

ORS Case Study

India

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Any opinions, findings, and conclusions or recommendations expressed in this material are those of the authors and do not necessarily reflect the views of the key informants, thought partners or reviewers.

1. Context

a. Country demographics

Over 1.2 billion people live in India, a country that spans 1.2M square miles (slightly more than one-third the size of the US).¹ With a purchasing power adjusted GDP of \$3,700 India dominates the South Asia subcontinent. India is divided into 29 states and seven Union Territories, with extraordinary heterogeneity in health systems and outcomes. Incomes in India's richest states are some five times higher than those in the poorest states; the gap is higher than in most other democratic countries.²

India is undergoing a massive urban transformation. One third of Indians live in urban centers and it is estimated that by 2030, 40% of people in India will live in urban areas – doubling the urban population within a span of 30 years.³ In Delhi, the capital, every household can choose from 80 practitioners within a 15-minute walking radius (Das & Hammer, 2007). Patients expect to receive a pill, tonic or injectable medicine from providers and polypharmacy (especially of banned or expired drugs) is rampant. Caregivers will “watch and wait” before seeking care. The preliminary results from PATH’s market research conducted in India demonstrated that caregivers believe that whatever product they use to treat the diarrhea, it does treat the symptoms.⁴ Caregivers’ top three therapy goals when treating diarrhea in India are to prevent the condition getting worse (87%), restore the child’s energy (73%), and stop the diarrhea motions (57%).

b. Population health

Only half the population has access to safe drinking water and less than one third has access to improved sanitation in India. HIV prevalence is less than 1%. Despite a decline in deaths from tuberculosis and elimination of polio cases, malnutrition rates among children are worse than in Sub-Saharan Africa; nearly half (47.9%) of children under-five are stunted.

India’s under-five mortality rate has declined from 114 deaths for every 1,000 live births in 1990 to 61 per 1,000 in 2011, a 46% reduction.⁵ This decline, however, is not sufficient to meet MDG4. Diarrheal diseases account for 212,229⁶ of the 1.68 million deaths of children under the age of five in India. India accounts for more than 20% of all deaths in children under-five.

c. Health system

India has one of the most highly privatized health care financing and delivery systems in the world. Quality of health delivery in the public sector in India is compromised by shortages in funding and human resources, drug stockouts, provider absenteeism and overall substandard level of care. Nearly 80% of outpatient visits take place in the private sector based on fee-for-service payments.⁷ 93% of all hospitals and 85% of all qualified physicians are in the private sector.⁸ Many different kinds of providers

¹ CIA Factbook, 2012.

² World Bank, 2008.

³ World Bank, 2012.

⁴ Simpson et al., unpublished 2012.

⁵ UNICEF, “A Promise Renewed”, 2012.

⁶ Liu L et al., Lancet 2012.

⁷ Ramani, 2005.

⁸ De Costa, 2008.

are found in the private sector, including qualified providers that practice allopathic medicine or alternative systems and unqualified providers with no formal medical education, called Rural Medical Practitioners (RMPs). Private providers have the largest market share.

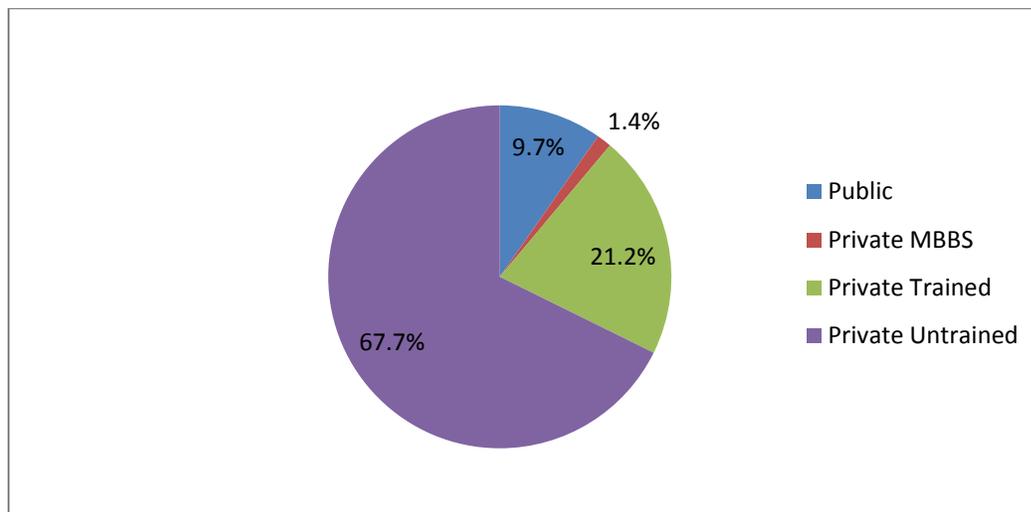


Figure 1. Market share by provider type (MAQARI, 2011)

In urban India, pharmacies are everywhere and the market is highly competitive. Owning a retail medicine business can be very lucrative, with little incentive to hire trained shop attendants but high profits to be made from selling antibiotics. In India, it is the exceptional pharmacy attendant who displays a genuine interest in learning about the medicines and ways to communicate with clients about appropriate medicine use. While it would be easier to suggest that a patient takes a longer course of medicine (e.g. five instead of three days of antibiotics) than to offer advice about irrational drug combinations, the attendant would undoubtedly lose money and risk their professional reputation as a result of their “good will”.⁹

India uses a five-year planning process to determine national goals and priorities. In the 1980s, the emerging middle class pushed privatization of services and state-of-the-art hospitals on par with international standards. Private practitioners benefitted from government subsidies for education and began to pressure authorities to loosen medical practice regulations. The IMF and World Bank encouraged privatization and subsequently, primary health centers suffered setbacks in funding with less money allocated to infectious disease-control programs in the 1990s.¹⁰

The Government of India (GoI) launched the National Rural Health Mission (NHRM) in 2005 to improve health care for the rural population, especially women and children, throughout the country with specific focus on 18 States which have weak public health indicators. Maternal health care, promotion of institutional deliveries, home-based newborn care, Integrated Management of Newborn and Childhood Illnesses (IMNCI) and routine immunizations are the key interventions under NHRM.¹¹ Anganwadi centers provide children under six years of age with health, nutrition and early childhood development services and nutrition and health services to pregnant and breastfeeding mothers. Anganwadi workers

⁹ Kamat & Nichter, 1998.

¹⁰ Rand, 2008.

¹¹ UNICEF, Coverage Evaluation Survey, 2009.

are not part of the “health system”; rather, they are managed by the Ministry of Women and Child Development.

A three-tiered system was developed to provide health care to all rural populations. At the lowest level, primary health care is provided to rural populations through a network of government-owned and operated primary health centers (PHCs, serving 30,000 people) and community health centers (CHCs, serving 120,000 people) offer secondary and specialist care. At the next level, the sub-center (serving 5,000 people) is the first contact point between the community and the primary health care system. Each sub-center is attended by one male and one female health worker (an auxiliary nurse midwife). District hospitals provide tertiary care.

d. Other meta-facts important to know (conflict, etc.)

The Indian subcontinent was partitioned into Hindu-dominated India and the newly created Muslim state of Pakistan after India’s independence from Great Britain in 1947. Severe rioting and migration ensued and an estimated half a million people were killed in the violence. India’s health policy originated in the nation-building activities during independence and the philosophy embodied by the Gol’s Bhore Committee Report, in which India’s poor health conditions were attributed to substandard sanitation, nutrition and health services.

2. Health system successes and failures

The GoI established the Control of Diarrheal Diseases (CDD) program under the Ministry of Health in 1978 with the objective to prevent under-five deaths due to dehydration caused by diarrheal diseases. Under the Child Survival and Safe Motherhood (CSSM) program, health education targeted caregivers to rapidly recognize and appropriately manage diarrhea. The CSSM program was integrated with other Reproductive and Child Health (RCH-I and RCH-II) programs during the GoI’s 9th plan period (1997-98).¹² ORS use rates in India were dismal for a long time but have accelerated in the past few years.

The Expanded Program on Immunizations began in 1978 and the Universal Immunization Program was introduced in 1985-86. Kerala and Tamil Nadu have 80% coverage of third dose DPT but less than half of children received the third dose of DPT in Uttar Pradesh, Bihar and Madhya Pradesh. Less than half of caregivers in India are aware of the importance of and need for immunizations; DPT3 coverage is 82.1% in the highest wealth quintile and 44.9% in the lowest quintile.¹³

The availability of health services in rural India is high and people seek care 96% of the time they are sick, however, conditions are poorly diagnosed and treatments are provided indiscriminately.¹⁴ Almost 80% of Indian prescriptions include an antibiotic, whether needed or not.¹⁵ Medical students learn this practice from seasoned physicians and, through mimicking senior doctors’ prescriptions, quickly adopt the view that it’s easier to give an antibiotic to ensure that you don’t miss something; diagnosis is rare and, even when one is made, a broad spectrum antibiotic is prescribed.

¹² Ministry of Health and Family Welfare. Child Health Programme in India. Accessed October 16, 2012. Available at: <http://mohfw.nic.in/WriteReadData/l892s/6342515027file14.pdf>.

¹³ International Institute for Population Sciences, District Level Household and Facility Survey, 2007-08.

¹⁴ MAQARI, 2011.

¹⁵ Vohra, 2012.

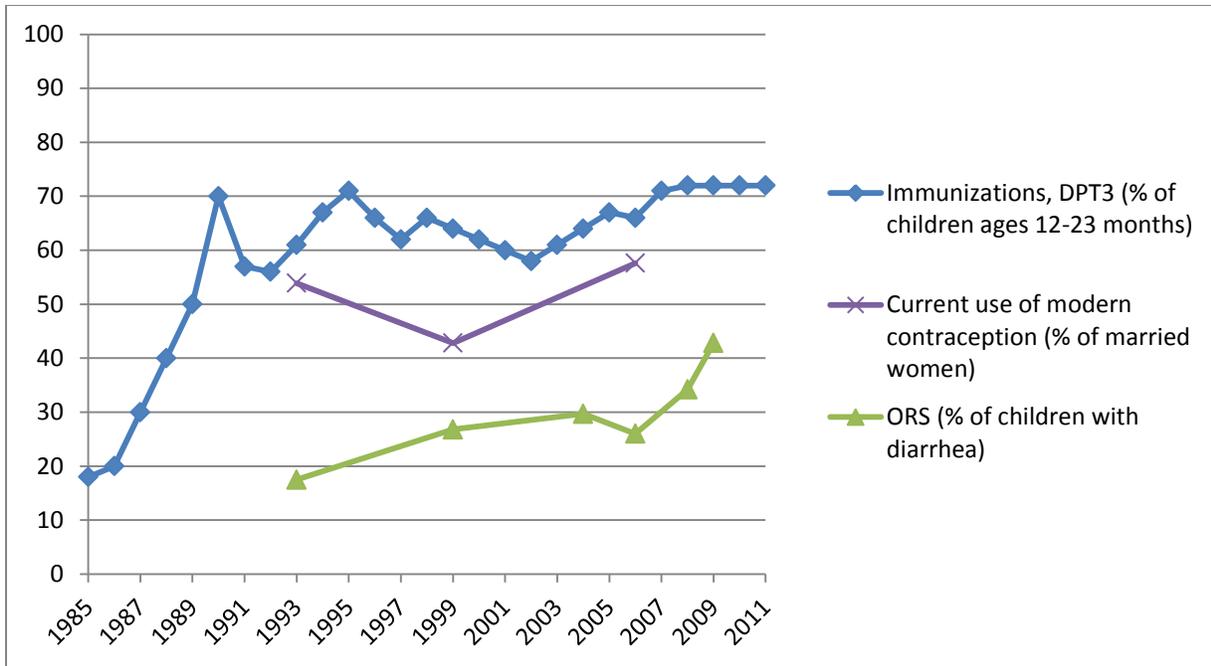


Figure 2. Health services utilization in India, 1985-2011. (Data sources: National Family Health Surveys 1992-93, 1998-99, 2005-06; District Level Household Surveys 2002-04, 2007-08; Coverage Evaluation Survey, 2009; UNICEF/WHO DPT3 estimates, 2012.)

3. State of ORS + Zn prior to scale-up effort

a. Assess status of ORS and ORS + Zn currently

Diarrhea incidence among children under five years of age in India has decreased from 3.1 to 2.5 episodes/child year between 1990 and 2010, respectively.¹⁶ According to the Coverage Evaluation Survey (2009), 67.8% of children with a recent diarrhea episode were taken to a health facility and 53.6% were treated with Oral Rehydration Therapy (ORT) or increased fluids, including 42.8% who received ORS. There is wide variation across the states with regard to treatment of diarrhea with any ORT or increased fluids (Figure 3) and with ORS packets (ranging from 56% in Kerala, 70% in Delhi, and 79% in Goa to 14% in Uttar Pradesh, 22% in Bihar, and 41% in Madhya Pradesh).¹⁷

¹⁶ Fischer Walker, 2012.

¹⁷ UNICEF, Coverage Evaluation Survey, 2009.

Table 1. Diarrhea care-seeking and treatment practices in India, 1992-2009 (NFHS & UNICEF/CES data).

	1992-93	1998-99	2005-06	2009
Knowledge of ORS (% of mothers of children with diarrhea)	.	.	73.0	.
Knowledge of ORS (% of mothers of young children)	42.7	62.4	64.9	.
Care-seeking for diarrhea (% of children with diarrhea taken to any health facility or provider)	61.2	63.4	59.8	67.8
ORS (% of children with diarrhea)	17.5	26.8	26.0	42.8
Antibiotic (% of children with diarrhea)	31.5	.	15.5	.
Pill or syrup (% of children with diarrhea)	.	52.8	.	.
Increased fluids (% of children with diarrhea)	13.8	22.2	10.2	9.7
Any ORT or increased fluid (% of children with diarrhea)	.	.	.	53.6
Other home remedy	41.5	.	.	42.8
Home remedy/herbal	.	3.8	7.5	.
Recommended home solution (% of children with diarrhea)	18.6	3.2	.	.
ORS or RHS (% of children with diarrhea)	30.6	.	.	.
Gruel (% of children with diarrhea)	.	14.9	20.2	14.5
ORS or gruel (% of children with diarrhea)	.	.	38.5	49.3
Zinc (% of children with diarrhea)	.	.	0.3	.

As of 2009, ORS coverage exceeded 66% in nine states: Arunachal Pradesh, Delhi, Goa, Haryana, Jammu & Kashmir, Karnataka, Manipur, Meghalaya and Tripura.

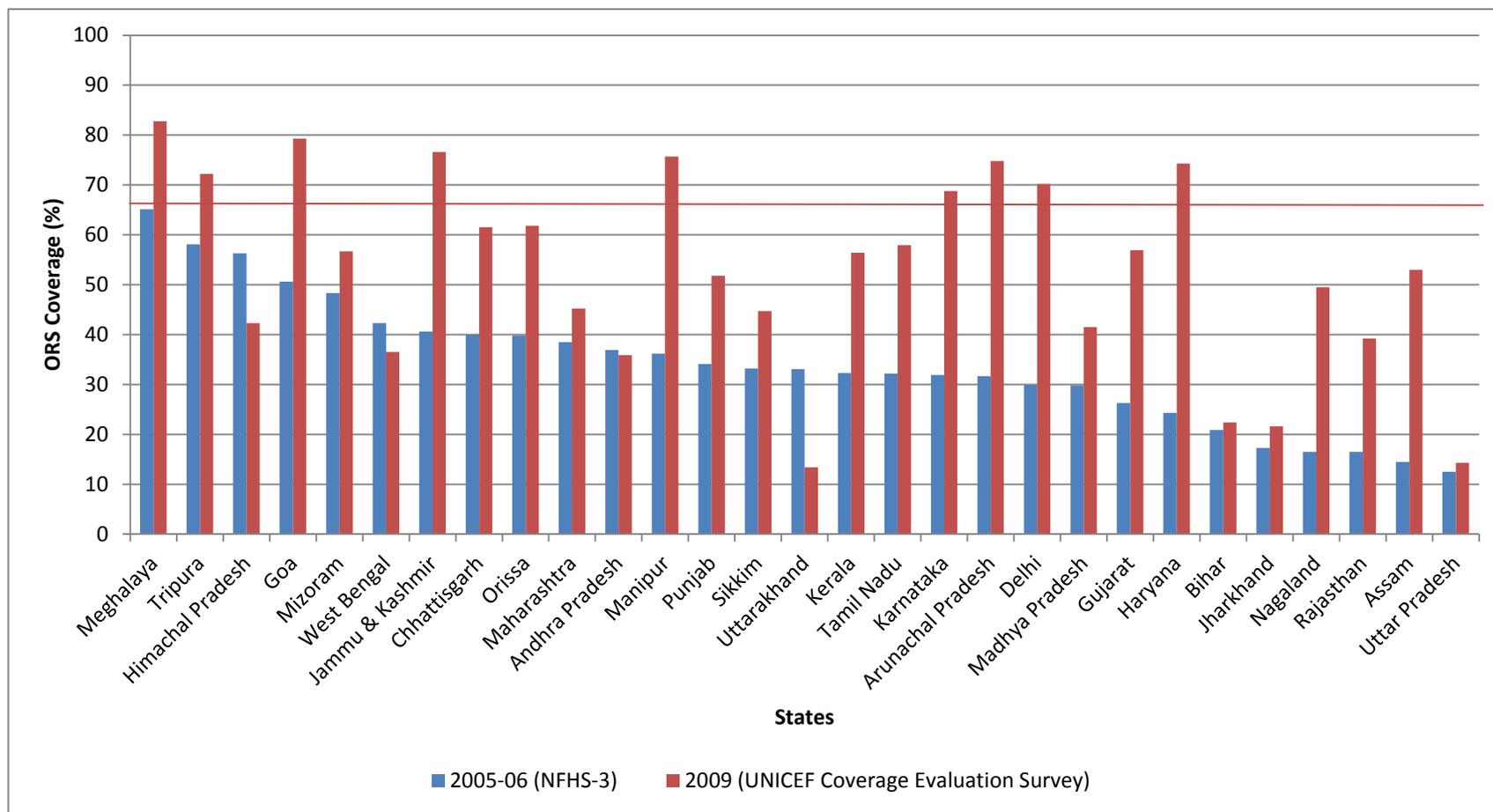


Figure 3. ORS used to treat recent episode of childhood diarrhea (NFHS, 2005-06; CES, 2009)

4. Approach to scale-up

a. Marketing campaign (incl. approach of major manufacturers and wholesalers)

UNICEF began promoting ORS packets in 1990, after which reportedly 18.6% of caregivers provided Recommended Home Solution (RHS) at home, more than ORS, but only half the frequency of “other home remedy”.¹⁸ Documentaries on childhood diarrhea and the use of ORS and the preparation of RHS were regularly shown in cinema theaters in the early 1990s and All India Radio aired messages on ORS and RHS. Simultaneously, the pharmaceutical companies had their own plans for scale-up: by 1992-93, already 31.5% were receiving antibiotics and 14.4% injections.¹⁹

The “WHO ORS Campaign for Diarrhea Management” was initiated by ICICI Bank (leading private sector bank in India) in 2000 as part of the USAID-funded Program for Advancement of Commercial Technology-Child and Reproductive Health (PACT-CRH). The project, known as ‘*Saathi Bachpan Ke*’ (SBK or ‘Friends of Childhood’), continues today under the Strengthening Health Outcomes through the Private Sector (SHOPS) project (USAID’s flagship initiative in private sector health). The program first promoted the use of WHO recommended ORS, to make it the first line of treatment for diarrhea. When low-osmolarity ORS was introduced in 2005 in India, the emphasis shifted to getting industry to adopt the new formula. The program expanded in 2006 to the “Complete Home Diarrhea Management Program”.²⁰

Technical assistance for the project was provided by Commercial Market Strategies (CMS) from 2000 to 2004 and subsequently by Private Sector Partnership – One (PSP-One) until 2007. CMS designed an integrated communications campaign to address the two main barriers to effective ORS use: a lack of awareness — by parents and physicians — that dehydration from diarrhea can cause death, and incorrect use.²¹ The campaign was launched as a partnership with six Indian ORS manufacturers, combining mass-media advertising, public relations, community outreach, and provider training and detailing. The campaign focused on urban areas of Uttar Pradesh, Uttaranchal, Bihar, Jharkhand, Rajasthan, Madhya Pradesh, Chhattisgarh, and Delhi (these states are home to almost half of India’s population) with the aim of getting all Indian manufacturers to produce products in compliance with WHO-recommended formulation. Population Services International, Dr Reddy’s Laboratories and Pharmasynth Formulations subsequently joined the campaign in 2005 when they launched their own brand of low-osmolarity ORS. These partners together accounted for almost 95% of the ORS industry.²²

The SBK program organized demonstrations for caregivers with young children in select cities of Uttar Pradesh and Delhi and sent mailers to doctors, asking them to prescribe WHO ORS in every episode of diarrhea. The program ran a Mystery Consumer Contest for pharmacists in which prizes were awarded to pharmacists who scored correctly on all three parameters (availability, visibility and recommendation of ORS) when field workers posing as customers visited to assess. Trained promoters made door-to-door

¹⁸ National Family Health Survey, 1992-93.

¹⁹ National Family Health Survey, 1992-93.

²⁰ Vyas, 2008: Working with Traditional Providers in Improving Health Outcomes in India. Accessed October 16, 2012. Available at: <http://www.shopsproject.org/resource-center/working-with-traditional-providers-in-improving-health-outcomes-in-india>.

²¹ SHOPS, Commercial Market Strategies, Country Profile: India, 2003.

²² PSP-One, 2008. Saathi Bachpan Ke- Promoting Diarrhea Management Through the Private Sector in Urban North India. Available at: http://www.shopsproject.org/sites/default/files/resources/4769_file_Sathi_Bachpan_Ke.pdf.

visits to 77,000 caregivers with children under five in 2003. The Delhi Transport Corporation and UTI Bank permitted the display of the campaign on their buses and ATM counters free of charge.



Figure 4. Logo to promote ORS (PACT-CRH, IIM)

The project created a logo to promote ORS (Figure 4). SBK ran TV ads stating that doctor-recommended WHO ORS is much more effective than conventional home-based remedies and flooded print media. By 2003, more than 400 articles repeating intended messages had run in the leading Indian newspapers and magazines. India's most popular soap opera, *Kyunki Saas Bhi Kabhi Bahu Thi*, integrated WHO ORS messages into one of its episodes, which was viewed by millions in the target audience, according to CMS. The day after the episode aired, a survey of 291 women revealed that 71 percent correctly recalled the campaign messages.²³

USAID created the Point-of-Use Water Disinfection and Zinc Treatment (POUZN) project and contracted with AED (now FHI360) to introduce zinc with ORT in India from 2005-10. The project was developed to create demand for zinc, ensure supply at an affordable price and increase use. The project worked almost entirely with the private sector, given care-seeking practices in India. In 2005, POUZN assessed 20 Indian pharmaceutical companies and selected seven with whom to collaborate to produce zinc. POUZN built on research conducted in Uttar Pradesh in 2007 for the PACT-CRH Project to design its rural strategy, during which NGOs were engaged as "detailers" to promote zinc directly to rural RMPs and drug sellers. Each detailer was responsible for about 200 RMPs and 50 drug sellers, whom they visited four to six times during a six-month period. Free samples were distributed to detailers to "prime" their prospective clients.

The Bill & Melinda Gates Foundation supports an expansion of POUZN, the Diarrhea Alleviation through Zinc and ORS Therapy (DAZT) Project, which began in November 2010 to create adequate, sustained supply and distribution of zinc and ORS in 18 Indian districts. The DAZT project creates an enabling policy environment, improves supplies to the points of care for childhood diarrhea and increases awareness and demand for zinc and ORS while improving compliance by caregivers.²⁴ To date, over 65,000 providers have been trained in the public sector alone.

²³ Commercial Market Strategies. Country Profile: India. Accessed October 15, 2012. Available at: http://www.shopsproject.org/sites/default/files/resources/1008_file_57_Country_Profile_India.pdf

²⁴ DAZT Project website: <http://www.dazt.org/project.html>.

As part of SHOPS' ongoing SBK campaign, Abt Associates organized health camps in Lucknow, Kanpur and Varanasi in 2011 to teach parents and children simple ways to prevent and manage diarrhea. The camps are held from May through July, when diarrheal disease is widespread in the region. At camp, parents, caregivers and children become quickly involved in the “edutainment” produced by the Abt team that teaches washing hands with soap, purifying water and rehydrating children suffering with diarrhea, although not specifically ORS. Key messages are reinforced through puppet shows, interactive games and quizzes.²⁵

b. Regulatory change

The GoI issued revised diarrhea management guidelines in 2007 to include low-osmolarity ORS and zinc supplementation as part of IMNCI.²⁶ ORS is included in the guidelines issued by the Indian Academy of Pediatrics, Indian Medical Association, NRHM, National Program for Treatment of Diarrhea, and National Essential Medicines List. ORS is covered under Schedule K, implying that rural providers (including ambulatory vendors and community health workers) are not required to obtain any sale license when stocking or selling the ORS formulation as prescribed by the GoI. There are no restrictions on prices because ORS and zinc are not considered as scheduled formulations under the Drugs Prices Control Order, 1995.²⁷

c. Development of improved product (& pricing)

The Cholera Research Centre of the Indian Council of Medical Research developed a way to distribute the ingredients (glucose and salts mixture) for oral rehydration in sealed polythene packets. There is good local manufacturing capability, with 22 ORS suppliers in India today.²⁸ Powder sachets of ORS lead the market (79% of market share) and come in two sizes: large (~20 grams) and small (~5 grams). Recent market research by CHAI (August 2012) suggest that retail prices range from USD\$0.07-0.10 and USD\$0.20-0.35 for small and large, respectively. “Orange” is a popular flavor.



Figure 5. ORS packets, Hind Pharma.

²⁵ Abt Associates, 2011. Available at: <http://abtassociates.com/NewsReleases/2011/7-6-11---Abt-Led--Edutainment%E2%80%9D-Health-Camps-in-Ind.aspx>

²⁶ MOHFW, Government of India, Revised Guidelines for Management of Diarrhoea in Children, 2007.

²⁷ USAID/Market Based Partnerships for Health, 2011. <http://mbph.in/pdf/Advocacy/ZincAdvocacyBrief.pdf>.

²⁸ Rehydration Project. Accessed October 16, 2012. Available at: <http://rehydrate.org/resources/suppliers.htm>.

d. Improving public and private provider knowledge

In the 1980s UNICEF pushed “the simple solution” with a series of promotions – slide shows, videos – and achieved a wide awareness of home sugar-salt solutions (SSS). Reportedly over two thirds (68%) of rural doctors (quacks) gave ORS in 1990 but in most cases, in small quantities and ancillary to antidiarrheals.²⁹

The National Diarrhea Management Plan, developed in 1985, was based on the need to reach mothers in their home, to convince them of the importance of preventing dehydration, and to teach them to make and use SSS. The entire program was built within the national health system; the Plan paid lesser attention to the needs of training health professionals, and hardly any to the private sector.³⁰

The Indian Medical Association reached out to rural practitioners with a massive standardization effort to retrain 65,000 members. By 1990, rural doctors perceived medication (capsules/tablets) to be the most important element in diarrhea management, and ORS only as an adjunctive treatment.³¹ A qualitative study done by MART for the DAZT program indicates that providers believe that parents only get the child to the clinic two days after the onset of the diarrheal episode and at that time the child needs a “real medicine” (antibiotics) and not ORS and zinc.³² Families expected to pay for medicines, and valued services for which they paid in dealing with diarrhea. “Free service and particularly free medicine was universally suspected of being low quality, weak and unimportant.”³³

When USAID launched PACT-CRH/SBK in 2000 to stimulate uptake of WHO ORS, only 21% of all ORS sold in India complied with the WHO formulation.³⁴ SBK worked with the Indian Academy of Pediatrics (IAP) and various medical schools and societies to encourage the Indian Medical Association to recommend for all General Practitioners) to use WHO ORS. A series of seminars were organized in state capitals (Ranchi, Lucknow, Jaipur, Patna and Bhopal), through which a strategic alliance was established with the IAP. The program developed a Doctor’s Handbook of Infant Diarrhea Management and the seminars leveraged media support to communicate the benefits of WHO ORS through interviews with pediatricians, which were published in newspapers.

The SBK program also taught parents and providers how to correctly prepare ORS. A team of trained promoters went door-to-door in Uttar Pradesh and Madhya Pradesh, visiting 200,000 caregivers. During these household visits, promoters explained the dangers of dehydration and diarrhea, demonstrated the correct method of ORS preparation, and provided free sample packets of ORS. Over 100 CMS staff called upon 28,000 ISMPs and 28,000 pharmacists to encourage WHO ORS use.

The national diarrhea control program evolved into Reproductive and Child Health programs (RCH-I and RCH-II) and included IMNCI. Frontline workers and health professional are trained in integrated management of newborns and sick children. RCH-II emphasizes improving home management of

²⁹ Rohde, personal communication, 2012

³⁰ Vishwanathan H, Rhode JE. Diarrhea in Rural India: A Nationwide Study of Mothers & Practitioners, All India Summary. New Delhi: Vision Books; 1990.

³¹ Ibid.

³² Bahuguna P. Personal communication, 2012.

³³ Vishwanathan H, Rhode JE. Diarrhea in Rural India: A Nationwide Study of Mothers & Practitioners, All India Summary. New Delhi: Vision Books; 1990.

³⁴ ORG Retail Audit, 2000.

diarrhea through behavior change communication to promote ORT, continued feeding and breastfeeding and use of appropriate antibiotics for dysentery. Since its inception in 2005, the NRHM has promoted ORS under RCH-II. Training in IMNCI varies by state; while public sector trainings are underway, zinc therapy for diarrhea treatment is not included in IMNCI and NRHM ASHA trainings.

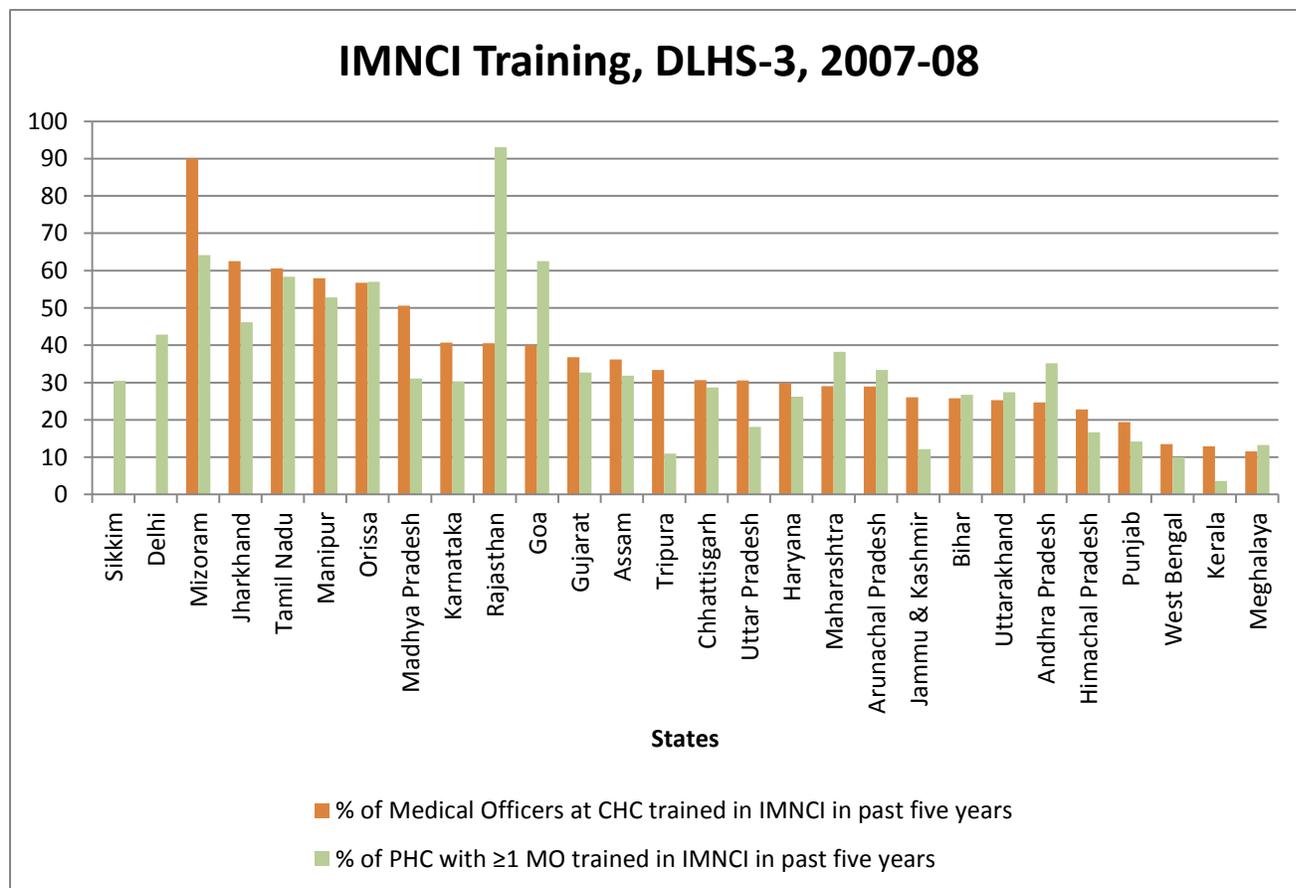


Figure 6. IMNCI training at community health center and primary health center levels, 2007-08.

According to the UNICEF Coverage Evaluation Survey (2009), most practitioners were aware of ORS but few actually prescribed it. Only 26% of practitioners stocked ORS with them and of those, almost half had open packets (most likely were probably re-dispensing it as medicine in smaller pouches). UNICEF conducted a 10-district, 10-state (Medak in Andhra Pradesh; Dibrugarh in Assam; Vaishali in Bihar; East Singhbhum in Jharkhand; Guna in Madhya Pradesh; Latur in Maharashtra; Koraput in Orissa; Krishnagiri in Tamil Nadu; Lalitpur in Uttar Pradesh; and Purulia in West Bengal) survey of providers’ diarrhea management practices in 2008.³⁵The majority (85-100%) of doctors practicing modern medicine claimed that they prescribed ORS but mothers’ reports suggested low level of ORS prescription. In the UNICEF ten-district survey in 2009, the proportion of children receiving injections during a diarrheal episode was 23%. Prescription audits of doctors have consistently shown very high usage rates of antibiotics in diarrhea: more than two-thirds of prescriptions given to children suffering from diarrhea included antibiotics.³⁶

³⁵ UNICEF, Management Practices for Childhood Diarrhea in India: Survey of 10 Districts, 2009.

³⁶ Shah et al. Indian Pediatrics, 2012;49: 627-649.

The Medical Advice, Quality and Availability in Rural India (MAQARI) Project examined provider practices (adherence to checklist of history questions and exams, ability to diagnose, treatment protocol) and variations in quality of care (urban vs. rural, public vs. private, case load and equipment). The findings suggest that work load does not seem to be the problem: the average public doctor sees 5 patients a day and spends 14 minutes per day seeing patients, while the average private doctor sees 4 patients per day and spends 12 minutes per day seeing patients.³⁷ The quality of care depends on knowledge and effort and, in the same MAQARI study, it appears that the private sector is less knowledgeable but the public sector exerts way less effort.

e. Increasing availability of supply in the public and private sector (incl. procurement)

ORS is highly available in the private sector but availability of ORS varies greatly by state (**Figure 7**). RCH-II tried to increase availability of ORS at community level through distribution at Aanganwadi centers and sub-centers. An outlet survey conducted by WHO/Health Action International (HAI) found that lowest price ORS (200ml) was available in 72% of private outlet and 0% of public outlets. The standard (1L) size packets of the lowest price ORS were available in 85.4% of private outlets in Orissa. The lowest price ORS (1L) was available in 90.2% of public outlets. In contrast, lowest price Ofloxacin was available in 84.1% of public outlets and 40% of private outlets (WHO/HAI, MSH 2009). The Delhi NCT 2011 survey shows 97.5% availability of ofloxacin in the private sector. This is what is actually (universally) sold to treat diarrhea now.

According to a market analysis by CHAI (2012), nearly half (49.4) of the 300 retail outlets surveyed in four districts of Uttar Pradesh currently stock ORS, whereas 12.6% currently don't stock ORS and 38% never stocked ORS. The reasons for not stocking ORS were cited as low demand (35%), low profit margin (15%) and not aware of ORS (10%). Through the DAZT project, the annual plan for 2012-13 has approved procurement of 200 million zinc tablets and 31.6 million ORS packets at the state level in Uttar Pradesh (UP). This is sufficient to treat around 14.2 million diarrhea cases which is around 25 – 27% of the expected total number of childhood diarrhea cases in UP. In addition the Kit A supply will be sufficient for an additional 4% of cases. Thus, it is assumed that the approval would enable treatment of up to 30% of all expected diarrhea cases among children.

Besides the procurement quantity of ORS and zinc products, another issue in the public sector has been the quality of the procured commodities, especially zinc tablets. Most states do not include quality specifications of zinc tablets in the rate contracts and therefore end up procuring zinc tablets of suboptimal quality. The Indian Pharmacopeia guidelines on zinc quality were released earlier this year and should be included in the state level rate contract.

³⁷ Holla, The Quality of Medical Care in India: Evidence from a Standardized Patient Study. MAQARI Project.

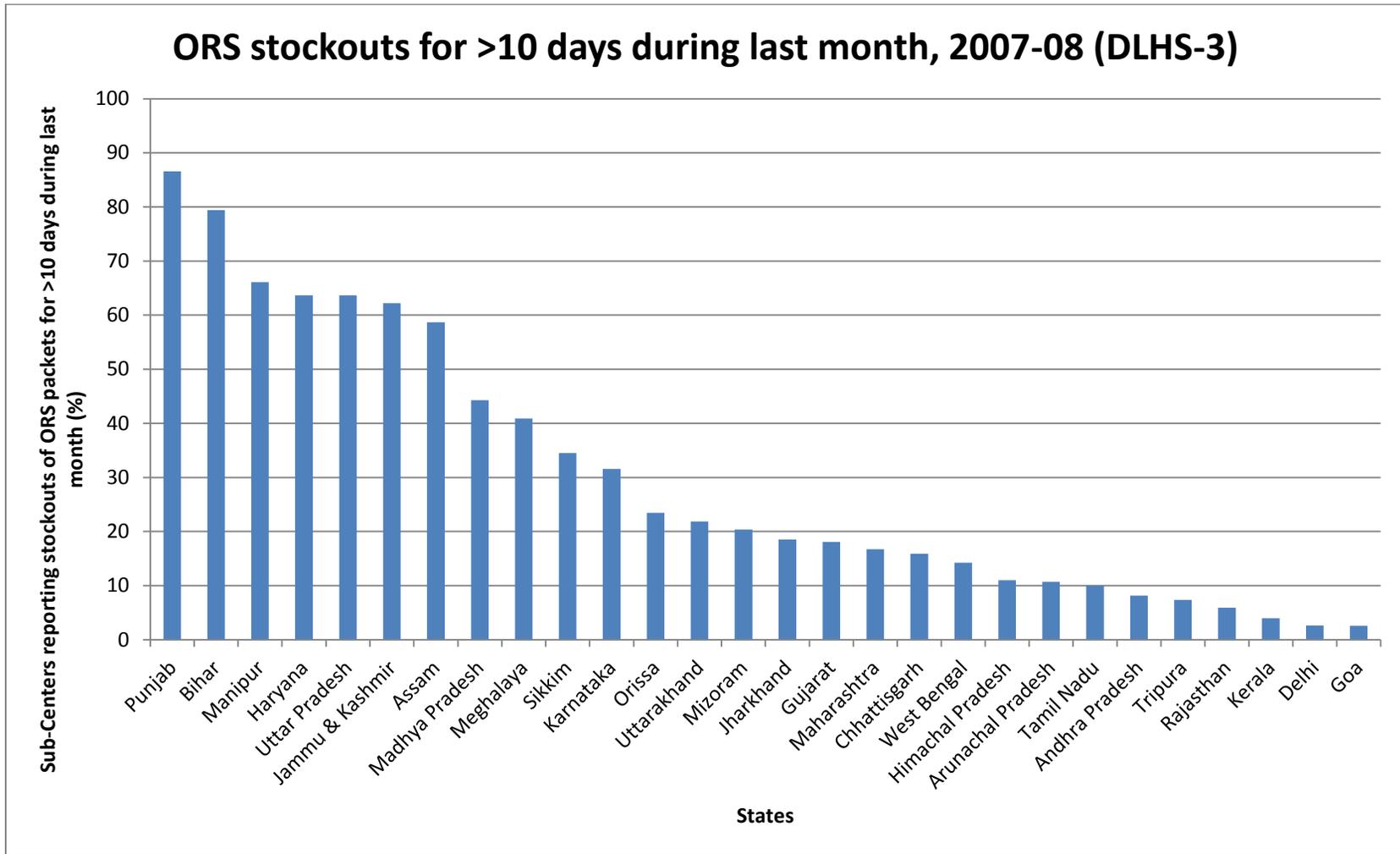


Figure 7. ORS stockouts, by state.

f. Financing- source and mechanisms

The average yearly budget from the GOI to the CDD program between 1978 and 1985 was Rs. 1 million (\$100,000).³⁸ USAID provided a total of \$29.8 million for the PACT-CRH program from July 1995 to July 2007). It's unclear what proportion of the total budget went to increasing consumer use of ORS and/or improving policy and regulatory changes in the private sector to achieve higher coverage of ORS.

5. Impact

a. How efforts change usage

ORS use hovered around 20% for several years before increasing to 43% in the most recent national survey. Use of antibiotics and other home remedies remains equally high, which is not surprising given the “love of antibiotics in India” (Vohra, 2012). Despite high antibiotic use, ORS has improved. The multi-year PACT-CRH/SBK campaign demonstrated that the use of ORS increased from 25% to 45% and sales of ORS increased by 37% (from 18,646 liters in 2001 to 23,199 liters in 2006). Under SBK, the Drug Controller of India approved the shift to a single low-osmolarity formula, the commercial sector invested in ORS promotion and the launch of new brands, significant resource commitments from the NRHM were made to support ORS and diarrhea management communication efforts, and National ORS Day was institutionalized. The diarrhea management program evolved over the years, from focusing on WHO formula ORS at inception, to covering all aspects of home based diarrhea management, and eventually in 2007 developed prototypes for introduction of zinc therapy in the private sector in India. The program constantly upgraded objectives and strategies keeping in mind both public health needs and policy and technology shifts and was closely informed through intensive market research with consumers and providers at every step.

Table 2. Saathi Bachpan Ke (SBK) Key Indicators for ORS Market Growth³⁹

Indicators	ORS Baseline 2002	ORS Endline 2005
Use of ORS among children who suffered from diarrhea in the last 2 weeks	25%	45%
Use of ORS as first line of treatment among children who suffered from diarrhea in the last 2 weeks	16%	33%
Use of pills or syrups and medicines as first line of treatment among children who suffered from diarrhea in the last 2 weeks	50%	35%
Proportion of caregivers spontaneously mentioning the use of home-fluids among the children who suffered from diarrhea in the last 6 months	31%	30%

(Source: PSP-One, Baseline and Endline Campaign Tracking Surveys, 2002 and 2005)

By the end of the POUZN project, providers were aware of zinc and recommending it, and the produce was produced locally. Pharmaceutical companies, using their own resources, were manufacturing

³⁸ Vishwanathan H, Rhode JE. Diarrhea in Rural India: A Nationwide Study of Mothers & Practitioners, All India Summary. New Delhi: Vision Books; 1990.

³⁹ PSP-One, 2008. Saathi Bachpan Ke- Promoting Diarrhea Management Through the Private Sector in Urban North India. Available at: http://www.shopsproject.org/sites/default/files/resources/4769_file_Sathi_Bachpan_Ke.pdf.

and/or distributing zinc—two signed on in 2005 and 22 were active by 2009.⁴⁰ In May 2008, 87 percent of RMPs prescribed an antidiarrheal or antibiotic in all cases of diarrhea; by August 2008, 68% recommended antibiotics. 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. 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.

b. Whether change was sustained

Diarrhea has long been considered a common, non-serious health problem – one that occurs frequently enough to be deemed inevitable.⁴¹ With 22 local manufacturers of ORS in India, on the surface, availability does not seem to be a problem. While there are multiple manufactures of ORS in the country the availability beyond urban and semi-urban areas still remains questionable as most manufacturers only have distribution capacity to these urban/semi-urban cities and towns. A market survey on the availability and uptake of ORS and zinc conducted by UNICEF in UP reported that ~50% of retail outlets did not stock ORS. The generally low levels of training in IMNCI among public sector providers and the lack of accountability among private sector providers render provider behaviors at best suboptimal but potentially very harmful, with wide use of antibiotics and inappropriate polypharmacy. The improvement in ORS coverage is recent (since 2005) so it may be too early to declare whether change was sustained.

c. Cost of scale-up effort

The funds allotted by GOI to the CDD program were grossly inadequate and, while USAID contributed nearly \$30M for PACT-RCH over 12 years, the market for high-end antibiotics in India hospitals was \$685M in 2010. Typical approaches to improve use of a low-margin product like ORS cannot compete with the pharmaceutical industry in India (which benefits from high consumer demand for medicines as well as unregulated prescribing practices).

6. Conclusion

a. What about context and approach was predictive of impact

ORS coverage increased after five years of SBK program implementation. The continuity of that project, and its private sector focus, appears to have had a favorable effect on changing behaviors around diarrhea treatment. While SBK has used effective marketing strategies for urban areas the real impact of an ORS and zinc campaign, in terms of uptake, can only be derived by bringing about sustainable behavior change in the rural areas, where ~70% of the population still lives and incidence of diarrhea is much higher due to poor hygiene and sanitation conditions. The marketing mix used by SBK might not be relevant in a rural context as most rural areas can't rely on media. The POUZN project and the DAZT project have revitalized ORS for diarrhea treatment through the introduction of zinc therapy, simultaneously creating a supply and beginning to generate demand for zinc.

⁴⁰ USAID/POUZN, 2010. http://pdf.usaid.gov/pdf_docs/PNADU434.pdf

⁴¹ Vishwanathan H, Rhode JE. Diarrhea in Rural India: A Nationwide Study of Mothers & Practitioners, All India Summary. New Delhi: Vision Books; 1990.

While ORS is available, outlet surveys don't track this low-margin product. Providers are too busy providing antibiotics as demanded by their clients – and perhaps fearful that if they refuse an antibiotic, a patient will spread the word that he or she is not a good doctor because an antibiotic wasn't provided when requested. Providers also give in to peer pressure to prescribe antibiotics rather than ORS. The provider practices have been highly predictive of impact.

b. Whether it was a 'good buy' or not

The traditional (USAID and UNICEF) approaches to diarrhea treatment, and the NRHM and RCH efforts to reach the most vulnerable populations were indeed good efforts. The pharmaceutical companies' ability to sway providers to push medicines and program the general population to demand medicines highlights their success in driving uptake of their products rather than driving ORS uptake.

c. What could have been done differently

Questions about the quality, costs and accessibility of care provided in the private sector have been raised in studies in India, the main concerns being the potential for unnecessary services, high prices or skimping on quality.⁴² One can't expect ORS use to exceed use of other, non-recommended medications without buy-in from providers, the government and the pharmaceutical companies to regulate prescribing practices. Weak diarrhea program monitoring in the public sector hasn't helped change ORS from low-priority status. Further, the product does not meet consumers' expectations (i.e., to stop the diarrhea). Caregivers do not recognize the severity of illness and often delay care-seeking ("wait and watch"), relying on home remedies for the first few days and then demanding a medicine that will stop the diarrhea once care is finally sought – seemingly not bothered by (or not aware of) the potential deleterious effects of inappropriate treatment. One of the key failures in sustaining demand for ORS is the supply chain constraints in the public sector leading to erratic procurement of ORS. Improvements in the standards of care and accountability of providers in the public and private sectors in India could possibly improve rationale treatment of diarrhea.

⁴² De Costa, 2008.

Summary

Component	Degree of success	Drivers of success/failure
Development of improved product (including pricing)	Med	<ul style="list-style-type: none"> • Good local manufacturing capacity • Orange-flavored, low-osmolarity ORS produced • People willing to pay for medicines and services in India (quality?)
Marketing campaign	Med	<ul style="list-style-type: none"> • Achieved 43% ORS coverage and high awareness • Population does not “buy into” ORS as first-line treatment
Regulatory change	Med	<ul style="list-style-type: none"> • Adopted ORS/Zn into IMNCI guidelines • Unregulated pharmaceutical industry and provider practices (high antibiotic and polypharmacy of medicines of questionable quality)
Improving private provider knowledge	Low	<ul style="list-style-type: none"> • Information on the private sector is sketchy, as public policy has left the private sector to its own devices with little regulation • Availability of providers in rural India is very high (and people use them) • Quality is very poor in both public and private sector <ul style="list-style-type: none"> ○ Public sector knows-more, does-little ○ Private sector knows-little, does-more • Fever, dehydration and young age prompts caregiver to prescribe antibiotics • Health workers not convinced of absence of any benefit of antibiotics • Demand for antibiotics by patients/parents is not common but expectation of a product/ medicine by parents is common
Improving public provider knowledge and increasing supportive supervision	Low	<ul style="list-style-type: none"> • Lack of motivated staff at most peripheral level • Lack of confidence of people in public health system • Health care providers are not convinced of benefits of ORS, and do not prescribe it despite knowing about it. (Perceptions that it does not stop diarrhea and is only indicated in dehydration; preference of intravenous fluids in case of dehydration)
Increasing availability of supply in the public and private sector	Med	<ul style="list-style-type: none"> • NRHM and RCH have made efforts to improve availability • ORS stock-outs common with government health functionaries but available in private sector • Parents, caregivers and providers are not convinced of benefits of ORS and therefore not demanding ORS • ORS not even tracked on availability surveys
Financing of scale-up	Low	<ul style="list-style-type: none"> • Not prioritized in national health system • Little interest by pharmaceutical companies • \$30M from USAID, cannot compete with pharmaceutical companies