



Introducing Improved Treatment of Childhood Diarrhea With Zinc and ORT in India:

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

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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 POUZN in India 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 use—thereby reducing the incidence and severity of diarrhea in children. To do this effectively required changing both patient and provider treatment patterns, while creating a viable marketplace for the product.

POUZN's mandate was to work on a national scale and to reach the most vulnerable groups, including those in rural areas. The project worked with India's vibrant pharmaceutical industry, providing assistance only when needed. Companies invested their own money for detailing, promotional materials, training, market research, public relations, and professional meetings. Thirty companies (up from 0 at project start) now produce and/or market zinc nationwide through their own supply chains and sales forces.

POUZN enlisted high level zinc champions and supported detailing efforts by manufacturers to stimulate the “cascade of influence” within the medical community. Key medical opinion leaders,

who play a critical role in influencing prescribing behaviors of both formal and informal health care providers, are now 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 POUZN to more than 900,000 treatment courses in the first year of the project, and rising to annual sales of 5.5 million courses in the final year.

At project midpoint POUZN designed and then scaled up an innovative pilot in Uttar Pradesh State to reach chemists and informal providers (rural medical practitioners), with the aim of expanding reach to the poorest and most vulnerable populations. Local NGOs trained by POUZN demonstrated that they could effectively “detail” zinc to these providers, accelerating

uptake of zinc and ORS in rural areas that are usually not covered by pharmaceutical firms' marketing efforts, and priming a change in behavior for the expected public sector roll-out.

The project conducted baseline and endline surveys of provider knowledge and prescription practices, and also evaluated an intensive demand creation pilot focused on members of self-help groups. In areas where the project had trained NGO detailers, private providers had significantly higher levels of awareness and knowledge about zinc, reported greater overall exposure to information about zinc, and recommended appropriate treatment at significantly higher rates than those in a control area. Zinc was also stocked at significantly higher rates by both chemists and RMPs in the intervention district compared to the comparison district (69 percent versus 24 percent).

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:

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.

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.

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 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.

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I. 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 important to the immune system and a deficiency can increase the incidence and severity of many diseases, including diarrhea; furthermore, diarrhea depletes zinc stores. Clinical research suggests that if children take 20 mg of zinc (10 mg for children under six months) for 10 to 14 days, the outcome is up to a 25 percent reduction in the duration of acute diarrhea and a 42 percent reduction in treatment failure or death caused by persistent diarrhea (WHO/UNICEF, 2009). An additional benefit of a complete zinc treatment course is reduced recurrence of diarrhea for two-three months. However, to prevent dehydration, which can be deadly, children need ORS or Oral Rehydration Therapy (ORT).¹

Both ORS and zinc treatment are relatively easy to produce and distribute, are safe, and do not produce serious side effects. However, as with any new practice or product, zinc treatment requires changes in usual behaviors—by health care providers and caregivers—as well as large-

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.

For more information visit: <http://pshi.aed.org/>

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.

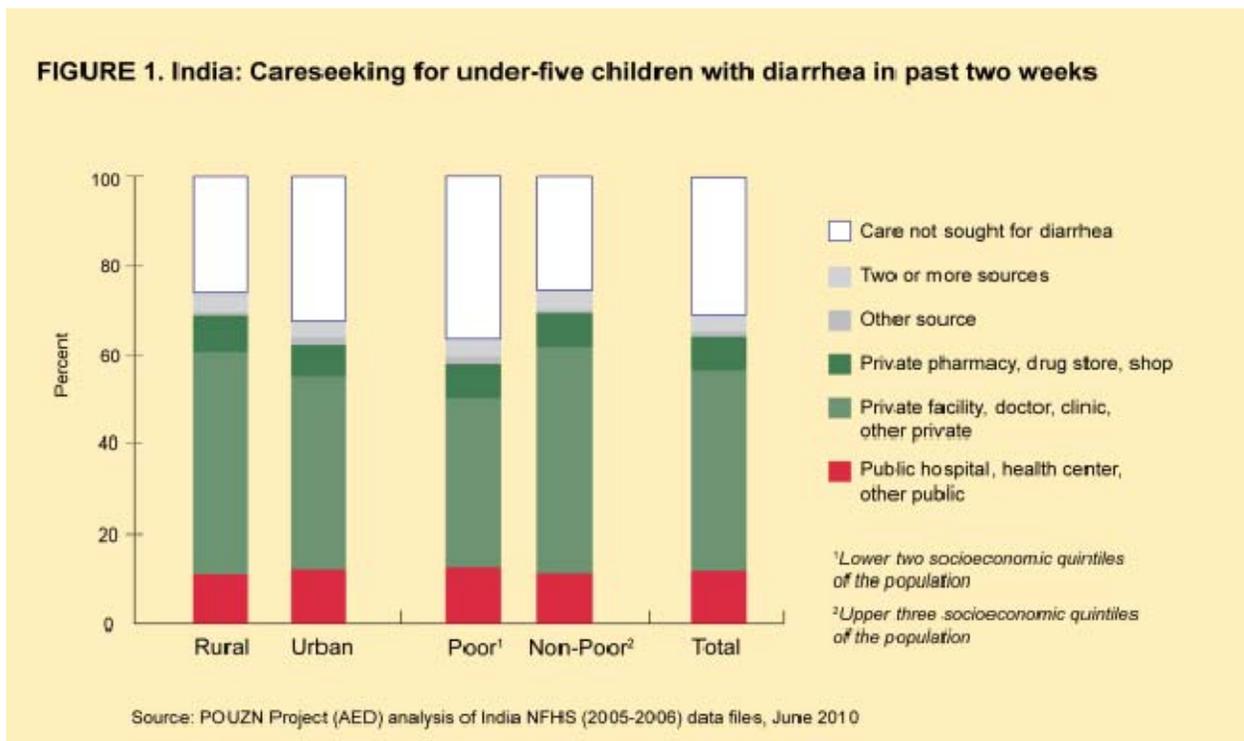
II. CONTEXT

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.

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

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 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 (see figure 1).

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 together with ORT.

III. POUZN GOALS AND INITIAL STRATEGY

POUZN's goal in India was to introduce zinc treatment and low-osmolarity 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 could be 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 's mandate was 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. In India, POUZN sought ways to:



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

- 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 already-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 the large pool of informal providers and consumers even in remote areas. Drug supply 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.

IV. PHASE I: CATALYZING 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 the top 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 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

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

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

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 2010, 30 firms were manufacturing and/or marketing 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 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



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

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. By project end, syrup accounted for 87 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 \$US1. New product introductions kept the price in this range.



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” 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 country wide from the Indian Association of Pediatrics (IAP) 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 typically very short, but frequent. In its first year, POUZN trained 1,200 medical representatives (or med reps) from four companies on diarrhea treatment with ORT and zinc, including selling techniques. The med 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.

SUCCESSFUL LEVERAGING OF RESOURCES

As more companies signed on and more health care providers were contacted, zinc sales rose.

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 anti-diarrheals). Early on, the companies marketing zinc could see more clearly the results of their comparative sales, which POUZN used to stimulate the competition.

Independent audit figures showed that companies sold about 905,000 courses of treatment in the first year of the project, rising to annual sales of 5.5 million courses by the end of March 2010.

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 \$550,000.

ACHIEVEMENTS:

Catalyzing the Availability of Zinc

- Pharmaceutical companies, using their own resources, are manufacturing and/or distributing zinc—two signed on in 2005 and 30 were active by 2010.
- 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).
- Sales steadily increased, from virtually zero at project start, to about 905,000 courses of treatment in the project's first year, rising to annual sales of 5.5 million courses by the end of March 2010.

V. MIDPOINT ANALYSIS AND REORIENTATION

At the project's midpoint in 2007, sales were climbing but not as much as desired, especially in 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 would lead zinc to be promoted to complementary audiences. (A company with a strong pediatric product line would focus on pediatricians, another company or division of the same one would target general practitioners, others would take zinc over-the-counter to drug sellers and the general public.) However, clinical research linking zinc to improved outcomes in children led all the companies to assign zinc to their pediatric sales divisions. Marketing to pediatricians was therefore saturated, but not to other prescribers.

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 levels of the pyramid, dissemination to lower levels was slower. This process of was taking place at a speed the pharmaceutical companies would categorize as typical for a low-to-medium priority product. However, in such a vast country, this pace meant zinc would not 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.

Work centered in Uttar Pradesh (UP), a state in northern India where POUZN's other intervention—point-of-use (POU) water disinfection—was already working with NGOs to emphasize the importance of preventing diarrhea. Start-up could be rapid. Further, the need was great in Uttar Pradesh. It is India's largest state, with a population of 190 million and 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 found that 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. The survey also found that 52 percent of caregivers in all SES groups who sought care for their children's diarrhea went to private providers, 9.5 percent went to a pharmacy, and 5 percent went to other shops, while 5.5 percent sought care in the public sector.

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 about 13 million people with an estimated two million children under five years of age.

VI. PHASE II: RURAL MODEL (PILOT LAUNCH)

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 registered 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, almost all providers (formal and informal, urban and rural) prescribed antibiotics and antidiarrheals, whereas very few prescribed 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, POUZN tested an approach to engage local NGOs to promote zinc directly to rural RMPs and drug sellers. The pilot was carried out in Bhiti, 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)—worked in turn 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 by the project. These individuals were required to have some education, to be outgoing, and to have credibility with their contacts. They were mostly male, as are almost all RMPs and drug sellers in the area.

POUZN held a training session for the detailers that covered both the technical content and the logistical procedures for reaching and interacting with 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 DVD designed for the NGO detailers to play for each RMP and drug seller on their initial contacts. (Portable players were also provided by the project). The DVD provided

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

a sort of “virtual influence from the top of the pyramid. It depicted a pediatrician and an RMP talking about zinc and watching their own video of Dr. Nita Bhandari, a leading pediatrician who had been involved in the Delhi clinical trials. The DVD was an ideal tool for capturing attention and conveying consistent and correct messages about zinc. It also underscored for the RMPs how receptive the country’s leading doctors are to this treatment.

The NGO detailers made shorter follow-up visits to each provider in order to reinforce behaviors and collect feedback. The project supplied a simple monitoring form and a series of basic

questions for them to ask about prescription practices and client satisfaction.

An assessment based on the monthly monitoring information showed that prescribing behaviors of RMPs improved substantially during the five-month long pilot. Not only did the informal providers who were contacted begin to prescribe zinc—they also less often prescribed harmful or inappropriate treatments (see box). 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.

ACHIEVEMENTS: Piloting the Rural Model

- At the start of the pilot in April 2008, 3.4 percent of the RMPs knew about zinc as a treatment for diarrhea. By July 2008, virtually all in the pilot area had knowledge of it.
- In June 2008 after two months of activity in the pilot area, NGO monitoring data showed that 59 percent of RMPs reported recommending zinc in cases of severe diarrhea. In August 2008, 84 percent said they made this recommendation.
- In May 2008, NGO monitoring data showed that 87 percent of RMPs reported prescribing 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 reported that they recommended an antibiotic in all cases (still too high, but a significant drop) and 32 percent said they reserved the treatment for blood in the stool only.

VII. PHASE II: RURAL MODEL (SCALING UP)

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 served 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 how to contact RMPs and drug sellers efficiently in their respective 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 to the RMPs, and provides a key to the sustainability of rural coverage.



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

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 of prescribers who represented good customers for suppliers. POUZN shared this information with the four companies selling zinc in Uttar Pradesh. To date, one has acted on this information, and the other three are considering their next steps. This “bridge” has benefits from both a commercial and public health point of view. It gives companies an economic incentive to become



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

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 a long-term NGO involvement) once the rural market has been primed.

Through feedback from the NGO detailers, POUZN learned some RMPs found that cost was a barrier to the very poor. 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 launched efficiently, once again, because of NGO connections already made in the point-of-use water disinfection program. The POU activities were integrated into existing networks of about 100 village self-help groups (SHGs), each including about ten to 20 women. (Members participate in microfinance activities and are also involved in various social efforts to improve the lives of their families and the community.) For the zinc “campaign,” POUZN collaborated with SHGs connected with one NGO. About 45 percent of the women targeted had children under age five. At a first monthly meeting, members learned about zinc as a treatment for childhood diarrhea. At the next meeting, they

were asked to bring an additional friend or family member to hear the same information. And they were also asked to share the information with

one other person in the community. Results are described in the next section.

ACHIEVEMENTS: 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.
- 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.
- The project conducted a small pilot to examine the potential of village self-help groups to spread the word about zinc in their communities.

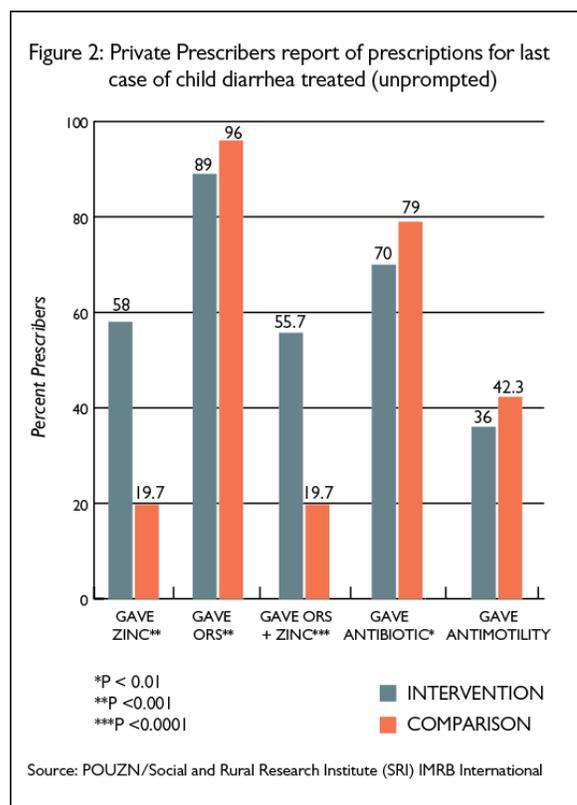
VIII. RESULTS—PRESCRIBER AND CAREGIVER PRACTICES

IMPROVING PROVIDER KNOWLEDGE AND PRACTICES

A final evaluation of the POUZN project focused on provider knowledge and prescription practices. The survey in June of 2010 included interviews with both chemists and RMPs in one intervention district (Barabanki) and one comparison district (Raibareli) in UP.³ The data suggest that, in areas where the project had trained NGO detailers, private providers had significantly higher levels of awareness and knowledge about zinc, reported greater overall exposure to information about zinc, and recommended appropriate treatment at significantly higher rates.

Prescription Patterns of Private Providers.

The survey asked RMPs and chemists what they “generally” prescribe to children under five with diarrhea. In the intervention area, 78 percent said they generally prescribe zinc, whereas only 27 percent in the comparison district mentioned zinc even when prompted. Figure 2 shows significant differences in key prescriber practices for the last consultation on childhood diarrhea. Without prompting, 58 percent of RMPs and chemists in the intervention area vs. 20 percent in the



comparison said they prescribed zinc. A similar percentage responded that they prescribed both ORS and zinc (the “gold standard”) for the last case of diarrhea (56 percent vs. 20 percent).

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

³ The survey was conducted by the Indian firm, Social and Rural Research Institute (SRI), IMRB International. The non-equivalent group survey interviewed 203 RMPs and 97 chemists in the intervention area and 197 RMPs and 103 chemists in the comparison area.

Prescriptions of ORS were generally high; however, more providers in the comparison area said they prescribed ORS for the last case of childhood diarrhea than those in the intervention area (96 percent vs. 89 percent).

High percentages of all providers mentioned that they prescribed antibiotics for the last case of childhood diarrhea they treated: 70 percent of intervention area providers and 79 percent of those in the comparison area. A large number of providers in all groups also prescribed anti-motility drugs: 36 percent in the intervention area and 42.3 percent in the comparison (the difference was not significant). These rates suggest that the intervention had a strong effect on zinc prescriptions, but was less or not effective in improving other practices.

Availability of Zinc and Knowledge of Zinc

Zinc availability was significantly higher in the intervention district: 69 percent of the RMPs/chemists in the intervention district

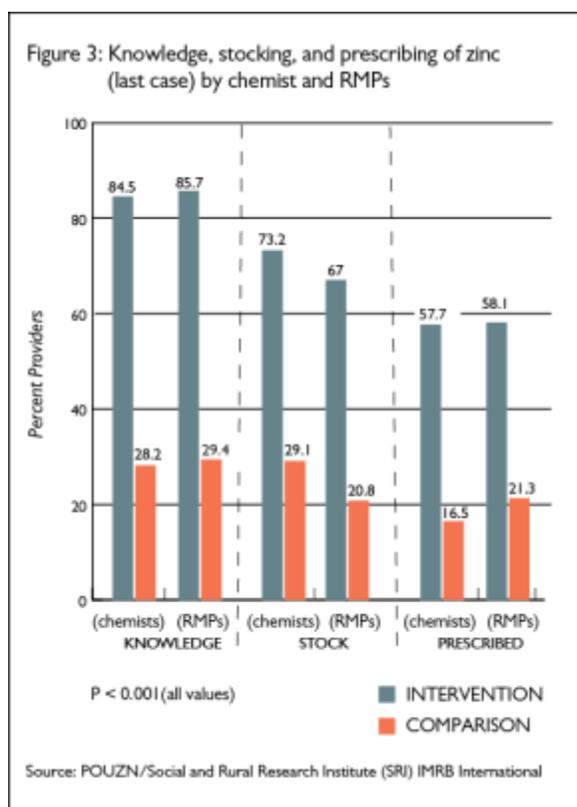
stocked zinc, compared to 24 percent of their counterparts in the comparison district. Similar differences were noted in reported knowledge about zinc. Moreover, these differences were consistent among both chemists and RMPs in the two districts (see Figure 3, which also includes prescribing behaviors).

The low levels of knowledge and stocking of zinc among chemists in the control areas were somewhat unexpected, because POUZN's private sector partners (med reps) were active in both intervention and control areas contacting this upper level of the pyramid.

Exposure to Messages. Among the RMPs and chemists who said they had heard about zinc, a majority (60 percent) identified NGOs (including those supported by the project) as their main source of information, compared to 4.6 percent for the comparison district⁴. This was the only significant difference in information sources cited by providers in the intervention and comparison districts (see Table 1 on next page). Other sources of information cited by more than 30 percent of providers (in both areas) included the mass media, doctors, and medical reps. These last two sources may also have been associated with project activities (via the hierarchy of medical influence and pharmaceutical detailing). There were no known mass media activity; it may be possible that RMPs confused it with the DVD player used by the NGO.

DEMAND CREATION PILOT

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



⁴ These NGOs work in many districts throughout UP, so the 4.6 percent of comparison providers who mentioned this source may have been influenced by them as well.

Treatment of Children with Diarrhea. Changes in caregiver knowledge and practices regarding

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

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

*p<=0.001

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

childhood diarrhea treatment were measured via baseline and endline surveys in March of 2009 and July-August 2010, respectively.⁵ Several factors may have affected the reliability (and replicability) of these data. The endline was collected during the diarrhea season (whereas the baseline was not). Members of self-help groups (all of those surveyed) are not a typical cross-section of women in their communities, but rather more progressive and empowered, and their behaviors are not predictive of those of other rural women. Finally, the NGO pilot with SHGs cannot be duplicated on a large scale for a number of reasons. With these caveats,

⁵ These surveys were also conducted by Social and Rural Research Institute (SRI), IMRB International. They were conducted with members of 50 self-help groups in Bhati Block of Ambedkar Nagar District: 120 women at the time of the baseline and 128 women at the endline, all of whom had a child under five who had experienced diarrhea in the last three months.

however, the information obtained from the surveys is of interest.

The proportion of children under five having diarrhea whom caregivers reported treating with zinc rose from 0 to 50 percent between baseline and endline. The proportion of those treated with zinc plus ORS rose to 31 percent. (The survey did not ask mothers how many days of zinc they gave a child.)

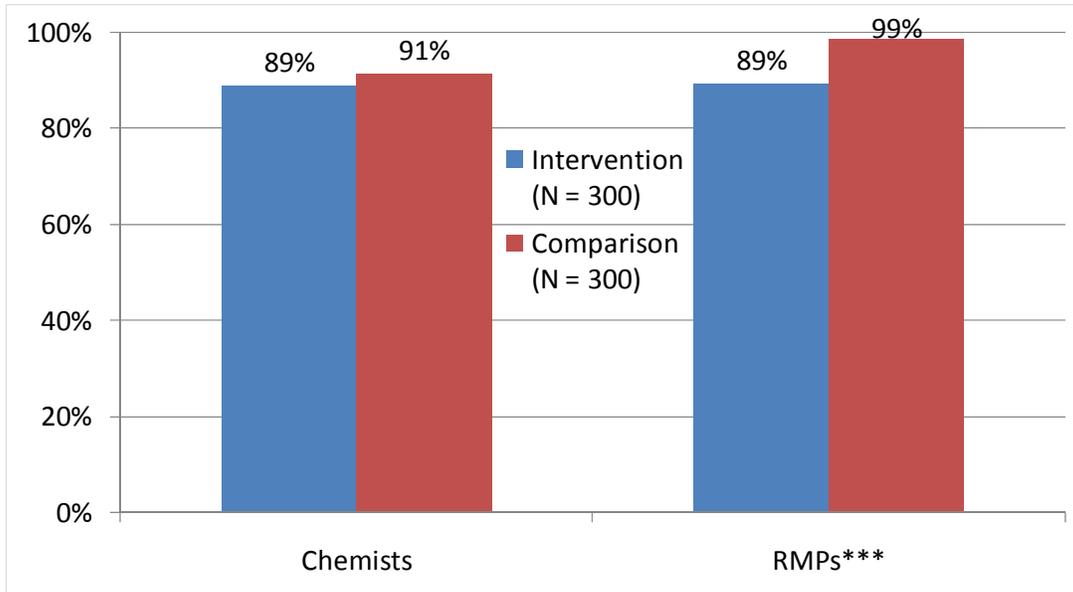
There was no significant change in the proportion of children who were treated with ORS.

Use of antibiotics was high even after this intensive pilot. Around 34.4 percent of children with diarrhea received antibiotics.

Knowledge. Caregiver knowledge of zinc and ORS among these SHG members increased significantly. The proportion of caregivers who mentioned spontaneously that zinc was an appropriate treatment for diarrhea rose from 0 to 56 percent; the proportion who mentioned ORS rose from 15 to 56 percent.

Mothers overwhelmingly cited PANI staff as the source of their knowledge about zinc (95 percent spontaneously and 99 percent with prompts.)

Source of Zinc. At endline, mothers were asked where “one might acquire zinc.” The majority indicated that PANI would be a source (see Figure 4 on next page). This is logical because PANI had recently opened its own social marketing arm and was offering its basket of products (ORS and zinc, POU methods) for sale.

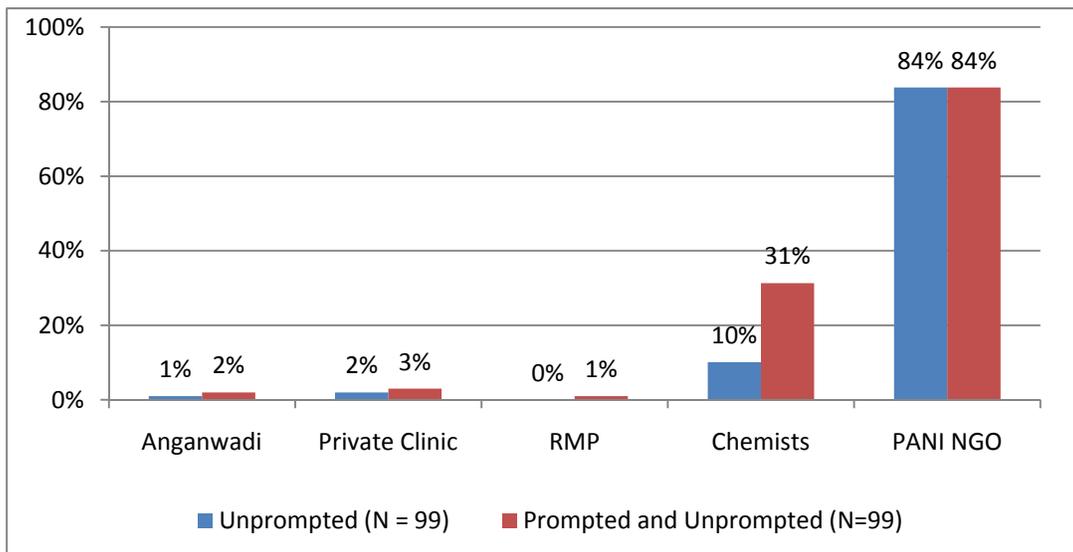


REFLECTIONS ON THE RURAL PILOT

This aspect of the intervention presents a conundrum, because the project's initial collaboration focused on promoting zinc prescriptions by RMPs based on their accessibility and popularity with rural communities. NGOs were engaged to support this process by detailing to providers, rather than distribute zinc. Additional availability of zinc can hardly be considered a minus. However, in the pilot, caregiver awareness of zinc being available at RMPs in particular (and to some extent among chemists) was low—which is a

concern given the high percentage of interviewees who said they learned about zinc from the project's NGO. On average, caregivers also thought they must travel about four kilometers to acquire zinc.

While the pilot was successful in improving knowledge about and use of both zinc and ORS in treating childhood diarrhea, and also in involving NGOs more closely in promoting these products, the apparent unintended effect—less attention on sustainable and scalable sources of zinc—was unfortunate. As demand creation activities are scaled up throughout India, it will be important to continue monitoring the actual



careseeking patterns of caregivers and support household awareness of all convenient sources of zinc.

IX. MOVING FORWARD BASED ON LESSONS LEARNED

MOVING FORWARD

USAID laid promising groundwork with this intervention. Links established between manufacturers and RMPs should endure and grow over time; involvement by NGOs in UP also promises to continue. Other donors have expressed interest in the rural model. In the short-term, work to expand the use of zinc must now focus increasingly on two areas:

Collaboration 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.

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. Once supply is in place and health provider support is obtained, demand creation among caregivers requires intense focus, given the challenges of competing treatments for diarrhea.

LESSONS LEARNED

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 challenges. POUZN found that partners drawn from India's



Thirty zinc products are now on the market.

strong pharmaceutical sector were willing to use their own resources to manufacture and distribute zinc. They took the necessary steps to register high quality products and tapped into their existing marketing channels to promote distribution and sales. POUZN 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 private sector will not operate in areas that do not yield adequate financial return. This is often the case for rural areas where additional infrastructure would be required to reach communities.

The public and private sectors have different objectives and move at different paces. 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. POUZN's mandate was to work with the private sector.

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

Key opinion leaders in both the public and 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 hierarchy of influence reaching other pediatricians, general practitioners, drug sellers, and ultimately informal practitioners.

High level opinion leaders need to assess the clinical research themselves and have the opportunity to consult with a credible source. 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.

To reach caregivers, begin with the prescribers and drug sellers upon whom they rely for advice. The advice of providers is a powerful influence on diarrhea treatment behaviors. Repeated contacts are needed to change prescribing practices. Pharmaceutical companies do this through face-to-face “detailing.” Reaching providers at scale requires a trade-off between the number of providers that can be reached and the number of visits possible to a single provider. POUZN found that a single visit was not sufficient to change behaviors.

Special efforts are needed to reach the rural, informal sector expeditiously. 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. 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.

Use of NGOs as “detailers” is a promising model that needs further study. Providers in India 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. The NGOs also saw promise in this model and two of them established social marketing arms, intending to provide a “basket” of health products (including their own brands of both zinc and point-of-use water treatment products) as well as smokeless stoves. However, given the large numbers of caregivers who said they purchased zinc from NGOs, and the relatively few who purchased from RMPs, the scalability and integrity of this approach to reach private providers *per se* needs to be monitored in a given area over time.

Full-scale demand creation among health care providers and caregivers is crucial to reinforce messages, raise awareness, and ensure that zinc with ORT is adopted as the 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 will be important (and in this large country, a major investment).

Zinc treatment competes with well-entrenched prescription behaviors and traditional treatment practices including harmful antidiarrheals, potentially inappropriate antibiotics, antisecretive drugs, and now

probiotics. ORS confronts the same problem. Very high percentages of 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. Tackling this vicious cycle will require time and a long-term investment. Confronting the use of inappropriate and harmful treatments head on, rather than just promoting the benefits of zinc and ORT/ORS, will be necessary.

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