

# Zinc Case Study

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Tanzania

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## **Disclaimer**

Any opinions, findings, and conclusions or recommendations expressed in this material are those of the authors and do not necessarily reflect the views of the key informants, thought partners or reviewers.

## 1. Context

Tanzania is the largest country in East Africa, covering over 940,000 square kilometers, including the islands of Mafia, Pemba and Zanzibar. Approximately 25% of the country is composed of national parks, game and forest reserves. The population is estimated at 43.6 million in 2012, over three-quarters (77%) of whom live in rural areas.<sup>1</sup> The population is unevenly dispersed throughout the country, with the population density ranging from 1785 per km<sup>2</sup> in Dar es Salaam to 12 per km<sup>2</sup> in Lindi region.<sup>2</sup> The per capita GDP (PPP) is \$1286.<sup>3</sup> In addition to HIV (prevalence ~7%), malaria, pneumonia and diarrheal diseases are the main health problems in Tanzania.

Tanzania's reductions in infant and child mortality are among the greatest in Sub-Saharan Africa. Tanzania reduced under-five mortality by 51% between 1990 and 2010, from 155 to 76 deaths per 1000 live births, suggesting that the country could reach their MDG 4 target. Despite progress in child survival, Tanzania ranks 10<sup>th</sup> among 24 developing countries with the largest numbers of children under five who are moderately or severely stunted.<sup>4</sup> The high stunting prevalence in Tanzania (44%) is not surprising given that Tanzania is one of ten countries with the highest diarrhea burden.

Administratively, the country is divided into 21 regions on the mainland and five regions in Zanzibar, subdivided into 129 districts, including 10 in Zanzibar. The public health system has a network of hospitals, health centers and dispensaries (clinics), with 6,000 to 10,000 people served by each facility.<sup>5</sup> The vast majority (90%) of the population lives within 5 km from a health facility. Tanzania suffers from inadequate staffing of health facilities: there are 0.1 physicians and 2.4 nurses and midwives per 10,000 people, much lower than regional average of 2.2 physicians and 9.0 nurses and midwives per 10,000 people.<sup>6</sup>

## 2. Health system successes and failures

Maternal and child health services were established in Tanzania in 1974 and the Expanded Program of Immunization (EPI) was initiated the following year. Shortly after, WHO recommended treating diarrhea with Oral Rehydration Solution (ORS), prepared by dissolving ready-made packets of ORS in water. Tanzania approached diarrhea control through Diarrhea Treatment Corners, or DTCs, which were established in every facility nationwide. Beginning in the 1980s, the Control of Diarrheal Disease Program (CDDP) in Tanzania was, as one key informant described it, "highly committed to promotion" of oral rehydration therapy (ORT). One strategy utilized by the CDDP was to educate school children, with the expectation that they would relay the messages home and educate their parents about ORT.

Health services were decentralized with Health Sector Reforms (HSR) started in 1994, giving local districts increased autonomy and control over their own health budgets and plans. Since HSR, public-

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<sup>1</sup> National Bureau of Statistics [Tanzania] and ICF Macro. (2011) Tanzania Demographic and Health Survey 2010.

<sup>2</sup> MOHSW Welfare & WHO. (2007) Tanzania service availability mapping : 2005–2006.

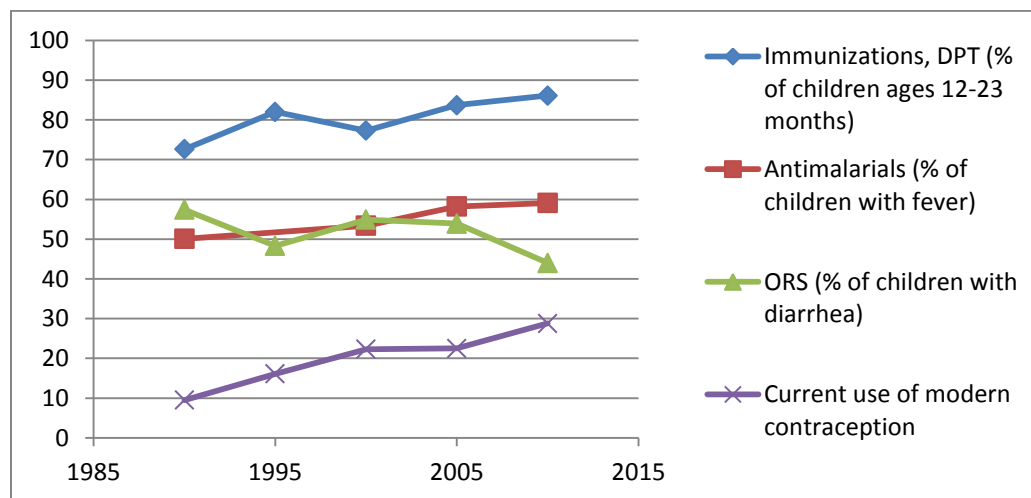
<sup>3</sup> World Bank (2012) World Development Indicators: Tanzania. Accessed May 17, 2012. Available at: <http://data.worldbank.org/country/tanzania>.

<sup>4</sup> UNICEF. (2009) Tracking progress on child and maternal nutrition: A survival and development priority.

<sup>5</sup> National Bureau of Statistics [Tanzania] and Macro International Inc. (2007) Tanzania Service Provision Assessment Survey 2006.

<sup>6</sup> World Health Organization (WHO) (2012) United Republic of Tanzania: health profile. Accessed June 4, 2012. Available at: <http://www.who.int/gho/countries/tza.pdf>.

private partnerships are actively encouraged. Children under the age of five and pregnant women are exempted from fees at government health facilities but, in practice, patients pay for drugs and supplies when they are out of stock at the facility.<sup>7</sup> Tanzania adopted the Integrated Management of Childhood Illness (IMCI) strategy in 1996 to improve the quality of care provided in health facilities for the major causes of child mortality (malaria, pneumonia, diarrhea, measles and malnutrition).



**Figure 1.** Health services utilization in Tanzania, 1991-2010. (Data from the Tanzania Demographic and Health Surveys conducted in 1991-92, 1996, 1999, 2004-05, and 2010.)

Tanzania was one of five countries included in the Multi-Country Evaluation of IMCI Effectiveness, Cost and Impact (MCE) funded by the Bill & Melinda Gates Foundation (BMGF). The main findings of the MCE were that children in districts implementing IMCI received better care than children in comparison districts.<sup>8</sup> Children were checked for the presence of diarrhea and correctly classified more frequently in IMCI districts than in comparison districts. For children who needed an oral medication (ORS and/or antibiotic and/or anti-malarial) and were prescribed one, 96% of caregivers in IMCI districts were counseled on how to administer the treatment, compared with only 18% of caregivers in comparison districts. ORS use was more common on average in IMCI than in comparison areas.

The health facilities in Tanzania remain highly utilized today but it appears that the performance of health workers as was observed during the MCE has deteriorated without training and supportive supervision. While Tanzania had higher rates of ORS use than most other African countries up to 2005, the rate has declined sharply in recent years (from 53.9% in 2005 to 44.0% in 2010). Caregiver-reported knowledge of ORS was consistently high (**Table 1**) over the past two decades but ORS usage declined and zinc usage is low.

<sup>7</sup> Manzi F, Schellenberg JA, Hutton G, Wyss K, Mbuya C, et al. (2012) Human resources for health care delivery in Tanzania: a multifaceted problem. *Hum Resour Health* 22;10: 3.

<sup>8</sup> Tanzania IMCI Multi-Country Evaluation Health Facility Survey Study Group: Armstrong Schellenberg J, Bryce J, de Savigny D, Lambrechts T, Mbuya C, et al. (2004) The effect of Integrated Management of Childhood Illness on observed quality of care of under-fives in rural Tanzania. *Health Policy Plan* 19: 1-10.

**Table 1.** Diarrhea case management in Tanzania, 1991-2010. (Data: Tanzania DHS)

Practice or treatment provided	1991-92	1996	1999	2004-05	2010
Knowledge of ORS (% of mothers of children with diarrhea)	93.0	87.1	.*	95.5	95.4
Care-seeking for diarrhea (% of children with diarrhea taken to health facility or provider)	59.5	56.3	63.2	47.0	52.6
Pill, syrup or antibiotic (% of children with diarrhea)	20.5	39.5	.	40.0	49.8
ORS (% of children with diarrhea)	57.4	48.3	54.9	53.9	44.0
Increased fluids (% of children with diarrhea)	30.4	56.6	31.9	36.4	18.2
Zinc (% of children with diarrhea)	.	.	.	.	4.7

\* (.) = Data not available.

### 3. Approach to scale-up

#### a. Regulatory change

WHO and UNICEF made a joint recommendation in 2004 for the use of zinc and low-osmolarity ORS, along with increased fluids and continued feeding of an appropriate diet, for the treatment of diarrhea.<sup>9</sup> With the advent of zinc and its inclusion in the revised WHO/UNICEF guidelines for diarrhea treatment, the USAID-led five-year Point-of-Use Water Disinfection and Zinc Treatment Project (POUZN) began in 2005 with the aim of revitalizing diarrhea treatment. POUZN worked with the MOHSW and the Tanzania Food and Drugs Authority (TFDA) to adopt a revised diarrhea treatment policy and helped build local capacity of a local pharmaceutical company. With advocacy from the Zinc Task Force (ZTF), the Ministry of Health and Social Welfare (MOHSW) in Tanzania adopted the revised UNICEF/WHO guidelines as policy in December 2006. The Tanzanian government updated the IMCI guidelines to include the new treatment protocol and added zinc and low-osmolarity ORS to the national essential medicines list in 2007.

#### b. Marketing campaign (incl. approach of major manufacturers and wholesalers)

The overarching goal of POUZN was to increase the availability and sustained use of ORS and zinc. The strategy was to advocate for rational diarrhea treatment, distribute low-osmolarity ORS and zinc treatment to public sector health posts, ensure the supply of quality zinc treatment and reformulated ORS in the private sector, and generate demand among health care professionals, drug sellers and child caregivers. The target was 20% zinc use among caregivers for a recent case of childhood diarrhea.

POUZN collaborated with the Pharmacy Council of Tanzania to provide updated guidelines to pharmacies in five major cities. The project created leaflets, point-of-purchase signs, T-shirts (as incentives for those making sales over a certain threshold), stickers, notepads with zinc treatment messages, fliers for clients, and other promotional materials.<sup>10</sup>

A local manufacturer, Shelys Pharmaceuticals Ltd., supported the sales, distribution and marketing activities of its *PedZinc* brand while POUZN sponsored demand creation activities (generic

<sup>9</sup> WHO, UNICEF (2004) Clinical management of acute diarrhoea. New York: WHO/UNICEF.

<sup>10</sup> POUZN Project (2010) Introducing Improved Treatment of Childhood Diarrhea with Zinc and ORT in Three Countries: A Public-Private Partnership Supported by the POUZN/AED Project. Washington, DC: Point-of-Use Water Disinfection and Zinc Treatment (POUZN) Project, AED.

communication). Shelys carried out “activations” at 20 key wholesalers responsible for sales to over 4,500 drug sellers in Dar es Salaam. Wholesalers were provided with 90 days of credit for a first supply of zinc to generate demand for the new product. Doctor/nurse detailing presentations were held in 650 health facilities in 19 mainland regions, reaching 5820 doctors and nurses. *PedZinc* and *Save*, Shelys’ low-osmolarity ORS product, were co-promoted as the new childhood diarrhea treatment that could be purchased locally.

The Tanzanian ZTF and POUZN coordinated the public and private sector communication plans, including a stakeholder workshop to develop key messages and a strategy. POUZN worked with the Tanzania Marketing and Communications Project for AIDS, Reproductive Health and Child Survival (T-MARC) to increase public awareness of zinc treatment by launching a radio media campaign and co-funding zinc product detailing and branding activities in 45 hospitals and 1353 pharmacies.<sup>11</sup>

T-MARC sourced the Media for Development Initiative to develop and coordinate the scriptwriting for the radio program series, *Mama Ushauri*, covering reproductive and child health issues. T-MARC worked with POUZN in the development of radio jingles and radio spot advertisements for the promotion of zinc treatment, setting aside a budget of \$50,000 for radio advertisements over a three-month period beginning in November 2007 prior to the stakeholders launch for zinc treatment in April 2008. POUZN also hosted caregiver events to promote the use of zinc and ORS, including outreach to caregivers through community-based "road shows".

### c. Development of improved product

Tanzania became the first African country to manufacture dispersible, taste-masked zinc tablets for treatment of diarrhea when Shelys launched their *PedZinc* product in 2007. Zinc was approved as an over-the-counter drug in 2009.



Since POUZN ended Shelys has created a diarrhea treatment kit called *ORAZINC* for distribution exclusively through the WHO/Muhimbili study. The co-packaged product includes two sachets of ORS and one blister pack containing 10 zinc tablets. Muhimbili University of Health and Allied Sciences is collaborating with the MOHSW and WHO on a pilot study in two districts to examine case management

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<sup>11</sup> T-MARC Annual Report (2007) Accessed June 11, 2012. Available at: [http://pdf.usaid.gov/pdf\\_docs/PDACN861.pdf](http://pdf.usaid.gov/pdf_docs/PDACN861.pdf).

of childhood diarrhea using alternative delivery strategies, including *ORAZINC*; the results are expected later this year.<sup>12</sup>

Although further advanced than in most of Africa, the pharmaceutical industry in Tanzania was just developing when POUZN started in 2005. Today there are seven licensed pharmaceutical manufacturers in the country; Shelys is the only one which produces ORS and zinc. Established as a private company in 1988, Shelys acquired Kenya-based Beta Healthcare to become the largest pharmaceuticals company in East Africa and exports drugs to Malawi, Congo, Zambia and Mozambique. As of March 2012, 100% of share holdings are with Aspen, the largest South African pharmaceutical manufacturing company.

#### **d. Improving public provider knowledge**

Given the generally high rates of care seeking from public facilities and private providers in Tanzania, POUZN worked closely with the private sector, with little focus devoted to health worker training in public facilities where IMCI had been implemented. POUZN created counseling cards for village health posts and a generic communications campaign targeting health providers to promote zinc treatment.

Shelys carried out seminars for doctors, nurses, and clinicians at major hospitals and clinics to provide clinical evidence for the new diarrhea treatment guidelines and to distribute reminders for behavior change to generate prescriptions for zinc. Leave-behind materials included prescription pads and pens, free samples, and quotations from the new national diarrhea guidelines.

The MOHSW delayed communicating the approval of zinc as a first-line treatment of childhood diarrhea to providers at public health facilities because cost remained a concern to the Ministry and the government Medical Stores Department (MSD) was reluctant to stock zinc while demand was uncertain.<sup>13</sup> As a result, many providers were unable to respond to the product detailing activities. Follow-up discussions were to be held with the MOHSW to advocate them to circulate a notification letter regarding the change in diarrhea treatment policy.

POUZN worked with UNICEF to provide supply (zero cost for commodities to MSD) of zinc (Nutriset brand) to MSD to address this problem. Information on zinc use was included in the letter attached to zinc supplies distributed by MSD. Roll out was not well coordinated as current system for drug distribution was through a 'pull' system. The providers did not know about the product and as a result could not 'pull' it. The project worked with management teams in ADDO regions and 'pushed' zinc supplies to health providers to 'kick-start' distribution through the public sector. As product uptake increased MSD put out tenders for zinc, which local Shelys responded to and supplied.

#### **e. Improving private provider knowledge**

Drug shops (*duka la dawa baridi*) were established in the 1970s to address the poor access to medicines for much of the population.<sup>14</sup> *Duka la dawa baridi* constitute the largest network of formally licensed

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<sup>12</sup>An Operational Study on the management of acute diarrhoea in Tanzania - Evaluation of new delivery strategies for Oral Rehydration Salts (ORS) and Zinc on use rate in children under five. Accessed June 11, 2012. Available at: <http://apps.who.int/trialsearch/trial.aspx?trialid=ACTRN12610000413022>.

<sup>13</sup> POUZN, 2010.

<sup>14</sup> Goodman C, Kachur SP, Abdulla S, Bloland P, Mills A. (2007) Drug shop regulation and malaria treatment in Tanzania--why do shops break the rules, and does it matter? Health Policy Plan 22:393-403.

outlets for basic essential medicines in Tanzania and are not legally required to be supervised by a pharmacist. Recognizing the popularity of drug shops and the need to upgrade the skills and prescribing practices of drug sellers and to ensure the quality of the drugs sold in such outlets, the government started an accreditation program in rural and peri-urban areas.

The BMGF funded Management Sciences for Health (MSH) to pilot a program in Ruvuma District from 2002 to 2006 accrediting selected Accredited Drug Dispensing Outlets (ADDOs) to sell 37 prescription drugs, as one component of the Strategies for Enhancing Access to Medicines (SEAM) Program. The SEAM Program sought to increase consumer demand for quality medicines and health services through training, accreditation, business incentives and regulatory enforcement. By the end of the program in 2005, 150 shops in Ruvuma were accredited by the TFDA.

In 2008, MSH's Strengthening Pharmaceutical Systems (SPS) Program (designed to improve governance in the pharmaceutical sector) collaborated with POUZN to train 395 ADDO dispensers and nine supervisors in the Morogoro region in the revised diarrhea treatment guidelines. The supervisors were also oriented on how to conduct supervisions in ADDOs using a standard checklist. The following year, SPS and POUZN held refresher trainings for 211 ADDO dispensers, 16 Council Health Management Team members, and nine supervisors of health zones in the Ruvuma region. Training activities included lectures, discussions, group assignments and supervisory visits to a sample of ADDOs. The trainings covered the following topics: general danger signs and symptoms related to diarrhea; diarrhea case management based on IMCI guidelines; benefits of combined ORS and zinc therapy; appropriate preparation and use of ORS; how to dispense and administer zinc.<sup>15</sup> Pre- and post-tests measuring participants' understanding of appropriate referral practices and diarrhea case management (including zinc therapy) showed test scores improved by 11% during refresher training. The average post-test score was 82%. Among 81 ADDOs visited in Ruvuma region during refresher training for ADDO dispensers in 2009, zinc was available in just 4% of ADDOs.

#### **f. Increasing availability of supply in the public and private sector (incl. procurement)**

Public facilities rely heavily on the public sector procurement agency (MSD) for supplies. Yet MSD has the capacity to meet just two-thirds of customer needs, making it difficult for public facilities to get the supplies and medicines they need.<sup>16</sup> Initially, UNICEF procured zinc tablets from Nutriset and distributed tablets to public health facilities and faith based organizations.

In the first six months after the product was launched, *PedZinc* was available in 462 pharmacies run by a registered pharmacist (about 60% of which are in the capital and almost all are in urban or peri-urban areas). Shelys is the leading supplier of locally produced essential medicines in Tanzania but it does not have an explicit policy or strategy focused on meeting the needs of the poor by providing access to essential medicines through local production and/or affordable pricing.

The MSD procures *PedZinc* but it is not available as a donor-funded essential medicine in the public sector because Shelys didn't have Good Manufacturing Practice (GMP) status. The reluctance to stock

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<sup>15</sup> Kimatta, et al. 2009. Refresher Training of ADDO Dispensers in the Revised Diarrheal Disease Management Guidelines and Reproductive Health Products, Ruvuma, Tanzania.

<sup>16</sup> Center for Pharmaceutical Management. 2003. Access to Essential Medicines: Tanzania, 2001. Prepared for the Strategies for Enhancing Access to Medicines Program. Arlington, VA: Management Sciences for Health. Accessed June 21, 2012. Available: [http://www.msh.org/seam/reports/CRO22304\\_SEAMWebsite\\_attach1.pdf](http://www.msh.org/seam/reports/CRO22304_SEAMWebsite_attach1.pdf).



zinc was summarized by one key informant: “No one is demanding it, so they’re not supplying without orders.” Another key informant suggested that, although providers know about zinc, the system does not make it easy to incorporate it into routine treatment, and described one major bottleneck: the order form for commodities includes ORS but not zinc. Thus, a special order form is needed when a facility or provider wishes to order zinc.

In 2007, as a follow-on grant to the SEAM Program, the foundation funded the (unsuccessful) East African Drug Seller Initiative (EADSI) to support nationwide expansion in Tanzania and elsewhere in the region over four years. Additional funding from the BMGF was provided to EADSI in 2008 to evaluate ADDO implementation and long-term sustainability. The results for eight regions in Tanzania show that the intervention did not increase access to zinc. There are 3,873 ADDOs in 15 regions,<sup>17</sup> or roughly one ADDO per 10,000 people.

A survey<sup>18</sup> to measure the availability and prices of 50 pediatric medicines in Tanzania revealed low availability of pediatric medicines in all sectors among the 143 facilities (public, private and NGO sectors) surveyed in 2009. Using a convenience sample, Health Action International determined that the mean availability of medicines on the national essential medicines list was 45.3% in the public sector and dispersible zinc tablets were available in 29.8%, 43.8% and 33.3% of outlets in the public, private and NGO sectors, respectively.<sup>19</sup>

#### **g. Financing- source and mechanisms**

The BMGF has supported the ADDOs with \$18.1M over three grants and 12 years by the end of the current grant to consolidate the ADDO program in Tanzania. POUZN was supported by USAID with \$1.3M over five years.

#### **h. Pricing**

Zinc is available throughout the country but is not available free of charge from public health facilities; when purchased in drug shops, it costs 2000 TSH (~US \$1.33) (May 2012). Shelys’ pricing for 10 tablets (one blister pack) of their brand, *PedZinc*, is 320 TSH (\$0.21) and Shelys’ *ORAZINC*, which contains two sachets of ORS and 10 zinc tablets, is priced at 600 – 650 TSH (\$0.40-0.43) (personal communication, May 2012). MSD supplies at discounted rates.

#### **i. Impact**

According to the 2010 Tanzania DHS, less than 5% of childhood diarrheal episodes were treated with zinc. POUZN aimed to achieve 20% zinc usage among caregivers but did not achieve this goal. Practices changed little during the project, with zinc usage estimated at 6% in 2009 and 9% in 2010. Only 22% of mothers reported that they had seen or heard a message about zinc in the preceding three months. POUZN evaluated provider behaviors using a mystery client survey and found that private providers in licensed pharmacies prescribed zinc for one-third of childhood diarrheal episodes and private providers in drug shops (including ADDOS) prescribed zinc for one-quarter of episodes. Providers of all kinds continued to prescribe antibiotics at very high levels (>80%). While POUZN was successful in catalyzing

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<sup>17</sup> Stallworthy G (2012) Trip report: Tanzania ADDOs and maternal health insurance vouchers.

<sup>18</sup> WHO and Health Action International (HAI), 2009.

<sup>19</sup> HAI, 2009.

government support for adopting zinc treatment with low-osmolarity ORS for diarrhea and getting a local manufacturer to produce the products, only the first few steps in scale-up of ORS/zinc were taken. The momentum to scale up diarrhea treatment seems to have died with the end of the project, and its funding, in 2010.

#### **4. Conclusion**

Thus, only a small proportion of children who need zinc have access to it. The poorly-functioning distribution system and health providers' lack of training in when and how to use zinc supplements remain major bottlenecks to ensuring that all children can be treated properly with recommended diarrhea treatments.

It seems that the DTCs had a positive effect on increasing caregivers' knowledge of ORS initially, but the DTCs dissolved by the time zinc was introduced as a treatment for diarrhea. As one key informant summarized, "DTCs weren't really being supported and they died away. It would be an ideal platform [for introducing zinc treatment with ORS]."

POUZN attempted to rejuvenate national interest in diarrhea case management with the introduction of updated guidelines. The biggest challenge may be the lack of perceived need by the market. POUZN identified that zinc treatment competes with well-entrenched prescription behaviors and will require more than simply "adding on" to another struggling brand, ORS. It seems that the manufacturer could be a good intermediary between private sector and the government if they can engage retailers; it's not clear to what extent (or whether) Shelys played this role. Scaling up zinc requires substantial marketing support in the private sector, educating consumers about the role of zinc – and how it differs from ORS and antibiotics, and the government and partners making zinc treatment for diarrhea a priority at all levels of the health care system.

## Summary

Component	Degree of success	Drivers of success/failure
Development of improved product (including pricing)	Medium	<ul style="list-style-type: none"> <li>• Zinc produced by local manufacturer</li> <li>• Should be provided free of charge from public health facilities but population forced to purchase from private sector when stocked out</li> <li>• Private sector supply not affordable to the majority of the population</li> </ul>
Marketing campaign	Medium	<ul style="list-style-type: none"> <li>• Radio jingles ran for short period and \$50,000 was probably insufficient to achieve much penetration or product identification</li> <li>• Message recall was low</li> <li>• Generic promotion and training material on diarrhea treatment</li> <li>• High knowledge of ORS among mothers, but low utilization</li> </ul>
Regulatory change	Medium	<ul style="list-style-type: none"> <li>• Zinc included on national Essential Medicines List</li> <li>• MOHSW delayed in communicating new diarrhea treatment policy to providers and including zinc as part of IMCI guidelines</li> </ul>
Improving private provider knowledge	Low	<ul style="list-style-type: none"> <li>• Trained ADDO dispensers, but too few dispensers and reach not sufficient to improve coverage and utilization of zinc</li> <li>• High utilization of inappropriate antibiotics</li> </ul>
Improving public provider knowledge and increasing supportive supervision	Low	<ul style="list-style-type: none"> <li>• IMCI adopted nationwide but no investment in training and supervision</li> <li>• IMCI facility-focused, unclear if enough facilities where everyone trained</li> <li>• IMCI focal person in each district not always engaged</li> <li>• No community IMCI and no community health worker program</li> <li>• Notification letter from MOHSW to facilities not sufficient to communicate approval of zinc</li> </ul>
Increasing availability of supply in the public and private sector	Low	<ul style="list-style-type: none"> <li>• Population density very low outside of capital city and not enough outlets selling quality essential products close to population</li> <li>• No cadre of community health workers to fill gap in service provision in geographic areas far removed from facilities and accredited drug outlets</li> <li>• Lack system modifications to initiate and sustain supply (e.g. order form does not include zinc)</li> </ul>
Financing of scale-up	Low	<ul style="list-style-type: none"> <li>• Lack of funding for IMCI (especially diarrhea) training and supervision</li> <li>• Despite donor support in country, relatively little focused on zinc</li> </ul>