

Boosting Product Development for Neglected Tropical Diseases

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Executive Summary: Global health research is marked by the “10/90” gap, where only 10% of resources are invested in therapies that affect the poorest 90% of the world’s population. This has caused a great inequity in the medical products available in the developed versus developing world. This paper focuses on the lack of adequate research and development (R&D) for medicinal products for Neglected Tropical Diseases (NTDs). NTDs affect the bottom billion of the world’s population and have been shown to perpetuate the cycle of poverty due to their ability to impair physical and cognitive development, negatively affect maternal and child health, and socially stigmatizing features. Product Development Partnerships (PDPs) are non-profit organizations that integrate funding from the public, private, academic, and philanthropic sectors to target neglected diseases for which there is no commercial incentive in the pharmaceutical industry. The PDP model is important in increasing R&D for neglected diseases. Through establishing a global fund for NTDs, incorporating financial incentives in NTD product development, and using global health diplomacy to improve international cooperation within a PDP structure, the product development pipeline for NTDs can be improved.

I. The Research and Development Crisis

The health needs of developing nations have long been neglected. Global health research is marked by the “10/90” gap, where only 10% of resources are invested in therapies that affect the poorest 90% of the world’s population (Malpani 2008). This has caused a great inequity in the medical products available in the developed versus developing world. There are a number of factors that have led to the lack of development of therapies for diseases that commonly afflict the developing world. First, countries where neglected diseases are endemic are often unable to fund research or lack the knowledge capital to succeed in producing therapies. Second, there is little financial incentive for pharmaceutical companies to produce vaccines or drugs for the developing world. While there are organizations committed to improving access to existing medications in the developing world, few institutions focus on the development of new pharmaceutical products. Even if academic research for neglected

diseases is funded, it is difficult to find pharmaceutical companies that are willing to translate basic scientific research into effective therapies, due to the lack of profits from producing such drugs. This leads to a significant gap between laboratory and clinical knowledge. In this paper, we will discuss the role of product development partnerships in reducing this gap, as well as market incentives that can be employed to encourage the utilization of these partnerships to encourage research and development for neglected diseases.

It is important to note the three distinct disease classifications utilized by the World Health Organization (WHO):

- Type 1: These diseases, such as diabetes, occur in both the Global North and Global South. Given the profit potential for therapeutics in the North, there is significant market push for research and development (R&D) related to these diseases.

- Type 2: These diseases, known as neglected diseases (NDs), include the “big three”, or HIV/AIDS, Tuberculosis (TB), and Malaria occur in both the Global North and South; however, the vast majority of cases are endemic to the developing world. There is some market push for R&D for these diseases, but not proportionate to the burden of disease.
- Type 3: These diseases are almost exclusively found in the Global South. Neglected Tropical Diseases (NTDs) and other diseases of poverty fall into this category. There is very little market incentive for R&D for this category of diseases (WHO 2012).

The lack of resource allocation for NDs (type 2 and type 3) is of utmost concern. The WHO has designated 17 diseases as NTDs. NTDs are a group of parasitic and bacterial diseases that primarily affect the bottom billion of the world’s population, or those that are living on less than US\$1.25 per day, and include diseases such as helminth infections, Chagas disease, and leishmaniasis. The term “neglected” is used to describe these diseases because they are significantly understudied relative to their impact on human health. Despite the fact that NTDs affect over 1.4 billion people, these diseases have mostly been eradicated in the developed world. The Global Burden of Disease Study estimates that parasitic infections alone killed over one million people in 2013, although this may be an under-estimate (Hotez and Herricks 2015). However, the largest burden from NTDs is disability (Hotez and Pecouli 2010; CDC 2017). NTDs have been shown to perpetuate the cycle of poverty because they impair physical and cognitive development, negatively affect maternal and child health, and can be socially stigmatizing (Procolo and Jommi 2014). In 2016, the United Nations included NTDs as a public health priority in the Sustainable Development Goals. While this highlighted the need to prioritize NTDs, significant efforts will need to be made to identify innovative methods to reduce the burden of NTDs to reach the goal of eradicating the NTD epidemic by 2030 (UN 2015). The lack of new effective and affordable medicines has been identified as a key factor that may hinder the achievement of eradication (Hotez and Pecouli 2010). Few new therapeutic agents for NTDs have been discovered in recent years. From 2000-2011, only five out of 850 new products developed were indicated for NTDs, out of which none was a novel

chemical entity (Pedrique et al. 2013). There is hope that some new therapeutics may be on the horizon, with 66 new products for NTDs entering phase 1 trials from 2000-2014, but this still only represents 1.65% of all phase 1 trials, indicating a persistent gap in innovation (Jain et al. 2017).

II. Product Development Partnerships

Given that drugs, vaccines, and diagnostics are important tools for the prevention and treatment of NTDs, innovative methods need to be utilized to provide funding for the development necessary to bring these products to market. About 20 years ago, Product Development Partnerships (PDPs) were created to produce health solutions for diseases endemic in the developing world. PDPs function as non-profit organizations that integrate funding from the public, private, academic, and philanthropic sectors to target neglected diseases for which there is no commercial incentive in the pharmaceutical industry (Topal 2014).

Private donors, such as the Bill and Melinda Gates Foundation, and governments, can use PDPs as a way to fund R&D for NTDs. While each PDP has a unique model and collaborates with different organizations, most PDPs focus on a particular disease or group of ailments for which they are trying to find a specific solution. PDPs can develop products such as diagnostics, drug therapies, or vaccines and using in-kind contributions and federal funding, different stages of development from basic research to actual marketing of the end product are managed by the PDP. The goal is to create a health solution at minimal cost and use any proceeds to continue research for neglected diseases (Mahoney 2011).

The structure of a PDP allows for significant cost control measures. Because PDPs function as collaborations between different partners, various organizations can be used at each stage of the development cycle in order to achieve the best results. Early research can be conducted at a certain university and later, pharmaceutical partners can aid in the creation of the end product. The partnership structure of PDPs also allows funds from different sources to be combined for greater impact. The capacity to manage different stages of execution in this way is a big factor contributing to the ability of a PDP to develop a drug, for example, at relatively low

cost, estimated between US\$115-240 million, compared to a pharmaceutical company alone where the cost may increase to US\$800 million (Malpani 2008).

III. Funding and Product Pipeline for PDPs

The PDP model for R&D supports 40% of the overall funding for diseases of poverty product pipeline. There are currently 16 major PDPs operating worldwide, each with multiple products for neglected diseases in development stages. HIV/AIDS, TB, and Malaria, often considered the “big three” poverty-related diseases, have been given major importance in PDPs such as the International AIDS Vaccine Initiative, the TB Alliance, and the Medicines for Malaria Venture. Products for the “big three” have improved significantly in developing countries due to the efforts of these PDPs, with 58% of the product pipeline for NDs focusing on these diseases. NTDs are the focus of fewer PDPs, but there are a number of vaccines and drugs that are in testing stages (BVGH 2019).

Since the concept of PDPs has been introduced, the product pipeline for neglected diseases has increased significantly. From 1975 to 1999, it is estimated that as few as 16 products for all neglected diseases were produced, while from 2000-2009, 26 additional products were Federal Drug Administration (FDA) approved (BVGH 2019). PDPs are making progress at a rapid pace with 20 new product approvals from the period of 2009-2013. A total of 60% of these approvals were for “big three” diseases, pointing to the progress that needs to be made with products for the 17 NTDs (Cohen et al. 2014). In a study of 31 NDs, 72.8% of the US\$3.1 billion invested worldwide by governments, the private sector, and other sources, in R&D for NDs went towards HIV/AIDS, TB, and Malaria, while 15 NTDs collectively received only 12% of the total investment (Institute of Medicine 2011). It is estimated, that the NTD burden amounts to roughly 46-57 million Disability Adjusted Life Years (DALY) lost each year, where each DALY equals one year of healthy life lost (Hotez et al. 2009). This burden is second only to HIV/AIDS, pointed to the need for effective therapeutic measures to be implemented. The substantial increase in products for NDs developed through PDPs indicates the success of the model, and increased funding and

resources for such partnerships can further enhance the development of drugs and vaccines for NTDs.

One of the main reasons for the success of PDPs is the ability to capitalize on existing scientific knowledge to redesign products in a cost-effective manner. Successes include a Meningitis vaccine, created by the Meningitis Vaccine Project, targeted at low-income countries in Africa that was dispensed for US\$0.50 per dose, with more than 217 million people vaccinated in 15 countries since initial implementation in 2010 (Meningitis Vaccine Project 2014). The Drugs for Neglected Diseases Initiative (DNDi), has implemented six products since its inception in 2003, including a pediatric drug for those afflicted with Chagas disease. The treatment can eliminate parasites in 90% of infected newborns up to age 2, and can be accessed at production cost by the ministries of health in countries where Chagas is endemic, such as Brazil, Argentina, and other Latin American countries (DNDi 2011). The Sabin Vaccine Institute, focused on long-term prevention of NTDs, currently has vaccines for Human Hookworm, and Schistosomiasis in Phase 1 clinical trials (Sabin Vaccine Institute n.d.). Given the parasitic nature of these diseases, which leads to cyclical reinfection in endemic areas, successful implementation of a vaccine would be revolutionary in reducing the burden of NTDs.

To date, PDPs have contributed to the successful introduction of 42 products for NDs (DSW 2019). By integrating partners from the global South and North, PDPs have made indispensable contributions to the product pipeline of neglected diseases by creating a framework that encourages R&D even when financial incentives are lacking.

IV. Policy Prescriptions

iv.i. Establishing a Global Fund for NTDs

NTD funding patterns show a disproportionate reliance on the United States. Investors from the US, both public and private, accounted for 33.5% of global NTD funding (Institute of Medicine 2011). If serious efforts to reduce the burden of NTDs are to be made, it is important for international stakeholders, including the governments of endemic countries, to invest in the product development for NTDs and create a more equitable funding distribution between

countries. A Global Fund for NTDs could establish a global framework for NTD funding and consolidate international efforts to reduce the burden of NTDs. By operating as a financing mechanism for PDPs that are participating in NTD research and development, PDPs can retain their role as primary implementers of product development through multilateral partnerships. A Global Fund could be created in two different ways, either through the development of an independent organization, or through an existing global health institution.

Establishing an independent Global Fund for NTDs could provide leadership and pooled funding specifically for NTD R&D. A Global Fund for NTDs could be modeled after the Global Fund to Fight AIDS, TB, and Malaria that was established in 2002, after the identification of these diseases as a global health priority. The Global Fund to Fight HIV/AIDS, TB, and Malaria was launched after recommendations by G8 countries and the United Nations. During its first 10 years of operation, more than US\$19 billion in 151 countries were invested in interventions and grants for the three diseases (Hanefeld 2014). The Global Fund to Fight HIV/AIDS, TB, and Malaria allocates resources based on individual country proposals for specific interventions. Evaluation of the fund showed that it was a catalyst in creating momentum for “big three” disease interventions and provided significant resources through increased private and public funding that would have otherwise not been allocated (Hanefeld 2014). Some advocates for increased NTD funding resources have called on the Global Fund to Fight HIV/AIDS, TB, and Malaria to include NTDs as a priority since NTDs are often co-endemic with the big three diseases (Hotez et al. 2008). While this suggestion allows for the use of the already established Global Fund resources, given the priority that has consistently been given to HIV/AIDS, TB, and Malaria, inclusion of NTDs in the already established Global Fund may not allocate enough financial resources to NTDs as a separate Global Fund for NTDs would.

An independent Global Fund for NTDs could operate in a mechanism similar to the Global Fund for the big three, with a board allocating funding to specific R&D proposals for NTDs and the WHO serving in an advisory capacity. Because of the operational and technical synergies that exist between NTDs and

HIV/AIDS/TB/Malaria, the boards of the fund could share knowledge with one another for maximizing cooperation (Molyneux et al. 2009). Because of the successful model of PDPs, an NTD fund could reward proposals that utilize international partnerships for the creation of cost effective products and create the financial resources necessary for the PDP model to be replicated and expanded upon. Most importantly, a Global Fund for NTDs would establish a sustainable global financing mechanism for NTD R&D, which could have important implications in the control and elimination of NTDs.

Ideal policy would require each country to contribute to R&D for NTDs according to their GDP and use this investment to establish a Global Fund for NTDs (Malpani 2008). This would ensure that each country, regardless of NTD burden or economic status, is participating in addressing the global health needs that NTDs pose.

Given the authority of the WHO, in terms of technical and implementation expertise in matters of global health, establishing a Global Fund for NTDs under the WHO management could provide the mechanism for global governance and international cooperation that is necessary to ensure effective R&D for NTDs. However, given that current financial support for the WHO has significantly declined, establishing a Global Fund under the WHO direction would be difficult unless countries can examine their current support of the WHO and re-commit to the importance of support of a prominent global health organization (Goldberg 2015).

iv.ii. Improving Incentive Mechanisms for Drug Development

Financial incentives to improve R&D for NTDs need to incorporate both push and pull mechanisms. Push mechanisms create funding sources that incentivize research input. The establishment of a Global Fund for NTDs would create a significant push mechanism that could spur significant progress in R&D. While push mechanisms are important to generate research interest for an issue, pull mechanisms, which reward research output, create an incentive that rewards successful innovation in research and development (Mueller-Langer 2013). Two potential pull mechanisms for NTDs, a priority review voucher, and a NTD prize fund can potentially motivate further

private and pharmaceutical company cooperation in PDPs for NTDs.

In 2006, the idea of a priority review voucher (PRV) was introduced as a concept to encourage R&D for NTDs. Incorporated into US law, a PRV, which fast-tracks review by the FDA, is given to a company that has successfully developed a vaccine or drug to treat neglected diseases. This voucher can also be sold to a third party for competitive market prices, with potential economic incentives estimated at upwards of US\$300 million (Ridley et al. 2006). Given the relatively new and experimental status of PRVs, there are ways in which the existing PRV structure can be improved. Current PRV legislation does not mandate the company to market the drug at affordable prices, which is necessary for any product developed for NTDs. Companies also do not have to demonstrate the innovative nature of their product, which should be a requirement for any company seeking the economic benefits of a PRV.

While the PRV incentive structure has already been implemented, another pull mechanism that has received political traction is the idea of a prize fund for NTDs. Prize funds incentivize innovation based on the public health impacts of the introduced therapy and require the medical product makers to waive their monopoly rights, which allows generic competition to reduce prices in the developing world (Malpani 2008). The Medical Innovation Prize Fund Act, which would establish a US-funded prize fund, has been introduced to the US Congress multiple times, but has yet to pass (US Congress 2013). The suggested prize fund would reward any innovative product with wide public health consequences, however if the criterion for the prize were narrowed for neglected diseases, the incentive could be targeted specifically to increase incentives for underfunded diseases.

The effectiveness of such pull mechanisms remains to be seen given the lengthy process of product development. There is concern that given the market for NTDs, organizations that are involved in NTD R&D recognize the lack of market incentives, but would be involved in product development anyways (Gaffney et al. 2019). However, such pull mechanisms can be an important factor in the increase in partnerships for PDPs, by creating an incentive for pharmaceutical

and private companies, with wide technical and product manufacturing expertise, to invest in R&D. Non-profit organizations that are involved can also utilize such pull mechanisms to further invest in future PDP products. A combination of push and pull mechanisms can be an appropriate strategy for stimulating product-oriented research for NTDs. While pull incentive mechanisms may not be the sole driving force behind the decision to pursue R&D for NTDs, industry members have responded favorably to the incentive, and this can lessen the funding gap that NTDs face (Robertson et al. 2012). Given the need to improve NTD R&D, such mechanisms also hold experimental value by allowing innovative ideas to be incorporated to determine the best way stimulate further research and development for NTDs.

iv.iii Global Health Diplomacy Through Global South Engagement

The PDP model for product development fits well with the concept of global health diplomacy, in which countries strengthen diplomatic ties through partnered pursuit of a public health goal. The US, as the leading global health contributor, has significant influence in global health policy. The US cites global health diplomacy as an effective way to express US compassion, strengthen fragile states through the promotion of health equity, and solidify or forge diplomatic ties with a country (US Department of State 2019). Furthermore, in 2009 the US Assistant Secretary of State promoted use of US global health diplomacy because it “promotes stability and growth, which can deter the spread of extremism, reduce the need for humanitarian and development assistance and create opportunities for stronger political alliances and economic relations” (WHO 2011). Because PDPs utilize international partnerships, PDPs that focus on NTDs can have a significant role in future US global health diplomacy, in particular by increasing diplomatic ties with emerging economies in the Global South.

The partner structure of a PDP facilitates international capacity building and diplomacy through the use of technology transfers and knowledge sharing. Current PDPs predominantly use North-South partnerships, however increasing South-South partnerships should also be encouraged. Emerging economies, including India, China, and

Brazil, have significant science and research capabilities, and are an untapped resource for NTD product development. In a study of 78 small to medium-sized biotechnology companies in Brazil, China, India, and South Africa, a combined total of 62 products for NTDs, with 34 in development stages, and 28 at market had been produced (Frew et al. 2009). The significant number of innovative products for NTDs produced by emerging economies demonstrates the capacity of these countries as potential partners in the NTD product pipeline. Given that NTDs are endemic in these countries, strengthening partnerships in these countries can build capacity and incentivize them to take leading roles in developing therapies, reducing the need for intervention from the Global North.

The DNDi organized its structure to enhance South engagement in NTD R&D. The seven founding partners of DNDi include four publicly funded organizations in the Global South NTD endemic countries of Malaysia, Kenya, India, and Brazil. Through wide use of partnerships in the Global South, DNDi is able to include capacity building as one of the main objectives of the R&D network (DNDi 2014). In 2010, DNDi facilitated a South-South technology transfer of an anti-malaria medication between India and Brazil. This knowledge sharing was one of the first South-South collaborations and a major health diplomacy step between Brazil and India. Shared manufacturing of the drug in both countries allowed for wide dispersal of the drug in multiple countries (DNDi n.d.). The facilitation of such collaborations can allow future PDPs to develop through Global South networks.

Increasing Global South engagement in NTD PDPs can be an important public diplomacy tool for the US. The US will not only strengthen its ties with emerging economies but can also be a key player in global health diplomacy between Global South countries. Furthermore, engaging Global South partners in the PDP structure will create a more sustainable approach to ensuring investment in R&D for NTDs and improving global health equity.

V. Conclusion

The public-private and international partnerships that are created by PDPs allow for the unique exchange of knowledge capital and for partners to specialize in one aspect of R&D for each disease, which accelerates the product development pipeline. The demonstrated potential for PDPs to develop products essential to global efforts to prevent, eliminate, and eradicate diseases that affect more than a billion people, confirm the need for sustainable funding and increased investment in the PDP structure. Since the inclusion of NTDs in the Sustainable Development Goals in 2015, there has been increased recognition of the cross-cutting nature of NTDs. Reducing the burden of diseases of poverty has been shown to reduce poverty and hunger, improve educational attainment, and engender economic growth, leading to vital reductions in the inequalities that plague the developing world. PDPs can be leveraged to deliver enhanced and equitable interventions for NTDs in marginalized populations and through improved US investment and advocacy, we can reach closer not only to the goal of eradicating NTDs by 2030 but also to the goal of improving global access to adequate health care, sanitation, and education.

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