GLOBAL HEALTH

Innovation Insight Series

Photo courtesy of DRW

DRW's chlamydia rapid test

DIAGNOSTICS FOR THE REAL WORLD II: Raising Funds for a Niche Solution

CAMBRIDGE, ENGLAND AND SUNNYVALE, CALIFORNIA

ESTABLISHED 2002

HELEN LEE, FOUNDER

THE PROBLEM/SOLUTION SPACE

Globally, *chlamydia trachomatis* infections are the most prevalent sexually transmitted bacterial disease.[1] When diagnosed promptly, chlamydia can be cured with a single dose of antibiotics.[2] However, because up to 75 percent of women and 50 percent of affected men are asymptomatic, millions of cases go undetected, and unintentional transmission is routine. While men rarely suffer long-term health problems from chlamydia, the infection can cause devastating complications for women. Up to 40 percent of women with untreated chlamydia will develop pelvic inflammatory disease (PID), which has long-

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term consequences including infertility, life-threatening ectopic pregnancy, chronic pelvic pain, and an increased risk of contracting HIV. Additionally, pregnant women can pass the infection to their infants, resulting in neonatal opthalmia (eye disease) and pneumonia.[3,4]

Efforts to control chlamydia traditionally rely on opportunistic testing, as well as targeted screening in high-risk groups. In developed countries, nucleic acid amplification tests (NAATs) are the gold standard for diagnosing the disease. However, because these tests are expensive and technically complex, they are not widely available in resource-limited settings. Another drawback to NAATs is the delay between testing and diagnosis, resulting from the time required to transport samples to a lab and then return a result.[5] Point-of-care tests for chlamydia, which allow for testing and treatment in a single visit, have been developed, but they lack sensitivity and can be unreliable.[6]

Photo courtesy of DRW

Health workers administer the CRT as part of a field trial in the Philippines

ABOUT DIAGNOSTICS FOR THE REAL WORLD

With a desire to help address the unmet diagnostic needs of patients in developing countries, Dr. Helen Lee raised R&D funding from the World Health Organization, the U.S. National Institutes of Health (NIH), and the Wellcome Trust to co-found the Diagnostics Development Unit at the University of Cambridge. She also started Diagnostics for the Real World (DRW), a spinout company, to manufacture and commercialize the technologies created at the university. DRW has locations in Sunnyvale, California and in Cambridge, England.

DRW's first product was a reliable, low-cost Chlamydia Rapid Test (CRT). Delivering results in less than half an hour, the CRT allowed providers to utilize a "test and treat" strategy. It was also easy to use, did not require skilled technicians or laboratory processing, and provided stable and robust results even in high heat and humidity. In combination with its affordability, the test's attributes would enable healthcare providers to screen and treat large numbers of patients, including high-risk groups and hard-to-reach populations that were typically accessed in the field. Lee believed that these characteristics made the CRT well suited to addressing the needs of patients and providers in developing countries.

ONE CHALLENGE: RAISING FUNDS FOR A NICHE SOLUTION

As Lee and her team worked on the product, they discovered that although chlamydia was a significant global health concern, it was not necessarily a top priority for the international nongovernmental organizations and health authorities that might provide funding or become the early, high-volume customers of the CRT. Moreover, without

such organizations raising awareness or advocating for expanded chlamydia screening, there was no ready-made market or large-scale demand for the CRT in developing countries. DRW would have to undertake the daunting and expensive proposition of creating the market for a test that was considered something of a niche solution.

To raise the money necessary to tackle this challenge, DRW needed a funding strategy that would support its focus on reaching patients and healthcare providers in developing countries. Lee did plan to sell the test at market price in developed countries like the United States and Europe in order to subsidize nearly at-cost sales in resource-poor settings.[7] However, she was adamant that first-world sales should not be the organization's primary focus. "We did this principally to meet the needs of the developing world," she reiterated.[8]

As a result of this focus, venture capital, which was a traditional funding source for start-up companies, was not a viable option for DRW. While VC firms might have been interested in the CRT as a point-of-care diagnostic for the developed world, Lee knew that they would not be enthusiastic about a company with a fragmented product line, a hard to penetrate target market, and limited profit potential to justify an investment. "VC companies are not interested in products for the developing world," she said. "By definition, you are working for a market that has no money."

Photo courtesy of DRW

The CRT was designed to deliver fast, accurate results in small clinics with limited resources

Although DRW had been approached by venture capital firms, the company did not pursue the overtures. "Meeting their needs for return on investment would have killed the company," Lee explained. Because venture funds focus on financial, not social impact, they would have required faster timelines than DRW could deliver given the technical complexity of its product. Moreover, Lee's definition of success involved deliberately limiting profits. "The founders voluntarily agreed to cap our profits at 15 percent," she said. DRW's goal was to make just enough of a return to become self-sustaining. Again, this philosophy was out of alignment with the traditional requirements of VC firms. With venture capital off the table as a source of financing, Lee and her team had to devise an alternate funding approach.

THE SOLUTION: DEVELOPING A BLENDED FINANCIAL STRATEGY

Lee found a solution in a diversified funding strategy that significantly broadened her access to grant and foundation funding. DRW had been set up as a for-profit entity in the U.S., with a wholly-owned for-profit subsidiary in England. In addition, Lee still had her nonprofit academic unit at the University of Cambridge. In part by design and in part simply by luck, each of the three different entities was able to access different funding streams.

In the U.S., DRW applied for funding from the NIH and the Small Business Innovation Research (SBIR) program. The SBIR program gives grants for domestic small businesses to engage in research and development opportunities for technologies with the potential for commercialization. "The SBIR funding stream is one of the best things for biotech start-ups in the U.S., which many of our counterparts in Europe look at with envy" Lee enthused. "In phase I, if you have a good idea, you can literally get funding from a garage. We did it from a one-room biotech incubation space." DRW also successfully applied for SBIR funds for its phase II efforts, and subsequently for clinical trials.

Meanwhile, the other two entities pursued different sources of funding. DRW's UK subsidiary applied for grants from the Technology Strategy Board, a public body that promotes, supports, and invests in technology research, development, and commercialization. The Diagnostics Development Unit at Cambridge was able to expand its nonprofit funding by applying for different types of grants from various foundations. "By having multiple sources of funding through multiple organizations, but all working towards one goal, we have managed to raise the funds we need," Lee said. "Essentially, the academic unit got research and development money, and DRW got money for product development and clinical trials." In all, Lee had raised roughly $65 million. DRW's capital structure was in all common shares, with the founders and scientists holding the majority of the stock, which allowed DRW maintain close control of its social mission. Over time, the funding streams for the different entities began to run together. "As we became more successful, some of our funders such as the Wellcome Trust and the NIH have been willing to give money to both the academic group and to the company, DRW," Lee said.

By having multiple sources of funding through multiple organizations, but all working towards one goal, I think we have succeeded.

Lee admitted that managing this mélange of funding sources was not without its challenges. Because the relative dollar amount of each individual grant was not always substantial, the organization had to apply for funding repeatedly. More problematic was the team's lack of control over when the funds were received. With the timing of application deadlines, decisions, and awards completely in the hands of the funders, there was no direct link to the cash flow needs of the organization. As a result, "[The funds] sort of show up at the time they show up," Lee said, which limited the organization's ability to optimize its plans.

As noted, a fundamental part of Lee's financial strategy for DRW was to eventually achieve sustainability. "We don't always want to be dependent on grants," she said. "If we are worth anything, we should be able to stand on our own feet from a commercial product sales point of view." Despite this objective, Lee was unwavering when it came to keeping the price of the CRT low for users in resource-limited settings. "DRW is a for-profit company, but not only for profit," she said.

"I think if we hadn't been very successful getting grant money and foundation funding, our company would not have survived," Lee concluded. Looking back, she speculated that instead of focusing on chlamydia, she should have started with a diagnostic test such as for HIV, where there was existing market demand and funding already in place. "I've learned

that it's not really about the need. It's all about the demand, which means following the money. Because, without funding, there are few options." She continued, "I've learned that you have to really identify the funding realistically and thoroughly. Otherwise a good idea and a lot of enthusiasm and idealism will not get you anywhere concrete."

NOTES

1 "Initiative for Vaccine Research (IVR) Sexually Transmitted Diseases," World Health Organization, 2012, http://www.who.int/vaccine_research/diseases/soa_std/en/index1.html (June 26, 2012).

2 J. Paavonen, W. Eggert-Kruse, "Chlamydia Trachomatis: Impact on Human Reproduction," Human Reproduction Update, 1999, Vol. 5, No.5 pp. 433-447, http://humupd.oxfordjournals.org/content/5/5/433.full.pdf (June 28, 2012).

3 "Pelvic Inflammatory Disease (PID) ---CDC Fact Sheet," September 28, 2011, http://www.cdc.gov/std/pid/stdfact-pid.htm (July 5, 2012).

4 "Initiative for Vaccine Research (IVR) Sexually Transmitted Diseases," op. cit.

5 L. Mahilum-Tapay, V. Laitila, J. Wawrzyniak, et al., "New Point of Care Chlamydia Rapid Test – Bridging the Gap Between Diagnosis and Treatment; Performance Evaluation Study," BMJ, December 8, 2007, 335(7631), pp. 1190-1194, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2128659/?tool=pubmed (June 29, 2012).

6 Ibid.

7 "Improved Disease Tests for the Developing World" [Audio Interview], Stanford Social Innovations Conversations, http://sic.conversationsnetwork.org/shows/detail3477.html (June 29, 2012).

8 All quotations are from an interview with Dr. Helen Lee conducted by the authors, unless otherwise cited.

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