PROPOSAL by Bangladesh, Barbados, Bolivia and Suriname

Chagas Disease Prize Fund for the Development of New Treatments, Diagnostics and Vaccines

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Executive Summary

In resolution WHA 61.21, the WHO is asked to consider the development of new financing mechanisms for R&D that de-link R&D incentives from product prices.

The governments of Bangladesh, Barbados, Bolivia and Suriname are attaching for discussion a proposal for the endowment of a prize fund to reward developers of new medicines, vaccines and diagnostics for Chagas Disease.

The proposal is an example of how a prize fund can be designed to increase treatments for a single neglected disease.

This proposal is based on an earlier proposal presented by the governments of Barbados & Bolivia in April 2008 during the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. During that process, several governments expressed support for undertaking further discussions on this proposal.

The Problem

Chagas disease (T. cruzi infection or American Trypanosomiasis) is a tropical parasitic disease caused by the parasite Trypanosoma cruzi, which is commonly transmitted to animals and people by insect vectors that are found only in the Americas (mainly, in rural areas of Latin America where poverty is widespread). The disease may also be spread through blood transfusion and organ transplantation, ingestion of food contaminated with parasites, and from a mother to her fetus.

It is estimated that as many as 8 to 11 million people in Mexico, Central America, and South America have Chagas disease, most of who do not know they are infected. If untreated, infection is lifelong and can be life threatening. The impact of Chagas disease is not limited to the rural areas in Latin America in which vector borne transmission occurs. Large-scale population movements from rural to urban areas of Latin America and to other regions of the world have increased the geographic distribution and changed the epidemiology of Chagas disease.

Chagas disease is a very painful, debilitating disease. As the disease progresses serious chronic symptoms can appear, such as heart disease and malformation of the intestines. If untreated, the chronic disease is often fatal. According to the WHO, the annual impact of Chagas disease is estimated at 649,000 DALYS and 13,000 deaths. It is one of the diseases targeted by the WHO TDR program.

Nearly all of the victims of Chagas disease are poor people living in developing countries. There is almost no private sector research for Chagas disease.

Only a handful of academic researchers have focused on this problem, and many academic and private sector researchers neglect to share information, materials or technology that may be relevant to this neglected but important R&D problem.

The 2006 WHO CIPIH Report offered the following comment:

> "most recently the genomes of the trypanosomes which cause Chagas disease have been published, the result of a cross-national collaboration including researchers in Africa and South America. While these advances are critical, the Science editorial accompanying publication captured the dilemma well: The Tritryp genomes are thus intrinsically interesting – but what will they contribute to the amelioration of disease? Because of their distinct evolution, trypanosomes present a plethora of potential drug targets, and potential drugs are almost certainly languishing in the chemical libraries of pharmaceutical companies…But we need resources and commitment on a far larger scale to transform drug targets into clinical successes. It is clear that the traditional pharmaceutical industry will not become effectively involved in this area, and the current promotion-and-reward system in academia does not attract or sustain the necessary human and financial resources. Consortia move slowly and are frequently restrained by similar problems, compounded by the egos of scientists and sponsors".

The Basic Proposal – a Chagas Disease Prize Fund (CDPF)

The proposal is to endow a prize fund to support innovations for the treatment Chagas disease. The fund, which would be endowed at $250 million or more[1], would be used to resource several innovation inducement prizes, including those for product development, and to induce the sharing of knowledge, materials and technology.

Administration

The Prize would be placed in the WHO or PAHO, following the policies of a Chagas Disease Prize Fund Committee (CDPFC). This committee would be appointed by the WHO or PAHO. Examples of entities from which members of the Committee might be drawn include::

1. WHO TDR
2. A top research institution,
3. A representative from a developing country government where the diseases is endemic, for example, for Chagas, a GRULAC government,
4. A donor organization, and
5. A Public Health Advocate

1 The $250 million is provided as a suggestion, based upon an initial economic analysis of the risk adjusted cost of developing new medicines for Chagas We believe that a Prize Fund of $250 million would stimulate the development of one or more new medicines for Chagas, particularly in light of other existing incentives, grants and other subsidies for the development of new medicines for neglected diseases, such as the US FDA priority review voucher if applied to Chagas and the orphan drug tax credit. However, we welcome the work of the EWG and others to provide analysis and evidence that a different figure would be more appropriate.

(civil society or patients organization)

Conflict of interest rules would be put into place. No employees of any organization represented on the committee could win the prizes.

The Chagas Disease Prize Fund Committee would appoint subcommittees and staff as necessary to carry out its work, including committees with special expertise on medical issues, and to consider standards for access.

The Chagas Disease Prize Fund (CDPF) would be used to support the following prizes:

The Chagas Disease Prizes

The Chagas Disease Prize Fund (CDPF) would be used to reward developers of new treatments that improve health outcomes for the populations at risk for Chagas disease. This would include new medicines, vaccines, or diagnostic devices. The following three types of prizes would be awarded by the CDPF:

1. Chagas Disease Product Prizes (CDPP),
2. Technology Challenge Prizes, and
3. Best Contribution Prizes.

The design of these prizes is described below:

Chagas Disease Product Prize for New Medicines and Vaccines

New medicine and vaccine products for the treatment of Chagas Disease will be eligible for the Chagas Disease Product Prize (CDPP).

No money should be disbursed from the CDPF for the CDPP until at least one new treatment or vaccine is introduced into the relevant market in developing countries that actually improved health outcomes for persons at risk or suffering from Chagas disease.[2]

Eligibility and Value of CDPP Prizes

Any **new** medicine or vaccine that is registered for use and meets minimum standards for efficacy and safety established by the CDPFC, and meets the appropriate standards for access, would be eligible for CDPFC payments in a given year, for a maximum of 12 periods (years) of eligibility.

New chemical entities, new fixed dose combinations, or new uses of known drugs would be eligible, so long as the application to Chagas Disease was not previously known and approved for treatment, and there is an improvement in prevention or treatment outcomes.

Once the Chagas Disease Prize Fund begins to make disbursements for the CDPP for new medicines

2 The term “new drug” is not restricted to new chemical entities.

and vaccines, it should award annual prizes equal to no less than $10 million for a single product in the market and no more than $25 million for multiple products in the market.

In cases where the there are multiple qualifying products, the prizes will be divided among the developers of the technologies on the basis of the relative positive impacts on healthcare outcomes. For example, if one product improved outcomes (benchmarked against existing treatment alternatives) by 10,000 DALYs, and a second product improved outcomes by 5,000 DALYS, the division of the prize fund rewards would be 10,000/15,000 = .67 for the first product, and 5,000/15,000=.33 for the second product.

Diagnostic devices

The CDPFC may designate some of the principal from the fund to reward innovations in the field of technologies to improve diagnostics for Chagas disease.

The money that is not awarded as product prizes will be invested in income-generating securities. The income will be used to fund the following prize programs to advance science and technology relevant to the treatment of Chagas disease:

Technical Challenge Prizes

Part of the money from investment earnings will be spent on innovation inducement prizes that focus on solving technical challenges, such as the type of prize competitions now being offered by firms like the Eli Lilly-launched start-up company, InnoCentive. These prize competitions could be managed in-house, or outsourced to firms or non-profit organizations with expertise in managing such innovation prizes.

Biannual “Best Contributions” Prizes

The other type of prize would be a biannual prize competition for the “best contributions” to the scientific and engineering know-how needed for new treatments for Chagas disease. The “best contribution” prizes, given every two years, would feature up to three prizes, if entrants were considered sufficiently good. No prizes would be given if there were no impressive entrants, and the money would be reinvested and re-allocated to the next round of prizes.

Developing Country Researcher Set-Aside

At least half of the rest of the “best contributions” prize money would be a set-aside for research teams working in developing countries.

Intellectual Property Rights for Chagas Disease Prize Fund

A licensing pool would be created under the name the Chagas Disease Licensing Agency (CDLA) in order to acquire and manage the needed rights in the relevant patents and know-how for the new medicines, vaccines or medical diagnostic tests. In order to make claims on any of the prizes, the winner must grant reasonable and non-discriminatory licenses to all patents and know how needed for competitive supply of the technologies. The licensing patent pool that is going to be created by

UNITAID for HIV-AIDS medications could serve as a model for such a licensing pool.

Human rights considerations

According to General Comment No. 14 (2000) of the Committee On Economic, Social And Cultural Rights (CESCR), on the The Right To The Highest Attainable Standard Of Health, essential health care facilities, goods and services should be available, accessible, affordable, acceptable and of appropriate quality.

This means facilities, goods and services must be affordable for all, including for socially disadvantaged groups.

In terms of acceptability, facilities products and services should be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned.

Health facilities, goods and services must also be scientifically and medically appropriate and of good quality, in light of the realistic options regarding the availability (or lack of) availability of skilled medical personnel, hospital equipment, safe and potable water, and adequate sanitation.

Standards for Access to Technologies

In addition to requirements regarding the licensing of intellectual property rights, the CDPF, after consulting with experts in relevant topics, will adopt standards for access to qualifying products eligible for the product prizes. These standards will address the issue of follow-on innovation, and access to products by health care workers and patients.

These standards will elaborate on these criteria:

1. The product must be available in sufficient quantities, to people who need it.

2. The Product must be registered for use in countries where Chagas is an important health problem.

3. The product must be acceptable, in the sense of being appropriate for the use for people who need it.

4. The product must be produced at badge level in an industrial way that would allow another company to produce it easily

5. The product must be affordable.

6. The product of be of acceptable quality.

7. The developer must be ready to transfer the technology immediately to any identified producer in the world, including the files, documentation and and data necessary for drug registration.

The CDPF may require as a condition of qualifying for a Chagas Disease Product Prize that the product is acceptable, manufactured in sufficient quantities and of acceptable quality, at affordable prices.

This may involve a price ceiling for products, either as a mandatory requirement, or as an optional requirement, that could be substituted for an alternative market penetration test. A market penetration test would be a requirement that the treatment was actually manufactured, distributed and used by a large enough population to provide evidence that the device would in fact be affordable and acceptable for target populations.

One particularly interesting version of the market penetration test would be where the product is manufactured and sold by one or more third parties without subsidies from the prize applicant, in order to establish the feasibility and sustainability of a competitive supply. Upon reaching sufficient scale of distribution, the standard for affordability and access could be satisfied.

The size of the market penetration test could be smaller for cases where a maximum observed price price was met. In cases where a maximum price is not used, the market test would have to be large enough to prove that the actual market price would likely be affordable to the target populations.

More complex would be the case were the prize applicant alone manufactured the product for an affordable price, and even distributes an initial supply, but where there is no assurance that the product supply would be sustainable at an affordable price, once the prize money was paid. In such a case, a contestant would be required to provide sufficient assurances, covered by financial guarantees, that the products will be manufactured in sufficient quantities and acceptable quality, at affordable prices.

Incentives for Collaboration and Access to Knowledge

In order to ensure that there are incentives for openness and sharing among researchers, the Chagas Disease Prize Fund money would be divided as follows: the winning entrant would get 90 percent of the prize money; the remaining 10 percent of the prize money would be given to unaffiliated and uncompensated (by the winning entrant) scientists and engineers that openly published and shared research, data materials and technology, on the basis of who provided the most useful external contributions to achieving the end result[3]. This would include research, data, materials and technology that were either placed in the public domain, or subject to open, non-remunerated licenses.

To qualify for the “best contributions” prizes, published research findings would have to be freely available on the Internet in full text and with relevant materials and research. As an incentive to journals to make articles available to the public for free, 10 percent of the “best contributions” prize given for a published article would be available to a peer-reviewed journal that published the article, on the condition that the journal makes the article available for free immediately upon publication.

Funding

The CDPF will be endowed by contributions from governments and private donors. The WHO and PAHO should consider possible funding mechanisms for the Chagas prize that can be reasonably implemented in both developed and developing countries.

Among the funding mechanisms that should be considered are:

1. Voluntary contributions

3 The division of the prize between 90%/10 % is a suggestion that seems an appropriate division to start a discussion on incentives for collaboration and access to knowledge.

1. Voluntary contributions to the CDPF, similar to contributions made to the Global Fund/TGF.
2. Voluntary contributions from individual tax returns.

2. Other Possible Funding Approaches
    1. National contributions based upon domestic pharmaceutical marketing expenditures.
    2. Fees associated with the merger of pharmaceutical companies, where at least one merging party employes more than 10,000 persons.
    3. Contributions based upon revenue from pharmaceutical royalty payments
    4. Contributions based upon the trade in shares of pharmaceutical company stocks.
    5. Contributions based upon cross-border financial transactions..

WHO/PAHO Meetings on this Proposal

The WHO should hold a meeting in September of 2009 to consider a proposal for a prize fund for the development of new treatments, vaccines and diagnostics for Chagas Disease. PAHO should organize a preliminary regional meeting in May/ June 2009 on the proposal.