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Operation ASHA: An Effective, Efficient, and Scalable Model for Tuberculosis Treatment

> "I know the color of that blood; it is arterial blood. I cannot be deceived in that color. That drop of blood is my death warrant. I must die."
>
> —John Keats, 1820. (The British poet died of tuberculosis at the age of 25)

The year was coming to a close, and the founders of Operation ASHA (OpASHA), CEO Sandeep Ahuja and President Shelly Batra, were looking back on their accomplishments; 2012 had been a great year for the nongovernmental organization (NGO). OpASHA had won the *Wall Street Journal* Technology Innovation Award in the health care category. Bill Gates tweeted "@MSFTResearch has teamed up with @OperationASHA to fight#**TB** in India. Better data = better outcomes." And Ahuja and Batra were invited to a number of national and international forums to talk about their work on tuberculosis treatment in India. The publicity enhanced OpASHA's profile, but Ahuja and Batra worried about sustainability. The government of India provided funding for diagnostics and medicines, but financial support for health care start-ups was rarely offered, and funding gaps constrained OpASHA's scalability. While lobbying the government for support was one route, Ahuja wondered if OpASHA could leverage its key assets and capabilities to generate additional sources of revenue. As multidrug-resistant TB (MDR-TB) began to rear its ugly head in India, Ahuja and Batra questioned if OpASHA, which until now had focused its efforts on drug-susceptible TB, should take up the task of addressing drug-resistant strains. Not only would OpASHA need a modified service delivery model, but its financing needs would be also higher, increasing the urgency to find pathways to sustainability. Parking their car at the shopping center, Batra and Ahuja proceeded to their favorite restaurant for lunch.

Tuberculosis

Tuberculosis (TB) is an infectious disease caused by *Mycobacterium tuberculosis*. The bacterium commonly affects the lungs, leading to pulmonary TB, but it can affect other parts of the body. Most infections in humans are asymptomatic (latent), especially in otherwise healthy persons; the human immune system "walls off" the bacteria. About 1 in 10 latent infections eventually progresses to active disease, which if left untreated can be fatal. Symptoms of pulmonary TB include coughing, sometimes with sputum or blood,

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chest pains, weakness, weight loss, fever, and night sweats. The disease is spread from person to person via droplets from the throat and lungs through sneezing and coughing. (See **Exhibit 1** for images of healthy and infected lungs).

About 9 million new TB cases were diagnosed in 2011, and 1.4 million people died of the disease.[1] Over 95 percent of TB deaths occurred in low- and middle-income countries, and it was among the top three causes of death for women ages 15–44.[2] Asia and sub-Saharan Africa accounted for 60 percent to 65 percent of all TB prevalence (see **Exhibit 2**).

Diagnosis

A complete diagnosis of TB consisted of a medical history review, physical exam, chest X-ray, and microbiologic smears and cultures. In practice, however, only one or two of these tests were actually used. The accuracy of the tests was measured by *sensitivity*—the ability to accurately detect who had TB, and *specificity*—the ability to accurately determine who did not have TB.

The Mantoux tuberculin skin test (TST) was often used to test for latent tuberculosis infection, but not active disease.[i] Acute pulmonary TB could be detected using a chest radiograph. Studies, however, demonstrated that the X-ray test had high specificity and low sensitivity—it could rule out TB infection better than it could confirm it. Serological tests for TB that entailed looking for antibodies in the blood were difficult to administer, and they often yielded inaccurate results. The World Health Organization (WHO) warned that these tests should not be used to diagnose active TB, and some countries had banned their use.

The more commonly recommended was sputum smear microscopy, which tested for acid-fast-bacilli (AFB) on sputum samples. To do the test, a series of special stains were applied to the smear—a very thin layer of the sputum sample on a glass slide—and examined under a microscope for signs of the TB bacteria. Sputum smear microscopy was inexpensive and simple, and workers could be trained to do it relatively quickly. In addition, the results were available within hours. Test sensitivity was only about 50 percent to 60 percent, but it could be improved with repetition. In countries with a high prevalence of both pulmonary TB and HIV infection, the detection rate could be even lower. Many people with TB and HIV coinfection had low levels of TB bacteria in their sputum and were recorded as sputum negative.[3]

For a definitive diagnosis of TB, a culture test was used to provide results on drug susceptibility and resistance. The main drawback was that the test took six to eight weeks to produce a result because the culture had to be grown in a laboratory. In addition, the test required expensive specialized equipment operated by trained personnel.

Treatment

Latent TB was treated using a single antibiotic while a combination of antimicrobial drugs, taken typically over a six- to eight-month period and delivered in two phases, were used to treat active TB. Treatment started with an intensive phase that lasted two to four months and was followed by a continuation phase, which lasted four months. (See **Exhibit 3** for the treatment categories, drugs, doses, and treatment regimens).

The TB treatment regimen had side effects including nausea, stomach pain, and headaches. The duration of the treatment regimen, severity of the side effects, and easy access to treatment facilities were some of the key reasons for treatment default. Incomplete treatment, not taking medication as prescribed, and low-quality medication all caused TB to progress to MDR-TB.

[i] The TB skin test involved injecting a small amount of fluid (called tuberculin) into the skin at the lower part of the arm. If, after 48 to 72 hours, the skin reacted by swelling, the person was most likely infected with tuberculosis bacteria.

Drug-Resistant TB

Resistance arose from genetic mutations, many of which could be detected using the molecular test Xpert MTB/RIF based on the GeneXpert platform.[ii] GeneXpert identified more than 98 percent of active TB infections—many that sputum smears had missed.[4] It could even determine whether bacteria were resistant to rifampicin, the most effective and widely used component of the four-drug cocktail commonly prescribed for TB. The Xpert MTB/RIF test was not only accurate, but results were available within a day. This was in sharp contrast to culture-based tests that took an average of 75 days.[5] In December 2010, WHO endorsed the technology and released recommendations and guidance for countries to use the new test. While treatment could commence following the test, WHO recommended conventional microscopy culture and drug sensitivity testing to monitor treatment progress and detect resistance to drugs other than rifampicin.[6]

At approximately INR[iii] 1.4 million (25,000 USD), the GeneXpert machine was expensive for a small NGO. Each test required a single-use cartridge at an additional per-test cost of approximately INR 1,083 (20 USD). Other operational challenges included an 18-month cartridge shelf life, the need for a stable electric supply, and annual machine recalibration.[7]

Treating MDR-TB required second-line therapy that lasted 24–27 months, including some in-hospital treatment. Many of the second-line drugs were injectables, and at more than INR 216,640 (4,000 USD) for a typical regimen, the drugs were significantly more expensive and had stronger side effects than first-line drugs. When the second-line therapy failed, the disease morphed into extremely drug-resistant TB (XDR-TB), a condition that had been reported in 70 countries. (See **Exhibit 4** for TB types.)

WHO DOTS Model

In 1999, WHO released its recommended guidelines for TB treatment, known as DOTS (directly observed treatment, short-course). The strategy consisted of five components:

- Government commitment, including political will at all levels, as well as a centralized and prioritized system of TB monitoring, recording, and training
- Case detection by sputum smear microscopy
- Standardized treatment regimen *directly observed* by a health care worker or community health worker for at least the first two months
- A regular drug supply
- A standardized recording and reporting system that allowed assessment of treatment results

WHO's DOTS model was widely publicized across the world using the Stop TB partnership.[8] The first Global Plan to Stop TB, a five-year plan for 2001–2005, was launched with the objectives of expanding DOTS and adapting it to MDR-TB and persons infected with both TB and HIV; improving tools by developing new diagnostics, new drugs, and new vaccines; and strengthening the global partnership. A Global Drug Facility (GDF) was established to assist countries in the procurement of high-quality anti-TB drugs. The Green Light Committee was created to promote access to, and rational use of, second-line drugs against MDR-TB strains, and to secure price reductions for some second-line drugs. The overall program was successful in rolling out DOTS in 22 high-burden countries, some of which were close to reaching a detection rate of 70 percent.

To sustain the momentum, a new plan for 2006–2015 with a budget of $56 billion was launched with the goal of halving TB prevalence and deaths by 2015 from 1990 levels.[9] The plan set targets that included a

[ii] The GeneXpert platform was developed in 2002 with support from the Department of Defense to test for biological threats such as anthrax using DNA analysis. Recognizing the diagnostic capabilities of the platform, researchers at medical centers throughout the world began to assess the machine's effectiveness in diagnosing tuberculosis with funding from the Bill and Melinda Gates Foundation, the Foundation for Innovative New Diagnostics, and the National Institutes of Health.

[iii] Indian currency; approximately 1 US dollar = INR 54 (March 2013).

new drug by 2010 with a short (one–two months) regimen by 2015, a point-of-care diagnostic test by 2010, and a new, safe, effective, and affordable vaccine by 2015. The plan also released a patient's charter that provided for a patient-centric model of care and several patients' rights, including:

- The right to free and equitable access to TB care
- The right to receive medical advice and treatment with dignity
- The right to information about availability of health care services for TB, medical diagnosis, and all aspects of treatment plan, drugs, and dosages
- The right to a second opinion
- The right to confidentiality
- The right to justice
- The right to organization
- The right to job and food security[10]

Tuberculosis Management in India

The National TB Program in India

With estimates of 500,000 deaths and 2.5 million new cases each year,[11] Lady Mountbatten[iv] declared in her 1948 address to the Tuberculosis Association of India, "Tuberculosis is one of the greatest scourges of India." As 2013 approached, with 1.96 million cases annually, the needle appeared not to have moved much. Undoubtedly, the country had made great strides in TB control, yet India had the highest TB burden in the world accounting for more than a fifth of global incidence (see **Exhibit 5**). TB in India was not only a major public health problem, but it had severe economic and social implications. Infected people could not go to work and lost their means of livelihood. The direct and indirect costs of TB amounted to an estimated INR 1.2 trillion (23.7 billion USD).[12] Every three minutes, two people lost their lives to TB. Some 100,000 infected women were thrown out of their homes annually to die of disease and starvation, while approximately 300,000 children dropped out of school because they or one of their parents had TB.[13]

Since the dawn of the 20th century, India had undertaken a number of efforts to combat TB, including public awareness campaigns, construction of patient facilities, research on treatment and control, and vaccination campaigns. (See **Exhibit 6** for a list of related efforts.) By the early 1990s, however, these efforts were still falling short. A 1992 review of the National TB Program (NTP) revealed that only 30 percent of patients were diagnosed and, of those, only 30 percent were treated successfully. The review, conducted by the government of India with assistance from WHO, highlighted India's managerial weaknesses, overemphasis on X-rays for diagnosis, and frequent drug shortages that led to low treatment completion rates. The government revitalized the national TB program with its launch of the Revised National TB Control Program (RNTCP) in 1993. Designed to deliver services through the existing public health infrastructure, RNTCP was based on WHO's DOTS program. It also used a national program for drug procurement, allocated drugs for the entire treatment course, decentralized diagnostics and treatment, provided additional supervision with subdistrict-level TB units, and introduced systems for monitoring and evaluation. After pilots across five states, RNTCP was rolled out as a national program in 1997. Responsibility for TB management was decentralized to the district and subdistrict levels with new diagnostic infrastructure supported by human resources to provide quality control, supervision, and monitoring. (See **Exhibit 7** for the district-level organization structure.)

[iv] Born in 1901 as Edwina Cynthia Annette Ashley, Lady Mountbatten was married to Lord Louis Mountbatten, the last Viceroy of preindependence India. After independence, Lord Mountbatten became the first governor general of India.

In 2006, the government declared that it had attained 100 percent DOTS coverage. By 2009, with a budget reaching $100 million, the country's TB management boasted four National Reference Laboratories supporting one Intermediate Reference Laboratory in each state and approximately 13,000 designated microscopy centers (DMC). The government reported treatment completion success rates of 87 percent for new smear-positive cases and a default rate of 6 percent (see **Exhibit 8**), successfully meeting the Stop TB targets. But drug-resistant TB was rearing its ugly head. In 2010, only 5 percent of smear-positive retreatment patients who needed drug susceptibility testing were screened, and only 2 percent of the estimated 99,000 patients with MDR-TB received second-line drug treatment through the RNTCP.[14]

Challenges of TB Control in India

A number of studies highlighted issues with program administration, monitoring, and reporting systems within TB management. In a 2004 study, the National Tuberculosis Institute in Bangalore reported a cure rate of just 67.9 percent for smear-positive TB cases—much less than the claimed rate of 85 percent to 86 percent by WHO and RNTCP[15]—sowing strong doubts in the government reporting system. While RNTCP claimed to provide nationwide coverage availability, diagnosis and treatment were not accessible in all regions. Distance to clinics, health worker absenteeism, inconvenient clinic hours, a lack of respectful communication between staff and patient, and inadequate counseling relevant to drug side effects were some of the common reasons why patients stopped treatment or received inadequate treatment.[16] In another study, 8 percent of patients missed treatment because the appropriate medicines were unavailable.[17] In yet another study, local experts estimated that 1 percent of the TB drugs procured by the government were substandard.[18] The same study revealed other weaknesses such as patients' inability to describe how they should take their medications after they left the health facility, as well as mismatches between stock records and actual inventories.

More important, the reported statistics also failed to reflect that more than half of all TB patients looked to the private sector for management of their disease. For example, in 2006, out of the INR 5 trillion (94 million USD) market for first-line, anti-TB drugs, only 25 percent of the drugs were purchased in the public sector. The remainder was consumed in the private sector, underscoring the importance of the private sector in TB treatment.[19]

In the highly unregulated private sector, poor diagnosis and inaccurate treatment regimens not only inflated costs for patients, but also delayed diagnosis, with potentially disastrous consequences. For example, the highly inaccurate serological test was usually the first line of diagnosis. Prescribed treatment regimens were highly questionable as well—one study concluded that:

"Only six of the 106 respondents wrote a prescription with a correct drug regimen. The 106 doctors prescribed 63 different drug regimens. There was tendency to overtreat with more drugs for longer durations. Only three of the 106 respondents could write an appropriate prescription for treatment of MDR-TB."[20]

Sociological and psychological factors also impacted the care-seeking behavior of patients in both rural and urban areas. TB carried a huge stigma in Indian society, which was reflected in the country's cultural beliefs about the disease's causes and its incurability. Patient beliefs regarding causes of TB included alcoholism, mental worry or stress, bad blood, heredity, promiscuity, witchcraft, divine retribution, and evil eye.[21] (See boxed insert "Perceptions of TB" for quotes from Indian citizens relevant to their cultural beliefs about TB.)

It was clear that TB control was not solely a medical problem; it was imperative that a social approach to correct the beliefs, biases, stigma, and ostracism associated with the disease be used in combination with accurate diagnosis and appropriate medical treatment.

Perceptions of TB:[22]

"Only when people are not respectful of social norms, killer diseases like TB and leprosy follow." (Emphasized by several people)

"It is impossible for a TB patient to get completely cured . . . Once a person gets infected, the disease will keep resurfacing," a woman said.

"You see, only bad women have this disease . . . those who drink, smoke, and have illicit relations with men . . . (The) community needs to boycott them completely as a form of punishment for their doing. This happens more in my village home, but here in (the) slums, people often have the tendency to tolerate women patients and be indifferent to them," according to one man.

"I got infected (with TB) at the time of childbirth . . . but I could not step out of my house for at least 45 days as per caste rules. Later, I went to the nearby doctor, who said I had TB," said a 22- year-old mother of two children.

"Finally, when blood came in my sputum, I confided to one of my close friends in the neighborhood and she told me that it could be TB . . . I went to the clinic and got myself registered without disclosing to my family . . . Soon I started to feel better. One day when my fiancé asked where I go daily with my friend, in my naiveness (sic), I told my fiancé in confidence since I knew he had suffered from the disease once. But to my horror, he told this to his parents and the marriage was called off," a teenager commented.

"When my husband heard about the disease, he immediately sent me back home, saying he did not want a sick and 'useless' wife with doubtful loyalty. At my village, I had no other means of treatment except the local traditional healer," a woman said.

PPM under RNTCP

Recognizing the need to involve the private sector, the government had incorporated public/private mix (PPM) as an important component in the RNTCP. In addition to engaging directly with public providers for TB treatment, RNTCP had engaged the private sector and NGOs under schemes that addressed TB control through advocacy, communication and social mobilization, sputum collection centers, sputum pickup and transport services, promotion of treatment adherence, improvement of TB control in urban slums, and others. For each of these services, RNTCP provided grants and other types of remuneration for services provided during initiation phases.[23]

Engaging the private sector, however, had not been without its challenges. A WHO report on TB control in India highlighted some of these challenges. Private practitioners and small NGOs found the intense supervision of RNTCP officials unpalatable and documentation requirements excessively burdensome. There was also concern about financial viability due to reported delays in payment of remuneration and incentives.[24] Reimbursement for detection and treatment under PPM was meager; INR 400 (7.39 USD) per patient was paid to medical doctors and INR 250 (4.62 USD) to other providers. There was also lack of trust between the government and the NGO community. In India, both had the reputation of being corrupt. Government officials worried that grants would not be used as intended, while NGOs claimed that government officials siphoned off portions of grants and remuneration. The absence of any classification system for NGOs made the task of providing remuneration to treatment facilities more difficult for district government officials. For those NGOs that did good work on the ground but faced difficulties with the bureaucracy, there were no problem resolution channels at the ministry, state, or central levels.

Public officials appeared to be wary of internationally funded NGOs that engaged in TB treatment. While such NGO projects ran well and achieved good results, most were eventually terminated due to a finite duration (usually three to five years) of funding. When the programs were terminated, patients were referred to government clinics for follow-up. Already overburdened, government clinics were usually unable to cope with the influx of patients, and performance dropped. An initial increase in performance followed by a degradation of performance did not reflect well on the management skills of district TB officers, making government officials wary of sanctioning similar projects in the future.

Other constraints to scaling the private sector partnership model included budgetary pressures, a lack of adequate staffing, and low priority for engagement with the private sector at district levels.[25]

External Support for TB Control

TB control in India was partially supported by grants from international aid organizations such as the United Kingdom's Department for International Development, The Global Fund, United States Agency for International Development (USAID), and the World Bank. The Global Drug Facility generated about half of all RNTCP's drug requirements. WHO provided technical assistance through a network of field-level consultants, who worked closely with district and state TB officers. In 2010, the Global Fund released a five-year, INR 10.2 billion (190 million USD) grant to India. The government of India was usually the principal recipient for such external grants. In addition to the government's central TB division, the other recipients were two main consortia—Indian Coalition Against TB (ICAT), the Indian affiliate of the International Union against TB, and World Vision-India.[26] These consortia in turn worked with 16 NGOs to implement the project. Beyond drug purchases, most of the international funding for TB control to the consortia went toward capacity building, systems, and case detection. For example, a film called Bulgham Bhai was produced and aired on national TV at a cost of INR 568 million (10.5 million USD). Funding for treatment was earmarked only for drug-resistant TB. Evaluation metrics for the projects included number of meetings held, number of awareness campaigns run, number of people made aware, and number of people trained. The main assumption was that system strengthening improved access and once the disease was detected, patients would avail themselves of free services available at government centers or local providers under PPM. Detection and treatment rates were measured for projects that dealt with drug-resistant TB.

While no official statistics were reported, it was estimated that NGOs receiving international donor funds spent INR 10,832 (200 USD) to INR 29,788 (550 USD) per detection. A project run by Populations Services International (PSI) among slum dwellers in the southern state of Karnataka that was funded by USAID reported a cost of INR 30,708 (567 USD) per patient for detection and treatment. Outside India, several NGOs in Asia and Africa supported by the Stop TB Partnership were reportedly spending INR 46,144 (852 USD) per detection.

Based on a consultative process carried out by the Country Coordination Mechanism (CCM), the Global Fund—the largest international financier of TB programs—selected implementation partners for grants. The CCM was a multistakeholder platform that included the government (in this case the RNTCP and the Ministry of Health and Family Welfare), civil society, NGOs, health practitioners, and the private sector. It ensured that all partners were implementing Global Fund programs. There had been some concern about the functioning of CCMs and their partnership engagement strategy to deliver cost-effective outcomes, so CCM reform was a component of the new Global Fund.

Operation ASHA Background

Prior to OpASHA's founding in 2006, Ahuja was the undersecretary of the Ministry of Finance for the government of India. Batra was an advanced laparoscopy surgeon, obstetrician, and gynecologist at a renowned private hospital in New Delhi, and an author, columnist, and 2010 Ashoka Changemaker award winner. She

served slum dwellers for more than a decade with free surgeries, primary care, medicines, and supplements. One Sunday morning in 1998, Ahuja got a call from Batra, whom he had met at a party, asking him for a donation of INR 5,000 (92 USD) to allow her to deliver a baby through a cesarean section for a poor mother who was unable to afford the procedure. She said she was doing the work pro bono and needed the money for supplies. In the following months Batra reached out to Ahuja several times with similar requests. In Batra's experience people seldom volunteered to help twice, but Ahuja was different. He took interest in Batra's work and organized a group of like-minded individual donors to guarantee funds that would allow Batra to continue her work.

Six years later Ahuja took a leave of absence and enrolled in the Master of Public Policy program at the University of Chicago. During orientation he met the members of his cohort group, several of who were professional advisors to large NGOs engaged in large-scale fund-raising work in the United States. To Ahuja this was a professional version of what he was doing for Batra back in India. The next summer, during his visit to India, Ahuja and Batra brainstormed to expand fund-raising efforts to address pressing needs in health care. Ahuja thought that raising money for surgeries would be hard because of the smaller scale of the impact, and health services such as HIV/AIDS, polio, and malaria that impacted large communities were already being targeted by large NGOs. After much deliberation, they settled on TB. India's TB burden was huge, and in spite of a large RNTCP infrastructure, treatment adherence was a major problem. But the disease was curable. Because the government already provided diagnosis and drugs that made up 75 percent of the overall cost for treatment, the funding needs for delivery would be small—and the potential for impact enormous.

In June 2006 Ahuja returned to India after completing his graduate degree. Before leaving the U.S. he registered OpASHA as a 501(c)(3) organization with support from people such as Henry Betts, the former chairman of the Rehabilitation Institute of Chicago, and Mike Traynor, chairman of the board of directors of Mount Sinai and Schwab Rehabilitation Hospital in Chicago. Back at his old job in India but with a renewed passion for addressing a pressing health problem, Ahuja used his spare time to research TB—the disease, the treatment options, and methods of service delivery. He and Batra met with various NGOs and attended several meetings with the health ministry.

Ultimately, they came to the conclusion that the government infrastructure broke down at the last mile of delivery. To implement the WHO-recommended DOTS program, OpASHA would have to establish treatment centers within walking distance of patients that provided flexible, extended hours. The basic model they had in mind would consist of a counselor and a provider. While the former moved about the community to detect and enroll people with the disease in a treatment plan and track patients who did not adhere to their plans, the latter would stay at the treatment center to administer treatment.

Under the RNTCP PPM program, they first obtained a memorandum of understanding with the government to operate treatment centers in the urban slums of Delhi. They chose to launch their initiative in Sangam Vihar, a slum of South Delhi with a population of more than 500,000. The initial search of small businesses for a possible treatment center location was unsuccessful; no one was willing to open one. Finally they recruited Pandit Rama Shankar Pandey, a Hindu priest, to open a treatment center at a local temple. They hired and trained a counselor and recruited field workers to create public awareness in the community about the treatment center, and on September 15, 2006, OpASHA launched its first center.

OpASHA Service Delivery Model

Community Last-Mile Approach

OpASHA's solution to last-mile service delivery was rooted in the community and consisted of two important elements. The first element was a treatment center managed by a provider, also referred to as

the community DOTS provider (CDP). CDPs provided space to place two racks that contained the necessary medications. The most important criterion used to identify a CDP was inclination to serve the community; ideal candidates included social workers, shopkeepers, doctors, chemists, and patients who had successfully completed treatment. The provider's space, located in a high-traffic area of a community and ideally within a 10-minute walking distance for a patient, became a treatment center. The center was open for extended hours, typically from 6 a.m. to 9 p.m., to enable patients to access treatment before or after their regular work schedules. The number of CDPs in a community was determined based on the community's estimated disease burden. OpASHA estimated that a CDP could manage a patient load of 60–70 patients a month.

The second important element of the solution was a counselor. On average there was a counselor for every two providers. Counselors were chosen from the local community and underwent a rigorous two-week training at the OpASHA training center that exposed them to details of the disease and associated common health issues like malnutrition, as well as practical problems faced in the field, and strategies to respond to such problems.

Recruitment and Training

The recruiting process started with identification of a provider or CDP; it typically took about a month to shortlist and recruit two good CDPs. Once a CDP was recruited, OpASHA hung posters at his or her location, indicating that the organization was hiring counselors. The organization sought out young people in the community, specifically candidates who had completed Grade 10 (the equivalent of a high school education) or above.[v]

OpASHA's leaders believed that good counseling must be patient-centered, empowering patients to make their own decisions. About 10 to 15 counselors were trained per session. Board and lodging were provided to trainees and counselors during the training period, and the state TB supervisor (STS) was also a resource person used during the training session. Aspects covered during the two-week training included identification of persons exhibiting symptoms, encouraging TB testing, and treatment counseling. For counseling to be effective, it had to be confidential, nonjudgmental, nondirective, empathetic, encouraging, and reinforcing. In addition to classroom training, counselors in training visited the local DMC to meet workers and went into the communities to shadow current counselors. During one of the classroom sessions, current counselors discussed with trainees issues and problems faced in the field to provide them with insight and solutions. Not only did the discussion provide trainees with practical advice, it also acted as a learning-exchange forum for current counselors. (**Exhibit 9** outlines some "Do's and Don'ts" imparted to the counselors.)

Counselors trained CDPs to register patients, ensure they took the necessary medications, and dispense over-the-counter (OTC) drugs as necessary. Counselors visited homes in the community to look for suspected cases. Because there was such a stigma associated with TB in the communities they visited, counselors were taught not to use the word *tuberculosis* and risk being asked to leave a home. Instead, counselors were trained in protocols that allowed them to assess, based on the symptoms, whether a person may have the disease.

Operations

Persons who presented symptoms of the disease often were in denial because they believed that TB was always fatal. They had to be convinced otherwise—that help was available, and diagnosis and treatment were free. For persons who exhibited symptoms of pulmonary TB, OpASHA provided instructions to go to the nearest DMC for testing. If patients were still uncomfortable, because they did not know how to navigate the services available at the hospital, the counselor would collect a sputum sample and take it to the DMC for testing. Test results were available within a day. Patients who tested positive were advised to consult the

[v] In the Indian education system, there is standardized exam at the end of the 10th grade. To pursue college studies, students must complete two more years of education (either in a high school or a college) before enrolling for a bachelor's degree.

DMC physician for a prescription and were encouraged to have their family members tested.

OpASHA counseling services also included:

- Information on the treatment cycle, the DOTS model, and the importance of proper nutrition
- Common side effects of the medication, such as acidity, nausea, and abdominal pain
- Free OTC drugs for the treatment of side effects through the treatment center

Counselors obtained a moral commitment from the patient to start and complete the six-month treatment regimen, which included the patient's personal plan of treatment for the next six months and promise to stay in the community throughout the duration of the treatment. Patients received information about the consequences of not following through with their treatment, including the potential for the disease to progress to MDR. It was emphasized that if they became MDR, they put their family, friends, and coworkers at risk for contracting MDR as well. Peer counseling was also made available through patients who had received treatment. Once patients committed to the six-month regimen, OpASHA began treatment.

For every new patient, the counselor prepared a treatment card with the patient's name, phone number, and current as well as a permanent address. Necessary drugs for the entire treatment regimen were procured from the district TB hospital. However, OpASHA provided six additional boxes of medicines at each treatment center that were allocated to patients on a first-come, first-serve basis, and it replenished stock each night. Once assigned, the box was marked with the patient's name and the date his or her treatment commenced. Counselors visited patient homes within 48 hours to provide counseling to patients and their families as well as build trust-based relationships within the community in sessions that lasted a minimum of 45 minutes. During this session, a counselor was expected to cover all information given in the New Patient Counseling Session Guidelines.

Counselors typically worked eight hours a day. They started their day at 7 a.m., spending the first hour tracking treatment defaulters from the previous day and attempting to reach them before they headed to work. From 8 a.m. to 11 a.m., counselors visited with the CDPs. Their afternoons were devoted to field rounds for detection and counseling. Counselors collected sputum samples as necessary and transported the samples to the DMC for testing. They were also responsible for obtaining drug supplies for their community's treatment centers.

Patients visited a treatment center at their convenience, but were encouraged to visit in the morning when the counselor was present. If the counselor was not present when a patient visited, the CDP administered the necessary medication. Each patient's visit was registered on a treatment card, and the center provided drinking water, disposable cups, and OTC drugs as necessary. A log of the number of patients at various stages of treatment was displayed on a blackboard and updated each week. Counselors collected the treatment card information and provided a report to the program manager monthly. (See **Exhibit 10** for pictures from a South Delhi treatment center.)

Organizational Structure

Between five to 12 counselors reported to a program manager, who was responsible for setting up new treatment centers and recruiting and training counselors, as well as monitoring their performance. Program managers received daily reports from counselors. They evaluated counselor performance and discussed performance gaps with them to suggest remedial action. Program managers were also responsible for managing accounts and finances for all counselors and centers under their supervision, including counselor incentive payments. (See **Exhibit 11** for the OpASHA organizational structure.)

Compensation

Program managers were salaried and earned about INR 7,000 (129 USD) per month. CDPs were remunerated based on the number of patients they served. Counselor compensation consisted of a base salary and incentives for detection and compliance. For the first three months after a new treatment center was opened, counselor compensation was a base salary of INR 3,000 (55 USD) a month. During months three through six, the incentive structure was based on detection; the counselor earned INR 120 (2 USD) per new patient detection. After six months the incentive structure became a sliding scale offering rewards for compliance or patient treatment defaults (a default was measured as two months of continuously missed dosage). **Exhibit 12** gives the compensation structure for CDPs and counselors. Counselors who were below OpASHA's performance standards (three defaults or more for three consecutive months) were fired.

Attrition and Career Path

Attrition rates among CDPs were low. For the 80 percent of CDPs who were local health care providers, dispensing TB treatment built trust with patients, prompting them to seek treatment for other conditions. For shopkeeper CDPs, participation in the OpASHA treatment program increased their foot traffic and sales of other goods and services.

For counselors, at a very basic level OpASHA provided a livelihood. They, however, most appreciated the recognition and respect they received from the community. It was not unusual to have patients seek their advice on treatment for conditions other than TB. OpASHA provided a career path—with experience, counselors could become program managers. The organization also encouraged its counselors to continue their college studies. Consequently, counselor job satisfaction was high.

Performance and Growth, and Sustainability

OpASHA quickly increased detection rates in the regions it served—in South Delhi alone, detections increased from 82 per 100,000 people in 2005 (before OpASHA was founded in 2006) to 160 cases per 100,000 in 2009 (**Exhibit 13**), while maintaining a default rate of just 3 percent. OpASHA also rapidly replicated its model across India.

OpASHA had converted to a top-down approach to its implementation in a new region after facing challenges pursuing a bottom-up approach where district health officials could delay the start of operations in their territories. OpASHA learned that if a state health secretary showed enthusiasm, the organization should build into its proposal operations in multiple districts so it could reach as many slums as possible. Buy-in from the state health secretary created a push from the top to district officials to co-operate with OpASHA. Population coverage of at least 200,000 was needed to set up an infrastructure of eight centers managed by four to five counselors who reported to a project manager. For example, for the central state of Madhya Pradesh, OpASHA proposed to work in three districts covering a population of 1.5 million (inclusive of rural areas where the smallest village had just 400 residents) for 80 centers. Activity at the centers, however, far exceeded OpASHA's original target, with population coverage of over 2.15 million and 4,359 patients enrolled across 101 centers.

Nevertheless, the government remained hesitant to work with NGOs on such a large scale. The government was supposed to pay 50 percent of the centers' expenses for the first six months of operation up front. Not only was there a risk of NGOs walking away with the money, but corrupt government officials could also slowly chip away at funds as they moved through the bureaucracy, and approval delays to launch new operations were not uncommon.

OpASHA's community approach worked well in urban areas with high population densities. In rural areas with low population densities, the organization deployed mobile counselors who had their own means of transportation, typically a two-wheeler. A large village nestled in a cluster of villages often acted as an OpASHA hub, with counselors using the home village as a base of operations. Servicing rural areas, however, was more expensive.

In the spring of 2010, Ahuja reached out to OpASHA board members and supporters to explore international expansion. Kyle Ortiz, a board member and legal expert teaching at a university in Phnom Penh, Cambodia, responded with an invitation to expand OpASHA's operations in that country. With 693 cases per 100,000 people, Cambodia's TB burden was one of the highest in the world. Further decades of conflict and economic hardship had weakened the country's health system. For a population with a per capita income of less than $2 a day, Cambodia needed a low-cost TB treatment model. Ortiz's wife, Sophie, who was from Cambodia, connected OpASHA to the Ministry of Health, the National TB Program Office, and the Ministry of External Affairs. In December 2010, OpASHA opened its first center in Cambodia. It rapidly achieved scale such that by 2013 the organization was serving more than 1 million disadvantaged people in 1,283 villages in Phnom Penh and Takeo, providing TB education, diagnosis, counseling, and treatment.[27] (See **Exhibit 14** for an illustration of OpASHA's aggressive expansion in India and Cambodia.)

Sustainability

To support the growth, OpASHA beefed up its executive staff, hiring a chief finance officer, chief technical officer, chief operations officer, human resources director, program manager, and communications/deputy director of fund-raising. Total per-patient cost—drugs, diagnosis, and treatment delivery—was estimated at INR 8,611 (159 USD). Under the RNTCP program, drugs for the complete treatment regimen (estimated value of INR 4,495 or 83 USD) were provided free through the government. Free diagnostics and physician consultation (estimated at INR 866 or 16 USD per patient) were also provided at DMCs.

OpASHA incurred a cost of INR 3,249 (60 USD) per patient, 85 percent of which went toward core service delivery. The remainder covered administrative costs. Under the RNTCP program, compensation had not kept up with the pace of inflation—the government reimbursed private partners only up to INR 1,733 (32 USD) for each patient who completed treatment.[vi]

"The government is very wary of releasing money without proper audit. Government officers believe that NGOs are corrupt and therefore are very cautious," Ahuja said.

Once an audit was complete, the district TB officer sent grants to the state TB officer for approval. The state TB officer then requested a release of funds from the treasury. All of these steps in the bureaucracy added several months to the process. OpASHA typically received payment 24 months after patients started treatment. In the meantime, OpASHA was forced to fund the cost of treatment.

"The process is far too complicated for small NGOs to comply. Recently during a conference gathering, many small organizations complained about reimbursement delays. The large, internationally funded NGOs are flush with money and do not bother to collect government reimbursement. It is the small guys who suffer, especially the local medical practitioner who delivers treatment," Batra said.

Navigating the government bureaucracy for timely release of funds was not easy.

"I have worked in the government previously, so I know how to work the system for timely release of funds. Other well-meaning NGOs may not be as lucky," added Ahuja.

[vi] In India, food inflation far exceeded the average inflation rate, placing upward pressure on salaries.

OpASHA's fund-raising efforts were geared toward establishing new centers and funding recurring operating expenses for two years until the organization received reimbursement checks from the government. The start-up and operation cost for a center for the first two years was INR 217,120 to INR 271,400 (4,000 USD to 5,000 USD). Ahuja tried to keep 20 percent of OpASHA's budget as a buffer to ensure that the organization would have the capability to set up pilot centers and guard against payment delays. About INR 2.7 million (50,000 USD) a year was raised through OpASHA in Chicago. Other donors, both individual and corporate, preferred to give money to the organization directly in India.

Leveraging Technology

In March 2010, OpASHA launched a pilot scheme to leverage biometrics-based technology for DOTS treatment delivery. The biometric system was a two-tier system consisting of:

- *Biometric client*—Low-cost, off-the-shelf devices (netbook, fingerprint reader, and cell phone)
- *Electronic medical record (EMR) system*—Back-end visualization and analysis of records through any computer with an Internet connection

The system, called eCompliance, was developed in collaboration with Microsoft Research and Innovators in Health. (**Exhibit 15** provides an illustration of the eCompliance system, and **Exhibit 16** gives technology specifications and costs.) With a user-friendly interface, the system was intuitive and easy to learn—counselors could be trained to use the technology in just two to four hours. New patients were enrolled to begin a medication regimen with registration of two of their fingerprints (one of each hand) along with their names and scheduled days of visit (**Exhibit 17**). A fingerprint database was stored on a netbook. To prevent tampering with the data, the system permitted the counselor only to register new patients or edit patient data. Subsequently, whenever the patient visited the treatment center, the visit was logged using fingerprint authentication. At the end of the day the patient log was uploaded to an electronic medical record (EMR) system through a central server using short messaging service (SMS) technology. The system automatically generated messages to counselors and program managers on patients who missed their medication, so the workers could follow up with patients to ensure they were sticking with their treatment regimens. Obviating the need for Wi-Fi connectivity, the system was efficient and cheap.

"Using this technology, we hope to get zero default rates, nipping the disease in the bud and turning the tap off on MDR TB," Ahuja said. "The technology, coupled with a GPS device, would be used for monitoring patients and counselors in the rural delivery model."

Deployment of the eCompliance system added another INR 217,120 (4,000 USD) to the start-up cost of a center. Assuming a technology life of three years, OpASHA estimated that the per-patient cost of the eCompliance system was no more than INR 150 (2.77 USD). The eCompliance system had been deployed in 78 centers serving more than 1,300 patients with more than 4,000 enrollments.

Next Steps

OpASHA had come a long way since its launch in 2006. The organization was gaining national recognition for its performance in treating TB, and it was achieving scale rapidly. OpASHA intervention efforts had averted over 360,000 new infections, created jobs, and developed entrepreneurs—all with a high social return on investment. But the journey had been frustrating. Government bureaucracy and delays and shortfalls in reimbursement, inadequate support for start-up investments, and almost no support for technology were some of the challenges. Ironically most internationally funded NGOs had detection costs that were 15 to 20 times higher than OpASHA's combined costs for detection and treatment. While OpASHA

would lobby the government to increase funding for service delivery, Ahuja did not want to bet on it. The organization had been shut out from participating in the consortia that sought international funding. So they had to also consider alternate strategies for sustainability.

Meanwhile, years of neglect to address basic TB had, as suspected, increased the incidence of MDR-TB, and the world community was just beginning to wake up to the extent of its prevalence in India. Diagnosis and treatment capacity for MDR-TB was severely constrained. With only one approved lab per state, there was a scarcity of diagnostic capacity. The treatment regimen for MDR-TB was much more expensive and intense, lasting 24–27 months. After the initial two weeks of in-hospital treatment, the remainder of the two-year treatment could be completed at home. Because of the severity of the disease and enhanced skills necessary to manage it, OpASHA estimated that it would have to upgrade the skills of the counselors and the treatment cost would rise to INR 54,280 (1,000 USD) per patient. Batra felt strongly about the need to address drug-resistant TB.

"We are on the brink of another epidemic, and it has no treatment. If TDR[vii] spreads, we will go back to the Dark Ages,"[28] she told *Time* magazine.

She believed that OpASHA could take up this difficult and important task, but it would put an even greater financial strain on the organization. After their lunch meeting, Ahuja and Batra reviewed some of OpASHA's key assets and capabilities—both technological and organizational. Was there a way to leverage one or more of these for additional revenue generation to ultimately move toward self-sufficiency?

[vii] *Totally drug-resistant* was a term used in India for drug-resistant TB that did not respond to many of the doses in the standard drug regimen.

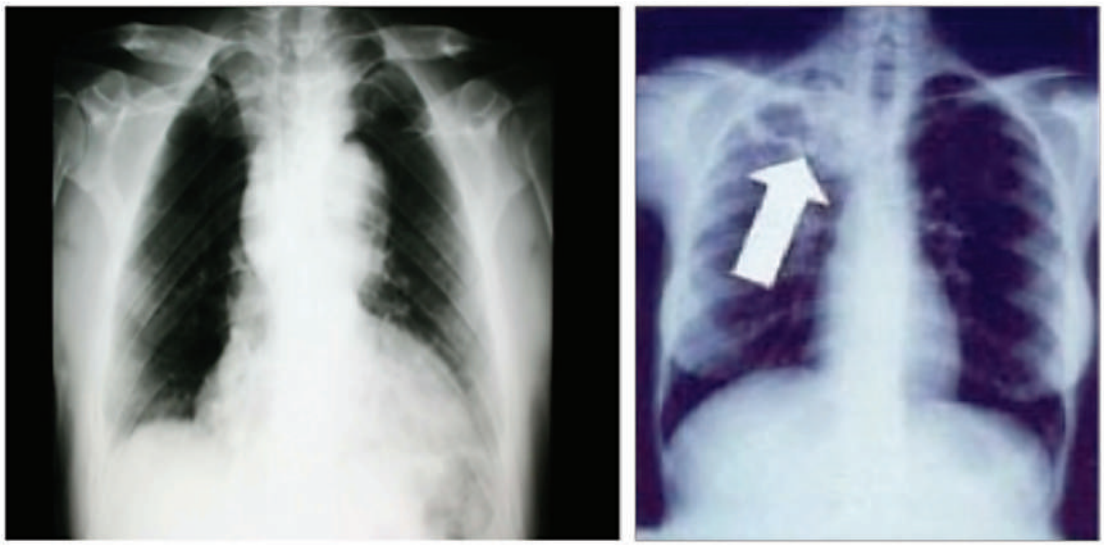
Exhibits

Exhibit 1

Infected Lungs

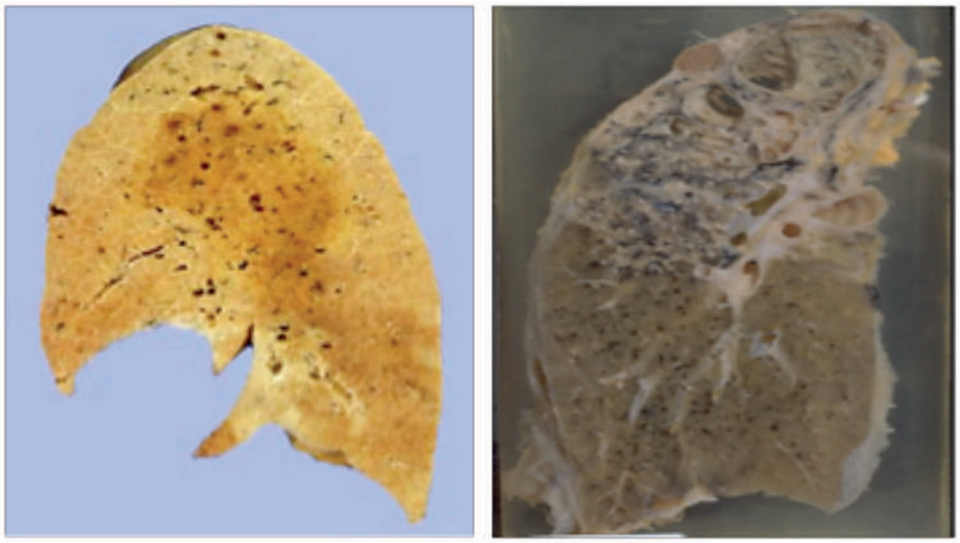
TB (Pulmonary Tuberculosis) "Punctures" the Lungs Chest X-Ray

Healthy **Infected**



Lung Cross-Section

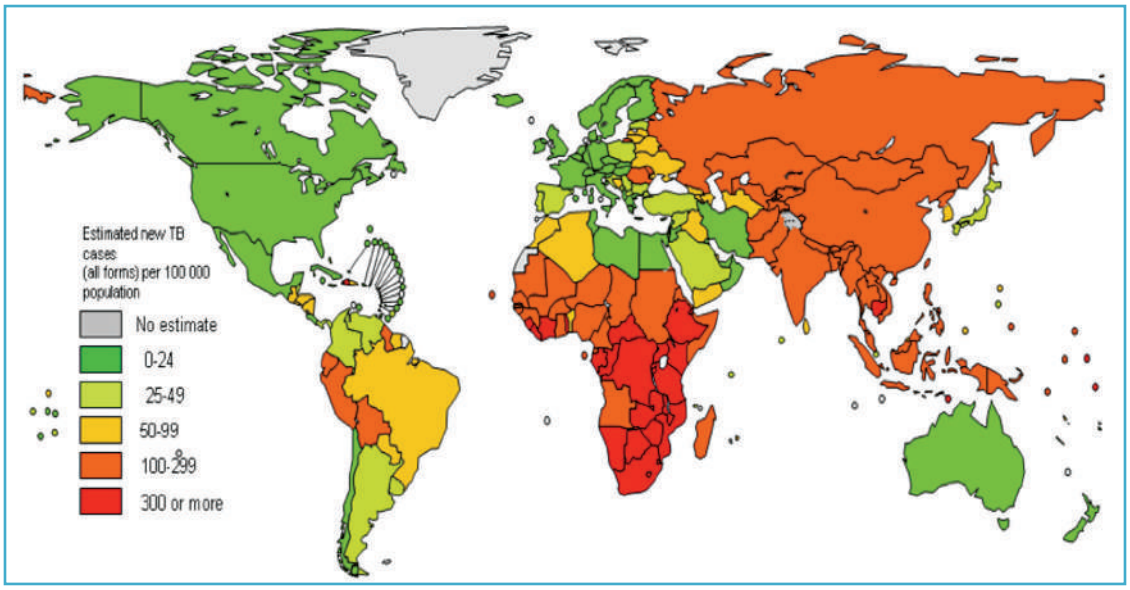
Healthy **Infected**



Source: Operation ASHA

Exhibit 2

Worldwide Prevalence of TB



Source: WHO Geneva; WHO Report 2009: Global Tuberculosis Control; Surveillance, Planning and Financing

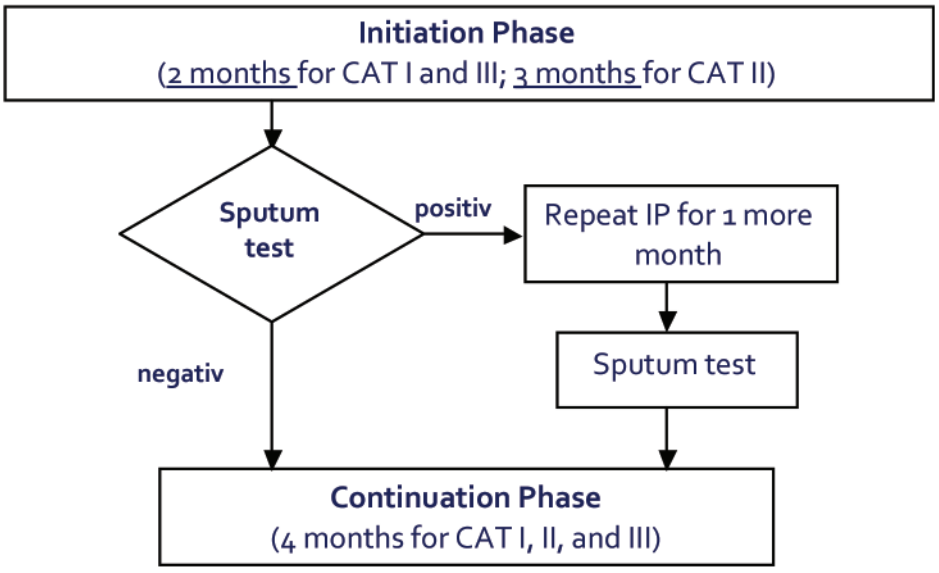
Exhibit 3

Treatment Categories, Drugs, Doses, and Regimen

Categories of Treatment	
CAT I	• New sputum-positive pulmonary TB cases • New sputum-negative pulmonary TB cases who are seriously ill • New cases of extra-pulmonary tuberculosis who are seriously ill • All new TB cases with known HIV-positive status
CAT II	• Sputum-positive relapse cases • Sputum-positive failure cases • Sputum-positive treatment after default cases • Others; extra-pulmonary relapse or failure
CAT III	• New sputum-negative pulmonary TB cases who are not seriously ill • New extra-pulmonary tuberculosis cases who are not seriously ill

DOSES	Medicine	Potency	Dosage
Initiation Phase (IP)	Isoniazid (H)	300 mg	2 tablets
	Rifampicin (R)	450 mg	1 capsule
	Pyrazinamide (Z)	750 mg	2 tablets
	Ethambutol (E)*	600 mg	2 tablets
Continuation Phase (CP)	Isoniazid (H)	300 mg	2 tablets
	Rifampicin (R)	450 mg	1 capsule

* Only for Category I and II patients



Source: Operation ASHA (author synthesis)

Exhibit 4

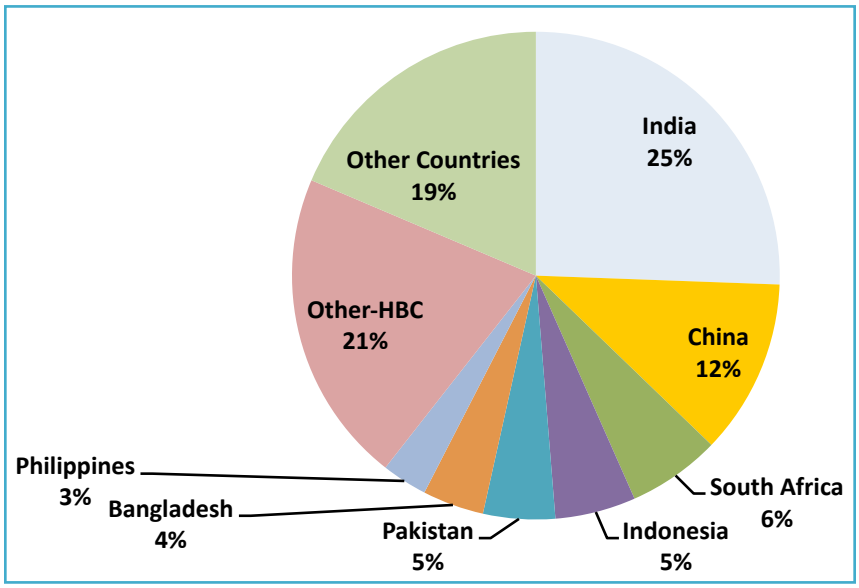
Types of TB

	"Basic" TB Disease	Multidrug-Resistant TB (MDR)	Extensive Drug-Resistant TB (XDR)
Description	• Occurs to LTBI carriers with immune deficiency • Patient under treatment infectious for three–four weeks • Untreated patient infects 10–15 others	• Occurs to patients not complying with protocol • Resistant to the two first-line antibiotics • MDR can be just as infectious as the basic TB	• Highly virulent strain, resistant to three or more of the six second-line drugs • Virtually untreatable
Primary Cause	• Exposure to patient	• Failure to treat "basic" TB	• Failure to treat MDR-TB
Number Patients Worldwide (vs. India)	• 13MM total (3–3.5MM) • 8MM new cases annually (2MM)	• 5–10% of basic TB cases (150–300,000)	• 20–25% of MDR cases
Mortality Rate	• 5–10%	• 80%	• Virtually 100%
Treatment/Cost Per Patient	• Six- to nine-month program of two main antibiotics • $130 (often subsidized)	• Cocktail of up to six second-line drugs • $5,000 (most patients in poor countries die)	• N/A (virtually untreatable)

Source: Operation ASHA

Exhibit 5

Annual TB Incidence



Source: Compiled by the author using data from the WHO Global Tuberculosis Report 2013.

Exhibit 6

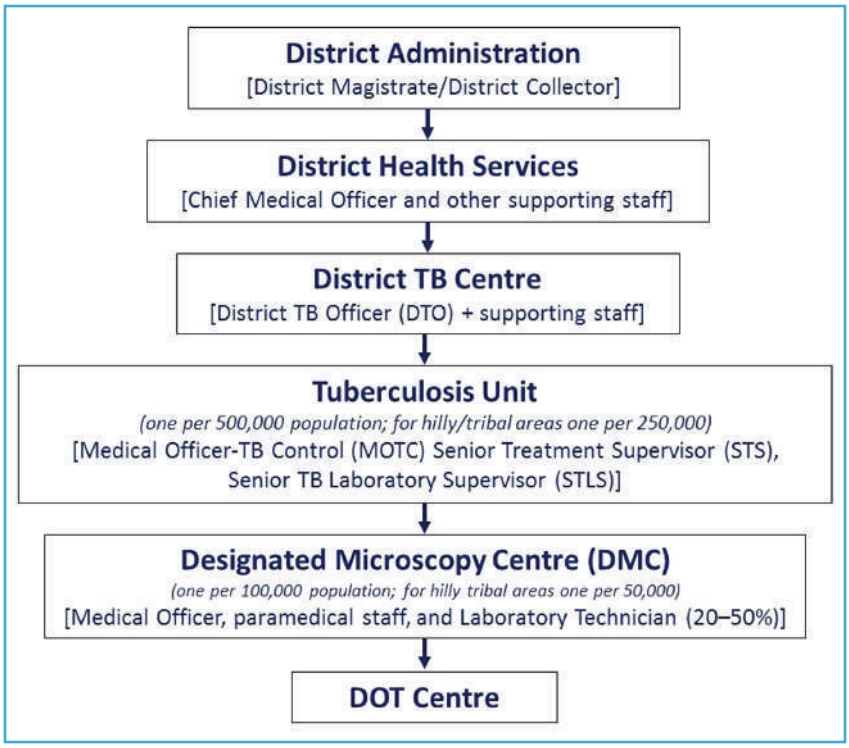
History of TB Initiatives before 1993

1906	First open-air sanatorium established in Tilounia, Rajasthan
1929	India joins the International Union Against Tuberculosis (IUAT); King George V Thanksgiving Fund is established to support TB education and prevention, establish clinics, and train health care workers
1939	TB Association of India is established to develop standard methods for managing TB and develop model training institutions
1943	Health Survey and Development (HSD) Committee is established with Sir Joseph Bhore as chairman, who recommends remodeling of the public health services
1948	Mass BCG immunization campaigns begin with aid from the International Union Against TB
1949	The HSD committee outlined a plan to manage an estimated 2.5 million TB patients with a TB clinic in every district and mobile clinics covering rural areas; the government of India establishes a TB division within the Directorate General of Health Services of the Ministry of Health
1956	TB Chemotherapy Center (later renamed the TB Research Center or TRC) is established in Chennai; TRC conducted studies on the feasibility and effectiveness of mass chemotherapy and showed that home-based treatment was as successful as hospital treatment
1959	The National TB Institute (NTI) is established to develop a National TB Control program (NTP) with the aim of establishing prompt diagnosis and ambulatory treatment
1961	NTP conducts a pilot program in Andhra Pradesh
1968	Study conducted in Tamil Nadu showed that BCG immunization did not offer effective protection against TB
1978	NTP covered 81 percent of the districts of India with self-administered 12- to 18-month treatment developed by TRC
1983	NTP pilots short-course chemotherapy (SCC) that reduced treatment regimen to six months in 18 districts
1986	SCC extended to 252 districts

Source: Extracted from *A Brief History of Tuberculosis Control in India*, World Health Organization, 2010.

Exhibit 7

District-Level Organizational Structure for TB Management



Source: Synthesized from *Revised National Tuberculosis Control Programme—An Overview*, Central TB Division, Ministry of Health & Family Welfare, New Delhi.

Exhibit 8

Treatment Outcomes for 1999–2009

	New smear-positive				New smear-negative				New extra-pulmonary			
Year	Success	Death	Failure	Default	Success	Death	Failure	Default	Success	Death	Failure	Default
1999	82%	5%	3%	9%	85%	4%	1%	9%	91%	2%	0%	6%
2000	84%	4%	3%	8%	86%	3%	1%	9%	91%	2%	0%	7%
2001	85%	5%	3%	7%	86%	4%	1%	8%	91%	2%	0%	6%
2002	87%	4%	3%	6%	87%	4%	1%	7%	92%	2%	0%	5%
2003	86%	5%	2%	6%	87%	4%	1%	7%	92%	2%	0%	5%
2004	86%	4%	2%	7%	87%	4%	1%	8%	92%	2%	0%	5%
2005	86%	5%	2%	7%	87%	4%	1%	8%	91%	2%	0%	6%
2006	86%	5%	2%	6%	87%	4%	1%	8%	90%	3%	0%	5%
2007	87%	5%	2%	6%	87%	3%	1%	8%	91%	2%	0%	5%
2008	87%	4%	2%	6%	88%	3%	1%	7%	92%	3%	0%	4%
2009	87%	4%	2%	6%	88%	3%	1%	7%	92%	2%	0%	4%

Source: RNTCP Annual Report 2011

Exhibit 9

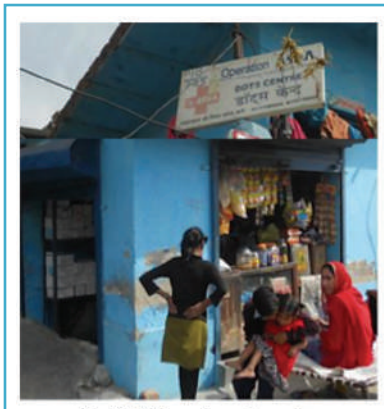
Some Do's and Don'ts of Counseling

DO's	DON'Ts
• Greet the patient • Offer a seat before interacting with the patient • Address the person by name or appropriate title but always with respect • Allow sufficient time for the interaction • Maintain eye contact • Emphasize that your job is to help them • Ask open-ended questions • Acknowledge and respond to each of their concerns • Paraphrase and summarize frequently to make sure that you understand the problem • Ask about family members • Treat the person with respect • Smile • Listen carefully to their point of view • Use nontechnical words • Help them to comply • Demonstrate that you are concerned about the patient • Convey that you understand their fears and apprehensions • Make them comfortable • Identify obstacles to their participation • Repeat important information in different ways each time you meet • Emphasize that they will be cured • Use examples from your own experience • Tell them that this is what you would recommend to your family members • Compliment the other person on what they have done well • Recognize their progress • Emphasize that their welfare is your concern/job	• Interrupt while the other person is speaking • Put down the other person • Perform other activities during the meeting • Ask difficult/embarrassing questions • Minimize or dismiss their concerns • Act superior • Assume the person knows their way to another person/room/office; give them proper guidance to their next destination • Argue with the patient • Assume you know all the answers • Use technical words • Treat them as your student • Tell them to comply • Assume you know their condition • Expect compliance without explanation • Ignore the efforts the other person has made so far • Overlook their fear and anxiety • Ignore or minimize practical barriers • Criticize their omissions/commissions

Source: Operation ASHA

Exhibit 10

Pictures from a Treatment Center in South Delhi


OpASHA treatment center


Boxes of drugs labeled by patient

Display of weekly status

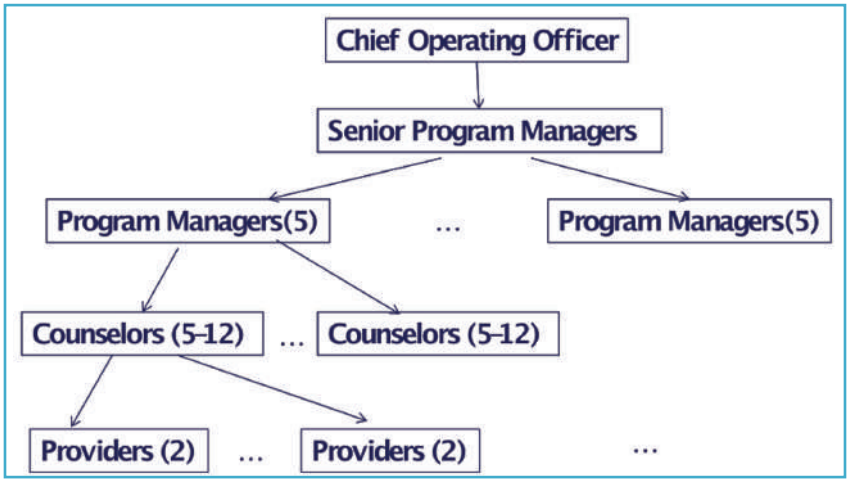

CDP and Counselor

Sample labeling

Source: Author

Exhibit 11

OpASHA Organizational Structure



Source: Operation ASHA

Exhibit 12

Compensation Schedules

Table 1

Compensation schedule for CDPs

Number of patients	Monthly payment (INR)
Up to 20	200
21–30	300
31–40	400
41–50	500
51–60	600
61–70	700
71 and above	750

Table 2

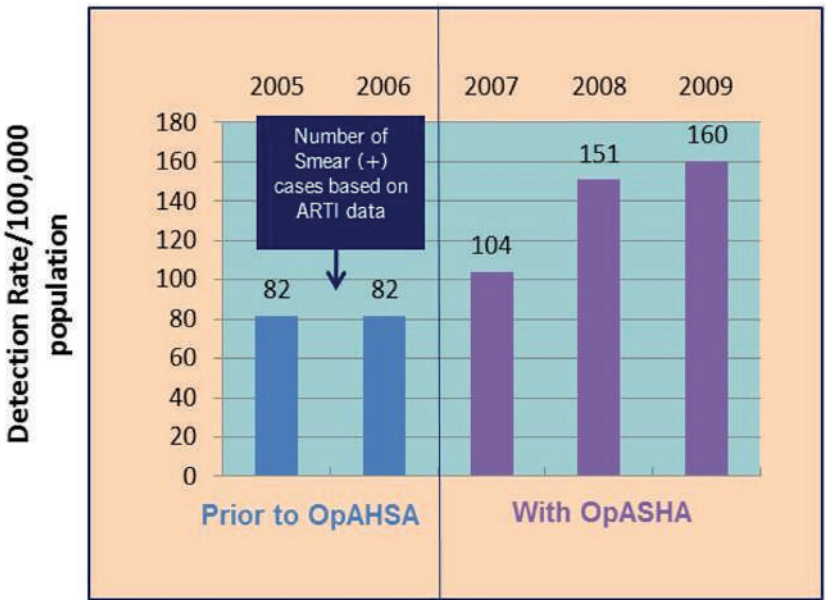
Compensation schedule for counselors

Defaults	Incentive (INR)
0	1,200
1–2	800
3	400
Greater than 3	0

Source: Operation ASHA

Exhibit 13

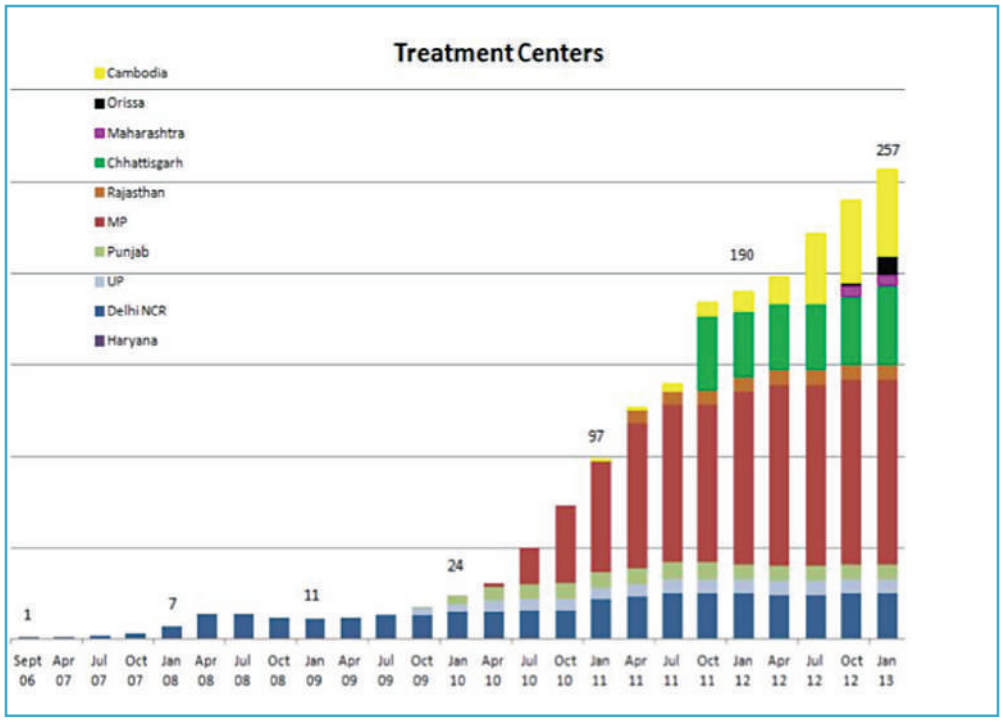
Annual Detection Rate of New Sputum-Positive Cases (S. Delhi)



Source: Operation ASHA

Exhibit 14

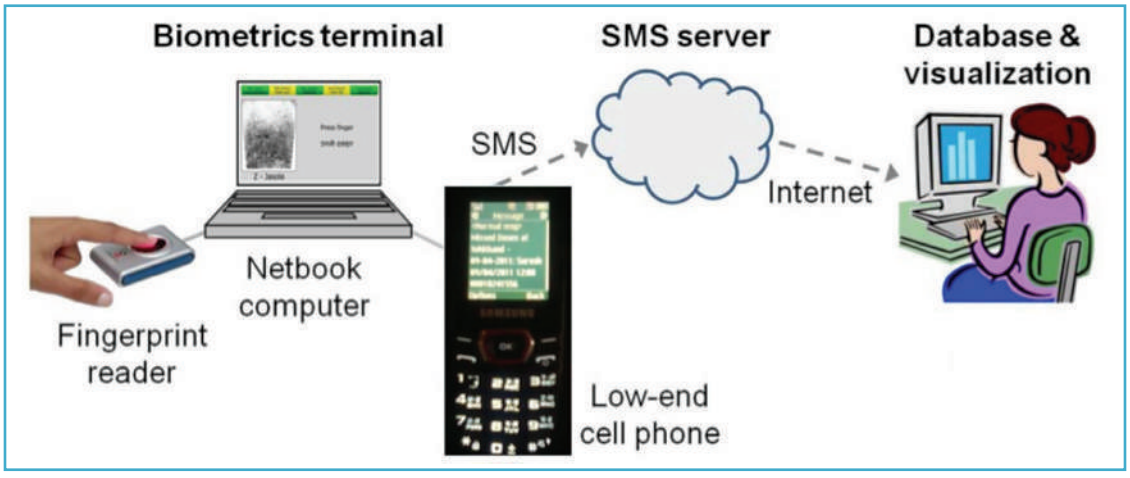
Aggressive Expansion



Source: Operation ASHA

Exhibit 15

eCompliance Software



Source: Operation ASHA

Exhibit 16

eDOTS Technology Components and Cost

Component	Implementation Choice	Cost (INR)
Netbook computer	Asus Eee PC 10005HA	14,300
Fingerprint reader	Digital Persona U.are.U 4500	4,000
Mobile phone	Nokia 1209	1,500
SMS plan	Reliance 1p pack (10 SMS/day)	< 200/year

Source: Operation ASHA

Exhibit 17

Patient Interaction with a Biometric Terminal

Source: Operation ASHA

Endnotes

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Notes

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