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BANGLADESH ZINC CASE STUDY



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Disclaimer

Any opinions, findings, and conclusions or recommendations expressed in this material are those of the authors and Skye Gilbert, Saul Morris, and Shelby Wilson of the Bill & Melinda Gates Foundation and do not necessarily reflect the views of the key informants, thought partners or reviewers.



OVERVIEW

Status:	Sustained Success
Major players:	ICDDR,B, MoHFW, Acme Laboratories
Financing:	Bill & Melinda Gates Foundation, ICDDR,B funding, & sales of product
Price:	\$0.18 for one treatment course, free in public sector
Regulatory change:	Zinc prescription → Over-the-counter product

FIGURE 1: KEY FEATURES OF BANGLADESH ZINC SCALE-UP

Bangladesh's success with the ORS scale-up program in the 1980s created a platform for the launch of other successful programs, one of which was the SUZY (Scale Up of Zinc for Young children) program. The zinc scale-up program in Bangladesh has been classified as a sustained success. The collaborations between the government of Bangladesh, the ICDDR,B (International Center for Diarrheal Disease Research, Bangladesh), and the private sector have proven essential to SUZY, which aims to increase the distribution of therapeutic zinc for diarrheal illness (Figure 1). The program began in 2006 and is continuing to expand. Flexibility, regulatory change, and social marketing are some of the key components that have led to early successes of the program, although some limitations to zinc use still exist in Bangladesh.

TABLE 1: KEY CONTEXTUAL INFORMATION ABOUT BANGLADESH

Statistic	Estimate	Source
Total population	149 M	(GHO 2012)
Under 5 population	19 M	(UNICEF 2008)
Under 5 mortality rate	53 per 1,000 live births	(BDHS 2011)
Human Development Index (HDI) ranking	146 of 187 countries	(UNDP 2011)
Gross National Income (GNI) per capita	\$1529	(UNDP 2011)
Life expectancy	63 years	(UNICEF 2008)

CONTEXT

DEMOGRAPHICS

Bangladesh is a very densely-populated South Asian country with 149 million people as of 2010 (Table 1). The majority of Bangladeshis live in rural areas, with 29% living in urban areas. Like many developing countries, a large portion (34%) of the population is under 15 years of age (GHO 2012). Bangladesh is relatively homogenous, with ethnic Bengalis comprising 98% of the population. Approximately half of the population is employed by the agricultural sector, and half is employed by the service sector (World Bank 2012).

Despite development gains since 1980, the country remains in the bottom quartile of the UN development index. Although the economy is steadily strengthening, per capita GDP is \$1529 and almost 50% of the population is estimated to live on less than \$1.25 per day (UNDP 2011). Since 1990, the proportion of Bangladeshis with access to improved drinking water has remained stable at about 80%, while access to sanitation has increased by 15 percentage points, from 40% to about 55% (GHO 2012). The under-5 mortality rate in Bangladesh is currently 53 per 1,000 live births, which is a sharp decrease from the rate observed in the early 1990s of 87 per 1,000 live births. Bangladesh is likely to



achieve the Millennium Development Goal (MDG) 4 objective for reducing under-5 mortality to less than 48 per 1,000 live-births by the year 2015 (BDHS 2011).

Bangladesh has a low prevalence of HIV (1 case per 1,000 population), but a high prevalence of tuberculosis (411 per 100,000 population). In addition to pervasive respiratory and diarrheal illnesses, vector-borne diseases are common. The rural population in Bangladesh has suffered long periods of food insecurity. In the 1990s, the prevalence of chronic stunting was the highest in the world, with up to 77% of children considered to be stunted. The prevalence has been declining, however, and is currently around 43% (GHO 2012).

HEALTHCARE SYSTEM

Bangladesh emerged from a war for independence from Pakistan in 1971. In the early 1970s, the health sector of the government was developed with the goal of promoting population control. Currently, the healthcare system is a mix of public and private initiatives. The government healthcare system of Bangladesh is divided into 7 administrative regions and further subdivided into 64 districts. While door-to-door community health care was a cornerstone of the system for many years, in 1998 national health policy shifted towards a static service-point oriented system. Although initially the public sector provided the widest coverage, the private sector's hospitals now outnumber the public sector. Between 1991 and 2001, the number of private facilities increased from 280 to 712. In the same time period, government facilities increased only from 610 to 670 (WHO SEARO 2007). According to the 2007 DHS, only 17% of mothers first accessed care from the public sector if their child had diarrhea, while 83% accessed private healthcare. Forty percent of those who first accessed private healthcare accessed a pharmacy. Currently, 1% of GDP is spent on healthcare (World Bank 2012).

International and nongovernmental organizations play major roles in the healthcare system in Bangladesh. Integral to the zinc scale up is the ICDDR,B which has a strong reputation for conducting relevant public health research and guiding programs in Bangladesh. Located in Dhaka, the research center has carried out important studies on the infectious diseases affecting Bangladesh, and has responded to major outbreaks and helped with national campaigns. ICDDR,B is funded by a multitude of sources, including many donor countries, the Government of Bangladesh, UN specialized agencies, foundations, universities, research institutes and private sector organizations and companies (ICDDR,B 2012).

HEALTH SYSTEM SUCCESSES AND FAILURES

The immense improvements in child survival in Bangladesh have been extolled as a success of the recent structural renovations of the healthcare system. Many of the gains in survival have been attributed to the empowerment of women through education, employment, fertility reduction, and microfinance. Bangladesh has improved gender equality in education; girls now outnumber boys in primary and secondary school (UNICEF 2012). Integrated management of childhood illness (IMCI) practice centers, initiated in the 1990s, have been increasing in number and are improving the quality of care of children. DPT3 vaccination rates have hurredled from 1% in 1980 to 95% in 2010 (Figure 2), and approximately 88% of children receive vitamin A supplementation (BDHS 2011).



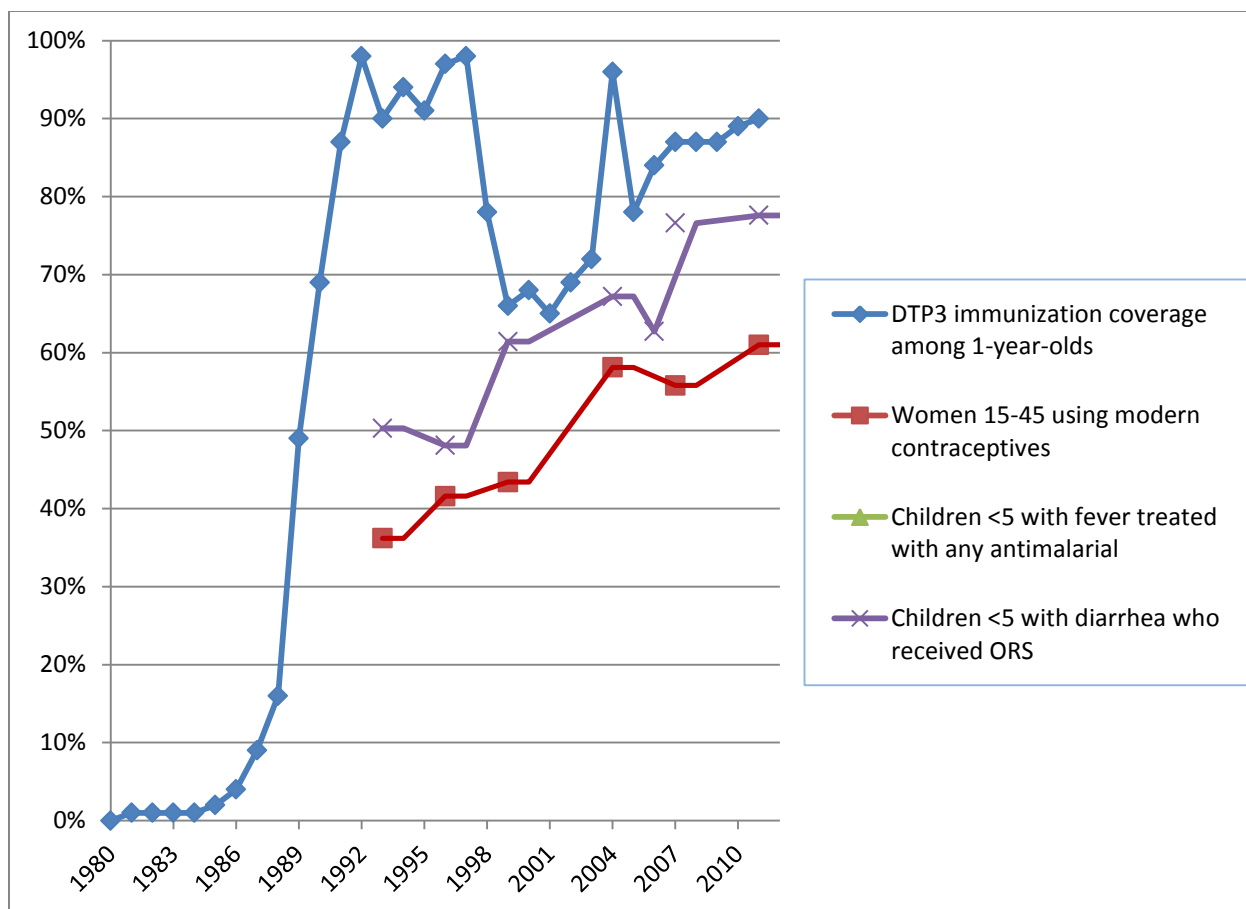


FIGURE 2: KEY HEALTH INDICATORS OF CHILD SURVIVAL IN BANGLADESH

The IMCI practice centers were launched in 1995 with the intention of clustering childhood illness interventions to avoid misdiagnoses. The program began in 24 care centers in Matlab Upazila (sub-district of about 400,000 people) and has expanded threefold since then (UNICEF 2012). A cluster randomized trial found that IMCI improved health-worker skills, health-system support, and family and community practices, which translated into increased care-seeking for illnesses in IMCI catchment areas (Arifeen, Hogue et al. 2009). In IMCI areas, exclusive breastfeeding was significantly increased (76% vs 65%, difference of differences 10.1%, 95% CI 2.65–17.62) and stunting was significantly decreased (difference of differences –7.33, 95% CI –13.83 to –0.83) (Arifeen, Hogue et al. 2009). The WHO also collaborated with the EHA (Emergency and Humanitarian Action) Unit to create an orientation package on IMCI for health workers in disaster situations (WHO 2003).

Despite the overall child survival gains, malnutrition continues to be a problem in Bangladesh. Although there has been a steady decline in chronic stunting, there are yearly fluctuations in acute wasting. The government provides nutrition support through an Area-Based Community Nutrition Program, but coverage is low and scale-up has progressed slowly (BDHS 2011; UNICEF 2012).

Because of geographic and environmental features, Bangladesh is subject to recurrent natural disasters like cyclones, floods, and droughts, which often lead to outbreaks of communicable diseases. The health system’s capacity to address these disasters has improved over time, but is still not considered sufficient to meet the needs of the population. Although there is a country-wide network of healthcare facilities,



management is centralized. When disasters occur, this centralization makes ensuring adequate supply of medicines and staff to distal health facilities difficult. Additionally, Bangladesh remains understaffed, with a nurse to population ratio of 0.14 per 1000 population (WHO 2007). Some of the holes left by the public healthcare system during emergencies are filled by local and international NGOs. Many of the NGOs operating under normal conditions, such as BRAC, have disaster response programs and have specifically allocated funds to emergency preparedness (Nagarajan 1998). The 2004-2009 National Plan of Action for Children, written by the Ministry of Women and Children Affairs, includes several commitments to providing preventive care and allocating resources for children in disaster areas (Ministry of Women and Children's Affairs 2005), underscoring the governmental commitment to action in times of natural disaster.

STATE OF ZINC DISTRIBUTION ACTIVITIES PRIOR TO SCALE-UP EFFORT

In the 1990s, research into zinc deficiency among children began to demonstrate that therapeutic zinc could shorten the duration of diarrhea and prevent future cases (Bhutta, Black et al. 1999). By the early 2000s, zinc as a therapy for diarrheal illness had been tested in several small clinical trial settings, with clear improvements in prognosis for children under five (Zinc Investigators Collaborative Group 2000). Much of the research on zinc was led by ICDDR,B in Bangladesh. Although ORS use was well established in Bangladesh by the late 1990s, there was concern early on that concurrent promotion of zinc would result in a decline in the use of ORS. Zinc is intended to supplement ORS because it reduces the duration of diarrhea, whereas ORS simply rehydrates patients after the loss of fluid during diarrhea. However, a study conducted in Bangladesh from 1998-2000 demonstrated that there would be no reduction in ORS use with the concurrent promotion of zinc; the zinc intervention group had higher rates of ORS use than the control group (Baqui, Black et al. 2004).

Also in 1998, the first large cluster randomized trial of zinc was conducted in Bangladesh by ICDDR,B in their Matlab Health Research Centre (Baqui, Black et al. 2002). In the intervention, community health workers trained mothers to administer zinc to children with diarrhea. Consistent with the clinical trials, investigators found 51% (95%CI 25%-94%) less mortality among children in the intervention clusters (Baqui, Black et al. 2002). At the same time, studies in other countries were also confirming the benefit of zinc in the community setting (Bhandari, Bahl et al. 2002). However, no national zinc programs had been initiated.

A study in 2003 estimated there was no zinc coverage at all in the 42 countries with the highest rates of childhood mortality, including Bangladesh (Jones, Stekete et al. 2003). Despite this, the scientific evidence for the benefit of zinc had built to a point where Bangladesh was prepared to implement a national scale-up. The Scaling Up Zinc for Young Children (SUZY) Project in Bangladesh was one of the first national effort to expand zinc treatment coverage for childhood diarrhea.



APPROACH TO SCALE-UP

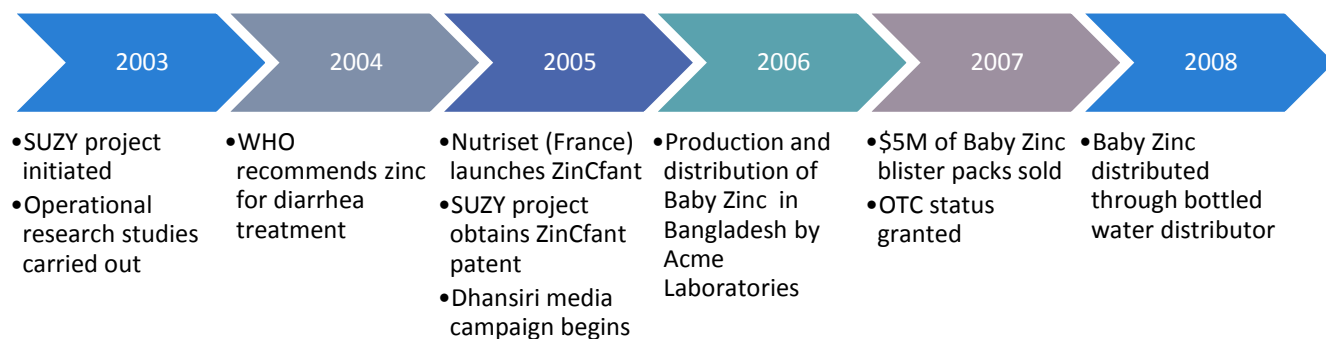


FIGURE 3: TIMELINE OF ZINC SCALE-UP

INITIAL STAGES

The SUZY project began in 2003, led by Charles Larson at ICDDR,B with partners in the Ministry of Health and Family Welfare (MOHFW) and Acme Laboratories. The SUZY Project also gained support from the Pediatrics Association, which gave validation to the zinc product. Although the SUZY project team decided to focus primarily on the private sector, the MOHFW created two governmental committees in support of the zinc scale up. The committees were able to write a policy that promoted the zinc program, which was approved in 2006. Additionally, they revised the national IMCI guidelines to include zinc therapy for diarrhea (Larson 2012).

The SUZY Project was financed through the ICDDR,B by public and private funding, with a large portion funded by the Bill & Melinda Gates Foundation from 2003 to 2008. Over the duration of the project, the total funding was approximately US \$8M, with about US\$1.5M used for promotion, US \$1.5M for research and US \$250,000 for continuing monitoring (Larson 2012).

Although the program began in 2003, the zinc product was not rolled out until 2006 (Figure 3). The first 3 years were devoted to research and preparation for scale-up. The SUZY team took a thoughtful approach to behavior change and adoption of social norms surrounding zinc use in Bangladesh. Drawing on sociology and communications theory, the team began by creating frameworks for the project with the goals of creating awareness of zinc, informing care-takers of the benefits of zinc over standard treatment, providing guidelines that were compatible with existing norms, providing simple instructions, informing care-takers of how easily zinc can be obtained, and suggesting that care-takers try it once without long term commitment (Larson, Koehlmoos et al. 2011).

Because the SUZY project was housed at ICDDR,B, research was given high priority and became a fundamental part of the process of scale-up. The research in the early stages of the project included surveys for safety and side effects of zinc, diarrhea management practices among clinical providers, formulation acceptability, product branding, willingness to pay for zinc, and a test of zinc provision to NGO providers (Larson, Koehlmoos et al. 2011). Several lessons were learned from these initial studies. The investigators found that 90% of healthcare provider visits for childhood diarrhea were to private providers. This led to an early, strong emphasis on the private sector, where they focused their initial distribution efforts (Larson, Saha et al. 2006).



Other studies clarified the preferences of providers and care-takers. Through provider perception studies, the investigators found that the most convincing messages were those of the preventive benefits of zinc (Larson, Koehlmoos et al. 2011). Studies with caretakers demonstrated that 98% of mothers properly adhered to instructions on the zinc blister pack (Figure 4), and would be willing to pay an average of \$0.45 (Akhter and Larson 2009; Larson, Koehlmoos et al. 2011).



FIGURE 4: BABY ZINC PACKAGING AND BLISTER PACK INSTRUCTIONS

Once the product was launched, monitoring and evaluation research continued with studies for intended and unintended consequences, barriers to drug vendor prescription of zinc, and understanding the promotion of zinc in the unregulated private sector (Larson, Koehlmoos et al. 2011).

PRODUCT FORMULATION

When evidence for the efficacy of zinc was growing in the late 1990s, the WHO had invited the French company Nutriset to design and produce zinc tablets for child consumption. These tablets had to be easily and quickly dispersible, mask the taste of zinc, and be inexpensive to produce. Nutriset designed the product ZinCfant® and launched it commercially in 2005 (ICDDR,B 2012). Their partner, Rodael Pharmaceuticals, produced the premix formula for the zinc tablets.

In Bangladesh, there was no formulation for a dispersible zinc tablet available on the market in the early 2000s. There were syrup formulations that were prescribed for a number of ailments, but the SUZY team decided that a dispersible tablet would be cheaper and, because of the novelty, easier to position solely as a diarrhea treatment (Larson, Koehlmoos et al. 2011). Although ZinCfant® would become available from Nutriset, the MoHFW had a strong preference to produce and distribute the product within Bangladesh. From 2004-2006, the SUZY project obtained the premix from Rodael Pharmaceuticals and processed it into tablets at a Bangladeshi pharmaceutical company called Square Pharmaceuticals (ICDDR,B 2012).

In July 2005, the SUZY team bought the patent for the ZinCfant formula from Nutriset and sought Bangladeshi companies to manufacture the tablets. Acme Laboratories, LTD in Bangladesh already had production infrastructure and won the exclusive contract for production. The confidential transfer of the formula occurred in the fall of 2006 (ICDDR,B 2012). Acme Laboratories began to produce Baby Zinc, a blister pack containing 10 tablets of 20mg (enough for one treatment course) for US \$0.18 a box (Acme Group 2012).

Blister packs of BabyZinc contain 10 tablets for the full course of treatment. Prices follow this approximate breakdown:



TABLE 2: PRICE AND PRODUCTION COSTS PER BLISTER PACK OF IN US\$

Revenue	\$0.18/blister pack
Raw Material	\$0.075
Manufacturing and Production	\$0.04
Distribution, Sales and General Admin.	\$0.05
Total Costs	\$0.165
Profit	\$0.015

(Larson 2012)

There was a low demand for zinc through the public sector in Bangladesh, which allowed the SUZY project to subsidize the product to distribute it to government health facilities (Larson, Koehlmoos et al. 2011). Those facilities were then able to provide it for free. This might not have been possible without external funding in a context with higher demand on the public sector health system (Larson, Koehlmoos et al. 2011).

In 2008, the Social Marketing Company (SMC) also created a zinc product called SMC Zinc®. The company began to produce zinc in coordination with Square Pharmaceuticals. A representative from SMC indicated that research into an improved product is necessary, because it may not be appropriately formulated to appeal to children (Rahman 2012).

DISTRIBUTION

Distribution of the Baby Zinc product began in 2006. The SUZY project ensured that demand would be high by recognizing the patterns of use: mothers would follow the advice of the unregulated private sector, and those unlicensed providers would follow the advice of the regulated sector (Larson, Koehlmoos et al. 2011). Rather than attempting to directly change the behaviors and norms of the end-users, they trained providers to deliver information in a trickle-down fashion. The support of the Bangladesh Paediatrics Association was integral to this shift in practice. Training was also conveyed to public providers in all sub-districts, as well as over 6,000 of 345,000 informal providers (Ahmed, Hossain et al. 2011) throughout the breadth of the country (Larson, Koehlmoos et al. 2011). In the first year of production, over \$5M of Baby Zinc blister packs were sold, exceeding the forecasted \$3M (ICDDR 2012).

SMC began distributing zinc in 2008 to nearly 100,000 chemist shops throughout the country, including through their Blue Star franchise program (total number of chemist shops unknown) (Rahman 2012). However, they have found that shops are not interested in purchasing zinc because there is low customer demand.

REGULATIONS

The WHO regards zinc supplements as a drug because the dosage for treatment of diarrhea is approximately 4x the recommended daily amount. However, individual countries can decide if they would like to change its status to over-the-counter (OTC). When the SUZY project was launched, Baby Zinc was still considered a prescription drug, so it had to be distributed through pharmaceutical representatives. Zinc has a lower profit margin compared to other Acme Laboratory products, which could dis-incentivize the drug representatives from promoting it. The SUZY team recognized this potential problem early and successfully sought an exemption to make zinc available as an OTC product (Larson 2012). The process took approximately one year (Larson, Koehlmoos et al. 2011). In 2008, after Baby Zinc became an OTC drug, the SUZY project was able to begin promoting it in retail shops. The



project is now distributing Baby Zinc through the infrastructure of a bottled water distribution system, so that zinc can be found in general retail shops (Larson 2012).

MARKETING CAMPAIGN

The SUZY Project wanted to accomplish three goals with their Baby Zinc media campaign: create awareness of zinc treatment, include zinc in management practices, and reach all care-takers throughout Bangladesh (Larson, Koehlmoos et al. 2011). Although initial discussions included SMC as the social media coordinator (Nasreen 2004), the SUZY project hired Dhansiri Media to carry out a national mass media campaign to market Baby Zinc. With the SUZY team, Dhansiri Media identified four key messages that they wanted to promote among care-takers:

- Baby Zinc is for treatment and prevention of diarrhea
- One tablet should be taken each day for 10 days
- Dissolve the tablet in water
- Use in conjunction with ORS

These messages were introduced in an extensive campaign including five television commercials, one radio commercial, press advertisements, articles, billboards, posters, stickers, sign boards, wall paintings and branded buses, launches, rickshaws, tinplate and hand fans (Figures 5 and 6). Dhansiri recognized television and radio as the quickest medium for circulating the benefit of zinc to the entire country. The campaign aired a drama serial, a health show and a radio drama (Wazed 2008). In early 2006, ongoing concerns about a replacement of ORS with zinc stimulated Dhansiri to ensure that ORS was mentioned in every zinc message (Cravioto 2007).



FIGURE 5: CARTOON TELEVISION COMMERCIALS CONVEYED THE ZINC MESSAGE



FIGURE 6: BABY ZINC BUS BRANDING IN DHAKA

The Dhansiri media campaign was not responsible for disseminating information to healthcare providers. In order to deliver Baby Zinc training and messaging to the private sector providers (both licensed and unlicensed), Acme Laboratories provided pamphlets and training through their drug



representatives (Larson, Koehlmoos et al. 2011). Approximately 2,000 sales representatives in every sub-district of Bangladesh were trained to promote zinc among healthcare providers (Larson, Koehlmoos et al. 2011).

The campaigns were successful in raising product awareness. By 2007, almost 95% of Bangladeshi mothers of children under 5 in urban and semi-urban locations, and 50% in rural areas, were familiar with Baby Zinc and the use of zinc as a treatment for diarrhea (ICDDR 2012). However, actual usage rates were lower and only 50% of licensed doctors were prescribing zinc as a treatment for diarrhea. This might be attributable to the untargeted mass media platform for the dissemination of knowledge, rather than a face-to-face interaction like the ORS scale-up (Larson 2012).

IMPACT

Ecological surveys following the zinc scale-up campaign found that caretaker awareness of zinc as a treatment for childhood diarrhea increased from 5% to 50% in rural areas and 90% in urban non-slum areas (Larson, Saha et al. 2009). The scale up of the use of zinc to treat diarrhea was considered moderately successful. The SUZY project achieved usage levels of 10% in rural areas and 25% in urban non-slum areas, from presumably negligible levels (Larson, Saha et al. 2009). The increase in zinc awareness and use had no adverse effect on ORS use, and may have increased ORS use. The 2007 Demographic and Health Survey (DHS) found that 61% of cases of diarrhea were treated only with ORS, 2.5% were treated with only zinc, and 20% were treated with both. There was significant disparity in use of zinc with ORS based on location (31.4% urban, 17.3% rural), mother's education (30% secondary, 16% no education), and wealth (30.4% wealthiest quintile, 11% poorest quintile) (BDHS 2007).

However, SMC has found that their zinc product does not move quickly, and providers are still reluctant to treat with zinc (Rahman 2012). The benefits in diarrhea treatment are not as visible as they are with ORS, and there is insufficient collaborative effort to promote it throughout the country (Rahman 2012).

CONCLUSIONS

The SUZY project in Bangladesh is an example of a zinc scale-up program that worked with diverse sectors and interest groups. ICDDR,B maintained ownership of the project, which allowed them to use their trusted reputation and to create a congruous scale-up framework. Although the MOHFW took a secondary role, their support was important in the process of scale-up. The zinc committees in MOHFW and the centralization of the Bangladesh government were important to promoting regulatory change and efficiently scaling-up. Possibly the most important facet to the partnership, however, was willingness of ICDDR,B and the MOHFW to work with the private sector.

The SUZY project was also flexible in addressing aspects of the Bangladesh culture and healthcare system to ensure wide distribution of zinc. A central lesson learned through the SUZY project was the importance of making zinc an OTC product. This resulted in zinc being more readily available in retail outlets, without relying on the prioritization of drug representatives. Although the marketing campaign successfully raised product awareness, especially in urban areas, it did not sufficiently increase uptake of zinc for treatment of diarrhea. Usage rates have plateaued at about 20-25%, despite high awareness levels. Future directions for the program include ensuring that practice-oriented (rather than knowledge-based) behavior change models are included in the structure of messaging and distribution.



The historical experience with ORS scale-up, the supportive government entities, and the ability to flexibly address aspects of Bangladeshi culture were key components that allowed the SUZY program to scale-up smoothly, although many limitations to the wide use of zinc still exist in Bangladesh.



APPENDIX 1:

EVALUATION OF ZINC SCALE-UP EFFORTS ACROSS SIX KEY COMPONENTS

Component	Degree of success (H/M/L)	Drivers of success/failure
Development of improved product (including pricing)	H	<ul style="list-style-type: none"> • Extensive research performed to determine product formulation to meet customer's demands • Transfer of technology from French manufacturer • Dispersible tablet, which is cheaper and easier to position solely as diarrhea treatment, than the syrup formulations prescribed for ailments. • Masked the taste of zinc • Priced at US\$0.18/blister pack (10%-20% profit margin) • ICDDR,B logo on packaging to encourage consumer confidence
Marketing campaign	M	<ul style="list-style-type: none"> • Approximately \$1.5M contributed by SUZY Project towards promotions – television and radio were the quickest medium for circulating the benefit of zinc to the entire country. • ORS mentioned in every message due to concerns that zinc would replace ORS • Message increased awareness, but actual usage remained low • Full 10-day treatment was not adequately promoted, and drug vendors typically sell 2-3 day dosages, so treatment was not effective and subsequent use discouraged
Regulatory change	M	<ul style="list-style-type: none"> • Zinc was originally licensed as a drug, which meant it had to be distributed through pharmaceutical reps, which placed it as a low priority due to small margins. • Received exemption from Bangladesh government to make it an over-the-counter product, allowing it to be distributed through the same channels as common items such as water.
Improving private provider knowledge	M	<ul style="list-style-type: none"> • Half-day workshops for pediatricians and educators, who then trained the unlicensed providers. • Promoted product with drug salesmen, but they did not promote the product because of lack of incentive • 50% of licensed doctors were prescribing zinc by 2007
Improving public provider knowledge	M	<ul style="list-style-type: none"> • Public providers provided Zinc for free but only accounted for 10% of zinc coverage • Government supported effort with regulatory help
Increasing availability of supply in the public and private sector	H	<ul style="list-style-type: none"> • Manufactured locally through technology transfer from French company • OTC status increased availability through normal retail outlets. • 8-10 manufacturers began producing zinc
Financing of scale-up	H	<ul style="list-style-type: none"> • \$8M of donor support from ICDDR,B and BMGF over 5 years



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