does the intervention change the price or supply of ORS and zinc at local pharmacies and patent and proprietary medicine vendors (PPMVs)?

Rationale: One concern about mass free distribution of health products is that it will distort the local markets, leading to less supply or lower prices.

III. Study design

This study will employ a cluster randomized trial design, randomizing wards in the state of Bauchi to either treatment (where <u>all</u> households with at least one child under the age of 5 will receive free pre-emptive ORS and zinc packets, coupled with information about the importance of proper treatment) or delayed-start control (delayed start, with care as usual during the evaluation period and intervention delivery post evaluation) groups. The intervention will be delivered by campaigners recruited from within the community by the Clinton Health Access Initiative (CHAI). The data for evaluation (including the baseline and endline household surveys) will be collected separately by RAND, who will contract a survey firm. For each survey wave, a random sample of households within each ward will be selected. More details on the intervention can be found in section **III.IV. Study Procedures**.

III.I. Study setting

Bauchi is the fifth largest state in Nigeria by geographic region and seventh most populous state (of 36), with a population of about 6.9 M, and with over 1.5 M children under the age of five.(12) The diarrhea prevalence in Bauchi is 34.1%, almost double the national average of

12.8%.(13) As with Nigeria, knowledge of ORS is generally high in Bauchi, with about 76% of the respondents of the most recent wave of DHS survey reporting that they have heard of ORS. ORS coverage in Bauchi is 35%, which is similar to the national average. Although zinc is recommended for all cases of diarrhea, only one in five cases in Bauchi are treated with zinc tablets.(13) Care seeking behaviors in Bauchi mirror those at the national level in Nigeria, as per the latest wave of DHS survey, with about 63% of cases seeking medical treatment. Care for diarrhea is more commonly sought from pharmacists or chemists (for 46% of cases), rather than other formal providers or clinic or hospital (private or public; 25.6%).(13)

The state has a Maternal and Child Health program, which aims to provide corresponding services in the state. Bauchi's Drug & Medical Consumables Management Agency (DMMA) manages all aspects of supply for health facilities under this program. Through their Drug Revolving Fund (DRF), a part of the state's annual budget was expected to be appropriated by the Bauchi State Ministry of Health to purchase medicines and supplies to be distributed to the health facilities across the state. Unfortunately, due to budgetary constraints, the DMMA has modified their programming to sell ORS and zinc packets to healthcare facilities rather than providing them free of charge. Though, currently, some commodities are distributed free of charge during the bi-annual MNCH weeks, within which zinc and ORS co-packs are distributed; however, the coverage for this event is limited. Moreover, the supply of ORS and zinc is generally limited in public facilities, and occasional stock-outs occur at the local health facilities. (14)

III.II. Sampling strategy

Sampling geographies

Our sampling frame will consider the local government structures in Bauchi. The state has 20 local government areas (LGAs), each with its own local government administration. Within each LGA, there are 10-20 wards or local administrative areas, for a total of 323 wards in the state. We will include all 323 wards in the study and will randomly assign them to either treatment group or delayed-start control group. We will randomly, yet systematically sample enumeration areas (EAs) from each ward for a total of 1,732 EAs, such that EAs do not cross state ward boundaries and are representative of the full state wards from which they are sampled. We will select EAs using a comprehensive list of all EAs in Bauchi. The selected EAs will be included at baseline and endline, but we will randomize the timing of data collection at endline over two waves (endline wave 1 over months 1- 6, and endline wave 2 over months 7-12 after the deliveries, with an equivalent time period for control) to

allow for analysis of how the effect of the intervention evolves over time (described in more detail in the endline data collection section).

Sampling households (baseline and endline)

Within each wave of data collection, we will sample at least 15, but ideally 20 eligible households from each EA based on our inclusion criteria described in the next section. Importantly, however, all listed households will be randomly assigned to either endline wave 1 or endline wave 2. Thus, while the same households could be resampled at baseline and endline, we would, to the extent possible, not resample the same households for both endline waves. Our analysis will be at the diarrhea case level, and since not all sampled households will have had a recent case of diarrhea, the composition of households included in the analysis at baseline and endline will be different even if we followed up with the same households at endline. Thus, re-visiting the same household at endline does not add value relative to drawing two separate random samples.

Enumerators will first create a list of all households with a child under five-years-old and with a caregiver who is at least 15 years old, within each EA. Enumerators will work with local officials and village chiefs to identify all eligible households. Once the list is created, 20 households will be randomly sampled from the list. If the EA has less than 20 households, we will sample all households. However, if the EAs have less than 15 households, we will replace the EA with another eligible EA[2]. We will have a reserve list of additional households in case a household is found to be ineligible when we make the visit or if we are unable to make the visit. With a diarrhea prevalence of 13% in Nigeria, we expect this is to yield an average of 2.6 cases per EA or about 4,503 cases over each wave of endline assessment for a total of about 9,006 cases over 12 months.

III.III. Inclusion/exclusion criteria

To be eligible for the intervention, the household must have at least one living child under the age of five at the time of the delivery; this is the sole inclusion criteria for the study. We will exclude households where the sole caregiver is not mentally fit to give consent, is unable to respond to the survey due to disability or is under 15 years old. Since the predominantly spoken language in Bauchi is Hausa, we expect to administer all study-related components in that language. In cases where the household does not speak Hausa, but does speak

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[2] EAs will be drawn from a list of buffer EAs that were randomly drawn from the NPC files but were not included in the main sample. Of these EAs, the ones that are a) never sampled or used for pilots, b) are >500m from the ward boundary based on a spatial merge, or are <500m from the ward boundary but are near another ward with the same treatment assignment will be considered as possible replacements.

English, we will administer the survey in English. We will exclude households where the caregiver does not speak Hausa or English. We expect this to exclude a small number of households only, as over 90% of the population in Bauchi speaks Hausa. We will additionally exclude any households that belong to nomadic tribes to minimize possible spillage and/or concerns associated with uncertainty of receipt of intervention; based on anecdotal data from Bauchi locals, the size of this population is relatively small and should not affect the representativeness of our sample.

III.IV. Study procedures

The intervention will involve pre-emptive distribution of two co-packs of ORS+zinc per child to every household with at least one child under the age of five. Each co-pack includes two sachets of ORS and one strip of 10 zinc tablets, enough to be able to treat two cases of child diarrhea. This research will evaluate the impact of one round of deliveries. The intervention and data collection procedures will be rolled out in the following phases:

Phase 1 – Listing
Enumerators will spend a day at the respective EAs, where they will work with local community leaders to identify and list all households with a child under the age of five and with a caregiver who is at least 15 years old. They will document the names and nicknames of the caregivers, the heads of households, number of children under the age of five in the household, as well as the household location. These lists will be used to sample households for the baseline and endline surveys. We expect it to take roughly one day to make the list. Enumerators will be blinded to the ward's treatment assignment.

Phase 2 – Baseline survey
At the end of the day the list is created, enumerators will use the list to randomly select 20 eligible households in each EA for the baseline survey. If the EA has between 15 and 20 eligible households, all the households will be sampled for the survey. Prior to starting the survey, the enumerator will verify the age of the caregiver, explain the goals and procedures pertaining to the study, and will obtain consent for data collection using one of two methods: if the caregiver is over 18 years of age, **or** if the caregiver is under 18 years old but is considered an emancipated minor based on the Nigerian laws[3], the enumerator will obtain verbal consent directly from the caregiver. If, however, the caregiver is under 18 years old

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[3] According to the Nigerian Federal Ministry of Health's 2014 *Guidelines for Young Person's Participation in Research and Access to Sexual and Reproductive Health Services in Nigeria*, a person who is between the ages of 13 and 17 will be considered an emancipated minor (and will have the ability to independently consent for themselves) if any of the following is true: a) the person has been granted the status of adulthood by a court order; b) the person has lived independent of parental guidance for a minimum of one (1) year; c) the person is married; d) the person is living on the street; or e) the person is the head of household.

and is not an emancipated minor, then the enumerator will obtain verbal consent from the parent/guardian of the caregiver, along with a verbal assent from the caregiver. Verbal consent will be obtained instead of written consent because some respondents might not be able to write. The baseline survey will then be administered using SurveyCTO in the participant's home. The survey will record information about the household, caretaker, and child characteristics, information about any recent cases of diarrhea (within the last 4 weeks) for all the child(ren) under the age of five, strategies for treating diarrhea, child mortality, and access to (and use of) care, among other things. In households where there was no recent case of diarrhea, the enumerators will collect basic demographics and child mortality information only and move on quickly to the next household. As such, participants will receive detergent sachets (worth approximately 0.33 USD each) for their time and participation in the survey, as is customary in Nigeria.

Phase 3 – Randomization strategy

We will randomize wards to treatment or control groups before baseline data are collected. We are randomizing at the ward level because this is the level at which campaigns of this type are generally rolled out. Sub-ward campaigns are operationally challenging and do not reflect real world practice. Randomization of wards will be stratified by local government area (LGA) such that an equal number of wards in each of the 20 LGAs will be assigned to treatment and control.

Within each LGA, we will **randomly assign** wards to either of the two groups listed below, and let the randomization dictate which of the two groups end up with an extra ward:

- *Group 1 – Delayed-Start Control (cN = ~162):* No intervention will take place until after endline data collection in completed, after which the wards in the Control group will receive the intervention. During the study period, the caregivers in this group will have standard access to ORS and zinc at local health facilities and pharmacies. Some community health workers (called Community Health Influencers and Promoters, and Services or CHIPS(16)) in control villages could make household visits; however, we do not expect any delivery of ORS or zinc in the control group as CHIPS are generally not the source of diarrhea treatment.(12)
- *Group 2 – Household Visit + Information + Free pre-emptive distribution of ORS (cN = ~162):* Campaigners recruited by CHAI will be paid NGN40 for each household visited in their catchment area that contain a child under 5 years old at the beginning of the study. During the distribution visits, the campaigners will train caregivers on the dangers of diarrhea and the importance of ORS and zinc use, among other things (including how to

prepare, use, and store ORS/zinc, benefits of the treatments, recommended health behaviors such as seeking care, and encouraging basic handwashing and hygiene practices). The caregivers will also receive a flyer describing the same information in their local language, for future reference. Campaigners will then distribute 2 ORS and zinc co-packs (each co-pack contains 2 sachets of ORS and 10 tablets of zinc) for free for each child under the age of five in the household.

The participant and the intervention implementer will not be blinded to the random assignment due to the nature of the intervention.

Phase 4 – Intervention implementation

The intervention will be implemented by CHAI. CHAI will recruit about 318 campaigners to deliver the intervention. Thus, each campaigner will cover 2-3 EAs based on ward assignment and logistical planning. The campaigners will be trained on the programmatic activities, including supply collection from the storage facilities, and intervention delivery. We expect it to take 2-3 months to complete all the deliveries.

Once the randomization has been completed, the campaigners will receive a small supply (100-500 co-packs) of ORS + zinc at a common LGA storage facility identified by CHAI in collaboration with the Bauchi Ministry of Health. The small supply ensures that the co-packs are not resold for profit-earning. The number of co-packs received by each campaigner, however, will be based on the number of beneficiaries in their catchment area. The campaigner will then visit each eligible household within their catchment area, counsel caregivers on the importance of ORS and zinc, and distribute the co-packs. Importantly, if the caregiver is not home or unavailable, the campaigner will make repeated attempts to deliver the intervention.

The pay-for-performance structure for distribution (noted earlier) is based on prior experiences that suggest that flat payments result in only about 60% intervention delivery.(5) To keep additional checks, CHAI will employ a system of verification and validation to calculate the payments for each campaigner. Moreover, the campaigner's performance will be monitored by a supervisor who will make supervisory visits to a random sample of households during the distribution period to ensure intervention fidelity. The co-packs will be restocked for each campaigner either during the monthly resupply and reconciliation meetings during the intervention period, or over the supervisory visits.

Campaigners will also be monitored through mobile devices (e.g., smartphones, tablets, etc.) that they carry. The mobile devices will have an app that campaigners will use to log their

activities, such as the date and time of household visits, number of households visited per day, number of ORS and zinc co-packs distributed (and photos of delivery for verification) per household, and geospatial location.

Phase 5 – Endline data collection

Endline data collection will start exactly 4 weeks after the initial deliveries. Each EA will be randomly assigned to have data collection occur in any of the four-week intervals over months 1-6 after intervention delivery (i.e., between weeks 5-8, weeks 9-12, weeks 13-16, weeks 17-20, weeks 21-24 or weeks 25-28), wherein data collection for each EA will be determined based on time since the deliveries occurred in that EA. This means that data collection will start before the delivery campaign has been completed, but only for EAs that have received the deliveries and have been assigned the corresponding period for endline data collection. As the endline wave 1 comes to an end, the EAs will follow the same random assignment as before to have data collection occur in any of the four-week intervals over months 7-12 post intervention delivery (i.e., weeks 29-32, weeks 33-36, weeks 37-40, weeks 41-44, weeks 45-48, or weeks 49-52). Random assignment of endline data collection timing will allow for an unbiased estimate of how time modifies the treatment effect.

To maximize statistical power in each month, we will stratify the timing of endline data collection by ward and treatment assignment such that 1-2 EAs are sampled from a ward within each month for data collection, with the sampled EAs being balanced across treatment and control wards, and that the EA assignment is carried out without replacement over each wave of the endline data collection. To carry out each wave of the endline surveys, the enumerators will utilize the list of randomly sampled households from each EA for that specific endline wave. Thus, households will be mostly different from those sampled in the baseline survey, but some households could be resampled; most household will not be surveyed at both endline wave 1 and endline wave 2. As before, verbal consent using one of the two methods will be collected prior to the survey data collection, and the surveys will be carried out at the participant's home. The endline survey will ask detailed questions about recent cases of diarrhea since delivery, types of treatment used, child mortality, and care-seeking behaviors for each child under the age of five in the household. We will also collect data relevant for implementation such as whether the households received a visit from the campaigner.

Unlike at baseline, (listed and) sampled households will remain eligible to participate in the survey if no children under 5 are in the household due to child mortality. This is to ensure that we accurately capture incidence of child mortality at endline. Enumerators will also ask

caregivers to show ORS packets, used or unused, as an additional (and objective) measure for ORS use and we will record packet counts. As with the baseline survey, participants will receive detergent sachets (worth approximately 0.33 USD each) for their time and participation in the survey.

During each wave of endline, enumerators will visit at least one and up to two pharmacies in each EA to ascertain whether ORS, Zinc, and diarrhea-related antibiotics are available at the pharmacy at the time of the visit and record the prices for each. Since this information is considered publicly available, we will not consent the pharmacists.

III.V. Data handling procedures[4]

In this study, we will collect four types of data:

- Listing data for sampling of households
- Household survey data for study measures
- Monitoring and tracking data of campaigners for progress tracking and programmatic cost assessment (including GPS data for location tracking)
- Publicly available data related to ORS and Zinc availability and pricing.

The first two types of data will be collected using SurveyCTO, a data collection software that is widely used for such studies. We expect the household survey to last about 60 minutes if the household reports at least one case of child diarrhea, and about 15-20 minutes otherwise. The data will be collected using a dedicated study tablet given to each enumerator. At the end of each day of data collection, the enumerators will review the data along with the site supervisors and study coordinators and will upload the data to the server. Any transfer of data between RAND and the survey firm will occur through Kiteworks, RAND's secure data transfer and storage platform.

We will also collect data to evaluate intervention delivery – this will be tracked using the implementation records, which will ask about number of households reached, dates when deliveries were made, any houses that were missed (and reasons why), any households that were revisited due to caregiver unavailability, number of attempts made for delivery, and number of co-packs delivered (if delivery made). Additionally, the campaigners will be given mobile devices which will use tracking technology to collect GPS data. These data will primarily be collected for programmatic evaluation and, though the secondary data will be shared with the evaluation team for identification of timing of the deliveries made within each EA, quality assurance, and heterogeneity analysis.

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[4] described in more detail in section **IX. Data Management & Safety**

IV. Outcomes

We will assess the impact of the intervention on the following outcomes:

IV.I. **Primary Outcome**

ORS Use (cases in last 4 weeks)

The primary outcome for the study and the outcome that will be used to assess RQ1a and RQ1b is self-reported ORS use for a case of child diarrhea that occurred within the last 4 weeks. This will be measured through a series of survey questions which ask caretakers who reported having a child who had a diarrhea episode in the past 4 weeks the following set of questions:

1. "Did you give *[child name]* anything to treat the Diarrhea?"
2. If yes to Q1, "can you tell me or show me what treatments you gave *[child name]* either home-prepared or from outside of home?" ***Do not prompt responses.***
3. If ORS not mentioned in Q2, "did you give the child any ORS to treat the diarrhea?"

Our main outcome variable will be a binary variable that is set to 1 if the respondent reports that they used ORS in 2 or 3 and to 0 if they reported that they did not use ORS in 2 and 3 or if they reported that they gave no treatment to the child in (1). We will conduct a sensitivity analysis where we use only the unprompted response from (2) to create our ORS use variable.

Our primary analysis for this outcome will pool data collected between weeks 5 and 28 (cases that occurred in the first six months after delivery) for RQ1a, and between weeks 5-52 (cases that occurred in the 12 months after delivery) for RQ1b. To answer RQ1.1, we will additionally examine monthly treatment effects over the full study period. See section V below for more details on analyses.

IV.II. Secondary Outcomes

We will examine the following secondary outcomes which correspond to the secondary research questions:

RQ2. **Zinc + ORS use**

RQ3. **Antibiotic use**

RQ4. **Zinc use alone**

RQ5. **Time to ORS initiation**

RQ6. **Exposure to unsafe drinking water**

RQ7. **Willingness to purchase new ORS packets**

RQ8.   **Child mortality; all cause and from diarrhea**

RQ9.   **Hospitalization from diarrhea**

RQ10. **Number of diarrhea episodes**

RQ11. **Care seeking outside the home**

RQ12. **Wastage of ORS and zinc packets**

RQ13. **Receipt of ORS and zinc delivery**

RQ16. **Missed days of schooling**

RQ17. **Prices and supply of ORS and zinc at local vendors**

Each of these outcomes are described in more detail below.

Diarrhea treatment outcomes (RQs 2-4)

We will follow an identical procedure for creating the secondary diarrhea treatment outcomes (listed above): All treatment outcomes will be set to missing if 1) no child under the age of five in the household was reported to have had diarrhea in the last 4 weeks, or 2) if the caretaker did not know whether the child was given the respective treatment. For antibiotics use, we will also conduct an analysis where we subset on cases that had blood in the stool, as this is a sign of bacterial infection and has implications for appropriate vs. inappropriate use.

Time to ORS Use (RQ5)

For ORS and zinc treatments, we are also interested in the time between the diarrhea episode initiation and the treatment initiation. It is recommended by the WHO that both ORS and zinc are started immediately after the first symptoms of diarrhea. We will measure this using the following question, which will be asked to all caretakers that report giving the respective treatment to the child.

> "How many days after the diarrhea began did you first give (CHILD NAME) [ORS/zinc]?"
> The enumerator will report '0' if treatment began on the same day as the diarrhea episode.

We will measure this in two ways. First, for our main analysis we will keep this variable with days as the units and truncate to 7 days to avoid influence of potential outliers. Second, we will also create a binary variable set to 1 if the caretaker started treatment on the same day that the diarrhea began.

Adverse outcomes: Exposure to unsafe drinking water and reduced willingness to purchase new ORS packets (RQs 6- 7)

Consumption of (potentially) <u>unclean water</u> for children exclusively breastfeeding (used for RQ6): We will create this variable using a series of questions about:

1) Child age in months
2) Whether child was exclusively breastfeeding prior to diarrhea episode. (RQ6)
3) Whether ORS was used to treat diarrhea.
4) Whether water to mix with ORS was boiled or treated in any way.
5) Main source of drinking water

We will restrict this outcome to children who are exclusively breastfeeding and code it to 1 if the child mixed ORS with an unclean water source that was not boiled or treated and to 0 otherwise. We will code this outcome as 0 if the child did not use ORS or if the child used ORS mixed with boiled or treated water.

In addition, we will conduct subgroup analyses to assess whether the intervention increased ORS use for children under-6 months old (the age up to which exclusive breastfeeding is recommended).

Willingness to purchase ORS packets (RQ7)

We will assess this outcome only for households who had at least twice as many diarrhea episodes as children in the house since the start of the intervention (theoretically could have used all the ORS that was delivered) and who did not have any ORS stored in the home when the child came down with diarrhea. We will assess this outcome in three ways.

1. We will assess our primary ORS use outcome for this subgroup.
2. We will assess whether the caretaker sought care for this episode.
3. We will assess whether the caretaker purchased ORS for this episode.

Note: If we only have three months of data, the sample used for this analysis will be very limited as most households will not have had multiple diarrhea episodes.

Child mortality outcomes (RQ8)

Our study is not powered to assess changes in child mortality unless effects are very large. Nonetheless, we will measure and analyze child mortality as this could be useful for future meta-analyses. We will ask all households (regardless of whether they had a case of diarrhea) whether any children under five residing in the household had died since the start of the intervention. If yes, we will inquire about the cause of death, and consider the following measures:

- Child mortality (all cause)

- Child mortality from diarrhea

We will supplement the data we collect on all cause child mortality with the District Health Information Software 2 (DHIS2), a platform that provides access to comprehensive health data through the health management information system across 80 low to mid income countries around the world. The quality of this data set is unclear and, thus, we are not yet sure of the extent to which we will rely on the DHIS2 data.

Hospitalization from diarrhea (RQ9)

To measure hospitalization from diarrhea, we will use a survey question asking respondents whether any children under five in the household were hospitalized since the start of the intervention period. If yes, we will ask why the child was hospitalized and whether the child was hospitalized due to diarrhea. We will also supplement our survey-based hospitalization measure with DHIS2 data if available.

Number of diarrhea episodes outcomes (RQ10)

We will collect data on incidents of diarrhea in both the baseline and endline surveys. We will use this to estimate the change in diarrhea incidence. Since evidence from prior studies suggest that using zinc as a supplement lowers the incidence of diarrhea in the future,(11) we will additionally assess the change of diarrhea incidence for children who had at least one case already since the start of the intervention (i.e. the probability of having two or more cases). This will have allowed them the opportunity to use zinc to treat the first case and (potentially) experience the preventive benefits.

We will supplement our survey data with data on diarrhea incidents per 1000 households from the DHIS2 platform.

Care-seeking outside the home (RQ11)

For this, we will ask the caretaker whether they sought care for their child's diarrhea from any source outside the home, and if yes, where they sought care. We will construct a binary indicator for whether care was sought and separate indicators for seeking care from different types of providers (public, private, pharmacy, etc.).

Assessing wastage (RQ12)

We will additionally evaluate to what extent the delivered ORS/Zinc co-packs were wasted. We define wastage as any of the following:

- Co-packs being used by others in the household or neighborhood
- Co-packs not being used at all as a consequence of no diarrhea incidence
- Co-packs being lost or stolen

Thus, we will additionally ask all caregivers whether 1) any of the ORS/Zinc co-packs are still at home and available for use, 2) if not, why (where we will provide a list of potential response option). Additionally, we will ask all households about other uses of ORS/Zinc, as in Nigeria, ORS may be consumed by adults as an energy supplement. We will validate the ORS/Zinc packets availability through the validation measure described in the Validation Measures section. We will then create binary indicators for each type of wastage to calculate proportions for each wastage category.

Assessing missed days of schooling (RQ16)

To assess missed days of schooling we will use two questions that record 1) if the child is currently attending an early education program and 2) how many days of school the child missed of this program in the last 4 weeks.

Assessing changes in price and supply of ORS and zinc at local vendors (RQ17)

To assess whether supply and price of ORS and zinc at local vendors changes as result of the intervention, we will have enumerators visit of convenience sample of one vendor (either a pharmacy or a PPMV) per enumeration area. Enumerators will record supply and prices from each vendor they visit and we will link this to treatment assignment using the EA ID. We will create a binary variable for supply (ORS in stock or not) and continuous various for the price.

IV.III. Sensitivity analysis and validation of self-report

Outcomes to assess intervention fidelity and the mechanism through which the intervention changes ORS use (RQ13, RQ15)

We will also measure and assess a variety of intermediate outcomes that help us assess whether the intervention was carried out effectively and whether the intervention appears to be working through the expected theoretical mechanisms.

- Binary outcome for whether household was **visited by a campaigner**
- Binary outcome for whether household **received a home delivery of ORS** (RQ13)
- Binary indicator for **obtained any ORS** (since start of intervention)
- Binary indicator for **obtained free ORS** (since start of intervention)

- Binary indicator for **ORS stored in the home** at time of survey
- Binary indicator for **ORS stored in the home** at time of diarrhea initiation (RQ15)
- Binary indicator for **obtained zinc** (since start of intervention)
- Binary indicator for **obtained free zinc** (since start of intervention)
- Binary indicator for **zinc stored in the home** at time of survey
- Binary indicator for **zinc stored in the home** at time of diarrhea initiation
- Caretaker knowledge of ORS

Sensitivity analysis to assess recall bias

We will also examine three measures (ORS Use, zinc+ORS, and antibiotic use) in the last 2 weeks as a robustness measure for the last 4 weeks. ORS usage in the previous 2 weeks may have a lower recall bias and thus likely be a more precise measure. However, 2-week recall will have smaller sample size due to the lower incidence of diarrhea, and thus we prefer to use the 4-week measure for our main analysis. If the 4-week recall measure is statistically significant and the 2-week recall is insignificant, but the effect is of a similar magnitude, we will interpret this as recall bias not influencing results. If the 2-week measure is quite different than the 4-week measure, we will interpret this as recall bias influencing results. We will also check sensitivity of our results to 7-day recall, which has been shown to be the optimal duration for measuring diarrhea prevalence.(17)

IV.IV. Validation Measures

Our primary outcome will be measured through self-report. To assess the validity of this self-reported outcome, we will use a more objective outcome that is not subject to self-report bias. We will ask households in the treatment group to show their ORS and zinc packaging regardless of whether they were used or not. We will then count opened and unopened packets and compare this with total number of packets delivered at endline, for households sampled at endline. The main measure we will use to assess validity of self-reported ORS use is whether households that reported using ORS had fewer unopened packets to show than were initially delivered.

Verification of Delivery

First, we will verify that treatment households received ORS packets delivered to their home (that is, that the distributor actually delivered the packet). Specifically, we will examine the following question:

- Binary indicator for whether household was visited by distributor and received free distribution of ORS in [insert month]
- If yes, how many packets of ORS household received from distributor.

We will also verify if a campaigner came to the household's community by overlaying the campaigner GPS coordinates with the households GPS coordinates.

Packet counting

Next, we will count the number of packets that household has left at endline.
We will use this measure to code a household as having used ORS if they had fewer opened packets than they were given by the campaigner.

We will estimate validity ONLY for households who received a delivery of ORS. In Wagner et al. (2019), of the households who reported ORS use for a child under five, 94% had fewer packets than they were given.

While this measure helps overcome self-report bias, it is not without limitations. This is not a perfect measure true ORS use because having fewer packets than initially delivered could be the result of the households losing the packets, giving them away, or using for a purpose other than treating child diarrhea.

Evidence of ORS use for current ORS cases

As another objective measure of ORS use that can be measured both in the treatment group and the control group, we will look for observable evidence of ORS use among households where the child is currently having a case of diarrhea and reported using ORS. We will ask the caretaker 1) if they have any mixed ORS liquid available to show, 2) if they could show the container they used to make the ORS, and 3) if they have any empty ORS packaging to show. We will assume that household whose child currently has a case of diarrhea should be able to show one of these pieces of evidence if they actually used ORS. We will analyze each of these objective measures separately and compare between the treatment group and control group (e.g. comparing the share of all households with a current case of diarrhea that could provide the respective evidence). We will also code a current case as having been treated with ORS if 1) they can show their empty ORS packaging OR 2) they can show the prepared ORS. We will also conduct these analysis restricting to households who reported using ORS to analyze if there is differential over-reporting of ORS use between the treatment group and the control group; if one group has a lower likelihood of producing evidence of preparing ORS when their child has an ongoing diarrhea case, this suggest differential over-reporting.

IV.IV. Other measures of interest (covariates)

We will collect several other measures of interest in order to assess baseline balance across treatment and control groups, to use as covariates in analysis, and to conduct heterogeneity analysis. These measures are as follows:

- Caretaker Characteristics: age, marital status, education attainment, number of children, employment, ever used/ heard of ORS, ever used/ heard of zinc, visited by campaigner in last 4 weeks, and if yes, whether received information about ORS/zinc use for treatment of child diarrhea.

- Child Characteristics: gender, age, frequency of diarrhea, concurrent fever, blood in stool, number of diarrhea cases since the delivery for each child under the age of 5 in the household.

- Household Characteristics: type of latrine (covered, uncovered, bush), main source of drinking water (piped, protected well/ borehole, open well, surface water (river, dam, lake, etc), main source of income (agriculture, private, sector, public sector, informal sector), monthly income.

- Baseline EA Characteristics: We will collapse the following information to the EA level using the baseline survey wave only:

  o Baseline ORS/zinc/Antibiotic use: A potentially important control variable is baseline ORS use, since this will adjust for potential preexisting differences in use between wards that were not balanced between groups after randomization. Moreover, baseline antibiotic treatment use at the EA level is likely a strong predictor of endline treatment use, and including it as a covariate will likely increase the power of our estimates. Since we will have different children at baseline and endline, we will not be able to control for each child's treatment use at baseline, which is why we will control for EA level treatment use. We will create this variable by taking the mean of each treatment variable (ORS, zinc, and antibiotics) for each EA at baseline, which represents the share of cases treated by the respective treatment.

  o Baseline CHIPS Visit in Last 4-Weeks: We will create this variable by taking the mean by EA

  o Baseline Access to Free ORS: We will create this variable by taking the mean of "is caretaker aware of free ORS" by EA.

  o Baseline Home ORS Storage: We will create this variable by taking the mean "currently have ORS stored in their home" (not just those with a diarrhea episode).

V. Analysis

V.I. Balance at baseline

We will evaluate the balance of outcomes and covariates across the treatment and control wards at baseline using the baseline data. We will additionally use a joint test for orthogonality to check whether baseline characteristics are jointly predictive of treatment or control group assignment.

V.II. Main Specifications

Our primary analysis will first focus on intention-to-treat (ITT) estimates of treatment group assignment on the outcomes of interest. We present all analyses in terms of ORS use (the primary outcome), but analogous analyses will be conducted for each outcome of interest, described in Section IV above. Our primary specification will pool all months of data and estimate the following linear probability model at the diarrhea case level i:

$$ORS_{iaw} = \beta_0 + \beta_1 T_w + \beta_2 ORS\_base_{aw} + \gamma_{lga} + \varepsilon_{iaw} \quad (1)$$

where ORS_{iaw} is ORS use for diarrhea case i in enumeration area (EA) a in ward w. T_w represents the ward treatment assignment, and thus β_1 (our estimate of interest) can be interpreted as the percentage point difference in ORS use between the treatment and control group over months 1-6 or months 1-12. Second, to account for potential imbalance in baseline ORS usage and to improve precision, we will include average EA-level ORS use at baseline (ORS_base) as a covariate. The term γ_{lga} is a fixed-effect for each of the 20 local government areas in Bauchi, which we used as randomization strata for ward random assignment. We will compare the results using the analogous logit model for sensitivity tests to ensure the results are not sensitive to the distribution assumptions of the model.

Our secondary specification will estimate monthly treatment effects by interacting treatment assignment with month m:

$$ORS_{iawm} = \beta_0 + \sum \tau_m (T_w \times month_m)$$
$$+ \sum \lambda_m month_m + \beta_2 ORS\_base_{aw} + \gamma_{lga} + \varepsilon_{iawm} \quad (2)$$

Each coefficient τ_m will yield the effect of the treatment in each month m. We will cluster standard errors at the ward level in all analyses as that is the level at which the intervention was assigned. We will also add local government area (LGA) fixed effects because some LGAs might have more households surveyed in a given month than others.

V.III. Additional Specifications

Additional Covariates

In additional specifications, we will also control for any caretaker, child, and ward-level characteristics that are unbalanced at baseline in order to account for potential differences between treatment and control groups that could confound our estimates. We will also use a double LASSO method for covariate selection to include in the regression in order to improve precision of the estimates and adjust for potential imbalance at baseline.(18)

Adjusting for spillovers of the intervention

Spillovers of the intervention could happen either because the campaigners go outside the ward boundaries and deliver ORS+zinc to control ward households or because the survey team goes outside of the ward boundaries and thus misclassifies the ward in the survey (which could misclassify treatment assignment). The main way we plan to avoid this being an issue is by excluding EAs that are close to ward boundaries from the surveys. However, there still could be some control households that receive campaigners. We will address this in three ways:

1. *Using GPS coordinates to classify treatment:* To ensure that enumerators crossing ward boundaries does not introduce measurement error in treatment assignment, we will overlay the household GPS coordinates with the ward geocoded shapefiles and classify treatment based on the ward in which the GPS coordinate falls.

2. *Measuring spillovers:* We will be able to measure spillovers of the intervention to the control areas by overlaying GPS coordinates of the campaigners with the GPS coordinates of the surveyed households. We will identify a household as exposed if there was a campaigner within 100 meters of their home. This will allow us to compare intervention exposure between the treatment and control areas which will help put our treatment effects in context (i.e. how conservative they are). We can also do this using the survey question asking about whether they received a delivery.

3. *Instrumental Variables:* We will then be able to use the treatment assignment as an instrument for intervention exposure (i.e. having a campaigner in the community) which will adjust for the fact that some control areas might have been exposed. This will allow us to estimate the causal effect of being exposed to the intervention vs. not, accounting for the fact that some people in control group were exposed (and maybe not everyone in the treatment group was exposed but hopefully nearly all will be).

Impact of home storage: Instrumental Variable Analysis

We also want to examine whether having ORS and zinc stored in the household preemptively (prior to a diarrhea episode) results in higher use as this is the main

mechanisms through which we expect the intervention to increase use. We will use a two-staged least squares approach to estimate the following set of equations:

$$Store_{iaw} = \beta_0 + \beta_1 T_w + \beta_2 ORS\_base_{aw} + \varepsilon_{iaw} \qquad (4)$$

$$ORS_{iaw} = \alpha_0 + \alpha_1 Store_{iaw} + \alpha_2 ORS\_base_{aw} + \varepsilon_{iaw} \qquad (5)$$

In the first stage regression, treatment assignment T_w is an instrument for $Store_{iaw}$, a binary indicator for whether or not households have ORS packets stored in the house. In the second stage we will estimate the effect of the predicted $Store_{iaw}$ on ORS use ORS_{iaw}. We note that this is might not be a valid instrument because it might not satisfy the exclusion restriction (being in an area with a high proportion of ORS could affect household usage even if they didn't get a delivery), but nevertheless this approach can help to assess the magnitude of the home storage effect.

Estimating spillover effects of the intervention

The treatment status of nearby communities could influence control communities through social networks and changing social norms. People in the control villages who frequently engage with people in treatment villages could end up using more ORS and zinc because others in their social network are using it or have it in their home. To estimate how much of the intervention effects spillover into control areas, we will classify control household base on their distance to treatment communities. We will split the control group into 3 groups base on the terciles of distance to the nearest treatment household and compare ORS use across the three distance groups. If there are spillover effects of the intervention, we would expect that control households that are closer to other treatment households would have higher ORS use compared to households that are further away from treatment households. We will also run some analysis that adjust for endogeneity of distance to ward boarders (e.g. households close to ward boarders could be different from households in the center of the ward) by comparing outcomes between close-to-ward-boundary households where the neighboring ward is a treated ward and close-to-ward-boundary households where the neighboring ward is a control ward. This adjusts for any endogeneity from being close-to-ward-boundary. These analyses are likely to be underpower and we consider them exploratory.

V.IV. Time to ORS Use

We will estimate the impact of time to ORS use after diarrhea initiation using both outcome measures described in Section IV above: (i) number of days since diarrhea started

(continuous) and (ii) a binary indicator for whether or not treatment was started on the same day as diarrhea (the recommendation by the WHO).

V.V. Heterogeneous Treatment Effects

In additional analyses beyond the main regressions specified above, we will estimate heterogeneous treatment effects using interaction terms between treatment status and a set of demographic and community-level variables of particular interest. We may estimate other dimensions of heterogeneity beyond what is prespecified below.

- Baseline ORS use (EA level)

- Age of child (individual level): the majority of diarrheal mortalities happen within the first year of life. We will use binary indicator variable for whether or not child is less than 12 months old. We will also test for heterogeneity by whether the child was less than 6-months old to help inform whether children who are exclusively breastfeeding are increasing ORS use, which could potentially be harmful.

- Severity of diarrhea episode proxied by concurrent fever and blood in stool (individual level): we will code a case as "severe" if either of these criteria are satisfied.

- Distance from the nearest location that distributes ORS.

- Whether child with a diarrhea episode resided in the household at the time the ORS+zinc delivery. At endline, some households will have had new children born after the deliveries and some households might have additional children living in their home that were not living there at the time of the delivery. Because the quantity of ORS+zinc is determined by the number of children under 5-years-old residing in the household during the campaign, households who gain a child under 5-years-old would have fewer ORS packets per child under-5. We expect the treatment effect to be stronger for the households who do not gain a child under 5-years-old after the campaign.

- Social network strength: We will assess heterogeneity in the effect of the intervention based on several measures of the household's social network. This will include 1) the number of other households with a child under 5-years-old within a 10-kilometer radius, 2) the number of other caretakers in the community that the caretaker interacts with, and 3) the frequency of social network interactions. We expect that households with a stronger social network will benefit more from the intervention because when these caretakers have used up their ORS, they have a larger community (who would have also received ORS deliveries) that they can get ORS from compared to caretakers with a weaker social network.

V.VI. Attrition and missing data

We are not following up with the same households so there is no concern about household specific attrition. However, we are following up with the same EAs and it is possible some EAs we survey at baseline will not be able to be surveyed at endline (e.g., if there is a flood or if there are security concerns). It is also possible that some surveys will not be completed, and we are missing outcomes data for some households. To test for sensitivity of our main results to EA level attrition and missing outcomes data, we will use Manski bounds (also referred to as extreme value bounds) where we assume all households in the treatment group who are missing data did not use ORS and all households in the control group with missing data used ORS, and vice-versa. In EAs that we are unable to conduct follow-up surveys, we will assume we would have surveyed the average number of households and the average number of diarrhea cases.

VI. Cost analysis

To support GiveWell in estimating the cost-effectiveness of the intervention, we will calculate the costs per child reached (RQ14) using CHAI's implementation data. This will be the total cost of implementing the intervention divided by the number of children who received a delivery. We will exclude all research costs from this calculation.

VII. Power calculations

Assuming a cRCT design with two-point data collection, a diarrhea prevalence rate of 13% (for a conservative MDE estimation) with an expected number of diarrhea cases per cluster of roughly 21 at endline, a control endline ORS use rate of 40%,(13) and a conservative intra-class correlation (ICC) of 0.2, we will be sufficiently powered to detect a minimum difference of 9.3 percentage points (p.p.) in ORS use between control and intervention groups over months 1-6.(19) Under the same assumptions, the study will be sufficiently powered to detect a minimum difference of 8.9 p.p. in ORS use between the two groups over the study period (12 months). The pooled estimate of the impact over six months and twelve months will be our primary analysis, but we will also conduct analyses to assess the impact in each month. However, since we will sample only 288 EAs per month, and to maximize power, we will expect to sample all 212 wards, these parameters will allow for a minimum detectable effect (MDE) in each of the twelve months following the deliveries of 12.1 p.p. per month. Table 2 shows what MDEs will be if the ICC is 0.15 or 0.1 instead of 0.2.

Table 1. Sample Size (endline)				
	Month 1-6	Month 7-12	Months 1-12	Per Month

EAs	1,732	1,732	3,464	288
Households	34,640	34,640	69,280	5,773
Diarrhea Cases	4,503	4,503	9,006	750

Table 2. MDE for pooled and monthly analysis			
ICC	Pooled (Months 1-6)	Pooled (Months 1-12)	Monthly (Months 1-12)
0.1	0.0721	0.0664	0.1090
0.15	0.0833	0.0787	0.1152
0.2	0.0932	0.0894	0.1210

VIII. Social network analysis and ORS sharing analysis

We will conduct an analysis of the extent to which households share their ORS with neighbors and the extent to which there are "within-treatment spillovers". For this, our objective is to assess whether caretakers who do not have any ORS available when their child comes down with diarrhea are more likely to use ORS if more of their neighbors do have ORS stored in their home. Because the number of caretakers with ORS stored in the home is endogenous, we will use time since deliveries as an instrumental variable to predict the share of caretakers in the community that have ORS stored in the home. We will include only cases for which the caretaker had no ORS available in their home when the child started having diarrhea for this analysis.

Second Stage: $ORS_{iac} = \beta_0 + \beta_1 \widehat{ShareORS}_c + X\boldsymbol{\beta_2}_{ac} + \varepsilon_{iac}$

First Stage: $ShareORS_{iac} = \alpha_0 + \alpha_1 Time_c + X\boldsymbol{\alpha_2}_{ac} + u_{iac}$

Where the first stage uses time since the ORS deliveries ($Time$) to predict the share of households that have ORS available in community C and the second stage uses the predicted share of households that have ORS available to predict the likelihood of ORS use. We expect α_1, the effect of time on having ORS available, to be negative. We expect β_1, the effect of more households having ORS available on ORS use, to be positive. We think the exclusion restriction is satisfied because time since ORS use is randomized. A key limitation of this approach is that the subset of households that used up their ORS in the early months of follow-up could be different than the subset that used up their ORS in the later months in

ways that are correlated with ORS use. We will include a vector of controls, X, that will control for these observable differences.

IX.   Study timeline

Items/Phases	Q1 Oct-Dec 2023	Q2 Jan-Mar 2024	Q3 Apr-Jun 2024	Q4 Jul-Sep 2024	Q5 Oct-Dec 2024	Q6 Jan-Mar 2025	Q7 Apr-Jun 2025	Q8 Jul-Sep 2025	Q9 Oct-Dec 2025	Q10 Jan-Mar 2026	Q11 Apr-Jun 2026	Q12 Jul-Sep 2026
Phase 0: Preparations & IRB	■	■										
Phase 1: Recruitment of Campaigners			■									
Phase 2: Pre-screening & Sampling			■	■								
Phase 3: Baseline survey & Randomization			■	■								
Phase 4: Intervention implementation				■								
Phase 5: Post-intervention follow-ups				■	■	■	■	■				
Data analysis & Preliminary results reporting					▣	▣	▣	▣	▣	▣		
Dissemination of findings								▣	▣	▣	▣	▣

X.   Data Management & Safety

IX.I. Data storage and safeguarding practices

Three main types of data will be collected:

- Sampling data for pre-screening of households
- Survey data for study measures

- Monitoring and tracking data for progress tracking and programmatic cost assessment (including GPS data for location tracking)

The first two types of data will be collected using SurveyCTO, a data collection software that is widely used for such studies. The SuveryCTO software has been vetted by RAND's Information Security services. We will use SurveyCTO to collect and deposit the raw data files into a secure server. SurveyCTO has sophisticated security features:

- SurveyCTO automatically encrypts all data in transit between any devices and the server if transmitted via Internet, and between the server and your computer.
- SurveyCTO encryption ensures the data is encrypted while at rest on the server as well as in the devices. Non-sensitive fields must be manually marked as publishable if you would like to access those variables without the encryption key.
- SurveyCTO encryption works by creating key pairs: 1) a public key that you can share and that SurveyCTO will use to encrypt your data and 2) a private key that you must protect, which will decrypt the encrypted data.
- The public key is copied and pasted into the SurveyCTO xlsform in the "public_key" column of the settings sheet and the private key is shared only with authorized staff with privileges to access sensitive data (e.g. personally identifiable information, PII).
- The server will be password protected and any sensitive data that is downloaded will be encrypted and thus inaccessible without the private key.

As such, the data will be collected using a dedicated study tablet given to each enumerator. At the end of each day of data collection, the enumerators will review the data along with the site supervisors and study coordinators, and will upload the data to the server. Any transfer of data between RAND and the survey firm will occur through Kiteworks, RAND's secure data transfer and storage platform.

We will also collect data to evaluate intervention delivery – this will be tracked using forms designed on Dimagi, which will ask about number of households reached, dates when deliveries were made, any houses that were missed (and reasons why), any households that were revisited due to caregiver unavailability, number of attempts made for delivery, and number of ORS packets delivered (if delivery made). Additionally, the campaigners will be given study-focused mobile devices which will use tracking technology to collect GPS data. This data will be collected using an application deemed suitable based on functionality and privacy requirements, and will be uploaded for quality assurance and productivity management. Each campaigner will be informed for such data collection with detailed information about data storage practices, risks and benefits, and will be asked to provide

written consent to allow for data collection. Each campaigner will additionally be assigned a unique identifier, after which their identifying information will be removed and crosswalk stored in a different, password protected location. All the data collected through this channel will additionally be transferred through Kiteworks only to those selected members of the study team that will be involved in data management, intervention monitoring, and analysis.

IX.II. Preserving confidentiality

All survey respondents will be assigned a unique identification number and the final data sets will be de-identified. The only direct identifying information collected on the survey will be the household GPS coordinates, name of head of household, child first name, child's month/year of birth and, as applicable, child's month/year of death. These will be removed and kept in a separate password protected file, on Kiteworks. Identifiable information will only be accessible to authorized evaluation staff, and the names of the respondents will never be used in any of the results of the evaluation.

XI. Ethical Considerations

X.I. Procedures for gathering informed consent

As noted earlier, the enumerators will visit sampled households in-person, explain the goals of the study carefully go over the consent form if the respondent expresses interest. The primary target participant is the primary caregiver for the child. If they are unavailable or absent, the household will be re-visited at another time. Up to three visits will be made. If after the third visit, an eligible respondent is still not available for the interview, the household will be excluded from the study and a replacement household will be selected.

Once an eligible respondent is available, the interviewer will provide information about the study in a way that is fully understandable for the participant. Participants will also be informed that they can exit the evaluation at any point in time without any consequences. The consent form will be written in the local language. Verbal consent (and in some instances verbal consent from parent/guardian along with verbal assent from the participant) will be obtained, as described below. In any case, the participants will not be asked to sign a copy of the informed consent or assent form given the low literacy rates in the region, and to preserve the participant's privacy.

In Nigeria, the age of consent is 18. Female heads of household, caregivers who are under the age of 18 but who may be considered emancipated minors based on the Nigerian laws[5], or caregivers of children over the age of 18 will be asked to provide informed verbal consent for participating in the evaluation. If the caregiver of children is under the age of 18, and cannot be considered an emancipated minor, the interviewer will obtain verbal consent from the presiding parent or guardian along with a verbal assent from the participant prior to data collection. We will maintain a list of back-up households that were randomly selected in case a selected household does not participate.

X.II. Potential risks from participation

The evaluation involves no more than minimal risks to the participants. Participants will be informed that the survey will last approximately one hour. Participant names and other identifying information will be kept confidential and linked to a unique participant identification code. Once data collection is complete, and the data has been entered into an electronic database, participant names and other identifying information will be removed and kept in a separate password protected file. Identifiable information will only be accessible to evaluation staff.

X.III. Potential benefits from participation, for the individual

All households in Bauchi with a child under 5 years old will ultimately receive a delivery of ORS/zinc through this trial. Study participants will additionally receive a detergent sachet (worth about 30 US cents) for their time at the end of the survey.

X.IV. Potential benefits to the community and society

This study will test the impact of a large, state-wide program aimed at increasing accessibility and use of ORS and zinc. The results from the evaluation will be used to inform the program's strategic approach towards achieving these goals. Thus, there are potential benefits to Nigerian communities of increased access to ORS and zinc, and better health outcomes for children with diarrhea.

X.V. Handling adverse events

All enumerators will receive training on Research Ethics for Behavioral and Social Sciences (through the CITI Program or equivalent) and will also be trained to identify, manage, and

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[5] According to the Nigerian Federal Ministry of Health's 2014 *Guidelines for Young Person's Participation in Research and Access to Sexual and Reproductive Health Services in Nigeria*, a person who is between the ages of 13 and 17 will be considered an emancipated minor (and will have the ability to independently consent for themselves) if any of the following is true: a) the person has been granted the status of adulthood by a court order; b) the person has lived independent of parental guidance for a minimum of one (1) year; c) the person is married; d) the person is living on the street; or e) the person is the head of household.

promptly report any adverse events to the site PI as well as the PI. Both, the PI and the site PI will report these events to the site IRB as well as HSPC (Human Subjects Protection Committee, RAND's Institutional Review Board) within a day of receiving such a report. The PI and site PI will additionally ensure that appropriate measures are taken to manage adverse events.

X.VI. Review by the Institutional Review Boards

The main institutional review board for this study would be located at the RAND Corporation (HSPC). HSPC will document all activities, changes to protocols, and adverse events pertaining to the study. We will additionally seek approval from the Nigerian National Health Research Ethics Committee (NHREC) and Bauchi state's Research Ethics Committee prior to beginning any study-related activities.

XII. Dissemination of findings

The findings from this study will be published in peer-reviewed academic journals and shared at conferences. Findings will also be shared with the government of Bauchi state.

XIII. Study team roles and responsibilities

The evaluation will be independently led by the RAND Corporation, with Dr. Zachary Wagner as the Principal Investigator, Nneka Osadolor as the site Principal Investigator, Dr. Stephanie Bonds as the Co-Investigator, and Ishita Ghai as the graduate research assistant/project manager. The program implementation will be led by the Clinton Health Access Initiative, and will include Dr. Chizoba Fashanu, Lekia Nwidae, and Felix Lam.

The RAND team and the CHAI team will collaborate on certain aspects of the program implementation, but RAND Corporation will independently monitor all data collection activities, along with the partnering survey data collection firm, and will run all the analyses for the study.

XIV. Study assumptions and limitations

- The study assumes a variety of statistics pertaining to diarrhea prevalence among children under the age of 5, ORS coverage, and ORS use, but most of these estimates are based on data collected from 2018 and the context is likely different.
- The study assumes that the effects of the intervention will last for the full study period, but it is likely that the effects fall well before the 12-month endline data collection begins. In an event that this occurs, the study team may decide to halt data collection.

- While the study overcomes a limitation in the previous version of this trial in Uganda (pertaining to short follow-up period), it still relies heavily on self-reporting of outcomes over a longer recall period, which may not be accurate.

XV. Funding sources

The study and intervention implementation will be funded by GiveWell and Effektiv Spenden; however, RAND will subcontract through CHAI for the study.

XVI. Conflicts of interest

All members of the evaluation team declare that there are no conflicts of interest.

XVII. References

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