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Introducing Improved Treatment of Childhood Diarrhea With Zinc and ORT in India, Indonesia, and Tanzania

**A PUBLIC-PRIVATE PARTNERSHIP
SUPPORTED BY THE POUZN/AED Project**

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ACRONYMS

ADDO	accredited drug dispensing outlets
AED	Academy for Educational Development
ASCODD	Asian Conference on Diarrhea Diseases and Nutrition
B-POM	Badan POM (the Indonesian National Agency of Drug and Food Control)
CD	compact disk
CHMT	Counsel Health Management Team
DVD	digital video disk
FAQ	frequently asked questions
GMP	good manufacturing practice
GP	general practitioner
HKI	Helen Keller International
IAP	Indian Association of Pediatrics
IBI	Indonesia Midwives Association
IDAI	Indonesia Pediatric Association
IDI	Indonesia General Practitioners Association
IDHS	Demographic and Health Survey
IIPS	International Institute for Population Sciences
IMA	Indian Medical Association
IMCI	Integrated Management of Child Illness
IMDI	Indonesia Medical Data Index
lo-ORS	low-osmolarity oral rehydration salts
MCH	maternal and child health
MOH	Ministry of Health
MSH	Management Sciences for Health
MoHSW	Ministry of Health and Social Welfare
MOU	Memorandum of Understanding
MSD	Medical Stores Department
NEDL	National Essential Drug List
NFHS-3	National Family Health Survey III
NGO	non-governmental organization
NRHM	National Rural Health Mission
ORT	oral rehydration therapy
ORS	oral rehydration salts
OTC	over-the-counter
PACT-CRH	Program for Advancement of Commercial Technology – Child and Reproductive Health
PANI	People's Action for National Integration
PMA	Pharmaceutical Manufacturing Association
POU	point-of-use water disinfection
POUZN	Point-of-Use Water Disinfection and Zinc Treatment Project
PSA	Public Service Announcement
Q & A	question and answer
RPM+	Rational Pharmaceutical Management Project

RMP	rural medical practitioner
SES	socio-economic status
SSS	Shashwash Sahbhagi Sansthan
TDHS	Tanzania Demographic and Health Survey
TFDA	Tanzanian Food and Drug Agency
UNICEF	United Nations Children's Fund
UNOPS	United Nations Operations Unit
UP	Uttar Pradesh, India
USAID	United States Agency for International Development
VHW	village health worker
WHO	World Health Organization

EXECUTIVE SUMMARY

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). Together, zinc and “lo-ORS” save lives and represent an enormous advance for public health. The new products also offer more of the attributes mothers say they want.

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

The project aimed to: 1) build a nationwide supply of zinc in all three countries; 2) support national policies and create an enabling environment for adoption of the new treatment; 3) influence the prescribing behaviors of providers and create demand among caregivers.

BUILDING SUPPLY

POUZN clearly demonstrated the effectiveness of using donor funds to catalyze the private commercial sector and begin building nationwide supplies of zinc for treatment of childhood diarrhea.

As of late 2010, 30 firms were manufacturing and/or distributing zinc in India. According to independent audit figures, sales of zinc on the commercial market reached more than 900,000 treatment courses in the first year of the project, and rose to annual sales of 5.5 million courses by the middle of the final year.

In Indonesia, ten manufacturers brought products to the market (supplying zinc for both the public and private sectors) in syrup and tablet form, and at both high and low price points. Total zinc sales by the end of POUZN’s 2009 fiscal year were almost 2 million courses.

In Tanzania, POUZN helped a local manufacturing company develop its capacity to produce zinc and upgrade its facilities in order to achieve Good Manufacturing Practices (GMP) status. This effort paved the way for an African company to supply zinc to neighboring countries. By the end of 2010, overall project sales through the private sector had reached 772,580 courses. A second firm has now applied to the government to register its own zinc products.



SUPPORTING AN ENABLING ENVIRONMENT

POUZN was also successful in catalyzing support for government policies essential to the roll-out of zinc in the public *as well as* the private sectors. Government tenders for the procurement of zinc in the public sector are underway. Zinc has been incorporated in national guidelines for Integrated Management of Child Illness (IMCI) and diarrhea programs, and is approved for over-the-counter sales in all three countries. Zinc has also been included in the national essential medicines lists of India and Tanzania, and is pending approval in Indonesia.

Critical to the acceptance of zinc as a new treatment norm, POUZN has created a core of champions at the top of the medical pyramid whose influence continues to cascade down the broader health provider community in each country. .

INFLUENCING PRESCRIBING BEHAVIORS AND CREATING DEMAND

The POUZN project negotiated agreements with its core commercial partners to leverage and train their medical representatives, which helped “push” zinc out into the top tiers of the market through company networks and powerful face-to-face promotion to health providers. Through this strategy, the private sector was allowed to carry most of the financial weight of bringing zinc to market. In addition, POUZN designed targeted strategies to reach potential suppliers and prescribers of zinc serving the poorest and hardest-to-reach households. In India, this meant working with unlicensed rural medical practitioners (RMPs); in Tanzania, small drug sellers; and in Indonesia, midwives

Given limited project resources, POUZN initially prioritized the building of support for zinc at the provider and policy level and later dedicated limited resources to demand creation in the general public. Given the high cost of broadcast media, POUZN only supported radio and television advertising when partners showed



POUZN reached providers in both sectors.

promising commitment to continue mass media promotion (such as the MOH in Indonesia)

CHANGES IN PROVIDER AND CAREGIVER PRACTICES

Research conducted in the three POUZN countries demonstrated changes in key indicators among providers, but showed less success in creating awareness and demand for zinc among caregivers themselves.

Providers. In each country, prescriptions for zinc rose—to rates of 58 percent in India among RMPs and chemists; 34 and 27 percent respectively among pharmacies and shops in Tanzania; and 73 percent among midwives in Indonesia.

Reported changes in other diarrhea-related practices were particularly impressive in Indonesia: research data showed almost universal prescription of ORS, and very low rates of antibiotic prescriptions (8 percent in the intervention area compared with 22 percent in the control area). In Tanzania, a baseline study collected through mystery clients revealed increases in ORS prescriptions from 36 to 52 percent in drug shops, but not in pharmacies. Prescriptions for antibiotics fell in Tanzania drug shops though remained high (86 to 81 percent), and were 10 points lower among trained ADDOs. There was however no change in pharmacies. Prescriptions for antibiotics remained high in India, 70 percent in the intervention area compared with 79 in the comparison area.

Caregivers. POUZN's goal was to achieve 20 percent zinc use rate among caregivers and increase ORS use by at least 25 percent over baseline. The Tanzania program achieved only 9 percent zinc use, and no significant change from baseline in either zinc or ORS use. There was, however, a significant drop in reported use of antibiotics (from 45 to 11 percent). Indonesia did not see any significant change in the use of recommended or non-recommended treatments by caregivers. Zinc use at endline (16 percent) was also not significantly higher than the comparison areas. ORS use (at 43 percent) was lower than might have been expected because virtually all midwives reported prescribing it. India achieved high increases in zinc use (0 to 50 percent) but none in ORS. The project did not have adequate data on the use of antibiotics to make an assessment of this practice among caregivers.

MOVING FORWARD

The POUZN project has demonstrated that commercial resources and networks can be successfully leveraged to build a manufacturing base, as well as a nascent market for introducing a new treatment such as pediatric zinc. Two main approaches can be drawn for future projects based on observed care-seeking patterns: In countries with high use of private sector products and services, and a well-developed local pharmaceutical industry, a classic pharmaceutical model with extensive marketing of zinc among the provider community is recommended. Once the provider support for the new treatment is sufficiently established, then the project can mobilize funds to start caregivers' education. The second approach, in less developed markets, aims to maximize access to zinc through multiple channels and partners, including the commercial and public sector, and donor-funded social marketing programs and NGOs.

While POUZN strove to launch sustainable markets for zinc, much more is needed to reach the level of supply that would be necessary to treat all childhood diarrhea cases in POUZN countries. However, supply is highly dependent on the level

of demand created through sustained education efforts at the provider and caregiver levels. Regardless of the model used to bring zinc to market, creating demand for ORS and zinc treatment implies overcoming a major stumbling block: the persistent reliance by health providers and caregivers on inappropriate treatments and products. Programs to introduce zinc must therefore be backed by multi-sectoral efforts to establish a better understanding of diarrheal disease, and achieve consistent use of appropriate treatments by caregivers, the only true measure of sustained health impact.

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I. INTRODUCTION

THE ROLE OF ZINC AND ORS IN REDUCING CHILDHOOD DIARRHEA

Worldwide, diarrhea is responsible for approximately 1.5 million childhood deaths a year and an estimated 17 percent of all child mortality (UNICEF/WHO 2009).

While child mortality rates continue to improve, rates of death due to diarrhea have been unchanged for a decade and more. Mortality is especially high among the rural poor. In the 1970s and 1980s, the introduction of oral rehydration therapy (ORT) and the first packaged oral rehydration salts (ORS), together with programs that brought about significant changes in both provider and caregiver practices resulted in major reductions in child deaths in many countries (UNICEF/WHO 2009). However, funding for child survival in general began to decrease in the 1990s. The introduction of Integrated Management of Child Illness (IMCI), also lessened the focus on community and family involvement in diarrheal disease, and ORS use rates stagnated, or decreased. According to data from 2005-2008, only 33 percent of children with diarrhea in the developing world were given ORS, with the lowest rates found in Africa and South Asia.

The development of new ORS formulations, together with the introduction of pediatric zinc, represents a significant advance in the control of childhood diarrhea. The newest formulation of ORS with lower osmolarity (both lower sodium and lower glucose levels) have been shown to reduce stool output and reduce vomiting when compared with older formulations.¹

¹ Low osmolarity ORS reduces stool output or stool volume by about 25% and reduces vomiting by almost 30% when compared to the original WHO/UNICEF ORS solution. See: <http://rehydrate.org/ors/low-osmolarity-ors-ga.htm>

Zinc for its part, plays an important role in the immune system. A deficiency in this essential mineral can increase the incidence and severity of diarrhea, as well as other diseases. Diarrhea also depletes zinc stores, leading to a vicious cycle. Clinical research shows that treating children under five with 20 mg of zinc (10 mg for those under six months of age) for 10 to 14 days, results in up to a 25 percent reduction in the duration of acute diarrhea, and a 42 percent reduction in treatment failure and death (WHO/UNICEF, 2009). Administering zinc also reduces the recurrence of diarrhea for about three months.

Thus, when used in combination, zinc and lo-ORS not only save lives and represent an enormous public health advancement, but also offers more of the attributes mothers say they want.

In 2004, the World Health Organization (WHO) and UNICEF recommended that national guidelines for the treatment of diarrhea be revised to include zinc therapy and the new low-osmolarity formulation of ORS (WHO/UNICEF 2004). These guidelines, together with the introduction of new products, have resulted in renewed worldwide efforts to address childhood diarrhea.

CHALLENGES IN PROMOTING APPROPRIATE DIARRHEA TREATMENT AND PREVENTION

Simple and affordable life-saving practices in the treatment of childhood diarrhea can be surprisingly difficult to mainstream, both in the general population, and within the provider community. Though ORT and ORS are effective in preventing death from dehydration, they do not do what mothers instinctively see as most important: stop the diarrhea. Even those mothers who report

giving ORS or ORT to their children often do not provide enough liquids for a sufficient duration.

Many caregivers also receive advice from healthcare providers who favor prescribing medical treatments for diarrhea. ORT and ORS may be widely recognized by the medical community in many countries, but zinc for childhood diarrhea is relatively new and has only recently been adopted by public health authorities.

Although laws vary by country, pediatric zinc belongs to a class of products considered “ethical” that must be prescribed by a doctor, and more often than not, sold through registered pharmacies. This status can be relaxed by the granting of Over the Counter (OTC) authorization, allowing the product to be sold without a prescription, and beyond the limited pharmacy network. In practice however, new ethical products are always introduced according to well established pharmaceutical industry norms that imply sustained marketing to the medical community. By-passing this step and attempting to market a new product directly to consumers, it carries the risk of a backlash from the medical community and is rarely attempted. Instead, pharmaceutical manufacturers typically ensure that new treatments are endorsed by medical experts and adopted by practitioners before deciding to “go OTC”. This decision implies not only obtaining a new classification authorization, but also deploying a direct-to-consumer marketing strategy.

Pediatric zinc for the treatment of childhood diarrhea faces entrenched prescribing practices that can be very difficult to change. Marketing pressure from manufacturers of profitable antibiotics, requests from mothers for anti-diarrheal products, and limited earning potential from the sale of pediatric zinc conspire to make it an “orphan product” in an area crowded with treatments for diarrhea.

The harmful and long-standing synergy between industry, providers and caregivers is a substantial barrier to the adoption of zinc for diarrhea treatment. Overcoming this barrier calls for appropriate behavior change strategies tailored to each audience, beginning with the medical community, and extending to the mainstream caregiver population.

THE POUZN PROJECT

To increase the availability and sustained use of zinc in conjunction with ORS, USAID created the five-year Point-of-Use Water Disinfection and Zinc Treatment Project (POUZN) in 2005. This publication focuses on AED/POUZN’s experiences in three countries—India, Indonesia, and Tanzania—introducing zinc treatment, along with low-osmolarity (lo-ORS), as a standard of care for treating children with diarrhea.

Overall project goals. The goal of the POUZN project in all three countries was to introduce zinc along with lo-ORS *nationwide*, and promote their use as the recommended treatment for childhood diarrhea. POUZN also had a strong mandate to reach the most vulnerable groups, including those in rural areas. USAID proposed a target of 20 percent zinc use among caregivers for a recent case of childhood diarrhea, and an increase in ORS use of 25 percent over baseline.

Table 1 puts these goals in perspective. The project faced significant barriers in all three countries in the form of competing products, and appropriate treatment approaches. Large numbers of mothers for example reported giving “less or no liquids” to their sick child, instead of focusing on rehydration. Despite high overall awareness of ORS, antibiotic, anti-motility, and other products dominated the market, with the exception of Tanzania, where the use of packaged ORS approached 54 percent. A major challenge for the project was to shift this overall picture through the introduction of zinc, and eventually reduce the use of inappropriate and often dangerous treatments.

TABLE 1:

Percent caregivers in three countries who gave recommended and non-recommended treatments for child diarrhea (last two weeks)

Country	Gave Recommended treatment			Gave non-recommended	
	ORS packet	Rec. home fluids	Increased fluids	Injection, pills, or syrups*	Less or no liquids
India	26	20	10	51.3	40.8
Indonesia	35	22	30	48.3	22.1
Tanzania	53.9	19.8	36.4	40	33.2

*Pills, syrups, and injections are most likely to include antimalarials, which are harmful for children under five years, or antibiotics, which are appropriate only in cases of bloody diarrhea (about 5-10% of cases)

Sources: India–DHS 2005-06; Indonesia–DHS 2007; Tanzania–DHS 2004-05

In all three countries and in all SES groups, many caregivers seek advice from shopkeepers.

To achieve its goals, the project aimed to:

- Build a competitive market for zinc, in which multiple commercial companies—manufacturers, distributors, and marketers—would be willing to produce and market zinc, and ultimately supply low-income communities with a low-cost, affordable product;
- Influence the prescribing behaviors of health providers, and generate demand for and appropriate use of zinc by caregivers;
- Create an enabling environment by supporting the development of clear national guidelines, and the endorsement of zinc treatment products by professional associations, as well as the public health sector.

The balance between these key interventions varied according to each country context, leading to three unique stories and important lessons learned.

Country contexts. At the start of the project in 2005, zinc was not available in appropriate formulation and doses in any of the three countries, with the exception of a limited supply used for clinical studies in India. This made close collaboration with local manufacturers a critical aspect of the intervention. Country strategies were adapted to the state of the local pharmaceutical industry, which is significantly more advanced in India and Indonesia than in Tanzania.

An equally important step was to identify predominant care seeking patterns among households in each country in cases of childhood diarrhea. The figures on page 4 provide an analysis by AED of DHS data showing care seeking patterns in urban and rural areas, as well as among households in the lowest two socioeconomic (SES) quintiles. (The red and green bars indicate groupings by public and private sources, respectively.)

India. The private sector provided the most care for children with diarrhea in India, even among the poorest families. According to data from the most recent demographic and health survey (NFHS-3), 38 percent of mothers in the lowest SES groups who sought care for a recent case of diarrhea, went to private health providers or shops. Nearly as many (36.7 percent) did not seek any treatment at all. Around 13 percent went to public health facilities.

Indonesia. The pattern in Indonesia was similar to that in India. The private sector provided a substantial amount of care for children with diarrhea, serving 38 percent of the poorest families compared with 18 percent seen by the public sector (BPS, 2007). The role of midwives (who may be employed simultaneously in the public and private sectors) was striking, with around 19 percent of rural families seeking their advice. Once again nearly a third of the poorest families did not seek care.

Tanzania. Of the three countries, Tanzania stood out for its high rates of care seeking in the public sector—and a slightly higher care seeking rate in rural areas. This unusually high rural rate may reflect the presence of a robust public health system in remote areas. Among the poorest families, 43 percent went to public providers, 4 percent went to private/religious facilities, and 12 percent reported going to pharmacies or shops. Even in the context of strong public services, however, 36 percent did not seek care.

POUZN’s role as a catalyst. In response to generally high rates of care seeking from private sources, and the need to build the manufacturing base for zinc, POUZN worked in close collaboration with private sector from the outset.

As time went on, the project worked increasingly with *both* the public and private commercial sectors, building on their respective strengths, facilitating communication, and creating synergies between their different programs.

The project saw its role as that of a catalyst, stimulating processes that would be viable over the long term. Supply, policy, training, and demand creation issues were addressed simultaneously, as obstacles in one area could stymie progress in the others. POUZN 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.

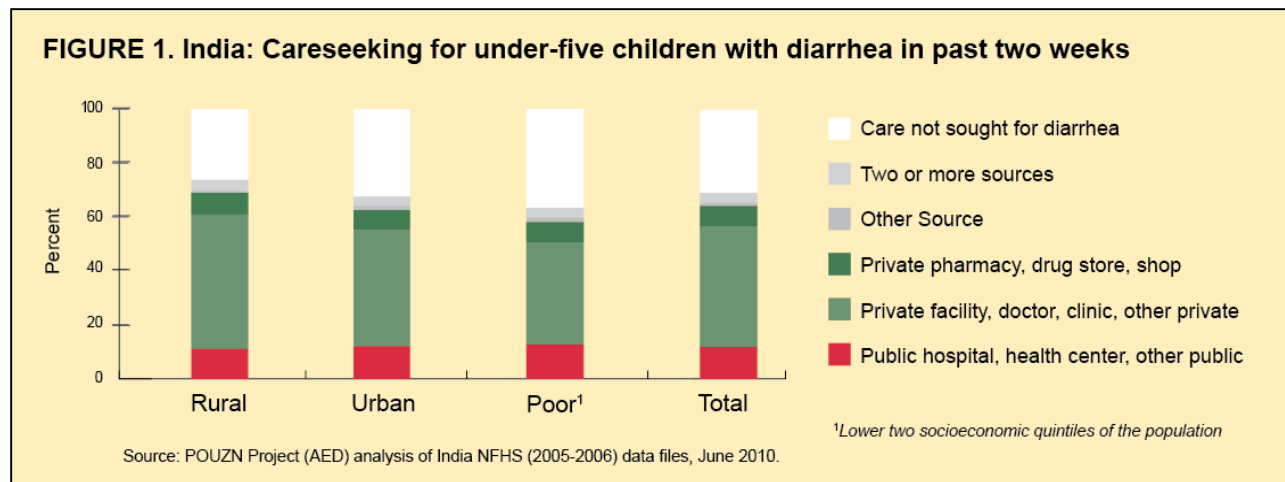


FIGURE 2. Tanzania: Careseeking for under-five children with diarrhea in past two weeks

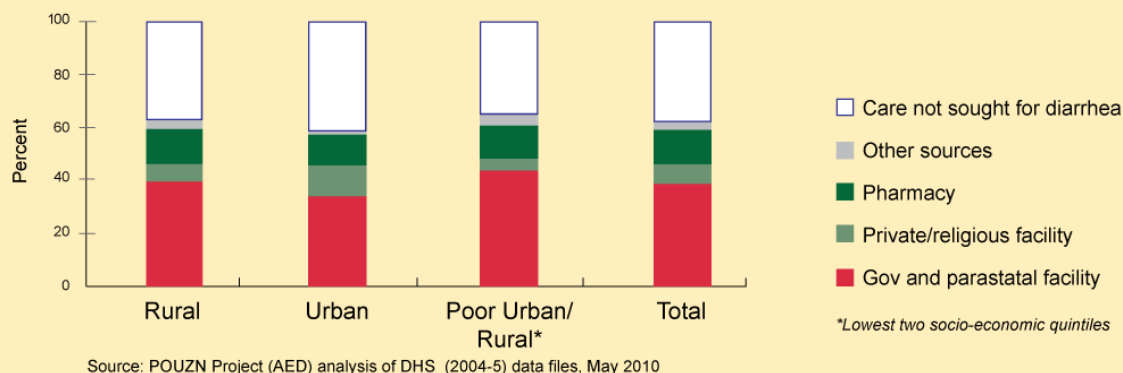
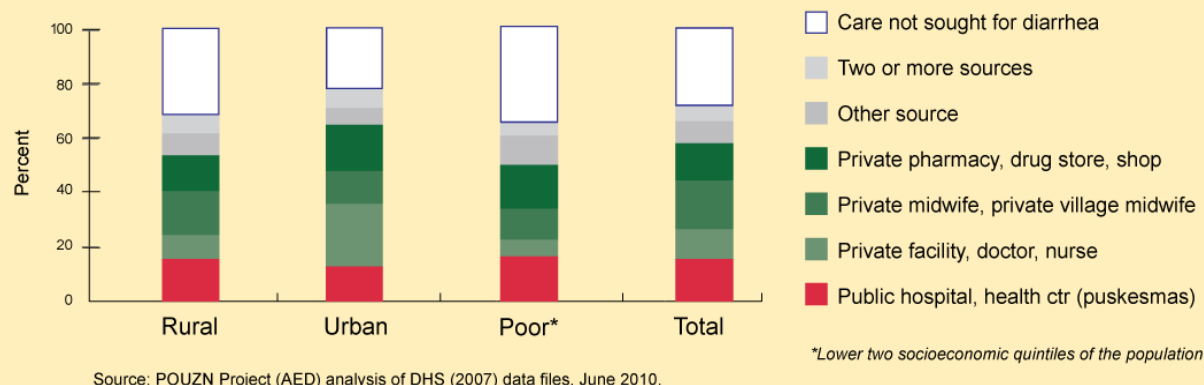


FIGURE 3. Indonesia: Careseeking for under-five children with diarrhea in past two weeks



NOTE: Tanzania: 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.

II. BUILDING LOCAL SUPPLIES OF ZINC

POUZN's foremost goal in all three countries was to stimulate local production of a sufficient and sustainable supply of zinc for treatment of childhood diarrhea nationwide. Emphasis on commercial production and commercial sales allowed the project to jump-start activities even before supportive government policies were entirely in place.

At the outset of each country program, POUZN carried out an assessment of the local pharmaceutical industry to identify strong manufacturers. The project established criteria related to production, quality assurance, distribution, promotional reach, and other corporate characteristics (see box). The goal was not to limit participation, but rather to accelerate the process with a committed team. The project adhered to the principle that involvement by more firms over time would improve competition and keep prices low.

Consistent with its role as a catalyst, POUZN aimed to provide assistance only where needed—in order to save costs, avoid building “parallel” donor-funded systems, and most importantly, build on the strengths of local businesses and their knowledge of the markets.

LAUNCHING ZINC IN THE CONTEXT OF STRONG ASIAN MANUFACTURING

Given the flourishing pharmaceutical sectors in both India and Indonesia, any company that decided to produce zinc was likely to have the resources to shoulder production and sales costs, and a network to market the product to providers and drug shops. The challenge was to stimulate this process.

POUZN's initial assessment of 20 drug manufacturers in India produced a short-list of seven promising partners. Two years later, a similar assessment in Indonesia identified an

initial ten companies, and narrowed its focus down again to seven.

Project staff set up one-on-one meetings with high-level decision makers in each of these

CRITERIA FOR SELECTING INITIAL PHARMACEUTICAL PARTNERS

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

- Rank in the national 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 (prescription drugs)
- 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.

companies to make the case for investing in zinc. They presented a tailored dossier including: 1) a summary of the clinical research about zinc as a state-of-the-art treatment and a complete bibliography; 2) WHO/UNICEF guidelines on zinc and ORS treatment for childhood diarrhea; and 3) a document on the manufacturing process for zinc tablets and syrup (WHO, 2007). POUZN staff was able to discuss the market and business potential for zinc and encouraged companies to

undertake their own feasibility studies. Each had the funds and the expertise to do so, and would have more confidence in their own analyses of market potential than any arguments from donors.

The project staff also believed that these manufacturers were best positioned to determine the preferences of their traditional customer base. POUZN therefore frequently took a “hands off” approach with respect to certain product features, or individual companies’ marketing and promotional strategies (see box.)

POUZN did help in all three countries to advocate with appropriate government agencies to fast-track registration of new products and also overcome other bureaucratic hurdles (discussed further in the next section). On average, the project helped reduce the time to market for new zinc tablets and syrups from the usual 18 months to six or nine.

India. The pharmaceutical industry in India embraced zinc within their pediatric product lines. In the project’s first year, seven Indian firms decided to manufacture and market zinc for the commercial market. Each of them developed, registered, manufactured, branded, and packaged zinc using its own resources. Following the initial seven, additional companies continued to enter the market every year. By late 2010, 30 firms were manufacturing and/or distributing zinc in India.

According to independent audit figures, sales of zinc on the commercial market started at more than 905,000 treatment courses in the first year of the project and rose to annual sales of 5.5 million courses by the middle of the final year. A course of zinc was priced between \$US.50 and \$1.00.

Indonesia. Manufacturers were initially concerned that zinc would be largely a public sector product, and that its price would be controlled by the government. Their fears were eventually allayed, and companies developed both cheap generic forms of the drug in

NEGOTIATING LOCAL PERSPECTIVES & INTERNATIONAL GUIDELINES

In all three countries POUZN operated on the principle that the commercial sector knows its own markets best. Sometimes this required a strategic “hands off” stance by the project; often it required negotiation.

WHO clinical trials used dispersible zinc tablets (dissolved in water or other fluids), because tablets contain a precise dose and are easy to store. However, many companies were convinced from their own data that caregivers preferred to give syrup to their young children. By end-of-project, manufacturers in all three countries had introduced zinc syrups. In India, syrups eventually accounted for 87 percent of zinc market sales.

None of POUZN’s partners chose to co-package zinc with ORS. The project did request that companies already producing ORS *co-promote* their two products in marketing materials. Others were asked to promote zinc *along with* ORT. All companies agreed.

anticipation of government procurements, and more profitable branded products for the private market.

Two companies launched three products (two tablets and one syrup) within the first 11 months of project implementation. Within one year, commercial sales reached 290,730 courses. By the end of the project, ten manufacturers had introduced products in both syrup and tablet forms and at both high and low price points (supplying zinc for both the public and private sectors). Total zinc sales by the end of POUZN’s 2009 fiscal year were 1.956 million courses. Prices ranged from roughly US \$.65 to \$3.50.

LAUNCHING ZINC IN AFRICA

Although further advanced than in most of Africa, the pharmaceutical industry in Tanzania was in its infancy when POUZN carried out its assessment in 2005-06. Three of five local companies were approached. One was reluctant to invest in a new product. A second wanted to wait until zinc was added to the essential medicines list, because an estimated 65 percent

of demand was projected to come through the public sector.

As a result, the project initially worked with only one partner—Shelys Pharmaceutical Company—and provided the company with substantial support. A key incentive offered by POUZN was technical assistance to Shelys in achieving Good Manufacturing Practice (or GMP) status for its new plant. This was a critical step as only companies with GMP status are permitted to submit bids for donor purchases of pharmaceuticals.

Shelys agreed to develop an outreach program for health providers, using its own medical representatives, and to supply AED with monthly plans and sales reports. As in India and Indonesia, the company also agreed to co-promote zinc and ORS. In July of 2007, Shelys began distributing Tanzania's first low-osmolarity ORS formulation under its ORS brand -SAVE.

POUZN also requested the assistance of the United States Pharmacopeia (USP), supported by another USAID contract, to assess Shelys' manufacturing and quality assurance processes, and contracted with CRMO Pharmatech, an India-based firm, to conduct a technical gap analysis. Shelys invested about \$1 million in recommended changes.

In April of 2007 Shelys produced the first African-manufactured zinc treatment for diarrhea in the form of dispersible tablets branded *PedZinc*. The product was priced at US \$.31-36 per treatment course. Within three months of the product's launch, sales reached around 25,000 courses in commercial outlets alone. By early 2010, overall



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

project sales through the private sector had reached 772,580 courses, and an additional 350,000 courses were being projected for that year. With a final WHO inspection scheduled for January 2011, Shelys is poised to become *the first African company approved by WHO and UNICEF to supply donor-funded essential medicines across the continent.*

In 2008 POUZN agreed to work with a second firm, Zenufa, which had completed a new facility in Dar es Salaam. Once again the project provided technical assistance through USP for upgrading 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's product, a syrup, is expected to be on the market in early 2011. In response to this initiative, Shelys proceeded to develop its own zinc syrup formulation to compete with Zenufa's.

III. SUPPORT FOR ENABLING POLICIES

The interconnectedness of *public policies* and *private sector decision-making* was apparent from the first moments of the project. Beyond the obvious need to register new products with regulatory food and drug agencies, policies and government actions necessary to grow the market included:

- Incorporation of zinc and lo-ORS in **national guidelines** for diarrhea/IMCI programs
- Incorporation of zinc in the **essential medicines list** (so it would be procured by public hospitals and health centers)
- Approval of zinc as a **program drug** (so it could be purchased with central health budget)
- Classification of zinc as an **over-the-counter drug** (for wide availability beyond pharmacies and for public advertising)
- **National tendering of bids** to procure zinc for the government stores
- **Budgeting for zinc purchase** by lower-level health departments

POUZN provided support to move all of these actions forward, most often as a member of the national Zinc Task Force (along with influential representatives from UNICEF and WHO), but frequently on a personal basis in one-on-one discussions with key officials. Areas of stated government concern about zinc focused on questions of *efficacy, funding, and safety*. Understanding the unstated concerns was often the biggest task, however. The bureaucracies and their issues were at least partly unique to each country. The box on the next page shows ministry offices involved Tanzania.

ESTABLISHING ZINC EFFICACY AND THE IMPORTANCE OF CHAMPIONS

Country ownership of clinical data about zinc was critical. Launching of zinc in India was largely possible because one of the first clinical trials had taken place in a low-income area of

Delhi, involving some of the country's top pediatricians (Sazawal et al., 1997). Their research laid the basis for a favorable reception of the WHO/UNICEF guidance by the Government of India. The Ministry of Health and Family Welfare recommended zinc as a treatment in 2007. The Central Drug Standards Control Organization also approved zinc as an over-the-counter medication in 2007. Zinc was not yet included in national diarrhea guidelines when POUZN began work in India, but the environment was positive.

The support of professional associations—representing the top of the medical “pyramid” and influencing the actions of the myriad tiers underneath them—was also central. POUZN coordinated with an early partner, Emcure Laboratories, to hold a medical symposium with 40 key opinion leaders country-wide from the Indian Academy of Pediatrics to hear the chief researcher of the Delhi trials present the data. This allowed them to delve deeply into the research in the company of their peers, and encouraged them to become “zinc champions” in their respective IAP chapters

In all three countries, POUZN worked to build a similar enabling environment for zinc by engaging officials in diarrhea control and IMCI departments, as well as professional associations, and creating a cadre of champions at the top of the medical pyramid. This core then provided influence and momentum for the adoption of a new treatment norm throughout the medical hierarchy. The project made sure that its commercial partners played a strong role in this process—building confidence in both the medical and the commercial sectors that a national supply of zinc was feasible and necessary. The commercial partners also shared in the cost of these efforts, via print materials and product samples.

A MINISTRY WITH MANY “ARMS”

POUZN worked with various departments of Tanzania’s Ministry of Health and Social Welfare. 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 affecting both private and public roll-out.

Tanzania Federal Drug Authority (TFDA)

- Register and regulate drugs
- Monitor drug quality
- Grant OTC status
- Certify ADDOs (private drug stores)

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

Medical Stores Department (MSD)

- Procure and distribute all drugs to government facilities

Council Health Management Teams (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)

FUNDING BARRIERS AND THE ROLE OF DONORS

Concerns in Tanzania centered on the tremendous upfront and ongoing cost implications of introducing new diarrhea treatment guidelines. In 2005 the country’s IMCI guidelines were due for multiple revisions and

the Chief Medical Officer believed these should be rolled out together. The training course for public health doctors would require US \$1 million, however, and the costs of supplying public health posts with zinc would be ongoing. At the urging of donors, the Ministry of Health and Social Welfare (MoHSW) had just taken on the financial burden of introducing new quadrivalent vaccines.

POUZN sought ways to jump-start the process and carry out groundwork that would stimulate fast action once policies were in place. Shelys’ MOU enlisted their support in reaching out to major professional associations in public and private hospitals. Building on good relations with the IMCI Department, POUZN was able to put zinc on the agendas of both the annual IMCI malaria conferences and zonal meetings on vitamin A supplementation held with regional and district medical officers. POUZN also worked closely with various levels of the IMCI Department to ensure that 25,000 printed copies of the recommended diarrhea guidelines would be ready for immediate dissemination.

Although revised guidelines were approved in 2007, cost remained a concern to the ministry, and the government Medical Stores Department (MSD) was reluctant to stock zinc while demand remained uncertain. The ministry, in turn, hesitated to disseminate the new guidelines and trigger *pull* effect from health facilities until adequate supply was assured.

This major roadblock was resolved when UNICEF agreed to fund an initial *push* (supply) of zinc out to all public health facilities. The agency offered to purchase a first six-month supply, estimated at 1.1 million courses of zinc. This tranche however was purchased from abroad as Shelys did not yet have GMP status.

Zinc was finally approved as an over-the-counter medicine in 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.) This meant that scripts for mass media programming were produced in anticipation of OTC approval, but broadcast was delayed until the last months of the project.

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.

ASSURING THE "FULL STATUS" OF ZINC

In 2005 the Indonesian government was enthusiastic about zinc and public institutions were ready to change national guidelines and partner with the private sector. Within months of project start-up, POUZN worked with USAID and collaborating development partners to incorporate zinc with ORT in IMCI and National Diarrhea Program guidelines.

In addition to fast-tracking product registrations, the National Agency of Drug and Food Control (B-POM) agreed to register zinc treatment as a pharmaceutical rather than a nutritional supplement and to allow OTC applications. POUZN partnered immediately with the government to enlist zinc as a "program drug," ensuring that it could be purchased by the Ministry of Health for distribution to provinces and districts across the country.



Zinc is approved for over-the-counter purchase in all three countries.

However, zinc was not included in the National Essential Drug List (NEDL), limiting use in hospitals and health centers. Public hospitals can use drugs outside the NEDL, but budgets are limited and purchases must be approved by the hospital's director and reported to the NEDL regulatory authority. The national review committee requested a post-marketing surveillance study to provide evidence that the drug is safe for children. POUZN began coordinating efforts with the Ministry of Health's Diarrhea sub-Directorate and external bodies, including WHO and UNICEF, to address the committee's concerns. The NEDL is revised once every three years, so the next opportunity for inclusion will be in 2011.

IV. INITIAL STRATEGIES TO SATURATE THE MARKET

In order to saturate the market with zinc, POUZN worked intensively with its commercial partners both to *push* zinc out to wholesalers and pharmacies, and to create an equally strong *pull* by stimulating demand among prescribers. This classic *push-and-pull* process was conducted in each country almost entirely through face-to-face and usually one-on-one interactions, following a “medical detailing” approach. Detailing, which refers to frequently repeated educational and promotional activities conducted by pharmaceutical company representatives (detailers) is the time-honored approach used by the pharmaceutical industry to introduce new products to the medical community.

The number of personal contacts involved in the introduction of a new high-priced drug can be staggering. A low-priced drug such as zinc usually gets little attention, so the collaborative agreements POUZN entered into with its partners were essential. To launch zinc within the public health system, the project supported a parallel process of push and pull, but with the considerable complications of national tenders for zinc and local budgeting.

PRODUCT DETAILING IN THE PRIVATE SECTOR

In India, project partners coordinated marketing activities through their own networks at their own expense. POUZN supported these efforts by training detailers, or medical representatives (med reps) on diarrhea treatment with ORT and zinc, emphasizing the new consumer benefits. In its first year, POUZN trained 1,200 med reps from four companies. They in turn reached 12,000 pediatricians (out of a total of 15,500 registered IAP members nationwide) and 20,000

general practitioners (out of an estimated 100,000 IMA members nationwide) through regular detailing, free samples, and promotional materials.

By the third year of the project, almost all pediatricians had been reached and the number of general practitioners contacted regularly approached 75,000.

In Tanzania, POUZN carried out refresher training for all of Shelys medical reps and created a FAQ sheet to support discussions with both providers and pharmacists. In Dar es Salaam, Shelys carried out “activations” at 20 key wholesalers responsible for sales to over 4,500 drug sellers. They provided 90 days of credit to each wholesaler for a first supply of zinc. This was coordinated with a comprehensive roll-out by Shelys’ detailers to pharmacies, in order to simultaneously generate a *pull* for the new supplies.

The project also collaborated with the Pharmacy Council of Tanzania to provide updated guidelines to pharmacies in five major cities. POUZN 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.

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.

Shelys also carried out seminars for doctors, nurses, and clinicians at major hospitals and maternal-child-health (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. Leave-behind materials included prescription pads and pens, free samples, and quotations from the new national diarrhea guidelines.

In 2007 alone, Shelys' medical reps reached 9,600 out of an estimated 14,800 health professionals country-wide.

In Indonesia, as in India and Tanzania, efforts began with key opinion leaders. POUZN addressed national meetings of the Indonesia Pediatric Association's (IDAI), the Indonesia General Practitioners Association's (IDI), and the Midwives Association's (IBI). The starting event was a plenary session on improved diarrhea treatment at the Asian Conference on Diarrhea Diseases and Nutrition (ASCODD). Conference participants received a CD with a collection of tools, including Q&A on zinc and ORS treatment, and a ready-to-deliver PowerPoint presentation, which they were encouraged to show colleagues at their own hospitals or universities. Private sector partners supported registration fees for targeted physicians and keynote speakers and printed new treatment promotional materials. Messages were also placed in professional magazines read by practitioners across the country.

In the third year of the project commercial partners regularly visited over 2,000 out of 3,000 pediatricians and reached an estimated 6,245 general practitioners. Zinc products were sold at 5,650 out of 7,400 pharmacies nationwide.

PRIMING GOVERNMENT PROCUREMENT

In Tanzania, POUZN helped prepare the public health sector for the important *push-pull* challenge early in the project by alerting the



Pharmaceutical detailers reached the top tier of providers in all three countries.

government offices responsible for drug budgets at local health facilities. These budgets are managed at the district level 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.

In Indonesia, in coordination with the National Diarrhea Program, the project sponsored zinc orientation meetings for hospital heads and District Health Offices across the country. Outreach included distribution of updated IMCI and National Diarrhea Program guidelines, together with FAQ booklets and posters with zinc messages. POUZN efforts reached all 7,000 health centers (Puskesmas) nationwide with updated information. Over 10,000 GPs (out of 50,000) were reached at 477 rural and urban DHOs in 33 provinces nationwide.

With encouragement from POUZN, the government issued a tender within one year's time to two manufacturing partners for nearly one million courses of zinc for distribution to the 33 provinces nationwide. By the third year of the project nearly 2.6 million doses were tendered for distribution in the public sector.

V. STRATEGIES TO ASSURE EQUITY, ACCESS, AND DEMAND

A classic market introduction strategy for zinc would eventually have “trickled down” to private providers serving the most vulnerable populations. This approach takes time, however, and depends on zinc becoming the norm—i.e., a popular drug requested even in remote areas.

The POUZN project had a mandate to ensure equity of access to zinc, and to reach those at highest risk of diarrheal disease. In all three countries, POUZN designed strategies to reach potential suppliers and prescribers of zinc serving the poorest households – those “at the bottom of the pyramid.”

These strategies were also tailored to care seeking practices prevalent among vulnerable populations. In India, this meant trying to reach rural medical practitioners; in Tanzania, small shop keepers; and in Indonesia, midwives. Activities began as pilots, and were gradually expanded, reaching around 5.5 million people in Indonesia, 10.7 million in Tanzania, and 13 million in India.

INDIA—DETAILING TO RURAL MEDICAL PRACTITIONERS

POUZN’s commercial partners in India had no direct contact with informal practitioners or retail outlets in remote areas.

Training a new cadre of detailers. To “bridge” this gap, the project launched a pilot in Uttar Pradesh state, where POUZN’s other intervention—point-of-use (POU) water disinfection—was already working with NGOs on preventing diarrhea. Research conducted in 2007 for the PACT-CRH Project.² showed that indigenous system medical providers (or

unlicensed providers such as rural medical practitioners, or RMPs) treated almost 63 percent of children under age three suffering from diarrhea.

The pilot took place in Bhati, a block in Ambedkar Nagar district with a population of around 100,000. The three NGOs—PANI, Pratinidhi,



A portable DVD was a successful behavior change tool for rural medical practitioners in India.

and Shashwat Sahbhagi Sansthan (SSS)—collaborated with their own networks of smaller NGOs to identify approximately 2000 RMPs and 500 drug sellers in their areas. POUZN offered a stipend to newly trained NGO “detailers” who visited these providers over a five-month period. POUZN’s pharmaceutical partners supplied free samples, just as they do for their own “reps.”

² The USAID-funded Program for Advancement of Commercial Technology-Child and Reproductive Health (PACT-CRH) operated in India from 1995-2007.

The project designed communication tools for both the detailers and their clients, including leaflets, posters, visual aids, and prescription pads. The most powerful tool was a short DVD designed to raise awareness and convey consistent and correct messages about zinc. Detailers were given sturdy portable DVD players. They were also given simple monitoring forms in order to track prescription practices and client satisfaction.

Following review of these data, the project streamlined the strategy (it was necessary to reduce visits from four to one in order to reach scale) and expanded the program to 100 blocks in all ten districts. Within this area, about 20,000 RMPs and 5,000 drug sellers served a catchment area of around 13 million people.

Linking rural outlets and suppliers. The NGO representatives primed the market in their areas and equally important, compiled information about the top 25 percent or so prescribers. POUZN shared this information with companies selling zinc in Uttar Pradesh—essentially identifying their prime customers. Creating such a “bridge” is crucial to encourage companies to commit to this new market. It gives them an economic incentive to become more active in the underserved areas and allows rural providers to learn about and have access not only to zinc, but also to other drugs and health products. It also allows for the removal of any subsidy (i.e., funding of long-term NGO involvement) once the rural market has been primed.

DEMONSTRATION AREA IN INDIA

Uttar Pradesh (UP) is India’s largest state, with a population of 190 million people. It has one of the highest rates of childhood mortality in India (about 70 children per 1,000 die in their first year of life). UP also has correspondingly high diarrheal morbidity and mortality. The NFHS-3 for UP found that only 12% of children under age three who had a recent case of diarrhea were given ORS: one of the lowest rates in the country and reflecting a decline since 1998-1999. The survey also found that 52% of caregivers in all SES groups who sought care for their children’s diarrhea went to private providers, 9.5% went to a pharmacy, and 5% went to other shops, while 5.5% sought care in the public sector.

TANZANIA—REACHING SHOP KEEPERS

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 *dukula-dawas*.

Reaching smaller drug outlets and health facilities. In 2009, (following approval of zinc as an over-the-counter drug) Shelys visited an average of 2,231 drug outlets on a monthly basis to provide updates and communication materials on the new IMCI guidelines.

AED’s social marketing project, T-MARC, also hired a marketing agency to conduct “trade activations” for both zinc and lo-ORS. Detailers visited rural outlets, provided marketing materials, offered deals on initial purchases, and ensured that outlets knew where supplies could be purchased and that local wholesalers had sufficient stocks to meet demand. The firm was contracted to cover 5,000 outlets (pharmacies, small shops, and also health facilities offering maternal and child health services) by October 2009. POUZN extended training for the detailers and provided them with educational materials.

Updating diarrhea prescribing practices by ADDOs. The government has taken on an ambitious project over the past several years to upgrade the skills of drug sellers and assure the quality of drugs sold in many of these outlets. Those that complete the training process successfully are known as *accredited drug dispensing outlets*—or ADDOs—and can prescribe certain essential medicines.

POUZN collaborated with the TFDA and USAID's RPM+ project in introducing new diarrhea treatment management guidelines into the training of these ADDOs. POUZN printed 5,000 job aids as well as manuals and designed a training-of-trainers program. The project also supported the training of CHMT staff who are responsible for supervising ADDOs, in addition to public dispensaries and health posts.



The project created simplified educational materials for ADDOs in Tanzania

By the end of the project, the ADDO program covered 12 of Tanzania's 21 mainland regions, including 2,300 drug outlets and 4,625 drug dispensers. In the last year, sales of zinc in ADDO regions reached levels similar to those in Dar es Salaam, indicating major expansion into rural areas.

INDONESIA—TRAINING MIDWIVES

As the Indonesian government planned orientations on zinc throughout the public health system, POUZN joined with them to test a

coordinated strategy with private sector partners to *push* zinc to the lower echelons of the cascade.

The project conducted a six-month pilot in Bandung City and Bandung District in West Java, an area with a population of around 10.7 million people and diarrhea prevalence slightly higher than the national average (DHHS 2007). The intervention coincided with government training for general practitioners.

Baseline research in the region on care seeking for childhood diarrhea revealed the importance of advice from neighbors (cited by 69 percent of mothers), midwives (31 percent), and community health centers (16 percent) (Nielsen, 2009). Midwives therefore became an important new target for the project.

POUZN encouraged its private sector partners to provide promotional items and ensure that zinc treatment was available in the area. The project also successfully advocated for procurement of 45,000 zinc courses by the local District Health Offices.

To support the public-sector roll-out, POUZN disseminated posters, FAQ booklets, and a DVD of presentation materials. The project partnered with the Bandung area District Health Offices to train 168 general practitioners, leaders at local Community Health Centers (Puskesmas), and 150 Diarrhea Program managers. In addition, POUZN collaborated with the Bandung chapter of the IBI (professional midwives association), to provide nearly 600 government and private midwives (44 percent of midwives in the area) with information on zinc and ORS. Zinc manufacturing reps attended the trainings to ensure products were available.

POUZN hired a professional marketing firm to detail pharmacies, drugstores, and midwives. During the pilot, promotional teams visited over 817 pharmacies, 287 midwives, and 56 drugstores. By the end of activity, zinc was available at 732 outlets.

Part of the intent of the pilot was to demonstrate to the zinc partners still focusing on promoting zinc treatment only to pediatricians, that GPs, pharmacies, and midwives were viable target audiences for expanding their sales. Three commercial partners subsequently decided to market zinc to these segments nationwide, despite limited sales forces.

PILOTS TO CREATE DEMAND

One of the cardinal principles of a health communication program is never to build demand for a product that is unavailable to the target group. POUZN therefore focused on creating demand among the general public late in the respective country programs and with varying levels of investment. Given the high cost of broadcast media, POUZN only supported radio and television programming when there was significant buy-in by partners—particularly the national government.

Indonesia. Indonesia was unique among the three countries in planning a coordinated communication strategy from the national level. The government saw the importance of consistent messages for improved diarrhea treatment and a “branded” approach with a logo. The government also saw the need to support this change in norms with mass media broadcasts.

POUZN assisted by convening a meeting of key opinion leaders, top pediatricians, and MOH officials to develop *Lintas Diare*, (“five behaviors”)—a graphic representation of messages regarding treatment of childhood diarrhea (see box). All zinc partners in both the public and private sectors adopted *Lintas Diare* for the promotion of diarrhea treatment.

Program staff also worked together with the MOH and IDAI, (the Indonesian pediatric association), to develop a “Zinc and ORS” campaign. Public service announcements (PSAs) were developed targeting mothers 18 to 35 years of age in different SES groups. Final

COORDINATED MESSAGES

Lintas Diare promoted five specific behaviors, depicted in a generic “logo” for diarrhea treatment, which was adopted by all public and private partners:

- Give Oralit (the WHO formula low-osmolarity ORS).
- Give zinc for 10 consecutive days to reduce duration and severity of diarrhea and reduce reoccurrence of diarrhea during the next three months.
- Continue breastfeeding and feeding during diarrhea.
- Do not give antibiotics unless bloody diarrhea and/or cholera occurs.
- Return immediately (to the doctor or health service) whenever fever, bloody feces, or repeated vomiting occurs or your child’s appetite significantly decreases.



versions were publicly endorsed by senior ministry officials; 60 and 30 second spots were developed in five languages for both television and radio and broadcast nationally for about 45 days beginning in May of 2010. POUZN provided funding for this relatively short mass media burst, but the Indonesian government has promised to continue the campaign.



The Indonesia mass media campaign included PSAs both with and without endorsements by the minister.

Tanzania. The Tanzanian government was also interested in collaborating with POUZN on demand creation activities for zinc. In 2008, the Tanzania Zinc Task Force asked the project to help design a strategy to coordinate public and private sector communication plans. POUZN held a workshop with key stakeholders including WHO to determine behavior change targets and key messages. The multi-channel strategy emphasized radio,³ 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 also developed storylines mentioning improved diarrhea management for its popular Mama Ushauri radio soap opera. Finally, POUZN participated in a Q&A radio session on zinc. All of these were aired in the final year, reaching an estimated 80 percent of the population.

The T-MARC project was also carrying out market day “activations” to promote reproductive health products, and POUZN was able to “piggyback” onto these to raise awareness of zinc. At market activations, music and skits attract visitors to counseling tents where a

³ TDHS 2004 indicated 58% of families owned radios. The Tanzania All Media and Products Survey (Steadman 2005) indicated 95% of the population listened to radio at least once a week.

promoter provides samples and explains their benefits. POUZN trained the promoters. By October 2009, T-MARC had reached about 67,000 people through its outreach program in nine regions of the country.

POUZN created counseling cards for village health posts and a model plan for community mobilization, utilizing NGOs to train village health workers and promote zinc through performances and mobile video units. POUZN funded the roll-out in village health posts throughout the Morogoro region.

India. Given India’s vast size and POUZN’s limited budget, the project designed only a small but very intensive demand creation pilot in the last year of the project to test the potential of a “word of mouth” campaign approach.

The pilot in Bhati district was conducted in collaboration with one of the same NGOs involved in detailing to RMPs and also in POUZN’s point-of-use water disinfection program. The POU activities were integrated into existing networks of about 100 village self-help groups (SHGs). Each of these groups includes about ten to 20 women. (Members participate in microfinance activities and are also involved in various social efforts to improve the lives of their families and the community.)

For the zinc “campaign,” POUZN provided information materials on zinc and designed a three-meeting strategy for diffusion of information into the wider community. At a first monthly meeting, members learned about zinc as a treatment for childhood diarrhea. At the next meeting, they were asked to bring a friend or family member, and finally each one was asked to share the information with one other person in the community.

Results of these different caregiver strategies, as well as the project’s interventions to improve provider prescription practices, are described in the next section.

VI. CHANGES IN PROVIDER AND CAREGIVER PRACTICES

In all three countries POUZN worked with local research agencies to evaluate changes in both provider and caregiver knowledge and practices in the intensive demonstration areas (see box).

In India and Indonesia, cross-sectional endline studies in 2010 examined the practices of targeted groups in the respective intervention areas as well as among similar providers in comparison areas. In Tanzania, the project compared practices across regions as well as from baseline to endline, and collected information on drug sellers' practices through visits by mystery clients.

Caregiver surveys were conducted in both 2009 (previous to full-scale implementation) and in

2010 in order to look at potential change over time.

CHANGES IN PROVIDER PRACTICES AND KNOWLEDGE

The project saw significant differences between intervention and control areas in several key indicators related to providers' knowledge and treatment of childhood diarrhea.

Providers in India. The endline survey in India asked RMPs and chemists what they "generally" prescribe to children under five with diarrhea. In the intervention area, 78 percent said they generally prescribe zinc, whereas only 27 percent in the comparison district mentioned

EVALUATIONS IN THREE COUNTRIES

INDIA: A cross-sectional endline survey of *provider* knowledge and prescription practices was carried out in June of 2010 by Social and Rural Research Institute (SRI), IMRB International. It included interviews with both chemists and RMPs in one intervention district (Barabanki) and one comparison district (Raibareli) in UP. The non-equivalent group survey interviewed 203 RMPs and 97 chemists in the intervention area and 197 RMPs and 103 chemists in the comparison area.

Changes in *caregiver* knowledge and practices were measured via baseline and endline surveys in March of 2009 and July-August 2010, respectively, in Bhati Block of Ambedkar Nagar District. Women from self-help groups with a child under five who had diarrhea in the last three months were interviewed: 120 women at baseline and 128 at endline.

TANZANIA: Baseline and endline surveys were carried out by TNS Research International in four regions with licensed pharmacies, ADDOs, and *duka la dawas* using female "mystery clients" posing as mothers of young children with diarrhea. The April 2009 baseline covered 1,989 providers and the May 2010 endline covered 597 providers.

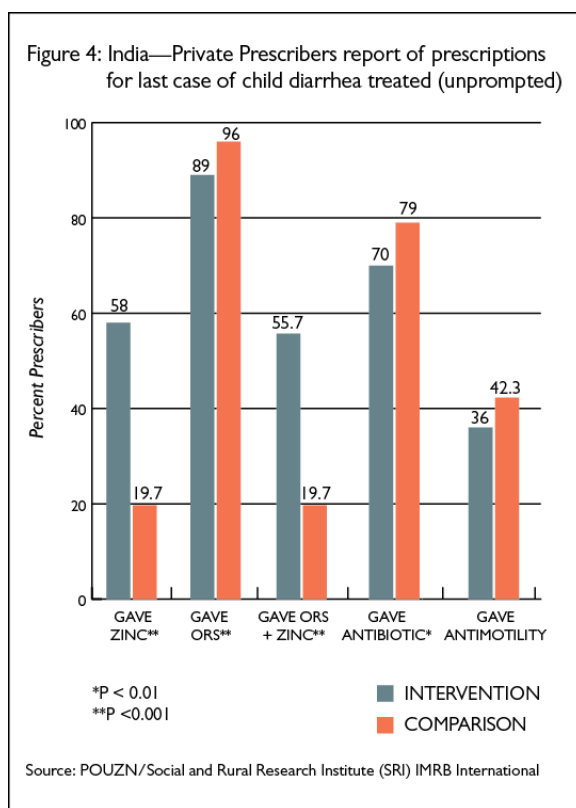
The *caregiver* surveys were carried out at these same times in three regions and included interviews with 621 mothers at baseline and 620 mothers at endline.

INDONESIA: A cross-sectional endline survey of *providers* was carried out by Synovate research company in June of 2010. It included interviews with 266 midwives who attended POUZN trainings in Bandung City and Bandung District, as well as 199 midwives in West Bandung District where trainings were not held.

The *caregiver* evaluation included a baseline survey in 2009 conducted by Nielsen with 506 caregivers in February/March 2009. The endline was conducted in August of 2010 by Synovate with 820 randomly selected caregivers from both the intervention and comparison areas. This group was augmented by oversampling with a booster sample of 406 mothers of children who had had diarrhea in the last two weeks.

zinc even when prompted. Figure 4 shows significant differences in key practices for the last consultation on childhood diarrhea. Without prompting, 58 percent of RMPs and chemists in the intervention area vs. 20 percent in the comparison group said they prescribed zinc. Similar percentages responded that they prescribed both ORS and zinc (the “gold standard”) for the last case of diarrhea.

Prescriptions of ORS were generally high; however, more providers in the comparison area



said they prescribed ORS for the last case of childhood diarrhea than those in the intervention area (96 percent vs. 89 percent).

High percentages of *all providers* mentioned that they prescribed antibiotics for the last case of childhood diarrhea they treated: 70 percent of intervention area providers and 79 percent of those in the comparison area (a significant

difference). A large number of providers in all groups also prescribed anti-motility drugs.

These rates suggest that the intervention had a strong effect on zinc prescriptions, but was less or not effective in improving other practices.

Zinc availability was significantly higher in the intervention district: 69 percent of the RMPs/chemists in the intervention district stocked zinc, compared to 24 percent of their counterparts. Similar differences were noted in reported **knowledge** about zinc. Moreover,

TABLE 2: INDIA

Sources of zinc information cited by those providers who had heard of it (spontaneous, multi-responses possible).

Source	Intervention	Comparison
Mass media (radio/TV/paper)	45.4%	49.4%
Hoardings/posters	29.3%	32.2%
Past experience	25.4%	25.3%
Doctors (private/government)	32.0%	31.0%
ANM	4.3%	2.3%
Anganwadi worker	3.9%	0%
ASHA worker	3.5%	2.3%
Friends/relatives	3.9%	5.7%
PANI/NGO*	60.2%	4.6%
Medical rep	32.8%	33.3%
Other doctor	13.3%	19.5%
Books/journals	18.8%	23.0%
Total number of providers	256	87

*p<=0.001

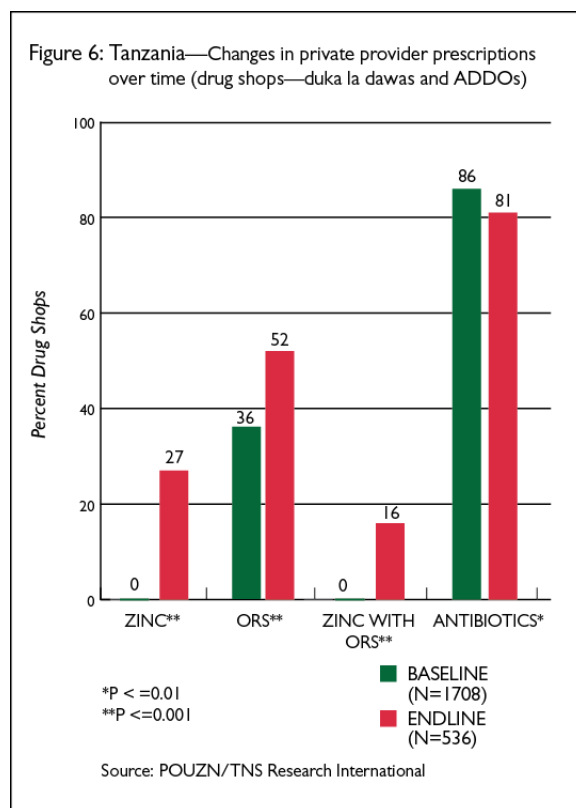
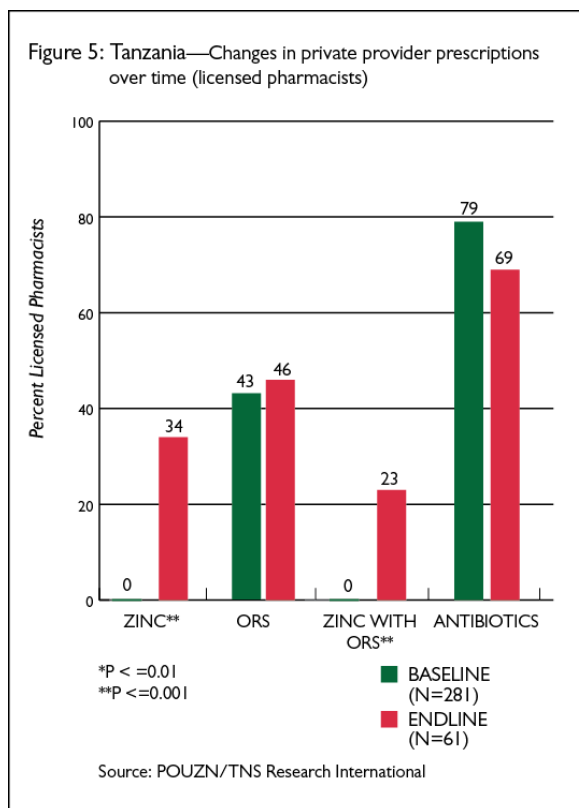
Source: POUZN/Social and Rural Research Institute (SRI) IMRB International

these differences were consistent among both chemists and RMPs in the two districts. The low levels of knowledge and stocking of zinc among *chemists* in the comparison areas were somewhat unexpected, because POUZN’s private sector partners (med reps) were active in both intervention and comparison areas contacting this upper level of the pyramid.

Among the providers who said they had heard about zinc, a majority (60 percent) identified NGOs (including those supported by the project) as their main **source of information**, compared to 5 percent for the comparison district. This was the only significant difference in information sources cited by providers in the intervention and comparison districts (see table 2 on previous page). Other sources of information cited by more than 30 percent of providers (in both areas) included the mass media, doctors, and medical reps. These last two sources, in

on the training of drug sellers, and the leveraging of an existing social marketing program.

Among providers in licensed pharmacies, prescriptions of zinc for childhood diarrhea rose from zero at baseline to 34 percent, and prescriptions for ORS plus zinc (the gold standard) rose to 23 percent. In shops (*dukas* and ADDOs combined) providers prescribed zinc to 27 percent of clients and zinc plus ORS to 16 percent of clients (see figures 5 and 6).



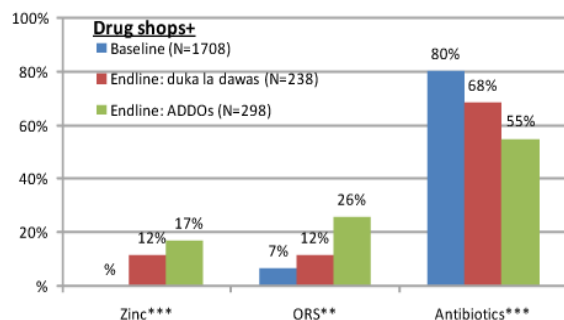
particular, may also have been associated with project activities (via the hierarchy of medical influence and pharmaceutical detailing).

Providers in Tanzania. Of the three countries, the quality of information about provider behaviors in Tanzania is likely to be particularly high because it was collected via mystery clients. The Tanzania experience is also unique because it measured the results of a strategy that combined commercial detailing of pharmacies, collaboration with the public sector

ORS prescriptions also rose significantly for providers in shops: from 36 to 52 percent. ORS prescriptions by pharmacists, however, did not change significantly.

Providers of all kinds continued to prescribe antibiotics at very high levels, though these prescriptions did fall significantly among providers in shops (from 86 to 81 percent at $p < .01$) and also fell in pharmacies, from 79 to 69 percent (though difference was not significant).

FIGURE 7: FIRST LINE ZINC, ORS AND ANTIBIOTIC PRESCRIPTIONS OVER TIME



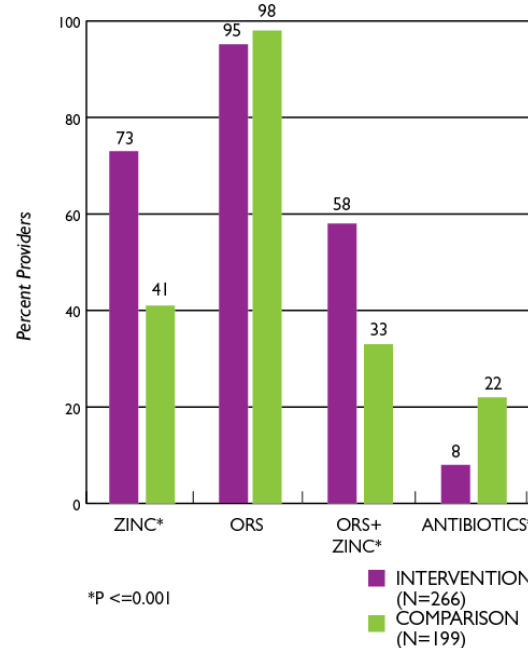
Antibiotic prescription by drug shops, as a first-line treatment has decreased significantly over time. (Figure 7)

The intensive training provided to ADDOs was reflected at endline in significant differences between their practices and those of untrained shop keepers. Most noteworthy—prescriptions for antibiotics were approximately 13 points higher among untrained shop keepers (dukas) compared to ADDOs, although all of these rates were cause for concern.

Providers in Indonesia. Reports by providers in Indonesia about their treatment patterns for diarrhea were the most impressive among the three countries.

The evaluation compared midwives who received POUZN-supported training with those who had not. Both groups were exposed to the national mass media campaign. Figure 8 above shows that midwives prescribed zinc at very high rates (73 percent among those who received POUZN training vs. 41 percent of the comparison group). Prescriptions for ORS plus zinc (the gold standard) were also high at 58 percent for the intervention and 33 percent for comparison providers. Nearly all midwives prescribed ORS. Equally important, very few prescribed antibiotics (8 percent vs. 22 percent), with the intervention group approaching a rate that may be appropriate.

Figure 8: Indonesia—Prescription patterns among midwives for last case of diarrhea



Source: POUZN/AED and Synovate

Significantly more midwives in the intervention area than in the comparison area said they were informed about zinc, but both indicated very high rates of exposure (99 vs. 89 percent). Table 4 shows the importance of multiple channels: the mass media, posters, doctors, training, and medical detailers. Nearly 87 percent in the intervention area and 43 percent in the comparison group said they had received training by the district health office or some group other than POUZN (while 19 percent in the comparison area, possibly a spillover, claimed they had received POUZN's training). This indicates that both areas were already being reached by information from the government, although this roll-out is moving slowly.

CAREGIVER PRACTICES AND KNOWLEDGE

POUZN's goal was to achieve 20 percent zinc use rate among caregivers reached by project interventions and increase ORS use by at least 25 percent over the baseline. Rates were lower

TABLE 4: INDONESIA

Sources of information about zinc among respondents who have heard about it (multiple responses allowed)

	Intervention (N=264)	Comparison (N=178)
Mass media (radio/TV/paper)	84.1	77.5
Posters***	89.8	67.4
Past experience**	42.1	28.7
Doctors (private/government)*	78.4	69.1
Friends/relatives	75.0	71.9
POUZN Training***	78.4	18.5
Medical Reps***	41.7	20.2
Books/ Journals***	64.8	37.6
Training by DHO/ Organization (Peers/ IB)***	88.6	43.3
Other	12.5	15.2

* p <= 0.05; ** p <= 0.01; *** p <=0.001

than expected in view of the provider data. India achieved high increases in zinc use but none in ORS. Tanzania did not achieve either goal, but saw a significant drop in use of antibiotics. Indonesia saw no significant change in use of recommended or non-recommended treatments.

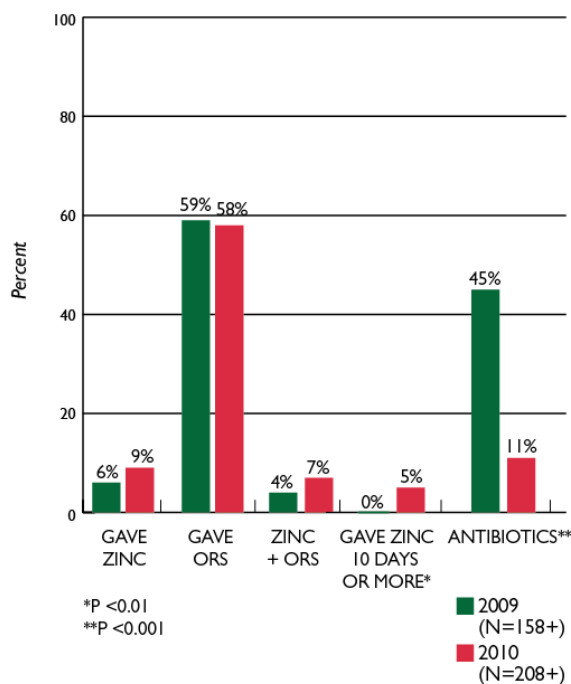
Caregivers in India. Across the three demonstration areas where caregiver practices were measured, zinc use rose most dramatically in India. Several factors may have affected the reliability (and the replicability) of data about caregiver practices in the small pilot with self-help groups. The endline was collected during

the diarrhea season (whereas the baseline was not). Members of self-help groups (all of those surveyed) are not a typical cross-section of women in their communities, but rather more progressive and empowered, and their behaviors are not predictive of those of other rural women. Finally, the NGO pilot with SHGs cannot be duplicated on a large scale for a number of reasons. With these caveats, however, the information obtained from the surveys is of interest.

The proportion of children under five having diarrhea whom caregivers reported treating with zinc rose from 0 to 50 percent between baseline and endline. The proportion of those treated with zinc plus ORS rose to 31 percent. There was no significant change in the proportion of children who were treated with ORS.

Knowledge of zinc and ORS among these SHG members increased significantly. The proportion of caregivers who mentioned spontaneously that zinc was an appropriate treatment for diarrhea rose from 0 to 56 percent; the proportion who mentioned ORS rose from 15 to 56 percent. Mothers overwhelmingly cited project-supported NGO staff as the source of their knowledge about zinc (95 percent spontaneously). The majority of caregivers (84 percent) also said the NGO would be a good source for zinc. However, few (only 1 percent) mentioned RMPs—the actual focus of detailing efforts.

Figure 9: Tanzania—Caregiver treatment of child's diarrhea (last two weeks)



reports of their diarrhea treatment practices revealed *lower rates of recommended behaviors* (both zinc and ORS) and also *lower levels of potentially inappropriate practices* (antibiotics) than would be expected from the provider surveys in that country. Moreover, practices changed little from baseline to endline, with the exception of a dramatic drop in giving antibiotics—which took place across regions. Treatment with zinc rose from 6 to 9 percent and treatment with zinc plus ORS rose from 4 to 7 percent. Neither of these changes were statistically significant. Treatment with ORS remained virtually the same (59 percent vs. 58 percent). However, antibiotic use showed a highly significant drop from 45 to 11 percent.

Exposure to messages about zinc and knowledge that zinc is an appropriate treatment for diarrhea were low across regions. A total of 22 percent of mothers said they had seen or heard a message about zinc in the last three months. Only 12 percent of mothers stated (unprompted) that zinc is an appropriate treatment for diarrhea.

Caregivers in Tanzania. In Tanzania, caregiver

TABLE 3: TANZANIA

Sources of zinc information cited at endline by those caregivers who had heard of it (spontaneous, multi-responses possible)

Source	Total	Morogoro	Mwanza	Dar es Salaam
Radio*	36.0%	13.0%	42.5%	34.6%
TV	14.0%	4.3%	13.8%	23.1%
Interpersonal communication with health workers (doctors, nurses, health facilities)*	75.9%	60.9%	84.1%	61.5%
Banner	10.3%	4.3%	10.3%	15.4%
Friends or relatives	27.7%	13.0%	28.4%	38.5%
Village health talk	4.41%	11.7%	0%	5.76%
Local pharmacist (including <i>duka la dawa</i> or ADDO)	11.8%	17.4%	11.5%	7.7%
Number of care givers who were exposed to zinc message	136	23	37	26

*p<=0.05

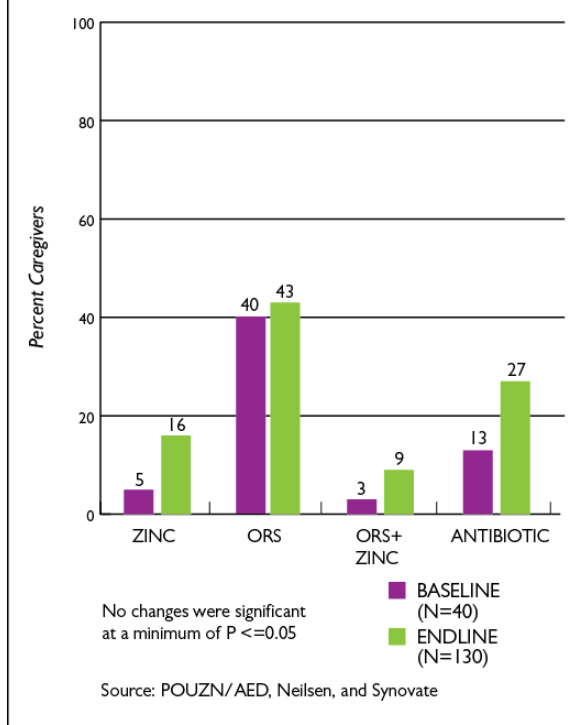
Digging more deeply—among caregivers who were aware that zinc is an appropriate therapy for diarrhea, 27 percent gave zinc to their child with diarrhea in the last four weeks. Mothers who were exposed to a message about zinc in the last three months were relatively more likely to have given zinc to a child who was sick with diarrhea. Across regions, by far the highest rates of message exposure were attributed to interpersonal communication (see table 3 on previous page). This may reflect the effectiveness of Shely’s promotional activities with health workers in facilities where the med reps conducted detailing. Radio was also an important source of messages, which may have been linked to the project-funded broadcasts.

The project anticipated higher rates of appropriate caregiver behaviors in Morogoro where ADDOs had received training and where the demand creation pilot with village health workers had been carried out. In fact, the highest rates were in Mwanza, where there had been no such interventions (12 percent use of zinc and 10 percent use of ORS plus zinc in Mwanza, vs. no reported use of zinc in Morogoro).

Caregivers in Indonesia. There was no statistically significant change among caregivers from baseline to endline regarding any key treatment practices. (Use of zinc among caregivers increased to 16 percent and use of ORS plus zinc increased to 9 percent, but these changes were not significant.) Figure 10 shows changes in practices (both positive and negative) but none reached a minimum significance of $p < .05$. Differences between practices in the intervention and comparison areas at endline (measured by including a booster sample) showed zinc use was slightly higher in the intervention area (16 percent vs. 13 percent) but this difference was also not statistically significant.

Knowledge about zinc did improve over time. About one in five caregivers (22 percent) knew that zinc is effective for treating diarrhea, up from 2 percent at baseline.

Figure 10: Indonesia—Caregiver treatment of childhood diarrhea (case in last two weeks)



CORRECT USE OF ZINC (TEN DAYS) BY PRESCRIBERS AND CAREGIVERS

Duration of zinc use is especially important and formative research indicated caregivers might not be willing to give the full course of treatment. The evaluations therefore looked at both prescriber and caregiver information about the number of days zinc was both prescribed and given.

Correct dose prescribed. In all three countries, at least half of prescribers who recommended zinc mentioned the correct dose, with particularly impressive rates in Indonesia.

Among RMPs in **India** who prescribed zinc, a little more than half (56 percent) of those in the intervention area and half (50 percent) in the comparison area prescribed it for ten days or more. (The difference was not statistically significant.) Among midwives in **Indonesia** who

prescribed zinc, nearly all in the intervention area (97 percent) reported that they prescribed it for ten days or more, compared to 85 percent in the comparison area (significant at $p < 0.001$). (The number of days zinc was prescribed was not assessed in Tanzania.)

Correct dose given. At endline in Tanzania, of those mothers who gave their children zinc, 63 percent reported giving the correct amount. In Indonesia, 37 percent of mothers in the intervention area who gave zinc reported that they gave it for ten days vs. 18 percent in the comparison area (the difference was not statistically significant however). The endline survey in India did not ask mothers how many days of zinc they gave a child.



The evaluation looked at both correct dose prescribed and correct dose given.

VII. CONCLUSIONS AND LESSONS LEARNED

CONCLUSIONS

POUZN clearly demonstrated the effectiveness of limited donor funds in **leveraging the private commercial sector** to begin building nationwide supplies of zinc for treatment of childhood diarrhea. The project provided key documentation and allowed manufacturers in all three countries to conclude for themselves that zinc made sense from a purely business point of view. In Tanzania, POUZN helped upgrade facilities of the only potential partner at that time to GMP status, paving the way for an African company to supply zinc to neighboring countries as well. Additional producers now continue to enter the markets in Tanzania, India, and Indonesia, offering consumers a range of product types and assuring prices remain competitive.

Beyond helping introduce zinc on the market, POUZN negotiated agreements with its core commercial partners that involved joint marketing planning, development of promotional strategies, and training of med reps. The project essentially allowed pharmaceutical companies to “carry the weight” of marketing zinc through their own networks and rolling out powerful face-to-face detailing operations. The private sector carried the initial financial costs of launching zinc many times over.

The project was also successful in **catalyzing support for government policies** necessary for a roll-out of zinc in the public as well as the private sectors. Government tenders for distribution of zinc in the public sector are underway. Zinc has been incorporated in national IMCI and diarrhea program guidelines and is approved for over-the-counter sales in all three countries. Inclusion of zinc on the national essential medicines list is still pending in Indonesia.

POUZN created a core of champions among key opinion leaders whose influence on other

providers is essential for establishing zinc as a new treatment norm.

The project also designed innovative strategies to reach providers consulted by the poorest and most remote families “at the bottom of the pyramid.” Evaluations in the three countries showed changes in key indicators among providers, but less success in creating awareness and demand for zinc among caregivers themselves.

While POUZN strove to launch sustainable

TABLE 5:
Rough estimation of courses of zinc needed in three countries each year*

Country	Number of children under five	Diarrhea incidence (2 weeks)	Courses of zinc needed*
India	126,642,000	9%	296,342,280
Indonesia	20,891,000	14%	76,043,240
Tanzania	10,502,000	13%	35,496,760

* Estimation does not take into account the effectiveness of zinc on the incidence of future cases, or the percent of cases that mothers currently do not treat at all (for whatever reason).

Sources: India – DHS 2005-6; Indonesia – DHS 2007; Tanzania – DHS 2004-5

processes with partners committed to the long term, only the first few steps on a very long road were taken during the life of this short project. The amount of zinc necessary to treat childhood diarrhea cases nationwide and on an annual basis is not yet available in any of the three countries (see box). Government procurement as well as training of health workers and volunteers is a slow process. Much still remains to be understood about what works and doesn't in terms of accelerating reach to vulnerable groups and creating demand among caregivers. Moving forward will require governments to actively embrace the roll-out of effective strategies and budget appropriately for childhood diarrhea, and for donors to help

overcome obstacles with their technical expertise and influence, as well as their financial support.

LESSONS LEARNED

Country ownership of clinical data about zinc was critical in POUZN countries. Launching of zinc in India was largely possible because one of the first clinical trials took place in a low-income area of Delhi involving some of the country's top pediatricians. The project conducted symposia in all three countries to encourage peer-to-peer discussion of the clinical evidence with worldwide experts. When doubts arose, there was no substitute for home-grown evidence. Zinc is still pending inclusion on the essential medicine list in Indonesia because the government wants to conduct its own post-launch safety studies.

Reaching Key Providers

The successful market introduction of a new pharmaceutical product requires a strong focus on the provider community. The difficulty of introducing a new ethical product such as pediatric zinc in the medical community should not be underestimated. Most new drugs introduced by pharmaceutical companies are backed by extensive studies demonstrating their efficacy and safety. For ethical and financial reasons, pediatric zinc has not benefited from comparative clinical studies and can be difficult to market to health providers who are increasingly trained in evidence based medicine. To circumvent this barrier, donor-supported zinc programs may be tempted to launch direct-to-consumer communication campaigns, particularly through the mass media. There is clearly a need to change caregiver behavior when it comes to treating and preventing childhood diarrhea. BCC campaigns can help mainstream a better understanding of diarrhea among mothers, stressing the need for rehydration and supplementation. However, contradictory medical advice and prescribing behavior by healthcare providers and pharmacists will inevitably create confusion and negate communication efforts unless they are

addressed simultaneously with, and preferably in advance of, direct-to-consumer campaigns.

The pharmaceutical industry demonstrates the power and the need for multiple face-to-face visits to change prescribing behaviors. POUZN found that more than one detailing visit was necessary to influence RMP practices in India, but also that "virtual" influence via a DVD was effective in rural areas. Project data on sources of information about zinc point to the need for reaching providers via multiple channels. However, interpersonal communication (including training) was consistently cited as a source of information by high proportions of providers. The ADDO training program being rolled out in Tanzania stood out as an effective vehicle for influencing advice given to the poorest families.

POUZN designed strategies tailored to the care seeking patterns of each country and was successful in changing several key practices of popular providers. To increase the chances for scale and sustainability, the project targeted existing channels (such as the ADDO training program), built on local strengths (such as the NGO presence in rural India), and tapped professional linkages (such as the association of midwives in Indonesia). The project effectively primed these different systems by creating materials, funding training, and paying detailers and marketing companies. None of these strategies will continue without further funding, however.

Interventions to reach the poorest populations were conducted in demonstration areas for limited periods of time. The scalability of these approaches and their long-term impact remains to be tested. In India, the project cannot yet predict whether zinc suppliers will maintain continuing links with high performing RMPs or with those in the most remote areas. Follow up by pharmaceutical companies in Indonesia to market aggressively with midwives and GPs is still to be seen. These are important questions. Furthermore, providers who were responsive are the "early adopters." It

is unclear what will be necessary to stimulate change among the larger cohorts in each country, or to produce consistent behavior among those who initially recommended zinc to their clients within just weeks of the intervention. The feedback loop from caregivers as they try this new product will clearly affect the answer to those questions.

Creating Caregiver Demand

The project focused on caregiver behaviors towards the end of the project when zinc became available to the public. The project also did not have the resources to invest in mass media, with the exception of relatively short bursts in Tanzania and Indonesia. Nevertheless, changes in caregiver practices were much lower than expected in view of the provider data. Many mothers consider diarrhea a fact of life and only seek care for serious cases. As supply is established in these countries, substantial investment needs to be made in creating demand at the household level through multiple channels and sustained at a level and duration not only to introduce a new product, but compete with other treatments (and no treatment) over time.

Over time and with scale-up, pilot programs may change in nature; intended as well as unintended effects should be monitored. In India, the NGO engaged in detailing to RMPs was also hired to conduct a small demand creation pilot with members of self-help groups. Simultaneous collaboration with the POU intervention under the project (promoting chlorine products and water filters to treat water) convinced this NGO to open a social marketing arm and begin selling their own branded health products. On the one hand this development was a celebrated project success—the birth of a new, sustainable and accessible supply of products to those hardest to reach. It may also have meant some diversion of focus. While the group achieved near spectacular levels of behavior change with the pilot SHG members, awareness of zinc availability at the local RMP (and to some extent among chemists) was very

low. This demonstrates the challenge of standardizing messages over time.

Affordability and the Role of Government
Introducing a new product in the private commercial sector may not meet the needs of all users, but is a significant step towards universal access.

Every program channeled through the private commercial sector must balance affordability and profitability considerations to be sustainable. POUZN was committed to reaching caregivers where they typically go for treatment, which for many is the private sector. In India, a complete course of zinc was priced between \$US.50 and \$ 1.00. The first product introduced in Tanzania was priced at \$.31-\$.36 per treatment course. In Indonesia, price levels ranged from roughly \$.65 to \$3.50. Among Tanzanian mothers who had ever purchased zinc, 61 percent said it was either not expensive or affordable, while 36 percent said it was expensive. Feedback from RMPs in India indicated that cost was a barrier to the very poor. This underscores the fact that the private commercial sector cannot always meet the needs of all users. However the presence of zinc in the private sector also increases its availability (at reduced prices) for government and donor-supported tenders. Thus the public and private sectors must work in tandem to ensure that all population groups have access to life-saving health products.

Products that face significant competition require more support

Zinc treatment competes with well-entrenched prescription behaviors and traditional treatment practices including harmful anti-diarrheals, potentially inappropriate antibiotics, anti-secretive drugs, and probiotics that are now popular in some places. ORS has been plagued by the same problem. Introducing zinc will require more than piggybacking onto this struggling “brand.” Zinc is also significantly different from other health products introduced through donor funded programs. It does not benefit from long standing use in the public health sector, and has virtually no backing from

the global pharmaceutical industry. Though it is deceptively simple, easy to use, affordable and safe, it is unlikely to ever receive substantial financial and marketing support in the private commercial sector. Nevertheless, sustained advocacy and support from public health authorities, research institutions, and NGOs can help achieve its routine prescription by the health provider community. Once pediatric zinc has been mainstreamed in this community, it is almost certain to be adopted by caregivers. Indonesia saw improvements in antibiotic use among both providers and caregivers. Notably, the *Lintas Diare* campaign included a message about restricting antibiotics. It is necessary to name and address the problem. At the same time, communication programs should be convincing and artful about promoting the actual benefits of *both* zinc and lo-ORS.

This *is* another golden moment for diarrhea control because the medical community can finally offer mothers not only what they need but what they want. The opportunity should not be lost.

REFERENCES

- AED. 2010. *Promoting Zinc and ORS for the Management of Childhood Diarrhea: Three Research Briefs respectively for Indonesia, India and Tanzania*. Drafts submitted to USAID December 9, 2010.
- Bhandari, Nita, Sarmila Mazumder, Sunita Taneja, Brinda Dube, Robert E. Black, Olivier Fontaine, Dilip Mahalanabis and Maharaj Bhan. 2005. A Pilot Test of the Addition of Zinc to the Current Case Management Package of Diarrhea in a Primary Healthcare Setting. *Journal of Pediatric Gastroenterology and Nutrition* 41: 685-687.
- BPS Statistics Indonesia, National Family Planning Coordinating Board, Ministry of Health, Macro International. 2007. *Indonesia Demographic and Health Survey*.
- Formative Research on Zinc Treatment as an Adjunct Therapy for Childhood Diarrhoeal Illness. April 2008. Ifakara Health Research and Development Centre in collaboration with Ministry of Health and Social Welfare, Tanzania, Helen Keller International/Tanzania, Paediatric Association of Tanzania.
- International Institute for Population Sciences (IIPS) and Macro International. 2007. *National Family Health Survey (NFHS-3), 2005-06, India: Key Findings*. Mumbai: IIPS.
- Macro International and Tanzania National Bureau of Statistics. *Tanzania Demographic and Health Survey 2004-2005*. Calverton, MD: ORC Macro.
- PACT-CRH. 2008. Promoting Diarrhea Management through the Private Sector in Rural North India (Saathi Bachpan Ke Program).
- Point-of-use Water Disinfection and Zinc Treatment for Diarrhea (POUZN) India: Zinc Endline Survey, RMPs and Chemists. June 2010. New Delhi: IMRB
- Point-of-use Water Disinfection and Zinc Treatment for Diarrhea (POUZN) India: Zinc Baseline Survey, Self-help Groups. April 2009. New Delhi: IMRB.
- Point-of-use Water Disinfection and Zinc Treatment for Diarrhea (POUZN) India Zinc Endline Survey, Self-help Groups. 2010. New Delhi: IMRB.
- Point-of-use Water Disinfection and Zinc Treatment for Diarrhea (POUZN) Indonesia: Zinc Baseline Household Survey. May 2009. Jakarta: AC Nielsen
- Point-of-use Water Disinfection and Zinc Treatment for Diarrhea (POUZN) Indonesia: Zinc Endline Household Survey. July/August 2010. Jakarta: Synovate Indonesia.
- Point-of-use Water Disinfection and Zinc Treatment for Diarrhea (POUZN) Indonesia: Zinc Endline Survey, Midwives. June 2010. Jakarta: Synovate Indonesia.

Point-of-use Water Disinfection and Zinc Treatment for Diarrhea (POUZN) Tanzania: Zinc Baseline Household Survey. 2009. Nairobi: TNS Research International.

Point-of-use Water Disinfection and Zinc Treatment for Diarrhea (POUZN) Tanzania: Zinc Baseline Mystery Client Survey. 2007. Nairobi: TNS Research International.

Point-of-use Water Disinfection and Zinc Treatment for Diarrhea (POUZN) Tanzania: Zinc Endline Household Survey. 2010. Nairobi: TNS Research International.

Point-of-use Water Disinfection and Zinc Treatment for Diarrhea (POUZN) Tanzania: Zinc Endline Mystery Client Survey. 2010. Nairobi: TNS Research International.

Saadé, Camille, Slater, Sharon. *Mobilizing the Commercial Sector for Public Health Objectives – A Practical Guide*, a BASICS - UNICEF publication, July 1996.

Sazawal, S., R.E. Black, M.K. Bhan, S. Jalla, A. Sinha, and N. Bhandari. 1997. Efficacy of zinc supplementation in reducing the incidence and prevalence of acute diarrhea—a community-based, double-blind, controlled trial. *American Journal of Clinical Nutrition* 66(2): 413-418.

Sunil Sazawal, Robert E. Black, Mahdi Ramsan, Hababu M Chwaya, Arup Dutta, Usah Dhingra, Rebecca J Stoltzfus, Mashavi K Othman, Fatma M Kabole. Effect of zinc supplementation on mortality of children aged 1-48 months: a community-based randomized placebo-controlled trial. *Lancet* 2007, 369: 927-34.

Social and Rural Research Institute/IMRB International. 2009. Diarrhea Treatment Knowledge and Practices Among Rural Medical Practitioners.

WHO/Unicef. 2004. Joint Statement on Clinical Management of Acute Diarrhea. Available at http://www.who.int/child_adolescent_health/documents/who_fch_cah_04_7/en/index.html

WHO/UNICEF. 2009. Why Children Are Dying and What Can Be Done. New York: UNICEF.

World Health Organization et al. 2007. Production of Zinc Tablets and Zinc Solutions. Geneva: WHO.

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