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Collaboration in times of crisis: A study on COVID-19 vaccine R&D partnerships

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ABSTRACT

Collaboration is central for initiatives and efforts in the race to fight COVID-19, with particular focus on fostering rapid development of safe and effective COVID-19 vaccines. We investigated the types of partnerships that have emerged during the pandemic to develop these products. Using the World Health Organization's list of COVID-19 vaccine developments, we found nearly one third of all vaccine candidates were developed by partnerships, which tended to use next-gen vaccine platforms more than solo efforts. These partnerships vary substantially between materials-transfer partnerships and knowledge-sharing partnerships. The difference is important: The type of sharing between partners not only shapes the collaboration, but also bears implications for knowledge and technology development in the field and more broadly. Policies promoting fair and effective collaboration and knowledge-sharing are key for public health to avoid stumbling blocks for vaccine development, deployment, and equitable access, both for COVID-19 and expected future pandemics.
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1. Introduction

Global leaders have recognized that collaboration and open science are essential to the medical and technological fight against COVID-19, as they have been with other grand global public health challenges, including climate change and antimicrobial resistance [1–3]. The call to promote collaboration has been backed-up by powerful stakeholders [4] and promising initiatives, such as unprecedented worldwide data-sharing [5]—including the genetic sequence of the COVID-19 virus [6]; unconventional partnerships [7]; and initiatives for sharing know-how, intellectual property and technologies [8]. One of the most important areas for collaboration, but also international competition, is the race to develop safe and effective vaccines for COVID-19.

Vaccine development collaborations may involve partnerships between private entities, public entities, or hybrids such as public–private partnerships (PPPs). PPPs typically include both private for-profit and not-for-profit organizations, share efforts and benefits, and are committed to social value and improved health [9]. They have played a particularly important role during the COVID-19 crisis [4,9–13]. PPPs have previously been used to steer up vaccine development and production or to supply developing countries in critical areas [11,14–18]. While a global pandemic presents different conditions, ambitions, and financial incentives than efforts against neglected regional or rare diseases [19], prior collaboration experience should inform our understanding of collaborations during the COVID-19 pandemic and moving forward [20].

While substantial prior effort has considered the make-up of collaborations, the style of the collaboration is also crucial. In particular, the type of sharing between partners not only shapes the collaboration but also bears implications for knowledge and technology development in the field and more broadly. We consider two different modes of collaboration: *sharing of knowledge and technological expertise (abbreviated "knowledge sharing")* and *transfer of materials, technical infrastructure & IP rights (abbreviated "materials transfer")*. In the first, the two partners share complementary expertise and information in an ongoing process, collaborating to develop technology and—crucially—increasing the future knowledge and capabilities of each partner. In the second, collaboration follows a model of serial innovation steps: one partner pursues early innovative steps, and then transfers the resulting materials, technical infrastructure, and intellectual property to another partner to pursue further steps. The most classic academic/industrial collaborations follow this model; academic partners typically provide know-how and contributions in early clinical development, partnering with private entities in later development stages to test

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drug candidates and bring products to market [21]. To be sure, these modes are overly simplified, and line-drawing is non-trivial. Other relevant factors include the existence of market power, the identity of collaboration participants, the equitable distribution of resulting products, and thorny topics in national and international law such as know-how disclosure, compulsory licensing, IP waivers, antitrust law and prizing issues. Policy interventions in collaborative dynamics could fruitfully increase the welfare gains from innovation.

An initial step in understanding collaborative complexity is characterizing the basic landscape. We aimed to investigate the types of partnerships that have emerged during the pandemic to develop COVID-19 vaccines and to identify relevant factors that characterize these partnerships. Our results suggest an opportunity for policymakers to help shift the collaborative landscape—which is robust—to increase the potential for knowledge-sharing, the development of fundamental insight, and the adequate production of resulting technological goods, both in this pandemic and the next [22,23].

2. Materials and methods

We collected the list of COVID-19 vaccines in clinical and preclinical development registered by the World Health Organization (WHO), updated May 11, 2021, including development stage, registered vaccine development, and type of vaccine platform [24]. The list included 283 registered vaccines: 99 in clinical and 184 in preclinical development. Each vaccine was coded as a solo development effort or a partnership of multiple entities depending on the number of developers registered in the WHO list; entity type was recorded. Vaccine platforms were coded as either *classic* (whole-inactivated virus; live-attenuated virus; protein subunit; or virus-like particle) or *next generation* (viral vector; DNA; RNA; Antigen-presenting cells) using the definitions by van Riel and De Wit [25]. All vaccine partnerships were investigated using Internet searches for texts describing each partnership from publicly available sources (such as press releases). For 12 such vaccines, the available text descriptions were too sparse for further analysis and thus these partnerships were excluded. Third, we conducted a deductive document analysis [26] of the text extracts to investigate whether each partnership could be characterized as partnership involved in either "knowledge sharing" or "materials transfer".

3. Results

We identified 93 partnerships with ≥2 entities and 190 single entities developing COVID-19 vaccines registered by the WHO. Of the 81 partnerships we deductively analyzed, we found that 71 had a company partner. Further, we found that 46 (56.8%) were involved in "*materials transfer*" and 35 (43.2%) in "*knowledge sharing*".

An example of a "*materials transfer*" partnership was the collaboration between the University of Oxford and the pharmaceutical company AstraZeneca. Oxford and its spinout company Vaccitech jointly own a proprietary platform for vaccine development. After creating a vaccine candidate, they sought a commercial partner for seeking regulatory approvals and supply agreements—an example of serial innovation between partners. The exclusive agreement with AstraZeneca included further development of the vaccine as well as large-scale manufacturing and distribution of the final vaccine [27–31].

An example of a "*knowledge sharing*" partnership was the collaboration between the companies BioNTech, Fosun Pharma and Pfizer. BioNTech and Pfizer agreed to collaborate on research and development governed by a joint steering committee as well as to work together to scale-up manufacturing capacity. For this, BioNTech would contribute multiple mRNA vaccine candidates and Pfizer would contribute its global vaccine clinical research and development, regulatory, manufacturing and distribution infrastructure and capabilities. In this partnership, BioNTech granted Pfizer *"an exclusive, sublicensable license in the Pfizer Territory under certain of [their] intellectual property, including [their] patents and know-how, relating to uridine RNA, modified RNA and replicons in the Pfizer Corona Field as well as certain intellectual property in-licensed by [them] from third parties, to use, research, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Corona Agreement.*" [32]. However, the commercialization rights were shared between the three companies. Pfizer had the commercialization rights worldwide excluding Germany and Turkey (which BioNTech covered) and excluding China, Hong Kong, Macau and Taiwan (which were subject to a separate collaboration between BioNTech and Fosun Pharma) [32–36].

Table 1 presents an overview of partnership composition and collaboration style. Half of all partnerships involving academics (51%) were "*knowledge sharing*" partnerships, compared to 43 % of industry-only partnerships and only 26 % of partnerships involving a government entity. There was no clear relationship between the use of classic versus next-generation vaccine platforms and the type of collaboration ("*knowledge sharing*" versus "*materials transfer*") (Table 2). Partnerships were slightly more likely to use next-generation platforms than solo efforts (Table 2).

4. Discussion

Our data shed new light on the landscape of collaboration and knowledge transfer in the context of COVID-19 vaccine development. Three key trends emerge.

First, while most vaccine development endeavors are still undertaken by firms alone, many partnerships have been formed to develop vaccines. We observed 93 partnerships within approximate a year. By contrast, a 2011 World Health Organization report on vaccine technology transfers identified only 101 cases of transfer over the prior two decades [37]. The WHO report found dominant transfer pathways to be either (a) transfers from industrialized to developing nations or (b) the use of centralized hubs or platforms for knowledge sharing [37]. The smaller bilateral transfers we focus on here fall outside those categories.

Table 1
Partnership compositions and collaboration styles involved in *sharing of knowledge and technological expertise* or *transfer of materials, technical infrastructure & IP rights* for COVID-19 vaccine developments.

Type of partnership	Sharing of knowledge and technological expertise* (number of partnerships)	Transfer of materials, technical infrastructure & IP rights* (number of partnerships)
Total	35	46
- company-only partners	10	13
- no company partner	4	6
- academic partner	18	17
- governmental partner	5	14
- military partner	1	1
- hospital partner	0	4
- non-for profit private, organizational partner	1	8

* Some partnerships fit multiple categories, thus the totals are smaller than the sum of partnerships in each category.

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Table 2
Types of vaccine platforms used in solo efforts or partnerships for development of COVID-19 vaccines

COVID-19 vaccine developer	Classic vaccine platforms	Next generation vaccine platforms	Other types of vaccine platforms	Total
Single entity	105	83	2	190
≥2 entities	40	41	0	81
- Transfer of materials, technical infrastructure & IP rights	24	22	0	46
- Sharing of knowledge and technological expertise	16	19	0	35

Second, of the collaborations that do take place, more are focused on transfer of materials—that is, serial innovation along a pathway—than active knowledge transfer and collaborative learning. Serial innovation where a product is taken along a chain of developers is certainly useful; however, such serial transfers do not facilitate the exchange of information more broadly and the development of knowledge at nodes of intersecting expertise [38].

Third, and following suit, we observe that among the participants in partnerships, those involving academic entities were more likely to include knowledge transfer, rather than just material transfer. Knowledge development and sharing by academics is useful but somewhat expected. It is discouraging that in a space where rapid innovation and understanding are both crucial, government and industry players are fairly unlikely (26% and 43%, respectively) to share and deepen underlying knowledge stocks. We also note that of those relationships involving knowledge transfer, some focus solely on unidirectional knowledge flows. For instance, the contract between Pfizer and Operation Warp Speed substantially limited the possibility of any government rights in resulting products or knowledge, stating that "[a]s between Pfizer and the Government, Pfizer shall hereby retain all of its rights, titles and interests in and to any and all inventions conceived and reduced to practice by Pfizer and/or BioNTech (i) as of the Effective Date of this Agreement ... Pfizer does not grant to the Government a license to practice any Subject Inventions on behalf of the Government"; resources and knowledge flowed in one direction only [39].

Our study, while comprehensive in addressing all WHO-registered efforts, was limited by the mixed availability of partnership agreements. Many were publicly unavailable, leading to reliance on, e.g., press releases rather than contracts. Partnerships with insufficient information were excluded from analysis. This limitation reflects a broader policy challenge: intellectual property and licensing deals are frequently so opaque as to obscure both policy and governmental analysis. Greater transparency would help understand what is actually on the table and what needs to be done.

Given the positive social externalities that may arise from sharing knowledge, such as greater fundamental understanding, increased cumulative innovation, and the ability to avoid demonstrably unproductive development pathways [40], policymakers should consider interventions to incentivize partnerships that involve such broader knowledge sharing, rather than merely materials transfer for serial innovation. Knowledge-sharing is particularly important for ancillary technology such as manufacturing methods. Setting aside contentious questions about the proper scope of monopolies for underlying products like vaccines or therapeutics, those monopolies, whatever their scope, should be governed by the explicit terms of patents or regulator-managed exclusivity—not the back-door reality that no one else has the knowledge necessary to manufacture a product otherwise available for competitor entry [40,41]. Sharing of any relevant knowledge, including fundamental knowledge, pertinent product-specific information, or ancillary technology, could lead to quicker vaccine development times and to enable sufficient global vaccine production to the benefit of public health [1,42,43].

The most straightforward tools to enhance such knowledge-sharing involve incentives such as public acknowledgement or simply money. In this context, government contracts, especially advance purchase orders, have been essential to de-risk up-front investments in vaccine development and capacity-building. Those contracts, both today and in the future, should include robust knowledge-sharing requirements [43]. Ideally, knowledge-sharing incentives or requirements would reach beyond the entities involved, but as an interim step, requiring knowledge-sharing between engaged parties would at least begin to create knowledge externalities. More drastic steps could include knowledge-sharing mandates tied to regulatory approval for products [44]. Of course, requirements cannot be too draconian, at the risk of decreasing innovation incentives too much on the front end [45].

Other means to facilitate knowledge-sharing include interoperable legal and technical infrastructures. Pools for IP and technology access [8] may be particularly relevant for pandemic responses, though they have received little voluntary update in the COVID-19 context.

Last but not least, it is important to note that collaborations and the selective sharing of commercially sensitive information between direct competitors and companies operating at different levels of the value- and supply-chain might disrupt competition in markets with long-term effects. Antitrust and competition authorities will therefore have to strike a delicate balance between upholding antitrust law, and the need to effectively collaborate in the fight against the pandemic. Where necessary, authorities should further clarify and improve their approaches, guidance and practical support on exceptions from antitrust rules in times of crisis. Companies seeking to collaborate and share knowledge should be enabled to receive confirmation about the legality of their actions as quick as possible. Good examples of such actions are the joint antitrust statement regarding COVID 19 by the US Department of Justice and the Federal Trade Commission [46] and the so-called comfort letters by the EU Commission [47], both clarifying the allowability of exchanging some commercially sensitive information in the COVID-19 context.

The WHO lists 70 diseases with pandemic outbreak potential [21], so while it is relatively late in the game for new requirements in the COVID-19 pandemic, it is especially important that preparedness for future pandemics take into account policies for promoting fair and effective collaboration and knowledge sharing while the lessons of COVID-19 are still fresh. As it becomes clear that the failure to do so has created a global stumbling block for COVID-19 vaccine development, deployment, and equitable access [48,49], it is time to ensure that future collaborations are better equipped and better incentivized to share their knowledge.

Author contributions

LCD contributed to the design of the study; collected, coded, analyzed and interpreted the data; and contributed to the drafting and editing of the manuscript. TM and WNP contributed to the design and interpretation of the study and to the drafting and edit-

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ing of the manuscript. All authors have approved the submitted version.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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