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TUBERCULOSIS PREVENTION PROJECT

Improving Quality of TB services under the New Service Delivery Mechanism in Georgia:

Key Recommendations

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LIST OF ACRONYMS

TB	Tuberculosis
PHC	Primary Health Care
NCDCPH	National Center for Disease Control and Public Health
NCTBLD	National Center for Tuberculosis and Lung Disease
MoLHSA	Ministry of Labor, Health and Social Affairs
IC	Infection Control
DOT	Direct Observed Treatment
MDR-TB	Multidrug Resistant Tuberculosis
ACSM	Advocacy, Communications, and Social Mobilization
NRL	National Reference Laboratory
LTBI	Latent Tuberculosis Infection
IPT	Izoniazide Preventive Treatment
WHO	World Health Organization
NTP	National Tuberculosis Program
DOTS	Directly Observed Treatment Short-Coursed Strategy
SSA	Social Service Agency
IDP	Internally Displaced Persons
PPD	Purified Protein Derivative
CB-DOTS	Community-based Directly Observed Treatment Strategy
USAID	United States Agency for International Development
XDR-TB	Extensively Drug Resistant Tuberculosis

1 EXECUTIVE SUMMARY

Georgia, with a population of 4.3 million people, continues to face challenges in improving access to and utilization of quality health services. In-patient and out-patient utilization rates for health services remain low due to various access related barriers. The low service utilization as well as verticalization of tuberculosis (TB) services has reduced the number of TB patients identified in the early stages of the disease. To improve the health status of the Georgian population, the government has initiated fundamental reforms of its health system with strong emphasis on privatization. Both primary health care (PHC) and hospitals have been privatized. A large number of hospitals have been built to meet the needs of local populations. The new privatized systems are responsible for providing curative and preventive care. People living below the poverty line receive state subsidized vouchers to purchase insurance while those living above the poverty line are responsible for buying their own insurance or pay directly from their pockets for services.

Under the new health system, it will be critical that appropriate mechanisms are established to ensure that TB suspects are actively identified in primary and hospital care settings and are referred to TB specialists for diagnostic and treatment services. Also, given that the private entities are building new or renovating old facilities, it is important to ensure that enough attention is paid to infection control (IC) to reduce/mitigate airborne spread of the disease.

Under the new structure, the National Center for Disease Control and Public Health (NCDCPH), the National Center for TB and Lung Disease (NCTBLD), PHC providers, and health care facility owners and investors will have specific roles in prevention and control of TB. The NCDCPH answers directly to the Ministry of Labor, Health and Social Affairs (MoLHSA) of Georgia. Likewise, other stakeholders involved in health and infectious diseases including TB, must comply with the regulations introduced by the Government of Georgia and the MoLHSA. To continue reducing TB associated morbidity and mortality, the program will need to emphasize the following:

Promotion of active case finding in an integrated service setting: To improve and increase early TB case detection, it will be critical that PHC and hospitals actively identify TB suspects and refer those identified to on-site or off-site TB facilities. Job aids and other capacity development strategies of general health care providers, as well as systems to monitor referrals from these facilities to TB facilities, will be critical. As integration of services becomes more established in primary care settings, it will also be important to explore appropriate means for expanding responsibilities of primary care providers related to TB case management and patient follow-up.

IC in co-located settings: As part of health reform, many TB facilities are being co-located within current community health centers and hospitals. It will be critical that in such situations appropriate infection control measure are utilized to minimize spread of air-borne infections. The healthcare facilities will need to develop targeted plans they can implement quickly. The NCDCPH and private service delivery organizations should develop: i) implementation plans and tools to improve IC; and ii) detailed plan for supervising and supporting IC activities in general medical facilities.

Quality DOT: All parties in the new system recognize the need for improving direct observed treatment (DOT) of TB cases with anti-TB and Multi-Drug Resistance (MDR) -TB drugs. There will be new stakeholders involved in this with varying levels of experience and there should be clear quality assurance tools developed and used for DOT. Under the new system, there is need for a lead organization to oversee and manage DOT. DOT funding will come from the state in the form of vouchers on a patient load basis (payment per patient diagnosed and treated). The professional associations should develop guidelines to standardize DOT as well as establish mechanisms to supervise the compliance of service providers with these guidelines. These guidelines should be endorsed by MoLHSA through guidelines accreditation board. DOT could be made more community-based and rely on PHC physicians and nurses working in villages and local communities as well as other community-based non-governmental organizations and the Georgian Orthodox Church. The program should consider providing incentives to people living below the poverty line for treatment continuation (including food vouchers and transportation vouchers).

Tackling the key areas identified above will require reviewing and in most cases revising or updating approaches related to:

Supervision: With multiple new public and private stakeholders in the system, there will be a number of "chains of command" with different lines of accountability. To overcome this problem, MoLHSA should identify a lead agency for supervision and support of the TB program. MoLHSA should convene a meeting of all stakeholders to identify the best strategy for supervising the TB program. Regular meeting (at least once a quarter) should be held with all stakeholders to discuss common issues and concerns.

Training: The integrated system will require training of providers on every level of the health system. So far, there are no defined competencies for the different providers and this makes targeted trainings a challenge. The TB program will need to develop: a list of competencies for all levels of providers as well as a training plan targeting these and coordinating with all groups including professional associations that provide training in the country. There would also be a strong need to develop provider skills in patient counseling and follow-up approaches.

Establishing quality indicators to track the program: The TB program is already providing regular data on key TB indicators (conversion rate, cure rate, treatment success rate, etc.). However, there is a need to record a number of other indicators to track the following: referrals of TB suspects from high volume and/or problem prone clinical services; treatment adherence by patients and providers; number of child contacts screened and put on IPT or TB treatment; among others. The current regional electronic database is an appropriate management tool for TB recording and reporting. Under the integrated system, personnel responsibilities for TB data collection need to be defined since the regional TB team database operator position has been eliminated.

Clinical structure and teams on the ground: The TB staff will now be employed directly by the general medical care facility owners. As such involvement of these new owners and their local facility managers will be critical for the success of an integrated TB service deliver program. It would be important that facility management supports the process of team building and integration of TB with various clinical services. Within the general medical facilities themselves, a supervisory and support system for the TB staff has to be detailed. Health service providers should hold regular facility-based staff meetings to discuss specific cases as well as provide ongoing training and problem solving support.

Patient centered approach: Integration has a strong potential to improve access to care, but requires providers to change longstanding attitudes related to patient care. Provider skills in counseling of patients and care givers will be critical for improving adherence and household level infection control. The integration of TB services into the general medical care facility has some potential to decreases TB-related stigma. At the same time, stigma reduction must be balanced with appropriate IC to ensure that a paradoxical increase in stigma does not occur. There will be a need to understand drivers for stigma and based on the findings develop advocacy, communications, and social mobilization (ACSM) materials that target stigma related to TB in specific communities and population groups.

The changes in the service delivery system also necessitate the review of systems related to:

Laboratory issues: In the new system, the NCDCPH will take over much of the TB lab work, with the exception of culture and drug sensitivity training (DST), which will remain with the NCTBLD/NRL. It is important to ensure the NCDCHP labs have supervision, support and coordinate well with the NCTBLD. The program should develop a clear communication and coordination plan between the NCTBLD/NRL and the NCDCPH.

Drug procurement and supply management: TB drugs and supplies are procured through the Global Fund/Global Drug Facility with the NCTBLD as the named sub-recipient. Other stakeholders may become involved in the storage and distribution of drugs. A detailed plan listing the roles and responsibilities of the various stakeholders is needed. The program should develop: an action plan for procurement and supply management which lists the roles and responsibilities of all stakeholders; and, a monitoring plan to ensure quality in drug procurement and supply management.

Many of the reforms in Georgia have been rapidly enacted and additional work will be needed to further determine needs as they arise to improve TB service access and delivery. Some of the other areas for consideration for long term improvement include:

LTBI/IPT: The proposed active contact tracing and treatment of latent TB infection (LTBI) has potential to decrease TB rates in Georgia. This is an intervention with proven effectiveness on a global scale. Multiple stakeholders within Georgia believe that this is a reasonable intervention, and the roles and responsibilities of different providers need to be defined. Detailed

implementation plans including training strategy for all levels of providers in LTBI/ Izoniazide Preventive Treatment (IPT) will be needed before rolling out this strategy.

Incentives for success: The newly integrated system is taking place within a public-private mix. While TB services will still be paid for by the state, they will be delivered in settings where profit is the driving motivation. TB care has never been shown to be profitable and there is a need for other incentives for success. The incentives at the facility, provider, and patient level, could include certificates of merit, designation as centers of excellence, provision of equipment, etc.

Ensure follow-up of discharged inmates with TB: Coordination for TB patients and suspects between the prison and civilian health sector is of concern in Georgia. The program should develop a strategy for ensuring that inmates with TB, once discharged from prisons, receive services from the local TB service points. The program should develop incentives for private TB service providers to provide coordinated care, especially given that most former prisoners will not have access to insurance.

Vulnerable populations: There are multiple vulnerable populations in Georgia who are at high risk for TB but have low likelihood of using the general medical facilities. These include persons living in Abkhazia. This population groups requires special attention and internal and external resources should be mobilized to address needs of this high risk group.

From this report, it is clear that there are multiple issues to be addressed to ensure increase in early case detection under the privatized health system in Georgia.

2 INTRODUCTION

In 2011, the Government of Georgia began a major health sector reform in the country. Key components of this reform include the privatization of health care services and the integration of previously vertical programs—including the National Tuberculosis (TB) Program—into primary care systems. While these changes have the potential to provide increased access to TB care along with quality improvement in TB services, concern remains about the handling of TB by the primary health care (PHC) system. There are now many stakeholders involved in TB control in Georgia—some public and some private—with varying degrees of TB experience and expertise. This report presents a situational analysis of the plan and progress for integrating TB care into PHC and for overall TB control in general. The first section presents an overview of the general TB pandemic and the new system for diagnosing and treating TB in Georgia. The second section presents areas in which activities will need to be focused to ensure a smooth transition from vertical to integrated care for TB. The final section will present proposed activities to support the integration of TB control into PHC. Examples from other countries that have moved to provide integrated TB and PHC services included as case series at the end of the document.

The term integration can be used to signify multiple things, but the World Health Organization (WHO) defines integration as

> *The management and delivery of health services so that clients receive a continuum of preventive and curative services, according to their needs over time and across different levels of the health system.*

There can be multiple benefits to both patients and providers when care is done in an integrated fashion. These can include improved access to care, improved continuity and quality of care, and increased communication between providers. The WHO is quick to note that integration of care should be viewed along a spectrum, should not be seen as a solution for inadequate health resources, and that there is very little data to support the actual implementation of integrated care delivery.

Integration of TB services into PHC poses some unique challenges, given the airborne spread of the disease, the stigma associated with TB, and the poor and vulnerable populations who are at increased risk for TB. Previously, TB control had been carried out through a vertical system managed by the National Center for TB and Lung Disease (NCTBLD). Under the new structure, a variety of public and private stakeholders will be involved in TB care, including the NCTBLD, the National Center for Disease Control and Public Health (NCDCPH), PHC providers, and health care facility owners and investors. The exact responsibilities and roles of each of these providers are still being discussed. The NCDCPH answers directly to the Ministry of Labor, Health and Social Affairs of Georgia (MoLHSA). All other stakeholders must comply with the regulations introduced by the Government of Georgia and the MoLHSA. Georgia has an international reputation for providing high-quality TB care and is poised to continue this strong work as part of TB integration. The program is more likely to succeed if resources and monitoring are directed in key areas presented below.

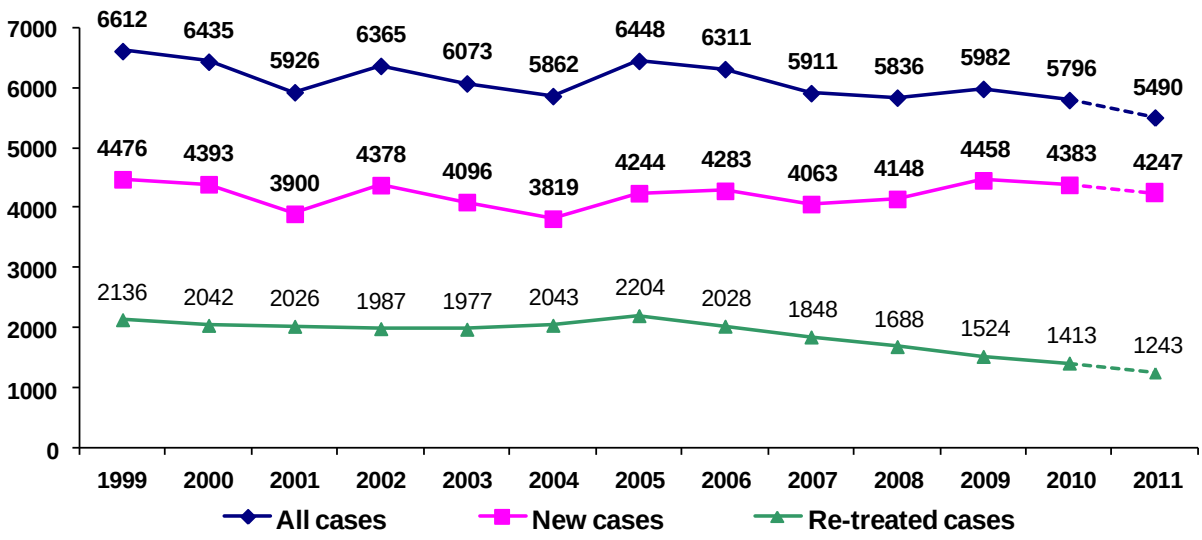
The data used to generate this report was collected from site visits and in-depth interviews with a range of participants. Interviews were carried out with the Ministry of Health, Public Health and Programs Division, the NCTBLD, the NCDCPH, PHC

directors and investors, hospital administrators, the Global Fund, the International Committee of the Red Cross, and a variety of physicians, nurses, and care providers. In addition, site assessments were conducted at two general medical facilities in Tbilisi and Sagaredjo. Finally, a review of the scientific literature was carried out to assess the international experience with TB and PHC integration. Case studies are presented at the end of this document.

2.1 TB in Georgia

Georgia currently has the fifth highest rate of TB in the European region with an estimated 100 incident cases per 100,000 population in 2010. Preliminary data from 2011 show a total of 5490 patients were registered for treatment in the National Tuberculosis Program (NTP). Of these, 4247 were new cases and 1243 were previously treated patients (see Figure 1). Outcomes among those with a positive sputum smear or culture are: success - 76%; default - 7%; died - 3%; failure - 2%; transfer out (moved to another country)- 1%; transferred to category IV treatment - 10%; not evaluated - 1%.

Figure 1: All Registered TB cases in Georgia (absolute numbers)



In terms of drug-resistant TB, 11.0% of patients newly diagnosed with TB in 2011 had multidrug resistance-TB (MDR-TB). This number was 31.5% among previously treated patients. Outcomes for these patients are still being analyzed. There were 1155 TB cases reported in the prison (21% of all reported cases) and 4335 reported in the civilian sector.

2.2 Previous Structure of TB and PHC Care Programs

Until December 2011, TB care had been provided as a vertical program in Georgia. The program was headed by the NCTBLD in Tbilisi. There were TB clinical and monitoring specialists working in each region through TB dispensaries. There were

also TB "cabinets" located under the jurisdiction of TB dispensaries, and there were "DOTS Spots" throughout urban regions. All labs had been run by the NCTBLD. There are 5 hospitals with 400 beds for TB care: 1 in Tbilisi (NCTBLD) which is the national reference TB hospital and one each in Abastumani, Batumi, Kutaisi and Zugdidi. Some of these are general Infectious Diseases hospitals with beds dedicated to TB care (i.e. Batumi). In remote regions, TB care can be provided by village doctors and nurses with supervision from the NCTBLD. Under the old system, patients could self-refer for TB diagnosis and care to TB dispensaries or cabinets and if diagnosed with TB, the costs of their care were free of charge. Self-referral was primary method for accessing TB services in the country.

A primary health care model is being proposed as the major system to be utilized for health care in Georgia as of 2012. The main providers of care will be family physicians, of which there are approximately 1800 in the country and who see an average of three patients per day. The public health teams in each municipality are tasked with increasing awareness regarding PHC. Although most Georgians are aware of the existence of their services, they still prefer to seek care from specialists. As a result, primary care physicians are widely under-utilized, with many patients preferring to go straight to secondary level care. For example, a preliminary analysis of TB patients receiving care at the NCTBLD in Tbilisi found that more than 77% were self-referred and only 14% were referred by PHC providers. This has an important bearing on TB case identification.

2.3 Integration of Services under the New Service Delivery System

At the end of 2011, the Georgian health care was privatized. Forty new primary health care service centers were built and launched throughout the country, and another 110 new facilities are slated for building in 2012. These include both hospitals and outpatient clinics which provide primary care services to the catchment population. These service centers house primary care physicians and nurses and a range of clinical sub-specialties. They also have X-ray facilities, clinical laboratories, inpatient beds and surgical services. They are owned by private investors who are contracted for the next seven years to provide care to the regional populations. It is within these facilities that TB care will now take place, and all regional TB dispensaries, cabinets and directly observed treatment short-course strategy (DOTS) spots have been integrated into these general medical facilities. Within the shared structure of these facilities, TB care is now physically integrated with other care services, and it is hoped that this model will improve quality of services for patients with known or suspected TB. Under this model, the five TB hospitals mentioned above will remain open. They will provide inpatient care for all patients with known or suspected TB needing inpatient services. This includes a growing number of patients with drug-resistant TB.

There are now multiple public and private stakeholders tasked with TB control in Georgia. These include the NCTBLD, the NCDCPH, the Social Service Agency of the Ministry of Health (SSA), non-governmental organizations (NGOs), the clinic owners, the clinic investors, and the Global Fund Projects Implementation Entity. This work will be supported by the Government of Georgia, private investors, USAID and the Global Fund.

TB Service provision: Although PHC providers will be expected to screen and refer patients for TB care, the TB services will still be provided by TB specialists and nurses. TB providers are now part of multidisciplinary teams based at general medical facilities and will be supervised and managed by the facility's management team. There is recognition of the need for additional support and monitoring to be provided by the NCTBLD. The details of this additional supervision and support need to be elaborated into operational plans.

In general, each medical service center will have 1 to 2 rooms dedicated to TB services. This includes a separate entrance, a room for sputum collection (although this could be done outside) and DOT, and a room for clinical services. The TB services will be staffed by at least one physician who is a TB specialist and one TB nurse. These providers will report to the clinic directors and to the NCTBLD. Clinical support will be provided by the NCTBLD under the regional TB teams. Each regional TB team will consist of a TB physician, TB nurse and a PHC supervisor. It has not yet been decided to whom they report and to whose staff they belong. Their responsibilities include: regional distribution of TB drugs, monitoring DOT, distribution of patient incentives (i.e. food vouchers), reporting and recording, preparing drug-resistant patients for enrollment into MDR-TB treatment, and follow-up for all the services listed above. A regional TB team will be responsible for supervising all the general medical facilities in their region. Some of the PHC investors and companies have facilities in multiple regions and within a single region there can be many investors and PHC providers.

2.4 DOT

There is a great need to strengthen DOT throughout the country. All stakeholders are aware of this. In the current system, the NCTBLD oversees DOT, but this is a rapidly changing area. There is a move to more community-based DOT. As the PHC clinics are only open Monday through Friday, except for emergencies, the NCTBLD has hired 130 nurses to work doing DOT on Saturdays. The quantity of nurses is not sufficient. There will be the need for other providers to assist with provision of quality DOT. This may include social workers, NGOs, clinic staff and potentially the PHC providers. In the future, it is expected that DOT nurses will be paid per DOT administered. The Public Health and Programs office at the MoLHSA has the administrative capacity to oversee this.

2.5 Laboratory Services

The NCTBLD/NRL reference lab in Tbilisi will remain the referral lab for the country. Other lab services are now being managed by the NCDCPH. This has been done by moving previous NCTBLD to the network of 10 NCDCPH labs throughout the country. These labs will be responsible for collecting sputum (and other specimens) from the general medical service centers, transporting this sputum to the NCDCPH labs, and performing smear microscopy on them. Cultures and full DST will be done by the NRL in Tbilisi, including GeneXpert® molecular testing. TB cultures plus Hain® molecular testing will be done in Kutaisi. The NCDCPH is responsible for sample flow, including returning results to the general medical facilities. The NCTBLD will also assist with the transport of specimens and results.

The NCDCPH labs are well-equipped and have proficiency testing provided through a quality monitoring program of the Centers for Disease Control (CDC, USA).

2.6 Drug Supply

There have been several proposals for managing drug supply. Different stakeholders have varying ideas about who will be responsible for specific areas. According to the NCDCPH, they are willing to oversee drug procurement and distribution as they do for vaccines. However, anti-TB drugs are procured by the Global Fund via the Global Drug Facility—a highly specialized procurement system—and one with which the NCTBLD is familiar. The NCTBLD also has a system of quality monitoring for TB medications. In addition, the Global Fund pays for a majority of the TB drugs in Georgia, with the NCTBLD as a sub-recipient of the Global Fund grant. As the procurement stands, the central pharmacy at the NCTBLD is responsible for procuring and distributing TB drugs in each region via the regional coordinator. The Global Fund is unable to grant a request from the NCDCPH to be added as a Global Fund sub-recipient.

2.7 Recording and Reporting

All TB facilities maintain a number of registers for recording patient information. These facilities also conduct quarterly cohort analyses and send the aggregated reports to regional supervisors. In addition, the service points are also responsible for filling a specific form for each patient who completes treatment. These forms are entered into a database at the regional level. This electronic database was coordinated through the NCTBLD but decentralized and delegated to regional levels. The data was entered into the system by a regional database operator. This operator entered and cleaned the data and was responsible for monitoring the data entry of multiple complicated forms.

Under the new structure, there is no longer a regional database operator. The people now responsible for data entry, cleaning and quality checking are the regional coordinators (whose other responsibilities are stated above) or PHC-based staff for whom this will be an additional responsibility. Data entry and management staff will need training and supervision. Recording and reporting are vital parts of assessing program outcomes and quality. If the data inputted into the system are of unsure quality, this will affect the entire program.

2.8 Insurance/Payment

One goal of the Ministry of Health is to provide individuals with an opportunity to buy private insurance. For poor and vulnerable populations, the MoLHSA provides an insurance package purchased by the government for vulnerable populations (such as internally displaced persons (IDPs), orphans, and people living below the poverty line). Teachers are also provided with the same insurance package. It is estimated that there are approximately 1 million Georgians currently covered by the MoLHSA-provided insurance package. By the end of 2012, this service package will be expanded to cover pensioners and children under the age of 6. Once implemented, this program will cover 50% of Georgians, and the remaining 50% will need to be

privately insured. In addition to this, there is a village health care program that covers the costs of PHC consultation for persons living in rural areas.

If a person has insurance, he or she can choose and see the PHC provider free of charge. If referred for TB services, all fees are covered by the state. If a person does not have insurance and is not a beneficiary of the village health care program, he or she must pay to see the PHC provider. If the provider refers the patient to TB services for diagnosis and treatment, all costs will be covered by the general medical facility through an agreement with the state. There is no longer an option for patients to self-refer to TB services. In rural areas, village doctors are also able to refer patients to TB services at no charge to the patient. (TB Program, 2010, approved by MoLSHA, TB program, 2011 approved by MoLSHA, TB program, 2012 approved by MoLSHA)

In order to encourage general medical service centers to provide TB services, the MoLHSA will pay a general medical facility a fixed cost per patient diagnosed and treated for TB. The monies given to the general medical facility will depend on the number of TB patients for whom they are providing care. This will be done in the form of a "virtual voucher". There is a cap to the amount of money given to a general medical facility per TB patient. The cap will be adjusted annually based on analyses of spending. According to the SSA at the MoLHSA, all PHC providers and TB specialists in the general medical facilities are offered a monthly salary that is not based on the number of patient visits.

2.9 HIV/TB Integration

Georgia remains a low-burden HIV country with a general seroprevalence of <1%. Even in this setting, there is a concerted effort to test all TB patients for HIV. This will remain the responsibility of the TB staff at the PHC centers and HIV lab testing will be done by the NCDCPH labs. If a TB patient is found to have HIV, he or she will be referred to the National AIDS Center or one of its 3 affiliates for HIV care. There will be no HIV treatment services offered at the general medical facilities.

2.10 Monitoring and Evaluation

There are several proposed programs for monitoring and evaluation that are currently under consideration. With regards to the laboratory monitoring this will be done by the NCDCPH. With regards to the TB diagnosis and treatment program, this will be supervised by the NCTBLD. Many stakeholders have voiced concern over the supervision and monitoring of TB physicians and nurses in the PHC, and a more detailed plan needs to be elaborated. The general medical facilities will be monitored by the owners and investors. There is a move towards accreditation of these centers but this does not yet exist. As a regulatory body, the MoLHSA has final supervisory control over the PHC clinics. If there are disputes anywhere along the way, there is a national mediation service that can be used to resolve them.

2.11 Contact Tracing and IPT program

One major new initiative in TB control in Georgia is the roll out of a nationwide contact tracing and IPT (Izoniazide Preventive Treatment) program. Under this new initiative, NCDCPH will do home contact tracing with a team of its epidemiologists. These epidemiologists will work in conjunction with an NCTBLD nurse to place PPD

tests and to arrange for follow up with the TB team in the general medical facility. PPD positive contacts will undergo chest X-ray screening. If the X-ray is positive, the contact will undergo sputum testing and be started on TB therapy. If the contact is PPD positive but has no signs of active TB and the chest X-ray is negative, he or she will be offered IPT for 6 months if they fit into one of the following risk groups: children under 5; on corticosteroids; on hemodialysis; comorbid diabetes mellitus; s/p transplant; HIV positive; or a documented new converter. If successful, IPT will be rolled out to all persons with a positive PPD. In addition, the NCDCPH and NCTBLD are considering the 12 week INH/rifapentene regimen.

This is an important new initiative, but there has already been a major pushback—primarily from TB physicians and nurses—about the utility of this strategy. The NCDCPH and NCTBLD need support in training and publicizing this intervention among both PHC providers and TB providers as well as the general public.

3 FOCUS AREAS FOR TRANSITION AND PROPOSED ACTION STEPS

During the course of multiple interviews conducted with key stakeholders in Georgia, and based on review of the scientific literature on other countries that have attempted privatization and integration of TB care (see section on international experience), a number of areas have been identified as needing support and strengthening in the transition. These are described below as well as proposed action steps to address them.

3.1 Enhanced TB Case Finding and Identification within High Volume Clinical Services

Currently the majority of village physicians, PHC and hospitals service providers are not actively screening patients for TB. Most of the TB patients are self-referred to TB facilities. Increasing involvement of family physicians can enhance early case detection. This would not only require skills development of family physicians and tools (job aids) that they can use to improve their capacities in identifying TB suspects while seeing patients in various settings. Various stakeholders involved in TB services would need to develop strategies for ensuring that TB suspects are actively sought out in clinical settings and referred to TB clinics for further laboratory work and treatment if required. The key provider competencies for increasing case detection include:

- Recognizing signs and symptoms related to TB;
- The process and procedure for making patient referrals to TB services;
- Basic clinical monitoring of patients on TB therapy, including adverse effects and “red flags” indicating a need for immediate clinical intervention

Once these competencies are established, then training sessions can be targeted accordingly. This will likely make the training more effective. In addition, refresher trainings will need to be done yearly. Other means of ensuring better retention of newly gained knowledge will be done through: quarterly collaborative meetings at the rayon level among TB and non-TB service providers; text messaging to PHC

providers, provision of a monthly "bulletin" on TB in PHC settings; and a joint national conference for TB and PHC providers.

The management of LTBI must also be included as an intense training topic for TB providers. PHC providers should also be aware of this new TB control effort and know how to refer patients for screening.

3.2 Infection Control at Co-located Sites offering TB and Other Health Services

Many TB suspects and patients will now be receiving care and services in the same building where others seek health care. This includes children, pregnant women, and patients with other immune compromising conditions, such as diabetes and kidney disease. While the new general medical facilities have been built according to basic IC standards, there is great concern that these basic IC measure will not suffice to ensure that there is no nosocomial spread of TB. Although TB patients and suspects will have a separate entrance to the clinic, they will be sharing waiting room space while undergoing X-rays and laboratory tests. Current IC practices do not appear adequate for patients or for health care personnel.

In addition, some owners of the general medical facilities have asked that there be a "tiered" system for different levels of general medical facilities. In their smaller (i.e. 15 bed centers) facilities, where construction has been completed, it is quite difficult to incorporate the changes necessary to safely care for TB patients with the general PHC population. In some of their larger facilities (i.e. 70-bed facilities), there is much better infrastructure to provide care for TB patients with the other PHC patients in a safe way.

Each facility needs an IC assessment, including a patient flow assessment. MoLHSA will have to develop standards for these assessments in partnership with various stakeholders. There also needs to be a clear IC policy in each facility and an IC monitor for patients and providers who have suffered an exposure. Consideration should be given to the timing of X-rays and lab draws (i.e., have the TB suspects wait until the end of the day) but this could impose undue burden on TB suspects. Health care personnel (including the cleaning staff of the clinics) should be provided with personal protective equipment (i.e., N95 masks). Likewise, TB suspects should be provided with surgical masks to wear in order to decrease their infectiousness while in the facility. This could lead to stigmatization among TB suspects, but care must be taken to have strict infection control practices. If even one pregnant woman receiving antenatal care at the PHC or one child receiving vaccines at the PHC develop TB, the entire NTP will be held responsible for spreading the disease. The providers will have to take active role in promoting IC approaches in congregated settings as well as at patient's homes. Active patient and care giver education will need to be provided to ensure that patients do everything to reduce the risk of infecting other family members.

A system will also need to be developed whereby those facilities that do not have appropriate IC practices are put on probation or considered to be closed until they improve their IC. This is under the authority of the MoLHSA. The MoLHSA needs to provide adequate licensing mechanisms to prevent operation of facilities that do not meet minimum IC guidelines. Furthermore, these guidelines need to be updated and

distributed to the new facilities with an action oriented plan for implementation. It needs to be clear who has the authority to impose these kinds of sanctions on the clinic.

3.3 Quality DOT

All stakeholders mentioned the need to improve the quality of DOT that patients receive. It is widely acknowledged that there are weaknesses in the current system that needs to be addressed. A number of new public and private stakeholders in addition to the NCTBLD will be involved in this. There is no lead agency appointed to oversee DOT. A clear system and structure for quality DOTS will need to be established in the model of integration and privatization.

There are multiple strategies that can improve the quality of DOT. The medical literature has documented multiple effective strategies for quality DOT. A majority of successful models rely on community-based DOT (CB-DOT). This means that rather than having to come to clinic every day for their medications, TB patients are able to receive their medications at home or at a convenient locations. This reduces the burden placed on TB patients. CB- DOT also allows for early recognition of side effects and close monitoring of contacts.

There are multiple potential individuals in the newly integrated system that could be involved in CB- DOT. The Global Fund project has money for 130 community nurses to work on DOT; however, these 130 individuals are not sufficient to improve the quality of DOT throughout Georgia. Other health personnel that could be deployed in CB-DOT include family health and village nurses, social workers, and other non-traditional groups such as the Georgian Orthodox Church. NGOs should also be involved in CB-DOT.

Finally, there should be some type of incentive for patients and their families (below the poverty line) to remain compliant with therapy. This could include a transportation voucher or food voucher either monthly (if patients are compliant) or at the completion of therapy. These incentives have been proven in multiple settings to improve DOT. Although there may be some concern about costs of such incentives, the international literature supports that this is a cost-effective measure, especially when one considers the costs of a patient abandoning treatment.

The TB program will need several management strategies to achieve the above. These include:

3.4 Supervision System

There is a need to develop a new system for supervision and support of the TB teams in the general medical facilities. These TB providers are now part of the multidisciplinary teams at each of the PHCs. As such, they are directly responsible to the PHC. In addition, service providers will need to be supervised and supported by TB experts at the NCTBLD. Under the Global Fund Round 10 Grant, a regional TB team is supervised by Regional Coordinator through a regional supervision. Regional supervision is quarterly, four times per year. In addition to that, central supervision occurs four times per year and again, supported from Global Fund Round 10 Grant. Supervision must now include the PHCs, and there is a need for these two systems to

work together. This structure has the potential to cause management conflicts. While a mediation system is available nationally, it has not been used under these circumstances before. The current system has the potential to hold the NCTBLD responsible for TB activities but the NCTBLD has little authority and control over how these activities are carried out in the integrated PHC system.

Georgia is working to develop an accreditation system. There is currently no formal system for managing general medical facilities which are considered by the NCTBLD and/or the NCDCPH to be providing sub-optimal TB services. In the meantime, it is recommended that all stakeholders have a clear plan for areas of responsibility and authority. In addition, stakeholders should have regular joint conferences (both locally and centrally) to discuss any systems and supervisory issues.

3.5 Training

The professional associations in consultations with MoLHSA should propose a list of expected competencies for PHC providers in the management of TB patients. Once these competencies are identified, there will be a need for training all providers within the newly integrated system, including the PHC providers. In some countries the goal of integration has been to have PHC providers actually provide TB care themselves (see South Africa case study). In others, the goal of integration has been to ease the screening and referral process, and the integration has only been a physical relocation. It is important to be clear about the goal of integration and what is expected of all the providers in order to adequately target trainings.

Under the Global Fund Project, some PHC providers undergo an intense and very elaborate training on TB, including management of MDR-TB and Extensively drug resistant- TB (XDR-TB) cases. URC is currently analyzing data from a small study of PHC providers who have undergone this training. A study from Canada found that if training and guidelines are too complicated, PHC providers do not retain knowledge from trainings about TB, especially if they manage only a few TB patients in their practice. Thus, the training of PHC providers will need to be concise and focus on their expected competencies (i.e. screening, referral and potentially assisting with DOT).

3.6 Outcome Focused Evaluations using Quality Indicators

The facility-level paper-based system is well managed at the TB clinics. The TB staff record patient specific data in lab (sputum registers), new TB patient register, retreatment register and MDR register. Once every quarter, data from these registers is aggregated and reported to higher levels. In addition, the clinic staff, with support from regional TB coordinators, also prepares individualized paper-based patient reports that are inputted into a national electronic TB register. The NCTBLD-managed decentralized electronic database has been managed by a regional database operator who did data entry, data cleaning, database management and generated timely regional reports. That regional electronic database is still an appropriate management tool for TB recording and reporting. Under the integrated system, there is a need to designate the people who will be responsible for data entry and up-keeping of the system, since the regional NCTBLD database operator position has been eliminated. The data entry and management is not a simple task, and forms can

be up to 18 pages long. If the data is not entered and quality assured, its significance in monitoring and providing trusted outcome data will be limited.

The current system does not specify who will be responsible for data entry and quality assurance. It appears that some of this work will be shifted to TB regional coordinators who already have a number of responsibilities. Some may also be shifted to staff in the PHC and NCDCPH. Because the data entry is not straightforward, these staff will require training and monitoring during the transition. Rather than hire a new cadre of workers, it is recommended that the regional database operators be funded to continue their work as part of the Regional TB team.

Data from other countries suggest that integrating TB services with PHC can lead to a marked improvement in screening and case detection. However, several countries have found that although detection is improved, patient outcomes either remain the same or can WORSEN under an integrated system (see Case Study from Moldova). It will be important to take an outcome-oriented approach to TB integration and include outcome-based measures in program evaluation.

In addition, it will be important to follow other meaningful program indicators based on outcomes such as appropriate referral from PCH providers (i.e. what percentage of persons presenting with TB signs and symptoms are referred) and actual case finding (as opposed to increased percentage of patients referred by PCH providers (this will naturally increase if patients no longer have the option to self-refer). Another outcome measure should include number of days from time of first symptoms to presentation at the general medical facility. A set of clear outcome indicators need to be established, including treatment success rate (i.e. cure and treatment completion), percentage of patients receiving regular DOT, and increased case detection rates of TB. Similarly, the program should also monitor number of contacts per patient by age (children and adults and by sex) screened for TB.

Finally there is the need to explicitly state and define the goals and objectives for the integration of TB into PHC. These targets should have clear and realistic quantitative values. In addition, they should be discussed and agreed upon by technical professionals involved in TB care and PHC.

3.7 Clinical Structure and TB Teams on the Ground

The current system of integration and privatization means that the NCTBLD or some other entity will have to work with the general medical facilities to supervise the clinical TB teams in the general medical facilities. They will also be in charge of overseeing the activities of the Regional TB Team. There is a need for a set structure for TB Team composition. There is also a need for clear policies on how the NCTBLD will remedy any perceived problems with the structure and function of the clinical teams and their clinical workspace.

The PHC managers and clinic owners are responsible for overseeing the provision of clinical services at the general medical facilities with input into clinical management of TB by the NCTBLD. The NCTBLD should have some authority within the PHC to make decisions that are directly related to patient care and the provision of clinical services. This should be clearly stated in a policy manual with explicit procedures for how this will be done.

Within each clinic there should be quarterly (or even monthly, depending on the number of TB patients) conferences held with the TB clinical staff and the PHC clinical staff. During these conferences, patient cases could be discussed as well as topics of clinical interest to the PHC and TB providers.

3.8 Patient-Centered Approach

The current system of privatization and integration is at high risk of losing the population most susceptible to TB in Georgia. While privatization can introduce efficient and streamline procedures into health care, it is essential to remember that the goal of private health care systems is to generate a profit for investors. While high-quality care can be provided to patients with a variety of diseases under privatization, global experience has found that privatization tends to be very problematic for persons with TB. In general TB is not a disease that generates a profit for private health care facilities. In addition, most TB patients are unable to afford private insurance, and – because of their TB—are often not working in positions that would provide them with insurance. At the same time, the group most at risk for TB—men and women between the ages of 25-44—often do not fit the specific requirements for state-sponsored insurance. While one might propose a scenario where TB suspects and patients are provided with high quality care through privatized health facilities, stakeholders must be equally prepared for the possibility that patients most at risk for TB will not be eligible for insurance and will have to pay out of pocket for access to a PHC provider whose role they do not understand.

The United States has a long history of privatization and the use of primary health providers to coordinate patient care. In the 1970s, the vertical TB program—provided via county health departments—was dismantled and TB services were integrated into PHC. This included TB diagnostic and treatment service, supervision of programs, monitoring and reporting, training, and infection control. At the same time, patients were required to have private insurance to access primary care, except for the old, the very poor, and the disabled (see case study on the U.S/New York City). The results of this—coupled with the onset of the HIV epidemic, were a rise in the number of TB cases and a substantial increase in the number of patients with drug-resistant TB. This was most notable in New York City. Instead of accessing TB services through their PHC providers, most patients (who were uninsured and had to pay out of pocket for PHC services) sought care in the informal health system and only presented to self-pay at health facilities when their symptoms were extreme or they needed emergency care. These patients had worse outcomes and longer delays to diagnosis and treatment, not because the PHC providers were not educated about TB referral but rather because few of them would pay out of pocket to see PHC providers until critically ill. There was no supervision of TB services in this new system and no coordinated monitoring or outreach efforts. Thus, the state only became aware of problems with the integrated system when TB had reached epidemic proportions.

The MoLHSA has committed to paying private general medical facilities a set amount through virtual vouchers for all TB patients being cared for at general medical centers. This amount is capped and will be re-calculated annually. It will be important to ensure that facilities do not try to spend less per TB patient than they are allocated in order to inflate their profits. Because profits is the main driving force for the investors behind these private general medical facilities. For example, if PHC centers are given

500GEL per TB patient per year, it is vital that these facilities not deny patients needed tests, medications, or procedures that would increase expenditures and thus decrease the profit margin for the general medical facilities. For example, if routine diagnosis and follow-up care for TB patients costs 200 GEL per year, then the PHC investors can earn a profit of 300GEL per year. If however, a patient needs a biopsy or an ultrasound or medication to manage neuropathy, this will increase the costs above 200GEL and cut into the profit of the PHC. Monitoring this will require a great amount of diligence, and it is not clear who has the authority to oversee the investors in the private PHC to ensure such behavior does not occur.

In addition, patients with TB are often living in dire socioeconomic situations. Their food, housing and transportation needs must be met in the new system. These things are vital to ensuring quality DOTS. A designated agency for addressing these issues needs to be named.

It is crucial that the newly integrated system have a patient-centered approach to care and makes accessing TB services easier for persons with known or suspected TB. Quality surveys should be planned at each center in which patients and providers are interviewed about accessibility of services. In addition, an interim research project in selected communities should be done at 6-9 months into the integration process to identify people who are not able to access TB services to identify the specific barriers and take measures to address them. All persons should have guaranteed access to PHC.

3.9 Laboratory

In the new system, the NCDCPH will take over much of the TB lab work, with the exception of culture and DST which will remain with the NCTBLD/NRL. It is important to ensure the NCDCPH labs have the supervision, support they need and that they coordinate well with the NCTBLD. There have been reports of vehicle-related delays in the system (with days' worth of specimens needing to be thrown out. There is also concern from funders that there are no standards for disposal of bio-hazardous waste materials and that the NCDCPH labs are not as well equipped as they need to be.

There is a great deal of discussion on lab management among the key stakeholders. There is a need for policy and planning documents to be developed regarding respective roles and responsibilities. Responsibilities should be explicitly expressed in a document that is agreed to be all parties and by funding agencies, there must also be development and implementation of a clear communication and coordination plan between the NCTBLD and the NCDCPH

3.10 Drug Procurement and Supply Management

TB drugs and supplies are procured through the Global Fund/Global Drug Facility with the NCTBLD as the named sub-recipient. Other stakeholders may become involved in the storage and distribution of drugs. A detailed plan listing the roles and responsibilities of the various stakeholders is needed.

Ensuring a quality drug supply for TB care is one of the key activities in TB control programs. In order to maintain adequate stocks of quality drugs through the Global

Fund, there must be development of an action plan for procurement and supply management which lists the roles and responsibilities of all stakeholders. In addition, there is a need for development of a monitoring plan to ensure quality in drug procurement and supply management.

The program will also need to develop strategies to reduce the overall TB burden in the country. These strategies may include the following aspects:

3.11 Latent TB Infection (LTBI)/Isoniazid Preventive Therapy (IPT)

A major effort in the new system will be contact tracing, testing for LTBI and the offering of IPT to selected populations. This is an important effort to introduce in the country and will likely decrease the reservoir of potential TB cases in the future. As a new initiative, there will be a need for training and supervision of all levels of providers around this issue. In addition, the NCDCPH will be in charge of epidemiology and contact tracing, while the NCTBLD will be in charge of administering PPD and managing contacts. Thus, there will be a need for a close working relationship between these two stakeholders. The role of the owners of the private clinics will need to be elaborated in this effort.

An operational plan for implementing LTBI needs to be developed and implemented, with clear roles and responsibilities for all levels of providers. An evidence-based training on LTBI and IPT needs to be developed and made mandatory for all TB providers in the country. There is a great deal of skepticism concerning this topic and intense efforts will be needed to ensure it is adopted by the TB teams. To ensure program success, an incentive structure should be established for providers and clinics to offer the therapy.

3.12 Stigma

One proposed reason for integration is to lessen the stigma of TB and for TB patients. By having these individuals cared for with the general population, it is hoped that TB-related stigma will decrease. This needs to be measured and monitored closely. It may turn out to be a benefit of the integrated system but there are infection control measures that must be put into place to avert nosocomial transmission of TB to the general clinic population. These include separate entrances for TB patients and the need for personal protective measures for healthcare workers caring for TB patients (including general lab staff and the X-ray technicians who are also dealing with the non-TB patients). These measures may contribute to a paradoxically increased level of stigma.

Intensified IC measures will be needed in the clinics as outlined above. It is hoped that with factual information and the means of protecting themselves, that PHC health care workers will be able to diminish the stigma associated with TB. A program for monitoring stigma should be included in health general medical facility and a monitor for each facility named. General medical facilities should also be targeted for general TB ACSM activities as another way to decrease stigma. Appropriate posters and other TB messaging should be placed in the general medical facilities.

3.13 Incentives for Success

In the privatization of health care, one key incentive for investors and owners is profit. Yet even with the government system of reimbursement and virtual vouchers, it is not likely that there will be much of a profit incentive for the private owners. In order to ensure successful outcomes and high quality TB care there will need to be careful consideration of other incentives for the investors, the providers and the patients.

Consider providing incentives for general medical facilities that provide outstanding TB care based on patient indicators and outcomes. These could include awarding successful clinics a certificate or even naming them "Centers of Excellence." Some financial incentive should also be considered, i.e. a 1-5% increase in total TB reimbursement for general medical facilities that performed well in the previous year. Monitoring of these centers will be crucial if there is to be some financial incentive, as it is possible to inflate numbers and results when there stand to be monetary gains.

Providers should also be given some type of certificate for achieving excellent results. For PHC providers, this could be based on the percentage of patients properly referred or for the percentage of referrals diagnosed with TB who have positive outcomes. For TB providers, this could be based on percentage of patients with positive outcomes or percentage of patients with >90% adherence.

Finally, patients should also be offered incentives. This is discussed in more detail in the "DOTS" section above but could include transportation vouchers, food vouchers, etc.

3.14 Ensure Follow-up of Discharged Inmates with TB

Other health care reform policies are being enacted in the prison sector. The prison and civilian sector will coordinate with one another. This poses unique problems for the management of TB. The TB problem in the general population is fueled by what is happening in the prisons. This is even more true for persons with drug-resistant TB. Currently, the links between the prison TB program and the NCTBLD are weak, but they do exist. Prison TB personnel regularly interact with NCTBLD personnel. In addition, there is a "hotline" established between the NCTBLD and the prison TB care system to allow for notification when prisoners with TB—especially those with MDR-TB—are being released. Follow-up care in the community for the discharged prisoners has needed strengthening for some time. This may be due to general weakness of the Georgian primary care system such as poor patient registration system, no call and recall system, poor linkages between different level of services and between sectors. There was no motivation in the past for public providers to take care of discharged prisoners. The proposed privatized system does not have any provisions for linking care with the prison sector. There will be a need to motivate the private PHCs to incorporate prisoners into their service delivery, as these individuals are often uninsured and dealt with harshly by society. While this may not be important for other health problems, coordination between the prison and civilian sectors are vital in managing TB.

Coordination with the prison health sector is vital to ensuring the success of the privatization and integration of TB services into general medical facilities. Clinics should have a referral phone or "hotline" for patients being transferred out of the

prison while on TB treatment. Clinics should be required to have an operating procedure/plan for coordination with the prisons.

3.15 Vulnerable Populations

There are multiple vulnerable populations in Georgia who are at high risk for TB but have low likelihood of using the general medical facilities. These include persons living in Abkhazia. Under the current system, there is no outreach provided to these populations, and lead agency needs to be designated with responsibility for these vulnerable groups. While the current system allows for the management of TB patients and suspects within the PHC system, the outreach function of the prior system led by the NCTBLD appears nowhere in current plans. Outreach to vulnerable populations—who are likely to be uninsured and not able to use PHC systems AND to be at increased risk of TB—must occur to control TB in Georgia.

The integrated system does not provide for outreach and TB care among vulnerable populations. There needs to be designation of an agency (i.e. the NCTBLD) with responsibility for these populations, including funding for this work and a means of providing TB diagnosis and treatment for them.

4 CONCLUSIONS

Georgia is at a crossroads with the potential to develop some exciting programmatic changes in TB control. The new integrated system may offer easier access to high quality TB diagnostics and treatment services for a larger population. There is great potential for increased collaboration between TB services and PHC service as well. It is important, however, that the quality of TB care not decline, and that increases in case detection rates be matched by improved outcomes for all individuals within the system. Attention must be given to improving infection control; improving the quality of DOTS; and taking a patient-centered approach to TB care. Close monitoring and supervision of clinical care must be provided, and there needs to be a manner of supervisory integration from both the NCTBLD and the private health care providers. Care must be taken to ensure the voucher payment system does not lead to obstacles in patient access and does not paradoxically lead to a lower level of patient care for those with suspected and diagnosed TB. Efforts are needed to strengthen the program of LTBI screening and treatment. Incentives for patients, providers and health centers should be considered as a method for quality improvement. Quarterly conferences with the PHC staff and TB staff should be held to discuss scientific advances, review cases, and engage in collective problem-solving.

If the above mentioned issues are taken into consideration and the reform is done properly, the proposed integration of TB care and PHC could lead to improvements in TB and MDR-TB patient management and outcomes. If the potential problem areas above are not addressed, the privatization and integration of TB services into general medical facilities could be a public health disaster. Given how much Georgia has invested in its TB programs, every care should be taken to ensure a smooth and successful transition.

5 ANNEXES

5.1 Annex A: Case Studies

5.1.1 Case Study: United States/New York City

Background

High income country (48,147 USD GDP)

Low rates of TB (3.6 per 100,000)

High number of physicians (2.3 per 1,000 population)

Low number of TB specialists

Private insurance; public insurance for the very poor, very old, or very young

Primary health center model of care

TB care provided through public health programs, county-based; mandatory

Situation

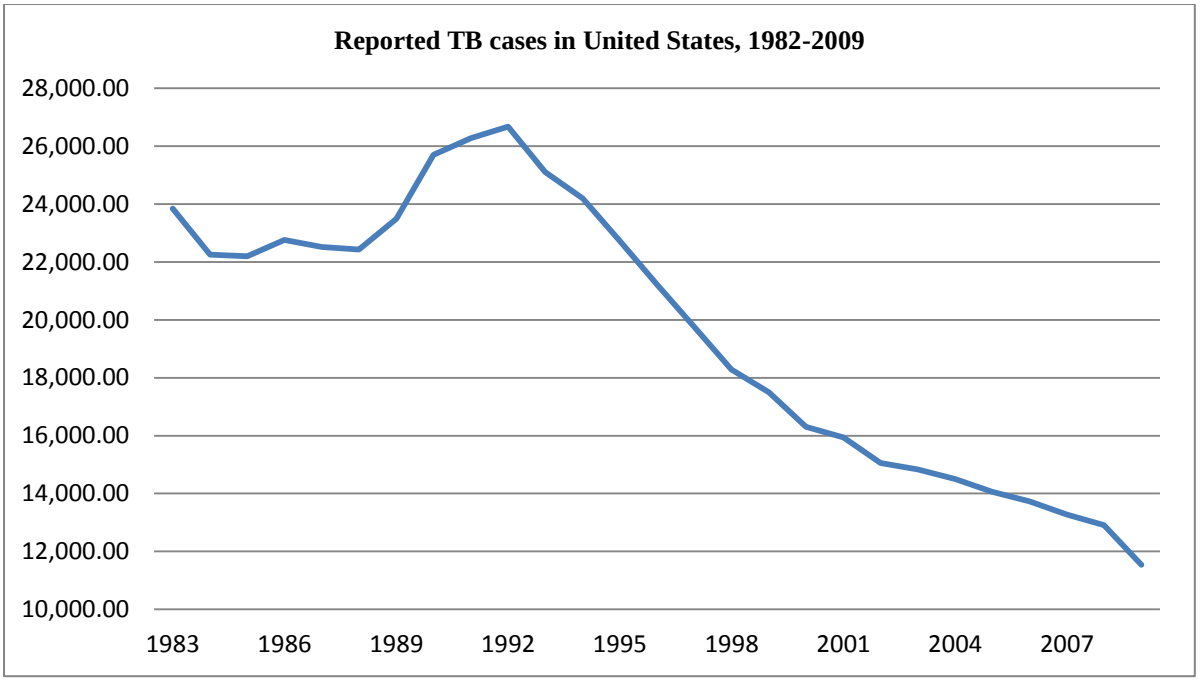
In the mid- to-late- 1970s, there were several reforms that took place in U.S. healthcare and with TB in particular. First, the 1970s saw impressive declines in TB case in the U.S., leading many experts to claim the U.S. was close to "TB elimination." At this time, TB control services were managed by a vertical TB control public health program based at the county level. Because of the perceived successes in TB control and the decreasing number of patients, TB public health services were drastically cut. In 1960, for example, there were a total of 2,400 inpatient TB beds in New York City. TB staff number more than 1,500, and there were 24 TB clinics/dispensaries in the city. By 1983, there were no TB dedicated hospitals or beds, 8 TB clinics/dispensaries, and fewer than 140 dedicated TB staff in the city.

There were several other factors besides perceived "success" in TB control that lead to the dismantling of TB control via public health programs in New York City. First, there was a move to eliminate vertical programs in health care in the U.S. and instead to have a model of integrated care which would be centered at PHCs. Second, there was a move to private insurance coverage for patient previously managed in the public health system. Finally, there was little recognition of the other services provided for TB patients by the public health system, including infection control monitoring and training, contact tracing, and DOT. It was assumed these activities would be "picked up" by the PHC facilities.

Outcomes

TB cases had been steadily declining in the U.S. This decline stopped in 1983, and in fact, TB cases began to rise steadily from 1986 onward reaching a peak in 1992 (see graph below[1]).

[1] CDC Report of Tuberculosis in the United State, 2009



In New York City, the number of TB cases tripled between 1977 and 1992. In some areas of New York City—most notably Harlem—TB prevalence peaked at a rate of 222 cases per 100,000 population. It was estimated that 1 in 5 patients in New York City in 1991 had MDR-TB, and among newly diagnosed TB patients in New York City, MDR-TB was found in 10.1%. Between 1979 and 1994, it is estimated that an excess of 20,000 TB cases were seen and this cost the government of New York City more than 400 million USD.

Much of the increase in TB reported in New York City was attributed to the HIV pandemic, which was a major problem in the city beginning in 1981. Data show, however that only 40-45% of the excess TB cases could be attributed to HIV. The remainders of cases were felt to be due to the dismantling of the public health infrastructure around TB and its failed integration into PHC. Other factors associated with the loss of New York City public health TB program included poor DOT and poor infection control practices.

In 1992, as a response to the rise in TB cases, the U.S. government put substantial efforts into rebuilding the vertical TB public health program in New York City. The budget was increased from 4 million to 17 million USD annually. Hundreds of nurses were re-hired and new physicians were hired and trained. While screening patients for potential TB and knowing appropriate referral steps were maintained as activities for PHC providers, the newly invigorated TB public health program took responsibility for confirming diagnosis, started and monitoring therapy, DOT, contact tracing, and infection control. TB suspects must be referred to TB services by PHC providers, but once TB is confirmed, the patient is then cared for by the TB public health service.

Lessons Learned

There are several important lessons to be learned from the New York City experience with TB. First, while integration with PHC can lead to improved access for diagnosis for patients, outcomes can be poor if patients are not followed and treated by TB specialists and nurses. Dismantling the public health vertical TB structure lead to a situation where there was little DOT, reduced contact tracing, little support for infection control, and loss of clinical services from TB providers. Because few TB cases are seen in the U.S., most PHC providers do not have much experience caring for TB or implementing the important "non-clinical" steps that are crucial in TB care. When these changes converged with the HIV pandemic, a disastrous situation occurred in New York City, leading to high prevalence rates, and high rates of both primary and acquired MDR-TB.

Although no direct causal links can be made, when the vertical, public health TB programs were re-built, TB prevalence in the U.S. and in New York City began to decline. A robust TB control system now exists again in the U.S. with a vertical TB public health system providing treatment, DOT, contact tracing, infection control, and supervisory/monitoring activities while PHC providers are responsible for screening and increased referral to the public health TB program. The U.S. appears to be on track to possible TB elimination in the coming decade.

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5.1.2 Case Study: Moldova

Background

Low-middle income country (2,500 USD GDP)

High rates of TB (178 per 100,000)

High number of physicians (2.64 per 1,000 population)

High rates of drug-resistant TB (65% among previously treated patients)

Recent privatization of TB services

Low rates of HIV (general seroprevalence of 0.5%)

Situation

Moldova is a country surrounded by the Ukraine and Romania that gained its independence from the Soviet Union in 1991. Approximately 3.4 million people live in Moldova. Moldova has some of the highest rates of drug-resistant TB in the world, with more than 65% of patients with a history of previous treatment having MDR-TB.

Moldova only adopted the DOTS strategy in 2001. In this same year, the government of Moldova initiated a PHC model of care and a national health insurance infrastructure. Prior to this, TB services were provided in what was perceived to be a poorly functioning vertical program with a case detection rate of only 37%. TB care was supposed to be provided at TB hospitals, but most of these were closed in 1999 due to lack of funding. It was hoped that integration into primary health care facilities would improve case detection rates and patient outcomes.

Outcomes

Little has been written about the outcomes seen in Moldova after this transition was made. In one study looking at data for each year from 2001 to 2005, case detection rates improved with implementation, reaching 65% in 2005. Hundreds of media campaigns were launched, and hundreds of TB doctors and thousands of PHC provider received TB training. These accomplishments were diminished, however, by the fact that success rates did not improve at all during this time period, with rates stable at about 62.5% for all 5 years assessed. Surveillance data from 2008-2010 show that case detection rates peaked in 2008 at 70% and fell off in 2009 (68%) and 2010 (63%). Furthermore, treatment success rates never went above 65% and there were in 2008, 2009, and 2010 62%, 61%, and 53%. This cannot be attributed solely to the PHC integration and insurance; Moldova has exceptionally high rates of drug-resistant TB. It is concerning, however, that TB detection in Moldova is on the decline and treatment success rates never improved. Current reports from the PHC system find that the demand for TB services outweighs the supply and facilities have either closed, are working under extreme conditions, or no longer treat individuals with TB.

Lessons Learned

The experience in Moldova has several important lessons. First, early in the transition to PHC and TB integration, process indicators all looked promising. There were noted increases in case detection rates, thousands of providers underwent training on

TB, novel partnerships were developing, and mass media campaigns were launched throughout the country. Outcome indicators—especially measures of treatment success—never improved, and, in fact, have fallen off in recent years. There may be many factors contributing to the poor success rates seen in Moldova, especially high rates of drug-resistant TB. In spite of all the work put into PHC integration and national insurance, TB patients in Moldova are in fact worse off today than they were prior to these interventions.

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5.1.3 Case Study: South Africa

Background

Middle income country (10,977 USD GDP); incredible inequality

Extremely high rates of TB (970 per 100,000)

Low number of physicians (0.77 per 1,000 population)

Low number of TB specialists

In wealthy areas, private insurance; a majority of South Africans pay users fees for service; TB and HIV services provided free of charge.

Nurse driven primary health center model of care

TB care provided through public health programs and NGOs

High rates of HIV (general seroprevalence of 18%)

Situation

South Africa is one of the highest burden HIV countries in the world. It is also one of the highest burden TB countries in the world, and a majority of TB patients are co-infected with HIV (>70%). In addition, parts of South Africa suffer from extreme shortages in health care workers, with more than 70% of physician posts and 60% of nurse posts vacant. National statistics often underestimate the burden of TB and HIV because of the massive inequalities that characterize health care in South Africa. Although apartheid officially ended in 1994, there is a deep degree of inequity in the South African health care system. White South Africans—who are generally wealthy and suffer from the diseases of resource-rich countries such as cancer and heart disease—have private insurance and are cared for in private hospitals. These hospitals are well-staffed and their quality is similar to those in the U.S. and Western Europe. Black and colored South Africans are cared for in public hospitals where they must pay user fees; these populations also suffer from high rates of TB and HIV. These public hospitals are woefully understaffed and quality of care is felt to be relatively low, often lacking such basics as electricity, adequate beds, and laboratory support services. Also of note, the White South African population has very low rates of HIV and TB, while the Black population suffers from the highest rates of HIV and TB in the world.

As HIV and TB continued to increase among Black South Africans, it became clear that the public health system was grossly unprepared to manage these two public health problems. While patients were supposed to be able to access primary care services at village clinics, most such clinics were not staffed or if staffed had only a public health nurse. TB and HIV care was provided at specialized centers but most patients could not afford transport or other costs to get to these centers. Furthermore, if they did arrive at these centers, they were often placed on waiting lists to initiate treatment. This vertical system of TB care was quickly overwhelmed, and a majority of patients with signs and symptoms of active disease were never diagnosed and ever fewer were offered treatment for TB.

In the primary care setting for Black South Africans, a large majority of patients presenting to clinics had either HIV or TB or both. Thus public health nurses and medical providers saw a large number of patients with TB and HIV. In fact of the 60-75 patients seen by a nurse or physician per day in the primary care clinics serving Black South African, a majority of them (65-80%) have HIV or TB.

The lack of physicians and TB specialists in South Africa coupled with the high rates of TB and HIV in the Black South African population lead to a national movement to integrate both HIV and TB services into primary care. This was not merely a physical relocation to improve patient access but rather a transfer of medical service responsibility for TB and HIV from vertical programs to the public health nurses and PHC providers themselves. Although the National TB Program and National AIDS Program do much of the supervising, training and procurement of medications, it is now the responsibilities of public health/primary care nurses to diagnose and initiate treatment for both TB and HIV in the public health setting. Patients with HIV and/or TB are not required to pay user fees at the clinics.

Outcomes

The integration of TB and HIV care into the PHC clinics in South Africa has led to a dramatic increase in the number of Black South Africans who are able to access TB and HIV diagnosis and treatment. Prior to the integration program, it was estimated that less than 10% of Black South Africans were able to received diagnosis of and treatment for TB. With the integration, that number is now estimated at more than 50%. Complicated patients can still be referred to specialty services, but most persons can initiate treatment from their nurse or PHC provider at the local clinic.

There are several areas of concern about this integration process. First, there has been little systematic monitoring of patient outcomes and quality of care under the newly integrated system. It is true more patients are able to access services, but there is little assessment of the quality of these services. In addition, the nursing workforce is shouldering a great deal of responsibility and “burnout” rates and staff turnover are extremely high (estimated at more than 50% of staff per year). This is likely due to the large number of patients seen per day by providers (median 65-70 patients) and the increasingly complex services these PHC providers have to take responsibility for.

Lessons Learned

In a setting with a high rate of TB, a low number of trained TB specialists, a low number of primary care physicians and a high number of patients with TB seen daily in the primary care setting, a proposed program of true PHC/TB integration may be one way to increase access to TB diagnosis and treatment. In South Africa, diagnosis of TB (and HIV) as well as initiation of therapy has now become the responsibility of public health and PHC nurses and PHC providers. While it is clear that this can improve access to diagnosis and treatment for persons in a high burden setting, there are multiple potential concerns in terms of quality of care, PHC workload, and supervision and support services for the PHC providers. This fully integrated model may be the best alternative in high burden TB settings that suffer from extreme health care worker shortages. In settings with high rates of TB and high number physicians and of TB specialists, a fully integrated model with PHC providers responsible TB diagnosis and treatment may not make sense, especially if the PHC providers see a low number of TB suspects in their daily clinical practice.

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5.2 Annex B: Site Visits

5.2.1 Site Visit at Primary Health Center in Tbilisi

Location: Tbilisi #1 Medical-Prophylactic Center, Municipality of Tbilisi

Director/Insurance: Archil Gedenidze

Date of Visit: February 14, 2012

Assessment

This is a large, multi-building complex that will be integrating TB dispensary #1 into its services. The PHC has worked very closely with the NTP regional coordinator for Tbilisi to develop and implement the TB care plan.

In general, the center offers a wide range of services for both inpatients and outpatients. It has a functional chest X-ray and offers a range of lab services. The TB service area is currently being prepared to accept patients. A tour of this area was conducted.

The TB services will be housed in a building that is separated from the other services and joined by outside walkways. The TB services have their own separate entrance and courtyard. There is a large amount of space in the TB services and separate rooms for physician evaluation, DOT, sputum collection, and patient care. There is a large communal waiting area. There are also work areas for nurses and physicians and registers will be able to be confidentially maintained and stored. There is potential for good natural ventilation, and the room has many windows allowing for a great deal of UV light.

Patients needing blood analyses and other diagnostic lab testing will remain in the TB area, and a lab technician from the general clinic will obtain their samples. For chest X-rays, TB patients will have to go to the facility X-ray which is located on the 4th floor of the main building and it is necessary to take a lift to get there. Administration is considering the placement of UV light in the elevator but has also requested purchase of an additional X-ray machine for the TB center with funds from the Mayor of Tbilisi.

PHC doctors who provide clinical consultation are located in a nearby building with the general population and a short distance walk to the TB services. Persons who present to the clinic with signs and symptoms of TB must be seen by a PHC physician and then referred to the TB services. Once diagnosed with TB, patients can present to the TB area of the center directly.

The geographic region served by this PHC facility directly corresponds to that of TB Dispensary #1. TB staff at the PHC facility are all from the former dispensary and are on a three month contract with the PHC administration. Supervision is jointly provided by the PHC administrators and the NTP, and the regional TB coordinator for Tbilisi works very closely and well with the PHC facility.

PHC staff and administrators have some concern regarding infection control within the facility, especially with those patients referred for X-ray who have to take the lift to the 4th floor and wait in a common area with other PHC patients. They are hopeful that having the TB patients integrated with the rest of the facility will decrease stigma,

although they note that their general population may be scared of being in the same facility with TB patients.

This appears to be a facility that is well-equipped to deal with integration of TB services into the PHC facility. They remain correctly concerned about IC, especially with regards to X-ray facilities. They have a close working relationship with the NTP regional coordinator. Monitoring of the facility will be needed once construction and integration are complete, but #1 Medical-Prophylactic Center has potential to serve as a model of good practices for others during the national integration process.

5.2.2 Site Visit in Sagaredjo

Location: Geo-Hospitals Primary Health Care facility, Sagaredjo

Director/Insurance: Geo-Hospitals, Vienna Insurance Group

Date of Visit: February 15, 2012

Assessment

This is a single-building, newly built hospital in the Sagaredjo region that has integrated a local TB dispensary into its PHC facility and services. There are currently 26 known TB patients receiving care here (19 pan-susceptible cases, 6 MDR and 1 XDR). In addition to that, 2-3 persons per week are referred to the TB services for diagnosis. There is one TB physician and one nurse in the facility and there are a total of 5 primary care physicians who provide clinical consultation to a total of 12-15 patients per week. The center also has a lab and an X-ray. The facility offers inpatient services for 15 patients and has a trauma/casualty area that functions 7 days a week. The hospital was originally built for surgical services, but they are now providing integrated outpatient PHC for a number of specialties, including cardiology, oncology and TB.

TB services are currently provided in one small room in the PHC facility. There is no separate entrance to this area. Patients must register at a common desk with all other patients and although the waiting area for known TB patients is in a separate corridor, there is direct airflow exchange with the general waiting area. Furthermore, the common X-ray is located right next to the TB services and patients awaiting X-ray share the same space with patients awaiting TB care.

The room in which TB care is provided is small and there is little space for the doctor, nurse and examination table. There is one window in the room and only a small (15 cm x 10 cm) vent in the left upper corner of the room. There are no UV lights available. Medications and registers are stored in this small TB room, and the registers are kept confidentially in a locked desk drawer in the area.

TB suspects must present to PHC providers prior to being referred to the TB services. If they do not have insurance, they must pay 20 GEL to see the PHC provider. If they are diagnosed with TB, the remainder of their care is covered by the state, which gives a set amount to the facility for each TB patient under their care.

Providers, administrators and investors are hopeful that the integration will improve access to quality services for TB patients and to other specialists they may need to see during the course of their TB treatment. They also think there will be improved communication between TB specialists and other providers since they are housed in the same unit. There are regular staff meetings attended by all providers in the facility, and these can be used to discuss common patients and to provide case-based trainings to providers. They also hope that PHC physicians and nurses can be trained to provide DOT and assist in the management of TB patients, while allowing the TB providers to retain some autonomy.

The providers, administrators and investors also expressed some concerns. They feel they did not have time to adequately prepare for the integration and are deeply concerned about infection control in the facility. It is unclear to them to whom they

are to turn for guidance and assistance, especially in dealing with infection control policies.

In addition, the team remains concerned about communication with village doctors and nurses. They are concerned because there is no means of communication with these village doctors and nurses and feel that true integration should encompass strengthening ties with these providers.

The facility in Sagaredjo has fully integrated TB services into the PHC facility, but there are significant concerns about this. In general, they feel they were inadequately prepared to open their facility for TB services. They have not been able to make infrastructure changes that would allow for proper infection control and are concerned—correctly so—about the possibility for nosocomial transmission of TB within this facility. They are unclear on where to seek advice regarding IC policies and TB policies in general. There is no joint monitoring being done with the NTP. This facility represents a setting in which the rapid integration of TB services into the PHC program has great potential to see decreased rates of utilization (because of the 20 GEL payment) and increased transmission of TB in the setting of woefully inadequate infection control practices. All levels of providers are aware of these but are unclear on whom to turn to for assistance in these matters.