



BUILDING BRIDGES WITH NORTH KOREA: ENGAGING THROUGH HEALTH DIPLOMACY

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A resurgence in tuberculosis (TB) following the famines of the 1990s in the Democratic People's Republic of Korea (DPRK or North Korea) led to an unprecedented collaboration to address a very serious and expanding epidemic.

Before 2008, DPRK worked with the World Health Organization (WHO) and later the Global Fund to Fight AIDS, TB, and Malaria (GFATM), to design and update their tuberculosis control program to provide drugs to patients who were diagnosed with pulmonary TB by clinical assessment or conventional acid-fast microscopy. In 2008, the Ministry of Public Health (MoPH) identified a need to conduct culture and drug susceptibility testing to identify patients with drug-resistant disease. This required a renovation and upgrade of their National Tuberculosis Reference Laboratory (NTRL), building on incomplete initial work begun by WHO. Subsequently, a delegation from the MoPH approached John Lewis and Sharon Perry of the Center for International Security and Cooperation (CISAC), and Dr. Gary Schoolnik of the School of Medicine at Stanford University for assistance. This led to the formation of an unprecedented collaboration, which remains active and effective even in the current political climate.

Initial partners included CISAC, members of the Stanford School of Medicine, TB laboratory scientists from the San Francisco Bay Area, and volunteers from Christian Friends of Korea (CFK), a Christian faith-based organization that has worked extensively in DPRK for nearly 20 years, particularly supporting local TB sanatoriums (<http://cfk.org/>). Initial funding and support for the laboratory development project came from CFK, Stanford's Walter H. Shorenstein Asia Pacific Research Center, and the Nuclear Threat Initiative (NTI), a nonprofit, nonpartisan organization with a mission to strengthen global security by reducing the risk of use and preventing the spread of nuclear, biological, and chemical weapons in order to build trust, transparency, and security. A description of NTI's early role in this effort can be found at <http://www.nti.org/about/projects/TB-Threat/>.

Early work in this project included the design and renovation of the NTRL facility in Pyongyang. After the facility was reconstructed, laboratory equipment and supplies were procured, initial training in laboratory techniques and biosafety began, and instructions on the specific responsibilities of National TB Reference laboratories were established. These steps were accomplished with the help of largely volunteer CFK construction crews and facilities engineers and Bay Area microbiology laboratory experts. With help from Jason Rao of the American Society for Microbiology, Stanford University (Dr. Schoolnik) was able to obtain additional funding from the Richard Lounsbery Foundation. Together with funding from Zero TB World, this enabled the hiring of a full-time TB laboratory expert, Dr. Kathleen England. The following text box is a narrative of Dr. England's work, a description of the challenges, and a glimpse of the rewards of constructive humanitarian engagement.

The DPRK TB program is currently making strong efforts to improve the diagnostic and treatment program for drug-resistant tuberculosis. The Ministry of Public Health strongly recognizes the need to improve multidrug-resistant TB (MDR-TB) case detection and treatment for the nation. One of the most successful endeavors over the past five years includes the renovation of, and diagnostic advancements at, the National Tuberculosis Reference Laboratory (NTRL) in Pyongyang. Currently, the NTRL has the ability to perform WHO-recommended diagnostics, which include fluorescent acid-fast microscopy, culture-based TB identification methods, drug susceptibility testing by conventional culture methods, and molecular testing using GeneXpert technology. The laboratory staff are currently undergoing proficiency testing and method validation studies to demonstrate the level of performance required to obtain accurate and reliable results. Once proficiency and competency are attained, the laboratory will be able to implement national surveillance programs for both TB and MDR-TB, properly monitor MDR-TB patients under treatment, and perform a national drug resistance survey. Under direct guidance of Stanford's technical advisor, the NTRL is working through



N95 respirator fit testing for staff working with TB cultures.

the laboratory accreditation process outlined by the Global Lab Initiatives sponsored by WHO and the STOP TB partnership. The NTRL and National Toxicology Program are dedicated to achieving international accreditation. Attaining this goal would demonstrate a national commitment to the outside world to “STOP TB” in DPRK.

Use of advanced technology like the GeneXpert in limited-resource countries has been proven to be the most effective diagnostic tool for rapid identification of MDR-TB around the world. The method is simple and sustainable; it requires very little infrastructure. The technology demonstrates how modern science can find practical solutions for the diagnosis of epidemic diseases like TB for limited resource countries.

CHALLENGES FACING TB PROGRAMS IN NORTH KOREA



1. Limited national resources
2. Outside donors unable to help
3. Sanctions, sanctions, sanctions
4. Decaying national infrastructure
5. Dated diagnostic technology, expertise

Despite these challenges, improvements have been made by the efforts of individuals, local physicians, health care workers, laboratorians, and members of the nation's public health system, oftentimes at risk to their own health and safety.

In less than two hours, the GeneXpert assay identifies if a patient has TB and if the organism is carrying a specific genetic marker for resistance to the TB drug rifampicin, which serves as a reliable proxy for MDR-TB. Implementation of this technology in the DPRK could be a “game changer.” Having the ability to rapidly screen patients and identify those susceptible to traditional TB drugs and those who need special MDR therapy provides a critical tool that can significantly affect the course of the current epidemic. The rollout of GeneXpert technology in the DPRK can greatly impact the ability to expedite treatment for thousands of MDR-TB patients. As the program expands over the next year, increasing the capacity for GeneXpert testing will be critical.

Progress with current and future laboratory developments is slow, because the DPRK laboratory faces many limitations. The project is particularly impacted by internal infrastructure shortages. One of the most serious at this time is the lack of an uninterrupted supply of power to the NTRL facility. Extended power outages and frequent fluctuations affect culture-based diagnostics, can damage equipment, lead to spoilage of sensitive reagents and testing materials, and disrupt daily workflow. Diagnostic activities are further impeded by limitations on the import of needed equipment and TB diagnostic materials from reputable international vendors into DPRK. Often vendors are reluctant to sell the supplies needed for ongoing operation of the DPRK NTRL for fear of running afoul of export control restrictions. The maintenance of a continuous and reliable supply chain is essential. Also, the development of a national specimen referral program has been impeded by internal logistical challenges because special permits are required for travel between regions in DPRK, transport vehicles and money for gasoline coupons are scarce, and rural road conditions are challenging.

At present, the biggest impediment to program development and patient treatment is funding. Expanding diagnostic capacity and increasing the drug supply for MDR-TB is extremely expensive. Because of current politics, there has been a decrease in the level of support from U.S. foundations and philanthropic

organizations and individuals for humanitarian aid to the DPRK. Loss of external support for the national TB program could halt progress and allow the TB situation to expand further out of control and beyond the borders of the DPRK.

Even with all the external challenges and politics, the Ministry of Public Health continues to regularly allow U.S. partners into the country to work closely and productively with their citizens for extended periods of time. This clearly shows that they recognize the gravity of their situation and are working diligently to control TB in their country. Furthermore, through our collaboration, we have witnessed many individuals, local physicians, health care workers, laboratorians, and members of the nation's public health system, who dedicate their lives to serving and caring for those afflicted with this debilitating and life-threatening disease, even at great risk to their own health and safety. The work and commitment by the Ministry and all those involved is truly commendable.

Dr. England has worked with many partners in an effort to bring about continuous and lasting progress. The good will and trust established between the MoPH of the DPRK toward the CFK enabled this project to begin and continue on a good footing. Dr. England and Stanford University (Dr. Schoolnik) also work closely with WHO, UNICEF, and Global Fund partners who continue their work in DPRK indefinitely to ensure a lasting impact.

Cultural differences in the structure of organizations and systems of quality management have presented a challenge. Dr. England and others have found that the desire of the NTRL staff to seek international accreditation has helped them to accept international standards for quality assurance and to incorporate those standards into their daily practices. The Global Laboratory Initiative (GLI) Stepwise Process Towards Laboratory Accreditation (<http://gliquality.org/>) has also proven to be a very useful tool in promoting the acceptance and introduction of quality testing.

Dr. England's experiences and activities over the past 2 years have fostered relationships with laboratory staff and Ministry colleagues. On her most recent visit in November 2013, she and other CFK travelers engaged in a volleyball match with mixed members of the Ministry and sanatoria staff. For Mother's Day, 2012, the laboratory staff at NTRL gave Dr. England a cake in recognition of her being a mother. The staff further implied that she was like a mother to the laboratory, providing the nurturing and support they needed to make significant progress and achieve many of their goals. Through these small interactions and exchanges, person-to-person contacts, and good will, relationships built with trust toward the achievement of a shared goal can be models for building bridges with the DPRK. ■

KATHLEEN ENGLAND, Ph.D.

Kathleen England, Ph.D., a tuberculosis (TB) diagnostics specialist, has worked in international TB programs under the NIH in China, Medicins Sans Frontiers in Mongolia, and Stanford University School of Medicine In North Korea. Kathleen's position with Stanford involved the management of the DPRK National TB Reference Laboratory project, and she was laboratory advisor for the DPRK National TB Program. Currently, Kathleen serves as the Laboratory Technical Officer for an International TB foundation that supports over 20 countries.



EDWARD DESMOND, Ph.D.

Edward Desmond, Ph.D., was involved at the beginning of the North Korea laboratory project and has served intermittently as a volunteer for the project. He is a Diplomate of the American Board of Medical Microbiology.

