

COVID-19: Institutional politics was crucial to success of vaccine technology transfer in Brazil

May 8 2023, by Maria Fernanda Ziegler



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When the World Health Organization (WHO) declared COVID-19 to be a global pandemic in March 2020, laboratories and pharmaceutical

companies were already developing vaccines, and Oswaldo Cruz Foundation (Fiocruz), an arm of the Brazilian health ministry, began looking for partners to produce a vaccine against the disease in Brazil.

Fiocruz is Latin America's leading biomedical institution. From the outset, its team wanted a [technology transfer](#) agreement that would enable it to produce the entire vaccine at its Bio-Manguinhos facility in Rio de Janeiro. To achieve this goal, its prospecting was guided by criteria such as the stage reached by a prospective partner in developing a vaccine and its suitability to Brazil's vaccination infrastructure, as well as technological factors and manufacturing characteristics.

Technology transfer agreements concerning vaccines typically take ten years to be concluded, but Fiocruz negotiated an agreement with AstraZeneca in only ten months. Thanks to local production, the AstraZeneca formula represented more than 50% of the doses administered in Brazil at the height of the pandemic, when vaccines were needed and none were available on the world market.

"Technology transfer is easier said than done, even under normal circumstances and in a world without a pandemic. It's important to know how the partnership between Fiocruz and the Anglo-Swiss pharmaceutical company came about, as a case study with implications for future initiatives involving technology transfer for increased vaccine production in middle-income countries like Brazil," said Elize Massard da Fonseca, a professor at Getúlio Vargas Foundation's Department of Public Administration (GEP-FGV) and first author of an article on the subject published in the journal *Research Policy*.

The case study shows how the Fiocruz-AstraZeneca partnership materialized and how this achievement at the height of a pandemic can be mined for strategies to assure successful technology transfer projects in future. It was part of two broader research projects supported by

FAPESP and conducted in partnership with the London School of Economics (LSE) in the United Kingdom. Other articles have previously been published on the projects, as well as a book in which the researchers analyze the response to the pandemic in various countries.

The partnership between AstraZeneca and Fiocruz was not the only one that resulted in a supply of COVID-19 vaccines for Brazil. Butantan Institute, which belongs to the government of São Paulo state, entered into what is known as a fill-and-finish agreement with Sinovac Biotech to receive, package and distribute the vaccine produced by the Chinese pharmaceutical company.

Two Brazilian private-sector companies, Eurofarma and União Química, signed technology transfer agreements regarding the BioNTech-Pfizer and Sputnik-V vaccines respectively, but neither has yet been produced in Brazil.

"Fiocruz was the only institution that negotiated a partnership involving actual technology transfer. The vaccine was entirely produced in Brazil. Another important feature was the licensing agreement enabling Fiocruz not only to produce the AstraZeneca vaccine but also to make modifications to it if necessary, including adaptations to combat novel variants of the virus," Fonseca told Agência FAPESP.

In the [case study](#), the researchers highlight key success factors in the partnership, such as Fiocruz's know-how in bioreactor cell culture and protein purification, which led AstraZeneca to see it as a valued partner; regulatory support and flexibility on the part of ANVISA, Brazil's health surveillance agency; and political factors such as agility, transparency, and the existence of a legal framework that permitted technology transfer for products still under development.

"The Fiocruz case is a standout for both speed and the magnitude of the

challenge represented by the need to learn to implement novel technology in the midst of a pandemic, with disruption of supply chains everywhere. Their success was due to a combination of political skill, ANVISA's willingness to talk and adapt its approval procedures, and the existing capacity at Bio-Manguinhos to produce vaccines. Transparency and the existence of an appropriate regulatory framework were also very important factors," Fonseca said.

The negotiations on technology transfer took place, the authors note in the article, in the context of "Brazil's response to the COVID-19 pandemic [which] was characterized by former President Jair Bolsonaro's (2019-2022) anti-science approach, including his consistent downplaying of the health threats posed by SARS-CoV-2, his refusal to follow the WHO guidelines on non-pharmaceutical interventions [such as social distancing and face covering], and his attempts to discredit vaccination."

Fiocruz was "very skillful at diplomacy," Fonseca said. "The team were consensus builders and managed to win political support for BRL 2 billion in funding for the deal with AstraZeneca. In June 2020, members of Brazil's National Congress visited Bio-Manguinhos to see the plans for the vaccine factory firsthand. Talks were held about funds there and then. At the end of the day, the Bolsonaro administration authorized and funded the technology transfer deal, but it did so reluctantly in order to face off against Dória." São Paulo State Governor João Dória was then negotiating to buy the Chinese vaccine. "The time was ripe for Fiocruz to get backing from the federal government. It was in Brasília's interest."

Building a consensus to back technology transfer is no easy task, she added. "Many important people and organizations don't see the point of transferring technology and producing locally rather than buying from the supplier with the lowest price. AstraZeneca's vaccine was the least expensive. Surprisingly, Covaxin [produced by Indian company Bharat

Biotech] was one of the most expensive, costing more than ten dollars per dose, whereas AstraZeneca's cost a bit more than three dollars," she said.

Production capacity

The choice of vaccine was also a key success factor, Fonseca added. "It was in the interest of Oxford [University] and AstraZeneca to build a global production network, and Bio-Manguinhos was an important partner for them because it had the capacity in bioreactors and processes that suited the technology to be disseminated by the pharmaceutical company," she said. "Moreover, Fiocruz already had many years of experience with technology transfer and sufficient knowledge to adapt that company's processes."

Management at Bio-Manguinhos considered the vaccine developed by Oxford University (UK) in partnership with AstraZeneca particularly suitable because at the time it was at an advanced stage of development and used viral vector technology, which matched the Rio de Janeiro facility's existing competencies and infrastructure.

"They believed all this would also assure agility in the process of producing the vaccine here. Fiocruz prospected the world market very thoroughly at the start of the pandemic to find out which vaccines Bio-Manguinhos could be adapted for, technologically speaking. CoronaVac, for example, required a biosafety level 3 [BSL-3] laboratory, which Bio-Manguinhos didn't have and would have taken over a year to build," Fonseca said.

The vaccine marketed by Janssen (Johnson & Johnson) also used viral vector technology but at the time was in the early stages of development. The products offered by BioNTech-Pfizer and Moderna were even less suitable because they were mRNA vaccines. Their high adaptability was

attractive, and they had reached an advanced stage of development, but they would have required construction of new infrastructure and development of new competencies, all of which would have been extremely challenging and time-consuming, especially in mid-pandemic.

"AstraZeneca's vaccine is a non-replicating viral vector vaccine, so the gains from technology transfer were huge. Bio-Manguinhos acquired the know-how to produce this technology and can use it in the long term to produce other vaccines or react faster to future epidemics. In the near term, the gain is being able to make adaptations to novel variants of concern," Fonseca said.

Buying a promise

Implementation of the AstraZeneca-Fiocruz technology transfer agreement began while the [vaccine](#) was still undergoing clinical trials and before it was approved for use by the general public. The Brazilian health ministry therefore had to use a specific solution called for by Brazilian law, which according to the researchers was an "order to commission technology" (ETEC in the Portuguese acronym), a procurement procedure whereby public-sector institutions can partner in the development of technologies for which regulatory approval is still pending. ETECs are legal under the 2004 Innovation Law, and the 2016 Science, Technology and Innovation Code.

"It's important to highlight the transparency of the entire process conducted by Fiocruz. We also point out the lessons to be learned for other contexts or situations requiring technology transfer, not only in Brazil and not just during a pandemic. It's crucial to build a political consensus, and the basis for this has to be transparency. This type of agreement in low- and [middle-income countries](#) with high levels of corruption is seen as risky. You're buying something that doesn't exist yet. That's why it was so important to have transparency and regulatory

flexibility," Fonseca said.

More information: Elize Massard da Fonseca et al, Vaccine technology transfer in a global health crisis: Actors, capabilities, and institutions, *Research Policy* (2023). [DOI: 10.1016/j.respol.2023.104739](https://doi.org/10.1016/j.respol.2023.104739)

Provided by FAPESP

Citation: COVID-19: Institutional politics was crucial to success of vaccine technology transfer in Brazil (2023, May 8) retrieved 18 April 2024 from <https://medicalxpress.com/news/2023-05-covid-politics-crucial-success-vaccine.html>

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