



**CENTER FOR GLOBAL
HEALTH DELIVERY–DUBAI**
HARVARD MEDICAL SCHOOL

PROCEEDINGS

Innovations and Positive Disruptions in the Supply Chain for Second-Line Drugs



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in the Supply Chain
for Second-Line Drugs**

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1.0 Introduction

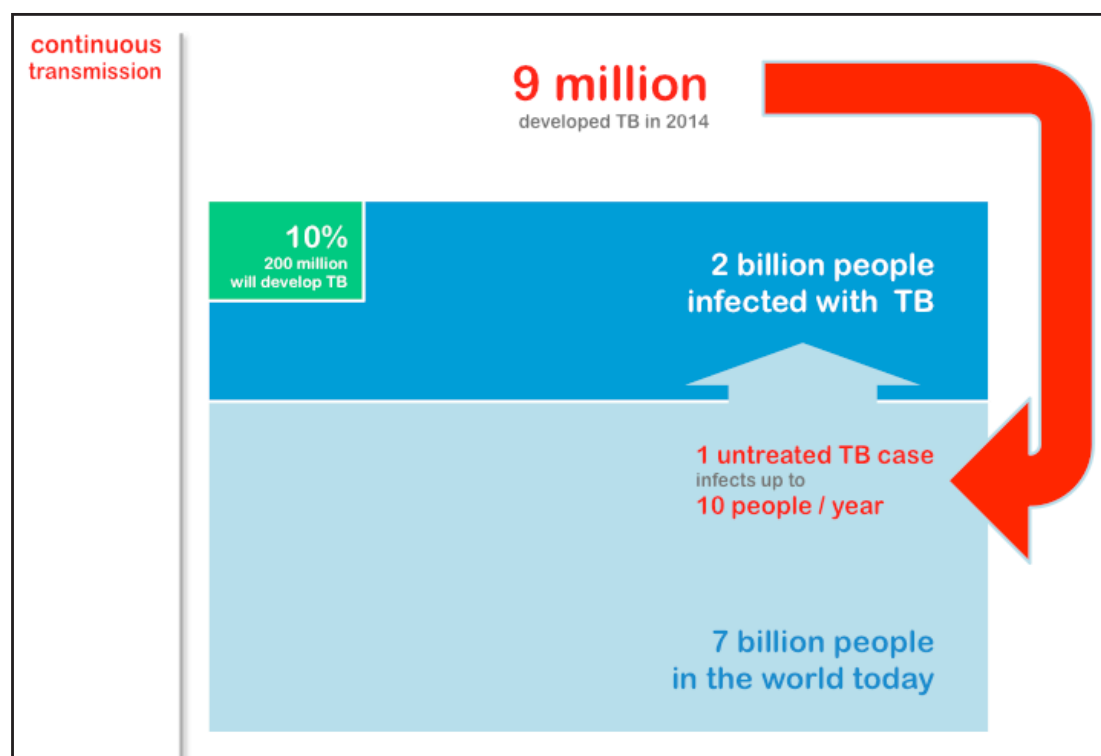
On Wednesday, April 16, 2015, over 63 experts convened for the Innovations and Positive Disruptions in the Supply Chain for Second-Line Drugs workshop, hosted by the newly established Harvard Medical School Center for Global Health Delivery–Dubai, in Dubai, United Arab Emirates. The workshop's aim was to discuss innovations in the supply chain for second-line drugs, as well as new approaches to expand global access to second-line tuberculosis medication.

This meeting brought together public health professionals, TB researchers, social entrepreneurs, clinicians, and policy-makers from over a dozen countries to discuss reforms and innovations to the global supply chain for second-line TB drugs. Participants represented non-governmental organizations, hospitals,

social businesses, academic research institutions, national and global health organizations, pharmaceutical companies and foundations. Represented organizations included The Global Fund, Partners In Health, Clinton Health Access Initiative, TB Reach, Interactive Research and Development, Operation ASHA, Stop TB Partnership, Otsuka, Eli Lilly & Co., Pfizer, Inc., and Janssen Pharmaceuticals, among many others.

Presentations covered new market-based tools for improving the supply chain, relevant reforms in other disease areas in the past, institutional reforms at multilateral or bilateral agencies, and new international cooperation among the BRICS countries (Brazil, Russia, India, China, and South Africa), which are home to 40% of the world's TB cases and 55% of the world's multidrug-resistant (MDR) TB cases.

Figure 1. Global burden of TB¹



Source: Keshavjee presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai. Adapted from Dr. Lucica Ditiu, Stop TB Partnership

¹ WHO Global Tuberculosis Report 2014; CDC 2013; Styblo Bull Int Union Tuberc Lung Dis 1985; Basu et al. Proc Natl Acad Sci U S A. 2009

The day focused on practical suggestions to overcome existing weaknesses and to create new pathways for quality drugs to reach programs and patients who urgently need them.

Throughout, the presenters identified areas for intervention in the supply chain in the near future. The end of the day covered the feasibility of BRICS country collaboration for

expanded TB drug access and approval, as well as an overview of the applicable intellectual property regimes that may impact access to future therapies against TB.

Box 1-1 Tuberculosis and drug-resistant tuberculosis basics²

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.

²Source: <http://www.cdc.gov/tb/publications/factsheets/drtb/mdrtb.htm>

2.0 MDR-TB drug supply chain: moving forward



2.1 SUPPLY CHAIN CHALLENGES AND BOTTLENECKS³

Center Director Salmaan Keshavjee began the day's activities with an overview of the major dynamics at play in the second-line drug market for tuberculosis from a public health perspective.

2.1.1 NEED AND BURDEN

Keshavjee's key points included the following facts laid out in layman's terms, that:

- There may be more TB patients overall than we think.
- We also know that we are likely underestimating the growth of MDR-TB, given its curiously static epidemiology over the last decade.
- The spectrum of multidrug resistance is increasing in high-burden areas and in certain geographical areas.

Citing a study that found a nearly 400% increase in TB case-finding by engaging the private sector,⁴ Keshavjee suggested that notified TB rates may be a gross underestimate of the burden of all forms of TB (Fig. 2).

Keshavjee shared information on hotspots within countries (e.g., Mumbai, India), as well as regional hotspots (e.g., former Soviet Union), directing specific attention toward the discrepancies between resistance rates reported by countries to the WHO versus data reported in the scientific literature.

2.1.2 DEMAND AND ACCESS

Keshavjee noted that demand depends on finding patients, yet not enough patients are being diagnosed. Demand also depends on patients accessing treatment, yet unfortunately, not enough patients are being treated. Actual quantified demand does not come close to potential demand. Keshavjee stressed that a focus on the public sector alone in many settings has been a barrier in terms of addressing the depth and breadth of the TB situation in many settings.

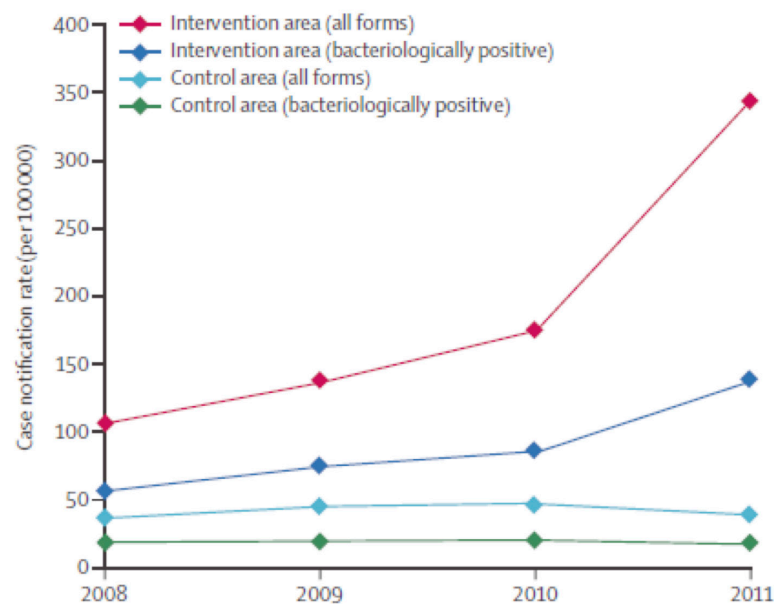
³ This section is based on the presentation by Salmaan Keshavjee, Harvard Medical School, U.S. / Center for Global Health Delivery, Dubai, U.A.E.

⁴ Khan et al Lancet Infect Dis 2012

Access may be linked to affordability when the cost of treatment is too high, noted Keshavjee. Prohibitive cost is a key barrier to access to MDR-TB treatment, with treatment costs consuming a significant portion of some national TB budgets.⁵ Drugs used to treat MDR-TB are more than 200 times more expensive

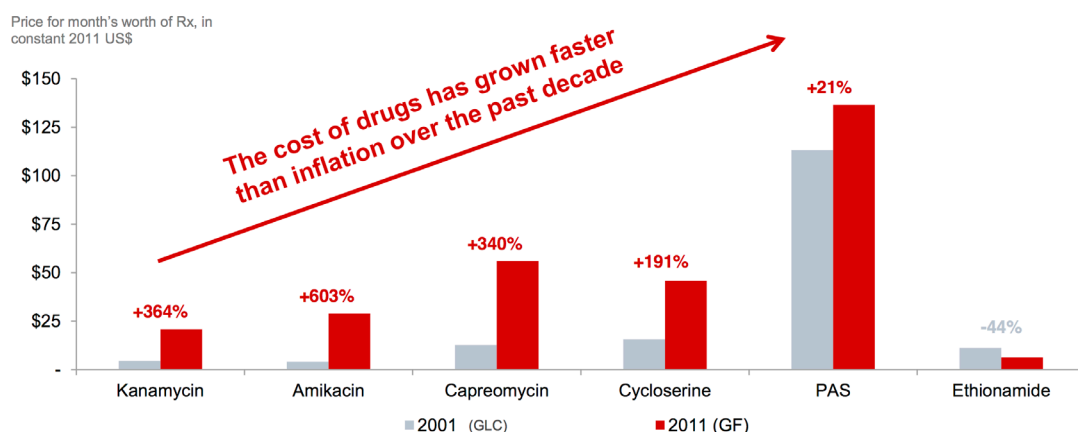
than the drugs used to treat drug-susceptible TB. The costliest drugs in most MDR-TB regimens are para-aminosalicylic acid (PAS), cycloserine, capreomycin, and moxifloxacin.

Figure 2. How much are we underestimating the number of TB patients?



Source: Keshavjee presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai. From Khan et al Lancet Infect Dis 2012

Figure 3. Drug cost increase, 2001–2011



Note: Prices were adjusted for inflation using the average of inflation estimates from the U.S. Office of Management and Budget and the Congressional Budget Office. Percentages indicate changes between median GF and lowest GLC-quoted prices.

Abbreviations: GLC, Green Light Committee; GF, Global Fund grant recipients

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

⁵MSF DR-TB Drugs Under Microscope (2nd ed.); Pooran et al. PLoS One 2013

Keshavjee explained that since 2001, prices have increased significantly for the currently most expensive drugs (PAS, cycloserine, and capreomycin) as well as for kanamycin and amikacin, in a trend that outpaces inflation (Fig. 3):⁶

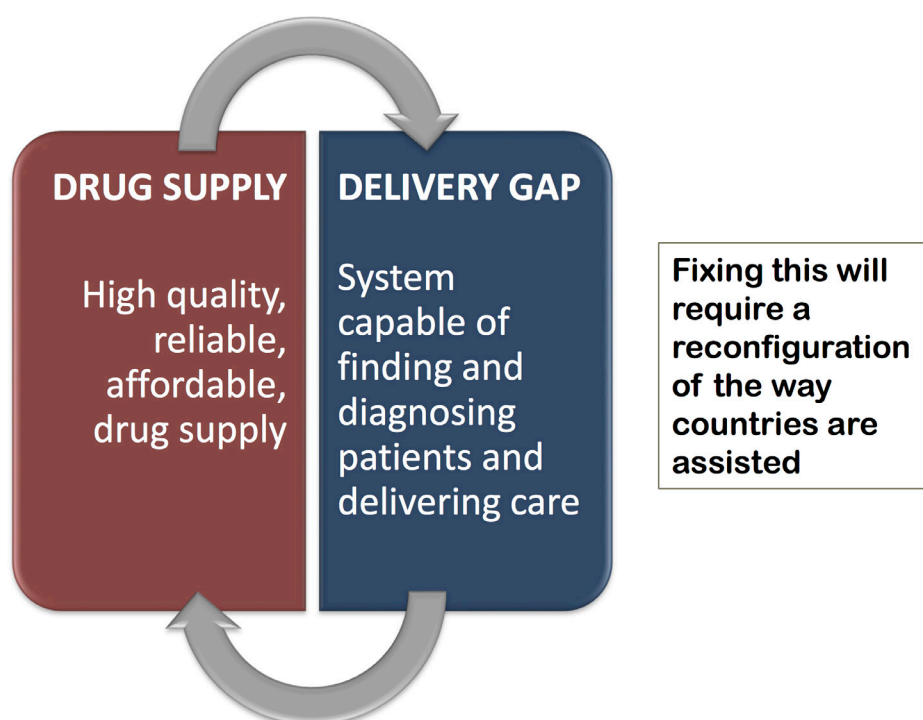
The average quality-assured, 24-month second-line drug regimen costs between US\$4,788 and US\$5,786 per patient, according to Keshavjee. This range is equal to or greater than the per-capita gross domestic product (at purchasing power parity) of 15 of the 27 high-burden MDR-TB countries in 2012. This limits universal access without question, regardless of delivery limitations. The bargain that some countries make is to procure non-quality-assured drugs from domestic or regional manufacturers.

Keshavjee stressed that in terms of access, lack of capacity to deliver quality care (due to many factors) is a significant barrier. Cost of

second-line regimens is a key factor, but given the full subsidization of drugs for programs via the Global Fund mechanism, a cost reduction for medications alone, while helpful, would not necessarily spur a change in delivery capacity. With the Global Fund subsidy, the cost of the medicines is close to zero, suggesting that demand should equal need; this is not the case. The capacity to deliver care is also a structural issue in terms of the resources (human and financial) available for TB programs versus those available for other disease areas, as well as the comprehensive (and thus resource-intensive) nature of successful MDR-TB programs.

A comprehensive solution is required, according to Keshavjee, because demand and access will only be ensured if systems to deliver the care - including medications - to patients are in place (Fig. 4).

Figure 4. Drug supply and the delivery gap



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

⁶Hwang and Keshavjee, PLoS Med 2014

Box 2-1 Forging a new path to treat MDR-TB

Keshavjee outlined a strategy for addressing the situation moving forward:

1. **The problem:** The MDR-TB burden is growing, treatment can cost \$5,000 or more per patient, and drug prices have increased dramatically (21%–603%), outpacing inflation. Reducing the high cost of treatment could improve patient adherence and the efficiency of donor and government funding. Cost reduction will have to be coupled to the ability to increase treatment capacity.
2. **The current approach:** Only <10% of MDR-TB patients in need are being treated in programs of known quality and are receiving quality-assured second-line drugs.
3. **The solution:** Demand cannot be considered in isolation to the delivery gap; we need to apply lessons learned from other contexts (especially advance market commitments and other market-shaping interventions); we need to address additional challenges, including WHO prequalification, variation in country regulatory standards, and supply chain hurdles (including drug formulations).
4. **The goal:** reduce MDR-TB regimen cost to <\$1,000 per patient, and create systems that can help countries achieve universal access to treatment.

2.2 Global supply chain challenges for MDR-TB scale-up⁷



Tom Nicholson's presentation sought to integrate the global perspective with the viewpoints of institutions such as the Global Drug Facility (GDF) and the Stop TB Partnership, who approach supply-chain issues from different perspectives in terms of barriers, institutional headwinds and market forces.

A first step is to identify the market and government failures at play. Market failure is largely due to lack of private sector incentives to provide care to MDR-TB patients in any kind of systematic way, arising from institutional arrangements and market forces. National governments and multinational government institutions have failed to resolve the lack of care to date, despite impressive progress. Nicholson attributed this failure to historical and institutional factors, limited scope of delivery products, and high cost of second-line drugs, among many other factors. He stressed that the situation cannot be allowed to continue.

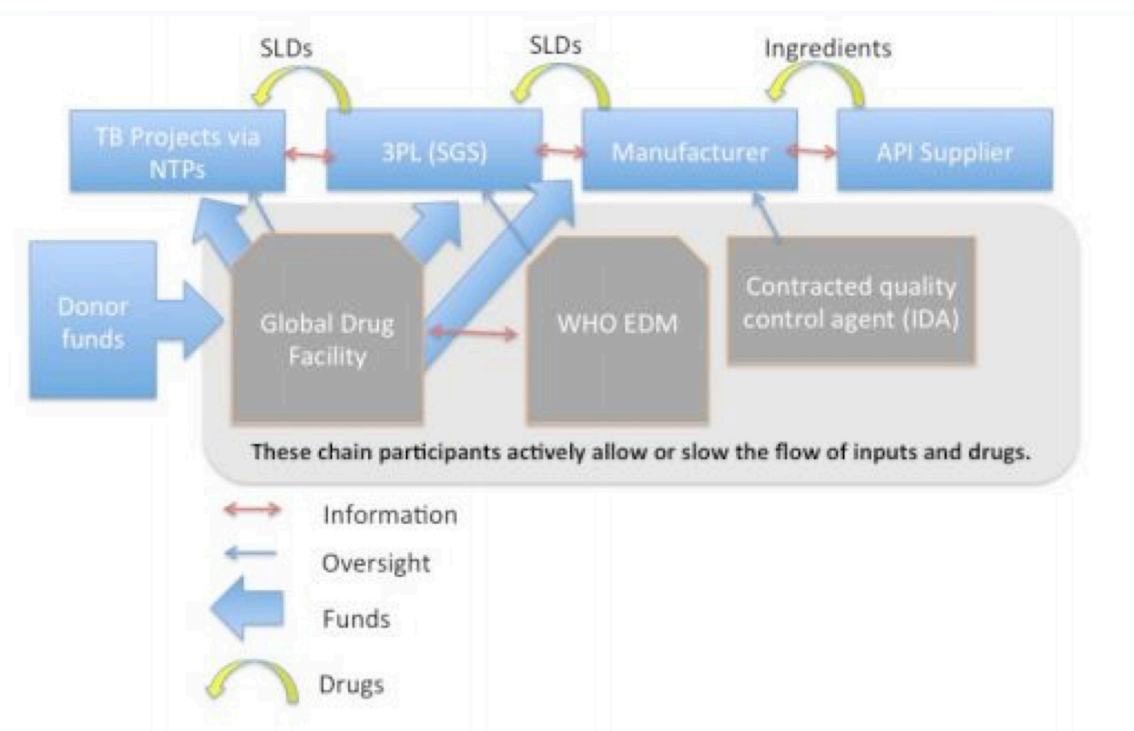
2.2.1 KEY CHALLENGES FACING TB DRUG-SUPPLY CHAIN

Nicholson provided an overview of the core challenges faced by the TB drug supply chain. Overall, the TB treatment gap is significant and the rate of change of TB incidence and prevalence is relatively static over recent decades; therefore, drug-susceptible TB rates are decreasing very slowly. Currently, with only 1 in 4 MDR-TB cases diagnosed at all, the rate of missed cases remaining curiously static.

Inadequate diagnostic capacity and ineffective policies reliant on passive screening for case detection are only slowly being addressed. He noted that TB REACH/Stop TB Partnership are doing good work to address this. However, limited in-country diagnostic capacity effectively caps the number of cases that can be identified, and high-burden countries are generally not actively searching for TB cases.

⁷This section is based on the presentation by Tom Nicholson, Duke University Sanford School of Public Policy, U.S. (Ed: Nicholson was speaking, and crafted his talk accordingly, in lieu of a presentation by Joel Keravec, then-Manager of GDF, who had to cancel on the way to the meeting).

Figure 5. Basic map of GDF procurement supply chain: a structurally limited supply chain integrator



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

Forecasting reliability and regularity are poor, due to the expense of second-line drugs but also due to lack of capacity among those who are doing the forecasting. Annual or semi-annual forecasting schedules lead to poor information about market dynamics for MDR-TB among procurement agents and drug producers alike.

Incentives are weak for new active pharmaceutical ingredient (API) manufacturers and drug manufacturers to enter the market; there are institutional provisions to improve drug quality in place (e.g., the WHO prequalification program), but dynamics emerge—once one supplier is in the market—that limit the interest from other firms to enter as well. Institutional delay, such as the sluggish rate at which applications for prequalification are accepted, represents a high barrier to entry.

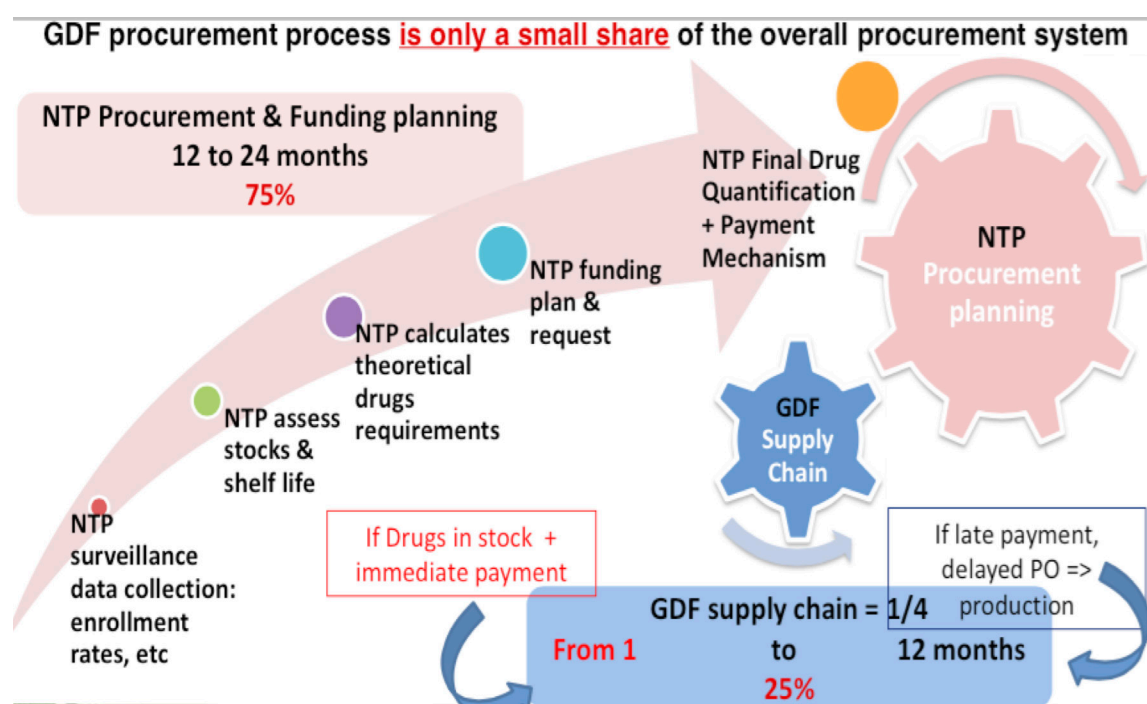
Information about the market is difficult to collect because no entity captures comprehensive information about the TB situation

in a given location. National tuberculosis programs (NTPs) often collect only basic information about TB diagnoses and outcomes, and a substantial proportion of cases globally are “missed” by NTPs either because they are not diagnosed at all or because they are not reported to the NTP. In the private sector, providers often neglect to report TB cases to authorities, and they may provide patients with TB regimens of variable combinations and duration.

Characteristics of the second-line drugs themselves are unhelpful, varying widely in terms of manufacturing complexity. Limited shelf life of drugs (24 months) coupled with small order sizes gives rise to complex dynamics of supply and demand.

On the global scale, third-party logistics for second-line drugs are slow through the GDF. Strategies such as introducing competition and eliminating preferential

Figure 6. Current TB supply chain process



Source: Nicholson presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery—Dubai. Courtesy: Joel Keravec, GDF

treatment could lead to efficiency gains in second-line drug third-party logistics.

Nicholson emphasized that addressing this set of challenges will necessitate a simultaneous, multi-faceted response to see a significant effect: that is, a twin approach spanning drug delivery and drug access issues. This type of massive coordinated response will be critical to controlling MDR-TB and reducing TB mortality.

2.2.2 GDF PROCUREMENT SUPPLY CHAIN

The procurement shipments that the GDF is facilitating represent only a small percentage of the overall drugs being procured against TB and, even within that category, the GDF only integrates part of that chain (Fig. 5).

An effective supply chain integrator should be involved in all stages of the process. However, in this particular situation, there are

areas that are out of the control of the only supply chain integrator, in this case the GDF. In addition, when the GDF or other entities are in fact involved, it is generally to slow down or suspend a process—not to facilitate a process when something is going well. Nicholson characterized this situation as a one-way ratchet: it can slow things down effectively, but accelerating things is difficult.

The current TB supply-chain process is a lengthy one, with the GDF in the past attributing responsibility for about 75% of the activities involved in this process to NTPs. Following required actions by an NTP, if the drug is in stock and payment is immediately available—two conditions which very often do not hold—then the GDF is involved in the quality-assured purchase, which can take anywhere from 1 to 12 months (Fig. 6).

Figure 7. Mapping critical vulnerabilities for TB supply chain



Source: Nicholson presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai. Courtesy: Joel Keravec, GDF

A new initiative is the strategic rotating stockpile, incorporating a guarantee fund and a central Strategic Rotating Stockpile. Some regional stockpiles have been created to address acute situations in other parts of the world; Nicholson posed the possibility raised before by the GDF that these strategic stockpiles are potentially being overused given their original intent, and thus are not feeding into better forecasting practices.

To participate in the new quality assurance program through the GDF, a new manufacturer of a second-line drug must:

- Earn approval from the European Medicines Agency, the U.S. Food and Drug Administration, or another stringent authority (which are overwhelmingly found in North America/Europe)
- Pass relatively slow WHO prequalification measures to assure efficacy, safety, and

quality. This step's delays are primarily due to "bandwidth" issues, as noted in the 2012 Workshop summary⁸

- Complete in-country registration with national regulatory authority (NRA)

2.2.3 KEY SECOND-LINE DRUG CHALLENGES

Nicholson outlined the major second-line drug challenges that contribute to supply-chain efficiency issues and instability on the supply and demand sides (Fig. 7).

Lack of standardized regimens is a ubiquitous problem, making it difficult to forecast demands for individual drugs based on estimates of numbers of patients. On the supply side, availability of APIs is a key limitation, with the cost of APIs accounting for between 30% and 60% of final drug costs or the most expensive and high-risk drugs according to supply chain vulnerability. Limited competition among API

⁸ IOM 2012

suppliers is present due to predictable monopolistic tendencies. The risks of price spikes and counterfeit products are pervasive, as are the potential slowdowns from differentiated requirements on multiple levels with regard to documentation needed for final customers.

Citing GDF's previous publications, Nicholson highlighted key interventions for linking supply with demand and managing production capacity and allocation. Regular forecast and quarterly data collection would enhance better predictability. Early warning stock-out systems, flexible procurement funds, and global strategic stockpiles are also crucial. Components of an interventional risk management / risk-based approach would include:

- Engaging stakeholders for concerted actions with suppliers towards commitment and capacity investment
- Better data collection and sharing for planning
- Balancing short-term interventions (e.g.,

packaging ordering, shipment schedule, label ordering, resources schedule allocation) with long-term interventions (e.g., capacity planning and allocation, active ingredient schedule, regulatory changes, and HR planning)

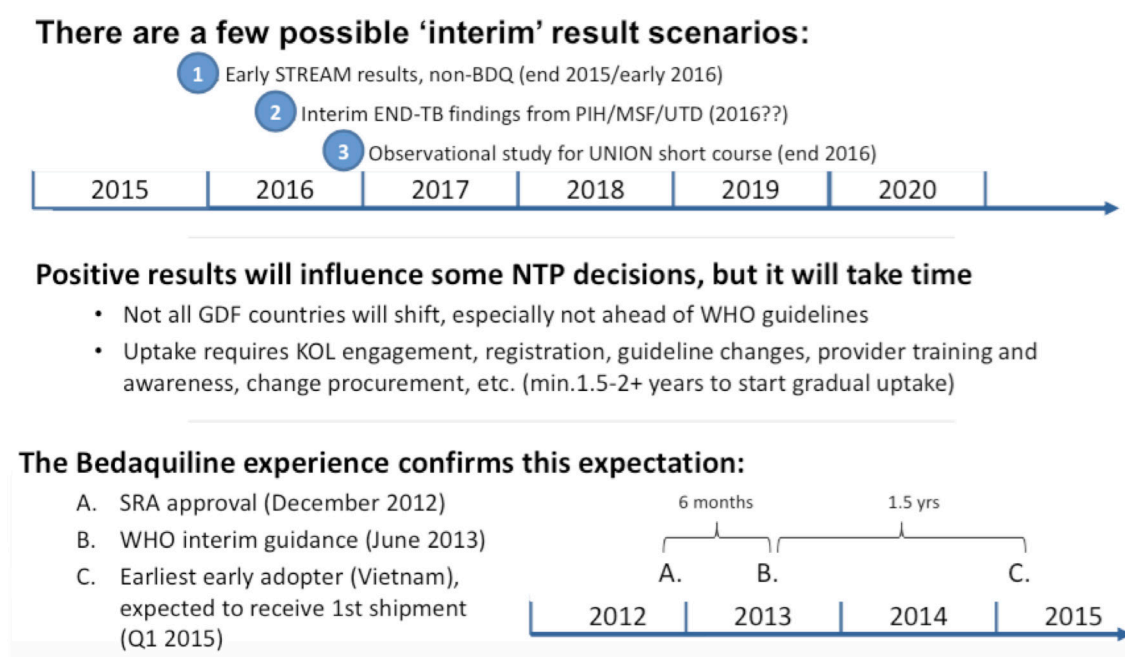
- Addressing the risk of vertical integration in terms of potential monopoly or supply vulnerabilities

2.2.4 LOOKING FORWARD

Nicholson noted that projecting forward, significant changes in procurement patterns are not likely until 2017 or even later. However, there are possible interim scenarios (Fig. 8).

Nicholson remarked that though the dynamics are frightening, there are reasons for optimism. Other industries' experiences have shown that these challenges, while rarely found all in one market, are surmountable. There is widespread recognition of these dynamics now, and growing discontent with the status quo.

Figure 8. Projected changes in procurement patterns



Source: Nicholson presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai. Courtesy: Joel Keravec, GDF

2.3 Supply chain project examples⁹



2.3.1 LILLY MDR-TB PARTNERSHIP

Dan Collins described the work of one of Lilly's global health programs, the Lilly MDR-TB Partnership.¹⁰ Its mission is to engage partner organizations with novel ideas to improve healthcare systems in countries that presently include China, India, South Africa, and Russia. Doing so involves working with in-country partners to address challenges in HCP diagnosis and treatment, as well as ongoing patient support, but also around access to safe and quality-assured medicines at the country and global levels. The model involves working in a pilot area of the country to research and develop a "Research, Report and Advocacy" framework, which means using research to demonstrate that a program will work, making that research available freely, and advocating for scale-up.

A key component of the Lilly MDR-TB Partnership, the Lilly TB Drug Discovery

Initiative, is a nonprofit, public-private partnership effort launched in 2007. Its objective is to accelerate early-stage TB drug discovery and development by systematically screening extensive private molecular libraries.

2.3.2 LILLY'S TECHNOLOGY TRANSFER OF CAPREOMYCIN AND CYCLOSERINE

Collins explained that Lilly's MDR-TB Partnership is built upon the company's legacy in infectious disease. Around the same time that Lilly was exiting the anti-infectious disease medications business, it was becoming apparent that two of their drugs—capreomycin and cycloserine—were effective components in an MDR-TB treatment regimen. Initially the drugs were made available at concessionary prices to encourage MDR-TB treatment, but this practice was unsustainable, and the MDR-TB patient base was expected to expand beyond Lilly's capacity to keep manufacturing enough

⁹ This section is based on the presentation by Dan Collins, Global Health Programs, Eli Lilly and Company, U.S.

¹⁰ The other component being the Lilly NCD Partnership (diabetes care) in Brazil, India, Mexico, and South Africa.

drugs. The decision was made to transfer the technology to make these medicines to manufacturers in high-burden countries. It was a multi-year process that resulted in facility upgrades and increased overall manufacturing capacity in some cases. The experiences and lessons have been published in a White Paper¹¹ surveying the market, regulatory, and supply-chain challenges encountered. In addition to the technology transfer, Lilly wanted to offer health delivery support to these same high burden countries and to the global health community, leading to the establishment of the Partnership.

2.3.3 MDR-TB QUALITY-ASSURED DRUG SUPPLY AND ACCESS

As a large corporation and pharmaceutical company, Lilly seeks to promote collaboration and action to address MDR-TB quality-assured drug supply and access. Collins highlighted two recent projects¹² to improve global drug-supply forecasting that are funded by the Partnership.

Data Dictionary

The Data Dictionary is an effort to create common standards and definitions to improve the data flow between existing eHealth systems for MDR-TB within countries, and for data consolidation globally.¹³ One specific goal was to align Management Sciences for Health's QuanTB system and the GDF's global forecasting and early stock-out warning system. The Data Dictionary was successfully launched in 2014 and is now available for all countries, regardless of the type of information systems they utilize.

Country MDR-TB Drug Management and Quantification

The Country MDR-TB Drug Management and Quantification project seeks to help strengthen countries' abilities to manage and forecast drug supplies. Primary objectives are to ensure an uninterrupted supply and quality-assured treatment for MDR-TB patients

and to contribute to an accurate global forecast, thus enhancing suppliers' ability to plan. Countries receive support in multiple areas:

- Assessment of existing dataflow and systems
- Creation of country-specific drug management plans
- Training for and assistance with implementation of QuanTB and the data dictionary as tools for quantification
- Analysis of second-line drug forecasts and assessing potential actions
- Reporting of forecasts to the GDF global early warning system
- Technical assistance to ensure regular updates and ad-hoc troubleshooting

2.3.4 EFFORTS TO ENGAGE PRIVATE SECTOR HEALTHCARE PROVIDERS IN INDIA

With the view to potentiating the Zero TB Cities Project in Chennai, Collins shared more specific details about the Lilly MDR-TB Partnership's work engaging with the private sector in India. Given the complexities of India's health system and the variable standards of care in the private healthcare sector, the Partnership identified three key needs to target:

- Better training for healthcare providers at state and regional levels
- Replicable approaches to engage with private healthcare institutions and providers
- Effective ways to engage with practitioners of traditional medicine, especially in rural areas

Their approach was to focus on healthcare providers in both private and public sectors by offering training programs, as well as creating linkages between private healthcare providers and public systems in order to ensure that

¹¹ Lilly 2014

¹² Past efforts have included hosting a 2012 Innovation Summit to focus on improving the SLD supply chain, and serving as coordinator for the now-defunct Second-line Drug Access Improvement Initiative.

¹³ Led by KNCV and involving representatives from 14 countries and global organizations (WHO, MSH, Partners In Health, etc.)

patients receive the proper continuum of care. The overarching goal was to contribute to progress towards the Revised National Tuberculosis Control Program's (RNTCP) objective of "universal access to early quality diagnosis and quality TB care for all TB patients" and to improve treatment completion and success rates. A parallel effort is in place to engage the wide-ranging sector of private providers to increase the demand for quality-assured second-line drugs in India.

2.3.5 KEY POINTS FROM DISCUSSION

Aamir Khan¹⁴ mentioned that the three projects Collins described are areas already being explored by the bigger group (on previous meeting days), specifically with regards to the last project in Chennai, suggesting that understanding how to engage higher-level licensed private providers is really critical. Khan mentioned the Expanding New Drugs for TB (endTB) project, which seeks to expand use of the new drugs bedaquiline and delamanid in treatment regimens for MDR-TB (Khan's organization is the implementing partner for endTB in Jakarta, Dhaka, and Karachi). Khan mentioned that in the context of endTB, they are planning to roll out the new drugs in the private sector, focusing on private pulmonologists, not general practitioners. They did not want to engage general practitioners, nor did the national TB control program (NTP), in treating MDR-TB. The fact that initiatives in Chennai and the three cities in the endTB project are targeting the private sector is critical. He signaled his intent to engage more and share more learning.

Khan tied this discussion into the Zero TB Cities Project discussion that occurred two days earlier, by contending that this

is also another argument for focusing on the city level rather than the national level. Starting at a city level seems more manageable and acceptable, and it encourages more government support, he added.

Participants noted that in India, pulmonologists in private practices generally keep MDR-TB patients a secret. They do not want to notify authorities, and the patients are content not to be notified, as they also want to remain unnoticed. Sunil Kapoor¹⁵ argued that indeed many people depend on general practitioners, and that some patients would rather risk death than go to the public sector. He noted that the leading chemists (pharmacists) of Delhi say that the demand for second-line drugs is erratic. They are cautious about short shelf life, bad lots, and other issues of concern. They are poorly educated about the drugs, and the data are limited, especially from the pulmonologists in corporate hospitals. There are hardly any pulmonologists in the private market in India, and general practitioners are reluctant to report patients because they are afraid of losing other patients due to fear of MDR-TB. Kapoor noted that the response to much of this should be more education on the disease, particularly transmission dynamics.

Shifting gears, André de Mello e Souza¹⁶ asked which manufacturers received Lilly's transfer of TB technology; Collins replied that the transfers went to JSC Biocom in Russia, Zhejiang Hisun Pharmaceutical in China, Shasun Pharmaceuticals in India, Aspen Pharmacare Holdings in South Africa, and one group in the US.

¹⁴ Aamir Khan, Interactive Research and Development, Karachi, Pakistan

¹⁵ Sunil Kapoor, Harrow Respiratory Medical Center, India

¹⁶ André de Mello e Souza, Instituto de Pesquisa Economica Aplicada, Brazil

Q&A Highlight: Bold change from pharmaceutical companies?

Keshavjee questioned whether the Lilly initiatives in fact represent bold change; he noted that pharmaceutical companies have been engaged in activities that support access to treatment for a while and that the gap lies with the national TB programs. For example, he pointed out that Lupin Pharmaceuticals opened the door to MDR-TB treatment in India through their sales representatives and by training doctors; without this avenue, one simply could not receive treatment from any other source during the late 1990s and early 2000s.

Keshavjee noted that the real innovation would be for NTPs to adopt mechanisms that allow them to better integrate with private diagnostics and care providers. In Indonesia, there was pushback from the NTP on this score. The NTP argued that private sector treatment of MDR-TB should not be happening; patients should all be going to government centers. However, in practice, patients did not want to follow those rules, and it took a year and a half for the NTP to acquiesce. Keshavjee concluded that it would indeed be bold for the NTPs to allow access to public sector drugs for pulmonologists in the private sector, and to allow them to treat patients under a mechanism that is not under NTP control.

Collins agreed that signs of NTPs' willingness to engage the private sector is the reason why there is hope that the Zero TB Cities Project will garner government enthusiasm—the RNTCP of India has already been very engaged, which is unique. Having the government be a champion of any initiative is critical.

Collins also replied to the point that pharmaceutical companies engage in activities that support access to treatment all the time; he agreed, but he would argue the situation with MDR-TB is different and complicated. Sales representatives are not really involved because the products are generics, and there is a difference for them to come in to educate doctors. The model is similar, but incentives for the private sector are important to make their participation helpful. Noting the assumption that doctors have apprehension from NTPs, Collins wondered how the TB community could incentivize providers to treat and follow up on patients in a variety of ways, and notify government authorities appropriately.

3.0 Pooled procurement as a key issue



3.1 POOLED PROCUREMENT FOR ANTIRETROVIRAL DRUGS: REFLECTIONS FOR TB¹⁷

Sana Mostaghim reflected on the experiences of the Clinton Health Access Initiative (CHAI) with pooled procurement of anti-retroviral drugs (ARVs) for treating pediatric HIV, and expounded on some of its potential applications to the TB drug procurement space.

3.1.1 POOLED PROCUREMENT: OVERVIEW

Mostaghim defined pooled procurement as essentially bringing together purchases that otherwise would not be combined. He explained that procurement can be consolidated across one or more dimensions:

- Geography: placing combined orders for several countries together

- Time: placing synchronized orders to cover requirements over a pre-defined period (e.g., one quarter)
- Products: buying the same products (e.g., same labeling, packaging, formulation)
- Purchasing and partner entities: creating a consortium of multiple buyers and/or procurement agents

Consolidating procurement facilitates more affordable and sustainable access to drugs for patients by offering a range of potential advantages both to suppliers and to buyers. Buyers benefit from increased negotiating power, improved lead times, better discipline in forecasting and quantification, reduced resource requirements (by dividing fixed procurement costs), and enhanced ability

¹⁷ This section is based on the presentation by Sana Mostaghim, Clinton Health Access Initiative, U.S.

to negotiate with suppliers to keep emergency stock in their warehouses. Manufacturers benefit from receiving fewer, larger orders at regular intervals in consolidated orders that meet minimum batch-size requirements, longer production campaigns that drive economies of scale, reductions in API inventory and holding costs, and lowered risk of carrying residual inventory of full packaged product and expiry write-offs.

The pediatric HIV market proved an ideal candidate for these benefits. It featured a relatively small global patient population (approximately 760,000), a market unevenly distributed over many countries, multiple packs and formulation types, small dosages that require large product-pack batch sizes, and a prohibitively high price (annual regiment price of \$1,500 in 2006).

3.1.2 CHAI-UNITAID PEDIATRIC ANTIRETROVIRAL DRUG PROCUREMENT PROJECT

In 2006, CHAI became the implementing partner for the UNITAID pediatric¹⁸ and second-line ARV projects. Its aims were to close the gap between the rates of adult and pediatric HIV treatment, and to improve the marketplace for pediatric and second-line ARVs by using pooled procurement to lower prices, increase the number of high-quality suppliers, and accelerate the development of new and improved products.

Mostaghim described some of the salient characteristics of CHAI's pooled, centralized procurement process. CHAI Program Managers were responsible for centralized volume allocation, and Procurement Agents handled centralized order placement, tracking, and execution. A common quality control agency carried out pre-shipment inspections and lab testing; manufacturers shipped orders directly to countries. The procurement was propelled by an integrated effort on both the demand and supply sides of the marketplace (Fig. 9).

The project ultimately catalyzed a significant expansion in patients' access to drugs, indicated by:

- Five-fold increase in the number of children on treatment (250,000 in 2009)
- Decrease in average annual price of pediatric ARVs
- 93 new stringent regulatory authority approvals between 2007–2009

3.1.3 REFLECTIONS ON KEY SUCCESS FACTORS THAT ARE RELEVANT FOR TB

Geography

Mostaghim remarked that TB procurement was already partially consolidated across different countries for donor-based purchases. The GDF platform is in place to receive, consolidate, and fulfill orders from TB programs around the world. Utilizing the GDF for quality drugs is required for all Global Fund funding recipients and optional for domestic programs.

Timing

Drug manufacturers are limited by minimum batch requirements. Manufacturers will not produce a particular product until orders meet the minimum batch requirement—generally several thousand packs—because producing a smaller batch risks incurring losses from carrying stocks that fall below country shelf-life requirements. At present, country orders for TB medicines are not placed at regular or synchronized intervals (Fig. 10). In the absence of order coordination among buyers who require less than the minimum batch size, supply timelines can become highly unstable and prolonged.

Product selection

Product selection, Mostaghim noted, is another option for pooling. The market for second-line TB drugs currently spans an extensive range of options, with certain core ingredients but many different permutations of formulations, packaging, labeling, and so forth.

He described how the pediatric ARV market was in a similar situation at the start, which

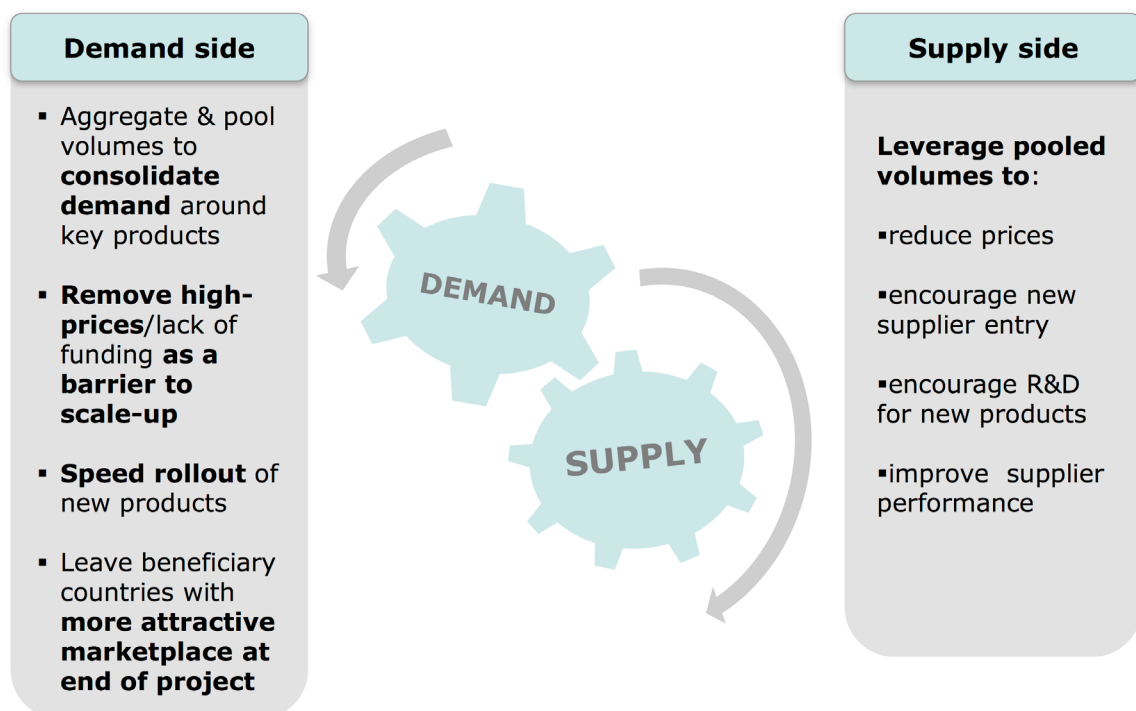
¹⁸ Pediatric products include first- and second-line ARVs, OI medications, diagnostics, and ready-to-use therapeutic food (RUTF).

was an impediment to sustainable marketing. The Interagency Task Team (IATT) was established to address this issue by providing a forum for information sharing and consensus building among its members (currently 5 United Nations agencies and 23 global partners). The Pediatric Working Group sub-committee created the IATT Optimal Pediatric

Formulary List, including strict selection criteria and a defined process in place for revisions. Selection criteria for formulations included:

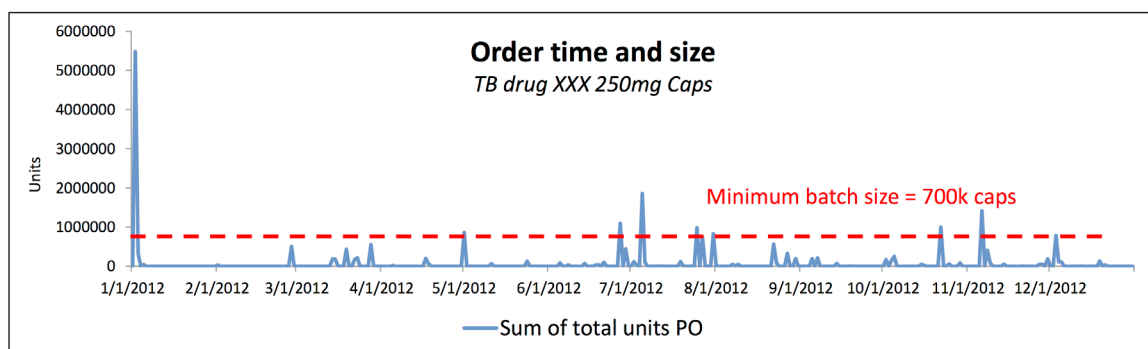
- WHO recommendation to ensure safety and efficacy
- Availability in resource-limited settings
- Stringent regulatory authority/WHO

Figure 9. Procurement as an integrated effort of demand and supply sides



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

Figure 10. Order time and size for TB drugs vs. minimum batch size



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

prequalification approval

- User-friendliness for prescribing, administering, and adhering to treatment
- Supply chain optimization (easy to store, transport, and distribute)
- Flexible dosing for a wide range of dosing options
- Comparable cost with similar drugs and formulations

Mostaghim suggested the possibility of consolidating the formulary of TB second-line drugs around the optimal drug choices based on current evidence and normative guidance. He offered a detailed illustration about how this might work. Given that there are around 40 available options for treating MDR-TB, eliminating inferior options would decrease the number of products. New drugs can then be evaluated as they enter the market, in keeping with current recommendations.

After the number of products on the market has been reduced, a next step is to identify cases of clinical equivalence between the remaining drugs. Choosing just one of them to include in a standard MDR-TB regimen for a country is another way to simplify procurement. Having physically similar drugs with the same ingredients, albeit different packaging, adds complexity but not competition (no difference in product). Selecting only the essential stock-keeping units¹⁹ can have a large impact upon reducing pill burden logistically and can enable better dosing. Consolidating volumes and suppliers can increase order sizes to meet minimum batch requirements and provide more reliable lead times for suppliers, as well as increasing competition. From the NTP's perspective, it may ease forecasting and supply-chain management.

Buyers and Partners

Mostaghim highlighted multi-party market-shaping arrangements as a further growth opportunity for TB, citing the example of the Pediatric ARV Procurement Working Group (PAPWG) as a possible model to adapt. Comprising diverse partners and stakeholders,

its goal is to plan and implement the coordination and policy changes required to ensure that the market for pediatric HIV commodities remains stable and that fragmentation of demand across multiple buyers does not compromise the gains in efficiency, lead times, supply security, and prices achieved through the UNITAID Pediatric Project.

He stressed that there are multiple levels of working with the market beyond just realizing the optimal values of transaction-level procurement: working with both the supply and demand sides of the market; ground-level engagement; demand generation; building management tools; and supporting training and mentoring delivery programs.

3.1.4 KEY POINTS FROM DISCUSSION

During this Q&A session, the group lamented the overall tone of TB meetings versus the urgency and clarity of demands among HIV activists and even policy-makers. Mostaghim noted that the fundamental conditions are there for healthy TB therapy markets, just as they were for pediatric HIV drugs. The tone and energy is a separate issue, though it is of course related to the complexity of the TB regimen for each patient. He cited governmental commitment, as seen in South Africa, as cause for hope (in terms of political buy-in) for scale-up of MDR-TB treatment.

Sunil Kapoor noted that procurement in India is slow and inefficient (2–4 month delay before order initiation by the government) and asked Mostaghim to comment; he responded that both country-level stock management and central- or lower-district level stock management could be improved, but there are also ways to address uncertainty at the central procurement level, e.g., buffer stock, financial flexibility, and so forth. He identified the basic problem as a lack of a clear forecast in the first place, which would lead to clear quantification of need and a more efficient ordering process.

Ana-Maria Ionescu²⁰ noted that there were intrinsic complications to simplifying regimens in terms of choice and variability for the marketplace. Mostaghim agreed that it

¹⁹ Based on criteria such as meeting daily dosing needs for all weight-bands, reducing pill burden, and standardizing pack size.

²⁰ Ana-Maria Ionescu, Janssen Pharmaceuticals, Global Public Health

is relevant and would need to be taken into consideration, depending on the specific case of the product being analyzed. If the product is clearly out of guidelines and not preferred, he argued, it is possible that the supplier would suffer. The entire approach, according to Mostaghim, should not be just about pruning options, given the need to be sensitive to this supply landscape. Rather, the question he posed was: what is the ability of suppliers making a similar drug in different packaging to have a universal registration approach?

Responding to a question regarding the QuantTB tool, he replied that it has a lot of value and is beginning to bear fruit, but warned that poor inputs into a good tool will not necessarily yield meaningful results.

Nicholson urged that the group combine strengths, but synthesize existing GDF arrangements (wherein third-party logistics suppliers are not competing on competitive bases and are treated preferentially) with a new way, in which competing third-party logistics suppliers can facilitate the manufacturing postponement or late-stage customization that needs to happen. He argued that even if all standards are aligned, the machinery is not there to provide second-line drugs comprehensively through the GDF right now, given that it started as a pilot project and expanded on a limited foundation. He argued that all of the complementary approaches need to happen at once, to strengthen the overall effort generally and the

BOX 3-1 Improving supply by managing forecast variability in country

Throughout the discussion, participants from private industry offered parallel examples of programs in Africa, such as those supplying ARVs and contraception, facing the same challenges regarding private markets as TB. Recommendations for improving supply by managing forecast variability in country included:

- ***Consolidate the forecast at the point furthest from the market***
- ***Simplify what is brought into market and hold inventory at the point before the last point of differentiation***
- ***Hold enough in inventory at acceptable cost to manage in-country supply***
- ***Focus less on in-country forecasting (which may not be a solvable problem now) and focus more on how to simplify in-country administrative requirements***
- ***Improve government alignment, as a key challenge is different requirements in different (often neighboring) countries, with the net effect being lack of synergy between markets***
- ***Do not assume that the industry is not actually seeking a more standardized approach. Industry may in fact be seeking an approach that is easier for users to access, but allows for more efficiency and more effective competition, rather than only seeking to maintain complexity***
- ***Consider reforming governmental administrative requirements for accepting drugs***

Mostaghim asked that those present not overlook the GDF mechanism currently in place, which does address some of the needs above.

GDF mechanism specifically. For example, having a relationship with third-party logistics suppliers in multiple regions, instead of single Europe-based suppliers, would only be successful with increased activity on the demand side and the kind of regimen innovation that Mostaghim described.

Jacob Creswell²¹ agreed and expanded on this idea. In thinking through treatment delivery, the community is successfully treating one person for every three people who die from MDR-TB every year. For all of the people notified today, there is the potential for 300,000 treatments, but only 100,000 are presently being treated. He noted that much would have to happen to drive scale-up; gains can be made in terms of consolidating products and orders.

Of these 100,000 patients getting treatment globally, 20,000 or more are in India. Creswell wondered about how many of these treatments are supported by the Global Fund, and how much contribution comes from countries. In India, he noted, one can buy medications already at less than \$1,000 per treatment. He remarked that cost is not an issue for many of these countries. Currently, countries may put in an application to the Global Fund saying they will treat 2,000 patients, but then they only test contacts of MDR-TB patients and re-treatment cases, and find 46 new MDR-TB patients to treat. He noted that part of the reason why Nigeria, Indonesia, the Democratic Republic of the Congo, and other countries are returning money to the Global Fund is because they do not have the necessary systems and algorithms in place to find MDR-TB patients. Creswell posed the question: in the BRICS countries, how many of the patients receiving treatment are having their treatment supported by the Global Fund, and where are the efficiencies to be had?

Keshavjee noted that the Russian Federation does not receive Global Fund money anymore. Drugs are obtained based on their local markets so their cost is not zero; in fact, there is an issue that some provinces cannot access treatment because they do not have resources. Keshavjee also noted that in India, one third of drugs are purchased through the Global Fund,

with the rest purchased in their own open market. In Indonesia, he noted, which has 21,000 MDR-TB patients, they have only treated 750 patients over a 4-year period, even with free diagnosis and medicines provided through Global Fund financing. Thus, the second-line drug markets in many high-burden countries remain diversified, as these countries are not buying from the GDF for most purchases, despite its key role.

Mariatou Tala Jallow²² urged the group to think beyond the GDF paradigm, and on how the assembled experts might improve the supply chain for TB in a comprehensive way. She stated that the group should not prioritize price, because the Global Fund is a pooled procurement mechanism driving prices down; but rather the group should consider value added, e.g., quality, sustainability, and so forth, to meaningfully talk about access for patients.

The GDF is important, but is not the core of the discussion, she said. Given that 80% of GDF procurement is through Global Fund financing, this is as much a Global Fund issue as anything else, Jallow argued. She asked what the assembled group could do within the market to be able to engage better with suppliers and what additional leverage can the group have within the market that goes beyond TB? The angles brought up included leveraging common elements of HIV and TB in order to position the TB market better overall. She also tried to put the regulatory possibilities in context, given that the TB market is the least “donor-dominated” market among the Global Fund’s disease areas, and this would prohibit a single quality standard.

Keshavjee asked why, if the Global Fund is buying more than a billion dollars of HIV and Malaria drugs (probably from some of the same manufacturers as TB drugs), they are not pooling orders for TB, Malaria and HIV drugs together. Jallow responded that for the Global Fund it is a politically sensitive issue, but that discussions are underway in terms of engagement with Indian manufacturers along the lines of longer-term supply arrangements.

²¹ Jacob Creswell, TB REACH, Stop TB Partnership, Switzerland

²² Mariatou Tala Jallow, Global Fund, Switzerland

3.2 Pooled procurement of medicines in the Organization of Eastern Caribbean States (OECS) countries²³



Francis Burnett shared the experience of centralizing procurement of medicines among the Eastern Caribbean States, comprising nine countries²⁴ and a combined population of around 1 million. The countries formed an economic union, the Organization of Eastern Caribbean States (OECS), with a shared currency to create a single financial space for free movement of capital goods. The OECS strategy involves aggregating resources and avoiding duplication of similar efforts, such as pooled procurement. He noted that the cost of administration alone is very high.

Financial constraints have rendered it difficult for individual OECS member governments to adequately finance medicines, 95% of which must be imported into the region. Founded in 1986 on the tenet that access to medicines is an essential human right, the OECS Pharmaceutical Procurement Service (PPS) has a mandate to maximize healthcare services of the OECS countries through pooled procurement and management of pharmaceuticals and related medical supplies.²⁵

3.2.1 OECS PHARMACEUTICAL PROCUREMENT SERVICE (PPS): ESSENTIAL FEATURES

The OECS/PPS was established to bolster member countries' ability to manage their drug supply chains by selecting and purchasing only the most essential medicines. The World Bank has shown that procurement is the pillar of drug supply chain management²⁶ that can offer the most efficiencies for cost saving. A key component of the OECS pooled procurement strategy is to provide member governments with the evidence base to purchase the best and most cost-effective medicines.

Emphasizing that the purpose of centralized procurement is to empower countries, Burnett described how the OECS features country-based committees to ensure a sense of full participation. Payments are made through countries' respective accounts at the OECS Central Bank. Suppliers will offer the best price if they have confidence in

²³ This section is based on the presentation by Francis Burnett, Organization of Eastern Caribbean States (OECS), St. Lucia.

²⁴ Anguilla; Antigua and Barbuda; British Virgin Islands; Dominica; Grenada; Martinique; Montserrat; Saint Lucia; St. Kitts & Nevis; St. Vincent & the Grenadines

²⁵ Initially financed with USAID funding, the OECS/PPS was able to become self-financing in 1989 by charging member countries a small administrative fee.

²⁶ The others being prescribing, selection, forecasting, distribution, and warehousing.

the procurement agency, and pooled procurement ensures that suppliers are paid on time. Built into the system is restricted international bidding, which ensures that supplies are prequalified and conform to good manufacturing practices. Medicines are subsidized or dispensed free of cost at the point of service in member countries.

The drug portfolio has expanded from 200 items in 1986 to 840 items (with 50 suppliers) in 2015.

Burnett provided an overview of the tendering, ordering, and payment cycle (Fig. 11).

He noted that accurate forecasting from countries has proven to be a continuing problem, so they currently use past consumption multiplied by a factor to forecast increased demand for subsequent years.

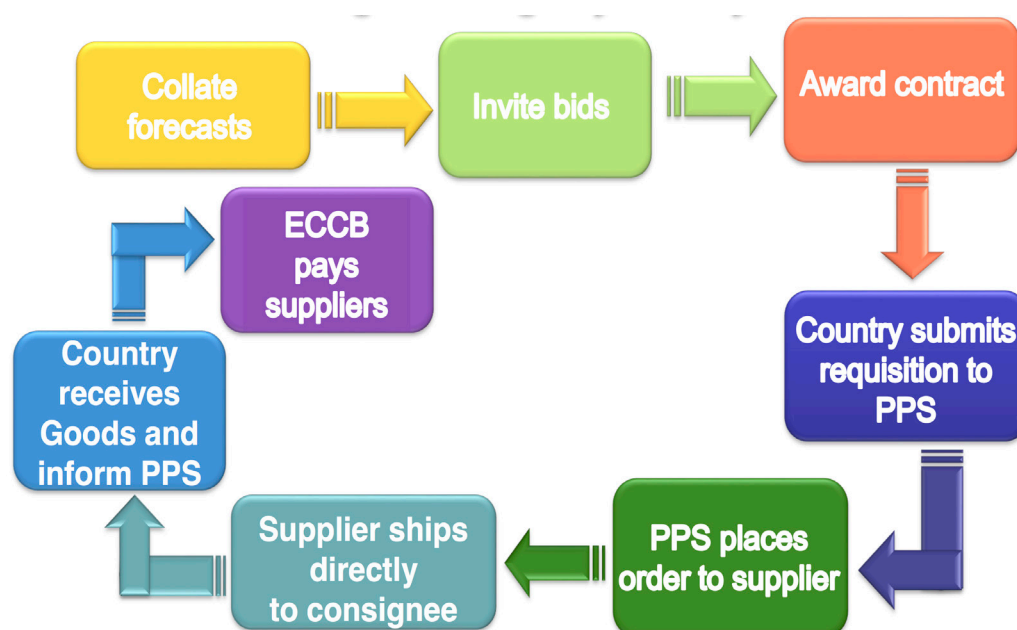
3.2.2 BENEFITS OF POOLED PROCUREMENT

Burnett described the economic and non-economic advantages of pooled procurement across and within borders.

A centralized procurement system generates economies of scale; over time, the OECS/PPS has been able to achieve a 20% unit cost reduction on medicines. Forming a monopsony with a single buyer and several sellers in the marketplace almost inevitably decreases the cost of goods by improving bargaining power. With OECS/PPS, suppliers negotiate a fixed, common price over an extended period of 18 months, whereas before, suppliers in some cases had been offering different prices to different countries in the OECS.

Burnett identified a set of non-economic, value-added benefits of centralized procurement. Buying the same market basket of goods from a restricted number of suppliers simplifies and enhances quality assurance. Training, research, and monitoring and evaluation can be coordinated. It fosters regional cooperation and integration; regular sharing of information, technology, and experience; and the harmonization of formulary manuals and standard treatment guidelines. Finally, the strict code of ethics put in place to ensure

Figure 11. Tendering, ordering, and payment cycle



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

transparent and rational procurement practices builds confidence among clients and suppliers. These measures are important in the context of evidence suggesting that up to 40% of procurement financing can be lost due to misappropriation and embezzlement.

3.2.3 ACCESS TO MEDICINES: MONITORING AND EVALUATION

To ensure that patients receive the medicines they are prescribed, the OECS/PPS has implemented a monitoring and evaluation system for access to medicines. They target a number of health centers that are geographically dispersed in countries to quantitatively determine whether patients are receiving their prescribed medications (Fig. 12).

He stressed the pooled procurement is not just a matter of lowering drug costs, but ensuring that they are good quality and available when patients need them.

3.2.4 OECS/PPS CHALLENGES

Despite having a Central Bank, there are some issues with late payments due to countries' failing to reimburse the bank within the prescribed period. He pointed to poor forecasting as the biggest impediment to their supply chain management efforts. He described donations by well-meaning organizations as giving rise to challenges of management, warehousing, and forecasting. Despite member countries being contractually obligated to purchase medications through the program, purchasing outside the cartel still happens occasionally. Because they are a small market, even with their demand aggregated, suppliers will sometimes give preference to purchase orders from larger markets.

OECS/PPS pooled procurement has produced significant benefits for the Eastern Caribbean countries. Not all interventions require significant resources: removing operational impediments and administrative barriers can have a significant impact.

3.2.5 KEY POINTS FROM DISCUSSION

Sowedi Muyingo²⁷ noted that the benefits of pool and bulk procurement are clear, but that pooling does not necessarily mean centralizing. He also argued that bulk pooling might not necessarily get you the best prices. In fact, by locking in prices, opportunities may be missed for economic benefits. Based on Sowedi's experience in Uganda, key challenges are price-fixing and agreeing on the terms of tender for pricing for one year without allowing room for flexibility. Jallow argued that the benefits of pooled procurement are not limited to cost alone: sustainability, information sharing, and market intelligence are also benefits, as can be seen in the pediatric ARV example. Overall, Sowedi noted that the GDF should be applying a more open approach with the private sector, as the Global Fund has done for ARVs.

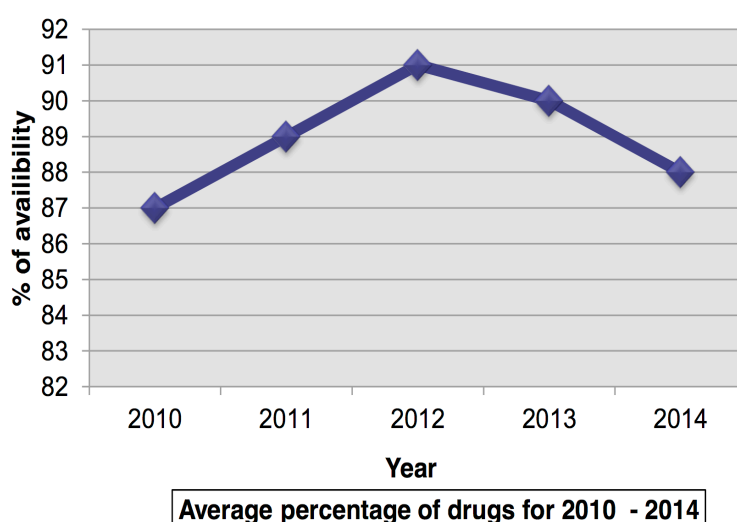
Burnett replied that in the OECS market, the countries are small, so generally, it is advantageous for them to pool resources together to get a common price. They call it "coordinated, informed buying." This way, price does not fluctuate dramatically within a period. For example, ARV cost has been relatively stable for the last year or two. In his context, he sees it as more beneficial to negotiate a fixed price for a year than to allow for fluctuations and thus complicate the tender. However, if there is a dramatic decrease in the API cost (50% of the final cost of a product), they will accept a lower cost (not a higher one).

Burnett continued that capacity is a key factor; one should look at the management of medicines and commodities, not just acquisition cost. Indeed, the OECS office he directs has a program assisting countries with forecasting, software skills, training, and continuing medical education. Monitoring the purchase orders, placing the purchase orders, and so on can be more expensive in terms of labor cost than the cost of medicine. He construed the cost of ARVs as almost insignificant due to Global Fund support—there should be no barrier to patients getting medicines. Governments by themselves tend to have inefficient mechanisms of tendering, contracting, and procurement. In the

²⁷ Sowedi Muyingo, Medical Access Uganda Limited, Uganda

Figure 12. Quantifying access to medicines, OECS

$$\text{Percentage of prescribed medicines that were dispensed} = \frac{\text{number of medicines dispensed} \times 100\%}{\text{number of medicines prescribed}}$$



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

context of the entire drug supply management chain, he contended that it is over 10 times more advantageous for a country to be part of this organized procurement network than not to be.

Sowedi expressed concern that while this may have temporary advantages, it is unclear what will happen when PEPFAR or the Global Fund are no longer on the scene, as is essentially the case with TB. Efforts should focus on pooled procurement beyond the Global Fund level, at individual countries' levels, with a larger regional pool, possibly with the help of donors, and with these same successful models with demonstrated sustainability.

Kapoor noted that TB occurs largely in tropical countries where high temperatures and humidity lead to environmental degradation of medicines. The state of drugs and efficacy is a "micro" concern but with a "macro" effect. He lamented that some fish are treated with more respect than medicines. The short shelf life of expensive drugs makes them spoil very easily, and the wasting of drugs reduces efficacy. He asked Burnett what tools he used for

forecasting and what factors other than past consumption the OECS takes into account.

Burnett replied that it depends on the class of medication, but that drug consumption is mostly stable with conservative increases each quarter, given large spending on chronic treatments in OECS.

Rigveda Kadam²⁸ asked what other indicators for access to medicines are used, such as supply interruptions. Burnett outlined four indicators:

1. Availability of medicines each day of the year
2. Inventory variation, which measures the quality of inventory control
3. Total amount of medicines physically in stock versus the amount in the electronic database, as well as typical supply chain indicators (availability, stock out, data, formulary, and stability indicators)
4. An indicator for ARVs is the value of expired medications versus the value of medicines procured²⁹

²⁸ Rigveda Kadam, Clinton Health Access Initiative, India

²⁹ His group purchases about 15 ARVs. In OECS area, they have approximate 1200 patients on ARVs, so they spend about \$120,000 a year.

Keshavjee asked whether, given that they are doing some forecasting for countries, there are times that they throw away drugs. Burnett replied that there are times they throw away expired stock. The average shelf life of most medicines is 2–3 years; about 12 months has elapsed by the time it is manufactured and shipped to the Caribbean. He remarked that small amounts of expired medicines are inevitable in any supply chain, and are not always attributable to forecasting, but rather the short shelf lives of commercial medicines and shipping times. He emphasized that this is an aspect of demand unpredictability that can be addressed by buffer stocks. He also noted that expired medicines do not become toxic the next day, so sometimes it is a bigger risk not to use them than using them when they are several days expired.

There was a lengthy discussion on the thresholds or “official” points of expiry, which can happen for many reasons. When it comes to actually getting products from the manufacturers, the Global Fund has requirements that products have 75% shelf life, Jallow noted. When it comes to the light-volume countries, delivery must be taken into consideration, but a financier like the Global Fund can mandate that the supplier have fresh production for subsequent deliveries.

Keshavjee pointed out that he was fascinated by Burnett’s success and commended his work to date. He noted that the system currently seen for TB is, in essence, “entity X is buying for entity Y using entity Z’s money”: this creates a moral hazard for obvious reasons. In contrast, the OECS is buying drugs for its own use, which ensures that it acts in its own interest.

Burnett closed by commenting that integration in the region is key, characterizing the OECS as “an economic family” with a single currency. They began by aggregating medicines, and once the HIV/AIDS crisis became important, they added supplies to their orders; in fact, 50% of the portfolio is now medical supplies. He stressed the importance of maximizing the benefit of limited resources. Keshavjee agreed and tied the idea to the larger TB landscape in the sense that a program cannot give second-line drugs without ancillary drugs, which are still not sold by the GDF, and so are purchased on the regular market separately (either by patients themselves or TB programs).

4.0 Potential BRICS country collaboration for expanded TB drug access³⁰



Photo Credit: Rede Fonte

4.1 WHAT INSTITUTIONAL PROVISION HAS BEEN AND MAY BE MADE IN BRICS SETTINGS TO WORK TOGETHER ON TB DRUG ACCESS, AND SCALE-UP ISSUES?

4.1.1 GLOBAL SIGNIFICANCE OF THE BRICS

André de Mello e Souza explored the institutional provisions within the BRICS countries—Brazil, the Russian Federation, India, China, and South Africa—to promote TB drug access and scale-up of treatment. BRICS countries account for over a quarter of the world's geographic area and GDP, and roughly 40% of the world's population. BRICS was not a political coalition until 2009, when it

established the political objective of exerting influence in global institutions such as the International Monetary Fund and World Bank.

Health ministers from the BRICS countries convened for the first time in Beijing in 2011 and have since launched several initiatives, such as the Technological Cooperation Network Initiative (2013) to promote the transfer of and access to technologies—such as information and communication technologies—that promote increased availability and lower prices of medicines in developing countries. The same year, the BRICS Framework for the Collaboration in Strategic Health Projects was established, comprising three dimensions: public health, health care systems, and biomedical sciences.

³⁰ This section is based on the presentation by André de Mello e Souza, Instituto de Pesquisa Economica Aplicada, Brazil

4.1.2 BURDEN OF TB IN BRICS COUNTRIES

WHO data show that BRICS countries' burdens of TB are quite high (Table 1).

Collectively, in 2013 the BRICS accounted for 43% of all incident cases of TB and for 40% of all TB-related mortality. Together, China and India are home to 34% of incident cases (2013) of the estimated global burden of TB. Brazil alone accounts for about one third of the Western hemisphere's estimated burdens of TB and MDR-TB. China, India, and Russia account for 52% (2013) of the global burden of MDR-TB. South Africa accounts for 30% of the estimated global number of incident cases of TB-HIV co-infection.

Development aid has often overlooked the burden of TB in the BRICS: for example, USAID considers the BRICS countries ineligible for aid. Consequently, the BRICS provide 96% of the funding for their own TB initiatives. De Mello e Souza argued that it would be beneficial for Official Development Assistance to be available to the BRICS for several reasons; not only do they account for a proportionately large share

of the global burden of MDR-TB, but they could provide an advantageous platform for programs such as multilateral arrangements among developing countries.

4.1.3 INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO NEW TB DRUGS

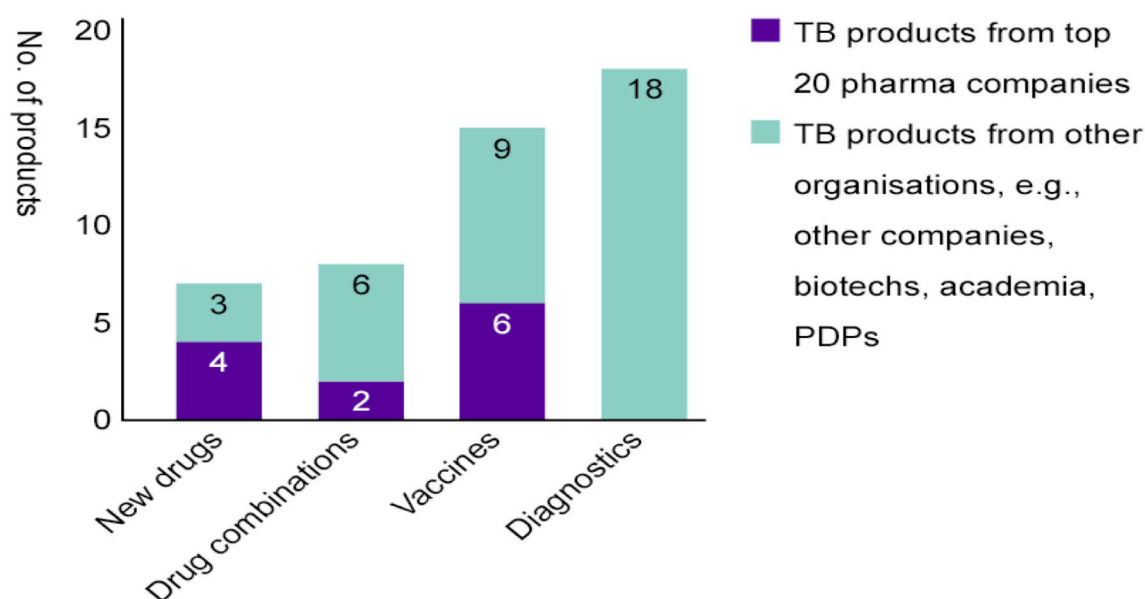
De Mello e Souza explained that there has been a failure of the market for TB drugs and other neglected diseases because pharmaceutical companies are not incentivized to enter the market. To rectify this situation will require either research and development by state entities, or incentives provided by the state to the private sector. According to the Treatment Action Group, global spending on TB research and development declined by US\$30.4 million between 2011 and 2012, and the Phase I drug pipeline is currently empty. He described how intellectual property rights can intensify market failure when pharmaceutical companies funnel resources into other drugs with more financial potential, which tend to be treatments for the health problems of the rich³² (Fig. 13):

Table 1. BRICS TB Burden

	Brazil	China	India	Russia	South Africa
2011 population (million)	197	1,348	1,241	143	50
Total TB Cases reported (2011)	84,137	911,884	1,515,872	159,479	389,974
% MDR-TB among new cases (2011)	0.91	5.7	2.1	20	1.8
% MDR-TB among relapse cases (2011)	5.4	26	15	46	6.7
TB-associated deaths (2011)	5,600	47,000	300,000	22,000	25,000
TB death rate per 100,000 (2011)	3	4	24	16	49
% TB patients HIV-positive (2011)	20	2	6	5	65
Total 2012 budget (US\$ Millions)	86	367	219	1,204	--
% Domestic financed (2012)	91	--	54	100	--

Source: de Mello e Souza presentation at April 2015 TB Innovation Workshop hosted by HMS Center for Global Health Delivery–Dubai (2011 data)

³² He cited the example of AstraZeneca's abandoning early-stage research and development for malaria, TB, and neglected tropical diseases to focus instead on cancer, diabetes and hypertension.

Figure 13. TB products currently in clinical trials from top-20 pharmaceutical companies³³

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

Those TB products that were in clinical trials in 2012 are likely to already be patent-protected in BRICS countries. Experience suggests that patents create monopolies and reduce access to drugs, while less expensive generic versions push the price of a brand name down. De Mello e Souza predicted that intellectual property rights might create monopolies that would render more than half of the seven new drugs developed for treating MDR-TB unaffordable.³⁴

4.1.4 DRUG PRICING IN CONDITIONS OF HIGH INCOME INEQUALITY

De Mello e Souza pointed to an argument sometimes made that when drug companies are present in poor countries, they are likely to lower the price of drugs because people cannot afford them. As the price declines, the volume of sales increases significantly. However, in conditions of more income inequality, the price elasticity is much lower, and therefore revenue is maximized by higher prices and lower volume of sales.

4.1.5 INTELLECTUAL PROPERTY RIGHTS PROTECTION AND AIDS TREATMENT IN BRAZIL

In the late 1990s, Brazil's AIDS Treatment Program was the first of its kind to guarantee free and universal access to ARVs to everyone in a country. De Mello e Souza characterized the program as groundbreaking because it contradicted the conventional wisdom on health policy, which held that developing countries should concentrate on prevention rather than treatment. He explained that Brazil stood in strong opposition to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in 1995, but failed to exploit the 10-year transition period for drug patenting, and a new intellectual property rights law came into force in 1997. AIDS non-governmental organizations pressured the government to provide free and universal ARV therapies, but imported ARVs were too

³³ Sources: Access to Medicine Index 2012; WHO; Treatment Action Group; Stop TB Partnership

³⁴ For instance, Johnson & Johnson's bedaquiline, Sequella Inc's SQ109 compound, and Otsuka Pharmaceutical's delamanid have patents granted or pending in high-burden BRICS countries. Pfizer's compound sunitinib has patents in Brazil and China, but not in India.

expensive. The agreement permitted government production of unpatented ARVs that were commercialized in Brazil before 1997, so state labs began manufacturing unpatented ARVs using active ingredients imported primarily from India. Threats of compulsory licensing allowed the government to negotiate price cuts for patented ARVs with multinational companies: if companies did not provide appropriate price discounts, the government would issue a compulsory license and break the patent monopoly (e.g., Merck's efavirenz was compulsory licensed in 2007). ARV prices plummeted, as did death rates, TB infections, and hospitalizations (Fig. 14).

Brazil purchased so much API that drug prices were driven down. Despite an increase in the number of patients, the cost of treatment decreased significantly. The U.S. government acted on behest of patent-holders by pressuring Brazil with sanctions (1986) and a WTO panel (2001).

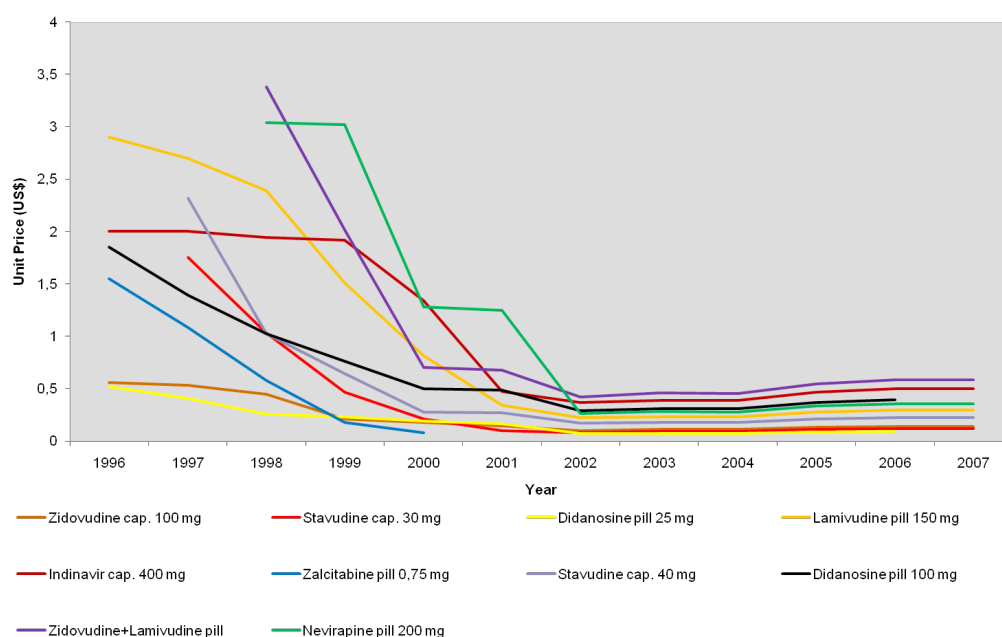
The sustainability of Brazil's program is challenged by lack of manufacturing capacity and uncertainties surrounding the supply of active ingredients from India, increasing ARV costs and rendering threats of compulsory licensing less credible. However, new public-private partnerships have been established between the government and pharmaceutical multinationals to jointly produce ARVs.³⁵

4.1.6 INTELLECTUAL PROPERTY RIGHTS PROTECTION OF DRUGS IN INDIA

India is the fourth largest producer of pharmaceuticals in the world and the largest exporter of generic medicines to developing countries. Nearly half of all drugs used to treat AIDS globally are produced in India, and the country exports drugs to more than 150 countries.

India also strongly opposed TRIPS, but unlike Brazil, it did exploit the full 10-year

Figure 14. Costs of unpatented anti-retrovirals in Brazil, 1996–2007



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

³⁵ Far-Manguinhos and Bristol/Nortec for the production of atazanavir by 2016; LAFEPE and Merck/Nortec for the production of raltegravir by 2016.

Box 4-1 How can the BRICS be compelled to act on TB?

Given the impact of TB in the BRICS and in many developing countries, during their 2014 meeting in Brazil the BRICS health ministers issued a communiqué agreeing to develop a cooperative plan to target TB. The approved plan includes the development of a common approach to:

- Providing universal access to first line anti-TB medicines for all patients within BRICS countries, as well as in low- and middle- income countries
- Encouraging scientific research and innovation for diagnostics, treatment, and TB service delivery (including for drug-resistant TB)
- Sharing technologies, identifying manufacturing capacities, and determining means of financing
- Aspiring towards a 90-90-90 TB target: 90% of vulnerable groups screened; 90% cases diagnosed and started on treatment; and 90% treatment success rate

De Mello e Souza noted that as a declaration of intentions, the communiqué has no real teeth, but it may have political significance. It does include measurable treatment targets, but it makes no mention of the important issue of quality-assured drug procurement. The key challenge will be to make TB a politically salient issue, but unfortunately, the epidemiology of TB (socially and politically) is not sufficient to make it a relevant issue in many contexts. In this respect, he urged that making significant progress against TB will necessitate extending the responsibility for doing so beyond the health ministers to finance ministers, ministers of foreign affairs, international trade ministers, and multi-lateral organizations such as the WHO and UNITAID. He suggested that in addition to technical support, think tanks and business can also serve as valuable channels for political influence. Ultimately, finding new and potent ways to frame the core consequences of unchecked TB is crucial: framing options include the human rights, the economic impact, and the national security perspectives. He called for adopting ambitious measures like those that have been effective against HIV/AIDS.

transition period afforded by TRIPS.³⁶ However, amendments in 1999 and 2002, and a 2004 decree, garnered criticism for ignoring the flexibilities permitted by both TRIPS and the Doha Declaration. Two major changes in the new Indian intellectual property rights law are the granting of patents for pharmaceuticals, and the extension of the patent term to 20 years. The new law does provide ample grounds for compulsory licensing (including the failure to supply exportation markets with goods patented in the country), and such licenses may be granted to the private sector and to many producers.³⁷ There are mechanisms in place to provide for pre- and post-grant oppositions to patents. Many of the provisions of Indian intellectual property rights laws are currently being challenged in court, and jurisprudence still being created.³⁸ In 2015, the major challenges to the patent law and India's potential to export generics worldwide are a Free Trade Agreement with the European Union and a proposed bilateral investment treaty with the United States, which threaten to change data exclusivity and patent linkage provisions in Indian law.

4.1.7 INTELLECTUAL PROPERTY RIGHTS PROTECTION AND AIDS IN SOUTH AFRICA

South Africa has the highest number of both prevalent and incident cases of HIV/AIDS in the world. A 1999 bill permitted the Health Ministry to engage in parallel importation and facilitated the issuing of compulsory licenses for pharmaceuticals South Africa, which led to retaliatory threats from the United States and a lawsuit by the major multinational companies in 2001 in the Pretoria High Court. The former government resisted measures to extend ARV treatment by questioning its effectiveness, but AIDS treatment policy was ultimately implemented largely in response to lawsuits filed by activists and judicial decisions. Currently, Aspen Pharmacare produces

most of the patented ARVs used in South Africa through voluntary licenses. As of 2015, no substantive examination of patents has been made in South Africa, and as a result, thousands of patents have been registered to cover minor or trivial developments that can block local production or importation of lower-priced generic medicines.

4.1.8 INTELLECTUAL PROPERTY RIGHTS COOPERATION WITHIN THE BRICS COUNTRIES

De Mello e Souza suggested that there is ample ground for collaboration in intellectual property rights, noting that the BRICS (excluding South Africa) are of great concern to the United States.³⁹ However, their potential cooperation with respect to intellectual property rights would face the opposition of powerful interests. India, Brazil, and South Africa (IBSA) defended very similar positions regarding intellectual property rights in international regimes.⁴⁰ The New Delhi IBSA Summit Declaration (October 15, 2008) expressed an agreement regarding the need for trilateral cooperation on global standards for intellectual property rights protection.

Widely diverging experiences among the BRICS with respect to both intellectual property rights and access to medicines increase the potential for fruitful cooperation. For instance, South Africa may learn from Brazil and India about carrying out substantive examination of patents; Brazil needs access to Indian active ingredients, and may learn from Indian legislative innovations in reforming its 1997 intellectual property rights law and from South Africa's use of voluntary licenses and its regulation to ensure price transparency in the pharmaceutical sector.

De Mello e Souza pointed out that transnational cooperation has already been happening in an ad hoc fashion among these countries, with a notable case being Brazil's and India's refusal of the patent for the ARV

³⁶ India's legislation was only changed to conform to TRIPS in 2005.

³⁷ The law seeks to prevent "ever-greening" and frivolous patents by stipulating that "an inventive step involves technical advances as compared to the existing knowledge or having economic significance or both," and that "a pharmaceutical substance is a new entity involving one or more inventive steps."

³⁸ Novartis tried to challenge Section 3(d) of the Indian IPR law in Chennai High Court, but failed.

³⁹ BRIC score lowest on Intellectual Property Protection Index of U.S. Chamber of Commerce

⁴⁰ Doha Declaration (WTO, 2001) and Paragraph 6 TRIPS Amendment; Development Agenda (WIPO, 2007); World Health Assembly Resolutions (WHO).

tenofovir. The BRICS Intellectual Property Offices Cooperation Roadmap was launched in 2013, seeking to improve efficacy and promote free exchange of information. De Mello e Souza conceded that one major contradiction that emerges when considering intellectual property rights protection in BRICS economies is that countries are incentivized to provide less protectionist intellectual property rights laws to facilitate greater access to essential medicines at lower prices. However, such lax systems would not protect incremental innovations of in-country producers, but only the radical and substantive innovations made primarily by foreign producers.

4.1.9 SUMMARY AND WAYS FORWARD

Though health does not appear as a priority on the BRICS agenda, cooperation on health-related issues is possible and progressing because promoting health is a generally agreed-upon goal, according to de Mello e Souza. However, intellectual property rights and drug costs are not the only barriers to collaboration. Cooperation will require addressing political and redistributive issues, overcoming coordination and collective-action problems, and increasing delivery capacity to match the increasing number of patients.

De Mello e Souza emphasized that health issues become politically salient through the actions of activists, not merely by their significance in terms of mortality and morbidity. These actors occupy little political space in non-democracies, so IBSA democracies therefore may have a greater chance of advancing cooperation on health issues amongst themselves than do the BRICS countries. Furthermore, India, Brazil, and South Africa are more similar to each other in terms of capacities than they are to the more economically powerful China or to Russia, which is not a developing country. The politically focused BRICS coalition has subsumed and weakened IBSA, which tends to be better equipped to drive concrete cooperation projects. But because BRICS is a loose coalition, de Mello e Souza called

into question its potential willingness to face strong external pressure to reform global intellectual property rights rules as well as its ability to resist cooptation by the West.

4.1.10 KEY POINTS FROM DISCUSSION

Editor's note: This discussion took place before the formal launch of the New Development Bank (the BRICS countries' development bank)

Peter Yu⁴¹ disagreed with de Mello e Souza's characterization of challenges in the BRICS countries as rooted in strong protection of intellectual property rights. Yu made the argument that BRICS countries are unclear on incremental innovation, so they need strong intellectual property rights protection. Some countries have been able to tailor their patent system to cover incremental innovation, but do not cover breakthrough innovation effectively. A good example, he said, was India's old system, in which there was protection for a process patent, but not a product patent. Yu shared de Mello e Souza's concern about how they can make adjustments under the TRIPS regime. But the challenge will be how to handle intellectual property rights when pharmaceutical companies in these countries aim for breakthrough innovation, and increasingly, start to see the benefit of stronger patent protection. Yu argued that it seems that the BRICS countries will move towards a model that focuses on breakthrough innovation.

Keshavjee noted that at this moment, the access questions around TB are quite different from those around HIV, given that there are unlikely to be new TB drugs other than bedaquiline and delamanid in the near future. Nicholson asked what are the alternate channels being pursued by IBSA, to which de Mello e Souza answered that IBSA has been emptied and weakened by BRICS itself. When South Africa joined, IBSA became a subset of BRICS (in a move initiated by China). IBSA has not had a summit since 2011.

Regarding the recognition of quality-assured drugs in different countries, de Mello e Souza noted that countries would need to rely on each other. He suggested that perhaps

⁴¹Peter Yu, Drake University Law School, U.S.

Brazil and South Africa have more reliable quality assurance systems than the others, so maybe they could move bilaterally. Kes-havjee noted that there is potential for even subsets of BRICS countries to work together on drug supply; two or three countries could buy from each other rather than go through a third party (like the GDF or IDA). He pointed out that while Brazil is not a drug supplier on the global market for the Global Fund or GDF because it does not have a stringent regulatory authority, it does make TB drugs.

Burnett noted that de Mello e Souza mentioned bilateral collaboration, and suggested that the BRICS countries should explore that opportunity by starting slow. He noted that the OECS began with six countries, and others joined later. Politically accountable governments are the strong binding force for the program, Burnett noted, and he urged de Mello e Souza to look at the common forms of government between Brazil and South Africa.

Various participants pointed out that while the idea of creating cooperative systems among BRICS countries is appealing, some aspects of the existing relationships among BRICS countries may present a challenge. Examples included:

- Geopolitically, there are many mutual suspicions to allay among the BRICS countries.
- Drug supply relationships among BRICS countries are complex. For instance, Brazil is dependent on APIs from India, which is a potentially threatening situation for Brazil. On the other hand, India is dependent on APIs from China. In addition, 80% of HIV, TB, and malaria drugs come from India, and India wants to protect that market.
- The procurement systems within India and the ability of the government to manage its own procurement without depending on external agencies are limited.

De Mello e Souza agreed that challenges exist, and argued that while health ministers are all committed, other actors have to be involved, and that the governments themselves should be more wholly committed to health as a priority rather than as a side effect of economic development.

Jallow mentioned that when it comes to TB, the markets are getting more fragmented. Much was achieved in the ARV market, she argued, because countries took a stand from the onset. In TB, from the Global Fund perspective, donor financing is never going to be high enough to make an impact on the market. BRICS countries are spending a lot on TB, but it is fragmented. Therefore, the issue is how the BRICS can shape the market and get prices down. The challenge, she argued, is who should take the lead and push for this kind of advocacy. WHO continues to develop guidelines, but it is not in the position to catalyze change in terms of implementation. An organization outside the United Nations bodies is needed, Jallow argued. The GDF, for example, is in talks with Brazil about using their own funds to procure drugs. If Brazil is spending more of their own funds annually on drugs than what is spent through the GDF, she asked why the collaboration is going in this direction. Brazil could align with the GDF to shape the market, and it needs some kind of leadership outside of the WHO to be able to sustain such a political push.

Cori Vail⁴² noted that things are already happening to show there is cooperation within the BRICS. New BRICS working groups on TB are promising, and reducing the number of key drugs for MDR-TB down to a third of the typical regimen today would also be helpful. She echoed earlier statements to start small in order to build cooperative mechanisms and momentum.

⁴² Cori Vail, Janssen, U.S.

Nicholson noted that he has had many conversations with academics who claimed that there would never be a BRICS development bank. But now, the announcement of the New Development Bank has been made, and the BRICS are waiting for the financial institutions to sign off, which seems likely to happen [Editor's note: the BRICS development bank has been funded as of September 2015]. Five years ago, the BRICS were not talking about health except in terms of very general targets. But, he argued, accountability politics is how these types of political movements start. He advocated for picking a certain area that is bounded in the TB space, and that is not ambitious (and thus not threatening to any domestic drug producers), and then funding a small delivery project to show best practices, even if just between two countries. Nicholson argued that a bilateral project between India and Brazil could be done relatively cheaply, given their infrastructures and mutual strengths. Numerous bilateral arrangements have accomplished similar goals in other fields. If there are people committed to developing clear structures for these ideas at the BRICS, Nicholson argued that they can be implemented in a way that is

not confrontational even to IP regimes, and that also has some chance of success given the historically unique cooperation over the last ten years between member countries.

Other participants asked de Mello e Souza to elaborate on his position on whether intellectual property protection is helpful or not. He replied that there is political tension in emerging economies on this issue. In some countries, companies are able to carry out incremental innovations and be recognized with protections by patent regimes for these. Under a less protectionist intellectual property rights system, certain local companies will not benefit because patents are only granted for the radical, deeper innovations of foreign companies and not process innovations. He explained that while there is pressure in Brazil and India for a more protectionist system to benefit local companies, the trade-off is an increase in cost and decrease in access to essential goods such as medicines.

4.2 An overview of the political landscape in BRICS regarding essential medicines: a look at collective action options⁴³



4.2.1 RATIONALE FOR COLLECTIVE ACTION BY BRICS COUNTRIES

Peter Yu provided an overview of potential options for collective action among the BRICS countries with respect to their current political landscapes. He began by citing several reasons in support of collective action. It can:

- Shape a pro-development agenda
- Articulate more coherent positions among the BRICS countries
- Create a united front to take advantage of their negotiating and manufacturing capacities
- Establish a powerful voice for developing countries in the international arena
- Provide economies of scale and scope
- Bind participating members together

He noted that each of the BRICS countries is advantageously linked by geography to its respective region,⁴⁴ which will help

promote regional cooperation. Even though BRICS started as a political entity promoted by investment banks and economists, the geographic distribution of the BRICS countries makes them a logical group to spearhead efforts to improve access to medicines by way of regional groupings. They have numerous strengths, e.g., strong manufacturing and negotiating capacities; a lucrative middle-class market with many potential customers, which entices pharmaceutical companies to develop and distribute drugs; and less vulnerability to development-related problems. They serve an active leadership role in the developing world.

4.2.2 OPTIONS FOR COLLECTIVE ACTION

Yu suggested several possible configurations for collective action. Within BRICS, partial alliances are more likely to take place than a full BRICS coalition, the establishment of which requires significant coordination. In addition, the BRICS countries might join with

⁴³ This section is based on the presentation by Peter Yu, Drake University Law School, U.S.

⁴⁴ South America, Central/Eastern Europe, South Asia, East Asia, and Africa

middle-income countries that share similarities with the BRICS. Given the potential growth of other middle-income countries, Yu emphasized that it is important not to be fixated on the BRICS countries and ignore the potential role that other middle-income countries could play. He noted that among the top-30 economies with a gross national income of less than US\$15,000 per capita and considerable volumes of high-technology exports are China, Brazil, India, Russia, Indonesia, Argentina, South Africa, Thailand, Malaysia, and the Philippines.

While the BRICS countries can work with governments of developing countries, Yu suggested that they would also work with the private sector or NGOs within developing countries on issues related to access to medicine. In addition, there is also a chance that the BRICS countries would align with the stance taken by developed countries in terms of intellectual property protection, thus undermining the potential for collaboration within developing countries.

4.2.3 OPTIONS FOR BRICS COLLECTIVE ACTION

International norm-setting

Yu situated the discussion of pharmaceuticals in the context of the Doha Declaration. The August 30th decision set up a waiver, and the TRIPS art. 31bis was the first proposed amendment to the TRIPS Agreement, which is now going through the ratification process—this amendment allows countries with insufficient or no manufacturing capacity to import generic versions of patented pharmaceuticals (compulsory licensing). Within the WTO, an amendment has to be ratified in order to take effect; ratification of the amendment has been extended every two years (5 times so far), and it is not certain whether the required two-thirds of the WTO membership will agree to it during this period.

Many discussions on intellectual property rights enforcement have taken place in the WTO TRIPS Council, which is responsible for administering the TRIPS agreement. Yu also discussed the WTO Dispute Settlement Body. While an effective forum for discussion, because it is very expensive⁴⁵ to take a case to the Dispute Settlement Body, the use of the mechanism is not equitable for all countries. While smaller countries may not even try to use the mechanism, the BRICS countries have the resources to do so, and this process can be effective, particularly if countries are lodging joint complaints.⁴⁶

According to Yu, the World Intellectual Property Organization's (WIPO's) development agenda, which started as a response to the effort to negotiate a Substantive Patent Law Treaty, is a frequent topic of discussion. There is now much discussion within the organization on both the development agenda and the strong intellectual property rights protection. Most recently, the organization negotiated a treaty⁴⁷ that establishes copyright exceptions to facilitate the creation of versions of copyrighted publications that are accessible to the visually impaired. This action suggests that the organization is willing to engage in discussion about special exceptions for people in need.

Advocates often turn to the WHO, as an international institution set up under UN auspices, as well as to human rights forums. Public health and human rights discourses often enter into intellectual property rights discussions, and debates around access to medicine. However, he cautioned that statements from these forums are often closer to recommendations than ministerial declarations in terms of substantive impact, and that these forums have limited power to set international intellectual property norms.

⁴⁵ Based on 2004 figures, one claim costs about \$300,000-\$400,000, and cases of complaint with respect to a patent dispute can involve more than one claim.

⁴⁶ For example, Brazil and India have made two complaints about seizure of generic drugs in transit. They claimed that the drugs would be seized by customs in transit airports (e.g., Amsterdam and Hamburg, which were transit stops, not final destinations, for the shipments). The claim is that the drugs should not have been seized because they were not being sold in the transit countries. At that time, India was planning to negotiate a free trade agreement with the European Union; thus they were able to get the European Union to change their customs procedures. Yu predicted that this change will make it easier to negotiate the free trade agreement.

⁴⁷ The Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled

Yu remarked that the BRICS countries are included among neither the 11 countries negotiating for the Anti-Counterfeit Trade Agreement nor the 12 countries negotiating for the Trans-Pacific Partnership. Some of the BRICS Countries (China and India) are negotiating the Regional Comprehensive Economic Partnership, but it is unclear how this will play out, given that the latter Partnership includes seven members of the Trans-Pacific Partnership. He posited that there are unlikely to be two different regimes in Asia, so only one will likely prevail. Yu commented that at the moment, there is more intellectual property rights discussion in the Trans-Pacific Partnership than the Regional Comprehensive Economic Partnership.

Intellectual property reform

Elaborating on the previous discussion, Yu highlighted the need to understand WTO TRIPS flexibilities, citing Section 3(d) of Indian patent law, which raises the standard with respect to the inventive step—it should be clear what an inventive step is. Compulsory licenses, or government-use provisions, are a key factor that exists in the United States as well. A major problem is the lack of data exclusivity and concerns about whether clinical trial data can be protected, e.g., should it be based on fair commercial use or will a special regime be set up to protect clinical trial data. Enforcement will need to play a role in ensuring drug safety. Generally, Yu suggested

that BRICS countries are well placed to explore different models of innovations, including:

- Patent protection
- Liability rules (torts)
- Prizes (advanced purchase commitment)
- Public funding / subsidies
- Public-private partnership
- Open innovation
- Public domain

In between patent protection and the public domain, there are different types of rules and systems that can provide incentive for innovation. BRICS countries can explore the types of options that would be most effective in promoting access to medicine within the region.

Regulatory coordination

Potential options for regulatory coordination include:

- Efficacy, quality, and safety inspections
- Drug registration and approval
- Harmonization of technical standards
- Use of bioequivalence studies
- Use of clinical trial data
- Information sharing mechanisms

BOX 4-2 Resource allocation and the New Development Bank as a paradigm shift

Yu reminded the group that resource allocation is ultimately about funding supply, so the yet-to-be-established BRICS bank is a significant issue (at the time of publication, the New Development Bank (NDB) has been established). Yu stressed that when the NDB is established, it will be a game changer in much of the supply discussion. A key question will be whether it is able to allocate resources for stockpiles or rotating stockpiles. In terms of procurement, he suggested that the BRICS countries could be used as bases for regional supply centers. If the BRICS countries are willing to commit resources in advance, then advance purchase commitments could make the market much more attractive. Other areas where the NDB could contribute include research and development for drug development and manufacturing technology, support for new financing and contracting structures, and prizes and other new incentive schemes. Yu maintained that given the BRICS countries' collective resources, they have substantially more economic power than other countries.

Yu suggested that community-wide harmonization of standards among the BRICS countries is unlikely, but there are opportunities for streamlining and cooperation with fast-track processing. For example, implementing a patent prosecution highway would mean that the outcome of a claim examined by one patent office would be recognized by the other countries' offices.

Technical cooperation

It can be difficult to determine what kind of technology to transfer, as well as the kind of training and technical assistance needed. Sharing of best practices is an issue that is often included in policy language, but less often taken as an actual action.

Infrastructural development

Yu noted that infrastructural development is quite important, and is feasible with more resources as countries are already working together. China has been very active in Africa, both for good and for bad, so TB programs or other health delivery projects could take advantage of that capacity for project implementation in Africa. BRICS countries are ahead of other countries in terms of working out logistical issues, and they may be able to share their experiences in this area.

4.2.4 CONCLUSION: CAUTIOUS OPTIMISM

Yu concluded on a note of cautious optimism, stating that there are many promising features that could facilitate cooperation. However, he suggested that it will not be easy, citing the occasionally contentious relationship between China and India as an example of a significant challenge. In addition, he said that China in particular is eager to work with and emulate more advanced countries such as Germany or the United States, in addition to working with similarly-situated BRICS countries.

Going forward, some of the challenges to greater collective action among the BRICS countries that are not specifically related to intellectual property protection or access to medicine, but that will nonetheless be important, are:

- Historical conflicts
- Border disputes
- Economic rivalries
- Cultural differences
- Xenophobia and nationalism
- Mistrust and resentments

Yu referred to earlier studies predicting that given the same rate of growth, the BRICS will overtake the developed countries' economies within 40 years. Conceding that there are many factors that could impede their growth trajectory, he suggested that BRICS collective action would provide for a promising solution to drug access issues, delivery of care, and institutional cooperation. But if things do not go as expected, it is crucial to prepare for how to adjust mid-stream.

4.2.5 KEY POINTS FROM DISCUSSION

Keshavjee highlighted the potential for fast-tracking needed medicines between BRICS countries as very promising, even if it is not full harmonization. Yu replied that the difficulty is figuring out the appropriate areas for fast-tracking—registration will be easier than safety inspection, for example. More work has to be done looking into fast-tracking, he said.

Keshavjee elaborated on Nicholson's earlier comment, suggesting that two or more of the BRICS could delve deeply into the issue

of fast-tracking in the TB space. Yu was cautiously supportive of the prospects, and noted that the global effort for HIV/AIDS could be an example, in terms of innovative challenges to the IP regime in Brazil. Fast-tracking needs to be a process that can be used across different diseases, Yu argued. It is much harder to single out TB or malaria and to change the regulatory process for that particular disease area, but that does not mean that countries may not be willing to try. For example, China is much more willing to do economic experiments in places that are further away from Beijing, so they do not have to worry about the impact on the whole country. As a starting point, he suggested isolating TB as a disease area with consensus on the need for action, and not requiring dramatic change in the entire regulatory process.

Participants asked why BRICS countries would be interested in collaboration with each other rather than using the existing WHO prequalification system. Yu replied one reason is that if they want to expand beyond the prequalification regime, they might want a system that is recognized among BRICS countries in order to show that they have an inclusive process. Yu suggested that the BRICS countries might want to create an alternative or complementary structure if they are dissatisfied with the current available structures for drug qualification. He mentioned that one of the drivers behind the establishment of the New Development Bank was that BRICS countries were frustrated by the existing international economic structure in general terms, and this could be an example of reforms for BRICS to undertake in terms of reordering economic and international institutional structures.

Collins asked Yu to suggest things that would be a “win-win” for BRICS countries—for example, sharing best practices, which could lead to progress without political risk. Yu again argued that it is difficult to find similar current

experiences, for various reasons. China is less transparent than it used to be, and less willing to acknowledge the scale of its health problems, although reporting accuracy is getting better. Usually Brazil and India are the leaders pushing the development agenda and health efforts, which may affect how fully they are integrated into BRICS decision-making. The big question, Yu noted, is what types of things will get China to work with the other BRICS countries and how they can leverage their new position. Yu’s overall answer to Collins’ question was that it is more important to look forward to what areas can galvanize support, rather than look back for success or failure stories, because the landscape is very different.

An industry representative commented on regulatory coordination, arguing that one can see from the bedaquiline experience that a regulatory effort to file in different countries provides a benefit for the company commercializing the drug. There is a huge advantage for any company coming into this space, she said. All of the BRICS countries do the job of registering a new drug relatively well, so fast-tracking is more reasonable than full harmonization. She expressed concern over the proposal to create a process just for TB; given that there may not be too many drugs in the pipeline, the special regulatory process might not be used.

Yu argued that while it would be very helpful to get countries to cooperate with each other with regard to patents, the individual countries need to have a certain quality track record before there can be trust, and there are other reasons that can prevent cooperation. For example, within China, there is much talk about combining intellectual property offices for more effective enforcement. However, offices do not want to give up personnel, budget, and control over propaganda and censure. These factors are not related to intellectual property at all, but they still prevent cooperation, he noted. Yu argued that a first priority should be

to look at factors like budget, personnel, and administrative structure that would prevent cooperation. One reason some countries are more willing to cooperate on patent issues is the TRIPS Agreement's harmonization of standards; however, other areas are not as harmonized. Yu predicted that eventually BRICS leadership will see the problem created by lack of access to pharmaceuticals.

De Mello e Souza noted that politically, the reason it is difficult to bring TB to the forefront of any agenda amongst the BRICS countries (and other countries) is that even though TB brings significant losses, these losses are diffuse and not highly visible. Given the way that the Severe Acute Respiratory Syndrome outbreak changed the way that China approached significant health issues, he wondered if it would take a catalytic event to make TB more salient.

Yu agreed, and noted that it is instructive to think about the H5N1 and H1N1 flu outbreaks and how media covered them because they were new—there was a scare factor. The problem with TB is that the epidemic has been going

on for so long; the statistics are not as salient to the public or to the mainstream media for coverage. The group then had a longer discussion on the “branding,” informational campaigns, and political leverage that should or should not be pursued around TB. The group agreed that policy makers and governments needed to see more examples of specific places where the right pieces were put into a comprehensive program in resource-challenged settings with clearly positive results. The “cost-effectiveness” arguments regarding TB treatment are numerous, but these pale in comparison with projects that can demonstrate the transformative power of high-quality drugs paired with high-quality programs.

5.0 Synthesis / Conclusion

The day's activities spanned the many technical, political, institutional, and economic questions surrounding the supply chain challenges in the second-line drug market. Innovative ideas were put forth, new partnerships proposed, and key recommended reforms were detailed. The different market fundamentals of the second-line TB drug supply chain, as

compared to drugs for other diseases, presented the group with a challenge, but also with an opportunity to think about the creative role that may be played by the BRICS bloc to drive further access to high-quality TB medications in high-burden countries.

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Appendix A. Agendas



**CENTER FOR GLOBAL
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MEETING AGENDA

Exploration Innovations and Positive Disruptions in the Supply Chain for Second Line Drugs

16 April 2015

8:30	Shuttle bus will pick up participants at Hyatt lobby	
8:45 – 9:00	Registration	
9:00 – 9:05	Welcome	Salmaan Keshavjee
9:05 – 9:10	Goals for the day	Thomas Nicholson
9:10 – 9:50	A brief review of past and ongoing GDF initiatives for improving the supply chain, and a look forward at challenges in global uptake of quality-assured TB drugs on the demand and supply side	Joel Keravec
9:50 – 10:15	Discussion: Identifying any remaining supply chain challenges that can be addressed by new ideas and mechanisms going forward? Is the primary issue the lack of care delivery scale-up to drive a “virtuous cycle”?	Salmaan (facilitator)
10:15 – 10:45	A review of two supply chain projects focusing on incentives and forecasting in high-burden settings (Dan Collins, Lilly MDR-TB partnership)	Dan Collins
10:45 – 11:00	Coffee Break	
11:00 – 12:15	Discussion points, among other identified issues: How might we use past and ongoing improvements in the supply chain to push for higher TB patient enrollment in high-burden countries?	
12:15-13:15	Lunch Break	
13:15-13:45	Pooled procurement for ARVs: Relevant reflections for TB	Sana Mostaghim
13:45-14:15	How have national governments in other contexts worked together to pool demand for pharmaceutical products? Drawbacks and benefits from 10+ years of pooled procurement (Burnett, OECS), brief Q&A	Francis Burnett
14:15-14:45	What institutional provision has been and may be made in BRICS settings to work together on TB drug access, and scale-up issues? (Andre de Mello e Souza, DINTE, IPEA)	Andre de Mello e Souza
14:45-15:15	Coffee Break	
15:15-15:35	An overview of political landscape in BRICS regarding essential medicines, a look at collective action options (Peter Yu, Drake University)	Peter Yu
15:35-16:15	Discussion: Should new multilateral tools be considered that can support ongoing multilateral efforts in a practical way? Can these be supported by BRICS or coordinated action by high-burden countries?	
16:15-16:30	Closing Remarks	
16:30	Shuttle back to Hyatt	

Appendix B. List of Participants



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LIST OF PARTICIPANTS

Exploration Innovations and Positive Disruptions in the Supply Chain for Second Line Drugs

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