New Dots A Novel System for Increasing Compliance to TB Treatment

Team Members*:

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Background:

One-third of the world carries tuberculosis (TB), and of those 14.6 million have an active case. These numbers are both shocking and tragic because there is a technical solution to the tuberculosis problem – a cure for the disease. However, because the treatment is long and complicated, involving a six-month, multiple-drug regimen and uncomfortable side effects, it is often avoided or forgotten by patients in developing countries. The result is that in most developing settings only 15% percent of patients who begin treatment will finish it unless they are closely monitored. These failures mean that incidence of TB is on the rise, and drug-resistant strains are, worryingly, becoming more prevalent.

The best solution to have yet been found for this problem is the Directly Observed Therapy, Short-course (DOTS) system. This system achieves high rates of treatment adherence (around 85%) because healthcare workers observe patients take their drugs every day. Although effective, DOTS is extremely expensive – between \$70 and \$150 per patient – and human resource intensive. The high costs and deficit of trained health workers mean that the most rural and poor areas have low rates of DOTS penetration, with little hope that DOTS can feasibly be extended to those areas.

Project Summary:

Our solution, New Dots, is a combination of customized incentives with a novel remotemonitoring program that both encourages and facilitates enforcement of compliance. The remote monitoring program consists of urinalysis test strips that detect whether patients have taken one of the most commonly used TB drugs. A positive result will reveal numerical codes on the test strips (much like pregnancy tests). These codes can then be reported to a central database by cellular phone (or another mechanism, depending on the regional context).

New Dots helps monitor TB patients in disadvantaged areas where the lack of infrastructure, expense, or population density makes DOTS extremely difficult to implement. Furthermore, our system has the potential to be more effective at reduced cost - under 45 dollars per patient – and is thus an attractive alternative for organizations currently using DOTS.

We are presently conducting a pilot study in Nicaragua in partnership with CIES (Centro de Investigaciones y Estudios de la Salud), the research arm of Nicaragua's Ministry of Health, which is responsible for the oversight and evaluation of DOTS in that country. With their

assistance, we will be testing the feasibility of both our urinalysis test strips and reporting/monitoring system over the course of six months (September 2007 – February 2008).

While DOTS is widely available in most urban areas in Nicaragua, penetration remains low in rural areas, making it an ideal country for testing the New Dots system by comparing it against the "old" DOTS. By receiving feedback from patients and health care workers on our system's ease of use, efficacy, etc., we hope to develop our product to the point where it can be easily implemented for TB patients around the world.

Furthermore, an NGO in Bihar, India and a clinic in Karachi, Pakistan have expressed interest in conducting studies using the New Dots monitoring system early next year. We currently have team members working in Indonesia and Tanzania, and they are also investigating the possibility of additional trials at their respective sites.

Development of our monitoring system alone will give health workers a powerful tool for remotely assessing patient drug compliance. Coupled with incentives, New Dots could provide complete supervision of a patient's drug regime remotely, increasing compliance with TB treatment while simultaneously decreasing the cost of treatment monitoring. In the end this means fewer people dying preventable deaths, reduced morbidity and the economic and social hardships that accompany disease, and greater empowerment of health agencies to tackle other challenging problems.

All of the members of the New Dots team remain committed to developing the New Dots system in the coming months and years.

Past Work & Future Steps

- Dec. 2006: Team members first met.
- Jan. 2007: Submitted preliminary proposal for feedback from IDEAS team.
- Feb. 2007: Began designing experiments to manufacture prototype of strip. Began working out business plan. Acquired lab space.
- Mar. 2007: Submitted development grant for lab equipment and chemicals.
- Apr. 2007: Successfully made prototype test strip. Received Institutional Review Board (IRB) approval for working with urine samples of TB patients.
- Summer 2007: Optimization of product. Latest version of test strip has "hidden" codes appear more quickly & clearly; we are continuing to work on this. Also working on decreasing strip production times and design of accessory equipment (a device to hold the strip for sample taking, etc).
- Sept. 2007-Feb. 2008: Conducting a two-month feasibility study and a six-month efficacy study in Nicaragua.

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Your support is propelling our project forward and it is exciting and compelling to see this work through. Thank you also for your leadership in organizing the MIT IDEAS Competition's "TB Challenge," which was the ultimate spark for efforts such as this, and which will hopefully not only bear fruit in products and schemes for battling TB, but also lay seeds for new ideas and projects to address many more challenges in this world.

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