CENTER FOR GLOBAL
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PROCEEDINGS

Innovating Tuberculosis Care Delivery in High-Burden Settings

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Harvard Medical School Center for Global Health Delivery Dubai
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TABLE OF CONTENTS

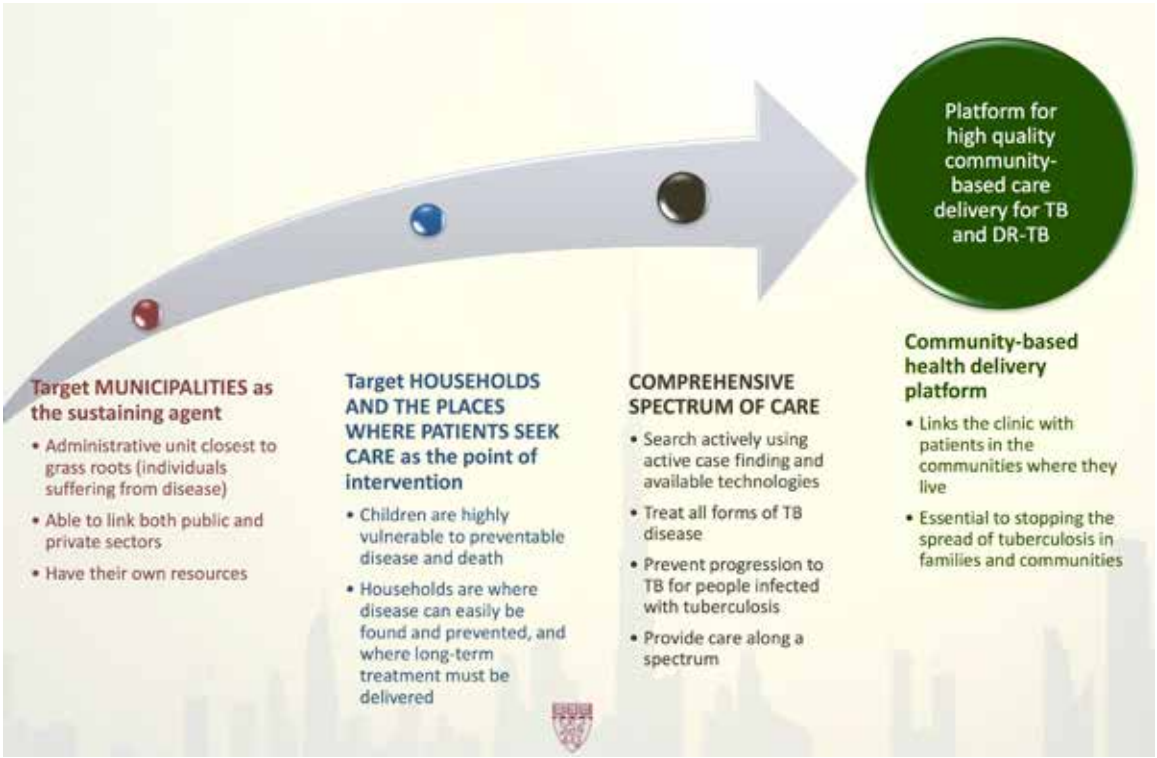
1.0 Introduction

On Wednesday, April 15, 2015, over 62 experts convened for the Innovating TB Care Delivery in High-Burden Settings workshop. This workshop was hosted by the newly established Harvard Medical School Center for Global Health Delivery– Dubai, in Dubai, United Arab Emirates. The workshop's stated goal was to gather experts in TB detection and treatment to discuss innovations found in the private sector in high-burden countries, which may be utilized to strengthen TB programs and create viable new TB treatment models. This meeting addressed the significance of the private market for TB care in key countries, how the strengths of both public and private sector approaches may be synthesized in an effective way to combat TB while continuing to prioritize accountability, and the prospects for scaling up such approaches.

The workshop and discussion brought together researchers, care providers, policy-makers, and industry and non-governmental representatives from more than 15 countries across Asia, Africa, the Americas, and Europe. Represented organizations included the Aurum Institute, Partners In Health, the Global Fund, Interactive Research and Development, Pakistan's National TB Program, Operation ASHA, the Organization of Eastern Caribbean States (OECS), Stellenbosch University, the Clinton Health Access Initiative, the Stop TB Partnership, and Janssen Global, among many others.

The global struggle against both drug-susceptible and drug-resistant TB has largely focused on programmatic and clinical responses to the disease through the public sector. However, government TB programs

Figure 1. Changing the TB treatment paradigm



Source: Keshavjee presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai.

Box 1-1 Tuberculosis and drug-resistant tuberculosis basics[1]

What is tuberculosis (TB)?

Tuberculosis (TB) is a disease caused by bacteria that are spread from person to person through the air. TB usually affects the lungs, but it can also affect other parts of the body, such as the brain, the kidneys, or the spine. TB is treatable and curable; however, persons with TB can die if they do not get the correct treatment in a timely fashion.

What is multidrug-resistant tuberculosis (MDR-TB)?

When TB bacteria are resistant to an anti-TB medication, it means that that medication can no longer kill the bacteria. Multidrug-resistant TB (MDR-TB) is caused by bacteria that are resistant to both isoniazid and rifampin, the two most potent anti-TB drugs. Without the ability to use these two drugs, TB treatment regimens are longer, more toxic, and can be less effective.

What is extensively drug-resistant tuberculosis (XDR-TB)?

Extensively drug-resistant TB (XDR-TB) is a type of MDR-TB that is resistant to both isoniazid and rifampin, plus the backbone of the second-line anti-TB regimen: fluoroquinolones and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin).

Because XDR-TB is resistant to the most potent TB drugs, patients are left with treatment options that are much less effective.

TB is of special concern for persons with HIV infection or other conditions that can weaken the immune system. These individuals are more likely to develop TB disease once they are infected, and also have a higher risk of death once they develop TB.

in high-burden countries are often unable to finance the comprehensive approach needed to effectively find all patients, treat them effectively, and support them through care. In addition, populations most likely to be affected by TB are those situated within particularly challenging socio-economic and public health environments. As TB diagnosis and treatment (particularly for drug-resistant TB) can involve expensive diagnostic tests and drugs, complicated treatment regimens, and significant side effects, TB patients and their families often cannot afford quality care. Many patients in high-burden countries pay out of pocket, utilizing drugs of unknown quality or regimens without key drugs.

The group outlined the key areas where the flexibility and innovation found in the private sector may be a significant factor in strengthening existing TB programs and creating viable new models that take into account the need for rigorous reporting and supervision. Workshop organizers and participants repeatedly emphasized that these approaches and discussions should all feed into the broader concept of a comprehensive TB program in the 21st century: a patient-centered, evidence-based model that adapts to local settings, provides a spectrum of care, and looks to communities and households first as it tackles TB transmission at its root—while strengthening institutional TB care and improving the policy environment (Fig. 1). Commitment to this approach was strengthened by the preceding and following days' workshops and events.

[1] Source: http://www.cdc.gov/tb/publications/factsheets/drtb/mdrtb.htm

2.0 Innovations in TB Care Delivery

2.1 A REVIEW OF THE PRIVATE SECTOR IN HIGH TB BURDEN COUNTRIES: APPLICATIONS FOR ZERO TB CITIES[2]

Jacob Creswell reviewed the role of private-sector engagement in countries with high burdens of TB, with the view to potential applications for the Zero TB Cities Project. He opened by emphasizing that while estimates of global TB incidence and prevalence vary from year to year, the only data known for certain is the number of new and relapse TB cases that countries officially submit to the WHO. This number has hovered around 6 million since 2008.[3] While notification rates have remained largely unchanged, prevalence and incidence estimates will continue to rise as better data become available; this widening gap between the notifications and the estimates encompasses the so-called "missing" TB cases.

He pointed to barriers along the lengthy TB patient pathway from exposure to treatment as contributors to why notification rates are stagnant. A person who develops active TB must recognize the symptoms, access care, have their symptoms recognized accurately by a healthcare worker, receive an accurate diagnostic test, and be put on treatment with a notification; only then will the national TB program (NTP) capture the information (Table 1):

Table 1. Barriers and possible interventions in patient pathway to TB care.

Barriers	Patient Pathway to TB Care	Possible Interventions
	Exposure	
	Infection	
	Active TB	
□ Lack of knowledge, poor information □ Misperceptions, stigma, perceived poor quality of services	Patient recognizing symptoms	□ Awareness raising □ Mass media □ Community engagement □ Information and education
□ Distance □ Cost of transportation, testing □ Loss of wages □ Time spent, opportunity costs	Accessing care	□ Expanded coverage □ Community outreach □ Mobile clinics □ Task shifting
□ Lack of proper training □ Poor index of suspicion for TB	Health worker recognizing symptoms	□ Systematic facility screening □ Better training □ Improved screening algorithms
□ Insensitive tests and screening algorithms □ Delays to give results	TB diagnosis	□ Improved diagnostics □ Improved screening algorithms
□ Weak linkages between public-private sectors □ Poor internal reporting systems □ Drug stock outs	TB treatment and notification	□ Engagement of all care providers □ Improved information and supply systems

Source: Keshavjee presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai.

[2] The section is based on the presentation of Jacob Creswell, TB REACH, Stop TB Partnership, Switzerland.
[3] WHO Global Report 2014


Men collect TB medications from an in-house pharmacy at the Taluka Hospital, Sehwan. Pakistan.

Photo credit: Stop TB Partnership, Shehzad Noorani

2.1.1 SHIFT IN PUBLIC-PRIVATE MIX FOCUS: FROM NATIONAL TB PROGRAMS TO PATIENTS

Over the last 15 years, public-private mix (PPM) efforts have targeted the specific set of patients diagnosed by private providers who have no linkage with the NTP. Patients in the highest-burden countries tend to seek care initially in the more easily accessible private sector, rather than in public facilities.[4] While patients may have to pay a small fee for private-sector care, waiting times are shorter, clinic hours are more convenient, transportation costs are lower, and there is a perception that care is better than in a public facility. Creswell acknowledged that this perception might be founded in some cases, but there is real reason for concern about the huge range of treatment regimens prescribed by private practitioners and the fact that individuals diagnosed with TB in the private sector often pay for their anti-TB medications out-of-pocket.[5]

Early PPM efforts to engage care providers were almost always NTP-driven, reliant on passive case-finding, and dedicated to ensuring providers' compliance with standardized treatment guidelines, to which many private providers were not amenable. Recently, PPM has since become more nuanced and complex, and driven by all types of partners.[6] The ethos has evolved to focus on what is best for the patient, which has spurred more engagement from private providers.

2.1.2 BARRIERS TO CASE NOTIFICATIONS

Patient must recognize symptoms

Creswell explained that prevalence surveys employ a generally accepted methodology of cluster screening communities for TB. This involves asking individuals about symptoms and screening everyone in the community with chest X-ray, followed by smears and cultures. He cited data from a prevalence survey in Indonesia showing that 60% (260) of detected cases were culture-positive and smear-negative, and 40% of prevalent cases did not report any symptoms. Thus, large proportions of people who do not report symptoms diagnosable via chest

[4] Utilization of private care in 10 of 22 HBCs: Pakistan (86%); Bangladesh (86%); Cambodia (77%); India (77%); Nigeria (66%); Indonesia (71%); Uganda (65%) Congo DRC (56%); Kenya (56%); Philippines (52%). [Harding, April, and Alexander S. Preker, eds. Private participation in health services. Vol. 434. World Bank Publications, 2003.

[5] Udwadia ZF et al PLoS ONE 2010; Achanta S et al. PLoS ONE 2013

[6] E.g., social business, social marketing, charity hospitals, PMDT, and systematic screening.

X-ray and culture. In contrast, only two thirds of 165 smear-positive cases reported symptoms, meaning that just 25% of overall prevalent TB cases would be found through an algorithm reliant on smear microscopy for people with symptoms.

Accessing care and high-risk groups

Creswell described a community outreach effort in rural Ethiopia in which health extension workers conducted household screening, collected sputum for referral, prepared slides for examination and supervised treatment. Because TB detection had previously relied in large part on passive case-finding, case notifications jumped by over 2,500 patients in a single year and the proportion of patients with successful treatment outcomes improved from 77% to 93%.[7]

A study of nomadic populations in Nigeria—another marginalized group with poor access to care—carried out primarily symptom-based screening during market days.[8] Notifications increased by 50%, and nomads accounted for one third of the overall notifications at the state level. He emphasized that they tested 50,000 people to get 2,500 cases, raising concern about the specificity of smear (i.e., false positives) over such a large number of tests.[9] He thus recommended using as specific a test as possible, such as Xpert MTB/RIF, for large active case-finding efforts.

Because older people have such high rates of TB, a third study cited by Creswell targeted this population in Cambodia using mobile-based symptom survey, X-ray, and Xpert MTB/RIF as part of an active case-finding intervention. It generated a huge increase in notifications among people of all ages, but especially among older people.

Need for better diagnostics

Creswell used Xpert MTB/RIF and a recently published intervention in Eastern Nepal[10] to explore the impact of diagnostic method on case notifications. The testing algorithm was based in the routine passive services and required three sputum smears, chest X-ray, then Xpert MTB/RIF in nine districts. While bacteriologically confirmed TB notifications increased, the number of notified

smear-negative cases declined sharply, yielding an overall number of pulmonary TB notifications that was much lower than expected. Creswell attributed this drop to clinicians' hesitance to diagnose TB in patients with negative Xpert MTB/RIF results(whereas previously they had empirically treated patients with negative smear results), and cautioned against over-reliance on a single diagnostic test because Xpert MTB/RIF is not 100% sensitive.[11]

Creswell also stressed that using Xpert MTB/RIF in a passive setting (e.g., a private clinician's office) will not in itself yield more TB patients. Better diagnostic tests increase sensitivity, but only among the people who have come into the office or have been referred as TB suspects. He called for heightened focus on finding ways to reach more people in order to make a substantial impact.

2.1.3 INCREASING THE IMPACT OF INTERVENTIONS: CONCLUSIONS AND WAYS FORWARD

Creswell stressed that new thinking in PPM will achieve results, if funded, but that achieving an impact will cost money. As more cases are found, the marginal cost of finding another case will continue to rise. He concluded by summarizing important considerations in increasing the impact of case-finding efforts:

- Identifying and assessing current barriers is critical to moving forward, and should not be focused just on adding new providers.
- To find more cases, the number of people tested must increase.
- Many TB cases yielded by interventions will not be additional, in that they would have eventually accessed care in the

[7] Yassin M et al.PLoS ONE 2013
[8] John S et al.IJTBLD 2015
[9] He commented that in every prevalence survey, active case finding will generate a fair number of false-positive smear results.
[10] John S et al IJTBLD 2015
[11] He cited more robust studies that demonstrate this (Theron et al; Durovni et al.)

health system anyway.

- Better tests in isolation only reach those attending facilities.
- 40%–50% of patients with bacteriologically confirmed TB may not complain of symptoms; most of those without symptoms need more than smear microscopy to make a diagnosis.
- Active case-finding with smear microscopy may potentially result in false positives; more specific diagnostics should be used.

2.1.4 KEY POINTS FROM DISCUSSION

Gail Cassell[12] questioned whether the 50% of patients who are asymptomatic but bacteriologically positive are Xpert MTB/RIF positive. Creswell explained that Xpert MTB/RIF is not used in prevalence surveys in a way that could answer that question, as it is generally used to test only smear-positive patients. However, he noted that there is fairly good data to predict how sensitive Xpert MTB/RIF would be. Cassell highlighted the need for a test to detect smear-negative, asymptomatic patients.

Giorgio Roscigno[13] and Salmaan Keshavjee[14] discussed the lack of a good diagnostic tool for point-of-care testing, with Roscigno asking how active case-finding could be improved; Keshavjee pointed out that laboratory testing of sputum is insensitive, expensive, and labor-intensive, even when sputum is collected by community health workers. Creswell pointed out that smear microscopy is less expensive than Xpert MTB/RIF, but depending on the active case-finding approach, there are options such as using chest X-ray to reduce the number of smears tested in the laboratory. Sunil Kapoor[15] raised another issue related to sputum smear microscopy, suggesting that most private labs report negative results without appropriate testing to avoid handling infectious sputum.

Referring to the Nepal data, Liesl Page-Shipp[16] cautioned against overestimating the power of Xpert MTB/RIF or any other single intervention in the context of a failing health system; she urged for a continued push toward developing new diagnostics appropriate for different settings.

Creswell noted that the yield from contact investigation in homes is relatively small (<10%); it is also roughly the same for smear-negative and smear-positive TB. With respect to Creswell's position about additionality in case finding, Mercedes Becerra[17] emphasized that not all case-finding strategies are equal, with household contact tracing being significantly more efficient in yielding cases than other methods. Further, she maintained that while it may not generate huge numbers of cases, it is the best way to find children earlier when it is easier to diagnose, treat, and prevent them from dying.

Aamir Khan[18] stated that he also has experience with clinicians who do not believe patients who are Xpert-negative could have clinical TB disease, and suggested that the model of targeted X-ray screening from the Cambodia intervention could be replicated to great effect with mobile, less expensive X-ray machines, software for automated reading, and Xpert MTB/RIF testing. Guido Geerts[19] remarked that it would be possible to make digital mobile X-ray technology available at a feasible price by combining orders from multiple projects or systems (e.g., digital X-ray plus computer-aided detection) to lower costs.

[12] Gail Cassell, Harvard Medical School / Infectious Disease Research Institute, U.S.
[13] Giorgio Roscigno, NEXT, South Africa
[14] Salmaan Keshavjee, Harvard Medical School, U.S. / Center for Global Health Delivery, Dubai, U.A.E.
[15] Sunil Kapoor, Harrow Respiratory Medical Center, India
[16] Liesl Page-Shipp, Aurum Institute, South Africa
[17] Mercedes Becerra, Harvard Medical School, U.S.
[18] Aamir Khan, Interactive Research and Development, Pakistan
[19] Guido Geertz, Delft Imaging Systems, The Netherlands

2.2 Reaching the hard-to-reach[20]

Photo credit: Dave Chidley

Luke Disney's presentation explored human mobility as a driving, dynamic factor behind modern society, and therefore one that deserves the attention of health programs, including TB programs. He described the development of the North Star Alliance in Sub-Saharan Africa to offer a perspective on how health providers go about forming health initiatives among nontraditional partners. North Star is a program focused on delivering healthcare to highly mobile populations along the road transportation infrastructure.

In the context of the Zero TB Cities Project, Disney urged the group to be conscientious of the people moving in and out of cities; he noted that 90% of people travel by land despite the focus on disease transmission via air travel.

2.2.1 CREATION OF THE NORTH STAR ALLIANCE

In the early 2000s, the World Food Program, responding in Southeastern Africa, was unable to source adequate local transport to deliver resources; further research revealed that transport companies were losing truck drivers at such high rates to communicable diseases such as TB, malaria, and particularly HIV, that a large gap was opening in the supply chain. For a variety of administrative and operational reasons, these drivers were often spending more than two-thirds of any given month on the road, with much of their time spent in truck stops, which are hubs of the commercial sex industry. Disney explained how this kind of extreme mobility among drivers, coupled with lack of economic opportunity among sex workers, drives high transmission rates of disease at these "hotspots."

The North Star Alliance was created to provide logistical assistance to the World Food Program to deal with this problem by finding a way to offer clinical services that to both truck drivers and sex workers along transportation routes. The first intervention was to set up a network of flat-pack containerized health units. The Alliance currently manages 32 clinics in 13 African countries that see an average of almost

[20] This section is based on the presentation of Luke Disney, North Star Alliance, The Netherlands.

300,000 people per year, with a planned scale up of 60% (25 clinics) within 18 months (Fig. 2):

Figure 2. North Star Alliance clinic locations

Source: Keshavjee presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai.

Disney noted that health technology platforms have been critical to operational efficiency, allowing clinics to be planned and built based on existing infrastructure, disease prevalence patterns, and movement patterns in existing populations. POLARIS is an advanced clinical location and services optimization tool, and MESEDI is a patient-focused medical services directory and mapping application. At the core of the program is COMETS, a basic primary healthcare platform suitable for resource-limited settings that offers an electronic health passport system and the ability to securely collect, analyze, and report data. Disney noted that they chose a primary healthcare platform to frame the clinics as places to get healthy, and to avoid the stigma associated with seeking treatment for a condition such as HIV.[21] Fingerprint identification enables continuity of care across clinics by providing clinicians access to client health information, with the potential for referral services, medication dispensing, and data tracking for operational research.

2.2.2 STAR DRIVER LOYALTY PROGRAM

Disney explained that while 94% of drivers who have used the services report being very satisfied with their care, only around 30% of potential service users were actually accessing them, and most drivers were only coming in once. To foster engagement, the North Star Alliance and partners[22] devised the Star Driver loyalty program. Enrolled participants receive Star Driver certification after four visits to the clinic for HIV screening and occupational health tests. In the background, they promote Star Drivers as superior drivers, which improves drivers' employability and general self-esteem. The aim is to establish a self-sustaining program providing value to the trucking community that extends to the supply chain community and to the public health world. Data from the first phase indicate that these certification incentives seem to be enticing increasing numbers of drivers to take part in the program.

2.2.3 CULTIVATING EFFECTIVE PARTNERSHIPS

The North Star Alliance has worked with over 70 different public-private partners, according to Disney, with the objective of adding value and magnifying the results of existing efforts of corporate partners, governments, and national healthcare systems. In this context, public-private partners are not private healthcare providers, but private-sector non-traditional actors with vested interests and financial means. He stressed that developing effective partnerships requires time and effort: being a good partner requires clearly understanding your organization's strengths and ability to add value without focusing on taking credit for the partnership's successes.

2.2.4 KEY POINTS FROM DISCUSSION

Disney clarified that the clinics are mobile, but they are not typically moved once set up—communities provide land for free in most settings; moving units around drains resources and causes management problems. He noted that mobile populations will come to the clinic if it is in the right place. To address power

[21] The most common disease among drivers is currently hypertension, with diabetes and Hepatitis C also on the rise.
[22] Including Johnson & Johnson corporate citizenship, marketing assistance from Janssen, and financial support from USAID.

losses, the units have power-sensitive settings and they are starting a project with Philips to install solar panels to power the units instead of relying on mains. This is a new feature, because the clinics are inexpensive to set up,[23] but solar power is expensive. The clinics have basic lab facilities, but North Star is seeking partners to expand laboratory capacity in settings without lab facilities nearby for referrals.

Roscigno asked whether a patient who initiates TB treatment in one clinic could continue it in other locations. Disney replied that they try to ensure that the clinics work in a uniform way to facilitate long-term care. The patient management system allows clinics to have access to any patient information. Treatment algorithms have been a challenge, particularly with HIV care, because countries mandate different protocols; they are working with partners to devise the first cross-border treatment protocol for Zambia, Zimbabwe, South Africa and DRC.

Creswell queried what proportion of truckers on the road are reached by the program; Disney responded that there is no reliable data, but the best estimate for long-distance truck drivers on the road in sub-Saharan Africa is about 260,000.

Asad Zaidi[24] asked if the North Star Alliance has experimented with additional revenue streams to ensure longer-term sustainability and scale-up operations. Disney replied that currently, the corporate sector finances 35%, traditional global donors fund 53%, and the remainder is from government funding and licensing software to other NGOs. Though their client population is too small for micro-insurance, North Star will be piloting South Africa's new low-income health insurance program. He clarified that fees for service would be at odds with their aim to remove the financial barriers to accessing healthcare.

Highlight from Q&A Session

Keshavjee: *How will your technology help us in cities?*

Disney: We try to extend the reach to people who are falling outside. Everyone looks at urban settings because there is enormous bang for buck. The basic concept is working with smaller facilities and linking them into city facilities, especially if the flow of the population is going that way: it's low-hanging fruit. We've also tried to provide this linkage with our electronic health passport system, we've tried export data via standardized coding, ICBC II. We've also built it on an SQL database from Microsoft for sharing information.

"The basic concept is working with smaller facilities and linking them into city facilities, especially if the flow of the population is going that way: it's low-hanging fruit."

–Luke Disney

[23] Around $15,000 for the unit and $50,000 on average for everything else including management, shipping, set up, etc.
[24] Asad Zaidi, Interactive Research and Development, Karachi, Pakistan

2.3 Utilizing social enterprises for TB Control[25]

Photo credit: Andrew Reed Weller

Noting that potential advances of TB control are constrained only by the limits of creativity, Imran Zafar advocated for the use of social enterprises for the purposes of TB control. He defined social enterprises as sustainable businesses that use commercial infrastructure and strategies to target social and public health impact with the view to improving communities and people's lives. The private sector can contribute efficiency, energy, systems, and incentives to the public health arena.

2.3.1 POSSIBLE MODELS OF SOCIAL ENTERPRISE

Zafar sketched three models of social enterprise. Purely commercial social enterprises prioritize profit maximization, but they operate in sectors that target social impact. These might include laboratories and physicians in the private sector.

Non-profit social enterprises, such as NGOs, place a higher priority on health impact; donor funding is, and remains by design, the primary source of sustainable revenues. Some commercial revenues are generated (e.g., by charging a small subsidized price) and help to bring commercial infrastructure and strategies to bear on public health problems. Zafar characterized this approach as incorporating ways of bringing the private health structure into public health problems.

Hybrid social enterprises prioritize sustaining health impact. However, unlike the non-profit model for which donor funding is the primary revenue stream, hybrid models utilize a combination of revenue streams with the objective of establishing a longer-term commercially sustainable enterprise. Donor funding remains a major revenue stream, with the goal of allowing basic services targeting social impact to continue operating by means of fees and prices, which may be subsidized.

[25] This section is based on the presentation by Imran Zafar, Interactive Research and Development, Pakistan.

2.3.2 USING SOCIAL ENTERPRISES TO ADD VALUE AND INCREASE EFFICIENCY IN PUBLIC HEALTH

Social enterprises should be considered for any activity to which private sector efficiency might add value, Zafar maintained. He introduced several advantages offered by social enterprise models. Sustainability for core operations is a key goal. That said, he recommended that improved targeting for subsidies is just as important: he argued that to a degree, people should be able to afford the service being offered, and it should not be free. He suggested that public sector entities and NGOs should avail themselves of useful lessons to be learned from efficient management strategies situated in the private sector, such as management of stock and subsequent processes.

Zafar outlined several practical steps to take when considering and/or implementing a social enterprise intervention:

- Analyze a program to determine discrete objectives, activities, and gaps
- Identify market opportunities and consumer needs
- Contract out work on a pay-for-performance basis, with monitoring and oversight by public-sector professionals
- Encourage and invest in the set up of commercially viable businesses

Turning to specific applications for global health, Zafar likened marketing for social enterprises to education in public health: creating a need for patients to recognize that TB is a problem that they need help to manage. A potential opportunity could be contracting an expert public health marketing company to generate opportunities for targeted case-finding campaigns using resources and infrastructure in the private sector. Diagnostic innovations were cited as an example of private sector expertise that the public sector is not as qualified to carry out. Similarly, Zafar referred to treatment, counseling, and support as additional components that could be contracted out and that would benefit from the contributions of the private sector.

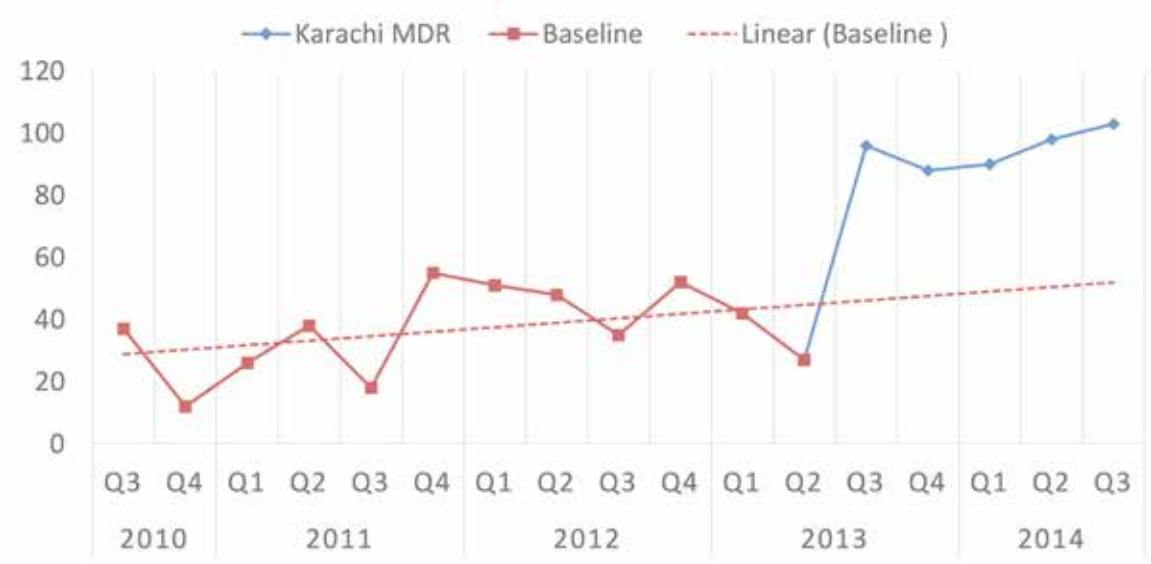
Cautioning that commercial viability is ultimately dependent on local economic conditions and types of revenues, Zafar emphasized that business ethos, systems, and strategies must be based on local market conditions. By involving the right people, carrying out extensive market research, and persevering, sustainability is possible. Strategically leveraging capital investments and donor funding with related business lines could help to increase revenues and achieve sustainability

2.3.3 CASE STUDY – COMMUNITY HEALTH SOLUTIONS

Community Health Solutions (CHS) is a diagnostics business that was set up in Pakistan as a social business with three arms. Active case-finding in the private sector involved working with general practitioners for screening and bringing patients into dedicated diagnostic centers. Patients were given treatment in the private sector. The third arm, support for public sector case finding and treatment, had to be adjusted when it became apparent that transitioning to a social enterprise model and charging a small fee on a sliding scale for chest X-rays required a change of course to make it potentially sustainable. Some of the key changes included:

- Shifting from the use of a large number of screeners to assigning relationship officers to physicians in the private sector, giving physicians back the power to screen
- Offering market-competitive discounted pricing for chest X-rays (between $3–$5 USD) and increasing referral fees for physicians to be consistent with the market
- Increasing outreach and adjusting the shifts and operating hours at the centers to be more convenient for users
- Providing outcome-based (rather than process-based) incentives
- Changing structure from a vertical, head-office-based system to a decentralized, matrix structure

Figure 3. New MDR-TB cases notified (Karachi), 2010-2014



Source: Zafar presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai.

As of the first quarter of 2015, there have been marked increases in the number of paid chest X-rays performed (over 3,000) and total revenue (over $9,500 USD), and a significant increase in the number of MDR-TB cases notified (Fig. 3).

2.3.4 KEY POINTS FROM DISCUSSION

Cassell remarked on the need to appreciate the other key private sector assets of drug development, commending the Institute of Microbial Chemistry's funding of 14 products from the profits of kanamycin as a success story.

Keshavjee referred to data showing overwhelmingly that user fees for poor people reduce access and increase mortality, and questioned how best to reach that segment of the population. Zafar responded that donor subsidies and private sector contractors could facilitate access, and they are willing to contribute. Cassell maintained that using numbers to convince donors about the size of the market is the best strategy to encourage investment.

To Zafar's contention that there is no business in treatment support, Roscigno countered that home care is a potentially huge business for TB and other diseases that the government could easily outsource to the private sector.

Geertz commented that for companies with a focus on social impact, profit it is a necessity but profit maximization is not —surplus profit is reinvested.

Noting that private-sector financial involvement has historically waited for public sector movement and support, Creswell praised a government voucher program in India used to pay for treating TB patients referred from the private sector.

TB drugs are imported exclusively through the NTP in Uganda, according to Sowedi Muyingo,[26] who advised that not all countries have easy access to private sector involvement. Zafar agreed that the public sector often views "private for-profits" with suspicion, but recommended staying engaged and trying to identify and address current needs. Persevering and making a profit, but operating with less cost and more impact than the current strategy, will ultimately convince the public sector. Keshavjee agreed that it is a challenge to engage with the private sector to reach the poorest patients, a situation likely compounded in countries with NTPs who manage TB in a top-down, unintegrated manner.

[26] Sowedi Muyingo, Medical Access Uganda Limited, Uganda

Ramya Ananthakrishnan[27] argued that a very strong private-private partnership could play a significant role in mitigating the impact of disease on patients in a sustainable way. In India, private providers often prefer to refer patients to a private hospital or center for TB care services rather than to a public health facility.

Stressing that many patients pay too much money for bad care, Aamir Khan advocated for gearing the system toward providing better care, sustaining core functions, and scaling up. Zafar pointed out that most TB patients are getting care; the goal should be to improve free, paid, and subsidized standards of care. Echoing concerns about quality of care in the private sector, Sanjay Sarin[28] remarked that it is not just a matter of driving best practices but addressing the problem of lack of accreditation and standardization in private labs and hospitals by working with the government to develop healthcare quality standards. Zafar's caveat was that working with the private sector to develop the regulatory framework that will then be enforced on them could potentially be fraught. Roscigno mentioned private labs within public hospitals as an example of an effective PPM. Harkesh Dabas[29] pointed out that two states in India have already outsourced all of their diagnostic requirements to the private sector, where it generally costs 30% less than the public sector. Disney reiterated that partnerships require collaborating on a small scale to understand commonalities among partners before progressing to the larger scale.

Cori Vail[30] remarked that for-profit companies are increasingly interested in quantifying and measuring the social impact of projects. With regard to the project in Chennai, she recommended looking at it as a whole and determining where efficiency can be increased in the current system. By then treating it as a market with specialized constituents, it is possible to show how the project can be carried out better and less expensively than any other way.

Keshavjee emphasized that just because systems are entrenched does not mean that they cannot change. Given that countries return tens of millions of dollars to the Global Fund, the challenge is not merely funding. It is to work with the TB systems on bringing change to bear on both how data is used to identify and better help patients and to overcome the dogma around the way TB programs are run. Mariatou Tala Jallow[31] concurred regarding the need to find ways to integrate public sectors, private sectors, and NGOs with complementary roles.

[27] Ramya Ananthakrishnan, Resource Group for Education and Advocacy for Community Health (REACH), India.
[28] Sanjay Sarin, Becton Dickenson & Co., India
[29] Harkesh Dabas, Clinton Health Access Initiative, India
[30] Cori Vail, Janssen, U.S.
[31] Mariatou Tala Jallow, Global Fund, Switzerland

2.4 Innovative model for delivery of TB services[32]

Shelly Batra

2.4.1 TB LANDSCAPE IN INDIA

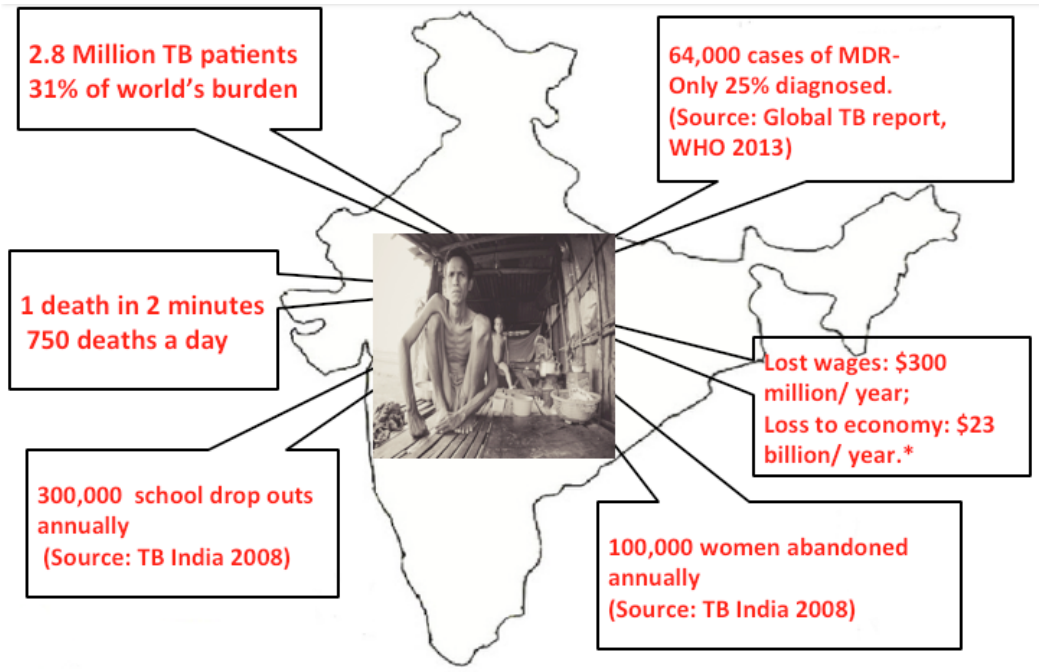
Batra presented the efforts of Operation ASHA (OpASHA), an innovative model for the delivery of TB services that has been implemented in India since 2006. TB, she argued, is currently India's biggest public health crisis; India is home to almost one-third of the world's overall TB burden (nearly 3 million cases) (Fig. 4).

Batra provided a critical overview of the Directly Observed Therapy Short-course (DOTS) model currently implemented by India's Revised National TB Control Program (RNTCP). She explained that although the DOTS model is generally adequate in government TB hospitals and diagnostic centers, the existing public TB-control infrastructure lacks the crucial "last-mile" connectivity to provide adequate access to services for residents of slums and villages. Local treatment centers are tasked with distributing medications, but centers are scarce, difficult to access, and have limited hours. Abject poverty in these areas and the length of time it takes to treat all forms of TB[33] make it very difficult for patients to complete treatment.

She outlined an additional set of challenges that further compounds these problems. The social stigma of having TB can cause patients to hide their symptoms, lose their jobs, to be abandoned by their families, and to live in self-imposed isolation. Overcrowded, overburdened public facilities are unable to put a support system in place for these patients, or to provide them with education and counseling about TB and the importance of adhering to treatment. Quackery among informal providers is rampant in India, according to Batra. The large network of informal providers, which also includes practitioners of indigenous/traditional medical systems, delivers treatment that is very often incomplete, irregular, and inadequate. She noted that formal providers often make serious errors as well; a study found that only three of 106 formal providers could issue an appropriate prescription for MDR-TB medication. Lack of electronic data engenders a system that is rife with inaccuracy, human error, widespread data manipulation to meet targets, and the absence of accountability and transparency.

[32] This section is based on the presentation of Shelly Batra, Operation ASHA, India.
[33] Average treatment durations: 60 visits over 6 months for DS-TB; 790 visits over 2 years for MDR-TB; life-long visits for XDR-TB and TDR-TB.

Figure 4. TB in India, the biggest public health crisis



Source: Batra presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai.

She reported that this convergence of factors has predictably led to a very high default rate among TB patients, and this lack of treatment completion propagates drug resistance.

2.4.2 OPASHA: INNOVATIVE MODELS TO DELIVER TB CARE IN SLUMS AND RURAL AREAS

Batra described how OpASHA was designed to fill the gaps in the government program by implementing local, comprehensive TB-care models in slums and rural areas, with an emphasis on fostering community involvement and empowerment. It was founded on the principles of taking the best models to scale with a premium on devising low-cost, high-impact, scalable, replicable models with measureable impacts.

OpASHA's urban slum model places strategically located and widely accessible TB centers for delivering DOTS in the premises of community partners: e.g., chemists, informal providers, places of worship, qualified doctors, shopkeepers, housewives, and priests. The centers have extended hours of operation to be more convenient for patients who cannot afford to miss work or lose wages. To ameliorate the social stigma of TB, these DOTS centers are essentially camouflaged. This scheme ensures that informal providers do not lose their patients and offers the prospect of leveraging the trust of local socio-religious leaders.

OpASHA employs local DOTS providers who belong to the communities they serve and are thus familiar with local customs, geography, and other setting-specific needs. The workers are specially trained to carry out detection, delivery of short-course anti-TB chemotherapy under direct observation, and patient tracking. They receive performance-based salaries, and are much more cost-efficient than doctors performing the same functions would be.

OpASHA's rural model consists of a mobile DOTS system delivered by providers on foot, bicycles, or motorcycles, who carry medications and technology in backpacks. Batra explained that by implementing this model they are able to reach the "unreached"—people in remote tribal areas, for example.

2.4.3 OPASHA: TECHNOLOGY INNOVATIONS

eCompliance platform

In collaboration with Microsoft Research, "eCompliance" technology was developed with the primary objective of ensuring treatment accuracy and adherence among TB patients. Batra explained that providers' limited knowledge about TB treatment as well as lack of treatment supervision contribute to a host of problems, including:

- Patients missing doses
- Untracked patients
- Inaccurate record keeping
- Data manipulation
- Inadequate and/or delayed follow-up
- Absenteeism among field staff

The eCompliance platform helps ameliorate these problems by using a patient's electronic fingerprint on the DOTS worker's tablet to confirm every dose. Encrypted patient data is sent to a central SQL database, where patient records are logged in an electronic medical record reporting system with the capacity for web-based reporting. If a patient misses a dose, the patient, health worker, and program manager are all alerted via SMS. The technology is designed to be user friendly for semi-literate and even zero-literate persons, with a color-coded interface and minimal text. Batra remarked that it is also relatively low-cost because it runs on commercially available, "off-the-shelf" components.

Batra maintained that eCompliance is beneficial on multiple levels. It has a positive impact on morale at the patient and community levels. At the provider level, it ensures the integrity of DOTS, eliminates unsupervised doses, reduces human error, and enhances providers' skill sets. At the management level, it inculcates multi-level accountability and transparency, facilitates accurate incentives, prevents absenteeism, and lowers costs.[34] The technology is adaptable for other applications that require ensuring adherence.

Lab Alert system

The Lab Alert system replaces a manual lab register with an electronic version. A positive sputum test triggers text messages that are sent to the patient, provider, government supervisor, etc. The system can reduce the lag time for treatment by up to 60% (from 17 to 7 days) and helps to reduce the number of patients lost to follow-up. Batra reported that the technology has already been deployed in India and Cambodia.

2.4.4 OPASHA: JUSTIFICATION FOR INCENTIVE-BASED COMPENSATION

Batra criticized the RNTCP's structured approach to compensation (fixed salaries) as rewarding processes rather than results, and thus promoting inefficiency. In contrast, OpASHA compensates workers with a results-oriented approach that rewards outcomes but still mandates good processes. She suggested that incentives are the most effective utilization of funds invested in semi-skilled workers, because it saves costs when poor performers are weeded out and increases worker satisfaction when good performers earn more. Preventing improper utilization of the public health infrastructure can parlay into improved detection rates, decreased default rates, and better provision of care.

2.4.5 OPASHA: GROWTH AND SCALE-UP

Batra reported that since its rollout almost 10 years ago, OpASHA now has around 250 treatment centers in 14 different areas.

Scale-up efforts faced multiple challenges, according to Batra. Government entities can be resistant to acknowledging that TB is a real problem among their populations, and are sometimes responsible for misrepresenting TB statistics. They are not always willing to engage with NGOs, and the funding they provide is not always sufficient or timely. Non-governmental issues recognized by Batra include the challenges of maintaining quality, engaging effectively with local communities, and securing funding.

[34] Cost of each eCompliance terminal as of April 2015 is $245 USD; cost per patient is $3.55 USD.

Enablers for scaling

Batra identified six key enablers for scaling, each of which is linked to a specific function or stakeholder:

- Hiring local people
- Having a training manual in place that can be modified per local customs
- Striving for low cost and high impact
- Measuring impact and outcomes
- Ensuring easy replicability
- Maintaining flexibility while adhering to core principles

2.4.6 OPASHA: RESULTS

Batra reported that OpASHA has had the following impact to date (Table 2).

OpASHA's 2014 results were better than those of the RNTCP in the areas of loss to follow up (OpASHA: 3%; RNTCP: 36%), case detection as a percentage of prevalence rate (OpASHA: 76%; RNTCP: 50%), and treatment success rate (OpASHA: 87%; RNTCP: 32%).[35] Turning to a cost-to-treat comparison, Batra maintained that it costs the United States 212 times more than OpASHA to treat a single case of drug-susceptible TB ($17,000 vs. $80, respectively) and 134 times more to treat a case of MDR-TB ($134,000 vs. $998, respectively).

2.4.7 KEY POINTS FROM DISCUSSION

With regard to generating new cases, Batra explained that patients are referred in two ways. TB hospitals refer patients and deliver medications to the clinic nearest the patient. Incentivized community workers also seek out patients in households and social settings. In 2014, 10,000 new patients were enrolled in India and 2,500 new patients in Cambodia (typically, about half are detected by the government and half by OpASHA).

Creswell pointed out that the TB REACH cost data ($850 per case) provided in her presentation are actually for additional case

Table 2. OpAsha results

Patients treated fully	42,118
Treatment success rate	86.9%
Default rate	<3%
TB infections averted	228,708
Jobs created for semi-literate youth	194
Part-time workers	161
Cost of creating a job	$4,000
Social return on investment	3,217%

Source: Batra presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai.

[35] Wingfield et al. PLoS Med 2014

detection, and are inclusive of all costs. Batra responded that their costs are divided into cost of detection (i.e., new cases detected by providers and enrolled in treatment) and cost of treatment. She clarified that the cost is $27 for each additional case detected in India, attributing the low cost to utilizing existing government infrastructure and local people.

Andrew Codlin clarified that for TB REACH, "additional cases" actually means an "additional notification," based on historical trends, trend adjustments, and comparisons with contemporaneous control districts where interventions are not working. The key question is to determine the number of cases who were treated who would not have been treated in the absence of the project. TB REACH has several examples of excellent projects that implement new diagnostics, screen, and test, but after analyzing the official NTP surveillance data, they are exactly on trend or marginally above it. This indicates that they have made very little impact on the number of people treated in that area. Rather than looking at cost per case detected, TB REACH is interested in interventions that are impactful by finding cases that would not be treated without that intervention.

Muyingo related that Uganda has similar problems with regard to data manipulation and patient tracking, and "double dipping" of patient loads, at multiple clinics. He questioned whether the e-compliance tool can be adapted for HIV, remarking that the Ugandan minister has banned e-health pilots in the country due to oversaturation. Only technology that is proven to work and scale up is allowed. Batra reiterated that the e-compliance tool could be upgraded for any application requiring adherence. Various speakers raised some concerns about finger printing patients and issues of patient dignity as well as privacy and data safety.

[36] Andrew Codlin, TB REACH, Stop TB Partnership, Switzerland

2.5 Utilizing new technologies to improve TB service delivery[37]

Ali Habib described the host of advantages that electronic data collection and mobile health (mHealth) technologies can offer to improve TB service delivery. Electronic data collection offers improved data quality, easier backup and storage, faster reporting, easier analysis, and remote, secure access. Utilizing mHealth provides ease of use in geographically dispersed programs and settings with limited infrastructure, efficient data collection in the field (e.g., mass screening), and real-time access to data for improved flexibility and follow-up. When open-source technologies are available, the code is available to use and adapt with liberal licensing and without cost.

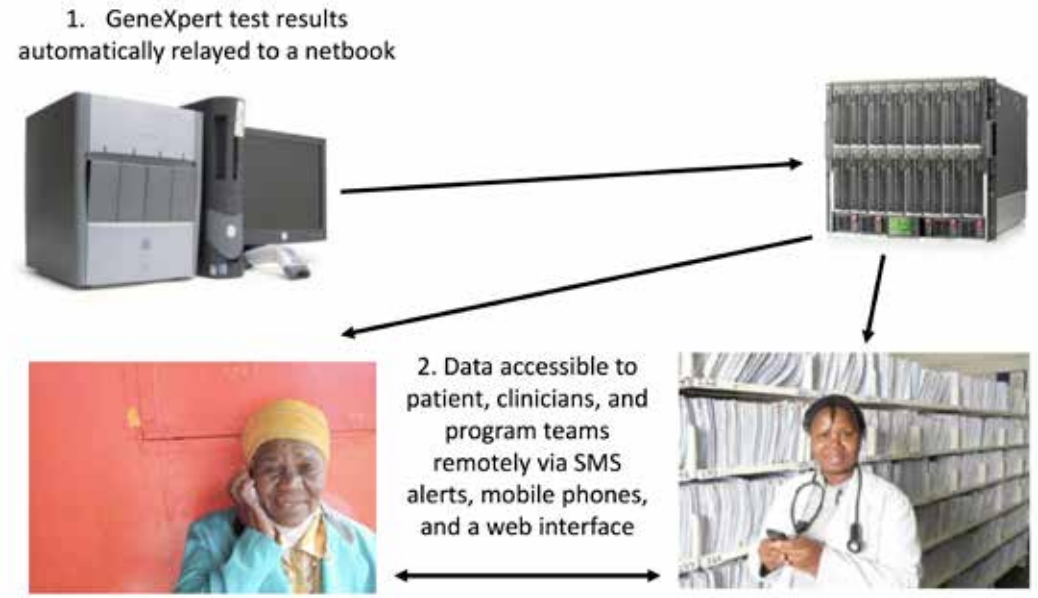
Habib presented an overview of several new platforms with the potential for significant contribution to the TB space. He cautioned, however, that the development of new technology is a lengthy process, and new technology is not a guaranteed fix for all existing problems. The cost of change to a new system requires investments of time, effort, and money for development and testing.

2.5.1 ELECTRONIC RESULT REPORTING: XPERT SMS

Because labs are often at a significant distance from TB treatment sites, getting results to treatment providers as quickly as possible can lead to shorter time to treatment. GeneXpert has reduced the time it takes to obtain a result, but those results are still often manually reported. Xpert SMS is an automated GeneXpert reporting platform that effectively brings results closer to patients (Fig. 5):

[37] This section is based on the presentation from Ali Habib, Interactive Research and Development (IRD), Pakistan

Figure 5. Xpert SMS automated GeneXpert reporting platform



Source: Habib presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai.

2.5.2 MEDICAL RECORD SYSTEM: OPENMRS

OpenMRS is an open-source, web-based medical record system that is standards compliant, extensible, and customizable for the requirements of specific countries and settings. Interactive Research and Development (IRD) has done major implementations of OpenMRS in Pakistan, Nepal, Tajikistan, Bangladesh, Indonesia, and South Africa. TB-specific features include drug charts, treatment pages, reports of drug needs, lab monitoring, and WHO standard reports.

2.5.3 INTEGRATED MOBILE DATA COLLECTION: OPENSRP

OpenSRP is a mobile data collection platform under development that offers integrated data collection for a range of different diseases and health records, so there is no need to build a new platform and train staff to record patient data about each different disease. The collected data feeds into an electronic medical records system, such as OpenMRS. Fig. 6 depicts a sample mobile interface for OpenSRP.

2.5.4 KEY POINTS FROM DISCUSSION

Oommen George identified the barrier of adapting software to changes on the ground as a project progresses; Habib noted that OpenMRS and OpenSRP include forms that do not need a programmer to build or change them. Customization is improving, and pitfalls can be avoided by doing the proper groundwork.

Creswell commented that technology innovations will necessitate some kind of agreed-upon networking system to link multiple laboratory tests. Habib explained that as long as vendors are open to their data being collected, the technology already exists.

Codlin raised the issue of barriers to e-health interventions and fragmentation of data. Habib remarked that technology scales relatively simply; it is the operation on the ground that is less likely to scale easily. Tech silos expose the need for a standard of communication for transferring and sharing data, but willingness to share data is a key barrier to interoperability. Communicating the value of data sharing among stakeholders is crucial.

Ana-Maria Ionescu[39] underlined the problem of replication and mentioned the need for some

[38] Oomen George, Abt Associates, India

Figure 6. OpenMRS sample mobile interface

Source: Habib presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai.

sort of action-oriented policy recommendation rather than merely consensus-based recommendations. In that context, Khan reminded participants that WHO, Global Fund, PEPFAR, USAID and other organizations involved in shaping global health policies should endorse standards, but not software. They should encourage the transition from apps to software and support the development of consortiums with aggregating capacity across multiple institutions to share technology.

[39] Ana-Maria Ionescu, Janssen Global Public Health

3.0 Summary / Synthesis

Innovation, particularly in health care, is a vague and increasingly ubiquitous term but the day's events highlighted the potential for innovative approaches against TB. There is massive potential for not only technological progress, but also new, transformative policy and implementation methodologies that save lives. This is also true for the detection, treatment, and prevention of TB.

With TB, as with other diseases, the key to success for any new technological or policy innovation is generally to assess whether the new technique or tool passes muster in terms of distributional equity, adaptability, affordability, and compatibility. These should mesh to an extent with existing institutional arrangements, technological infrastructure, and cultural norms.

One theme that was explored during the day's proceedings was the idea of "disruption," which places less weight on the ease of integration of new tools, and values pure creativity and ultimate efficiency rather than compatibility. This is a key part of developing a comprehensive response to TB that is in tune with the reality of the patients' lives, rather than, for example, the entrenched interests of flawed TB treatment programs or dysfunctional private TB care providers. Disruption is a form of catalytic innovation and should be embraced given the 1.7 million lives that are lost each year to TB.

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APPENDIX A.

MEETING AGENDA

Innovating TB Care Delivery in High-Burden Settings

15 April 2015

8:30	Shuttle bus will pick up participants at Hyatt lobby	
8:45 – 9:00	Registration	
9:00 – 9:15	Welcome, Overview and goals for the day	Salmaan Keshavjee
9:15 – 9:35	Global TB care landscape: review of the private sector in high-burden countries	Jacob Creswell
9:35 – 10:20	The potential of social business models for TB control	Imran Zafar
10:20 – 10:50	Coffee break	
10:50 – 11:25	A regional approach for mobile workers and vulnerable populations	Luke Disney
11:25-12:15	Discussion: Designing innovative models for service delivery. How to avoid path dependence and use all available tools?	Imran Zafar (facilitator)
12:15-13:15	Lunch Break	
13:15-14:00	Innovative delivery model in practice: incentives, informal providers, and the challenges of scaling up	Shelly Batra
14:00-14:45	Utilizing new technologies to improve TB service delivery	Ali Habib
14:45-15:15	Coffee Break	
15:15 – 16:00	Discussion: innovation in context. How might we link new approaches to TB care delivery to other disease areas?	Aamir Khan (facilitator)
16:00: 16:05	Closing Remarks	
16:05	Shuttle back to the Hyatt	

APPENDIX B.

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