
Vaccine research and development (Charlotte Raymond Photography/International AIDS Vaccine Initiative/Flickr/CC BY-NC-ND 2.0)

Memo to DFAT: fund vaccines

By John Godwin
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In 2017, DFAT announced $75 million funding for development of new drugs and diagnostics for TB and malaria (Product Development Partnership (PDP) Fund 2018-2022).

A troubling feature of the announcement was DFAT's failure to commit funding to vaccine research and development (R&D). Why support "diagnostics and therapeutics", but not vaccines?

Vaccines are without doubt the most powerful public health tool for disease eradication. No major human infectious disease has been eradicated without a vaccine against it. Every year, vaccines avert three million deaths. Vaccines have eradicated smallpox and enabled a 99% reduction in polio incidence globally, and have dramatically reduced infant mortality.

The failure to invest in new vaccines for TB and malaria is inconsistent with other aspects of DFAT's new Health Security Initiative. Vaccine research is not entirely off the DFAT agenda. The website for the Indo-Pacific Health Security Initiative states that there *will* be new DFAT support for vaccine R&D. But DFAT has clarified that this reference does not apply to products supported through the Product Development Partnerships (PDP) Fund, but instead relates to "rapid vaccine development as part of the international response to a disease outbreak". So DFAT will fund 'rapid' research into vaccines for new disease threats, but not for fighting the more deadly epidemics that we have been battling for centuries.

So why is DFAT shutting the door on funding vaccine research for well-established diseases such as TB and malaria, the infectious killers that impose the highest disease burdens? In December, DFAT published the evaluation of the PDP Program 2013-2018 and its response. These documents shed light on DFAT's thinking.

The evaluation notes that AusAID included vaccines in its initial PDP grants, through funding Aeras, a TB vaccine PDP. However, funding to Aeras was terminated in 2014 due to the low potential for a new vaccine to be available within five years, with vaccine development considered to be a higher risk, longer-term process than the development of

drugs and diagnostics.

The evaluation recommended that DFAT's new PDP program fund new drugs and diagnostics, and that DFAT "re-enter the vaccine development space" if additional funding becomes available "after an initial three-year investment."

The report notes that re-investing in vaccines will offer "a more balanced, holistic, value-chain portfolio (i.e. toolbox, not tool) approach" and that a diversified portfolio inclusive of vaccines is "critical for future regional public health security." If so, why wait?

The rationale for DFAT not including vaccines in the 2018-2022 program appears twofold. First, it is attractive to delay vaccine funding to a future date when the R&D pipeline will be further advanced, and therefore the risks reduced. Secondly, in 2018 a new player will enter the field, with the establishment of the Bill and Melinda Gates Foundation Medical Research Institute (BMGF MRI). If BMGF is willing to bear the financial risks of vaccine R&D, why should DFAT?

But do these arguments stack up? They are based on the assumption that BMGF MRI will leave no room for vaccine PDPs. This is a mistake. BMGF MRI will be US-based and will not be focused on the late stage clinical trials required to prove vaccine efficacy. PDPs will continue to play a leading role in coordinating costly, large scale vaccine trials in developing countries.

And why drop the ball when it comes to vaccine R&D simply because it's considered risky and long term? It is true that TB and malaria vaccine pipelines are not as advanced as drugs and diagnostics, precisely because of historical under-investment in vaccines. Further starving vaccine PDPs of funding is hardly going to help.

In her post on this blog on DFAT's Health Security Initiative, Mary Moran also made the argument for DFAT's PDP Fund to support vaccines as higher risk, higher impact products. The failure to plan long-term contradicts DFAT's commitment to a "full innovation life cycle approach" to product development, a recommendation that DFAT accepted in its management response to the evaluation.

A brief look at the TB field illustrates the challenges. The BCG vaccine is the only TB vaccine available. It's nearly a century old and has limited efficacy in adults. While treatment advances will help reduce deaths, the only guarantee of TB eradication is a new vaccine.

The TB vaccine R&D field is gaining momentum. There are 13 vaccines undergoing clinical trials, including Phase 3 trials in China and India, and multiple candidates at the pre-clinical

stage. Key partners in these clinical trials include PDPs (Aeras) and pharmaceutical companies. For example, Aeras is working with GlaxoSmithKline on a Phase 2 efficacy trial that will provide results in 2018. Results from several other efficacy trials will become available over the next three years, providing data that will accelerate vaccine development. A new vaccine within a decade is possible. But it will take a significant increase in resources to achieve critical breakthroughs. It is not a good time for donors to be risk averse in this area.

In 2018, two policy drivers should be shaping DFAT policy in this area. The first is the global battle against Anti-Microbial Resistance (AMR), a priority of the 2017 G20 meeting. Drug resistant malaria and TB are a major component of the broader problem of AMR, and impose immense burdens on our region. Vaccines are the only long-term solution to this. New drugs alone are insufficient because they are prone to resistance. Vaccine prevention of drug-resistant TB and malaria represent the most cost-effective long-term strategy for responding to drug resistance.

The second major policy driver is the UN High Level Meeting on TB to be held in September 2018. In preparation, a Global Ministerial Conference on Ending TB was held in late 2017, which issued the Moscow Declaration calling for states to mount a global push for an effective vaccine by 2025.

It is these policy drivers, rather than risk aversion, that should be shaping DFAT priorities. The clock is ticking. In 2018, Australia should step up and demonstrate unambiguous leadership by funding the full complement of tools – vaccines, as well as drugs and diagnostics – for fighting the biggest infectious killers affecting our region: TB and malaria.

Disclaimer: The author received payment from Aeras, a TB vaccine PDP, in relation to this blog.

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