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TREATING CHILDHOOD DIARRHEA WITH ORT AND ZINC IN INDONESIA: ENGAGING THE PHARMACEUTICAL INDUSTRY AND PRIVATE PROVIDERS

Lessons Learned from the POUZN/AED Project



June 2010: **DRAFT**

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ACRONYMS

ASCODD	Asian Conference on Diarrhea Diseases and Nutrition
B-POM	Badan POM (the Indonesian National Agency of Drug and Food Control)
GMP	good manufacturing practice
GP	general practitioner
IBI	Indonesia Midwives Association
IDAI	Indonesia Pediatric Association
IDI	Indonesia General Practitioners Association
IDHS	Demographic and Health Survey
IMCI	Integrated Management of Childhood Illness
IMDI	Indonesia Medical Data Index
NEDL	National Essential Drug List
NGO	non-governmental organization
ORS	oral rehydration salts
ORT	oral rehydration therapy
PMA	Pharmaceutical Manufacturing Association
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

Zinc is widely recognized as a highly effective and inexpensive way to treat childhood diarrhea. However, the challenge of introducing a new product and encouraging people to use it—particularly those at “the bottom of the pyramid”—is substantial. In 2005, the U.S. Agency for International Development (USAID) created the Point-of-Use Water Disinfection and Zinc Treatment (POUZN) Project and contracted with AED to introduce zinc in combination with Oral Rehydration Therapy (ORT) in India, Tanzania, and Indonesia.

The premise of the project was that the private sector could play a key role in creating demand for the product, ensuring supply at an affordable price, and, ultimately, increasing its usage, thereby reducing the severity and incidence of debilitating diarrhea in children. To do this effectively required changing both patient and provider treatment patterns, while creating a viable marketplace for the product.

Today in Indonesia, zinc prescriptions are increasing, and producers are recognizing a viable market for the product and therefore manufacturing and selling it. AED/POUZN has effectively engaged other stakeholders as well, from the government who enthusiastically adopted zinc treatment as part of its national guidelines and is now working to raise awareness and proffer national distribution, to national associations who complement the pharmaceutical industry in helping to increase zinc awareness in key populations.

The case study that follows recounts the story of a strong public-private effort developed to establish a sustainable model for ongoing zinc distribution in Indonesia. It provides the context for and goals of the project and the various phases of the project. It looks to the future for next steps and summarizes the principal lessons learned during

the project. This case study is presently a draft and will be updated when ongoing evaluation efforts are completed.

The following lessons may prove useful for further work in Indonesia, and may be applicable to other countries:

Coordinating outreach among the public and private sectors can substantially accelerate success. USAID established an Indonesia assessment team to identify opportunities and needs in both the public and private sectors. As a result of the assessment, POUZN coordinated complementary outreach approaches across both sectors. The project served as an honest broker for public health, catalyzing activity by helping to fully mobilize the potential capabilities of each sector. Doing so accelerated market entry and product distribution by quickly matching public policy incentives and guidance with private sector capacity and resources.

The balance between supply and demand creation is a delicate one and should be approached carefully. Demand without supply is a risk to program success. Supply without demand risks dis-incentivizing private sector investment. Efforts should carefully coordinate zinc introduction in ways that match recognition of

the need with availability of the product. In the case of Indonesia, this meant ensuring a supportive public policy environment while building private manufacturing capacity, educating clinicians, and developing coordinated messages across both the public and private sectors.

A sustainable marketplace for a new product can be created *quickly* under the right conditions—however, sustained efforts are needed. Once producers recognize the value that a new product offers them, they will contribute their own resources, as long as appropriate public policy components are in place. Guidelines need to be updated. Registration processes need to be streamlined. Health practitioners need to be well informed. With this foundation, Indonesia went from no manufacturers of zinc to five manufacturers selling nine different products in just two years' time. However, disparities in treatment exist. Sustained efforts are needed to change well entrenched prescription and caregiving behaviors for a product as yet unknown to many for its effectiveness.

Competition spurs innovation and helps increase demand and availability of the product. As hypothesized, the establishment of a marketplace led to diversity in products, prices, and distribution, increasing both availability and access to the product. Additionally, as more manufacturers entered the marketplace, the level of outreach multiplied, with additional marketing arms and existing distribution relationships brought to bear on zinc promotion.

A motivated public sector is a valuable facilitator for success. A public sector that is motivated to establish policies facilitating adoption of zinc (e.g., establishing a timely registration process, approving zinc as an essential drug) can serve as a catalyst for both private sector investment and public sector distribution. This is especially the case in environments such as Indonesia, where the public sector provides a

significant portion of care. In all cases, the public sector is essential for enabling activities such as establishing zinc as a programmatic drug and incorporating it into national diarrhea guidelines.

Private partners operate within a disciplined decision-making framework that should be understood and spoken to. It is their financial responsibility to their owners (oftentimes shareholders) to continuously choose investments yielding the strongest returns. Zinc promoters should be prepared to make and demonstrate the business case, and to pursue other options when the business case is not there. POUZN successfully convinced private industry in Indonesia to both invest in zinc production and expand its outreach to key influencers when the business case for doing so was not originally apparent. It did so by working with private partners to outline a viable business opportunity worthy of investing scarce corporate resources.

Key opinion leaders in both the public and private sectors (including top pediatricians) are crucial zinc champions. Once they sign on, their endorsement attracts the support of others in the health sector through a cascade of influence reaching other pediatricians, general practitioners, drug sellers, and other practitioners. This is a critical component of an enabling environment, as it facilitates uptake in treatment.

By carefully assuming initial risks, donors can pave the way to sustainable indigenous interventions. POUZN demonstrated the viability of zinc production and sales to the private sector. It encouraged valued enhancements in the public sector. By strategically investing limited resources to attract and build investments over time, the project has increasingly realized what is now largely a sustainable indigenous intervention to reduce childhood mortality associated with the incidence of diarrhea.

Establishing common messages agreed to by both sectors is a useful way to amplify promotion and help to assure quality outreach.

When messages are consistent, outreach across sectors is complementary. Furthermore, when both sectors understand and have agreed to the ground rules, promotional and distribution activities can proceed with little need for adjustment. A clear rationale exists whenever adjustment is necessary (e.g., messaging is off, or a product does not meet agreed-upon dosages).

Promoting "diarrhea treatment" versus "zinc treatment" can build on initial popularity, leveraging existing recognition of ORS (if successful), and reinforce ORT. Indonesia had already seen strong successes in the reduction of diarrhea prevalence. Treatment was well understood and popular among caregivers and the health community. Leveraging "diarrhea" as opposed to focusing on "zinc" helped to build on an existing awareness for treatment, while at the

same time reinforcing the need for ORT as an established mainstay of diarrhea management.



Promoting "diarrhea treatment" versus "zinc treatment" can leverage existing recognition of ORS (pictured above).

HIGHLIGHTS OF THE INDONESIA ZINC PROGRAM

- An enabling environment was established within one year of implementation. Zinc treatment was incorporated into national guidelines and declared a program drug. Badan POM, the Indonesian National Agency of Drug and Food Control (B-POM), agreed to fast-track the registration of zinc by local manufacturers, reducing the timeline from eighteen months to nine. A common message strategy was developed and agreed to across both the public and private sectors.
- Within 11 months of implementation, two companies offered three products. Within one year, private sales reached 290,730 courses; sales to the public sector reached 474,500; and the Indonesian government had tendered 969,100 courses for distribution nationally. One year earlier, no zinc products had been sold in Indonesia.
- The number of products available more than tripled in two years, as did the number of manufacturers. Zinc treatment was available in nearly half of pharmacies nationwide, and is expected to have increased substantially with entry of new manufacturers and products, together with execution of Year 3 activities. Zinc products have been launched in different formats, at different price levels, spanning all segments, and making zinc available to a wide population.
- An expansion pilot leveraging private sector resources, established distribution uptake in over 75 percent of sales outlets across the Bandung area in West Java, one of Indonesia's highest diarrhea prevalence areas, further demonstrating the potential effect of active promotion to increase product availability.

NEW DISCOVERIES FOR IMPROVED OUTCOMES

In 2004, the World Health Organization and UNICEF recommended zinc and low-osmolarity oral rehydration salts (ORS) for inclusion in national guidelines for diarrhea management (WHO/UNICEF, 2004), based on research funded in part by the U.S. Agency for International Development (USAID).

Zinc is an important component of the immune system and a zinc deficiency can increase the incidence and severity of many diseases, including diarrhea; furthermore, diarrhea depletes zinc stores. Research shows that if children take 20 mg of zinc (10 mg for children under six months of age) for 10 to 14 days, the outcome is a 25 percent reduction in the duration of acute diarrhea and a 40 percent reduction in treatment failure and death caused by persistent diarrhea (WHO/UNICEF, 2009). An additional benefit of a complete zinc treatment course is the reduction of the reoccurrence of diarrhea for about three months. To prevent dehydration, however, which can be deadly, children also need Oral Rehydration Therapy (ORT), including solutions made from ORS, recommended home fluids, or increased fluids (BPS, 2007).

With clinical proof and WHO's official recommendation, zinc treatment has moved from promising concept to widespread introduction. Both ORS and zinc treatment are relatively easy to produce and distribute, both are safe, and neither causes serious side effects. Nonetheless, as with any new practice or product adoption, the acceptance of zinc treatment requires changes in usual behaviors—by health care providers and caregivers—as well as large-scale manufacture

OVERVIEW OF POUZN/AED

Duration of project: 2005–2010

Locations: India, Indonesia, and Tanzania

Overall Goal:

Reduce one of the leading causes of illness and death among children worldwide—diarrhea—through two proven methods:

- Preventing diarrhea by disinfecting drinking water at its point-of-use
- Treating diarrhea with zinc treatment and ORT

Goals of Zinc Program in Indonesia:

- Introduce zinc with ORT as standard treatment for childhood diarrhea on a national scale, with emphasis on coverage by the private sector.
- Ensure supply of the product, create demand and changes in prescription behaviors by providers, and support an enabling environment.

For more information, visit:

http://pshi.aed.org/projects_pouzn.htm

and distribution of quality products to accessible outlets.

To increase the availability and sustained use of these interventions, USAID created the Point-of-Use Water Disinfection and Zinc Treatment Project (POUZN Project) in 2005. This publication focuses on POUZN's experiences in Indonesia introducing zinc treatment along with ORT as a standard of care to treat children with diarrhea from 2007 to 2010.

CONTEXT

PREVALENCE AND CLINICAL SUPPORT

With a government committed to improved diarrhea management, Indonesia has seen strong reductions in morbidity and mortality related to diarrhea over the last three decades. The public sector has intensively promoted ORT and continued feeding, including breastfeeding, since the late '70s. Mortality from diarrhea has dropped from 400,000 annually in 1974 to approximately 20,000 in 2007 (WHO/UNICEF, 2009).

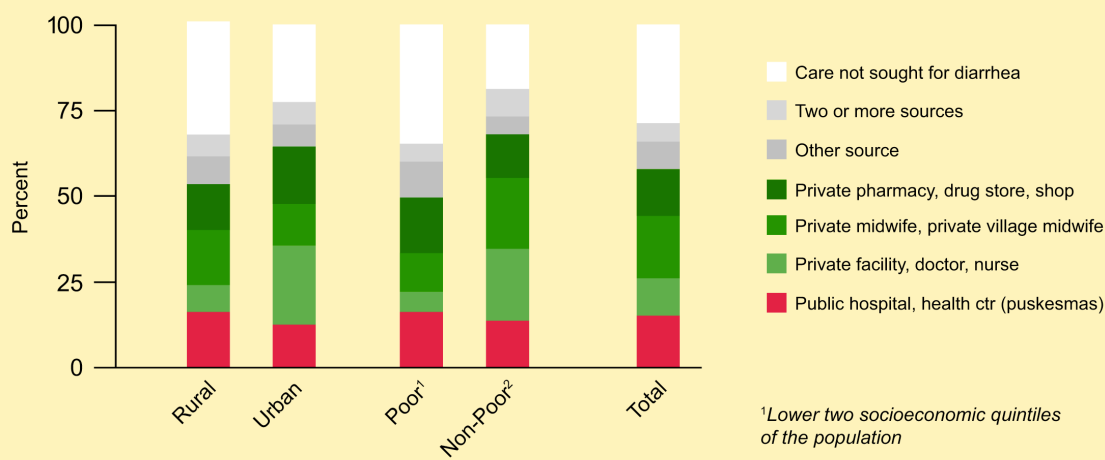
While success is evident, prevalence remains high. The Indonesia Demographic and Health Survey 2007 found that 14 percent of children under age five were reported to have had diarrhea during the two weeks prior to the survey (BPS, 2007). Treatment was sought for 74 percent of these cases. Solution prepared from packets of ORS was provided to 35 percent. ORT was provided to 54 percent (BPS, 2007).



Healthcare practitioners are vital sources of health care delivery in Indonesia.

Healthcare practitioners, including pediatricians, general practitioners, and midwives, are important sources of health care delivery for diarrhea treatment, and represent a key audience for intervention. Figure 1 shows the distribution of careseeking behaviors, by sociodemographic status, for parents whose children under the age of five had diarrhea in the past two weeks, as reported by the Indonesia Demographic and Health Survey 2007 (BPS, 2007). Of note, the

FIGURE 1. CARESEEKING FOR UNDER-FIVE CHILDREN WITH DIARRHEA IN PAST TWO WEEKS



Source: POUZN Project (AED) analysis of DHS (2007) data files, June 2010.

¹Lower two socioeconomic quintiles of the population

²Upper three socioeconomic quintiles of the population

private sector provided a substantial amount of care for children with diarrhea, working with 47 percent of cases, as compared to 17 percent of cases seen by the public sector (BPS, 2007).

AN ENVIRONMENTAL ASSESSMENT

In late 2006, USAID assembled a team of national and international experts to explore opportunities and barriers associated with national uptake of zinc across Indonesia's nearly 17,000-island archipelago. Having worked in India and Tanzania for nearly two years, POUZN supported the assessment team in a strategic exploration of opportunities and barriers associated with the introduction of zinc in both the public and private sectors.

With respect to the public sector, efforts indicated that the Indonesian government was both enthusiastic and well prepared to introduce zinc as a primary strategy for diarrhea treatment. Public institutions were ready to change national diarrhea guidelines and to partner with the private sector in providing zinc treatment.

A robust private sector appeared interested in and ready to distribute zinc treatment across Indonesia. Demand for diarrhea treatment had increased substantially year-over-year from 2006 to 2007, with sales of probiotic treatments growing 63 percent and ORS growing 22 percent. The private sector had proven itself able to meet that demand, driving products to scale rapidly and at low cost using well-developed commercial capacities, including tested product development, marketing, and distribution assets. Notably, products it developed could benefit other countries in the region, including Vietnam, Cambodia, Laos, and Myanmar.

The USAID assessment team concluded in March 2007 that Indonesia was well suited to the introduction of zinc treatment for diarrhea as an adjuvant to ORT, and that the private sector could play a leading role in the introduction of zinc to the market. The project committed to working with both sectors simultaneously and with equal emphases. This became the heart of its approach going forward.

POUZN GOAL AND INITIAL STRATEGY

POUZN sought to build on Indonesia's previous success in reducing diarrhea mortality—success that had established a national platform of providers and associations well aware of diarrhea treatment through ORT and continued feeding. POUZN's goal in Indonesia was to introduce zinc treatment, in combination with ORT, as a standard childhood diarrhea management by increasing access to the product, improving knowledge and correct use of the treatment, and supporting an enabling environment for these changes. The project sought to achieve these ends through approaches that were both scalable and sustainable over the long term. While the main objective was to reach caregivers and improve the health of their children, the project also targeted the many individuals and groups who had an impact on caregivers, including doctors and other health professionals (both formal and informal), and a wide range of drug sellers.



POUZN targeted caregivers for improved diarrhea treatment through ORT and zinc.

POUZN embraced a mandate in Indonesia to work on a national scale after having implemented its approach in India (the world's second largest country) and Tanzania (the first

country to introduce branded zinc treatment of diarrhea in sub-Saharan Africa). Primed with lessons learned from two years of prior implementation in very different contexts, the three-year project (2007–2010) worked with budgets of \$150,000 and \$330,000 in its first two years. From the outset, it was necessary to focus resources strategically.

Efforts mobilized multiple sectors, including a motivated public sector, a robust private sector, and an active development sector. From the outset it was important to harmonize these efforts, helping them to complement one another's activities. Working in Indonesia, POUZN sought ways to:

- Create an enabling environment through support for clear national guidelines, and continuous public sector investment.
- Create a vibrant, competitive market for zinc in which multiple Indonesian commercial companies—manufacturers, distributors, and marketers—would produce, distribute, and promote high-quality and affordable zinc.
- Influence the prescribing behaviors of health providers and generate demand among caregivers.

POUZN's initial strategy was to build on the pharmaceutical marketing model that creates demand through an existing "cascade of influence" in the health sector (see Figure 2 on page 18). With this model, new ideas and treatments begin with key medical opinion

leaders who influence physicians, whose adoption of a new practice, in turn, influences other health practitioners and drug sellers, eventually reaching and encompassing informal providers and consumers. Another way to envision this process is through a "push-pull" framework, in which pharmaceutical companies "push" products to consumers by encouraging the medical community to proscribe them, while "pulling" drugs from the medical community by encouraging consumers to ask their physicians directly. POUZN began its efforts with a "push" strategy starting at the top of the "cascade of influence" in years one and two. It added a "pull strategy" in year three with national direct-to-caregiver marketing.

The balance between creating supply and promoting demand for a new product is a delicate one. One of the cardinal principles of a health communication program is never to promote demand for a product that is unavailable or inaccessible to the target group. POUZN chose to focus resources initially on public policy and private investment, while coordinating "cascade" marketing efforts to key medical opinion leaders, pediatricians, and general practitioners. These efforts were designed to ensure the timely introduction of zinc, together with an improved diarrhea treatment regimen that matched demand with supply produced by the private sector.

PHASE I: HARMONIZING EFFORTS

POUZN's first goal was to harmonize public and private sector efforts. While the private sector played a preeminent role in health care delivery, most health care providers in Indonesia worked from within the government system. Both sectors were vibrant and active and needed to be approached simultaneously.

THE PUBLIC SECTOR APPROACH: CREATING AN ENABLING ENVIRONMENT

On the public sector side of the equation, efforts needed to build on Indonesia's current diarrhea treatment infrastructure that had been so successful to date. This meant working to ensure that guidelines and regulations were updated, a clear messaging strategy was developed, and the groundwork was laid for purchasing supply through public resources.

Policy and National Guidelines

The Indonesian government was enthusiastic about the introduction of zinc as part of an improved treatment for diarrhea. However, groundwork needed to be laid to translate that enthusiasm into a reality conducive to public distribution and private investment. Efforts began immediately with USAID and collaborating development partners to incorporate zinc as an effective complementary treatment with ORT into the Guidelines on the Integrated Management of Childhood Illness (IMCI) and National Diarrhea Program guidelines. Both sets of guidelines were updated within months of startup, grounding future efforts in the most up-to-date guidance for diarrhea treatment and prevention.

Regulation

Regulation served as another critical lever in shaping the environment. The government

managed a registration process for new pharmaceutical products that could take up to eighteen months to complete. Because they were enthusiastic about zinc introduction as a public health product and recognized the private sector as a critical partner for intervention, B-POM, the Indonesian National Agency of Drug and Food Control, agreed early to fast-track registration of zinc down to a period of nine months. In a corporate world where efficiencies often drive decision-making, this was a key victory in ensuring a speedy time-to-market as an incentive for corporate investment. B-POM also agreed to register zinc treatment as a pharmaceutical drug, not a nutritional supplement, and to allow over-the-counter (OTC) applications from manufacturers. The government augmented these efforts by writing a letter to the Indonesian Pharmaceutical Manufacturing Association (PMA) requesting interested members to manufacture zinc treatment in accordance with the WHO/UNICEF recommendations.

Consistent Messages

It was also critical to develop a consistent messaging strategy for diarrhea treatment that could be used across the public and private sectors. POUZN worked with representatives from both arenas, together with NGOs and donors, to develop a consistent communication strategy for improved treatment of diarrhea.

The outcome was LINTAS DIARE (shown on page 16), a set of simple communication messages targeting specific behaviors for treatment of children under five with diarrhea.



LINTAS DIARE promoted five specific behaviors, pictured above in Bahasa Indonesia, and described below in English:

- 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 antibiotic unless bloody diarrhea and/or cholera occurs.
- Return immediately (to doctor or health service) whenever fever, bloody feces, or repeated vomiting occur or child's appetite significantly decreases.

The message was adopted universally across both sectors and promoted through conferences, trainings, medical detailing, and medical publications.

Supply

POUZN partnered immediately with the Indonesian government to enlist zinc as a "program drug," ensuring that it could be purchased by the Ministry of Health (MOH) for distribution to provinces and districts across the country. Having incorporated zinc as a complementary resource to ORT into national guidelines for diarrhea treatment, the Indonesian government moved to securing supply. With encouragement from POUZN, a zinc request of 969,100 courses was submitted in 2008 to two corporate partners for fulfillment. Within a year's time, nearly one million courses of zinc had been purchased for distribution nationwide. An additional 100,000 courses were sold to three Provincial Health Offices for distribution to district health offices and health centers (Puskesmas).

THE PRIVATE SECTOR APPROACH: ENCOURAGING MARKET ENTRY

While POUZN coordinated outreach in the public sector, it needed to move quickly to encourage investment by the private sector. It was critical to get zinc to market in a manner that coincided with public sector efforts to promote and purchase the treatment.

POUZN worked quickly to identify and elicit a number of private sector partners. A core perspective of the program is that stronger markets (with more competitors) allow for greater promotion, extended coverage, expanded consumer choice, and ultimately lower prices. However, partners need to be selected with a long-term perspective in mind, ensuring their intentions go beyond short-term gain to a more perpetual institutional viability.

Project staff assessed potential partners via a set of criteria already used in India and Tanzania, looking at production, quality assurance, distribution, promotional reach, and general corporate characteristics (see box

below). During the initial project assessment, corporate partners had expressed concerns that zinc was a public sector product, not necessarily primed for private investment and promotion.

CRITERIA FOR SELECTING INITIAL PHARMACEUTICAL PARTNERS

POUZN's assessment of pharmaceutical company capabilities focused on a wide range of factors:

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

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

These perceptions had to be overcome to encourage market entry.

Based on this assessment, POUZN staff visited directly with seven of the top ten pharmaceutical companies in Indonesia, making a credible case for investing in this new product. In these initial meetings POUZN provided a carefully designed package of materials, including: 1) a convincing summary of the clinical research about zinc as a state-of-the art treatment, along with 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 discussed the market and business potential for this new treatment and requested that a company, if interested, undertake its own feasibility study of the market. These early efforts, together with the emerging conducive policy environment, helped to motivate what would eventually grow to seven of the top ten companies in Indonesia developing a zinc treatment not only for the Indonesian market, but also for several other countries in the region.

In keeping with a strategy of building local ownership and sustainability, POUZN's role was a supportive one, providing targeted assistance to partnering companies designed to facilitate fast progress and encourage stronger investments. Those that decided to move ahead with introducing zinc treatment developed, registered, manufactured, branded, and packaged zinc using their own resources and marketing it through their own systems.

Within 11 months of intensive project startup, two companies had registered three products (two tablets and one syrup) and generated private sector sales of nearly 85,000 courses. An additional five companies had submitted products for registration by B-POM. The marketplace was up and running.

IMPROVING TREATMENT

As noted earlier, Indonesia had intensively promoted oral rehydration therapy (ORT), together with continued feeding, including breastfeeding, since the late 1970s. However, while health professionals and, to a certain extent, the public, had a reasonably good knowledge of diarrhea management, they were unaware of the effects of zinc treatment in decreasing duration and severity, and in providing a preventive effect against diarrhea.

Additionally, anti-diarrheals and antibiotics served as popular medicines given by caregivers to children with diarrhea, an unnecessary practice POUZN hoped to mitigate through improved diarrhea treatment promotion efforts.

The Cascade Marketing Strategy

POUZN and its partners initiated a cascade marketing strategy, a proven technique used by the pharmaceutical industry for new product launches, to promote improved treatment to health care providers across the country. The strategy concentrated first on reaching key opinion leaders at the top of the hierarchy of influence in health matters. Efforts then moved to gaining the support of pediatricians and general practitioners (GPs). In later phases of the project, POUZN would move toward more aggressively targeting pharmacies (apoteks), nurses, midwives, and caregivers at large through general public outreach efforts.

FIGURE 2: CASCADE OF INFLUENCE



The cascade of influence represents a successful pharmaceutical marketing model applied to the diffusion of zinc in Indonesia.

Key Opinion Leader Outreach

Efforts began in 2008 with the incorporation of a plenary session on zinc treatment at KONIKA, the Indonesia Pediatric Association's (IDAI) national congress hosting 3,000 pediatricians (nearly all pediatricians in Indonesia). Project

staff advocated for zinc's inclusion on the agenda, and arranged for Dr. Olivier Fontaine from the World Health Organization (WHO)—an internationally recognized expert in diarrhea, micronutrient, and other nutritional interventions—to present the latest scientific information, together with improved treatment messages, on diarrhea management.

Professional Mobilization

Efforts continued throughout the year, reaching the Indonesia General Practitioners Association's (IDI) annual conference, the Midwives Association's (IBI) Annual Congress, and 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 and their local chapters of the IDAI throughout the year. These efforts were coordinated in conjunction with private sector partners, who provided support, including registration fees for targeted physicians, lunch symposia, keynote speakers, and printing and distribution of improved treatment promotional materials. They were complemented by placement of messages in medical magazines read by practitioners across the country.

Product “Detailing”

POUZN also supported the pharmaceutical companies' own marketing networks. The established practice is for company representatives to “detail” products: that is, present the product benefits to doctors, other health providers, and pharmacists, and provide free samples. The contacts are often very short, especially in busy, urban clinical settings, but frequent. POUZN initiated pilot efforts with detailers by providing an initial training on zinc detailing to doctors. Later efforts would work to saturate the cascade through the mobilization of

multiple corporate partners whose divisions spanned a diversified portfolio of professionals.

ESTABLISHING THE BASELINE

As distribution took hold and the marketplace continued to develop, POUZN invested in an assessment of caregiver behaviors to establish baseline indicators for the project. A household survey was administered to 506 mothers in Bandung and its surrounding area—a densely populated region of the country with a population of well over 8 million people (Nielsen, 2009). The intent was to outline initial zinc-related behaviors and to better understand the knowledge and attitudes underlying those behaviors.

Among the sample of mothers taken, 18 percent had children with diarrhea in the previous month. Just over half of those mothers said they sought advice on treatment. Notably, only 4 percent were advised to give zinc; 3 percent actually treated their children with zinc (Nielsen, 2009).

The strongest sources of information for mothers who sought advice were neighbors (69%), midwives (31%), clinics (16%), health centers (6%), and general practitioners (6%). The bottom of the cascade was clearly a key target for influencing caregivers' treatment decisions (Nielsen, 2009).

The survey revealed, as expected, that mothers were generally unaware of zinc. Nearly all (99%) could not think of a location at which they could purchase zinc. Just 2 percent said they could remember messages related to zinc as a treatment for diarrhea (Nielsen, 2009).

While use and awareness were in line with expectations, general treatment behaviors revealed opportunities for strong uptake. For example, 84 percent of mothers whose children had diarrhea treated their children with some type of medicine. A large majority (92%)

indicated that they would purchase and use zinc together with ORS the next time their child had diarrhea (Nielsen, 2009).

A CRITICAL TURNING POINT

Taken in total, this assessment served as a critical turning point for the project. It confirmed what marketers would term a “latent” demand for zinc—demand for a product yet to be created. Further, it clearly identified critical influencers for future outreach: midwives, village health clinics (puskesmas), and community health centers (posyandus) emerged as strategically important targets for zinc adoption.

These findings had substantial implications for the project. Through initial efforts, private sector partners had invested heavily in marketing to the top of the cascade, especially to key opinion leaders and pediatricians. However, due to institutionalized market segmentation strategies, they had not focused on general practitioners, drug sellers, midwives, or community health practitioners. This left critical segments of the population untargeted. POUZN would need to adjust course to realize additional public health benefits through coordination with both the public and private sectors.



Midwives and community health practitioners emerged as critically important strategic influencers.

ASSESSING RESULTS:

The Marketplace Is Established

- The policy environment shifted substantially to enable zinc production and distribution. The MOH integrated zinc treatment into national guidelines and declared zinc treatment a program drug, thereby allowing its procurement and supply to the public health system. The regulatory body, B-POM, agreed to fast-track the registration of zinc by local manufacturers, reducing the timeline from eighteen months to nine.
- A national marketplace for commercial zinc production—coordinated from research and development to production and marketing—emerged. Two companies launched products within the first 11 months of intensive implementation. An additional five companies had submitted products for registration by B-POM.
- Public and private sector partners agreed to a coordinated marketing strategy, eliminating the potential for disparate or even contradictory messaging, and amplifying the strength of a national message for improved treatment through zinc and ORT.
- Activities were initiated to reach health care providers with improved treatment messages down the cascade of influence. Zinc was supported by key opinion leaders. Notably, outreach efforts included private sector partners coordinating marketing activities through their own detailing infrastructures at their own expense.
- Production and sales emerged. Within the first eleven months, 85,000 courses were sold on the private market. Within one year, private sales reached 290,730 courses; sales to the public sector reached 474,500 courses; and the Indonesian government had tendered 969,100 courses for distribution nationally. One year earlier, no zinc products had been sold in Indonesia.

PHASE II: ACCELERATION THROUGH THE CASCADE

After just one year of intensive intervention, many of the building blocks for introducing zinc at scale were in place: supportive guidelines and regulations; competitive manufacturers; mobilized professional associations; and coordinated messaging. When findings about relatively untargeted key influencers emerged, next steps were clear: POUZN needed to focus attention on accelerating promotion through the cascade to GPs, pharmacies, midwives, and community health practitioners, while continuing coordination of complementary outreach across the public and private sectors.

COORDINATING AN EXPANSION PILOT

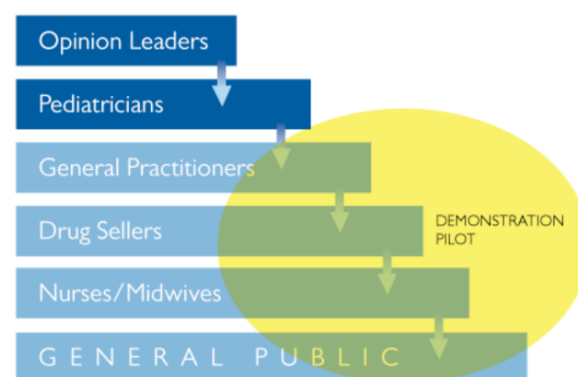
POUZN initiated a six-month expansion pilot designed to test and demonstrate the effects of concentrated promotion to the lower echelons of the cascade. The intent was to show that GPs, pharmacies, and midwives represented viable target audiences for pharmaceutical investment.

Pilot implementation was selected for Bandung. This represented an ideal location, as activities would be matched by the efforts of additional public sector programs training 100 GPs. The pilot could also take advantage of household survey findings, providing insight into regional care seeking behaviors.

POUZN pilot activities followed a two-pronged approach, working to encourage uptake by outlets and providers, while at the same time stimulating awareness and demand among caregivers. In outreach to outlets and providers,

POUZN hired and trained a professional marketing firm to detail pharmacies, drugstores, and midwives. Promotional teams were directed to repeatedly reach all 679 drug sellers and 269 midwives in Bandung throughout the pilot period.

FIGURE 3: CASCADE OF INFLUENCE



The demonstration pilot targeted lower echelons of the "cascade" to demonstrate viability for sustained private sector investment in reaching key influencers.

All private sector partners were informed and consulted during the pilot's development. In support of the pilot, each was asked to provide promotional items and to ensure that zinc treatment was available in the expansion area. Post pilot assessment was planned to test for behavior change and demand creation, including use of a "mystery client" exploring the quality of treatment recommendations provided by sales outlets during the intervention.

By all accounts, the project was a success. During the pilot, over 1,100 outlets (817

pharmacies, 287 midwives, 56 drugstores) were visited by detailers, exceeding a target of 960 outlets. This led to substantial success in the adoption of zinc sales by pharmacies and drug stores. By the end of activity, zinc was available at 732 outlets, exceeding the project's goal of 672. Zinc and LINTAS DIARE poster displays had been posted at 497 outlets (345 pharmacies and 152 midwives), exceeding a target of 480. Two pharmaceutical companies committed to new activities targeting pharmacies and drug stores for promotion. One company committed to targeting GPs. Among these organizations, one company began targeting midwives. However, their coverage was limited due to the extent of their sales force. The project is currently awaiting household endline data about changes in caregiver treatment awareness and behavior.

SUSTAINED PUBLIC SECTOR SUPPORT

While key policy victories had been established early on, one substantial barrier remained. Zinc treatment was not included on the National Essential Drug List (NEDL), updated every three years, impeding the ability of hospitals and public health centers to include zinc in their formularies. The national review committee responsible for developing the list requested a post-marketing surveillance study to provide evidence that the drug is safe for children at the recommended course. Accordingly, POUZN began coordinating efforts with the Ministry of Health's Diarrhea sub-Directorate and external bodies, including WHO and UNICEF, to address the review committee's concerns in preparation of the next NEDL revision in 2011.

Additionally, POUZN continued to support market introduction efforts by working with B-POM to fast-track registration for new products. The project coupled this outreach with

discussions advocating for increases in zinc funding in the federal budget, together with zinc procurement through government dollars, and zinc distribution to provinces, districts, and health centers.

By continuing its government partnership efforts, POUZN helped to connect four private sector partners to a tender of 1,000,000 courses by the MOH for distribution to 33 provinces nationwide. The program also maintained and strengthened ties with its government partners.

SUSTAINED PRIVATE SECTOR SUPPORT

As POUZN moved into its second full year of implementation, four additional manufacturers were expected to launch their zinc brands, bringing five new brands to market (see Table 1).

Seizing these launches as new opportunities to further national adoption of zinc treatment, POUZN worked individually with each partner on a number of fronts. Project staff supported the development of marketing plans, working to ensure outreach across both the private and public markets with an emphasis on reaching pediatricians, general practitioners, pharmacies, and midwives. Staff also supported the development of promotional materials to ensure consistent communication using the LINTAS DIARE message. POUZN continued to train medical representatives to maintain effective detailing on appropriate zinc treatment. In some cases, POUZN was able to connect private partners to institutional purchasers (central and district governments), enabling large-scale public distribution. In one instance, POUZN assured quality product development, advising a corporate partner to reduce their dosage from 14 tablets to 10 tablets per the LINTAS DIARE guidelines.

TABLE 1: PRODUCTS TO MARKET

COMPANY	BRAND NAME	PRODUCT FORM	INTRODUCED
Kimia Farma	zinc generic	Tablets	November 2007
Kimia Farma	DIAZINK	Tablets	January 2008
Indo Farma	ZINKID	Syrup	February 2008
Indo Farma	zinc generic	Tablets	June 2008
Kalbe Farma	Zn-DIAR	Tablets	February 2009
Combiphar	ZINCPRO	Syrup	May 2009
Combiphar	ZINCPRO	Tablets	May 2009
Novell	OREZINC	Dry Syrup	May 2009
Kalbe Farma	ZINCARE	Tablets	May 2009
Interbat	INTERZINC	Tablets	Summer of 2010
TEMPO Scan	ZIDIAR	Syrup	June 2010
TEMPO Scan	ZIDIAR	Tablets	July 2010

POUZN complemented these efforts with continued support for conference and medical education. Project staff successfully advocated for the addition of “zinc as a diarrhea treatment” to an IBI national meeting with over 2,000 midwives from across Indonesia in attendance (a strategy neatly complemented by detailing efforts associated with one partner's ob-gyn product-line to midwives). POUZN trained over 3,000 GPs on “zinc as a diarrhea treatment” at the IDI Continuous Professional Development Conference. Both organizations partnered subsequently on the development of accreditation round table discussions addressing diarrhea management with nearly 1,200 general practitioners in over nine major cities. Project staff also coordinated support for the 2009 ASCODD conference, supporting symposium registration fees of 25 influential doctors, co-sponsoring a speaker, and coordinating distribution of *Lintas Diare* promotional materials by private sector partners. Two manufacturers, including Indonesia's largest pharmaceutical company (and strongest marketing outreach arm), launched new products at the event. These efforts bore substantial fruit. Total zinc sales by the end of POUZN's 2009 fiscal year

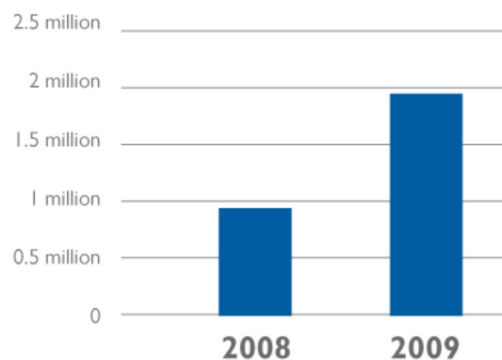
were 1.956 million courses, surpassing the program's internal goal by 30 percent. Commercial partners reached an estimated 2,070 pediatricians and 6,245 general practitioners. Zinc treatment was available in nearly 50 percent of all pharmacies covered by the partners nationally. As predicted by the POUZN approach, a stronger market (with more competitors) had increased promotion, extended coverage, and expanded consumer choice—zinc products had been launched in different product formats (syrup, dry syrup, and tablets), at different price levels (ranging from roughly \$0.65 to \$3.50), spanning multiple segments and making zinc available to a wide population. Notably, much of the effort was shouldered in a sustainable way through existing pharmaceutical investment, distribution, and marketing infrastructures.

ASSESSING RESULTS IN EARLY 2010:

Acceleration through the Cascade

- POUZN successfully advocated for a Ministry of Health tender of 1,000,000 courses for distribution to 33 provinces nationwide.
- Four new producers entered the marketplace, adding five new brands by August 2009, with three additional brands expected for registration in 2010.
- Medical education efforts reached more than 2,000 midwives, 2,070 pediatricians, and 6,245 general practitioners.
- Zinc treatment was in nearly half of all pharmacies nationally.
- Total zinc sales after two years reached 1.956 million courses, surpassing the program's goal by 30 percent.
- Pilot efforts succeeded in encouraging more than 75 percent of sales outlets in Bandung, the nation's second largest metropolitan area, to carry zinc, and convinced private partners to invest in targeting GPs and midwives.

FIGURE 4: INDONESIA DISTRIBUTION



PHASE III: AMPLIFICATION AT SCALE

By the end of its second year, POUZN had convinced several manufacturers to target pharmacies, drug stores, and GPs; and two additional manufacturers were expected to enter the marketplace with three new brands. The lower echelons of the cascade were giving way to sustained outreach. While gaps remained in outreach to pharmacies, drug stores, and GPs, those were now closing as manufacturers began reaching them with increasing amounts of intensity. However, significant gaps remained in the number of midwives promoting zinc, and, increasingly important, caregivers were largely untargeted.

Year three of the project is now underway. Efforts are focused on intensifying the level of outreach to midwives. As represented in Figure 1 earlier in this document, the Indonesia Demographic and Health Survey 2007 showed midwives as a substantial provider of diarrhea care across rural (19 percent), urban (15 percent), lower-income (14 percent), and higher-income (20 percent) groups (BPS, 2007). POUZN has initiated a high-intensity outreach effort to midwives nationally, in collaboration

with IBI, updating and distributing training materials across the country, and supporting private partners in reaching midwives directly. Building on the efforts of its Phase II expansion pilot, and working in collaboration with the regional IBI chapter, the program is now testing an enhanced training throughout the Bandung area. Efforts are also focused on coordinating a strong "pull" strategy, going directly to caregivers with messages to use ORT and zinc for diarrhea treatment. Sustained efforts will continue in the public and private sectors to support policymakers and increase public distribution, assist manufacturers in marketing and outreach, and partner with professional associations in spreading zinc awareness to key medical practitioners. A national radio and television media campaign will serve as a primary platform to reach caregivers, while simultaneously incentivizing additional pharmaceutical investments in key populations and a public sector focus on expanded supply.

This case study will be updated as placement, sales, and evaluation data are analyzed.

LESSONS LEARNED

1. Coordinating outreach among the public and private sectors can substantially accelerate success. USAID established an Indonesia assessment team identifying opportunities and needs in both the public and private sectors. As a result of the assessment, POUZN coordinated complementary outreach approaches across both sectors. The project served as an honest broker for public health, catalyzing activity by helping to fully mobilize the potential capabilities of each sector. Doing so accelerated market entry and product distribution by quickly matching public policy incentives and guidance with private sector capacity and resources.

2. The balance between supply and demand creation is a delicate one and should be approached carefully. Demand without supply risks public backlash. Supply without demand risks dis-incentivizing private sector investment. Efforts should carefully coordinate zinc introduction in ways that match recognition of the need with availability of the product. In the case of Indonesia, this meant ensuring a supportive public policy environment, while recruiting private manufacturing capacity, educating clinicians, and developing coordinated messages across both the public and private sectors.

3. A sustainable marketplace for a new product can be created *quickly* under the right conditions—however, sustained efforts are needed. Once producers recognize the value that a new product offers them, they will contribute their own resources, as long as appropriate public policy components are in place. Guidelines need to

be updated. Registration processes need to be streamlined. Public health practitioners need to be educated. With this foundation, Indonesia went from no manufacturers of zinc to five manufacturers selling nine different products in just two years' time. However, disparities in treatment exist. Sustained efforts are needed to change well entrenched prescription and caregiving behaviors for a product as yet unknown to many for its effectiveness.

4. Competition spurs innovation and helps increase demand and availability of the product. As hypothesized, the establishment of a marketplace led to diversity in products, prices, and distribution, increasing both availability and access to the product. Additionally, as more manufacturers entered the marketplace, the level of outreach multiplied, with additional marketing arms and existing distribution relationships brought to bear on zinc promotion.



Indonesia went from no manufacturers of zinc to five manufacturers selling nine different products in two years' time.

5. A motivated public sector is a valuable facilitator for success. A public sector that is motivated to establish policies facilitating adoption of the innovation (e.g., establishing a timely registration processes, approving zinc as a program drug) can serve as a catalyst for both private sector investment and public sector distribution. This is especially the case in environments such as Indonesia, where the public sector provides a significant portion of care. In all cases, the public sector is essential for enabling activities such as establishing zinc as a programmatic drug and incorporating it into national diarrhea guidelines.

6. Private partners operate within a disciplined decision-making framework that should be understood and spoken to. It is their fiduciary responsibility to owners of the firm (oftentimes shareholders) to continuously choose investments yielding the strongest returns. Be prepared to make and demonstrate the business case, and to pursue other options when the business case is not there. POUZN successfully convinced private industry in Indonesia to both invest in zinc production and expand its outreach to key influencers when the business case for doing so was not originally apparent. It did so by working with private partners to demonstrate a viable business opportunity worthy of investing scarce corporate resources.

7. By carefully assuming initial risks, donors can pave the way to sustainable indigenous interventions. POUZN demonstrated the viability of zinc production and sales to the private sector. It encouraged valued enhancements in the public sector. By strategically investing limited resources to attract and build investments over time, the project has increasingly realized what is now largely a sustainable indigenous intervention

to reduce childhood mortality associated with the incidence of diarrhea.

8. Key opinion leaders in both the public and private sectors (including top pediatricians) are crucial zinc champions. Once they sign on, their endorsement attracts the support of others in the health sector through a cascade of influence reaching other pediatricians, general practitioners, drug sellers, and other practitioners. This is a critical component of an enabling environment, as it facilitates uptake in treatment.

9. Establishing common messages agreed to by both sectors is a useful way to amplify promotion and assure quality outreach. When messages are consistent, outreach across sectors is complementary. Furthermore, when both sectors understand and have agreed to the ground rules, activities can proceed with little need for adjustment. A clear rationale exists whenever adjustment is necessary (e.g., messaging is off, or a product does not meet agreed-upon dosages).

10. Promoting "diarrhea treatment" versus "zinc treatment" can build on initial popularity, leveraging existing recognition of ORS (if successful), and reinforce ORT. Indonesia had already seen strong successes in the reduction of diarrhea prevalence. Treatment was well understood and popular among caregivers and the health community. Leveraging "diarrhea" as opposed to focusing on "zinc" helped to build on an existing awareness for treatment, while at the same time reinforcing the need for ORT as an established mainstay of diarrhea management.

A LONG-TERM VISION

As POUZN Indonesia moves into its third year of implementation, program staff are working to extend the market's contours to needed frontiers by intensifying midwife and general practitioner outreach, coordinating direct-to-caregiver promotion, and supporting outreach efforts in preparation for intensified public investment.

The program is taking an aggressive approach to targeting midwives, GPs, and caregivers, sharing costs with manufacturers who commit to including zinc treatment in their coverage of new segments, such as midwives and GPs. It is taking an equally proactive approach to targeting caregivers through the development of a nationwide mass media campaign.

Additionally, in preparation for the essential drug review, POUZN is working with key public sector partners to establish safety evidence in hopes of allaying previous national concerns about the treatment. Doing so could establish zinc on the 2011 NEDL, enabling much broader public sector purchase and distribution of the product.

Beyond these strategies, additional efforts will likely be needed to realize broad national uptake of improved diarrhea treatment through zinc and ORT. The public health community is well aware of the translational gap between research

and practice. In the long term, the following directions may help to expand the use of zinc in Indonesia:

Systematizing large-scale public sector outreach as a supplement to private sector efforts. While private efforts have led the way in developing a sustainable market, they may not extend coverage beyond urban centers to remote rural areas.

Further incentivizing corporate investment in outreach to GPs, midwives, and community health practitioners who appear to provide much of the valued caregiving guidance for mothers. If corporate partners can be convinced to target these segments, both sustainability and reach should grow substantially.

Coupling industry development efforts with intensified mass media campaigns to create a new social norm and ensure that zinc and ORS treatment becomes a top-of-mind decision whenever a child is suffering from diarrhea.

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