

Financing the Control of Tuberculosis

Financial Innovations Lab® Report



November 2015



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Financial Innovations Labs® bring together researchers, policymakers, and business, financial, and professional practitioners to create market-based solutions to business and public-policy challenges. Using real and simulated case studies, participants consider and design alternative capital structures and then apply appropriate financial technologies to them.

Acknowledgments

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This report was prepared by Caitlin MacLean.

About the Milken Institute

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Introduction

Recent epidemics of infectious disease, including Ebola in West Africa and swine flu in India, have brought to international attention the sudden debilitation of whole communities and the economic impact this can wreak on global growth. During the course and aftermath of disease outbreaks, support mobilizes for health services and new drug and vaccine development; governments remain on high alert; media coverage intensifies; and donor institutions deploy massive fundraising appeals.

These responses are important and essential, yet not every contagious disease receives this attention. Tuberculosis (TB), once called the silent killer, is one of those falling out of the spotlight.

Two billion people—roughly a third of the world's population, and mostly in poorer countries—carry TB bacteria in their systems as they go to work, to school, and back home again to their families. Fortunately, only 5 to 10 percent of those infected will fall ill with active TB, even though it takes little more than a cough or sneeze to infect an additional 10 to 15 people. The disease is a leading cause of death in certain populations; in 2013 alone, more than 1.5 million people died from TB.

The treatment and prevention of TB presents numerous challenges. The TB vaccine has been in use for nearly a century but is widely acknowledged to be ineffective because of increasing disease resistance to it. Diagnostics are either quick but costly or inexpensive but slow. Drug treatments are also expensive, and the regimen can take months. New strains of the disease create additional complications. And because TB bacteria thrive in compromised immune systems, those with other illnesses or conditions, especially people who are HIV positive, are more likely to contract and die from TB.

Given the complexities of an airborne disease like tuberculosis, coordination among the agencies and organizations is critical. This is a disease that knows no borders; yet collaboration in vigilance for detection, containment, and treatment plans must be shared across a nation, a region, even across continents.

This kind of effort takes significant capital expenditure. Governments, aid agencies, and organizations like the Geneva-based Global Fund to Fight AIDS, Tuberculosis and Malaria now fund the bulk of the programs to address TB. Yet an estimated \$2 billion annual funding gap remains for prevention, diagnosis, and treatment programs. Traditional donor funding and domestic resource allocation are not enough. The solution will likely be found in a better mix of public and private capital, including new types of financing options that attract institutional investors—from pension funds and sovereign wealth funds to family offices and endowments.

To this end, the Milken Institute organized two Financial Innovations Labs, in London and Johannesburg (South Africa's TB rates are among the highest in the world), to bring together investors, donors, global health experts, government leaders, and industry executives to discuss innovative financing options that could attract new and smarter money for TB control. The first Lab, in London, resulted in a list of prioritized options; the second used South Africa's gold mines as the context in which to build a pilot project to implement one of the models. The following report summarizes the outcomes from the two sessions, including a road map for moving the models forward, with specific structural elements to solicit further discussion and feedback.



Issues and Perspectives

THE HEALTH BURDEN

Someone contracts TB every second. The majority of the deaths from these infections, over 95 percent, are in low- and middle-income countries. There is also a strong coincidence with HIV, given that TB is more likely to be fatal in cases when the immune system is compromised. TB causes one-fourth of all HIV-related diseases.

To complicate matters, the disease has mutated over the years to include multidrug-resistant strains, called MDR-TB. Developing countries show a higher prevalence of MDR-TB because of less rigid treatment plans: drug resistance often occurs after a patient has stopped treatment before completing its full course or has been prescribed a treatment that was incorrect in terms of dose or length of time. In 2013 nearly 500,000 people developed MDR-TB, according to the World Health Organization.

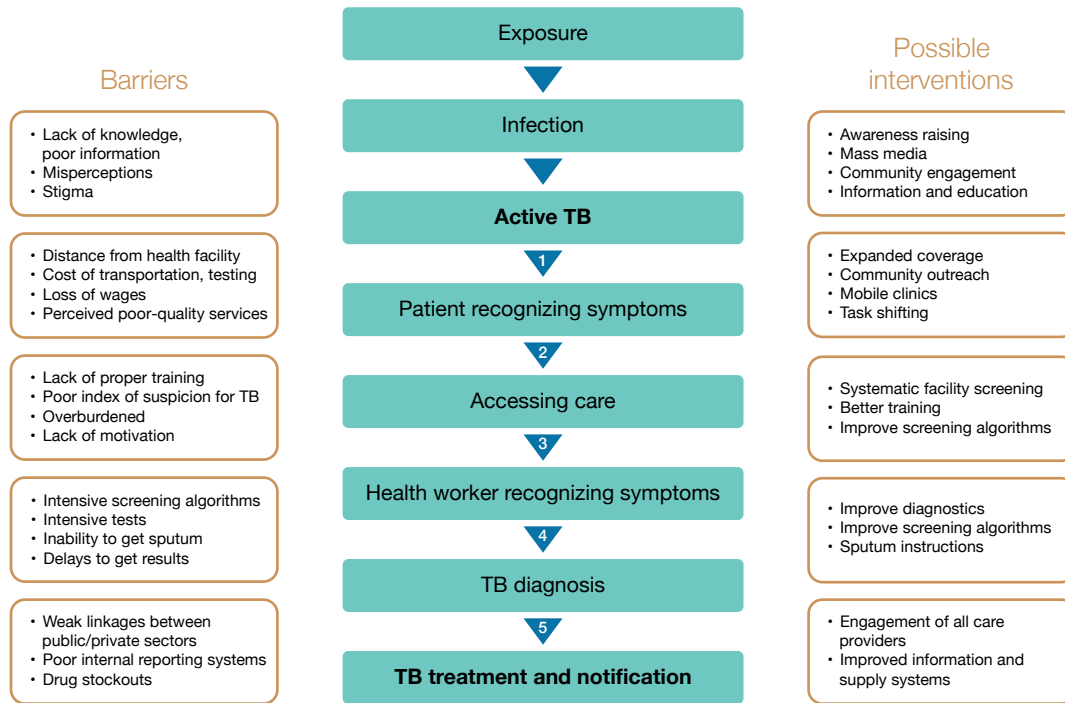
CONTROLLING TB

The battle to defeat TB requires a host of interventions, from vaccines and treatment to testing and education. Unfortunately, the science has not kept pace with the disease. The vaccine is over 100 years old and is acknowledged within the scientific community to be ineffective. Consequently, the vaccine is not widely used in developed countries, such as the United States, but is rather used for targeted populations at greater risk, such as health workers. The tools to identify and treat TB are outdated as well. While there have been many new advancements in diagnostics and treatments, their adoption has been slow, given the costs and that high-prevalence countries often lack budgets for cutting-edge tools.

Because identifying active TB can be a challenge, diagnosis often requires multiple tests. For more than a century, this has included a skin test, but chest X-rays and cultures are also used. TB symptoms may develop slowly, over months—so that by the time the person seeks help, he or she could have infected others, yet it can take days or even weeks to get results from these tests. A fast yet less effective diagnostic method requires a microscope and is called sputum smear microscopy, or SSM. The primary treatment tool is a drug regimen developed in the 1960s. The treatment includes multiple pills per day for six months for TB cases, or 24 months for MDR-TB. The ideal treatment protocol is the directly observed treatment, short course (DOTS) as part of an all-encompassing control strategy that would include long-term political and financial commitment from governments, a quality diagnosis, standardized short-course treatment (none exists at the moment), a well-stocked supply of drugs, and ongoing recording and reporting.

Apart from the challenges of developing TB diagnostic and treatment tools, other barriers include a lack of education about its symptoms and contagion risks, minimal-quality medical services in developing countries where TB is prevalent, and insufficient patient monitoring and evaluation. As seen in figure 1, at every step of disease control, there are issues as well as potential solutions, all of which require better investment.

FIGURE 1 | The challenges of TB control



Source: “Improving Tuberculosis Case Detection: A compendium of TB REACH case studies, lessons learned and a monitoring and evaluation framework,” Stop TB Partnership.

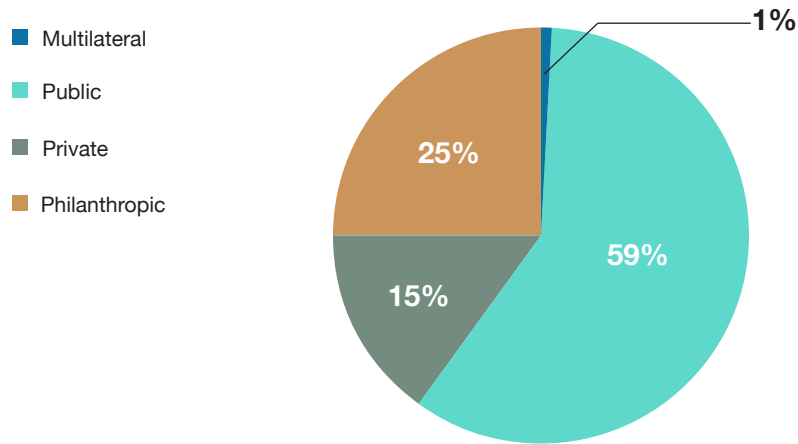
CURRENT FUNDING LANDSCAPE

Each country’s efforts to control TB are funded primarily by domestic resources for its health services budget, and by donors, and binational and multinational donor partnerships (e.g., aid agencies based in other countries). Funders like pharmaceutical companies and private foundations, such as the Bill & Melinda Gates Foundation, support research and development costs for better drugs and vaccines. As figure 2 illustrates, the public sector, in both developed- and developing-country budget allocations, still funds the majority of R&D efforts.

The World Health Organization has reported that required annual levels of funding include \$8 billion for the general control of TB and an additional \$2 billion for R&D. Current funding is estimated to be around \$6 billion a year from the various sources listed above. This leaves nearly a \$2 billion funding gap each year.

This spending, large though it may seem, is far outweighed by the economic impacts of the diseases on a country or region. Economists have also suggested that if TB incidence stays at current rates, the global economy could see nearly \$12 billion in losses each year. The World Bank has also estimated a decrease of 4 percent to 7 percent of country GDP, depending on prevalence of the disease and the corresponding loss in worker productivity. The WHO suggests that the average TB patient loses three to four months of work time. To treat a patient with TB, a country must spend nearly US\$100–\$500, with the standard course of drugs alone costing around \$20. To treat a case of MDR-TB, governments could spend, on average, nearly \$10,000 in low-income countries and nearly \$50,000 in developed countries, with drug treatments alone costing nearly \$5,000.

FIGURE 2 R&D allocation per year by donor type

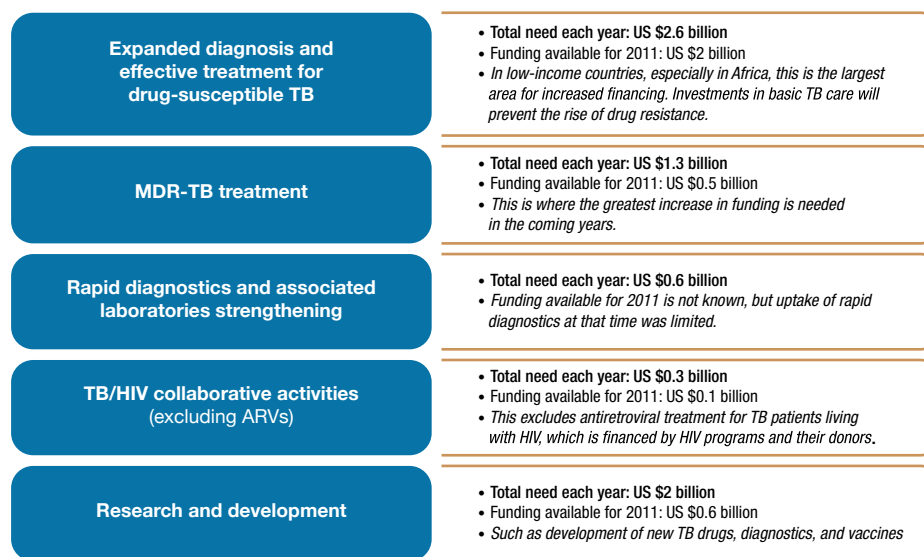


Source: “Report on Tuberculosis Research Funding Trends,” Treatment Action Group, 2014.

FUNDING GAPS BY INTERVENTION

Across the spectrum of TB control interventions and activities, significant funding gaps aggregate to the \$2 billion referenced earlier. As seen in figure 3, diagnosis and treatment require the bulk of the funding over the period of 2014–2016, while R&D similarly needs multiple billions.

FIGURE 3 Priority areas for investment: 2014–2016



Source: Tuberculosis Financing and Funding Gaps Fact Sheet. World Health Organization and the Global Fund to Fight AIDS, Tuberculosis, and Malaria. World Health Organization 2013.

Funding for TB control comes predominately through donor grants. Very little has come from more market-based sources, such as investment funds or debt financing that may include expectations of a return on capital. This expectation has limited funding options to sources that are predominately philanthropic. However, innovative financing models have recently been utilized to address TB. For example, the Global Health Investment Fund, a \$108-million JPMorgan Chase impact investing fund that is partially guaranteed by the Gates Foundation, has made investments in new, rapid-result TB diagnostics. While not all interventions across the TB control spectrum will be able to move beyond grants and into alternative forms of financing, many activities may generate enough financial or economic return that they could benefit from more innovative financing models. Lab participants reviewed some of these models that could scale up funding, diversify sources of capital, and pay for more successful, better-coordinated disease programs.

Case Study: South Africa

THE BURDEN

South Africa has the third-highest incidence of TB in the world after China and India. It also has the second-highest incidence of MDR-TB after India; in 2013, that incidence was 860 per 100,000 people.

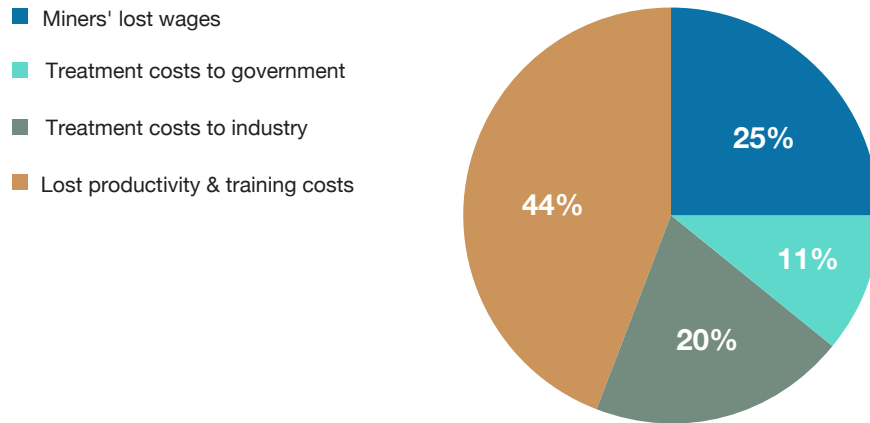
Within South Africa, a high concentration of TB patients work in the mining industry, which in 2013 employed more than 500,000 direct workers and another 500,000 indirect workers and where TB rates currently run as high as 2,500–3,000 per 100,000 workers, or 10 times the WHO designation for a health emergency. Looking at a sample year, 2009, the mining sector reported 167 fatalities from work-related accidents, but almost 1,600 deaths from TB. Most of those deaths occur in gold mine workers. Silica dust in these mines causes the lung disease silicosis, which weakens the immune system against TB. However, TB occurs as well in other mining operations.

The diagnosis and treatment of miners is complicated. Not only is diagnosis costly, but workers tend to avoid testing because of the stigma of disease: TB can put them out of work for the duration of their treatment, from weeks to six months or more. Testing in “peri-mining communities,” adjacent to the mining districts that house families and related workers, can be difficult because of minimal or nonexistent formal health services infrastructures. Once a worker is diagnosed, treatment is similarly challenging and costly. In South Africa, mining companies are required by law to provide treatment, but not all companies comply. An informal survey done by the country’s Ministry of Health revealed that of 63 mines surveyed, only 40 offered their employees access to on-site TB health services. Many of these mines are small and medium-size, though the larger companies can afford to treat their employees. A significant portion of workers are migrant; when these itinerant workers get sick, they often just leave the area, which contributes to the serious public health issue of tuberculosis control.

The economic burden of TB on the mining industry in South Africa is significant, as shown in figure 4. Lost productivity alone can cost the sector more than \$568 million per year, and is particularly disruptive when one considers that the extractive industries represent 60 percent of the country’s exports and, in 2012 at least, 17 percent of GDP.

In addition to direct costs to the employer, there are costs to the community. South Africa’s Ministry of Health has estimated that not only are the 500,000 miners affected by TB, so are nearly 1 million others, including partners/spouses, children, and other family members.

FIGURE 4 Breakdown of annual costs of TB on mining in South Africa

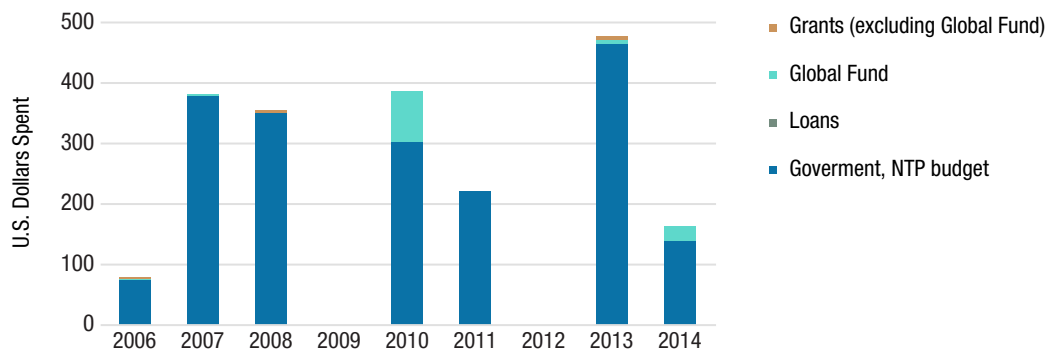


Source: “Investing in the Future: The Potential Impact of New Tuberculosis Vaccines on Mineworker Health and Productivity” Policy Brief. Aeras: Advancing Tuberculosis Vaccines for the World, January 2014.

CURRENT FUNDING

South Africa’s budget allocation for TB control in 2014 was US\$162 million. As figure 5 illustrates, most of this came from the Treasury, but funding was also channeled from the Global Fund through the government. Most of this latter funding comes in the form of grants for TB programs, including prevention and treatment.

FIGURE 5 South Africa’s annual budget allocation for TB



Source: World Health Organization

NEXT STEPS

In October 2014, the Government of South Africa, with assistance from the World Bank, prepared an action plan as part of a proposal to the Global Fund to address TB in the mining sector. An extensive review process resulted in an outline for high-impact interventions and the rollout of a coordinated effort to initiate these activities, initially thought to cost \$127 million but unfortunately was only funded at \$30 million. Notwithstanding the current budget allocation from the public sector, and from existing donors, even for this one proposal a nearly \$100 million gap remains.

Financial Solutions

Financial Innovation Lab participants in London and Johannesburg reviewed funding models that could attract new types of investors and donors to support TB control programs ranging from R&D to treatment. During the London Lab, participants prioritized a list of possible models that could provide everything from grants to debt and equity capital. During the Johannesburg session, participants outlined which of these models would be most applicable for the South Africa and its mining industry.

SOLUTION

1

MICRO-LEVIES/TAXES

Taxes and micro-levies on consumer goods have been shown to be successful in generating resources for global health. The most-cited example is a small tax on airline ticket purchases. Started in 2006 in France, the tax has now spread to Cameroon, Chile, Congo, Madagascar, Mali, Mauritius, Niger, and South Korea, and supports the health initiative UNITAID to invest in treatments for HIV/AIDS, tuberculosis, and malaria. From a tax of around \$1 for economy-class tickets and \$40 for business-class seats, UNITAID has raised nearly \$1.2 billion over the five-year period 2007–2012.

Based on this successful model, Lab participants discussed the potential to create a tax or micro-levy on some part of the global gold market, given the link between mining and TB. The funds generated could be deployed as grant capital for organizations doing anything from R&D to prevention and treatment.

Across the spectrum of extraction, processing, consumption, and finance, there are a number of points at which a tax could be levied. For the sake of a simulation of potential revenues, Lab participants reviewed taxes at the production point, consumption point, and in financial trading.

As seen in table 1, the Milken Institute ran various scenarios at the three stages listed to determine what levels of funding could be expected. The most lucrative tax would be on consumption of consumer products globally, nearly \$105 million per year at a 0.1% tax rate. Production taxes, in the United States, Australia, or Africa, could also be sizable, at nearly \$20 million annually.

Lab participants agreed that any tax or levy would be difficult to implement. At the production stage, for example, mining companies would need to be persuaded to support a tax, even though the gold industry is suffering from low profit margins in the sharp downturn in the commodity cycle. In July 2015 alone, the South African gold mining index dropped 24 percent. A tax at the point of consumer purchase could also be politically difficult where communities are quick to reject new taxation proposals. At the point of financial trading, it would take support from various exchange platforms to implement the tax, since they could lose business to other exchanges. However, it is worth noting that the French and UNITAID have considered a general financial transaction tax, and early feedback indicates that some investors surveyed do not have an adverse reaction to the concept, so long as the right percentage was priced out. More work would need to be done to fully understand the viability of any transaction tax and what the real potential is to generate enough capital to justify the experiment.

Application to South Africa

As the country has not yet agreed to the airline tax, participants were unsure as to the political viability of a levy on gold. Historically, the financial community in the country has been opposed to any new taxes. However, future simulations could price out country-specific options.

TABLE 1 Taxation options

Gold Tax Options		
Production Tax	Total Production (in millions)	Tax at .1% (in millions)
Global mine supply (annual)	\$134,020.00	\$134.02
U.S.	\$8,600.00	\$8.60
Australia	\$11,000.00	\$11.00
Total Tax on Producers in US and Aus (annual)		\$19.60
Top Five African Producers		
South Africa	\$6,077.00	\$6.08
Ghana	\$3,646.00	\$3.65
Sudan	\$2,998.00	\$3.00
Mali	\$1,823.00	\$1.82
Tanzania	\$1,621.00	\$1.62
Total Tax on Producers in Africa (annual)	\$16,165.00	\$16.17
Consumption Tax (Luxury and Investment)	Total Consumption (in millions)	Tax at .1% (in millions)
Global jewelry demand (annual)	\$104,389.20	\$104.39
U.S., Canada, Europe demand (2014, using average US\$ oz./price in 2014)	\$8,389.00	\$8.39
Investment (total bar and coin)		
Average annual demand (5-year average)	\$62,382.00	\$62.38
U.S., Canada, Europe demand (2014, using average US\$ oz./price in 2014)	\$10,160.00	\$10.16
Tax on Exchange Traded Funds (ETFs)	Total Shares Outstanding (in millions)	Tax at .01% (in millions)
GLD	27,114	\$2.71
IAU	6,325	\$0.63
Total Revenue on ETFs		\$3.34
Gold Futures Tax	Total Value of Monthly Contracts (in millions)	Tax at .0001% (in millions)
Total contracts at 3,250,000 at \$118,200 each	384,150	\$0.38
Annual Tax Revenue		\$4.61

Source: ESG Managers.

SOLUTION
2

SOCIAL IMPACT BOND

Social impact bonds are performance-based contracts that place an economic value on social services to attract upfront funding. Originally used in the United Kingdom, a SIB (rhymes with “rib”) is a funding tool for service providers that don’t generate profits but rather provide some type of cost savings to a government or corporation. Instead of offering investors a financial return based on activities, the outcome payer—the entity that sees the cost savings—agrees to pay investors their principal and a return determined by the level of cost savings. The model has been successful in attracting funding from investors who would not normally have allocated capital to the issue at hand. In New York City, Goldman Sachs sold a SIB on recidivism to its clients, and a second SIB was similarly promoted by Bank of America Merrill Lynch. Apart from appropriately pricing social services, the model also catalyzes new investment, a critical design feature when attempting to bridge large financing gaps.

Lab participants discussed the potential to create a SIB to fund a portfolio of interventions to address TB. The targeted approach would likely be later-stage than R&D, and would therefore focus on diagnosis and treatment, due to the need for the outcomes to be realized and quantified in three to five years. Drug discovery can take anywhere from 10 to 15 years, and therefore would not be the best application for a SIB.

Participants in both the London and Johannesburg sessions discussed the challenges of implementing a SIB around TB. They acknowledged that it would be difficult to collect and aggregate data, especially for basic epidemiological studies and to monitor and evaluate current cases and existing programs. To price out the cost savings of a particular program, they concluded, it would be necessary to construct a baseline in order to demonstrate eventual success. Therefore, more work would be required on the front end to gather data on cases in a particular country or region before implementing this financing model.

Application to South Africa

During the Johannesburg Lab, participants discussed the potential application of a SIB if sufficient baseline data could be gathered and aggregated. Incentive for the model could be based on the idea that the country’s mining companies lose an estimated \$560 million per year in productivity and that new interventions could provide the cost savings needed to support a SIB. Mining companies would not have to put in upfront capital for these interventions, but would rather be the outcome payers and only pay if the programs successfully lower their health costs associated with TB. This model, therefore, could work even in a time of commodity downswings because there is no need for the mines to make large expenditures before seeing results. The SIB could feature an outcome fund in which the public sector also puts in funding, given that the government would also see cost savings in the form of lower health-care costs.

Based on this general concept, participants agreed that a TB SIB could focus on activities around ex-miner communities. This group, including miners who are no longer actively working and their families, is particularly at risk because after leaving a mine, workers lose access to health services, including testing. Diagnosing and tracking the ex-miners is a critical step to controlling the disease in the peri-mining communities. The SIB would provide upfront capital from investors to support the activities of various service providers working in the areas around mines.

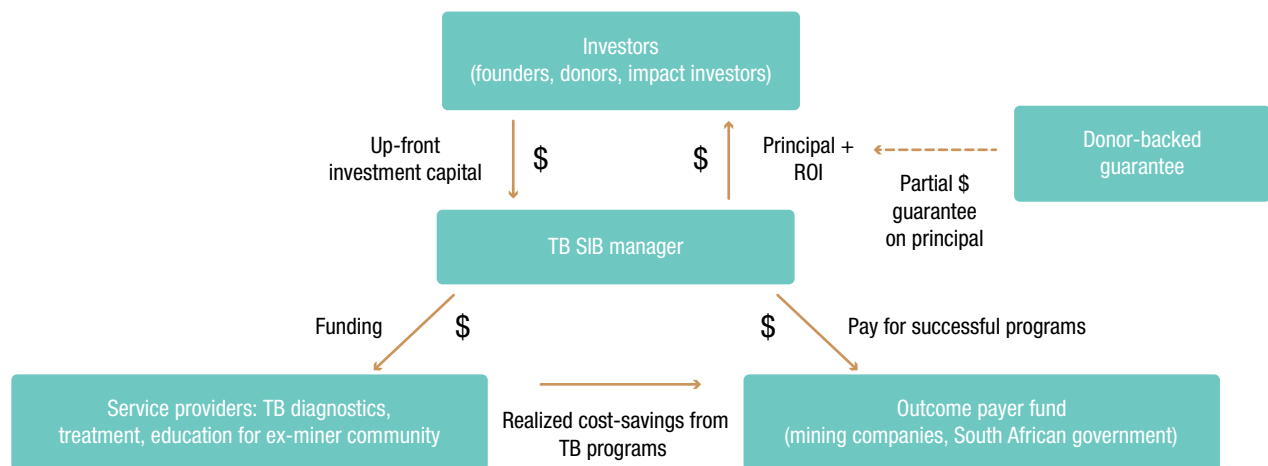
Activities could include:

- improved diagnostics (e.g., an increase in mobile units that can move from community to community)
- better access to treatment (e.g., better facilities in the peri-mining communities)

- education programs for TB prevention for miners and their families to remove the stigma and understand the benefits of diagnosis and treatment
- coordination of ex-miner payment schemes (ex-miners are eligible for government-sponsored compensation programs to cover health-care costs due to the occupational hazard)

These interventions would have both social and financial benefits. The social impact would be generated from the reduced disease burden and the increased productivity of a population with fewer active TB cases. The financial benefits would be realized by government and mining companies through the reduced costs incurred to treat patients. The government would also benefit from increased tax revenues from a more economically productive population. While both would require detailed work to quantify, this savings would form part of the capital that the outcome payer returns to the investors, as shown in figure 6.

FIGURE 6 || A social impact bond model



Sources: Social Finance and Milken Institute.

The SIB design process would include potential metrics for success that must be clearly quantifiable, and a causation must be shown to the cost savings. The metrics could include:

- number of work days missed
- number of ex-miners tested for TB
- number of ex-miners accessing health-care services in a community
- overall diagnostic rates for a certain community
- reduction of overall TB burden (after a baseline is established)

Participants agreed that more work is needed to define success and articulate the best set of interventions to realize cost savings to the mining companies and government.

SOLUTION
3

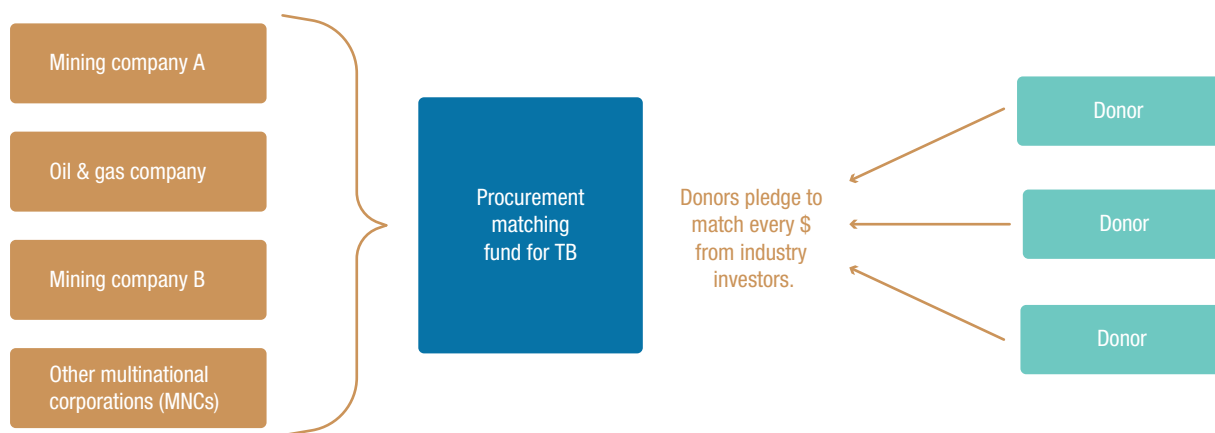
POOLED DONOR TRUST

Donor-based trusts are pooled funds that distribute grants to organizations to meet defined social outcomes. Their main feature is the multidonor approach, which is meant to better coordinate funding for programs while raising awareness for issues that need additional attention. Donors tend to operate in silos, and as such, funding can be sporadic and difficult to navigate for the recipients.

Trusts can help simplify the grant-making process and maximize impact. For example, the recently launched Power of Nutrition trust, housed with the World Bank and UNICEF, is a \$200 million fund that aims to bring efficiency to funding around undernutrition and shine a brighter light on the specific health goals around stunting and wasting. The fund requires an in-country match of capital, which is one of the benefits of a pooled trust—the idea is to bring new attention to a cause and add cachet to funding the issue because of the donor reputations in the group.

Participants discussed the potential for a pooled donor trust to support R&D for tuberculosis, specifically coordinating among mining companies and other extractive industries. Figure 7 shows how the fund could feature a match from donors, where every dollar brought in by the mining industries would generate an additional dollar of funding from a foundation or aid agency. A recent example is a fund in Equatorial Guinea created to support the development of a malaria vaccine and capitalized by three oil companies and the government. Given the amount of work the oil companies do in the country, having an effective malaria vaccine could translate into significant cost savings for health care and improved productivity.

FIGURE 7 Pooled donor trust



Source: Milken Institute

Application to South Africa

Mining companies in South Africa could seed a pooled donor trust. Participants discussed how companies, especially those struggling in the down commodity swing, could channel capital into the fund. Other trusts have been capitalized by a mix of cash and shares—for example, a mining company could give shares to the fund, instead of cash, and these could be held or sold, as matched by the donors.

Regardless of the funding structure, the mining companies present at the Johannesburg Lab discussed potential challenges of a pooled donor fund. Current restrictions limit where they can focus their corporate social responsibility efforts, they said; in South Africa, mining companies must put their funding toward programs within the communities where they operate their mines. Therefore, any pooled donor trust would need to seek overlap with the mining companies' various activities.

SOLUTION
4

INVESTMENT GUARANTEES AND LOAN PRODUCTS

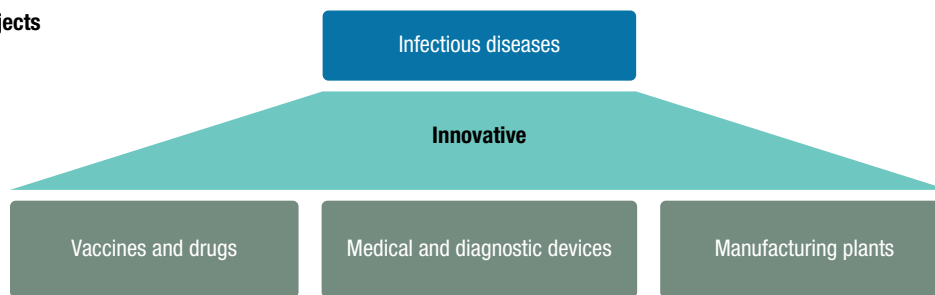
For many years development finance institutions and other international lenders have provided debt capital to companies working in the life sciences sector. However, much of this financing has targeted companies working on diseases that have commercial markets. While a potential TB vaccine and improved diagnostics could have long-term profit potential, the drug manufacturers have suggested that the only market for the products will be public sector, meaning that there would be limited or no profit-making possibility.

For those parts of the TB value chain that could generate profit—such as vaccines or diagnostics as mentioned above—there is an opportunity to explore low-cost or no-cost financing provided by the international finance institutions. Lab participants discussed one such funding program, developed by the European Investment Bank (EIB). The EIB has a history of funding innovation, but predominately in sectors that are purely commercial. Recently, it launched a new funding program within its InnovFin initiative, for R&D and production of products for infectious diseases.

As seen in figure 8, the financing could support small- to medium-size companies, as well as mid-cap or large firms. The fund could provide capital for up to seven years. The loans could be used to help fund clinical trials, bringing products to market, or other related activities.

FIGURE 8 | InnovFin Infectious Diseases

Eligible projects



- Projects which have passed preclinical stage and for which clinical validation is needed for further development
- Loan amount: **min EUR 7.5m, max EUR 75m**
- Loan maturity: **up to 7 years**
- Currency: **EUR and local currency**
- Pricing: **commensurate to the risk incurred**

Source: European Investment Bank.

Application to South Africa

The EIB's funding program is limited to those companies that have some sort of European presence; however, this type of funding could be explored through development banks, such as the African Development Bank, which could provide similar loan terms and tenures. More work needs to be done to structure loan programs to work with the specific nuance of the infectious disease field, especially given the market projections.

Conclusion

Tuberculosis is not a disease of the past. It kills over a million people each year and has become a public health disaster. It is also an economic disaster for countries whose GDPs are linked to industries, like mining, that carry a high burden of the disease. The time to act is not tomorrow—it was yesterday, last week, last year.

What must be done to control and eventually eradicate TB? The solution lies in a host of interventions, from R&D for new drugs and a functioning vaccine, to better day-to-day management of the disease and better education and awareness of the chilling health consequences.

All this takes funding, and much more than the current levels allow. To bridge the capital gap, we need new types of financing models to attract a wider variety of donors and investors, including the private sector. It will be essential to maintain coordination among all the relevant stakeholders—mining companies, foundations, institutional investors—to fund this effort.

Social impact bonds, low-cost debt financing, pooled donor trusts—all these can help to bring new and more sustainable sources of funding to the interventions desperate for working capital. The next step is to build and implement models to show how these innovative financing solutions can support high-impact programs to end TB, if not for this generation, then for the next, and the next, and many more to come.



APPENDIX

Financial Innovations Lab Participants

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APPENDIX

Financial Innovations Lab Participants

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