RAND HEALTH

Estimating the Global Health Impact of Improved Diagnostic Tools for the Developing World

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Diseases such as tuberculosis (TB), malaria, HIV/AIDS, and bacterial pneumonia continue to take a heavy toll worldwide, leading to millions of deaths annually and posing a special burden in developing regions of Africa, Asia, and Latin America. Many factors might help improve health outcomes in resource-poor countries, including better nutrition, public health programs, and improved access to clinical care, including diagnostics and treatment.

Access to appropriate diagnostic tools is an essential but often less-emphasized component in the evaluation and improvement of global health. Diagnostics are critical for identifying the presence and cause of disease and for determining an appropriate course of treatment. Accurate diagnostics can help eliminate wasted treatments and target therapy to those who need it, while easy-to-use tools providing a rapid diagnosis can allow therapy to start sooner. However, many currently available diagnostic tools are not effective in developing countries, often because they are too complicated or too expensive to use.

Recent RAND Corporation research, sponsored by the Bill & Melinda Gates Foundation, sought to assess how higher-quality and more-accessible clinical diagnostic tests could improve health outcomes in the developing world for a number of common diseases, including bacterial pneumonia, TB, malaria, and sexually transmitted diseases. The research shows that new diagnostics have the potential to save millions of lives annually, especially if the diagnostics are easy to use and widely accessible in the developing world.

Key findings:

- **New diagnostic tools for tuberculosis, malaria, HIV/AIDS, bacterial pneumonia, and other diseases have the potential to save millions of lives annually in the developing world.**
- **To achieve maximum benefits, tests should be easy to use and widely accessible, i.e., capable of being performed without clean water, electricity, or trained staff. Test results should be available within two hours or less.**
- **Access to treatment is critical to achieving the benefits of a new diagnostic.**
- **Much of the benefit of new diagnostics would result from reducing overtreatment with antibiotics.**

The Need for New Diagnostics Is Great

RAND worked with the Gates Foundation to create a global diagnostics forum, which brought together experts in relevant diseases, representatives from the diagnostics industry, and experts in modeling the potential effects of new diagnostic tools. RAND worked with forum members to identify diseases likely to benefit from new diagnostics, including the following:

- *Bacterial pneumonia*, which remains the primary cause of death among children under five years old in developing countries
- *Antenatal syphilis*, which is a significant cause of adverse pregnancy outcomes, including stillbirth, among women in the developing world
- *Malaria*, which accounts for more than 1 million deaths annually among children under five years old in sub-Saharan Africa
- *TB*, which is a leading cause of disease and death worldwide, with approximately 2 billion people infected and 2 million deaths annually.

The high incidence of deaths from these diseases is due in part to the shortcomings of existing diagnostic methods. Most high-performing

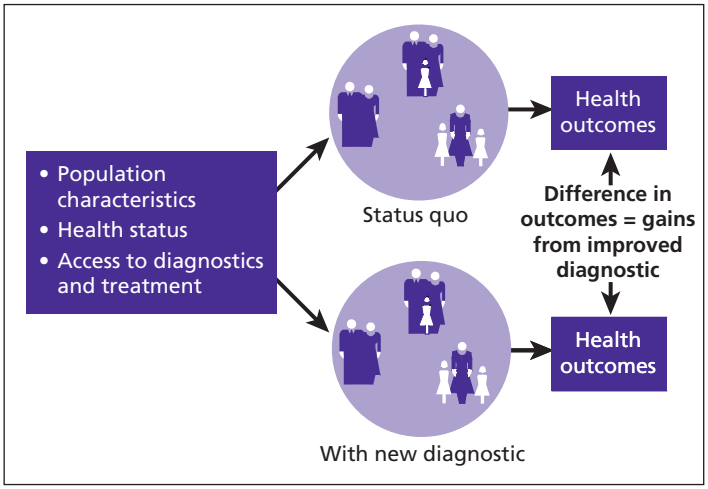
diagnostic tools were developed for use in industrialized countries and, thus, are typically too expensive and overly complex for use in the developing world. For example, many existing tests require relatively sophisticated infrastructure support, including electricity and well-equipped laboratories, and must be performed by highly trained staff. Moreover, many existing diagnostic tools require patients to return to a clinic a day or two later to get test results, which is not possible for many poor people.

As a result of the lack of accurate diagnostic tools that can be used effectively in the developing world, many diseases are currently diagnosed, at best, using clinical methods alone. For example, health care providers are trained to look for symptoms of disease, such as, in the case of bacterial pneumonia, elevated respiratory rate and inward movement of the chest wall in breathing. The results from such approaches can be difficult to interpret, and, as a result, some patients do not get needed treatment, while others are treated unnecessarily. Overuse of antibiotics has led to an increase of antibiotic resistance—and an increase in associated deaths—in many developing countries.

RAND Modeled the Benefits of New Diagnostics

To understand the potential effects of new diagnostics, RAND developed a model to estimate the global health benefits of new diagnostics and to determine what the tests would need to look like to achieve these benefits—both in terms of how accurate the tests need to be and in terms of the level of infrastructure required to perform the tests. As illustrated in Figure 1, each disease model compared health outcomes in today's world with those possible in the world with a new diagnostic. The difference in health outcomes between the two worlds represents the gains achieved from the new diagnostic.

Figure 1
Model for Evaluating the Benefits of New Diagnostics



In the model, access to the new diagnostic depends on the level of infrastructure required. Tests requiring *advanced and/or moderate infrastructure* would require access to a hospital or urban clinic and associated infrastructure, including electricity, clean water, well-equipped laboratories, and trained clinicians. In contrast, tests requiring *minimal infrastructure* could be performed in a rural clinic without electricity or water by staff with minimal training. Tests requiring *no infrastructure* could be performed in the home or village and would require no expertise to use (e.g., a candy-coated slip of paper that could be put in a coughing child's mouth to determine whether he or she has TB, pneumonia, or malaria).

A Significant Benefit Is Possible from New Diagnostics

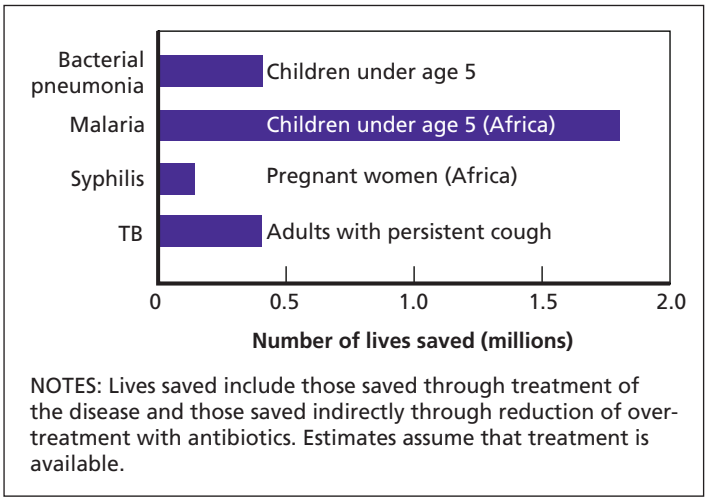
Some examples of the significant health benefits that the research found possible with new diagnostics are shown in Figure 2:

- A quick, easy-to-use test for bacterial pneumonia could save at least 405,000 children's lives each year.
- A widely accessible, easy-to-use diagnostic for antenatal syphilis would save at least 138,000 lives and avert more than 148,000 stillbirths annually.
- A rapid, easy-to-use test for TB could save approximately 400,000 lives per year.
- A test for malaria that requires no laboratory infrastructure could save nearly 300,000 lives and avoid almost 450 million unnecessary treatments (resulting in more than 1 million additional lives saved) annually.

To Achieve Maximum Benefits, Tests Should Not Require Clean Water, Electricity, or Trained Staff

While improving the *accuracy* of diagnostics over current levels is important, the analysis found that it is even more impor-

Figure 2
Lives Saved from the Introduction of New Recommended Diagnostics



NOTES: Lives saved include those saved through treatment of the disease and those saved indirectly through reduction of over-treatment with antibiotics. Estimates assume that treatment is available.

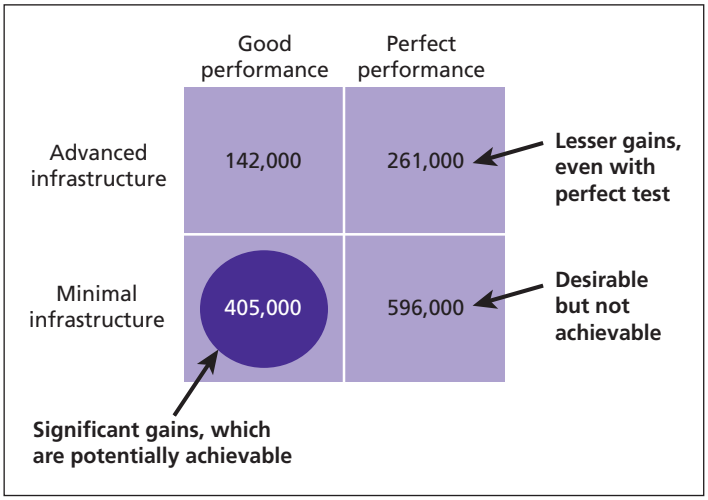
tant to improve *access* to new diagnostics by developing tests that can be performed with little or no infrastructure support (e.g., clean water, electricity, laboratory facilities, trained staff). As shown in the table, access to advanced infrastructure is extremely limited in certain parts of the developing world, especially Africa. For example, a test requiring advanced infrastructure would be available to only 28 percent of the population in Africa, while a test requiring only minimal infrastructural support would extend access to 75 percent of the population.

An example of the benefits of improved access is shown in Figure 3, which displays the number of lives saved from a new diagnostic for bacterial pneumonia under four different scenarios. The bottom right quadrant shows the results for a "perfect" test—i.e., one that is both high performing and widely accessible. While the results produced by such a test (596,000 lives saved) are clearly desirable, they are not achievable, given the infrastructure support required for such high-performing tests. Of greater interest is the comparison of the results shown, respectively, in the upper right quadrant and the lower left quadrant. The test requiring advanced infrastructure saves a relatively low number of lives (261,000)—even with perfectly accurate performance—compared with the test requiring only minimal infrastructure (405,000), even though the latter has less than perfect performance.

Percentage Access to Health Care Infrastructure

Region	Access to advanced infrastructure	Access to at least minimal infrastructure
Africa	28	75
Asia	58	87
Latin America	90	95

Figure 3
Comparison of Lives Saved by a New Diagnostic for Bacterial Pneumonia



Similar results were found for other disease models. In fact, the research found that, for some diseases, such as malaria, currently existing tests perform well enough to produce significant benefits, as long as access to these tests can be extended though investments in training and capacity building and the development of good logistical supply chains.

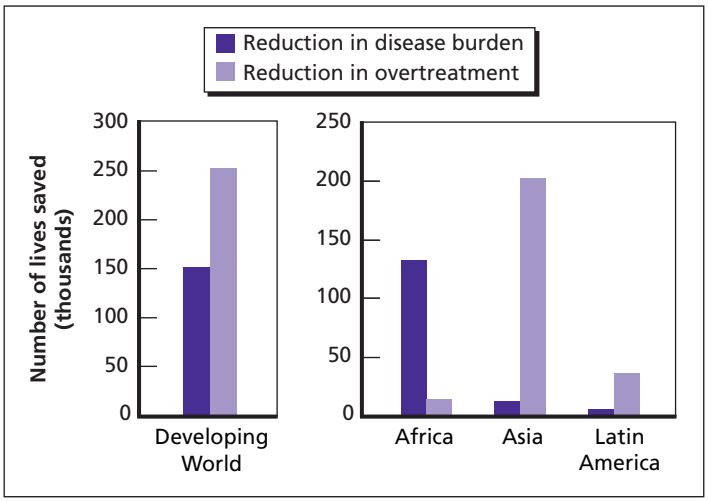
It should be noted that access to treatment, which is assumed in most of the disease models, is also critical to achieving the benefits of a new diagnostic. Test results should also be available quickly, generally within two hours or less.

Much of the Benefit of a New Diagnostic Would Result from Reductions in Overtreatment

The research also found that much of the benefit of new diagnostics would be due to reducing overtreatment with antibiotics. Current tests are typically better at identifying people with disease than eliminating those without. In other words, many tests result in a number of *false positives*, i.e., inaccurate diagnoses of people who appear to have the disease being tested for, but whose symptoms are actually due to another, undiagnosed, condition. By providing a more accurate indication that an individual does not have a particular disease, a new diagnostic could significantly reduce the harm associated with the overuse of antibiotics.

An example is shown in Figure 4, which indicates that approximately 250,000 of the 405,000 lives that could be saved with a new diagnostic for bacterial pneumonia would be the result of reductions in overtreatment. The right side of the figure indicates that the relative benefits of new diagnostics would differ by region. Most of the benefit of reducing the disease burden would occur in Africa, where access to tests and antibiotic treatments for bacterial pneumonia is currently limited. In contrast, most of the benefit from reducing over-

Figure 4
Relative Benefits of a New Diagnostic for Bacterial Pneumonia



treatment would occur in Latin America and especially Asia, where overuse of antibiotics is a significant problem.

Similar results were found for many other diseases, most notably in the case of malaria, for which a new, widely available diagnostic would avert as many as 450 million unnecessary treatments per year.

It should be noted that reducing the overuse of antibiotics will involve overcoming cultural barriers, in addition to developing new technological solutions. In many parts of the developing world, the results of diagnostic tests are not easily accepted, especially if a test indicates that a child does *not* have a particular condition and if the test provides no clear direction for treatment of another illness. Thus, when new, more accurate diagnostics are introduced, it will be crucial to ensure that health care and pharmacy workers are trained not only to use the diagnostics but also to educate patients and caregivers about the benefits of the new tools. Training in differential diagnoses will also be crucial, so that, if one disease is determined not have caused a patient's symptoms, the disease causing the condition can be accurately identified.

The Way Forward

The results of this study clearly indicate the significant global health benefits of new diagnostic tools for the developing world. As the analyses show, the right tools could save millions of lives if they are made widely accessible and if appropriate treatments are available.

These findings should encourage policymakers, scientists, technology developers, investors, and diagnostic companies to work together to accelerate the development and delivery of new diagnostic solutions. A coordinated approach is needed so that appropriate diagnostics can achieve the promised impact. ■

This Highlight summarizes RAND Health research reported in the following publications:

Determining the Global Health Impact of Improved Diagnostic Technologies for the Developing World, London, U.K.: Nature Publishing Group, supplement, December 2006. As of October 10, 2007:
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"The Right Tools Can Save Lives," *Nature*, commentary, Vol. 444 (7120), December 7, 2006, p. 681.

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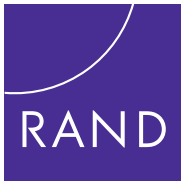

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