Treating and Eliminating Neglected Tropical Diseases:

A Diverse Approach Modeled by Soil-Transmitted Helminth Initiatives

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Introduction

The World Health Organization defines neglected tropical diseases (NTDs) as those that "persist exclusively in the poorest and most marginalized communities, and have been largely eliminated elsewhere and thus are often forgotten."[1] They estimate that over one billion people are affected by at least one of the 17 diseases currently classified as NTDs, accounting for approximately 534 thousand deaths per year.[2] These diseases thrive in impoverished areas, which lack sanitation, adequate housing, access to clean water, and available health care. The presence of these diseases is also poverty promoting due to impaired childhood development and reduced worker productivity.[3] Most of those affected live on less than $1.25 per day.[4]

Soil-transmitted helminths (STHs), a group of NTDs commonly known as intestinal worms, are parasites that serve as major contributors to morbidity, or disease incidence, in developing countries.[5] More than 2 billion people worldwide are affected by STHs, with infections caused by the consumption of contaminated substances or by the penetration of the skin by larvae in the soil.[6] The World Health Organization uses the metric disability-adjusted

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[1] "Ten Facts on Neglected Tropical Diseases." World Health Organization. Accessed at <http://www.who.int/features/factfiles/neglected_tropical_diseases/ntd_facts/en/index.html> on 10 Jan 2011.
[2] Kealey, Alison and Robert Smith. "Neglected Tropical Diseases: Infection, Modeling, and Control." Journal of Health Care for the Poor and Underserved 21.1 (2010): 53.
[3] Kealey and Smith, 56.
[4] "About NTDS." Global Network for Neglected Tropical Diseases. Accessed at <http://globalnetwork.org/about-ntds> 10 Jan 2011.
[5] Wani, Showkat, Fayaz Ahmad, Showkat Zargar, Ayesha Amin, Zubair Dar, and Pervaiz Dar. "Intestinal helminthiasis in children of Gurez valley of Jammu and Kashmir State, India." Journal of Global Infectious Diseases 2.2 (2010): 91.
[6] "World Health Organization and partners unveil new coordinated approach to treat millions suffering from neglected tropical diseases." World Health Organization. Accessed at < http://www.who.int/mediacentre/news/releases/2006/pr60/en/index1.html> on 24 Jan 2011.

life years to measure the burden of disease in years lost of healthy life.[7] STHs cost 39 million disability adjusted life years annually worldwide[8] due to growth retardation, impaired cognitive development and nutritional deficits resulting from infection.[9] While STHs do not cause high mortality, the high morbidity rates and the resulting reductions in quality of life of those infected are significant. The disease burden of STHs necessitates a global focus on effective methods of treatment and prevention. The following sections of this paper discuss two successful strategies in addressing the global challenge of STH infections with social entrepreneurship: reorganization and innovation.

Reorganization of Existing Networks and Resources

Southeast Asia has a high burden of STHs. Prevalence in school age children in the Philippines was demonstrated to be over 50%,[10] while a study in the Gurze Valley of Jammu and Kashmir States of India indicated that close to 75% of school aged children are infected with intestinal helminthes.[11] Deworming treatments and reducing the incidence of STHs in the impoverished areas of Southeast Asia are essential for achieving the lower poverty levels, higher

[7] "Health statistics and health information systems." World Health Organization. Accessed at <http://www.who.int/healthinfo/global_burden_disease/metrics_daly/en/> on 24 Jan 2011.
[8] "Soil-Transmitted Helminth Infection Fact Sheet." Institute for OneWorld Health. Accessed at <http://www.oneworldhealth.org/img/pdfdownloads/STH %20Fact%20Sheet.pdf> on 10 Jan 2011.
[9] Wani et al.
[10] Belizario, Vincente Y. Jr., Winifreda U. de Leon, Yvonne F. Lumampao, Marilyn Benedith M. Anastacio, and Cyndi Mae C. Tai. "Sentinel Surveillance of Soil-Transmitted Helminthiasis in Slected Local Government Units in the Philippines." Asia Pacific Journal of Public Health 21 (2009): 28.
[11] Wani et al.

education rates, and reduced clinical burden for HIV/AIDS and malaria strived for in the Millennium Development Goals.[12]

Current control strategies include some improvements of social determinants such as education, sanitation, clean water systems, but mostly rely on mass drug administration. The WHO established a target of treating 75% of all school-age children at risk of morbidity for shistosomiasis and STHs by 2010. Despite the low cost of treatment—standard drugs costing less than $0.05 per course—many countries in Southeast Asia, like in other regions of the world, have not mobilized resources and institutions to achieve this target.[13] WHO data showed that in 2009, Bangladesh, India, Indonesia, and Thailand all had national coverage of treatment for school-age children below 25%, with coverage in Thailand lower than 1%.[14]

However, Cambodia is an example of success, demonstrating treatment strategies worthy of scaling up. In 2004, more than 70% of children in Cambodia were infected with STHs, yet by 2009, 100% of schoolchildren were receiving regular treatments for STH infections.[15] Cambodia organizes this mass drug administration through a school-based deworming program. Focus is placed on treating children because studies have shown that with proper and early treatment paired with effective teaching strategies, children have the potential to recover the significant

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[12] "The evidence is in: deworming helps meet the Millennium Development Goals." World Health Organization. Accessed at < http://whqlibdoc.who.int/hq/2005/WHO_CDS_CPE_PVC_2005.12.pdf> on 10 Jan 2011.

[13] Department of Control of Neglected Tropical Diseases. "Neglected Tropical Diseases." World Health Organization. 2006. Accessed at <whqlibdoc.who.int/hq/2006/WHO_CDS_NTD_2006.2_eng.pdf> on 10 Jan 2011.

[14] "Soil-transmitted helminthiasis: Countries x indicators." World Health Organization. 2003-9. Accessed at <http://www.who.int/neglected_diseases/preventive_chemotherapy/sth/db/index.html?units=minimal&region=SEAR&country=all&countries=all&year=all> on 24 Jan 2011.

[15] Department of Control of Neglected Tropical Diseases. "Neglected Tropical Diseases." World Health Organization." 2009. Accessed at <whqlibdoc.who.int/publications/2009/9789241598705_eng.pdf> on 10 Jan 2011. p22.

loss of intellectual development due to the growth-impairing effects of STHs. Additionally, the treatment of children produces a positive externality by reducing community transmission.[16]

To implement this plan, the Cambodian government organized periodic trainings for health staff to deliver education kits and treatment medicines to schools biannually.[17] Additionally, the National Malaria Centre orchestrated a network of provincial health departments, nongovernmental organizations, and other parties interested in contributing resources to the deworming program.[18] The strength of Cambodia's program is derived from a strong government commitment and organization. By centralizing efforts and support groups the program is able to efficiently collect a significant amount of resources. Furthermore, by utilizing an existing institution, the primary school system, the program requires little new infrastructure and can rely on a sustainable mechanism for the medicine delivery. A key factor in the success of Cambodia's treatment program is the reduction of transaction costs and the ease of implementation.

The Global Network for Neglected Tropical Diseases has focused on the delivery of essential medicines also by lowering the barriers of cost and coordination.[19] The Global Network formulated a rapid-impact package that treats the seven most common NTDs (including STHs)

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[16] Brooker, Simon, Archie CA Clements, Don AP Bundy. "Global epidemiology, ecology and control of soil-transmitted helminth infections." Advances in Parasitology 62 (2006).
[17] Western Pacific Regional Office. "Review on the Epidemiological Profile of Helminthiases and their Control in the Western Pacific Region, 1997-2008." World Health Organization. 29 April 2008. Accessed at < http://www.wpro.who.int/internet/resources.ashx/MVP/Helminths+10+Year+Review+_reformatted+v2_.pdf> on 25 Jan 2011.
[18] Urbani, C., et al. " Control of Soil-Transmitted Helminth Infections in Schoolchildren in Cambodia: Implications for an Integrated Approach." Controlling Disease due to Helminth Infections. Ed. D. W. T. Crompton, et al. Geneva: World Health Organization, 2003. 201-209. Accessed at < http://www.who.int/wormcontrol/documents/en/Controlling%20Helminths.pdf> on 24 Jan 2011.
[19] "Treatment Tools." Global Network for Neglected Tropical Diseases. Accessed at <http://globalnetwork.org/what-we-do/treatment-tools> on 10 Jan 2011.

with a package of four drugs, costing only $0.50 per person per year. Working with the pharmaceutical industry, they have received the largest drug donations in history, summing to a value of greater than $1 billion, from major companies such as Merck & Co., GlaxoSmithKline, Pfizer, and Johnson & Johnson. Acting as a middleman between philanthropic pharmaceutical companies and countries in need, and combining multiple essential medicines into one package reduces the organizational costs for treatment programs. This leads to more effective and efficient programs similar to the one in Cambodia. Furthermore, The Global Network has entered into long-term partnerships with the pharmaceutical industry, promoting sustainability of programs and reduced costs.

The effectiveness of this type of initiative has been demonstrated by the accomplishments of the Carter Center. Coordinating the donations and distribution of medications, the Carter Center has achieved success with a program similar to that of The Global Network aimed at treating and eliminating onchoceriasis, or river blindness, in the Americas.[20] 2007 marked a great triumph for this initiative, the Onchocerciasis Elimination Program of the Americas (OEPA), when Colombia became the first country in the world to stop river blindness transmission. The strength of the OEPA results from the partnerships that gather economic, political, and technical support together into one initiative.[21] Likewise, The Global Network initiative is notable for its consolidation of resources and the potential of its programs to effect significant change in global health issues.

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[20] "River Blindness Program." The Carter Center. Accessed at <http://www.cartercenter.org/health/river_blindness/oepa.html> 26 Jan 2011.

[21] Blanks, J. F. Richards, F. Beltrán, R. Collins, E. Álvarez, G. Zea Flores, B. Bauler, R. Cedillos, M. Heisler, D. Brandling-Bennett, W. Baldwin, M. Bayona, R. Klein, and M. Jacox. "The Onchocerciasis Elimination Program for the Americas: a history of partnership." Pan American Journal of Public Health 3.6 (1998): 372.

The strength of The Global Network's strategy, like that of Cambodia, lies in the reduction transaction costs to the nations other health organizations. Cambodia and The Global Network have developed simplified methods of medicine delivery, employing current networks—the school system and philanthropic structure, respectively—to create efficient programs to treat STHs, and more broadly neglected diseases.

Bolstering the System of Solutions with Innovations

While the section above described successful methods of utilizing existing resources to provide more efficient treatment strategies, the combined system of a rapid-impact package delivered through a network of schools is not enough to effectively reduce the global burden of STHs. Paul Hawken, in his book *Blessed Unrest*, stresses the need for diversity among social entrepreneurial activities. He outlines a concept of social immunity, one in which many initiatives that attack the problem from a variety of angles, alone achieve incremental success but together form a strong system.[22] To strengthen the fight against STHs, other programs and innovations are necessary.

There is a documented concern about the efficacy of the current treatments used both by the Cambodia government and the Global Network. Some studies suggest that these established treatments might be inadequate to reduce prevalence in high-intensity regions.[23] Furthermore, because the treatments do not prevent future infection and must be repeated frequently, drug resistance may occur.[24] While resistance has not been detected in a study of human STHs yet, two organizations are addressing the hypothesized future issues. They have begun to develop

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[22] Hawken, Paul. Blessed Unrest. New York: Penguin Books, 2007. 144.
[23] Hotez, Peter. "Hookworm and Poverty." Annals of New York Academy of Science 1136 (2008): 42.
[24] Ibid.

alternate and innovative solutions to global problem of STHs, following Hawken's theory of strength in diversity.

The Institute for OneWorld Health (iOWH) is working with the Bill and Melinda Gates Foundation to develop a new, safe, effective, and affordable drug to treat STHs.[25] iOWH, under the leadership of Victoria Hale formed a model of nonprofit drug development after becoming the first non-profit pharmaceutical company in the U.S. in 2001. They already have had success creating a drug to treat one NTD visceral leishmaniasis, and thus have the potential to contribute significantly to the world of STH treatment. However, this drug development is currently in the exploratory phase, only the first step of a long process of drug development. Additionally, based on recent press releases, it appears that iOWH and the supporting grants from the Gates Foundation are more focused on diarrheal diseases and malaria. The lowering in priority of a new STH drug speaks to the dependence of the project's sustainability on the commitment of its supporters. iOWH, like many social entrepreneurial initiatives, relies on philanthropy and thus is bound by the interests of its donors. While the iOWH initiative to develop a new STH drug is an example of innovative diversity in its own right, the unsustainable nature of the program also serves as further evidence of Hawken's thesis about the importance of diversity of solutions. With an uncertain future for a new STH treatment, other solutions are needed to address the growing concern of STH drug resistance.

There is a current drive to develop a vaccine due to this threat of resistance and the fact that current treatments are not long-term cures for STHs. The challenge in creating vaccines for NTDs is that normal investing and manufacturing processes cannot occur. Most vaccines follow a "trickle-down" path, meaning that pharmaceutical companies take a prudent risk by financially

[25] Institute for OneWorld Health. Accessed at <http://www.oneworldhealth.org> on 10 Jan 2011.

investing in researching and development of products with the knowledge that profit is possible from the market for vaccines that exists in developed countries with high willingness-to-pay values. Vaccines can only enter the markets of developed countries after the costs decrease, often decades after the initial innovation.[26] When developing vaccines for NTDs, a higher risk is involved due to a lack of a guaranteed market. Thus the companies must produce at low costs from the start, manage integration into the health systems of developing countries, and identify finance opportunities to support their social venture.[27] The advance market commitment (AMC) is a strategy being pioneered by the GAVI Alliance to manufacture and distribute vaccines in the developed world, forcing a change from the "trickle-down" path. As of January 2009, 11 countries were receiving support from GAVI to receive the pneumococcal vaccination. This is possible because in facilitating the AMC, GAVI helped match pharmaceutical producers and countries together in a market. The standard AMC structure includes a price guarantee allowing the country to commit their own budget and aid money to a set plan.[28] It also involves agreed upon market size or quantity that lowers the risk, which producers take in manufacturing, by guaranteeing a market in which they can recover their investment.[29]

The Sabin Vaccine Institute, a nonprofit research organization also in partnership with the Bill and Melinda Gates Foundation, is currently attempting to create a vaccine for

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[26] Bethony, Jeffrey M., Rhea N. Cole, Xiaoti Guo, Shaden Kamhawi, Marshall W. Lightowlers, Alex Loukas, William Petri, Steven Reed, Jesus G. Valenzuela, and Peter J. Hotez. "Vaccines to combat the neglected tropical diseases." Immunological Reviews 239 (2011): 262.
[27] Bethony et al., 263.
[28] Barder, Owen, Michael Kremer, and Ruth Levine. "Making Markets for Vaccines: Ideas to action." Center for Global Development (2005). Accessed at <www.cgdev.org/doc/books/vaccine/MakingMarkets-complete.pdf> on 26 Jan 2011. p4.
[29] "Pneumococcal AMC: Frequently Asked Questions." Gavi Alliance. Accessed at < http://www.vaccineamc.org/files/FAQs2009.pdf> on 24 Jan 2011.

hookworm, a STH.[30] They employ a pioneering framework of product development partnerships, similar to AMCs, working with the academic, industry, and contracting sectors along the vaccine development chain to coordinate and support the research and development phase.[31] They also rely on partnerships with national health ministries and international manufacturers to facilitate the market and production of the vaccines. In particular, the Sabin Vaccine Institute is focusing their efforts on Brazil. With coverage of treatment for school children below 0.2% in 2009,[32] Brazil is in need of a new treatment or prevention program. Interestingly, Brazil is one of the few developing nations that are self-sufficient in vaccine manufacturing.[33] For this reason, the Sabin Vaccine Institute is focusing their efforts in Brazil where Dr. David Diemert is leading the research on a human hookworm vaccine. Currently, the vaccine is undergoing clinical trials with the hope that it will move to the manufacturing stage soon. Diemert's plan is for the Sabin Vaccine Institute to delegate much of their manufacturing to their Brazilian partners Instituto Butantan, a biomedical institute, and Fiocruz, a vaccine manufacturer. This is one strategy they are using to ensure the lowest manufacturing costs and thus the lowest possible prices for future consumers. Yet, despite their progress and the significant grants from the Gates Foundation for research and development, the Sabin Vaccine Institute acknowledges an additional challenge post-production. Because the demand for this vaccine resides in the world's poorest countries, and there is always concern about a limited commercial market for their product.

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[30] "About the Vaccine." Sabin Vaccine Institute. Accessed at <http://www.sabin.org/ vaccine-development/vaccines/hookworm/about> on 10 Jan 2011.
[31] Barder, Owen. "CDG Breif: Vaccines for Development." Center for Global Development. April 2006. Accesed at <www.cgdev.org/files/7366_file_Vaccines2.pdf> on 25 Jan 2011. p5.
[32] "Soil-transmitted helminthiasis: Countries x indicators." World Health Organization. 2003-9. Accessed at <http://www.who.int/neglected_diseases/preventive_chemotherapy/sth/db/index.html?units=minimal&region=all&country=bra&countries=bra&year=2009> on 24 Jan 2011.
[33] "Survival: The Hidden Invaders." BBC/Rockhopper.tv. 29 Nov 2008. Accessed at <http://www.sabin.org/news-resources/video/survival-hidden-invaders> on 23 Jan 2011.

Conclusion

The examples discussed above demonstrate the power and potential of both reorganization and creation in social entrepreneurship. Cambodia's national treatment program restructured the STH treatment sector of their health care strategy to be aligned with their reliable and sustainable schooling system while The Global Network collects drug donations to converge treatments into one easy rapid-impact drug package. The Institute for OneWorld Health and the Sabin Vaccine Institute instead focus on the innovation of a new treatment and a new vaccine, respectively. There are strengths and weaknesses of all four systems, but when matched together, the diverse ecosystem of entrepreneurial solutions becomes a strong contender against the global issue of STH infections. This multi-tiered approach against STHs can be scaled and model to address other neglected tropical diseases. Reformatting existing institutions to make processes more efficient and diversifying strategies for treatment and prevention are key factors in combating global disease endemics.

However, despite the demonstrated urgency of the problem of neglected diseases burdening a large percentage of the world's poorest population and promoting the persistence of poverty in affected regions, NTDs are still prolific and often ignored on the global scale. Financial barriers are the most significant factor in this continuing problem. Impoverished countries face high morbidity but have little funding or infrastructure to support the development of new drugs and their widespread administration. Concurrently, the organizations and programs discussed above are, despite their significant change-making potential, largely reliant on long-term funding from donor organizations to make their efforts both possible and sustainable. With the aid of innovative and supporting research, future projects of governments and nonprofit organizations should aim to establish programs and commitments that are more financially self-

sustaining, like advanced market commitments, to address the global issues of insufficient funding.

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