Retrospective Analysis of ORS and Zinc Market Shaping Efforts

For additional information, contact:
Andrea Bare
abare@umich.edu
Table of Contents

ACRONYMS /ABBREVIATIONS 3

ACKNOWLEDGEMENTS 3

INTRODUCTION 4

BACKGROUND ON DIARRHEA; ORS AND ZINC MARKETS 4

MARKET SHORTCOMINGS 5

SELECTING AND IMPLEMENTING THE MARKET INTERVENTION 6

POUZN INTERVENTION: 2005 - 2010 7

RESULTS 10

CHALLENGES AND LESSONS LEARNED 12

SUMMARY 12
**Acronyms /Abbreviations**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADDO</td>
<td>Accredited Drug Dispensing Outlets</td>
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<td>CME</td>
<td>Clinical</td>
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<td>GMP</td>
<td>Good Manufacturing Practices</td>
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<td>LMICs</td>
<td>Low-and-Middle-Income Countries</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<td>ORS</td>
<td>Oral Rehydration Solution</td>
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<td>POUZN</td>
<td>Point-of-Use Water Disinfection and Zinc Treatment</td>
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<td>PSI</td>
<td>Population Services International</td>
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<td>SHOPS</td>
<td>Strengthening Health Outcomes through the Private Sector</td>
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<td>SSA</td>
<td>sub-Saharan Africa</td>
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<td>USAID</td>
<td>United States Aid for International Development</td>
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<td>WB</td>
<td>World Bank</td>
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<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
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**Acknowledgements**

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Introduction
This case study focuses on two USAID-funded projects that included market-shaping interventions for ORS and zinc. The Point-of-Use Water Disinfection and Zinc Treatment (POUZN) Project was a five-year project funded by USAID that was designed to expand access to and use of point-of-use (POU) water disinfection as well as use of zinc products for the prevention and treatment of diarrhea. USAID funding for continuing to promote the use of ORS and zinc was subsequently provided through the Strengthening Health Outcomes through the Private Sector (SHOPS) project.

Background on Diarrhea; ORS and Zinc Markets
Despite reductions in all-cause mortality, diarrhea remains the second leading cause of death among children under 5 years of age. It is estimated that among children under 5 years of age living in low- and middle-income countries (LMICs), an average of 2.9 diarrhea episodes occur per child year. Oral Rehydration Solution (ORS) and zinc supplementation are first-line recommended treatments to routinely address and prevent future episodes of diarrhea.

In late 2004, WHO/UNICEF issued their joint statement recommending zinc and ORS as the preferred diarrhea treatment. However, despite their presence and proven effectiveness, coverage and use was anticipated to remain low for many years in many parts of the world, regardless of treatment source (public or private). If scale up of public and private sector markets could be accelerated, significant public health impact would occur sooner and many additional lives would be saved.

In many countries, particularly in Asia and sub-Saharan Africa (SSA), at least 50 percent of treatment for childhood diseases is sought from private sector sources; thus they are important players in addressing high diarrhea prevalence in these countries. Rapid and sustainable scale up of ORS and zinc within the private health sector requires a deeper understanding of the market for these products. The ORS and Zinc market is characterized by the presence of a combination of demand side and supply side inefficiencies. Demand side factors such as poor awareness, lack of “perceived effectiveness” of ORS or zinc as compared to antibiotics; and supply-side factors such as poor availability, product not pushed/promoted strongly by wholesalers and retailers, combined with unaffordability for the very poor together create a “low uptake trap” where poor uptake leads to poor availability, poor distribution channel incentives to promote, and higher prices which in turn further exacerbate the poor consumer uptake.
The way the market for ORS and zinc functions varies from significantly from country to country. While it is relatively easy to manufacture ORS and zinc at acceptable quality and relatively small scale, and so many countries are capable of manufacturing these products, only in some countries, such as India, are there very strong pharmaceutical manufacturers that can contribute significant investment capital and leverage existing sales networks and “detailing” capabilities to scale up sales for a new product. Second, governments take different stances with regards to awarding their purchases to local manufacturers to de-risk their start-up. Last, the way in which distributor, medical provider and caregiver awareness and preference for new products can be fostered differs from country to country. Thus, in addressing the “low uptake trap,” it is important to develop understanding of each country’s market and tailor a market shaping intervention that is appropriate to that setting.

Market Shortcomings
Symptoms relating to low uptake for ORS and zinc included low sales rate, high prices and poor availability of product observed at retail points. Surveys conducted with consumers had revealed that while the majority of caregivers know about zinc, they may not consider it as effective as an antibiotic; they may not know where to purchase the product or if it is even available at a location convenient to their home; and for lower wealth quintiles, price may be a barrier.

Root Causes
Root causes for the above symptoms vary by country. Generally speaking, the root causes that were identified include:

- Import costs, taxes and tariffs, which resulted in high prices for imported ORS and zinc,
- Lack of promotional push by manufacturers,
- Low channel margins which led to low channel push,
- High cost of credit leading to lack of working capital (true across all products),
- High perceived attractiveness of antibiotics, and
- Low perceived attractiveness of ORS and zinc, which have historically been viewed as a) a placebo (ORS)—not stopping the diarrhea or b) a nutritional supplement (zinc) rather than a treatment product.

The first four root causes mentioned above relate to manufacturers and the sales channel. Manufacturers are likely to be unwilling to enter the market because margins are low and demand is low for a brand new treatment protocol that neither retailers nor consumers know
anything about. Also, entering a brand new market is difficult without the volumes that institutional sales provide. If the public sector is receiving its supplies via UNICEF donations, there is no incentive to purchase locally and bolster local industry. These institutional sales provide a buffer for manufacturers while they build the commercial market from scratch. Keeping the price low so that the product is affordable results in low margins and in turn that means few funds are available for marketing a new product. In countries with no local manufacturers, high import taxes/tariffs, transportation/shipping costs, may impact importer margins and availability.

The last two root causes relate to caregiver uptake. In considering diarrhea prevention and treatment, caregivers make choices among a set of products. Diarrhea can result from a variety of both bacterial and viral intestinal pathogens. Bacterial pathogens rarely cause diarrhea — the exception being cholera outbreaks and an antibiotic can treat those cases. Rotavirus vaccine can prevent some viral diarrhea but is costly and not yet widely available. Patients/caregivers do not perceive the vital lifesaving qualities of ORS in the prevention of death by dehydration but want a “real medicine” that will stop the diarrhea immediately. Uncomplicated diarrhea is self-limiting and zinc plays a vital role in strengthening the body’s own immune system to fight off the viral pathogens and creating immunity against the next viral invasion for 2-3 months. ORS and Zinc do not provide immediate relief of symptoms. Zinc needs to be given for 10 days and this regimen is very difficult for caregivers to follow. Thus, consumers want antibiotics, which they have used in the past, not realizing that they are ineffective—the diarrhea stops on its own in a few days. So essentially, it is the difficulty in following the 10-day zinc regimen combined with misconceptions among service providers and caregivers that antibiotics and other prescription drugs are more effective than ORS and/or Zinc that keep uptake of ORS and zinc low.

Selecting and Implementing the Market Intervention

In late 2004, when WHO/UNICEF issued their joint statement recommending zinc and ORS as the preferred diarrhea treatment, planners at USAID realized that for the program to be effective, this new protocol would need to be promoted through both public and private sector channels. Given different approaches to the challenge, USAID, in 2005, awarded task orders to both the Academy for Educational Development (AED) and Abt Associates (Abt) to implement the POUZN project. AED implemented programs in Tanzania, Indonesia and India. Abt Associates Inc. in collaboration with Population Services International (PSI) implemented zinc programs in Benin, Madagascar, Nepal and Pakistan. The project was completed in 2010. In 2010, USAID obligated funds to Abt under the SHOPS project to continue this work. SHOPS is currently implementing private sector zinc/ORS programs in Ghana, Nigeria, Uganda and Kenya.
POUZN Intervention: 2005 - 2010

As introduced previously, the Point-of-Use Water Disinfection and Zinc Treatment (POUZN) Project was a 5-year project funded by USAID that was designed to expand access to and use of point-of-use (POU) water disinfection and zinc products for the prevention and treatment of diarrhea.

The POUZN project, which included both market shaping and programmatic efforts, used both commercial and social marketing approaches in the private health sector to increase access to diarrhea prevention (low-cost water disinfection products) and treatment products (zinc along with ORS) for caregivers of children under five. In countries without local pharmaceutical manufacturing capacity, POUZN used a social marketing approach, importing both zinc and ORS products from suppliers in India or France, repackaging the products into a diarrhea treatment kit and supporting demand generation through interpersonal and mass media channels. Cost of packaging and demand creation was subsidized by USAID.

In Nepal, Pakistan, Tanzania and Indonesia, POUZN teams encouraged local pharmaceutical companies to manufacture and market the zinc supplement. Ministries of Health (MOH) also contributed by streamlining product registration, creating policy to allow for over-the-counter sales, endorsing local manufacturers’ products and in some cases actually purchasing product for their own public sector clinics. POUZN staff made the business case to the firms, partnered with public sector on development of training materials, provided cost-shared marketing grants, supported the cost of training/sensitizing retailers, pharmacists and clinical providers about the new treatment protocol, and financing mass media campaigns to generate consumer (and provider) demand.

Ensuring Consistent Supply by Incentivizing New Manufacturers

To improve access to quality diarrheal disease treatments in the private health sector, the POUZN project enlisted several market shaping interventions. A large component of market shaping activities involved stimulating more manufacturers to be engaged in the production of high quality ORS and zinc treatments. At the project’s start in each implementation country, either strong potential manufacturers were identified based on their current production lines, quality assurance and control activities, supply distribution network, promotional reach and other corporate characteristics or where no local pharmaceutical industry existed, products were imported from reliable international sources and marketed by partner social marketing NGOs. Key POUZN project objectives were to expedite the entrance of new manufacturers providing quality products and over time, improve manufacturing competition and lower product prices, wherever possible.

In 2005, zinc was a brand new diarrhea treatment product and few manufacturers had any idea that it was more than a nutritional supplement included in multivitamin products. In Nepal,
both the MOH and the POUZN team convinced three local manufacturers (Deurali-Janti Pharma, Nepal Pharmaceutical Laboratory, and CTL Pharmaceuticals) to consider producing zinc treatments. In Pakistan, two local firms were already manufacturing syrups and suspensions (ADCO and Zafa), encouraged by zinc champions within a zinc coordinating body at the national level. POUZN worked with both of these firms and convinced two additional firms (Macter and Genix) to enter the market with zinc products. In Tanzania, POUZN worked with one local firm (Shelys) to improve the quality of their product and prepare them for Good Manufacturing Practices (GMP) certification. In Indonesia, POUZN convinced five local pharmaceutical companies to enter the zinc market.

By and large, these firms entered the market because they saw both the need and the potential market and understood both that the MOH was prepared to purchase product for their own uses and that the project was there to support the demand creation efforts with both providers (through training and detailing) and consumers (through mass media campaigns). Abt’s POUZN team provided marketing incentives (Nepal) and cost-shared marketing grants (Pakistan, Ghana, Nigeria) to support each manufacturer’s own marketing plan for product introduction. The marketing grant covered brand advertising, additional detailers and sales representatives, sponsorship of clinical meetings, printing of promotional materials and giveaways, etc.

In contrast, in India, which has a very strong pharmaceutical manufacturing base, companies invested US $2.4 million of their own money in activities to create awareness and demand, such as detailing, promotional materials, training, market research, public relations, and professional meetings. Thus, Indian manufacturers went well beyond matching USAID’s investment of US $550,000.

Creating Interest Through the Sales Chain, from Distributor To Caregiver
POUZN worked through existing distribution channels whenever possible, supporting the individual firms’ product detailers, medical representatives, pharmacy and drug shop owners, and health care practitioners with new training—both direct training and participation at continuing medical education seminars (CMEs), marketing materials and accompanying demand generation activities. In Tanzania, the POUZN project co-promoted zinc through pharmaceutical wholesaler “activations.” Activations included providing 90 days of credit to each wholesaler for their first supply of zinc. The wholesaling credit was coordinated with a comprehensive product roll-out by the local manufacturer’s detailers at pharmacies to ensure a sufficient product “pull” from further down the supply chain. Marketing at rural pharmacies and drug outlets included providing marketing materials, offering deals on initial supply purchases and ensuring business owners were aware of locations where they might purchase supplies on a regular basis. Last, mass media was used to create awareness and change perceptions of ORS and zinc at the caregiver level. As Vicki MacDonald, Child Health Advisor for
the SHOPS project at Abt stated, "You need to address low demand for zinc through two channels, mass media and directly to (healthcare) providers. Mass media is especially useful in markets where a lot of treatment seeking behavior is happening through the private sector."

**Influencing National Treatment Guidelines and Regulatory Policy**
The POUZN project also supported changes to national policy and regulatory guidelines. POUZN collaborated with national regulatory authorities to update diarrhea treatment guidelines for private sector care providers and advocated for over-the-counter status for zinc. In Tanzania, POUZN supported the introduction of new guidelines for accredited drug dispensing outlets (ADDOs). The POUZN project also helped push newly registered zinc products into the mainstream distribution system by co-financing marketing or providing marketing materials to pharmacies, drug shops, midwives, and other private sector healthcare providers.

**Implementation**
In countries without a local pharmaceutical industry, the POUZN teams successfully imported, packaged and marketed a diarrhea treatment kit containing two sachets of ORS and a blister of the full 10 and 20 mg zinc treatment. The kit sold for about US$1.00 at full price in commercial outlets in Benin and Madagascar and for the subsidized price of about US$0.35 in poor rural areas at the specific request of USAID. The marketing of these products was highly subsidized by the USAID project.

In all other countries, POUZN and SHOPS teams have been and are working with local manufacturers (Nepal, Pakistan, Ghana, Nigeria, Indonesia, India and Tanzania) and importers (Nigeria and Uganda) to assure that quality products are available at affordable prices. Programs in each country were carefully coordinated through a national coordinating mechanism (zinc task force) that jointly planned the intervention and supported it through policy and regulatory changes. Manufacturers in all POUZN Abt and SHOPS countries have appreciated demand generation efforts and marketing grants—often contributing considerably more than the required 50 percent cost share. While the project teams may have signed MOUs and marketing grants with selected firms in each country, any new firm coming into the market was eligible for the same support.

Vicki MacDonald, Child Health Advisor for the SHOPS project at Abt, commented on the importance of public sector purchases in enabling success for local manufacturers, saying, "For products with very small margins, you benefit from a base of public sector support to de-risk the market. Allow for institutional sales to local manufacturers, it helps kick start their local promotional efforts.” In the POUZN project, the level of government support to local manufacturers through institutional purchases varied widely by country. For example, in Nepal there were three private manufacturers and no government procurement support. In Pakistan
two local manufacturers launched in 2007, were supported by the government through big institutional contracts. And, in Benin, although there were no local manufacturers, the strategy was built around adding zinc to an already successful countrywide ORS program, which included major government purchases from PSI.

Zinc treatment for diarrhea was a brand new concept in 2005. POUZN strategy at this initial stage was based on experience in social marketing and on implementing the “manufacturers’ model”- working with local pharmaceutical companies that had successfully scaled up production and sales of other health products. At the start of the POUZN project, it wasn’t known what media messages and/or interpersonal messages would work. Social marketing approaches were adapted and improved over the years. All companies have seen considerable increases in sales over the short-term. Ministries of health have been further convinced of the quality of local product and have purchased large quantities for the public sector that have helped to sustain the nascent private sector until the product is better known among consumers and demand is constant.

Market interventions primed supply chain actors with information about the benefits of ORS and zinc. The interventions also provided a number of manufacturers with co-financing and/or co-promotion of resources that helped fast track the entrance of new zinc products along with ORS.

Collaborative public private partnerships with MOH and the private sector working in harmony to ensure access through both public and private channels, select and nurture zinc champions, and work with regulatory bodies to streamline the registration process and ensure OTC status, can be highly successful. POUZN and SHOPS teams worked with Ministries of Health to assure that policies and protocols were in place and in some cases (Nepal) trained public sector providers.

Particularly in the second generation programs under SHOPS, the project is partnering with professional associations and regulatory agencies to reach and train providers and continue that interaction through supportive supervision.

**Results**

Both qualitative and quantitative results have been measured to assess impact of the interventions on the markets and on use of ORS and zinc for treatment.

Taking India as an example, the results illustrate the broad effect of the POUZN project’s market shaping intervention on the network of manufacturers, attitudes and preferences of influencers, sales and availability and demonstration of viability of new approaches.
• Twenty-two companies (up from zero at project start) now produce and/or market zinc nationwide through their own supply chains and sales forces. Companies invested their own money for detailing, promotional materials, training, market research, public relations, and professional meetings. Since the project began, the project has leveraged US$7 million from the commercial sector on a USAID investment of US$1.52 million.

• Key medical opinion leaders, who play a critical role in influencing the prescribing behaviors of both formal and informal health care providers, are strong supporters of zinc treatment.

• Their support, in turn, continues to play a role in zinc’s growing acceptance by 15,000 pediatricians, 75,000 general practitioners, and more than 100,000 pharmacists and other providers, including India’s large number of informal medical practitioners and drug sellers (as of March 2010).

• Demand for zinc, as measured by sales, increased from essentially zero before the start of the POUZN project to more than 10.6 million courses of treatment sold between 2005 and 2009.

• Availability of zinc in rural drug shops increased from zero to 50 percent in the target areas.

• Local NGOs trained by POUZN in the state of Uttar Pradesh demonstrated that they could effectively promote improved diarrhea treatment to rural providers, accelerating uptake of zinc and ORS in the areas that are usually not covered by pharmaceutical firms’ marketing efforts and priming a change in behavior for the expected public sector roll-out.

Overall, the POUZN and SHOPS projects have helped ensure consistent access to quality diarrheal disease treatment options. In each of the current implementation countries SHOPS is measuring product availability through retail audits; project teams are confirming that ORS and zinc availability has increased considerably.

Local manufacturing has usually meant that prices have been kept low and affordable. Prices ranged from US$0.45 for the 10-day zinc treatment to US$1.00 for the complete diarrhea treatment kit. POUZN and SHOPS project teams have encouraged multiple firms to enter the market to ensure competition and drive the prices down. Sales of zinc have risen dramatically in each country. In a single year in Nepal, 260,000 treatments were sold; in Pakistan sales of zinc by all firms increased 75 percent during the one year that the project was active (compared to a 45 percent increase the previous year) to 1.93 million treatments in 2010.

In all countries, the project teams implemented household surveys in order to understand whether the products were reaching the target end user (children under five years) and if zinc was being correctly administered along with ORS for the full ten days. These surveys have been rich, valuable sources of information on caregivers’ knowledge, attitudes and practices concerning diarrhea management and the impact of demand generation activities. The
The majority of caregivers surveyed stated that zinc was affordable and users stated that they could find the products close to their homes.

The POUZN and SHOPS market shaping interventions have disrupted the cycle of poor demand and supply, intervening to address both sets of factors. The POUZN project demonstrated that local pharmaceutical firms would enter the market when they are sure that accompanying demand creation activities will lead to increased sales, even if the profit margins are small. However, despite this project’s interventions, ORS and zinc use remains sub-optimal. In multiple POUZN countries, while increases were observed in the use of ORS and zinc by caregivers of children under five years of age, these products were often sold in combination with other medicines and/or increases in uptake were less than use rates recorded for other treatment options such as anti-diarrheals. In many countries the duration of the intervention was as little as one year. On the other hand, in Benin, where a longer intervention was used, use increase from 31 percent in 2009 to 54 percent in 2011. Programs aimed at improving use of ORS and zinc must intervene to increase demand and stimulate sales for sufficient enough time – at least a few years to generate profit margins sufficient for manufacturers to invest long-term in stimulating market demand.

**Challenges and Lessons Learned**

The low profit margins of ORS and zinc continue to contribute to the weak economic incentives for stocking to insure consistent availability. Initial facilitation of new manufacturing sources, demand creation targeted at both consumers and retailers and onetime credit incentives for wholesalers have improved initial interest in the ORS and zinc product markets but, without sustained efforts over a number of years, will not correct the market imperfections.

Other challenges include a lack of high quality data for forecasting product sales. (While need can be forecasted, it is sales which is more difficult.) Without transparent and aggregate demand information manufacturers may be hesitant to enter or remain engaged in these product markets. In addition, in the public sector, given multiple competing interests vying for fixed MOH budgets, there continues to be a lack of resources to retrain staff or purchase zinc supplies. Donor fatigue also results in insufficient funding for longer-term (activities lasting over 5 years) market stimulation. These factors combined propagate existing challenges in the ORS and zinc product markets.

**Summary**

From 2005 to 2010, the POUZN project implemented a product launch market shaping intervention to develop the market in seven countries. For each country, the market shaping intervention included multiple actions to address supply, demand and registration issues for
ORS and zinc. Sales have increased, prices are coming down and the market is gaining speed. Further understanding is being developed about costs of local manufacturing (especially given credit costs and access) and about channel, customer and provider perceptions, spending and choice with regards to diarrhea prevention and treatment, in order to take further steps to develop the market as desired.

The main benefits of a product launch intervention include:

- The limited time intervention involves actions along the private sector chain from manufacturers through the channel to consumers, thus creating an initial demand stimulus while at the same time establishing a working, motivated chain for the future,
- Interventions are based on an understanding of local markets and tailored for each country,
- Using sampling, point of sale surveys combined with supplier and channel interviews can be used in advance to identify problems and post-intervention to assess results.

A product launch intervention is a local intervention that enables and/or accelerates scaling up of the market based on motivating, educating and incentivizing key actors.