Willingness to use and pay for a new diagnostic test for active tuberculosis in HIV-positive and HIV-negative individuals: Results from Benin, Peru, and Tanzania
Willingness to Use and Pay for a New Diagnostic Test for Active Tuberculosis in HIV-positive and HIV-negative Individuals: Results from Benin, Peru, and Tanzania

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<tr>
<td>ANOVA</td>
<td>Analysis of variance</td>
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<tr>
<td>CAME</td>
<td>Centre d’Achat des Médicaments Essentiels et Consommables Médicaux/Center for the Purchase of Essential Medications and Medical Consumables</td>
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<tr>
<td>CFA</td>
<td>Communauté Financière Africaine/African Financial Community (Currency used in Benin)</td>
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<td>CHS</td>
<td>Center for Human Services</td>
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<td>CHWs</td>
<td>Community Health Workers</td>
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<tr>
<td>DOTS</td>
<td>Directly Observed Treatment Short Course</td>
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<td>DPM</td>
<td>Directorate of Pharmacies and Medicines</td>
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<tr>
<td>DST</td>
<td>Drug sensitivity testing</td>
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<tr>
<td>ESSALUD</td>
<td>Social security system (Peru)</td>
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<td>FBO</td>
<td>Faith-based organization</td>
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<td>GDF</td>
<td>Global Drug Facility</td>
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<td>GDP</td>
<td>Gross Domestic Product</td>
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<td>GNI</td>
<td>Gross National Income</td>
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<tr>
<td>HBM</td>
<td>Health Belief Model</td>
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<tr>
<td>HIV/AIDS</td>
<td>Human immunodeficiency virus/acquired immunodeficiency syndrome</td>
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<tr>
<td>INS</td>
<td>National Institute of Health (Peru)</td>
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<tr>
<td>LTBI</td>
<td>Latent tuberculosis infection</td>
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<tr>
<td>MDR-TB</td>
<td>Multi-drug resistant tuberculosis</td>
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<td>MODS</td>
<td>Microscopic observation drug-susceptibility assay</td>
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<tr>
<td>MOH</td>
<td>Ministry of Health</td>
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<td>MOHSW</td>
<td>Ministry of Health and Social Welfare</td>
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<tr>
<td>MSD</td>
<td>Medical Stores Department</td>
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<tr>
<td>NACP</td>
<td>National AIDS Control Program</td>
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<tr>
<td>NGO</td>
<td>Nongovernmental organization</td>
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<tr>
<td>NTCP</td>
<td>National Tuberculosis Control Program</td>
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<td>NTP</td>
<td>National Tuberculosis Program</td>
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<tr>
<td>NTLP</td>
<td>National Tuberculosis and Leprosy Program</td>
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<tr>
<td>OLS</td>
<td>Ordinary least squares</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase chain reaction</td>
</tr>
<tr>
<td>PLWHA</td>
<td>People living with HIV/AIDS</td>
</tr>
<tr>
<td>S/.</td>
<td>Peruvian nuevos soles</td>
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<tr>
<td>SSM</td>
<td>Sputum smear microscopy</td>
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<tr>
<td>STI</td>
<td>Sexually transmitted infection</td>
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<tr>
<td>Tsh</td>
<td>Tanzanian shillings</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WTP</td>
<td>Willingness-to-pay</td>
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<tr>
<td>XDR-TB</td>
<td>Extremely Drug-Resistant Tuberculosis</td>
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**FOREWORD**

The spread of infectious diseases is a critical global health concern. Despite recent progress in the availability of powerful drugs, many treatable infectious diseases continue to exact a terrible toll worldwide, particularly in developing countries. The World Health Organization (WHO) estimates respiratory disease to be a leading cause of infant death in countries with high childhood mortality rates. Malaria is estimated to cause 1–3 million deaths and 500 million–5 billion episodes of clinical illness, mostly in Africa. In 2005, an estimated 2.3 million children worldwide were living with HIV/AIDS, 2 million of them in sub-Saharan Africa. About a third of the world’s population is infected with the tuberculosis (TB) bacillus, and as many as 2 million people die of the disease each year. Among people with HIV/AIDS, TB is the leading cause of death. The highest rates of TB are in some of the world’s poorest countries, exacting an enormous economic toll. Likewise, sexually transmitted diseases, such as gonorrhea and Chlamydia, pose significant health risks, with prevalence rates as high as 40% even in low risk populations in Africa. Syphilis remains a major health problem during pregnancy, with an estimated prevalence rate as high as 18% among pregnant women attending antenatal centers in Africa. Diarrheal diseases affect an estimated 1–4 billion children under age five in developing countries, resulting in about 2.5 million deaths (85% of which occur in the poorest parts of the world); in some countries these diseases account for more than 20% of all deaths in children under age five.

In order to make treatment accessible, it is essential to identify those who require treatment; to administer and monitor appropriate treatment; and, importantly, to prevent overtreatment, which can cause the spread of drug-resistant microbes. At present, the diagnostic tools used in developing countries have many limitations and are largely inadequate for addressing health needs. There is a growing need to develop and test better and more accessible diagnostic tools for several infectious diseases, tools that would be particularly tailored to developing-country realities. In response, the Global Health Diagnostics Forum of the Bill and Melinda Gates Foundation recognized in 2004 the importance of access to appropriate and accurate diagnostic tools in order to evaluate and improve global health. The forum recommended focusing on six diseases or syndromes that cause among the highest disease burdens in the developing world: acute lower respiratory infections (ALRI), HIV/AIDS, diarrheal diseases, malaria, TB, and sexually transmitted infections.

In 2007 the Gates Foundation awarded a grant to the Center for Human Services (CHS) to research potential demand for diagnostic tests for five of these disease areas: ALRI, HIV, malaria, TB, and STIs. Research on potential demand for diarrheal disease diagnostics was deferred pending further technical and clinical discussion. CHS is advancing the Gates Foundation’s vision of accelerating access to existing vaccines, drugs, and other tools to fight diseases that disproportionately affect developing countries and of identifying new health technologies that would be effective, affordable, and practical in resource-poor settings in the developing world.

CHS conducted research to evaluate potential demand for new diagnostic tests and identify factors that might affect that demand among consumers and within the public, private for-profit, and private non-profit health sectors. This report on tuberculosis diagnostics is one of a series of reports from that research. The research objectives were to:

- Estimate consumer willingness to use and pay for new diagnostic tests,
- Examine the factors that influence consumer willingness to use and pay for these tests,
- Examine the extent to which health care providers and program managers see diagnostic tests for these illnesses as priorities in their countries, and
- Describe a few specific past experiences with the introduction of new diagnostics into specific countries to identify issues that should be considered before introducing new tests in the future.

The research includes six reports, one for each diagnostic included in the study:

- A test to screen for syphilis in pregnant women as a routine part of antenatal care;
• A test for gonorrhea and chlamydia in high risk asymptomatic populations;
• A test for (HIV) in children under 18 months of age;
• A test for active TB in HIV-positive and HIV-negative patients;
• A test for malaria in children under age five; and
• A test for bacterial ALRI in children under age five.

For purposes of this study, syphilis was considered separately from gonorrhea and chlamydia because the target population for syphilis screening (pregnant women) was different from the target population for gonorrhea and chlamydia (high-risk asymptomatic populations such as commercial sex workers).

The project covers four countries: Benin, India, Peru, and Tanzania. Results for Benin, Peru, and Tanzania are presented as part of the report for each diagnostic. Each report provides country demographic and epidemiological profiles along with information on the current standard of diagnosis. In addition to literature, information for the study comes from health worker interviews and consumer surveys and focus groups. The interviews provide data on the degree to which health professionals at different management and service-provider levels are satisfied with the current diagnostic standard or see a need for a newer technology. The surveys and focus groups offer perspectives on consumer willingness to pay, factors that influence willingness to pay, and consumer preferences about different types of diagnostic samples (e.g., blood, urine, sputum, etc.). CHS is conducting additional research in India and will publish those results separately.

Case studies examine past experiences with introducing diagnostic tests as a way of smoothing the way for introduction of new diagnostics as they become available. The four case studies being completed as a part of this project include:

• Discussion about the adoption of rapid syphilis tests in Tanzania,
• Development and introduction of microscopic drug susceptibility testing to diagnose TB and test for multi-drug resistant TB in Peru,
• Use of malaria rapid diagnostic tests by volunteer community health workers in remote areas of the Peruvian Amazon, and
• Use of STI diagnostics in the private sector in India.

For more information on the project and for copies of other reports, please contact the Bill & Melinda Gates Foundation or visit its website: http://www.gatesfoundation.org.
EXECUTIVE SUMMARY

Tuberculoses claimed 1.7 million lives worldwide in 2007, when 9.27 million new cases of active TB presented. TB is a growing global public health problem and a major cause of morbidity and mortality in many countries, particularly in Africa and Asia.\textsuperscript{11,13,14}

Although rapid and accurate diagnosis is a fundamental element of international TB control strategies, millions of people remain undiagnosed and untreated. Inferior diagnostics perpetuate the social and economic losses accompanying TB-related death and disability, which impact individuals of all ages across all levels of society. Inadequate diagnostic tests also leave communities vulnerable to the spread of infection. Rising rates of drug resistant TB and the associated spread of HIV increase the urgency for superior diagnostic tools\textsuperscript{11,15}

Every year more than US $1 billion is spent on diagnostics for TB worldwide. Developing countries conduct 73% of TB diagnostic testing and account for about a third of global expenditures on TB testing. The traditional methods of testing used in the developing world necessitate repeat testing and regularly cause significant delays, patient losses to follow-up, and misdiagnoses. Newer technologies are too expensive and complex to be practical in most low resource settings. New and improved diagnostics, adapted to the needs of higher burden countries are in great demand; an improved TB diagnostic test could save an estimated 400,000 lives annually by improving case management, disease control, and health outcomes\textsuperscript{11}.

The purpose of this study was to determine the potential market for a new TB diagnostic in developing countries. Specific objectives included assessing health system interest in a new diagnostic and potential consumer willingness to pay for same. In addition, the study explored desired characteristics for a new diagnostic among consumers and health care providers. To fulfill these objectives, the Center for Human Services (CHS) performed extensive field work in Benin in West Africa, Tanzania in East Africa, and Peru in western South America. Field work is underway in India; results from that research will be written up separately.

Three principal methodologies were used: in-depth interviews with health care providers and program managers, a consumer willingness to pay (WTP) survey implemented in three regions of each country, and consumer focus groups to further explore survey findings and factors that influence consumer willingness to pay for and use a new TB diagnostic. During interviews with providers, study team members asked about disease priorities, current diagnostic approaches, the perceived need for a new diagnostic test, and the desired characteristics of such a test if needed. Interviewees included program managers at the national and district levels as well as front-line clinicians. CHS recruited participants from the public, private for-profit, and private non-profit sectors in both rural and urban areas. The consumer WTP survey included questions on each respondent’s socio-economic background, health-seeking behavior, and willingness to pay for a new diagnostic test for TB. Contingent valuation was used to determine the maximum amount consumers would be willing to pay in each country. Consumer focus groups explored consumers’ perceptions of the most important health problems in their community; concerns about TB and other diseases included in the overall study; perceptions about severity, susceptibility, contagiousness, and perceived motivators; and barriers to TB diagnosis. Focus group participants also commented on survey results to help clarify why survey respondents may have expressed a willingness to pay more for one diagnostic than another or geographic differentials in WTP, among other issues. Focus groups were designed using the Health Belief Model (Appendix B) as a theoretical framework. The body of the report more fully describes the methods.

Findings from the three study countries, Benin, Tanzania and Peru, demonstrate willingness on the part of people suspecting they might have TB to pay for an improved diagnostic. In addition, they also demonstrate that health systems and health providers see such a test as a high priority. This suggests that the potential market for such a test would be substantial. Consumer perceptions related to TB, specific areas of need, and desired test attributes all shed light on the likely characteristics of that market.
Consumer Perceptions Related to Tuberculosis

Consumer focus group participants in the study countries were very aware of TB and recognized it as a highly contagious, airborne disease. Interviewees saw themselves as more susceptible to TB than to HIV/AIDS because little can be done to prevent TB infection. Those free of active disease ostracize those who are ill with TB for fear of falling ill themselves. Those already ill become embarrassed and ashamed because they recognize the danger they pose to others. The resulting stigma discourages many from seeking diagnosis and treatment and stimulates others to seek diagnosis and treatment in secret to avoid ostracism.

Respondents were also very conscious of TB’s economic impact on the family. In many cases, the person stricken is a bread-winner and unable to work during treatment. Beyond income loss, the family must bear additional costs related to diagnosis and treatment, which often include payments for services and transport even where diagnosis and treatment are free.

On the other hand, there is widespread recognition that TB is curable, albeit it with a long and arduous treatment. While most focus group participants viewed diagnosis and treatment as a priority worth paying for, others suggested that for the welfare of the community, any cost barrier should be eliminated.

Present and Future Diagnostic Tests for Tuberculosis

Some health providers thought that sputum smear microscopy (SSM) is beneficial because it interrupts disease transmission and is practical for low resource settings; others found it inefficient and insufficiently sensitive.

Current diagnostics suffer problems throughout the process, including procurement and distribution of supplies, samples, and results; inadequate training, supervision, and quality control; inadequate and/or expensive technology; inaccurate testing and difficulties of detection in children, PLWHA, and extra-pulmonary cases; and defaulting of patients due to slow provision of results and the need for multiple testing, among others.

Many health providers considered an improved and rapid diagnostic test for TB a high priority, especially if it would increase patient access to early diagnosis and reduce the default rate. The ideal test could be performed and analyzed at the primary care level since transportation costs may prevent patients from going to referral facilities.

Tanzanian health providers felt that diagnostics would be improved if reliance on microscopes, electricity, the cold chain, and multiple specimens could be eliminated. Several stressed that an improved test should be heat-stable and have a high predictive value. Providers also mentioned that a rapid test would help reduce loss to follow-up. Peruvian providers associated the need for new diagnostics with their serious MDR-TB and XDR-TB problem. While pleased with the introduction of the MODS and Griess methods, they echoed concerns of providers in the other countries about the general capabilities of the health system to provide an adequate environment where accurate testing could be applied – even if a new diagnostic test were developed.

Both providers and focus group participants were asked about their preferences for sample types that could be tested as a substitute for sputum. The conclusion of both groups was blood, for reasons both medical and anthropological.

In summary, both providers and patients see new TB diagnostic tests as a high priority. Ideally, a new test should use blood samples; require little or no laboratory equipment or infrastructure; and be rapid, accurate, and inexpensive.

Willingness to Pay for a New TB Diagnostic Test

The consumer survey shows unequivocally that most people are willing to pay for a new TB diagnostic: Of those surveyed, 92% indicated a willingness to pay some amount and named a maximum price.
In each country people said they were willing to pay a wide range of maximum prices. The responses in each study were stated and analyzed in the local currency. To facilitate the analysis, the entire range of responses was divided into 11 price ranges. To demonstrate the gamut of responses, the lowest and highest of those ranges was translated into U.S. dollars (Table 1) accompanied by the percentage of respondents who said they were willing to pay at that price level. The table shows that at the lowest levels, most people are willing to pay, but 5%–15% of the population are unable or unwilling to pay for services at the highest level. It also shows that eventual prices for diagnostic TB tests would be highly dependent on the countries where they are applied.

<table>
<thead>
<tr>
<th></th>
<th>Lowest Price Range</th>
<th>% WTP</th>
<th>Highest Price Range</th>
<th>% WTP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benin</td>
<td>&gt;0 - $1.19</td>
<td>86%</td>
<td>&gt;$11.87</td>
<td>4%</td>
</tr>
<tr>
<td>Tanzania</td>
<td>&gt;0 - $0.43</td>
<td>89%</td>
<td>&gt;$4.24</td>
<td>11%</td>
</tr>
<tr>
<td>Peru</td>
<td>&gt;0 - $1.84</td>
<td>90%</td>
<td>&gt;$18.37</td>
<td>10%</td>
</tr>
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</table>

Figure 1 shows the percentage of respondents WTP at each price interval. Note that while the actual amounts of each interval varied between countries, the percentage of respondents WTP at each interval corresponded fairly closely. As the prices increased, the percentage of those WTP decreased. Thus, for example, at the third interval, about 50% would be WTP – and conversely, about 50% could be excluded from testing at that price level.

An analysis of the socio-economic characteristics of the respondents in each segment from all three countries demonstrated considerable similarity. People in segment D were generally urban, had a high education, frequently had a university degree, and were usually among the top two wealth quintiles. They were also often clients of private health care services. About half the people in segment A were in the two lower wealth quintiles, had relatively less education (primary and secondary), and worked as urban or agricultural laborers. They tended to seek health services in the public sector. The other segments tended to be a mix between the two extremes.

WTP was also affected by regions, but there was relatively little difference between urban and rural populations. Another factor that can play an important role is health insurance.
At the top end of the spectrum there is a group of 15%–20% willing to pay significantly more for TB diagnostic tests than the rest. However, it is important to remember that not all respondents were TB patients and that TB is primarily a disease of poverty, which translates to small, overcrowded quarters, poor nutrition, poor disease resistance, and marginal disposable income. Thus, we cannot assume that TB patients will be evenly distributed among either wealth quintiles or price segments. More likely, they will be clustered in the lower two segments – with a few cases in the higher segments as well.

If a price were to be set at the upper limit of the third interval, the prices would be equivalent to: $3.56 in Benin, $1.28 in Tanzania, and $5.51 in Peru. Even at these levels, about half the population might be excluded from testing. Furthermore, the administrative costs involved in exonerating large numbers of people from full or partial payment would be excessive, would create longer patient waiting times, and could themselves become a barrier to testing.

A better strategy from a public health point of view would be to charge at the lowest level. This would amount to little more than a co-payment and would ensure that price is not a barrier.

**Impact of the Structure of TB Services**

In most countries, TB services are almost exclusively provided by the public sector for several good reasons. At the secondary and tertiary levels, specialized pulmonary/TB institutions can concentrate scarce personnel and lab resources while limiting contagion. Despite its drawbacks, a single public sector system is far easier to regulate and supervise than disparate individual providers.

More important is the clear preference for a single public system on the part of the international community. Specifically, the Global Drug Facility (GDF) and the Global Fund exert significant influence on the organization and delivery of TB services. GDF offers good quality drugs at low prices due to volume purchasing. Provision of these drugs, however, comes with the condition that they be provided to patients free. GDF also has a strong preference against making TB drugs available on the open market to avoid possible abuse by the private sector.

During the last several years, the Global Fund has provided significant support to national TB programs in many countries, specifically to stimulate DOTS, improve laboratories and diagnostics, provide training, and pay for both first- and second-line drugs, often purchased through GDF. The Global Fund also supports educational campaigns, which have raised awareness of TB and the fact that it is curable, and advised people suspecting they might have TB to avail public sector services where the drugs will be provided free. Thus, in most places, the private sector plays no role in TB: Private providers are shut out of the market for lack of access to drugs and specialized diagnostic services unless they are linked to the public national TB program. This is unlikely to change for many years.

**The Market for a New TB Diagnostic Test**

Thus far, we have implied that new TB diagnostic tests would require professional intervention for collection and interpretation. However, should an inexpensive and accurate over-the-counter test be available, as with pregnancy tests, it would revolutionize TB diagnosis and possibly lead to significant reductions in incidence by encouraging early detection through self-testing. Not only would self-testing help overcome the stigma barrier, but tests could be given to all contacts. The market for such a test could easily reach 50 million or more per year into the foreseeable future. While the challenges of creating such a test are formidable, the benefits would be great. Produced in mass, such a test could be very lucrative even at a low price. Self-diagnosis might function as an initial screening test, with positive results triggering a facility-based confirmatory diagnosis prior to treatment.

In terms of facility-based tests, since the public sector is the primary source of TB services, government funding is unlikely to be sufficient even where political commitment is high. This insufficiency includes diagnostic tests and laboratory supplies. While most potential TB patients would accept a minimal co-payment, it seems unlikely that development, production, and distribution costs for a new test could be
covered by patients, the government, or both. On the other hand, the Global Fund might well purchase large quantities of a new cost-effective replacement for SSM or a better diagnostic for non-pulmonary and pediatric TB. The Global Fund would then stimulate use and fund training for the new test. In this case, cost-recovery/profit would depend on international funding with governments and patients contributing some smaller amount.

The market for such a test is tremendous since the high-burden countries include some of the most populous in the world: China, India, Indonesia, Nigeria, the Russian Federation, South Africa, and Brazil. Diagnostic kits could be channeled through GDF, providing access to most high-burden countries. India alone has a third of all TB cases worldwide.

Finally, a fourth class of test is sorely needed: a rapid and accurate test for MDR, which accounts for 5% of all TB cases. The importance of such a test can hardly be over-emphasized. The economic consequences of MDR are staggering: The current GDF price for treating a single smear positive patient is about US$ 29; the cost of treating one MDR patient can easily be $6,000–$10,000 or more. Further spread will aggravate the problem and could overwhelm some health systems. Both governments and international organizations would welcome more-rapid MDR diagnostics with the potential to reduce MDR incidence. In this case, even a relatively expensive test would be cost-effective and would certainly find a market.

**Recommendations**

1. Producers of diagnostic tests are strongly encouraged to pursue development of innovative tests for TB, as an effective test for initial case detection would be highly attractive to patients, countries, and the international organizations that would serve as the initial market.

2. Such a test should be sensitive, rapid, and inexpensive. Providers and patients in this stuffy suggested that the basis be blood sampling. Other desirable characteristics include no reliance on microscopes, electricity, the cold chain, and multiple specimens.

3. Tests should be developed for mass production, both to have an impact on disease and to provide cost recovery and profit-making opportunities at a low sales price.

4. Producers should be encouraged to develop an inexpensive over-the-counter TB test, as this could revolutionize the fight against TB by stimulating early detection, side-stepping resistance to testing from stigma, and providing a low-cost means for contact testing, all potentially contributing to a significant reduction in incidence. The market for such a test would be many times greater than the current market for passive case finding and thus potentially highly profitable.

5. Producers are also encouraged to develop tests to improve the sensitivity of suspected extra-pulmonary and pediatric TB cases. Producers should leverage the annual funding for clinical trials offered by the Stop TB Partnership and others.

6. To defray some of the cost of new diagnostic test, national TB programs could charge a low co-payment. Suspected patients have clearly stated that they are willing to pay for such a test. The price, however, must be adjusted to the characteristics of the country and region so as not to create a barrier to testing.

7. Given our findings that as prices increase from a minimum level, the percentage of people willing to pay drops off rapidly, setting a price above the minimum and then partially or fully exonerating large numbers of persons is not recommended as it would lead to high administrative costs, additional patient waiting time, and an additional barrier to services.
INTRODUCTION

Tuberculosis (TB) is a growing global public health problem and a major cause of morbidity and mortality in many countries, particularly in Africa and Asia, which respectively account for 31% and 55% of all cases worldwide.\textsuperscript{11,13,14} An airborne, infectious disease, TB is both preventable and curable, yet 2007 witnessed an estimated 9.27 million new cases of active TB worldwide. These cases led to 1.7 million deaths. About 15% of new TB cases are also positive for HIV.\textsuperscript{16}

Although rapid and accurate diagnosis is a fundamental element of international TB control strategies, millions of people remain undiagnosed and untreated for this disease. TB can affect anyone – regardless of age or socio-economic status – and causes much social and economic hardship for individuals, families, and communities. Inferior and inadequate diagnostic tests only perpetuate this problem and leave many vulnerable to this infection. There is an urgent need for improved, practical diagnostic tools in developing countries to combat the rising rates of drug resistant strains of TB and the associated spread of HIV.\textsuperscript{11,15}

Globally, significant resources are invested in TB prevention and treatment programs, with more than US$ 1 billion spent each year on TB diagnostics. About 73% of TB diagnostic testing and a third of global expenditures on TB testing occur in developing countries. However, the types of tests commonly used in these countries are not very accurate and require repeat testing, often resulting in significant delays, misdiagnoses, and patient losses to follow-up. Newer technologies are available but are often too expensive and complex to be practical in most resource-poor settings. There is a growing demand and need for new and improved diagnostics suitable for use in countries with high levels of TB; indeed, an improved TB diagnostic could save about 400,000 lives annually by improving case management, disease control, and health outcomes.\textsuperscript{11,14}

BACKGROUND

Global Epidemiology of Tuberculosis

Latent tuberculosis infection (LTBI) is extremely prevalent worldwide; an estimated 2 billion people – a third of the world’s population – are infected with M. tuberculosis. As of 2006, 14.4 million people worldwide were sick with active tuberculosis. While the global incidence of TB appears to be on the rise, case notification rates have decreased in several regions of the world over the past two decades, except in sub-Saharan Africa and Eastern Europe. Cases of TB are concentrated in developing countries with 80% of cases in 22 high-burden countries.\textsuperscript{14,17,18}

TB-related illness and death disproportionately affect men and women during their most economically productive years. A weak immune system is a major risk factor for developing active TB, so while TB rates are higher among adults, infants and children are actually at higher risk of contracting the infection. Children are also more likely to develop extra-pulmonary TB and TB meningitis, which can result in deformities, paralysis, deafness, blindness, and mental retardation.\textsuperscript{14,18-21}

The TB epidemic is fueled by the emergence of multi-drug resistance and the spread of HIV. In fact, HIV infection is the highest known risk factor for activating LTBI. Globally, approximately 8% of new TB cases are among people who are HIV positive, and TB is the principal cause of illness and death in people living with HIV/AIDS (PLWHA). For sub-Saharan African countries with high HIV rates, the extremely high prevalence of LTBI worldwide is particularly worrisome, and Africa accounts for 85% of incident HIV-positive, TB cases worldwide.\textsuperscript{5,11,13} The gender distribution of TB in sub-Saharan African countries is also of concern: HIV infections are steadily increasing among young women, making them more vulnerable to TB and ultimately increasing the burden of disease among that population.\textsuperscript{11,13,18,22}

As of 2006, most countries had documented strains of drug-resistant TB. Surveillance studies reported nearly 300,000 new cases of multi-drug resistant TB (MDR-TB) worldwide. Fewer data are available on the prevalence of extremely drug resistant TB (XDR-TB); however, with the exceptions of some Eastern
European countries and South Africa, among countries that have reported absolute numbers, the global proportion of XDR-TB cases is low.\textsuperscript{17,23}

<table>
<thead>
<tr>
<th>Box 1. TB Facts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High-burden countries:</strong> The WHO has identified 22 countries as being highly burdened by TB. These countries have 63% of the world’s population yet account for approximately 80% of the estimated number of new TB cases occurring worldwide each year; some of these countries also have the highest incidence rates of TB per capita.</td>
</tr>
<tr>
<td><strong>Types of TB:</strong> MDR-TB is TB with resistance to, at least, isoniazid, and rifampicin. XDR-TB is TB with resistance to, at least, isoniazid and rifampicin and to any of the fluoroquinolones and to one of the following injectable drugs: amikacin, capreomycin, kanamycin. Both MDR-TB and XDR-TB are more expensive and difficult to treat.</td>
</tr>
<tr>
<td><strong>DOTS Strategies:</strong></td>
</tr>
<tr>
<td>DOTS, an internationally recommended TB control strategy, was developed in the mid-1990s and has been implemented in 182 countries. It has five essential components: political commitment, diagnosis by sputum smear microscopy, short course treatment with standard first line drug regimens, a reliable drug supply, and a recording and reporting system that allows assessment of individual patient outcomes and overall program performance.</td>
</tr>
<tr>
<td>DOTS-Plus, a strategy for the management of cases with multi-drug resistance, was developed by the WHO and partner agencies in the late 1990s. It is based on the same principles as the DOTS strategy but includes use of sputum cultures and drug susceptibility tests for diagnosis and the use of second-line as well as first-line drugs.</td>
</tr>
<tr>
<td>Stop TB was developed by WHO in 2005 and was designed to guide TB control efforts from 2006 to 2015. It builds on the DOTS and DOTS-Plus strategies and has six major components: pursuing expansion and enhancement of DOTS; addressing TB and HIV coinfection, multidrug resistant TB, and other special challenges; helping to strengthen health care systems; engaging all health care providers; empowering patients and communities; and promoting research. The strategy underpins the second &quot;Global Plan to Stop TB,&quot; which covers the same period.</td>
</tr>
</tbody>
</table>

**Disease Control Strategies**

Comprehensive approaches to TB control have been implemented worldwide. In 1995, the World Health Organization (WHO) and partners formally launched a worldwide initiative, the Directly Observed Treatment Short-course (DOTS) strategy, to control TB. DOTS was widely implemented with varying levels of quality and coverage. Despite overall success, studies showed that DOTS alone was insufficient to achieve global TB control. In 2006, the more comprehensive Stop TB Strategy was launched to expand the scope of DOTS and meet TB-related Millennium Development Goals.\textsuperscript{6,7}

Diagnostics help international TB control programs to:

- Implement STOP TB,
- Coordinate TB and HIV/AIDS activities, and
- Arrest the spread of MDR-TB.

While the primary TB control priorities are the rapid and accurate diagnosis and treatment of patients with active, infectious TB, each country’s specific diagnostic priorities depend on its burden of disease, as well as its economic situation and health system resources.\textsuperscript{14,18}

**Key Aspects of Diagnosis**

Prompt and accurate TB diagnosis relies on a series of behaviors and actions by both patients and providers. Passive TB case detection requires that individuals first recognize the signs of illness that warrant medical care and then seek that care in a timely manner.\textsuperscript{24} Barriers to care-seeking identified in other studies include:

- Inappropriate choice of providers;
• Poor quality of care at health facilities;
• Poor recognition of danger signs;
• Conflicting illness beliefs; and
• Logistic challenges (e.g., lack of geographic access, transportation, or money; poor road conditions; and opportunity costs).24,25

Opportunity costs present a major barrier to TB diagnosis for patients in developing countries. The requisite collection of three sputum samples over a period of two or more days is particularly burdensome to the patient who must sacrifice time and lost income to complete the process. Some patients also delay seeking diagnosis of TB symptoms for fear of stigma, discrimination, and social isolation. For women – whose economic and social status is often more vulnerable than men’s – additional household and childrearing responsibilities may present further delays.2,26

Also, developing countries often lack adequate numbers of trained and qualified laboratory personnel, particularly in peripheral health facilities. These personnel are further overburdened by the large caseloads in countries with high TB levels, especially since each patient submits multiple samples for sputum smear microscopy (SSM).11 6,14 Heavy workloads and supply shortages frequently result in unmotivated staff.14

Access to reliable laboratory services is critical to TB disease control, yet in many countries such services are often weak and under resourced.2,27-29 Many peripheral health facilities lack proper laboratories, and in cases where some laboratory infrastructure exists, facilities often lack consistently functioning equipment, supplies, and even utilities.11,30 This is a key concern for TB control programs, since controlled specimen examination is essential to accurate patient diagnosis and management.2 The lack of technical expertise and proper infrastructure means decreased accuracy of laboratory results and delays in patient diagnosis – delays that lead to losses to follow-up and ultimately hamper efforts to control the spread of disease.

**Diagnostic Tools**

Relatively recent technological developments in genetics, microelectronics, materials science, biology, and nanotechnology have led to great advancements in TB diagnostic tools. Nevertheless, techniques for diagnosing TB in developing countries have changed little over the past century. These countries often lack the infrastructure to support and the capital to afford newer and more complex diagnostic tools and therefore continue to rely on older, slower, less sophisticated tools.14,31

In many developing countries, TB diagnosis is made by detecting acid-fast bacilli in stained smears of expectorated sputum specimens, identifying those patients who are both most infectious and most in need of treatment. However, this process is fraught with problems – logistic challenges, poor working conditions, and inherent weaknesses in the test itself (low sensitivity) – and the microscopy process detects only about 20–30% of TB cases. A glaring weakness in the SSM technique is that it does not detect drug resistance, which is problematic given the growing threats of MDR-TB and XDR-TB.14,31

Also, while SSM services are generally available in countries with high TB burdens, drug sensitivity testing (DST) coverage remains very limited.
Table 1 describes several available tests for active TB and resistance to first-line drugs, including each test’s advantages and limitations. No method meets all the criteria necessary to fulfill the global diagnostic need of being both sensitive and specific for all stages and types of active TB across patient groups, inexpensive, simple to perform, rapid, and adapted to limited-resource settings.14

Box 3. Diagnosis in Special Cases

Diagnosis of extra-pulmonary TB, MDR-TB, and XDR-TB, as well as TB in children and HIV-infected individuals pose additional challenges to developing countries.

The clinical pattern of TB is atypical in HIV-positive patients and difficult to distinguish from other illnesses. The sensitivity and specificity of different tests is also affected by an individual’s age and HIV disease stage. Both extra-pulmonary and smear-negative TB are more common in immunocompromised patients, resulting in poorer treatment outcomes and higher early mortality rates.2,3 Appropriate specimens can be difficult to obtain from extra-pulmonary locations, which tend to have fewer M. tuberculosis bacilli and exacerbate the difficulty of bacteriological detection by microscopy.2 A higher incidence of smear-negative pulmonary and extra-pulmonary TB cases in people infected with HIV highlights the need for rapid diagnostic tests in settings of high HIV prevalence.6,8,9

Children with active TB often present without the typical signs and symptoms of the disease, which complicates diagnosis, and are frequently unable to produce the sputum needed for SSM.9

MDR-TB and XDR-TB complicate TB diagnosis. Detection of drug resistance through culture is slow, and many developing countries lack access to the resources and infrastructure needed to implement more costly drug resistance testing methods. Rapid diagnosis and determination of the sensitivity of the strain to drugs is essential to ensure improved treatment outcomes and reduced transmission.2
Table 1. Current methods of TB detection

<table>
<thead>
<tr>
<th>Diagnostic tool/method</th>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Detection of Active TB</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Imaging methods, i.e. chest x-ray, MRI, ultrasound</strong></td>
<td>Fast</td>
<td>Nonspecific</td>
</tr>
<tr>
<td></td>
<td>High sensitivity in HIV-patients</td>
<td>Relatively expensive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Special equipment not readily available in developing countries</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Requires power source</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Very unreliable in high-HIV prevalence settings</td>
</tr>
<tr>
<td><strong>Direct bacterial demonstration methods, i.e., sputum smear microscopy [SSM] and enhancements</strong></td>
<td>High sensitivity in high-TB prevalence settings</td>
<td>Low sensitivity (35–70%), particularly in children and patients with HIV and extra-pulmonary TB</td>
</tr>
<tr>
<td></td>
<td>Detects the most infectious cases</td>
<td>Requires well trained technicians</td>
</tr>
<tr>
<td></td>
<td>Inexpensive</td>
<td>May require repeat (2 or 3) visits</td>
</tr>
<tr>
<td></td>
<td>Widely established</td>
<td>Cannot distinguish between drug sensitive and drug resistant TB</td>
</tr>
<tr>
<td><strong>Culture</strong></td>
<td>Diagnostic gold standard</td>
<td>Requires 2–6 weeks rather than days for results</td>
</tr>
<tr>
<td></td>
<td>More sensitive than SSM</td>
<td>Requires specialized personnel, equipment and biosafety measures</td>
</tr>
<tr>
<td></td>
<td>Allows species identification (important in developed countries)</td>
<td>Requires a dependable source of water and power</td>
</tr>
<tr>
<td></td>
<td>Allows drug susceptibility testing</td>
<td></td>
</tr>
</tbody>
</table>

Source: 14, 31–33

1 New tools and methods have been developed to improve the sensitivity and efficiency of microscopy, including front-loaded smear microscopy, LED fluorescence microscopy, and bleach microscopy.

2 Some culture media and automated systems are able to reduce the visual detection period to one to three weeks.
<table>
<thead>
<tr>
<th>Diagnostic tool/method</th>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| Genotypic amplification, (i.e., nucleic acid, PCR, RFLP) | Rapid results (available in several hours)  
High specificity (98–100%)  
High sensitivity (>95%,) in sputum that is acid-fast bacilli (AFB) smear-positive  
Shows promise for materials other than sputum (i.e., blood, lymph, bone marrow, gastric aspirate, cerebrospinal fluid, urine, bronchial aspirate, and lavage), although results have considerable variability | Expensive³  
Complex  
Lower specificity under field conditions  
60–70% sensitivity in smear-negative, culture positive specimens⁴  
Lab contamination can lead to false positives and considerable down time or revamping of lab |
| Serology | Simpler than smear microscopy  
High negative predictive value  
Rapid results (within 1 hour)  
Involves simple technology  
Relatively inexpensive  
More convenient when obtaining specimens from extra-pulmonary cases and children suspected of having pulmonary disease | Sensitivity is highest in patients with smear-positive disease, but much lower in smear-negative cases, children, and patients with extra-pulmonary disease or HIV  
Cannot reliably distinguish active TB disease from latent infection with M. tuberculosis  
Cannot distinguish M. tuberculosis from other mycobacterium species |
| Mycobacteriophage assay | Rapid results (48–72 hours)  
No dedicated equipment required  
High sensitivity in smear positive specimens  
Semi-quantitative results  
May be most useful in high-burden countries; South Africa study showed, 70.3% sensitivity and 99% specificity in previously untreated TB patients | Low sensitivity in smear-negative culture-positive specimens  
Requires technical expertise  
Evaluated only on sputum specimens |

³ In-house tests may be less expensive, but are also more time-consuming.

⁴ Recently developed amplification tests may have better sensitivity in smear-negative specimens while retaining the same high degree of specificity.
**Detection of Drug Resistance**

<table>
<thead>
<tr>
<th>Detection Method</th>
<th>Reference Standard</th>
<th>Cost</th>
<th>Performance</th>
<th>Special Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid media - Proportions method, resistance ratio</td>
<td>Reference standard</td>
<td>Expensive</td>
<td>Slow (generally 2–3 months)</td>
<td>Problems associated with large volume of radioactive materials</td>
</tr>
<tr>
<td>and absolute concentration method</td>
<td>Relatively inexpensive</td>
<td>No sophisticated equipment required</td>
<td>Relatively inexpensive</td>
<td>No sophisticated equipment required</td>
</tr>
<tr>
<td>Liquid media - Automated BACTEC 460 TB radiometric</td>
<td>Results (including identification)</td>
<td>Expensive</td>
<td>Relatively rapid (7–14 days)</td>
<td>Problems associated with large volume of radioactive materials</td>
</tr>
<tr>
<td>method</td>
<td>available within 10–12 days</td>
<td>Expensive</td>
<td>Faster and more sensitive than solid media performance</td>
<td>Problems associated with large volume of radioactive materials</td>
</tr>
<tr>
<td>BD BACTEC™ MGIT™ 960 SIRE Susceptibility testing of M.</td>
<td>Relatively rapid (7–14 days)</td>
<td>Expensive</td>
<td>Reliably performs for first- and second-line indirect drug sensitivity testing</td>
<td>Problems associated with large volume of radioactive materials</td>
</tr>
<tr>
<td>TB (MGIT: mycobacteria growth indicator tube)</td>
<td>Highly sensitive and specific in sputum smear positive cases</td>
<td>Relatively expensive</td>
<td>Reliably performs for first- and second-line indirect drug sensitivity testing</td>
<td>Problems associated with large volume of radioactive materials</td>
</tr>
<tr>
<td>Molecular amplification, e.g., Hain GenoType Assay</td>
<td>High sensitivity and specificity in sputum smear positive cases</td>
<td>Expensive</td>
<td>Reliably performs for first- and second-line indirect drug sensitivity testing</td>
<td>Problems associated with large volume of radioactive materials</td>
</tr>
<tr>
<td>Phage-amplified biological (PhaB) assay</td>
<td>Results available within 2 days</td>
<td>Expensive</td>
<td>Reliably performs for first- and second-line indirect drug sensitivity testing</td>
<td>Problems associated with large volume of radioactive materials</td>
</tr>
<tr>
<td>Microscopic observation drug-susceptibility (MODS)</td>
<td>Relatively inexpensive</td>
<td>Expensive</td>
<td>Reliably performs for first- and second-line indirect drug sensitivity testing</td>
<td>Problems associated with large volume of radioactive materials</td>
</tr>
<tr>
<td>assay</td>
<td>High agreement with reference standard</td>
<td>Expensive</td>
<td>Reliably performs for first- and second-line indirect drug sensitivity testing</td>
<td>Problems associated with large volume of radioactive materials</td>
</tr>
<tr>
<td></td>
<td>Relatively rapid (results in 7-14 days)</td>
<td>Expensive</td>
<td>Reliably performs for first- and second-line indirect drug sensitivity testing</td>
<td>Problems associated with large volume of radioactive materials</td>
</tr>
<tr>
<td></td>
<td>Detects M. tuberculosis in sputum and identifies MDR-TB with greater sensitivity and speed than Löwenstein– Jensen or automated mycobacterial cultures.</td>
<td>Expensive</td>
<td>Reliably performs for first- and second-line indirect drug sensitivity testing</td>
<td>Problems associated with large volume of radioactive materials</td>
</tr>
<tr>
<td></td>
<td>Reliance on microscopy skills similar to those used for smear microscopy</td>
<td>Expensive</td>
<td>Reliably performs for first- and second-line indirect drug sensitivity testing</td>
<td>Problems associated with large volume of radioactive materials</td>
</tr>
</tbody>
</table>

**DATA COLLECTION METHODS**

The study occurred in Benin, Peru, and Tanzania from March 2007 to April 2009. In addition to literature reviews, study team members made two extended field visits to each country. During these visits, team members collected data on both health provider and consumer perspectives on perceived need for, willingness to use, and willingness to pay (WTP) for diagnostics for six diseases: AIDS, tuberculosis, malaria, syphilis, sexually transmitted infections (STIs), and acute lower respiratory infections (ALRI). Field work in India will be completed by the end of July 2009, with results published in September. Specific approaches to collecting data on health systems and consumer perspectives are described below.

**Health Systems Perspectives**

In each country, CHS conducted semi-structured, in-depth interviews with public and private sector health personnel – physicians, laboratory technicians, program managers, and pharmacists – to explore their perspectives on factors relevant to new diagnostics tests. CHS asked health providers about their views on current diagnostic testing approaches and unmet diagnostic needs, as well as past experiences with adopting new diagnostic tools. The study conducted 29 health provider interviews in two regions of
Benin, 42 interviews in three regions of Peru, and 59 interviews in three regions of Tanzania. Those interviewed included national and district-level managers as well as front-line clinicians. To the extent possible, CHS interviewed directors of key national programs relevant to the six diseases. Interviews also included private for-profit and non-profit program managers and clinicians. Appendix A has a list of all persons interviewed for this component of the study, along with their affiliations and interview dates.

Consumer Perspectives

CHS evaluated consumer willingness to use and pay for new diagnostic tests in three phases: (1) preliminary focus group discussions, (2) willingness to pay surveys, and (3) follow-up focus group discussions.

Preliminary focus group discussions

CHS conducted two to three preliminary focus group discussions in each country to establish base prices for the WTP surveys and to adapt the survey instruments to local circumstances. In these focus groups, which included providers or consumers, a trained facilitator explained the purpose of the study and then asked participants to discuss what amounts people might typically pay for a diagnostic test. These amounts served as starting points for the iterative bidding process used to determine mean willingness to pay in the survey. The facilitator also asked participants to explain local terms used for diagnostic tests so that survey questions would be understandable to those surveyed.

In Benin, CHS set the starting prices at 1,000 Communauté Financière Africaine (CFA or African Financial Community) for the pneumonia, syphilis, HIV, and STI diagnostics and at 500 CFA for the malaria and TB diagnostics. In Tanzania, the starting prices for the syphilis, HIV, TB, and STI diagnostics were 500 Tanzanian shillings (Tsh) and at 200 Tsh for malaria and pneumonia. In Peru, the base price was set at five Peruvian nuevos soles (S/. 5.00) for all diagnostics.

Willingness to pay surveys

CHS then conducted surveys to assess consumer WTP for improved diagnostic tests. Each survey had about 40 questions, including sections to collect socio-demographic information, ask about previous health-seeking behavior that might shed light on WTP, and (then) ask about WTP itself.

To assess respondent willingness to pay, the surveys used a process called contingent valuation (See Figure 1). In this approach, the interviewer briefly explains the benefits of a hypothetical new diagnostic test; asks whether the respondent would be interested in using such a test if it were available; and if so, whether he or she would be willing to pay something for the test. If the respondent indicates a willingness to pay, the interviewer suggests the base price determined in the preliminary focus group discussions. If the respondent is willing to pay this base price, the interviewer then asks about a higher price, increasing the initial amount by a specific increment. This process continues until the respondent says that he or she would not be willing to pay the price reached. For respondents unwilling or unable to pay the starting price, the interviewer uses the same process, but asks about a lower amount. This information is then used to calculate mean and median willingness to pay.

Sampling approach

CHS used purposive sampling to recruit participants for the survey. This means that participants were selected based on the likelihood that they will have useful opinions or knowledge about the question of interest. For instance, the parent of a young child is more likely to have an opinion about the value of a diagnostic for malaria or ALRI in children under five than would a single adult or an adult whose children are grown. For this reason, we carried out surveys about ALRI and malaria diagnostics in health facilities that provide services for young children, recruiting adults with young children to participate.

For similar reasons, we recruited pregnant women receiving antenatal care as participants for the syphilis and HIV diagnostics surveys. Adults in curative care were surveyed about TB and STI tests. We had initially hoped to recruit participants for the STI survey solely from STI clinics and participants for the
TB survey solely from among TB patients or their family members, but we were unable to identify specialized health facilities for these conditions in each health sector (public, private for-profit, private non-profit). As a result, we carried out STI surveys with adults seeking curative care (but not necessarily STI testing or treatment) at facilities that provided STI services. Similarly, we recruited participants for the TB survey from among adults seeking curative care (but not necessarily for TB) at facilities that provided TB services.

Figure 1. Contingent valuation approach to measuring consumer willingness to pay

The Peru survey sample, collected between late August and December 2007, included 1478 respondents from Lima, Iquitos, and Arequipa. The Tanzania sample, collected during April 2007 and April 2008, included 1735 respondents from Tanga and Dar es Salaam. CHS surveyed 1118 people from three regions of Benin (Cotonou, Bohicon, and Parakou) from January to February 2008. However in Benin, one group of participants (n=287) was asked about both malaria and ALRI while a second group (n=292) was asked about both HIV and syphilis, so the effective sample size was 1,697. The sample size of 250 individuals per diagnostic test was calculated to obtain a study power of 80% with a 95% confidence interval. The sampling frame was designed to include participants from both urban and rural facilities at different levels of care as well as a mix of participants attending public, private for-profit, and private not-for-profit facilities. Table 2 describes the sampling frame used in each country.
Table 2: Sampling frame for willingness to pay surveys

<table>
<thead>
<tr>
<th>Diagnostic</th>
<th>Urban Public</th>
<th>Urban For-profit</th>
<th>Urban Not-for-profit</th>
<th>Rural Public</th>
<th>Rural For-profit</th>
<th>Rural Not-for-profit</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>252</td>
</tr>
<tr>
<td>HIV</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>252</td>
</tr>
<tr>
<td>ALRI</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>252</td>
</tr>
<tr>
<td>Syphilis</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>252</td>
</tr>
<tr>
<td>Chlamydia and gonorrhea</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>252</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>42</td>
<td>252</td>
</tr>
<tr>
<td>Total</td>
<td>252</td>
<td>252</td>
<td>252</td>
<td>252</td>
<td>252</td>
<td>252</td>
<td>1512</td>
</tr>
</tbody>
</table>

Analysis

Several studies have measured consumer WTP for health care or goods in developing countries.\textsuperscript{34-36} These studies found that demographic and socio-economic factors, costs of obtaining health care, and facility characteristics influence such WTP. Thus, CHS considered how socio-economic variables affect WTP for the six diagnostic tests.

CHS calculated a wealth index for each individual, based on the Demographic and Health Survey methodology.\textsuperscript{37} This approach uses information on ownership of assets, numbers of persons per bedroom, building materials used in the home, toilet facilities, and water source to generate a weighted wealth index. The variable weights are generated using factor analysis. In this study, the variable weights are taken from World Bank studies on socio-economic differences within each study country.\textsuperscript{38}

Based on the results, CHS estimated the mean, median, and mode of consumer WTP for each of the new diagnostics. These amounts were then disaggregated by wealth levels, educational levels, rural/urban location, gender, type of facility, and region. CHS used analysis of variance (ANOVA) to test for statistically significant differences in WTP based on respondent demographic characteristics. Ordinary least squares (OLS) regression was used to identify factors that influenced the amount one was willing to pay.

In the OLS regression analysis, the dependent variable (WTP for the diagnostics) was transformed logarithmically since the data were skewed. Log transformation is widely used to improve precision and diminish the effect of outliers.\textsuperscript{39} The log regression coefficients were adjusted using the smearing technique to account for the bias caused by the transformation.\textsuperscript{40}

Follow-up focus group discussions

CHS conducted the follow-up focus group discussions to explore factors influencing consumers’ willingness to use and pay for diagnostic tests. These discussions helped explain why survey respondents said they would be willing to pay more for certain types of diagnostics than others. The groups also helped explain why consumers expressed a preference for one type of sample (e.g., blood, urine, sputum) over another. Finally, the discussions explored consumer perceptions about each illness and the benefits of and barriers to seeking diagnostic testing. CHS designed the focus group discussions using the Health Belief Model (HBM), a theoretical framework developed by the U.S. Public Health Service in the 1950s to explore U.S. consumer behavior related to TB diagnosis. It has since been used in many other contexts in both the U.S. and internationally. Appendix B describes the HBM and its applicability to this study.
**Sampling approach**

Table 3 contains the target sampling frame for focus groups. In November 2008, CHS conducted 12 focus group discussions with 8 to 11 members per group in Cotonou, Bohicon, and Parakou in Benin. In March 2009, CHS conducted 9 focus group discussions with 7 to 9 members per group in Dar es Salaam and Tanga, Tanzania. In March and April 2009, CHS conducted 10 focus group discussions with 8 to 10 members per group in Lima, Arequipa, and Iquitos, Peru. Since these discussions involved STIs, CHS organized each group as either exclusively male or exclusively female. Female facilitators led the groups of women, and male facilitators those of men. CHS will conduct 24 focus groups in India once preliminary WTP survey data become available.

**Table 3: Sampling frame for focus groups**

<table>
<thead>
<tr>
<th>Country</th>
<th>Urban</th>
<th>Rural</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>Benin</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>India</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Peru</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Tanzania</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>

**Analysis**

All focus groups were digitally recorded and the recordings transcribed. Focus groups in Benin were conducted in Fon, then transcribed into and analyzed in French. Focus groups in Tanzania were conducted in Swahili, then transcribed into and analyzed in English. Focus groups in Peru were conducted, transcribed into, and analyzed in Spanish. All transcripts were imported into ATLAS.ti®, a qualitative data analysis software package. The HBM informed the analysis process. CHS developed codes for each illness, for each HBM component, and for specific factors mentioned by participants as influencing WTP. Study team members then applied the codes to each transcript and developed reports that allowed them to summarize relevant themes for each country. These summaries then served as the basis for the relevant sections of this report.

**Profiles of Study Countries and Research Findings**

The study countries share many of the same health system weaknesses and similarities in their epidemiological profiles.

**Benin**

Benin is a small, ethnically diverse country located along the coast of West Africa and having an estimated population of 9 million. Despite being one of the first African nations to successfully transition from military rule to democratic government since 1960 independence, Benin remains one of the poorer sub-Saharan African nations. At US $570, the gross national income (GNI) per capita is much lower than the sub-Saharan African average of US $952. More than a third (37%) of the population live in poverty, and 20% are classified as extremely poor. Like many other African nations, Benin has a young population: 46% are under age 15. Levels of education are lower than in other West African nations, particularly in rural areas and among women. Benin has a population growth rate of 3% and a relatively large urbanized population rate (45%).
Overview of the health system

Despite a functional and increasingly decentralized health system, health regulations are not uniformly enforced, creating disparities in the quality of care available to different sectors of the population. With 86% of the population living within five kilometers of a health facility, geographic access to health services is relatively high; however, many facilities lack the infrastructure, equipment, and staff necessary to provide priority services. Resource disparities are particularly common in rural areas.41

Benin’s public health system has three levels, comprised as follows:

1. Central: the Ministry of Health (MOH), central directorates, and the National Referral Hospital;
2. Intermediate: departmental directorates for health and departmental referral hospitals; and
3. Peripheral: health zones, including zonal referral hospitals, commune health centers, arrondissement health centers, private health facilities, and village health units.41 Benin has 34 health zones, each providing coverage for approximately 210,000 persons. Designed to increase access of care, enhance community participation, and advance decentralization of health services, health zones encompass both public and private providers.

Benin has a diverse, largely unregulated, private health sector of varied trained medical practitioners, traditional practitioners, pharmacies, laboratories, for-profit and religious nonprofit facilities, medical equipment and pharmaceutical suppliers, private voluntary and mutual health insurance companies, and nongovernmental organizations (NGOs). Religious, nonprofit facilities are well integrated into the national health system and several operate as zonal hospitals and collaborate with the MOH.41

The private pharmaceutical sector is under the purview of the MOH Directorate of Pharmacies and Medicines (DPM), but regulations governing this sector are essentially unenforced. DPM supervises most public, and some private, procurement and distribution through the parastatal central procurement agency, Centre d’Achat des Médicaments Essentiels et Consommables Médicaux (Center for the Purchase of Essential Medications and Medical Consumables; CAME), a government-owned enterprise. Procurement and distribution of medicines needed for AIDS, TB, malaria, and vaccine programs are managed through Global Fund-supported programs.41

International partners and bilateral donors contribute to the health sector. Compared to other sub-Saharan African countries, the Beninese government invests slightly less of its total public spending in health (8% versus 9%, respectively). Private household spending accounts for 51% of total health spending. Despite unit price market regulation of medicines, most household expenditures on health are spent at pharmacies, most of which are privately owned and operated, rather than funneled through the public health sector.

A relatively small proportion of the population has health insurance coverage. There are three main sources of insurance: the Beninese Social Security Fund, which offers formal sector employees and their families partial coverage for health care costs; private insurance firms, which offer more comprehensive coverage packages; and community-based health insurance schemes. Additionally, an Indigent Fund, established through the MOH, subsidizes health facility user-fees for the most impoverished citizens to reduce financial barriers to health services.41

Tuberculosis in Benin

Despite extreme poverty, Benin has a higher life expectancy than average for the sub-Saharan Africa region (58.6 versus 51 years, respectively). In 2006, 135 per 100,000 people were infected with TB.42,43 The HIV epidemic is generalized with 1% of the population HIV positive. In 2006, 15% of newly recorded cases of active TB were also HIV positive, and 7% of all TB cases in Benin were HIV-positive.17,42,43,45

TB diagnosis is performed primarily by SSM. When possible, chest x-rays are used to support diagnosis. Clinicians also rely on a simple clinical algorithm to diagnose TB sputum smear negative cases. National recommendations recently changed the recommended time period to complete SSM: from three to two...
days. Most laboratories use classic microscopy with a Ziehl-Nielsen stain; however, LED fluorescence microscopes are used at the central level. The National TB Program (NTP) plans to de-centralize fluorescence microscopy to regional laboratories in 2009.

Initial TB diagnosis by SSM is generally provided free to Beninese, but health facility administrators may charge patients at a subsidized price (the equivalent of about US $1 for SSM). Patients requiring culture or chest x-ray pay additional fees associated with these tests. If they test positive, all SSM tests required for monitoring patient response to treatment are provided free.

As of 2006, less than 1% of newly recorded cases of active TB were MDR-TB. The National Mycobacterium Reference Laboratory in Cotonou, the central reference lab, is the only facility equipped to do cultures and DST. DST is reserved for previously treated patients.

The central reference laboratory also coordinates TB activities among all intermediate and peripheral laboratories charged with monitoring TB patients. Intermediate laboratories provide technical assistance, training, and supervision to peripheral labs.

Case notification rates in Benin are low: As estimated in 2006, only 45% of the 90 new cases of active TB per 100,000 people were notified of their condition. The relatively low number of smear labs (55) working with the NTP limits notification. Select private sector facilities, primarily mission facilities, serve as part of the public TB network; these facilities function as MOH-recognized screening and treatment centers and perform the same standard of diagnosis and care. The government provides necessary supplies and capacity-building activities, so TB tests are free at all facilities within the network. Other private sector centers are generally unable to perform diagnoses and either send sputum samples to network facilities or refer patients. Benin began a community-based sputum sample collection system in 2007 to address limited access to diagnosis at certain health centers. Still in its pilot phase, this program is being evaluated for scale-up.

Health systems perspectives

The efficacy, practicality, and financial, logistical, and human resource costs of existing technologies shaped health providers’ perspectives on the need for improved TB diagnostics in Benin. Many considered an improved diagnostic a high priority, especially given the length of treatment.

Respondents expressed clear ideas on the ideal characteristics of a TB diagnostic that could increase patient access to early diagnosis:

\[
\text{The ideal would be to have a rapid test like [that for] for HIV and have the results 15 minutes later with 100% sensitivity and 100% specificity, but that doesn’t exist. That’s the ideal. In the meantime, we have what we have; we have microscopy.}
\]

One provider thought SSM offered the best cost–benefit ratio among existing diagnostics for TB because it: 1) identifies the most infectious cases of TB, 2) can be widely implemented in low resource settings, and 3) can be used by well trained technicians without superior qualifications.

Most health providers cited lack of sensitivity as SSM’s primary limitation. Others mentioned certain patients’ inability to cough up the necessary sputum. Despite these challenges, many providers thought the overall quality of testing could be ensured through proper supervision, oversight, and training. Several respondents described SSM’s higher lack of sensitivity in diagnosing HIV-positive patients and persons with extra-pulmonary TB as another weakness. Some suggested that although culture processing was time-consuming, it could improve TB diagnosis in PLWHA. Two respondents explained that although molecular biology was currently unrealistic due to insufficient infrastructure, it would be superior to current tests. Despite the long wait for culture results, one health provider suggested that it would be better to end treatment for a person not suffering from TB after receiving results in two months than to complete eight months of unnecessary treatment.
Although laboratory personnel work to give patients their test results within three days, opting to wait for test results can be challenging for patients. One doctor said, “[Patients] who aren’t from here wait for their test results. It’s a choice to get yourself treatment or not.

Procurement processes also pose difficulties to public health providers, particularly processes interwoven with those of external donors like the Global Fund. One provider described the Global Fund procurement system as “cumbersome” and explained that requesting and receiving necessary supplies can take months, making it difficult for facilities to maintain their stock. Providers also said that the procurement system’s inflexibility and intervals between procurement cycles can cause delays. Providers also believed that available stock is distributed poorly. Additionally, they cited the absence of reliable suppliers in-country as an obstacle that forces the NTP to request supplies from abroad, causing further delays.

Some interviewees attributed procurement problems to limited coordination and diverging priorities among procurement agents, donors, and health care providers. One provider cited an example of valuable laboratory equipment being “derailed” to someone’s home village due to a lack of communication between the government and donors. Another thought that while health care providers were concerned with procuring the best quality test available, procurement agents tended to prioritize profit margins or cost recovery in the case of non-profits.

The MOH organizes trainings to inform health personnel and technicians of new diagnostic methods and protocols. A hospital-based doctor reported:

[Introduction of a new diagnostic tool or method] is communicated through trainings, health worker associations…in a cascade. We gather and train a certain number of trainers and then gradually…everyone becomes informed. This is the method: training before use. Anything that contributes to improving the detection of diseases is welcome. It’s always good to introduce something that can help [a doctor] make a diagnosis, rather than treating with your eyes closed…[or] by probability. [Introducing new diagnostics] should not cause problems; there should not be any barriers.

Respondents described the introduction of new diagnostics into the health system as an uncomplicated process; they explained that a new diagnostic would first need to be tested at the central level to ensure feasibility. One provider recalled that when fluorescent microscopes were introduced for TB diagnosis, they were first implemented at the central level and then evaluated. Then the NTP made plans to scale up this technology to the intermediary level in regional labs.

Some health providers thought that although an increase in price for a new diagnostic would not necessarily pose a problem for external funders, it would be unwise to rely too heavily on external aid. One respondent recounted a time when the Global Fund cut Benin’s funding for a nine-month period, leaving them unable to cover human resource costs or buy reagents. This interviewee believed that Benin would consider adopting an improved test if the cost was comparable to that of current diagnostic modes; otherwise policymakers would hesitate to risk not being able to cover the cost of the test.

**Consumer willingness to purchase and use a diagnostic test**

More than 90% of Beninese consumers interviewed about the six study diseases indicated that they were interested in using and willing to pay for diagnostic tests. Figure 2 indicates that they were willing to pay more for TB, syphilis, and STI tests than for malaria, ALRI, or HIV tests.
Survey respondents’ average age in the TB WTP survey was 33.5 years. The sample was 59% female and 62% Christian, and 27% Muslim. Only 6% reported practicing a traditional religion. Married respondents accounted for 77% of those interviewed. Respondents interviewed at public facilities accounted for 49% of the sample, compared to 26% at mission and 22% at private for-profit facilities. In addition, 36% lived in rural areas, and 42% had less than a full primary education. A mere 4% had some form of health insurance. At the time of the study, 421 Communauté Financière Africaine (CFA or African Financial Community) equaled US $1. On average respondents traveled 29 minutes to reach a health facility and paid 581 CFA for transport.
Table 4. Benin: Sociodemographic characteristics of TB survey respondents

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Respondent % (N=269)</th>
<th>Respondent’s spouse % (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>33.5</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>41.3% (111)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>58.7% (158)</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>17.8% (48)</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>76.6% (206)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>5.6% (15)</td>
<td></td>
</tr>
<tr>
<td>Religion:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Traditional</td>
<td>6.3% (17)</td>
<td></td>
</tr>
<tr>
<td>Muslim</td>
<td>26.8% (72)</td>
<td></td>
</tr>
<tr>
<td>Catholic</td>
<td>37.9% (102)</td>
<td></td>
</tr>
<tr>
<td>Protestant</td>
<td>3.7% (10)</td>
<td></td>
</tr>
<tr>
<td>Other Christian</td>
<td>20.8% (56)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>4.5% (12)</td>
<td></td>
</tr>
<tr>
<td>Education level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; Primary</td>
<td>41.6% (112)</td>
<td>45.4% (85)</td>
</tr>
<tr>
<td>Primary</td>
<td>23.4% (63)</td>
<td>18% (34)</td>
</tr>
<tr>
<td>Secondary</td>
<td>27.5% (74)</td>
<td>23% (43)</td>
</tr>
<tr>
<td>Technical</td>
<td>1.1% (3)</td>
<td>1.6% (3)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>6.3% (17)</td>
<td>12% (22)</td>
</tr>
<tr>
<td>Urban</td>
<td>63.6% (171)</td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>36.4% (98)</td>
<td></td>
</tr>
<tr>
<td>Region</td>
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<td></td>
</tr>
<tr>
<td>Cotonou</td>
<td>30.8% (83)</td>
<td></td>
</tr>
<tr>
<td>Bohicon</td>
<td>31.2% (84)</td>
<td></td>
</tr>
<tr>
<td>Parakou</td>
<td>38% (102)</td>
<td></td>
</tr>
<tr>
<td>Facility type</td>
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<td></td>
</tr>
<tr>
<td>Public</td>
<td>49% (132)</td>
<td></td>
</tr>
<tr>
<td>Mission</td>
<td>26% (71)</td>
<td></td>
</tr>
<tr>
<td>Private For-profit</td>
<td>22% (58)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>3% (8)</td>
<td></td>
</tr>
<tr>
<td>Have health insurance</td>
<td>4% (11)</td>
<td></td>
</tr>
<tr>
<td>Average travel time (minutes)</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Average travel cost</td>
<td>CFA 581</td>
<td></td>
</tr>
</tbody>
</table>

Health-seeking behaviors
Of Beninese survey respondents who reported seeking care for an illness within the previous 12 months, 74% reported doing so in the formal health sector while 15% visited a non-biomedical provider, such as a traditional healer. Laboratory diagnostic tests were recommended to 58% of respondents who went to a biomedical facility, and nearly all reported consenting to the tests. On average, respondents reported having paid 5937 CFA for diagnostic tests prescribed on the day of the survey. These tests may have
been for TB or another illness, since participants were recruited from among adults seeking any type of curative care. Respondents reported being willing to pay an average of 2345 CFA for a TB test. While this amount is less than half the average amount participants reported actually paying for diagnostic tests on the day of their visit, it is slightly more than the 2339 CFA they reported being willing to pay across all six diagnostics.

**Willingness to pay for TB diagnostic tests**

Based on the initial focus group findings, the WTP bidding for a TB test started at 500 CFA and increased in increments of 1000 CFA depending on the respondent’s reply. Some indicated a willingness to pay an amount outside the predetermined cost parameters; however, due to the survey design, the amounts they selected tended to cluster in increments of 500 CFA. Of 269 respondents, 10 were not willing to pay for a TB diagnostic; the other 259 expressed willingness to pay between 200 and 20,000 CFA. Figure 3 shows that WTP declined sharply as the price reached about 3000 CFA and then declined gradually before dropping sharply again as the price rose above 4500 CFA. Viewed from another angle, 98% were willing to pay for TB diagnostics at 200 CFA, but once the price reached 500 CFA, 14% were unwilling to pay; above 1000 CFA, nearly 50% were excluded.

**Figure 3. Benin: Consumer willingness to pay for TB diagnostics at each price range**

The figure groups respondents into four market segments to categorize consumer willingness to pay for TB diagnostics by price range:

- **Segment A:** Consumers willing to pay no more than 1000 CFA,
- **Segment B:** Consumers willing to pay 1001–2000 CFA,
- **Segment C:** Consumers willing to pay 2001–3000 CFA, and
- **Segment D:** Consumers willing to pay more than 3000 CFA.

Market segmentation enabled a determination of which characteristics these groups share and an understanding of the factors driving market response at each price level. The figure highlights these markets and illustrates the proportion of the population that fall into each segment at a given price range.

Nine of the 10 respondents not willing to pay lived in Parakou region and had a primary education or less. Seven of the 10 lived in rural areas and were in the lowest two wealth quintiles; six attended a public
health facility. Reliable conclusions cannot be drawn about the socio-economic makeup of this sample given its small size.

Table 5 shows that socio-economic and demographic characteristics differ among market segments. Among respondents willing to pay 3000 CFA or more, segment D, 86% were urban compared to slightly less than 60% in segments A and B. Most consumers in all four segments attended public health facilities, but greater proportions of those willing to pay 2000 CFA or more, segments C and D, attended mission facilities. About two-thirds of consumers in segments A and B were female, and about half had not exceeded a primary education. Nearly half those in segment A were in the bottom two wealth quintiles compared to around 40% in segments B and C and only 15% in segment D. Segment D consumers were more likely to live in Cotonou, be in the two highest wealth quintiles, and have completed secondary education than those in other segments.

These data indicate that consumers willing to pay more for TB diagnostics tended to live in Cotonou and urban areas and to attend mission facilities. Those willing to pay less tended to be female and have lower levels of education and income.

### Table 5. Benin: Selected socio-economic characteristics of respondents willing to pay within different price ranges for a TB diagnostic (CFA, 2008, N=259)

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>50% (5)</td>
<td>34% (30)</td>
<td>36% (22)</td>
<td>47% (32)</td>
<td>52% (22)</td>
</tr>
<tr>
<td>Female</td>
<td>50% (5)</td>
<td>66% (58)</td>
<td>64% (39)</td>
<td>53% (36)</td>
<td>48% (20)</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; Primary</td>
<td>50% (5)</td>
<td>49% (43)</td>
<td>52% (32)</td>
<td>32.3% (22)</td>
<td>24% (10)</td>
</tr>
<tr>
<td>Primary</td>
<td>40% (4)</td>
<td>23% (20)</td>
<td>21% (13)</td>
<td>26.4% (18)</td>
<td>19% (8)</td>
</tr>
<tr>
<td>Secondary</td>
<td>10% (1)</td>
<td>22% (19)</td>
<td>25% (15)</td>
<td>32.3% (22)</td>
<td>40% (17)</td>
</tr>
<tr>
<td>Technical</td>
<td>0.0% (0)</td>
<td>1% (1)</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>5% (2)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>0.0% (0)</td>
<td>6% (5)</td>
<td>2% (1)</td>
<td>9% (6)</td>
<td>12% (5)</td>
</tr>
<tr>
<td>Wealth quintile</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>50% (5)</td>
<td>23% (20)</td>
<td>26% (16)</td>
<td>13% (9)</td>
<td>10% (4)</td>
</tr>
<tr>
<td>2</td>
<td>20% (2)</td>
<td>26% (23)</td>
<td>16% (10)</td>
<td>23% (16)</td>
<td>5% (2)</td>
</tr>
<tr>
<td>3</td>
<td>20% (2)</td>
<td>22% (19)</td>
<td>18% (11)</td>
<td>20% (13)</td>
<td>24% (10)</td>
</tr>
<tr>
<td>4</td>
<td>10% (1)</td>
<td>17% (15)</td>
<td>25% (15)</td>
<td>13% (9)</td>
<td>31% (13)</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>0.0% (0)</td>
<td>12% (11)</td>
<td>15% (9)</td>
<td>27% (21)</td>
<td>31% (13)</td>
</tr>
<tr>
<td>Zone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>30% (3)</td>
<td>57% (50)</td>
<td>56% (34)</td>
<td>70% (48)</td>
<td>86% (36)</td>
</tr>
<tr>
<td>Rural</td>
<td>70% (7)</td>
<td>43% (38)</td>
<td>44% (27)</td>
<td>29% (20)</td>
<td>14% (6)</td>
</tr>
<tr>
<td>Facility type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public**</td>
<td>60% (6)</td>
<td>63% (54)</td>
<td>46% (27)</td>
<td>38% (25)</td>
<td>49% (20)</td>
</tr>
<tr>
<td>Mission</td>
<td>30% (3)</td>
<td>23% (20)</td>
<td>20% (12)</td>
<td>37% (24)</td>
<td>29% (12)</td>
</tr>
<tr>
<td>Private for-profit</td>
<td>10% (1)</td>
<td>14% (12)</td>
<td>34% (20)</td>
<td>25% (16)</td>
<td>22% (9)</td>
</tr>
<tr>
<td>Region</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cotonou****</td>
<td>10% (1)</td>
<td>16% (14)</td>
<td>23% (14)</td>
<td>40% (27)</td>
<td>65% (27)</td>
</tr>
<tr>
<td>Bohicon</td>
<td>0.0% (0)</td>
<td>53% (47)</td>
<td>34% (21)</td>
<td>17.5% (12)</td>
<td>10% (4)</td>
</tr>
<tr>
<td>Parakou</td>
<td>90% (9)</td>
<td>31% (27)</td>
<td>43% (26)</td>
<td>42.5% (29)</td>
<td>26% (11)</td>
</tr>
</tbody>
</table>

* Difference statistically significant (by OLS) at the 0.10 level.
** Difference statistically significant at the 0.05 level.
*** Difference statistically significant at the 0.01 level.

Note:
Reference category for region is “all other regions.”
Reference category for facility type is “all other facility types.”

Significant influences on willingness to pay
Bivariate analysis indicated statistically significant differences in willingness to pay by wealth quintile and spousal level of education. On average, those in the highest wealth quintile were willing to pay 3031 CFA, 900 CFA more than those in the lowest (ANOVA p=0.10). Respondents whose spouses were university educated were willing to pay 3145 CFA, 700 CFA more than those whose spouses had incomplete primary education or less (ANOVA p=0.05).

Willingness to pay also differed significantly by geographic region and zone: On average, urban respondents were willing to pay 2515 CFA, 500 CFA more than rural respondents (ANOVA p=0.10). Cotonou residents were willing to pay an average of 3168 CFA, 800 CFA more than those in Parakou and twice as much as those in Bohicon (ANOVA p=0.01).

**Figure 4. Benin: Willingness to pay for TB diagnostics, by region**

Although the average amounts consumers were willing to pay differed significantly between certain socio-economic strata, most of these differences disappeared after controlling for other factors. However, significant differences remained between locations (Cotonou residents were willing to pay 733 CFA more than others [OLS p=0.01]) and by type of health facility (those seeking care at a public health facility were willing to pay 311 CFA more than those at other facilities [OLS p=0.05]). Figure 4 shows that Cotonou residents were especially willing to pay more than those in other regions in the lower price ranges. As the price increased to 3000 CFA, the lines intersect, suggesting that region becomes less important in determining willingness to pay at high prices.

Illness concepts
Although TB was viewed as serious, most focus group participants noted its treatability as a moderating factor in its severity. One said, “There are facilities that people with [TB] go to. They are cared for and find relief.”

While treatment availability diminished perceptions of disease severity, the treatment’s length and regimented nature were viewed as obstacles to recovery and affected perceptions of illness gravity. One said, “[TB] is a serious disease. Even when you go to the hospital, if you don’t follow the treatment properly it becomes even harder. Even when you follow the treatment, it may take six months to a year.”
One participant referenced the socio-economic impact on households as evidence of TB’s severity, saying, “Those who suffer from TB – I guess an adult, a father of a family – illness may prevent him from working to support his family. That is why TB is [a very serious disease].”

This quotation illustrates how a chronic illness that predominantly affects adults of working age can reduce household economies. The speaker sees the illness as going beyond the individual to compromise the entire household’s financial viability and stability. TB infection may also reduce a family’s social status.

Most focus group participants saw themselves as highly susceptible to TB: They cited their exposure to environmental risk factors and TB’s infectiousness. They were aware of the public health threat their living conditions and people with infectious TB pose:

- Every day we leave our homes, and dust is everywhere and children also play in the sand. [Adults] also are not spared. Machines release smoke. There is too much pollution. Even in our bedrooms dust is everywhere, despite daily cleaning. Our children play on the floor.
- TB [is very easy to contract] because everyone is exposed since we eat and drink everywhere. People declared sick – it’s they who isolate themselves. Those who are not [isolated] live with us and can contaminate us at any time.
- Tuberculosis [is the easiest illness to catch] because it’s very contagious. A person with TB just has to spit on the ground, and if you breathe the air there, you get sick. Whereas AIDS and syphilis are difficult to catch: All you have to do is control yourself a bit [to avoid being infected by HIV].
- It’s true; tuberculosis [is an easy disease to contract] because you cannot even eat with someone who has TB, because TB is contagious, while, you can eat with someone who has AIDS.

These quotations also reveal participants’ perceptions of the degree of inability to prevent being infected with TB. Frequent comparisons between the degrees of personal agency in contracting STIs as opposed to TB illustrate that participants view STIs as avoidable by choosing certain behaviors such as monogamy, whereas TB transmission was not necessarily linked to voluntary behaviors.

Most focus group participants also perceived significant stigma attached to TB infection; they explained that people known to have TB are often socially isolated. The observable symptoms of TB are also seen as embarrassing to the sick individual and making public interactions uncomfortable:

- If you are a man and you cough, it is not good at all. People will flee from you.
- TB is the disease we are most ashamed of because in a crowd you are the only one to cough without stopping, you are uncomfortable in a crowd and it hurts very badly. You cannot stay around a lot of people. You are coughing night and day everywhere you are. It’s very embarrassing.

Factors influencing willingness to purchase and use diagnostics

Focus group participants discussed general reasons to choose a public, private, or mission facility. Several reported that mission hospitals frequently subsidize visits, so participants expected to pay less there than at public facilities where prices tend to be higher and fixed. Some respondents attributed this difference in pricing to dissimilar mentalities about providing care:

- In mission hospitals, they feel pity for the people, for how to get everyone to be able to pay the price. That’s why the price is low. But in public hospitals, they do not “love their neighbor” as in mission hospitals. So for [public hospitals], you have to have money to receive care. That’s how they think.

Respondents also pointed out that costs tended to be higher at private facilities than public ones. Several noted better reception as a reason to choose a private facility, claiming that private facility personnel are more welcoming and provide better care than those in public facilities. Respondents also said that public
facilities tend to be overcrowded and to provide slower service. They attributed these differences to private sector financial incentives to treat customers better:

[In the private sector], it’s how you receive customers that determines if you have a lot of patients. In public hospitals, it’s the [academic] degree that determines if [staff] work there; at the end of the month, they have their salary whether they worked or not. But in the private sector, it’s the way someone works that allows him to support his wife and children. That is why we spend more in a private hospital than in a public hospital. In the public hospital, they receive you, but are too slow.

In private hospitals, the staff work well and perform their tasks better. That is why whatever the cost in these hospitals, we are willing to pay. But in the public sector, whether you have money or not, the staff neglects you because their salaries are low. That is why when people go to the private sector, they are willing to pay more.

Despite complaints about the lack of customer service in the public sector, some respondents expressed greater confidence in the abilities of public health care personnel:

This is a problem of trust…. It’s the confidence [patients] have in public health centers…. When the private sector finds someone who says he is a health care worker, they hire him without confirming, while in the public sector, they have you take a proper test.

The choice of facility type also depended on the disease. Participants noted that public facilities are more likely to manage TB cases than private or mission ones. For some, this explained greater willingness to pay for a public facility TB test:

[People would pay more for a TB test at a public facility] because public hospitals treat the more complicated diseases. Public hospitals are better equipped to treat TB than private centers. The public sector handles the most serious diseases, and tuberculosis is a very serious disease.

Perceptions of TB as serious and highly contagious also influenced some participants’ thoughts on payment. These participants argued that the barrier of cost should be reduced to protect public health. One said, “Since [TB] is serious, I suggest that the test be free, so many people will take it. Because this disease can decimate the population.”

*Desired test characteristics*

Although nearly a quarter of survey respondents claimed they did not have a preference of TB test sample type, just over a third said they would prefer a diagnostic test that uses blood. Focus group participants had non-disease-specific ideas about their sample preference. Several expressed confidence in the blood’s ability to reveal illness, claiming that blood is a “fundamental” part of the human body, a vehicle or repository in contact with all organs and pathogens:

If it is a question of preference about samples, I prefer blood, because whatever disease you suffer from, it begins in the blood before coming to other parts of the body.

I also prefer a blood test, because blood circulates throughout the whole body and can reach wherever the disease is. It scans everything that is in the body. In the blood you can detect all diseases.

I also prefer blood…. You see how water from a river flows and collects everything in its path, this is how the blood drains all waste from the body. In the blood, we can quickly detect diseases.

Focus group participants also alluded to the ready availability of blood as an advantage over stool or urine samples, which patients may not be able to provide as easily. Some did prefer a urine sample, citing as reasons: Urine is easier and less painful to give than blood; sick people lack blood; and with a blood sample you cannot be sure the needle used is clean. Few preferred a stool sample, but some acknowledged that stool allows disease detection.
Tanzania

Located along the east coast of Africa, the United Republic of Tanzania transitioned from independence in 1961 to a socialist state, then a multiparty democracy with a level of stability that has eluded its neighbors. Despite political stability and economic growth, high disease burdens and low levels of education pose challenges to development in Tanzania. The GNI per capita of US $400 is much lower than the sub-Saharan African average of US $952. Approximately 36% of the population of about 40,000,000 live below the poverty line. The annual growth rate is 2%, and the population is both young (44% are below age 15) and primarily rural (36% live in urban areas).

Overview of the health system

The Tanzanian health system comprises a public sector, a private sector (of NGOs, for-profit groups, and faith-based organizations [FBOs]), and parastatal organizations. Tanzania has a large public health system: More than 80% of health facilities are owned by the government. The system has five levels:

1. National referral hospitals,
2. Regional general hospitals,
3. District hospitals,
4. Health centers, and
5. Dispensaries.

The private sector provides about a third of health services, and private shops and kiosks distribute drugs widely throughout the country. When Tanzania was a socialist state, all health care was provided by the government, and private practice was banned, although the government did maintain a relationship with FBOs. As the country moved toward a more market-oriented economy and the state could provide more than half of health care needs, choice of facility type was opened to consumers. The eventual recognition of the private sector by the public health system after 2002 led to improved health outcomes, including higher vaccination rates.

The geographic distribution of facilities is almost even throughout the country: More than half (52%) of registered health centers are in rural areas. Decentralization has helped meet the needs of the mostly rural population, but the generally poor state of rural roads limits access to referral services.

Public institutions and FBOs and NGOs registered with the Ministry of Health and Social Welfare (MOHSW) attain diagnostics centrally through the MOH Medical Stores Department (MSD). Funding for supplies is provided through various programs, such as the Tanzanian National TB and Leprosy Programme (NTLP). Private facilities buy diagnostics directly from individual pharmacies in small quantities at very high costs.

The government, donors, NGOs, private organizations, and households provide health financing: At 47% households contribute the greatest proportion of total health care financing, while donors and the government provide nearly equal proportions, 22% and 23%, respectively. Compared to other sub-Saharan African nations, Tanzania is more dependent on external funding for health. The government spends approximately 4% of its GDP on health, slightly less than the regional average of 5%. The government spends about 13% of its total spending on health.

Formal sector employees receive social health insurance through the National Health Insurance Scheme, which provides coverage to approximately 3% of the population. Community-based insurance provides the option of health coverage to 48 primarily rural districts. Micro-insurance schemes exist for people employed in the informal sector. There is also a limited amount of private health insurance available to those who can afford it.
**Tuberculosis in Tanzania**

The life expectancy in Tanzania is 51.5 years. As of 2006, 459 per 100,000 people were infected with active TB. High HIV rates have significantly impacted the epidemiology of TB in the country: With 6% of adults (age 15–49) and 140,000 children (age 0–14) living with HIV/AIDS, risk for TB is high. An estimated 18% of new TB cases are HIV positive. In 2005 Tanzania piloted TB/HIV activities in three districts, but challenges to successful scale-up of TB/HIV services in Tanzania include 1) an unreliable supply of HIV test kits; 2) limited access to antiretroviral services maintained at regional and district hospitals while TB clinics are decentralized to the dispensary level; 3) lack of human resources in this specialized area; and 4) lack of infrastructure at many existing health facilities to successfully implement collaborative activities.

<table>
<thead>
<tr>
<th>Box 5. The History of TB Control in Tanzania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tanzania holds an interesting place in the history of TB control. The National Tuberculosis Programme, launched in 1978 under the direction of Dr. Karel Styblo, helped form the basis of the WHO DOTS strategy and showed that supervised therapy was a realistic goal in developing-country settings. Despite recording more than 25 years of improving coverage and case notification rates – for example, from 2005–2006 new active cases of TB fell by 4% nationwide – Tanzania remains one of the 22 high-burden countries and has the highest TB prevalence and TB death rates among the four study countries.</td>
</tr>
</tbody>
</table>

Tanzania has 690 smear labs, three culture labs, and a DST lab working with the NTLP. In 2007 the NTLP promoted the use of LED fluorescence microscopy to improve case detection in peripheral areas of the country where need and potential impact were likely to be greatest. TB case notification rates were low in 2006: Of the 312 new cases of all forms of TB for every 100,000 people, only an estimated 48% were notified of their condition. More urbanized regions such as Dar es Salaam and Arusha tend to have the country’s highest case notification rates.

The distribution of TB diagnostic services is enhanced by a public–private partnership: Approximately 10% of SSM is done by for-profit facilities, 30% by FBOs, and 60% through the public sector. The government provides certified private facilities with supplies, so TB tests are free in every sector.

An estimated 1% of new active TB cases are MDR-TB. Samples from patients failing treatment are transported to the Central TB Reference Laboratory for DST, often resulting in delays and/or specimen contamination. Tanzania has begun to scale up more rapid and sensitive liquid cultures and DST at national and regional reference laboratories to improve diagnosis.

**Health Systems Perspectives**

The accuracy, feasibility, and costs of both new and existing TB diagnostics concerned Tanzanian health providers. Many felt that diagnostics would be improved if they could stop relying on microscopes, electricity, the cold chain, and multiple specimens. Others felt that diagnostic tests for children in particular should not be invasive, suggesting a finger stick blood sample instead of intravenous blood collection. Respondents gave specific reasons why these characteristics would improve TB diagnosis. One interviewee described SSM as a “robust” but “cumbersome” diagnostic whose quality assurance component was difficult to ensure. Providers also mentioned that a rapid test would help to reduce losses to follow-up, as would a test that could be performed and analyzed at the dispensary level, since transportation cost may impede patients from going to referral facilities.

Procurement was cited as a major barrier to effective diagnosis in Tanzania. Some providers attributed difficulties with product procurement to the multiplicity of programs delivering supplies to individual health facilities. They felt this creates confusion about which source provides different commodities. These respondents went on to explain that once a request for supplies is received by vertical programs, such as the NTLP, program staff assess quantities of stock at MSD and allocate resources to all facilities.
based on availability. Although these respondents understood that this procurement cycle is intended to ensure fair distribution, one not based solely on who requests stocks first, they explained that it causes delays at the health facility level.

Although in general the MSD was described as very inefficient, the private sector in Tanzania faces specific barriers to procurement. One respondent believed that the inability of private providers to purchase in bulk through MSD compromises the quality of products available for patients. This interviewee explained that prices are much higher outside the MSD network, prompting providers who want to make a profit to buy less expensive, lower quality products.

The Tanzanian interviews produced further comments on conditions in the private sector. One interviewee cited the following reasons that people choose the private sector despite out-of-pocket costs: 1) shorter waiting times, 2) more attention from health workers, and 3) more reliable drugs and supplies. These providers described numerous challenges to survival that private facilities faced. One provider explained that cost sharing is causing a shift away from faith-based facilities, which still charge user fees to cover salaries and that higher salaries in government-operated facilities also prompt health workers to leave faith-based facilities. According to this respondent, this compromises the care of these patients who perceive the quality of care as superior to the public sector. These patients continue to visit private facilities, but are now seen by less qualified staff. This is particularly problematic in rural areas where FBOs provide more than 50% of health services and hospitals tend to be faith based. Another provider explained that although all facilities can participate in national health insurance schemes, FBOs are reluctant to do so because reimbursement is often delayed and the process is “cumbersome.” This respondent added that facilities are often refunded at a lower rate if the insurance providers claim that services were not provided according to standard.

When considering introduction of new diagnostics into the Tanzanian health system, one health provider suggested that the per-unit cost of a diagnostic should be contingent on the disease burden. This respondent explained that in Tanzania it would reasonable for a TB test for children to cost more than a malaria test because there are comparatively few cases of childhood TB. Some health providers also broached the subject of morality in introducing new diagnostics, stating that if the international health community determines that a diagnostic is important and the national health system agrees to introduce it, the government has a moral obligation to ensure supplies. Should governments abandon older technologies, manufacturers of these products may cease to exist, and if the government is unable to afford new technologies without donor assistance, it will face a major challenge to future diagnoses.

**Consumer willingness to purchase and use**

Of those consumers interviewed in Tanzania about TB, malaria, ALRIs, HIV, syphilis, and other STIs, 94%–97% indicated that they were interested in using and willing to pay for diagnostic tests. Figure 5 indicates that Tanzanian consumers were willing to pay more for STI and TB tests than for HIV, malaria, ALRI, and syphilis diagnostics.
The average age of these respondents was 34 years, and 56% were married. The overall level of education was low: Nearly 70% of respondents had not gone beyond a primary education. Two-thirds of the study group self-identified as Muslim. Over half (59%) of interviews were conducted in public facilities. At the time of the study, US $1 was equivalent to 1176 Tanzanian shillings (Tsh). On average, respondents traveled 42 minutes and paid 949 Tsh in travel costs to reach a health facility (Table 6).
Table 6. Tanzania: Sociodemographic characteristics of TB survey respondents

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Respondents % (N=312)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>34.0</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>36.2% (113)</td>
</tr>
<tr>
<td>Married</td>
<td>56.1% (175)</td>
</tr>
<tr>
<td>Other</td>
<td>6.4% (20)</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
</tr>
<tr>
<td>&lt;Primary</td>
<td>13.5% (42)</td>
</tr>
<tr>
<td>Primary</td>
<td>57.0% (178)</td>
</tr>
<tr>
<td>Secondary</td>
<td>22.8% (71)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>5.5% (17)</td>
</tr>
<tr>
<td>Other</td>
<td>0.6% (2)</td>
</tr>
<tr>
<td>Religion</td>
<td></td>
</tr>
<tr>
<td>Muslim</td>
<td>60.9% (190)</td>
</tr>
<tr>
<td>Christian</td>
<td>33.3% (104)</td>
</tr>
<tr>
<td>Other</td>
<td>1.3% (4)</td>
</tr>
<tr>
<td>Zone</td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>48.4% (151)</td>
</tr>
<tr>
<td>Rural</td>
<td>51.6% (161)</td>
</tr>
<tr>
<td>Region</td>
<td></td>
</tr>
<tr>
<td>Dar es Salaam</td>
<td>4.2% (13)</td>
</tr>
<tr>
<td>Tanga</td>
<td>95.8% (299)</td>
</tr>
<tr>
<td>Facility type</td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>59.0% (184)</td>
</tr>
<tr>
<td>Private</td>
<td>41.0% (128)</td>
</tr>
<tr>
<td>Average travel time (minutes)</td>
<td>42.5</td>
</tr>
<tr>
<td>Average travel cost (Tsh)</td>
<td>949</td>
</tr>
</tbody>
</table>

Health-seeking behaviors
Almost half of respondents suffered an illness episode in the four weeks preceding the survey; of these, 86% reported seeking care in the formal health sector while 2% sought care from a non-biomedical provider such as a traditional healer. Laboratory diagnostic tests were recommended to 74% of the respondents who went to a biomedical facility for evaluation, and 85% of that percentage reported consenting to the tests. On average, respondents reported having paid 2121 Tsh for diagnostic tests prescribed on the day of the survey. These tests may have been for TB or for a variety of other illnesses, since survey participants were recruited from among adults seeking any type of curative care. Respondents reported a willingness to pay an average of 2488 Tsh for a TB test, 17% more than they reported actually having paid for a diagnostic test on the day of their visit and 25% more than what survey respondents reported being willing to pay across all six diagnostics studied.

Willingness to pay for TB diagnostic tests
Based on the initial focus group findings, the WTP bidding started at 500 Tsh for a TB test and increased in increments of 300—400 Tsh, depending on each consumer’s reply. Some respondents indicated a willingness to pay an amount outside the predetermined cost parameters. Despite the survey design, the amounts consumers agreed to pay tended to cluster in increments of 500 Tsh. Of 312 respondents, nine reported that they were not willing to pay for a TB diagnostic; the other 260 expressed willingness to pay
between 200 and 20,000 Tsh. Figure 6 shows that consumer willingness to pay declined sharply as the
prices increased to 1500 Tsh, and then declined gradually before dropping sharply again as the price
passed 4500 Tsh. At 500 Tsh, 90% were willing to pay for a TB diagnostic, but once the price exceeded
1000 Tsh, more than half were unwilling to pay.

**Figure 6. Tanzania: Consumer willingness to pay for TB diagnostics at each price range**

![Diagram showing consumer willingness to pay for TB diagnostics at each price range.](Image)

The figure groups respondents into four market segments to categorize consumer willingness to pay for
TB diagnostics tests by price range:

- **Segment A:** Consumers willing to pay no more than 1000 Tsh,
- **Segment B:** Consumers willing to pay 1001–1500 Tsh,
- **Segment C:** Consumers willing to 1501–3000 Tsh, and
- **Segment D:** Consumers willing to pay more than 3000 Tsh.

Market segmentation enabled a determination of which characteristics these groups share and an
understanding of the factors driving market response at each price level. The figure highlights these
markets and illustrates the proportion of the population that fall into each segment at a given price range.

Nearly 90% of the nine respondents who were not willing to pay for a TB diagnostic were Tanga
residents, lived in rural areas, and attended private for-profit clinics. Most had not completed more than a
primary education. However, this small sample precludes reliable conclusions about the socio-economic
makeup of this group.

Table 7 indicates socio-economic and demographic trends across market segments. Although the
proportion of respondents who had completed primary and secondary education did not increase
substantially as WTP increased, smaller proportions of consumers who had not completed primary school
fell in segments C and D. Increased willingness to pay was thus not necessarily associated with being
better educated, but less uneducated. Given that most surveys were conducted in Tanga rather than Dar es Salaam, Tanga naturally dominates in all four segments. The proportion of urban respondents increases
with willingness to pay higher prices.

Wealth is clearly associated with increased willingness to pay higher prices. More than half of
respondents willing to pay more than 1500 Tsh, segments C and D, were in the top two wealth quintiles.
Alternately, 55% of those in segment A were in the bottom two wealth quintiles.
Table 7. Tanzania: Selected socio-economic characteristics of respondents willing to pay within different prices for a TB diagnostic (Tsh, 2007–2008, N=312)

<table>
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<tbody>
<tr>
<td>Education level</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>&gt;Primary</td>
<td>0</td>
<td>25.3% (22)</td>
<td>17.1% (12)</td>
<td>6.5% (6)</td>
<td>3.8% (2)</td>
</tr>
<tr>
<td>Primary</td>
<td>77.8% (7)</td>
<td>51.7% (45)</td>
<td>55.7% (39)</td>
<td>62.4% (58)</td>
<td>54.7% (29)</td>
</tr>
<tr>
<td>Secondary</td>
<td>0</td>
<td>21.8% (19)</td>
<td>20.0% (14)</td>
<td>22.6% (21)</td>
<td>32.1% (17)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>22.2% (2)</td>
<td>1.1% (1)</td>
<td>4.3% (3)</td>
<td>7.5% (7)</td>
<td>7.6% (4)</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>1.1% (1)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Wealth quintile</td>
<td>***</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>0</td>
<td>36.5% (31)</td>
<td>16.4% (11)</td>
<td>19.8% (18)</td>
<td>9.4% (5)</td>
</tr>
<tr>
<td>2</td>
<td>33.3% (3)</td>
<td>20.0% (17)</td>
<td>20.9% (14)</td>
<td>26.4% (24)</td>
<td>17.0% (9)</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>16.5% (14)</td>
<td>19.4% (13)</td>
<td>25.3% (23)</td>
<td>18.9% (10)</td>
</tr>
<tr>
<td>4</td>
<td>33.3% (3)</td>
<td>16.5% (14)</td>
<td>20.9% (14)</td>
<td>14.3% (13)</td>
<td>22.7% (12)</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>33.3% (3)</td>
<td>10.6% (9)</td>
<td>22.39% (15)</td>
<td>14.3% (13)</td>
<td>32.1% (17)</td>
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<tr>
<td>Zone</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Urban***</td>
<td>88.9% (8)</td>
<td>36.4% (32)</td>
<td>40% (27)</td>
<td>49% (46)</td>
<td>70% (37)</td>
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<tr>
<td>Rural</td>
<td>11.1% (1)</td>
<td>63.6% (56)</td>
<td>60% (42)</td>
<td>51% (47)</td>
<td>30% (16)</td>
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<tr>
<td>Facility type</td>
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<td></td>
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<tr>
<td>Public</td>
<td>11.1% (1)</td>
<td>69.0% (60)</td>
<td>58.6% (41)</td>
<td>61.3% (57)</td>
<td>47.2% (26)</td>
</tr>
<tr>
<td>Private for-profit***</td>
<td>88.9% (8)</td>
<td>31.0% (27)</td>
<td>41.4% (29)</td>
<td>38.7% (36)</td>
<td>52.8% (28)</td>
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<td>Region</td>
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<td></td>
</tr>
<tr>
<td>Dar es Salaam</td>
<td>11.1% (1)</td>
<td>3.4% (3)</td>
<td>5.7% (4)</td>
<td>2.1% (2)</td>
<td>5.7% (3)</td>
</tr>
<tr>
<td>Tanga</td>
<td>88.9% (8)</td>
<td>96.6% (84)</td>
<td>94.3% (66)</td>
<td>97.9% (91)</td>
<td>94.3% (50)</td>
</tr>
</tbody>
</table>

* Difference statistically significant (by OLS) at the 0.10 level.
** Difference statistically significant at the 0.05 level.
*** Difference statistically significant at the 0.01 level

Notes:
Reference category for wealth quintile is 1, the poorest 20% of the population.

**Significant influences on willingness to pay**
As in Peru and Benin, the bivariate analysis revealed statistically significant differences in consumer willingness to pay by wealth quintile and education level. On average, consumers in the highest wealth quintile were willing to pay 3361 Tsh, more than double those in the lowest quintile would pay (ANOVA p=0.01). Respondents who were university educated were willing to pay 4400 Tsh, more than three times as much as those who had not completed primary education (ANOVA p=0.01).
WTP also differed significantly by geographic zone and type of facility attended: On average, urban respondents were willing to pay 3252 Tsh, about 74% more than those in rural areas (ANOVA p=0.01). Consumers at private health facilities were willing to pay an average of 3099 Tsh for a TB test, 46% more than those at public facilities (ANOVA p=0.01).

**Figure 7. Tanzania: Willingness to pay for TB diagnostics, urban versus rural**

Although the average amounts consumers were willing to pay differed significantly between certain socio-economic and demographic strata, after adjusting for other factors, significant differences remained between facility type, wealth quintile, and geographic zone. Urban respondents were willing to pay 282 Tsh more than their rural counterparts (OLS p=0.01). Figure 7 shows that as the price of a TB test rises above Tsh 1750 greater proportions of urban residents are increasingly willing to pay for diagnostics.

**Figure 8. Tanzania: Willingness to pay for TB diagnostics, public versus private facilities**

Consumers at private facilities were willing to pay 213 Tsh more than those at public facilities (OLS p=0.01), and with each increase in quintile, WTP increased 164 Tsh (OLS p=0.01). Figure 8 illustrates that a comparable proportion of consumers at private and public facilities was willing to pay for TB diagnostics below Tsh 1000. As the price increased, consumers at private facilities were willing to pay slightly more until the price increased to Tsh 2500. At that price point the gap between the proportion of consumers willing to pay for tests at each facility widens, suggesting that at higher prices facility type is more important in determining willingness to pay. Married participants were willing to pay 246 Tsh more than unmarried ones (OLS p=0.01).

**Illness concepts**

As in Benin, the availability of treatment lessened some focus group participants’ perceptions of the severity of TB. Government provision of medicine at no cost to patients seemed to contribute to
perceptions of TB as manageable. It was also noted that early diagnosis and treatment are important to prognosis:

I think it is not dangerous. If a person with TB is tested and introduced to medicine, the severity ends.

TB is not very severe because if it is diagnosed at its early stages it is curable…. If someone catches TB and gets proper treatment it heals.

However, for some participants, the length of time and effort necessary to be diagnosed and treated for TB posed a number of challenges, including the difficulty adhering to a strict drug regimen:

[TB] is treatable although it takes long to know whether one has TB. It can take up to six months to diagnose TB, and also the treatment takes very long. That’s why we decided [it is not easy to treat].

TB [involves] treatment difficulties. [The treatment] has a lot of restrictions, which for some people are difficult to adhere to, so they die because of that.

A sick person is put into long drug regimens, and the medicine causes many problems in the body of the patient. The person cannot work and after six months of being on drugs, a person has to go for testing and a doctor has to approve your healing, and if [the patient is] not yet healed, [the doctor] has to put the patient in second round. This is very difficult.

Similar to Benin, some participants considered contracting TB as outside of their personal locus of control, classifying it as a disease from “God” rather than a result of being “careless” as with other communicable diseases:

TB is a disease from God, because other illnesses are treatable easily. All other illnesses a person can get it by being careless, but TB is not from being careless.

Several participants similarly compared TB to STIs as a way to explain their limited ability to protect themselves from this disease:

We say [TB is very severe] because it is transmitted through air and many people are infected, but the other illnesses are transmitted through sexual intercourse, and you can protect yourself. But a person cannot prevent him-/herself from catching TB.

STIs are obtained willingly, but it is different with TB, which can be obtained in public transport, in crowded places, and is transmitted by air.

Perceptions of ability to limit personal exposure to the risk factors of TB were linked to participants’ comments on disease severity. To the degree that participants’ believed they could control their environmental exposure to risk factors, they did not perceive it as a “problem” for them:

[TB is not very] serious because it depends on where one lives. If it is [an] overcrowded area, it is a problem. But if you live in a place with enough ventilation, it is not a problem.

Focus group participants’ were aware of some of the risk factors for TB, such as poverty, overcrowding, and poor ventilation, all present in their communities, but they also expressed ignorance as to how to prevent TB transmission within households:

For sure, the environment here contributes a lot to TB transmission: hard work, dust, people do not care about their health, poor feeding, and poor income that cannot fulfill a person’s daily needs.

It is easy to get TB because it is transmitted through air and also through sharing utensils with an infected person. In our community it is easy to get TB, because people cannot tell who is infected and who is not, and normally we share almost everything in the household.

Most people are not aware of how to prevent these illnesses. [This ignorance of prevention] increases when there is a person with TB in a household [and the others in the household] do not know how to prevent it from spreading.
Most Tanzanian focus group participants perceived TB as “embarrassing.” Much of the stigma attendant to TB was associated with the illness’s communicable nature and the resulting isolation TB-infected individuals experience; participants mentioned that family, friends, and neighbors will avoid TB patients to avoid contracting the disease:

- The weaker you become, the more people discriminate against you, because [TB] transmits easily. People may even stop eating with you, so when you are told you have TB, you start feeling uncomfortable, which is why it’s embarrassing.
- Normally, TB is transmitted through air, so if you hear someone has TB you will definitely walk away… even if he/she is your sibling. Also[isolation occurs] because it takes long to heal, so even the people who are taking care of you get tired, and they have other things to deal with, so they start avoiding you.

These quotations also illustrate that in addition to fear, social rejection can eventually result from the burden on caregivers of constant, long-term care for this chronic illness.

TB was frequently likened to HIV/AIDS as a stigmatizing illnesses, but while much of the shame attached to AIDS seemed to be linked to its incurableness and the socially and morally unacceptable behaviors associated with the disease, the stigma associated with TB related more to fear of contagion. Participants described the social exclusion of TB-infected individuals as a way to limit their personal vulnerability to the disease:

- As far as stigma is concerned, it’s better with AIDS than way it is with TB. I mean that because [TB is] transmitted through air, it’s easy for people to avoid you. If you put two people together – one with TB and the other with HIV/AIDS – and ask people to choose who they want to sit with, they will definitely choose the one with AIDS.
- HIV/AIDS is more embarrassing, but when you come to how it is spread, TB is more dangerous.

Comparisons between TB and HIV/AIDS also reveal that the diseases’ shared symptoms can lead people to experience embarrassment because others may think they have HIV/AIDS:

- If a person has the TB virus and begins coughing, he begins to lose weight. People start pointing at you, and others can say you have some other illnesses [like] HIV/AIDS. Others may think you have HIV, and that is when you become embarrassed.

The previous quotation illustrates that, as in Benin, the fact that TB symptoms cannot be easily concealed is a source of embarrassment, not only because it causes the individual to be labeled as sick, but because it leads community members to speculate that they may have an even more “severe” and stigmatizing disease such as HIV, which may cause others to label him/her as irresponsible and of poor character.

**Factors influencing willingness to purchase and use diagnosis**

The shared symptoms of illnesses also influenced focus group participants’ WTP for diagnostic tests in order to identify illness etiology:

- HIV and TB mostly need diagnostic tests because it is not easy to distinguish TB symptoms from HIV [symptoms], because they are almost alike.
- Because their symptoms are not clear, if you have TB you can lose weight just like [someone] who is suffering from AIDS, diarrhea, or severe malaria....That’s why we are saying in order to diagnose malaria, pneumonia, TB, and HIV/AIDS, you must undergo a diagnostic test.

There are three or four different types of TB; there is blood TB and bone TB. That’s why you find people suffering, because they don’t know what they are suffering for. Mostly, they know TB is just coughing, when they cough they know it is TB, but they don’t know it could be the symptom for other illnesses. And sometimes people think they are HIV-positive just because they have TB, but they haven’t [been] tested, and yet their minds run to HIV/AIDS.
Participants also recognized that diagnosis was necessary to start appropriate treatment and slow disease progression. One said, “TB needs a test because you can get it [TB], and if you don’t go for a test you get more affected.”

**Desired test characteristics**

Focus group participants differentiated between intravenous blood samples, referred to as “big blood,” and less invasive samples such as finger stick samples. Participants seemed to have greater faith in the ability of “big blood” to test what they perceived as more severe illnesses: “Big blood is for testing illnesses like TB, HIV, and typhoid.”

**Peru**

Located on the western coast of South America, Peru is a geographically and ethnically diverse country. Its population of about 27.5 million is growing at a rate of 1% per year. Thirty-one percent of Peruvians are under age 15. ³ A third of Peruvians live in or near the capital, Lima, and 73% live in urban areas. The World Bank classifies this country as a lower, middle-income country; 11% of the population live below the poverty line. The 2007 GNI per capita, US $3450, was lower than the US $5540 average for Latin American and the Caribbean. Peru’s per capita income masks great differences in wealth; income disparities are among the highest in the world. ⁴⁴, ⁵⁶ In 2003 the wealthiest 20% of the population accounted for 57% of national income or expenditures, while the poorest 20% accounted for only 4%. ⁵⁷ Literacy among those over age 15 is high: In 2000 it was reported at 93%. ⁵⁸

**Overview of the health system**

Despite the existence of services for the poor, numerous barriers limit access to public services, including direct costs and opportunity costs. ⁵⁶ Health services are also not sufficiently decentralized to the poorest areas of the country. ³ Inadequate referral systems pose another barrier to care. ³, ⁵⁸

The Peruvian public health system is composed of:

1. The Ministry of Health (Ministerio de Salud or MINSA);
2. Services for salaried personnel provided by the social security system (ESSALUD); and
3. Services for the armed and public forces. ⁵⁶, ⁵⁹

Peru’s public sector is large and includes 51% of the hospitals, 69% of the health centers, and 99% of the health posts. The public laboratory network includes 16 regional laboratories and the national reference center, the National Institute of Health (INS). ⁵⁸ Private sector services are primarily used by those with higher incomes, and the largest portion is based in Lima, where 70% of the overall health market resides. ⁵⁶, ⁵⁹, ⁶⁰

According to 2004 reports, household spending and employer contributions account for the majority of health financing. ⁵⁸ Approximately 8% of total government spending is on health. External aid accounts for 2% of total health spending. ⁶⁰

As of 2000, households were the primary source of health financing, accounting for 37% of spending. The formal economy, through ESSALUD, accounts for 35% of health spending. The government pays 24% of health expenditures and other sources, including international donors, cover about 4% of health costs. ⁵⁹

In 2001 the Comprehensive Health Insurance program was created to provide coverage for those under age 18 years, pregnant women, and some impoverished populations. As of 2004, 32% of the population used this health insurance. ESSALUD is mandatory for salaried workers; in 2004 it insured 18% of the population. Private sector insurance is also available. ⁵⁹

The General Office of Medications, Supplies, and Drugs is the authority on medications, reagents, and medical equipment. ⁵⁹
Tuberculosis in Peru

Average life expectancy in Peru is 73 years. In 2006, 187 of every 100,000 people in Peru had active TB. At 0.4% HIV prevalence among adults is the lowest of all the study countries. HIV/AIDS cases tend to be concentrated in major urban areas of the country, and only 2% of new TB cases were HIV-positive in 2006.\textsuperscript{3,61} Peru has a relatively high rate of drug resistant TB. In 2006, 5% of new cases were MDR-TB.\textsuperscript{62}

<table>
<thead>
<tr>
<th>Box 5. The History of TB Control in Peru</th>
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| Like Tanzania, Peru holds a unique place in the history of global TB control. Peru became the first high-burden country to successfully implement DOTS, as demonstrated by the noted decline in disease incidence between 1991 and 1999.\textsuperscript{1} Although the Americas have the lowest TB prevalence rates in the world (44 per 100,000 people), the region includes a few high-burden countries, such as Haiti and Brazil. With only 5% of the region’s population, Peru is home to a fourth of all reported TB cases in the region.\textsuperscript{3}

Peru also played an important role in the global fight against drug resistance: Northern Lima served as a pilot area for testing the effectiveness of drug therapy on endemic MDR-TB: This led to the eventual adoption of drug therapy recommendations for MDR-TB by the WHO and international community.\textsuperscript{1,3}

Diagnosis is commonly performed through a combination of SSM, chest x-ray, and clinical diagnosis. Children, PLWHA, and patients with suspected extra-pulmonary TB are diagnosed through more expensive techniques, including bronchio-alveolar washing and gastric lavage. To control MDR-TB, the NTCP decentralized first-line DST to selected, accredited laboratories for screening purposes. In 2005 the Peruvian National Reference Laboratory validated and decentralized the direct Griess method, a rapid diagnostic test, to district laboratories to improve access to early diagnosis and treatment. This colorimetric method, which uses nitrate reductase reaction to indicate TB growth on solid medium, reduced the median time from sputum collection to DST result from 99 days to 31 days.\textsuperscript{9} Since then microscopic observation drug-susceptibility assay (MODS) has also been integrated into the national technical norms. The Comités de Evaluación de Retratamientos Intermedios (Committees to evaluate intermediate retreatments or CERI) also work with the NTCP to evaluate drug resistant TB cases.

Peru’s case notification rates are also higher than in the other study countries; in 2006 the WHO estimated that 77% of people with new cases of active TB were notified of their condition. This is likely due in part to Netlab, an automated health information network that posts the results of samples processed in the national laboratory, allowing physicians and certain patients instant access. In 2006 the WHO estimated that Peru had 350 smear labs, 67 culture labs, and 7 DST labs working with the NTCP.\textsuperscript{62}

Health systems perspectives

Several providers associated the need for new TB diagnostics with the relatively recent increases in MDR-TB and XDR-TB cases in Peru. They praised the introduction of MODS and the Griess method as major improvements in the detection and case management of drug resistant TB.

As in the other study countries, providers cited increased accuracy and efficiency as desirable characteristics of a new diagnostic tool that could improve notification and case management. Others noted that an easier to obtain sample, namely blood, would further facilitate TB diagnosis.

Despite favorable responses to new DST tools, existing weaknesses in the Peruvian health care system caused providers to question whether new diagnostics could be effectively expanded nationwide. Some felt that without political will to ensure the provision of materials and reagents, the coordination of logistics, and the availability of trained staff, even a rapid, reliable, cost-effective diagnostic tool would fail to function as intended. Several providers noted that a lack of laboratory supplies in public health establishments already impeded proper functioning of SSM. As evidence of this, one interviewee reported that on occasion staff had purchased sputum containers with their own money.
In addition to supply shortages, many providers mentioned that a general lack of personnel qualified to conduct lab work for treatment monitoring was a problem. Some explained that NTCP personnel, who are often hired on a contract basis, receive low wages and are denied benefits, such as job stability and social security. As a result, NTCP staff are poorly motivated to perform their tasks. Furthermore, personnel reported that laboratory spaces are generally insufficient and lack the ventilation, equipment, and supplies necessary to prevent contagion. These frequent breaches in laboratory biosecurity measures trigger fears of infection among health personnel.

Other providers cited deficient procurement systems as probable barriers to the successful scale-up of rapid TB testing in certain areas of the country. One provider cited the only moderately successful turnover of supply procurement from external donors to the INS as an example of unsatisfactory procurement systems. Health providers also cited low prices as a major requirement for new diagnostic tests. Although SSM is provided at no cost in public facilities, patients may have to pay out of pocket for additional procedures before being enrolled in the NTCP. Still others worried that the external cooperation currently necessary to introduce and maintain a DST such as MODS would mean a lack of long-term sustainability.

Some providers referenced techniques to facilitate the introduction of new diagnostic tools. One provider suggested that improved cost-effectiveness could persuade decision-makers to adopt a new test; he gave the example of avoiding treating secondary cases of MDR-TB by providing DST up front. This same person suggested that putting policy into practice requires a “champion”; this provider attributed the successful uptake of MODS in part to a leader in the NTCP. This individual advocated for MODS despite resistance from the INS. This same provider believed that the data presented by his team played an important role in convincing the leader of the NTCP of the efficacy of MODS. Other providers also agreed that a well-designed and implemented research process was essential to the successful introduction of a new diagnostic tool.

In addition to scientific evidence, one provider highlighted the importance of collaboration with key actors. He explained that it is easier to translate research findings into policy when decision-makers have a stake in advancing an agenda. Otherwise, there is an increased risk of resistance from stakeholders who may have invested in a different tool. One provider cited the INS, which was still invested in the Griess methodology, and subsequently viewed MODS as a competitor. This provider explained that a new technology very rarely serves as an immediate replacement of an existing technology; in practice it takes time for a new test to be adopted as the standard, so often two tests are used simultaneously.

The lack of collaboration and communication between the INS and the NTCP regarding DST was a recurrent theme in the interviews. One provider said that these disagreements trickled down to regional NTCP representatives and regional reference laboratories, further eroding communication about which method to use. Political tensions were also said to detract attention from follow-through on improvements to the NTCP network, including staff training and supervision and reducing delays in both reporting and sample transport.

Transporting samples to reference labs was said to present more of a challenge is some parts of the country than others. One provider reported observing sputum samples transported in paper bags in the absence of proper coolers or containers. He also cited a time-motion study in Peru that revealed that inefficient transportation of sputum samples resulted in opportunity costs.

**Consumer willingness to purchase and use diagnostic tests**

Of the consumers interviewed in Peru about TB, malaria, ALRIs, HIV, syphilis, and other STIs, 90% indicated that they were interested in using and willing to pay for diagnostic tests. As Figure 9 indicates, Peruvian consumers were willing to pay more for TB, HIV, and STI tests than for malaria, ALRI and syphilis.
The average age of survey respondents questioned about TB in Peru was 35.6 years (Table 8). The sample was 57% female, and more than half of respondents were married. Just over half lived in rural areas, and almost 80% had completed secondary education or higher. A larger proportion of the population, 26.7%, had health insurance than in other study countries. At the time of the study, US $1 was equivalent to 2.72 Peruvian nuevos soles (S./). On average respondents traveled 27 minutes and spent S./ 2.00 in travel costs to reach a health facility.

**Health-seeking behaviors**

Slightly more than half the respondents reported suffering an illness episode in the four weeks preceding the survey; of these, 96% reported seeking care in the formal health sector while 2% sought it from a non-biomedical provider such as a shaman. Laboratory diagnostic tests were recommended to 48% of the respondents who went to a biomedical facility, and 96% reported consenting to the tests. Respondents reported having paid an average of S./ 45.20 for diagnostic tests prescribed on the day of the survey. These tests may have been for TB or for a variety of other illnesses since survey participants were recruited from among adults seeking any type of curative care. The same respondents reported willingness to pay an average of S./ 25.90 for a TB test, almost as much as the average S./ 26.00 these respondents reported being willing to pay for all six diagnostics studied.
Table 8. Peru: Sociodemographic characteristics of TB survey respondents (N=273)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Respondents (N=273)</th>
<th>Respondents’ spouse</th>
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</thead>
<tbody>
<tr>
<td><strong>Average age (years)</strong></td>
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<tr>
<td><strong>Gender</strong></td>
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<tr>
<td>Male</td>
<td>43% (118)</td>
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<tr>
<td>Female</td>
<td>57% (155)</td>
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<tr>
<td><strong>Marital status</strong></td>
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<tr>
<td>Single</td>
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<tr>
<td>Married</td>
<td>60% (164)</td>
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<tr>
<td>Other</td>
<td>9% (24)</td>
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<tr>
<td><strong>Education level</strong></td>
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</tr>
<tr>
<td>&lt; Primary</td>
<td>3% (8)</td>
<td>1.2% (2)</td>
</tr>
<tr>
<td>Primary</td>
<td>17.5% (48)</td>
<td>23.8% (39)</td>
</tr>
<tr>
<td>Secondary</td>
<td>50% (136)</td>
<td>46.3% (76)</td>
</tr>
<tr>
<td>Technical</td>
<td>17.5% (48)</td>
<td>14% (23)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>12% (33)</td>
<td>14% (23)</td>
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<tr>
<td><strong>Zone</strong></td>
<td></td>
<td></td>
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<tr>
<td>Urban</td>
<td>48.7% (133)</td>
<td></td>
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<tr>
<td>Rural</td>
<td>51.3% (140)</td>
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<tr>
<td><strong>Region</strong></td>
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<tr>
<td>Lima</td>
<td>36% (98)</td>
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<tr>
<td>Arequipa</td>
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<tr>
<td>Iquitos</td>
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<td><strong>Facility type</strong></td>
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<tr>
<td>Public</td>
<td>41% (113)</td>
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<tr>
<td>NGO</td>
<td>22% (59)</td>
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</tr>
<tr>
<td>Private for-profit</td>
<td>37% (101)</td>
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<tr>
<td><strong>Have health insurance</strong></td>
<td>26.7% (73)</td>
<td></td>
</tr>
<tr>
<td><strong>Average travel time (minutes)</strong></td>
<td>27</td>
<td></td>
</tr>
<tr>
<td><strong>Average travel cost (S./)</strong></td>
<td>2.00</td>
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*Willingness to pay for TB diagnostic tests*

Based on the initial focus group findings, the WTP bidding started at S./ 5.00 for a TB test and then doubled, depending on each consumer’s reply. Some indicated a willingness to pay an amount outside the predetermined cost parameters, but due to the survey design, the amounts they agreed to pay tended to cluster in increments of S./ 5.00 to 10.00. Of the 273 respondents surveyed, 22 reported that they were not willing to pay any amount for a TB diagnostic; the others reported a willingness to pay S./ 1.00–300.00.

Figure 10 shows that consumer willingness to pay declined sharply as the price rose to about S./ 30.00 and then declined gradually before dropping sharply again as the price exceeded S./ 45.00. At S./ 5.00, 90% were willing to pay for TB diagnostics. Once the price passed S./ 10.00, more than half were unwilling to pay.
This figure groups respondents into four market segments to categorize consumer willingness to pay for TB diagnostics tests within certain price ranges:

- **Segment A**: Consumers willing to pay no more than S/. 10.00;
- **Segment B**: Consumers willing to pay S/. 11.00–20.00;
- **Segment C**: Consumers willing to pay S/. 21.00–30.00;
- **Segment D**: Consumers willing to pay more than S/. 30.00.

Market segmentation also enabled a determination of which characteristics these groups share and an understanding of the factors driving market response at each price level. The figure highlights these markets and illustrates the proportion of the population that fall into each segment at a given price range.

Nearly 60% of the 22 Peruvians unwilling to pay for a TB diagnostic were from Arequipa (Table 9). Only 9% of them attended an NGO rather than public or private for-profit facility. In addition, 68% had completed secondary school and about 40% were in the two lowest wealth quintiles. However, this small sample precludes reliable conclusions about the socio-economic makeup of this group.

Although a fairly even proportion of respondents in each market segment lived in urban and rural zones of Peru (which can be explained by the mostly peri-urban sample of respondents from Lima), The table shows that other socio-economic and demographic characteristics differ across market segments. Wealth is clearly associated with increased WTP higher prices. More than half of respondents willing to pay more than S/. 20.00, segments C and D, were in the top two wealth quintiles. Alternately, more than 50% of those in segment A were in the bottom two wealth quintiles. Across the markets most respondents had completed secondary school, but those in segments C and D tended to be better educated, with higher representation in technical schools and universities.

As willingness to pay increased across the market segments so did attendance at NGO facilities, and attendance at public medical facilities declined. Respondents willing to pay more also tended to live in Lima and have health insurance.

These data suggest that consumers who were willing to pay more for TB diagnostics tend to be wealthier, better educated, have health insurance, live in Lima, and attend NGO clinics. Those willing to pay less were less likely to have completed post-secondary education and more likely to fall into lower wealth quintiles.
Table 9. Peru: Selected socio-economic characteristics of respondents willing to pay different prices for a TB diagnostic (S/., 2007, N=273)

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<tbody>
<tr>
<td>Gender</td>
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<tr>
<td>Male</td>
<td>50.0% (11)</td>
<td>45.6% (41)</td>
<td>28.6% (18)</td>
<td>45.8% (22)</td>
<td>52.0% (26)</td>
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<tr>
<td>Female</td>
<td>50.0% (11)</td>
<td>54.4% (49)</td>
<td>71.4% (45)</td>
<td>54.2% (26)</td>
<td>48.0% (24)</td>
</tr>
<tr>
<td>Education level***</td>
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</tr>
<tr>
<td>&lt; Primary</td>
<td>0.0% (0)</td>
<td>3.3% (3)</td>
<td>4.8% (3)</td>
<td>2.1% (1)</td>
<td>2.0% (1)</td>
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<tr>
<td>Primary</td>
<td>13.6% (3)</td>
<td>26.7% (24)</td>
<td>25.4% (16)</td>
<td>10.4% (5)</td>
<td>0.0% (0)</td>
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<td>Secondary</td>
<td>68.2% (15)</td>
<td>51.1% (46)</td>
<td>50.8% (32)</td>
<td>47.9% (23)</td>
<td>40.0% (20)</td>
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<tr>
<td>Technical</td>
<td>13.6% (3)</td>
<td>14.4% (13)</td>
<td>11.1% (7)</td>
<td>22.9% (11)</td>
<td>28.0% (14)</td>
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<tr>
<td>Tertiary</td>
<td>4.6% (1)</td>
<td>4.4% (4)</td>
<td>7.9% (5)</td>
<td>16.7% (8)</td>
<td>30.0% (15)</td>
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<tr>
<td>Wealth quintile</td>
<td></td>
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<tr>
<td>1 (lowest)</td>
<td>13.6% (3)</td>
<td>32.2% (28)</td>
<td>21.7% (13)</td>
<td>12.8% (6)</td>
<td>6.1% (3)</td>
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<tr>
<td>2</td>
<td>27.3% (6)</td>
<td>21.8% (19)</td>
<td>21.7% (13)</td>
<td>14.9% (7)</td>
<td>16.3% (8)</td>
</tr>
<tr>
<td>3</td>
<td>31.8% (7)</td>
<td>18.4% (16)</td>
<td>25.0% (15)</td>
<td>21.3% (10)</td>
<td>10.2% (5)</td>
</tr>
<tr>
<td>4</td>
<td>18.2% (4)</td>
<td>13.8% (12)</td>
<td>23.3% (14)</td>
<td>19.2% (9)</td>
<td>28.6% (14)</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>9.1% (2)</td>
<td>13.8% (12)</td>
<td>8.3% (5)</td>
<td>31.9% (15)</td>
<td>38.8% (19)</td>
</tr>
<tr>
<td>Zone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>54.6% (12)</td>
<td>45.6% (41)</td>
<td>50.8% (32)</td>
<td>41.7% (20)</td>
<td>56.0% (28)</td>
</tr>
<tr>
<td>Rural</td>
<td>45.5% (10)</td>
<td>54.4% (49)</td>
<td>49.2% (31)</td>
<td>58.3% (28)</td>
<td>44.0% (22)</td>
</tr>
<tr>
<td>Facility type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>45.5% (10)</td>
<td>52.2% (47)</td>
<td>42.9% (27)</td>
<td>33.3% (16)</td>
<td>26.0% (13)</td>
</tr>
<tr>
<td>NGO**</td>
<td>9.1% (2)</td>
<td>12.2% (11)</td>
<td>22.2% (14)</td>
<td>27.1% (13)</td>
<td>38.0% (19)</td>
</tr>
<tr>
<td>Private for-profit</td>
<td>45.5% (10)</td>
<td>35.6% (32)</td>
<td>34.9% (22)</td>
<td>39.6% (19)</td>
<td>36.0% (18)</td>
</tr>
<tr>
<td>Region</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lima</td>
<td>27.3% (6)</td>
<td>31.1% (28)</td>
<td>33.3% (21)</td>
<td>43.8% (21)</td>
<td>44.0% (22)</td>
</tr>
<tr>
<td>Arequipa***</td>
<td>59.1% (13)</td>
<td>30.0% (27)</td>
<td>25.4% (13)</td>
<td>27.1% (13)</td>
<td>30.0% (15)</td>
</tr>
<tr>
<td>Iquitos</td>
<td>13.6% (3)</td>
<td>38.9% (35)</td>
<td>41.3% (14)</td>
<td>29.2% (14)</td>
<td>26.0% (13)</td>
</tr>
<tr>
<td>Have health insurance***</td>
<td>9% (2)</td>
<td>20% (18)</td>
<td>28.6% (18)</td>
<td>37.5% (18)</td>
<td>34% (17)</td>
</tr>
</tbody>
</table>

* Difference statistically significant (by OLS) at the 0.10 level.
** Difference statistically significant at the 0.05 level.
*** Difference statistically significant at the 0.01 level

Notes:
Reference category for region is Lima.
Reference category for facility type is “all other facility types.”
Reference category for health insurance is “no health insurance.”
Reference category for education level is “less than primary education.”

**Significant influences on willingness to pay**

Similar to the bivariate analyses in Benin, there were statistically significant differences in the consumer willingness to pay by wealth quintile and education level. On average, consumers in the highest wealth quintile were willing to pay S/. 35.00, more than twice as much as those in the lowest (ANOVA p=0.01). University-educated respondents were willing to pay S/. 45.00, more than three times as much as those who had completed only primary education (ANOVA p=0.01).
WTP also differed significantly by geographic region and by the amount respondents spent on travel to reach a health facility. Lima residents were willing to pay an average of S/. 31.00 for a TB test, 16% more than those in Arequipa and 53% more than those in Iquitos. (ANOVA p=0.10) Respondents also reported a willingness to pay S/. 87.00 for a TB test if they spent more than S/. 2.00 to reach a health facility; this is 3.5 times more than those who spent no money on transport were willing to pay (ANOVA p=0.10).

Figure 11. Peru: Willingness to pay for TB diagnostic test, by insurance status

Although the average amounts consumers were willing to pay differed significantly between certain socio-economic and demographic strata, after adjusting for other factors, significant differences remained between education and geographic region only. Although no significant difference appeared between willingness to pay in Iquitos and Lima, Arequipa residents were willing to pay 38% less than those in Lima (OLS p=0.01). Education (or wealth quintile as a proxy) was the most consistent predictor of increased WTP across all analyses in Peru. Respondents were willing to pay an increase of S/. 5.00 for each additional level of education (OLS p=0.01). Consumers seeking care at NGO facilities were willing to pay S/. 2.00 more than those at either public or private for-profit facilities (OLS p=0.05). Respondents with either private or state health insurance were willing to pay S/. 3.00 more than those with none (OLS p=0.01). Figure 11 illustrates that as the price of a TB test increases to S/. 35.00, even consumers with health insurance were less willing to pay. This suggests that at higher prices, health insurance is less important in determining willingness to pay.

Illness concepts
Although some Peruvians considered HIV to be more severe, TB was the only illness that all focus groups listed as one of the most important illnesses in their community. Like respondents in the other study countries, most Peruvians described TB treatment as long and arduous. Although they noted that TB is curable, and therefore less deadly than HIV/AIDS, many focus group participants told stories of treatments lasting for years and seriously straining the body. Although it was unclear whether they were referring to latent TB or the residual damage to the lungs following TB treatment, several participants did not believe that TB treatments provided a complete cure:

With TB, I think that you’re left with sequelae, if I’m not mistaken…. You can’t be cured 100%.

The treatment to cure you lasts six months and is a treatment of daily pills,…that’s what I know.
But you’re never, never, never the same after.

Participants universally agreed that, like HIV, TB requires a laboratory or biomedical diagnosis. Relative disease severity was also mentioned as a key reason to pay more for TB, HIV, and STI diagnostics than for malaria and ALRI. Participants believed that it is worth paying for a diagnostic to be able to “rule out” a serious illness to have peace of mind, especially if the disease could be treated if diagnosed promptly. Others believed that because TB progresses slowly, it is less imperative to diagnosis than pneumonia. Fear was an important motivator in decisions to be tested:
There’s a high mortality rate [for TB, HIV and STIs], and, apart from that, when you hear about these types of diseases, it’s really scary, you know? So if someone says to you, “Listen, we’re going to rule out that you have [one of these diseases],” it’s one of the first things you want to do.

The risk posed to communities and families by the highly contagious nature of TB influenced participants’ perceptions of TB disease severity. Many attributed TB infection to a weak immune system due to lack of proper nutrition. Focus groups discussed the infectiousness of TB relative to HIV and other STIs. Many participants tended to associate STI and HIV infection with the more “liberal” attitudes of adolescents. They also said they were unable to protect themselves from exposure to TB bacteria by exercising personal responsibility. TB contagion was described as indiscriminate; people could be infected without even realizing they were exposed:

I think the most contagious disease is tuberculosis because the microbe is there in the environment: A person with tuberculosis can’t get too close to someone who doesn’t have it because through speaking – the sputum – this person could spit and infect you just like that, you catch it. AIDS, on the other hand, that’s a problem of sexual contact. It can be passed through the blood, but tuberculosis is stronger.

It could also be that someone has infected me with TB and I don’t know, but already I’m infecting my family, my husband, my children.

If I had a girlfriend, then I’d infect her, too, unconsciously, through a kiss.

Other factors influencing willingness to purchase and use diagnostics
Along with disease severity, contagion, and prevalence, participants also cited the following factors as reasons they would pay more for certain tests: geographic region, zone, income, and concerns about the type of sample used.

Respondents thought that people living outside Lima or in rural areas would be willing to pay less for diagnostics. One rationale for this was that disease prevalence was lower outside of Lima:

Here in Lima, there’s a large population, and the more people there are, the higher the risk of illnesses. On the other hand, in a small village – Arequipa is pretty small, Iquitos is pretty small – maybe there are fewer chances of being infected from the number of people.

Participants also believed that people in rural areas benefit from “healthier” lifestyles; so they were less likely to prioritize diagnosis:

While it’s cold [in rural areas], the food is natural. For instance, if you make chicken soup there, the animal is naturally fed with grasses, corn, and other natural foods of the countryside. If you come to eat chicken soup in Lima, this chicken is pure hormones: pills and injections. I don’t know, here in a month you have a chicken ready to eat, but in the countryside, no, a chicken is ready to eat in five or six months or a year. That’s the difference…. Nutrition is better and their health is stronger.

People from the countryside take care of themselves better, I believe. Better eating, the environment is a bit cleaner than here in the city. There, people run less risk of getting sick than people who live here in the city.

Focus group participants also explained that in the event they needed a diagnosis, people from the country tend to rely on traditional medicines, while those in urban areas looked down on shamans (curanderos).

Because of their culture, [people outside Lima may be willing to pay less for diagnostic tests]. This is because normally they think that their medicines [are sufficient]…or believe enough in natural medicine remedies that are cheaper. They’ve had these for ages… so they prefer to take these before going to the hospital and buying medicines, since they don’t believe much in doctors.
Peruvian participants also cited the fact that urban populations have better health care infrastructure and tend to earn more money as reasons they would be willing to pay more. These participants also noted that those outside Lima tend to have less education and less information to make informed health choices.

Participants highlighted several barriers to diagnostic testing. Fear of learning that one was infected with a serious illness such as TB or HIV was a commonly mentioned motive for not getting tested:

People say, “I’d just as soon not go to the doctor… if he’s going to tell me I have [a fatal illness], I’d rather die without knowing it” or “Why would I want to know what it is if I’m going to die anyway?”

Not surprisingly, cost is another important barrier: Consumers with limited resources have to make choices about how to prioritize their needs. One participant explained why it can be difficult to convince some parents to spend even a small amount on diagnostics for themselves:

Their hands are tied. They tell me, “If I go to the doctor, let’s suppose the office visit costs 5 soles, but with those 5 soles, I make my lunch.” So I say, “But think about the fact that you’re getting sicker. You can eat now, but tomorrow you won’t be able to eat. One day without eating won’t kill you… get tested, don’t treat yourself, because then you’ll wind up with resistance to [the medicine]. So then they say, “But, no, what am I supposed to do about [feeding] my children?” So for most of them, it’s about lack of money.

Other reasons participants gave for refusing diagnostic tests included: long waiting lines, maltreatment by health workers, discrimination, and embarrassment. Some explained that they preferred going to a private clinic and paying more for a test to avoid the annoyance of long waits at public facilities. Some participants expressed reluctance to get tested for fear that the process itself might cause infection:

They might use a contaminated needle…. You have to buy it in a pharmacy, and sometimes they recycle them, they wrap them up in new packaging and resell them, so you could get infected with a lot of diseases that way, even HIV.

Another aspect of fear relates to the belief that having blood taken for a diagnostic test might leave a person anemic or weak or that their blood might be sold. Though such concerns might seem strange to someone with even a fairly basic understanding of medicine and human physiology, they are fairly common among people with a limited education who do not realize that the body regenerates blood and that the small quantity typically needed for a diagnostic test would have no effect on a patient’s health.

**Desired test characteristics**

Peruvian focus group participants shared more comments on preferred test characteristics than their Beninese and Tanzanian counterparts. As in the other study countries, Peruvian participants listed blood as the first preference for sample type, stating that blood is more “complete” and makes it possible to detect all illnesses:

He prefers a blood sample because it’s more complete, right? Let’s suppose I have some disease “X” and the doctor tells me, we can make a diagnosis with any of the four [blood, sputum, urine, stool], right? But I would want the blood test, mostly because that way I can find out if I have some other disease apart from the one I already know about, right? It’s not that way with urine: Blood is more complete.

My wife was pregnant, so I took her there to get a pregnancy test, and they told me: We have urine tests and blood tests, and the blood tests cost a little more, but they are more effective – the blood test is more effective for everything…. So I chose the blood test. It costs a little more, but it’s more accurate.

However, sample preferences depended on participants’ criteria. The efficacy of a blood sample was one criterion; simplicity and comfort were criteria for others. Urine was cited as the easiest sample to give. Some people disliked giving blood samples because they were afraid of needles. Some noted that blood samples can be painful and an inexperienced technician might “stab” patients several times. Others
claimed that they become faint or their blood pressure drops when they have a blood sample taken. Interestingly, participants seemed to prefer the perceived accuracy of a blood test over a lower cost or less invasive sample type:

[Given the choice between a urine sample and a blood sample, I would choose] blood, because I believe that with blood, I’m giving the doctor [the best way] to detect the illness quickly. It helps the doctor, and that’s good for me, too, right?

Ideal type of sample also depended on symptoms or disease. For TB, participants preferred sputum smear. They also stated that sputum is an easy sample to give, can be done at home or at a health facility, and is neither embarrassing (like a stool sample) nor painful.

CONCLUSIONS AND RECOMMENDATIONS
Findings from our three study countries, Benin, Tanzania and Peru, demonstrate willingness on the part of people suspecting they might have tuberculosis to pay for an improved diagnostic. In addition, they demonstrate that health systems and health providers see such a test as a high priority. This suggests that the potential market for such a test would be substantial. Consumer perceptions related to TB, specific areas of need, and desired test attributes all shed light on the likely characteristics of that market.

Consumer Perceptions Related to TB
Tuberculosis has had a constant presence in high-burden countries, and indeed worldwide, for millennia. Consumer focus group participants in our study were very much aware of its presence and recognized TB as a highly contagious airborne disease that is difficult to avoid in crowded settings. Interviewees saw themselves as more susceptible to TB than to HIV/AIDS because they can do little to protect themselves from infection, particularly if a household member has contracted the disease. For TB – unlike HIV/AIDS – avoiding specific individual behaviors will do little to reduce risk. Those without active disease ostracize those who are ill with TB for fear of falling ill themselves. Those already ill become embarrassed and ashamed because they recognize the danger they pose to others. The resulting stigma discourages many from seeking diagnosis and treatment and stimulates others to seek diagnosis and treatment in secret to avoid embarrassment and isolation.

Respondents were very conscious of TB’s economic impact on a family. In many cases, the person stricken is a bread-winner and unable to work during treatment. Beyond income loss, the family must bear additional costs related to diagnosis and treatment, which often include payments for services and transport even where diagnosis and treatment are free.

On the other hand, there is widespread recognition that TB is curable, even if the treatment is long and arduous. This may be the result of educational campaigns carried out by governments during recent years, stimulated and supported by the Global Fund and others. While most focus group participants viewed diagnosis and treatment as a priority worth paying for, others suggested that for the welfare of the community, any cost barrier should be eliminated.

Present and Future Diagnostic Tests for TB
The benefits and problems related to current diagnostic tests for TB are well documented and the specifics of each type of test are summarized in Table 1 and discussed at length elsewhere. The end result is that “the majority of patients are detected with advanced (smear-positive) disease, after having already transmitted the disease to their close contacts. Smear microscopy is less sensitive in HIV co-infected patients and culture is slow and too difficult to implement in many settings.” Some health providers thought that SSM was beneficial because it interrupts disease transmission and is practical for low resource settings, but others found it inefficient and insufficiently sensitive. One provider summed up the conclusion of many, describing SSM as a robust but cumbersome method whose quality is difficult to assure.
Current diagnostics suffer problems throughout the process, including procurement and distribution of supplies, samples, and results; inadequate training, supervision and quality control; inadequate and/or expensive technology; inaccurate testing, and difficulties of detection in children, PLWHA, and extrapulmonary cases; and defaulting of patients due to slow provision of results and the need for multiple testing.

Many health providers considered an improved and rapid diagnostic test for TB a high priority, especially if it would increase patient access to early diagnosis and reduce the default rate. The ideal test could be performed and analyzed at the primary care level, since transportation costs may impede travel to referral facilities.

Tanzanian health providers felt that diagnostics would be improved if they could eliminate reliance on microscopes, electricity, the cold chain, and multiple specimens. Several stressed that an improved test should be heat stable and have a high predictive value. Providers also mentioned that a rapid test would help to reduce losses to follow-up. Peruvian providers associated the need for new diagnostics with their serious MDR- and XDR-TB problem. They were pleased with the introduction of the MODS and Griess methods, but echoed the concerns of providers in the other countries about the general capabilities of the health system to provide an adequate environment where accurate testing could be applied – even if a new diagnostic test were developed.

Both providers and focus group participants were asked about their preferences for sample types that could be tested as a substitute for sputum. The conclusion of both groups for reasons both medical and anthropological, was blood. There was also a preference that diagnostic tests for children should not be invasive. Thus respondents suggested a finger stick rather than intravenous blood collection.

In summary, both providers and patients see new TB diagnostic tests as a high priority. Ideally, a new test should utilize blood samples; require little or no laboratory equipment or infrastructure; and be rapid, accurate, and inexpensive.

**Willingness to Pay for a New TB Diagnostic Test**

The consumer survey shows unequivocally that most people are willing to pay for a new TB diagnostic: Of all those surveyed, 92% indicated a willingness to pay some amount and named a maximum price. As shown in Table 10, there are differences among the three countries, but 5%-15% of the population are unable or unwilling to pay. This finding is corroborated by many other experiences worldwide. There also seems to be minimal difference between WTP in urban versus rural populations. In all three countries, consumers reported a willingness to pay more for TB than for malaria or ALRI. WTP for TB compared to diagnostics for syphilis, gonorrhea and Chlamydia, and HIV/AIDS varied from country to country, though consumers consistently identified TB as a high priority illness.

<table>
<thead>
<tr>
<th>Country</th>
<th>Total Surveyed</th>
<th>WTP Surveyed</th>
<th>% WTP</th>
<th>Total WTP Urban</th>
<th>WTP Rural</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benin</td>
<td>269</td>
<td>259</td>
<td>96.3%</td>
<td>98.8%</td>
<td>95.2%</td>
</tr>
<tr>
<td>Tanzania</td>
<td>305</td>
<td>271</td>
<td>88.9%</td>
<td>88.7%</td>
<td>85.2%</td>
</tr>
<tr>
<td>Peru</td>
<td>273</td>
<td>249</td>
<td>91.2%</td>
<td>90.2%</td>
<td>92.1%</td>
</tr>
<tr>
<td>Total</td>
<td>847</td>
<td>779</td>
<td>92.0%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The mean price respondents from each country were willing to pay varied considerably (figures are based on currency exchange rates at the time of our survey):

- **Benin**: US $5.57
Tanzania  US $2.12  
Peru    US $9.52

But these numbers themselves don’t reveal very much, because results from each country show a wide
range of maximum prices people were willing to pay (see Table 11). Clearly, any eventual price for a
diagnostic test will depend on the country in which it is used. Note the WTP percentages drop off
significantly between the high and low prices.

Table 11: High and low ranges of maximum willingness to pay

<table>
<thead>
<tr>
<th></th>
<th>Lowest Price Range</th>
<th>% WTP</th>
<th>Highest Price Range</th>
<th>% WTP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benin</td>
<td>&gt;0 - $1.19</td>
<td>86%</td>
<td>&gt;$11.87</td>
<td>4%</td>
</tr>
<tr>
<td>Tanzania</td>
<td>&gt;0 - $0.43</td>
<td>89%</td>
<td>&gt;$4.24</td>
<td>11%</td>
</tr>
<tr>
<td>Peru</td>
<td>&gt;0 - $1.84</td>
<td>90%</td>
<td>&gt;$18.37</td>
<td>10%</td>
</tr>
</tbody>
</table>

Figure 12 shows the percentage of respondents WTP at each price interval. It is interesting to note that
while the actual amounts of each interval varied between countries, the percentage of respondents WTP at
each interval corresponded fairly closely. As the prices increased, the percentage of those WTP
decreased. Thus, for example, at the third interval about 50% would be WTP – and conversely, about
50% could be excluded from services at that price level.

If a price were to be set at the upper limit of the third interval, significantly less
would be charged: Benin = $3.56, Tanzania = $1.28, and
Peru $5.51. Even at these
levels, about half might be
excluded from services. Plus, the administrative costs
involved in exonerating large
numbers of people from full
or partial payment would be
evercessive, create longer
patient waiting times, and could themselves become a barrier to services.

To further facilitate our analysis of each country, we separated the pricing intervals into four segments.
Each of the first three segments correspond to two intervals of increasing prices. The fourth segment
corresponds to the highest five intervals. The figure shows the percentage of respondents WTP at each
price interval. For instance, at the high end of segment A (for example US $2.37 for Benin), 60–70%
would be willing to pay. However, charging that price would also exclude 30–40% of the population
from using the test.

There is a steep regressive dip through segment C, at which level only 15%–20% are WTP; after that
there is little price elasticity through the 9th interval followed by a small portion of the population willing
to pay just about anything. An analysis of the socio-economic characteristics of the respondents in each
segment demonstrated considerable between-country similarity. People in segment D were generally
urban, had a high education, frequently had a university degree, and were usually in top two wealth
quintiles. They were also often clients of private health care services. About half of people in Segment A
were situated in the two lower wealth quintiles, had relatively less education (primary and secondary), and worked as urban or agricultural laborers. They tended to seek health services in the public sector. The other segments tended to be a mix between the two extremes.

WTP was also affected by region. For example, people living in Cotonou, the coastal capital of Benin, were willing to pay significantly more than those in the interior. This makes sense, since Cotonou, though not the political capital, is the urban and economic center of the country. Another factor that can play an important role is health insurance: In Peru, there are various insurance mechanisms, and people enrolled in them were willing to pay more, presumably because their insurance would cover at least part of the cost.

At the top end of the spectrum there is a group of 15%–20% willing to pay significantly more for TB diagnostic tests than the rest. Depending on the country, the maximum amount this group is willing to pay could possibly cover the costs of the test itself: US $16.50 in Peru and US $10.68 in Benin. To the contrary, in countries where the economic situation is more marginal, the maximum this group is willing to pay may still be relatively low, such as Tanzania at about US $3.82.

However, it is important to remember that not all respondents were TB patients, and that TB is primarily a disease of poverty, which translates to small, overcrowded quarters, poor nutrition, poor disease resistance, and marginal disposable income. Thus, we cannot assume that TB patients will be evenly distributed among either wealth quintiles or price segments. More likely, they will be clustered in the lower two segments, with a few cases in the higher segments as well.

A better strategy from a public health point of view would be to charge at the lowest level. This would amount to little more than a co-payment, but would ensure that price is not a barrier to testing, a gateway to services. An indicator of the lack of financial resources for some patients is the improvement of treatment compliance when food supplements and/or the payment of transport costs are provided as an incentive.

Impact of the Structure of TB Services

Many survey respondents were interviewed in for-profit and non-profit private clinics and hospitals and sought most of their health services at those institutions. Together with many focus group participants, they articulated the well-established reasons for preferring private sector services: shorter waiting times, better quality of care, and availability of drugs and other materials. These preferences, however, are largely irrelevant to TB services, except in cases where an NGO or mission hospital is linked to the public system.

In most countries, TB services are almost exclusively found in the public sector for several good reasons. At the secondary and tertiary levels, specialized pulmonary/TB institutions can concentrate scarce personnel and lab resources while limiting contagion. Increasingly, the specialized elements of the public sector system are being expanded through case detection and DOTS practiced at the primary care level, including diagnostic and laboratory services in some places.

TB is curable when the entire standardized process is followed with precision. Despite its drawbacks, a single public sector system is far easier to regulate and supervise than disparate individual providers. As a means of expanding case detection, some countries are beginning to experiment with linkages to private sector institutions. But where they exist, these linkages generally represent a very small percentage of the system. If unregulated, they pose a serious risk for spreading MDR TB when DOTS regimens are not rigidly followed.

More important is the clear preference for a single public system on the part of the international community. Specifically, the Global Drug Facility (GDF) and the Global Fund exert significant influence on the organization and delivery of TB services. GDF buys anti-TB drugs and distributes them to about 70 countries through donations or direct sales; it offers good quality drugs at low prices due to volume
purchasing. Provision of these drugs, however, comes with the condition that they be provided to patients free. GDF also expresses a strong preference against making TB drugs available on the open market to avoid possible abuse by the private sector. Technical assistance teams visit each country annually to assist in preparing drug procurements for the coming year and to use the provision of good quality, inexpensive drugs as a lever to push improvements in national TB programs.

During the last several years, the Global Fund has provided significant support to national TB programs in many countries, specifically to stimulate DOTS, improve laboratories and diagnostics, provide training, and also pay for both first- and second-line drugs, often purchased through GDF. The Global Fund also supports educational campaigns, which have raised awareness of TB and the fact that it is a curable disease, and advised people suspecting they might have TB to come to public sector services where the drugs will be provided free. Thus, in most places, the private sector plays no role in TB: private providers are shut out of service provision for lack of access to drugs and specialized diagnostic services unless they are linked to the public sector’s national TB program. This is unlikely to change for many years.

A provider complaint in all three study countries was the poor quality of the public sector logistics system for drugs and diagnostic tools. Part of the response to this complaint has been to manage national TB programs vertically, with the Global Fund providing vehicles for delivery of drugs and other supplies as well as for supervision. Logistics are such a weak link that some providers expressed doubts that any new diagnostic could improve TB control.

Peruvian doctors mentioned another obstacle: It is unlikely that any innovation would be scaled up immediately without parallel experimentation with existing diagnostic tests. Innovations will always face resistance by the both the medical and the political establishment until both efficacy and cost-effectiveness can be demonstrated locally or in a significant number of similar settings.

The Market for a New TB Diagnostic Test

The international community’s failure to pursue active case detection is another problem in need of a solution. Thus far, we have implied that new TB diagnostic tests would require professional intervention for collection and interpretation, but should an inexpensive, accurate over-the-counter test emerge, such as those for pregnancy, it could revolutionize TB diagnosis and possibly lead to significant reductions in incidence by encouraging early detection through self-testing. Not only would self-testing be a means to overcome the stigma barrier, but tests could be given to all contacts. The market for such a test could easily reach 50 million or more per year into the foreseeable future. While the challenges of creating such a test are formidable, the benefits would be great. Produced in mass, such a test could be very lucrative even at a low price. Self-diagnosis might function as an initial screening test, with positive results triggering a facility-based confirmatory diagnosis prior to treatment.

In terms of facility-based tests, since the public sector is the primary source of TB services, government funding is unlikely to be sufficient even where political commitment is high. This insufficiency includes diagnostic tests and laboratory supplies, which halted in Benin for nine months when the Global Funded curtailed disbursements. This is not atypical. While most potential TB patients would accept a minimal co-payment, it seems unlikely that development, production, and distribution costs for a new test could be covered by patients, the government, or both. On the other hand, the Global Fund might well purchase large quantities of a new cost-effective replacement for SSM or a better diagnostic for non-pulmonary and pediatric TB. The Global Fund would then stimulate utilization and fund training for the new test. In this case, cost-recovery and profit would depend on international funding, with governments and patients contributing some smaller amount. The market for such a test would be tremendous since the high-burden countries include some of the most populous in the world: China, India, Indonesia, Nigeria, the Russian Federation, South Africa, and Brazil. Diagnostic kits could be channeled through GDF, which would give them access to most high-burden countries: India alone accounts for a third of all TB cases worldwide.
Finally, a fourth class of test is sorely needed: a rapid and accurate test for MDR TB. The importance of such a test can hardly be overemphasized. The economic consequences of MDR are staggering: The current GDF price for treating a single smear positive patient is about US $29; the cost of treating one MDR patient can easily be $6,000–$10,000 or more. Five percent of all TB cases are now MDR. Further spread will aggravate the problem and could overwhelm some health systems. Both governments and international organizations would welcome more rapid MDR diagnostics with the potential to reduce MDR incidence. In this case, even a relatively expensive test would be cost-effective and certainly find a market.

Summary

Our study suggests that most people are willing to pay some amount for a new and effective TB diagnostic test. Recovering the costs of development, production, and distribution from individual purchases would require setting prices high enough that they would become a significant barrier. A small co-payment, however, could be charged to defray some of the costs.

TB services are provided almost exclusively through the public sector. NTP funding from governments is typically limited and often cannot cover needed drugs, supplies, or materials for laboratories and diagnostic tests. Some governments could represent direct markets for new and innovative test, but the most likely market in the medium term consists of multilateral donors, with support channeled principally through the Global Fund. In this scenario, introduction of a new test would probably be accompanied by promotion, training, and monitoring. Should an efficacious and cost-effective test become available, it seems certain that it would find a massive market, resulting in benefits from improved case detection and compliance, as well as generating profits for the producer, even if sold at low prices. Additionally, a more sensitive test is needed for detecting extra-pulmonary and pediatric cases. The market would be smaller than that for tests designed to detect active cases, but such a test could also serve as a check on all smear negative patients.

Given the extreme costs involved in treating MDR-TB, there is an urgent need to develop a rapid means of detecting such cases and initiating treatment as soon as possible to reduce the risk of infecting others. In this situation, even a relatively expensive test would be welcomed as cost-effective. Governments and the international community would much prefer to spend money on rapid diagnosis than on large amounts of costly medicines. However, experience with MDR tests in Peru also suggests that governments and the TB community would have to be convinced of the safety and efficacy of any test prior to adopting it. Further, both testing and treatment might require donor support.

Recommendations

1. Producers of diagnostic tests are strongly encouraged to pursue development of innovative tests for TB, as an effective test for initial case detection would be highly attractive to patients, countries, and the international organizations that would serve as the initial market.

2. Such a test should be sensitive, rapid, and inexpensive. Providers and patients in this study suggested that the basis be blood sampling. Other desirable characteristics include no reliance on microscopes, electricity, the cold chain, and multiple specimens.

3. Tests should be developed for mass production, both to have an impact on disease and to provide cost recovery and profit-making opportunities at a low sales price.

4. Producers should be encouraged to develop an inexpensive, over-the-counter TB test, as this could revolutionize the fight against TB by stimulating early detection, side-stepping resistance to testing from stigma, and providing a low-cost means for contact testing, all potentially contributing to a significant reduction in incidence. The market for such a test would be many
times greater than the current market for passive case finding and thus potentially highly profitable.

5. Producers are also encouraged to develop tests to improve the sensitivity of suspected extra-pulmonary and pediatric TB cases.

6. Producers of diagnostic tests for TB should leverage the annual funding for clinical trials offered by the Stop TB Partnership and others.

7. To defray some of the cost of a new diagnostic test, national TB programs could charge a low co-payment. Suspected patients have clearly stated that they are willing to pay for such a test. The price, however, must be adjusted to the characteristics of the country and region so as not to create a barrier to testing.

8. Given our findings that as prices increase from a minimum level, the percentage of people willing to pay drops off rapidly, setting a price above the minimum and then partially or fully exonerating large numbers of persons is not recommended as it would lead to high administrative costs, additional patient waiting time, and an additional barrier to services.
APPENDIX A: HEALTH PROVIDERS AND PROGRAM MANAGERS INTERVIEWED FOR THE DIAGNOSTICS COST ANALYSIS PROJECT

Benin

Dr. Dissou Affolabi, Biologist and Assistant Professor of Microbiology, National Reference Laboratory for Mycobacteria. Cotonou. 8/9/2007 and 3/21/2009.


Dr. Guy Aouanou, Chief of Pediatrics, Hôpital Saint Jean de Dieu. Tanguïeta. 3/16/2009.


Mr. Romain Dahoui, Biotechnologist, Medical Center St. Jean. Cotonou. 8/11/2007.

Dr. Alfred Dansou, Director of Pharmacy and Medications. Cotonou. 8/9/2007.

Dr. Alexandrine L. Dazogbo, Manager of Youth and Adolescent Reproductive Health Program, UNFPA. Cotonou. 3/20/2009.


Dr. Abdel Aziz Fagbemi, Manager of Medical and Reagent Stocks for the National AIDS Control Program. Cotonou. 8/8/2007.


Dr. Fernand Guedou, Director of Health Research. Cotonou. 8/9/2007.


Joseph Essodina Ndayake, Biomedical Analysis Technician and Laboratory Director, Hôpital Saint Jean de Dieu. Tanguïeta. 3/15/2009.

Dr. Elvis Nkounkou, Gynecologist, Centre Nationale Hospitalier Universitaire. Cotonou. 3/19/2009.

Dr. Aguima Tankoano, Director, Health Care Improvement Project. Bohicon. 8/5/2007

**Peru**

Dr. César Bonilla, Director, National Tuberculosis Strategy. Lima. 4/14/2009
Dr. Juan Cornejo del Carpio, Director, Chagas Program, Regional Directorate of Health. Arequipa. 4/1/2009.
Dr. Lenin del Cuadro, Director, Reference Laboratory, Iquitos Directorate of Health. Iquitos. 4/3/2009.
Dr. Fredy Delgado, Director, Reference Laboratory. Arequipa. 4/1/2009.
Dr. Javier Ferreyros, Director, Pediatras Asociados. Lima. 3/31/2009.
Dr. Amalfi Gallegos, Former Laboratory Director, Honorio Delgado Hospital. Arequipa. 4/3/2009.
Dr. Lenka Kolevich, Infectologist, Hospital del Nino. Lima. 4/6/2009.
Dr. Aldo Luchetti, Adjunct Director, IMPACTA/IMENSA. Lima. 8/21/2007.
Dr. Carlos Manrique, Director, Regional Directorate of Health. Iquitos. 4/2/2009.
Dr. Juvenal Mendoza, Gynecologist, Hospital San Jose-Callao. Callao. 4/6/2009.
Captain Alejandro Mercado Noriega, Chief, Department of Infectious Diseases, Naval Hospital. Callao. 3/30/2009.
Dr. David Moore, Cayetano Heredia University. Lima. 8/24/2007 and 3/30/09.
Dr. Victor Nuñez, Pulmonologist, Hospital de la Policia, TB Control Program. Lima. 4/7/2009.
Mary Luz Perea Quispe, Biologist, Reference Laboratory. Arequipa. 4/1/2009.
Dr. Willy Pozo, Pediatrician, Hospital del Nino. Lima. 4/7/2009.
Dr. Cesar Ramal Asayag, Chief of HAART (Highly Active Anti Retroviral Therapy). Iquitos Regional Hospital. Iquitos. 4/2/2009.
Dr. Maria Esther Ramirez, IMPACTA/IMENSA. Lima. 8/21/2007.
Dr. Hugo Rodriguez, Director for Peru, PAMAFRO (Malaria control project, Andean Health Organization). Iquitos. 4/3/2009.


Dr. Angel Rosas Aguirre, PAMAFRO (Malaria control project, Andean Health Organization). Lima. 3/31/2009.

Dr. Zully Ruiz Vargas, Pulmonologist, Maria Auxiliadora Hospital. Lima. 4/8/2009.


Dr. Sixto Sanchez, Director of Epidemiological Investigation, National Institute of Health. Lima. 8/21/2007.

Dr. Pedro Saona Ugarte, Obstetrician/Gynecologist, Cayetano Heredia Hospital and San Felipe Clinic. Lima. 3/31/2009.

Dr. Karina Sebrian, Infectologist, Maria Auxiliadora Hospital. Lima. 4/8/2009.

Dr. Peter Spangenberg, Partner, Pediatras Asociados. Lima. 3/31/2009

Dr. Eduardo Ticona, Principal Investigator/Former Director of National Malaria Control Program, Dos de Mayo Hospital. Lima. 8/18/2007.

Dr. Antonio Tukumoto, Head of Pulmonology and Infectious Diseases, Peruvian Armed Forces Hospital. Lima. 8/24/2007.

Dr. Julio Valdivia. Chief, Department of Medicine and PROCETS, Goyeneche Hospital. Arequipa. 4/2/2009.


Tanzania

Dr. Aziz Abdallah, Pediatric HIV Care and Treatment Officer, Columbia University, ICAP. Dar es Salaam. 4/03/2007.

Dr. Lakha Al Nur, Managing Director, Oyster Bay Pharmacy. Dar es Salaam. n.d.


Mr. V. Barongo, Warehouse Officer, Medical Stores Department. Mwanza. n.d.


Dr. Chonde, TB Laboratory Director, Ministry of Health and Social Welfare. Dar es Salaam. n.d.


Geert Haverkamp, Program Director, PHARMACESS. Dar es Salaam. n.d.


Dr. Innocent, Chief of Tuberculosis Control, Magu District, Ministry of Health and Social Welfare. Magu. n.d.


Dr. Pastory Kahbi, Acting District Medical Officer and Director, Magu District Hospital. Magu. n.d.

Dr. Amos Kahwa, Researcher, National Institute for Medical Research. Dar es Salaam. n.d.


Dr. Paul Kimanzi, Country Director, AMREF. Dar es Salaam. n.d.

Dr. Lameck Kipilyango, Senior Warehouse Officer and Acting Area Manager, Medical Stores Department. Mwanza. n.d.


Mr. M. Lubisi, Receiving/Dispatch Supervisor, Medical Stores Department. Mwanza. n.d.

Dr. Dominique Luboja, Regional Health Officer, Mwanza. 4/23/2007


Dr. Mfungo Marero, Director Care and Treatment, National Malaria Control Program. Dar es Salaam. 4/03/2007.


Dr. Julius Massaga, Director, Center for Excellence in Malaria Interventions. Dar es Salaam. 4/03/2007.

Dr. Peter McElroy, PMI Advisor, U.S. Centers for Disease Control. Dar es Salaam. n.d.


Mr. Kaisi Mnabukula, District Health Administrator, Ministry of Health and Social Welfare. Magu. n.d.
Dr. Fabrizio Molteni, Malaria Technical Advisor to National Malaria Control Program, Research Triangle International. Dar es Salaam. n.d.

Dr. Suzy Mosha, Physician, Vingunguti Clinic. Dar es Salaam. 3/14/2009.

Dr. Mary Moshana, Sexually Transmitted Infections Program Officer, National AIDS Control Program, Dar es Salaam. n.d.

Dr. Godwin Munuo, TB/HIV Specialist, Association of Private Health Facilitates of Tanzania (APHFTA). Dar es Salaam. 4/20/2007.

Dr. Suleiman C. Muttani, Hospital Director, Temeke Municipal Hospital. Dar es Salaam. 4/16/2007.

Dr. Alex Mwita, Program Director, National Malaria Control Program. Dar es Salaam. 4/17/2007.

Jared O. Ndigege, Accountant/Administrator, Association of Private Health Facilitates of Tanzania (APHFTA). Dar es Salaam. 4/20/2007.

Lucy Nderimo, Acting Director, Tanzanian Medical Stores Department. Dar es Salaam. 4/20/2007.


Dr. David Ocheng, Lab Director, African Medical and Research Foundation (AMREF). Dar es Salaam. n.d.

Dr. Samuel Ogillo, Program Manager, Association of Private Health Facilitates of Tanzania (APHFTA). Dar es Salaam. 4/20/2007.


Tim Rosche, Country Director, JSI Deliver. Dar es Salaam. n.d.


Dr. Patrick Swai, Senior Project Management Specialist, HIV, PEPFAR. Dar es Salaam. n.d.


Dr. Joseph Temba, Director, Tanzania Commission for AIDS (TACAIDS). Dar es Salaam. n.d.


APPENDIX B: THE HEALTH BELIEF MODEL
The Health Belief Model (HBM) is a widely-used theoretical model focusing on individuals’ attitudes and beliefs to predict and explain health behaviors. This study adapted the model to illustrate how clients make decisions around diagnostic testing. The follow-up focus group discussions used the modified HBM as a theoretical framework, and the qualitative analysis also draws on HBM constructs.

Figure 1. Adapted Health Belief Model

According to the modified HBM, an individual’s decision to seek diagnostic testing is informed by the following perceptions:

**Perceived Severity**: An individual is unlikely to seek diagnosis or treatment of an illness they don’t perceive as serious.

**Perceived Susceptibility**: An individual is unlikely to seek diagnosis of an illness to which they don’t feel susceptible. For diagnostic testing of an asymptomatic illness, the person must believe that he or she can have the disease without symptoms.

**Perceived Benefits and Barriers**: An individual is more likely to receive testing if they perceive that the benefits of diagnostic testing outweigh the barriers. Note that since the perceived benefits of testing are linked to treatment, a person must perceive an illness as treatable in order to recognize the benefits of testing.

Understanding consumers’ perceptions of illnesses severity, their susceptibility to the illnesses, and the barriers and benefits to getting tested can help explain some aspects of the WTP survey results. An understanding of consumers’ perceptions can also inform the design of health communication messages around the introduction of new diagnostic tests.
REFERENCES


