POSITION PAPER FOR CONFERENCE AT MIT, DEC 2020

Vaccines for All: Challenges and Potential Solutions for Equitable COVID-19 Vaccine Distribution

Joseph Bae[4,6], Susan Blumenthal[2,3], Jagjit Dhaliwal[1], Shirley Bergin[2], Sanjay Sarma[1,5] and Ramesh Raskar[1,2,4*]

[1]Massachusetts Institute of Technology, 02139 Cambridge, USA.
[2]MIT Media Lab, 02139 Cambridge, USA.
[3]New America, 20005 Washington, D.C., USA.
[4]PathCheck Foundation, 02139 Cambridge, USA.
[5]MIT Auto-ID Labs, 02139 Cambridge, USA.
[6]Renaissance School of Medicine, Stony Brook University, 11794 Stony Brook, USA

*Correspondence:
https://web.media.mit.edu/∼raskar/
[2]MIT Media Lab, 02139 Cambridge, USA
Full list of author information is available at the end of the article

Abstract

As several COVID-19 vaccine candidates are being approved for human use, governments around the world are preparing comprehensive frameworks and protocols to address potential obstacles for equitable distribution. In this paper, we identify challenges for vaccine distribution in four core areas - supply chain logistics, monitoring of health outcomes, recipient engagement, and public health communication. Inequitable vaccine allocation, variation in vaccine efficacy and the duration of immunity, barriers to multi-dose adherence, and widespread misinformation are among the most critical issues that must be addressed. While many of these challenges have been previously identified and planned for, some have not been thoroughly addressed to target the needs of diverse population groups for which significant health disparities have been identified.

To address these challenges, governments and private sector corporations have partnered to develop public health policies, vaccine administration frameworks, and technological solutions. In this paper we describe both traditional and modernized solutions to challenges in vaccine distribution and compare the merits of each approach. We firmly believe that privacy-oriented, interoperable digital solutions can help ensure the equitable distribution of vaccines for all.

Keywords: COVID-19; Vaccines; Healthcare information management; Privacy

1 Introduction

As of late 2020, the World Health Organization (WHO) reported 164 COVID-19 vaccine candidates in preclinical evaluation and 48 undergoing clinical trials, with several nearing approval for widespread distribution [1, 2, 3]. The use of new vaccine technologies including mRNA and adenoviral vector platforms, government programs and funding such as that provided by the United States' Operation Warpspeed, and international collaborations such as the COVAX initiative are largely responsible for the remarkable speed at which new COVID-19 vaccines have been developed [4, 5, 6, 7].

Nonetheless, the development of a COVID-19 vaccine is only the first step to widespread public vaccination. Difficulties in equitable distribution, thorough monitoring of health outcomes in diverse population groups, individual engagement, and transparent public messaging are four general categories of challenges that must be addressed as COVID-19 vaccines are made available to the public.

Comprehensive solutions to several of these critical challenges are still being developed, and unanswered questions still remain due to the unprecedented circumstances of global vaccine distribution and monitoring. In this paper we describe several key challenges to equitable vaccine distribution and detail the relative strengths and weaknesses of a variety of solution approaches. It is hoped that these insights might help inform government strategies to ensure equitable vaccine distribution for all.

2 Challenges to Equitable Vaccine Distribution

Equitable Vaccine Distribution: User-Centric Challenges

Logistics	Health Outcomes	Citizen Engagement	Communication
Equitable prioritization Cold chain storage and transit	Effectiveness and safety monitoring for diverse populations Long-term effects of vaccines using new platforms	Two-dose adherence Privacy of individual data aggregation and reporting Vaccine passports	Societal mistrust History of medical discrimination for minority populations Rumors and misinformation

Figure 1 Summary of user-centric challenges to equitable vaccine distribution.

2.1 Challenges in Reaching Recipients

The global vaccination of individuals will require coordination between nations, corporations, and non-profit organizations. Three logistical challenges to this process are described below, with a significant emphasis on their consequences for the equitable distribution of COVID-19 vaccines.

2.1.1 Production

The international demand for COVID-19 vaccines is projected to outpace vaccine production for several years [8, 9]. In light of these supply shortages, international organizations including Gavi, the Coalition for Epidemic Preparedness Innovations, and the WHO have partnered to launch the COVAX initiative to "accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world" [5]. However, current approximations still suggest that 32 wealthy countries accounting for about 17% of the world's population have already purchased up to 50% of the available COVID-19 vaccine doses expected to be produced through the end of 2021 [8]. This inequity in vaccine distribution is reminiscent of similar historical disparities such as those observed in the H1N1 pandemic [10, 11].

2.1.2 Prioritization

Most proposed frameworks for COVID-19 vaccine distribution suggest that healthcare workers as well as long-term care facility residents and caregivers should be the first to be vaccinated, but plans diverge from that point [12, 13, 14, 15]. Future eligibility criteria must be carefully structured to be inclusive and equitable, addressing socioeconomic disparities in prioritization.

Once vaccine prioritization guidelines are established, privacy-focused processes must also be developed for confirmation of an individual's eligibility for vaccination if this eligibility is contingent upon occupational status or protected health information/pre-existing medical conditions.

2.1.3 Distribution

The distribution of hundreds of millions of vaccines across countries will require careful coordination between regional and national governments, vaccine manufacturers, shipping companies, and, in some cases, non-profit organizations. Furthermore, many COVID-19 vaccines in development will require storage at subzero temperatures including those developed by Pfizer and Moderna which require storage at -80°C and -20°C, respectively [16, 17]. The complexity of widespread vaccine distribution and the necessity for cold storage necessitates the monitoring and tracking of COVID-19 vaccine shipments to ensure efficient allocation and proper storage throughout transit.

Shortages of dry ice and appropriate refrigeration equipment will pose challenges to all in distributing COVID-19 vaccines, but threaten to most significantly influence low-resource areas in the U.S. and developing countries [18, 19, 20]. This can potentially widen health outcome disparities should vaccines be rendered less effective by these storage conditions. Furthermore, there have been recent concerning reports of phishing and data attacks on vaccine distribution and cold chain companies, indicating the importance of secure systems across the entire pipeline of vaccine distribution [21, 22].

2.2 Challenges in Empowering Recipients to Report Health Outcomes

The rapid development of COVID-19 vaccines has included the use of mRNA and adenoviral vector vaccine platforms, technologies that have not previously been approved for widespread use in humans [7]. While Phase III clinical trial data for both Moderna and Pfizer's mRNA vaccine candidates have produced exceptional results with reported efficacies of greater than 90% each, it is important that effective monitoring systems be put in place to evaluate the long-term performance and potential side effects of novel COVID-19 vaccines [2, 3, 4].

2.2.1 Efficacy

Despite the encouraging results of Phase III clinical trials for several COVID-19 vaccines, there remains the possibility for discrepancies between those results and real-world or Phase IV data [23, 24]. This challenge might be more significant for adenoviral vector vaccines for which differing levels of pre-existing vector immunity may be a concern [25, 26]. Furthermore, certain populations such as such as children, immunocompromised individuals, and pregnant women were not thoroughly represented in Phase III trials, and it is possible that effectiveness of COVID-19 vaccines might differ in these populations [27, 28]. The fact that safety and efficacy have not yet been evaluated for any current COVID-19 vaccines in children under the age of 16 presents significant hurdles to in-person schooling and a return to work for parents [27]. Supply chain errors could also result in less effective vaccines being distributed to certain populations and geographies. Effectiveness monitoring systems must be implemented to identify discrepancies in vaccine efficacy among diverse populations as they occur so that they may be corrected when possible.

Finally, whether novel COVID-19 vaccines prevent asymptomatic COVID-19 infection and disease transmission remains to be studied; primary endpoints for both the Moderna and Pfizer Phase III clinical trials were the prevention of symptomatic or clinically apparent infection by COVID-19 [2, 3, 4]. Further studies must be performed to determine whether these vaccines are effective in reducing asymptomatic COVID-19 infection before public health policies including mask-wearing, social distancing, and other practices are relaxed [4].

2.2.2 Duration of Immunity

Because Phase III studies for COVID-19 vaccines have thus far taken place over the course of several months, the duration of immunity conferred by these vaccines is unknown [2, 3, 29, 30]. It is possible that this duration may differ among diverse population groups, particularly in the case of seniors due to the process of "immunosenescence" [31].

2.2.3 Side Effects

Concerns regarding side-effects rank among the most significant deterrents to vaccine hesitancy in the United States [32]. Previously, mRNA vaccines have been observed to rarely cause severe reactogenic effects including autoimmune complications, systemic inflammation, and flu-like illness [33]. Recent anaphylactoid reactions reported for two individuals among the first to receive Pfizer's COVID-19 vaccine in the United Kingdom underscore this issue, and have prompted the Medicines and Healthcare products Regulatory Agency to issue new guidelines cautioning against the vaccination of those with a history of severe allergic reactions [34]. Adenoviral vector vaccines have also previously been shown to cause potentially concerning side effects. Two previous vaccines using this platform were shown to increase susceptibility for HIV infection in clinical trials, something that must be accounted for in the development and monitoring of COVID-19 vaccines using the same platform [35, 36]. Finally, findings in other diseases and COVID-19 animal studies have described the possibility for vaccine-enhanced infection in COVID-19 [37].

2.3 Challenges in Vaccine Recipient Engagement

A recent study found that as many as 49% of Americans might be unwilling to receive a COVID-19 vaccine [32]. In order to increase this proportion, care must be taken to develop guidelines and solutions emphasizing individual privacy and health outcomes.

2.3.1 Vaccine Incentives and Motivation

Governments choosing to implement either positive or negative reinforcement strategies to motivate individuals towards vaccination must carefully balance public health goals against individual freedoms [38]. Increasing the proportion of the population that has been immunized against COVID-19 carries with it clear public health benefits, but care must be taken not to mandate vaccination for individuals such as those with certain medical conditions that might undermine safe immunization [13].

2.3.2 Follow-up Tracking and Multi-Dose Reminders
Many COVID-19 vaccines in development will require two-dose vaccination schedules to achieve full immunogenecity [39]. Effective recipient reminder protocols must be established to ensure that individuals receive the appropriate second dose of a COVID-19 vaccine.

2.3.3 Data Privacy
Multiple vaccine distribution and administration systems have been developed by both private and public sector entities [40, 41, 42, 43, 44, 45]. In some cases, the organizations producing these tools have not yet publicly disclosed the privacy guidelines in place for the use and protection of private individual information.

Data privacy concerns also exist for potential digital health passport technologies [46, 47]. As immunization status and eligibility for vaccination constitute individual health information, it is important that these passport technologies emphasize security and privacy to prevent the potential for discrimination [48].

2.4 Challenges in Communication
The unprecedented nature of the COVID-19 pandemic and vaccine development require clear communication between governments, companies, and the public. In the United States, mixed stances by government officials and healthcare experts have resulted in uncertainty and fear [49]. A greater emphasis must be placed on cohesive, transparent messaging by national and local officials and influencers.

2.4.1 Trust
Recent studies have shown that up to 49% of the United States population are not inclined to receive a COVID-19 vaccine and that individuals are less likely to accept a COVID-19 vaccine under FDA emergency use authorization (EUA) rather than full FDA approval [32, 50, 51]. These concerns can be partially assuaged by widespread and transparent communication concerning the improvements in technology, dramatically increased funding, and governmental protocols that enabled the rapid development and approval of COVID-19 vaccines [4, 6, 52].

Polls have also suggested that minority populations such as black Americans are among those least likely to choose to be vaccinated for COVID-19 due to mistrust in healthcare systems that have previously discriminated against them [32, 53]. Additional fears exist for marginalized populations for whom early vaccine prioritization might appear to be vaccine experimentation [54].

Finally, the importance of continued adherence to public health measures including mask-wearing and social distancing following COVID-19 vaccination must be conveyed to the public [4].

2.4.2 Misinformation

In the United States, the Trump administration has been criticized for opposing public health officials on practices such as mask-wearing [49]. Furthermore, several physicians expressing anti-masking and anti-quarantine views have fueled resistance to adherence to public health guidelines [55]. Misinformation spread on social media has also been a significant contributor to anti-vaxer beliefs, and continues to proliferate in the setting of COVID-19 [56, 57, 58].

3 Developing Solutions

3.1 Traditional Solutions

3.1.1 General Population Solutions

Solutions that are not specifically targeted to individuals including public broadcasting, national hotline implementation, and advertisement campaigns are one approach to address challenges in vaccine distribution. Public service announcements across traditional media platforms including television, SMS, billboards, etc. might be employed to inform the public of vaccination prioritization frameworks and distribution locations. They might also be used to advertise and incentivize immunization and adherence to second-dose vaccination while providing further education regarding COVID-19 vaccines. A national hotline could be instituted for adverse event and efficacy reporting, enabling the short and long-term monitoring of health outcomes.

These approaches preserve individual privacy and are extremely accessible to all individuals in a population. However, they are also non-interactive and potentially less effective when compared to other methods that might more effectively engage individuals.

3.1.2 Paper-Based Solutions

In order to confirm eligibility for vaccination during different prioritization phases, the use of either employee IDs or government provided eligibility forms could be instituted. Vaccination records and second-dose reminders might be recorded on physical cards similar to those commonly used for pediatric immunization schedules. These could also serve as proof of vaccination or immunity passports.

Paper-based solutions to vaccine administration challenges are simple and accessible. While generally privacy-preserving, personal information might be compromised if physical records are lost and are then inaccessible for proof of vaccination. Furthermore, there is the potential for the development of counterfeit record and identification cards.

3.2 Digital Solutions

3.2.1 Web Solutions

Centralized, web-based systems including the Vaccine Administration Management System (VAMS) developed for the CDC have the potential to comprehensively monitor and record the vaccine administration pipeline [59]. At least 12 states have agreed to implement VAMS and it is likely that others will follow suite [60]. VAMS facilitates both vaccine logistics and inventory management for clinics as well as vaccine administration details for individuals. Individual contact, demographic, and medical history information is all stored in VAMS as well as details regarding employment, vaccination status, and insurance information [61].

Vaccine Solution Platforms to Empower Citizens			
Broadcast	**Paper/Card**	**Web**	**Smartphones and Apps**
Public service announcements	State ID to validate priority vaccination status	Centralized data collection and monitoring systems	SMS alerts
National hotlines for adverse event reporting	Immunization cards and reminders	V-Safe and Vaccine Adverse Event Reporting System (VAERS)	Decentralized privacy-preserving apps for scheduling, reminders, vaccine verification and crowdsourced safety reporting
	Digitally-signed QR code printouts	Vaccine Administration Management System (VAMS)	

Figure 2 Vaccine solution platforms to empower citizens.

Systems have also been developed for health outcome reporting including the Vaccine Adverse Events Reporting System (VAERS) [62]. This system enables the monitoring of any adverse effects and events in vaccinated populations and is accessible to both healthcare providers and individuals. VAERS serves as a centralized repository of adverse events for vaccines and has been in use since 1990 [62].

Systems such as VAMS and VAERS are powerful tools for monitoring and facilitating the distribution of vaccines in the United States. They are centralized systems that collect data at a national level, enabling the identification of country-wide problems and trends. Furthermore, they perform multiple functions and leave little room for ambiguity or user error. Despite these benefits, both state officials and private parties have expressed concerns over the volume of data reported to centralized vaccine monitoring systems [20, 63, 64]. Even if appropriate measures are taken to secure this personal information, its collection might serve as a deterrent to vaccination for many individuals.

3.2.2 App Solutions

App-based solutions for vaccine distribution and monitoring might serve as an individual-centric approach to many of the challenges outlined above. A mobile application would mirror the functionality of web-based solutions while storing user data on an individual's device rather than a centralized repository. Verification for vaccine eligibility in various roll-out phases, appointment and multi-dose reminders, adverse event reporting, and immunity records could all be stored locally on a user's device, while securely reporting de-identified data for population-level data accrual.

App solutions benefit from being accessible and engaging to the general population. They have the potential to provide all relevant information to an individual in one platform. Furthermore, app solutions can be developed in a privacy-focused manner, avoiding the collection of sensitive personal information in large centralized data repositories. While this does not eliminate the possibility for attack on individual users' information, it does lower the probability of mass user data compromise. However, despite privacy-oriented design and implementation, app solutions may be inaccessible for certain populations and might still be mistrusted by the public if educational messaging is not effectively performed.

4 Conclusion

Even as several COVID-19 vaccines approach approval for widespread use, key challenges remain to their equitable distribution. In this paper we have highlighted several of these challenges and have analyzed them for their potential consequences on individual health outcomes among diverse population groups.

As technology continues to be more fully integrated with public health practices, we believe that future digital solutions should be developed with an emphasis on individual engagement and participation. This approach ensures the prioritization of individual health outcomes, with the potential for concomitant improvements in community public health. We believe that these decentralized systems can be created in a privacy-focused manner, ensuring that an individual's data is protected while also enabling large-scale monitoring of vaccine effectiveness and side effects. In the meantime, proven public health measures including mask-wearing, social distancing, and hand-hygiene must be encouraged both before and after COVID-19 vaccination.

Global cooperation and advances in technology have resulted in the rapid development of very efficacious COVID-19 vaccine candidates. The same forces must now be harnessed in a transparent, privacy-oriented manner to ensure the equitable and effective distribution of lifesaving COVID-19 vaccines for all.

Competing interests
The authors declare that they have no competing interests.

Acknowledgements
We are grateful to Riyanka Roy Choudhury, CodeX Fellow, Stanford University, Adam Berrey, CEO of PathCheck Foundation, and Paola Heudebert, co-founder of Blockchain for Human Rights for their assistance in discussions, support and guidance in writing of this paper.
We also thank Darshan Gandhi, Jil Kothari, Sheshank Shankar, Jonah Bae, Vivek Sharma, Parth Patwa, Rohan Sukumaran, Sethuraman T. V., Vanessa Yu, Himi Mathur, Maurizio Arseni, Thomas Kingsley, Krutika Misra, Srinidhi Murali, Kasia Jakimowicz, Rohan Iyer, Ashley Mehra, Alex Radunsky, Priyanshi Katiyar, Sunaina Anand, and Shailesh Advani for their contributions.

Author details
[1]Massachusetts Institute of Technology, 02139 Cambridge, USA. [2]MIT Media Lab, 02139 Cambridge, USA. [3]New America, 20005 Washington, D.C., USA. [4]PathCheck Foundation, 02139 Cambridge, USA. [5]MIT Auto-ID Labs, 02139 Cambridge, USA. [6]Renaissance School of Medicine, Stony Brook University, 11794 Stony Brook, USA.

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