Cuba’s Effective and Cheap Cholera Vaccine

08/05/2015

Dr. Rafael Fando, from Cuba’s National Scientific Research Center, has been working to develop a cholera vaccine since he graduated from medical school in 1993.

This scientific research entity was created 50 years ago, right?

Rafael Fando: Exactly. The center was founded in 1965. It was the first scientific institution of its kind in Cuba, and many of the research centers and researchers working at different institutions around the country emerged from it.

What is the average age of the scientists working at the center?

RF: Around 40 years.

What kind of research is conducted here?

RF: We conduct biomedical research in 3 areas: the development of natural products, environmental studies and biological products designed to prevent infectious diseases.

Why work in the development of a cholera vaccine, when the disease has practically no incidence in Cuba?

RF: It was an idea Fidel Castro had in 1991, when an epidemic broke out in Peru. We were going through the most difficult years of the Special Period economic crisis. The idea came up because no pharmaceutical company was willing to address the issue, because it is not a vaccine that can generate much profit. Several research centers began the work, some with an inactive variant and we with a live, single-dose vaccine.

Cholera vaccines are aimed at poor populations in underdeveloped countries, so it’s ideal for a single dose to do the trick.

Were you a student at the time?

RF: That's right. I was doing my graduating project at this center, isolating monoclonal antibodies for the cholera toxin. When I graduated, I started working in the development of the vaccine here.

Did you ever imagine you would one day head this research work?

RF: I never imagined it, but it was interesting. We had a team of highly-dedicated people, from veteran researchers to the youngest of the lot, and everyone worked non-stop from 7 am to 9 pm.

Cuba's vaccine could cost 20 times less than the Swedish one and could be afforded by the poor countries that need it most. Photo: Raquel Perez Diaz

Work on this vaccine has been going for nearly 25 years. Why so long?

RF: Cuba doesn't have enough resources so as to allow us to quickly develop a vaccine for a disease that is practically non-existent in the country. We've made progress whenever there's been financing for the work.

The first vaccine test candidates were secured in 96 and, that same year, we began clinical trials. We did more tests afterwards. In 2006, we managed to conduct a trial in Mozambique, but the project was later aborted. We resumed it in 2013, when we secured funding to set the costly vaccine assessment system in motion.

When cholera broke out in Haiti and we had some cases in Cuba, we resumed the work, in coordination with the Finlay Institute, so as to obtain experimental vaccine lots. We also worked with the Pedro Kouri Institute, which is responsible for clinical evaluations.

Have you ever received international support?

RF: Never. The funding for this project is fully Cuban, save for the trial conducted in Mozambique, which was co-funded by that country's Ministry of Public Health.

Why does the World Health Organization (WHO) believe it is important for Haiti?

RF: They are facing a broad cholera epidemic and, coincidentally, the vaccine we've been developing has the same serotype as the strain that affects Haiti. The advantage of our vaccine is that, if you administer it properly, it offers people protection against subsequent infections.

How much work still remains before you have a viable vaccine?

RF: We have to complete the phase 2 clinical trials. We would then have to set up a plant that will manufacture enough vaccines. We would also have to pre-qualify the vaccine, that is to say, certify it with the WHO.

We must locate a fairly significant cholera outbreak to assess our vaccine in a phase 3 study, where we can evaluate its safety and effectively.

In our trials, the vaccine has provided 100 % protection against cholera and in 80 % of cases it could prevent the bacterial infection in individuals. This prevents the spread of the disease, acting as a kind of barrier.

Photo: Raquel Perez Diaz

If cholera vaccines already exist, why not use those?

RF: Because those vaccines are aimed at the travelers' market. A single dose costs 40 euros and you need 2. It's not a vaccine countries affected by cholera, which are the poorest, can use.

How much would the Cuban vaccine cost?

RF: Our vaccine could compete with India's, which requires 2 doses and costs US $ 3.70 each. Some 300 thousand doses of the vaccine will be administered in Haiti, for a total of US $3 million, a sum of money that cannot be paid by countries that suffer cholera.

The advantage of our vaccine is that we can offer a better price and, since we can administer it in a single dose, we can spare these countries a vaccination campaign, which is more expensive than the vaccine itself.

Could relations with the United States facilitate some form of collaboration in this field?

RF: It's going to make academic exchange much easier, without a doubt. In 1999, I traveled to the United States to take part in a congress about cholera, but they've denied me a visa every other time I've been invited. I hope we can now establish better links and even secure investments to be able to develop this product.

Currently, we can manufacture lots of up to 4000 doses in Cuba, but that is not enough. There are plans of making a small investment aimed at producing 250,000 doses a year, but that would still not be enough. We are planning to set up a manufacturing plant in the Mariel Special Development Zone, so as to secure foreign investment. We would need about US $40 million. With that funding, we could have the vaccine ready in 3 years.