USAID – DIV Final Questions. October 15, 2012

1. **How many centers will we randomize, Updated evaluation plan, including specific study questions, number of sites (broken out by those in India and Cambodia), approach to randomizing the study/control groups, estimated power of the study.**

Evaluation Plan

Two studies will determine the following:

1) **QUANTITATIVE EVALUATION:** What is the quantitative effectiveness of eDOTS in reducing the number of missed doses and treatment default by tuberculosis patients? Details are given below.

2) **QUALITATIVE EVALUATION:** How does the performance of other NGOs and public health institutions in contiguous areas compare to OpASHA's centers using eDOTS? And what are the qualitative perception of eDOTS by various users?

1) QUANTITATIVE EVALUATION

The study will randomize 138 centers. 104 biometric devices will be used for the intervention group. The number of devices is determinant on the number of counselors in the intervention group. A fixed terminal is located at each center in the treatment group (69 terminals) and each counselor will carry their own terminal (35 terminals) to verify missed dose follow up.

The primary outcome will be patient compliance (measured by sputum test, self-reported compliance). The RCT's secondary outcome will study counselor attendance (measured by random checks, patient reports). Other extensive surveys will find cost savings comparisons, patient satisfaction/trust, CDP commitment/ job satisfaction.

Baseline (1 month)

- Counselor/CDP Surveys: Total 69 surveys will be conducted; one counselor for 2 centers.
- Patient Surveys (Entry): Total 690 surveys will be conducted; 5 entry patients per center.
- Incidence of missed doses and default in all centers participating in the RCT (before randomization) and geographical areas contiguous to RCT areas.

End-line (1 month)

- Counselor/CDP Surveys: Total 69 surveys will be conducted; one counselor for 2 centers.
- Patient Surveys (Exit): Total 690 surveys will be conducted; 5 exit patients per center.
- Increase in patient income after treatment for both Drug Sensitive (DS)-TB and MDR-TB.
- The cost of treating one MDR-TB case by OpASHA with and without eDOTS in comparison to other NGO's and public health institutions working in the same area
- Comparison of the incidence of missed doses and defaults in (a) the test group, (b) the control group, and (c) geographical areas contiguous to RCT areas.

Intervention Monitoring (12 months)

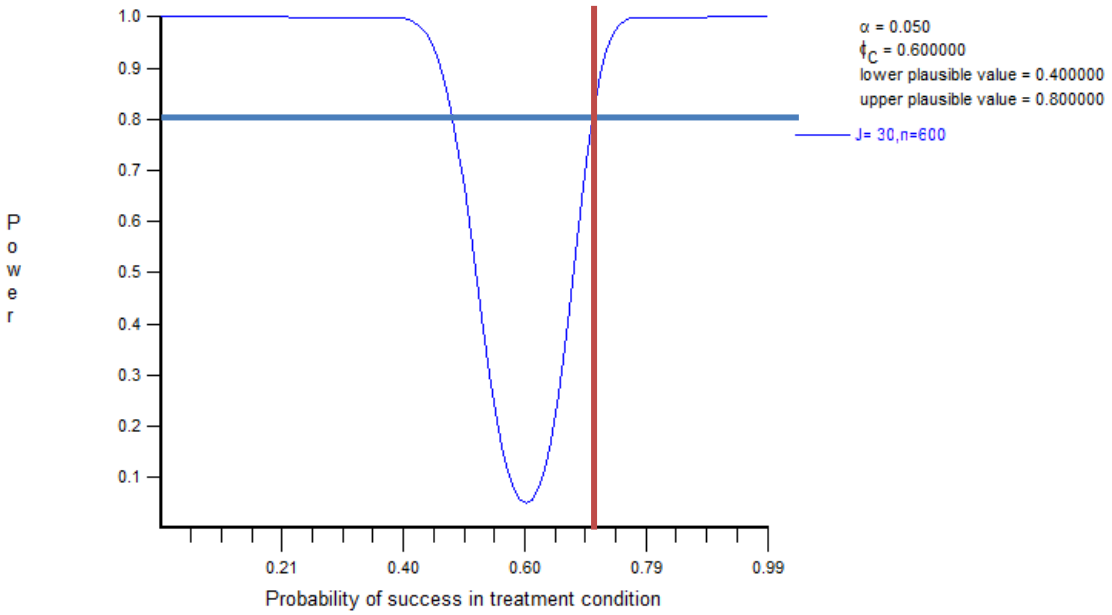
- Random checks of counselors' attendance and patients' pill intake
- Systematic checks of patients' defaults and reported "transfer outs" and deaths
- Loss in income by DS-TB and MDR-TB patients

Power of the Study

For these power calculations, we have focused on the following outcomes.

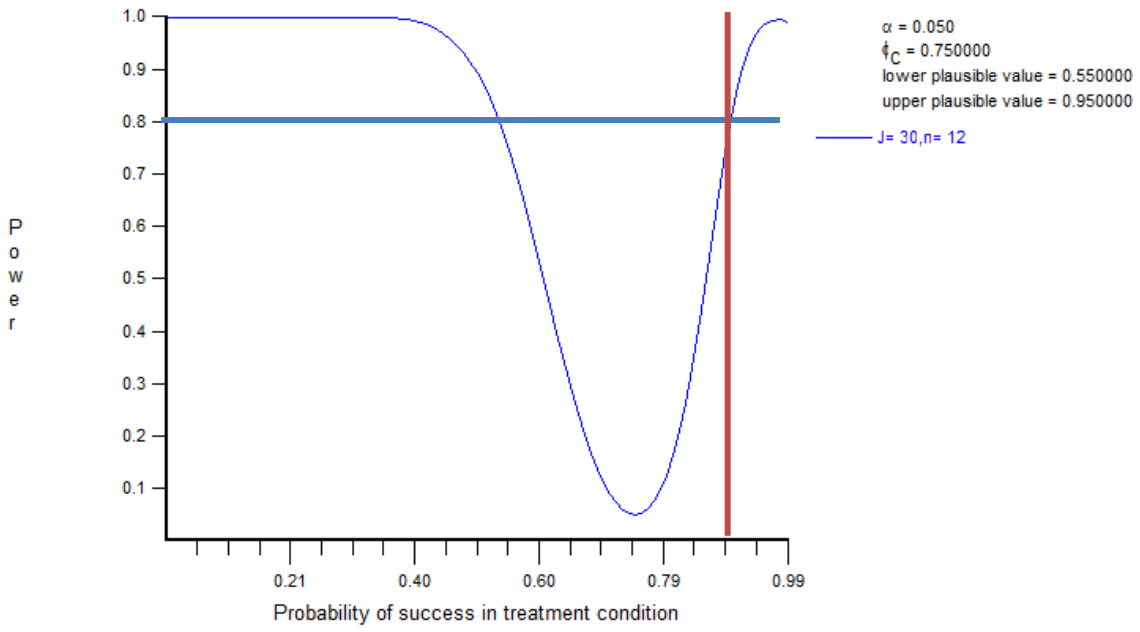
- **PRIMARY OUTCOME:** Patients' compliance with the treatment. Random checks will also be used to monitor actual pills' intake by the patients. Since each counselor operates two centers, each center provides medicine to 50 patients at a given point in time, and each patient is supposed to go to its center every other day, we will have a total sample of 35 counselors per group and 600 observations of individual patients' pill intake for each counselor.
  Assuming that patients have a 60% likelihood to take their pills on average in the control group, this will enable us to detect, with a power of 80%, and with 95% confidence, an increase in pill intake by 11 percentage points. The assumption of 60% likelihood of taking the pills is based on OpASHA's past experience with TB patients.

  Again, this estimate gives a lower bound of our real power, as it does not take into account the covariates that we will use to increase the preciseness of our impact estimate.



- **SECONDARY OUTCOME:** Counselors' absenteeism: we will conduct random checks of counselors' presence at the center once every month, providing a sample size of 35 counselors per group and 12 observations per counselor (since each of them will be maintained in the experiment for a total of 12 months).

  Assuming that counselors have a 75% likelihood to be present at their center on average in the control group this will enable us to detect, with a power of 80%, and with 95% confidence, an increase in presence by 15 percentage points. Again, this assumption of 75% presence is based on internal quality auditing reports and from our experience working with counselors.
  Note that this estimate gives a lower bound of our real power, as it does not take into account the covariates that we will use to increase the preciseness of our impact estimate.



Ultimately, the RCT will comprehensively assess the impact of biometric intervention in tuberculosis and MDR-TB treatment. A summary is given below. Details can be found in the Project Implementation Plan.

<u>Approach to Randomization</u>

In OpASHA, each counselor runs two TB treatment (DOTS) centers. Pairs of DOTS centers operated by the same counselor will be used as the unit of randomization. These pairs will be randomly assigned to either a intervention group (implementing eDOTS) or a control group (not implementing eDOTS). This random assignment will be stratified at the city level, ensuring that the impact measurement is unaffected by any difference across cities or across counselor status. The trial will be extended to 69 counselors and 138 TB treatment (DOTS) centers run by OpASHA.

The study will be randomized at the state/country level. The stratification breakdown is as follows:

1. India (128 centers, 65 counselors, ~9,900 patients)
    - Madhya Pradesh (97 centers, 49 counselors, ~7,500 patients)
    - East/West Delhi (8 centers, 4 counselors, ~600 patients)
    - South Delhi (18 centers, 9 counselors, ~1,400 patients)
    - Bilaspur (5 centers, 3 counselors, ~400 patients)
2. Cambodia (10 centers, 10 counselors, ~800 patients)
    - Takeo Province - provided USAID approval is granted for running the RCT in Cambodia. If Cambodia is not approved, an additional 10 centers from India (Moradabad) will be added to the RCT. Thus, the sample size and other figures in this document will not change.

There will be an equal number of counselors in both the intervention and the control group. All patients will be directed to the treatment center closest to them. All patients' treatment status (DS- or MDR-TB) will be known before the treatment regardless of which group they are placed in.

The randomization process will be stratified at the state and country level. Because of this, we expect the number of DS- and MDR-TB patients to be balanced between the intervention and control groups. This process will also allow researchers to eliminate confounding because of cultural and geographic contexts, and eliminate any one area from skewing the results. For example, it has been noted that a small sample size in Cambodia may bias the results due to differences in country contexts. However, our method of randomization will allow researchers to analyze such results separately if necessary. On the other hand, including a second country will hopefully mean that the results can be extrapolated to other regions/ country with greater confidence than if the trial was carried out only in one country.

Furthermore, India is country of continental size. Within India, the RCT will cover a diverse group of cultural, political, and geographic settings. Given such internal diversity, Cambodia is not very different. Particularly in lower-income areas, Cambodia's TB patients hold similar psychological patterns as those in India. This may be because of India's large influence on Cambodia from 5th century Indian kings, who ruled over Indochina. Further, Buddhism, which is practiced by more than 95% of Cambodia's population, was exported from India. So the psyche of Cambodians, especially the disadvantaged is perhaps not very different from Indians in a similar situation.

2) QUALITATIVE EVALUATION

A second study will be carried out parallel to the randomized control trial. The study will first compare Operation ASHA's results to other NGOs and public health departments in areas that are geographically contiguous to areas served by OpASHA. The data collected from Operation ASHA will be directly compared to official reports filled by the Government of India and Cambodia's (pending) National TB Programs.

In addition, the perception of eDOTS users will be evaluated through extensive surveys and interviews. The survey questions will be written and conducted with Jameel Poverty Action Lab South Asia to gauge how various users (counselors, providers, and patients) view the system. Following are several questions and goal of the study and more are described in the Indicator Chart:

- Do counselors view eDOTS as improving the treatment program?
- Does Biometrics help to persuade patients to come to the center?
- Do counselors/providers earn more respect from using eDOTS?
- What is the level of understanding on the part of patients of the purpose of eDOTS?

2. Updated project implementation plan.

Updated project Gantt Chart

Milestone	Month / Activity	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
1	Update Evaluation Plan and Project Implementation Plan	■																										
	Determine list of key performance indicators	■																										
2	Procurement and Installation of Biometric Devices		■	■																								
	Software and Equipment Quality Audit			■																								
	Confirmation of Drug Inventories			■																								
	Randomization of OpASHA's Centers			■																								
	Training and Distribution of biometric terminals			■																								
3	Collect Baseline Data and KPIs defined in Milestone 3		■	■																								
	Submit Baseline Report Including All KPI's defined in Milestone 3			■																								
	Monitoring Trial Centers				■	■	■	■	■	■	■	■	■	■	■	■	■											
4	Submit Progress Report to USAID as defined in Milestone 4						■																					
5	Submit Midterm Report to USAID as defined in Milestone 5												■															
6	Submit Progress Report to USAID as defined in Milestone 6																		■									
	Collect Endline data via surveys																■	■	■	■	■	■						
	Compile Endline data																					■						
7	Submit report on data collection and preliminary findings as defined in Milestone 7																					■						
	Begin Writing Final Project Report																						■	■	■	■	■	
8	Submit Evaluation Report as defined in Milestone 8																								■			
	Submit Final Project Report to USAID																											■

3. List of indicators (including health outcomes) that will be tracked by the program, and method and frequency of data collection.

Indicator	Method of data collection	Frequency of data collection
Number of patients per group (study and control)	• After randomization, the number of patients in each center will be added for both groups	After the initial Baseline report, the data will be continuously monitored. OpASHA will record this information in monthly reports for internal records. All changes will be reflected throughout the

		progress reports according to the milestone schedule.
Number of counselors/supervisors per group	• This number will be determined after the randomization. Any changes in this number will be documented	After the initial Baseline report, the data will be continuously monitored. OpASHA will record this information in monthly reports for internal records. All changes will be reflected throughout the progress reports according to the milestone schedule.
Number of supervisors (providers) per group	• This number will be determined after the randomization. Any changes in this number will be documented	After the initial Baseline report, the data will be continuously monitored. OpASHA will record this information in monthly reports for internal records. All changes will be reflected throughout the progress reports according to the milestone schedule.
Number of Machines Deployed and the number of machines functioning properly	• This number will be determined after the randomization. No changes to this indicator are expected	This data will be submitted in the Baseline and Progress reports. Any changes to this indicator will be reflected in the regular progress reports.
Number of DOTS facilities participating in the program/number of DOTS facilities in the study area (broken out by public/NGO/private if applicable)	• This number will be determined after the randomization. Any changes in this number will be documented	This data will be submitted in the Baseline and Progress reports. Any changes to this indicator will be reflected in the regular progress reports.
Number of DOTS facilities participating in the control area/ number of DOTS facilities in the control area (broken out by public/NGO/private if applicable)	• This number will be determined after the randomization. Any changes in this number will be documented	This data will be submitted in the Baseline and Progress reports. Any changes to this indicator will be reflected in the regular progress reports.
Prior to the start of the study, sputum conversion rate among the previous cohort of patients enrolled in TB treatment at DOTS facilities participating in the study and at the DOTS facilities in the control areas.	• This data will be determined from all centers participating in the RCT before the randomization. Post-randomization, this data will be taken from all DOTS facilities.	This data will be submitted in the Baseline report. This indicator will also be monitored post-randomization, and will be submitted with all progress reports.
Prior to the start of the study, case notification rate within the study/control areas	• This data will be determined from all centers participating in the RCT before the randomization. Post-randomization, notification rats will be taken from all DOTS facilities.	This data will be submitted in the Baseline report. This indicator will also be monitored post-randomization, and will be submitted with all progress reports.
Prior to the start of the study, treatment outcomes by type (cure, completed, failure, default, death, transfer) among the previous cohort of patients enrolled in TB treatment at DOTS facilities participating in the study and at the DOTS facilities	• This data will be determined from all centers participating in the RCT before the randomization. Post-randomization, this data will be taken from all DOTS facilities.	This data will be submitted in the Baseline report only. A similar indicator for current patients in the study will be submitted with all progress reports.

in the control areas.		
MDR treatment costs at baseline for OpASHA clinics, and clinics that will be used as a comparison for cost effectiveness analysis (i.e., NGOs, government, private, etc)	• Comprehensive cost records on eDOTS will be maintained through receipts and studied to calculate the total cost per patient. This data will be compared to data taken from the control group and public health institutions and NGOs working in contiguous areas.	MDR treatment costs will be taken from other institutions and submitted in the Baseline report as a comparator. This data will also be collected at the end of the intervention period for use in the Final Project report
Costs incurred to-date for eDOTS. This will include the setup of biometric system (procurement and installation), Biometric machine server, cellphones/internet, other equipment or maintenance costs for the biometric machines, financial incentives provided to counselors, salaries, and any social support provided to the patients.	• Exhaustive records and receipts will be maintained for the RCT. Those amounts will be compiled into the regular progress reports.	This information will be maintained continuously by project management and researchers. Updates will be submitted in the Progress reports and will be totaled and finalized in the Final project report.
The case notification and case detection rate within the study and control area	• This number will be collected from weekly reports submitted by the counselors and compiled into formal reports	OpASHA will record this information in weekly and monthly reports for internal records. The information will be submitted to USAID DIV in the Progress reports as outlined in the milestone schedule.
Treatment outcomes by type (cure, completed, failure, default, death, transfer) within the study/control areas	• This number will be collected from the biometric reporting system (intervention group) and from manual monthly reports (control group)	Data from the reporting system will be updated multiple times per day. For the control group, this indicator will be collected on a monthly basis.
Patient's compliance with treatment based on the number of missed doses and the number of patient defaults	• Random checks to monitor actual pills' intake by the patients	Throughout the experiment. Baseline and end-line patient data being collected 2 months over the course of the 12 month intervention. The baseline will help determine the number of missed doses through the use of treatment cards.
Counselor Absenteeism	• Random checks of counselors' presence at the center (control group) and biometric attendance (intervention group)	At least once every month
Number of defaults in all centers	• Through the use of TB registers and monitoring of reported "transfer out" to another center or death	Throughout the experiment. Baseline and end-line counselor and patient data being collected 2 months over the course of the 12 month intervention. The baseline will help determine the number of defaults through the use of TB registers.
Satisfaction of the patients with the	• Via patient surveys	Throughout the experiment.

treatment		Baseline and end-line patient data being collected 2 months over the course of the 12 month intervention.
Satisfaction of the counselors with the eDOTS system	• Via counselor surveys	Throughout the experiment. Baseline and end-line counselor data being collected 2 months over the course of the 12 month intervention.
The cost of treatment comparison with and without eDOTS by OpASHA and by other NGOs/ public health department	• Comprehensive cost records on eDOTS will be maintained through receipts and studied to calculate the total cost per patient. This data will be compared to similar data taken from public health institutions and NGOs.	Once, at the end of the intervention period. This indicator will be submitted in the Final Project report.
Quantification of the amount eDOTS reduces MDR-TB	• Default rates will be directly compared between the control and study group. The study's (eDOTS) default rates will also be compared to the default rates of the control group and prominent TB organizations and government programs across the world	Throughout the experiment. Baseline and end-line counselor data being collected 2 months over the course of the 12 month intervention.
The number of lives saved by eDOTS as a result of preventing of MDR-TB.	• The mortality rate in the eDOTS group will be compared to the control group and the WHO's TB mortality figures to evaluate the impact. This difference will be divided by the total cost of the eDOTS intervention to calculate the cost per life saved.	Once, at the end of the intervention period
The costs saved by patients accessing local MDR-TB treatment, such as lost wages and transport costs to access the physician and medicines.	• These costs will be calculated through patient surveys and government data.	Throughout the experiment via surveys and questionnaires.
Cost incurred by patients in accessing DOTS treatment for DS-TB and MDR-TB.	• This will be calculated through patient surveys and will be compared to the loss in income during treatment and the afterward increase in productivity to determine the economic loss prevented by DS-TB and MDR-TB treatment.	Once, at the end of the intervention period
The total accrued benefit to the families and children through the prevention of MDR-TB.	• This data will use WHO or World Bank figures to determine the indirect impact of treating TB and preventing MDR-TB	Once, at the end of the intervention period
The next steps that will be required	• This indicator will be provided by	Once, when submitted in the final

to achieve the intended scale up plans, including noting potential partners that are interested and/or commitments made by stakeholders such as the Governments of India and Cambodia	senior management	project report

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To whom it may concern,

This document certifies the completion of Milestone #2 of Grant No. AID-OAA-F-12-00040 to Operation ASHA for "Turning the Tap Off on Multi Drug Resistant TB and Extensively Drug Resistant TB". All activities within India listed below have been completed.

1. Procurement and installation of biometric machines for 138 DOTS centers and 69 counselors.
2. The biometric machine equipment/software is fully functioning for all intended users.
3. OpASHA clinics have access to a full supply of appropriate TB drug treatment regimen for the study patients

Sandeep Ahuja, CEO

April 03, 2013

Achievement of Milestone 3

Grant No. AID-OAA-F-12-00040 to Operation ASHA for "Turning the Tap Off on Multi Drug Resistant TB and Extensively Drug Resistant TB"

Baseline Report

Treatment Data

Collection of baseline data for this Evaluation began in January 2013. One survey team is involved in each city. The team consists of a surveyor and a monitor. Both of them report to the supervisor (one per city) who then reports to the Field Manager (one per state). The Field Manager provides updates to the Research Associates and a Regional Survey Manager on a weekly basis. All field issues are discussed in a monthly meetings.

Important s survey/monitoring tools that are used to collect the data are given below.

a) Patient surveys – to understand the socio-demographic conditions and perspectives of the patients
b) Counselor surveys – to understand the socio-demographic conditions and perspectives of the counselors
c) Random checks and Center monitoring form – to monitor the activities in the center and measure counselor and patient attendance

City after city was covered. The whole exercise was complete by March 2013. The next month was spent in collating and analyzing the data. Simultaneously, historical data was also collected and collated.

The total number of centers under randomization is 138 (10 more than needed as per the Grant Agreement). This includes 63 treatment centers in the intervention area ~~group~~ and 75 in the control area~~group~~. All these facilities belong to Operation ASHA. Given the fact that randomization was done at the city level, this is an entirely possible distribution.

Table below summarizes the above details.

Table 1: **Number of participating facilities**

	Total
Number of all DOTS facilities in treatment and study area (run by other agencies except OpASHA: 474; those run by OpASHA: 138, total 612)	612
Number of DOTS facilities participating in the program	138
Number of DOTS facilities participating in this evaluation in the treatment area (all are run by OpASHA)	63
Number of DOTS facilities participating in this evaluation in the	75

Comment [jmb1]: Please expand about this process – who are the survey teams, what instrument(s) did they use, etc. It is helpful if the milestone report can be a bit of a standalone document so we do not have to refer back to the application for details like these.

Comment [OA2]: Details have been added in this paragraph.

Comment [jmb3]: Thank you for the edits.

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Comment [jmb5]: The intention of this indica is to represent all DOTS facilities in the study area those operated by OpASHA and those operated b others (govt, private, etc). This figure can be generated to the best of OpASHA's knowledge.

Comment [OA6]: First row in this table now gives total number of DOTS centers in the treatm and study areas.

Comment [jmb4]: Thank you for the edits.

control area (all are run by OpASHA)	
Number of Supervisors	9

93 machines/ eDOTS units have been deployed at centers in the treatment area. ~~intervention group.~~ The technical staff ~~Operation ASHA~~ spent two weeks in each city carefully installing the devices, training ~~the~~ counselors and registering and enrolling ~~the~~ patients on each machine. All the machines have been connected to the server and have been~~are~~ sending data regularly.

The Research Team simultaneously ~~created the monitoring tool that would regularly~~ collected data on patient visits at the DOTS centers. The monitoring ~~would~~ also includes random checks and accompanying counselors during home visits.

Authoritative published data on TB patients is available in India only for sputum positive patients (this is logical, because only such patients can infect others and are a threat to society). This data is published by the Government[1] and has been considered as the baseline prevalence for 2012. The baseline for OpASHA is total number of cases detected in 2012 from the internal data of OpASHA. It is pertinent to mention that OpASHA's internal data is authenticated with the District TB Officer on a monthly basis. This data is given below for each city. Figures in the last column show Operation ASHA's contribution towards detecting patients in different cities. For example, in Bhopal, ratio~~n~~ of number of cases enrolled by Operation ASHA was 37.8% of the number of sputum positive cases enrolled in the district. This data, separated for treatment and study areas is given in Table 2A (This actually eliminates the need for Table 2, which has been left only because it was part of the original write up I sent you).

Table 2: **Case detection rates 2012**

City	Sputum Positive patients diagnosed in district as per Government data	OpASHA Detections	OpASHA Detection Rate (%)
Bhopal	3454	1307	37.8
Gwalior	2234	1056	47.3
Indore	3284	532	16.2
Jabalpur	2468	1119	45.3
Sagar	1971	343	17.4
Korba	665	203	30.5
Raipur	2288	153	6.7
Durg/Bhilai	1260	125	9.9
East Delhi	5307	267	5.03

[1] TB 2012 Annual Status Report, Published by the Central TB Division, Government of India, March 2012 <Src: http://www.who.int/whosis/whostat2006TuberculosisDOTSDetectionRate.pdf>. RNTCP's Annual Status Report of 2012 has information pertaining to the first three quarters of 2011 and the last quarter of 2010. These were the latest figures available on the date of comparison. For OpASHA also, latest figures have been used, which are for 2012.

Comment [jmb7]: The number of supervisors should be broken down by control and treatment areas.

Comment [OA8]: The supervisors look after work city-wide, which includes control as well as treatment areas.

Comment [jmb9]: Thank you for the edits.

Comment [OA10]: Details about the period covered in the Govt Report has been added in the footnote.

Comment [jmb11]: A point of clarification – these actually 2011 data? Often TB figures are on year late given that patients need to go through a course of treatment to determine their outcomes That is relevant to know if the figures are being compared to OpASHA's 2012 data.

Comment [jmb12]: The FOG requires OpASH to provide the case detection rate in both the control and treatment areas prior to the start of t study. However, these figures seem to represent % of government data that OpASHA generated. I that the case?

Case detection rate is typically calculated by divic case notification/sputum positives. Please provic those figures for the treatment and control areas these can be generated by government data for t catchment areas or by OpASHA, or a combinatior

Comment [OA13]: Table 2A inserted below gives case detection rates separately for control a treatment areas prior to the start of the study. Ye it gives OpASHA detections as a % of Govt detections.

Table 2A: Case detection rates by city and control/ study areas

City	Sputum Positive patients diagnosed in district as per Government data	Treatment Area Centers	Treatment Area Detections	Treatment Area Detection Rate (%)	Control Area Centers	Control Area Detections	Control Area Detection Rate (%)
Bhopal	3454	12	612	17.7%	13	695	20.1%
Gwalior	2234	12	334	15.0%	13	722	32.3%
Indore	3284	8	192	5.8%	10	340	10.4%
Jabalpur	2468	12	486	19.7%	13	633	25.6%
Sagar	1971	2	72	3.7%	6	271	13.7%
Korba	665	3	71	10.7%	6	132	19.8%
Raipur	2288	8	92	4.0%	8	61	2.7%
Durg/Bhilai	1260	4	54	4.3%	4	71	5.6%
East Delhi	5307	2	98	1.8%	2	169	3.2%
TOTAL		63	2011		75	3094	

In addition to all the above, b~~B~~aseline figures for the following indicators were also assessed.

- Number of patients per group (study/control)
- Number of counselors per group
- Number of supervisors per group
- Sputum conversion rate among the previous cohort of patients enrolled in TB treatment at DOTS facilities participating in this evaluation in the study and ~~at the DOTS facilities in the~~ control areas.
- Prior to the start of the study, treatment outcomes by type (cure, completed, failure, default, death, transfer) among the previous cohort of patients enrolled in TB treatment at DOTS facilities participating in this evaluation ~~e study and at the DOTS facilities~~ in the study and control areas.

They are given in the table below.

Table 3: Sputum conversion rates, Case notification rates and Patient outcomes (2012)

	Treatment Area[2] [1]	Control Area[3] [2]
Number of centers	63	75
Number of counselors	32	38
Number of patients (2012)	2011	3094
Sputum conversion rate	63.4	66.1
Case notification rate	207.7	322.4
Treatment outcome – Cure	59.9 (36%)	95.3(40%)
Treatment outcome – Complete	69.7(40%)	108.9(46%)
Treatment outcome – Failure	2.7(2%)	5.2(2%)
Treatment outcome – Default	4.8(5%)	6.0(6%)
Treatment outcome – Death	8.4(11%)	8.7(5%)
Treatment outcome – Transfer	4.8(6%)	3.3(1%)

[2], [3] Data for OpASHA is based on actuals for 2012 and for the Government, according to Annual Status Report of 2012

Comment [jmb14]: Thank for the above edit to clarify the data tables.

One additional comment –
To correspond with international definitions, the labels on "Treatment Area DETECTIONS" and "Control Area DETECTIONS" should read "Treatm Area NOTIFICATIONS" and "Control Area NOTIFICATIONS." Then the Detection Rate colum will match with the typically used formula of notifications/sputum positives. Using 'detections may cause some confusion among technical colleagues since those figures are actually notifie cases yet to be confirmed (detected). This is not required change, but please note that complying with internationally used definitions may help as OpASHA speaks about results within the TB community.

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Comment [jmb15]: For ease of review, it wo be helpful to put all required indicators on one ta if possible rather than several separate tables – both in this report and subsequent reports that require updates to these data points.

Comment [OA16]: As different tables have different column headings and provide entirely different data, a single table would become complicated and difficult to interpret. Therefore, have not changed the tables. If you still prefer, pl inform me and we will make an attempt.

Comment [jmb17]: This table is fine. Thanks

Comment [jmb18]: Do you mean treatment and control AREAS for these data, rather than GROUPS? It does not seem feasible to have 2012 data on the groups given that the study had not y begun.

Also, what are the data sources cited? There are footnotes attached to the citations.

Comment [OA19]: Yes, we mean AREA, not group. Footnote has been added.

Comment [jmb20]: The case notification rate India nationally is around 115. Please provide a fe notes as to why the rates are so much higher in these areas.

Comment [OA21]: Reason for such high figur has been added below the table.

Comment [jmb22]: Is this representing the % patients who complete their treatment course? If so, why is the control group over 100%? And, completion is typically not represented in that wa rather it is the % of patients who complete treatment but are not cured, defaulted, died, etc is usually a much lower % (for India nationally it is usually around 2%).

Comment [OA23]: This is not %, but simple average. Details are given in the second paragrap below Table 3.

Comment [jmb24]: Thanks for the edits to th table/below. Please see a comment related to th treatment outcomes below, however.

It may be mentioned here that case notification rate in the above table is much higher than the national average in India. Such high detection is common in areas served by OpASHA. It may indicate success of OpASHA's methodology of active case finding and community involvement. That could be the subject of a separate analysis/ evaluation. [4]

The figures in Table 3 for Treatment: Cure, Treatment Complete, Failure, Death and Transfer are average numbers for the treatment and control areas. These are NOT percentages. To calculate each of these parameters, all cities in each state are grouped and simple average is taken, which gives state-wide average. Simple average is taken a second time, over the state-wide averages, to arrive at the figure in Table 3.

Comment [jmb25]: It is not clear why OpASH does not comply with international standards for these figures. Treatment outcomes are typically expressed as a percentage/rate rather than an average. If OpASHA continues to use averages, treatment outcomes facilitated by OpASHA interventions cannot be easily compared with oth outcomes generated by comparable clinics/etc. Please let me know if I am misunderstanding.

Cost data

Baseline cost data for Multi-Drug-Resistant-TB has also been collected. A list of all the NGOs/ organizations who work with MDR patients in any way was obtained from the nodal TB care agency: Partnership for TB Care and Control in India (http://www.tbpartnershipindia.org/). Of the 35 NGOs that are involved, most provide a limited number of services. For example, German Leprosy and TB Association provides only counseling for patients who are detected at Government laboratories and are subsequently treated by Government DOTS centers. Only a few organizations are providing the full set of services, i.e. treatment and counselling. They were contacted. TB-Alert shared their salary and expense data, which has been used for the analysis below. Data was collected in the period Feb-April 2013 and was subsequently analyzed. To assess financial burden on patients in accessing treatment, costs incurred by patients w~~as~~ere also collected and analyzed. The results are given below.

Table 4: **MDR treatment costs at baseline for OpASHA clinics and Comparison Group**

Costs incurred (in $) Forex rate: $1= INR 54	**OpASHA**	**Comparison Group: TB-Alert India**
Cost incurred by NGO	460	829
Cost incurred by patient in accessing medicines at the clinic/ DOTS center	129	344
Cost incurred by patient in accessing public hospitals for physician consultation and tests	101	101
TOTAL	**600**	**1184**

Comment [jmb26]: We understand the proc noted above to obtain comparison data, but plea clarify if these figures represent one group that is serving as a proxy for the others, or if these figure are the average amounts spent by several groups Please cite the specific group(s) that is serving as comparison.

Comment [OA27]: Organization's name is no specified

Comment [jmb28]: Please clarify what speci costs are included in this figure.

Comment [OA29]: Cost heads are now mentioned below the table

Comment [jmb30]: Thank you for these clarifications.

Following expense heads were considered for the above analysis: Field Supervision, Recruitment and Trainings, Rent for office space and Consumables.

Challenges:

One main challenge for research team is to understand the way eDOTS system ~~devices are~~ is ~~being~~ used in practice by counselors, providers and patients. ~~.~~ For example, if a counselor does not properly assimilate the training fully, she may not be able to take finger prints of all patients successfully. This would indicate a higher rate of missed doses that actual. To ameliorate this problem, lessons learnt during the pre-installation stage and training on the system in various cities and states, were incorporated in design of the survey/ monitoring tool. This ensured that everyone involved understood well how to use the system.

Attrition among counselors poses another challenge. We wish attrition could be totally eliminated, but in the real world, that is only wishful thinking. Imagine that a counselor who has been randomized leaves OpASHA. The center allotted to him is now without a counselor. So a new counselor is recruited and allotted to that center. In this process, the allocation of biometric devices to centers, and hence to patients, remains random, but the new counselor may be subject to a bias in recruitment. For example, the HR Team may tend to select those who are relatively better in using technology if the HR Team knows that the center where the counselor will work has a biometric machine. To reduce this bias, OpASHA is recruiting new counsellors in a quasi-random manner by keeping the HR Team "blind", i.e. deliberately ignoring whether the new counselor will work at a center in a treatment area or a control area. This minimizes the bias. On top of that, through the counselor surveys, it is also verified whether there is any imbalance in the skills or experience of the new counselor compared to existing counselors. If a serious difference comes out, the new (replacement) counselor may be excluded from the study altogether.

For counselors who leave, a survey is administered to capture their responses about the use of the biometric device and interaction with patients (midline+).

~~The a~~The ~~nalysis~~analysis and data above completes Milestone 3.

Comment [jmb31]: Why is this a challenge? Please provide more details.

Comment [OA32]: It has been explained in th additional text that has been inserted below.

Comment [jmb33]: What does this mean?

Comment [OA34]: The description above and below this phrase brings out its meaning.

Comment [jmb35]: Thank you, these points clear now.

Achievement of Milestone 4

Grant No. AID-OAA-F-12-00040 to Operation ASHA for "Turning the Tap Off on Multi Drug Resistant TB and Extensively Drug Resistant TB"

The total number of treatment centers under randomization is 130. This includes 61 centers in the Treatment Group and 69 in the Control Group. All these facilities belong to Operation ASHA. Further details are given below.

Table 1: Overview

	Treatment Group	Control Group
Number of centers in the study	61	69
Number of counselors in the study	31	34
Number of counselors who left the study	10	6
Sputum Conversion rate	79.6%	90.4%
Number of patients in the study	256	354
Number of supervisors in the study	9	
Number of supervisors who left the study	3	

Table 2: Costs incurred till July 2013 ($)

	($)
Set up of biometric system (procurement + installation)	45,628
Biometric machine server	1,734
Cell phones/internet	1,450
Other equipment or maintenance costs for the biometric machines	13,902
Financial incentives provided to counselors	7,595
Salary paid to counselors	38,922
Program staff salary	151,083
TOTAL	**260,314**

This leaves a surplus of $9,686, which has been utilized to continue the work and meet the next milestone.

Study has been going on very well in 8 cities, namely Bhopal, Gwalior, Indore and Sagar in Madhya Pradesh; Raipur, Durg/ Bhilai, Korba in Chhattisgarh; and East Delhi.

However, some challenges were faced in one city, Jabalpur.

Comment [U1]: What is the timeframe for these figures, given that the table below is 5 months old?

Comment [U2]: Please provide the formula for calculating these figures.

Also, please provide a short summary of the actions OpASHA takes when a patient does not sputum-convert.

Comment [U3]: Please provide more current cost data or include an explanation why it is not available

Comment [U4]: The milestone requires an overview of implementation to-date, including an update on each study. USAID needs more information than this to satisfy the milestone requirement. Milestone 1 outlined two studies (below) and we expect an update on the implementation to-date of each one:

QUANTITATIVE EVALUATION: What is the quantitative effectiveness of eDOTS in reducing the number of missed doses and treatment default by tuberculosis patients? The primary outcome will be patient compliance (measured by sputum test, self-reported compliance). The RCT's secondary outcome will study counselor attendance (measured by random checks, patient reports). Other extensive surveys will find cost savings comparisons, patient satisfaction/trust, CDP commitment/ job satisfaction.

QUALITATIVE EVALUATION: How does the performance of other NGOs and public health institutions in contiguous areas compare to OpASHA's centers using eDOTS? And what are the qualitative perception of eDOTS by various users? The study will first compare Operation ASHA's results to other NGOs and public health departments in areas that are geographically contiguous to areas served by OpASHA. The data collected from Operation ASHA will be directly compared to official reports filled by the Government of India National TB Program.
In addition, the perception of eDOTS users will be evaluated through extensive surveys and interviews to gauge how various users (counselors, providers, and patients) view the system.

Comment [U5]: Milestone 1 outlined the following locations, which differs from this list. When and why were changes made?

- Madhya Pradesh (97 centers, 49 counselors, ~7,500 patients)
- East/West Delhi (8 centers, 4 counselors, ~600 patients)
- South Delhi (18 centers, 9 counselors, ~1,400 patients)
- Bilaspur (5 centers, 3 counselors, ~400 patients)

Challenges

Performance of OpASHA's Program Manager and one counselor in that city had deteriorated. We decided to fire them. The District TB Officer (DTO) went beyond his powers and pressurized us to retain them. He threatened to stop the free supply of anti-TB drugs if we did not agree to his demand.

As a matter of principle, we do not yield to such pressures because of many reasons. First, retaining non-performers lowers the morale of all staff in the medium and long term and hurts results and finally patient care. Secondly, if you yield once, it encourages other officers in that city, and subsequently in other cities, to raise similar demands.

We invested substantial effort in trying to convince the DTO to drop the demand, more so because the eCompliance trial was in progress. Our Senior Program Manager and COO traveled to the city and met him personally. I spoke to him on the telephone and offered to visit him personally. He did not budge. Finally, we had to let go so we could retain our well-established Standard Practice of not yielding to unreasonable demands of government officers that may adversely affect our program.

Simultaneously with discussing the matter with the DTO in Jabalpur, OpASHA had taken mitigating action in Bhubaneshwar. There were only 12 centers in Bhubaneshwar (state of Orissa). None of them was part of the trial. The program was expanded with addition of 6 more centers and all of them were included in the trial by shifting the eCompliance machines form Jabalpur to Bhubaneshwar.

This way, 130 centers are still part of the study, 2 more than envisaged under the Agreement.

Comment [U6]: If the DTO made good on his threat to stop the supply of anti-TB drugs to OpASHA centers in Jabalpur, what happened to the patients who may not yet have completed treatment? How was the continuity of their care ensured?

Achievement of Milestone 5

Grant No. AID-OAA-F-12-00040 to Operation ASHA for "Turning the Tap Off on Multi Drug Resistant TB and Extensively Drug Resistant TB"

Midline Report

Overview

Data collection for baseline of the eDOTS study began in January 2013. Counselors in 5 cities in Madhya Pradesh (Bhopal, Indore, Sagar, Gwalior and Jabalpur) were randomized in March 2013 and those in Chhattisgarh (Raipur, Durg, Korba) and East Delhi were randomized in April 2013. Operations in Jabalpur were shut down in May 2013 (of which the details were mentioned in the the last Milestone report). In August, baseline survey and monitoring data was collected in Bhubaneswar, Orissa. In September 2013, 9 counselors from this city were randomized into the study.

Baseline surveys have been administered to all new counselors, midline questionnaires to counselors who have completed the 6 month mark in the cities under study (43 until November 2013) and midline plus to those who left the study before completing 6 months. The endline survey for counselors who complete 12 months in the experiment and the endline plus survey for those who leave between 6 – 12 months of the intervention have been finalized.

Table below gives an overview of the study

Table 1: Overview

	Treatment Group	Control Group
Number of centers	61	69
Number of counselors in the study	31	34
Number of counselors who left the study	8	10
Number of supervisors in the study	9	
Number of supervisors who left the study	3	
Number of machines in use and functioning properly	64	
Number of machines deployed	86	

Patient surveys, through which information about the socio-demographic characteristics of the TB patients and their relationship with the Operation ASHA counselors and other healthcare providers are collected, are ongoing in all study areas. Until November 2013, 1575 adult and 140 child surveys have been administered.

Table 2: Case detection rates by city and treatment/ control areas (Aug - Nov 2013)							
City	Sputum Positive patients diagnosed in district as per Government data	DOTS centers in Treatment Area	Detection in Treatment Area	Detection Rate in Treatment Area (%)	DOTS centers in Control Area	Detection in Control Area	Detection Rate in Control Area (%)
Bhopal	3099	12	128	4.13%	13	193	6.23%
Gwalior	2276	12	244	10.72%	12	367	16.12%
Indore	3556	8	61	1.72%	10	112	3.15%
Sagar	1871	2	17	0.91%	6	65	3.47%
Korba	644	3	35	5.43%	6	31	4.81%
Raipur	2306	8	59	2.56%	8	41	1.78%
Durg/Bhilai	1516	4	19	1.25%	4	37	2.44%
East Delhi	5549	2	33	0.59%	2	7	0.13%
Bhubaneswar	573	10	32	5.58%	8	57	9.95%
TOTAL		**61**	**628**		**69**	**910**	

Source: TB 2013 Annual Status Report, Published by the Central TB Division, Government of India, March 2013. RNTCP's Annual Status Report of 2013 has information pertaining to the first three quarters of 2012 and the last quarter of 2011. These were the latest figures available on the date of comparison. For OpASHA also, figures are used for the period of Aug-Nov 2013

No: of cases notified (A)/No: of cases estimated for that year (B)
<Src: http://www.who.int/whosis/whostat2006TuberculosisDOTSDetectionRate.pdf>

The J-PAL team has been using digital data collection methods to keep real-time records of monitoring data as well as details about day-to-day operations, thereby greatly improving data quality standards. The J-PAL field-staff attended a refresher training after the 6 month mark of the intervention which was helpful in providing valuable feedback on field operations, survey and data collection methods, and in boosting the spirits of the team.

Software development for the patient surveys is complete and data is currently being entered. Cleaning of the incoming digital monitoring data is also ongoing.

In addition to the above, midline figures for the following indicators were also accessed.

- Case notification rate within the treatment/ control areas
- Sputum conversion rate of patients
- Treatment outcomes by type (cure, completed, failure, default, death, transfer) within the treatment/ control areas

Table 3: Sputum conversion rates, Case notification rates and Patient outcomes (Aug - Nov 2013)

	Treatment Group	Control Group
Number of patients in the study	602	936
Sputum conversion rate	72.7	87.5
Case notification rate	33.61	68.82
Treatment outcome – Cure	37%	38%
Treatment outcome – Complete	40%	42%

Treatment outcome – Failure	1%	2%
Treatment outcome – Default	6%	7%
Treatment outcome – Death	6%	6%
Treatment outcome – Transfer	10%	5%

Forthcoming activities:

In the coming months, the J-PAL team will develop software for entering counselor data into a comprehensive database. Data entry and cleaning will also commence once the software is ready. The team plans to begin wrapping up field operations by April 2014 for Madhya Pradesh and May 2014 for Delhi and Chhattisgarh.

Following is the summary of the costs incurred on the study till Nov 2013

Table 4: Costs incurred till Nov 2013	**USD**
Set up of biometric system (procurement + installation)	47,106.01
Biometric machine server	1,733.60
Cell phones/internet	2,487.20
Other equipment or maintenance costs for the biometric machines	15,282.92
Financial incentives provided to counselors	12,631.64
Salary paid to counselors	65,805.79
Program staff salary	1,93,370.43
TOTAL	**3,38,417.59**

There is a deficit of $68,418, which has been utilized till the end of Nov 2013.

Challenges:

In October 2013, for about a week, Operation ASHA removed the biometric devices from all the treatment centers in Indore due to issues with the District TB Office. The devices were re-installed in these centers after the problems were sorted out. We plan to extend the study by a month in Indore as a way to redress the disruptions in operations. The event has also been recorded in the field log of the study.

As mentioned in the previous report, counselor turnover continues to pose a challenge for the study. Operation ASHA is working to mitigate the effects of new appointments on the randomized design of the evaluation.

For J-PAL, developing the software for the digital data collection entailed rigorous testing and editing of the multiple drafts as well as re-training staff. This process has now been finalized and data collection is now streamlined.

Achievement of Milestone 6

Grant No. AID-OAA-F-12-00040 to Operation ASHA for "Turning the Tap Off on Multi Drug Resistant TB and Extensively Drug Resistant TB"

The experiment has run for 12 months in Madhya Pradesh (Bhopal, Gwalior, Indore and Sagar) and 11 months in Chhattisgarh (Raipur, Korba and Durg) and East Delhi. We will wrap up field monitoring in May in all cities except for Bhubaneswar, where the experiment will go on until September 2014. The reason is that Bhubaneshwar was included in the Intervention at a later date to compensate for premature closure of the Intervention in Jabalpur. Because of the late start in Bhubaneshwar, midline survey is in progress.

In all cities, midline plus survey to those who left the study before completing the Study are being administered. The endline survey for counselors who complete 12 months in the experiment and the endline plus survey for those who leave between 6 – 12 months of the intervention have also been finalized and will be done soon.

Patient surveys, through which information about the socio-demographic characteristics of the TB patients and their relationship with the Operation ASHA counselors and other healthcare providers are collected, are ongoing in all study areas.

The J-PAL team has been using digital data collection methods to keep real-time records of monitoring data as well as details about day-to-day operations, thereby greatly improving data quality standards.

Software development for the patient surveys is complete and data is currently being entered. Cleaning of the incoming digital monitoring data is also ongoing. But it is a time consuming process and is taking much longer than we had expected.

In addition to the above, endline figures for the following indicators will be collected soon in most cities (except Bhubaneshwar, because of reasons mentioned above).

- Case notification rate within the treatment/ control areas
- Sputum conversion rate of patients
- Treatment outcomes by type (cure, completed, failure, default, death, transfer) within the treatment/ control areas

At the start of the study, we had bought Asus netbooks, which formed part of eCompliance units. Unfortunately, they had a problem with their hard disk. Many of them broke down at random, in different cities, at various centers. It took a lot of effort and resources to repair them, even though hard disks were replaced for free by the manufacturer because the machines were within the warranty period. We even discussed internally whether hard disks in all the Asus machines could be "made" to crash to we could get the manufacturer to replace all of them at one go. But it was not possible to organize such a "crash". The manufacturer was asked to replace all hard disks in view of the high defect rate. The manufacturer did not agree.

In spite of repairs, some machines in every city started giving trouble at regular intervals. Finally, we decided to replace some of them.

After the Study started, we have been able to develop a new variant of eCompliance, which uses 7” Andriod Tablets instead of netbooks. A picture of this system is given along-side. A picture of the original netbook based system is also shown, for comparison.

Original eCompliance on netbook computer

New eCompliance technology on Android tablets

In terms of functionality, tablet based eCompliance units are exactly the same as the original ones. However, because tablets and netbooks use different technologies, it is not possible to combine them in a single city.

Therefore, it was decided to replace all units in one city with the new tablet based eCompliance units. This was done in Bhopal. Spare netbook based units were used in other cities to replace the ones that were giving frequent trouble. This has solved the problem and now the system is doing well.

It may be underscored that the problem arose basically because a particular lot of Asus netbooks had serious manufacturing defects. It had nothing do with eCompliance software or handling by field workers. This view is reinforced by the fact that eCompliance units that were using Lenovo or other netbooks did not give any such trouble.

Milestone specific details/ number are given below.

Table 1: Overview

	Treatment Group	Control Group
Number of centers	61	69
Number of counselors in the study	31	34
Number of counselors who left the study	10	12
Sputum Conversion rate	90.9	97.0
Number of patients	159	209
Number of supervisors in the study		9
Number of supervisors who left the study		4

It may be noted that Sputum Conversion Rate is very high in both cases. However, the one in the Control Group is higher than in the Treatment Group. A question may be asked here: why is it so and isn't it expected that the Treatment Group should deliver better results. We have deliberately not investigated this question at this stage because an investigation may send a signal to the field staff to increase performance in the Treatment Group in comparison to the Control Group. This will introduce a bias and vitiate results of the Study. This is not desirable. So such differences will be analyzed only at the end of the Study.

Costs incurred up to this stage are given below.

Table 2: Costs incurred till Mar 2014	**USD**
Set up of biometric system (procurement + installation)	47,919.38
Biometric machine server	1,733.60
Cell phones/internet	3,499.82
Other equipment or maintenance costs for the biometric machines	20,628.41
Financial incentives provided to counselors	17,565.03
Salary paid to counselors	102,863.21
Program staff salary	273,440.37
Liabilities raised (Payments for the concerned period, but yet to be paid because of technical/ administrative reasons)	25633.11
TOTAL	**493,282.93**

This leaves a surplus of $45,110 which is being utilized to continue the work.

Study has been going on very well in all the 9 cities, namely Bhopal, Gwalior, Indore and Sagar in Madhya Pradesh; Raipur, Durg/ Bhilai, Korba in Chhattisgarh; East Delhi and Bhubaneshwar.

Challenges:

A few challenges were related to the quality of hardware that was procured at the beginning of the study. The issues faced have already been discussed above.

Also as mentioned in the previous report, counselor turnover continues to pose a challenge for the study.

Achievement of Milestone 7

Grant Number AID-OAA-F-12-00040 to Operation ASHA for "Turning the Tap Off on Multi Drug Resistant TB and Extensively Drug Resistant TB"

This report is the penultimate report because the Intervention is nearing completion. This report discusses the final activities. Therefore, its pattern is deferent from earlier reports.

This Intervention is nearly complete at most sites: Madhya Pradesh (Bhopal, Gwalior, Indore and Sagar), Chhattisgarh (Raipur, Korba and Durg) and East Delhi. It is still continuing in Bhubaneswar because it was included in the Intervention at a later date. Scrutiny and entry of data are going on and will continue for the next few months.

The Intervention randomized 66 counselors across nine cities. During the Intervention period, 22 counselors dropped out of the Intervention and were replaced by new counselors, who then also became a part of the Intervention. Attrition has been similar across both treatment and control groups. This is obvious from the table below.

Table 1: Counsellor enrolment and attrition in the experiment

City	No. of Centers	Counselors Initially Randomized	Dropped Out	Joined during intervention[1]	Counselors who completed the experiment	Counselors currently in experiment
Treatment:	**61**	**31**	**10**	**11**	**25**	**5**
Madhya Pradesh						
Bhopal	12	6	1	1	6	0
Gwalior	12	6	3	3	6	0
Indore	8	4	1	1	4	0
Sagar	2	1	0	0	1	0
Delhi						
East Delhi	2	1	1	3	1	0
Chhattisgarh						
Raipur	8	4	0	0	4	0
Korba	3	2	1	1	2	0
Durg/Bhilai	4	2	2	1	1	0
Orissa						
Bhubaneswar	10	5	1	1	0	5
Control:	**69**	**35**	**12**	**10**	**29**	**4**
Madhya Pradesh						
Bhopal	13	7	1	0	6	0
Gwalior	12	6	2	2	6	0
Indore	10	5	0	0	5	0
Sagar	6	3	5	5	3	0
Delhi						
East Delhi	2	1	1	1	1	0

[1] In the cases of centers where the previous counselor left

Chhattisgarh						
Raipur	8	4	2	1	3	0
Korba	6	3	0	0	3	0
Durg/Bhilai	4	2	1	1	2	0
Orissa						
Bhubaneswar	8	4	0	0	0	4

Data Collection

Baseline data collection was started in January 2013.

Entire activity of data collection, including baseline, midline and end line, was completed in June 2014 in the states of Madhya Pradesh, Chhattisgarh, and Delhi. In Bhubaneswar, data collection activities are in progress. Various means and instruments of data collection are explained below and in greater detail in Annex 1.

(a) Counselor Surveys

Baseline, midline and end line counselor surveys have been administered to all the counselors enrolled in the experiment in Madhya Pradesh, Chhattisgarh and Delhi, while baseline and midline surveys have been administered to counselors in Bhubaneshwar. Midline+ surveys were administered to those counselors who left the experiment before completing 6 months in the experiment. Similarly, end line+ surveys were given to the counselors who left the experiment after 6 months in the Intervention but before Intervention completion.

Table 3: Counselor data collection till date

Survey Type	Number of surveys administered
Baseline	59
Midline	57
Midline+	12
End line	43
End line+	2
Total:	**173**

(b) Patient Surveys

Questionnaires are administered at patients' houses, eliciting information about the socio-demographic characteristics of patients, their relationship with Operation ASHA counselors and

other healthcare providers throughout the course of the Intervention in Madhya Pradesh, Chhattisgarh, and Delhi. Data collection is still going on in Bhubaneswar.

Table 4: Patient data collection till date (state-level)

State	Adult Surveys	Child Surveys	Total
Madhya Pradesh	3400	387	3787
Delhi	278	32	310
Chhattisgarh	1100	53	1153
Orissa	346	28	374
Total:	**5124**	**500**	**5624**

Field Management, Data Monitoring and Quality Checks

(a) Field team Structure

Field team structure consisted of a project associate, field managers, supervisors, monitors, and surveyors, in the descending order of reporting hierarchy. Surveyors were primarily responsible for administering surveys. Each city had a supervisor and one to two monitors depending upon the size of the city. There were three field managers who were in charge of three to four cities each. The field managers report to the project associate—responsible for overlooking the day-to-day field operations—who then would report to the research associate. The specific roles of the field-staff are further explained in sub-sections below.

Training:

All filed staff is trained properly. Short refresher sessions were also conducted for all during each monthly meeting over the course of intervention. Field-staff attended extensive refresher training after the 6 month mark of the intervention.

(b) Monitoring and quality checks

In order to monitor the quality of patient and counselor survey data coming in as well obtain key information surrounding counselor absenteeism, activities at the center, patient follow ups, and biometric device usage, various monitoring mechanisms were put in place.

Center and Mobile Monitoring:

Counselors were randomly visited at least twice a month by a monitor to observe and keep record of all counselor-patient interactions for a day, and in case of treatment counselors, to keep record of biometric device usage information as well. In order to observe patient follow up process (those who were not able to come to the center that particular day of monitoring visit), a

monitor had to accompany the counselor during at least one home visit. The monitors would fill out a digital form using a mobile phone and upload the data the same day for the RA to be able to access.

Random Checks:

A field manager would randomly visit centers at least once a month to make a quick record of counselor activities and fill out a short digitized form. Random checks only happened in the stationary centers.

Sampling patients and tracking them

Supervisors had to fill out digitized sampling forms to maintain record of which patients had to be surveyed. The surveyors were then responsible for filling out a digitized patient tracker form that had information related to the patients with known survey completion status.

Back Checks:

Field managers and scrutinizers positioned at the office engaged in back-checks of 10% percent (randomly selected) surveys done. Back-checks involve administering a survey that borrows a subset of questions from the survey instrument that was originally administered. The matching of the data obtained from back-checks with data obtained from the actual survey gives insight into various issues such as data forgery and systematic errors in the ways some questions might have been originally asked by the surveyors.

Data Cleaning and Entry

About 1700 patient surveys have been entered till date. The rest will be entered over the next few months. Data scrutiny is ongoing and entry will subsequently follow. Data on monthly summary reports of the centers and the data on counselor salary was systematically collected and has been cleaned for analysis.

Challenges

Cleaning up of the data is taking more time and effort than was originally thought of.

Data collection from the areas that are geographically contiguous to areas served by Operation ASHA is also required for comparison. This is taking a lot of time and effort than was initially expected. TB control in most of the contiguous areas is carried out directly by the Government/ public health department. Many of their officers prepare data only when it is required for annual reports. This has caused a complication that their data for the period of the Intervention may not even have been collected/ collated.

Another issue is that Government functionaries do not follow a uniform practice in collating the data. Two different practices are being followed. In one format, outcomes are collected month wise, i.e., they refer to the number of outcomes in a particular month even though those patients would have been enrolled in treatment in different months initially (because the treatment can last for six to nine months). However, in the second format, outcome status of a patient cohort

that was enrolled in a particular month (in the past) is recorded. Thus this would require collecting, over many months, the progress of the cohort. Cohort-wise reports can only be prepared at the end of nine months at the earliest (again because TB treatment could extend up to 9 months). We are trying very hard to ensure the data sets are similar and hence comparable.

Annex 1

Type of Data	Purpose	Indicative Measures	Collection
Counselor Surveys 1. **Baseline:** administered prior to randomization 2. **Midline:** administered after 6 months 3. **Midline+:** at exit from experiment if this is before 6 months in the experiment 4. **End line:** after 12 months in the experiment 5. **End line+:** at exit from experiment if the exit is after 6 months but before 12 months in the experiment	The counselor surveys will allow us to observe counselor level outcomes - the effects of biometric monitoring on performance, motivation and job satisfaction, and the quality of care – and analyze their relationship to counselor characteristics.	- Counselor socioeconomic indicators - Strategies for detection and default prevention - Quality and range of care provided - Commitment - Satisfaction with job and organization	Counselor surveys are administered to counselors at the appropriate time by a senior experienced surveyor, usually a field manager or the project associate.
Patient Surveys 1. **Range 1:** administered during the 1stmonth into treatment 2. **Range 2:** administered at the 6 months of treatment (i.e. complete or nearing completion) if Range 1 was administered. 3. **Range 2.1:** given if Range 1 was administered and the patient defaults before completing the 6 months treatment course.	The patient surveys allow us to observe patient level outcomes - quality of care received TB and other health outcomes, awareness of TB care and treatment - analyze these effects by socioeconomic sub-group, and examine the effects of biometric device usage on patient outcomes, beliefs, and behaviors.	- TB related health outcomes - Quality of care received - Interactions with counselor - Knowledge of TB - Use of and impression surrounding biometric device usage - Other interactions with healthcare providers - Impact and	Field staff visit each center about once a month to select the appropriate survey Range. Patients are then administered the survey usually at the patient's home at the earliest possible date. Patients will be followed up with another round of survey (Range 2 or 2.1)

4. **Range 3:** at the 6 months of treatment (i.e. complete or nearing completion) if Range 1 was not administered. 5. **Range 3.1:** given if Range 1 was not administered and the patient defaults before completing the 6 months treatment course.		severity of disease on overall health - Socioeconomic indicators	if they are given Range 1.
Patient treatment information 1. **Treatment card:** daily TB treatment (pills) log maintained by the counselor for each patient 2. **District level TB registers:** central repository of data on all TB patients, their assignments to counselors, their TB test results and TB status (default)	Treatment cards will allow us to analyze patient compliance and counselor treatment standards (regularity). Used in conjunction with our independent monitoring data, we will also be able to examine underreported missed pills. Registers are the primary source of detection and default numbers. They also provide baseline prevalence and patient numbers.	- Daily missed pills - Ongoing TB test results - Detection - Default	Field staffs take photographs of treatment cards from the centers. They also visit the district medical centers to record the patient data in the TB lab registers which will be used to cross check the patient data obtained from the centers.
Monitoring data 1. **Center monitoring and Mobile monitoring:** observation and recordkeeping of all counselor-patient interactions for a day and biometric device usage information in the case of treatment counselors (at least twice a month that include accompanying the counselor during at least one home visit) 2. **Random Checks:** Each center is randomly	The monitoring data allows us to corroborate treatment card data (did reported missed pills on the observation day match our data), observe irregularities in missed pill reporting (does this increase on the monitoring day), the quality of counselor follow up on missing patients (home visits), and details	- Number of patient visits - Mode of visit (in person, relative pick up, counselor home visit) - Counselor absenteeism	In case of center and mobile monitoring, field staffs make bi-monthly unannounced (and irregular) visits to observe an entire day's TB services. This is done across treatment and control so there is a uniform monitoring effect. In the case of center

visited at least once per month in addition to center monitoring.	regarding use of biometric device in the case of treatment centers. It also allows us to record counselor attendance and assess their performance. Random checks by a senior field staff help to keep check of the cases where our field staffs' monitoring patterns might have become predictable over time; they also gather quick information regarding counselor presence and activities, and patients' presence and activities.		monitoring, at least one of those visits has to include a home visit where a counselor is following up on a patient who could not come to the center. For random checks, field managers randomly visit centers at least once a month.

Grant Number AID-OAA-F-12-00040 to Operation ASHA for "Turning the Tap Off on Multi Drug Resistant TB and Extensively Drug Resistant TB"

Achievement of Milestone 8: Final Evaluation Report

July 30, 2015

1. Introduction

This Study assesses the impact of eCompliance biometric technology on improvement in adherence to DOTS regimen of tuberculosis (TB) treatment and consequent reduction in default[1] and drug resistance. It also determines the costs involved in treatment of both drug sensitive and drug resistant tuberculosis.

DOTS (Directly Observed Therapy – Short Course) is an internationally accepted therapy for TB treatment. The most difficult part of implementing DOTS is the Directly Observed component. This requires that the patient take between 42 and 70 doses of medicine, over 6-9 months, in the presence of an observer. Unfortunately, patients are unable to adhere to this stringent requirement, stop taking medication, default, contract drug-resistant TB, thus generating MDR (Multi-Drug-Resistant TB) cases.

eCompliance has been developed by Operation ASHA (OpASHA for short) and applied to DOTS treatment since 2011. It performs three main functions. The first is enrolling new patients in the system with their fingerprints. Thereafter, the system requires that every patient provide a fingerprint for every dose that should be taken under observation. This generates incontrovertible evidence of simultaneous presence of the observer and the patient.

Second main function of the eCompliance is to upload the data to a server regularly, which sends updates of missed doses to the concerned counselor and supervisor. The counselor is then required to provide further counselling to the patient and convince him to join the therapy again. During these meetings also, the counsellor, who carries an eCompliance unit with him, has to take the fingerprint of the patient. This ensures absolute accuracy with no room for error.

Finally, the data sent by eCompliance units is downloaded into a web-based Electronic Medical Record (EMR) system. The EMR is able to produce a number of reports at the click of a button.

The Study randomized the roll-out of eCompliance across 130 DOTS centers in four states in India: Madhya Pradesh, Delhi, Chhattisgarh and Odisha. This allowed determination of the impact of using eCompliance in DOTS treatment on a series of outcomes:

1. Adherence and defaults
2. Attendance of counselors

[1] A patient is said to have committed a “default” if he does not show up for a single observed dose for a period of two months. To clarify, if a patient misses doses for say 3 weeks and then resumes, he will not be treated as a defaulter.

3. Assessment of eCompliance by counselors and patients

The impact is measured using various data sources to allow for cross-checking of information, assessing prevention of data manipulation and ensuring robustness of results. For this, comprehensive patient and counselor surveys, random checks conducted by the research team and data submitted by supervisors have been used.

The Study conclusively shows that eCompliance reduces default by 20 percent in the Treatment Group compared to the Control Group (which does not use eCompliance). This impact is large. Not only that, it is very important because of the massive risks and externalities associated to defaulting. This result is likely driven by a better adherence of the DOTS strategy in centers equipped with eCompliance. The results are particularly reliable because of the large sample size of more than 3,000 patients and geographical spread over nine cities in four states in India.

Reduction in default leads to improved patients outcomes and substantial reduction in MDR. This also has massive financial implications. Expansion of eCompliance to entire Delhi will reduce MDR. Reduction in expenses for treating MDR will be15 times more than the investment needed to install the system. That is, financial return on installing eCompliance is 15 times the cost of installing it. If financial benefits of TB treatment and prevention of economic loss are included, the financial return goes up to a huge 246 times. There is no doubt that eCompliance should be expanded worldwide, as soon as possible.

Counselors and patients generally welcomed the introduction of eCompliance. Counselors also suggested certain modifications. These are discussed in detail below.

In addition to the above, supervisors submitted weekly and monthly data that was used to compare default rate among the Treatment Group, Control Group and other NGOs and public health department, which are working in areas geographically contiguous to the areas served by OpASHA. This data does not provide reliable results, presumably because of errors in the data collected and maintained manually by supervisors.

The cost of treating patients of both DST and MDR TB were calculated, for OpASHA, other NGOs and the public sector, based on data from patient surveys. OpASHA practically reduced the cost suffered by patients for accessing DOTS to nearly zero, with highly accessible DOTS centers. Methodology, analysis and results have been described in detail in the following sections, which are organized as follows.

a. Sections 2 and 3 provide background on Tuberculosis in India, eCompliance and Study areas.
b. Sections 4 and 5 describe the sample and data collection.
c. Sections 6 and 7 present characteristics of counselors and patients.
d. Section 8 presents data reported by supervisors.
e. Sections 9 and 10 bring out the impact of eCompliance on attendance and behavior of counselors and supervisors.
f. Section 11 is the key section, which discusses the impact of eCompliance on adherence and default.
g. Section 12 describes assessment of eCompliance by counselors and patients.
h. Section 13 is another key section that brings out quantitative value for reduction in MDR that eCompliance brings about.
i. Sections 14-16 discuss cost implications of eCompliance.
j. Sections 17 and 18 bring out cost of treatment.
k. Section 18 describes challenges faced during the Study.
l. Section 19 bring out the conclusions
m. Sections 20 and 21 discuss the dissemination strategy and costs of the Study.

2. Background

2.1 Tuberculosis

TB remains the largest infectious killer worldwide. It claims nearly 1.8 million lives annually or one every 20 seconds. Those who suffer are mostly poor. Nobel Laureate Bishop Desmond Tutu succinctly states, “TB is the child of poverty, and also its parent and provider”. Even in developed countries, where TB had been nearly eradicated, it has come back with a vengeance. Worse than that, the bacteria is mutating into untreatable forms like TDR/ XXDR (Totally Drug Resistant TB/ Extra-extensively Drug Resistant TB) as a result of failure of Public Health programs and indiscriminate use of antibiotics.

TB is also a serious social-economic problem. *World Economic Forum* states, “nearly 1/3rd of over 11,000 (business leaders worldwide) expect TB to affect their business … serious(ly)”. In India alone, indirect economic loss is US$23bn annually. Not only that, 100,000 female patients are thrown out by families every year to die of disease and starvation. 300,000 youngsters join the rank of child labor annually mostly because a parent is suffering from TB, loses a job, and the child needs to support the family (Government of India).

1000 people die of TB every day in India, even though the Government's National TB Program (RNTCP) provides free treatment and effective first-line antibiotics for all patients. RNTCP also provides second line drugs for MDR TB for a large number of patients. The key challenge continues to be ensuring that patients complete the full course of treatment. They default, which leads to MDR TB. That is why it is extremely important that default is reduced and eliminated. Easier said than done, because in order to be cured, the patient needs a cocktail of up to 5 drugs on a strict schedule: three days per week continuously over a 6- to 9-month period. Following only a few months of the treatment, the symptoms of TB disappear - but the side effects of the drugs remain. This leads patients to discontinue treatment early.

To reduce default, India and other countries have adopted the delivery model known as Directly Observed Therapy - Short Course (DOTS). In the DOTS model, medicines are kept in locally established care centers and patients ingest each dose under direct observation by a health worker. The health worker is also expected to maintain individual treatment cards to track doses and improve follow up. Observation by the health worker, bringing health care services closer to communities and maintenance of treatment cards is expected to prevent non-compliance.

While the implementation of DOTS has improved adherence and treatment success rates, the system still suffers from certain shortcomings, some of which are linked to the paper-based format of the record system. The first shortcoming is the human error and deliberate omissions. The second is inadequacy of real-time follow-up in case of missed doses, which ultimately leads to default. Counselors, who are in charge of monitoring dose intake and following up as needed, have little incentive to commit time and efforts to this additional work in the absence of rigorous monitoring.

OpASHA also follows DOTS. A short description about OpASHA's methodology is given below.

OpASHA also follows DOTS model of TB treatment for all its patients. In urban areas, it ties up with local micro-entrepreneurs, who stock medicines and observe the dose.

Indian Government (RNTCP) follows intermittent dose regimen, i.e. a patient should take medicines every alternate day. So, some patients are required to take medicine on MWF (Monday, Wednesday, Friday) schedule. Others take it on TTS (Tuesday, Thursday, Saturday) schedule. OpASHA groups patients in one area for one of these schedules. So, for a center in area A, say, all patients will be on MWF schedule. Most patients at this center will on these days. A nearby center is kept at TTS schedule. Thus, the two centers are busy on alternative days, though they are open all days, and a patient who may have missed a dose on Monday

can take it on Tuesday, as required by the DOTS regimen. On the ‘busy’ day, a health worker hired by OpASHA, known as counselor, spends two hours at the DOTS centers. These are the hours when the largest number of patients visit the center to swallow the dose. Thus, the counselor is able to concentrate on alternate centers on alternate days: attending to one center on MWF, and the other center on TTS. This helps OpASHA reduce costs on hiring, recruiting and remuneration of counselors.

The counselors are also responsible, in geographical area of centers entrusted to them, for locating symptomatics, getting them tested, diagnosed and enrolled in treatment. They also phone and meet patients who have missed a dose and convince them to re-join the therapy.

In rural areas, OpASHA’s counselors are required to travel by motorcycle, to every village that has a patient, provide DOTS at a location selected by the patient (his house or farm etc). They also spend substantial time in a village, by turn, to look for symptomatics etc. like in urban areas.

The DOTS centers are located in non-overlapping and scattered areas and the counselors are permanently assigned to a pair of DOTS centers. Each DOTS center in urban areas usually covers a radius of approximately one kilometer (0.6 miles) and a population of nearly 20,000. In rural areas, each center covers 2-3 contiguous/ neighboring villages with total population of nearly 10,000. Thus, each center has a well-defined catchment area.

During the course of treatment, the patient may have to travel because of unavoidable reasons like death in the family or important religious ceremonies. In this case, counselors are authorized to provide up to one week of advanced dose to the patient, which he may take without observation. These are known as un-supervised doses. Counselors can provide unsupervised doses twice during the treatment period, for one week each time. This is in accordance with the National TB (RNTCP) Guidelines.

OpASHA has developed eCompliance to move to an automated adherence system and eliminate the shortcomings of the paper based recording system. The following section briefly describes this technology.

2.2 eCompliance system

Within a few months of starting the first DOTS center in 2006, OpASHA realized that DOTS cannot be rigorously implemented with a high success rate, at a low cost, without using technology. It carried out an analysis of the needs a technology would have, to fulfill this need. Sometime later, it tied up with Microsoft Research to develop the prototype, which was built in 2010. It used 10" laptops. A SMS dongle connected it to a server. A fingerprint reader was attached through a USB port to the laptop to record fingerprints. This is shown in figure 1.

Figure 1: Netbook based eCompliance Unit

Soon after the advent of iPad and tablets in 2011, more so when the tablets became cheaper than laptops, OpASHA decided to employ tablets. It developed an entirely new software, on its own. The current system uses tablets, which have a SIM card inside, and connect it to the server. Tablets provided many advantages: lower cost, better portability and internet connectivity through SIM card in the tablet, eliminating the need for SMS dongle. In terms of functionality, the laptop and tablet based system are absolutely identical. However, this Study was well on its way by the time software for tablets was developed. So most of the Study used laptop based eCompliance. Pictures of the tablet based system are shown in figure 2.

At urban (stationary) centers, eCompliance uses the counselor's fingerprints to record her daily arrival and departure time from the center. In addition, whenever a new patient starts taking medicine at the center, both her index fingers are registered and a profile created in the system. If for some reasons, index fingers do not have clear

Figure 2: Tablet based eCompliance unit

fingerprints, other fingers are registered. Her fingerprints are then taken each time she comes to the center to take medicine during the full course of the treatment. The system thus automatically keeps track of all doses in a simple compliance log. Its user-friendly interface allows counselors to easily view each patient's dose history and access the list of patients who have missed a dose anytime in the past. Figures 3 and 4 show how different types of information can be accessed by the counselor instantly on his eCompliance machine.

At rural/ mobile centers, the counselor is required to travel to each village. He travels to a different set of villages on alternate days (MWF and TTS). Each of these set of villages is said to constitute a center.

In rural areas, because eCompliance does not have a fixed location like the urban centers, both the counselor and the patient have to provide fingerprints simultaneously to log a dose as an observed dose. Time difference between the first simultaneous fingerprint of the patient + counselor and the last, is taken as the time spent by counselor on the job.

eCompliance ensures that only observed doses are reported as observed. There is no such check in the paper-based record system, because all the counselor is required to do is to put a tick mark on the paper card when a patient has taken a dose.

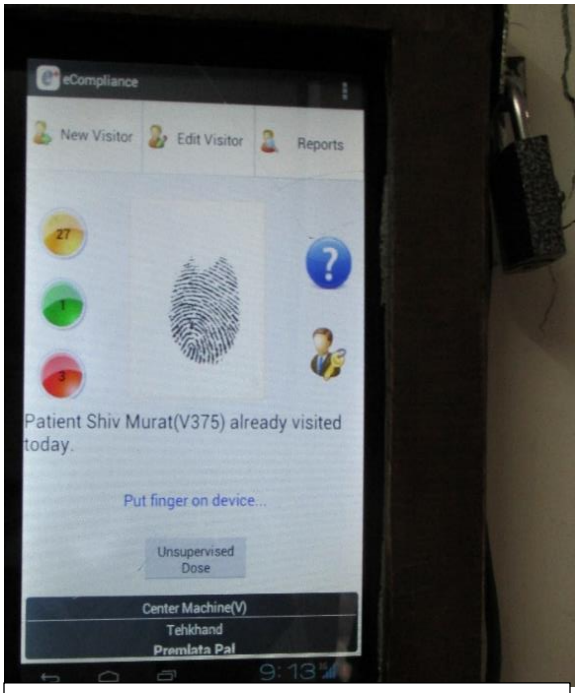


Figure 3: Patient fingerprint identified and record shown

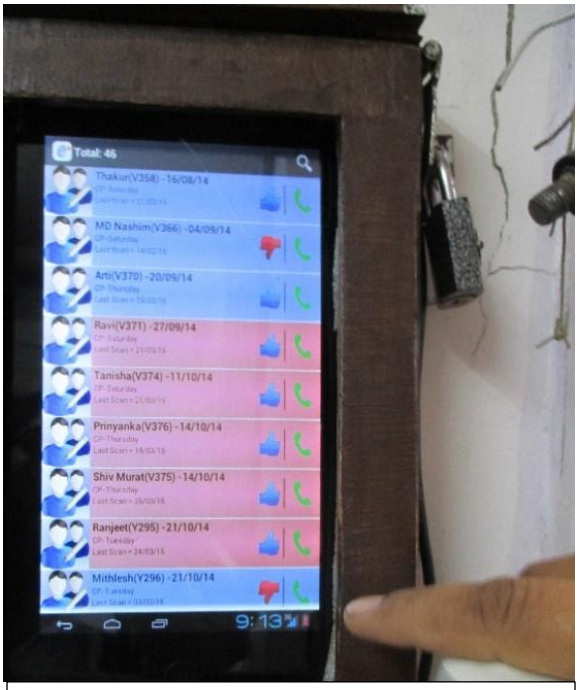


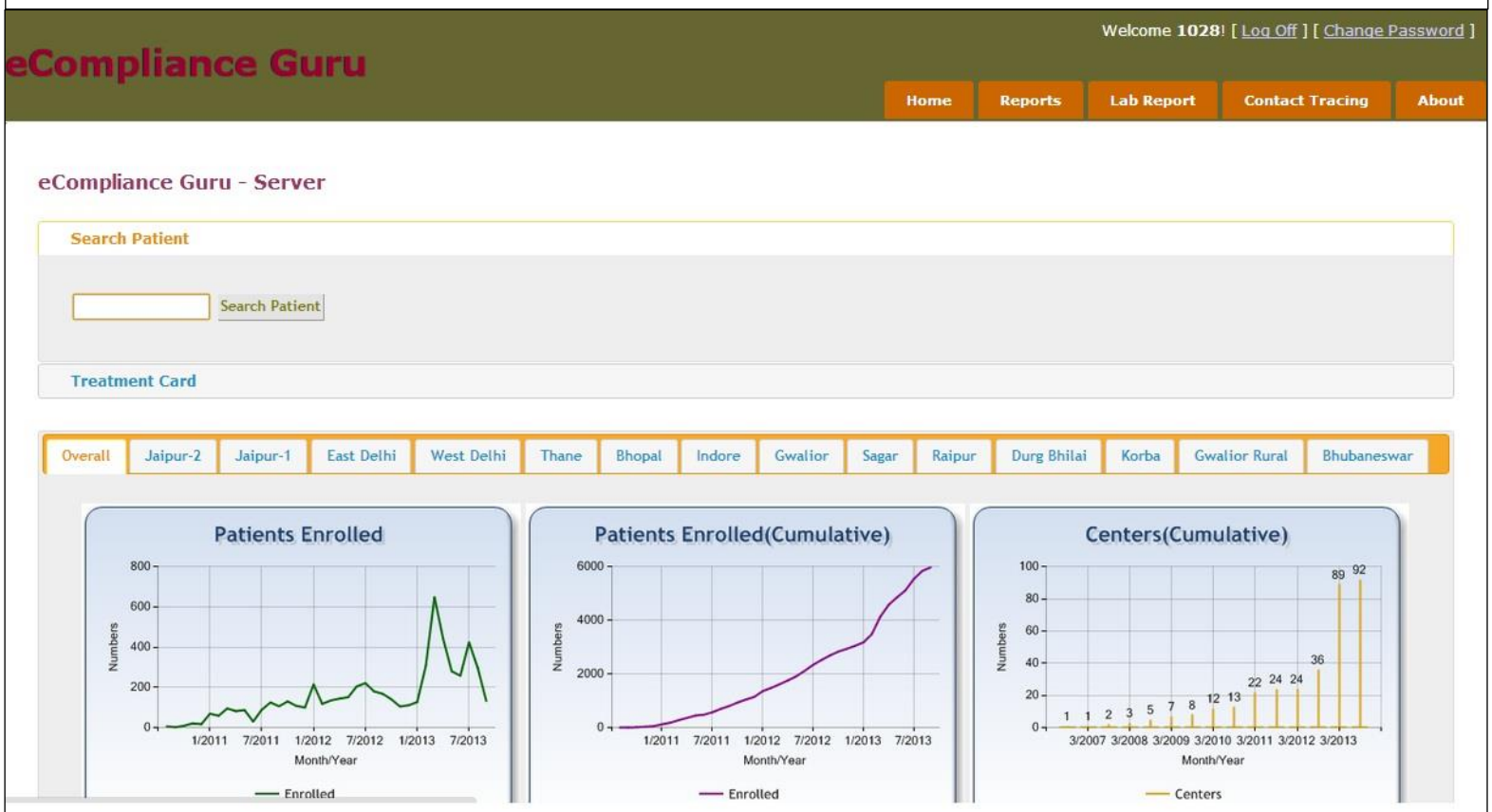
Figure 4: eCompliance terminal with provider examining list of patients who visited that day

eCompliance regularly loads the data on the Cloud, from which it is downloaded to a server in OpASHA's New Delhi office. The server sends a sms to every counselor, at 10pm every night. This sms provides a list of patients who have missed a dose that day. The counsellor is required to phone the patient or visit him within 48 hours, provide further counselling and the dose and convince him to join the therapy again.

In rural areas, the eCompliance unit is always with the counselor. In urban areas, one unit is installed permanently at the center (in a wooden case, nailed to wall, to ensure safety). Another unit is carried by the counselor in her bag. Both units can be synchronized with each other either through blue-tooth or data on the server. Thus, both units have identical data all the time.

Counselors are also required to take fingerprints when they visit a patient at home and provide a dose. This fingerprint immediately marks the patient – counselor meeting and removes the patient from the list of those who have a missed dose. Thus, eCompliance system provides a fool-proof list of patients who have missed even a single dose, to the counselors. The same data is available through EMR to supervisors all the time.

Figure 5: Home page of the Electronic Medical Record



OpASHA has made many improvements to eCompliance over time. For example, for a patient who is scheduled for a follow up test, eCompliance issues an animated alert, every time the patient takes a supervised dose, starting one week before the date on which the test is scheduled. This works as a reminder to both the patient and OpASHA's counselor, ensures timely testing and uninterrupted continuation of therapy.

The server enters the data in the EMR, which is a web-based reporting platform and can be accessed by the supervisors anytime, anywhere, with a user id and password, through the internet. It can also be used to prepare all reports that are needed by District TB Officers, State TB Officers and OpASHA. A snapshot of the home page of the EMR is shown in figure 5.

Work flow with eCompliance is shown in figure 6.

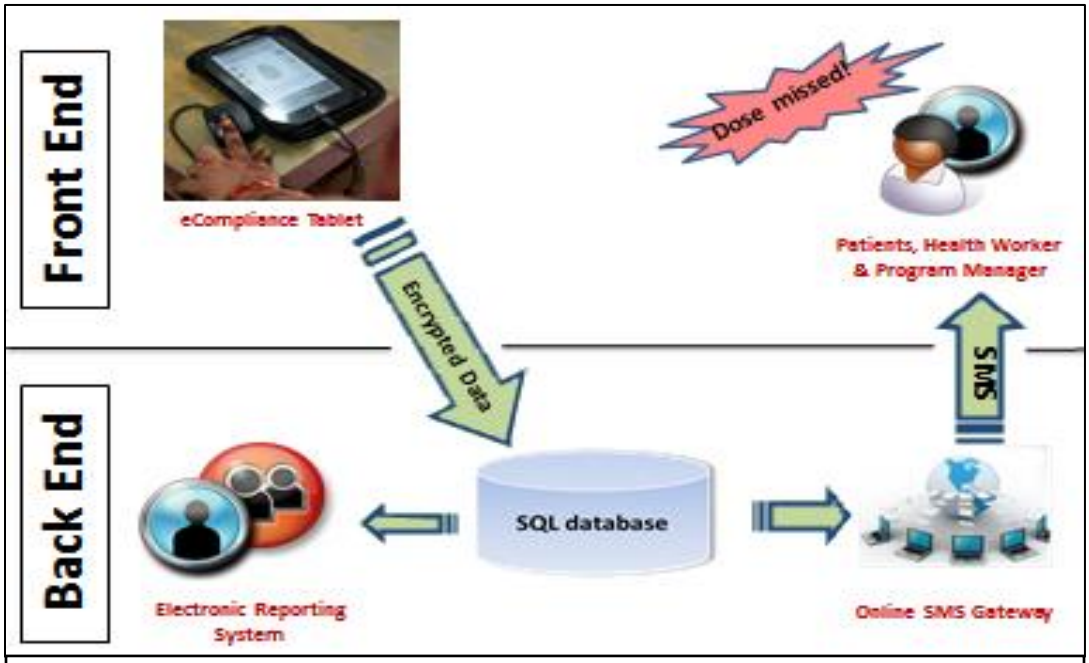


Figure 6: Work flow with eCompliance

In eCompliance, data is stored in three different places: eCompliance units, on the Cloud, and in a server located in New Delhi. Regular communication between them ensures that the data is always updated. Even if it is lost on one particular eCompliance unit because of a technical problem, it can be uploaded again, through the internet, in no time.

3. Implementation of the Study

The Study included 65 counsellors across nine cities in four states of India. It took place from 18 March 2013 till 15 May 2014 in the state of Madhya Pradesh (MP), 15 April 2013 till 15 May

2014 in the states of Delhi and Chhattisgarh, and 10 September 2013 till 10 Sept 2014 in Odisha. Surveys of counsellors and patients started before these 'start' dates and continued beyond the 'end-dates'. Figure 7 below shows the geographical location of the Study areas.

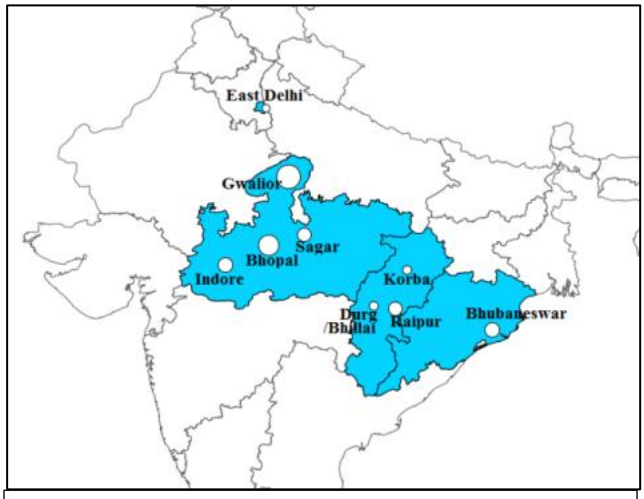


Figure 7: Geographical location of the Study area

Counsellors were randomized into two groups for the Randomized Control Trial (RCT): the Control Group and Treatment Group. The latter Group used the eCompliance technology. Otherwise, they were identical. During the Study period, 24 counsellors left their job and dropped out of the Study. Attrition was similar across the Treatment and Control Groups. New counselors joined in their place, who then also became a part of the study, thus increasing the number of counselors who were incorporated into the Study. It is analyzed and shown below that attrition and joining of new counselors did not affect the Study. As a matter of fact, as a general rule, increase in number of subjects improves the robustness of the Study. This way, the attrition was helpful. Table 1 presents an overview of various numbers. Table 2 presents city wise and state wise break-up.

Table 1: Overview

Description	Treatment Group	Control Group
Number of centers	61	69
Number of counsellors in the study	30	35
Number of counsellors who left the study	12	12
Number of patients	2064	3355
Number of machines in use and functioning properly	93	
Number of machines deployed	93	
Number of supervisors in the study	9	
Number of supervisors who left the study	4	

Table 2: Counsellor enrollment and attrition in the Study				
City	No. of Centers	Randomized Counselors	Dropped Out	Joined during Study
Total:	130	66	24	21
Madhya Pradesh				
Bhopal	25	13	2	1
Gwalior	24	12	5	5
Indore	18	9	1	1
Sagar	8	4	5	5
Delhi				
East Delhi	4	2	4	4
Chhattisgarh				
Raipur	16	8	2	1
Korba	9	5	1	1
Durg/Bhilai	8	4	3	2
Odisha				
Bhubaneswar	18	9	1	1

4. Study setup and data sources

4.1 Study setup

Before the Study began, counselors were paid an incentive linked to achieving low default. This would have interfered with the Study and biased the impact of eCompliance in uncertain ways. Therefore, the first step was to eliminate/ stop paying default-linked incentive. OpASHA knew, from experience, that this may increase default in both the Control and the Treatment Groups, but this was a necessary cost to determine the true impact of eCompliance. So, default-linked incentive was abolished for the period of the Study.

The Study was conducted across nine cities in four states, namely Madhya Pradesh, Delhi, Chhattisgarh and Odisha. Each OpASHA counselor operates two DOTS centers, usually in his own community/ village or close to his home. The randomization was done at the counselor level and stratified at the city level, such that each pair of centers operated by a counselor was randomly assigned to the Treatment Group (that used eCompliance) or to the Control Group. The study duration spanned an average of 13 months in each city. Counselors were initially trained for two hours on the following.

1. How to use eCompliance and enroll patients on the system
2. Ensure that data is uploaded to the Cloud regularly

3. Examine the list of all patients as well as the list of those who have missed a dose
4. For patients who have missed a dose, the date of the last dose

As mentioned above, each center has a well-defined catchment area. This limits the scope for interactions between counselors and spill-over effects.

4.2 Data sources

4.2.1 Program and administrative data

Such data is available from many sources. It is described below.

Treatment card must be maintained for every patient enrolled in a DOTS center by the concerned counselor (see Figure 8). Cards provide information about the number and identity of newly detected patients, month after month. Counselors are required to enter in the card whether a scheduled observed dose has been taken by a patient or not. If a patient misses a

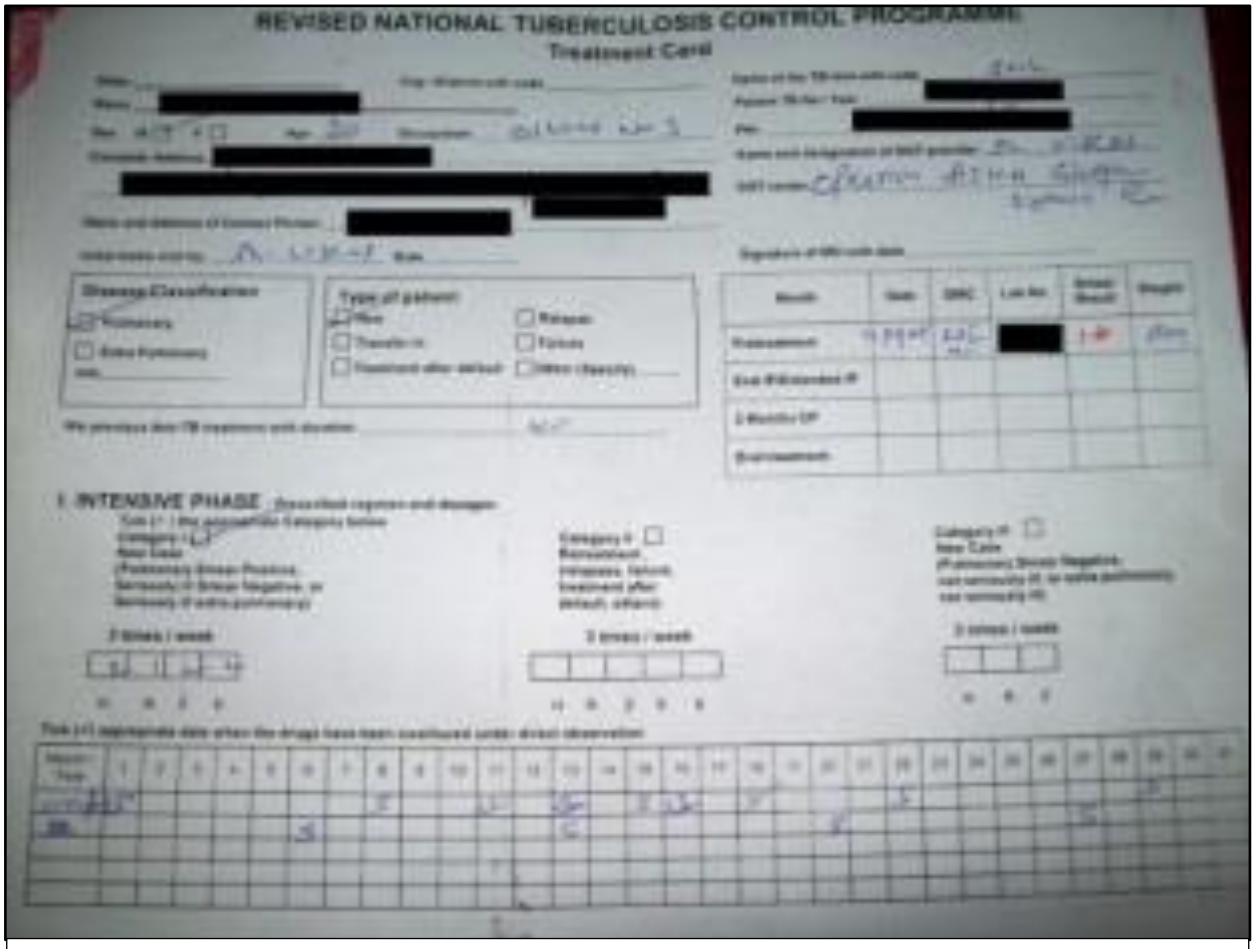


Figure 8: Treatment card maintained manually

Name: [redacted]

Sex: [redacted] Age: [redacted] Occupation: [redacted]

Complete Address & Telephone number: [redacted]

Name and Address of Contact Person & Telephone Number:

BPL Category - Yes/No/Not Known: [redacted]

Aadhar No. if Available: [redacted]

Initial home visit by: [redacted] Date: [redacted]

Disease Classification: Pulmonary

Site::

Type of Patient: New

H/O PREVIOUS ANTI-TB Treatment-- a) YES/NO : No b) Duration: c) Year of last episode :

d) RNTCP/Others with Treatment Regimen :

ASSOCIATED ILLNESS - Diabetes/Hypertension/HIV/Others:

HISTORY OF SMOKING - Yes/No: No Duration: If Stopped Since When:

Family H/O Smoking - Yes/No: No Duration: If Stopped Since When:

Patient TB No / Year:

PHI:

Name and designation of DOT provider & Tel. No. [redacted]

DOT Centre: [redacted]

Signature of MO with date:

Month	Date	DMC	Lab No.	Smear Result	Patient Weight
Pretreatment	12/09/2014	C6	465	2+	44
End IP					
Ext-IP					
2 Months CP					
End treatment					

I. INTENSIVE PHASE - Prescribed regimen and dosages:

Category (Category I / Category II / Category III): CAT-I

H: R: Z: E: S:

Month/Year	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
September2014																				✓			✓		✓		✓			✓	
October2014		✓		✓			✓		✓		✓			✓		✓		✓			✓		✓		✓			✓		✓	
November2014	✓			✓		✓		✓			✓		✓		✓																

II. CONTINUATION PHASE

Prescribed regimen and Dosages:

H : R : E :

Month/Year	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
November2014																						✓							✓		
December2014						✓							✓							✓							✓				
January2015			✓							✓							✓							✓							✓
February2015							✓							✓							✓							✓			
March2015							✓							✓							✗							✗			

Figure 9: Treatment card downloaded from EMR. Dose with tick and circle indicates unsupervised dose.

dose, action taken also has to be entered by the counselor. Updating of doses and action taken is required to be updated daily.

An identical image of the Treatment Card is maintained by EMR (figure 9). Details of observed doses are entered automatically by the software, based on the fingerprinting data communicated by the eCompliance units. Other data like weight, address etc is communicated by counselors and entered by a data entry operator in OpASHA's head office in New Delhi.

Weekly report of missed doses is prepared by the supervisors, based on the data provided by counselors from the Treatment Cards.

Salary sheets and center wise reports are prepared monthly by supervisors. Center wise report contains data on the number of new patients enrolled, new cases of default, in addition to the data on outcomes such as transfer outs, death, and treatment failure. Salary sheets mention the salary of each counselor for a given month, broken down into three components (basic

salary, a variable part depending on the number of enrollments by the counselor in that month and allowances/ fringe benefits).

TB registers and lab registers are kept by Government TB (RNTCP) officers, who centralize the treatment cards generated by all centers in the area, whether operated by OpASHA, Government or other NGOs. These registers list the name and address of all enrolled patients, dates and results of their initial and follow-up sputum tests and outcome of the treatment.

4.2.2 Survey data

Counselor surveys were usually administered thrice, the first one (baseline) right before the installation of the eCompliance, the second one (midline) during the middle of the Study, and the final one (endline) at the end of the Study. For the counselors who left the job during the Study, an augmented midline or endline survey was administered with an additional section on leaving the job. These surveys provide detailed information on the counselors' socio-economic background, motivation when starting their job and work history. They also provide information on daily work activities. In case of counselors with the eCompliance, surveys also had questions on experience with eCompliance.

Patient surveys were collected throughout the course of the Study. A large number of 3409 patients in the Treatment and Control Groups were surveyed for socio-economic characteristics. Potential respondents were identified through a sampling process which was carried out monthly by an enumerator. The enumerator identified all patients who would be given one of the following surveys, and shared the lists with surveyors. Stages at which surveys were done are given below. After the sample of patients was determined, appointment sheets were prepared for each patient to be interviewed. These contained details that would help locate and identify the patients (such as name, address and phone number), and allowed surveyors to record information on whether or not the visit was successful and, if not successful, for which reason. Three attempts were made to locate the patient before they were declared "Not Found". This category of patients was also verified in the back-checks (see below) to ensure correctness.

- Range 1: baseline for patients who were beginning treatment.
- Range 2: endline for patients who had completed treatment, whose baseline was administered.
- Range 3: augmented endline for patients who had completed six months of treatment but who were not administered baseline, likely because their treatment had started before the Study began. Additional questions in this survey compared to the normal

endline survey mostly related to socio-economic characteristics otherwise collected at the baseline.

- Range 2.1: augmented endline for patients who defaulted out of the treatment, and whose baseline was administered. This survey had questions related to the patient's reasons and circumstances for defaulting.
- Range 3.1: augmented endline for patients who defaulted out of the treatment, and whose baseline was not administered. Survey questions related to the patients' reasons and circumstances for defaulting, and socio-economic characteristics that would have been otherwise collected at the baseline.

Back-checks were performed for a random 10 percent of the patients in the sample (both those surveyed and those reported as 'not found') to verify that they were visited by the surveyors and that the survey was completed accurately. The first back-check attempt would be made through phone calls by a designated back-checker in Delhi. In case the patient could not be reached by phone, an enumerator would make a field visit to find the patient. The back-check survey included approximately 15 questions of the full survey. The back-check questionnaire answers were then compared with the original survey data. Back-checks ensured that the surveyors preformed their duties honestly.

4.2.4 Monitoring data

Monitoring data was collected by the survey staff from two sources. One was the treatment cards. Second were their visits to the DOTS centers or mobile areas to observe counselor and patient attendance, counselors' activities at the center and during visits to homes and villages. Each center received an average of 1.92 monitoring visits per month: Table 3 refers.

Table 3: Number of monitoring visits

State	City	Average visits per centre per month
Madhya Pradesh	Bhopal	1.69
	Gwalior	1.58
	Indore	1.17
	Sagar	1.45
Chhattisgarh	Korba	2.32
	Durg/Bhilai	2.46
	Raipur	2.26
Odisha	Bhubaneswar	2.31
Delhi	East Delhi	4.33
Overall average		1.92

Days of the visits were chosen randomly. On these days, the survey staff reached the center at the time it was scheduled to open in the morning and stayed till the counselor finished his work, around early afternoon. In case of mobile counselors, the surveyor would accompany the counselor on his motorcycle. The surveyor kept a systematic record of the following data for each visit:

- Whether the center was open at the scheduled time and if the counselor was present
- Arrival and departure time of the counselor
- Names of all the patients enrolled in the center, along with administrative details such as TB number/lab number and treatment start date
- Names of the patients who came to the center to take the medicine
- Names of patients for whom a relative picked up medicine for the patient
- Cases in which the counselor was planning to visit the patient personally
- Cases where the counselor actually visited the patient at home. In this case, the surveyor accompanied the counselor to the patient's home.
- Details of eCompliance usage, if any

Sampling tracker and patient tracker were maintained digitally by survey staff for all patients who were sampled into the Study and for all patients who were surveyed (or attempted to be surveyed). While the former dataset contains information about patient's name, address, TB number, lab number and treatment start date, the latter dataset contains the same information in addition to the outcome of the attempted surveys.

Additional details of data collection are given in Annex 1.

4.2.4 Cost data

Another purpose of this Study is to gauge the costs that patients incur to access treatment for TB in OpASHA, other NGOs and the public sector (RNTCP). This goes well beyond OpASHA patients (who constitute the Treatment and the Control Groups). For this, a separate survey of 134 patients selected from all three categories: OpASHA patients, patients served by other NGOs and patients served by Government (RNTCP) DOTS centers, was carried out. These patients were selected at random from various cities. The patients were asked about the time and transport costs they spend in commuting to the DOTS center. A similar study was carried out for 10% of MDR patients with OpASHA. Other NGOs did not agree to provide access to their MDR patients for this purpose.

It is a well-known fact that cost of medicines varies widely depending on the buyer and brand. Public sector (RNTCP) pays the least, because of huge volumes it procures: about 1.5 million packs a year. Individual patients pay substantially higher prices, more so because many physicians prescribe expensive brands. Somewhere in between is the price for generic drugs. Most inexpensive generic version of the drug, which is available across the country, from a highly reputed and perhaps the largest manufacturer worldwide (Lupin) has been considered as the representative price for this Study. This was considered as the most likely price that would be paid by TB patients from disadvantaged background. Cost of these drugs was considered = Maximum Retail Price (MRP) printed on drug packs in accordance with Government rules. This is the price normally charged by pharmacies.

Again, there is a huge variation in charges for tests, physicians and hospitals. So, patients were surveyed for the typical hospital they went to, for reasons other than TB. Cost of diagnostic tests and hospital admission is based on such a hospital.

5. Sample Description and Balance Checks

For the RCT, the initial sample was composed of 66 counselors. 24 of them left the job and dropped out over the course of the Study (Table 2 above). 21 replacements joined and entered the Study. Thus, the overall sample comprised of 87 counselors. Table 2 and Figure 7 above show the geographical distribution of counselors in the sample. 50 operate DOTS centers in Madhya Pradesh, 21 in Chhattisgarh, 6 in Delhi and 10 in Odisha.

Attrition and joining of new counselors is analyzed in Table 4, which shows that this did not introduce any selection bias.. Panel A shows the estimates obtained from regressing a dummy variable indicating whether the counselor dropped out over the course of the Study and a dummy variable for whether the counselor joined during the Study. The likelihood of a counselor dropping out or of a replacement to be found is not significantly affected by the random assignment of eCompliance to centers. Counselors' attrition is also not significantly affected by any other socio-demographic characteristics, exposure to technology, performance or motivation at baseline. This indicates that results of the RCT are not be affected or biased by the staff turn-over.

However, some other interesting conclusions can be drawn. For example, counselors in Sagar and Delhi were significantly more likely to leave the job (and be replaced by new counselors). Men and counselors without prior work experience were respectively 38 and 30 percentage

points more likely to drop out. This data will be used by OpASHA to improve its recruitment practices. In effect, this Study will be useful well beyond its initial scope.

Table 4: Impact of counselor attrition

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
Panel A: Impact on attrition (counselor dropped out during the intervention)											
Treatment	0.03	0.09	0.00	0.04	0.01	0.06	0.01	0.02	0.00	0.01	0.04
	(0.10)	(0.09)	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)	(0.11)
City fixed effects											
Bhopal		-0.02									0.04
Gwalior		0.22									-0.07
Indore		0.01									-0.06
Sagar		0.50**									0.53**
Delhi		0.56***									0.70**
Raipur		0.02									0.03
Durg/Bhilai		0.24									0.37
Chhattisgarh		0.08									-0.01
Age			-0.01								-0.01
gender (male)				0.15							0.38**
religion (Hindu)					0.11						0.15
educational level											
other diploma/non-formal						-0.348					-0.41
twelve and below						-0.059					-0.05
under three years of university						-0.118					-0.20
work experience before OA							-0.112				-0.30**
pre-exposure to technology								0.16			-0.03
baseline performance											
number of detections past month									0.00		0.00
number of default prevention activities									0.03		0.06
remembers last patient sent for sputum testing									-0.17		-0.09
baseline motivation											
joined OA for social cause										0.09	0.08
recommended OA to someone in past 6 months										-0.10	-0.10
Observations	86	86	86	86	86	83	86	86	86	82	80
R-squared	0.00	0.20	0.02	0.02	0.01	0.02	0.01	0.03	0.05	0.02	0.39
Mean in Control Group	0.27	0.27	0.27	0.27	0.27	0.27	0.27	0.27	0.27	0.27	0.27
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
Panel B: Impact on replacement (counselor joined mid-intervention)											
Treatment	0.05	0.09	0.01	0.04	0.06	0.04	0.05	0.04	0.03	0.04	0.05
	(0.09)	(0.09)	(0.09)	(0.09)	(0.10)	(0.10)	(0.10)	(0.09)	(0.09)	(0.10)	(0.12)
City fixed effects											

Bhopal		-0.02									0.09
Gwalior		0.22									0.24
Indore		0.01									0.05
Sagar		0.50**									0.56**
Delhi		0.56***									0.61*
Raipur		0.02									0.14
Durg/Bhilai		0.24									0.38
Chhattisgarh		0.08									0.22
Age			-0.01**								-0.02*
gender (male)				-0.02							0.06
religion (Hindu)					-0.10						-0.09
educational level											
other diploma/non-formal						-0.259					-0.10
twelve and below						-0.028					0.06
under three years of university						0.09					0.07
work experience before OA							0.03				0.07
pre-exposure to technology								0.10			-0.14
baseline performance											
number of detections past month									-0.01		0.00
number of default prevention activities									-0.04		0.00
remembers last patient sent for sputum testing									-0.18		-0.10
baseline motivation											
joined OA for social cause										0.02	0.04
recommended OA to someone in past 6 months										0.00	0.07
Observations	86	86	86	86	86	83	86	86	86	82	80
R-squared	0.00	0.20	0.05	0.00	0.01	0.02	0.00	0.01	0.07	0.00	0.28
Mean in Control Group	0.22	0.22	0.22	0.22	0.22	0.22	0.22	0.22	0.22	0.22	0.22

Notes: Clustered standard errors are in parentheses. ***, **, * indicate significance at 1, 5 and 10%. We take a health worker as the unit of observation and include all health workers whose baseline was done and for whom we have their treatment status.

Now we need to show that the counselors and patients in the Treatment and Control Groups are identical.

6. Counsellor Baseline Characteristics

For the RCT to give proper results, it needs to be ensured that randomization of counselors and patients does not produce any initial differences between the Treatment and Control Groups. This will ensure that both Groups are identical in all respects, except for the use of

eCompliance. To examine this, characteristics of counselors and patients in both Groups were compared.

Table 5: Baseline summary statistics of the counsellors

	Control group		Treatment group		Full Sample		*P-value* Treatment = Control	Number of obs.
	Mean	SD	Mean	SD	Mean	SD		
Male	0.78	0.42	0.68	0.47	0.73	0.45	0.33	86
Age	32.1	7.99	29.4	6.29	30.8	7.31	0.08	86
General caste	0.31	0.47	0.51	0.51	0.41	0.49	0.06	86
Hindu	0.73	0.45	0.90	0.30	0.81	0.39	0.04	86
Highest education level achieved								
Other diploma/non-formal education	0.02	0.15	0.03	0.16	0.02	0.15	0.96	83
Class 12 and below	0.60	0.49	0.65	0.48	0.63	0.49	0.67	83
Under three years of university	0.16	0.37	0.25	0.44	0.20	0.41	0.33	83
Graduation	0.21	0.41	0.08	0.27	0.14	0.35	0.08	83
Work experience								
Any previous work experience	0.82	0.39	0.66	0.48	0.74	0.44	0.08	86
Number of years of work experience	8.81	5.45	8.72	4.80	8.77	5.12	0.93	82
Any previous experience in the social/NGO sector	0.18	0.39	0.12	0.33	0.15	0.36	0.48	86
Lives in one of the areas covered by the centers	0.49	0.51	0.63	0.49	0.55	0.50	0.21	85
Assets								
Has electricity	1.00	0.00	0.95	0.22	0.98	0.15	0.14	84
Has tap water	0.67	0.47	0.45	0.50	0.57	0.50	0.04	83
Rents an apartment or house to a third party	0.11	0.32	0.18	0.39	0.14	0.35	0.35	83
Owns land	0.53	0.50	0.48	0.51	0.51	0.50	0.60	85
Exposure to technology								
Knows how to use a computer	0.56	0.50	0.59	0.50	0.57	0.50	0.78	86
Knows how to use the internet	0.45	0.50	0.50	0.51	0.48	0.50	0.68	84
Has an email account	0.44	0.50	0.37	0.49	0.41	0.49	0.46	86
Has a social networking account	0.36	0.48	0.32	0.47	0.34	0.48	0.71	86
Months spent in the Study	10.1	4.84	10.0	4.85	10.0	4.82	0.95	86

Note: For each variable, standard deviations in both the control group and the treatment group are reported and the p-value of the difference is indicated. The unit of observation is the counselor.

Mean values of relevant parameters for each individual Group of counselors and the full sample are given in table 5 below. It also shows p-values for tests comparing means across the Control and the Treatment Groups.

Table 5 shows that p-values are high in most cases. This indicates that both the groups of counselors were identical at baseline. Some other general conclusions about counselors can

also be drawn from this table. For example, Counselors are 30.8 years old on average. 73 percent are men and 41 percent belong to the general caste. A majority of counselors have only finished school. 74% counselors have had previous work experience, but only 15 percent had worked in the social/NGO sector. They have worked an average of 8.77 years. 55 percent of the counselors live in a neighborhood where one of the centers that they operate is located.

Next we will examine the summary statistics of the patients.

7. Patient Baseline Characteristics

A total of 3409 patients were surveyed at least once over the course of the Study. Table 6 shows their geographical distribution.

Table 6: Geographical distribution of health workers and patients

State	City	Number of Health workers with assigned treatment status and at least a baseline	Number of patients who were surveyed at least once
Madhya Pradesh	Bhopal	14	731
	Gwalior	16	992
	Indore	10	336
	Sagar	9	251
Chhattisgarh	Durg/Bhilai	6	150
	Korba	6	215
	Raipur	9	238
Delhi	East Delhi	6	190
Odisha	Bhubaneswar	10	306
TOTAL		86	3409

Statistical description of the socio-demographic characteristics of these patients is given in Tables 7 & 8. Patients are 34 years old, on average. There is a slight majority of men (58 percent). They belong to the most deprived classes in India: the Scheduled Castes and Scheduled Tribes, or Dalits (33 percent) and Other Backward Classes (36 percent). Only 18 percent belong to the General category. Half of them have always lived in the same place. Patients are 86 percent Hindu. 30 percent of them cannot read or write. 22 percent have no schooling at all. This indicates that OpASHA serves the most disadvantaged.

Table 7: Patient summary statistics (socio-demographic characteristics)

	Control group		Treatment group		Full sample		*P-value* Treatment = Control	Number of obs.
	Mean	SD	Mean	SD	Mean	SD		
Male	0.57	0.49	0.58	0.49	0.58	0.49	0.90	3407
Age	34.3	16.5	33.4	16.2	33.9	16.4	0.29	3398
Caste categories								
Doesn't know	0.05	0.21	0.05	0.21	0.05	0.21	0.90	3402
General caste	0.17	0.38	0.18	0.38	0.18	0.38	0.96	3402
OBC	0.36	0.48	0.35	0.48	0.36	0.48	0.81	3402
SC	0.23	0.42	0.27	0.45	0.25	0.43	0.22	3402
ST	0.09	0.28	0.08	0.27	0.08	0.28	0.69	3402
Minority	0.10	0.30	0.07	0.26	0.09	0.28	0.51	3402
Religion								
Hindu	0.84	0.37	0.88	0.33	0.86	0.35	0.38	3386
Muslim	0.14	0.35	0.11	0.31	0.13	0.33	0.45	3386
Other	0.02	0.14	0.02	0.12	0.02	0.13	0.44	3386
Literacy								
Cannot read or write	0.30	0.46	0.30	0.46	0.30	0.46	0.92	3404
Can read but not write	0.04	0.19	0.04	0.20	0.04	0.19	0.87	3404
Can read and write	0.67	0.47	0.66	0.47	0.67	0.47	0.86	3404
Education								
No schooling	0.22	0.42	0.21	0.41	0.22	0.41	0.57	3407
If any schooling								
Pre-primary	0.02	0.14	0.02	0.15	0.02	0.14	0.65	2652
Primary	0.48	0.50	0.51	0.50	0.49	0.50	0.23	2652
Secondary	0.44	0.50	0.41	0.49	0.43	0.50	0.34	2652
Undergraduate and more	0.06	0.24	0.05	0.22	0.06	0.23	0.37	2652
Size of the Household	5.66	2.48	5.47	2.18	5.58	2.36	0.09	3327
Migration Status								
Always lived here	0.52	0.50	0.48	0.50	0.50	0.50	0.16	3403
Lived here for more than 10 years	0.14	0.34	0.16	0.37	0.15	0.36	0.14	3403
Lived here for 6 to 10 years	0.09	0.28	0.10	0.30	0.09	0.29	0.21	3403
Lived here for 1 to 5 years	0.16	0.37	0.17	0.38	0.17	0.37	0.71	3403
Lived here for less than a year	0.09	0.28	0.09	0.28	0.09	0.28	0.84	3403

Notes: For each variable, the means and standard deviations in both the control group and the treatment group are reported and the p-value of the difference indicated. The unit of observation is the patient.

Patient's previous exposure to TB and medical history was also examined and is given in Table 8. 25 percent of patients previously had TB. 41 percent of the patients interviewed belong to a household where at least one member had TB since they were born.

Based on the high p-values for all parameters in the above tables, we conclude that the two groups of patients, the Treatment Group and the Control Group are identical at baseline.

Table 8: Patient summary statistics (past TB exposure and medical history)								
	Control group		Treatment group		Full sample		*P-value* Treatment = Control	Number of obs.
	Mean	SD	Mean	SD	Mean	SD		
Panel A: Past exposure to TB								
Vaccinated against BCG	0.71	0.45	0.71	0.45	0.71	0.45	0.96	3021
If vaccinated, mark visible	0.8	0.41	0.78	0.42	0.78	0.41	0.67	2207
TB history								
has previously had TB	0.26	0.44	0.25	0.44	0.26	0.44	0.64	3388
if yes, number of times	1.22	0.56	1.24	0.67	1.23	0.61	0.68	874
someone in family had TB since patient was born	0.39	0.49	0.44	0.50	0.41	0.49	0.03	3378
number of family members with TB in the past 5 years	0.67	0.81	0.97	1.19	0.81	1.01	0.02	1382
Panel B: Previous medical consultations								
Consulted someone at least once in past 3 months	0.18	0.39	0.16	0.37	0.18	0.38	0.49	3395
Facility type								
Private doctor	0.44	0.50	0.47	0.50	0.45	0.50	0.74	598
Private hospital	0.20	0.40	0.22	0.42	0.21	0.41	0.75	598
Govt. referral hospital	0.12	0.33	0.12	0.33	0.12	0.33	0.98	598
Govt. doctor	0.10	0.30	0.08	0.28	0.09	0.29	0.61	598
Local dispensary	0.07	0.25	0.04	0.19	0.06	0.23	0.27	598
Others	0.07	0.25	0.07	0.25	0.07	0.25	0.98	598
Service received (on the 1st visit)								
Medication	0.64	0.48	0.67	0.47	0.65	0.48	0.47	576
An injection	0.36	0.48	0.43	0.50	0.39	0.49	0.21	546
A drip	0.13	0.33	0.14	0.35	0.13	0.34	0.69	525
An Operation	0.05	0.22	0.04	0.19	0.05	0.21	0.53	511
Estimated amount spent in Rs. (on the 1st visit)	939	3210	807	1987	886	2784	0.54	572
Notes: For each variable, we report the means and standard deviations in both the control group and the treatment group and indicate the p-value of the difference. The unit of observation is the patient.								

In a nutshell, the randomization for both counsellors and patients is reliable. The Control and the Treatment Group were identical. It is time to examine the results of the Study.

8. Data reported by supervisors

Supervisors provide various reports on a monthly basis. This are based on the treatment cards.

In manual recording, i.e. in the Control Group, the cards are filled by the counselors themselves, once a week or even once a fortnight This is reflected in the common observation received from surprise visits in which cards are frequently found to be out of date, even though the cards should ideally be filled on a daily basis, immediately after the patients swallows the dose. Obviously, treatment cards are highly prone to human error. Furthermore, the counselor must

take action to contact/ meet the patient after every missed dose, provide the dose and further counseling to bring the patient back into treatment. Thus, each entry of a missed dose in the Card entails action. So, counselors are likely to not enter missed doses on the cards to save on their time. Thus, the cads may subject to human error and manipulation. Therefore, reports based on these cards are prone to error.

On the other hand, reports for the Treatment Group are updated daily, on the basis of fingerprint records of patients and counselors.

Because of the different methodologies followed to prepare reports by supervisors, it is expected that comparison between these reports will not be meaningful. This is fully borne out in table 9, which shows data for the baseline and end of the Study reported by supervisors: p-values are quite high, indicating that reported results are insufficient to distinguish performance between the Treatment and Control Groups.

Table 9: Results reported by supervisors

	Baseline		Endline		
	Treatment	Control	Treatment	Control	p-value
Number of centers	59	70	61	69	
Number of counselors	32	38	30	35	
Number of patients	2011	3094	2064	3355	
Sputum conversion rate	63.4	66.1	97.9	98.0	0.13
Case notification rate	207.74	322.47	207.9	324.3	0.93
Treatment outcome – Cure rate	36%	40%	35%	36%	0.60
Treatment outcome – Completion rate	40%	45%	47%	49%	0.56
Treatment outcome – Failure rate	2%	2%	2%	2%	0.78
Treatment outcome – Default rate	5%	6%	6%	5%	0.28
Treatment outcome – Death rate	11%	5%	5%	6%	0.41
Treatment outcome – Transfer rate	6%	2%	5%	2%	0.05
Total outcome	100%	100%	100%	100%	

Table 10: Impact of eCompliance on counselor activities

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	Was the counselor present during monitoring		Was the centre open during monitoring		Did anyone from OpASHA visit today		Number of hours the counselor was present during the shift		Number of patients who did not receive treatment today despite being on the schedule	
Treatment	0.03	0.03	-0.02	-0.01	0.04	0.04	0.37	0.31	-0.12	-0.10
	(0.04)	(0.03)	(0.02)	(0.01)	**(0.02)****	**(0.02)****	**(.18)****	**(.11)*****	(0.29)	(0.19)
City fixed effects		Yes		Yes		Yes		Yes		Yes
Observations	4590	4590	3733	3733	2145	2145	3740	3740	1397	1397
R-squared	0.00	0.07	0.00	0.06	0.00	0.04	0.01	0.12	0.00	0.15
Mean in Control Group	0.62	0.62	0.96	0.96	0.08	0.08	2.13	2.13	1.25	1.25

	(11)	(12)	(15)	(16)	(17)	(18)
	Did the counselor make any home visit today		Did the counselor take any break during monitoring		Number of breaks counselor took from work during monitoring	
Treatment	0.04	0.04	0.06	0.04	0.08	0.05
	(0.03)	**(0.02)***	(0.07)	(0.03)	(0.11)	(0.06)
City fixed effects		Yes		Yes		Yes
Observations	3129	3129	1621	1621	1621	1621
R-squared	0.00	0.05	0.00	0.20	0.00	0.14
Mean in Control Group	0.14	0.14	0.34	0.34	0.48	0.48

Notes: Clustered standard errors are in parentheses. ***, **, * indicate significance at 1, 5 and 10%. A day-long monitoring instance is taken as the unit of observation. The data was obtained from process monitoring.

However, the design of this Study was robust and captured sufficient data to arrive at proper results. This is discussed in the following sections.

9. Impact of eCompliance on attendance and accountability of counselors

Monitoring visits of surveyors were used to determine the impact of eCompliance on activities and attendance of counselors. The results are given in table 8 below.

Counselors in the Treatment Group, i.e. those using eCompliance are present an additional 22 minutes per shift, equivalent to a 17 percent increase in attendance. This result is significant at 5% level. Not only that, the counselors in the Treatment Group equipped with eCompliance are significantly more likely to visit patients at home, a 29 percent increase in likelihood (column 12). This is significant at the 10% level.

The above has wide implications. Counselors in both the Treatment and the Control Groups are paid the same amount of money for their time. So, increase in time on the job translates into improved productivity of counselors substantially.

10. Impact of eCompliance on accountability of supervisors

Table 10 offers another interesting conclusion: DOTS centers with eCompliance are more frequently visited by the supervisors, with the probability of visit going up by 50% in the Treatment Group in which the counselor has eCompliance (columns 5 & 6). This is statistically significant at the 5% level. Clearly, supervisors take greater responsibility for work done by counselors in the Treatment Group. This is more interesting when viewed in the context that each supervisor manages a city, and has both types of counselors reporting to him: those with eCompliance and without. But the supervisor pays greater attention to the counselors with eCompliance. In other words, eCompliance improves accountability of supervisors towards counselors with eCompliance. This is an interesting externality. It proves OpASHA's belief that eCompliance has impact beyond improving adherence: it improves the entire system of DOTS delivery and administration. This belief was one of the primary reasons for OpASHA to invest heavily in the development of eCompliance when it started the TB treatment program.

11. Impact of eCompliance on adherence

The research team collected data directly from patients about their adherence and behavior, irrespective of entries in the treatment cards. Thus, it was found that 8.8 percent patients defaulted.

The reasons for default are presented in table 11. 29 percent of the patients defaulted because they felt that the treatment had no effect on them. Another 23 percent defaulted because of side effects of TB drugs. The third most likely reason for default was that the patients thought they

had been cured (16 percent). These results will be used to improve counseling of patients by OpASHA in the future.

Table 11: Reasons for default			
		%	N
Completed full course of medication?			
	Yes	55.1	2457
	No, I am still taking pills	36.1	2457
	No, I stopped taking pills	8.8	2457
Why did you stop treatment early			
	Due to side effects of medicine	22.7	216
	I felt better	12.5	216
	I thought I was cured	15.7	216
	Went to my village/home/native place	5.1	216
	I began another treatment for my illness	12.5	216
	The treatment had no effect	29.2	216
	Inconvenient to go to my DOTS centre	1.9	216
	Doctor told me I do not have TB	1.9	216
	Due to my work schedule	2.8	216

Next, the results of adherence and default in the Treatment and the Control Group were compared. The regression to test this result is given by the following equation.

$$Y_i = \alpha_1 + \beta_1 T_i + \sum_c \delta_{1c}^i + \varepsilon_{1i} \qquad (1)$$

where Y_i is the treatment compliance indicator for patient i, T_i is a dummy equal to 1 if the patient was allocated to a counselor in the treatment group and 0 otherwise and δ_{1c}^i are city fixed effects (the level of stratification). The key coefficient of interest is β_1 which estimates the difference in treatment compliance outcome induced by the treatment. In this and all other regressions, standard errors are adjusted for clustering at the counselor level since the randomization was conducted at this level.

The results are presented in table 12. Patients in the Treatment Group, i.e. the ones attending DOTS centers equipped with eCompliance are 2 percentage points less likely to default, a 20 percent reduction over default in the Control Group, which was recorded at 10 percent (col. 1 and 2). This difference is statistically significant at the 10 percent level.

Table 12: Impact on patient treatment compliance, patient-counselor interaction and patient satisfaction assessed by the research team

	Defaulted		Occasionally sent someone else to get the pills		Counselor gave medicine for a week or longer duration together		Percentage pills missed during treatment	
Panel A: Impact on treatment adherence								
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Treatment	-0.02	-0.02	-0.22	-0.21	-0.06	-0.08	0.16	0.13
	(0.02)	**(0.01)***	**(0.04)*****	**(0.04)*****	(0.04)	**(0.02)*****	(0.45)	(0.28)
City fixed effects		Yes		Yes		Yes		
Observations	2459	2459	3218	3218	3307	3307	2318	2318
R-squared	0.00	0.02	0.06	0.10	0.00	0.08	0.00	0.03
Mean in Control Group	0.10	0.10	0.37	0.37	0.28	0.28	1.9	1.9

Panel B: Impact on the interaction with counselor and patient satisfaction										
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	Interaction with OA counselor increased since treatment		Counselor warned/warns when pills not taken		Counselor gives advice related to TB		Counselor supports/supported during treatment		Confident to talk about self-health issues with the counselor	
Treatment	0.03	0.02	0.07	0.03	0.02	0.02	0.01	0.02	0.00	0.00
	(0.03)	(0.01)	0.05	0.03	(0.02)	(0.02)	(0.07)	(0.02)	(0.02)	(0.01)
City fixed effects		Yes		Yes		Yes		Yes		Yes
Observations	3290	3290	918	918	3292	3292	3305	3305	3254	3254
R-squared	0.00	0.55	0.01	0.18	0.00	0.05	0.00	0.35	0.00	0.03
Mean in Control Group	0.25	0.25	0.71	0.71	0.89	0.89	0.21	0.21	0.92	0.92

Notes: Clustered standard errors are in parentheses. ***, **, * indicate significance at 1, 5 and 10%. We take a patient as the unit of observation and include all those patients who either completed treatment, or had gone through treatment for a significant period of time. Panel A reports the impact of biometric device on variables related to patient treatment compliance as self-reported by the patient. Panel B reports the impact of biometric device usage on variables related to the patient's interaction with the counselor and the patient's satisfaction with the counselor.

Panel A also brings out possible causes of improvement. Each of them is described below.

1. Patients in the Treatment Group are 21 percentage points less likely to send someone else at the DOTS center to pick up the drugs on their behalf (significant at the 1 percent level) (col. 3 and 4).
2. In addition, the patients in the Treatment Group are 8 percentage points less likely to collect a set of pills for a duration of one week or more in a single visit (significant at the 1 percent level) (col. 5 and 6).
3. In effect, the number of supervised doses goes up by 29 percentage points (=21%+8%).

4. Improved attendance of counselors in the Treatment Group equivalent to a 17 percent increase in attendance as discussed earlier.
5. Increase in likelihood of home visit by counselor by 29 percent as discussed earlier.
6. Increase in visits to centers by supervisors in the eCompliance Group as discussed earlier.
7. It is less clear whether the drop in the likelihood to interrupt treatment is driven by an improvement in the patient / health worker interaction, either in terms of frequency, quality or patient satisfaction. The coefficients on these indicators are not significant at the 10 percent level (Panel B). However, they all go in the expected direction.

Overall, the above results suggest that eCompliance is a powerful tool for enforcing the DOTS strategy as compared to manual/ non-eCompliance system, which has so far been common across the world. eCompliance maintains high integrity of DOTS at the counselor as well as supervisory level and reduces default by 20%. Its impact on preventing MDR will be examined below.

Points 1-5 above definitely lead to the conclusion that there is a higher percentage of supervised doses and lower percentage of missed doses in the Treatment group than in the Control Group. This conclusion was used to assess the reliability of reports submitted by supervisors and clearly shows that supervisor reports are unreliable, a possibility that has already been discussed earlier. The results are interesting and have been described in Annex 2, even though they are not statistically significant and have no bearing on the results of this Study.

Reduction in default definitely leads to reduction in MDR. But before we discuss that, it will be good to analyze the reaction of counselors and patients to the eCompliance technology.

12. Perception of eCompliance

eCompliance produces important results like reduction in default, increase in productivity of the counselors and increase in accountability. So how do various stakeholders react to it? Following discussion answers these questions.

12.1 Counselors

Even before eCompliance was put to use by counselors, nearly a quarter of them (24%) felt that the technology will be very useful. A majority of counselors also felt that eCompliance will be useful. Only a tiny number: 3% thought eCompliance would cause negative impact. Figure 10

indicates this. There was no substantial change in this view after the counselors had been exposed to eCompliance. Figure 11 illustrates this.

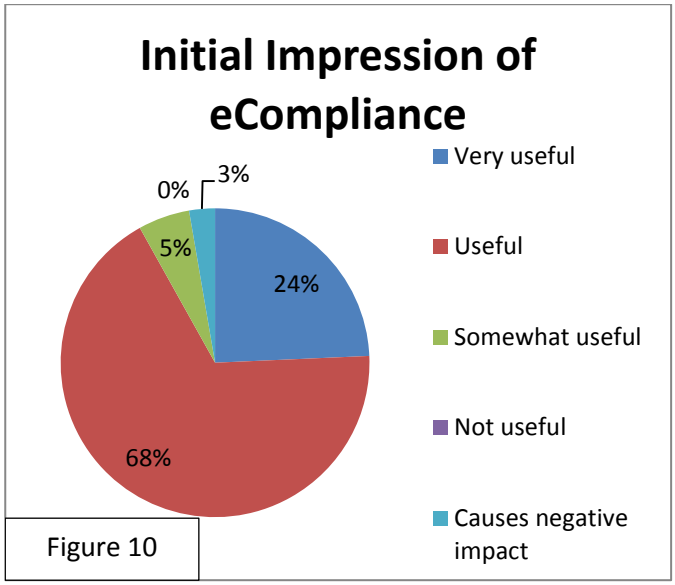


Figure 10

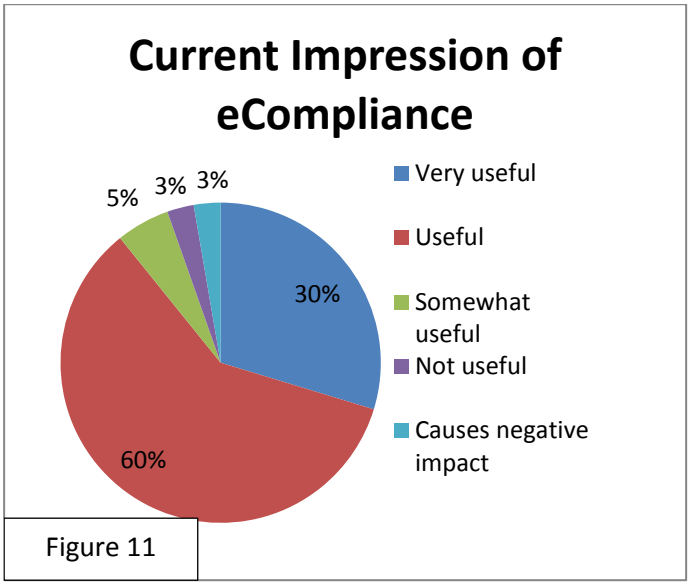


Figure 11

55% of the counselors found that eCompliance increases their workload as shown in Figure 12. This may have to do with the fact that the eCompliance makes counselors (in the Treatment

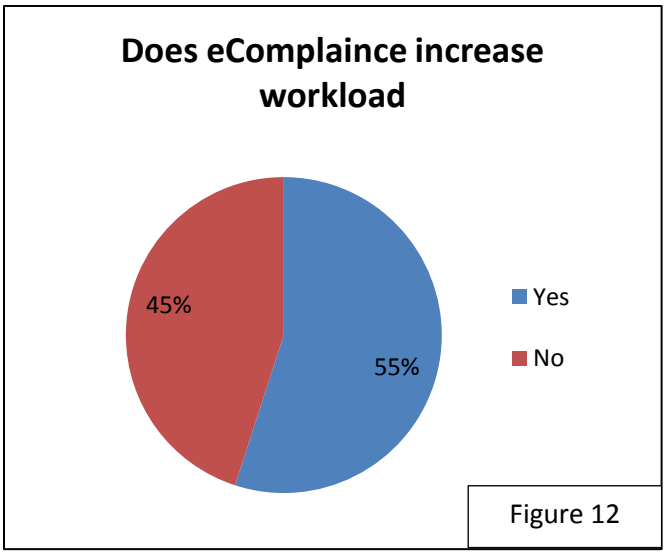


Figure 12

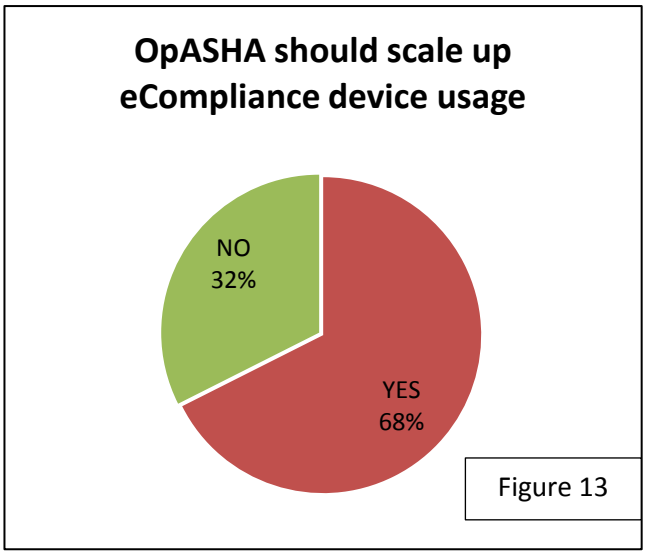


Figure 13

Group) spend more time at the center and visit patients' homes more often compared to counselors who do not have eCompliance (the Control Group) as discussed above.

68% of the counselors stated that eCompliance should be scaled up to all DOTS centers, rather than limiting its application to only the Treatment Group (figure 13). This is an interesting conclusion in view of the fact that eCompliance makes counselors and supervisors work harder and be held more accountable. Perhaps, counselors are willing to work harder, if they are given

effective technology, to improve patients' lives. In other words, eCompliance is perhaps able to kick in an altruistic motive among staff to help patients more, compared to the Control Group.

Not only that, 62% of the counselors found using eCompliance challenging. This is shown in Figure 14. The reasons for stating that using eCompliance is challenging have to do both with the technology and the added weight of carrying it around for the entire day. Details are given in figure 15.

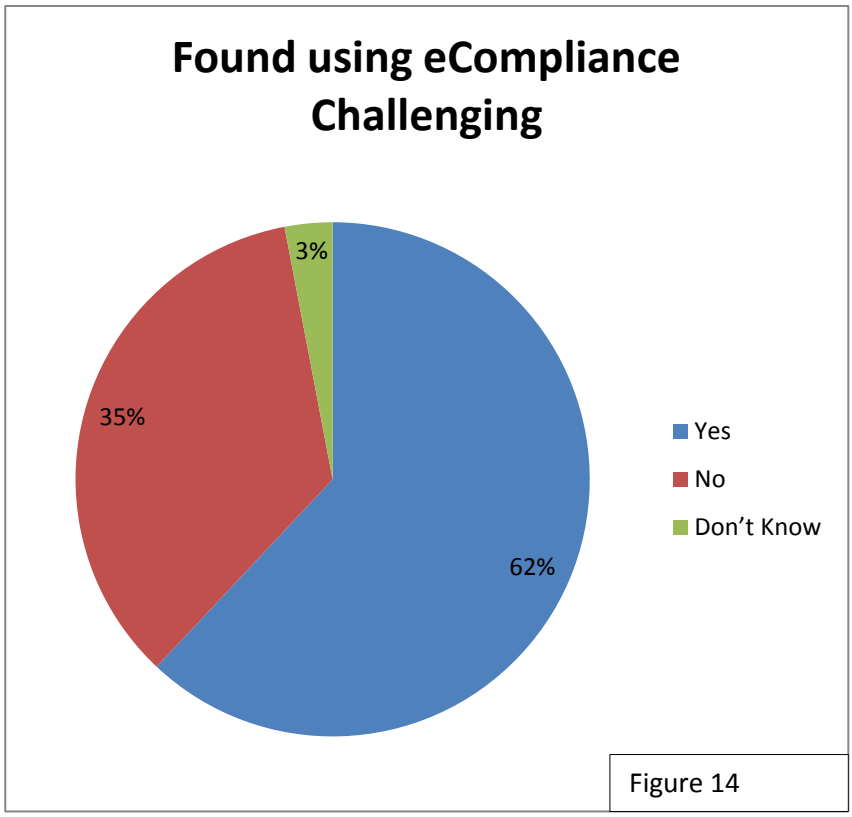
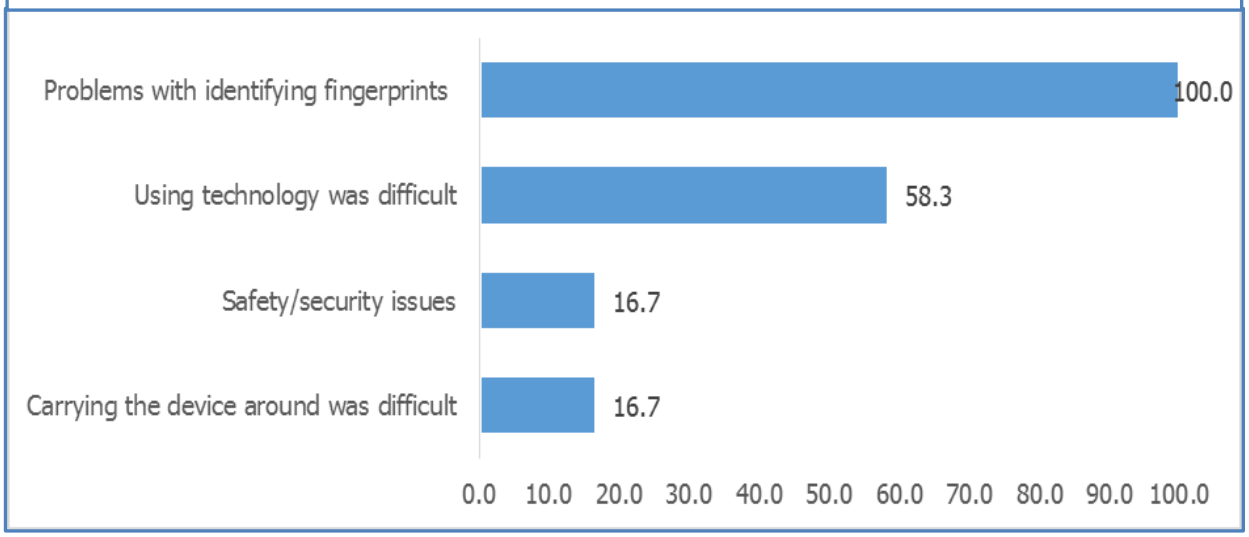


Figure 14

Counselors also suggested changes that could improve their experience with eCompliance. These are described in figure 16. Some proposals are related to technology and network connectivity, some others are perhaps motivated by additional work caused by eCompliance. One suggestion

Figure 15: What aspect of using eCompliance did the counselors find challenging?



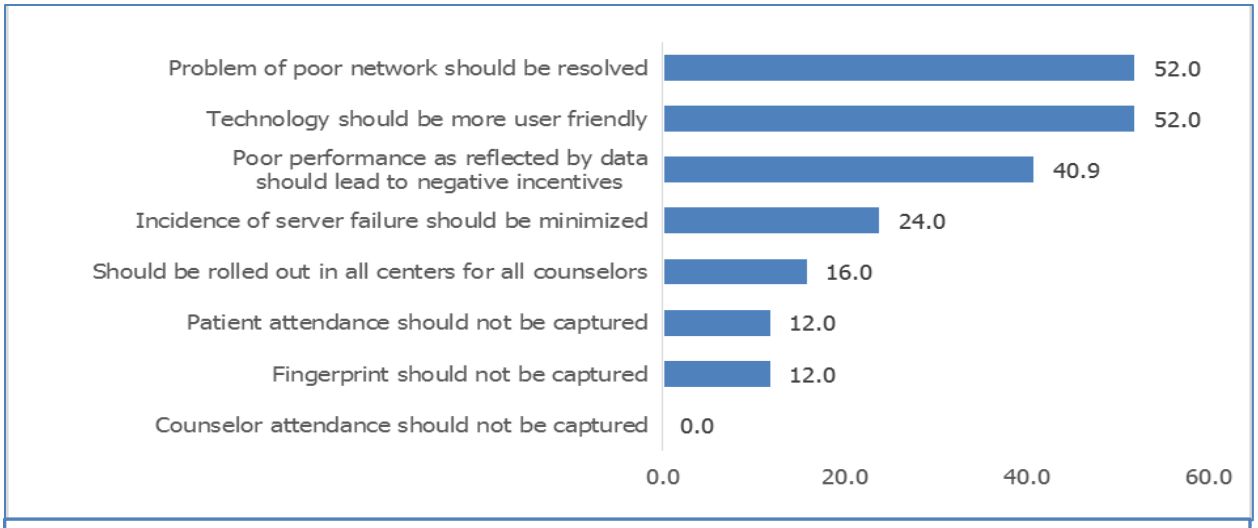


Figure 16: What aspects of eCompliance could be changed/ improved?

is very interesting: 'poor performance as refllected in data (from eCompliance) should lead to negative incentives'. Perhaps counselors who are using eCompliance are aware of lower level of hours spent on work and relative lack of accountability in the Control Group. This is not surprising, because none of the counselors was using eCompliance till the Study started. So, perhaps they likely felt that the counselors in the Control Group were still 'getting away' with fewer number of hours spent on the job and lower accountability for tracking patients who miss a dose and wanted such behavior to be punished with negative incentive.

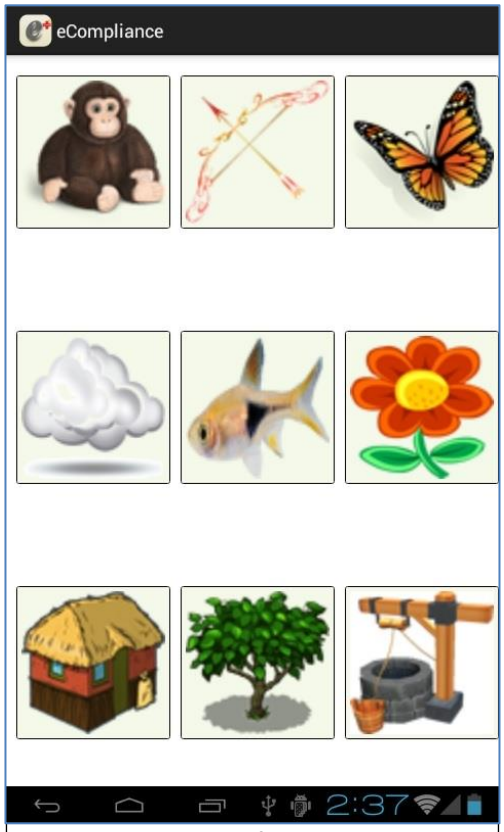


Figure 17: Screen of the eCompliance Version that uses pictures to identify patients

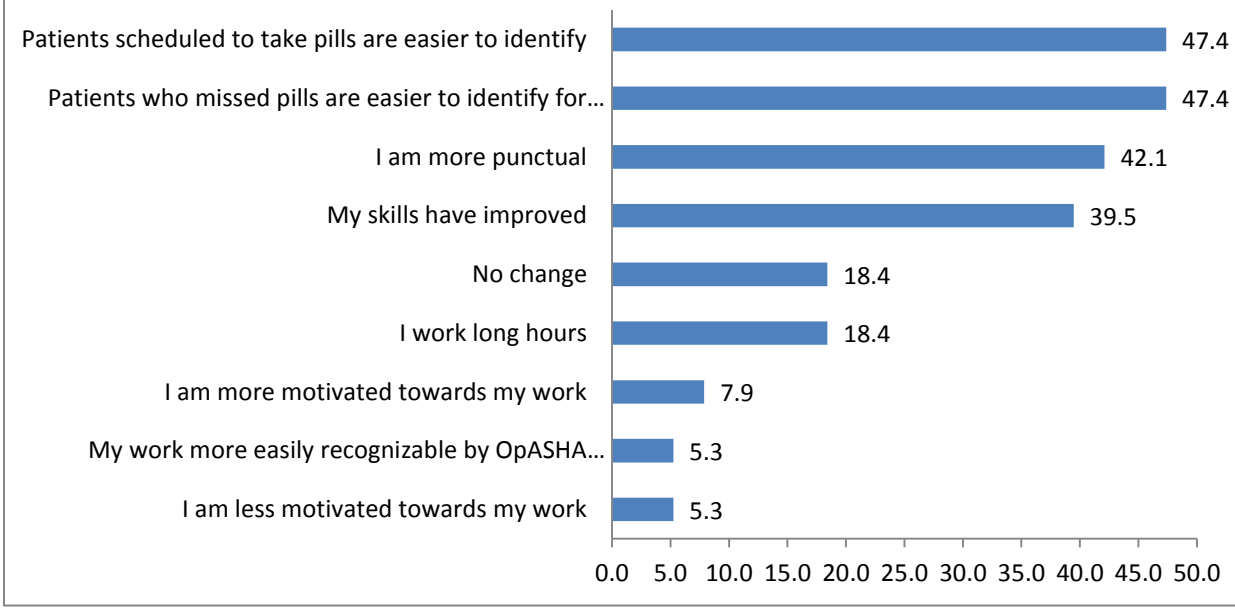
Many of challenges and suggestions mentioned by counselors have already been taken into account while developing new versions of the software for tablets. For example, tablets are easier to carry than laptops. Not only that, reliable 2G internet network is now available across the country. This is far more reliable than the

earlier sms coverage. So, instances of ‘poor network’ have mostly been eliminated. So, tablet based eCompliance now uses 2G connectivity, although it remains possible to use sms for another country, which may only have sms coverage.

OpASHA also decided to use an improved fingerprint reader. So, the tablet based eCompliance uses Futronic FS88 instead of Digital Persona that was used with the laptops. The new reader is much faster and responds more quickly. It has given good results in the field for a year now. Also, total weight of the tablet based system at 400 grams is nearly 4 times less than the original laptop based system. The new system is also much smaller. So, portability has become a non-issue.

Not only that, for counselors who may be totally illiterate in India or other countries, OpASHA has also developed a text-free version of eCompliance software that uses pictures to identify patients. The screen of such a tablet is shown in Figure 17. In this version, patients are registered and identified by pictures instead of names. Every time the patient puts his fingerprint on the reader, the same picture appears on the screen. The patient is also given a small card (like a business card) that has the same picture. Box of medicine for the patient also carries this picture. The box of medicine meant for the patient will also have that picture printed on it. So, there will be no chance of error.

Figure 18: What did eCompliance change for you



The Counselors also stated that that eCompliance has improved their skills and made them more punctual. It has also made it easy to identify patients who have missed a dose. These are perhaps obvious results. These conclusions have been drawn from Figure 18.

The other group who are impacted by eCompliance are the patients. Their perception is discussed in the next section.

12.2 Patients

Patients are nearly equally divided, with half the patients welcoming eCompliance as shown in the diagram 19. 3% had no opinion. 47% did not welcome it. This could be because eCompliance makes them adhere to DOTS more often, i.e. taking under observation doses that are scheduled to be taken under observation. Perhaps, it will require additional counseling of patients for them to realize that eCompliance helps them by taking observed doses more often and prevents the deadly MDR.

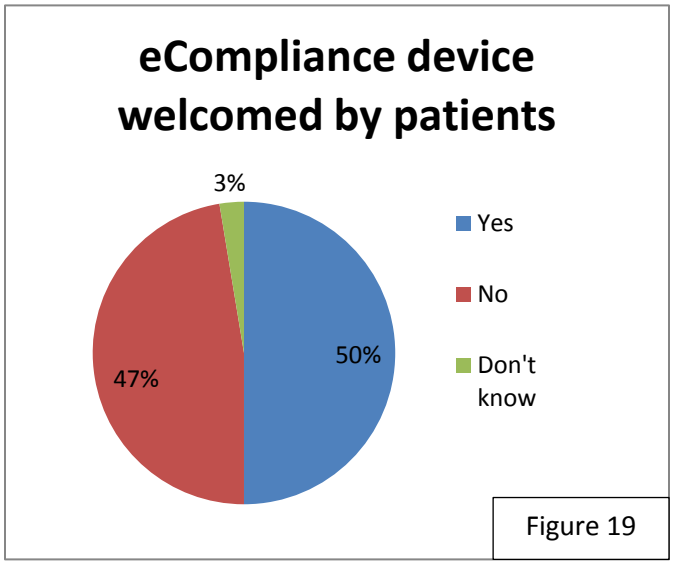


Figure 19

So, eCompliance improves attendance of counselors, accountability of all staff, improves adherence and reduces default and thus prevents MDR. In the next section, quantitative impact of eCompliance in reducing MDR has been calculated.

13. Quantification of the amount eCompliance reduces MDR-TB

50% percent of patients who default on treatment of DST-TB will become MDR-TB patients. The number of patients who defaulted in the Control Group was 132. Had eCompliance been used in the Control Group, it would have reduced the default by 20% = 26 patients. In other words, additional 26 patients would have completed the treatment and only 106 patients would have defaulted. Of the 26, 50% = 13 patients would have not contracted MDR TB. The mortality rate because of MDR TB is 80% (http://www.cdc.gov/mmwr/preview/mmwrhtml/00031296.htm and https://en.wikipedia.org/wiki/Multi-drug-resistant_tuberculosis). So 10 patients would not have died had eCompliance been used in the Control Group.

The conclusion is that eCompliance reduces default by 20%, number of patients who

contract MDR by 10% and deaths by 8%. Prevention of MDR also provides substantial financial benefit to the patients, their families and children. This is discussed below.

14. Financial benefit of eCompliance

TB India 2013 (Government of India) states that life-time increase in income of a patient after TB treatment is $13,935, presumably because of increased productivity. Also, the Indian economy saves $12,235 for each person treated, in indirect costs. So for each patient treated, total financial benefit is $26,170. These estimates are based on the earning capacity of TB patients and number of years they go on earning after the treatment. None of these factors depend on the type of TB.

So, for 26 additional patients in the Control Group who would have completed the treatment if eCompliance had been employed for this Group also, the total financial benefit is $680,420. Of course, the patients also do not have to undergo the trauma of MDR and long and highly toxic treatment.

In a nutshell, application of eCompliance to the Control Group would have prevented 10 deaths and generated $680,420 in financial return.

15. Comparison of cost between Treatment and Control Groups

Total expenses incurred on e-Compliance including procurement, installation, maintenance, network expenses (sms and internet) and salaries of implementation staff come to $186,954 during the Study. 112 patients defaulted in the Treatment Group. But for eCompliance, based on the conclusions obtained above, the default would have been 140. So, eCompliance prevented 28 defaults, saved 14 patients from contracting MDR and prevented 11 deaths.

Treatment of 28 patients, who were prevented from defaulting, generated additional financial benefit of $732,760. So, eCompliance generated a net benefit of $732,760-$186,954 = $545,80. In other words, Return of Investment (ROI) of eCompliance isf 291%. In addition to this, eCompliance also prevented 11 deaths.

There could be another way of assessing the benefit of eCompliance. If the total cost of eCompliance for this Study is assumed to be invested in saving lives, the cost per life saved is $186,954/11 = $16,996, a small amount indeed.

In effect, eCompliance is not only a life-saving technology, it offers excellent cost benefit

ratio.

16. Cost benefit analysis

Table 13 shows savings and return on investment if the National TB Program (RNTCP) implements eCompliance in Delhi, which has 196 large Government run DOTS centers (known as DMCs). The data of TB patients and default has been taken from the latest data available in

Table 13: Cost savings with eCompliance in Delhi				
(Data has been taken from TB India 2014, page 73, unless specified otherwise)				
(All figures are in Indian Rs unless specified)				
		Number of patients enrolled	Default rate	Number of defaults
New smear positive		13,854	5%	693
New smear negative		8,399	3%	252
New extra pulmonary		17,466	2%	349
Retreatment	Relapse	4,045	7%	283
	Failure	548	9%	49
	TAD	1,932	13%	251
Total		**46244**		**1,878**
Total defaults			4%	1,878
Reduction in defaults with eCompliance			20%	376
Additional patients treated				376
Reduction in number of MDR patients			50%	188
			Amount/patient	
Cost of treatment of each MDR patient to the Government			200,000	
Direct savings to Government				**37,552,400**
			$3,333	$625,873
Additional income of patients (TB India 2013)			836,100	313,975,616
Savings in economic loss (TB India 2013)			734,100	275,672,168
Total financial return				**627,200,185**
				$10,453,336
Cost				
Number of RNTCP Centers (knows as DMCs)		196		
Cost of eCompliance for each center		13,000		
Total cost				2,548,000
				$42,467
Direct return to Government		**15**	**times of investment**	
Total return		**246**	**times of investment**	

public domain, i.e. from TB India 2014 (Government of India). Financial benefits of treating TB were mentioned in TB India 2013, and have been mentioned earlier in this report. Cost of treating MDR TB has been taken from http://www.indianredcross.org/sg-message-24march2014.htm. Calculations are shown in table 13.

The cost of implementing eCompliance at all 196 centers would come to $42,647. It will prevent 376 (20%) of the 1,878 defaults that were observed. This will mean that 376 additional patients would be treated at the DST TB stage, instead of defaulting. 188 MDR cases would be averted and 150 lives would be saved. Direct reduction in cost of treatment for the National TB Program would be $625,873, a return of 15 times on investment. If additional income of patients and prevention of economic loss are included, the return goes up to 284 times.

Some critics may argue that cost of eCompliance used in the above calculations is conservative. But even if the costs are raised by twice, the minimum financial return would still 7.5 times or 750% of the investment. Prevention of deaths is a bonus. Most public (or even private) projects cannot even dream of this kind of return. The benefit of installing eCompliance across India or world can only be imagined.

17. Cost of treatment

This Study also calculated cost of treatment of TB patients. The cost includes the following components. This principle applies both to DST and MDR TB.

- Cost of physician consultation and tests (both initial, during and on completion of the treatment)
- Cost of initial work up for MDR TB patients (there is no such cost for DST TB patients because the treatment is entirely domiciliary).
- Cost of medicines
- Cost of transportation to the treatment center to swallow drugs under observation. In rural areas, OpASHA counsellors travel on motorcycles to patients' location. So, there is no cost on this account to OpASHA's patients.
- Cost of time spent in commuting and accessing the drugs and tests
- Loss of income for the period the patient is unable to work

Cost for Category I drugs comes to Rs. 731, and Category II drugs to Rs. 2018. With Cat II cases at 13.72% (pages 74 and 75, TB India 2014), the average comes to Rs. 907.52.

Patients in Delhi went to Batra Hospital, a middle rung hospital in Delhi and similar hospitals in other cities. So, various fee charged by this hospital were taken as representative for tests, physicians and hospital charges. The charges are worked out for 'general ward', which houses 6-8 patients in a single large room. This fits with the economic profile of OpASHA's patients.

Cost of physician consultation and tests (both initial and on-going) is Rs. 350 per consultation and Rs. 75 for sputum test.

Based on the above, costs for both DST and MDR TB are calculated below.

17.1 *Cost of DST treatment*

This analysis was done for OpASHA, another NGO that shared the data and Government centers. Details are given in table 14.

Table 14: Cost of treatment for DST TB	(all figures in Rs unless specified otherwise)		
	Average commuting time		
	To OpASHA center	To other NGO center	To Govt center
Commuting time	16	36	64
Average daily earning (10.5 hours a day, 26 days a month)	237		
Cost of commuting time	6.02	13.54	31.98
Cost of transport	0.00	10.00	20.00
Cost per trip	6.02	23.54	51.98
Cost of accessing DST DOTS	361.14	1412.57	3118.57
Cost of accessing DST DOTS ($)	$6.02	$23.54	$51.98
Period pt is unable to work (months)	28.4		
Loss of wages due to absence from work	6723.32		
Number of trips for observed doses (average Cat I and II)	60		
Total cost to patient	7084.46	8135.89	9841.89
Total cost to patient	$118.07	$135.60	$164.03
Number of visits to the physician	5.48		
Physician consultation	350		
Total physician cost	1918		
Cost of initia tests (for detection: sputum + X-ray)	290.07		
Cost of sputum tests (follow up)	239.90		
Cost of medicines	907.52		
Total cost borne by Government	3355.49		
Total cost borne by Government ($)	$55.92		

Total cost	10439.95	11491.38	12639.85
Total cost ($; $1 = Rs 60)	$174.00	$191.52	$210.66

An interesting observation is that OpASHA reduces patients' cost of accessing DOTS to practically zero. The reason is that OpASHA centers are located in urban slums at a distance of nearly every mile (1.6 km) and close to key exits/ entrances to slums. So, patients can access them on the way to work or on the way back, without having to spend any money on transport, and with very little investment of time. In villages, OpASHA counselors go to every village whenever a patient needs an observed dose.

17.2 Cost of MDR Treatment

MDR drugs have severe side-effects. Therefore, the patient is admitted for 10 days, on an average, for initial tests and ensure that side effects are properly taken care of. The cost of this work-up is Rs. 39,140. This is worked out again for the costs at Batra Hospital. Reasons have been discussed above. Most patients normally go for this to a Government hospital, which does not charge disadvantaged patients. So, this cost is borne by the Government (RNTCP).

Total costs are shown in the table 15.

Table 15: Cost of treatment for MDR TB	(all figures in Rs unless specified otherwise)		
	Average commuting time		
	To OpASHA center	To other NGO center	To Govt center
Commuting time	16	36	64
Average daily earning	237		
TO THE DOTS CENTER			
Cost of commuting time	6.02	13.54	31.98
Cost of transport	0.00	10.00	20.00
Cost per trip	6.02	23.54	51.98
Number of trips to DOTS center	620		
Cost of accessing DOTS	3731.81	14596.57	32225.24
Cost of accessing DOTS ($)	$62.20	$243.28	$537.09
TO THE HOSPITAL			
Time spent: commuting + hospital (hours)	7 (so the patient is unable to work that day)		
Cost of time spent	237.00		
Cost of transport	40.00		
Cost per trip	277.00		
Number of trips to the hospital	49.5		
Cost of accessing the hospital	13711.50		

Cost of accessing the hospital ($)	$228.53		
Period pt is unable to work (days)	41.25		
Loss of wages due to absence from work	9776.25		
Total cost to patient	27219.56	38084.32	42001.49
Total cost to patient ($)	$453.66	$634.74	$700.02
Cost of Initial work up in the hospital	39140		
Number of visits to the physician	49.5		
Physician consultation	600		
Total physician cost	29700		
Cost of tests (initial, for detection)	3500		
Cost of follow up tests	5000		
Cost of medicines	159225		
Total cost to Government	236565		
Total cost to Government ($)	$3,942.76		
Total cost	263784.97	274649.73	278566.90
Total cost ($)	$4,396.42	$4,577.50	$4,642.78

In addition to the above, OpASHA, invests Rs 24,840 ($414) in providing DOTS to its MDR patients. This analysis was done for another NGO (TB Alert), which shared the data. Their cost is Rs. 44766 ($746).

18. Challenges

The implementation was not without challenges, which is to be expected for a Study of this size and complexity, more so when work in spread over 9 cities, across 4 states, and has a very large number of partners like dozens of local micro entrepreneurs, 9 District TB Officers and their staff of over 100 people, 4 State TB Officers and many others.

The biggest challenge was collection, cleaning up and collation of immense data that was collected and used in the Study. A digital software application was used for this. However, a totally unforeseen event occurred. The company that had provided the software shut down in the middle of the Study. So the field staff had to switch to manual monitoring till another software was implemented later. However, it was ensured, with investment of additional effort, time and staff, that monitoring was consistent and of high quality, throughout the Study.

Another glitch, which involved hardware, was faced. At the start of the Study, OpASHA had bought mostly Lenovo and Asus netbooks, which constituted eCompliance units. Unfortunately, ASUS netbooks had a problem with their hard disk. Many of them broke down at random, in

different cities, at different times, at various centres. It took a lot of effort and resources to repair them, even though netbooks were within the warranty period and hard disks were replaced free by the manufacturer. We even discussed internally whether hard disks in all the Asus machines could be “made” to crash at one go, so the manufacturer would replace all of them and we would prevent recurring problems. But such a mass “crash” is not technically possible. In spite of free repairs, break downs kept creating problems. Finally, we decided to replace some of them.

Therefore, all eCompliance units in one city (Bhopal) were replaced with the new tablet based eCompliance units. It may be reiterated that netbook and tablet based eCompliance units have identical functionality. Spare netbook based units were used in other cities to replace the ones that were giving frequent trouble. This solved the problem permanently.

It may be underscored that the problem arose primarily because a particular batch of Asus netbooks had manufacturing defects. It had nothing do with eCompliance software or handling by field workers. This view is reinforced by the fact that eCompliance units that were using other brands of netbooks like Lenovo, Samsung or Acer, did not give any such trouble.

19. Conclusion

This report provides new results for a Study conducted in nine cities across four states of India, where eCompliance was randomly allocated among 130 DOTS centers between March 2013 and September 2014.

eCompliance allows digital tracking of TB counselors’ attendance at the DOTS center as well as patients’ treatment adherence and observed doses. This leads to reduction in default by 20% and provides immense health and financial benefits to all stakeholders.

Improvement in adherence and treatment success rate is likely driven by two factors. First is the easier tracking of missed doses and evidence of corrective action being generated with the use of eCompliance. Second is improved patient behavior.

An overwhelming majority of counselors find eCompliance useful. They were able to use the technology quite well and deliver better results in the Treatment Group. This required only two hours of training. This implies that eCompliance is easy to learn and operate for persons with low/ limited literacy. Half the patients also like eCompliance.

In conclusion, eCompliance is a powerful tool for enforcing the DOTS strategy, reducing default, turning the tap off on MDR and preventing deaths. eCompliance also offers very high financial return on investment.

20. Dissemination Strategy

Dissemination will be done by all stakeholders involved. Details follow.

20.1 Operation Asha

Operation ASHA is inspired by the results and wants to disseminate them in a big way. First will be a workshop in Delhi. USAID and National TB Program (RNTCP) will be requested to lead it. Cost Benefit analysis presented above should be of great interest to RNTCP.

Now that the Study is over, randomization is not needed and OpASHA will immediately expand eCompliance to all its 194 centers in India. Expansion of eCompliance to all OpASHA centers in Cambodia will also be taken up.

OpASHA will also share Study results, immediately on approval of the final milestone by USAID, with the following group of NGOs/ donors/ experts:

1. Global Fund, World Bank, IFC, bilateral donors like EU, DFiD, DFATD, NORAD, SDA, AusAID and JICA
2. CHMI, SEAD Accelerator at Duke University, Rockefeller Foundation, 3ie, conferences and academia abroad
3. Dasra, Villgro, Samhita, Intellecap and academia in India
4. 78 innovative organizations that are covered by a paper published by Center for Health Market Research (CHMI) on http://healthmarketinnovations.org/programs/search?f[0]=im_field_profile_health_focus%3A38
5. Nearly 1,100 partners of the Stop TB Partnership.

Anticipating approval by USAID soon, an exercise to familiarize organizations at 3 and 4 with the basics of OpASHA technology above has already been started.

One of the Principal Investigators now works with the World Bank and is part of the team that is advising India's Central TB Division and Ministry of Health on the future course of the National TB Program (RNTCP). This will be helpful too.

20.2 Donor Organizations

DIV as well as other related agencies like HESN will hopefully disseminate the results through their website, newsletter and conferences.

20.3 Direct outreach to stakeholders

Under the 12th five-year plan of the Revised National Tuberculosis Control Programme (RNTCP), the central TB commission of India has placed increased focus on results obtained from rigorous impact evaluation studies. Given the climate of receptiveness toward evidence-based policy, we hope that the results of this Study will contribute significantly to the policy and practice on tuberculosis treatment in India, at the Central, State and district levels.

20.4 Academic Papers and Conferences

The principal investigators and research staff will produce an academic paper describing the results of the study. This paper will be written and published in top international development and economics journals. The results will also be presented at top universities both within India and internationally. We expect to present our findings at numerous academic conferences both in India and abroad, in the hope of spurring further research into related areas of study from other prominent economists.

20.5 Media

Operation Asha and PIs will do their best to maximize coverage of the study results in Indian media and to produce outreach materials that present the results in a highly accessible manner.

We anticipate that, as a result of these efforts, e-compliance technology will play a prominent role in the national dialogue over TB control. A recent segment on a highly popular Indian television news show highlighted Operation Asha's work and, in particular, the promise of e-compliance technology for reducing treatment defaults. The final results of a rigorous impact evaluation should further heighten interest in the adoption of such technology on a large scale.

21 Cost of Study

Cost incurred so far is tabulated below.

Table 16: Costs incurred till Dec 2014	**in USD**
Set up of biometric system (procurement + installation)	49,665.98
Biometric machine server	1,754.84
Cell phones/internet	5,732.09
Other equipment or maintenance costs for the biometric machines	27,724.13
Financial incentives provided to counselors	26,424.32

Salary paid to counselors	142,431.93
Program staff salary	644,171.27
Liabilities raised (Payments for the concerned period, but yet to be paid because of technical/ administrative reasons)	18,708.67
TOTAL	**916,613.22**

Entire grant will have been spent the moment all pending expenses are paid. Actually, there will be a shortfall of $19289.22. This is a small shortfall (2.1%). We have requested a few donors to take care of this. USAID does not need to pay any extra amount.

Annex 1: Means and instruments of data collection

Type of Data	Purpose	Indicative Measures	Collection
Counselor Surveys 1. **Baseline:** administered prior to randomization 2. **Midline:** administered after 6 months 3. **Midline+:** at exit from Study if this is before 6 months in the Study 4. **End line:** after 12 months in the Study 5. **End line+:** at exit from Study if the exit is after 6 months but before 12 months in the Study	The counselor surveys will allow us to observe counselor level outcomes - the effects of biometric monitoring on performance, motivation and job satisfaction, and the quality of care – and analyze their relationship to counselor characteristics.	- Counselor socioeconomic indicators - Strategies for detection and default prevention - Quality and range of care provided - Commitment - Satisfaction with job and organization	Counselor surveys are administered to counselors at the appropriate time by a senior experienced surveyor, usually a field manager or the project associate.
Patient Surveys 1. **Range 1:** administered during the 1stmonth into treatment 2. **Range 2:** administered at the 6 months of treatment (i.e. complete or nearing completion) if Range 1 was administered. 3. **Range 2.1:** given if Range 1 was administered and the patient defaults before completing the 6 months treatment course. 4. **Range 3:** at the 6 months of treatment (i.e. complete or nearing completion) if Range 1 was not administered. 5. **Range 3.1:** given if Range 1 was not administered and the patient defaults before completing the 6 months	The patient surveys allow us to observe patient level outcomes - quality of care received TB and other health outcomes, awareness of TB care and treatment - analyze these effects by socioeconomic sub-group, and examine the effects of eCompliance usage on patient outcomes, beliefs, and behaviors.	- TB related health outcomes - Quality of care received - Interactions with counselor - Knowledge of TB - Use of and impression surrounding eCompliance usage - Other interactions with healthcare providers - Impact and severity of disease on overall health - Socioeconomic indicators	Field staff visit each center about once a month to select the appropriate survey Range. Patients are then administered the survey usually at the patient's home at the earliest possible date. Patients will be followed up with another round of survey (Range 2 or 2.1) if they are given Range 1.

treatment course.			
Patient treatment information 1. **Treatment card:** daily TB treatment (pills) log maintained by the counselor for each patient 2. **District level TB registers:** central repository of data on all TB patients, their assignments to counselors, their TB test results and TB status (default)	Treatment cards will allow us to analyze patient compliance and counselor treatment standards (regularity). Used in conjunction with our independent monitoring data, we will also be able to examine underreported missed pills. Registers are the primary source of detection and default numbers. They also provide baseline prevalence and patient numbers.	- Daily missed pills - Ongoing TB test results - Detection - Default	Field staffs take photographs of treatment cards from the centers. They also visit the district medical centers to record the patient data in the TB lab registers which will be used to cross check the patient data obtained from the centers.
Monitoring data 1. **Center monitoring and Mobile monitoring:** observation and recordkeeping of all counselor-patient interactions for a day and eCompliance usage information in the case of treatment counselors (at least twice a month that include accompanying the counselor during at least one home visit) 2. **Random Checks:** Each center is randomly visited at least once per month in addition to center monitoring.	The monitoring data allows us to corroborate treatment card data (did reported missed pills on the observation day match our data), observe irregularities in missed pill reporting (does this increase on the monitoring day), the quality of counselor follow up on missing patients (home visits), and details regarding use of eCompliance in the case of treatment centers. It also allows us to record counselor attendance and assess their performance. Random checks by a senior field staff help to keep check of the cases where our field staffs' monitoring	- Number of patient visits - Mode of visit (in person, relative pick up, counselor home visit) - Counselor absenteeism	In case of center and mobile monitoring, field staffs make bi-monthly unannounced (and irregular) visits to observe an entire day's TB services. This is done across treatment and control so there is a uniform monitoring effect. In the case of center monitoring, at least one of those visits has to include a home visit where a counselor is following up on a patient who could not come to the center. For random checks, field managers

	patterns might have become predictable over time; they also gather quick information regarding counselor presence and activities, and patients' presence and activities.		randomly visit centers at least once a month.

ANNEX 2: Study of missed doses and default from data reported by supervisors[2]

The results of the RCT and discussed above have proved that patients in the Treatment group are 21 percentage points more likely to take a supervised dose (table 12, column 3 and 4). This result is robust to a significance level of 1%. Does the data reported by supervisors also indicate more supervised doses and fewer missed doses in the Control Group? This question is discussed below.

The data for missed doses was collected in the following ways.

- For the Treatment Group, it was collected from Electronic Medical Record (EMR) system that forms back-end of eCompliance. The result was: 24% missed doses.
- For the Control Group, each counsellor was asked to compile and submit data of missed doses to the supervisors at the end of the week. Supervisors compiled it and sent to the Program Management Office. These reports indicated only 4% missed doses. This is six times less than the Treatment Group. What is the truth? What is happening here.

One finds that there is a key difference in the procedure for collection of data between the Study Group and the Control Group. This is discussed below.

To register a supervised/ observed dose in the Treatment Group, it is mandatory for a patient to reach a DOTS center or meet a counsellor at another location like the patient's house/ farm. At this location, a supervised dose is logged by eCompliance only and only when both the

[2] The report of this Study is complete without this Annex. The only rationale for this Annex is that the comparison discussed here was mentioned in the original proposal submitted to DIV. The original hypothesis was that this comparison will produce statistically significant results. However, this hypothesis has not come true, which is quite logical in the scheme of things. Trials may prove some hypotheses, disprove others and leave some open for further testing.

counsellor and the patient give fingerprints simultaneously. There is NO provision to record a supervised dose through a key board or any other way. Not only that, once a patient misses consecutive doses for two months, the eCompliance automatically moves the patient to a default status. After that, neither the counsellor nor the supervisor nor anyone else can change his status. Thus, the technology makes it impossible to manipulate either a supervised/ observed dose or default.

On the other hand, in the Control Group, the counsellor is expected to put a tick in a box against the date on which the patient should have taken a supervised dose. This is prone to human error. As explained earlier, the Treatment Cards are filled up at weekly/ fortnightly intervals, simultaneously for a large number of patients, which compounds human error.

Secondly, whenever a patient does not show up, the counsellor must put a cross in the Treatment Card, follow up with the patient with a phone call and subsequently a personal visit. The counsellor has to enter the results of the phone call/ follow up visit, on the Treatment Card, and report details to the supervisor, on a weekly basis. Any missed dose that has not been followed up is viewed adversely and the counsellor is reprimanded. Continuous failure to follow up on missed doses may even lead to loss of job for the counselor.

In effect, each missed dose must be followed up and obviously increases counsellor's work. This leads to a situation in which the counsellors game the system by 'showing' that most patients take necessary doses under supervision. Only in unavoidable situations, counselors show patients to have missed a supervised dose. An example of such an unavoidable situation is a sputum positive patient who is required to undergo a follow up sputum test every two months, but does not reach the lab. So there is no follow up report. The patient cannot be shown to be continuing on treatment without this report. In a nutshell, counselors game the system to reduce their workload.

Large possibility of human error and gaming can easily explain much lower percentage of missed doses the Control Group than in the Treatment Group.

In other words, the reason for higher missed doses in the Treatment Group is elimination of human error and gaming by digital eCompliance technology. The same reasoning applies to reported default.

Default to DOTS treatment in the Treatment, Control and Contiguous Areas

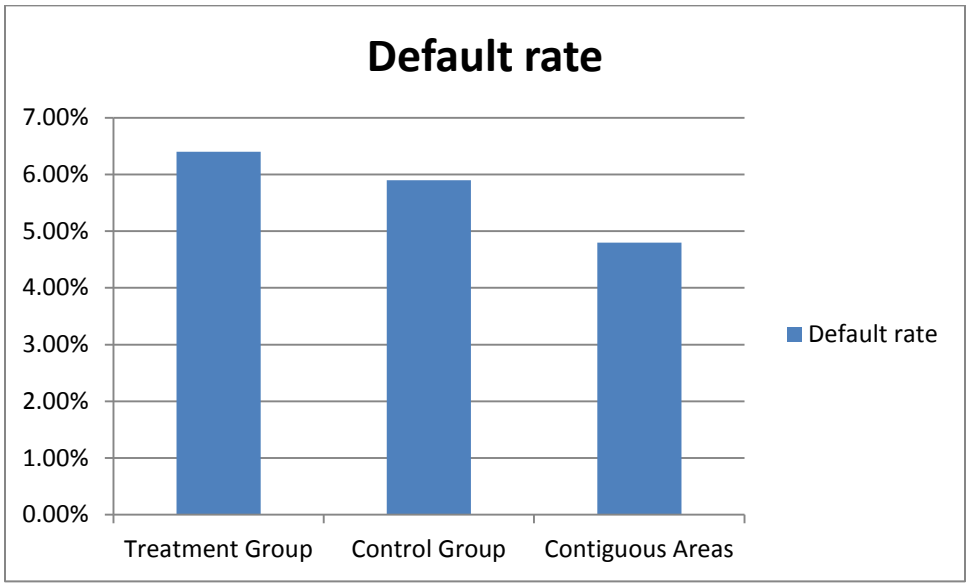
The data for default was collected in the following ways.

- For the Control Group, data of defaults was derived from the.
- For the Control Group, each counsellor was asked to compile the data of defaults, based on manual Treatment Cards, and submit it to the supervisors, who in turn, compiled it on a monthly basis and submitted to the Program Management Office.
- The supervisors were asked to find out number of patients, who had defaulted, and total number of patients enrolled, during the same period as this Study, for patients in areas served by other NGOs and the National TB Program (RNTCP), which are geographically contiguous to areas covered in the Study. These were obtained by registers/ paper records maintained by respective organizations, which are again based on paper records and Treatment Cards.

The total number of defaults in the Treatment Groups, Control Group and the Contiguous Areas are given in Table A. The figure below plots these numbers in a bar diagram.

Table A

	Treatment Group	Control Group	Contiguous Areas
Default rate	6.4%	5.9%	4.8%



Again, it is interesting to note that the Treatment Group, with eCompliance, apparently had the “highest” default rate of 6.4%. The Control Group was slightly lower at 5.9% and the Contiguous Area was at 4.8%. This was very much expected on the basis of the observation of missed dose percentages discussed above.

To satisfy academic curiosity, a regression analysis (table B) of reported default rates

between the Treatment and Control Groups was carried out. It does not show any statistically significant results.

Table B: Impact of eCompliance usage on defaults				
	1	2	3	4
VARIABLES	Monthly default	Monthly default	Monthly default	Monthly default
Treatment	-0.00345	0.0279	0.0226	0.0633
	(0.0308)	(0.0347)	(0.0467)	(0.0512)
time variance interaction effect			Yes	Yes
city fixed effects	Yes	Yes	Yes	Yes
Counselor controls		Yes		Yes
Observations	1,794	1,736	1,794	1,736
R-squared	0.028	0.056	0.028	0.057
Robust standard errors in parentheses				
*** p<0.01, ** p<0.05, * p<0.1				

In a nutshell, data reported by supervisors cannot be depended upon for proper analysis or policy making. This makes eCompliance a necessary tool, not only to deliver and administer DOTS strategy, but also to collect proper data for decision making.