Vaccine Technology Transfer in a Global Health Crisis

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Remarkable Technology Innovation and Vaccine Uptake

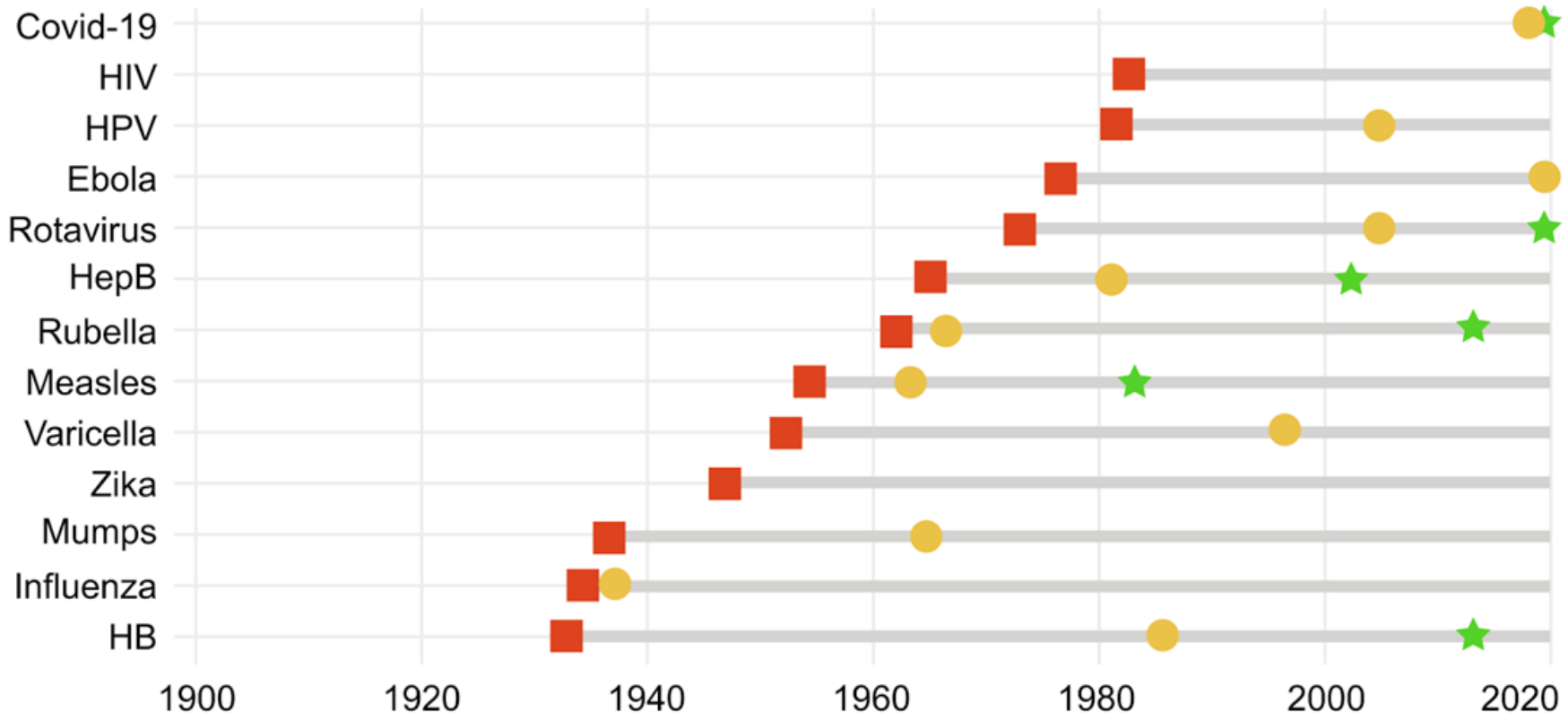


Fig. 1. The time from identification of a microbe to substantial vaccination has continued to shorten (adapted from [8]). ■ Identification of microbe; ● First vaccine developed; ★ 40% vaccinated.

Source: King ML. How manufacturing won or lost the COVID-19 vaccine race. Vaccine. 2024 Feb 15;42(5):1004-1012

Inequality in Drug Substance Production

Vaccine	Origin Country	Output (billions)	DS Producers
AstraZeneca	UK	2.9	11
Bharat	India	0.35	1
BioNTech-Pfizer	Germany-US	3.21	2
CanSino	China	0.31	1
Janssen	US	0.4	2
CIGB	Cuba	0.04	1
Finlay	Cuba	0.02	1
Moderna	US	0.9	2
Novavax	US	0.03	2
Sinopharm	China	2.6	1
Sinovac	China	2.8	1
Sputnik	Russia	0.28	3

Source: Airfinity May 2022 in Shadlen, 2022 https://hdl.handle.net/10438/32564

Challenges in Increasing Vaccine Supply during COVID-19

Drug Production, Synthetic Drugs

- Remove intellectual property rights
- Multiple producers enter the market

Why This Doesn't Work for Vaccines

- Complexity of Vaccine Production
  - Knowledge from original companies
- Regulatory Approval
  - No easy pathway for 'generic' vaccines
  - New clinical trials: time-consuming and costly





The AstraZeneca – BioManguinhos Tech Transfer

- AstraZeneca – BioM partnership
- 50% COVID-19 vaccines used in Brazil (late 2021)
- Politics, regulation, and capabilities matter -- in Brazil and beyond

BioM's prospecting and evaluation candidates.

COVID-19 vaccine developer	Platform	Development stage[a]	Technology readiness level[b]	Adequacy[c]	Existence of a licensed vaccine for human use using the same platform
Oxford/AstraZeneca	Nonreplicating viral vector	Phase II/III	TRL7	++++	No
CanSino Biological	Nonreplicating viral vector	Phase II	TRL 6/7	++++	Yes
Moderna	Nucleic acid (mRNA)	Phase II	TRL 6 /7	+++++	No
Johnson & Johnson	Nonreplicating viral vector	Pre-clinical	TRL 4/5	++++	No
Pfizer/BioNTech	Nucleic acid (mRNA)	Phase I/II	TRL 6/7	+++++	No
Sinovac Biotech	Inactivated virus	Phase I/II		++	Yes
Novavax	Protein sub-unit	Phase I/II		+++	Yes
Inovio Pharmaceuticals	Nucleic acid (DNA)	Phase I	TRL 5/6	++++	No
Clover Biopharmaceuticals	Protein sub-unit	Phase I	TRL 5/6	+++	Yes
University of Queensland	Protein sub-unit	Pre-clinical	TRL 4/5	+++	Yes
Gamaleya Research Institute of Epidemiology and Microbiology	Nonreplicating viral vector	Phase I	TRL 5/6	++++	No
Sinopharm	Inactivated virus	Phase I/II	TRL 6 /7	++	Yes
Bharat Biotech	Inactivated virus	Pre-clinical	TRL 4/5	++	Yes

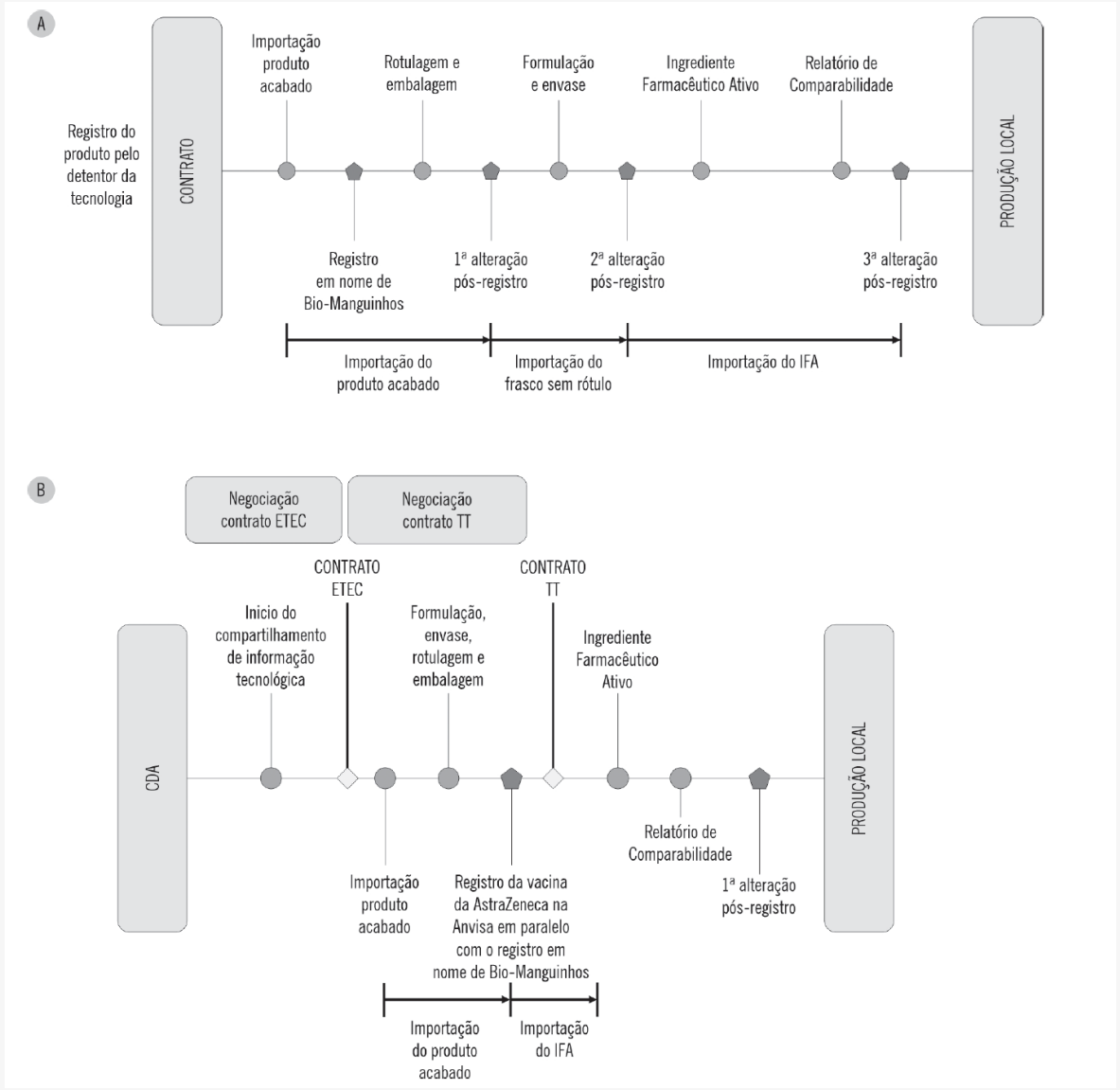
Advantages: development stage, BioM's capabilities and redeployment opportunities (yellow fever and interferon facilities), AZ willing to partner

Source: Adapted from Fialho et al. (2022).

[a] As of June 26, 2020 (date of the decision for the AstraZeneca partnership).

[b] Technology Readiness Level (TRL) is an index that evaluates the progress of early-stage technological projects, ranging from 1 (still in conceptualization stage) to 9 (demonstrated usefulness).

[c] Flexibility and versatility of the technological platform with regard to eventual adjustments to vaccine targets.



Capabilities and streamlining tech transfer

Two stages:

- Fill and finish
- Full technology transfer

AZ sent info before signing the TT agreement – BioM signed an NDA

Parallel activities: teams working at different steps of TT (e.g., quality control, regulatory issues, etc)

Political and Strategic Context



The health minister and the president of Fiocruz delivering the COVID-19 vaccine



Members of Congress from multiple parties visiting BioM/Fiocruz, July 2020



Fiocruz receiving an award from the Auditing Court for transparency in the COVID-19 project

Regulatory Flexibility

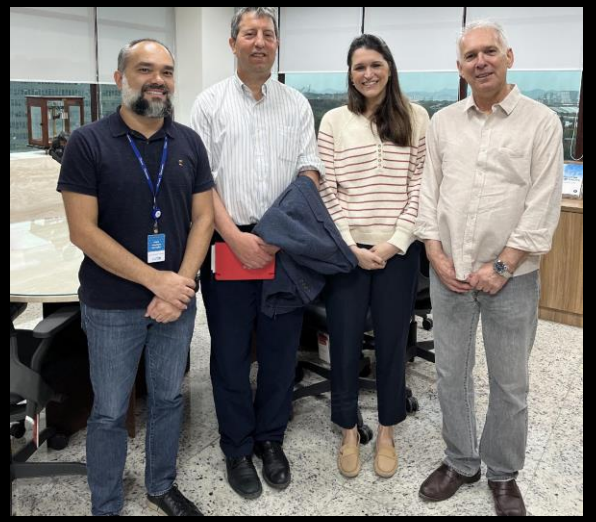
"ANVISA could have said [document] accepted or not accepted, but instead the agency helped building up the [streamlined production] process. They were part of the process, not a passive agent." (BioM Informant)



Lessons

- Capabilities: BioM was a useful partner given its experience and its know-how was crucial to fast-track tech transfer.
- Regulation: Prompt guidance on adapting manufacturing, clinical trials, and dealing with unforeseen challenges.
- Politics matter but are little acknowledged in international guidelines.





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Vaccine technology transfer in a global health crisis: Actors, capabilities, and institutions

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ABSTRACT

The COVID-19 pandemic, which featured international pharmaceutical firms seeking to build global manufacturing networks to scale-up the supply of vaccines, has generated heightened interest in understanding the role of firm-to-firm technology transfer. While considerable attention has been given to tracking the extent of international vaccine technology transfer, we know little about how partnerships were established and work in practice. Understanding the challenges that such projects face, and how such challenges may be overcome, is crucially important. This paper provides an account of the partnership between the British-Swedish multinational pharmaceutical company AstraZeneca, the vaccine developer that has engaged in the most technology transfer and built the widest global manufacturing network, and Bio-Manguinhos, a public laboratory linked to Brazil's Ministry of Health. The case study demonstrates the importance of capabilities and regulatory flexibility. Moreover, the analysis highlights the role of political factors that affect the process of technology transfer, and innovation more broadly. Because of the risks involved and the need to quickly mobilize existing capabilities and build new ones, as well as the imperatives of coordinating among manufacturing and regulatory processes and allocating resources to make such arrangements feasible, technology transfer projects need to be enabled politically. Looking forward, the case study has implications for initiatives to expand technology transfer for broadened production of vaccines in the Global South.

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Dependency, Capacity, and Agency: Austerity and Leadership Failures in Brazil's Homegrown COVID-19 Vaccine Efforts

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Abstract

Differential access to life-saving COVID-19 vaccines reveals the inequitable distribution of wealth and power in the global system. While several countries have developed homegrown vaccines to avoid being priced out of markets dominated by transnational drug companies, Brazil—a country with a significant research and pharmaceutical base—lagged behind those of other middle-income countries. Why? This paper blends insights from dependency theory and the theory of global capitalism to demonstrate how political coalitions, leadership, and normative frameworks negatively affect state capacity and technological development. First, austerity in public investment in research, development, and innovation prior to and during the pandemic limited the amount of resources necessary to create homegrown vaccine candidates. Second, political leadership informed by science denialism did not prioritize the development of vaccines and even discouraged their use. The analysis of vaccine development in Brazil reveals that having a pharmaceutical base and strong leadership committed to scientific principles and backed by a political coalition seeking to expand social democratic rights play a vital role in developing treatments and responding to health crises.

Keywords Covid-19 · Vaccines · Brazil · Dependency · Global capitalism · Research and development · Industrial policy



Gaps and New Opportunities

- The political economy of pharmaceutical regulation
- LMIC National Regulatory Authorities' different procedures and approval times
- Explain variation

Country	Vaccine	Regulatory authorization	Vaccination started
UK	Pfizer	Dec 02, 2020	Dec 08, 2020 with Pfizer
USA	Pfizer	Dec 11, 2020	Dec 14, 2020 with Pfizer
Mexico	Pfizer	Dec 11, 2020	Dec 24, 2020 with Pfizer
Chile	Pfizer	Dec 16, 2020	Dec 24, 2020 with Pfizer
Argentina	Pfizer	Dec 22, 2020	Dec 29, 2020
Argentina	Sputnik	Dec 23, 2020	Dec 29, 2020 with Sputnik
Colombia	Pfizer	Jan 05, 2021	Feb 17 2021
Brazil	AZ	Jan 17 2021	Jan 17 2021 with Sinovac
Brazil	Sinovac	Jan 17 2021	Jan 17 2021 with Sinovac

How were vaccines regulated? What were the procedures and political challenges?

Thank you!

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