LAD CASE STUDY

Evaluating Social Programs: The Case of World Health Partners-Sky

Karthik Sivaram

LAD

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Smitha Shah's Decision

It is December 2016. Smitha Shah, executive director of the Gates Foundation's India office, is in her corner office on the 25th floor of the Adani Tower in New Delhi's business district. Everyone but Shah has left; she can now concentrate on a special task without the distraction of daily administrative duties. Bill Gates himself, chairman and trustee of the foundation, has requested that she review a grant made by the foundation. Authorization for disbursal of the next tranche of funds may depend upon her recommendation. The grant in question was unconventional and highly experimental. Made to the non-governmental organization World Health Partners (WHP), the grant supported implementation of a private sector-led health program to combat childhood diarrhea and childhood pneumonia. The program sought to reach remote areas in the Indian state of Bihar through telemedicine based on social franchising. In an evaluation funded by the Gates foundation, a group of academics found no significant effect associated with the intervention. Shah was aware that the academic study had limitations. Nevertheless, the published evaluation results had recently been picked up by news media and brought the Gates Foundation under public scrutiny for its funding of the program. Yet WHP was something of a posterchild for innovations in health care delivery; in 2013 it received a prestigious award from the Skoll Foundation for innovative approaches to healthcare delivery in remote areas. Although Shah had not personally approved the WHP grant, she had managed it for the previous three years. While she is convinced that neither the study results nor the press coverage do justice to the program or its potential, she recognizes that they raise valid concerns. What should Shah recommend in her report?

Introduction

In the summer of 2010, Nitish Kumar, Chief Minister of Bihar, met with Bill Gates and invited the Gates Foundation to help with development efforts in the state of Bihar; specifically he wanted the foundation to provide technical assistance to accelerate progress toward the state's health and nutrition goals.

Bihar was, and continues to be, one of the least developed states in India; it was then home to the third largest population of poor people among all the Indian states (see Appendix A). In 2010, its Human Development Index was 0.05 compared to the national average of 0.38[i], ranking 27th out of 28 states in India. This is reflected in poor healthcare infrastructure and delivery in Bihar. There was just one healthcare provider and 0.4 doctors per 1000 in population, considerably lower than the national average of 1.9 and 0.6 respectively (See Appendix B). It was to improve this situation that Kumar sought Gates' help through the foundation.

Bill and Melinda Gates Foundation

The Bill and Melinda Gates Foundation (BMGF) was established in 1994 (then known as William H. Gates Foundation) by Bill Gates, one of the richest men in the world at the time, and his father (William H. Gates) out of the basement of their Seattle home. The foundation sought to support charitable and philanthropic activities in the US. In 1997, an endowment of $2 billion was created, which continued to grow over the years. In 2006 it received a massive boost due to a pledge from Warren Buffet, then the third richest man in the world, to donate most of his wealth to BMGF. In 2010 the total endowment of the Gates Foundation had grown to $38 billion, making it the largest private foundation in the world. Almost $20

billion came from the personal fortune of the Gates family itself. The foundation is committed to spending the entire endowment within 50 years of the deaths of Bill and Melinda Gates, and in 2010 it distributed grants amounting to almost $2.5 billion[ii] (see Appendix C). This figure exceeds the healthcare budgets of most of the countries in which the foundation operates.

The foundation has four grant making programs – (i) the Global Development Program, (ii) the Global Health Program, (iii) the Global Policy and Advocacy Program, and (iv) the United States Program. Each of these programs is subdivided into Program Strategy Teams (PSTs) that focus on a specific issue. For example, under the Global Health Program there are PSTs for tuberculosis, pneumonia, and so on. Each PST formulates a strategy for meeting its core objectives and makes grants to organizations based on that strategy. These strategies are usually informed by the latest scientific research, tend to emphasize technical solutions, and are often motivated by bold targets. Bill Gates' target of reducing child mortality rates by half within 20 years is a prime example.

The foundation also emphasizes use of technical metrics to make decisions about fund allocations and track the progress and impact of grants. For instance, "Dollar-per-DALY" is a common metric the foundation uses to determine its allocation of resources across various issues. DALY is an acronym for disability-adjusted life year that is increasingly used in global health literature; it is a measure of the number of years of healthy life lost due to severe illness or premature death in a given population. This metric ensures that the foundation's focus is on areas of maximum impact, avoiding over commitment of resources where the marginal cost of a DALY saved is high.

Organizational Structure

The Gates Foundation and the PSTs maintain headquarters in Seattle, Washington. All PSTs are staffed with in-field experts, academics, and business professionals (often with consulting backgrounds), and are allocated funds with which to award grants. Each PST is led by a director, who reports directly to the Executive Leadership Team (chaired by Bill Gates, Melinda Gates, and William Gates Sr.). The PSTs have near complete autonomy in use of their funds. They seek out organizations whose work aligns with the strategic direction formulated by the PST and administer grants. These grants are almost always made without expectation of financial return. However, the grantee is expected to submit an implementation plan with project milestones, often in the form of process-level metrics. The total grant amount is released in tranches conditional on achieving these milestones. Although the PSTs select the grant recipients, they are not directly involved in management and administration of grants. This is usually done by a Program Officer (PO) based in the same country as the grantee. A PO typically manages 3-4 grants and acts as liaison between the grantee and the foundation. POs do not take part in the day-to-day functioning of the grantee, but they conduct weekly check-in calls and make field visits once a fortnight. The POs are usually young professionals in the early stages of their careers who tend to switch jobs and/or organizations within about two years, so they often do not fully see through projects that they have developed and launched. Throughout their duration, most grants are managed by multiple POs.

In countries where the BMGF has a significant number of grantees, there is often a regional office – as is the case with India. The office in New Delhi is led by a director and a team of executives who work collaboratively with the PSTs to source and evaluate potential grantees. However, the decision to award a grant is made by Seattle-based PSTs. The POs who manage

grants in India report to the leadership in India. Although POs do not report directly to the

PSTs, they nonetheless function as the liaison for PSTs to track the progress of the grant.

The Global Health Program

Bill and Melinda Gates were reportedly inspired to start their foundation after reading an

article about millions of children in poor countries who die from diseases long ago eliminated

in the U.S. Thus the foundation's initial and enduring focus has been global health. Indeed,

the three organizations receiving the greatest amount of funding from BMGF are GAVI

(Global Alliance for Vaccines and Immunization), WHO (World Health Organization), and

the Global Fund to Fight AIDS, Tuberculosis and Malaria; all focus on global health (See

Appendix D). By 2010, it was estimated that BMGF's grants had helped vaccinate 250

million children in poor countries and prevented five million deaths[iii]. In May 2009, an

editorial in the prestigious medical journal *Lancet* praised the BMGF for "a massive boost to

global health funding . . . The Foundation has challenged the world to think big and to be

more ambitious about what can be done to save lives in low-income settings. The Foundation

has added renewed dynamism, credibility, and attractiveness to global health [as a cause]."[iv]

In this manner, BMGF became a global leader in concepts of healthcare delivery in resource-

poor settings. In 2008, Bill Gates transitioned from a day-to-day role at Microsoft to full-time

work with BMGF, lending its efforts significant momentum.

The Gates Foundation in India

The foundation's healthcare work in India began in 2003 with *Avahan* – an initiative aimed at

reducing the spread of HIV/AIDS in India. In five years *Avahan* was able to create a large-

scale HIV/AIDS intervention program operational in six states with a combined population of

300 million; by 2009, the foundation had pledged a total of $338 million for this project.[v] The

intervention was widely acknowledged as successful; a study published in *The Lancet Global Health* estimated that it had prevented over 600,000 HIV/AIDS infections between 2003 and 2013.[vi] Further, BMGF also had some success with grants aimed at improving child and maternal care and polio vaccination. According to the foundation's website (since changed), there are three basic elements to its strategy in India - i) using partnerships to leverage public and private resources to influence policy; (ii) using state projects as "incubators of innovation;" and (iii) underscoring the role of technology.[vii] The emphasis was on working with state governments and grassroots organizations. Consequently, Nitish Kumar, Bihar's Chief Minister, was eager that the Gates Foundation help bolster the state's efforts to improve healthcare. Kumar was less interested in the funding provided by the Gates Foundation than in its crucial technical expertise in designing and implementing health care delivery. Bill Gates, for his part, was impressed with Kumar's progressive agenda and accepted his request. In early 2010, it was decided that the Gates Foundation and the Government of Bihar would sign a Memorandum of Understanding to collaborate in the matter of public health.

The Bihar Strategy

The memorandum outlined the scope for collaboration on a number of areas related to healthcare delivery. The major focus would be on reproductive health and nutrition, but the foundation was also interested in looking at interventions targeting childhood pneumonia and diarrhea, tuberculosis, and visceral leishmaniasis (Kala-azar). Most of BMGF's efforts were to be in collaboration with the public sector because creating new channels for healthcare delivery in Bihar posed formidable challenges. Since almost 90% of the population lived in remote, poorly connected rural areas, rather than to attempt the complex task of creating completely new delivery channels to these areas, the foundation would work to improve the reach and quality of the existing public sector infrastructure.

However, the Indian healthcare sector was growing increasingly dependent on private providers and out-of-pocket expenditures, so it was also decided that a few innovative private sector approaches would be supported. In 2010, it was estimated that the private sector accounted for 63% of all beds available, with 70% of the new beds created between 2002 and 2010; although in terms of total health care expenditure (as % of GDP), India lagged behind the average for Lower Middle Income Countries, the share of out-of-pocket expenditure in healthcare was almost double the average (See Appendix E). This was particularly true in Bihar, where public expenditure on healthcare was just 4.1% and per capita public expenditure was the lowest among major Indian states (see Appendix F). Therefore, given that private providers accounted for most of the available healthcare, there was a compelling case for a private sector approach in healthcare delivery.

It was with the private sector in mind that a Request for Proposal (RFP) was issued seeking innovative approaches to healthcare delivery. The RFP sought a proposal that would use a single private sector delivery channel to address four diseases – childhood pneumonia, diarrhea, tuberculosis, and visceral leishmaniasis. According to Anand Sinha, who served as PO for this project from 2012 to 2014, "It was thought that bundling multiple services together through a single effective delivery channel could lead to the realization of significant efficiency gains." The private delivery channel concept was the brainchild of Guy Stallworthy, a senior PO based in Seattle. Stallworthy strongly believed that leveraging the private sector was critical to achieving the sort of improvement in health outcomes sought by the foundation. However, not everyone in the organization supported this view; Sinha recounts, "Not everybody shared Guy's enthusiasm [for this strategy]. This was especially true with the India office, which had few personnel with private sector experience."

Nonetheless, in 2011, World Health Partners (WHP), an NGO, was awarded a grant for $23 million to implement a telemedicine-enabled social franchising model. The grant funding was composed of contributions from four different PSTs – Pneumonia, Enteric and Diarrheal Diseases, Infectious Diseases (visceral leishmaniasis focus), and Tuberculosis. WHP was led by Gopi Gopalakrishnan, a former colleague of Stallworthy at Population Services International. It was not uncommon for grants to be awarded to persons known to the BMGF network. Indeed, the same *Lancet* article that praised BMGF for its efforts noted, "Grant-making by the Gates Foundation seems to be largely managed through an informal system of personal networks and relationships rather than by a more transparent process based on independent and technical peer review."

The grant would be disbursed in tranches conditional on WHP's meeting certain "implementation milestones." These milestones were largely output metrics such as the number of franchisees and patient footfalls, which were determined during the grant approval process itself. The decision to approve the grant was made at the headquarters in Seattle; however, the Gates Foundation office in New Delhi was given the responsibility of monitoring and administering the grant.

WHP-Sky Program

The WHP-Sky program logic held that lack of access to high quality primary and preventive care led to poor health outcomes in rural areas. For many reasons, access to a medical doctor or to public sector facilities for primary care was nonexistent in most parts of rural Bihar. The resulting vacuum in healthcare was filled by informal Rural Health Providers (RHPs) of various types, with private-sector providers accounting for some 70% of market share.[viii] Few

of these providers were doctors or employed doctors with formal medical training. Instead, the providers were rural "entrepreneurs" who, at best, had some basic medical experience, such as working as an aide at a medical clinic in the city. At worst, they were quacks peddling pseudo-scientific methods as medical treatment to unsuspecting patients. These providers nonetheless served as a functional healthcare delivery channel for a number of socio-economic reasons. According to a BMGF executive familiar with Bihar, "RHPs are most often the first ones approached by community members due to a degree of trust among them for reasons such as the fact that they accept in-kind payment." Therefore, regardless of the quality and type of care provided, RHPs were viable business operations across rural Bihar that demonstrated the people's willingness to pay. The WHP-Sky Program consequently set out to improve the quality of care provided by RHP's through a combination of proper training, incentives, and telemedicine technology, hoping that patients would recognize this improvement in quality and be willing to pay higher fees for it. Given the extensive reach of RHPs, this approach was seen as an efficient means of leveraging an existing delivery channel to improve health outcomes among the population at large.

Social Franchising Model

WHP's intervention was inspired by the growing popularity of social franchising in international development. In 2014, social franchising companies in developing countries provided health care services to almost twenty-eight million people for a range of conditions including family planning, reproductive health, and pediatric care[ix]. Although heterogeneous, all social franchising programs include a franchisor, who creates a brand and defines a bundle of services and delivery protocols, and franchisees, who affiliate themselves with the brand but operate independently (within parameters established by the franchisor). Franchisees pay a subscription fee, and in return, the franchisor provides brand-name marketing and

standardization of service delivery through explicit protocols for service delivery, training, and supply chain management. Similar franchise models are successfully deployed by fast-food chains such as McDonald's and Burger King.

In the same vein, WHP sought to deliver higher quality primary healthcare by recruiting existing rural health providers as franchisees. In return for a franchising fee, the franchisees would receive access to WHP's telemedicine facility, training for personnel, branding, and marketing. According to a senior WHP executive, "Providers were trained on the use of technology, healthcare skill enhancement and detection and treatment of the four disease areas of focus. As the providers could not leave their business for very long, we had to break down the training into phases: the introductory training was residential and extremely intensive. We followed it up with *in situ* training imparted at their own centers by our field personnel which was followed up with brief refresher training."

The telemedicine facility would allow the franchisee to offer the patient consultation with a qualified medical doctor through video conference. Hence the aim of the WHP-Sky program was to enlist rural health providers who met minimum standards determined by specific criteria and thereby improve the quality of healthcare they could offer. Because patients had already shown willingness to pay substantial out-of-pocket fees for poor quality private sector care,[x] it was believed that they would be willing to pay slightly higher fees for better quality, enabling franchisees to cover costs and earn profits. Rather than making required capital expenditures for building independent presence and credibility, the franchise method appeared a quicker and more efficient way to ensure access to remote areas. In design and scope, the WHP-Sky program thus presented an ambitious plan with the potential for fast growth and significant reach into the remotest villages of Bihar.

Franchising telemedicine was not a wholly new idea. World Health Partners (WHP) had demonstrated a similar model in delivering family planning and maternal health services in Uttar Pradesh (UP), an adjoining state comparable to Bihar in terms of development. However, the success of this model was unclear, and no rigorous evaluation had been undertaken. Indeed, empirical studies from around the world on the effectiveness of social franchising lacked conclusive evidence. According to Dr. Manoj Mohanan, an academic specializing in health policy, "Despite the rapid growth of social franchising programs and their use of new technologies, there is little rigorous evidence on their impact on population health at scale—or even on the individual assumptions embedded in the underlying theory of change that are summarized above. Many studies have focused on improvements in the quality of care or increases in service use. However, almost none have employed sufficiently rigorous methods to justify inclusion in Cochrane Reviews. One recent exception is a social franchising and health care workforce expansion program in Myanmar that increased the treatment of diarrheal illness with oral rehydration solution containing zinc."[xi] Because of this uncertainty, Program Officer Stallworthy was eager to present rigorous evidence in support of the franchise model and it was decided that a Randomized Controlled Trial (RCT) by an external evaluator should be conducted beginning shortly after the launch of WHP-Sky.

WHP-Sky Model Evolution

For the purposes of this case study, the WHP-Sky program may be understood through its major iterations: 1) the Hub and Spoke Model and 2) the Two-Tier Model

1. **The Hub and Spoke Model**

The WHP-Sky program was originally intended for implementation through a Hub and Spoke Model with the goal of enlisting 20,000 franchisees across the 12 districts. It was conceived as a quick and efficient method of growth. Based on this plan, WHP would recruit franchisees to set up SkyHealth Telemedicine facilities - the hubs - in areas with good internet connectivity (See Appendix G). Franchisees were charged a fee of about $500 by WHP in 2014 and were expected to invest in setting up a center, at a cost of approximately $1000. They also received training from WHP through a six-day workshop in diagnosing and treating infectious diseases. The hubs were then expected to leverage their networks to recruit affiliate healthcare providers in peripheral areas who would source referrals for a fee. In return, through proprietary software, the hubs could offer patients consultation with specialist doctors based in WHP's facility. The software was designed not only to allow the doctor to converse with the patient, but also to examine vitals such as pulse and blood pressure. Further, the hubs were obligated to train their spokes in diagnosis and basic care of common illnesses, such as recommending the use of Oral Rehydration Solution for diarrhea. WHP would also provide its franchisees with access to branded drugs, a network of diagnostic labs, and marketing materials.

The franchise model failed to achieve the pace of expansion that WHP had originally envisaged. There were simply not enough takers to set up hubs, and the hubs found it difficult to recruit enough spokes. Faced with pressure to meet implementation milestones required for the disbursal of the next tranche, WHP began to loosen the criteria for quality used in recruiting franchisees. In some cases, new franchisees had no previous experience in health care. Despite such measures, WHP continued to find it difficult to grow as

planned. As a result, the organization had to consider adoption of an alternative model affording deeper penetration.

2. The Two Tier Model

This alternative model was primarily designed to address the problem of slow growth. Instead of simply recruiting hubs with the expectation that the hubs would enlist peripheral providers (spokes), WHP decided to recruit both hubs and spokes. In this pursuit, it created a two-tier franchise system. The first tier was essentially the same as the hub and continued to be called SkyHealth; the second tier – called SkyCare – was composed of rural health providers with modest facilities but located in remote areas. The SkyCare franchisees were charged a franchising fee of about $17. They were given training through a three-day workshop in providing basic primary care and were provided with branding and marketing material. They were also given access to doctors in WHP's central facilities through mobile phone, for which WHP charged about $0.17 per consultation. WHP also provided branded drugs and access to a network of diagnostic labs.

Theory of Change

The WHP-Sky program went through significant iteration and evolution during its implementation. Although it maintained a social franchising structure and provision of telemedicine facilities, the program failed to achieve a stable scalable model in the first four years. Given the experimental nature of the intervention, this shortcoming was to be expected. However, the lack of success challenged fundamental assumptions in the theories of change underlying the program. These assumptions may be understood as demand-side and supply-side theories.

1. **Demand Side**

Health policy specialist Mohanan of the study team Collaboration for Health System Improvement and Impact in India (COHESIVE) points out the assumptions behind the demand side theory of change. "First, even if a new technology (broadly defined to include devices, process improvements, and organizational changes) can solve a problem faced by end users, the theory of change assumes that there is adequate demand for that technology. Second, the theory assumes either that the franchisee has a sufficiently large market share or that the adoption of the new technology will increase the use of franchisee health providers. Third, the theory assumes that franchisee health care providers will effectively use the technology in a way that actually improves service quality. Finally, the theory assumes that these improvements in quality will translate into improvements in population health."

2. **Supply Side**

Grant Miller, another COHESIVE affiliate, explains the supply side theory of change as follows: "In the hub and spoke model, the objective seemed to be to have the 'spoke' rural health providers refer more complicated cases (requiring more medical expertise) to the hub but for the spoke provider to manage simpler ones. But because hub providers were to receive a referral fee, a key issue was the size of the referral fee relative to what the spoke provider could earn for treating a patient. If higher, there would be an incentive to over-refer, and if lower, these would be an incentive to under-refer. We were interested in doing some work to figure out if a more nuanced referral system might not do better."

A team from the COHESIVE study group made early field visits to Uttar Pradesh to observe the predecessor to WHP-Sky and to gain an *ex ante* understanding of the planned WHP model. They raised concerns about untested assumptions, both on the demand- and supply-side, embedded in WHP's approach. For example, what constitutes good quality medical care in the view of rural residents of Bihar? And to what extent would they demand WHP services? Would they trust a telemedicine service that involved talking to a stranger over the internet? Given such doubts, would RHPs sign up in the numbers WHP expected? The COHESIVE team expressed these concerns to both WHP and the Gates Foundation and proposed researching the questions before implementation, but neither the foundation nor WHP thought it necessary or expedient at that point.

Implementation Issues

Although adoption of the two-tier model ensured faster growth, many of the problematic issues from the previous model persisted. Inadvertent selection of low-quality RHPs increased. The majority of new recruits were SkyCare facilities. Since they were small operators, scattered across rural areas, it proved difficult to closely monitor their compliance with established protocols. Lack of monitoring further increased the risk of enabling quacks and opportunistic providers who could seriously undermine the brand promise of quality health care. While the shift to two-tier made it easier for WHP to meet implementation milestones, the resulting impact on health outcomes through delivery of higher quality service remained unclear.

Moreover, demand for telemedicine services proved weaker than expected, and paying doctors to be available for calls was a huge cost for WHP. Several compounding and unforeseen issues led to this cost. First, the internet infrastructure was incapable of ensuring

seamless use of the software, making the entire process cumbersome and discouraging use. Second, the franchisees were required to pay WHP each time a patient consulted with a doctor using the telemedicine facility. Such payments proved to be a huge disincentive for franchisees since it required them to raise their fees or reduce their margins. Third, the franchisees continued to insist on access to the facility even though they rarely made use of it. The presence of the computer in their facility served to increase credibility among patients and justified higher fees. Thus, telemedicine became more a marketing tool than a means of adding actual value to care delivery.

Concerns within BMGF

Within BMGF, serious concerns arose about WHP's limited control over peripheral providers. "In our field visits it seemed like the WHP field operators were only concerned with ensuring smooth operations and functioning of the telemedicine facility and not ensuring quality control of the care provided," states Anand Sinha, the PO for this grant from 2012-2014. Furthermore, the four different PSTs that contributed money to the grant had vastly different expectations. The PSTs for Pneumonia and for Enteric and Diarrheal diseases were the largest contributors and saw this intervention as a way for SkyCare centers to quickly identify and locate cases of childhood pneumonia and diarrhea. After identification, centers were supposed to ensure the necessary simple treatment, like ORS (Oral Rehydration Solution) in the case of diarrhea, or else make a referral to the SkyHealth center in case of complications. This directive fit the primary and preventive care mission of the WHP-Sky program.

However, the Tuberculosis PST saw SkyCare as a way to build a robust public-private partnership that would leverage existing public infrastructure for treatment of tuberculosis.

They wanted the franchisees to identify and collect sputum samples from suspected patients. The samples would then be sent to the public sector hospitals for diagnosis, and drugs from the public sector were to be distributed through the franchisee to the patient. The Tuberculosis PST hoped that this interaction would create a robust relationship between public and private providers. The public sector, however, wanted nothing to do with these informal providers, seeing it as their mission to shut down such providers. Thus they were reluctant to accept samples from members of the WHP network. The franchisees likewise saw little benefit in this deal. "The franchisees were not keen to just be middlemen to the public sector, they wanted to treat the cases themselves because they wanted to be perceived as doctors," explains Anand Sinha. Similarly, the Visceral Leishmaniasis (VL) PST was interested in using the network to identify at-risk communities and subsequently spray for elimination of Sand Fly larvae, a use at odds with the social franchising model.

Inevitably, the differing expectations, compounded by implementation issues, ensured that none of the PSTs were entirely satisfied with the progress of the grant. In mid-2013, the Tuberculosis PST, led by Peter Smalls, decided to pull out of the grant and focus on another initiative under the sole administration of WHP.

A clash of cultures also arose within BMGF between the Seattle and Delhi offices. According to Anand Sinha, "Private sector interventions were not something the Indian team was familiar with and didn't see it as a priority. They wanted to devote their resources towards the public sector focused initiatives and therefore the WHP grant was relatively neglected." Furthermore, although the personnel in the Delhi Office, including Shah, had not been involved in the grant making decision, they were nonetheless expected to manage it. Guy

Stallworthy, who had championed the grant, left BMGF in 2014, meaning that responsibility for the grant's success or failure ultimately rested with the Delhi Office.

The COHESIVE Group

In 2010, a study proposal submitted by COHESIVE (Collaboration for Health System Improvement and Impact Evaluation in India) to evaluate the WHP-Sky Program was also accepted by the Gates Foundation and received a grant of $3 million. COHESIVE's objective was to inform policy in the Indian health scenario through conducting rigorous behavioral research and studies that evaluate the impact of programs. Researchers affiliated to COHESIVE had previously evaluated health programs in India, although not in Bihar. Manoj Mohanan and Grant Miller, both COHESIVE affiliates, together with colleagues Kim Singer Babiarz, Jeremy Goldhaber-Fiebert, and Marcos Vera-Hernandez, responded to the foundation's invitation and submitted a proposal to conduct a Randomized Controlled Trial (RCT.)

The primary objective of the trial under the auspices of the Bihar Evaluation of Social Franchising and Telemedicine project (BEST) was to provide evidence of the performance and effectiveness of the WHP-Sky program through a Randomized Controlled Trial (RCT) study design. The study, extending from 2011 to 2014, would measure both key service delivery metrics and population-level health outcomes of the intervention regarding childhood diarrhea and pneumonia, tuberculosis, and visceral leishmaniasis. Thus the study would not only look at the effect of the program on disease-related health outcomes, but also evaluate the quality of care (provider knowledge and effort) as well as other indicators of primary healthcare success. These outcome measures were decided upon in consultation with BMGF. Whether the choice of outcome measures was appropriate, given the design and

scope of the intervention, remains unclear. "It was not reasonable in my opinion to expect a primary and preventive healthcare intervention to impact population level outcomes for tuberculosis and visceral leishmaniasis," maintains Dr. Grant Miller. Nevertheless, these outcomes were included in the research design. In consultation with WHP and the Gates Foundation, the academics formulated a comprehensive plan that delineated control and treatment areas as well as timelines for measurement.

Randomized Controlled Trials

RCTs are generally considered the "gold-standard" in development economics. They involve an experimental setup, like a drug trial, to determine the causal effect of an intervention on the desired outcome variables. In this pursuit, comparable sets of target populations are identified and a baseline measure is conducted. Then the intervention is randomly applied to half the set – called the "treatment group," while the other half remains unexposed – the "control group." The crucial aspect of the study design is random selection of treatment and control; this ensures that no other factors (called confounders) determine whether a target population receives the treatment. Thus, the difference between treatment and control in the outcome variables can be entirely attributed to the intervention since all confounders have been eliminated.

After allowing reasonable time for the intervention to take effect, the two groups are again surveyed. Using various statistical techniques, the existence, or lack thereof, of a causal effect of the treatment on desired outcome measure can be empirically demonstrated. Although there are limitations to the generalizability of conclusions to different contexts, RCTs offer reliable proof for the effectiveness of social programs before implementation on a large scale. However, they are expensive, lengthy, and require strict administration. Yet RCTs have come

to dominate academic literature in development economics with top journals almost exclusively publishing papers based on such studies. Academics accordingly relish the opportunity to conduct them.

Evaluation Implementation Plan

The baseline for evaluation of the Sky program was established as between June-September 2011, with a follow-up to be done 3 years later. For the evaluation, 80 "study clusters" across 11 districts were randomly selected from 360 "study clusters." Evaluators selected clusters that were catchment areas surrounding an eligible "central village" that might become a SkyHealth (hub) telemedicine center. Eligibility was based on availability of broadband, existing healthcare infrastructure, and potential investors in the franchisee network.

Within these study clusters, evaluators planned to estimate the effect of WHP programs on a variety of dimensions. These included estimating the effect of the intervention (treatment) on health outcomes, treatment practices, and provider choice and cost for childhood diarrhea and pneumonia (TB and VL were included initially but dropped in the final publications)[xii]. Estimates were based on a representative household survey in the cluster area of all households with at least one five-year-old child.

Additionally, the team planned to estimate the effect of the intervention on provider quality and effort through interviews and vignettes as well as unannounced, standardized patient visits. The outcomes of interest were provider knowledge of appropriate treatment of childhood diarrhea and pneumonia (through interviews and vignettes) and actual provider performance regarding the same (through standardized patient visits). The interviews and

visits would help directly determine whether a WHP-affiliated provider performed better than other RHPs.

Change in Study Design

The series of changes in the implementation model affected the evaluation as well. By design, an RCT requires clear separation between treatment and control groups (and maintenance of randomized group assignment). In Sky's case, the treatment and control groups were established before the implementation of the program and did not take into account the successive program iterations. In early 2014, as data was being collected for the follow-up survey, evidence of contamination began to arise; WHP franchisees were appearing in areas marked as control. The result was a series of tense exchanges between WHP and COHESIVE with no clear resolution. According to Anand Sinha, "The relationship between COHESIVE and WHP soured and they refused to cooperate with each other. Both were suspicious of the other and saw them as working to undermine the other." From COHESIVE's perspective, WHP had little incentive to strictly respect the study design if there were operational advantages to implementing in control areas. As for WHP, positive evaluation offered limited benefit compared to the potential damage from negative findings. Certainly another constraint on areas of operation was unwelcome.

It soon became clear that severe contamination fatally compromised the RCT. This failure was not well received by the academics, but it remained possible to use the collected data to evaluate effectiveness of the intervention through quasi-experimental study designs. COHESIVE opted for an approach commonly known as Difference-in-Differences, which approximates an experimental setup when randomization is not possible. That is, it was impossible to eliminate or net out all confounders on the outcome variables since the clusters

that received exposure to WHP-affiliated providers were not entirely random. There may be underlying factors, such as density of RHPs in a cluster,that increased the probability of WHP-affiliated providers being present in the area as well as better health outcomes. As a result, it was not possible to estimate the sole effect of WHP-affiliated providers on health outcomes. As evidenced, a Difference in Differences approach is less rigorous in its causal inference than an RCT.

Evaluation Results

The evaluation results were to be published in the form of two papers in academic journals of repute. The first, regarding the demand side, was published in *Health Affairs*, a peer-reviewed journal, in its October 2016 issue. Results showed no significant effect of the WHP-Sky Program on improvement in population level health outcomes and treatment practices with regard to childhood diarrhea and pneumonia (See Appendix H and I). However, the paper did note that WHP-affiliated providers accounted only for 3.5% of all health care providers and 6% of all private health providers in the study clusters. That is, WHP franchisees had a relatively small market share in the areas surveyed[xiii].

Similarly, in a separate publication under review in 2016 regarding the supply side, results showed no significant difference in provider knowledge and effort in providing appropriate treatment in areas with WHP-affiliated providers compared to areas without them (See Appendix J and K)[xiv]. Although it oversampled WHP-affiliated providers, this study could not measure the effect of WHP-affiliation at the provider level.

In October 2016, based on these papers*, National Public Radio* published an article questioning the efficacy of the intervention. The article mentioned that the program was

funded by the Gates Foundation and that World Health Partners had received the prestigious

Skoll Award for Social Entrepreneurship in 2014.[xv]

Conclusion

In deciding the fate of the grant, Shah must take a holistic view of the project and the

stakeholders involved. She must acknowledge that even though the evaluation by

COHESIVE is not perfect in design, it raises questions about the efficacy of the program.

However, it is also true that the evaluation was done while the implementation model was

undergoing considerable change and remained unstable. These flaws in evaluation call into

question the Gates Foundation's 2010 decision to appoint an RCT for evaluation of a new

and completely untested program. Similar questions arise regarding the implementation

milestones set by the Gates Foundation that WHP was required to meet, as well as the

varying objectives of the four PSTs making the grant. Beyond these considerations, it is

without a doubt troubling that the WHP programs had limited control on their franchisees and

the quality of care provided. Taking all these factors into consideration, Shah must decide

whether or not to recommend continued disbursal of funds for this grant.

Appendices

Appendix A: Bihar

Source: www.emaps.org

Capital	Patna
Districts	38
Total Area	94,163 km2(36,357 sq mi)
Area rank	13th (Among Indian States)
Population (Total)	103,804,637 (2011)
Population (Rank)	3rd (Among Indian States)
Population Density	1,102/km2 (2,850/sq mi)
HDI	0.050 (2010)
HDI rank	28th (Among 29 Indian States)
Literacy	63.8% (2011)

Source: Wikipedia

Appendix B: Health Care Indicators across 18 most populous Indian States

States[1]	Health workers (per 1000)	Doctors (per 1000)	Nurses (per 1000)	Population (% of total population)	Rural population (%)	% births attended by skilled personnel
Andhra Pradesh	2.1	0.8	0.8	7	67	69
Assam	1.4	0.3	0.6	3	86	33
Bihar	1.0	0.4	0.3	9	89	30
Chhattisgarh	1.6	0.4	0.6	2	77	29
Delhi	4.5	1.5	1.5	1	0	60
Gujarat	1.7	0.4	0.6	5	57	62
Haryana	2.0	0.8	0.5	2	65	43
Jharkhand	1.4	0.4	0.6	3	76	28
Karnataka	2.1	0.7	0.8	5	61	67
Kerala	3.8	0.6	1.9	3	52	98
Madhya Pradesh	1.6	0.5	0.6	6	72	36
Maharashtra	2.9	0.8	1.1	9	55	63
Orissa	2.0	0.3	1.3	3	83	44
Punjab	2.7	1.1	0.8	2	63	64
Rajasthan	1.4	0.4	0.5	6	75	44
Tamil Nadu	2.3	0.6	1.0	6	52	89
Uttar Pradesh	1.3	0.6	0.3	16	78	29
West Bengal	2.4	0.7	1.0	8	68	54
India	**1.9**	**0.6**	**0.7**		**69**	**48**

1. States are ordered by alphabetic order.

Source: Rao et al (2008), MOSPI (2013) and DLHS (2006)

Source: OECD

Appendix C: Bill and Melinda Gates Foundation Grants in 2009 and 2010

For the Years Ended December 31, 2010 and 2009
Amounts in thousands

	2010	2009
PROGRAM AREAS		
Global Development	489,797	677,170
Global Health	1,485,337	1,826,446
United States	380,966	488,827
NON-PROGRAM AREAS		
Family Interest Grants	97,774	42,379
Charitable Sector Support	12,352	7,134
Employee Matching Gifts & Sponsorships	4,119	3,238
Total	**2,470,345**	**3,045,194**

For the Year Ended December 31, 2010
Amounts in thousands

Global Development $489,797

United States $380,966

Non-Program Grants $114,245

Global Health $1,485,337
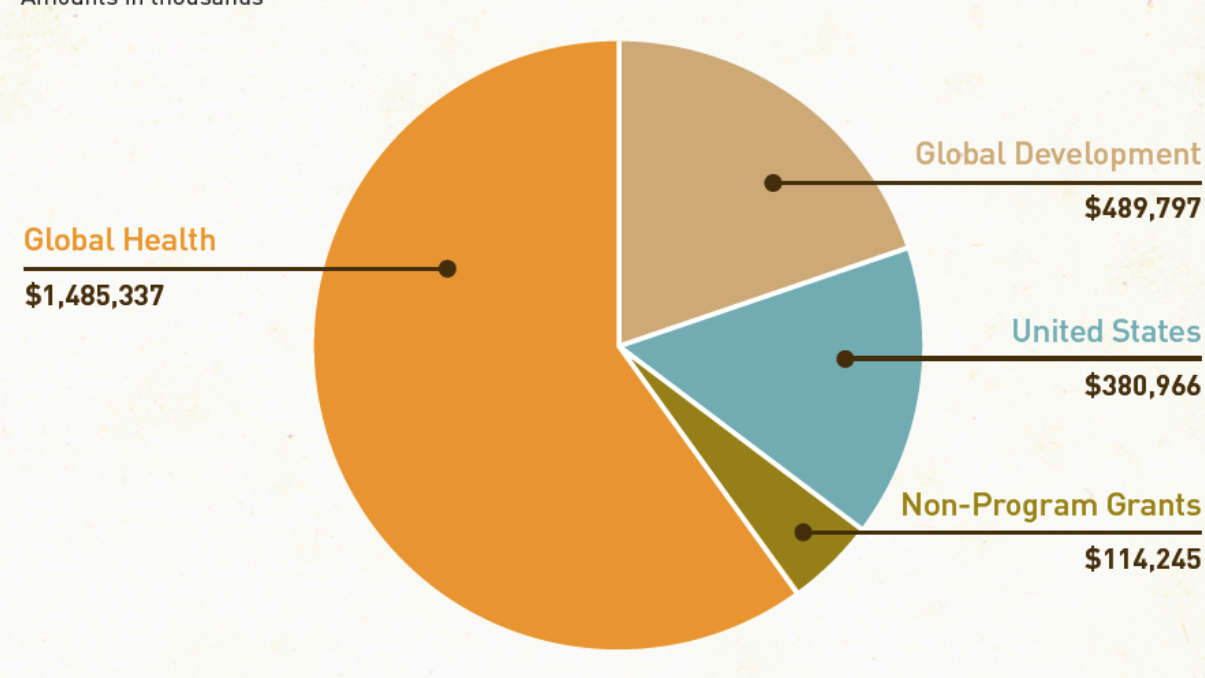
Appendix D: Breakdown of Grants in Global Health in 2010
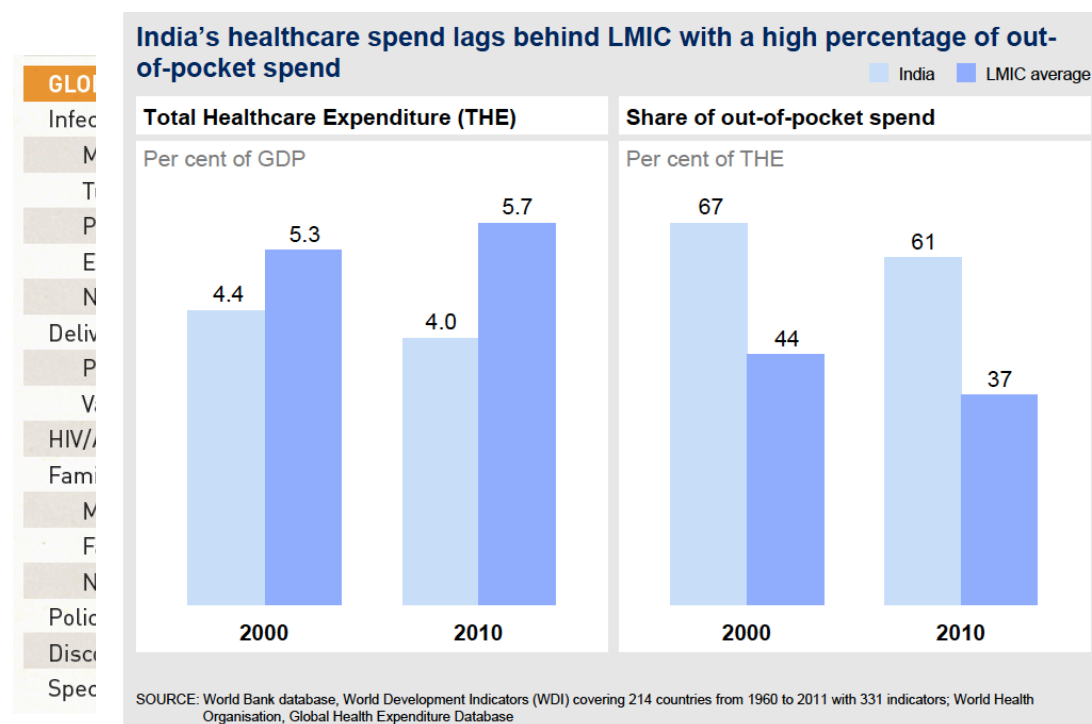
Appendix E: Private vs Public Expenditure on Healthcare in India
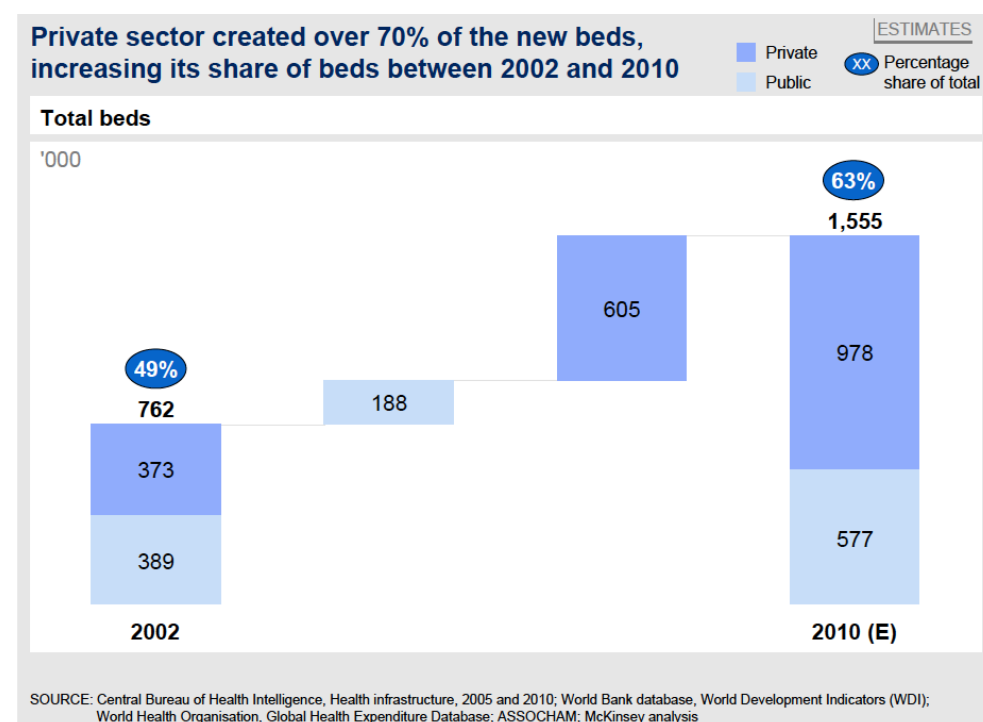
Source: McKinsey & Co.

Appendix F: Healthcare Spending Across Indian States

	Per capita public (Rs.)	Per capita private (Rs.)	% of state government spending
	2004-05[1]		
Himachal Pradesh	630	881	5.0
Kerala	287	2,663	4.7
Punjab	247	1,112	3.0
Karnataka	233	597	3.8
Tamil Nadu	223	1,033	3.4
Maharashtra	204	1,008	2.9
Haryana	203	875	3.0
Gujarat	198	755	3.1
Andhra Pradesh	191	870	3.2
Rajasthan	186	575	3.9
Orissa	183	719	4.4
West Bengal	173	1,086	4.3
Assam	162	612	3.1
Madhya Pradesh	145	644	3.2
Uttar Pradesh	128	846	3.9
Bihar	93	420	4.1

States are ordered in terms of per capita public spending, in descending order.

*Source: OECD*

Appendix G: A SkyHealth Facility in Bihar

Source: Duke Global Health Initiative

Appendix H: Effect of WHP-Sky Program on Childhood Diarrhea

Effects of the World Health Partners Sky (WHP-Sky) Program on the appropriate treatment, use of health care services, and prevalence of childhood diarrhea in Bihar, India, 2011–14

◆ Effect of having any WHP-Sky provider

◆ Effect of the numbers of WHP-Sky providers
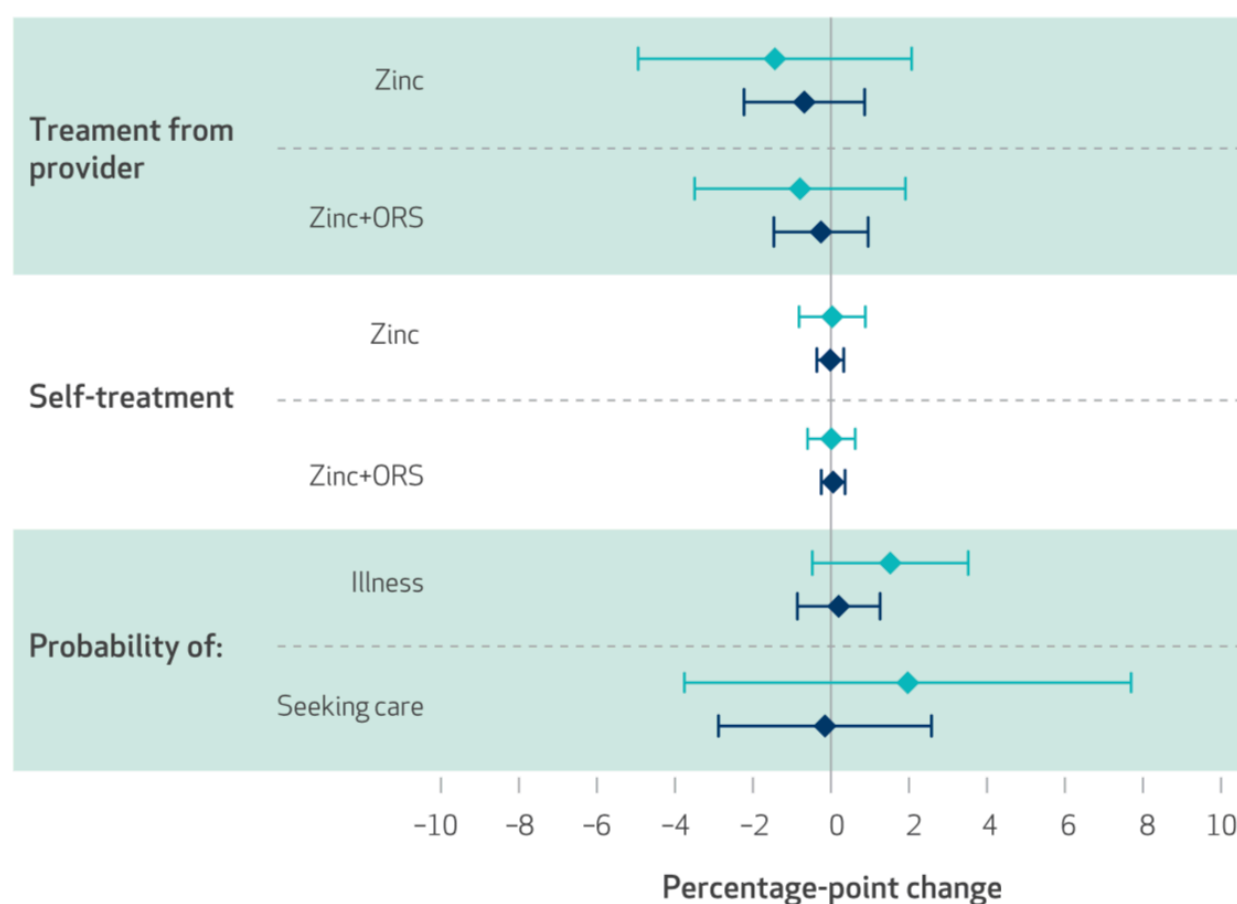
SOURCE Authors' analysis. **NOTES** For each outcome, the point estimates and 95 percent confidence intervals (indicated by the whiskers) correspond to program effect sizes estimated using multivariate difference-in-differences models fitted using ordinary least squares regression. For regression details, see the text. The point estimates for effect of number of WHP-Sky providers shown in the exhibit are interpreted as the effect of having an additional provider. "Self-treatment" refers to treatment administered at home without consultation. ORS is oral rehydration solution.
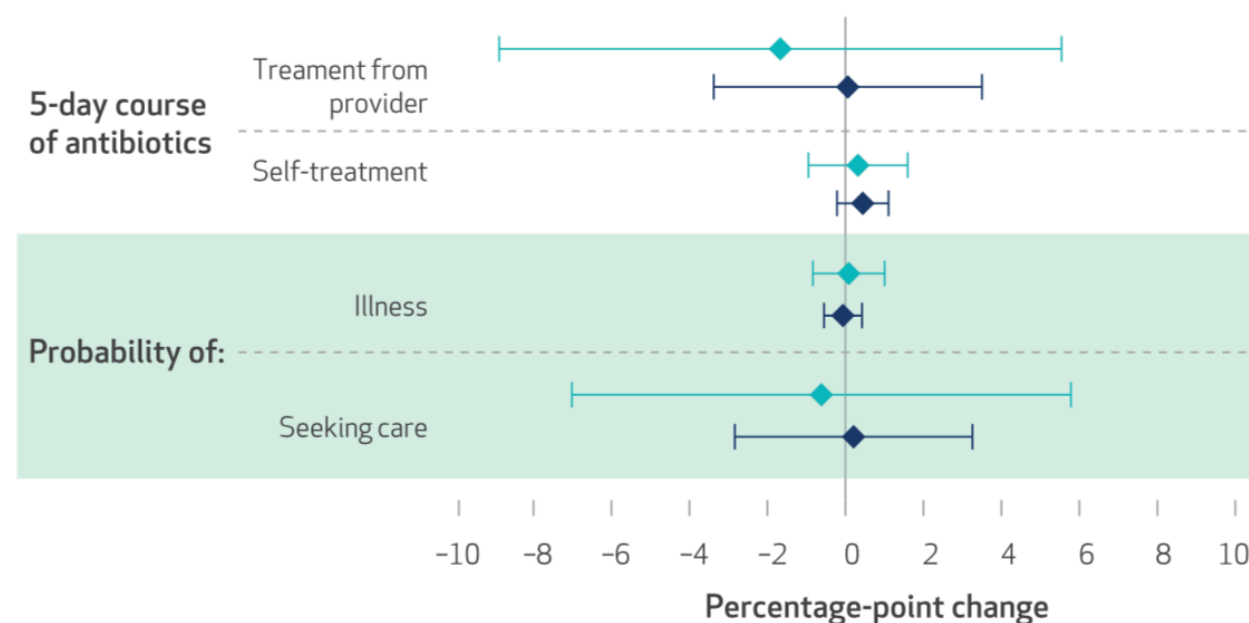
Source: Mohanan, Manoj, et al. "Effect of a large-scale social franchising and telemedicine program on childhood diarrhea and pneumonia outcomes in India." Health Affairs 35.10 (2016): 1800-1809

Appendix I: Effect of WHP-Sky Program on Childhood Pneumonia

Effects of the World Health Partners Sky (WHP-Sky) Program on the appropriate treatment, use of health care services, and prevalence of childhood pneumonia in Bihar, India, 2011–14

◆ Effect of having any WHP-Sky provider

◆ Effect of the numbers of WHP-Sky providers

5-day course of antibiotics
- Treament from provider
- Self-treatment

Probability of:
- Illness
- Seeking care

Percentage-point change: −10 −8 −6 −4 −2 0 2 4 6 8 10

SOURCE Authors' analysis. NOTES For each outcome, the point estimates and 95 percent confidence intervals shown correspond to program effect sizes, as explained in the Notes to Exhibit 3. Further regression details are in the text. The point estimates for effect of number of WHP-Sky providers shown in the exhibit are interpreted as the effect of having an additional provider. "Treatment" refers to a five-day course of antibiotics.

Source: Mohanan, Manoj, et al. "Effect of a large-scale social franchising and telemedicine program on childhood diarrhea and pneumonia outcomes in India." Health Affairs 35.10 (2016): 1800-1809
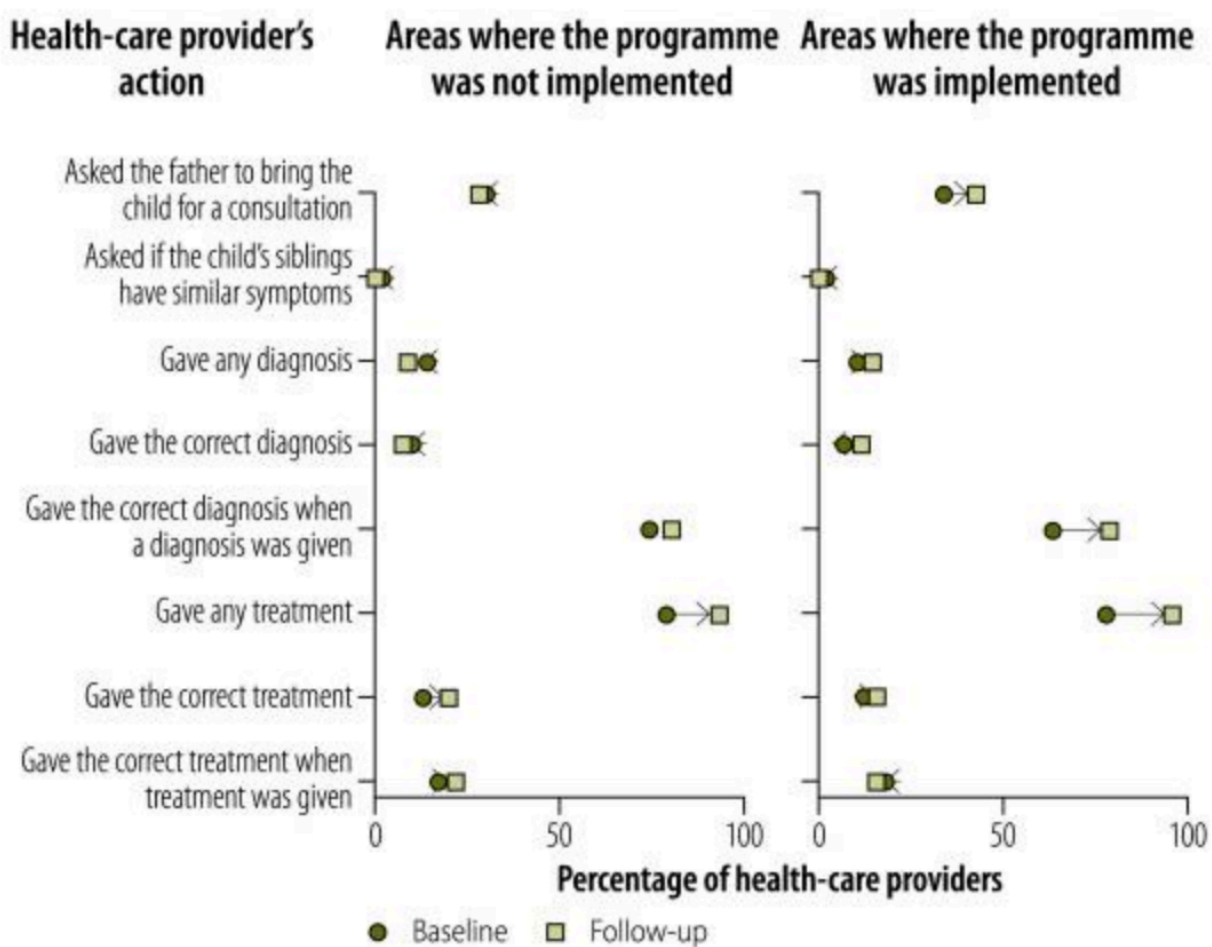
Appendix J: Health Care Provider's Action in the Case of Childhood Diarrhea
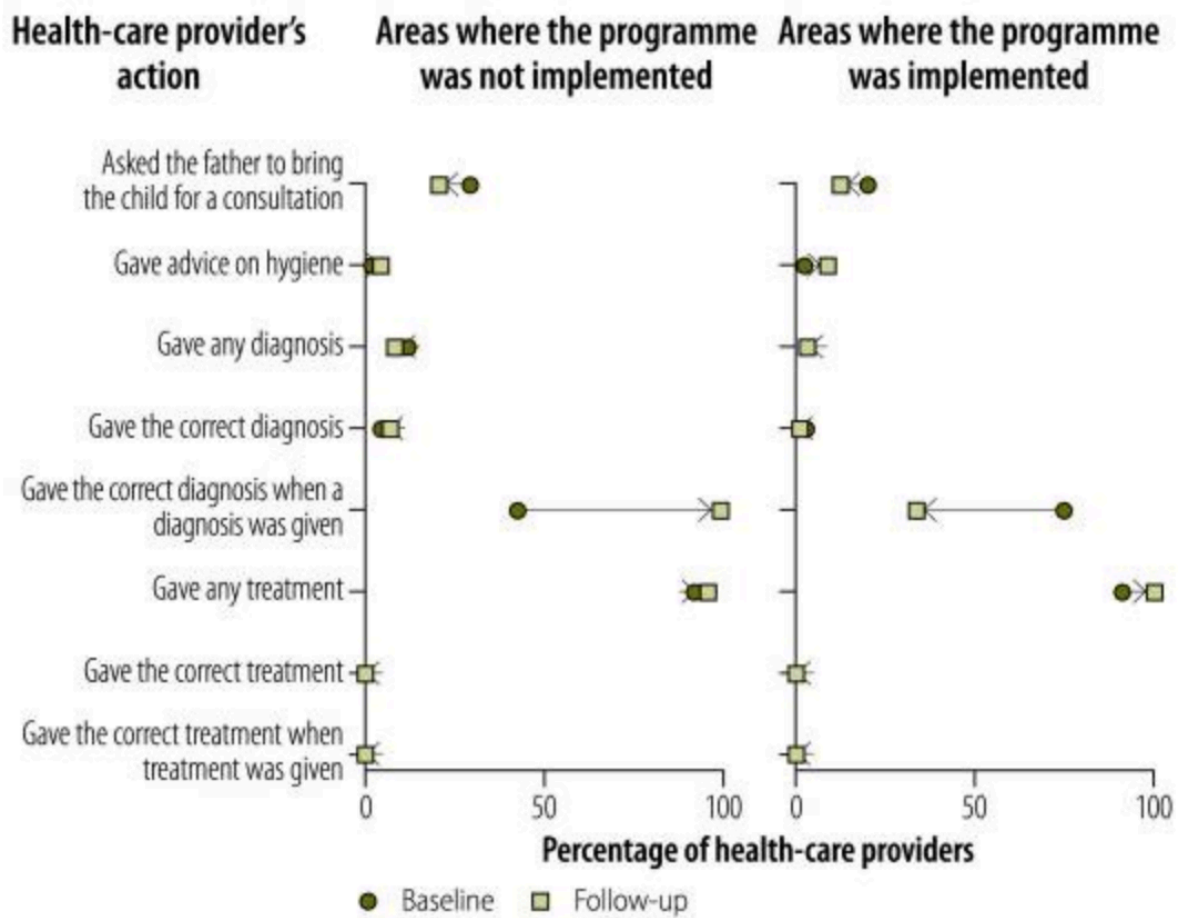
Source: NCBI

Appendix K: Health Care Provider's Action in the Case of Childhood Pneumonia

Endnotes

[i] Mukherjee, Sacchidananda, Debashis Chakraborty, and Satadru Sikdar. "Three decades of human development across Indian states: Inclusive growth or perpetual disparity?" *National Institute of Public Finance and Policy, New Delhi, India* (2014).

[ii] From the Annual Reports of the Gates Foundation

[iii] https://www.theguardian.com/world/2010/jul/12/bill-and-melinda-gates-foundation

[iv] The Lancet, "What has the Gates Foundation done for global health?" (2009): 1577.

[v] https://docs.gatesfoundation.org/Documents/Avahan_FactSheet.pdf

[vi] Pickles, Michael, et al. "Assessment of the population-level effectiveness of the Avahan HIV-prevention programme in South India: a preplanned, causal-pathway-based modelling analysis." *The Lancet Global Health* 1.5 (2013): e289-e299.

[vii] http://archive-org.com/page/3175096/2013-11-17/http://www.gatesfoundation.org/How-We-Work/General-Information/How-We-Develop-Strategy

[viii] Das, Jishnu, Alaka Holla, Aakash Mohpal and Karthik Muralidharan. "Quality and Accountability in Health Care Delivery: Audit-Study Evidence from Primary Care in India." *American Economic Review*,106.12 (2016): 3765.

[ix] Viswanathan R, Seefeld CA. "Clinical social franchising compendium: an annual survey of programs: findings from 2014" [Internet]. San Francisco(CA): University of California, San Francisco, Global Health Sciences Global Health Group; 2015 Jul [cited2016 Aug 19]. Availablefrom:http://www.sf4health.org/sites/sf4health.org/files/wysiwyg/Social-Franchising-Compendium-2015.pdf

[x] Das, Jishnu, and Jeffrey Hammer. "Money for nothing: the dire straits of medical practice in Delhi, India." *Journal of Development Economics* 83. 1 (2007): 1-36.

[xi] Mohanan, Manoj, et al. "Effect of a large-scale social franchising and telemedicine program on childhood diarrhea and pneumonia outcomes in India." *Health Affairs* 35.10 (2016): 1800-1809.

[xii] For full account of the methodology see pg 1802 Ibid

[xiii] Pg: 1804 Ibid

[xiv] Mohanan, Manoj et al. "Evaluation of a social franchising and telemedicine programme and the care provided for childhood diarrhoea and pneumonia, Bihar, India" *Bulletin of the World Health Organization* vol. 95,5 (2017): 343-352E.

[xv] https://www.npr.org/sections/goatsandsoda/2016/10/22/497672625/a-new-health-care-project-won-awards-but-did-it-really-work