ESSENTIAL MEDICINES INITIATIVE INDIA

Scale-up Strategy for Diarrhea, Pneumonia and Malaria Treatment
FOREWORD

India has made consistent progress in reducing child mortality, nearly halving the rate between 1990 and 2010. While many children’s lives have been saved as a result of this steady decline, further progress is needed. To reach the Millennium Development Goal #4 – reducing child mortality by two-thirds by 2015 – there is need to build on the past successes and further decrease the current child mortality rate of 63 per 1000 live births to 38 per 1000 by 2015.

While ambitious, accelerating the decline in child mortality in India is possible. The Government of India is strongly committed to achieving MDG #4 and to providing the children of India, with equitable access to cost effective and quality health care. It is against this backdrop that the Ministry of Health, under its flagship program National Rural Health Mission (NRHM), is working to increase access and to strengthen the quality of child health services, and has several large-scale efforts underway. This includes, but is not limited to, service delivery by Accredited Social Health Activist (ASHAs), the Integrated Management of Neonatal and Childhood Illness (IMNCI) strategy, the Universal Immunization Program (UIP), the National Vector Born Disease Control Program (NVBDCP) and the inception of a Central Procurement Agency (CPA) to improve the availability of Reproductive and Child Health (RCH) drugs and commodities for malaria control.

In addition to these ongoing efforts, there is an opportunity to accelerate improvements in the survival of children who suffer from pneumonia and diarrhea – which represent the single two greatest drivers of child mortality and together lead to the death of over a half million children annually in India. For both of these conditions, affordable treatments currently exist but are underutilized. Accelerating the scale up of these treatments is a high priority for the Ministry of Health as they represent one of the greatest opportunities to hasten the decline of child mortality. Improving access to these medicines in a short-time frame will require strong leadership and coordinated action of public and private sector stakeholders. For diarrhea treatment in particular, the private sector will play a large role in achieving sale-up targets as the majority of caregivers currently seek treatment for diarrhea from private providers.

This document provides details of how scale up will be achieved – building on existing child health initiatives while also identifying new opportunities for enhanced efforts. The plan addresses the collaboration that is needed among key stakeholders to ensure that target treatment coverage levels of 80% are reached by 2015. Overall, this plan represents an ambitious, yet promising opportunity for India to accelerate progress toward MDG #4; while the strategy is based on the current needs and gaps, it is anticipated that the recommended actions will be revised in the coming months and years as new opportunities arise and evolve.

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Abbreviations

ACT  Artemisinin-Combination therapies
AL   Artemether-Lumefantrine
ANM  Auxiliary Nurse Midwife
ASHA Accredited Social Health Activist
AS-SP Artesunate-sulfadoxine-pyrimethamine
AYUSH Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy
CPA  Central Procurement Agency
DCGI Drug Controller General of India
FDC  Fixed-Dose-Combination
GOI  Government of India
IAP  Indian Academy of Pediatrics
IMA  Indian Medical Association
IMC  Indian Medical Council
IMNCI Integrated Management of Neonatal and Childhood Illnesses
KAP  Knowledge Attitude and Perception
KOL  Key Opinion Leader
MDG  Millennium Development Goal
MI   Micronutrient Initiative
MoHFW Ministry of Health and Family Welfare
MoU  Memorandum of Understanding
MR   Medical Representative
NGO  Non-governmental organization
NHSRC National Health System Resource Center
NRHM National Rural Health Mission
NSSK Navjaat Shishu Suraksha Karyakram
NVBDCP National Vector Borne Disease Control Program
ORS  Oral Rehydration Salts
ORT  Oral Rehydration Therapy
OTC  Over the Counter
PHC  Primary Health Centre
PPP  Public Private Partnership
RDT  Rapid Diagnostic Test
RMP  Rural Medical Practitioners
RSBY Rashtriya Swasthya Bima Yojana
SMS  Short Message Service
TRG  Technical Resource Group
UNICEF United Nations Children’s Fund
WHO  World Health Organization
1. Executive Summary

An unacceptable number of children continue to die of treatable conditions every year. Worldwide, six million children die yearly as a result of common, preventable, and treatable conditions, and India accounts for nearly 25% of these child deaths. Within India, one-third of child mortality is attributed to diarrhea, pneumonia and malaria, causing over a half million child deaths each year.

The majority of diarrhea, pneumonia, and malaria deaths can be averted through the prompt use of safe, highly effective, and inexpensive treatments for each condition – zinc and oral rehydration salts (ORS) for diarrhea, amoxicillin for pneumonia, and artemether-lumefantrine (AL) for malaria. However, these critical medicines are not yet reaching the children who need them. Currently, only 35% of children with diarrhea in India are receiving ORS and less than 2% are receiving both zinc and ORS. Likewise, the percentage of children receiving the recommended treatment for pneumonia is 14%. While current malaria treatment coverage with artemisinin-based combination therapies is unknown, it is assumed to be low based on previous data.

With only four years left to achieve the Millennium Development Goals, there is a need to substantially accelerate progress to reduce child mortality by two-thirds by 2015. In pursuit of this, India has been strengthening and expanding access to immunizations and child health services more broadly. However, diarrhea and pneumonia mortality are expected to remain high in the near term since current immunization and prevention efforts are unlikely to produce the full impact needed to achieve MDG4 by 2015. In light of this, the Government of India and its partners have prioritized improvements in treatment coverage for children with diarrhea, pneumonia and malaria; increasing access to these essential treatments is a ripe, cost-effective, and scalable opportunity to significantly hasten progress on child mortality in the near term. Indeed, achieving target treatment levels of 80% for these three conditions has the potential to save the lives of more than 100,000 children in India annually.

The government’s ongoing efforts are already improving the reach and quality of health services in the country, through health systems strengthening programs led by the National Rural Health Mission (NRHM) and the push towards universal health insurance through the Rashtriya Swasthya Bima Yojana (RSBY) program. Both initiatives provide a platform to enhance efforts to reduce child mortality by 2015. This includes strengthening child health delivery services at the community level through Accredited Social Health Activists (ASHAs), a cadre of female community health workers trained and supported by NRHM, and reviewing treatment guidelines to reflect the recommended therapies for diarrhea, pneumonia and malaria.

In conjunction with these government efforts, additional steps must be taken to overcome barriers specific to accessing the recommended treatments to these three conditions and for child health services overall. Although ambitious, the actions necessary to reach target treatment levels are known and possible to implement in the coming four years. The key challenges and proposed solutions for each of the three primary childhood conditions are summarized here.

Diarrhea: Most caregivers and providers are not aware that zinc should be given along with ORS as the recommended treatment for diarrhea. In comparison, awareness of ORS amongst caregivers and providers is high, though usage is low due to a preference for treatments perceived to provide immediate relief. As a result of these knowledge gaps and misperceptions, there is limited demand for ORS and zinc, especially in rural areas. The government aims to overcome these barriers by launching a large-scale demand generation effort, using innovative marketing techniques to reach caregivers and field work forces to rapidly change prescribing behavior in both the public and private sectors. In particular, this will include targeted efforts to educate and influence the prescribing practices of Rural Medical Practitioners (RMPs), since the majority of caregivers seek treatment from these informal private sector providers, and re-branding ORS and zinc as a co-therapy by introducing a co-packaged product. Overall, there is significant opportunity to rapidly improve treatment coverage for zinc and ORS, since nearly three-quarters of caregivers are already seeking treatment for their child’s diarrhea episode.

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**Pneumonia:** Efforts to improve pneumonia treatment coverage focus on three key areas: (1) increasing the percentage of caregivers who seek treatment outside the home (which is currently only 14%),\(^9\) (2) improving diagnosis of pneumonia in the public and private sectors, especially at the community level; and (3) shifting the first-line treatment for pneumonia from cotrimoxazole to the WHO-recommended treatment, amoxicillin. The success of these efforts will rely heavily on improved symptom recognition among caregivers and providers alike, and greater urgency in care-seeking. This will be achieved by educating caregivers through large-scale Behavior Change Communication (BCC) efforts, in addition to equipping RMPs and ASHAs with the knowledge and tools required to accurately diagnose children.

**Malaria:** While malaria represents a much smaller share of child mortality, currently estimated at 1%,\(^10\) there are two targeted opportunities to meaningfully improve malaria treatment. First, there is an opportunity to switch from the current recommended first-line treatment of to a simplified fixed-dose-combination (FDC) regimen that has the potential to improve patient adherence and increase availability through ASHAs by streamlining procurement. Second, there is the potential to improve diagnosis through expanded access to Rapid Diagnostic Test (RDTs) in the public and private sectors.

To achieve the desired treatment levels for these three conditions and to successfully implement the solutions proposed above, the approach must strengthen ongoing child health initiatives while simultaneously capitalizing on new opportunities to hasten impact in the near term. While the barriers to scaling up access to pneumonia and malaria treatment will be addressed through cross-cutting child health interventions, there is an opportunity to significantly increase coverage of zinc and ORS through an additional set of diarrhea-specific interventions in the private sector. The five primary interventions include the following:

**Cross-cutting interventions**

- **Large-scale social marketing campaign to generate demand for recommended treatments:** Following formative research on caregiver behavior, targeted messages aimed at reversing misperceptions and bridging knowledge gaps about diarrhea, pneumonia and malaria will be communicated using innovative marketing techniques that combine community engagement with targeted media and communication efforts. Government of India’s aim is to gather fitting consumer insights by the end of 2012; the marketing campaign will be launched between January to March 2013 with the objective of increasing awareness levels about appropriate treatment for diarrhea, pneumonia and malaria before the monsoon season when the prevalence of these diseases is the highest.

- **Improved practices of Rural Medical Practitioners (RMPs) through consistent communication:** Aiming to close the gap in information flow, RMPs will be educated on correct diagnosis and treatment of diarrhea, pneumonia and malaria, followed by regular skill building visits to convert knowledge into practice. This effort will commence between October to December 2012 so that the key messages during this effort can be reinforced with the social marketing campaign.

- **Improved treatment skills and supplies of Accredited Social Health Activists (ASHAs):** Building on NRHM efforts, ASHA drug kits and training modules will be updated and institutionalized to include the recommended treatments for diarrhea, pneumonia and malaria. Regular detailing to convert knowledge into practice will follow these activities. Child health experts at the MoH will revise the ASHA training and drug kits guidelines throughout 2012 and the new training modules and guidelines will be in effect from January 2013.

**Diarrhea-focused interventions**

- **Create supportive environment for zinc scale-up, including over-the-counter (OTC) status and a co-packaged product:** An affordable co-packaged product of zinc and ORS will be introduced in the private market, offering an opportunity to not only re-brand the products as the new gold-standard treatment for diarrhea, but also enabling more rapid scale up by capturing the 35% of caregivers who are already accessing ORS for diarrhea treatment. Changing the status of zinc to OTC will allow for broader distribution and commercial marketing of the co-packaged product. The Child Health group at the MoH will work closely with the Drug Controller General of India to classify zinc as OTC product by the end of 2012.

- **Expand the distribution of zinc and ORS to rural markets through private sector partnerships:** Partnerships will be formed with pharmaceutical and consumer product companies to develop a business case that aligns incentives for increasing investment in sales/promotion of zinc and ORS and for expanding distribution to remote areas. Through these strategic alliances a wide availability of zinc and ORS will be ensured in the private sector, the aim would be have these products easily accessible by then end of 2012 to match the upswing in demand due to the launch of the social marketing campaign.

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The program will be implemented nationwide starting with high childhood morbidity burden states of Madhya Pradesh, Uttar Pradesh and Bihar. The initial estimated resource needs to fully implement this plan in these three states are roughly Rs. 5.9 billion ($119 million USD) over the next four-year period.

With the potential to save the lives of more than 100,000 children annually, this Essential Medicines Initiative represents an ambitious yet feasible approach to reduce child mortality in India – and to achieve MDG4 by 2015. Through the strong government leadership and the active participation of both public and private partners, it is possible to implement the interventions in this plan at scale and to transform the landscape of child health services in India.

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2. Situation Analysis & Strategic Content

2.1 Child mortality and overall access to healthcare

**Causes of child mortality**

Over the past 20 years, India has made steady progress in reducing child mortality. In 1990, for every 1,000 live births in India, an estimated 115 children died before reaching the age of five, totaling more than 3 million deaths per year. In 2010, this has substantially decreased: child mortality has almost halved and is now 63 deaths per 1000 live births. This is an important reduction. Yet still, this implies that almost 1.7 million children in India die before the age of five. Hence, there is still a significant effort needed to reach India’s MDG4 target of reducing under-five mortality to only 38 deaths per 1000 live births by 2015.

Taking a closer look at the underlying causes of child mortality in India, it is clear that a large proportion of child deaths are due to preventable and easily treatable illnesses such as pneumonia (20% or 371,605 deaths) and diarrhea (13% or 237,482 deaths). A small share of childhood deaths is attributable to malaria (1%). In terms of incidence, diarrhea affects millions of children in India with roughly 246 million cases reported yearly. For pneumonia, about 43 million cases per year are reported.

**Figure 1 – Causes of child mortality in India**


**Table 1 – Overview of childhood disease burden in India**

<table>
<thead>
<tr>
<th></th>
<th>Pneumonia</th>
<th>Diarrhea</th>
<th>Malaria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual new cases</td>
<td>43 M</td>
<td>246 M</td>
<td>~100,000</td>
</tr>
<tr>
<td>Annual deaths</td>
<td>&gt;350,000</td>
<td>~225,000</td>
<td>~1,000</td>
</tr>
</tbody>
</table>


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18 UNICEF Report Diarrhea: Why children are still dying and what can be done 2009
Although patterns vary across states, the vast majority of caregivers in India seek healthcare in the private sector.\(^{20}\) This is particularly the case for diarrhea and malaria; for pneumonia, the majority of caregivers do not seek treatment at all or find solutions at home.\(^{21}\) Currently, there are no evaluation mechanisms in place to assess the treatment/prescription practices of public or private providers.

**Figure 2** – Care seeking behavior

![Careseeking Behavior for Pneumonia, Malaria, and Diarrhea](image)

<table>
<thead>
<tr>
<th>Disease</th>
<th>Private Sector Treatment</th>
<th>Public Sector Treatment</th>
<th>Home/No Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumonia</td>
<td>7.0%</td>
<td>7.0%</td>
<td>86.0%</td>
</tr>
<tr>
<td>Malaria</td>
<td>50.0%</td>
<td>20.0%</td>
<td>30.0%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>58.0%</td>
<td>16.0%</td>
<td>26.0%</td>
</tr>
</tbody>
</table>

Source: UNICEF - Management Practices for Childhood Diarrhea in India (2009); Interview with WHO India team

Private health providers could either be qualified/licensed specialists or small informal practitioners who may or may not be licensed to provide care. The latter group of practitioners are referred to as Rural Medical Practitioners (RMPs) and forms a large proportion (~65%) of private healthcare providers.\(^{22}\)**Figure 3** – Composition of the healthcare landscape in India

![Distribution of Health Providers in India](image)

Source: Centre for policy research: “Mapping medical providers in rural India 2010”

Limitations in the governance of India’s healthcare system has resulted in RMPs becoming a prominent source for health service delivery in the country, especially in rural areas. RMPs typically consult 20-50 patients every day,\(^{23}\) and charge a relatively low

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\(^{21}\) UNICEF Report Diarrhea: Why children are still dying and what can be done 2009

\(^{22}\) Centre for policy research: “Mapping medical providers in rural India 2010”

\(^{23}\) Interviews with RMPs in Lucknow, Uttar Pradesh
consultation fee of 10 – 20 Rs ($0.20-$0.40). In general, these practitioners have gained the trust of caregivers, especially in remote areas where they are typically the most easily accessible form of healthcare.

While India has a robust pharmaceutical industry with numerous manufacturers, a consistent supply of drugs to rural areas remains a challenge. Most manufacturers cannot afford to have sales and distribution channels that reach remote areas, which means rural pharmacists have to visit the closest major town to refresh their stocks. Since RMPs usually only prescribe drugs that are available at the nearby pharmacy, latent demand, which might encourage distribution of new drugs to rural areas, is rarely captured. However, intense competition and price regulations on prescribed drugs positively impact their affordability.

The structure of public health provision in India is complex and varies by state. In general, public sector providers that practice at primary health centers usually hold an MBBS degree and are well respected amongst the community. In some cases, public sector providers also hold employment at private dispensaries as a secondary source of income. At the community level, public health provision is delivered by Accredited Social Health Activists (ASHAs), females who have been chosen through a comprehensive selection process conducted by various community groups and trained by the Government of India (GOI) under the NRHM program to address critical health challenges. There are more than 800,000 ASHA workers in India, and the scheme continues to be a cornerstone focus of the NRHM. ASHAs also act as depot holders for essential commodities like ORS, Iron Folic Acid Tablets (IFA), emergency contraceptive pills and condoms, and also provide medical care for minor injuries and tuberculosis. Though not paid a formal salary, ASHAs are incentivized under various performance metrics. The state governments procure medicines for public sector facilities through a structured tendering process, and the federal and state governments share the procurement for ASHA drug kits (85% Federal, 15% State).

### 2.2 Access to Diarrhea Treatment

While the GOI has recommended the use of ORS and zinc for diarrhea treatment, in practice, only 35% of children <5 with diarrhea receive ORS, and only 1.3% receive zinc. Further, only ORS can be sold over-the-counter; formally, zinc can only be purchased with a prescription. Both drugs are included on the essential medicines list, and can be used by ASHAs, provided availability. The cost of a sachet of ORS is 5 - 15 Rs ($0.10 - $0.30), while zinc is slightly more expensive at 20 - 35 Rs ($0.20 - $0.70).

<table>
<thead>
<tr>
<th>Recommended Treatment</th>
<th>OTC Status</th>
<th>Cost of Single Course</th>
<th>Coverage</th>
<th>Primary Alternative</th>
<th>Cost of Single Course</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORS</td>
<td>Yes</td>
<td>Rs 5 – Rs 15 ($0.10 - $0.30)</td>
<td>35%</td>
<td>Antibiotics</td>
<td>Rs 26 - 36 ($0.50 - $0.70)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>IV Fluids</td>
<td>Rs 100 - 150 ($2.00 - $3.00)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Injections</td>
<td>Rs 50 - 80 ($1.00 - $1.60)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tonics</td>
<td>Rs 30 - 100 ($0.60 - $2.00)</td>
</tr>
<tr>
<td>Zinc</td>
<td>No</td>
<td>Rs 20 – Rs 35 ($0.20 - $0.70)</td>
<td>1.3%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

While the burden of diarrhea in India seems large, it is in fact concentrated in a few states: the top 3 states account for about 50% of the total number of deaths due to diarrhea. Reducing the incidence of diarrhea in the top five highest-burden states could save over two-thirds of under 5 deaths due to this condition.

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24 Interviews with RMPs in Lucknow, Uttar Pradesh
Figure 4 – Diarrhea mortality burden per state

![Number of U-5 Diarrheal Deaths By State](image)

Source: "UNICEF Report Diarrhea: Why children are still dying and what can be done 2009"

2.3 Access to Pneumonia Treatment

Unlike diarrhea, pneumonia is difficult to diagnose; therefore, there is no conclusive data on the burden of disease in children. Similarly, there are no coverage evaluation surveys on access to correct treatment of this disease (i.e. amoxicillin or an alternative but more expensive amoxicillin-clavulinate combination). These treatments are available in the private sector at a minimum of Rs 40 - 50 ($0.80-$1.00).

Table 3 – Cost & coverage of recommended pneumonia and treatment and primary alternatives

<table>
<thead>
<tr>
<th>Recommended Treatment</th>
<th>OTC Status</th>
<th>Cost of Single Course</th>
<th>Coverage</th>
<th>Primary Alternative</th>
<th>Cost of Single Course</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin (pneumonia)</td>
<td>No</td>
<td>Rs 40 – 50 ($0.80 - $1.00)</td>
<td>14%29</td>
<td>Cephalosporins</td>
<td>Rs 150 - 200 ($3.00 - $4.00)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Combination antibiotics (co-amoxyclov)</td>
<td>Rs 100 - 150 ($2.00 - $3.00)</td>
</tr>
</tbody>
</table>


2.4 Access to Malaria Treatment

Similar to pneumonia, malaria is difficult to diagnose compared to diarrhea, and thus a consensus on the number of deaths caused by malaria has not been reached. The National Vector Borne Disease Control Program (NVBDCP) has initiated intensified malaria control projects in the highest burden districts of central and northeast India with support from the World Bank and Global Fund. This has dramatically increased the availability of artemether-lumefantrine (AF) in the public sector of the targeted districts. Across the country, AF, the correct treatment for malaria, is available in the private sector at Rs 160 ($3.10). In contrast, proper diagnosis with either RDTs or microscopy is rarely performed and empirical treatment with injectable artemisinin derivatives and chloroquine prevails.

<table>
<thead>
<tr>
<th>Recommended Treatment</th>
<th>OTC Status</th>
<th>Cost of Single Course</th>
<th>Coverage</th>
<th>Primary Alternative</th>
<th>Cost of Single Course</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artemether-lumefantrine (uncomplicated <em>P falciparum</em> malaria)</td>
<td>No</td>
<td>Rs 160 ($3.10)</td>
<td>N/A&lt;sup&gt;31&lt;/sup&gt;</td>
<td>Artesunate injection</td>
<td>Rs 150 – 300 ($3.00 - $6.00)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Chloroquine</td>
<td>Rs 30 - 50 ($0.60 - $1.00)</td>
</tr>
</tbody>
</table>

Source: Adult and child malaria mortality in India. Lancet 2010

<sup>30</sup> Times of India. India’s malaria figures grossly underestimated? Web< http://articles.timesofindia.indiatimes.com/2011-04-23/india/29465949_1_malaria-deaths-malaria-cases-health-ministry>
<sup>31</sup> National Coverage coverage of artemether-lumefantrine has not been measured yet
3. Key Barriers to Access and Current Efforts

3.1 Assessment of barriers to access

As highlighted in the previous section, many children with diarrhea, pneumonia or malaria often do not have access to or receive appropriate treatment – either due to the large share of caregivers that do not seek treatment at all, frequent misdiagnosis, or the provision of inappropriate treatment even when diagnosis is made correctly. In table 5, a high-level description of the key barriers across the three conditions is provided.

<table>
<thead>
<tr>
<th>Table 5 – Barriers to access to essential medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cross-disease</strong></td>
</tr>
<tr>
<td>▪ Poor recognition of signs and symptoms and appropriate treatment due to lack of knowledge</td>
</tr>
<tr>
<td>▪ Delay in seeking treatment due to financial constraints, use of home remedies, lack of transport, competing responsibilities</td>
</tr>
<tr>
<td><strong>Diarrhea</strong></td>
</tr>
<tr>
<td>▪ High awareness of ORS but low usage</td>
</tr>
<tr>
<td>▪ Preference for treatments that offer “immediate relief” such as antibiotics and antidiarrheals</td>
</tr>
<tr>
<td>▪ Insufficient level of care-seeking behavior</td>
</tr>
<tr>
<td>▪ Relatively high price of combined zinc and ORS treatment relative to alternative treatments</td>
</tr>
<tr>
<td><strong>Pneumonia</strong></td>
</tr>
<tr>
<td>▪ Irrational antibiotic combinations are more commonly prescribed than amoxicillin alone</td>
</tr>
<tr>
<td>▪ ‘Facility-level IMNCI’ roll-out has been slow where amoxicillin is recommended as first-line treatment</td>
</tr>
<tr>
<td><strong>Malaria</strong></td>
</tr>
<tr>
<td>▪ ACTs don’t have an OTC status while chloroquine does and is widely available at low cost</td>
</tr>
<tr>
<td>▪ Provider preference for injectable artemisinin derivatives</td>
</tr>
</tbody>
</table>
3.1.1 Patient barriers

3.1.1.1 Cross-disease patient barriers

Poor recognition of signs/symptoms and inappropriate treatment due to lack of knowledge
Almost no caregivers are aware of ORS and zinc as a single therapy for the treatment of diarrhea. Further, caregivers often recognize fever but may just treat their child at home although fever could be a sign of pneumonia and/or malaria. One study in a malaria-endemic area showed that less than half of children with a febrile illness were receiving prompt treatment, but that within 48 hours of the onset of symptoms, over 30% of children received care from less qualified providers who were not licensed to legally prescribe allopathic medicines for any disease.

3.1.1.2 Diarrhea-specific patient barriers

Insufficient care-seeking behavior
Roughly one-quarter of caregivers either try to treat diarrhea through home remedies or do not seek any treatment at all. Diarrhea is typically not perceived as life-threatening unless it is persistent or blood is found in the stool.

Limited awareness about zinc therapy for diarrhea treatment
Low awareness of zinc therapy as the primary treatment for diarrhea amongst caregivers is one of the key reasons for low uptake of the product in India. Less than 2% of caregivers use zinc during a diarrheal episode. To date, government awareness campaigns on diarrhea treatment have only highlighted the benefits of ORS use and have not addressed the importance of zinc therapy.

Figure 6 – Awareness & Utilization of zinc/ORS among caregivers


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High awareness of ORS but low usage
Following decades of government and NGO campaigns regarding the use of Oral Rehydration Therapy (ORT) for diarrhea, awareness of ORS amongst caregivers is high. However, caregivers perceive ORS as a product that can be easily substituted by home remedies. Additionally, caregivers prefer a product that provides immediate cure or treatment, which likely explains the rationale for the continued irrational use of antibiotics, antidiarrheals, injections and IV fluids for diarrhea treatment.

Figure 7 – Treatment for Childhood Diarrhea

![Treatment Received for Childhood Diarrhea (%)](image)


3.1.1.3 Pneumonia-specific patient barriers

Lack of awareness about signs and symptoms
The Integrated Management of Neonatal and Childhood Illness (IMNCI) algorithm defines pneumonia as fast breathing, given a cutoff of breaths per minute depending on the child’s age. Severe pneumonia is defined as a child with ‘difficult or fast breathing’ plus any of the four IMNCI danger signs (unable to drink or breastfeed, lethargic or unconscious, convulsions, vomiting), stridor, or chest in-drawing. While caregivers should seek care immediately when a child has pneumonia based on fast breathing, they often do not recognize this as a sign of a potentially life-threatening disease.

Current Efforts
- Government has been promoting the use of ORS for diarrhea treatment through radio and television
- Under NRHM, the state governments have been undertaking awareness campaigns/efforts about the severity of the signs and symptoms of malaria and pneumonia though various IEC tools (posters, billboards, etc.)
- For prevention of diarrhea and pneumonia, intersectoral initiatives between NRHM, the Ministry of Women and Child Development and the 'Total Sanitation Campaign' promote appropriate Infant and Young Child Feeding Practices (especially exclusive breastfeeding for the first six months) and frequent hand washing, both of which reduce the risk of acquiring these diseases
### 3.1.2 Supplier / provider barriers

#### 3.1.2.1 Cross-disease supply barriers

**Public sector - Incorrect diagnosis of severe cases by community health care workers**
Rapid diagnostic tests (RDTs) for malaria are not typically available at the community level, especially in rural areas. While ASHAs and Auxiliary Nurse Midwife (ANM) workers are trained on diagnosing severe cases of pneumonia and malaria, they often cannot do so in the absence of appropriate diagnostic tools.

**Public sector - Irregular supplies of appropriate drugs at the community and facility level**
Despite recent, promising efforts to improve procurement systems in the public sector, stock-outs of essential medicines are not uncommon. Additionally, the current consumption-based forecasting mechanism often leads to procurement orders that are matched to meet historic demand rather than projected future changes in total demand or changes in provider or patient preferences.

**Private sector - Irregular supply of drugs in remote/rural areas**
Most manufacturers do not see a benefit in setting up a distribution system beyond class I and class II (population>100,000) towns. Pharmacists in class III and class IV towns have to procure their drugs by visiting a stockist in the nearest major town. Small pharmacists do not get any credit terms from the stockists, and they usually wait till they have sufficient cash to refresh their stocks, causing business loss and stock-outs.

<table>
<thead>
<tr>
<th>Current Efforts</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Community health workers are being trained on the ASHA, IMNCI and Navjaat Shishu Suraksha Karyakram (NSSK) modules that focus on skill building to facilitate effective assessment/diagnosis &amp; management/treatment</td>
</tr>
<tr>
<td>- In order to improve procurement and supply chain of public sector commodities, a Central Procurement Agency (CPA) is being established</td>
</tr>
<tr>
<td>- Government and professional bodies like IMA and IAP issue guidelines on appropriate treatment and diagnosis to reduce ambiguity amongst providers</td>
</tr>
<tr>
<td>- The national TB program is working with private chemists and providers to administer DOTS</td>
</tr>
<tr>
<td>- Innovative pharmaceutical manufacturers have been using a network of NGOs to increase their rural outreach by providing an integrated solution to health problems</td>
</tr>
</tbody>
</table>

#### 3.1.2.2 Diarrhea-specific supply barriers

**Private sector - Well entrenched prescribing behavior of private sector providers**
Providers are under pressure to provide treatments perceived to address the immediate symptoms of diarrhea to sustain credibility and customer loyalty; this includes antibiotics, antidiarrheals and IV fluids. The WHO, Indian Medical Association (IMA), Indian Academy of Pediatrics (IAP), GOI and UNICEF have published standard treatment guidelines for diarrhea treatment, but knowledge of these guidelines is limited, especially in the rural areas. A recent survey in Ujjain revealed that less than 1% of prescriptions were in sync with the published guidelines on diarrhea treatment.\(^3\)

**Private sector - No OTC status for zinc**
The Drug Controller General of India (DCGI) has categorized ORS as an over-the-counter (OTC) drug. Zinc, however, has not yet been categorized as OTC. Clinical evidence suggests that zinc therapy not only reduces the incidence of diarrhea but also reduces the chances of hospitalization due to other diseases, like pneumonia, without any side effects. The ambiguity around the official status of zinc restricts pharmaceutical companies from marketing their product directly to caregivers. Additionally, this lack of clarity also means that zinc cannot be distributed through non-licensed pharmacy outlets like grocery stores and corner shops.

**Public sector - Zinc not available at the community level (ASHA kits); frequent stock-outs of zinc and ORS at facilities**

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\(^3\) Pathak D, Pathak A, Marrone G, Diwan V, Lundborg CS. Adherence to treatment guidelines for acute diarrhoea in children up to 12 years in Ujjain, India
While ASHAs in many states are mandated to dispense zinc while treating a child with diarrhea, zinc is not yet available in their kits due to gaps in the current procurement mechanism. A recent survey conducted in the states of Chhattisgarh and Orissa to gauge the availability of ORS and zinc in public sector facilities revealed the following results:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Chhattisgarh Availability (%)</th>
<th>Orissa Availability (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Public</td>
<td>Private</td>
</tr>
<tr>
<td>Zn Sulfate dispersible tablet (20 mg)</td>
<td>29</td>
<td>0</td>
</tr>
<tr>
<td>ORS packet (1L solution)</td>
<td>93</td>
<td>87</td>
</tr>
</tbody>
</table>

Source: Antony KR, Jain V, Puni KK, K Jain Puni. Survey of the availability and prices of children's medicines in Chhattisgarh state, Swain TR. What children's medicines are on our shelves and how much do they cost? (The Orissa Story)

Public sector – Exclusive focus on price and a lack of product specification leads to sub-optimal formulations

The public sector drug procurement tenders lack details on product specifications (such as taste masking dispensability and QA) and supplier selection is based solely on price. This leads to the procurement of low priced but sub-optimal formulations for various national programs.

Current Efforts

- Zinc was added to the national Essential Medicine List (EML) in 2011, and also to the EMLs of the states of Orissa, Chhattisgarh and Madhya Pradesh, indicating the increasing priority of scaling up the usage of zinc for diarrhea treatment
- The availability of zinc in ASHA kits is likely to improve with the inception of the CPA
- MI is providing technical and programmatic support to State Health Society, Bihar for implementing the Childhood Diarrhoea Management programme in 15 districts of Bihar. The purpose of the three-year programme is to facilitate mainstreaming and scale-up of therapeutic zinc supplementation and ORS for diarrhea treatment
- FHI 360, in partnership with a consortium of organizations, is implementing the ‘Diarrhea Alleviation through zinc and ORS Therapy’ (DAZT) project to reduce and rationally manage childhood diarrhea in Uttar Pradesh and Gujarat; this private sector project intends to educate informal providers on appropriate diarrhea treatment and ensure availability of ORS and zinc by strategically partnering with local pharmaceutical suppliers

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35 Source: Antony KR, Jain V, Puni KK, K Jain Puni. Survey of the availability and prices of children's medicines in Chhattisgarh state, Swain TR. What children's medicines are on our shelves and how much do they cost? (The Orissa Story)
3.1.2.3 Pneumonia-specific supply barriers

Difficulty in diagnosing pneumonia

Appropriately diagnosing pneumonia, within both the private and public sectors, is a challenge. IMNCI and F-IMNCI guidelines do not mandate the use of automated breathing counters that would allow providers to determine the cut-off for ‘fast breathing’ in a child according to age group.

Cotrimoxazole instead of amoxicillin as the preferred treatment for community-based management

Cotrimoxazole for 5 days is currently the preferred treatment for community-based management of pneumonia, while severe pneumonia should be referred to a facility. Recent evidence suggests that there is resistance to cotrimoxazole which may render the treatment ineffective, while a 3 day course of amoxicillin has been shown to be effective for pneumonia\textsuperscript{36} and a 7 day course of amoxicillin can treat severe pneumonia (cough and fast breathing with lower chest in-drawing) as part of community case management.\textsuperscript{37}

Current Efforts

- ASHAs are trained in IMNCI to assess children with ‘cough or difficult breathing’
- At the community level, amoxicillin has been included in the guidelines (but only as an alternative for cotrimoxazole)
- IAP’s ‘Blow away pneumonia campaign’ targets private providers
- WHP is developing a mobile phone respiratory rate counter application for the private providers to facilitate effective diagnosis

3.1.2.4 Malaria-specific supply barriers

Artesunate-sulfadoxine–pyrimethamine (AS-SP) is treatment of choice in the national Malaria program

The NVBDCP recommends artemesunate-sulfadoxine–pyrimethamine (AS-SP) co-packs as the treatment of choice; however, this treatment is not recommended by the WHO, as it isn’t an FDC and may result in caregiver noncompliance with the regimen. Additionally, accurate ordering of pediatric AS-AP is especially complex, leading to more frequent stock-outs. In particular, different strengths of color-coded co-packs are given according to age group, not weight bands, and all co-packs have to be procured for all age groups making forecasting and supply chain management a challenge.

Lack of proper diagnostic tools for providers and pharmacies

In the private sector, few providers or pharmacies use diagnostic tools (such as microscopy or RDTs) to test a patient for malaria, and therefore often prescribe empirically antimalarial and antibiotic treatment. The most commonly prescribed treatment is intramuscular injections of an artemesinin derivative (artesunate, arteether, etc) which requires the caregiver and patient to return on two consecutive days and, if the treatment isn’t strictly adhered to, may result in artemesinin resistance.

Current Efforts

- Discussions are ongoing about moving away from AS-SP
- The procurement and supply chain for ACTs is likely to improve with the inception of CPA
- Oral artemesinin monotherapy formulations have been banned by the government to prevent emergence of resistance to artemesinin derivatives
- Government malaria treatment guidelines have been issued to guide the private sector providers


4. Proposed Program of Targeted Interventions

4.1 Vision and Program Overview

Reducing child mortality continues to be an urgent priority for the Government of India, and the goal of this strategy is to reach 80% coverage of the recommended treatments for diarrhea, pneumonia and malaria among children by 2015. The program will commence in Madhya Pradesh, Uttar Pradesh and Bihar - the three states that confront the highest burden of childhood morbidity and mortality\(^{38}\) – and will then be expanded to other high burden states.

<table>
<thead>
<tr>
<th>Summary of Targets</th>
<th>(Draft - under revision)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td>ORS &amp; zinc</td>
<td>1.3%</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>N/A</td>
</tr>
<tr>
<td>AL</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Although ambitious, these targets are feasible and can be achieved by implementing the five overarching interventions outlined in this section. These activities seek to strengthen existing child health services while also capitalizing on new opportunities, such as changing the prescribing behavior of private sector providers who are often unaware of the recommended treatments for these common child conditions, even though they are the “first line of defense” for many caregivers. In addition, public-private partnerships (PPPs) with pharmaceutical manufacturers are proposed to increase distribution of recommended treatments, especially to rural areas. While bold, these approaches have the potential to accelerate progress toward the achievement of MDG4 by 2015.

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Launch large-scale social marketing campaign to generate demand for recommended treatments</td>
<td>Cross –cutting</td>
</tr>
<tr>
<td>2) Create supportive environment for zinc scale-up, including OTC status and a co-packaged product</td>
<td>Diarrhea-focused</td>
</tr>
<tr>
<td>3) Partner with pharmaceutical manufacturers to expand the distribution of ORS and zinc to rural markets</td>
<td>Diarrhea-focused</td>
</tr>
<tr>
<td>4) Improve practices of Rural Medical Practitioners (RMPs) through consistent communication</td>
<td>Cross –cutting</td>
</tr>
<tr>
<td>5) Improve treatment skills and supplies of Accredited Social Health Activists (ASHAs)</td>
<td>Cross –cutting</td>
</tr>
</tbody>
</table>

While the interventions are designed to be coordinated and integrated with existing child health platforms, they are also tailored to address the unique barriers for each condition. For diarrhea, the aim of this strategy is to break the ‘market trap’ that currently inhibits increases in zinc/ORS coverage by simultaneously improving demand for and supply of the products. The greatest focus will be placed on increasing awareness of and demand for the products among both consumers and health providers through large-scale, creative marketing and other effective and easily scalable behavior change techniques. These demand generation efforts will overcome historical impediments to demand for ORS and zinc by rebranding the products based on the latest consumer research and employing an efficient public-private model for influencing private providers. The program will use the rising demand to convince manufacturers and distributors to increase supply and promotion of optimally designed (e.g.\.)

co-packaged) and affordable products. This overall approach will be enabled by critical improvements to the policy environment, including the reclassification of zinc as an over-the-counter (OTC) product, increased public sector distribution, and mobilization of additional local leadership and funding.

For pneumonia and diarrhea malaria, efforts will focus on improved recognition and care-seeking of the signs and symptoms by caregivers as well as increased availability and use of diagnostic tools, especially at the community level. In addition, shifting first-line treatment from cotrimoxazole to amoxicillin at the community level is a critical component of the pneumonia strategy. For malaria, shifting from AS-AP to the fixed-dose-combination AL is an important policy priority.

Overall, the interventions will be sequenced to first ensure that product availability and distribution mechanisms are secured prior to the launch of large-scale marketing and behavior change efforts. As such, the early efforts will focus heavily on securing OTC status, establishing co-packaged product options, and developing pharmaceutical partnerships to expand distribution channels. At the same time, preliminary work will be underway to design and prepare for aggressive launch of the social marketing and behavior change interventions for RMPs and ASHAs – and to “go live” with these activities once the product availability and distribution channels are in place. The graphic below provides an initial overview of the expected sequencing.
4.2 Description of Targeted Interventions

**Intervention 1: Launch large-scale social marketing campaign to generate demand for recommended treatments**

**Rationale**

The primary barriers to achieving uptake of the recommended treatments for diarrhea, malaria and pneumonia are caregiver misperceptions and knowledge gaps related to the severity, diagnosis and treatment of the three conditions. Changing these caregiver behaviors requires a strategy that leverages multiple communication channels to deliver targeted, educational and viral messages. Social marketing is a strategy that the Government of India has historically employed to change caregiver behavior and drive uptake of recommended health products. **This is especially the case for condoms, which have reached annual sales of over 1 billion following a campaign that engaged the private sector with a subsidized product while generating consumer demand.** The most recent diarrhea-focused social marketing campaign in the country, led from 2002-2007 in the urban areas of 8 states, is another example of how a coordinated effort between the public and private sectors to generate and fulfill demand can yield an increase in the uptake of a health product.

**Details**

The national social marketing campaign will target caregivers, including mothers, fathers and grandmothers in rural and urban areas to increase the usage of the recommended treatments for diarrhea, malaria and pneumonia. In line with the overall strategy, the campaign will first be launched in Madhya Pradesh, Uttar Pradesh and Bihar for two years (2012-2014), and then considered for scale-up in other high-focus states. The campaign will be timed to align with seasonality patterns and complementary interventions, recognizing the importance of ensuring product availability at the launch of the campaign. For diarrhea, this includes the introduction and availability of an ORS and zinc co-packaged product in the private sector. For pneumonia and malaria, this includes the availability of amoxicillin and AL in the ASHA treatment kits, following the proposed policy changes in ASHA standard treatment guidelines. A standard process will be followed to identify the key messages for overcoming caregiver misperceptions and knowledge gaps for each condition and the communication channels to prioritize in order to reach the target audience. Lessons from historical social and commercial marketing campaigns will be considered in the design of the communication strategy, in addition to innovative ideas that leverage new media channels such as SMS, mobile video and mobile games.

**Required Activities**

**Activity 1.1 Conduct Knowledge, Attitudes and Practice (KAP) studies:** KAP studies will be executed in each intervention state to understand the key misperceptions and knowledge gaps related to the severity, diagnosis and treatment of diarrhea, pneumonia and malaria. Historical data will be used where available.

**Activity 1.2 Design innovative communication strategy:** Data from the KAP studies will be used to establish the communication strategy, which will outline the campaign messages, priority communication channels by state, and opportunities for customization (e.g. language). The campaign will incorporate best-in-class marketing techniques to determine the most effective messages and mediums to reach rural and urban market segments. The social marketing team at the Ministry of Health will oversee the campaign, which will be designed by a recognized communications firm, selected through a competitive bidding process. For diarrhea, messaging focused on the rebranding of ORS and zinc as a single, co-packaged therapy will be included. For pneumonia and malaria, messages conveying the severity of the disease and techniques for recognizing symptoms will be included.

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39 "FORMATIVE RESEARCH FOR DEVELOPING COMMUNICATION STRATEGY TO PRIVATE SECTOR." FHI-360-MART Study
**Activity 1.3 Identify Key Opinion Leaders**: A key opinion leader shown to resonate with the target audience will be identified to endorse the campaign messages. This strategy has shown to improve the recall of messages amongst caregivers, as campaigns become synonymous with celebrated personalities.

**Activity 1.4 Mass media campaign**: A consistent campaign will be disseminated through multiple mass media channels, with a focus on radio, which has shown to be the most effective medium in rural areas. Given the high cost of mass media spots, partnerships with media houses will be explored. Previous campaigns have shown to achieve a visibility to spend ratio of 200%, meaning that for every media spot paid for, one was aired for free. Strategies such as shortening long-form adverts into shorter “force multipliers” have been found to increase the reach and frequency of campaigns.

**Activity 1.5 Community-level outreach**: Creating interactive experiences at the community level that integrate the campaign’s key messages are often the most effective method of changing behavior in rural and low-income areas. Street theater and door-to-door education will be considered in additional to other new ideas.

**Activity 1.6 Marketing collateral**: Posters, stickers, flipbooks and training manuals will be produced to reinforce the campaign branding and provide reference materials to caregivers, RMPs and ASHAs. Flipbooks designed with images that relay messages through storytelling have been shown to resonate with caregivers in rural areas.

**Activity 1.7 Public-Private Partnerships (diarrhea)**: Public sector commitment to demand generation activities for diarrhea treatment will be used to partner with pharmaceutical manufacturers to introduce an ORS and zinc co-packaged product and distribute it to rural areas.

**Activity 1.8 Monitoring and Evaluation**: Ongoing monitoring of the reach, reaction and number of media impressions will be conducted for the duration of the campaign to ensure objectives are being met. In the third year of the program, an evaluation of the campaign will be conducted to measure progress on caregiver behavior change and target outcomes. Based on the results of the evaluation, the campaign will be refreshed to align with the stage of caregiver behavior change identified.

**Critical Considerations**

**Campaign timing**: The impact of the social marketing campaign on target outcomes rests heavily on the strategic planning and execution of interventions 1, 2 and 3. This will require ample coordination among and commitment from relevant stakeholders to achieve precise alignment between demand generation and supply availability. Sufficient human resources should be concurrently deployed to manage the parallel workstreams, in addition to a centralized project management team.

**National and state coordination**: Coordination between national and state program teams will be critical to establish a campaign strategy, including a consistent message that will be communicated through state-specific channels using relevant languages and terms.

**Lessons Learned**

1. **Direct communication is the most effective way to reach low-income and rural populations**: After running for 3 years in India, the “Saathi Bachpan Ke” campaign, aimed at increasing the use of ORS and home diarrhea management techniques, learned that low-income populations were not being reached by the mass media channels being used. This recognition led to the design of a supplementary strategy utilizing street theatre performances to convey five key messages. Following 540 street theater performances, the usage of ORS or

home diarrhea management techniques in the low-income areas increased by 29% when compared to control areas. Similarly, the “Pulse Polio Immunization” campaign included a variety of programs designed to directly interact with community members. The execution of puppet shows, school rallies and video screenings included entry and exit surveys that showed an increase in the level of caregiver knowledge on polio vaccination.

2. **Demand generation should precisely match supply availability**: Although the “Saathi Bachpan Ke” campaign led to an increase in the usage (25% to 45%) and sales (10% YOY) of ORS in the target program areas, the level of uptake required to drastically reduce childhood mortality and achieve the MDGs by 2015 is still far off. One reason reported for the limited impact of the campaign was the misalignment between the campaign launch and product availability, due to logistical challenges. This weakness in planning may have jeopardized the perceived credibility of the campaign.

3. **Celebrity endorsement can influence caregiver decision-making**: This strategy was most notably used in the Pulse Polio Immunization campaign with revered Bollywood actor, Amitabh Bachchan. Over 60% of caregivers surveyed after the campaign reported that the television and radio spots, which both featured Amitabh Bachchan, were very influential in their decision to get their children vaccinated.

**Intervention 2: Create supportive environment for zinc scale up, including OTC status and co-packaged product**

**Rationale**
The introduction of a co-packaged ORS and zinc product into the market presents an opportunity to overcome the disparity in the awareness, use and availability of each product, in addition to reviving supplier interest in the diarrhea treatment market. Leveraging the already high awareness and comparatively high usage of ORS could increase the awareness and uptake of zinc. Further, ORS could benefit from being rebranded within a co-pack as a “new” and more effective “dual” treatment for diarrhea. This strategy has been pursued in Benin and Madagascar with outcomes that illustrated the importance of a strong social marketing campaign to support such a product introduction. Learning from this experience, changing the status of zinc to OTC will be critical to support the product introduction since it will allow pharmaceutical manufacturers to more widely distribute the product (i.e. in channels such as grocery stores) and pursue commercial marketing activities.

**Details**
Leading pharmaceutical manufacturers in the ORS and zinc market will be encouraged to introduce a co-packaged product into the market to increase the awareness, use and availability of both products for diarrhea treatment. Concurrently, state governments will be encouraged to procure a co-packaged product for public health facilities and ASHAs for the same reasons. These efforts will be closely aligned with the proposed demand generation activities outlined in Intervention 1. This will require building consensus amongst government institutions, development partners and professional bodies (i.e. IMA, IAP) followed by formal documentation to the Drug Controller General of India (DCGI) to facilitate decision-making within the core consultative committee. Introduction of the co-packaged product in the private market will draw upon the experience of an India-based NGO who has introduced a co-packaged product in the public sector channels (Primary Health Centers, ASHA workers, Anganwadi Workers) of 5 districts in Bihar. To date, the organization has distributed 900,000 units of the co-packaged product, which includes 2 large sachets of ORS (21.8g) and 14 tablets of zinc.

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44 Social Marketing Zinc to Improve Diarrhea Treatment Practices - Findings and Lessons Learned POUZN
45 Social Marketing Zinc to Improve Diarrhea Treatment Practices - Findings and Lessons Learned POUZN
Required Activities

**Activity 2.1 Position Paper**: Publication of a position paper by the IAP and WHO outlining the importance of zinc uptake among children and advocating for its OTC status can be facilitated to build general momentum and influence the final decision by the DCGI.

**Activity 2.2 Consensus Building**: Conferences with all stakeholders (suppliers, development partners) including representatives from the office of the DCGI can be held specifically to build consensus for the OTC status of zinc.

**Activity 2.3 Assess market potential and develop “business case” for co-packaged product**: Research will be conducted to assess the market potential for an ORS and zinc co-packaged product. This includes analysis of historical sales trends and meetings with pharmaceutical companies and state governments to gauge interest.

**Activity 2.4 Establish forecast and profile for co-packaged product**: Based on the assessment of the market potential for a co-packaged product, a forecast will be created to influence buy-in from pharmaceutical manufacturers and state governments. The forecast will take into account the impact of the proposed demand generation activities and potential public sector tenders on sales. Further, the ideal features of a co-packaged product will be outlined in a product profile document to share with pharmaceutical manufacturers. Drawing from past efforts, this profile should include: cost-effective packaging, ORS flavors, dispersible & taste-masked zinc tablets, and a clear treatment instruction pamphlet to encourage adherence.

**Activity 2.5 Negotiate volume-based price with contract manufacturer(s)**: Since most pharmaceutical manufacturers outsource the production of ORS and zinc to contract manufacturers to leverage volume-based cost efficiencies, a co-packaged product will be negotiated with this intermediary under similar conditions. Achieving volumes sufficient to offset potential increased packaging costs will be critical.

**Activity 2.6 Obtain buy-in from leading pharmaceutical manufacturers and influence tender practices of state governments**: The business case for a co-packaged product will be presented simultaneously to leading pharmaceutical manufacturers in the ORS and zinc markets and state governments, as a signal to both sectors of the pending change in standard packaging for diarrhea treatment. Further, pharmaceutical manufacturers will be offered the option to use a standard government-endorsed logo on the product, designed to offer credibility and influence caregiver adoption.

**Activity 2.7 Register co-packaged product with Drug Controller General of India (DCGI)**: Once buy-in has been achieved from a subset of targeted pharmaceutical manufacturers, the co-packaged product will be registered with the DCGI and issued a license allowing public sale. This license has already been issued to an existing India-based NGO for a pilot project in Bihar, India, illustrating limited barriers to entry.

Critical Considerations

**ORS market landscape**: The ORS market is dominated by one pharmaceutical manufacturer despite participation in the market by over 30 companies. In some cases, ORS has become synonymous with the brand of this particular pharmaceutical manufacturer. Achieving buy-in from this company will be critical; otherwise, there is a risk of the co-packaged product being crowded out by the dominance of this brand.

**Price Impact**: Leading pharmaceutical suppliers feel that there will be an increase in the price of zinc products immediately after zinc is granted OTC status, as the cost of marketing an OTC product is typically passed on to the consumer until the product crosses a certain sales volume threshold. However, with the increasing volumes, the competitive forces in the market also increase, bringing down the price of the product. Further, given the number

46 Interview with leading contract manufacturer in India

of ORS and zinc brands in India, the co-packaged product will have to be competitively priced in comparison to the individual products in order to achieve uptake. Research has indicated that a co-packaged product (2 large ORS sachets, 14 tablets of zinc) can be procured from a pharmaceutical manufacturer for Rs. 18 ($0.36 USD) and sold at the retail level for Rs. 26.14 ($0.52 USD). This is 50 - 65% less than purchasing the individual products.

**Product Quality:** Given the currently low and inconsistent sales volumes (zinc market is only worth $4.1 million) and the intensified competition (>33 zinc manufacturers) in the zinc market, manufacturers would not like to introduce a sub-standard product (non taste-masked, non dispersible) due to the fear of losing market share; moreover, about 85% of zinc products are sold in a syrup formulation, which must contain sugar to make it palatable for children.

**Lessons Learned**

1. **Packaging:** The design of the packaging for the co-package of ORS and zinc should balance cost and aesthetics. Too many colors on the packaging can significantly increase cost, while too few colors and limited images may deter caregivers from purchasing.

2. **Standard Logo:** The diarrhea-focused “Saathi Bachpan Ke” campaign in India used a standard logo to unify disparate aspects of the strategy. The logo was offered to pharmaceutical manufacturers to use on the packaging of ORS, and reinforced in all mass media and print materials. Partners reported that association with the campaign and logo enabled the company to be seen as committed to child health.

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**Intervention 3: Establish partnerships with pharmaceutical manufacturers to expand the distribution of ORS and zinc to rural markets**

**Rationale**

Currently, the distribution channels of leading ORS and zinc manufacturers only extend to Class I and Class II towns, as they are constrained by limited capacity to invest in rural sales and marketing and have limited visibility to the market potential of rural areas. As a result, availability of ORS and zinc at retail channels in micro-interior and rural areas is inconsistent. Given that these areas confront the highest burden of diarrhea and most commonly access healthcare from the private sector, extending the distribution of ORS and zinc to rural areas is critical to achieving the outlined targets. Public-private partnerships between NGOs and pharmaceutical manufacturers are recommended in industry reports as an effective strategy to encourage increased distribution, since initial costs and risks are shared. In particular, this intervention will aim to build on the successful partnership model being tested by an international NGO in Uttar Pradesh and Gujarat to expand access to ORS and zinc in rural areas, and leverage the lessons and best practices of the model to implement at broader scale.

**Details**

Partnerships with 3 to 5 leading ORS and zinc manufacturers will be forged to increase distribution of the products to private sector providers (i.e. chemists, RMPs) in rural areas targeted for demand generation activities. Those manufacturers that have decided to introduce an ORS and zinc co-packaged product will be prioritized. A business case outlining the market potential of increased distribution of ORS and zinc to the targeted rural areas, accounting for the impact of demand generation activities, will be used to persuade pharmaceutical manufacturers to engage in a Memorandum of Understanding (MOU). A cash-based incentive structure will be considered following the market potential assessment to support capital costs of increasing distribution and accelerate reaching the breakeven point.

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48 IMS October Sales Survey
**Required Activities**

**Activity 3.1 Assess market potential of a public-private partnership (PPP):** Data from existing PPPs aimed at increasing the distribution of drugs to rural areas will be assessed to better understand the market scope of such strategy.

**Activity 3.2 Establish business case for rural distribution:** Data from the market assessment, in addition to assumptions on the impact of proposed demand generation activities, will be used to devise a business case that outlines a sales forecast for ORS and zinc in targeted rural areas. Consumer insights gained from KAP studies and RMP listing data will also be included in the business case, where possible. This analysis will be used to persuade leading pharmaceutical manufacturers to engage in a PPP.

**Activity 3.3 Forge partnerships with pharmaceutical manufacturers:** The business case will be presented to leading ORS and zinc manufacturers, particularly those committed to developing a co-packaged product, to forge a PPP designed to increase distribution to areas targeted for demand generation. Once buy-in has been achieved, pharmaceutical manufacturers will be required to enter into an MOU that outlines distribution commitments in further detail (i.e. areas, frequency of distribution, product quality, product price). A one-time incentive will be considered to subsidize the initial costs of increasing distribution to rural areas, which may be used to offset human resource costs.

**Activity 3.4 Monitoring and Evaluation:** Commitment to the MOU will be monitored by evaluating the availability and sales of ORS and zinc brands at private sector retailers in targeted rural areas. Spot checks and mystery shopping techniques will be considered.

**Critical Considerations**

**Duration of MOU:** The duration of the MOU should closely align with rigorous analysis of a realistic break-even point for increasing distribution to rural areas, otherwise sustainable availability of ORS and zinc may be compromised.

**Lessons Learned**

1. **Brand-agnostic demand generation activities can encourage distribution and investment in commercial marketing:** In the diarrhea-focused social marketing campaign “Saathi Bachpan Ke,” partnerships were formed with nine leading ORS manufacturers in India to stimulate growth and expand distribution of the product to the program areas. As part of the MOU signed, manufacturers committed to participating in program activities, managing the quality of ORS products produced, and increasing availability to retail channels in the program areas. In return, demand generation activities were conducted to increase usage and sales of ORS. To remain competitive, manufacturers independently invested a total of Rs 5 million in brand-specific commercial marketing activities.

2. **Rural sales and marketing of one brand may attract participation from other brands:** Demand generation activities for ORS and zinc currently being conducted through an exclusive PPP in Uttar Pradesh and Gujarat, between an NGO and two small pharmaceutical companies, have found that efforts have stimulated the entry of additional pharmaceutical companies.
**Intervention 4: Change prescribing behavior of Rural Medical Practitioners**

**Rationale**

Only about 20% of health care services are delivered by the public health sector, while the private sector delivers the balance of 80%. As discussed previously (barriers section), the private sector primarily consists of unqualified, self-styled health care practitioners, called Rural Medical Practitioners (RMPs), who exist in very large numbers in rural areas and are the preferred channel for first line treatment. An effort to train RMPs on the effective management and treatment of diarrhea, pneumonia and malaria, followed by endeavors to constantly detail these providers using behavior change techniques, can significantly improve the uptake of the recommended first-line treatments and convert knowledge into practice. This intervention is based on the model of an international NGO operating in select districts in Uttar Pradesh and Gujarat, initiated in early 2008, when only 3.4% of RMPs in the study knew about zinc and about 87% RMPs prescribed antibiotics for all cases of diarrhea. Within eight months of the rigorous detailing efforts, virtually all RMPs were aware of zinc treatment for diarrhea and about 89% recommended it for diarrhea treatment.

**Details**

RMPs can be trained to the same level as the public sector community healthcare workers (CHWs) as these two groups have the same level of education, specific chapters of ASHA trainings on effective diagnosis and treatment of high burden diseases (pneumonia, malaria and diarrhea) can be expanded to include RMPs. The maximum impact of this intervention can be achieved in the states of Uttar Pradesh, Madhya Pradesh and Bihar, as the concentration of RMPs is extremely high in these states. However, gathering alternative resources to facilitate these trainings is vital for the overall success of this intervention due to the shortage of public sector resources given the high population of these states. Furthermore, as most pharmaceutical manufacturers limit their detailing efforts to tier I or tier II towns, most RMPs and pharmacists in rural areas are not aware of the new and appropriate products to be used for the treatment of common childhood conditions. An intrapersonal approach to behavior change is critical in the introduction phase of new concepts like zinc, amoxicillin and AL for the treatment of diarrhea, pneumonia and malaria.

**Required Activities**

**Activity 4.1 Mapping Exercise:** RMPs are generally difficult to locate as they operate from either home or a modest facility; in order to observe greatest impact from this intervention, a mapping exercise to identify the location of RMPs will be conducted so that maximum number of RMPs can be reached.

**Activity 4.2 NGO Staff Training:** Selected NGO volunteers will be trained on GOI and WHO appropriate treatment guidelines for pneumonia, malaria and diarrhea; these trained volunteers will then be tasked to train RMPs. RDTs can be made available at the training venue for RMPs to buy immediately after the training sessions.

**Activity 4.3 Information Sharing:** An effort will be rolled out to inform all the identified RMPs about the day and venue of the training; posters and flex-boards will be used to share this information. In addition, NGO workers will also visit each RMP and share the importance of these training sessions through intrapersonal communication.

**Activity 4.4 Accreditation:** To further enhance participation, RMPs can also be offered a special accreditation (‘certificate signed by a government official’) for successfully completing the training workshop.

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50 "Not Enough Here-Too Many There- Health Workforce in India." WHO. Web
<http://www.whoindia.org/LinkFiles/Human_Resources_Health_Workforce_in_India_-_Apr07.pdf>.


52 About ASHA—"Ministry of Health & Family Welfare-Government of India"- Government of India.
Activity 4.5 NGO Management: One NGO per district (~100,000 RMPs) can be assigned the task of training and detailing RMPs in that region. Given the degree of complexity and the size of the task, every NGO can be asked to assign 2-3 staff members dedicated to the training and detailing efforts. One project manager per district can be assigned to supervise the activities of the field force and to track progress of the effort overall.

Activity 4.6 Message Creation: Specific messages on the preventive benefits of using zinc for diarrhea treatment and the importance of effective diagnosis for malaria and pneumonia will be crafted before launching the detailing effort. Simple yet effective messages will delivered by the field force about the correct use and dosage of ORS and zinc and about the recommended treatment for pneumonia (amoxicillin) and malaria (AL). RMPs can also be detailed on the accurate technique of using RDTs for diagnosing malaria during a detailing session.

Activity 4.7 RMP/Pharmacy Detailing: A field force will be used to visit RMPs to reinforce the key messages of the ASHA trainings on the effective diagnosis and treatment for diarrhea, pneumonia and malaria. To ensure abundant stocks/availability of the products that RMPs are detailed on, the field force will also reach out to pharmacists and share the same information about appropriate treatment with them to influence their stocking decisions.

Activity 4.8 Detailing Tools/Message Retention: Videos and letters from KOLs highlighting the appropriate treatment for diarrhea, pneumonia and malaria can be used by the field workers to influence providers to follow the standard treatment guidelines. The field team will also put up IEC/BCC posters at RMP clinics and pharmacies to increase the overall retention of the targeted message.

Critical Considerations

Training Modules: To avoid duplication of efforts, the ASHA modules will be leveraged to train RMPs. However, before this can take place, the ASHA modules have to be updated to include the use of zinc, amoxicillin and AL as first line treatment for diarrhea, pneumonia and malaria.

Training Duration: The duration of the training should be limited to 1-2 days to minimize the opportunity cost for RMPs.

Training strategy: Due to the anticipated large quantity of RMPs in the target states (Uttar Pradesh, Madhya Pradesh, and Bihar), a selection strategy must be established to effectively manage time and resources. Criteria considered may include average weekly volume of prescriptions, proximity to chemist, and willingness to be trained.

Product supply: Training and detailing efforts should precisely align with the availability of recommended first-line treatments at private sector retail channels. A gap in supply availability can quickly compromise the credibility of the detailer, and negate all RMP behavior change efforts.

Detaller Monitoring: Previous efforts have shown that frequent monitoring of detailers is required to ensure that information is being disseminated to RMPs in a way that encourages behavior change. By sending daily SMS updates on performance metrics, and having a hands-on field management team, poor performance can be quickly addressed and improved.

Lessons Learned

1. Reinforcement of task force to accredit RMPs: In 2007, the GOI constituted a special task force to examine the Accreditation, Training and Integration of Private Rural Medical Practitioners. The task force also suggested engaging these informal providers by facilitating theoretical and practical trainings, but no progress has been made on the recommendations of this task force. An effort to reconstitute this task
force and revisit its recommendation can be instrumental in integrating RMPs in the overall health care system.\(^5\)

2. **Contract for behavior change:** Learning from the INFECTOM project in Pakistan, an approach to have RMPs sign specific contracts committing to making specific changes in behavior can also be considered as a part of this activity; the prescription of ORS as first line treatment for diarrhea rose from 55% to 81%\(^6\) in Pakistan after this adoption of this approach.

<table>
<thead>
<tr>
<th>Intervention 5: Change prescribing behavior of Accredited Social Health Activists (ASHAs)</th>
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<tbody>
<tr>
<td><strong>Rationale:</strong></td>
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<tr>
<td>ASHAs are the primary channel for public health delivery at the community level; however, their training modules and drug kits do not currently include the recommended treatments for diarrhea, pneumonia, and malaria in children. This is the result of outdated treatment guidelines, which directly inform the content of training modules and commodity procurement plans. Changing the treatment guidelines at the national level will have a trickle-down effect to the state-level since NRHM will share the revised treatment guidelines with the state offices, which then have the green light to allocate a portion of their “flexi-pool budget” to procure the recommended commodities.</td>
</tr>
<tr>
<td>The recommended policy changes should be followed by training ASHAs on correct case management of diarrhea, pneumonia, and malaria, and detailing ASHAs to reinforce training and change prescribing practices. Previous studies have found that ASHAs often lack the knowledge to adequately carry out their responsibilities. This is a result of limited refresher trainings to update skills and address questions and reservations, and few job aides to reference. Periodic assessments of ASHA knowledge levels, in addition to performance evaluations, are recommended to measure the effectiveness of training and customize future instruction.</td>
</tr>
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<tr>
<th>Details</th>
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<tbody>
<tr>
<td>Accredited Social Health Activists (ASHAs) are Community Health Workers who were originally conceptualized as mere ‘health promoters’ but are increasingly assuming the role of service providers. They are equipped with drug kits, procured by individual state governments but funded by NRHM, which currently contain ORS for diarrhea and chloroquine for malaria. In some cases, Auxiliary Nurse Midwives (ANMs) supply zinc and cotrimoxazole tablets to ASHAs after receiving them through the Reproductive and Child Health Drug Kit scheme. In Central and Northeast India, ASHAs in districts supported by the World Bank and the Global Fund are receiving artesunate-sulfadoxine-pyrimethamine (AS-SP) and rapid diagnostic tests (RDTs) to treat uncomplicated Plasmodium falciparum malaria.</td>
</tr>
<tr>
<td>To standardize the inclusion of zinc, amoxicillin and AL as first line treatments for community case management of diarrhea, pneumonia and malaria, a recommendation to change the treatment guidelines must be conveyed to the Ministry’s Child Health Division’s Technical Resource Group (TRG) and include details on the specifications of the treatment. Once the policy change has been instituted, the revised treatment guidelines will be with NRHM offices in states with the highest burden of child mortality. This then allows the state to procure the recommended treatments and include them in their state-level budget. Further, a revision in the treatment guidelines signals the National Health System Resource Center (NHSRC) to revise the training modules and reporting formats/documents for the ASHAs. Resources will have to be leveraged to conduct training for ASHAs on the updated modules.</td>
</tr>
</tbody>
</table>

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\(^6\) Global Communication Diarrheal Diseases web <http://www.globalhealthcommunication.org/tool_docs/76/behavior_change_perspectives...-_chap_4_-_diarrheal_diseases.pdf>
**Required Activities**

**Activity 5.1 Treatment Guideline Recommendation:** Specifications of new treatments to be added to the ASHA modules have to be submitted to the TRG, which meets once a year, for consideration. This submission must include details on dosing, product regulatory status, formulation, shelf life, etc. Institutionalizing this change is anticipated to take six months. Once complete, the products will be eligible for procurement at the state and federal level using NRHM budgets.

**Activity 5.2 Planning and Budgeting:** The federal and state-level governments share the cost of procuring medicines for ASHA drug kits. The federal government covers 85% of the cost and the state government covers 15% of the cost. Ensuring that a sufficient budget is allocated for the procurement of the recommended treatments added to the ASHA modules – zinc, amoxicillin and AL – before the beginning of a new fiscal year (March-April), will be critical to reduce delays in changing ASHA prescribing behavior.

**Activity 5.3 Revamp ASHA training modules:** Once the TRG approves the recommended changes for the ASHA modules, supporting materials, including the training manuals (modules 6 and 7 include diarrhea, pneumonia and malaria), reporting formats and health management information systems will be updated. The NHSRC will lead this effort in collaboration with relevant partners.

**Activity 5.4 ASHA training roll out:** A one-day refresher training course will be offered to all ASHAs using a condensed syllabus highlighting the recommended treatment changes for diarrhea, pneumonia and malaria. The State Health Systems Resource Centres are responsible for planning and executing trainings at the district level.

**Activity 5.5 Reinforcement through Detailing:** The detailing program proposed for RMPs (see Intervention 4) will be extended to ASHAs to ensure that knowledge gained from training is put into practice.

**Activity 5.6 Monitoring and Evaluation:** Ongoing monitoring of ASHA prescribing behavior will be monitored through data captured in the programs health management information system, in addition to caregiver surveys and mystery patient programs.

**Critical Considerations**

**Overlap with IMNCI:** The Integrated Management of Neonatal and Childhood Illness (IMNCI) program is the main child health strategy under RCH in NRHM and consists of a 12-day training curriculum, which includes the recommended treatments for diarrhea, pneumonia and malaria. State governments have been planning to roll out this training program to all ASHA workers, Anganwadi workers (AWW) and Auxiliary Nurses, but logistical challenges have slowed progress. In Madhya Pradesh, only 18 districts have been trained on IMNCI, of the 50 districts in the state. Coordinating with the plans for continued IMNCI rollout will be critical to avoid duplication of efforts, resources and trainings for ASHAs on the same topics.

**5. Budget**

The preliminary budget for India’s Essential Medicines Initiative—focused on the three highest burden states of Uttar Pradesh, Madhya Pradesh and Bihar which serve a total under-five population of 59M children— is estimated to cost USD 119M over four years. The projected expenses for each of the five primary interventions are outlined below, with the most significant expense expected for the procurement the recommended drugs (amoxicillin, ACT-AL, zinc and ORS) and associated training of ASHA workers. However, it is important to note that this initial budget estimate is inclusive of costs that will be leveraged from government and partner contributions; in early 2012, these opportunities for leverage will be further refined, and the related budget estimates, and projected gaps, will be updated accordingly.
### Budget summary per intervention - Diarrhea, pneumonia and malaria treatment scale-up

<table>
<thead>
<tr>
<th>Intervention 1 - Demand generation &amp; IEC/BCC</th>
<th>2012 (Year 1)</th>
<th>2013 (Year 2)</th>
<th>2014 (Year 3)</th>
<th>2015 (Year 4)</th>
<th>Total 2012-2015</th>
</tr>
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<tbody>
<tr>
<td>Activity 1.1 Review of caregiver/provider knowledge, attitude and perception</td>
<td>$331,320</td>
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<td>Activity 1.2 Communication Strategy</td>
<td>$333,080</td>
<td>$300,000</td>
<td>$333,080</td>
<td>$300,000</td>
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<td>Activity 1.3 Production of communication tools</td>
<td>$1,287,000</td>
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<td>Activity 1.4 Media Buy Direct Communication &amp; Free Sampling</td>
<td>$4,333,010</td>
<td>$4,162,510</td>
<td>$4,327,510</td>
<td>$4,162,510</td>
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<td>Activity 1.5 Monitoring &amp; Evaluation</td>
<td>$495,000</td>
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<td><strong>Intervention 1 Total</strong></td>
<td>$6,779,410</td>
<td>$5,962,510</td>
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<tr>
<th>Intervention 2 &amp; 3 - Zinc to Over-The-Counter (OTC) &amp; Pharma partnership for co-pack and increased distribution</th>
<th>2012 (Year 1)</th>
<th>2013 (Year 2)</th>
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<tr>
<td>Activity 2.1 Build a consensus on OTC status of Zinc</td>
<td>$19,250</td>
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<td>Activity 2.3 OTC Application</td>
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<td>Activity 3.2 Supplier Engagement</td>
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<td>Activity 3.3 Government Engagement</td>
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<tr>
<th>Intervention 4 - Training for RMPs and NGO Detailing</th>
<th>2012 (Year 1)</th>
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<tr>
<td>Activity 4.1 NGO Contracting</td>
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<td>Activity 4.2 NGO Training</td>
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<td>Activity 4.4 RMP Detailing</td>
<td>$1,514,260</td>
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<td>$7,783,629</td>
<td>$2,877,765</td>
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<tr>
<th>Intervention 5 - Zinc, amoxicillin and arteether-lumefantrine available ASHA drug kits and update ASHA training modules</th>
<th>2012 (Year 1)</th>
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<th>2014 (Year 3)</th>
<th>2015 (Year 4)</th>
<th>Total 2012-2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity 5.1 Update the ASHA training modules and add technical specifications for the products</td>
<td>$17,160</td>
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<td>Activity 5.2 Inform states to include changes in annual action plan 2012-2013 (flexi-pool budget)</td>
<td>$6,385,080</td>
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<td>Activity 5.4 Monitor procurement/supply chain management and program indicators</td>
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<td>Activity 5.5 M&amp;E Activities</td>
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<td>$22,677,088</td>
<td>$20,328,973</td>
<td>$15,631,330</td>
<td>$69,552,525</td>
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