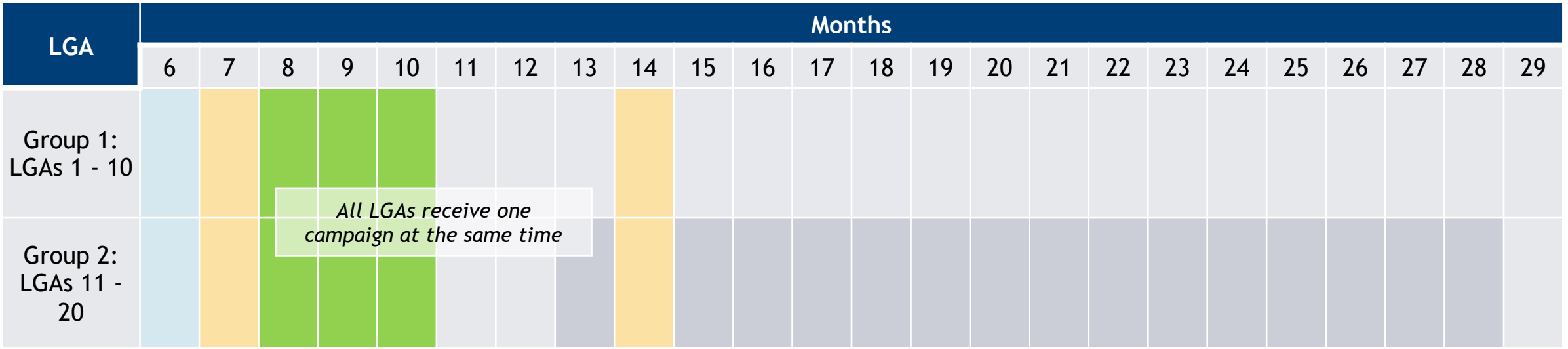
CLINTON HEALTH ACCESS INITIATIVE

ORS+Zinc to reduce diarrheal deaths

July 2023

Design 1: Pre-post design across all 20 LGAs



Pros

- All LGAs receive the intervention, provides relatively fast estimates on coverage change

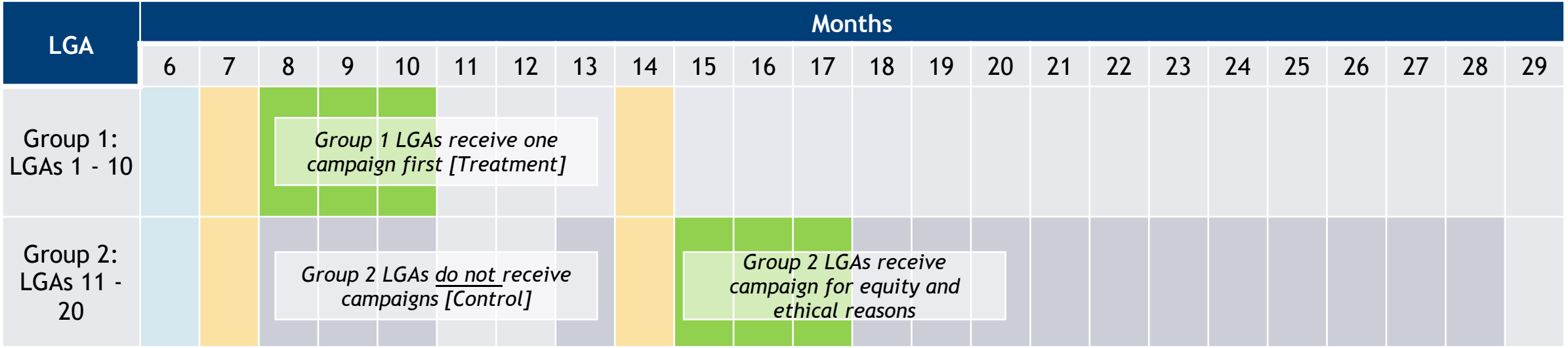
Cons

- Cannot decisively attribute the change in coverage to the campaigns

Legend

- *Prep for trial*
- *Data collection*
- *Implementation: Campaign 1*
- *Implementation: Campaign 2*

Design 2: Clustered RCT with one campaign



Pros

- Attribute the change in coverage directly to the campaigns led by CHAI
- Relatively shorter duration of the evaluation when compared to a step-wedged trail

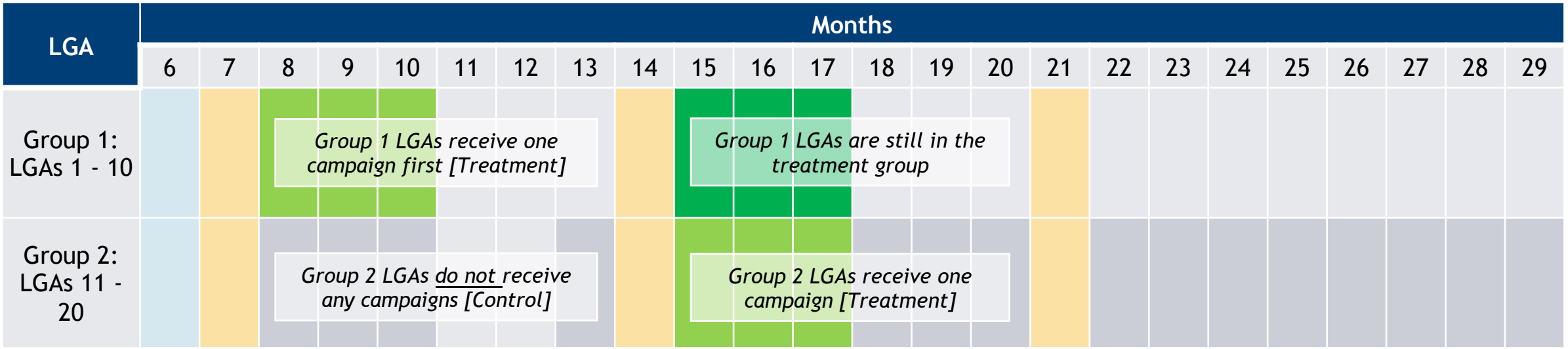
Cons

- While we may roll out the intervention in the control LGAs for ethical and equity reasons, we will not gather additional information on this rollout to measure its effect

Legend

- *Prep for trial*
- *Data collection*
- *Implementation: Campaign 1*
- *Implementation: Campaign 2*

Design 3: Step-wedged trial with one campaign



Pros

- Attribute the change in coverage directly to the campaigns led by CHAI
- Launch campaigns in all LGAs (as part of the evaluation) and mirror implementation as per program plans
- Monitor effect of consecutive campaigns on coverage in Group 1

Cons

- Costlier and longer evaluation due to additional data collection point

Legend

- *Prep for trial*
- *Data collection*
- *Implementation: Campaign 1*
- *Implementation: Campaign 2*

DHIS2 and DHS data may supplement data collected during the trial to track changes in public health system utilization and validate estimates

	dhis2	The DHS Program – Demographic and Health Surveys
Description	• Monthly reports from health facilities on select health and performance indicators	• Cross-sectional population-based household survey conducted every 5 years with the next survey planned for Oct 2023 to Jan 2024
Data collected	• Number of under-5 children with diarrhea seen • Number of under-5 children with diarrhea receiving both ORS and zinc	• Number of under-5 children with diarrhea • Number of under-5 children taken to a place for care and the source of care • Number of under-5 children with diarrhea receiving ORS, zinc, and ORS and zinc
Potential use case	• Track changes in public health system utilization after campaign rollout	• Validate baseline ORS and zinc coverage estimates collected by the trial
Limitations	• Gaps in reporting completeness and quality • E.g., Out of 1,358 facilities in Bauchi, 346 (25%) did not report any diarrhea case in 12 months	• Microdata from DHS is typically available 6-12 months after the completion of data collection

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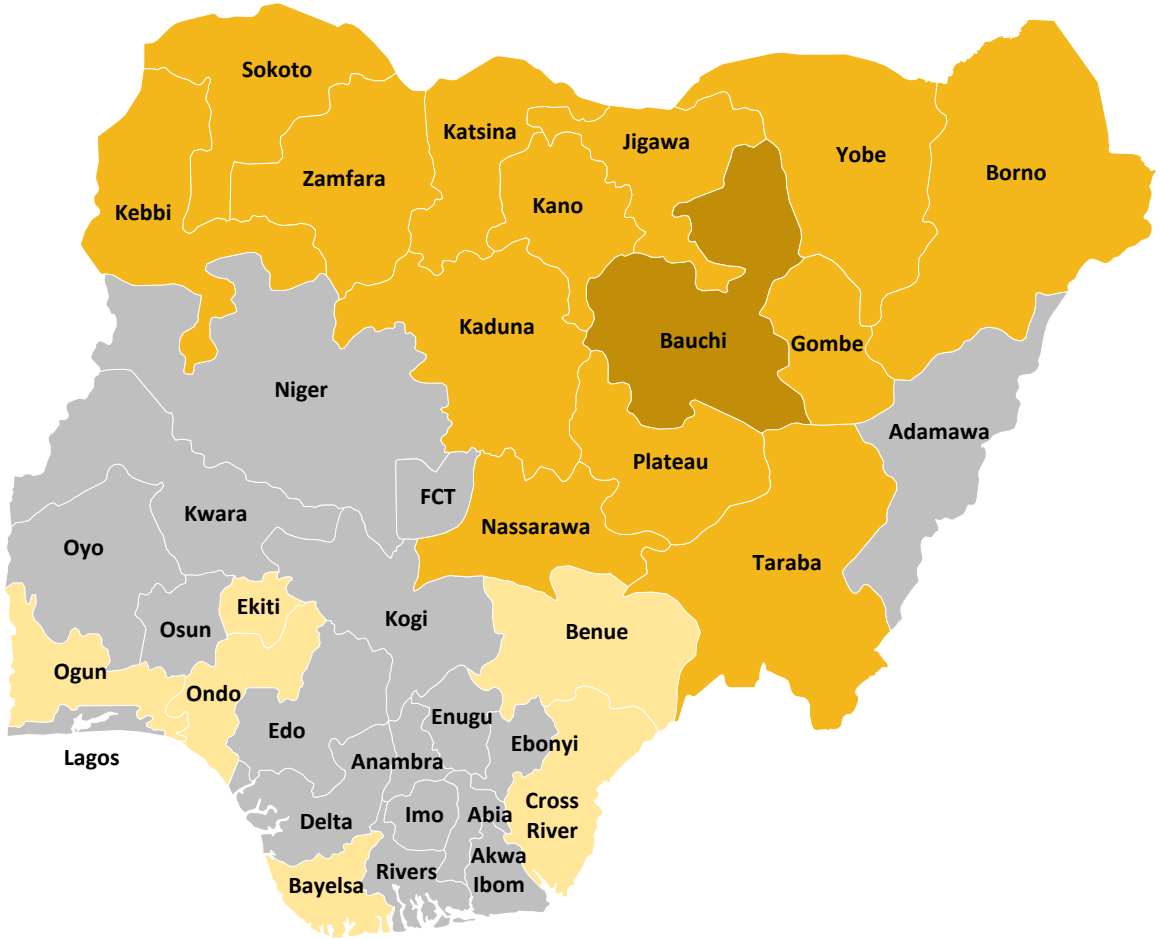
June 2023

Many sociocultural, economic, health, and development factors will affect the replicability of the ORS/Zinc program in other states

Key factors	Hypotheses
Baseline ORS coverage	• States with similar ORS/zinc coverage levels will be equally challenging to change coverage levels • States with low ORS/zinc coverage levels will be easier to increase coverage than states with higher coverage
Home management	• States with similar rates of home management of diarrhea
Disease burden & risk factors	• Populations with similar underlying risk factors (e.g., undernutrition, water & sanitation, etc.) are likely to benefit similarly from the program
Ruralness /Urbanization	• Degree of ruralness will affect cost-of-delivery as more dispersed populations and weaker road networks will make beneficiaries harder to reach
Sociocultural similarity	• Populations with similar sociocultural similarlity are likely to trust and participate in the program (i.e., be convinced to use ORS and zinc)
Socioeconomic similarity	• Socioeconomic status is associated with health outcomes and many other health behaviors, and therefore, populations with similar socioeconomic situations are likely to benefit similarly from the program

Based on these factors, Bauchi results would inform expectations in 19 other Nigerian states covering 19m children (61% of the under-5 pop.)

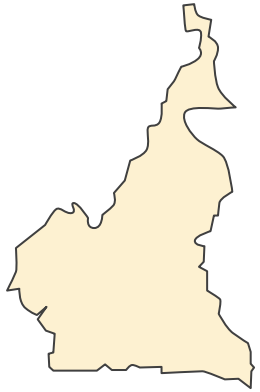


Group	Overview (Median, Ranges)
 Bauchi	- 1.5 million children under-5 - Majority does not use ORS (54%) - Large proportion manages at home (42%) - High U5MR (31 per 1,000) - Population density (142 per sq. km.) - Predominantly Muslim
	- 13 states = 15 million children under-5 - Majority does not use ORS (Med=58%, Range=47-67%) - Mixed sources of care (Med=42%, Range=25-64%) - High U5MR (Med=27, Range=20-41 per 1,000) - Pop. density (Med=136, Range=56-650 per sq. km.) - Predominantly Muslim states
	- 6 states = 4 million children under-5 - Majority does not use ORS (Med=72%, Range=57-87%) - Mostly manages at home (Med=50%, Range=42-64%) - Moderate U5MR (Med=16, Range=13-20 per 1,000) - Pop. density (Med=256, Range=169-515 per sq. km.) - Predominantly Christian states

Analysis in "State Archetype" tab: https://docs.google.com/spreadsheets/d/1phx50uBxpMlGBx58mslm-tF2SnoNUo70vCGSwWzsKSA/edit?usp=sharing
UNICEF 2021 MICS survey https://mics-surveys-prod.s3.amazonaws.com/MICS6/West%20and%20Central%20Africa/Nigeria/2021/Survey%20findings/Nigeria%202021_MICS_SFR_English.pdf
Nigeria Open Data - Population and road length data https://nigeria.opendataforafrica.org/
Nigeria Multidimensional Poverty Index (2022) https://www.nigeriapovertymap.com/

Bauchi may be informative of other African countries where ORS use is low and home care is high, though further investigation is needed

Cameroon

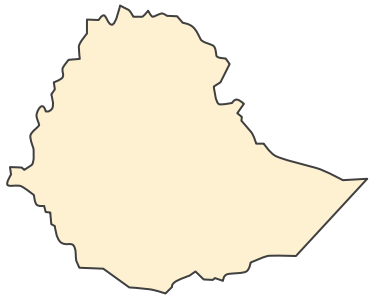


U5 population	4.1 million
Not using ORS	82%
Cared for at home	44%
U5MR	16 per 1,000
Diarrhea burden	21%

DRC

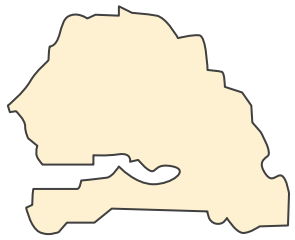
U5 population	16.8 million
Not using ORS	70%
Cared for at home	55%
U5MR	11 per 1,000
Diarrhea burden	13%

Ethiopia



U5 population	16.8 million
Not using ORS	70%
Cared for at home	55%
U5MR	11 per 1,000
Diarrhea burden	13%

Senegal



U5 population	2.6 million
Not using ORS	74%
Cared for at home	53%
U5MR	9 per 1,000
Diarrhea burden	13%

Key components of monitoring and evaluation plan

Component	Planned activities
Implementation monitoring	• Provide campaigners and supervisors smartphones, and develop a monitoring app to track campaign activities, including enrolling households into the program and deliveries of ORS/zinc
ORS/zinc coverage measurement	• Independent household surveys will be conducted with a representative sample of households to measure changes in ORS/zinc usage for diarrhea episodes
Operational research	• Targeted research studies may be conducted to answer important operational questions (e.g., do other members of the household use the ORS/zinc meant for children) • These studies may be embedded within the program implementation monitoring or coveage surveys • See slide 8 for potential operational research questions
Impact evaluation	• Randomized control trial tracking a cohort of children under-5 and measuring mortality • Details on sample size and costing TBD

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May 2023

Free, home delivery of ORS would reach the largest share of diarrhea cases not currently using ORS in Nigeria

Estimated number of diarrhea cases not receiving ORS by source of care

Country/State*	Total diarrhea episodes	Not receiving ORS			
		Total	Managed at home	Managed by private provider	Managed by public provider
Nigeria	84,600,000	48,400,000	21,000,000	21,000,000	6,400,000
-Bauchi	4,700,000	2,560,000	1,550,000	650,000	360,000
-Borno	4,300,000	2,350,000	1,350,000	800,000	200,000
-Gombe	1,500,000	900,000	500,000	200,000	200,000
-Jigawa	5,800,000	3,350,000	1,550,000	1,150,000	650,000
-Kaduna	4,800,000	2,400,000	1,500,000	600,000	300,000
-Kano	12,100,000	7,000,000	4,000,000	2,400,000	600,000
-Katsina	8,500,000	5,600,000	4,500,000	400,000	700,000
-Kebbi	5,100,000	3,200,000	2,200,000	800,000	200,000
-Sokoto	3,800,000	2,400,000	1,550,000	600,000	250,000
-Yobe	2,100,000	1,000,000	450,000	300,000	250,000
-Zamfara	2,300,000	1,100,000	600,000	400,000	100,000

Source: UNICEF 2021 MICS survey
https://mics-surveys-prod.s3.amazonaws.com/MICS6/West%20and%20Central%20Africa/Nigeria/2021/Survey%20findings/Nigeria%202021_MICS_SFR_English.pdf
*High-burden states selected based on low ORS coverage and diarrhea burden found in UNICEF 2021 MICS

CHAI and the MOH will design and implement mass ORS/zinc distribution campaigns as an effective means of increasing coverage

Program design

- Collaborate with MOH to design, organize, and implement a diarrhea control campaign
- MOH and CHAI recruit and train CHWs and/or volunteers to map households with children under-5 and distribute ORS/zinc
- CHWs/volunteers provide educational sessions and materials to mothers and caregivers on using ORS/zinc and preventing and managing diarrhea
- Campaigns are timed before the rainy season, when incidence of diarrhea is highest
- Independent monitors/supervisors validate campaign activities

CHAI's previous experience

- In India, CHAI worked with the MOHFW to launch the Intensified Diarrhoea Control Fortnite (IDCF) in 2014, and supported implementation and monitoring of activities in Madhya Pradesh
- In Nigeria, CHAI and the World Bank are implementing mass distribution of a package of nutritional interventions (including ORS/zinc) in Kano

Research & Evidence

RCT in Uganda demonstrated "free and convenient" distribution of ORS/zinc reduced non-users 47%

Wagner Z, Asiimwe JB, Dow WH, Levine DI (2019) The role of price and convenience in use of oral rehydration salts to treat child diarrhea: A cluster randomized trial in Uganda. PLOS Medicine 16(1): e1002734. https://doi.org/10.1371/journal.pmed.1002734

Based on a program delivery mechanism of mass distribution, CHAI updated key BOTEC parameters to reflect the program design

Parameters	Previous value	Changes made
ORS/Zinc costs	• ORS=$0.09, Zinc tablet=$0.02, and ORS/zinc co-pack=$0.44 (Source: 2015 MSH pricing guide) • 1 treatment (3 ORS + 10 zinc) = $0.55 (inflation adjusted)	• ORS=$0.07, Zinc tablet=$0.01, and ORS/zinc co-pack=$0.57 (Source: 2022 UNICEF SD ORS/zinc market report) • 1 treatment (3 ORS + 10 zinc) = $0.40 (inflation adjusted)
Cost per child reached	• Multiply commodity costs by a factor of 2.25 to reflect delivery costs (Source: R4D pneumo) • Pneumonia treatment is clinic-based, which is different from ORS/zinc which can be administered at home	• Based on CHAI's work in Kano, delivery costs of ORS/zinc (inclusive of product) were $1.70 per household reached • No major impact to CE as 2.25 multiplier results in $1.72 • We conduct sensitivity analysis to examine how results change if costs were varied due to geography (see slide 6)
Cost to NGO	• NGO costs were calculated based on cost per child reached (row 40) and number of ORS/zinc users under the program (row 17) • Assumes perfect targeting of delivery	• Program design is more similar to Uganda RCT free and convenient distribution campaign • NGO costs is based on cost per child reached (row 40) and population target/ children under-5 (row 4)
Cost to government	• Assumes governement contributes costs equal to 100% of the NGO/program costs	• Removed governments costs. • In Nigeria, CHW program is not functioning or widespread • CHAI hired field team to distribute ORS/zinc
Coverage achieved	• Base model uses Uganda RCT "free" distribution which resulted in 40% reduction in non-ORS use	• Updated to 47% reduction in non-ORS to reflect "free & convenient" distribution • We conduct sensitivity analysis to example how results change if coverage results varied (see slide 7)

Areas of uncertainties in BOTEC to validate through the program are cost per delivery, coverage attained, and wastage of ORS/zinc

Parameters	Uncertainties	Approach to address uncertainties
Cost per new diarrhea case treated	• How does cost of delivery vary by geography & are there more efficient models of distribution? • CHAI's Kano program delivered ORS/zinc at $1.70 per household. In Uganda RCT, costs were $2.20 per additional diarrhea case treated	• Implement a program in high potential geographies and account for costs. • Test different models to efficiently target non-ORS users (e.g., semi-annual campaign vs. annual)
Coverage achieved and attribution	• Are coverage results replicable in other geographies? • In Uganda RCT, free & conveneint distribution led to 47% reduction in non-use of ORS • In Nigeria, coverage change is unknown	• Implement coverage study (i.e., annual household surveys) along with program implementation to measure changes in ORS coverage
IV/EV mortality adjustment	• Are mortality results replicable in today's context? Should more research be done? • Systematic review estimates 93% mortality reduction from ORS, but limited trials are from 1970's and 80's	• Mortality impact will require a larger program and/or longer evaluation period to measure mortality • Hold off until primary questions on cost and coverage are resolved or should impact evaluation be incorporated into program?
Other key questions	• If/how much wastage or mistargeting occur?	• Measure ORS/zinc wastage and misuse in household surveys

Holding coverage change constant, sensitivity analysis shows ORS/zinc is cost-effective across a range of delivery costs

CE in multiples of cash transfers, by cost per U5 child reached and state (Scenarios with CE>10x cash are highlighted in green)

		Nigeria	Bauchi	Borno	Gombe	Jigawa	Kaduna	Kano	Katsina	Kebbi	Sokoto	Yobe	Zamfara
U5MR		23.1	31.4	20.0	27.6	41.1	24.3	37.1	33.1	30.4	30.1	22.5	37.0
% diarrhea		17%	13%	24%	16%	11%	13%	11%	12%	13%	15%	21%	12%
Cost per U5 child reached*	$1.50	18.4	17.2	19.5	18.1	19.3	12.9	17.6	17.9	18.0	20.5	17.5	16.8
	$1.75	15.8	16.8	18.9	17.6	18.7	12.5	17.1	17.4	17.5	19.9	17.0	16.3
	$2.00	13.9	14.7	16.6	15.5	16.4	11.0	15.0	15.3	15.3	17.5	15.0	14.3
	$2.25	12.4	13.1	14.8	13.8	14.6	9.8	13.4	13.6	13.7	15.6	13.3	12.8
	$2.50	11.2	11.8	13.3	12.4	13.2	8.9	12.1	12.3	12.3	14.0	12.0	11.5
	$2.75	10.2	10.8	12.2	11.3	12.0	8.1	11.0	11.2	11.2	12.8	11.0	10.5
	$3.00	9.4	9.9	11.2	10.4	11.1	7.5	10.1	10.3	10.3	11.7	10.1	9.7

*Inclusive of ORS/zinc commodity costs of $0.76 per child to cover on average 2 annual episodes of diarrhea per child (or $0.36 per diarrhea case).

BOTEC: https://docs.google.com/spreadsheets/d/1phx50uBxpMlGBx58mslm-tF2SnoNUo70vCGSwWzsKSA/edit?usp=sharing

ORS/Zinc remains cost-effective at higher delivery costs if coverage achieved is also higher (i.e., greater reduction in deaths)

CE in multiples of cash transfer in Nigeria (national), by coverage change and cost per U5 child reached (Scenarios with CE>10x cash are highlighted in green)

Relative coverage increase		10%	20%	30%	40%	50%	60%	70%
Coverage target		50%	53%	57%	61%	64%	68%	72%
Cost per U5 child reached*	$1.50	4.2	8.0	11.9	15.7	19.6	23.4	27.3
	$1.75	3.6	6.9	10.2	13.5	16.8	20.1	23.4
	$2.00	3.2	6.1	9.0	11.9	14.8	17.6	20.5
	$2.25	2.9	5.5	8.0	10.6	13.2	15.7	18.3
	$2.50	2.6	4.9	7.3	9.6	11.9	14.2	16.5
	$2.75	2.4	4.5	6.6	8.7	10.8	12.9	15.0
	$3.00	2.3	4.2	6.1	8.0	10.0	11.9	13.8
	$3.25	2.1	3.9	5.7	7.4	9.2	11.0	12.8
	$3.50	2.0	3.6	5.3	6.9	8.6	10.2	11.9
	$3.75	1.9	3.4	4.9	6.5	8.0	9.6	11.1
	$4.00	1.8	3.2	4.7	6.1	7.5	9.0	10.4

*Inclusive of ORS/zinc commodity costs of $0.76 per child to cover on average 2 annual episodes of diarrhea per child (or $0.36 per diarrhea case).

BOTEC: https://docs.google.com/spreadsheets/d/1phx50uBxpMlGBx58mslm-tF2SnoNUo70vCGSwWzsKSA/edit?usp=sharing

Based on initial CE analyses and remaining uncertainties, a large-scale pilot would generate both high impact and evidence to refine BOTEC

Potential next steps

Implementation pilot in a Nigerian state

- Initial CE results and sensitivity analyses demonstrates ORS/zinc meets CE threshold of 10x cash across various Nigerian states
- Large-scale pilot would likely have a high impact on reducing diarrheal deaths

- Strong M&E using household surveys and program monitoring data could be embedded in the program to answer key uncertainties on cost-effectiveness, coverage attained, wastage, long-term results, mortality, and potentially test other intervention arms

Incubator study to investigate cost & coverage

- May not generate any new information beyond what we already have from existing programs and studies

- Sensitivity analyses suggets ORS/zinc remains cost-effective at a decent range of costs and coverage estimates

Large-scale RCT to examine mortality impact

- Will require a long period of observation or large number of children to evaluate differences in mortality between intervention arms and control

- Could be embedded within the implementation pilot