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

Lessons Learned from the POUZN/AED Project



March 2010

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ACRONYMS

AED	Academy for Educational Development
BIBCOL	Bharat Immunologicals and Biologicals Corporation Limited
CD	compact disk
DVD	digital video disk
GMP	good manufacturing practice
IAP	Indian Association of Pediatrics
IIPS	International Institute for Population Sciences
IMA	Indian Medical Association
NFHS-3	National Family Health Survey III
NGO	non-governmental organization
NRHM	National Rural Health Mission
ORS	oral rehydration salts
ORT	oral rehydration therapy
PACT-CRH	Program for Advancement of Commercial Technology – Child and Reproductive Health
PANI	People's Action for National Integration
POU	point-of-use water disinfection
POUZN	Point-of-Use Water Disinfection and Zinc Treatment Project
RMP	rural medical practitioner
SES	socio-economic status
SSS	Shashwash Sahbhagi Sansthan
UNICEF	United Nations Children's Fund
UNOPS	United Nations Operations Unit
USAID	United States Agency for International Development
UP	Uttar Pradesh, India
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 enormous. 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 India, zinc prescriptions are increasing and producers recognize the market for the product and are thus manufacturing and selling it. AED/POUZN has effectively engaged other stakeholders as well: from the government to provide an enabling environment for the private sector sale of zinc, to non-government organizations (NGOs) who complement the pharmaceutical industry in helping to make zinc more accessible to the public, particularly rural populations.

Despite these successes, zinc use has a way to go before it is universally accepted as the standard of treatment for diarrhea, especially in rural areas and among the less educated,

more traditional, and poorer communities. Many of the lessons learned during the initial five years of the project will be useful as stakeholders move forward with private sector projects involving zinc.

The case study that follows recounts the story of zinc introduction in India in the private sector. It provides the context for and goals of the project; the various phases of the project; and strategy adjustments. It looks to the future for next steps and summarizes the principle lessons learned during the project.

The following lessons may prove useful for further work in India, as well as be adaptable to other countries:

Zinc treatment is a new concept and competes with well-entrenched prescription behaviors and traditional treatment practices. Changing the habits of both providers and patients requires time and a long-term investment.

Key opinion leaders in both the public and the private sector (including top pediatricians) are crucial zinc champions.

Once they sign on, their endorsement attracts the support of others in the health sector through a pyramid of influence reaching other pediatricians, general practitioners, drug sellers, and ultimately informal practitioners.

Working with the private pharmaceutical sector is critical to ensure a long-term, competitively priced supply of zinc and sustained demand generation.

At the same time, the reach of pharmaceutical marketing (and “detailing”) is limited in rural areas, and the “trickle down” of influence across different strata of medical providers can take years. Reaching those most in need requires innovative strategies to “jump-start” the process and create bridges.

The balance between supply and demand creation is a delicate one. This project tested the effectiveness of face-to-face demand creation in areas where supply was assured. Sustained promotion to caregivers via multiple channels (including significant resources for mass media) is necessary for large-scale behavior change.

The public and private sectors have different objectives and time scales.

A project must work with both to increase coverage and attain national scale. Both sectors have a role to play in introducing and sustaining a new health behavior, with the roles contingent on the country context.

HIGHLIGHTS OF THE INDIA ZINC PROGRAM

- Twenty-two companies (up from 0 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 \$7 million from the commercial sector on a USAID investment of \$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.
- 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 0 to 50 percent in the target areas.
- Local NGOs trained by POUZN in 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.

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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, an essential micronutrient, is present in a nutrient-rich diet, but the daily diet of millions of children in India does not provide for sufficient stores. 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 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 in 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. However, to prevent dehydration, which can be deadly, children need ORS or Oral Rehydration Therapy (ORT).¹

With clinical proof and WHO's official recommendation, zinc treatment was ready to move from promising concept to widespread introduction. Both ORS and zinc treatment are relatively easy to produce and distribute,

¹For purposes of its survey, the National Family and Health Survey (NFHS-3) in India defined oral rehydration therapy as ORS, gruel, or increased fluids.

OVERVIEW OF POUZN/AED

Duration of project: 2005–2010

Locations: India, Indonesia, and Tanzania

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

Goals of Zinc Program in India:

- 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.
- Achieve effective reach to families within the poorest socioeconomic groups who are most vulnerable.

Resources for Zinc Program in India:

- \$1.518 million of total USAID funding over five years.
- One full- and one half-time staff people dedicated to zinc program.

For more information visit:

www.aed.org/project/POUZN

are safe, and do not produce serious side effects. However, as with any new practice or product adoption, zinc treatment requires

changes in usual behaviors—by health care providers and caregivers—as well as large-scale manufacture and distribution of quality products to accessible outlets.

To increase the availability and sustained use of these interventions, USAID created the

Point-of-Use Water Disinfection and Zinc Treatment Project (POUZN) in 2005. This publication focuses on POUZN’s experiences in India introducing zinc treatment, along with ORT, as a standard of care to treat children with diarrhea.

CONTEXT

India is home to an estimated 180 million children under the age of five. Infant and child mortality has decreased nationwide since 1992, but remains high. According to the most recent National Family and Health Survey (NFHS-3) in 2006-2007, more than one in 18 children die within the first year of life, and an additional one in 13 die before age five. Infant mortality in rural areas is 50 percent higher than in urban areas (IIPS and Macro International, 2007).

Diarrhea causes 18 percent of deaths of Indian children under age five — more than 380,000 children a year. This represents the largest number of deaths from diarrhea in any single country worldwide and more than one-fifth (22 percent) of global child mortality due to diarrhea. Many millions more children fall ill, leaving them vulnerable to other health problems.

According to NFHS-3, 9 percent of children country wide reportedly had diarrhea in the preceding two weeks (data which are very likely under-reported). Among these children, approximately 60 percent were taken to a health facility (slightly higher in urban than rural areas). Only 39 percent were treated with some kind of oral rehydration therapy, including 26 percent with an ORS solution and 20 percent with home-made gruel. More than one-quarter of children with diarrhea did not receive any type of treatment at all, and many received treatments that were inappropriate. Qualitative research by the independent research agency AMS in Uttar Pradesh (UP), Jharkhand, and Uttaranchal showed that most caregivers initially tried home remedies to treat diarrhea before seeking medical care, and

Diarrhea causes 18 percent of deaths of Indian children under age five — more than 380,000 children a year.

often used antidiarrheals (which can be harmful) and antibiotics (which are unnecessary except for bloody diarrhea).

More than three-quarters of caregivers who sought care for diarrhea treatment went to private health providers or shops, and the remainder went to public health facilities.

Caregivers in India tend to heed what health practitioners recommend to them (AMS). This is an asset to the introduction of zinc. Yet private sector health providers for children range from specialists with global reputations to a large range of informal and unqualified practitioners. The latter—termed rural medical practitioners (RMPs) in this project—provide a significant amount of the health care in rural areas. They may treat patients with both allopathic and homeopathic remedies but do not have formal medical training. Similarly, drug sellers in India range from well-stocked, licensed pharmacies to small, unlicensed outposts or market stalls.

One of the first clinical trials to establish the effectiveness of zinc took place in a low-income area of Delhi (Sazawal et al., 1997), involving some of the country's top pediatricians. Their research laid the groundwork for a favorable reception of the WHO/UNICEF guidance by the Government of

India and national medical associations, most notably the Indian Academy of Pediatrics and the Indian Medical Association. 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. Although zinc was not yet included in national diarrhea guidelines when POUZN began work in India, this was not a constraint to beginning work with the private sector.

Two local pharmaceutical companies had produced a limited amount of zinc for commercial sale in 2005 when the project began. The private sector potential, however, was enormous. India's large pharmaceutical sector has strong manufacturing, distribution,

and promotion capabilities. Any company that decided to produce zinc had the resources to shoulder the costs without any need for subsidies (in contrast to many developing countries), and a network to market it to providers and drug shops.

Overall, POUZN launched operations in a country with high mortality due to childhood diarrhea, especially in rural areas; a strong private health sector reaching all socioeconomic groups; a generally favorable policy environment for zinc on the national level; and a vibrant commercial pharmaceutical industry. All these factors were instrumental in how the project was designed and how it carried out its strategy to introduce zinc treatment and ORT.

POUZN GOAL AND INITIAL STRATEGY

POUZN's goal in India was to introduce zinc treatment and low-osmolality ORS as a standard childhood diarrhea treatment 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 are 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 targeted the many individuals and groups whose behaviors have an impact on caregivers, including pharmaceutical companies, doctors and other health professionals (both formal and informal), and a wide range of drug sellers.

POUZN embraced a mandate in India to work on a national scale and to reach the most vulnerable groups, including those in rural areas. This was an ambitious task. India is the world's second largest country, with a population of over one billion people. The five-year project (2005-2010) worked with an average annual budget of \$300,000 and hired only one and a half full-time in-country professionals (both with strong experience in the pharmaceutical industry). It was necessary to focus resources very strategically.

The project worked almost entirely with the private sector, given the robustness of India's pharmaceutical industry and the preference of all socioeconomic groups to seek advice from private providers for care of childhood diarrhea.



Caregivers in all socioeconomic classes prefer going to health providers in the private sector.

In India, POUZN sought ways to:

- Create a vibrant, competitive market for zinc, in which multiple Indian commercial companies—manufacturers, distributors, and marketers—would produce and market zinc, ultimately reaching low-income communities with a low-cost, affordable product;
- Influence the prescribing behaviors of health providers and generate appropriate demand among caregivers;
- Engage NGOs to penetrate more remote and hard-to-reach areas than commercial companies normally do, in order to reach rural providers and caregivers;
- Create an enabling environment through support for clear national guidelines, endorsement of zinc treatment products by professional associations, and public sector support.

POUZN's initial strategy was to build on the pharmaceutical marketing model that creates demand through an existing "pyramid of influence" in the health sector. New ideas and treatments begin with key medical opinion leaders who influence physicians, whose adoption of a new practice, in turn, influence other health practitioners and drug sellers—eventually reaching and encompassing the large pool of informal providers and consumers even in remote areas. The supply of drugs is also expanded through a "push-pull" process down the chain via medical reps from the pharmaceutical industry and up the chain from prescribers to drugstore outlets and their wholesalers and distributors.

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. Ultimately, sustained promotion to caregivers through multiple channels (including significant resources for mass media) is necessary for large-scale behavior change. POUZN did not attempt to stretch its limited resources to include mass media campaigns, although funds were originally reserved to provide matching grants to pharmaceutical companies to stimulate demand creation on their parts and further leverage funds from this powerful sector.

PHASE I: CATALYZING THE AVAILABILITY OF ZINC

POUZN's first goal was to stimulate a sufficient and sustainable supply of zinc.

SUPPLY WITHIN THE INDIAN CONTEXT

In 2005, POUZN carried out a capability assessment of 20 Indian pharmaceutical companies, looking at production, quality assurance, distribution, promotional reach, and general corporate characteristics. The project established a series of criteria for selecting firms it would actively pursue for collaboration. (See box.) The idea was not to limit involvement, but to work energetically with appropriate companies, assuring nationwide reach. In fact, one principle the project followed was that participation by more firms would improve competition and lower prices over time. POUZN project staff with experience in the pharmaceutical industry helped in targeting appropriate high-level decision makers within each of these companies (usually the managing director and marketing director), setting up meetings, and 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

CRITERIA FOR SELECTING INITIAL PHARMACEUTICAL PARTNERS

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

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

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

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. This approach was possible and appropriate in India, where companies have the capacity to conduct such analyses without donor funds and will be most convinced by their own process of gauging a new product's potential.

In the first year, seven of the firms contacted decided to manufacture and market zinc for the commercial market. In keeping with the strategy of building local ownership and sustainability, POUZN's role was a supportive one, providing assistance to the partnering companies only when needed. Those that decided to go ahead and introduce zinc treatment developed, registered, manufactured, branded, and packaged zinc using their own resources and marketed it through their own systems. Each year, more joined on. As of late 2009, 22 firms were manufacturing and/or distributing zinc.

A CONSUMER-DRIVEN PRODUCT STRATEGY

POUZN operated on the firm principle that India's commercial sector knows its own markets best, and has expertise to introduce a new product. The project did not create any parallel distribution or marketing campaigns, but rather worked within the partners' standard business practices and supported the development process when needed.

Sometimes this required a strategic "hands off" stance by the project, or negotiation of expectations by international partners. For example, in some countries zinc is co-packaged with ORS to reinforce the importance of both treatments. Companies in



Indian manufacturers were confident that mothers prefer syrups for young children.

India did not do this. POUZN, however, requested that companies already producing ORS co-promote their two products in marketing materials. Companies that did not produce a branded ORS product were asked to promote zinc along with ORT. Companies were thus able to adapt WHO/UNICEF guidelines according to their own market situations. WHO clinical trials used dispersible zinc tablets (dissolved in water or other fluids), because tablets contain the exact dosage and are easier to transport and store. However, the companies that introduced both tablets and syrup forms were convinced from their own data that consumers in India prefer to give syrup to their young children. After over three years on the market, syrup now accounts for 88 percent of market sales.

Affordability was another major project concern, in view of POUZN's target audience and the frequency that a poor child experiences diarrhea. Early in the project, a complete course of zinc was priced between \$US .50 and \$US 1. With increasing competition among a growing number of firms, this price is expected to gradually drop.



The policy was to “co-promote” zinc with ORS.

ENLISTING “ZINC CHAMPIONS” AND MEDICAL DETAILERS

POUZN undertook two interrelated activities to support the promotion of zinc, in keeping with the pyramid of influence within the health sector and the usual procedures of drug companies.

The project coordinated with Emcure Laboratories, one of the first of the interested firms, to hold a day-and-a-half long medical symposium and gather 40 top pediatricians from the Indian Association of Pediatrics (IAP) across India to enlist them as “zinc champions.” POUZN invited Prof. Sunil Sazawal, a zinc clinical expert affiliated with Johns Hopkins University and one of the researchers in the Delhi clinical trials, as the main presenter. This meeting enabled participants to delve deeply into the research

findings. In India, as in any country, it is important to have evidence that shows the *local* efficacy of a treatment; furthermore, the involvement of an internationally renowned clinician, who is also an Indian national, was invaluable in this case.

Symposium participants received a CD with a collection of tools including Q&A on zinc and ORS treatment, and a ready-to-deliver PowerPoint presentation that they were encouraged to show colleagues at their own hospitals or universities and their local chapters of the Indian Academy of Pediatrics (IAP). Emcure medical reps helped with local presentations and also followed up with additional contacts. The symposium participants thus became a cadre of influentials for disseminating the new treatment practices.

POUZN also supported the pharmaceutical companies' own marketing networks. The established practice is for company representatives to "detail" products: that is, they 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. In its first year, POUZN trained 1,200 medical representatives (or "reps") from four companies on diarrhea treatment with ORT and zinc, including selling techniques. The medical reps, 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 and distribution of promotional materials.

By the third year of the project, almost all pediatricians had been reached and the number of general practitioners contacted had more than tripled, to 75,000.

MATCHING GRANTS

POUZN initially planned to offer companies matching grants of around \$20,000 for extra efforts in expanding zinc marketing to rural areas. Most companies have approximately 200 products, limiting the attention they can pay to the promotion of a single product like zinc treatment. The project learned, however, that in the Indian market, this grant amount was not large enough to convince companies to take on the additional efforts and expense needed to reach further down the pyramid of influence. Depending on available funds, matching grants might be a more effective strategy in a country where marketing dollars would go further or where companies have fewer products.

Creating an Enabling Environment

POUZN participated in the Zinc Technical Advisory Group, which included the Government of India, UNICEF, other USAID-funded projects, and other health representatives. This group coordinated advocacy, qualitative research, and information-sharing activities to contribute to policy decisions about the role of zinc in diarrhea management guidelines.

POUZN also assisted BIBCOL, a parastatal manufacturing facility, in its distribution strategy for public supplies of zinc. The project liaised with the National Rural Health Mission (NRHM) and United Nations Operations Unit (UNOPS), which now includes zinc treatment in its primary care kits to public health workers.

To improve the monitoring of zinc use, the project convinced ORG MARG, the independent pharmaceutical audit firm, to create a sub-category for zinc treatment (within antidiarrheals). Early on, the companies marketing zinc could see more clearly the results of their comparative sales, which POUZN used to stimulate the competition.

SUCCESSFUL LEVERAGING OF RESOURCES

As more companies signed on and more health care providers were contacted, zinc sales rose. Independent audit figures showed that companies sold about 905,000 courses of treatment in the first year of the project, with total sales increasing to more than 10.6 million courses by the end of the project's fourth year.

POUZN's leveraging of USAID funds resulted in substantial investments by companies in getting the word out about zinc treatment. In the project's first two years, companies invested \$2.4 million of their own money for detailing, promotional materials, training, market research, public relations, and professional meetings, versus a USAID

investment of \$480,000. During four years, the project leveraged \$7 million from the

commercial sector on a USAID investment of \$1.52 million.

ASSESSING RESULTS: **Catalyzing the Availability of Zinc**

- Pharmaceutical companies, using their own resources, are manufacturing and/or distributing zinc—two signed on in 2005 and 22 were active by 2009.
- Key opinion leaders have been enlisted to back zinc treatment, resulting in supportive policies within powerful medical associations and influence on others within the health sector.
- Contacts by company sales professionals reached physicians nationwide. Across all companies, medical reps repeatedly contacted most of the country's pediatricians (members of IAP) and three-quarters of general practitioners (members of IMA).
- Donor funds leveraged private investments. Since the project began, the project has leveraged \$7 million from the commercial sector on a USAID investment of \$1.52 million.
- Sales steadily increased, from virtually zero at project start, to about 900,000 courses of treatment in the project's first year, to a total of 10.6 million treatment courses by the end of 2009.

PROJECT MIDPOINT: ANALYSIS AND REORIENTATION

At the project's midpoint in 2007, several factors caused POUZN to re-examine what it could accomplish and to adopt new strategies. Sales were climbing, but not as much as desired – especially in the rural areas.

Two important factors surfaced. The first was related to the simple fact that zinc treatment is for children. The project had hoped that working with different manufacturers with various strengths would lead zinc to be promoted to complementary audiences. For example, one company with a strong pediatric product line would focus on pediatricians, another company or division of the same company would target the general practitioners, and others would take zinc over-the-counter directly to drug sellers and then the general public. However, the clinical research linking zinc to improved outcomes in children was both an advantage and a detriment in this regard. All the companies initially assigned the product to their pediatric sales divisions. Marketing to pediatricians was therefore saturated; to other potential prescribers, this was not the case.

A related issue was the lack of direct contact by these companies with informal practitioners or retail outlets in remote areas. While repeated contacts by medical reps could speed up the process of adoption at the upper layers of the pyramid, dissemination to lower levels was slower. This process of

progressing down through the pyramid was taking place at a speed the pharmaceutical companies would categorize as typical for a low-to-medium priority product such as zinc. However, in a vast country such as India, the pace would not allow zinc to reach rural health providers for at least eight years.

Thus, in 2007, POUZN added a new approach: promoting zinc in rural areas directly to the health providers and drug sellers on whom caregivers rely. This rural model is ongoing.

Work has centered in Uttar Pradesh (UP), a state in Northern India where POUZN's other intervention—point-of-use (POU) water disinfection—was active. The POU project was already working with NGOs in this area and emphasizing the importance of preventing diarrhea. Start-up could be rapid. Further, the need is great in Uttar Pradesh. It is India's largest state, with a population of 190 million. The state 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 Uttar Pradesh shows that 52 percent of caregivers in all SES groups who seek medical care for their children's diarrhea go to private providers, 9.5 percent go to a pharmacy and 5 percent to other shops, while 5.5 percent seek care in the public sector. Also according to NHFS-3 data,

only 12 percent 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.

This phase of the program began as a pilot in one block (about 100,000 people) in UP. It

expanded to 100 blocks in ten districts in the state, covering a catchment area of approximately 13 million people with an estimated two million children under five years of age.

PHASE II, PILOT: LAUNCHING THE RURAL MODEL

POUZN was able to build on research conducted in Uttar Pradesh in 2007 for the PACT-CRH Project², also funded by USAID, to design its rural strategy. The research showed that indigenous system medical providers (or unlicensed providers such as rural medical practitioners) treated almost 63 percent of children under age three suffering from diarrhea. Caregivers saw these practitioners as the most accessible to them in terms of time, place, and cost, and regardless of their education, as experienced and knowledgeable. As confirmed by the NFHS-3 and other studies, almost all doctors (formal and informal, urban and rural) prescribed antibiotics and antidiarrheals, whereas very few prescribe ORS – either with these other treatments or alone – and virtually none prescribed zinc.

ENGAGING NGOS AS “DETAILERS”

To reach rural providers and their sources of supply more expeditiously, rather than waiting for the message to trickle down slowly through the “pyramid of influence,” POUZN tested an approach to engage local NGOs to promote zinc directly to rural RMPs and drug sellers.

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

The pilot took place in Bhati, a block in Ambedkar Nagar district, with about 2,000 RMPs and 500 drug sellers. At the beginning of the intervention, in April 2008, no RMPs prescribed and no drug sellers stocked zinc. POUZN selected three organizations through a request for proposals process, outlining tasks expected of the NGOs and support to be provided by the project. The three groups—PANI, Pratinidhi, and Shashwat Sahbhagi Sansthan (SSS)—in turn worked with their own networks of smaller NGOs. They were responsible for conducting surveys in their catchment areas in order to identify and map RMPs and drug sellers. They also selected staff members to become “detailers,” with a stipend provided through the project. These individuals were required to have some education, be outgoing, and have credibility with their contacts. They were mostly male, as are almost all RMPs and drug sellers.

POUZN held a training session for the detailers that covered both the technical content and the logistical procedures for reaching and interacting with the RMPs and drug sellers. Each detailer was responsible for about 200 RMPs and 50 drug sellers. POUZN helped them plot out itineraries that would allow them to visit their clients in “waves,” for a total of four to six visits per provider during a six-month period. These new detailers, like pharmaceutical reps, received free samples to “prime” their prospective clients.

SUPPORT MATERIALS AND MONITORING TOOLS

The project designed communication tools for both the detailers and their clients. These included leaflets, posters, visual aids, and prescription pads. The most powerful support was a 12-minute POUZN-created DVD that the NGO rep could play for the RMP or drug seller on a DVD player, also provided by the project. The DVD depicted a pediatrician and an RMP talking about zinc and watching their own DVD of Dr. Nita Bhandari, a leading pediatrician who had been involved in the Delhi clinical trials. The DVD ensured a consistent and correct message about zinc. It also underscored for the RMPs how receptive the country's leading doctors are to this treatment, providing a sort of "virtual influence" for them from the top of the pyramid.

Subsequent, shorter visits to clients were made to reinforce behaviors and also provide feedback to the project. Detailers were given a short series of basic questions they were to

ask, one per visit, and a simple monitoring form on which to record answers.

Besides ensuring consistency in the contacts between the NGO reps and their RMPs/drug sellers, the series of questions provided a way to monitor changes in knowledge and prescribing behaviors.

An assessment (using monthly monitoring information) showed that prescribing behaviors of RMPs improved substantially during the pilot. Not only did these informal providers begin to prescribe zinc—they also less often prescribed harmful or inappropriate treatments. (See box on Results.) The DVD combined with a personal visit proved to be an effective way to communicate a standardized behavior change message to RMPs and drug sellers. NGO enthusiasm for the intervention was also high.

This pilot provided a solid foundation to take the new approach to scale (within the resource limits) elsewhere in Uttar Pradesh.

ASSESSING RESULTS: Piloting the Rural Model

- In May 2008, 87 percent of RMPs prescribed an antidiarrheal or antibiotic in all cases of diarrhea, while 13 percent recommended antibiotics only in cases of blood in the stool (correct behavior). By August 2008, 68 percent recommended an antibiotic in all cases (still too high, but a significant drop) and 32 percent reserved the treatment for blood in the stool only.
- In April 2008, 3.4 percent of the RMPs knew about zinc as a treatment for diarrhea. By July 2008, virtually all had knowledge of it.
- In June 2008 (after the intervention had begun), 59 percent recommended zinc in cases of severe diarrhea. In August 2008, 84 percent made the recommendation.

PHASE II, SCALE-UP: EXPANDING THE RURAL MODEL

In 2008 POUZN began to scale up the rural model to 100 blocks in ten districts in Uttar Pradesh. Within this area, about 20,000 RMPs and 5,000 drug sellers serve a catchment area of around 13 million people.

STREAMLINING IN ORDER TO SCALE UP

Feedback from those involved in the pilot provided the basis for necessary streamlining. POUZN and the partner NGOs developed a complete scale-up plan over a two-day meeting. POUZN conducted trainings for NGO trainers and, as in the pilot, provided communication materials and helped plan out how to contact RMPs and drug sellers efficiently within their areas. NGO detailers were asked to make just one visit to each new client rather than four or more, allowing them to handle more clients. The DVD was edited down to five minutes (allowing for a shorter visit, which was preferred by clients but still delivered necessary messages). Sturdier equipment was provided with additional external speakers.

CREATING A SUSTAINABLE BRIDGE

An informal rule of pharmaceutical marketing is that 20 percent of providers generate 80 percent of the prescriptions for any single drug. Certain providers will be strong supporters and will have busier practices and see more patients. This rule seems to extend



The goal of phase II was to reach rural medical practitioners and drug dealers through “detailing.”

to the RMPs, and provides a key to the sustainability of rural coverage. Since it is not economically viable to engage NGOs as detailers in perpetuity, POUZN designed a way for the pharmaceutical partners to target those RMPs with the highest potential in rural markets and take on the task themselves.

The NGO reps primed the market in their areas, and equally important, compiled information about the top 25 percent or so of prescribers. These represented good customers for suppliers. POUZN shared this information with the four companies now selling zinc in Uttar Pradesh.

To date, one has acted on this information, and the other three are considering their next



A five-minute DVD was the most powerful behavior change tool.

steps. This “bridge” has benefits from both a commercial and a public health point of view. It gives companies an economic incentive to become more active in the underserved rural areas, and it 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.

An in-depth survey of a small sample—59 RMPs and 30 drug stores in one block—illustrates the impact of the expanded intervention. Before the NGOs began making their rounds in this block, 3.4 percent of the RMPs prescribed zinc for treatment of

diarrhea, and no chemists stocked it. In comparison, a small sample of 56 RMPs and 35 drug stores in 2009 showed 79 percent of RMPs prescribed zinc and 70 percent of chemists recommended zinc.

Through feedback from the NGO detailers, POUZN learned that cost was considered to be a barrier for the very poor by some RMPs and drug sellers. This underscores not only the need to expand zinc treatment to the public sector, but to ensure that private providers know where they can refer patients, once zinc is available in the public system.

GOING DIRECTLY TO CAREGIVERS

POUZN focused primarily on building supply and changing prescriber habits to build a market for zinc. However, the project also tested a strategy in Basti district to reach caregivers (who already had access to zinc) through interpersonal communication and a word-of-mouth campaign.

This demand creation pilot was also launched efficiently because of NGO connections made in the point-of-use (POU) water disinfection program. The POU activities were integrated into existing networks of about 100 village self-help groups, each of which include about ten

to 20 women. They engage in small microfinance projects and are also involved in various social activities to improve the lives of their families and the community. For the zinc demand creation pilot, POUZN collaborated with self-help groups connected with one NGO. About 45 percent of the women in the groups targeted had children under age five. At a first meeting of their groups, the women learned about zinc as a treatment for childhood diarrhea. At the next meeting, they were asked to bring one other person to listen to the same information, and they were also asked to communicate the information to one other person in the community. The pilot is currently being evaluated.

ASSESSING RESULTS: Scaling Up the Rural Model

- The intervention showed that scale-up using NGOs to reach rural practitioners is feasible and effective: NGO detailers reached 20,000 RMPs and 5,000 drug sellers in about one year, although more frequent contacts are still needed.
- Starting from virtually no RMPs prescribing zinc or drug sellers stocking it, an estimated 79 percent of RMPs now prescribe zinc and 70 percent of chemists now stock it.
- POUZN developed a process to interest the private sector in using its resources to link with RMPs over the long term: The NGOs compiled a list of the region's "top prescribers," which was made available to pharmaceutical companies as an efficient bridge for contacting harder-to-reach communities. This also allows for continued and accelerated expansion without any subsidy (i.e., funding of long-term NGO involvement) once the rural market has been primed.
- POUZN is currently evaluating a pilot to test the potential of village self-help groups to spread the word about zinc in their communities.

LESSONS LEARNED

1. **For health providers, zinc treatment confronts well-entrenched prescription behaviors for childhood diarrhea, including harmful antidiarrheals, potentially inappropriate antibiotics, antisecretory drugs, and now probiotics. ORS faces these same challenges.** Zinc treatment for diarrhea is a new concept facing strong competition. Sustained education and promotional efforts are required to convince health providers to prescribe zinc as a first-line treatment of diarrhea with ORT/ ORS.

2. **Collaboration with the private pharmaceutical sector is a sustainable way to ensure a long-term and competitively priced supply of zinc.**

Tapping into their existing ways of doing business, however, presents both opportunities and drawbacks for development efforts. Private firms within India's strong pharmaceutical sector were willing to use their own resources to manufacture and distribute zinc. They have proven experience in producing a high-quality medicine, taking the necessary steps to register it, and tapping into their existing marketing channels to promote it. All this was tremendously helpful to the introduction of zinc, and the project found ways of negotiating important product details (such as co-promotion with ORT) and knew the importance of trusting company knowledge (such as consumer preference for syrups). However, the



More than 22 zinc products are now on the market.

private sector will not operate in areas that do not yield adequate financial Return. And this is often the case for rural areas where additional infrastructure is required to reach communities.

3. **Key opinion leaders (top pediatricians) are critical to enlist as zinc champions.**

Once they sign on, their endorsement helps bring about new practices among others in the health sector through a hierarchy of influence encompassing other pediatricians, general practitioners, drug sellers, and other providers, including informal practitioners. These opinion leaders need to see the research from a credible source and really examine it for themselves. In this case, the fact that the research was conducted in India by a renowned Indian researcher carried great weight. The meeting of top pediatricians was an important way to develop a cadre of zinc champions. Equally important was

their influence with their colleagues and other providers, including informal practitioners.

4. **To reach caregivers, begin with the prescribers and drug sellers upon whom they rely for advice.** In India, three-quarters of caregivers access the private sector for their health needs—a recommendation from their provider is a critical input in their decisions about taking care of their children. Providers need repeated contacts to improve the likelihood that they will prescribe a new treatment, even if medically proven. Face-to-face contacts with providers can change prescribing behaviors. Pharmaceutical companies do this through “detailing.” Reaching providers “at scale” requires a trade-off between numbers reached and number of visits to a single provider. POZN found that a single visit was not sufficient to change behaviors.
5. **Full-scale demand creation among health care providers is crucial to reinforce messages, raise awareness, and ensure that zinc with ORT is adopted as the standard of care.** Both caregivers and prescribers still turn to inappropriate antibiotics and antidiarrheals—prescribers say that caregivers expect them, and caregivers say they use what the prescribers’ advise. Zinc and ORT compete with these treatments as well as with other harmful practices, and will take time to become a standard of care. The balance between supply and demand creation is delicate with a new product; a cardinal rule of health communication programs is never to create demand for a product that is not accessible. The classification of zinc as an over-the-counter drug will

increase its availability. As zinc becomes more integrated into the medical culture and supply is assured in rural areas, a mass media campaign and other direct-to-consumer interventions have a place—with the caveat that in a country such as India, these require a large financial investment if any significant changes in behavior are to be expected.

6. **Special efforts are needed to reach the rural, informal sector expeditiously.** Once contacts are made, rural providers are receptive to messages about new treatments, especially when they can see the support of the formal medical establishment. Although the message about zinc as a treatment for childhood diarrhea may have ultimately reached rural providers, this organic process would have taken a long time to unfold. Short-cutting the process by making contacts directly with informal providers resulted in introducing zinc to poor rural families years earlier than would have otherwise occurred. Providers were quite receptive to visits by well-trained NGO representatives who could provide credible information. Furthermore, by identifying the top prescribers, the project helped the pharmaceutical companies enter into (and fund with their own resources) a previously untapped market that could not have been supported indefinitely with public or donor funds.
7. **The public and private sectors have different objectives and time scales, and a project must be sufficiently flexible to accommodate both. Both sectors have a role to play in introducing and sustaining a new health behavior, with the roles contingent on the country context.** The POZN project was established as a

USAID private-sector program. While the majority of people in India use the private sector for health care, both sectors are needed to make zinc accessible and affordable to the population. In India, promotion through the public sector will

help to reach the most poor and will add further credibility to the new treatment. Although POUZN focused on private suppliers and health care providers, working with the public sector contributed to a supportive policy environment.

A LONG-TERM VISION

POUZN is nearing the end of its five years in India. USAID laid promising groundwork with this intervention. It will take longer than the life of this project for zinc with ORT to make a sizable decrease in the number of deaths from childhood diarrhea, but the private sector and NGO links launched in this project should endure. Moreover, the Bill and Melinda Gates Foundation has agreed to fund an expansion of the work done under POUZN, and other donors are considering follow-on interventions to reach rural areas.

In the next year, POUZN will continue to work in Uttar Pradesh, re-contacting the RMPs and drug sellers, given that repeated contact results in higher prescription and stocking rates, and, ultimately, more use by caregivers.

In the long term, the following directions may help expand the use of zinc in India:

Increase demand for zinc and ORS treatment by working through multiple channels: with health care providers and drug sellers, but also directly to caregivers through interpersonal communication and education,

given the challenges of competing treatments for diarrhea.

Work with the public sector, especially state governments, to ensure that zinc is supported in policies and guidelines at all levels and is made accessible and without cost to the poorest caregivers of children under five years of age.

Once supply is in place and health provider support is obtained, develop both interpersonal and 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.

Oral rehydration therapy has been heralded as one of the major medical accomplishments of the 20th century. In its improved form, and in conjunction with zinc treatment, the 21st century has begun with a practical advance upon which to build that will save many more children around the world. This project suggests some promising ways to accomplish that goal.

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