

GHTC Webinar: Pooled Funding Mechanisms for Global Health R&D Summary Document

Introduction

On December 10, 2014, the Global Health Technologies Coalition (GHTC) held the first in a series of webinars to explore issues that could have an impact on the financing and coordination of global health research and development (R&D). The webinar series is intended to provide balanced information and a variety of perspectives on key topics and to contribute to the development of an informed and engaged constituency of product developers, advocates, and other stakeholders.

The first webinar was on the topic of pooled funding mechanisms for global health R&D. Panelists—who represent different perspectives and areas of expertise—included Mary Moran of Policy Cures, an expert on policy and financing; Robert Terry of the World Health Organization’s (WHO) Special Programme for Research and Training in Tropical Diseases (TDR) and Lara Pandya of the European & Developing Countries Clinical Trials Partnership (EDCTP), who are representatives from existing and proposed pooled funding mechanisms; and Andrea Lucard of Medicines for Malaria Ventures (MMV), a representative of a product development partnership (PDP). Claire Wingfield of PATH facilitated the webinar.

History and overview of pooled funding mechanisms

Mary Moran, Policy Cures

Definition. A pooled fund is essentially a coordinating body, whereby multiple donors contribute to one fund, which then utilizes that funding to support multiple projects. The idea behind pooled funding is that it will improve coordination and prioritization, reduce duplication, and identify and address gaps that need to be filled.

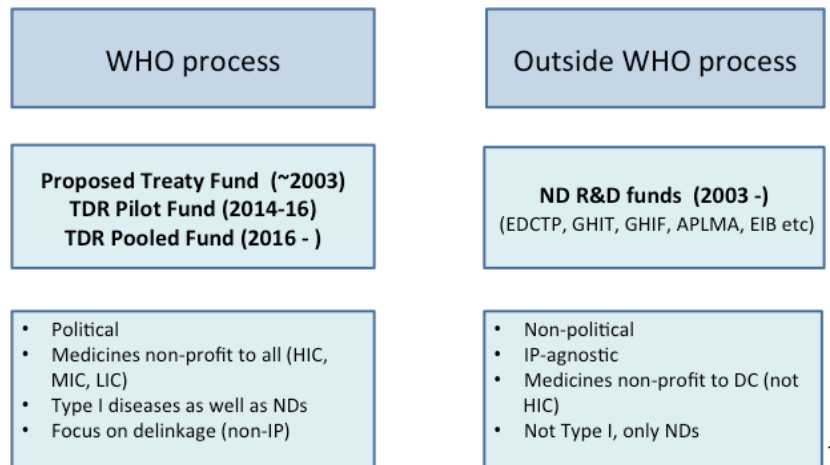
History of pooled funds. Historically, there are two categories of diseases. “Commercial” diseases (Type I), which are often chronic diseases such as cancer and diabetes that largely occur in rich countries, and “neglected” diseases (Type II and III), which are usually infectious diseases such as malaria and tuberculosis that primarily affect poorer countries. The private sector often conducted R&D for the chronic commercial diseases, while the public sector was responsible for R&D for neglected diseases (ND). This was primarily done through TDR, which was established in 1974 as the first pooled fund.

The AIDS drug crisis highlighted the problem of the commercial intellectual property system, under which R&D is funded through profits from sales to patients, known as linkage. This rendered AIDS treatment unaffordable and inaccessible to many people infected with HIV, and ultimately led to a proposal for an R&D treaty, which said that there should be publicly funded and developed drugs sold to patients at an affordable price. To do this, each country would put a percentage of their GDP into a pooled fund. The primary goal of the fund would be “delinking” the cost of R&D from sales to patients. R&D would be open source and conducted outside the traditional intellectual property (IP) and patent system.

Types of pooled funds. A resolution was passed at the 67th World Health Assembly (in 2014) to establish a pilot fund at the WHO, and if successful, there could be a pooled fund at WHO in 2016. This will be the first fund that is committed to delinkage for both

commercial and neglected diseases. In addition to the WHO fund, there are multiple funds that sit outside the WHO. The differences in the WHO process and the non-WHO process are highlighted in Figure 1.

Figure 1. Distinction between funds within and outside the WHO process



Courtesy of Mary Moran

The pooled funds outside of WHO focus specifically on R&D for neglected diseases. These funds tend to fall into two categories. There are the traditional public/philanthropic funds, which include industry, philanthropy, and public-sector funding. These are not-for-profit funds that focus on neglected diseases. Unlike the WHO process, these funds do work with the private sector and will fund R&D involving intellectual property. Examples of these funds are EDCTP, Global Health Innovative Technology Fund (GHIT), and the Asia-Pacific Leaders Malaria Alliance linked Fund (APLMA).

A new category of funds has started to emerge over the past year. These funds expect to get some return for private investors and want to bring in private capital. They expect to sell in developed country markets and use the profits from sales to reimburse the fund. The first of these funds is the Global Health Investment Fund (GHIF) set up by the Bill & Melinda Gates Foundation and other investors. The European Investment Bank is talking about still another fund that could also make profits in other markets.

In summary, in the current landscape there is a range of pooled funds, from funds that will not involve companies or IP and expect no profits; to funds that will work with companies and with IP, but expect no profits; to funds that work with companies and with IP, and do expect a profit. Funds also differ in the types of projects they will fund, whether it is projects that require partnerships in a specific country or region, or that focus on a particular disease or intervention.

Proposed WHO pooled fund

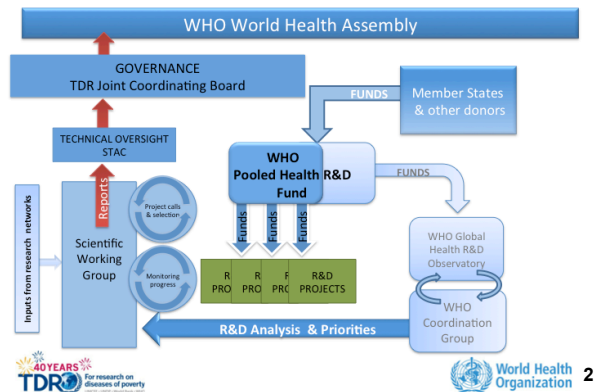
Robert Terry, TDR

The proposed pooled fund at WHO to support global health R&D is the result of 10 to 12 years of negotiation. It is not an R&D treaty, as there was little support for that model.

¹ Figure 1 acronyms: High income country (HIC), middle income country (MIC), low income country (LIC), European Investment Bank (EIB).

Rather, the proposed fund is a voluntary system, whereby WHO Member States will be responsible for putting funds into a joint enterprise, although the fund does not exclude other philanthropic donors. See Figure 2 for an overview of the proposed fund.

Figure 2. Proposed mechanism for a pooled fund to support global health R&D in WHO



Courtesy of Robert Terry

The fund will not only support R&D projects, but will also support a process for selecting priorities through a global health R&D observatory, which would monitor the R&D funding landscape globally.

Advantages. This fund is the first attempt at a globally negotiated R&D fund and has several potential advantages including:

- Agreement on global targets and priorities, which have not previously been clearly articulated.
- Opportunity to mobilize new resources and donors, for example by leveraging contributions from low- and middle-income countries (LMICs).
- Allows for shared risk and shared success.
- Should reduce transaction costs and streamlining requirements of grantees.
- Strong representation from disease endemic countries in the TDR governance structure.

Challenges. The fund will face some challenges including:

- Bringing together the political and the technical agenda and particularly making the political case for why this fund will add value.
- Size and sustainability of the fund.
- Setting realistic expectations for timescales and impact of this fund, bearing in mind that this will only be one of many of a range of tools that will be necessary to sustain global health R&D.

EDCTP model of pooled funding

Lara Pandya, EDCTP

Background and first program. EDCTP was established in 2003 as a co-decision of the European Parliament and European Council in response to the Millennium Development Goals and the challenges posed by HIV/AIDS, tuberculosis (TB), and malaria epidemics.

² Scientific and Technical Advisory Committee (STAC)

EDCTP is unique in that it is a multicountry, multistakeholder pooled funding mechanism with a focus on partnership between Europe and Africa. The first EDCTP program received Euro€200 million from the European Union (EU) and successfully leveraged at least another €200 million from European Member States and other third parties.

An evaluation of the first EDCTP program identified some limitations:

- The conditions imposed on funding, particularly the co-funding requirement at the project level, were burdensome and time-consuming on the applicant.
- Funding was restricted to public entities, so EDCTP could not fund PDPs or other private organizations.
- The scope was limited to HIV, TB, and malaria; and on Phase II and III trials.
- Calls for proposals were narrow—focused on specific diseases and interventions.
- The legal structure didn't allow for a true partnership between Europe and Africa, as African states could not be members of the Partnership.

Overview and changes in EDCTP2. The next iteration of EDCTP—EDCTP2—which will cover 2014 to 2024 was launched in December 2014. The EU has committed up to €683 million over the ten years of the program, conditional on matched cash or in-kind contributions from participating Member States. EDCTP2 is trying to leverage an additional €500 million from third parties, such as non-EU states, foundations, private sector companies, and development agencies.

EDCTP2 will try to address some of the challenges and limitations identified in the first EDCTP program:

- The legal structure has changed so that it is now a public-public partnership between sovereign states in Europe and sub-Saharan Africa, allowing EDCTP to expand its membership to include members from Africa.
- The scope has expanded to include other infectious and emerging diseases of particular relevance to Africa, Phase I through IV clinical trials, and health services optimization research.
- Greater funding allows for more ambitious, larger, and impactful projects.
- There will be a transparent operational process with annual work plans and upfront commitments.
- Calls will be much broader, less prescriptive, and bottom up, which will allow the research community to determine needs and priorities.
- For the majority of calls, projects will be funded 100 percent plus 25 percent indirect costs, removing the burden of securing co-funding from applicants at the project level.
- Any legal entity will be able to participate in EDCTP projects, addressing the previous restrictions on funding private organizations.

Advantages to pooled funding. From EDCTP's perspective, there are several advantages to pooled funding:

- Providing a means to better coordinate and to improve alignment and cost-effectiveness of programs and investments.
- Extending international cooperation in and between public and private partners, to maximize impact and ensure synergies are identified.
- Leveraging funding from European and African countries.
- Making available a larger pot of money for projects (e.g., a multicenter trial) that would be beyond the resource of a single agency.

- Reducing administrative burden on applications and inefficiencies through standardized practices.

Challenges. From EDCTP's perspective, there are also several challenges:

- Research funds tend to be more restrictive and tied to national research agencies and research goals. To be efficient, flexible, and to be able to achieve the advantages of pooled funding will require unrestricted cash co-funding.
- There is a need for better coordination to identify common areas of interest and mechanisms to jointly fund or coordinate funding in order to increase efficiency and allow for identification of synergies at an earlier stage.

Perspective from a product developer

Andrea Lucard, MMV

As a PDP, MMV is both a pooled fund, making contributions to research with funds from multiple donors, and a recipient of pooled funds. MMV has experience with most of the funds that have been discussed and considers this experience to be mixed.

Advantages to pooled funding. There are advantages to pooled funds, the most obvious being that there is funding available through these mechanisms. Pooled funding mechanisms also provide an opportunity to identify new partners. For example, the GHIT Fund not only provided funding, because they have a mandate to ensure that Japanese partners are engaged, but also helped to facilitate bringing Japanese partnerships on board.

Challenges to pooled funding. It is common for pooled funds to have certain requirements or conditions to be eligible for funding, be it region-specific partners or a focus on a particular disease or intervention. With so many pooled funds in operation with varying conditions and requirements, PDPs and other grantees may have to divide their portfolios and projects to meet these requirements. This may not be a significant challenge for PDPs with defined processes, but it could be quite daunting for a new organization unless that organization has a clear ability to understand how its portfolio and projects fit with the additional needs of the fund. As funds proliferate, this issue will become more and more complex.

For many PDPs, bilateral funding is their core and most important funding. There is a concern that bilateral donors may decide to contribute to pooled funds in place of grants to individual organizations, which could have a significant impact on the budgets of organizations that rely on these funds as well as the projects they are working to advance. At the same time, the efficiencies of working through a single funding pool, such as UNITAID, rather than all of the individual contributors to that pool is recognized. Bilateral and multilateral funding should be complementary.

From a PDP perspective, pooled funding requires a balance between the complexities of applying for funds from pooled funds with varying conditions, the efficiencies of dealing with a single agency representing multiple partners, and the importance of bilateral funding to the overall operations of the organization.

Potential implications of pooled funding

Mary Moran, Policy Cures

The purpose of pooled funds is to improve coordination and reduce duplication and redundancy. There are both pros and cons to pooled funds, largely in the design of the fund.

Advantages

- Pooled funds do make additional resources available and are an improvement in coordination amongst funds.
- Applicants can select the funds that match their mission and projects.

Challenges

- The funding picture is quite fragmented, with numerous pooled funds alongside bilateral funding.
- Funders and sovereign states may have concerns about putting money into a fund where the decisions are made by others.
- The level of conditionality can make it difficult for funders to see where they might fit in and add value.
- Most pooled funds lack a global pipeline approach and remain investigator and project-driven. There should be increased coordination and a strategic approach to identify gaps and prioritize funding.
- There are a number of products (e.g., vector control) that fall outside of any of the existing funds.
- Bilateral funds may choose to contribute to a pooled fund rather than a PDP or other organization, when in fact both types of contributions are essential.
- With limited funding and specific conditions, pooled funds support the R&D that matches the fund. If increased funding goes to a certain pooled fund, R&D will trend in that direction (e.g., increased investment in EDCTP may lead to more operation research rather than product development).

One interesting and key point that stemmed from this discussion is that pooled funding mechanisms may not be the most appropriate or effective vehicle for feeding the pipelines of global health interventions, and this may be the right role for national and international agencies.

Questions and Discussion

Have there been pooled funding mechanisms that have taken a portfolio approach rather than a project approach? There are examples within the sciences, for big projects like the European Organization for Nuclear Research (CERN) and the human genome project, but not in health. There is a fundamental issue of the desire for attribution for both the funders and the research organization, and this is a barrier to maximizing the efficiency of this approach. Further, portfolio management looks across geographies, sectors, and institutions to advance the most promising science, and the conditionality imposed by many funds makes it very difficult to do that. However, this is a role for the PDPs, which all maintain portfolios. If PDPs remain financially healthy, there will be multiple pipelines.

What had to change politically for the EDCTP to make changes for EDCTP2? There was recognition that EDCTP had demonstrated its ability to successfully work as a pooled funding mechanism and a realization that there was much more that the mechanism could achieve. The changes in EDCTP2, particularly including African countries as

members, sends a message to countries to get more involved and take ownership of the research and commit to supporting it. For example, now that South Africa is a full member of EDCTP, they can be encouraged to make more contributions, track their spending, and initiate projects. There seems to be strong political will among African countries to become more involved.

What needs to happen to get a country like the US to get engaged in a pooled fund?

The US is the largest public global health R&D funder in world, providing 70 percent of overall government funding to global health R&D. The National Institutes of Health (NIH) is the main source of this funding and is somewhat coordinated. It is unclear how to get the US involved on a global scale. It has the capacity and resources to make its own decisions, and there would need to be motivation and incentive to get them involved in a global pooled fund. Efforts are being made to increase coordination across US agencies by agreeing to common goals and priorities, which can be done without actually pooling funds. There are also initiatives to coordinate between pooled funds, for example a joint call between EDCTP and TDR. In order to effectively coordinate, it will be necessary to have a better understanding of the global landscape, including target product profiles, pipelines, what research and projects are being funded, and funding gaps.

What does it mean to leverage LMICs for the proposed WHO fund from a practical standpoint? WHO is getting commitments from Member States to give a certain amount to the fund, but there is an additional amount that will be used as a match for funding received by a LMIC. This might be one mechanism to leverage resources from these countries.

Can you say which countries have pledged to the proposed WHO fund and how much?

Not at this point. The fund has received around US\$10 million thus far, so it is still very small for global health needs, but it is quite often the case that it takes many years after a resolution for the funds to come in. This fund is one of the few instances where the funds overlap with the resolution, for many other resolutions it took many years for resources to flow. There is no lack of will, and quite a lot of interest in seeing what can be done within political constraints and a multiple array of priorities. Delinkage, fundamental to the fund, was highly controversial ten years ago, but has become more accepted.

One of the reasons that PDPs have been successful is that they are small and are able to move and adapt quickly. A downside to coordination is the slowness created by the need to coordinate many people, agendas, countries, and time zones. While there are benefits to coordination, we could lose in the process exactly what we have gained from being small and nimble. PDPs are small organizations that have specific expertise that can manage and advance products efficiently.

Has there been pooled funding applied to technology transfer and capacity strengthening?

This is a flagship program of EDCTP, alongside research and supporting product development. In its first program alone, EDCTP funded more than 500 trainings, and there has been a lot of capacity development at trial sites in sub-Saharan Africa. The EDCTP fellowship program will continue with the new fund, alongside support for the establishment of regulatory systems and ethics committees, and efforts to ensure that regulatory processes are more efficient. Centres of Excellence are also focused on building capacity and sustainability. TDR has focused on capacity building since its inception. Capacity building is something that should always be considered, in order to

build political will leading to indigenous and vibrant research in countries. This will be essential to building the local economy and getting out of a donor-driven cycle.

What are the administrative costs of pooled funding mechanisms? This is an important issue and needs to be addressed. Funds require quality assurance to ensure that the fund is being managed properly and efficiently but shouldn't be a huge amount of the fund. These costs should be kept as low as possible, but there has to be recognition that there is a cost to administering the funds correctly.

What is the impact of pooled funding on existing funding mechanisms, in particular bilateral aid, and how are these reconciled? Bilateral funding for the product development process is critical. At the same time, pooled funds like GHIT have brought in new partners and donors who would have been very difficult for PDPs themselves to bring forward. This should not reduce bilateral funding, but rather complement it. A larger pooled fund could not make up for elimination or even reduction of bilateral funding.

There is a need to distinguish between the value of getting more money and coordination. Pooled funds were meant to be a coordinating body, but in practice they are not doing that. It may be that coordinating and priority setting should be done outside the fund, and the fund could work towards the identified priorities. The value of the funds would be in raising new money in a way that is easy for funders. Currently, there are too many funds with too many conditions to effectively coordinate and conduct portfolio management. A separation between coordination and funding should be considered.

The webinar discussion covered some of the ways that pooled funds can be structured, what the fund aims to achieve through its structure, and the impacts on the global health R&D landscape. There is no single approach to global health R&D financing and coordination. There is a need to spread the risk and follow many leads; diversity is healthy and necessary. However, funding sources should be complementary, and there is a role for all players in funding and advancing R&D for new global health technologies.

Appendix A

Additional submitted questions

- What are the political issues with regard to a WHO pooled fund for health R&D?
- The global health research agenda must embrace implementation research on "upstream" determinants of health—including the social and political determinants. Is it even conceivable that pooled funding mechanisms can support this critical work?
- In the TDR program can we have a definition of "project" (e.g. element of specific R&D product work plan, a full product development program, or a product portfolio, like those of some PPDs)?
- Question for EDCTP: the website announcing Calls has not been functioning properly, which is an obvious challenge for those considering applying. Is there any hope this will be resolved soon? The clock is ticking on certain deadlines.
- The panelists have mentioned the potential efficiencies of pooling funding. Is it ever a risk that pooling large amounts of money into a single organization places major prioritization decisions into the hands of relatively few people? Or are there already mechanisms in place to ensure a diversity of voices behind pooled funds?
- Could you provide more detail (as much as possible) about: (1) The observatory and what it will do? (2) What it means to "leverage LMICs" from a practical standpoint? Thank you!
- Pooled funding by donors for implementing public health programs in my country (Nigeria) has not taken off over the years [because] donors think the fiduciary risk is very high. But pooling funds for R&D can be used to encourage public health scientists to venture into health research. How else can R&D be stimulated in Africa in a way that incentivizes public health researchers in Africa unlike basic science researchers who have more access to research funds?
- I would like to ask Mr. Terry to tell us a bit more about where they stand with the pilot fund that was launched earlier this year and that TDR is hosting. I know some meetings took place in the last few months and would like to hear what was discussed and decided. Did member states already contribute? Was the role of civil society in the process discussed?
- Many developing country R&D activities are based on bilateral agreements with donors or funders, would pooled funding jeopardize such local priority driven R&D?
- Have there been any key learnings that you can share with regards to the pilot fund—what's working well, not well, etc.?
- Please can you share more information on the senior fellowships for capacity strengthening in Africa?
- Under EDCTP2 is there a possibility for PDPs to receive core funding, i.e. funding of their ongoing consortia work?
- We should distinguish funding for country based R&D (WHO) from funding to fill the gap in products for [Neglected Tropical Diseases] (NTDs) (PDPs), and these should not be seen as competitors.

Appendix B

Assessment of webinar series

Several metrics were used to understand and assess the success and value of the webinar on pooled funding mechanisms for global health R&D, including audience participation rates and feedback from participants. A summary of these metrics is provided in this appendix.

Participation in webinar. In total, as of December 30, 2014, 156 people registered for the webinar, and 81 (53.6 percent) participated in the live event, from 21 countries and all regions of the world. An additional 59 individuals viewed the webinar online after the event. This demonstrates a strong interest in the topic and supports the continuation of the webinar series.

Audience feedback. Participants were asked to complete an evaluation at the end of the webinar, and 22 participants did so.

- Eleven participants indicated they had some knowledge of pooled financing mechanisms, six had no knowledge, and five had extensive knowledge prior to the webinar.
- Fourteen participants found the webinar to be very helpful, seven found it somewhat helpful, and one participant did not find it helpful.
- Participants with some knowledge of pooled financing mechanisms seem to have found this webinar most helpful, with 9 of the 11 participants (81 percent) indicating it was very helpful. Fifty percent of participants (3 of 6) with no knowledge of pooled financing mechanisms found the webinar to be very helpful, and 40 percent (2 of 5) of participants with extensive knowledge of pooled funding mechanisms found it very helpful.
- The majority of participants thought that having the panelists in one place (68 percent) and that video streaming the webinar (81 percent) was very important.
- When asked what could be done to improve future webinars, most respondents indicated an interest in more time for discussion and Q&A. There was also an interest in including perspectives from researchers working in various capacities. There were requests for slides and the webinar to be posted online, and this has been done. Presenters should also take into consideration that not all participants will be familiar with acronyms, and should make sure that they are made clear in the presentations.

Topics for future webinars. As part of the evaluation survey, participants were asked for their suggestions for future webinars. Responses included:

- Open source and intellectual property.
- How pooled funding mechanisms and other funds can develop strategic pipelines.
- Common evaluation criteria for grants.
- How R&D topics are identified for funding.
- How to bring in emerging donors.
- Addressing NTDs: changing social infrastructures to combat infectious diseases in low-income countries.
- How evaluation of global health R&D might be coordinated, so as to better feed into R&D planning/prioritization processes.

- Proportional allocation of available funds by disease types (infectious diseases, non-communicable diseases to include malignancies metabolic conditions, etc.).
- Effective fundraising strategies with the private sector.
- How to avoid fund competition between strengthening local R&D capacity and developing products for local needs with funding the "global NTD priority product gaps" particularly when this is through Product Development Partnerships that will never have portfolios that can address all global needs.
- Integration of "product development" agenda and a "people development" agenda. Implementation research into the social (i.e. cultural, political, economic, religious) determinants must be prioritized.

Overall Feedback

Overall, participants had very positive feedback on the webinar. They found it to be informative, engaging, and well-moderated. There were some technical issues for some participants, although it is difficult to know if those issues were on the side of the participant or the webinar production.