The U.S. Government will support the implementation of infection control recommendations at national, facility, community, congregate, and household settings and will tailor advocacy and communication efforts to these different levels. These efforts will include a concentration in high HIV burden settings including HIV clinics serving immunocompromised patients. In order to better understand the contribution of specific infection control measures to overall TB prevention and care and improve our programming, we will work with partners to develop, implement, and monitor outcome indicators for infection control measures and use the information gained to refine infection control policies, programs, and guidelines.

C. MANAGEMENT OF LATENT TB INFECTION

There is a strong evidence base supporting the treatment of persons with LTBI to prevent progression to active TB disease, especially for children and persons with HIV infection or other immunosuppressive conditions, Individuals with LTBI constitute an important reservoir of not only active TB, but also potential TB transmission. If someone with LTBI progresses to active TB, he or she will not only require services to address personal health issues, but also will likely become an agent for transmission of TB within his or her community. This cycle will continue for decades unless the risk of progression from LTBI to active disease is mitigated through improved LTBI detection, treatment initiation, and adherence; alleviation of the underlying clinical and population risk factors for progression; and/or a post-exposure vaccine. The U.S. Government will work with National TB Programs and National HIV Programs to determine which LTBI strategies should be prioritized, based on local epidemiology, high-risk populations, and care settings.

Despite the importance of addressing LTBI, many challenges to implementation of LTBI programs remain. There is no reliable gold standard to diagnose LTBI, and the decision to treat individuals with LTBI is largely based on a combination of imprecise tests, identification of risk factors for progression to active disease, and a determination of whether the benefits of treatment outweigh the the risks, such as side effects. As a result, coverage and adherence to LTBI treatment is poor. The U.S. Government's Global TB Strategy will work with countries to support targeted introduction and implementation of adherence and management strategies for the treatment of individuals with LTBI.

OBJECTIVE 3. STRENGTHEN TB SERVICE DELIVERY PLATFORMS

TB services are implemented and delivered at all levels of the health system from primary to tertiary. The national health system is the platform through which TB prevention, diagnosis, and treatment activities are introduced, expanded, and strengthened. It is, therefore, clear that the quality of this system has a direct impact on the provision of high-quality, patient-centered TB services. Although the U.S. Government's Global TB Strategy is not designed or able to address entire health systems, our efforts focus on strengthening key service delivery platforms for TB service delivery. We will assist countries to identify populations at high risk of TB and support improvements to the health settings in which they seek care. This will require a multi-sectoral approach and engagement of a range of partners including not only traditional government health agencies, but also affected communities and community organizations and the private sector – for-profit and non-profit. Through these partnerships, the U.S. Government will focus on strengthening drug policy and management, monitoring and evaluation systems, and human

resource development. There is inherent overlap and linkages between the objectives as each contributes to the others.

The U.S. Government's work to strengthen TB service delivery platforms will focus on:

- Increasing political commitment and leadership
- Improving and expanding comprehensive partnerships and informed community involvement
- Strengthening drug and commodity management
- Improving quality data, surveillance, and monitoring and evaluation
- Developing human resources

A. POLITICAL COMMITMENT AND LEADERSHIP

Scaling up sustainable interventions for TB care and treatment requires high-level political commitment and adequate financial and human resources. Central coordination under the national government's stewardship is essential. In supported countries, the U.S. Government will support government-led processes to develop NSPs for combating TB, as part of a comprehensive national health sector plan. NSPs should take into consideration the country's TB epidemic and its health system structure and functions, including procurement and supply systems, resource availability, regulatory policies, and private sector and community engagement. NSPs should be ambitious and comprehensive and include a budgeted operational plan, monitoring and evaluation framework, and technical assistance scheme. The U.S. Government will support country-led implementation, governance, and management of national strategic plans. Specific areas of focus will include:

- 1. The development of policy frameworks
- 2. Support for adequate resource allocation and resource management

- 3. Evidence-based analysis and decision-making
- Integration of insurance programs as well as social protection and poverty alleviation strategies

B. COMPREHENSIVE PARTNERSHIPS AND INFORMED COMMUNITY INVOLVEMENT

The U.S. Government believes that National TB Programs must involve affected communities and actively partner with civil society organizations and private stakeholders if they are to reach their potential. Accordingly, the U.S. Government will support national partnerships and coordination bodies that ensure appropriate representation and capacity or ability to strengthen programs.

The U.S. Government will facilitate sustainable partnerships across the health and social sectors and between these sectors and affected communities to develop a robust response to the TB epidemic. Efforts to fully utilize the unique skills and capabilities of civil society and other local organizations will be made so that TB programs can incorporate and harness the dynamism of them, especially in their work to reach vulnerable populations; mobilize communities: channel information in accessible and user-friendly formats; create demand for high-quality, patient-centered TB services; frame effective delivery models: and address other determinants of the TB epidemic. Partnerships with a range of organizations will be actively explored to ensure strong country led approaches.

The U.S. Government will also work closely with supported countries to reinforce successful implementation of Global FundTB grants. We will use our technical and programmatic expertise to help countries develop strong Global Fund grant applications and implementation strategies to maximize the impact of Global Fund resources for TB.

C. DRUG AND COMMODITY MANAGEMENT SYSTEMS

An uninterrupted supply of effective, affordable, and quality-assured TB drugs is a vital element of every national TB program. The U.S. Government will continue to support country efforts to develop reliable procurement and distribution systems for all essential TB medicines and supplies. These systems should ensure that TB medicines and supplies reliably reach all relevant health facilities. To this end, the U.S. Government will help National TB Programs plan, procure, distribute, and maintain adequate drug stocks. The U.S. Government will further encourage countries to make TB medications available free of charge to all TB patients, not only because many patients are poor and find medicines difficult to afford, but also because treatment has benefits that extend to society. For example, cure prevents transmission to others, decreases overall health system costs, and minimizes reduction in gross national product (GNP) and individually affected household incomes.

The U.S. Government will also work to improve the appropriate utilization of TB drugs globally and at country level. Among other activities, we will support the development, implementation, and monitoring of legislation governing the use of TB drugs by all providers. The U.S. Government will introduce and strengthen pharmacovigilance systems that monitor adverse drug reactions to all TB medicines, especially new drugs and/or regimens that are introduced. We will also work to expand and improve the use of fixed dose combinations and other tools, such as patient kits. Lastly, the U.S. Government will support maintenance of a global supply of affordable, quality-assured TB medicines to ensure that all countries and their citizens are able to access life-saving drugs.

D. QUALITY DATA, SURVEILLANCE, AND MONITORING AND EVALUATION

TB surveillance systems to track notifications and deaths, coupled with a strong monitoring and evaluation system to gauge progress and identify areas for improvement, are critical components of a National TB Program. The U.S. Government will work with supported countries to develop and improve systems to track TB disease burden in high-risk settings and among high-risk groups, accurately monitor trends, and quickly detect any resurgence of TB, so corrective actions can be implemented. In addition, supported countries and partners will institute upgrades to their routine monitoring systems using standardized methods based on data of documented quality; these surveillance systems will also be better able to monitor progress towards NSP targets.

The U.S. Government strategy will strengthen TB case notification and vital registration systems, including integration of case management and surveillance systems, improvements in the use of data for decision-making and in monitoring and evaluation, and in the introduction and expansion of regulatory enforcement. As appropriate, and in line with NSPs, the U.S. Government will also su pport the introduction and scale-up of case-based and/or patient-based electronic recording and reporting systems to improve TB surveillance. As appropriate and needed, the U.S. Government will continue to invest in national and global surveys and other data gathering to inform programs and policies.

E. HUMAN RESOURCES DEVELOPMENT

One of the most neglected but most important components of a successful TB program is the recruitment, development, and retention of qualified, skilled, and caring personnel. The development

and management of human resources is critical to providing high-quality, patient-centered TB care. The ability of a country to meet its health goals depends largely on the knowledge, skills, motivation, dedication, and appropriate deployment of the workers responsible for organizing and delivering health services. Many countries, however, lack sufficient human resources to deliver even the most basic of health interventions for a variety of reasons, including limited education and training capacity; migration of health workers within and across countries; mismatched skills and needs at the facility level; and demographic disparities. The U.S. Government will work with countries to develop and improve human resources for combating TB by:

 Developing and implementing national policies and plans for improving human resources for health

- 2. Integrating disease management at the primary health facility level
- 3. Promoting task shifting to increase the efficient and effective use of existing human resources
- Developing comprehensive approaches to pre-service and in-service clinical training, especially among those serving poor and neglected populations

OBJECTIVE 4. ACCELERATE RESEARCH AND INNOVATION

Global progress in the development and introduction of new tools and approaches for TB has been slow. However, biomedical research, largely supported through the NIH, has made great strides in our understanding of TB and the pathogen that causes it, and the translation of research funding into the

