

Progress over a Decade of Zinc and ORS Scale-up:

BEST PRACTICES AND LESSONS LEARNED



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Acronyms

CHAI	Clinton Health Access Initiative, Inc.
CHW	Community health worker
DAZT	Diarrhea Alleviation through Zinc and ORS Therapy Project
DHS	Demographic and Health Survey
EML	Essential Medicines List
FHI 360/AED	Family Health International/formerly the Academy for Educational Development
GAPPD	Integrated Global Action Plan for Prevention and Control of Pneumonia and Diarrhea
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GOBI-FFF	Growth monitoring, ORT, breastfeeding, immunization, female education, family spacing, food supplements
H4+	Partnership of six UN agencies (UNAIDS, UNFPA, UNICEF, UN Women, WHO, World Bank)
icddr,b	International Centre for Diarrheal Disease Research, Bangladesh
iCCM	Integrated community case management
IMCI	Integrated management of childhood illnesses
JSI	John Snow, Inc.
Lo-ORS	Low-osmolarity ORS
MCHIP	Maternal and Child Health Integrated Program
MCSP	Maternal and Child Survival Program
MI	Micronutrient Initiative
MoH	Ministry of Health
MSH	Management Sciences for Health
NDRA	National Drug Regulatory Authority
OTC	Over-the-counter
ORS	Oral rehydration salts
ORT	Oral rehydration therapy
POUZN	Point-of-Use Water Disinfection and Zinc Treatment Project
PSI	Population Services International
RMNCH	Reproductive, maternal, newborn, and child health
SC4CCM	Supply Chains for Community Case Management
SHOPS	Strengthening Health Outcomes through the Private Sector
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SMC	Social Marketing Company
SUZY	Scale-up of Zinc for Young children
UNCoLSC	UN Commission on Life-Saving Commodities for Women and Children
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Executive Summary

By end of 2015, diarrhea remained a leading killer of children under 5, claiming the lives of approximately 530,000 children annually. However, significant progress has been made over the past decade to scale up access to and use of zinc and ORS, which together are the WHO-recommended treatment for childhood diarrhea. In countries such as Niger, Kenya, and Nigeria, improvements in ORS coverage—defined as the percentage of children with diarrhea in the last two weeks who received ORS—were among the top interventions responsible for 5-11% of total deaths averted. Since the release of the *2004 WHO/UNICEF Joint Statement for Clinical Management of Acute Diarrhea*, strong political attention and technical support have been mobilized to facilitate country action. New global initiatives and frameworks have helped to elevate the profile of zinc and ORS as key interventions for child health. Building on this momentum, national governments and local partners have launched large-scale efforts that have effectively addressed local barriers to access.

Progress over a Decade of Zinc and ORS Scale-up: Best Practices and Lessons Learned aims to share these experiences. In particular, this report highlights specific interventions that have led to successful outcomes across four key objectives: 1) facilitating a strong enabling environment, 2) improving availability of high-quality and affordable supply, 3) improving knowledge and skills of health providers, and 4) generating demand among caregivers. A multi-pronged approach addressing all four areas is needed to achieve large-scale and sustained increases in zinc and ORS coverage. Simultaneous improvements of supply and demand in both public and private sectors are needed to maximize impact. Furthermore, successful implementation requires a concerted investment from multiple partners—including national governments, development partners, donors, and others. The success of such an approach has been demonstrated in Bangladesh, where 77% and 44% of children with diarrhea are receiving ORS and zinc, respectively, as of the end of 2015.

Case studies, lessons, and experiences were gathered from members of the Diarrhea & Pneumonia Working Group and other experts involved in child health programs. This report does not advocate for a “one-size fits all” approach, but rather discusses common challenges to scale-up across countries and solutions to address them. Finally, while important gains have been made since zinc and ORS were endorsed as recommended treatment, continued investment is needed to address the remaining challenges for achieving high coverage levels at scale and ensuring effective integration with other, related life-saving solutions.

The report is intended for those responsible for child health program design and execution, including national governments, implementing partners, donors, and policy makers who are interested in increasing utilization of zinc and ORS in the context of improving child health outcomes.

I. Introduction

BACKGROUND

Over the past decade, significant progress has been made toward the reduction of child deaths from diarrhea (see Figure 1.1). However, diarrhea remains a significant killer of children under 5 years old and is responsible for 9% of overall mortality—approximately 530,000 deaths per year (see Figure 1.2). Over 60% of these deaths occur in 10 countries: Bangladesh, Democratic Republic of Congo (DRC), Ethiopia, India, Kenya, Niger, Nigeria, Pakistan, Tanzania, and Uganda.¹ Few children receive the recommended treatment for diarrhea—oral rehydration salts (ORS) and zinc. In fact, just two in five children with diarrhea receive ORS, and the median coverage of zinc is only 1 percent in 49 countries with available data.²

ZINC AND ORS: THE RECOMMENDED TREATMENT FOR CHILD DIARRHEA

The WHO-recommended treatment for acute diarrheal disease is ORS and zinc supplementation and continued feeding. If scaled to 100% coverage, ORS could prevent up to 93% of diarrhea deaths, and zinc can reduce the duration of illness by 25% and prevent recurrence of disease for 2-3 months.^{3,4} This combined treatment is highly cost-effective and easily administered by caregivers in the home. WHO and UNICEF have recommended the use of ORS for the treatment of diarrhea since the 1970s and, in 2004, the two organizations released the **Joint Statement for Clinical Management of Acute Diarrhea**

updating their recommendations.⁵ Specifically, WHO and UNICEF encouraged the use of a new low-osmolarity ORS (Lo-ORS) formula and included zinc supplementation (see Box 1.1).

In 2006, WHO and UNICEF, in conjunction with USAID and the Johns Hopkins School of Public Health, released a new guideline, *Implementing the New Recommendations on the Clinical Management of Diarrhea*,⁹ which provided information to policy makers and program managers for the introduction and national

FIGURE 1.2. CAUSES OF UNDER 5 MORTALITY

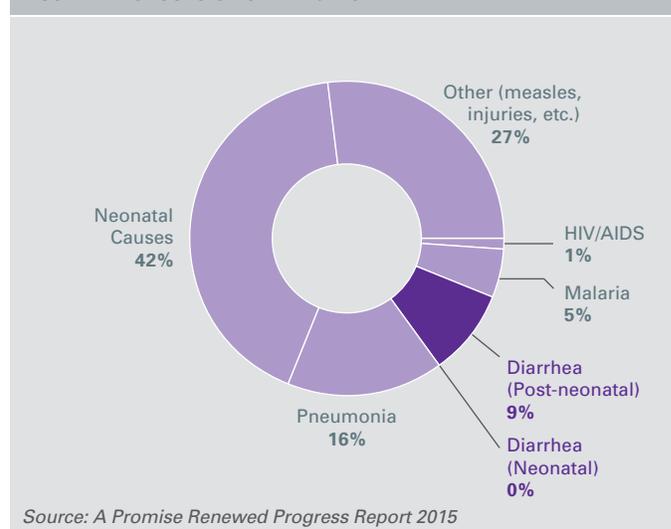
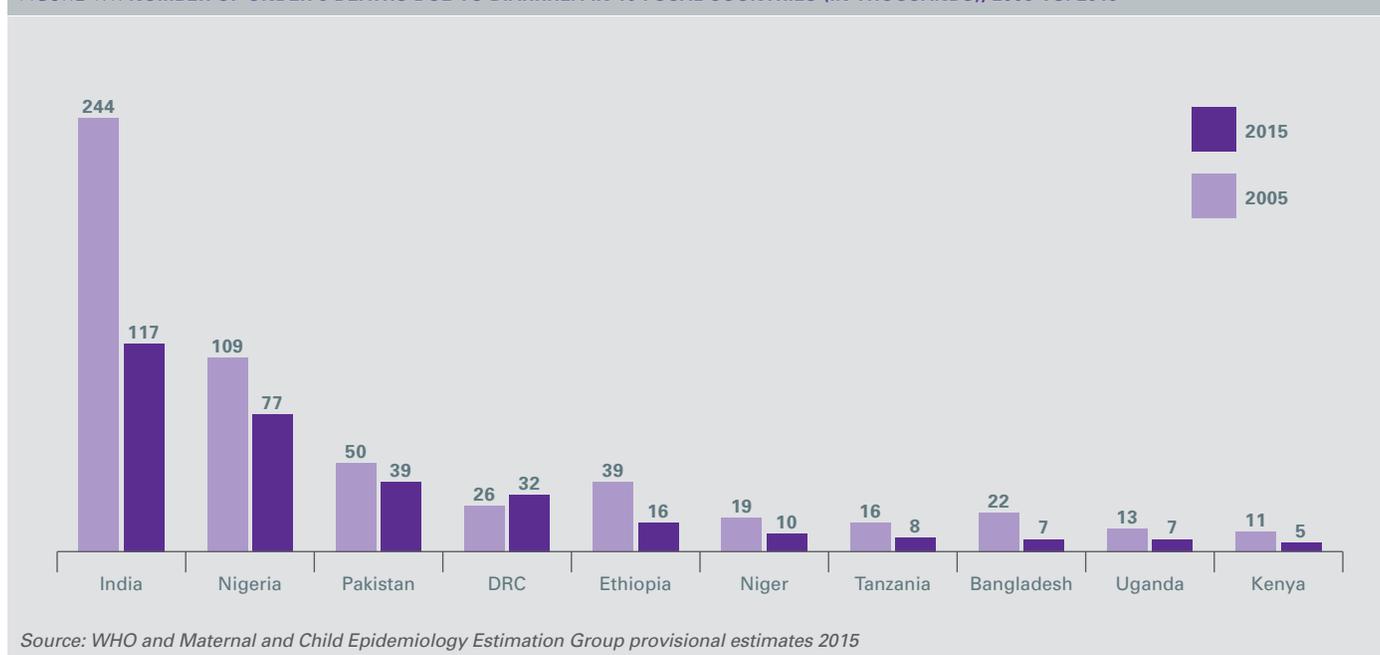


FIGURE 1.1. NUMBER OF UNDER 5 DEATHS DUE TO DIARRHEA IN 10 FOCAL COUNTRIES (IN THOUSANDS), 2005 VS. 2015



BOX 1.1. EVOLUTION OF TREATMENT RECOMMENDATIONS FOR CHILD DIARRHEA

Initially proven to be effective during the 1971 cholera outbreak in Bangladesh, oral rehydration therapy (ORT) has been called one of the most important health advances of the 20th century.⁶ Although first used for adult cholera, the treatment was so effective in reducing child mortality that WHO and UNICEF adopted a single ORS formulation regardless of age or cause of disease. In 1978, WHO launched the Programme for the Control of Diarrheal Diseases, working closely with UNICEF to promote ORS in addition to continued feeding and the rational use of antibiotics.⁷ In early adopter countries such as Bangladesh, the primary form of treatment was homemade ORS using sugar-salt solutions. Eventual concerns over the efficacy of homemade solutions due to minimal standardization and poor hygiene led to the adoption of premade ORS sachets.

In 1985, WHO issued a new recommendation for ORS that replaced sodium bicarbonate with sodium citrate, which increased its shelf life and reduced packaging costs. Despite the effectiveness of ORS in treating dehydration, these original formulations did not stop diarrhea or reduce its duration, resulting in low uptake by caregivers.

Throughout the 1990s, additional research was conducted to identify a more optimal ORS formulation. In 2004, UNICEF and WHO endorsed a new, Lo-ORS formulation of ORS—containing lower concentrations of glucose and sodium—that reduces both stool output and vomiting, as well as the need for facility-based intravenous therapy.⁸ Zinc was also recommended for both treatment and prevention. This joint statement highlighted three key pieces of evidence:

1. The development of an improved formula for ORS that was shown to reduce the duration of diarrhea episodes and limited the need for unscheduled intravenous fluids;
2. The demonstration of zinc's effectiveness in limiting the severity and duration of an acute diarrheal episode; and
3. Evidence that a 10-14 day course of zinc lowers incidence of diarrhea in the following 2-3 months.



scale-up of zinc and ORS. The document addressed strategies for translating the global recommendations into country-level action plans; common challenges for implementation, including product manufacturing, supply chain management, and monitoring and evaluation; a summary of the available evidence; and specifications for zinc products including dosage, cost, and packaging.

GLOBAL PRIORITIZATION OF ZINC/ORS

As early as the 1980s, ORS was recognized as a key intervention for child health when UNICEF Executive Director James Grant named ORS as one of four key interventions for improving child and infant health—others included growth monitoring, breastfeeding, and immunization (GOBI-FFF). Since the release of the *WHO/UNICEF Joint Statement*, zinc and ORS have been further prioritized as key interventions for decreasing under-5 mortality under additional global initiatives and frameworks.

In 2012, WHO and UNICEF released the *Joint Statement on Integrated Community Case Management (iCCM)* as an equity-focused strategy to improve access to essential treatment services for children, especially in hard-to-reach areas.¹⁰ To provide iCCM, community health workers (CHWs) are equipped, trained, supported, and supervised to diagnose and manage childhood illnesses. The joint statement highlights evidence that iCCM can improve coverage of life-saving treatments, including zinc and ORS, and outlines key components of the strategy, implementation support tools, and key indicators.

Later that year, the **UN Commission on Live-Saving Commodities for Women and Children** (UNCoLSC) was launched by UNICEF and UNFPA as part of the Secretary General's *Every Woman Every Child* movement. UNCoLSC, co-chaired by the Governments of Norway and Nigeria, released a report that identified 13 commodities—including zinc and ORS for child health—that are often overlooked but together could save the lives of more than 6 million women and children under 5 years. UNCoLSC identified key, interrelated barriers that prevent access to and use of these commodities, as well as 10 time-bound recommended actions. For zinc and ORS, key recommendations included shaping local delivery markets, strengthening product quality, increasing supply and awareness, increasing demand and utilization, improving provider performance and accountability, and supporting product innovation.¹¹

In June of 2012, the focus on child health was reinvigorated when nearly 180 governments and civil society organizations signed a pledge to stop women and children from dying of causes that are easily avoidable. **Ending Preventable Child and Maternal Deaths: A Promise Renewed** seeks to accelerate progress toward Millennium Development Goals 4 and 5—reducing child mortality and improving maternal health,

respectively—while building new momentum beyond 2015 to end all preventable maternal and child deaths by 2030. One of the five key actions of *A Promise Renewed* is investing in high-impact solutions such as zinc and ORS.

In recognition that diarrheal disease and pneumonia together are responsible for a quarter of child deaths—and are most effectively addressed through a coordinated approach—WHO and UNICEF published the **Integrated Global Action Plan for Pneumonia and Diarrhea (GAPPD)** in 2013.¹² This was accompanied by the release of the *Lancet Series on Childhood Pneumonia and Diarrhea* which outlined additional evidence to support the framework.¹³ GAPPD provides an integrated framework of evidence-based interventions for the prevention and treatment of pneumonia and diarrhea with the goal of ending preventable deaths from these illnesses by 2025. The action plan is designed for national governments and local partners responsible for designing and implementing country-level plans. GAPPD places particular emphasis on frontline health workers and community-based organizations for the execution of the strategy. Zinc and ORS are cited as key interventions for diarrhea control among other interventions, including exclusive breastfeeding, safe drinking water and sanitation, and rotavirus vaccination.

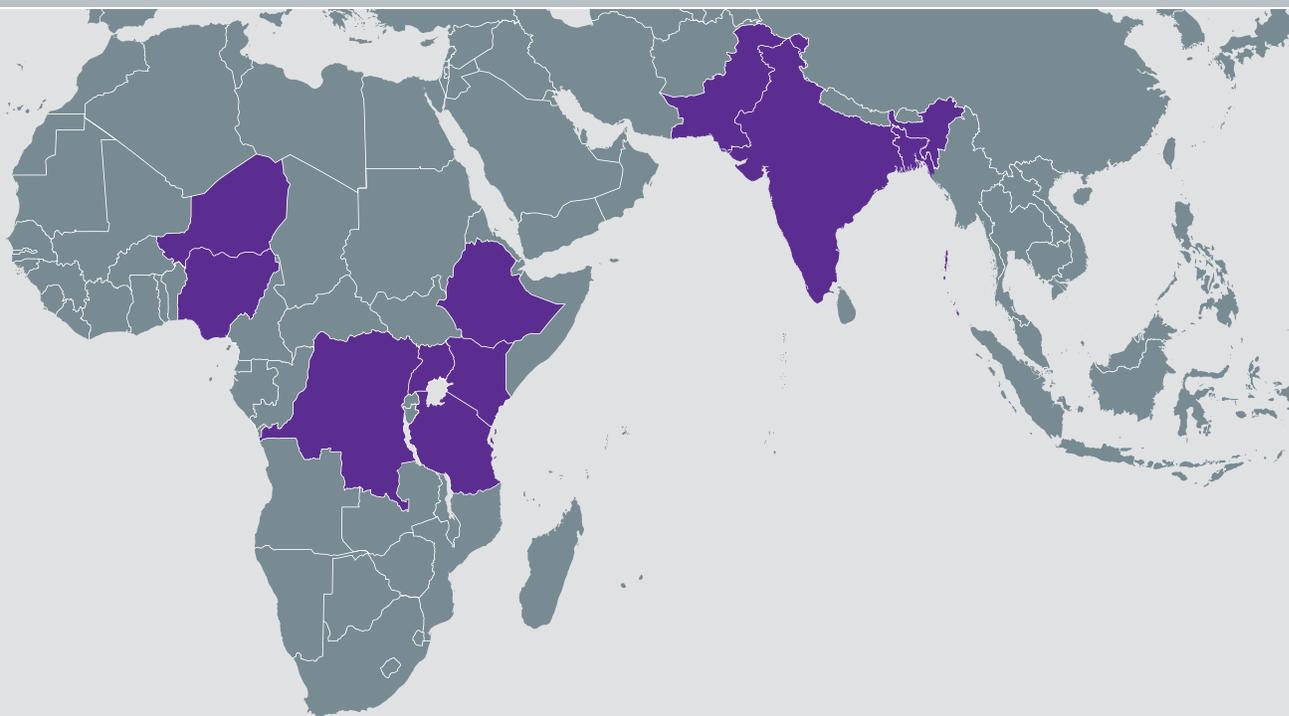
GLOBAL MOMENTUM & TECHNICAL SUPPORT

In addition to the global endorsements and declarations to tackle diarrheal deaths, there has been significant new attention, including funding and technical assistance, provided by partners and donors to support the scale-up of zinc and ORS in recent years.

In 2005, the **Global Zinc Task Force** was established with funding from the Bill & Melinda Gates Foundation through a collaboration of WHO, USAID, UNICEF, and the Johns Hopkins School of Public Health to address key issues affecting high-burden countries at global and regional levels to accelerate zinc adoption. The Zinc Task Force convened five regional advocacy and technical workshops and two country planning workshops to discuss policy changes, provided technical support to zinc manufacturer Nutriset to meet international good manufacturing practice standards, and created resources to support policy changes and program planning. These efforts helped to create political will and resulted in policy changes and revisions of the standard treatment guidelines.

Building on these efforts, the **Diarrhea & Pneumonia Working Group**, (see Figure 1.3) was established in 2011 with a broader focus of supporting increased coverage of both diarrhea and pneumonia treatment across 10 high-burden countries: Bangladesh, DRC, Ethiopia, India, Kenya, Niger, Nigeria, Pakistan, Tanzania, and Uganda. The Working Group is co-chaired by UNICEF and the Clinton Health Access Initiative,

FIGURE 1.3. DIARRHEA & PNEUMONIA WORKING GROUP



Focal Countries

Bangladesh, Democratic Republic of Congo, Ethiopia, India, Kenya, Niger, Nigeria, Pakistan, Tanzania, Uganda

Membership



Source: Diarrhea & Pneumonia Working Group Advocacy Brief, December 2015.

FIGURE 1.4. **TIMELINE OF GLOBAL ENDORSEMENTS AND MILESTONES FOR ZINC AND ORS**

1975	WHO and UNICEF agree on standard ORS formulation regardless of patient age or cause of diarrhea; UNICEF begins procurement and distribution of pre-packaged ORS
1979	BRAC scales up promotion of homemade sugar-salt solution in Bangladesh
1980	WHO establishes the Programme for the Control of Diarrheal Diseases, GOBI FFF created
1984	ORS formulation modified to include tri-sodium citrate
1990s	WHO conducts research on new ORS formulations
2003	WHO recommends new, improved Lo-ORS solution
2004	WHO/UNICEF Joint Statement recommends zinc supplementation added to ORS
2005	Zinc Task Force established; Zinc added to WHO EML
2006	WHO Operational Guidelines including zinc released
2009	CCM Taskforce formed
2011	Diarrhea & Pneumonia Working Group established
2012	WHO/UNICEF iCCM Joint Statement released; UNCoLSC Launched; A Promise Renewed Launched
2013	GAPPD launched
2014	Global Fund endorsement of integrated MNCH approaches

Inc. (CHAI) and consists of leading organizations working in child health representing the NGO, donor, and private sectors. Focal countries were selected based on disease burden, levels of treatment coverage, and partner presence. The Working Group provides technical assistance, resource mobilization, and monitoring and evaluation support to governments and local partners in the 10 focal countries. In addition, the Working Group serves as the UNCoLSC convener for child health commodities (zinc, ORS, and amoxicillin) working as a consortium of experts to facilitate global-level actions while simultaneously assisting with country-level implementation.

RESOURCE MOBILIZATION

Despite the number of children affected, diarrhea receives a disproportionately small amount of funding compared to other diseases such as HIV, malaria, and TB, and there is a lack of global financing mechanisms to support large-scale implementation efforts to increase utilization of zinc and ORS. However, since the inception of the Working Group in 2011, members have helped countries to identify and pursue global funding opportunities, which have led to increased investments in diarrhea treatment.

In 2013, **RMNCH Trust Fund**, a multi-donor trust fund, was established to help identify catalytic investments to support implementation of the recommendations of the UNCoLSC in eight “pathfinder” countries.¹⁴ Funding was allocated based on a country engagement process whereby the RMNCH Strategy and Coordination Team, H4+ partners,¹⁵ and national governments came together to support sharpened RMNCH-focused national plans and to improve alignment with related funding streams. Of the total US\$ 180 million funding approved, approximately 13% (US\$ 23 million) was allocated to activities supporting improved outcomes for child health.¹⁶ This included funding for activities such as procurement of zinc and ORS, trainings for public health providers (e.g., iCCM), local supplier engagement, supply chain and management strengthening, and support to ministries of health (MoH) to establish coordinating mechanisms.

In 2013, the Global Fund to Fight AIDS, TB and Malaria (GFATM) strongly endorsed improved MNCH integration and broader impact within its New Funding Model. Specifically, GFATM allowed countries to apply for funding to support selected components of the iCCM package under the New Funding Model.¹⁷ In early 2014, the **iCCM Financing Task Team**—a multi-organizational team of global partners led by UNICEF—was formed to provide technical assistance to priority countries interested in integrating iCCM into their malaria and/or health systems strengthening concept notes to GFATM. To date, an estimated US\$ 212 million across 12 countries has been committed by GFATM to support iCCM. Additional co-financing has been lev-

eraged from other donors, primarily for iCCM commodities not eligible for GFATM funding.

In addition to these global funding opportunities, most sources of large-scale funding for zinc and ORS scale-up (> US\$ 1 million) continue to come from a diverse range of individual donors, including bilateral organizations, private foundations, and corporations (see Table 1.1).

Included among these donors is a non-traditional funding source—mining companies—which have a strong presence in many countries with a high burden of diarrhea and a direct interest in investing and improving health outcomes in communities in which they operate. Recognizing this opportunity, the International Zinc Association, MDG Health Alliance,

UNICEF, GBC Health, UN Foundation, and USAID launched the **Mining Compact for Child Health** in 2012 to provide a platform for leading mining companies to join forces with governments, NGOs, industry associations, and civil society to grow and develop sustainable markets for zinc and ORS. To date, a number of mining companies have partnered with NGOs to support scale-up. For example, the Zinc Alliance for Child Health (ZACH)—a partnership between Teck Resources, Global Affairs Canada, and Micronutrient Initiative—was formed in 2011 and provides over US\$ 20 million to support zinc/ORS scale-up in countries including Burkina Faso, Ethiopia, India, Kenya, and Senegal. Other mining companies that have made specific investments to support scale-up to include BHP-Billiton, Hindustan Zinc, International Zinc Association, Lundin Foundation, Minerals and Metals Group, and Umicore.¹⁸

TABLE 1.1. DONORS PROVIDING NEW INVESTMENTS TO SUPPORT ZINC/ORS SCALE-UP, 2013-2015*

BILATERALS	PRIVATE FOUNDATIONS	CORPORATIONS /OTHER
Global Affairs Canada	Absolute Return for Kids	BHP-Billiton
Norwegian Agency for Development Cooperation	Bill & Melinda Gates Foundation	International Zinc Association
United States Agency for International Development	Children’s Investment Fund Foundation	McCann Health
	ELMA Philanthropies	GSK
	IKEA Foundation	Hindustan Zinc (Vedanta)
		Lundin Foundation
		Merck
		Minmetals Resources
		Reckitt & Benskiser
		Teck Resources
		Umicore

*Includes large-scale commitments (>US\$ 1 million since 2011) tracked by the Working Group. May not be inclusive of all investments made to support large-scale efforts.

Sources: Diarrhea Declaration of 2013 and 2014; Diarrhea & Pneumonia Working Group partner commitments summary 2014; and other publicly available sources.



II. A Framework for Measuring Success

THE FOUR-PRONGED APPROACH

The Diarrhea & Pneumonia Working Group was established to catalyze global increases in treatment coverage. At the time of its inception, only one-third of children with diarrhea in focal countries (with the exception of Bangladesh) received ORS and less than 1% received both zinc and ORS due to several factors. Health providers and caregivers were often unaware that zinc and ORS were the recommended treatment, leading to low demand. As a result, suppliers had limited incentive to

invest in distribution and promotion of these products. The political and partner environment further impeded the uptake of zinc and ORS through limited attention and funding as well as unfavorable regulatory conditions. In line with the global frameworks mentioned above—UNCoLSC, GAPPD, and WHO Operational Guidelines—the Diarrhea & Pneumonia Working Group aims to support country governments to overcome these barriers by promoting a four-pronged approach towards the overall goal of improving zinc and ORS coverage (see Figure 2.1).

FIGURE 2.1. FOUR-PRONGED APPROACH TO DRIVING SCALE-UP OF ZINC/ORS



Source: Diarrhea & Pneumonia Working Group Advocacy Brief, December 2015.

MEASURING SUCCESS OF TREATMENT SCALE-UP

To measure progress across the 10 focal countries, the Working Group developed and endorsed a common evaluation framework, including a set of standard performance indicators for diarrhea (see Table 2.1). The development process was led by the Monitoring and Evaluation (M&E) Subgroup which consulted with members from the Working Group as well as other global initiatives and experts.¹⁹ The Performance Indicators are revised on a regular basis as more evidence on the validity and appropriateness of new indicators becomes available.

The Performance Indicators are intended to inform global and country level discussions around evaluating national progress and facilitating alignment of M&E efforts across programs. At the global level, Working Group members have agreed to incorporate the indicators in their existing and planned M&E frameworks for diarrhea treatment scale-up programs and regularly report on progress against the indicators. At the country level, governments and local partners are encouraged to adapt the Performance Indicators to fit their local contexts based on available evidence and data sources. Joint M&E and planning efforts can be achieved through existing country coordinating mechanisms and through individual programs.

TABLE 2.1. PERFORMANCE INDICATORS FOR DIARRHEA TREATMENT SCALE-UP

#	INDICATOR	DEFINITION
D.1.	Diarrhea care-seeking	Proportion of children under age 5 with diarrhea in the previous two weeks who sought care from an appropriate healthcare provider ²⁰
D.2.	ORS coverage	Proportion of children under age 5 with diarrhea in the previous two weeks who received ORS
D.3.	ORS and zinc combined coverage	Proportion of children under age 5 with diarrhea in the previous two weeks who received zinc with ORS
D.4.	ORS and zinc availability	Proportion of health care treatment sources with ORS and zinc in-stock on the day of the survey
D.5.	National treatment guidelines	ORS and zinc is the recommended first-line treatment for diarrhea
D.6.	Zinc OTC status	Zinc is designated as an over-the-counter class drug
D.7.	Low-osmolarity ORS registration	At least one Lo-ORS product registered with National Drug Authorities
D.8.	Zinc registration	At least one zinc product registered with National Drug Authorities
D.9.	ORS and zinc are included in the EML and National Procurement List	ORS and zinc are included in the EML and National Procurement list

Source: Diarrhea & Pneumonia Working Group. Performance Indicators for Diarrhea & Pneumonia Treatment Scale-up. March 2015.



III. Progress over the Past Decade of Scale-Up

KEY INDICATORS FOR DIARRHEA

Following the above framework, progress has been achieved across key indicators for diarrhea—in the areas of treatment coverage, care-seeking, and policy and regulatory environment. Trends over the past decade across the 10 focal countries are presented below. Global data is also provided where available.

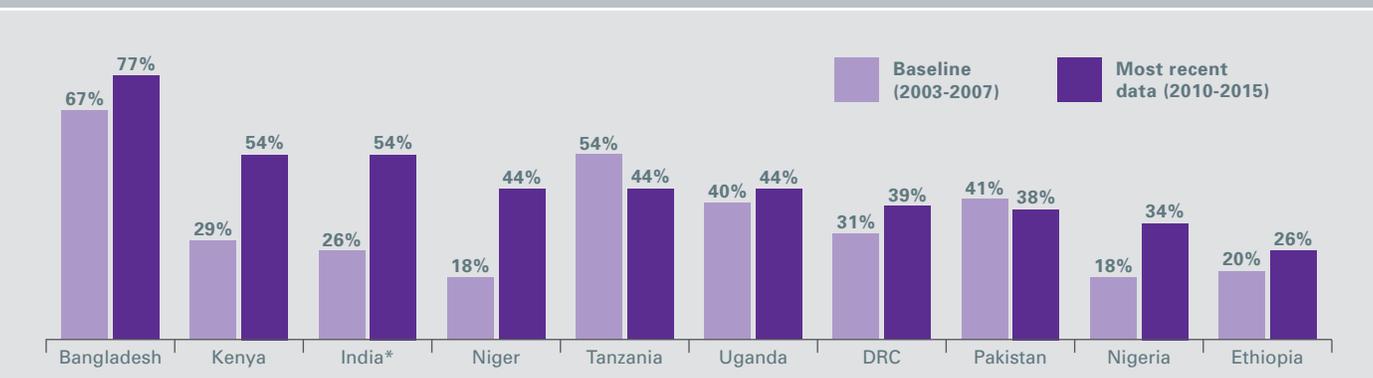
Treatment Coverage

Globally, treatment coverage—the percentage of children with diarrhea in the last two weeks who received zinc and ORS—has increased across the majority of focal countries (see Figures 3.1 and 3.2). Bangladesh is the highest performing country and has

reached coverage levels of 77% for ORS and 44% for zinc. Seven countries have achieved increases in ORS coverage of 5-40% in the past decade. In Tanzania, ORS coverage has dropped 10%, which is likely due to a decrease in funding for provider trainings, product availability, and dedicated resources for scale-up.²¹

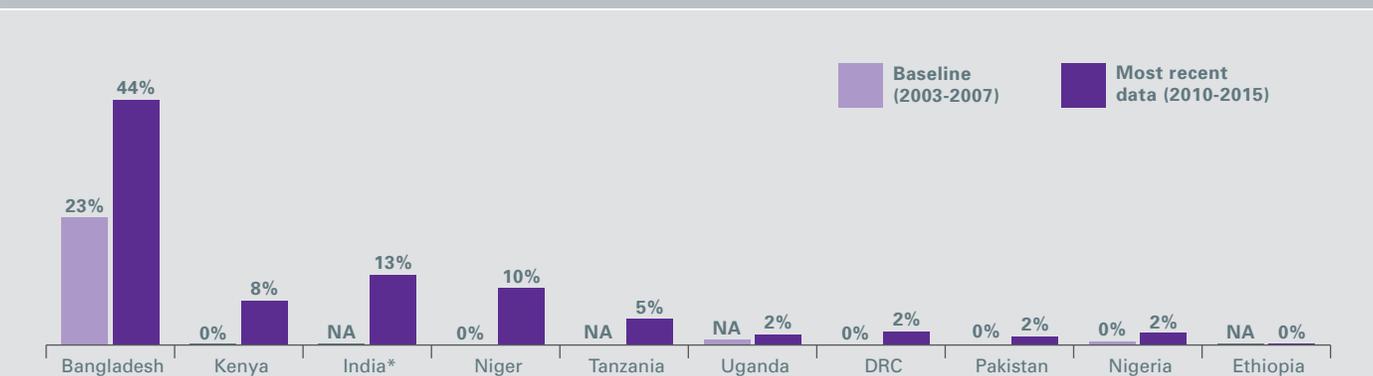
For zinc, most countries did not start measuring coverage in national household surveys until after 2005. Currently available data suggest only minimal increases across the 10 focal countries—including a 5-10% increase in coverage in four countries. However, it should be noted that DHS data in several countries are at least two years old, specifically for Ethiopia, DRC, Nigeria, Pakistan, Tanzania, and Uganda, and thus may not reflect the most recent coverage trends. For example, recent

FIGURE 3.1. ORS TREATMENT COVERAGE, 2005 VS. 2015 (10 FOCAL COUNTRIES)



*Note: The most recent ORS coverage data available for India includes ORS and all available home fluids.
 Source: Bangladesh DHS 2004/2014; DRC DHS 2007/2013; Ethiopia DHS 2005/2011; India DHS 2005-06/UNICEF RSOC 2015; Kenya DHS 2003/2014; Niger DHS 2006/2012; Nigeria DHS 2003/2013; Pakistan DHS 2006-07/2012-13; Tanzania DHS 2004-05/2010; Uganda DHS 2006/2011

FIGURE 3.2. ZINC TREATMENT COVERAGE, 2005 VS. 2015 (10 FOCAL COUNTRIES)



*Note: The most recent zinc coverage data available for India includes zinc and ORS+zinc combined.
 Source: Bangladesh DHS 2007/2014; DRC DHS 2013; Ethiopia DHS 2005/2011; India DHS 2005/UNICEF RSOC 2015; India DHS 2005/UNICEF RSOC 2015; Niger DHS 2006/2012; Nigeria DHS 2008/2013; Pakistan DHS 2012; Tanzania DHS 2010; Uganda DHS 2006/2011

data from partners' large-scale project evaluations suggest that even higher levels (~20%) of zinc coverage have been achieved in selected countries and will likely be evident in the next round of global DHS surveys.

Policy/Regulatory

National policies and the regulatory environment have also been critical indicators of treatment scale-up progress. According to *Countdown to 2015 for Maternal, Newborn, and Child Survival*—a global collaboration of academics, governments, international agencies, and others that track coverage of a core set of interventions across priority countries—few countries reported adopting national policies that reflected the latest WHO guidelines for diarrhea management (see Figure 3.3).

Due in large part to the support provided by the Zinc Task Force and partner efforts to advocate to MoHs and National Drug Regulatory Authority (NDRA) for policy change, at least 69 countries have updated their national policies to include both Lo-ORS and zinc as of 2015 (see Figure 3.4).

In 2008, ORS was also typically available in countries as an over-the-counter (OTC) product and could be distributed without a physician prescription; yet, zinc was not OTC thus limiting marketing and distribution efforts. According to the Zinc Task Force,²² zinc was not OTC in the 10 focal countries; however, by 2015, nine out of 10 countries have secured OTC status (see Figure 3.5 on next page). In Ethiopia, partners are working with the Federal MoH to develop the basic requirements needed for including zinc on the next revision of the OTC drug list.

FIGURE 3.3. COUNTRIES WITH NATIONAL ZINC/ORS POLICIES, 2008 (GLOBAL, 69 COUNTDOWN TO 2015 COUNTRIES)

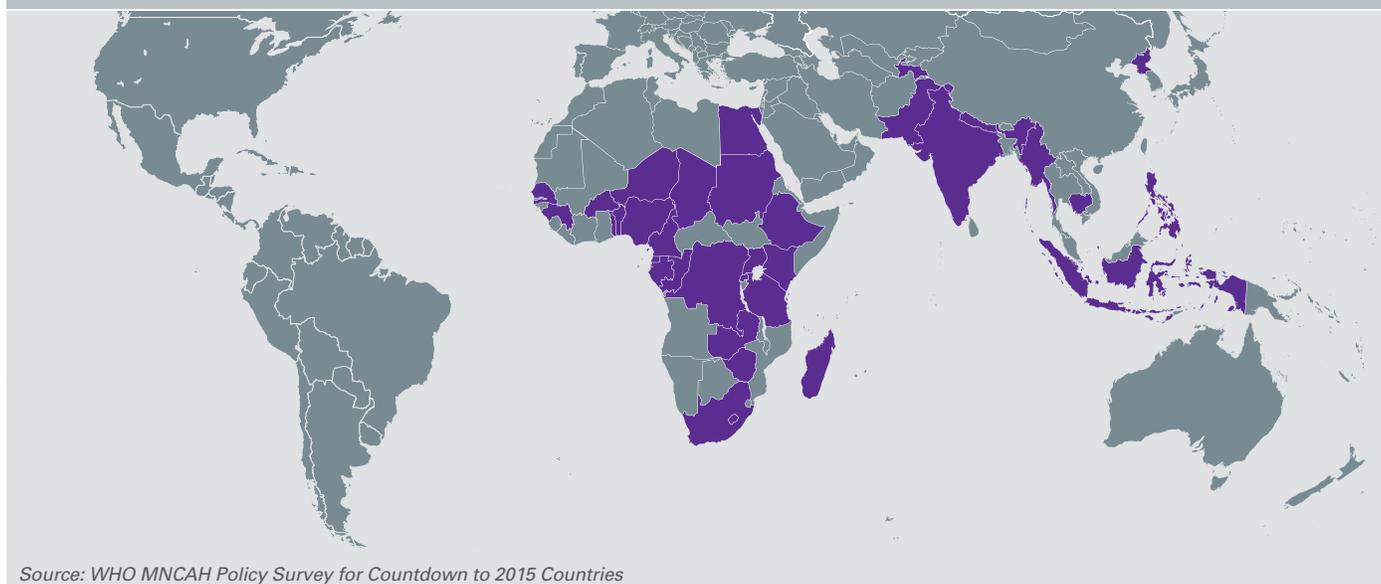


FIGURE 3.4. COUNTRIES WITH NATIONAL ZINC/ORS POLICIES, 2015 (GLOBAL, 69 COUNTDOWN TO 2015 COUNTRIES)

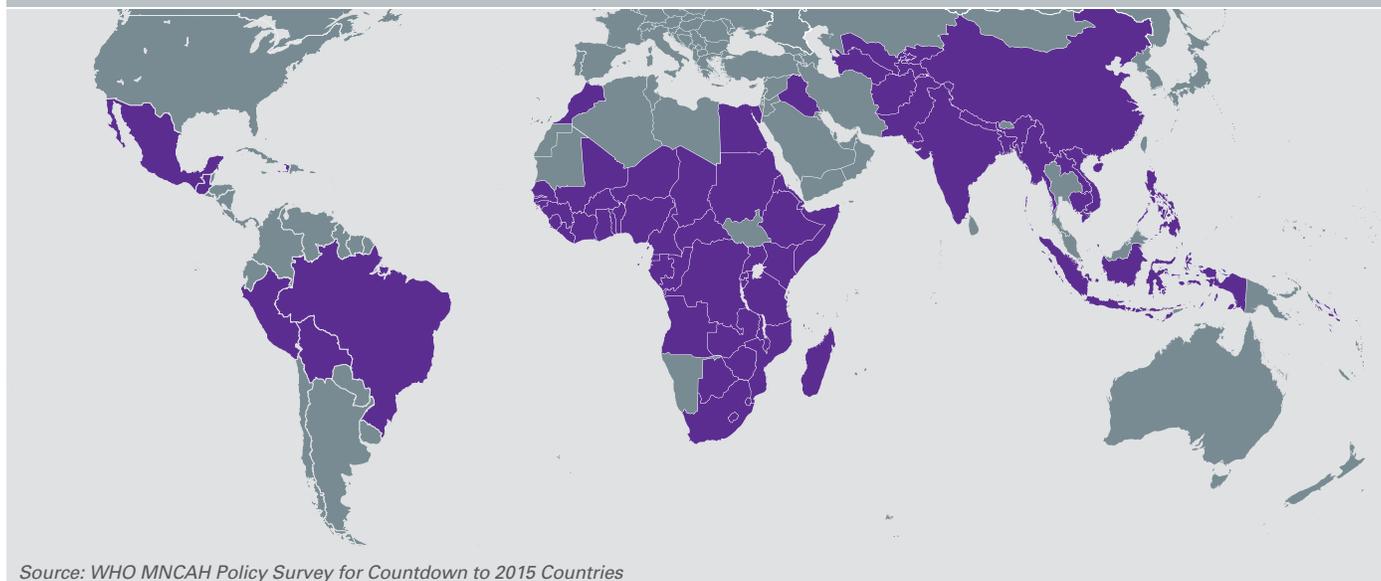


FIGURE 3.5. OTC STATUS FOR ZINC, 2005 VS. 2015 (10 FOCAL COUNTRIES)

	2005	2015
Bangladesh	No	Yes
DRC	No	Yes
Ethiopia	No	In Progress
India	No	Yes
Kenya	No	Yes
Niger	No	Yes
Nigeria	No	Yes
Pakistan	No	Yes
Tanzania	No	Yes
Uganda	No	Yes

Source: Zinc Task Force Final Report, 2007; Diarrhea & Pneumonia Working Group Dashboard, 2015.

Care-Seeking

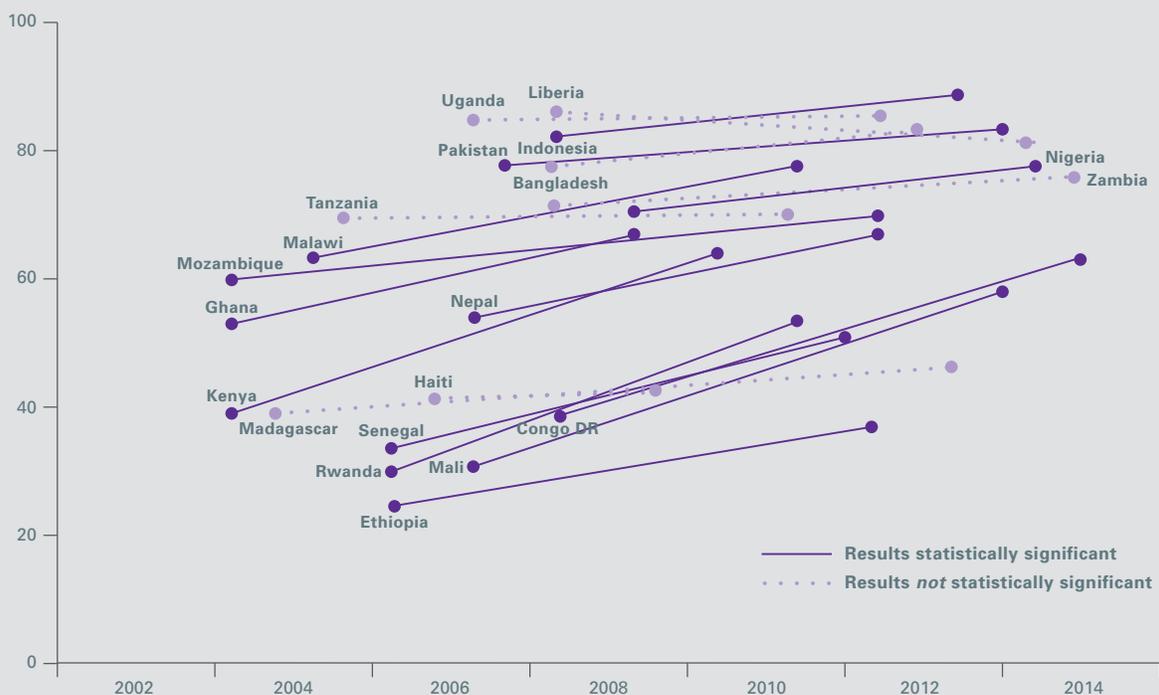
Care-seeking—the percentage of children with diarrhea in the previous two weeks who sought care from an appropriate health provider—has also increased. A recent analysis of DHS data indicates that care-seeking for diarrhea has improved in 13 of 20 USAID focal countries (see Figure 3.6). A closer look at overall care-seeking trends in the 10 Working Group countries highlight that while care-seeking levels of over 70% have been achieved in India and Nigeria, there is still room for improvement across the remaining countries (see Figure 3.7).

IMPACT OF ZINC/ORS ON REDUCTION IN DIARRHEA DEATHS

In several countries, improvements in zinc and ORS coverage have likely contributed to overall reductions in child mortality. In Niger, an analysis of national DHS data found a 5.1% annual rate of mortality reduction between 1998 and 2009.²³ Over the same period, ORS coverage increased by 14% and was estimated to be responsible for averting over 3,000 deaths among children (or 5% of total child deaths). This suggests that even more lives could be saved if further increases to zinc and ORS were achieved. Similarly, preliminary analysis of DHS data from Nigeria and Kenya demonstrate that increases in ORS coverage (by 10-20%) since 2006 were key drivers of child mortality reduction. **ORS was among the top five interventions responsible for total lives saved in both countries.**²⁴

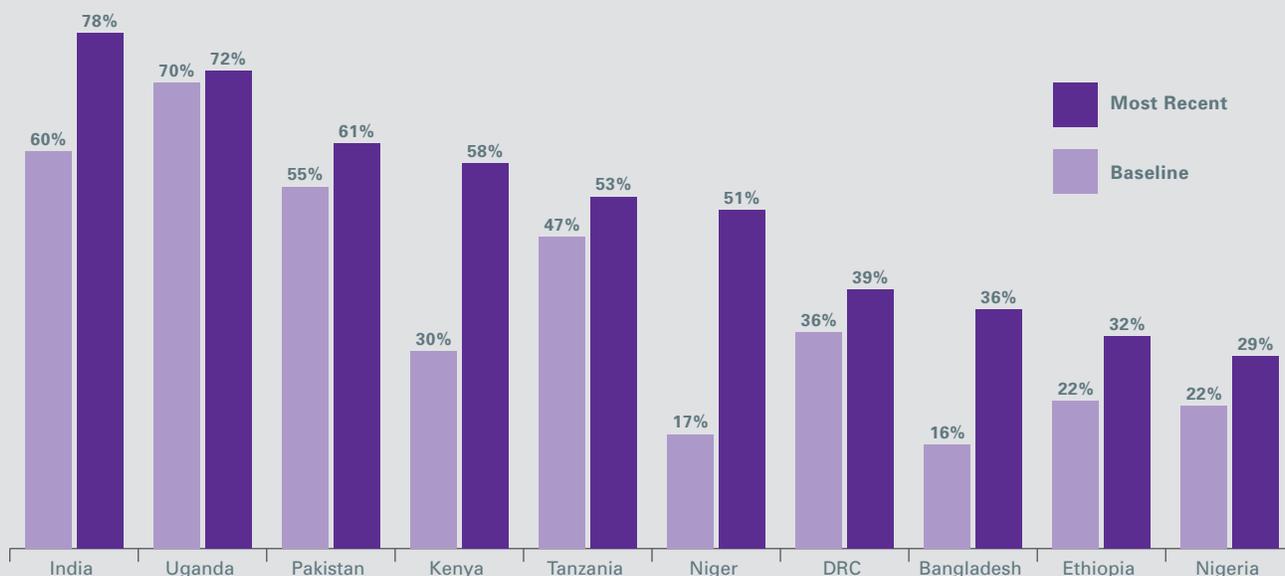


FIGURE 3.6. CARE-SEEKING FOR DIARRHEA, 2002 VS. 2014 (GLOBAL, IN 20 USAID FOCAL COUNTRIES)



Source: Secondary analysis of care-seeking trends in 20 USAID focal countries, conducted by DHS Macro, October 2014.

FIGURE 3.7. CARE-SEEKING FOR DIARRHEA, 2005 VS. 2015 (10 FOCAL COUNTRIES)



Source: Bangladesh DHS 2004/2014; DRC DHS 2007/2013; Ethiopia DHS 2005/2011; Kenya DHS 2003/2014; India DHS 2005/UNICEF RSOC 2013-14; Niger DHS 2006/2012, Nigeria DHS 2003/2013; Pakistan DHS 2006/2012; Tanzania DHS 2004/2010; Uganda DHS 2006/2011

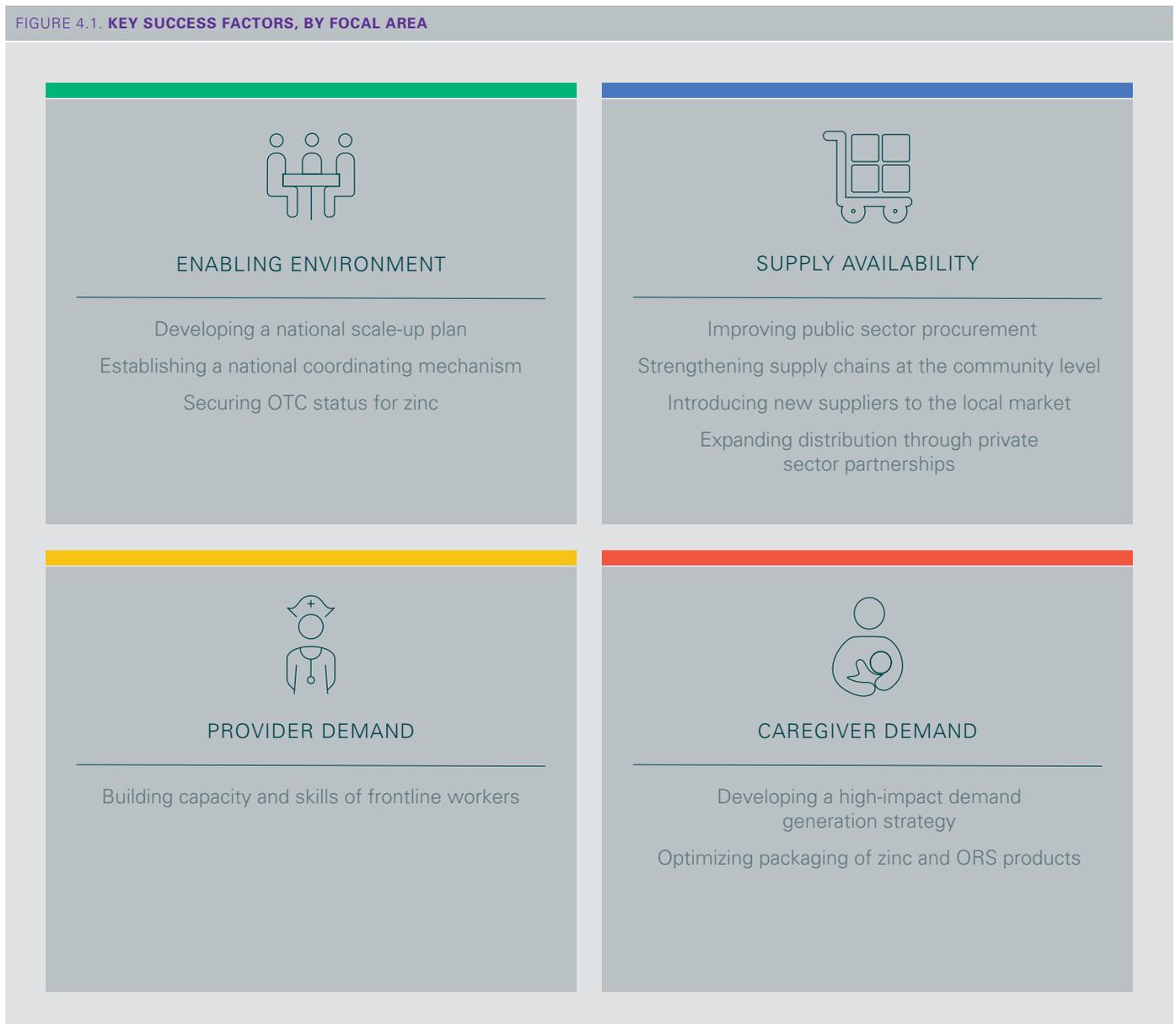
IV. Best Practices, Lessons Learned, and Global Resources

Since 2005, governments, partners, and donors have supported the implementation of large-scale programs to address low zinc and ORS coverage. For example, major multi-partner and country efforts focused on zinc and ORS included the Scale-up of Zinc for Young children Program (SUZY),²⁵ Point-of-Use Water Disinfection and Zinc Treatment Project (POUZN),²⁶ and the Diarrhea Alleviation through Zinc and ORS Therapy Project (DAZT).²⁷ These efforts, among others, have helped create an enabling environment, ensure widespread availability of high-quality, affordable supply, and improve demand among

providers and caregivers in both public and private sectors. Learnings from these country experiences have highlighted several success factors key to accelerating progress towards achieving these objectives (see Figure 4.1).

Specific approaches, results, lessons learned, and global resources are outlined in the following sections. The majority of examples reflect activities and coordinated efforts supported by the Diarrhea & Pneumonia Working Group members—both in the Working Group’s 10 focal countries and in other countries.

FIGURE 4.1. KEY SUCCESS FACTORS, BY FOCAL AREA



Case Studies

SECURING AN ENABLING ENVIRONMENT



IMPROVING SUPPLY AVAILABILITY



IMPROVING PROVIDER & CAREGIVER DEMAND





a. Developing a National Scale-up Plan

Background: In some countries, limited political will and attention have hindered improvements in diarrhea management, often as a result of competing national health priorities. In addition, an incomplete understanding of bottlenecks to commodity access has made it difficult to effectively scale up treatment and mobilize new resources for addressing these challenges.



Approach

Developing national plans for scaling up essential medicines—including zinc and ORS for treatment of child diarrhea—was a first step to aligning governments, partners, and donors around a common framework and driving integration within existing child health services. The Diarrhea & Pneumonia Working Group provided guidance and assistance during the process in the 10 focal countries.

Dedicated technical assistance

- › A dedicated partner in each country supported the government over a 3-4 month period. This partner was responsible for assisting the government to liaise with key stakeholders, convene workshops to review progress, and help develop initial strategy drafts.
- › The Working Group provided strategic guidance as well as technical reviews of draft plans.

Government buy-in

- › Country-specific presentations were also developed to support local advocacy efforts with governments to secure buy-in. Specifically, presentations summarized the national burden of diarrheal deaths, evidence on the effectiveness of zinc and ORS, key barriers to scale-up, and the potential impact of increased coverage on saving lives through evidence-based approaches.
- › Partners identified and engaged the appropriate levels of government (at both national and sub-national levels).

National Scale-up Plan

- › A first step was to work with the government to assess whether national child health strategies already existed

and if a separate national plan for child essential medicines was needed—or if related treatment interventions could be strengthened within an existing plan.

- › Where an existing plan could not be leveraged, a new national scale-up plan for child essential medicines was developed. This included a comprehensive approach to addressing barriers in both public and private sectors (see Box 1).
- › Final approval and endorsement of the national plan was secured from MoHs.

Lessons Learned

- Securing government leadership and ownership of the strategy development process from the beginning is crucial. In cases where technical assistance is needed, the government should select the appropriate partner to lead the process.
- Final endorsement of the national plan by governments is crucial. Countries that have been most successful in driving national progress are those that have held regular reviews of their plans and involved a wide variety of stakeholders to support implementation.
- Where feasible, national scale-up plans should be coordinated and integrated as much as possible rather than focusing on diarrhea treatment scale-up alone—for example, by including both diarrhea and pneumonia or by ensuring that diarrhea management and prevention is included in child health or wider RMNCH plans.
- National plans can help inform future strategy development and priority setting (e.g., UNCoLSC country plans, Global Financing Facility investment cases, etc.).
- National plans can be used to support engagements with the private sector as they help to demonstrate the government’s commitment to scaling up zinc and ORS.
- Commodities should be included from the beginning of the planning stage—not just guidance on procurement, but also for distribution to ensure all necessary activities and costs are considered.

Results

- **All 10 Working Group countries developed comprehensive, costed national strategies to scale-up child essential medicines, including zinc and ORS. Components of these plans have been incorporated into other relevant child health strategies (e.g., GAPPD and UNCoLSC country plans).**

BOX 1. Key Elements of National Scale-up Plans

- **Situational analysis and context:** This is a robust assessment of the national diarrhea context including existing child health efforts on which to build. Common barriers to scale-up across countries included inadequate care-seeking behavior, limited awareness of recommended products, supply chain challenges, limited access to reliable supply in the public sector, lack of incentives for private sector involvement, and regulatory issues (e.g., lack of favorable policies, product registrations).
- **Coverage targets:** Overall, partners set a target of at least 80% coverage of zinc and ORS by 2015 (the deadline for Millennium Development Goals). While ambitious, setting specific targets was important for driving progress.
- **Interventions:** Partners outlined a set of key interventions and activities to overcome bottlenecks to zinc and ORS access. Supporting evidence and lessons learned were also included where relevant.
- **Indicators:** An M&E framework summarized indicators to help track progress against each objective area.
- **Budget:** A detailed budget outlined specific costs required to implement each intervention, by year, and description of key assumptions.

Resources

Diarrhea & Pneumonia Working Group, Country Strategy Narrative Template and Budget Template

National Essential Medicines Scale-up Plan—NIGERIA

Local advocacy deck—NIGERIA



b. Establishing a National Coordinating Mechanism

Background: Significant financing resources and strong coordination are needed to ensure full implementation of national scale-up plans for child essential medicines. A well-coordinated approach in support of a unified, government-led scale up plan is needed to maximize the impact of all individual investments and minimize duplication.



Approach

National coordinating mechanisms play a critical role in managing and monitoring implementation. In most cases, coordinating mechanisms may already exist (e.g., Child Health Technical Working Groups), and it is a matter of ensuring these groups play an active role in the development and implementation oversight of scale-up plans. Several elements are necessary to ensure an effective, functioning mechanism:

Strong leadership and wide partner representation

- › A Chair, such as the MoH or appropriate government partner, should be selected to lead the coordinating mechanism and provide overall management and strategic oversight.
- › A Secretariat, often a partner organization or individual, can support the government Chair with strategic guidance and assistance in convening meetings and following up with partners on specific action items.
- › Wide representation from stakeholders, including relevant units within the MoH (e.g., program and commodity units) as well as partners from public and private sectors with programming in related areas strengthens overall contributions to implementation.

Clear group mandate and structure

- › A 'Terms of Reference' clarifies the overall purpose of the national coordinating mechanism, membership, partner roles and responsibilities, and reporting structure.
- › Subgroups can be formed to tackle specific technical issues and implementation gaps, leveraging a smaller group of partners to drive more targeted progress between meetings.

Partner mapping and joint work plan

- › A partner mapping summarizes the range of current and planned investments across all participating stakeholders and is a useful starting point for discussions and priority setting. The mapping should be regularly updated with new partner commitments and activities.
- › A joint work plan, highlighting partners and key activities, is effective for aligning resources to avoid duplication of efforts.
- › **EXAMPLE:** In Kenya, the Kenya Action Plan for Pneumonia and Diarrhea Working Group tracked nearly US\$ 13 million of funding across partners during fiscal years 2013-2015 to support implementation. The group identified critical implementation gaps of the national strategy (e.g., demand generation, low geographic coverage) and worked with members to redirect new funds to fill these needs.

Regular meetings

- › Frequent meetings (e.g., monthly or quarterly) allow regular reviews of partners' progress against the joint work plan, sharing of new partner data, and discussion of key issues.
- › An annual performance review meeting can help partners take stock of progress over the past year, identify gaps, and set priorities for the upcoming year.

Lessons Learned

- Government leadership and the identification of the appropriate lead is a key factor for success and continued momentum of partner activities. This ensures strong ownership of the national plan, encourages participation and open communication with partners, and increases accountability among members.
- National coordinating mechanisms should be part of (or linked to) existing child health Technical Working Groups.
- Regular attendance of participants from appropriate levels of partner organizations is needed to ensure effective follow-up.
- The National Strategy, work plan, and partner mapping were effective tools for identifying implementation gaps and redirecting partner resources as needed. When attempting to align resources and efforts, it is also important to recognize partner limitations and policies.

Results

- **EXAMPLE: The National Essential Medicines Coordinating Mechanism of Nigeria is co-chaired by the National Primary Health Care Development Agency and FMOH and consists of over 15 partners. By end of 2015, over US\$ 45 million in new funding was mobilized to support scale-up of child essential medicines. At the request of the FMOH, the group also prepared the child health component of the UNCoLSC country plan. Similar mechanisms at state level have also been established to drive progress and alignment sub-nationally.**
- **EXAMPLE: In Vietnam and Cambodia, PATH supported the formation of broad stakeholder groups to support favorable policy changes for zinc and ORS. By securing support from a range of stakeholders from Nutrition, EPI, and WASH in addition to treatment departments at MoHs, the stakeholders groups had an even stronger voice to advocate with provincial officials. As a result, the Cambodia and Vietnam MoH's launched new policies prioritizing zinc and ORS, among other interventions.**

Resources

Best Practices from National Scale-Up and Coordinating Mechanism — NIGERIA

PATH, Influencing Policies to Reduce Deaths from Diarrhea — CAMBODIA and VIETNAM



c. Securing OTC Status for Zinc

Background: In 2005, ORS was typically available in countries as an OTC product but zinc was not despite being safe to use without supervision of a trained health provider. As a result, zinc could not be sold in pharmacies or at retail outlets without a prescription and could not be advertised directly to caregivers.



Approach

In order to ensure widespread availability of zinc, particularly at the community level, partners worked closely with national regulatory authorities and other stakeholders to pursue the favorable policy change.

Pathway for necessary policy change

- › Regulatory laws varied by country, so it was critical to first understand the specific requirements and definitions for OTC status.
- › EXAMPLE: In India, the phrase “OTC” has no legal recognition. Instead, products that can be distributed outside of pharmacies (e.g., in retail shops) in villages where the population is under 1,000 are listed in Schedule K of the Drug and Cosmetics Rules.
- › EXAMPLE: In DRC, medicines are classified in one of two categories – médicaments en vente libre (products that can be freely sold, or OTC equivalent) or médicaments sans ordonnance (products that can only be sold on prescription). Zinc was classified in the first category.

Key decision makers and stakeholders

- › In most cases, the NDRA determined the status of zinc—as a medicine, nutritional supplement, or as an OTC product—but key decision makers varied by country.
- › A key stakeholder/sponsor was identified to drive the application process and ensure coordinated support around the application. This often included meetings with the relevant NDRA representative. The specific stakeholder authorized to submit an application for OTC status may vary by country and should be clarified from the start.

Evidence package

- › Depending on the requirements for policy change from the NDRA, applications typically required evidence demonstrating the efficacy, safety, and quality of zinc as well as evidence from research conducted in-country to address local conditions.
- › Letters of endorsements from MoHs, WHO and/or key programmatic partners in support of the policy change strengthened the application.

Lessons Learned

- It is critical to understand the regulatory landscape and to clarify the steps necessary to make a policy change before starting the OTC approval process.

- Approval by the legislature may be required to change pharmaceutical regulations; this process must be considered in the program timeline.

Results

- **By 2015, OTC status was secured in nine of the 10 focal countries supported by the Diarrhea & Pneumonia Working Group. In Ethiopia, zinc is being used without prescription in practice, but partners are working with the Food, Medicine and Healthcare Administration and Control Authority to include zinc in the official OTC list.**

Resources

[WHO Model Essential Medicines List \(EML\)](#)

[Zinc OTC Evidence Brief—INDIA](#)

[Zinc Task Force, list of research and evidence on zinc](#)



d. Improving Public Sector Procurement

Background: Strong public sector forecasting, procurement, and distribution are necessary to ensure consistent supply of high-quality zinc and ORS in public facilities and among community health workers. In addition, gains in the public sector can drive improvements in the overall market by improving consumer demand and encouraging increased investments from suppliers to introduce new products and expand distribution.



Approach

Close collaboration with national governments, National Medical Stores, and other public sector stakeholders across several areas helped to achieve an accurate and reliable supply of zinc and ORS.

Policy changes

- › Favorable policy changes at national and sub-national levels were pursued, specifically inclusion of optimal zinc and ORS products into standard treatment guidelines, EMLs, and procurement lists. Appropriate formulations were also registered, including the co-pack (ORS and zinc packaged together), where appropriate.

Government tenders

- › Public sector tenders were revised to reflect products and optimal specifications listed in National EMLs that improved ease of administration, dosing accuracy, patient adherence, cost, and quality (see Table 1).
- › Bids from manufacturers were evaluated to select the right products based on criteria such as appropriateness for pediatric populations in addition to cost.
- › EXAMPLE: In India, procurement laws for a high-burden state mandated that the MoH accept the lowest bid. The state MoH was interested in the cheapest bid for a zinc product, but it was not taste-masked. Micronutrient Initiative (MI) advocated to the MoH about the need to adopt the proper specification while also considering cost which led to procurement of the more appropriate formulation.

Access to pricing

- › Governments were linked to new low-cost suppliers to strengthen competitive pricing on tenders. At times, this included renegotiating prices on existing tenders where cost savings were possible.

- › Supplier forums were convened to improve awareness of tender opportunities and timelines among suppliers, which led to higher response rates from suppliers.
- › EXAMPLE: In Uganda, a tender for the co-pack was issued in 2012, but the initial price of the winning bid was high. Subsequently, CHAI shared a new price benchmark with NMS to facilitate its renegotiation with the supplier and, as a result, the cost of procurement dropped by 33%.

Quantification and forecasting

- › MoHs, procurement agencies, and partners quantified the amount needed to meet national demand, based on inputs including caseload, care-seeking patterns, and existing stock.
- › Quantifications were regularly reviewed and adjusted based on actual consumption.
- › EXAMPLE: Management Sciences for Health (MSH) supported the DRC MoH to use the UNCoLSC RMNCH quantification guide to estimate appropriate quantities of zinc/ORS as part of the quantification process for essential commodities. The team used the latest DHS data on national diarrhea prevalence, incidence, and care-seeking, as well as algorithms from the RMNCH Quantification Supplement to project expected cases and calculate estimated quantities of zinc tablets and ORS sachets needed. The calculations are being used for procurement planning and resource mobilization.

Commodity financing

- › Partners advocated to MoHs to allocate budget for zinc and ORS and explore other opportunities to use existing financing mechanisms. This included efforts to incorporate commodity procurement into health operational plans

to facilitate release of government funds, identify the most appropriate procurement channels, and develop and execute appropriate budgets.

- › EXAMPLE: In Bangladesh, icddr,b engaged with the MoH to include zinc and ORS funding as part of the Operational Plan revision process. While the effort required two years of dedicated support and follow-up, MoH is now procuring adequate quantities to meet demand.
- › EXAMPLE: In Nigeria, CHAI supported the Niger State MoH to extend a credit line between the MoH and suppliers for zinc and ORS (over a 90 day period), under the Drug Revolving Fund.

Optimal product switch

- › A product switch strategy, developed in collaboration with the government, facilitated the transition to new, more optimal products (e.g., zinc syrups to tablets, ORS to Lo-ORS, singles to co-pack, depending on the setting) (see Box 1).
- › To prevent product wastage, estimates of old stock were assessed and efforts were taken to avoid simultaneous circulation of both products to minimize confusion.
- › Clear communications to facilities and providers around the benefits of new products compared to suboptimal alternatives helped to sensitize stakeholders.

Lessons Learned

- Commodity donations can help accelerate product transitions, but should be time-limited with clear expectations of duration and government contributions, flexible in meeting the needs of the local context, and directed to governments to ensure sustainable supply.

TABLE 1. RECOMMENDED ZINC AND ORS SPECIFICATIONS

SPECIFICATIONS	ZINC	ORS
Dosage, strength, composition	10 or 20 mg (dispersible tablets) 10 mg/5ml or 20 mg/5ml (syrups)	1-L (or more optimal pediatric size depending on local conditions). Lo-ORS total osmolarity of 245 mOsm/l.
Taste masking	Yes	Acceptable if stability and efficacy are not compromised
Packaging	1 x 10 or 1 x 14 strips	Powdered sachet
Shelf life	>2 years	2-3 years

Source: Zinc Task Force, Memo on ORS and Zinc Specifications, 2013.

- Price should be considered prior to introducing a co-pack in the public sector. If the co-pack is more expensive than single units, public sector coverage may decline if the MoH budget is fixed. Several countries have demonstrated that the co-pack can be more affordable than single units, so this pricing should ideally be achieved prior to introduction in the public sector.
- Zinc can be successfully marketed as an accompaniment to ORS, without being co-packaged, in countries with relatively high ORS use (e.g., as shown in Nepal through POUZN and Bangladesh through SUZY).
- Careful quantification and supply planning is an essential step before procurement.
- Sufficient awareness and demand for zinc and ORS among caregivers and health facility providers should be generated to maximize the impact of product procurement and distribution.

Results

- **Seven focal countries—Bangladesh, DRC, India, Kenya, Nigeria, Pakistan and Uganda—have allocated domestic budgets to procure zinc and ORS.**
- **Seven focal countries—DRC, Kenya, India, Niger, Nigeria, Uganda, and Tanzania—have introduced co-packaged zinc and ORS in public health facilities.**

Resources

Zinc Task Force, Recommendations on Zinc and ORS Product Specifications

JSI and SIAPS, Quantification of Health Commodities, RMNCH Supplement: Forecasting Consumption of Select RMNCH Commodities. 2015

MSH, International Drug Price Indicator Guide

BOX 1. Facilitating Introduction of Zinc and ORS co-packs

Introducing a zinc/ORS co-pack (multiple ORS sachets and a 10-day course of zinc tablets) has been an effective strategy for improving uptake in the public sector, when certain conditions were in place:

- A local assessment to determine the potential need and impact of co-pack introduction
- A cheaper co-pack price compared to the combined cost of single products
- A clear MoH strategy to manage product transitions, including communication on any change in pack size and order requirements as well as key messages highlighting the rationale for the product switch
- Favorable policies (e.g., OTC status secured for both zinc and ORS)
- Product “bundling” of single units (with close monitoring of expiration dates for both products) prior to the switch to sensitize pharmacies and clinicians
- Buy-in secured from relevant MoH departments (e.g., Child Health, NMS)

EXAMPLES

- In one province of Guatemala, MI conducted a study that found that co-packing improved provider prescription practices and increased caregiver adherence.²⁸ Preliminary findings in Ethiopia also suggest similar improvements in patient adherence.
- In Kenya, CHAI worked with MoH facilities to “bundle” existing singles into ziplock bags to introduce the co-pack concept to health facilities and draw down existing singles stock. Public sector volumes for zinc/ORS treatment courses (including new co-pack products) have grown by over 35% since 2013.



e. Strengthening Supply Chains at the Community Level

Background: A functioning supply chain to deliver essential commodities to the community level is imperative, particularly in countries where most mothers seek care for diarrhea outside of health facilities. However, the supplies often do not reach CHWs in sufficient and reliable quantities due to constraints in the supply chain.



Approach

In 2010, John Snow, Inc. (JSI) implemented the Supply Chain for Community Case Management (SC4CCM) project to test innovative interventions to improve availability of essential commodities at the community level in three countries—Ethiopia, Rwanda, and Malawi—and to support national scale-up of proven best practices. In each country, different interventions were implemented, but each followed a consistent approach.

Supply chain bottleneck assessment

- › A detailed baseline assessment helped to diagnose supply chain bottlenecks. Only 24-49% of CHWs across the three countries had all iCCM commodities in stock primarily due to poor data visibility regarding CHW product use and requirements, lack of a robust quantification that included community level needs, and weak coordination between CHWs, health centers, and district managers.

Resupply procedures

- › Standard resupply systems were developed or improved to ensure that products flowed effectively and efficiently through the system based on CHW need. This involved close monitoring by CHWs of their stock levels, ensuring correct and routine reporting of product use to health facilities, and receiving regular resupply of adequate quantities.
- › Consumption and stock data helped to support decision making and problem-solving at all levels. For example, logistics management information systems (LMIS) and other tools (e.g., stock cards and resupply worksheets) facilitated data collection and aggregation.
- › **EXAMPLE:** In Rwanda, resupply procedures for CHWs were improved through standardization, simplification, and leveraging the existing organizational structure. Cell Coordinators led teams of CHWs and these coordinators were responsible for calculating resupply quantities,

collecting products from health centers and distributing them to the team (rather than asking each CHW to visit the health facility). This redesign allowed health centers to fill orders from 10-15 Cell Coordinators instead of over 100 CHWs each month.

- › EXAMPLE: In Malawi, cStock—a Rapid SMS reporting system, coupled with a web-based performance management dashboard—was developed. CHWs sent monthly SMS messages with stock information which were used to calculate resupply quantities and send a report to facilities to prepare orders. CHWs were then notified by SMS when their orders were ready for pick up and confirmed quantities they received by sending another SMS. The dashboard allowed district-level managers to monitor supply situations and provide additional supervision as needed.

CHW capacity and quality improvement

- › CHWs and managers were trained on supply chain fundamentals, and incentives were introduced to help improve motivation of volunteer CHWs.
- › Quality Improvement teams were formed to reinforce use of resupply procedures and help CHWs identify and problem solve supply chain challenges.
- › EXAMPLE: In Malawi, District Product Availability Teams—consisting of CHWs and health center and district staff—reviewed monthly cStock data against performance goals. The teams recognized and rewarded improved supply chain performance.
- › EXAMPLE: In Rwanda, quarterly incentive payments for CHWs were provided building on the existing performance-based finance system. Incentives were paid out based on regular CHW attendance at meetings, consistent reporting, and good inventory control practices.

National quantification and coordination

- › Support was provided to strengthen national quantification and coordination using CHW logistics data to ensure sufficient supply was available to meet needs at the community level.

Lessons Learned

- A demand-based resupply system helps to ensure sustained product availability at the community level. Having reliable consumption data at the community level gave CHWs the power to manage their stocks and receive resupply based on the information they provided.
- Supply chain management tasks and procedures should be clearly communicated to all levels—to CHWs as well as their supervisors and resupply points.

- Automating data collection provides more accurate and timely information for more responsive and informed decision making at all levels and allows data to be used for quantification at the national level.
- A standard resupply system for restocking should be established and documented.
- Structures and processes that promote teamwork and motivation help make a demand-based resupply system sustainable.
- Coordination and planning at the central level is crucial.

Results

- **In Malawi, the percentage of CHWs reporting logistics data monthly increased from 43% to more than 80%. 90% of drug store in-charges used stock to inform resupply quantities and 56% of CHW supervisors used cStock data for performance monitoring.**
- **In Rwanda, the intervention group had 22% greater product availability than the comparison group. In Malawi, CHWs in districts using cStock had 14% fewer stock outs or low stocks.**

Resources

SC4CCM, [Quantification Guide to Forecasting and Supply Planning for Procurement](#)

CCM Taskforce, [Quantification for CCM Webinar](#)

SC4CCM, [Manager's Tool to Improving Community Health Supply Chains](#)

SC4CCM, [Resupply tools \(stock card, resupply worksheet, and magic calculator\)](#)

CCM Taskforce, [Supply Chain Management Subgroup resources](#)

SC4CCM, [Strengthening Supply Chains at the Community Level: Findings from the SC4CCM Project in Malawi, Rwanda, and Ethiopia. Dec 2014](#)



f. Introducing New Suppliers to the Local Market

Background: In 2005, there were few high-quality suppliers of zinc and Lo-ORS products on the market in Africa and the high price of existing products limited availability. Although the potential market for zinc and ORS is large, the upfront time and financial investments required to introduce new products without proven demand presented a strong barrier to supplier entry.



Approach

To improve the local zinc and ORS market, partners—Abt, CHAI, ColaLife, FHI 360, United States Pharmacopoeia (USP), USAID—have worked with manufacturers to catalyze market growth.

Landscape assessment

- › Local manufacturers and importers were identified for potential engagement based on criteria such as interest, production capacity, distribution model, promotional reach, product fit, market position, and business health.
- › When local manufacturing was not feasible or optimal, first-line distributors were linked to low-cost, quality international suppliers for importation into the country.

The ‘business case’

- › Market intelligence helped to improve predictability of local demand for suppliers. This included robust market

forecasts highlighting realistic estimates of demand based on inputs such as diarrhea prevalence, care-seeking behavior, and current and expected utilization in public and private sectors.

- › Information from government partners (e.g., inclusion of zinc and ORS in national policies and planned orders) also assured suppliers of future public sector procurement.
- › EXAMPLE: POUZN (AED) hosted one-on-one meetings with high-level decision makers of local pharmaceutical companies and presented dossiers that included a summary of clinical research on zinc use, the latest WHO/UNICEF treatment guidelines, details on the manufacturing process for zinc tablets and syrups, and projections of potential zinc demand.

Supplier forum

- › Forums generated interest in the market potential for zinc and ORS among manufacturers, encouraging them to enter the market and highlighting MoH and public sector commitment.
- › EXAMPLE: In Uganda, CHAI brought together senior executives from all major manufacturers three times a year to review market updates and discuss strategies for scaling up essential commodities. The group discussed regulatory and policy updates, market data for zinc and ORS, MoH and NGO plans for demand generation activities, and innovations (e.g., improving sales force effectiveness through Customer Relationship tools).

Price negotiations

- › Various data points (e.g., willingness-to-pay data, supply chain margins, antibiotic prices) were triangulated to help develop theoretical ranges for price negotiations with suppliers.

- › Cost reductions were achieved by identifying opportunities to source cheaper active pharmaceutical ingredients, optimize formulations, or lower packaging costs.
- › **EXAMPLE:** In Nigeria, CHAI worked with a local manufacturer to propose adoption of cheaper raw materials and changes in packaging options (e.g., increasing the number of 1 liter (1-L) ORS sachets from three to 10 sachets per box for private informal providers). This led to a 20% cost reduction.

Technical assistance to meet quality standards

- › Specialist partners—such as USP—worked with manufacturers, offering support on technical gap analysis, production quality testing, and identification of areas requiring improvement to achieve local or international Good Manufacturing Practice certification.
- › **EXAMPLE:** In Tanzania, POUZN (AED) engaged with local manufacturer Shelys Pharmaceutical and provided technical assistance through USP and other technical experts to assess Shelys manufacturing and QA process. Shelys invested in the necessary upgrades and became the first African manufacturer approved by WHO/UNICEF to provide zinc across the continent.
- › **EXAMPLE:** In Zambia, ColaLife shared findings from consumer research and willingness-to-pay data with local manufacturer Pharmanova to produce a specially designed zinc and ORS co-pack kit (ORSZ). ColaLife also introduced Pharmanova to new market partners.

Product registration

- › Product registration timelines were accelerated by working closely with NDRAs. Areas of improvement included clear communication of standard specifications and registration requirements to manufacturer applicants, development of standard monographs, and designation of dedicated desk officers to help prioritize zinc and ORS dossiers.
- › **EXAMPLE:** POUZN (AED, Abt) assisted companies to advocate for government fast-track registration for new zinc products in India, Indonesia, Nepal, and Tanzania, which accelerated the approval process by 18 months, on average.

Lessons Learned

- While affordability is critical for product uptake, it is important to address other supply-side barriers (e.g., availability, suboptimal packaging, and quality) to ensure significant improvements.
- Zinc can be produced without technology transfer—the strategy pursued in early years in Bangladesh (see Section V) to improve supply. Local manufacturers, often with support

from partners, can achieve good standards of quality and are well equipped to distribute products through their existing supply chain.

- Clear signals of potential public sector demand (e.g., inclusion of zinc and ORS in government tenders) were critical for attracting new suppliers to the local market.
- During price negotiations, partners can help manufacturers align business interests (e.g., improving sales) with public health impact. Given the considerable investment required to launch a new product, manufacturers are interested in achieving a reasonable return on investment.
- Additional efforts are needed to ensure that price reductions achieved at import or ‘ex-factory’ (from the factory to the distributor) levels reach consumers at the retail level.
- Partners and donors with commodity financing should engage with local manufacturers on potential procurement opportunities for high-quality, affordable zinc and ORS. Financing and long-term commodity subsidization from external sources should be carefully considered as to not undermine the private market where local supply is available.
- Additional interventions may be explored to further improve affordability in the private market. For example, this may include working with the MoH to establish a national Recommended Retail Price or similar price guidance mechanism that aims to bring down treatment cost to consumers.

Results

- **With support from partners, more than 20 new ORS, zinc, and co-pack products have been introduced in local markets in Africa since 2005.**
- **The increased competition has led to significant reductions in wholesale price—for example, by 77% in Nigeria after the introduction of a number of new zinc and ORS products to the local market.**

Related Resources

Zinc Task Force, Supplies & Commodities Resources – list of zinc suppliers and product monographs

MSH Drug Price Indicator Guide



g. Expanding Distribution through Private Sector Partnerships

Background: The private sector is a major source of care for diarrhea—accounting for up to an estimated 70% of care-seeking in select Asian countries and 12-46% across African countries.²⁹ Zinc and ORS are often not available at the retail level and are perceived as low-demand, low-margin products. This results in limited investments in distribution to rural markets, where the highest number of children are dying from diarrhea.



Approach

Establishing partnerships with private sector actors along the supply chain—manufacturers, distributors, wholesalers, and retailers—can help stimulate increased rural distribution. Partners including CHAI, ColaLife, FHI 360, and SHOPS have engaged suppliers to help improve private sector availability.

Private market assessment

- › Given different local contexts, a detailed assessment of the private market landscape in each country was completed, including a mapping of major suppliers/distributors, the distribution process (e.g., the number of players in the chain, margins, etc.), and key barriers to availability.
- › While some systems are integrated, with suppliers operating distribution networks, wholesalers and third-party contractors were important players to target in others. Common problems included the lack of supply chains reaching rural areas, a large number of intermediaries, inefficiencies in existing supply chains, and poor quality products.
- › EXAMPLE: In India, independent private companies operate at every level of the supply chain, limiting the potential profitability of low-margin products like zinc and ORS in rural areas.
- › EXAMPLE: In Nigeria, commodities followed fragmented distribution channels to a multitude of retailers, resulting in high variability in price and inefficient penetration into rural markets.

Wholesaler and retailer activation

- › Wholesalers are an existing distribution channel that can be leveraged as a cost-effective option to push zinc and ORS to lower levels. Detailers were placed at wholesale outlets to promote zinc and ORS sales for a time-limited period (4-6 weeks) to clients, including informal providers and retailers who regularly visited the wholesaler to restock products. This promotion included information-sharing as well as initial purchase incentives.
- › EXAMPLE: In Tanzania, POUZN (AED) aided Shelys Pharmaceuticals to “activate” wholesalers by providing 90 days of credit to each wholesaler for the first zinc supply to drug sellers. This effort was coordinated with detailing (e.g., a marketing technique used by pharmaceutical companies to educate physicians about products) to retailers and providers by Shelys’ representatives to generate demand for new supplies for and from drug sellers.
- › EXAMPLE: In Nigeria, SHOPS implemented semi-annual, time-limited (2 weeks) activation efforts whereby specially employed detailers visited every hospital, clinic, pharmacy, and retail drug shop in focal states. Each was “branded”

with promotional materials and offered zinc and ORS for sale at a discounted price.

- › EXAMPLE: In Zambia, ColaLife incentivized existing micro-retailers to buy the new ORSZ, by training them on its benefits, distributing discount vouchers to rural customers via CHWs for a time-limited period, and running health center- and community-based awareness sessions.
- › EXAMPLE: In Tanzania, a network of Accredited Drug Dispensing Outlets (ADDOs) was created. Since CHWs in the country neither stock medicines nor provide treatment services, the ADDOs were established to safely stock products like zinc and ORS. As part of establishing the ADDO network, certain wholesalers were approved as ADDO-specific suppliers to ensure quality products.

New last-mile distribution businesses

- › In areas where existing distribution channels were weak, local NGOs and entrepreneurs were used to create new last-mile distribution. With short-term financial support, these partners built field forces to regularly detail rural providers with product information and distribute stock. Over time, these field forces became self-sustaining by expanding their scope to a broader basket of goods and using profits to support ongoing operating costs.
- › EXAMPLE: POUZN (AED and Abt) partnered with local groups, professional associations, and NGOs with existing cadres of community-based distributors to promote and sell zinc to caregivers in Benin, India, Indonesia, Madagascar, Nepal, and Pakistan.
- › EXAMPLE: DAZT (FHI 360) and CHAI employed field reps from pharmaceutical entrepreneurs who sold zinc and ORS to rural medical practitioners (RMPs) and chemists in India. The partners provided training and detailing materials but did not subsidize the product; the entrepreneurs were responsible for buying, selling, and managing their inventory. When providers realized the products’ benefits, many became regular users, regularly dispensing zinc and ORS for diarrhea cases in children.
- › EXAMPLE: In Madagascar, PSI strengthened the social marketing supply chain to supply zinc and ORS (among other commodities) to CHWs during the crisis. This system complemented the public sector system to assure availability of essential commodities for CHWs.

Marketing and distribution incentives

- › Local manufacturers were incentivized to integrate ORS and zinc and increase their investments in marketing and distribution.
- › EXAMPLE: POUZN (Abt) and SHOPS provided incentive grants to local manufacturers in Pakistan, Ghana, Kenya, Nigeria, and other countries to hire additional detailers,

conduct CME training for providers, produce marketing and point-of-sale (POS) materials, expand into rural markets, and air branded radio advertisements.

- › **EXAMPLE:** DAZT (FHI 360) signed a matching grant with manufacturers to increase marketing and accelerate introductions of zinc and ORS in rural markets. Once the products reached a determined level of sales, the program tapered off and marketing became self-sustained.
- › **EXAMPLE:** ColaLife provided a time-limited investment to local manufacturer Pharmanova to adopt and start producing the new designs for ORSZ kits. ColaLife later provided an enhanced design and brand name (Kit Yamoyo) for their use long-term in the Zambian market.

Lessons Learned

- Supply chains are organic and complex, thus it is important to clearly understand the gaps and inefficiencies in an existing system at each level. For example, understanding how commonly used diarrhea treatment (e.g., antibiotics), OTC products (e.g., paracetamol), and other fast-moving consumer goods flow through the supply chain can help identify solutions for zinc/ORS distribution.
- Demand is the major driver of supply and should be part of any expanded distribution effort. Investments from implementing partners and donors in marketing and demand generation (e.g., mass media) helped to encourage increased efforts from supplier partners.
- It can be difficult to determine the optimal duration for detailing to change dispensing practices. However, key factors typically include the rate of change (of dispensing practices) resulting from continued detailing, the cost of continued detailing, and alternatives to create a similar change in dispensing.
- To transition to a self-sustaining basket-of-goods model, partners should shift promotion and distribution efforts from zinc and ORS alone to include other higher-volume products. Timing the transition is therefore important to ensure that market demand for zinc and ORS is mature enough to sustain high coverage.
- For new, last-mile distribution businesses as well as intermediaries, partners with strong business acumen, good management, and strategic product selection for the basket of goods have proven to be most economically viable.

Results

Partners have facilitated significant increases in zinc and ORS volumes and availability in the private sector:

- **SHOPS:**
In Ghana, over 5M treatments of zinc were sold nationally by program end (September 2015) compared to baseline (January 2012).
- **ColaLife:**
In two remote districts in Zambia, availability of ORSZ treatments increased in private shops which led to an increase in coverage from less than 1% to 45% over a 12-month period.³⁰
- **DAZT (FHI 360):**
In India—specifically in 12 districts of Uttar Pradesh—1.8M zinc treatments were sold in the final program year (representing nearly a 600% increase from baseline).
- **POUZN (FHI 360):**
In India, 5.5M zinc courses were sold by program end (mid-2010) compared to 905,000 zinc courses sold at baseline (end 2006). Volumes also increased in Indonesia and Tanzania from virtually no zinc (at baseline) to nearly 2M and 600,000 courses, respectively.
- **CHAI:**
Midline results in Nigeria have shown increases in availability of zinc (from 15% to 54%), ORS (from 80 to 84%), and co-pack (from 15% to 52%). In India, availability has also increased in Uttar Pradesh (from 39% to 50% for ORS and 7% to 29% for zinc) and in Gujarat (from 52% to 75% for ORS and 23% to 54% for zinc).

Resources

Private sector market assessment—NIGERIA

USAID Country Assessment Tool for Introduction of Zinc in the Clinical Management of Diarrhea—MADAGASCAR



h. Developing a High-Impact Demand Generation Strategy

Background: Poor care-seeking behavior and preferences for alternative treatments are key drivers for low demand in many countries. Specifically, most caregivers do not perceive diarrhea to be serious, and do not seek care until it is too late. While some caregivers are moderately aware of ORS, virtually none are familiar with zinc, and providers often prescribe antibiotics.



Approach

A demand generation strategy that is well-tailored to address local barriers can help improve awareness and usage. A high-quality strategy includes several key elements:

Situation analysis

- › Understanding both provider and caregiver knowledge, attitudes and practices helped to identify common beliefs, misconceptions, and barriers to zinc and ORS uptake.
- › An analysis of media consumption patterns (e.g., radio vs. TV penetration) or other communication channels helped to identify a high-impact channel mix for implementation.
- › EXAMPLE: PATH conducted research in several countries, which revealed key insights about how caregivers and providers perceived diarrhea treatment (see Box 1).
- › EXAMPLE: In Zambia, ColaLife conducted community-level awareness sessions, which revealed the benefits of promoting zinc tablets when co-packaged with ORS. Although zinc was less well known, the ‘pills’ were seen as a more ‘medicinal’ component alongside ORS.

Identification of target audience and specific goals

- › Caregivers and providers were targeted with messages to improve knowledge about the purpose of zinc and ORS and their proper use. The strategy should define both primary and influencing target audiences, informed by market research.
- › The primary audience typically includes caregivers and the providers from whom they seek care (e.g., CHWs, drug shops, higher level facilities). The influencing audience may include clinical providers, fathers or male partners of caregivers, extended family members, or in-laws.
- › EXAMPLE: Based on KAP research conducted for providers, PSI uses a quantitative research methodology to develop detailed profiles of provider archetypes, which informs the overall marketing planning process.

Development of key messages

- › Key messages outlined the core information to be communicated to target audiences and incorporate local terminology and symbolism.
- › Simple (ideally addressing a single key barrier) and consistent messages disseminated across communication channels (TV, radio, detailing, etc.) and across partners helped to maximize effectiveness.

Selection of activities and interventions

- › Decisions were made around which messages were disseminated and through which channels and partners.

BOX 1. Findings from PATH research in India, Kenya, Zambia, Nigeria, and Burkina Faso

From 2010-2014, PATH conducted more than 3,500 quantitative and 1,500 qualitative surveys with caregivers and providers in Kenya, India, Zambia, Nigeria, and Burkina Faso. Common findings across countries included:

- Preventing the condition from getting worse, restoring the child’s energy, and stopping diarrhea are key objectives for most mothers in managing diarrhea.
- Dual therapy is the norm. The majority of caregivers and providers reported using/recommending both antibiotics and ORS.
- Both ORS users and non-users view antibiotics as the strongest medicine.
- Most caregivers are unsure of the amount of ORS to give to their child.
- Rehydration of a small child is a laborious and time-consuming effort.

Source: Zwisler G., Simpson E., Moodley M. Treatment of diarrhea in young children: results from surveys on the perception and use of oral rehydration solutions, antibiotics, and other therapies in India and Kenya. 2013. Journal of Glob Health; 3(1): 1-14.

Complementary communications strategies and multiple touch points may be necessary to raise awareness of and teach caregivers how to use zinc and ORS.

- › These activities were also accompanied by high-quality materials and print resources, updated to reflect the latest recommendations when needed.
- › EXAMPLE: POUZN (Abt) and SHOPS rolled out mass media campaigns combined with interpersonal communication activities to promote the use of zinc with ORS as a new diarrhea treatment in focal countries. For SHOPS, household survey data in Ghana revealed a strong correlation between having seen or heard a zinc-specific message and correct use of zinc and ORS.

Monitoring and evaluation

- › Measuring the impact of a demand generation campaign should include pre-testing of creative content as well as evaluating the impact of specific messages and use

of different communication channels on knowledge, attitudes, and practices.

Lessons Learned

- M&E activities should be continuous throughout the course of implementation—and inform appropriate adjustments to the strategy as needed—to achieve maximum impact.
- Simple messages are best communicated through mass media while more complex messages (e.g., how to mix ORS, dosing, etc.) should be communicated through interpersonal communication.

BOX 2. Reaching Caregivers at Scale in Bangladesh

In 1979, BRAC launched a decade-long project to target mothers directly, rather than working through the health system. The strategy started as a pilot in two villages and was later scaled nationally, reaching 12 million mothers. Key components of the program included:

- **Extensive volunteer network:** 80,000 community health promotion volunteers, each covering 300 households with comprehensive services.
- **Key messages:** A ‘7-point message’ included the key messages needed to teach caregivers how to correctly prepare and administer ORT in the home. Messages were refined as findings from research became available to better understand reasons behind high awareness, but low use of ORT.
- **Household demonstrations:** During 20-30 minute demonstrations, BRAC trained and employed teams of female health workers to teach mothers how to prepare ORT using pictures and other print materials. Each volunteer was supervised by a higher-level worker.
- **Key influencers:** Demonstrations were supplemented by additional outreach to key influencers of mothers, including males in the community, students, teachers, and village healers.
- **Monitoring and incentives:** Field staff visited 10% of households following the demonstrations to evaluate how well caregivers remembered the 7-point message. Results were used to determine monthly remuneration of female health workers.

Source: Chowdhury A. M., Karim F., Sarkar, S. K., et al. The status of ORT in Bangladesh: how widely is it used? *Health Policy Plann.* 1997. 12(1): 58-66.

- Key messages should stress reasons for taking zinc for the full 10-14 day treatment course. For example, this can be accomplished by adding clear messaging on zinc blister packs.
- When resources are limited, activities and specific communication channels should be priorities based on desired reach and frequency. For example, existing community structures and networks should be leveraged where possible.

Results

Partners have designed and implemented high-quality demand generation strategies informed by extensive formative research to improve awareness, knowledge and use of zinc and ORS. Specific examples include:

- **In Bangladesh, BRAC taught mothers how to mix homemade solution (see Box 2). SMC’s marketing campaign supplemented these efforts using a wide range of media, including TV. For zinc, SUZY supported TV and radio efforts and messaging emphasized the importance of combining zinc with ORS rather than using zinc as a replacement. This strategy led to significant and sustained increases in awareness.**
- **In Nepal, POUZN (Abt and PSI) used radio and TV to disseminate messages about appropriate diarrhea treatment. Caregivers who heard these messages were four times more likely to use zinc when their child had diarrhea, give ORS and zinc together, and provide zinc for the full 10 days.**
- **In Senegal, MI supported the MoH to launch a national, multi-media campaign to increase zinc and ORS use. The campaign included three radio spots, a traditional song, and one TV spot in local languages. After eight months of implementation, care-seeking for diarrhea outside of the home increased from 42% (baseline) to 52% (endline). In addition, awareness of ORS and zinc increased among non-users from 18% to 51% for ORS and 5% to 32% for zinc.**

Resources

Situation analysis: (1) SHOPS BCC Evidence for Diarrhea and Pneumonia; (2) PSI Qualitative Research FoQus Framework; (3) JHU Health Communication Capacity Collaborative (HC3) situation analysis example for ORS and Zinc

Strategy development: (1) JHU HC3 adaptable communication strategy; (2) JHU HC3 implementation ‘iKit’; (3) PSI Delta Model



i. Building Capacity and Skills of Frontline Health Workers

Background: Frontline workers—namely CHWs, retailers, and drug shops—are often the first and only point of care for child diarrhea, particularly in remote areas. Yet, the limited reach of frontline workers and inadequate knowledge, skills, and motivation are among the major barriers to timely delivery and uptake of zinc and ORS.



Approach

With appropriate training and supervision supported by partners, frontline workers were empowered to identify and correctly treat childhood diarrhea.

Training and guideline dissemination

- › Key training modules in country (e.g., iCCM) were regularly updated with evidence as reflected in the latest international treatment guidelines for child diarrhea, for example to ensure inclusion of zinc and ORS as recommended treatment. Where relevant, existing trainings (e.g., vaccines, malaria) were leveraged to incorporate key messages for diarrhea.
- › Public sector trainings were complemented by outreach to key influencers of frontline workers such as professional medical associations and regulatory bodies.
- › EXAMPLE: In Zimbabwe, MCHIP/USAID leveraged national policy authorizing treatment of malaria by village health workers to strengthen diarrhea management at community level.
- › EXAMPLE: In Pakistan, India, Indonesia, Madagascar, Nepal, Tanzania, and Pakistan, POUZN (Abt and AED) worked with medical associations to conduct sensitization sessions for clinicians, pharmacists and key pediatric opinion leaders.

SHOPS also worked through regulatory agencies in Ghana to reach and train private sector providers.

- › EXAMPLE: In Kenya, MI worked with the national training institutes for nurses and clinical officers (cadres that treat over 95% of all children) to introduce a new pre-service curriculum that reflected the WHO/UNICEF treatment guidelines for diarrhea with zinc and ORS.

Training tools

- › To supplement existing training modules, additional relevant materials such as picture-based manuals for low-literacy populations, audio-visual aids, and role-playing scenarios were used.
- › EXAMPLE: In South Sudan, Save the Children developed a training video to demonstrate real examples of childhood illnesses through scripted role plays as well as practice exercises. World Vision also developed a set of tools to aid CHWs in appropriate diarrhea management including flipcharts, recording, and referral forms.
- › EXAMPLE: In Uganda and Nigeria, SHOPS and CHAI worked with MoHs, manufacturers, and local NGOs to customize global adaptable tools for zinc and ORS, developed by the Diarrhea & Pneumonia Working Group, to support a range of training activities for private providers on zinc and ORS. This included job aids, training presentations, and videos.

BOX 1. Integrated Community Case Management

Integrated community case management (iCCM) is a strategy supported by UNICEF and WHO that centers on CHWs to increase access to quality care, including treatment, for children with malaria, pneumonia, and diarrhea, especially in hard-to-reach areas. Specifically, CHWs are trained, equipped, and supported to deliver commodities such as zinc and ORS. In addition to CHW training and supervision, other key components of the iCCM approach include supportive policies, supply chain management, communication and social mobilization, and M&E.

Studies of iCCM programs have found positive outcomes:

- **Improved quality of care:** In Ethiopia, health extension workers trained on iCCM were more successful at completing key clinical assessments and correctly classifying children with iCCM-covered illnesses than higher-level health workers.³¹
- **Timely and appropriate care:** In Zambia, care-seeking behavior to CHWs for diarrhea significantly increased following introduction of iCCM.³⁵ In South Sudan, 75% of mothers sought care for their child's diarrhea within 24 hours in intervention areas where CHWs were trained compared to 24% in comparison areas.³⁶
- **Improved treatment access and health outcomes:** In Rwanda, children receiving diarrhea treatment at the community level increased significantly while health facility use declined by 15% after iCCM implementation. The total under-5 mortality rate declined by 38% after nationwide introduction of iCCM between 2008 and 2011.³⁷

Supportive supervision and quality assurance

- › Building on formal training, supportive supervision improved knowledge and skills of frontline workers and focused on monitoring performance toward specific goals. Specifically, supervisors (most often health facility personnel) conducted routine visits to frontline workers or patient homes, which allowed them to better understand challenges that providers faced, address specific issues, and gather feedback from caregivers on services they received.
- › EXAMPLE: In Ghana, Nigeria, and Uganda, SHOPS developed a smart phone-based supportive supervision tool to aid inspectors in following up on trainings and monitoring diarrhea management practices in retail drug outlets. This tool also facilitated the delivery of on-the-job training to any staff who had not participated in the formal training sessions.
- › EXAMPLE: In 10 focal countries in Asia and Africa, MI worked with existing supervision structures and cadres to improve the quality of visits and monitoring as well as develop tools (e.g., checklists, training cards, teaching aids).
- › EXAMPLE: In Kenya, Mali, Rwanda, and Zimbabwe, MCHIP rolled out a mentorship program in which trained supervisors coached staff on applying the IMCI/iCCM Guidelines for treatment of diarrhea.
- › EXAMPLE: In 12 focal countries in Asia and Africa, Save the Children provided leadership and technical support to MoH for iCCM trainings (including diarrhea case management) by supporting supervision and overall technical quality.
- › EXAMPLE: In Uganda, MSH established the Supervision, Performance Assessment, and Recognition Strategy (SPARS), in which district-level supervisors worked to improve capacity of health workers to manage medicines through regular facility visits. The supervisors measured progress using a standardized assessment tool which included 25 indicators covering store management, stock management, prescribing and dispensing quality, and reporting quality.

Data utilization and accountability

- › Data gathered through supportive supervision was utilized to follow up with frontline workers in need of additional training. Data was also aggregated for use at national, state, and district levels to understand program issues and suggest corrective actions.

Certification

- › Accreditation programs, supported by governments and regulatory authorities, were rolled out particularly in countries with a high presence of private frontline providers

to help improve their skills and prescribing practices and ensure they were stocking high-quality zinc and ORS.

- › EXAMPLE: In Tanzania, MSH worked to upgrade ADDOs—informal drug shops—and brought them into the official regulatory system through a certification program.

Lessons Learned

- Trainings (including refresher trainings) should be integrated into existing platforms (e.g., iCCM, IMCI) to maximize use of limited resources.
- Data from CHW trainings should be available and monitored at various levels (facility, district, and higher levels) and integrated within national information systems to inform key decisions and program improvements.
- While training is an important component of iCCM, a well-functioning supply chain is also needed to ensure that CHWs receive the stock they need to deliver services; therefore, management of medicines and supply chain responsibilities should be an integral part of training and supervision to help prevent stock out, which are a common problem in many countries.
- Task-shifting distribution of ORS and zinc to frontline workers increases their level of legitimacy with caregivers.
- Working through national regulatory agencies to train, accredit and supervise private sector retailers is a cost-effective approach. This has allowed programs to build on existing regulatory structures while creating a more collaborative relationship between inspectors and frontline private providers.
- Extensive and ongoing supportive supervision of providers is necessary to ensure sustained knowledge and skills, quality of services, and adherence to protocols and record-keeping. This is especially true with private providers, as they are more likely to deviate from the standard of care (e.g., overprescribe medications).

Results

A number of partners have supported large-scale trainings and supportive supervision to improve awareness and prescribing practices among frontline workers. Key examples include:

- **In Ethiopia, between 2007 and 2013, UNICEF supported the government to train more than 27,000 health extension workers (HEWs)—representing 80% of HEWs in the country—on iCCM which resulted in correct treatment for 79% of children with diarrhea³¹ (see Box 1). In Niger, 2,560 Agents de Sante Communautaire (ASC) received six-month iCCM trainings. The ASCs achieved similar**

levels of correct classification and treatment for diarrhea compared to first-line health facilities.

- In Tanzania, MSH accredited more than 9,000 shops and trained more than 19,000 ADDO dispensers and 3,000 district and ward inspectors. 84% of selected ADDO dispensers knew the correct protocol for treating simple diarrhea while 95% knew how to manage bloody diarrhea.³² In Uganda, the SPARS strategy led to improvements in zinc and ORS coverage from 64% to 84% and decreases in cases treated inappropriately with antibiotics from 41% to 21%. The Uganda MoH is planning to scale up the SPARS strategy nationwide to all public facilities in the country.
- In India (Uttar Pradesh and Gujarat), MI trained approximately 140,000 frontline workers (approximately 90% of total ASHAs and AWWs in these regions) over three years.³³ Overall, 66% and 86% of ASHAs were aware of the correct zinc dosage in UP and Gujarat, respectively.
- In South Sudan, World Vision provided iCCM and refresher trainings to 100 home health promoters in one district—5% of the national total—over three years. This led to an 85% increase in knowledge of appropriate treatment for childhood illnesses (including zinc and ORS) and an 89% increase in correct prescriptions. In

addition, ORS coverage among children with diarrhea increased three-fold.³⁴

- In Pakistan, Save the Children trained 714 lady health workers in one district (100% of the total) over three years. Care-seeking increased from 77% to 94% and zinc coverage increased from 6% to 43%.
- In Ghana, SHOPS trained 10,000 OTC medicine sellers over three years. As a result, 60% of medicine sellers recommended zinc and only 9% recommended an antibiotic along with zinc and ORS (a decrease from 46% at baseline) and 70% were carrying zinc in their shops.

Resources

Global Zinc-ORS adaptable tools

UNCoLSC ORS/Zinc Toolkit for implementing health services

CCM Central, Tools for CHW supervisors



j. Optimizing Packaging of Zinc and ORS Products

Background: When used as recommended, zinc and ORS are highly effective treatments for diarrhea. Product packaging and presentation can strongly influence caregiver appeal and adherence and should be designed or updated accordingly.



Approach

To help improve product uptake, partners such as Abt, CHAI, ColaLife, PATH, and PSI have identified and facilitated adoption of optimal product presentations and packaging.

Caregiver market research

- › Caregivers and providers were interviewed to better understand the top local barriers to correct administration, willingness to pay, and end user acceptance for potential new concepts.
- › EXAMPLE: ColaLife interviewed 82 caregivers in rural Zambia during a year-long trial and found that caregivers had no standard way of measuring 1-L of water and had a strong preference for more appealing branding. Researchers also found that standard 1-L ORS sachets were appropriate for facility use, but too large for household use because it was often more than could be consumed by a child in 24 hours.^{38, 30}
- › EXAMPLE: PATH conducted market research with more than 2,000 caregivers and 500 pharmacy staff in India and Kenya also found that 1 liter of ORS was too much liquid for a child to consume, and there was often leftover that went to waste. Dissatisfaction with the ORS taste was more common in Kenya.³⁹
- › EXAMPLE: CHAI conducted focus group research with 119 providers and 555 caregivers in India, Uganda, and Nigeria and found that key barriers included poor taste of unflavored products, cumbersome and inaccurate preparation, and ORS wastage. Low awareness of ORS and zinc as dual therapy and poor compliance to zinc were also cited.⁴⁰

Concept/new product design

- › New concepts that addressed caregiver preferences were tested to identify the most optimal products. This included incorporating elements such as changes in pack design and pictorial instructions.
- › For new products, iterations on initial design were made based on feedback from the field to support further introduction at scale.
- › EXAMPLE: PSI designed the new diarrhea treatment kit OraselKIT® (two sachets of ORS, one blister pack of zinc, and instructional leaflet) for use in 13 countries. The package contents, logo, and insert were based on information collected through formative research.
- › EXAMPLE: ColaLife developed the Kit Yamoyo (“Kit of Life”) based on preferences of Zambian caregivers. The new package consisted of eight orange-flavored ORS sachets in smaller sizes (200mL), 10 zinc dispersible tablets, and soap. The packaging also served as a measurement vessel to facilitate correct ORS preparation. Following the pilot’s evaluation, ColaLife is refining the design to include four (instead of eight) ORS sachets, locally produced zinc, and new packaging formats that will maintain the measurement function while reducing costs and increasing compliance to the combined zinc and ORS therapy.

Partner buy-in and adoption

- › Regulatory approval was secured from NDRAs and MoHs for new product presentations or optimal products (e.g., co-pack, smaller sachet sizes).
- › Health facility staff and CHWs were sensitized to new products and their benefits.

BOX 1. Considerations for Product Optimization — Cross-cutting Recommendations*

- Smaller ORS sachet sizes to eliminate wastage of ORS and water and reduce contamination risk
- Flavored ORS and taste-masked zinc for improved palatability
- More attractive pack designs to increase caregiver appeal
- Kit packaging that can double as a measurement vessel
- Pictorial dosing instructions to facilitate correct dosing, mixing, and administration
- Co-packaged zinc and ORS to encourage purchase and use of products together

* As provided by ColaLife, CHAI, and PATH. Specific caregiver preferences should be evaluated by country to identify the most optimal products and presentations.

- › Local manufacturers were encouraged to adopt recommendations on improved product packaging and design.
- › EXAMPLE: In Myanmar, PSI conducted trainings for retailers and primary health providers on the new OraselKIT®. By the end of the session, providers were able to name the benefits of the product, the complete contents of the kit, and prepare the solution.
- › EXAMPLE: In Zambia, ColaLife secured approval from MoH and the Regulatory Authority for smaller ORS sachets (200mL) and the new Kit Yamoyo. They also convinced a local manufacturer to adopt the new kit and smaller sachet as well as new packaging that incorporated strong messaging (e.g., zinc for 10 days).
- › EXAMPLE: CHAI worked with Governments and local manufacturers of India, Uganda, and Nigeria to adopt smaller sachet sizes (200mL) and more attractive packaging designs with improved pictorial dosing instructions.

Lessons Learned

- The primary focus in new product innovation should be to deliver on caregiver needs based on actual evidence gathered from country-specific market research (rather than on assumptions of what caregivers ‘want’).
- When introducing innovation in product design or packaging, it is also important to ensure changes are complemented by improvements in distribution and geographic accessibility, appropriate regulatory approvals (e.g., registration, OTC status), and buy-in from key stakeholders (e.g., MoH, NDRA, local manufacturers) to maximize uptake.

Results

Improved product packaging and presentation have led to improvements in correct administration and caregiver acceptance. For example, this was demonstrated in the ColaLife trial with the introduction of the new Kit Yamoyo:

- **Users of Kit Yamoyo prepared ORS in the correct concentration 93% of the time while users of the standard 1-L sachet prepared it in the correct concentration only 60% of the time.**
- **Caregivers who used four 200mL sachets treated the child for longer (3.55 days) than those who used two 1-L sachets (2.75 days).**
- **Caregivers who prepared ORS correctly were 2.36 times more likely to perceive it as an effective treatment compared to caregivers that did not prepare the solution to the correct concentration.**

Resources

ColaLife resources on product design and functionality, distribution, marketing and voucher use, training, and evidence

CHAI, Optimal Zinc Product Presentations and Improvements—Research and Recommendations

v. Achieving Success at Scale: Bangladesh

To achieve large-scale increases in zinc and ORS scale-up, a multi-pronged approach—that addresses all four focal areas—is needed. The success of such an approach has been demonstrated in Bangladesh.

APPROACH AND RESULTS⁴¹

Key activities were implemented to address barriers to scale-up in both public and private sectors (see Figures 5.1 and 5.2). SUZY—implemented by icddr,b—helped to accelerate progress on zinc scale-up. Partnerships with the government, NGOs, and the private sector were also critical factors to success. As a result, Bangladesh has the world’s highest coverage rates of ORS (77%) and zinc (44%) (see Figure 5.3).

Lessons learned

- Strong political will from the Government of Bangladesh, including a long-term commitment to promote ORS and child health was critical. Locally generated evidence of safety and efficacy for both ORS and zinc proved influential in securing government support for scale-up.
- Extensive formative research, which identified gaps in knowledge and provided a deep understanding of consumer attitudes and behavior, shaped the design of SUZY and other national rollout efforts.
- Large-scale and long-term awareness-raising (including an annual media spend of US\$ 0.5 to 1M over three decades) helped to embed ORS in the public consciousness. Supportive and consistent messaging about ORS from all parties maximized impact.
- Targeting improvements beyond the public sector were critical. Engaging the private sector, by far the most widely used service in the country, provided an opportunity to embed sustainable practices.
- BRAC helped to ensure ORS was seen very early on as a ‘domestic/household’ product rather than a ‘medical’ one and SMC targeted users to stimulate demand that could be met through the existing retail sector.
- Piloting and operational research allowed opportunities to adapt activities in light of progress.
- While important achievements were made throughout SUZY implementation, an extension of the program and additional time for roll out could have helped to achieve long-term goals (e.g., changing consumer behavior rather than just raising awareness).

FIGURE 5.1. TIMELINES OF ORS AND ZINC SCALE-UP

ORS SCALE-UP

- 1960 - 1979**
 - Research demonstrates effectiveness of ORS to prevent mortality
 - 1979: Year of the Child (UNESCO)
 - BRAC shifts to focus on diarrheal illness
- 1980 - 1984**
 - Government of Bangladesh forms national oral rehydration project
 - BRAC pilot projects for homemade ORS
 - BRAC first and second phase of ORS program
- 1985 - 1989**
 - BRAC final phase of ORS program
 - GoB forms Control of Diarrheal Disease (CDD) Program
- 1990 - 1994**
 - SMC partners with BRAC and CDD to produce pre-packaged ORS (ORSaline)
 - SMC conducts marketing campaigns
- 1995 - 1999**
 - Marketing and distribution of ORSaline widens
- 2000 - 2004**
 - WHO recommends Lo-ORS
 - SMC shifts to L-ORS ORSaline-N
 - SMC builds in-country manufacturing plant

ZINC SCALE-UP

- 2003**
 - SUZY project initiated
- 2004**
 - WHO recommends zinc for treatment
- 2005**
 - Nutriset (France) launches ZinCfant
 - SUZY project obtains ZinCfant patent
 - Media campaign begins
- 2006**
 - Production and distribution of Baby Zinc in Bangladesh by Acme Labs
- 2007**
 - US\$ 5M of Baby Zinc blister packs sold
 - OTC status granted
- 2008**
 - Baby Zinc distributed through bottled water distribution

Source: University of Washington GHS Program, ORS/Zinc Bangladesh Case Study, 2013.

FIGURE 5.2. THE MULTI-PRONGED APPROACH IN BANGLADESH



ENABLING ENVIRONMENT

- The Government strongly and consistently supported ORS scale-up. The National Pediatrics Association also endorsed the use of zinc for child diarrhea.
- As part of SUZY, two committees — involving the Government and NGO partners — were established to support scale up. Key outputs included revising national policies for zinc, including integrating zinc into national IMCI guidelines.
- Zinc and ORS are both included on Bangladesh’s EML and national standard treatment guidelines.
- Zinc OTC status was secured in 2007 and this allowed broad distribution through pharmacies and grocery stores and advertising on national TV.
- A change in government policy was also required to allow work with providers in the informal sector (village doctors).



SUPPLY AVAILABILITY

- The Government now regularly allocates budget for zinc and ORS commodities in its operational plan. In the public sector, UNICEF supported government distribution of zinc in its project areas.
- Approximately 30-40 ORS brands are now available in the country. By the late 1990s, 80% of users were purchasing ORS from grocery stores or pharmacies. Social Marketing Company (SMC) established an effective distribution system and manufacturing facility in 2004; total ORS volumes sold increased from 52 million sachets in 1997 to 300 million sachets in 2011.
- Initially, dispersible zinc was only being produced by French manufacturer Nutriset ('ZinCfant'). SUZY facilitated a tech transfer from Nutriset to Acme Labs to produce zinc dispersible tablets locally ('Baby Zinc'). Zinc was distributed through Acme's existing channels for bottled water and SMC also distributed product to chemist shops in 2008. In Year 1 of SUZY, US\$ 5 million units of zinc were sold exceeding initial forecast levels of 3 million. Several companies are now producing zinc in the country.
- SMC plans to introduce a zinc/ORS co-pack in 2016.



PROVIDER DEMAND

- SMC targeted private providers — including pharmacists, drug sellers, and rural unlicensed practitioners — for training as they were the main source of care for children with diarrhea. Acme Laboratories also dedicated sales representatives to promote zinc among providers. Information on zinc was also provided to shop sellers using the bottled water distribution system.
- Zinc and ORS use was integrated into IMCI guidelines and trainings for staff at public health facilities, 12,000 community clinics, and village doctors. The goal was to cascade best practice through the system, with informal providers likely to follow the practice of public providers.
- Zinc and ORS are both included on Bangladesh’s EML and NSTGs.



CAREGIVER DEMAND

- Demand generation for ORS included extensive marketing campaigns, supported by SMC, which spanned a wide range of media, including TV commercials. During the 1980s and 1990s, its annual marketing spend was US\$ 1 million and is now around US\$ 500,000.
- ORS was promoted by 100,000 BRAC volunteer community health workers, which created business opportunities to buy and sell ORS sachets.
- For zinc, SUZY also emphasized marketing to raise awareness, informed by extensive market research. Messages stressed the importance of combining zinc with ORS rather than using zinc as a replacement for ORS.

FIGURE 5.3. INCREASE IN ZINC AND ORS COVERAGE, 1990-2015



Source: Bangladesh Demographic & Health Survey



vi. Remaining Challenges

To eliminate preventable deaths from diarrhea, increased investments are needed to strengthen treatment, prevention, and protection. This calls for a coordinated action between child health-related programs to ensure that children access life-saving interventions like zinc and ORS. While treatment coverage rates are increasing, it is necessary to address the remaining challenges to accelerate progress. Foremost, diarrheal disease needs to remain a priority on both global and national levels to ensure the gains of the past decade are not lost. This includes stronger national coordination within MoHs and other stakeholders and increased resources from donors and partners. New efforts should align with existing national strategic frameworks and leverage existing structures (e.g., iCCM) where possible.⁴² Diarrhea management must be part and parcel of all national child health strategies and policies, and full rollout of rotavirus vaccine should be prioritized where not already achieved.

Supply systems that deliver zinc and ORS should be further strengthened, particularly to ensure products are available in the most remote areas where most children die from diarrhea and that price reductions achieved at the manufacturer level reach all the way to the consumer. Suppliers' interest will need to be maintained beyond the quick sales to urban areas and large institutional buyers (e.g., MoHs). Ongoing efforts are needed to test and implement interventions for improving availability through the private sector (e.g. incentives for intermediaries).

On the provider side, continued investments in training and behavior change must be complemented by supportive supervision and continuous monitoring and evaluation to improve the quality of care delivered. Partners and donors should enhance efforts to attract, train, and retain a competent work force.⁴² This includes making sure that providers manage diarrhea appropriately, such as advising caregivers about the importance of seeking care outside of the home.⁴³ Further research into the patient-provider interaction and specifically the "know-do" gap could produce insights into providers' resistance to prescribing the recommended treatments and inform the design of higher-impact behavior change interventions.

Building demand for zinc and ORS is an essential component of scale-up efforts. Over the past decade, improvements to product presentation and formulation (e.g., taste-masked and zinc dispersible tablets as well as better tasting ORS) have made the products easier to use and more appealing to consumers. In addition, new product development research suggests that reducing ORS volume can also help improve consumer acceptance. Additional product innovations that improve the effectiveness and/or appeal to consumers could

help to further accelerate scale up rates as well. Continued attention should be paid to ensure correct use—that caregivers administer ORS and the full 10-14 day regimen of zinc—to ensure maximum effectiveness.

Finally, it is important to invest in better systems for harmonization of the collection of key indicators for measuring zinc and ORS and ensuring the information is shared throughout the system.⁴²

While many of the strategies for increasing zinc and ORS coverage are well defined and simply need to be brought to scale, ongoing research is needed (see Box 6.1). In particular, better understanding of care-seeking behaviors, quality of care in the private sector, and effective demand generation strategies—all within the local context—are critical for designing effective programs. Questions also remain surrounding the optimal coverage levels and how to ensure adherence.

BOX 6.1. RESEARCH QUESTIONS

- What are the most effective delivery strategies to ensure that ORS and zinc are reaching those children who need it most (e.g., living in remote areas, suffering from dehydration)?
- What is the most effective way to teach providers and caregivers about benefits of zinc and ORS?
- What is the optimal treatment coverage level to target for program efforts (e.g., 50%, 75%, 100%)?
- What is the optimal definition for diarrhea? How many and which children are still dying from diarrhea – and what are main drivers?
- What is the optimal length and dosage of zinc supplementation to ensure full patient adherence?
- How can we support a 'wise use' of antibiotics for diarrhea?

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Diarrhea & Pneumonia Working Group

The Diarrhea & Pneumonia Working Group, co-chaired by UNICEF and the Clinton Health Access Initiative, Inc. aims to reduce mortality and morbidity from child diarrhea and pneumonia by accelerating treatment scale-up in 10 high-burden countries accounting for over 60% of the global burden—Bangladesh, the Democratic Republic of Congo, Ethiopia, India, Kenya, Niger, Nigeria, Pakistan, Tanzania, and Uganda. The Working Group consists of members from over 50 organizations working in child health representing the NGO, donor, and private sector and provides technical assistance, resource mobilization, and monitoring and evaluation support to organizations and governments working in the 10 countries.

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