
Guaranteeing Equitable Access:

**Considerations
During Vaccine Development
Impacting Global Access**

November 2020



Introduction

This briefing has been developed by the Pandemic Action Network's Ending Barriers to Equitable Access Working Group. The Network is made up of over 40 partners from civil society, the private sector, health agencies, foundations, and media that have come together to fight COVID-19 and ensure an equitable, global response to the crisis. The Network advocates for global, equitable policies to help end the COVID-19 pandemic and to ensure governments and agencies take action now on pandemic prevention and preparedness that can help to halt future pandemics. The working group is focused on issues that could impede equitable access to people in low- and middle-income countries (LMICs) and vulnerable groups in particular.



Equity and ACT-A

The Network's partners are working hard to make sure the Access to COVID-19 Tools Accelerator (ACT-A) is fully funded to ensure that new COVID-19 tools may be able to reach all people who need them, without delay. As we work to help mobilize the US\$38bn needed, we are also committed to help ensure that ACT-A lives up to the promise of global equity, including by making sure that the tools being developed are well suited for LMICs. Suitability for LMICs requires certain characteristics that can differ from requirements

in high income countries with stronger health care systems. **Stakeholders that will ultimately use these vaccines — policymakers, public health officials, and communities — must be engaged early in the R&D process.** Too often, strategic and operational considerations for new vaccine uptake are deprioritized throughout the product's research and development (R&D) lifecycle, risking the development of products that are not suited for use in intended settings and/or will not achieve intended uptake.

Building in equity upstream

What is now also becoming clear is that there are a number of decisions product developers must make during the research, development, manufacturing and delivery stages that can have either staggering positive or negative impacts on global access to vaccines. **A vaccine that may be feasible for implementation in high-income settings may be entirely infeasible for LMICs because of three key differences:**

1. access to public health capacity and infrastructure (e.g., health workers, clinics, supply chain capacity)

2. affordability based on resources and financing mechanisms and

3. competing public health priorities such as continued need to ensure access to other vaccines (e.g., rotavirus, PCV, HCV) and other public health interventions amidst COVID-19 (e.g., WASH, access to essential medicines).

As a result, these decisions on characteristics of the vaccine candidates intrinsically determine who will realistically have access to that vaccine. As Gavi, CEPI and the WHO engage with industry partners involved in research, development, and manufacturing of COVID vaccines, we ask that early consideration be given to product characteristics that can have remarkable impact on equitable access in LMICs. Perspectives from end users and decision makers in LMICs need to be sought and taken into account.

Where to build in equity upstream?

Storage



The 42 candidate vaccines in clinical evaluation as of 2 Oct have **dramatically different storage requirements and associated stability profiles**, including ultra-cold storage requirements. Experiences introducing the RTS,S vaccine for malaria, and the Ebola vaccine in West Africa demonstrate the difficulty of scaling extreme cold-chain systems to cover the last mile—a challenge that would be even more present for COVID-19 given the number of vaccines that need to be delivered. Even stakeholders in high income countries have expressed concerns about making a vaccine available that will require ultra-cold chain systems. Prioritizing such (typically RNA-based) candidates dramatically limits access, especially in LMICs, due to supply chain difficulties. We note the recent decision by the Gavi Board not to invest in ultra-cold chain systems and the impact that will have on access to vaccines in LMICs, should those vaccines be the first that become available.

Dosage



The ideal vaccine is a single dose, however **the vast majority of vaccines in clinical evaluation as of 1 Oct require two doses**, which will also dramatically increase pricing given that countries will pay per dose.

Protective periods



As global decision makers prioritize which vaccines go forward, it is imperative that they also weigh the **benefits of vaccines with shorter protective periods that are easier to develop and produce**, with the logistical and health systems impacts of deploying these vaccines in LMIC settings.

Components and packaging



Global shortages of medical-grade glass, syringes (and syringe components) are a concern in the manufacturing and distribution of COVID-19 vaccines. Alternative packaging such as multi-dose ampules, blow-and-fill ampules, and multi-dose pouches exist and are potentially cheaper and more easily produced, but run the risk of incurring the need for significant retraining of health workers and lack of community acceptance given that they are considerably different from existing approaches used in LMICs.

Deal terms and distribution



It is vital that as countries sign up to the vaccines pillar of the ACT-A (COVAX), the spirit of ensuring equitable access for all is captured in the **legal details brokered between different stakeholders.** Allowing different, and potentially preferential, terms for different investors would undermine the central premise of ACT-A. The principles of equitable access, as well as what is needed to end this pandemic in the quickest way, must be taken into account in the upstream design of the distribution mechanisms and allocation frameworks that will guide how these vaccines will be dispersed across the world.

Vaccine characteristics to be considered¹

Decision/ Characteristic

Impact on Access

Indications and contraindications for use

Not all vaccines are appropriate for all populations; some may not be appropriate for immunocompromised patients, for example. The decision to pursue a candidate with this restriction would deny those populations access.²

Target populations

Similarly, not all vaccines are appropriate for general population use, including in pregnant or lactating women, or the elderly.³ Failure to include key populations (like children) in clinical trials will also delay access.⁴

Target efficacy and associated dosing

Previous vaccine development has shown that not all vaccines can achieve 70%+ efficacy especially with a single dose, which may require undertaking multiple-dose administration with the associated increased costs and supply chain requirements. As a result, greater aggregate population protection may be provided by opting for a single dose approach even if it provides a lower level of protection.

Durability of protection

The ideal vaccine is a single dose that confers highly effective, lifelong protection. Unfortunately such vaccines require extensive development and may not be available for some time. As a result a vaccine providing a shorter protective period that is easier to develop and produce may provide greater public benefit, though this will need to be balanced with the logistical and health systems impacts of constant immunization campaigns if protection is too short.

Route of administration

Historically, industry has viewed the single-use, pre-filled ampule and single-use auto-disable syringe as the “gold standard” for immunization programs in LMICs. Unfortunately this approach is highly resource-intensive and supply constraints on medical-grade glass and syringes may make this impractical for the current pandemic. In addition this approach would produce a monumental amount of biohazard waste.

Stability and storage requirements

Different vaccine technologies have dramatically different storage requirements and associated stability profiles. For example, the Ebola outbreak has demonstrated the difficulty of scaling extreme cold-chain systems to cover the last mile. Prioritizing such (typically RNA-based) candidates might enable easier administration from an increased efficacy/reduced dosing perspective, but dramatically increase barriers to access due to supply chain difficulties.

1) These characteristics are adapted from the COVID-19 vaccine target product profile developed by WHO: <https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines>

2) These decisions relate directly to the risk/benefit calculation for those specific populations and potential benefits vs. potential risks of continuing disease transmission.

3) See above 4) <https://downloads.aap.org/DOFA/AAPLettertoHHSandFDAChildreninCOVID19VaccineTrials.pdf>

Questions that need to be answered

Decisions on these product characteristics are happening now. There is an urgent need to consult stakeholders that can weigh in on aspects of vaccine design, and on other aspects of building equity in to COVAX processes upstream in order to maximize widespread access. There are several urgent questions that need answers on a range of issues. The key questions in terms of product development include the following:



Where and how are decisions about vaccine candidates, administration/delivery specifications, storage and packaging being made?



What decisions have already been made about the target product profiles and allocation for vaccines that will be scaled up through the COVAX Advance Market Commitment?



How are the views of public health officials, implementers and communities in LMICs actively being sought and included in these decisions?



How is this feedback being provided to vaccine manufacturers?



How do COVAX contracts with member countries and companies impact the availability of different vaccines to different countries and how is equitable access guaranteed, including through the allocation framework?

Conclusions and next steps



It is clear from the number of considerations that need to be taken into account that **careful planning needs to go into upstream decisions** to make sure LMICs and vulnerable populations are not disenfranchised downstream when tools come onstream. Although many early decisions have been taken, we have some time before the distribution

of vaccines will be a reality, and **it is imperative we work together across civil society and the private sector, across governments and international institutions and with those on the ground** who will have to deliver the tools and the vaccines to make sure ACT-A and COVAX live up to the promise of equitable access for all.