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# INTRODUCING IMPROVED TREATMENT OF CHILDHOOD DIARRHEA WITH ZINC AND ORT IN TANZANIA:

A Public-Private Partnership Supported by the POUZN/AED Project



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JUNE 2010

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# ACRONYMS

ADDO	accredited drug dispensing outlets
AED	Academy for Educational Development
CHMT	Counsel Health Management Team
GMP	good manufacturing practice
HKI	Helen Keller International
IMCI	Integrated Management of Child Health Initiative
lo-ORS	low osmolarity oral rehydration salts
MSH	Management Sciences for Health
MoHSW	Ministry of Health and Social Welfare
MOU	Memorandum of Understanding
MSD	Medical Stores Department
NGO	non-governmental organization
ORS	oral rehydration salts
ORT	oral rehydration therapy
OTC	over-the-counter
POU	point-of-use water disinfection
POUZN	Point-of-Use Water Disinfection and Zinc Treatment Project
RMP+	Rational Pharmaceutical Management Project
SES	socio-economic status
TDHS	Tanzania Demographic and Health Survey
TFDA	Tanzanian Food and Drug Agency
UNICEF	United Nations Children’s Fund
USAID	United States Agency for International Development
VHW	village health worker
WHO	World Health Organization

# EXECUTIVE SUMMARY

Zinc has been endorsed by both the World Health Organization and UNICEF as an effective treatment for diarrhea. However, the challenge of introducing a new product and encouraging people to use both oral rehydration therapy (ORT) and zinc treatment is large. In 2005, the US Agency for International Development (USAID) created the Point-of-Use Water Disinfection and Zinc Treatment (POUZN) project and contracted AED to introduce zinc treatment in combination with ORT in Tanzania, India, and Indonesia.

In Tanzania, POUZN aimed to work simultaneously with both the public and private commercial sectors—building on their respective strengths, facilitating communication, and creating synergies between their different processes. This dual focus was essential given the *careseeking patterns* of Tanzania’s most vulnerable groups, as well as the complex *interdependence* of roles between the public and private sectors in introducing and sustaining use of this new treatment.

AED effectively engaged stakeholders including the government of Tanzania, the private sector, the non-governmental (NGO) sector, and donors. Private sector partners were quickly found to create supply and, equally important, to develop demand for the product. Producers saw the potential for a sustainable market for zinc treatment in Tanzania, supported both by retailers and continued procurement by the public sector. In April of 2007 Shelys Pharmaceuticals produced the first African-manufactured zinc treatment for diarrhea and worked closely with POUZN to create demand for the

## OVERVIEW OF POUZN/AED

**Duration of project:** 2005–2010

**Locations:** India, Indonesia, and Tanzania

**Overall Goal:** Reduce one of the leading causes of illness and death among children worldwide—diarrhea—via two proven methods: preventing diarrhea by disinfecting water at its point-of-use and treating diarrhea with zinc therapy and ORT.

### Goals of Zinc Program in Tanzania:

- **Introduce zinc with ORT** as standard treatment for childhood diarrhea on a national scale, with dual emphasis on the public and private sectors.
- **In the government sector**, support adoption of new policies (including low osmolarity ORS and zinc treatment for childhood diarrhea, addition of zinc to the essential medicines list, approval of zinc as an over-the-counter drug); ensure supply throughout the system; support changes in prescription and counseling behaviors by providers.
- **In the commercial sector**, provide technical assistance to local pharmaceutical companies to produce and market zinc; ensure supply at pharmacies and small shops throughout the country.
- **Create demand** for and appropriate use by caregivers.

For more information visit: [http://pshi.aed.org/projects\\_pouzns.htm](http://pshi.aed.org/projects_pouzns.htm)



product among private sector providers and retailers.

The government sector, a critical player in Tanzania, revised its Integrated Management of Childhood Illness (IMCI) guidelines in 2007 and is now stocking zinc treatment for health posts across the country. NGOs contributed both as partners on the Tanzanian Zinc Task Force—which helped influence adoption of supportive policies—and as community-based organizations influencing local adoption. Donors, including USAID, have been important voices lobbying for adoption of zinc treatment in addition to oral rehydration therapy to treat diarrhea.

This case study describes the first four years of POUZN activities in Tanzania. Use of zinc is now increasing across Tanzania, including in rural areas where diarrhea mortality is highest. Nonetheless, challenges remain—particularly in improving caregiver acceptance of zinc treatment and ORT. Many of the lessons learned during the initial five-year project will be useful as stakeholders move forward promoting zinc treatment at scale. The case study covers the introduction of zinc treatment to Tanzania, both in the public and private sectors. Context and goals are discussed, as well as strategies implemented and adjustments made. The project looks to the future for next steps and summarizes lessons learned.

POUZN gathered lessons from the experience introducing zinc in Tanzania that will be useful moving forward and may be helpful to other programs:

**African manufacturers can produce quality zinc treatment products for distribution both domestically and**

**internationally.** Technical assistance is needed to help manufacturers meet international standards. If they see the potential market, they are willing to make the changes needed and to invest resources.

**The public and private sectors have different objectives and time scales, and a project must be flexible enough to mobilize and synergize their comparative advantages.** Both sectors have a role to play in introducing and sustaining a new health behavior such as zinc treatment, with their roles contingent on the country context. In Tanzania, the project worked simultaneously with both the public and private commercial sectors.

**Inclusion of zinc therapy in national diarrhea treatment guidelines is critical; it may be supported “in theory” by Ministries of Health who nevertheless face competing pressures for attention and resources.** In Tanzania, garnering support for zinc treatment was difficult because of multiple demands for limited child survival resources. Donor pressures can also exacerbate this problem. Building support, starting with the parts of the ministry most involved with diarrhea and pediatric concerns, ultimately helped secure policy changes and higher-level acceptance.

**Slow public sector procurement can affect uptake in countries with a large public health sector.** The government was reluctant to purchase zinc for the first time because of the expense, and also because it was impossible to project (and ensure) demand for the new product. UNICEF’s offer to procure the first one million treatment courses of zinc resolved this conundrum. Once zinc was available, facilities began dispensing and restocking the drug. By late 2009, after three years of implementation,

the government was ready to procure zinc from its own budget.

**Demand creation is needed at all levels to ensure both the “push” and “pull” of the product from the manufacturer through wholesalers, retailers, health facilities, and ultimately to caregivers.**

Introducing a new product like zinc requires “priming” several levels of the supply chain, as well as concerted behavior change strategies and materials. Activations and other marketing strategies need to focus on zinc (and ORS) rather than “bundling” it with other ongoing efforts.

**The most vulnerable caregivers often rely on advice from rural drug sellers; which must be part of an effective intervention.**

Given the informal health sector’s role in Tanzania and many other countries, it is imperative to consider the best ways of reaching these providers. Approval of zinc

as an over-the-counter (OTC) medicine was an important step for making zinc available in the large number of unregistered rural outlets. (OTC approval was also necessary in Tanzania before the project could undertake widespread promotion via mass media.)

**Zinc treatment for diarrhea is a new concept facing strong competition.**

In Tanzania, mothers have a preference for anti-pyretics and antibiotics. ORS faces this same competition and neither product “cure” a case of diarrhea, which is what caregivers desire. Furthermore, research in Tanzania showed that mothers believe ten days of zinc is “too much.” Sustained education and promotional efforts are required to ensure appropriate practices among prescribers, drug sellers, and caregivers.



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# I. INTRODUCTION

## THE ROLE OF ZINC AND ORS IN REDUCING CHILDHOOD DIARRHEA

In 2004, the World Health Organization and UNICEF recommended that national guidelines for treatment of diarrhea be revised to include zinc therapy and a new low-osmolarity formulation of oral rehydration salts (ORS). (WHO/UNICEF, 2004). The research behind this recommendation was funded in part by the U.S. Agency for International Development (USAID).

Zinc, an essential micronutrient, is present in a nutrient-rich diet, but the daily diet of most children in developing countries is insufficient in zinc as well as other micronutrients. Zinc plays an important role in the immune system and a deficiency can increase the incidence and severity of diarrhea as well as other diseases. Diarrhea also depletes zinc stores, leading to a vicious cycle. Research shows that, for children under five, taking 20 mg of zinc (10 mg for those under six months of age) for 10 to 14 days will result in a 25 percent reduction in the duration of acute diarrhea and a 40 percent reduction in treatment failure and death in persistent diarrhea (WHO/UNICEF, 2009). Recurrence of diarrhea is also reduced for about three months.

To prevent dehydration, which can be deadly, children need ORS or oral

rehydration therapy (ORT).<sup>1</sup> The new formulation of ORS with lower osmolarity (both lower sodium and lower glucose levels) leads to reduced stool output as well as reduced vomiting in comparison to the original formulation.<sup>2</sup> Together, zinc and “lo-ORS” save lives and represent an enormous advance for public health.

Lo-ORS and zinc treatment are relatively easy to produce and distribute, are safe, and do not produce serious side effects. However, as with adoption of any new product or practice, zinc treatment in particular requires changes in familiar behaviors—by health care providers and caregivers—as well as large-scale manufacture and distribution of quality products to accessible outlets.

To increase the availability and sustained use of these interventions, USAID created the Point-of-Use Water Disinfection and Zinc Treatment Project (POUZN) in 2005. This publication focuses on POUZN’s experiences in Tanzania introducing zinc treatment, along with lo-ORS, as a standard of care to treat children with diarrhea.

<sup>1</sup>For purposes of its survey, the Tanzania Demographic and Health Survey (TDHS) of 2004-5 defined oral rehydration therapy as solution prepared from ORS packets, recommended home fluids, or increased fluids.

<sup>2</sup> Low osmolarity ORS reduces stool output or stool volume by about 25 percent and reduces vomiting by almost 30 percent when compared to the original WHO/UNICEF ORS solution. See: <http://rehydrate.org/ors/low-osmolarity-ors-ga.htm>

## TANZANIAN CONTEXT

Worldwide, diarrhea is responsible for approximately 1.5 million childhood deaths a year and an estimated 17 percent of all child mortality (UNICEF 2009). In Tanzania, diarrhea is estimated to account for around 5 percent of child deaths. (Although this figure is probably low because it is based on data from facilities, and less than half of deaths take place in facilities.)<sup>3</sup>

The overall health situation has improved for Tanzanian children in the last two decades, and quite dramatically in recent years. Between 1999 and 2004, under five mortality dropped from 147 deaths for every 1000 live births to 112 deaths; infant mortality dropped from 99 to 68/1000. During this time, however, deaths due to diarrhea remained at virtually the same level.

ORS is recognized by a large percent of both mothers and providers as an appropriate treatment and the majority of caregivers seek some treatment for childhood diarrhea (using both government and private facilities). Making further improvements in practices remains a challenge, however.

**Care Seeking and Treatment.** According to the most recent Tanzania Demographic and Health survey (2004 TDHS), about 13 percent of children experienced diarrhea within the last two weeks—the same rate as in 1999.

Approximately 60 percent of mothers who had a child with recent diarrhea said they

<sup>3</sup> In Tanzania, the chief causes of childhood mortality are malaria (37 percent), anemia (25 percent), and pneumonia (16 percent) according to national HMIS statistics for 2002.

sought care. This varied little according to household wealth or a mother's education, or between urban and rural families. In fact, a slightly *higher* percentage of *rural mothers* sought care. This is especially unusual, and may reflect the robust government health system available in remote areas.

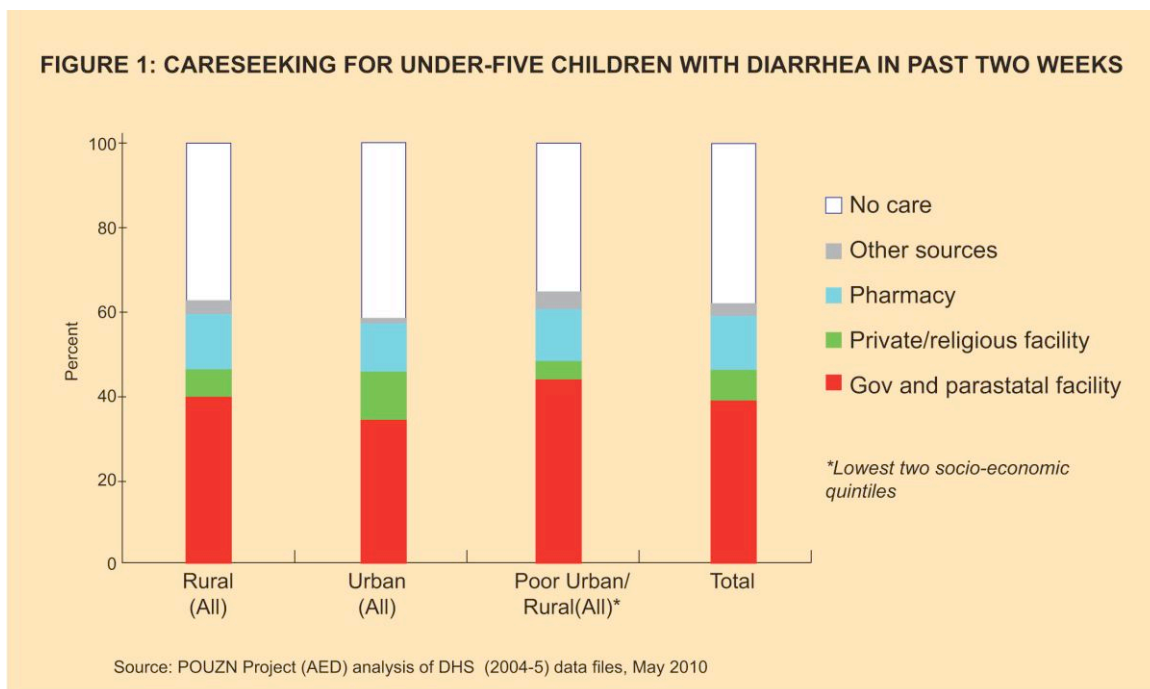
Figure 1 shows that mothers went to both public and private providers. Use of public facilities tended to decrease with economic status, higher levels of education, and urban residence. Overall, about 39 percent went to public facilities, 7.4 percent went to private/religious facilities, and 13 percent reported going to pharmacies.<sup>4</sup>

The vast majority (96 percent) of women with children under five years of age knew about ORS packets. For a recent case of diarrhea, 70 percent of children were given some form of ORT and 54 percent received packaged ORS. The number of mothers giving ORS packets varied only a percent or two by urban/rural residence, by educational level, or wealth.

Nevertheless, 40 percent of children received syrup or pills (which are likely to be inappropriate) and 16 percent received no treatment.<sup>5</sup> A significant proportion of children in the survey (one third) were offered less fluid than usual. And this trend was basically unchanged since 1999.

<sup>4</sup> The questionnaire included more than 15 possible responses to the question about where care was sought. "Shop" was not among the options. However, previous TDHS surveys combined pharmacies and "medical stores," and the percent who gave this response was similar to the percent who said they went to "pharmacies" in 2004-5.

<sup>5</sup> The only "appropriate" pills or syrups at this time could have been antibiotics, since zinc was not yet available. And antibiotics are only recommended for bloody diarrhea. According to the 1996 TDHS (the last time information was gathered about bloody diarrhea) among children who had diarrhea, 20 percent had blood in the stool, while 40 percent received pills or syrups.



**Diarrhea Treatment Policy and Availability of Essential Drugs.** When the project began in 2005, Tanzania had not yet adopted new diarrhea treatment guidelines. Also at that time, no African companies were producing zinc. Several Tanzanian companies produced ORS, but none produced a low osmolarity product. Access to quality essential medicines was also limited in rural areas. Only 375 licensed pharmacies operate in Tanzania, primarily in major cities. The rest of the population is served (in the private sector) by an estimated 5480 small drug outlets called *duka-la-dawa*, which, until recently, have not been approved to sell prescription medicines. Low quality and counterfeit drugs are a huge problem in Tanzania and throughout the continent.

## INITIAL GOALS AND STRATEGY

The goal of POUZN in Tanzania was to introduce zinc along with low osmolarity ORS *nationwide* as the new approved treatment for childhood diarrhea. The project aimed to work simultaneously with both the

public and private commercial sectors, building on their respective strengths, facilitating communication, and creating synergies between their different processes. This dual focus was essential given the *careseeking patterns* of Tanzania's most vulnerable groups, as well as the complex *interdependence* of roles between the public and private sectors in introducing and sustaining use of this new treatment.

Significant steps on the part of both sectors were required not only to assure the supply and distribution of two new products, but to promulgate revised treatment guidelines for childhood diarrhea and promote their acceptance by providers and the general public alike. Supply, policy, training, and demand creation issues were closely interrelated; obstacles in one area could stymie progress in the others.

The project aimed to facilitate all of these processes, with an understanding that the public and private sectors have different concerns, often speak "different languages," and move at different paces. An important principle of POUZN's role as a *catalyst* in

introducing zinc treatment was to support collaboration among a wide array of stakeholders. Another was to seek innovative links with international agencies,

sister development projects, and the media in order to overcome apparent barriers and speed progress.



## II. THE PROCESS OF POLICY CHANGE

The complex interaction between policy and supply issues, and public and private sector concerns, was apparent from the first day of the project.

In 2005 POUZN joined and supported a Zinc Task Force with representatives from the government, WHO, UNICEF, and international NGOs to advocate for adoption of new diarrhea treatment guidelines. The country's guidelines for the Integrated Management of Child Health Initiative (IMCI) were due for multiple revisions and the Chief Medical Officer believed it would be most efficient to roll these out in an integrated fashion. The five-day re-training course for all public health doctors would require \$1 million, however—and the costs of supplying all public health posts with zinc would be ongoing. Furthermore, the Ministry of Health and Social Welfare (MoHSW) had just dealt with the increased financial burden of introducing new quadravalent vaccines. The following year the MoHSW included lo-ORS in the national diarrhea guidelines (which had no cost implications for the government), but significant movement on zinc took two years.

POUZN sought ways to jump-start the process and to carry out groundwork that would stimulate fast action once policies were in place. Professional associations were important allies in advocating for the new policies.

### A MINISTRY WITH MANY “ARMS”

POUZN worked with various departments of the Tanzania Ministry of Health and Social Welfare to support the myriad activities necessary to assure zinc was affordable and accessible through the public sector.

Actions by the government were necessary in the broad areas of **1) policy change**, **2) product procurement**, and **3) promotion**. In some instances (e.g., gaining approval of zinc as an over-the-counter drug) members of several different departments needed to reach consensus before action could be taken. Below is a short list of the different ministry “arms” involved in launching zinc, and their multiple roles.

#### TFDA

- Register and regulate drugs
- Monitor drug quality
- Grant OTC status
- Certify ADDOs

#### IMCI Department

- Develop IMCI policies and guidelines

#### Pharmaceutical Supply Unit

- Ensure funds are provided to MSD for drug procurement
- Assist health facilities to forecast demand

#### MSD

- Procure and distribute all drugs to government facilities

#### CHMT (District/Regional Levels)

- Develop health plans (including budgets)
- Coordinate implementation of health plans
- Supervise training of district personnel and below
- Procure drugs from MSD (prepare budgets)
- Supervise/monitor ADDO performance

#### Health Education Unit

- Conduct health communication (radio, print, and TV)

POUZN supported presentations by a renowned zinc specialist on the WHO/UNICEF recommendations at annual conferences of the Medical Association of Tanzania, the Pediatric Association, the Association of Private Hospitals, and at Muhambili Hospital (the country's chief research hospital). The project worked closely with various levels of the IMCI Department to identify and resolve concerns about moving forward with a new policy, and paid for printing 25,000 copies of the recommended diarrhea guidelines so they would be ready for immediate dissemination.

The government of Tanzania adopted the new diarrhea treatment guidelines in July of 2007. The revised list of essential medicines (including zinc and lo-ORS) was adopted in November of 2007. Zinc was approved as an over-the-counter medicine in July of 2009. (The Drug Review Committee consists of members from several MOH departments and they required extensive time to review the evidence of zinc safety for over-the-counter use.)

## III. BUILDING A VIABLE SUPPLY CHAIN

### SUPPORT FOR A NEW AFRICAN PARTNERSHIP

During this extended period of advocacy with the government, POUZN meanwhile moved systematically to stimulate zinc production in the country and launch the product in the private sector. In 2005-6 the project carried out an assessment of Tanzanian drug manufacturers to identify those having the potential to produce and market zinc. The project sought a formal partner or partners. Criteria included multiple factors (see box). Of the five local pharmaceutical companies, three were promising. However, one company was reluctant to invest the necessary funds in a new product, and a second wanted to wait until zinc was added to the essential medicines list—since an estimated 65 percent of zinc demand in the country was projected to come through the public sector.



Shelys had constructed a new manufacturing plant in 2004 in anticipation of expanding its market.

**Forming a Mutually Beneficial Relationship.** POUZN therefore initially worked with one partner—Shelys Pharmaceutical Company. Shelys had constructed a new manufacturing plant in 2004 in anticipation of expanding its market

### CRITERIA FOR SELECTING INITIAL PHARMACEUTICAL PARTNERS

POUZN's assessment of pharmaceutical company capabilities focused on the following factors:

- Rank in Tanzanian market (sales revenue)
- Zinc production capacity (single or in multiple formulations)
- Willingness to take part in zinc project
- Export sales: percent and countries
- Field force (medical reps)
- Past experience with ethical marketing
- Past experience with over-the-counter marketing
- Past experience with rural marketing
- Past experience with social marketing
- Past experience covering paramedics (e.g., nurses, midwives)
- Past experience with institutional supplies
- Distribution network
- Research and development capabilities
- Manufacturing facilities (own or out-sourced)
- GMP status\*
- Production capacity for tablets/dispersible tabs & oral liquids
- Financial strength
- Corporate social responsibility work

\*Good Manufacturing Practice (GMP) is a status granted by WHO that indicates quality production.

beyond Tanzania, but had not yet been granted Good Manufacturing Practice (GMP) status by WHO/UNICEF—which is required to submit bids for donor purchases of pharmaceuticals. One of the chief incentives POUZN offered Shelys was technical assistance to achieve GMP status, which would be good for sales of zinc as well as other products. POUZN provided high level briefings to the company on the international zinc guidelines, and on all of the background research presented to the Tanzanian Food and Drug Agency (TFDA) supporting zinc registration.

The project also invited Shelys to attend meetings of the Zinc Task Force in order to hear firsthand how policy issues were proceeding and speak for private sector interests when appropriate.

POUZN and Shelys signed a memorandum of understanding (MOU) that outlined mutual responsibilities and benefits. These included a commitment to work together to create demand in Tanzania and to promote improved diarrhea management (including decreased use of inappropriate antibiotics). Shelys agreed to engage its medical representatives (or “med reps”) to reach health professionals, and to supply AED with monthly plans and sales reports.

Importantly, Shelys also committed to “co-promote” zinc with ORS. (In some countries zinc is co-packaged with ORS. In Tanzania, the two products are always promoted together.) In July of 2007, Shelys began distributing a low-osmolarity formulation of its own ORS brand *SAVE*, which became the first lo-ORS product in Tanzania. *SAVE* had been out of production for several years, and Shelys attributed renewed company interest to encouragement by POUZN and the T-MARC Project, one of AED’s sister projects.

### **Producing and Launching Quality Zinc.**

The partnership moved ahead quickly. POUZN brought in United States Pharmacopeia (USP) through another USAID contract to assess Shelys manufacturing and quality assurance procedures. USP determined that the new plant was well-designed and had excellent facilities (with the exception of a ventilation system that needed upgrading), but operating procedures were not completely in line with GMP standards. In July 2007 POUZN contracted with CRMO Pharmatech, an India-based firm, to conduct a gap analysis for upgrading procedures: from receiving to warehousing, production, cleaning, quality control, stability testing and shipping. Shelys invested about \$1 million to



Shelys agreed to co-promote zinc with ORS (including its own brand, *SAVE*) in all of its marketing materials.



*PedZinc* was first launched in commercial outlets.

implement the recommended changes. CRMO continued to provide advice to Shelys over subsequent months regarding zinc tablet documentation for the TFDA, preparation of a dossier to be submitted to UNICEF, and so forth.

As production neared, the Zinc Task Force lobbied with the Tanzanian IMCI Department to send a letter to the TFDA to fast-track the registration of zinc (from the customary 18 months to six or nine months).

In April of 2007 Shelys produced the first African-manufactured zinc treatment for diarrhea: dispersible tablets branded as *PedZinc*. It was affordably priced at 31-36 US cents per treatment course of ten tablets in a blister pack and attractively packaged.

POUZN and T-MARC supported launch events in Dar es Salam, Zanzibar, and Arusha, with major media coverage and promotions to the medical community. In the first three months on the market, sales reached around 25,000 courses, *solely in commercial outlets*.

### **ACTIVATING THE SUPPLY CHAIN**

As part of a strategy to ensure supply in the private sector, Shelys carried out “activations” at 20 key wholesalers in Dar es

### **In April of 2007 Shelys produced the first African-manufactured zinc treatment for diarrhea: dispersible tablets branded as *PedZinc*.**

Salaam that were responsible for sales to over 4,500 drug sellers. To *push* the product out, Shelys provided 90 days of credit to each wholesaler for a first supply of zinc. Communication with wholesalers was coordinated with a comprehensive roll-out by Shelys’ medical detailers to pharmacies in order to simultaneously generate a *pull* for the new supplies. (See also Demand Creation, below).

### **PRIMING THE GOVERNMENT SUPPLY SYSTEM**

The cost of introducing zinc in the public sector remained a concern to the Ministry of Health and Social Welfare even after adoption of the new diarrhea management guidelines. The government Medical Stores Department (MSD) was reluctant to stock zinc while demand was uncertain. The ministry, in turn, was reluctant to disseminate the new guidelines and encourage a *pull* by health facilities until adequate supply was assured.

Working through the Zinc Task Force, POUZN helped overcome this roadblock by approaching UNICEF to fund an initial *push* of zinc out to all public health facilities. UNICEF agreed to purchase a first six-month supply, estimated at 1.1 million courses of zinc. This tranche was purchased from a French manufacturer—the only UNICEF-approved source of zinc in the world at that time. In April 2009 the first

government supplies of zinc reached regional warehouses.

POUZN had also helped prepare for this important *push-pull* challenge early in the project by alerting the government offices responsible for drug budgets at local health facilities. These budgets are managed by Counsel Health Management Teams

(CHMTs). The project reached all districts in 11 regions, providing summaries of the improved diarrhea management guidelines and encouraging CHMTs to procure zinc supplies. POUZN also collaborated with Helen Keller International (HKI) to reach Regional Health Management Teams in all 21 regions of Tanzania to ensure CHMTs budgeted for zinc.



## IV. CREATING DEMAND

### CONDUCTING AND REVIEWING AUDIENCE RESEARCH

Targeted demand creation to stimulate both the *pull* and *push* for zinc was based on research with health providers, drug sellers, and caregivers. POUZN reviewed studies by other organizations and conducted qualitative research as well as a baseline study with caregivers to measure impact. The qualitative studies confirmed results of the 2004 TDHS—including widespread knowledge of ORS but a preference for pills and syrups (such as antibiotics and anti-pyretics) (see box).

As in many countries, a major challenge in Tanzania was to confront the common view among caregivers that ORS is inferior or insufficient because it cannot “cure” diarrhea, together with the entrenched expectations of drug sellers and providers that their clients will only be satisfied with antibiotics. The benefits of zinc as well as new lo-ORS provided an opportunity to break this cycle. Qualitative research showed *PedZinc* was acceptable to the target population in terms of color, size, and taste, and the blister packing was associated with high quality. (An early product test found that mothers objected to the slightly metallic taste of *PedZinc*, so the product was reformulated with a different masking agent.) However, the research also showed that caregivers would not be inclined to give the full ten-pill course to

children. This information shaped the promotional strategy and materials designed by POUZN.

#### WHAT DRUG SELLERS REALLY PRESCRIBE, WHAT CAREGIVERS REALLY WANT

POUZN carried out a “mystery client survey” in 2007 with drug sellers (both pharmacists and small drug outlets) in Dar es Salaam, Mwanza and four surrounding districts. The study looked at *products sold* for childhood diarrhea, *questions asked* by drug sellers before dispensing drugs, and *advice* given to clients.

The top three drugs offered were antibiotics (67 percent), ORS (37 percent) and antipyretics (31 percent.) ORS was only offered as a *first* drug to a client in 7.4 percent of cases. Mystery clients typically had to ask for “any other treatments” to obtain a recommendation for ORS. The results were largely consistent for different kinds and locations of drug outlets.

In a study carried out by USAID’s RPM+ project in 2007<sup>1</sup> of small accredited drug outlets (or ADDOs, discussed further below), interviews with drug sellers partly contradicted information gathered by mystery clients from the same outlets. Owners stated that they did recommend ORS for diarrhea (98 percent), but only 15 percent of mystery clients were actually prescribed ORS. A full 80 percent of owners said they believed antibiotics were appropriate for uncomplicated diarrhea.

Finally, qualitative research carried out by IFAKARA2 in 2007 showed the causes of diarrhea were widely misunderstood in rural areas. ORS is widely known and used, but patients are dissatisfied if only ORS is prescribed, because they don’t believe it can cure diarrhea.

<sup>1</sup> The Rational Pharmaceutical Management project, or RPM+, is funded by USAID and managed by Management Sciences for Health (MSH).

<sup>2</sup> In collaboration with the Johns Hopkins University and USAID’s A2Z project, which is managed by AED.

## MAKING THE CASE TO INFLUENTIALS

Advocacy with high level medical influencers in the very first months of the project provided the first sparks at the “top of the medical pyramid” for a cascading process of awareness raising and support for zinc. Shelys’ MOU with the project enlisted them actively in POUZN’s efforts to stimulate attention among the major professional associations at public and private hospitals. Seminars with the country’s top medical professionals focused on the clinical basis for changing the management of diarrhea.

POUZN took a very opportunistic approach to reach the upper tier of public health physicians in the project’s early months, given the government’s reluctance to create demand while supply was uncertain. Building on good relations with the IMCI Department, POUZN (working with WHO, UNICEF, and Shelys) was able to put zinc on the agenda of the annual IMCI *malaria* conference in July 2008. This event was attended by all of the country’s Regional Medical Officers and many District Medical Officers. Again, the focus at this level was on the clinical basis for changes in diarrhea management, although both Shelys and UNICEF also discussed supply issues.



POUZN targeted the prescribing behaviors of both private and public physicians.

Participants were enthusiastic and passed a resolution endorsing zinc and lo-osmolarity ORS, ensuring availability of the drugs, and reviving “diarrheal treatment corners” in health facilities.

A second opportunity to address Regional and District Medical Officers was offered via the regular *vitamin A* supplementation meetings held at zonal levels. POUZN gained participation in these meetings through collaboration with Helen Keller International and the AED-managed A2Z project. These meetings clearly were responsible for increasing the distribution of zinc from MSD stores down to health posts and dispensaries.

## COORDINATING THE PUSH-PULL BETWEEN PROVIDERS AND DRUG SELLERS

**Private Providers—Doctors, Clinicians, Nurses, and Others.** The project worked hand-in-hand with Shelys to coordinate the push-pull between private providers and drug sellers once *PedZinc* was on the market. POUZN carried out refresher training for all of Shelys medical reps, covering the clinical evidence for zinc/ORS and key selling points for discussions with clients. The project created a FAQ sheet to support discussions with both providers and pharmacists, and conducted simulations as part of the training.

Led by its top regional medical reps throughout the country, Shelys carried out seminars for doctors, nurses, and clinicians at major hospitals and MCH centers. They presented slides with the clinical evidence for zinc and lo-ORS, conducted interactive Q&A sessions, and distributed reminders to reinforce behavior change and generate prescriptions for zinc. They also gave out

complimentary samples of *PedZinc*—at this time the only zinc product available in Tanzania. Shelys created leave-behind materials including prescription pads and pens, while POUZN publicized key quotations from the guidelines and made the actual clinical studies available electronically on request.

In 2007 Shelys’ medical reps repeatedly visited doctors, nurses, and midwives in hospitals and other health facilities. Shelys reached 9599 of an estimated 14800 health professionals country-wide in these three categories.

**Pharmacies.** 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 and danglers, 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 to motivate sellers as well as potential clients.



Shelys ensured that all 375 pharmacies in the country had information about zinc

Shelys’ detailers aimed to visit each targeted outlet several times, providing complimentary stock and ensuring that retailers knew which wholesalers could re-supply them with zinc and lo-ORS. Visits were then made to wholesalers in the region letting them know reps had been out priming

the market. In its first six months on the market, sales of *PedZinc* were up to 32,000 courses. Shelys ensured that all 375 pharmacies in the country received information on lo-ORS and zinc treatment.

***Duka la Dawas/ ADDOs.*** In 2009, (following approval of zinc as an over-the-counter drug) Shelys visited an average of 2,231 drug outlets per month to provide updates and communication materials on new IMCI guidelines.

Additional contacts with retailers were made by the T-MARC Project through “trade activations” for both zinc and lo-ORS. Trade activations involve promoting the products to drug store staff, offering deals for first purchase, providing in-store promotional material, and ensuring both that outlets know where the product can be purchased again, and local wholesalers have sufficient product to meet demand. T-MARC’s mandate was to improve the availability and visibility of zinc among 25 percent of all drug sellers countrywide. T-MARC was already experienced in conducting activations for reproductive health products, working primarily with Mega Unity, a marketing agency. Mega Unity was contracted to cover 5,000 outlets (pharmacies, small shops, and also health facilities offering maternal and child health services) by October 2009. POUZN provided training for detailers as well as leave-behinds and promotional materials, and assisted in creating a monitoring plan.

In Tanzania, pharmacies only serve major cities. In rural areas and many urban neighborhoods, people rely on small retail outlets for purchasing over-the-counter drugs, along with a varying array of inexpensive household goods. The TFDA prohibits the sale of prescription medicines



POUZN created simplified, graphic materials for ADDOs.

at these general stores, but they are invariably available. To provide the great majority of Tanzanians with more reliable and convenient access to essential medicines, the government has taken on an ambitious project over the past several years of upgrading the skills and assuring the quality of drugs in many of these outlets. Those that complete the process successfully are known as *accredited drug dispensing outlets*—or ADDOs—and can prescribe essential medicines (see box).

## IMPROVING ACCESS TO QUALITY DRUGS THROUGH ADDOS

Until recently, the most accessible source of medicines for most poor Tanzanians has been small neighborhood shops that are not actually licensed to sell prescription drugs. The owners, who typically are literate but have no training as either pharmacists or health providers, dispense over-the-counter medicines and other drugs, and are often relied on to diagnose symptoms and offer advice.

In 2007, Tanzania had 5480 of these drug shops, or *duka la dawas*, and only 375 pharmacies.

With assistance from the Gates Foundation and later USAID, Management Sciences for Health (MSH) began working with the Tanzanian food and Drug Authority (TFDA) to train and accredit selected owners and employees of these already popular and accessible outlets to provide essential medicines. This new, upgraded level of drug shops is known as *accredited drug dispensing outlets*—or ADDO.

Shop owners and employees take courses in both management and medical aspects of the ADDO “business.” Those who go through the program receive legal authorization to sell approved essential prescription drugs (only those designated by the TFDA); benefit from a marketing campaign to promote use of ADDOS; and gain access to microfinance and links to health financing schemes.

In areas reached by the ADDO program, the TFDA also deputizes local government officials to inspect shops to ensure ADDOs maintain standards and non-accredited shops do not compete unfairly by continuing to sell prescription drugs.

A total of 3,825 *duka la dawas* are now accredited as ADDOs, representing 70 percent of outlets in eight regions in Tanzania. By the end of the project, the ADDO program will have covered 13 of Tanzania’s 21 mainland regions.





The project collaborated with MSH to conduct training-of-trainers for health workers.

POUZN collaborated with the TFDA and Management Sciences for Health (MSH) in introducing new diarrhea treatment management guidelines into the training of these ADDOs. The project designed both refresher training for shops that had already been upgraded, and a revised IMCI chapter for the regular “course.” POUZN printed 5,000 job aids as well as manuals for the training, and designed a training-of-trainers program including role plays for different client scenarios. POUZN also supported training for the CHMT staff, who are responsible for supervising ADDOs—as well as all public dispensaries and health posts in their districts. By year four of the project, sales of zinc in ADDO regions reached levels similar to those in Dar es Salaam—indicating major expansion into rural areas. By the end of the project, the ADDO program will have covered 13 of Tanzania’s 21 mainland regions, reaching areas where

almost 70 percent of mainland diarrhea cases occur.

#### **Public Sector Facilities and Providers.**

Given the huge expense and the slow process of revising and formally rolling out the complete IMCI treatment module for government providers, POUZN focused on providing ideas and materials to “jump-start” adoption of improved diarrhea treatment by public providers and facilities. The project worked with WHO and UNICEF, the IMCI Department, and key Regional Medical Officers to develop a wall chart on diarrhea management, roll-up banners with four rules for diarrhea management, and leaflets with important IMCI updates (including ORS and zinc preparation and use). POUZN funded the printing of 10,000 wall charts and 10,000 leaflets for distribution to all 3257 public health facilities.

The project had early contacts with all CHMTs about zinc because of their role in budgeting at the district level. CHMTs also received training as part of POUZN's program to reach ADDOs.

The project collaborated with MSH to train 240 health workers with supervisory roles on new case management guidelines, reaching 60 districts in ten regions—or about 35 percent of the total number of supervisors who in turn will provide on-the-job training to prescribers. POUZN will continue to train CHMTs across the county to ensure ongoing public sector support.

The formal public sector launch of zinc took place in 2009 with the participation of high level MoHSW officials, support by POUZN, and extensive coverage by the media. Following this, the MoHSW revised the diarrhea management guidelines in IMCI training manuals for use at zonal training centers (including for refresher training of health workers).

## CHANGING CAREGIVER ATTITUDES AND BEHAVIORS

Direct promotion of zinc to the general public was the last component of POUZN's demand creation strategy because of the need to ensure access in all public facilities. These concerns did not constrain publicity at the time of the private sector launch in 2007, however, which included television coverage and a play produced by local comedians promoting ORS and zinc.

In 2008, the Tanzania Zinc Task force requested that POUZN take the lead in designing a strategy to coordinate public and private sector communication to caregivers about zinc. The project held a day-long workshop with key stakeholders



The project launched a variety of zinc promotional activities at the village and health post level.

including WHO to determine behavior change targets and key messages based on available audience research. The multi-channel strategy emphasized radio,<sup>6</sup> community mobilization at markets, and one-on-one counseling by village health workers.

In anticipation of OTC status, a necessary step to advertise a drug in Tanzania, POUZN created generic radio advertisements and jingles for both zinc and ORS. These were approved for broadcast by the TFDA in 2009. The T-MARC project, in collaboration with POUZN, developed storylines mentioning improved diarrhea management for its popular Mama Ushauri radio soap opera, which reaches 1.1 million listeners. POUZN also participated in a Q&A radio session to improve consumer understanding. In year four of the project, these were aired four times weekly on Radio One, Radio Free Africa, Radio Tanzania, and Zenj FM. Broadcast messages will eventually reach 80 percent of Tanzania's population.

<sup>6</sup> TDHS 2004 indicates 58 percent of families own radios. The Tanzania All Media and Products Survey (Steadman 2005) indicates 95 percent of the population listens to radio at least once a week.



The T-MARC project was also a strong partner in mobilizing community interest in zinc. The project was already carrying out market day “activations” to promote reproductive health products, and POUZN was able to piggyback zinc onto this intervention. At market activations, music and skits attract visitors to counseling tents that supply information about health products, and a promoter explains their benefits. POUZN provided information materials and training on zinc to the promoters. By October 2009, T-MARC had reached about 65,000 people through activations in five regions.

POUZN has also created materials and a model plan for community mobilization via village health posts operated by the government. POUZN contracted with non-

governmental organizations (NGOs) in both urban and rural areas to train village health workers (VHWs) and promote zinc through performances and mobile video units. Each village health post received a set of counseling cards for use with caregivers. POUZN funded the rollout in village health posts throughout the Morogoro region.

The project conducted a baseline study of caregiver attitudes and practices in three regions of Morogoro in 2008. A follow-up evaluation will be conducted in 2010. Once impact data are available, POUZN will share these with the government, and encourage further support for the public sector rollout after the project has ended.

## V. RESULTS AND MOVING FORWARD

In the first four years of the project POUZN met its major goals for introducing zinc in Tanzania and established momentum that ensures sustainable supply and improved practices in both the public and private sectors.

The government of Tanzania adopted new diarrhea management guidelines, added zinc and lo-ORS to the Essential Medicines list, and allowed sales of zinc over-the-counter. These actions by the public sector were crucial. The government's Medical Stores Department now stocks both lo-ORS and zinc, and district-level CHMT's regularly order supplies for public health posts. Zinc has also been launched in Zanzibar (see box).

Through partnership with POUZN, Shelys Pharmaceutical Company became the first African manufacturer of zinc. With a final WHO inspection scheduled for 2010, Shelys is poised to become the first African company approved by WHO and UNICEF to supply donor-funded essential medicines across the continent.

Commercial sales increased over time and by early 2010 exceeded 600,000 courses—in comparison to no sales at the beginning of the project. POUZN can project commercial sales of more than 400,000 treatment courses of zinc in 2010.

In partnership with TFDA and MSH, POUZN re-trained all ADDOs registered to date, and the improved diarrhea management treatment protocols are being introduced to new ADDOs as this program expands across the country. This collaboration will continue to be critical in making zinc accessible in rural areas.

### MOVING FORWARD IN ZANZIBAR

The island of Zanzibar, which has a population of around 400,000 people, is officially part of the United Republic of Tanzania but has semi-autonomous government structures including its own Ministry of Health. Public distribution of essential medicines in Zanzibar is funded by the Danish. For a number of reasons, therefore, the process of introducing zinc in the public sector was able to move ahead more quickly in Zanzibar.

In 2008 POUZN supported a two-day workshop in collaboration with WHO focusing on the benefits of zinc and attended by Ministry of Health officials and key pediatricians and other stakeholders. Participants were enthusiastic about incorporating the new treatments in IMCI and created work plans to roll out zinc and lo-ORS. The MOH tasked POUZN with ensuring progress through a zinc task force in Zanzibar. New diarrhea management guidelines were adopted in February 2009 and the list of essential medicines was revised to include lo-ORS and zinc the following month. Zinc was also approved for sales over-the-counter at that time.

A POUZN consultant assisted with the roll-out, which included designing approaches and materials for promoting zinc and lo-ORS and discouraging use of antibiotics among different target audiences.

By mid-2009, 70,000 treatment courses of zinc were distributed to all health facilities in Zanzibar.

In 2008 a second pharmaceutical firm expressed interest in working with POUZN under the same conditions as Shelys. Zenufa, a company originally based in the Democratic Republic of Congo, built a new facility in Dar es Salaam and the project provided technical assistance through USP for necessary upgrading of operations. In April of 2010 Zenufa received permission from TFDA to register their zinc product for sale on both a prescription and over-the-counter basis.

Zenufa produced their zinc in syrup form because their marketing department was convinced this would be most popular for young children. Introduction of this new product onto the market spurred additional

interest by Shelys, who is now also developing a zinc syrup.

As this document is drafted in year five of the project, the primary challenge is to continue demand creation among the public at large. The Ministry of Health and Social Welfare is rolling out a POUZN-designed strategy to create awareness at the village level and improve counseling by village health workers. AED's T-MARC project is also launching an immediate and long-term strategy for behavior change among multiple groups. The strategy will provide support for ongoing communication activities, including mass media, as well as new efforts with NGOs active at the ward and community level.

## VI. LESSONS LEARNED

POUZN gathered lessons from the experience introducing zinc in Tanzania that will be useful moving forward and may be helpful to other programs:

**The public and private sectors have different objectives and time scales, and a project must be flexible enough to mobilize and synergize their comparative advantages. Both sectors have a role to play in introducing and sustaining a new health behavior such as zinc treatment, with the roles contingent on the country context.** In Tanzania, the project worked simultaneously with both the public and private commercial sectors. This dual focus was essential given the care seeking patterns of Tanzania’s most vulnerable groups, as well as the complex interdependence of roles between the public and private sectors in introducing and sustaining use of this new treatment. At times the commercial strategy could move forward very rapidly despite slower movement in the public arena. At times, policy and approval issues required sensitive advocacy before either strategy could move forward. For example, without government support, it was not possible to promote zinc via radio—which hindered private sector uptake.

**African manufacturers can produce quality zinc treatment products for distribution both domestically and internationally.** Technical assistance is needed to help manufacturers meet international standards. If they see the potential market, they are willing to make the changes needed and to invest resources.

**Inclusion of zinc therapy in national diarrhea treatment guidelines is critical; it may be supported “in theory” by ministries of health who nevertheless face competing pressures for attention and resources.** In Tanzania, garnering support for zinc treatment was difficult because of multiple demands for limited child survival resources. Donor pressures can also exacerbate this problem (in this case, the government had recently responded to donor pressures to introduce quadravalent vaccines). Building support gradually, starting with the parts of the ministry most involved with diarrhea and pediatric concerns, ultimately helped secure policy changes and higher-level acceptance.

**Slow public sector procurement can affect uptake in countries with a large public health sector.** The government was reluctant to purchase zinc for the first time because of the expense, and also because it was impossible to project (and ensure) demand for the new product. UNICEF’s offer to procure the first one million treatment courses of zinc resolved this conundrum. Once zinc was available, facilities began dispensing and restocking the drug. By late 2009, after three years of project implementation, the government was ready to procure zinc from its own budget.

**Demand creation is needed at all levels to ensure both the “push” and “pull” of the product from the manufacturer through wholesalers, retailers, health facilities, and ultimately to caregivers.** Introducing a new product like zinc requires “priming” several levels of the supply chain,

as well as concerted behavior change strategies and materials. Activations and other marketing strategies need to focus on zinc (and ORS) rather than “bundling” it with other ongoing efforts.

**The most vulnerable caregivers often rely on advice from rural drug sellers; these outlets must be part of an effective intervention.** Given the role that the informal health sector plays in Tanzania and many other countries, it is imperative to consider the best ways of reaching these providers so they make appropriate recommendations to caregivers. The ADDO program in Tanzania was a critical channel for improving access to zinc and improving case management of diarrhea among children. Approval of zinc as an over-the-counter medicine was an important step for making zinc available in the large number of non-registered rural outlets. (OTC approval

was also necessary in Tanzania before the project could undertake widespread promotion via mass media.)

**Zinc treatment for diarrhea is a new concept facing strong competition.** In Tanzania, mothers have a preference for anti-pyretics and antibiotics. ORS faces this same competition. Even though both providers and mothers are aware of ORS, mothers are not satisfied with it because it doesn’t “cure diarrhea,” and providers are reluctant not to give mothers what they want. “Piggybacking” zinc onto ORS is therefore far from a sure way of creating demand for the product. Furthermore, research in Tanzania showed that mothers believe ten days of zinc is “too much.” Sustained education and promotional efforts are required to ensure appropriate practices among prescribers, drug sellers, and caregivers.

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