

Researchers propose strategies to speed global vaccine availability

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In a new paper published in the journal *Vaccine: X*, public health experts from Columbia University Mailman School of Public Health, the University of Oslo, and Spark Street Advisors highlight actions to



accelerate access to vaccines globally. The paper reviews the vaccine research and development process and proposes areas where reforms could increase access, speed time to market and decrease costs—from R&D to manufacturing and regulation to the management of incentives like patents and public funding.

The COVID-19 pandemic has highlighted the importance of vaccines as public health and pandemic preparedness tools and amplified the importance of issues ranging from equitable distribution to reliable supply of quality, affordable vaccines. Delays in time from the first dose in a high-income country to introduction at scale in a low-income country can take years. These delays are driven by several challenges, some of which are unique to the vaccine development ecosystem. The authors write that the patenting and overall intellectual property (IP) protection are complex, regulatory oversight is rigorous, manufacturing processes require technical support or know-how transfer from the innovator, and market dynamics create obstacles to delivering at scale. To address these challenges, the authors propose several opportunities to accelerate the availability of vaccines in low and middle-income countries:

1. Regulatory harmonization. Regulatory agencies around the world are increasingly recognizing the need to harmonize their approval process to enable efficiencies to save both time and money—something particularly important with regard to new technologies. For example, mRNA and DNA vaccines have the greatest potential of speeding the development processes, and the recent approval of mRNA vaccine against COVID-19 brings promise for fully establishing regulatory pathways for these innovations. While mRNA vaccines do pose some challenges for low-income settings, in particular their requirement for ultra-cold storages, there are ongoing efforts to try to address this issue, including the establishment of a COVID-19 mRNA vaccine



- technology transfer hub.
- 2. Manufacturing capacity building. In order for vaccines to be deployed quickly and at scale, manufacturing capacity must be in place to allow for sufficient scale up when demand is high. Given the substantial know-how required, access to facilities is not enough; low-income countries and regions must also have sufficient know-how about manufacturing processes. This will require freedom to operate around patents and investment in technology transfer. To face the unprecedented need and opportunity for rapid and massive worldwide availability of COVID-19 vaccines, new business models have emerged with agreements between originator companies and manufacturing companies operating in different geographical and market environments.
- 3. Streamlined IP arrangements. With regard to IP arrangements, biopharmaceutical manufacturers and governments have made use of governmental compulsory licensing, patent oppositions, IP pools and voluntary IP licenses and technology transfer to advance access to new technologies. Although this has been limited in the field of vaccines, improving transparency and creating more streamlined IP arrangements could contribute to increased diversity of supplier which will also help alleviate supply constraints.

"The COVID-19 outbreak and steps that have been taken to speed time to market could act as a catalyst for other vaccines," says senior author Nina Schwalbe, MPH, adjunct assistant professor of Population and Family Health. "While still very much a work in progress, the advancements demonstrated through the R&D of COVID-19 vaccines give promise that many of the challenges to efficient and equitable vaccine development can be successfully addressed with adequate financing and political will."



More information: Ole Kristian Aars et al, Increasing efficiency in vaccine Production: A primer for change, *Vaccine: X* (2021). DOI: 10.1016/j.jvacx.2021.100104

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