RESEARCH

Challenges of Equitable Vaccine Distribution in the COVID-19 Pandemic

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Abstract

As several COVID-19 vaccine candidates approach approval for human use, governments around the world are preparing comprehensive standards for vaccine distribution and monitoring to avoid long-term consequences that may result from rush-to-market. In this early draft article, we identify challenges for vaccine distribution in four core areas - logistics, health outcomes, user-centric impact, and communication. Each of these challenges is analyzed against five critical consequences impacting disease-spread, individual behaviour, society, the economy, and data privacy. Disparities in equitable distribution, vaccine efficacy, duration of immunity, multi-dose adherence, and privacy-focused record keeping are among the most critical difficulties that must be addressed. While many of these challenges have been previously identified and planned for, some have not been acknowledged from a comprehensive view to account for unprecedented repercussions in specific subsets of the population.

The logistics of equitable, widespread vaccine distribution in disparate populations and countries of various economic, racial, and cultural constitutions requires careful planning and consideration for global vaccine success. We also describe unique challenges regarding vaccine efficacy in specialized populations including children, the elderly, and immunocompromised individuals [1, 27]. Furthermore, we report the potential for understudied drug-vaccine interactions as well as the possibility that certain vaccine platforms may increase susceptibility to HIV infection [77, 14]. Given these complicated issues, the importance of privacy-focused, user-centric systems for vaccine education and incentivization along with clear communication from governments, organizations, and academic institutions is imperative. These challenges are by no means insurmountable, but require thorough consideration to avoid consequences that span a range of disease-related, individual, societal, economic, and security domains.

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

1 Introduction

The severity of the COVID-19 pandemic has ushered in an unparalleled period of rapid vaccine research and development as the pandemic continues its international spread. As of November 17, 2020, the WHO reports 48 vaccines in clinical evaluation and 164 candidates in preclinical evaluation [73]. If any number of these vaccine candidates is approved for widespread use, we anticipate multi-level challenges in distribution, access, clinical outcomes, patient compliance/privacy, and communication. In this work, we divide this cluttered landscape of challenges into four distinct categories: those challenges involving logistics, health outcomes, user-centric issues, and communication. We further examine the consequences of these challenges, focusing on their impact on disease spread, individual behavior, society, the economy, and data privacy. The world's manufacturing processes and supply chains are underprepared for the task of widespread vaccine distribution. Currently, complete frameworks and pipelines for vaccine allocation, distribution, and administration have not been fully developed in all countries internationally, and early proposals fail to account for all potential challenges and obstacles to equitable vaccine coverage.

Furthermore, there exist many challenges in assessing the effectiveness of a vaccine and its long term effects on health outcomes. The relative novelty of leading vaccine candidate platforms cause concerns regarding their long-term efficacy and side effects, and the incredible speed of their development must be supplemented by long-term followup of vaccinated individuals.

There also exist several challenges surrounding user privacy and behavior in the setting of COVID-19 vaccination. Concerns surrounding individual mistrust, the importance of booster vaccination, and data privacy all must be addressed.

Finally, several challenges arise in proper communication of vaccine information between governments, companies, and the general public. In the current era of misinformation, mass superstition, and the politicization of science, clear and transparent communication will be vital to the success of widespread vaccination.

In this early draft, we explore in-depth the various challenges associated with vaccine development and administration in the COVID-19 pandemic. We also provide insight into the consequences of failing to overcome these obstacles, and highlight the need for comprehensive digital solutions.

	Logistics	Health Outcomes	User Centric	Communication
Current Approaches	Visibility into Manufacturing, Shipping Interoperability	Aggregate Monitoring and Evaluation	Awareness Behavior Nudges, Incentives	Timely and Customized Messaging
Difficult Challenges	Cold chain Prioritization of regions and high-risk users Equitable access	Efficacy: Durability Safety: Side effects, adverse reactions Spread by vaccinated user to others	Multi-dose adherence Privacy of user data Trust in safety Health Passports	Political interference Social Media messaging/ distrust

Figure 1 Summary of challenges in vaccine distribution.

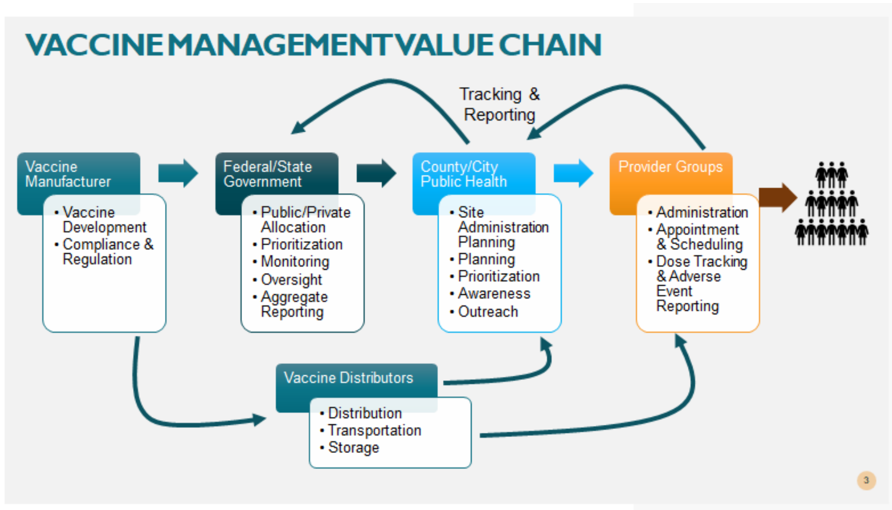

Figure 2 A generalized pipeline for vaccine distribution. Challenges can arise at multiple points within this process.

2 Background

2.1 The Landscape of Vaccine Development

The current progress in COVID-19 vaccine development can be attributed to both advances in vaccine technologies as well as to historically unparalleled international support and cooperation. In the United States, the Trump administration implemented Operation Warpspeed, a program designed to optimize vaccine regulatory tracts, fund vaccine development, and begin vaccine manufacturing even before approval for distribution [39]. International organizations Gavi, the Coalition for Epidemic Preparedness Innovations and the World Health Organization have partnered to launch the COVAX initiative, aimed at making vaccines accessible and distributable to all nations [34]. These efforts have contributed to the success of several recent vaccine trial outcomes including Pfizer and Moderna's recent Phase III trials with reported efficacies of greater than 94% for each vaccine candidate [46, 56]. However, challenges still remain in the production, distribution, and monitoring of these and other COVID-19 vaccines.

2.2 Challenges Identified by the Biden Administration

President-elect Joe Biden has already established a COVID-19 taskforce that has outlined a general approach for the new administration's efforts in combating the pandemic [10, 9]. The Biden team references important issues in restoring public trust in science through transparent and educational dialogue, making vaccine availability equitable among different demographics and economic classes, and ensuring transparency in the determination of efficacy and safety of vaccines. However, other challenges remain unaddressed. It is our hope that the present work provides further detail into the many challenges facing widespread vaccine distribution as well as the consequences if those challenges remain unmet. These insights might supplement the future presidential administrations approach to vaccine distribution.

2.3 Challenges in Vaccination for Previous Infectious Diseases

The development of vaccines in the setting of previous epidemics and pandemics have encountered numerous challenges including the advent of viral antigenic shifts and drifts, coordination and communication, and pre-existing health issues.

Viral antigenic shifts and drifts occur when a virus strain changes over time, causing a current vaccine to be rendered less effective. Antigenic shifts generally are defined as dramatic, radical genetic changes whereas antigenic drifts occur gradually over time [19]. For example, the H1N1 virus underwent an antigenic shift in 2009 enabling it to have much quicker spread when compared to the H1N1 virus observed in 1918 [19]. These changes to a virus can make it much harder to vaccinate, as new vaccines often must be developed for every change. Additionally, if a virus shifts during vaccine production (a scenario which could apply to SARS-CoV-2), the entire development of a vaccine will be thrown off and much research rendered obsolete.

Another obstacle for vaccine development is coordination and communication: both on a national and international scale. When dealing with widespread pandemics, it is essential that response forces coordinate together to resolve the pandemic. The importance of coordination was seen in the H1N1 pandemic of 2009, in which communication proved to be both a strong point in the global response and a weak point. Many response forces such as the DOC were successfully activated and international collaboration did occur. However, many of the challenges imposed by the H1N1 pandemic also stemmed from miscommunications. For example, the WHO (who was largely responsible for global coordination) was criticized for not taking into consideration research from multiple groups. Due to this, vaccine testing was somewhat crippled, especially in phases 4 and 5 where the WHO convened with only a subset of their committee [32]. There was also ineffective public communication, with a lack of media reports during phase 6 of the testing [32].

While communication can be easily facilitated in countries with large scale mass media, it is not so easily done in less developed countries with fewer communication resources. In some cases, these countries might rely on direct human communication of medical news and guidelines. The H1N1 pandemic also highlighted the importance of observing infection and vaccination in multiple populations. For instance, it was observed that the H1N1 virus' effect on pregnant women was quite severe, and safe vaccination of pregnant women was therefore made a priority [69]. Many of these challenges are also applicable to the future of COVID-19 vaccination development and deployment.

3 Logistics

The complexity of planning the production, allocation, distribution, administration, and monitoring of large quantities of a COVID-19 vaccine pose both obvious and non-obvious challenges. Of utmost importance is that these challenges are addressed equitably with an understanding of the intersectionality between uniform, large-scale logistical challenges and the varied landscape of governments and populations. We have identified five key logistical challenges that must be addressed for a proper global recovery from the COVID-19 crisis.

3.1 Challenges

3.1.1 Production

Despite large levels of government and outside funding, the demand for COVID-19 vaccines internationally outstrips current supply chains. In America, the CDC has indicated that a COVID-19 vaccine may not be widely available to the general public until the middle of 2021[45]. The proper allocation of the limited number of vaccines that will initially be available in addition to the need for increased manufacturing capability are two obvious challenges that must be addressed.

3.1.2 Prioritization

Most frameworks for vaccine distribution suggest that healthcare workers should be the first to receive a potential vaccination, but plans diverge from that point. Organizations including the National Academy of Health, the WHO, and others all have developed their own allocation guidelines [48, 75]. A current CDC framework for vaccine distribution does exist, but is limited due to ambiguity in how efficacious novel vaccines might be and how many might be available in initial phases [17].

Once thorough guidelines are adopted within a given jurisdiction for vaccine distribution, additional challenges may arise in confirming the eligibility of an individual for vaccination. For instance, if an occupational group or individuals with pre-existing conditions are designated for early vaccination, it can be difficult to confirm an individual's eligibility without overstepping privacy concerns or causing undue logistical burdens. Current medical record systems in the US are non-uniform, making the confirmation of an individual's pre-existing condition status difficult. Furthermore, there are data and privacy concerns that must be considered when distributing vaccines on the basis of health statuses or conditions. This is especially relevant in settings where a patient's information must be stored in order to facilitate follow-up booster vaccination events or monitoring of long-term side effects.

3.1.3 Distribution

There are anticipated difficulties in the pipeline to properly store and distribute a COVID-19 vaccine. The "cold chain" references the necessity for some COVID-19 vaccines that are currently undergoing clinical trials (including those developed by Pfizer and BioNTech) to be stored at sub-zero temperatures during both transport and shortage [63]. Often, dry ice is relied upon in each of these processes, and there is some concern that the US will experience dry ice shortages during the distribution of these vaccines [66]. Pharmaceutical-grade glass vials capable of withstanding sub-zero temperatures might also experience shortages in this setting [66]. In some countries, storage facilities may lack vaccine-qualified refrigerators, potentially greatly affecting the efficacy and storage life of vaccines [38]. Furthermore, a proper data framework is not in place to monitor the transport and storage conditions of vaccines distributed widely across multiple countries, and it may be difficult to ensure that a shipment of vaccines has been properly stored throughout transit. This is especially important in the setting of international shipping of vaccines in which storage conditions can be more difficult and costly to maintain.

In the US, it is more than likely that vaccine transport will rely heavily on shipping companies including UPS and FedEx due to their previous experience in transporting vaccines for illnesses such as the seasonal flu [66]. However, populations that might be most prioritized for vaccination (health-care workers, elderly, those with serious comorbidities, etc.) are not evenly distributed across the US [71].This can pose a challenge in determining where best to allocate vaccine doses and how to properly enact that distribution. An enormous challenge will be the proper coordination of local, state, and federal agencies with manufacturers and shipping companies to ensure proper distribution of vaccines across the country. Improper digital or technological pipelines leave open the opportunity for errors in the proper tracking and transport of vaccine shipments, potentially creating scarcities and surpluses if vaccines are not properly routed to their intended destinations. This is particularly concerning in countries where inconsistencies in internet, satellite, and data storage infrastructure might prevent centralized monitoring of vaccine distribution.

There also exists issues in determining where and whom should be responsible for vaccination of the general public. In developed nations such as the United States, existing healthcare and pharmaceutical infrastructure will likely be relied upon for dissemination of vaccines. However, issues still remain as to the responsibility of vaccination administration to specific populations such as indigenous populations, federal employees, etc. [63]. In developing nations, sufficient levels of centralized vaccination locations for large swathes of the population may not exist. In these cases, an appropriate vaccination framework must be developed. Mass-transit of individuals from remote locations to centralized urban centers for vaccination can have dire consequences for disease spread, but a failure to provide access to vaccines might also marginalize these populations. In these countries, another difficulty may arise in monitoring the mobility of individuals who are constantly migrating. This challenge is compounded in monitoring vaccine distributions in countries where large segments of the population cannot be identified by a standardized identification or address [47, 4].

3.1.4 Equity

Equitable distribution of a potential COVID-19 vaccine is an enormous challenge. This has been highlighted previously in the distribution of the H1N1 vaccine [65]. Economic and racial disparities in vaccine distribution can be exacerbated by inappropriate or unequal eligibility criteria, and it is imperative that government institutions ensure that appropriate guidelines are in place to prevent these disparities. Equitable distribution of the vaccine can also be a challenge on the international scale, as wealthier and more influential nations may have increased access to limited vaccine doses. Prohibitive costs might bring these national differences in vaccine access into sharp focus. Previous data demonstrates discordances in vaccination rates along economic lines both dependent on individual wealth within countries and national wealth on the international stage. Wealthier individuals and nations tend to have higher rates of vaccination whereas less wealthy entities tend to have lower rates [44, 16].

3.1.5 Record Keeping/Follow-up

Following vaccine administration, obtaining and maintaining secure and thorough records for patients will pose several challenges. These records are crucial in understanding which segments of the population have been vaccinated to guide distribution as well as public health policy. Furthermore, these records might be used to monitor long term efficacy and sequelae of vaccination while also ensuring compliance to the two dose regime currently employed by most vaccine candidate frontrunners. Secure, universal, and accessible health information storage systems are in short supply, and the development of such a system for COVID-19 vaccination recordkeeping will be an enormous challenge. However, proper implementation of such a framework can have enormous societal and individual benefits.

3.2 Consequences

While the primary effects of unaddressed logistical consequences are plainly ineffective distribution of vaccines, there are nuanced complications surrounding equity affecting multiple spheres of public life. These consequences must be evaluated, and plans must be put into place to alleviate their effects should they become realized.

3.2.1 Disease Spread

A lack of proper digital frameworks to monitor vaccine allocation, distribution, and storage may result in inefficient vaccination of populations, leading to preventable disease transmission. Vaccines that are lost, transported to incorrect geographic locations, or rendered ineffective by improper storage conditions are wasted tools to combat the spread of COVID-19. Furthermore, inadequate monitoring systems can dramatically hinder investigative procedures into vaccine distribution or storage errors, allowing supply chain issues to persist longer than necessary.

3.2.2 Individual Behavior

A few primary consequences might be observed in individual behavior due to inadequate logistical preparation for COVID-19 vaccine distribution. First, individuals in areas where supply chain errors cause reduced vaccine availability will simply be less able to receive a COVID-19 vaccine. These individuals might then be less likely to obtain a vaccine when supply shortages are corrected in their area due to a desensitization from the necessity to receive a vaccine. Alternatively, an individual who is unable to obtain a COVID-19 vaccine due to a lack of availability might choose to travel elsewhere for vaccination. This might increase mobility patterns leading to disease spread. Finally, incompetent logistical planning of vaccine distribution might engender mistrust in the government for individuals, potentially decreasing the likelihood of vaccination or compliance with other health policies.

3.2.3 Societal Impact

Consequences noted for individual behavior above might be observed more broadly in societal behaviors, and more widespread mistrust in government competence might be stimulated. Furthermore, logistical inadequacies leading to disparities in vaccine distribution might further widen socio-economic divides between races and classes.

3.2.4 Economic Impact

The economic burden of logistical errors in vaccine production, distribution, and storage can be most obviously understood in the economic cost associated with correcting misdirected vaccines. Considerations for the wasting of vaccines must also be made if transportation or storage conditions are inadequate. Furthermore, these logistical challenges can cause large economic damages due to preventable increases in disease spread and outbreaks, exacerbating the already dramatic economic effects of COVID-19.

3.2.5 Security/Bad Actors

Insufficient monitoring of the complete supply chain of vaccine production, distribution, and storage also lends itself to attack by bad actors. If a country does not carefully monitor the total pipeline of vaccine distribution, there may be opportunities for theft and counterfeit vaccine delivery. Furthermore, privacy concerns can arise in numerous areas along the pipeline of vaccine distribution and administration. Private information including health records will undoubtedly be collected for some individuals receiving a COVID-19 vaccine, and solutions must be in place to safeguard against improper usage or access of this data. It is imperative that privacy be safeguarded to the highest possible extent in developing systems to track vaccinated patients and to provide reminders for second-dose administration.

3.3 Need for Technology Solutions

It is imperative that systems are put in place to coordinate and monitor the distribution and administration of COVID-19 vaccines. Vaccine distribution must be coordinated across a variety of private and public sectors including governments, manufacturers, and transport agencies. Constant tracking and monitoring of where vaccine shipments are currently located both in space and in the distribution pipeline must be achieved through a comprehensive, uniform digital framework. Furthermore, systems must be put in place to identify errors in vaccine storage. Additionally, steps must be taken to ensure equitable distribution of vaccines. Ideally this will be achieved using a transparent methodology that enables the public to directly observe that there are no unintended biases in vaccine distribution. Finally, a privacy-focused approach to vaccination and patient follow-up must be implemented to observe the efficacy of vaccination and to develop understandings of vaccination rates and follow-up vaccination adherence. This record-keeping system will also be crucial in understanding the long-term efficacy and effects of vaccines in diverse populations.

It is also important to note that poorer nations suffer more acutely from many of the challenges outlined in vaccine distribution and administration, indicating the great importance for the deployable digital solutions outlined above.

4 Health Outcomes

Due to the unprecedented and rapid development of current COVID-19 vaccines, there exists a dearth of relevant clinical data on the long-term efficacy of many of the most promising vaccine candidates. However, the limited amount of data provided on current vaccines in development as well as previous knowledge of similar vaccine platforms can lend insights into some of the challenges that might be faced in the deployment of these vaccines.

4.1 Challenges

Vaccine Platform	Examples	Challenges
mRNA	Pfizer and BioNTech, Moderna	1. No current mRNA vaccines used widely in humans 2. Side effects and mechanism of immune reactivity to mRNA not fully understood
Viral Vector	Astrazeneca, Johnson & Johnson	1. Immunity to viral vector may reduce the efficacy of boosters/repeat vaccination a. Disparities exist in pre-existing immunity to adenoviral vectors 2. May be contraindicated with some drugs
Inactivated	Sinovac	1. Efficacy in immunocompromised may be reduced a. Immunosuppressive drugs are one cause
Live attenuated	Multiple candidates in preclinical testing	1. Contraindicated in immunocompromised individuals a. Interactions with chemotherapy and other immunosuppressive drugs.

Figure 3 Current vaccine technologies and potential challenges. [56, 46, 64, 22, 77]

The COVID-19 pandemic has inspired the use of novel vaccine platforms. These technologies have enabled the observed rapid development of promising vaccine candidates, but the fact they have not been widely used previously requires a degree of caution and study as they are implemented. Key concerns are the potential reactogenicity of mRNA vaccines, as well as potential issues in multiple dose regimens and HIV susceptibility for adenoviral vector vaccines.

4.1.1 mRNA Vaccines

mRNA vaccines are a very new technology that has been suggested to be ideal for rapid vaccine development in the setting of pandemics. To date, there have been no mRNA vaccines authorized for widespread public use in preventing any viral illness, but previous clinical trials have examined their efficacy with promising results [59]. Pfizer and BioNTech as well as Moderna also recently have reported positive preliminary results of Phase 3 trials for COVID-19 vaccines using mRNA platforms, demonstrating greater than 90% efficacy and no serious adverse events [56, 46]. However, these results represent findings from only a small fraction of the total patients enrolled in the study, and the long-term efficacy of the vaccines remains to be studied [56, 46]. Potential challenges previously observed in the setting of other mRNA vaccines include serious reactogenic effects to vaccination as well as potential concerns over relatively weaker immunogenic responses using this platform [53]. mRNA vaccines for COVID-19 that are developed will need to be observed closely to determine whether reactogenic effects are more prevalent in certain populations, and whether the length of conferred immunity is substantial enough to be useful for public health applications.

4.1.2 Adenoviral Vector Vaccines

Another relatively new technology for COVID-19 vaccine development involves the usage of **adenoviral vectors** containing genetic coding sequences for COVID-19 antigens. While a more extensively studied platform than mRNA vaccines, there are very few vaccines on the global stage that have been approved for use in any illness using adenoviral vectors. In the setting of COVID-19, Johnson & Johnson as well as Astrazeneca are currently developing vaccines using various adenoviral vector platforms; both candidates have recently resumed trials following adverse events that were deemed to be most probably unrelated to vaccination [41, 3].

The primary challenge to adenoviral vector vaccines lies in potential prior host immunity to the viral vector, potentially reducing the efficacy of the original or booster vaccinations [64]. Furthermore, prior host immunity to adenoviral vectors is nonuniform; for example, some studies have suggested a larger serological immunization prevalence in sub-Saharan Africa for several adenovirus subtypes when compared to Europe and the United States [22]. If trials do not adequately account for this fact, an adenovirus vaccine might be dramatically less effective in these populations.

Additionally, two previous adenoviral vector vaccines for HIV were found in clinical trials to increase susceptibility to HIV infection in certain vaccinated patients [30]. There is some concern that the use of adenoviral vectors for COVID-19 vaccines might induce this same susceptibility in some demographics [14].

Finally, there is some indication that viral vector vaccines may be contraindicated in patients receiving certain drug regimes such as some used in the treatment of multiple sclerosis [77]. The effects of drugs on vaccinations are not currently thoroughly studied but should be considered, especially in the setting of a relatively nascent technology such as adenoviral vectors.

4.1.3 Duration of Immunity

The duration for which a new COVID-19 vaccine might confer immunity is currently unknown. While clinical trials have thus far demonstrated the safety and efficacy of vaccine candidates, there is still a lack of understanding of how long any vaccine might produce immunity to COVID-19. Currently, estimates are best made based upon the immune response to other, similar coronaviruses as well as studies on the lasting serological response to natural COVID-19 infection [29, 28]. Each of these suggest that immunity to COVID-19 may not last more than 12 months, and may be even shorter in vaccinated individuals [29, 28, 72]. If the duration of immunity is not well-understood prior to widespread vaccine distribution, it will be imperative for proper tools to be in place for the monitoring of new COVID-19 infection in vaccinated individuals. In scenarios where vaccines for COVID-19 only confer short-lived immunity, protocols to most ideally vaccinate the population at regular intervals will need to be developed and supported by appropriate tools.

4.1.4 Efficacy of Immunity

Though current trials have reported high efficacies of greater than 90% for the Pfizer and Moderna COVID-19 candidates, the potential for lower efficacies must be addressed [56, 46]. It is possible that immunity may wane over time, and previous clinical trials have produced results that were not consistent with future performance of a drug/vaccine. Furthermore, variation in the efficacy of individual vaccine doses or lots might be observed due to varying production, storage, and transport conditions. In the setting of diverging vaccination efficacy, tools must be in place to monitor individuals across a broad spectrum of demographic and geographic windows in order to identify causes of varied immunity. Should a vaccine be shown to be uniformly less effective than indicated by clinical trials, procedures must be in place for optimal vaccination strategies and coordination with other preventative policies must be established to prevent renewed COVID-19 outbreaks. A vaccine with lower efficacy can still be useful (as observed in the case of influenza vaccines), but must be coupled with appropriate procedures and policies accounting for this reduced efficacy.

4.1.5 Vaccination of Special Populations

Current vaccine trials have attempted to accurately assess efficacy across a broad range of racial groups and age ranges [55]. Thus far, results from several Phase 3 studies appear to be promising [56, 46]. However, there is still concern over the immediate and long-term efficacy of vaccine immunogenesis in specific populations such as the elderly, children, and immunocompromised individuals [1, 37]. Elderly individuals often undergo a process termed "immunosenescence" which can hinder immune response to vaccination [27]. While these concerns have prompted companies such as Pfizer to enroll a large proportion of elderly individuals into their COVID-19 vaccine trial, it is still unknown whether the long-term efficacy may differ between patients in different age groups [56]. In line with FDA guidelines, the efficacy and safety of current COVID-19 vaccine candidates has not been explored in pediatric populations, and it is possible that these trials will not occur for some time to come [31]. Individuals may become immunocompromised due to a variety of health conditions, organ transplant operations, or medications for diseases such as cancer. Previous vaccines have had varied efficacies and morbidities manifested in these populations, and future COVID-19 vaccines remain to be completely studied in this setting.

4.2 Consequences

Aside from obvious effects of lower efficacy vaccines or potential side effects, close attention must be paid to the variance of these effects in various demographics and populations. Unequal health outcomes in the setting of vaccination can have dramatic effects across all levels of society and must be prepared for and mitigated.

4.2.1 Disease Spread

The consequences of ineffective or short-lasting vaccines are self-evident. Further, these issues are made more complicated by the potential for varied effects among different populations. It will be crucial to understand whether disparate long-term effects or the length of immunity conferred by vaccines are disparate in different populations (including the special populations outlined above). A failure to identify and understand these disparities could lead to prolonged disease spread in specific communities or populations.

4.2.2 Individual Behavior

Recent polls have suggested that vaccine efficacy and reactogenicity are among the most critical determinants in individual willingness to obtain a COVID-19 vaccine [60]. Transparency in reporting real-world efficacies and side effects in various populations is imperative in ensuring that individuals are willing to receive vaccines as they become more available. Additionally, the duration of immunity conferred by vaccines must be communicated to individuals to inform behavior. While the CDC and Dr. Anthony Fauci have suggested that mask-wearing and social distancing will still be needed to optimally combat disease spread even after vaccine distribution, it is likely that vaccinated individuals will be more lax in adherence to these guidelines [26, 18]. It is therefore important that the public be kept well-informed of both the efficacy and length of immunity that they should expect to obtain following vaccination.

4.2.3 Societal Impact

Differing vaccine efficacy in diverse populations has the potential to create imbalanced prevalences of disease spread and transmission. This might lead to prejudice and social tension among different demographic groups. Varied vaccination efficacy and lengths of immunity might also influence communal adherence to social distancing and mask-wearing guidelines. Finally, misinformation and a lack of transparency regarding the relative efficacy, side effects, and length of immunity for COVID-19 vaccines might engender unnecessary fear, rumors, and concern in populations.

4.2.4 Economic Impact

The timeline of immunity and vaccine efficacy must be well-understood to develop cost-efficient public vaccination regimes. Systems must be in place to identify which vaccines are most efficacious in differing populations. Furthermore, liability compensation programs have been instituted by governments to sponsor vaccine development, leaving governments responsible for reparations in the setting of negative health outcomes caused by vaccination. Ultimately, the most powerful effect of vaccine efficacy on the economy lies in the potential of widespread vaccination to return the economy to some semblance of normality.

4.3 Need for Technology Solutions

The rapid pace of COVID-19 vaccine development has been a boon for the fight against disease spread while engendering caution and concern in those worried about the safety and efficacy of a quickly developed product. A uniform system for both top-down and participatory monitoring of health outcomes for vaccinated individuals can overwhelmingly address these concerns. Such a system must prioritize individual privacy while also retaining enough information to disentangle the effects of a COVID-19 vaccine across multiple demographic groups.

5 User-Centric Issues

In addition to high-level issues regarding the logistics of high-volume vaccine distribution and effectiveness of new vaccine candidates, it is crucial to consider various issues that are directly pertinent to individual behavior. Citizens must choose to become vaccinated, and incentivizing that behavior will require proper solutions to several challenges.

5.1 Challenges

5.1.1 Trust in the System

According to a recent study, 71.5% of individuals surveyed from 19 different countries would be likely to take a COVID-19 vaccine, with 61.4% relying on their employer's recommendation [43]. These numbers vary significantly across countries with up to 90% of those in China and as little as 55% of those in Russia indicating that they would be likely to receive a COVID-19 vaccine [43]. Governments will need to contend with the challenge of raising these numbers in order to widely distribute vaccines. To do so effectively, there must be an understanding of which demographics, economic classes, education levels, and geographic locations contain individuals least likely to seek vaccination. Gaining user trust relies on a combination of transparency and clear, effective planning from governments. The challenge of creating these clear lines of communication and pandemic response guidelines in a rapidly evolving disease landscape is a challenge that many governments are finding difficulty in overcoming.

5.1.2 Follow-up Tracking and Multi-Dose Reminders

Among the current top COVID-19 vaccine candidates, most require two-dose vaccination schedules [74]. While these multi-dose regimens are certain to require additional costs and logistical challenges, they have been shown to increase immunogenicity in vaccinated individuals [70, 35]. The importance of developing systems to record individuals who have received one or two doses of the vaccine and to remind individuals to receive a second booster vaccine will be of utmost importance. Paper-based reminders introduce a risk of loss of data due to difficulty in managing and recording a physical paper trail. Furthermore, paper-based reminders pose a greater risk for data spoofing and there are confidentiality concerns related to loss of reminders/records. Systems must also address the monitoring and reminding of individuals that are dependent on others for health care and vaccine obtainment including children and disabled individuals.

5.1.3 Data Privacy

The CDC offers various high-level software tools to assist state and local governments including the Vaccine Tracking System (VTrckS) and PANVAX [20, 21]. Other digital products have also been developed by Palantir Technologies Inc., Salesforce, the Maryland Department of Health, Accenture, and SAP in order to address various challenges in vaccine distribution and administration [42, 61, 2, 51]. These tools could be utilized for identifying and allocating vaccines to high-priority populations, but the lack of privacy guidelines in place to protect sensitive patient data is concerning. For instance, several of these companies have neither disclosed what collected private health information might be used for nor whether any privacy safeguards have been set in place to protect an individual's name, race, location, travel history, and past health records [42] . This personal data might be used maliciously in the setting of data spoofing and data breaches.

5.1.4 Vaccine Incentivization and Motivation

While an individual's own health and well-being is an obvious incentive for both initial and booster-shot vaccination, the government will need to make advances in motivating large portions of the population to become vaccinated. A recent study reported that as many as 49% of Americans are inclined towards not receiving a COVID-19 vaccine, with primary deterrents being concerns over side effects and low efficacies [60]. Governments will need to work to motivate these individuals towards vaccination while grappling with ethical concerns regarding individuals' right to refuse vaccination. Incentivization of vaccination could occur through the implementation of both positive and negative reinforcements for those choosing to be vaccinated and those choosing to forgo vaccination, but again the delicate ethical balance between public health and individual freedoms will need to be addressed [13].

5.2 Consequences

In a world that continues to place increased importance on individual liberties, vaccine frameworks that do not attempt to build user engagement and trust will have dramatic consequences.

5.2.1 Disease Spread

A failure to properly motivate individuals to vaccination and adherence to booster doses can obviously have direct consequences on disease spread. Lower vaccine adoption rates will lead to decreased levels of population immunity and therefore higher disease prevalence.

5.2.2 Societal Impact

Left unaddressed, the above user-centric issues can result in population level trends in mistrust and low rates of vaccination. Vaccination frameworks must be designed with user behavior in mind lest societal norms outweigh scientific and government guidelines. Explicitly, if focused systems are not set in place to guide users through the process of vaccination and follow-up, society will dictate its own acceptable standards for these processes which may not align with official recommendations.

5.2.3 Economic Impact

A balance between resource investment and return must be made in designing an incentive structure for vaccination and adherence to multi-dose vaccination. Additionally, data privacy breaches can result in large scale fraud and economic loss when instigated by malfeasant parties or result in losses via lawsuits when the result of improper precautionary measures.

5.2.4 Security/Bad Actors

Technologies seeking to address issues in vaccine distribution pipelines must take thorough measures to protect user data and privacy, such as individuals' consent for collecting sensitive information before disclosing their identity. To obfuscate the sensitive personal information, one could guarantee privacy using cryptographic techniques such as hashing, private set intersection, secret sharing and fully homomorphic encryption [57, 67, 58, 8, 7]. The government, public health department, policymakers, or companies should introduce robust data security measures to minimize security risks. Thus, avoiding numerous possibilities for malicious access and use of private health information.

5.3 Need for Technology Solutions

Technological solutions and backing are crucial in assisting and protecting against the most important issue of data theft and breach, indirectly helping to create a sense of trust among users. These tools must be personalized, real-time, and come from trusted sources such as public governments. These tools should also enable participation in large observational studies, and enable passive user engagement without unnecessary user input in order to set reminders, schedules, etc. Finally, these tools must be transparent, enabling a user to understand the use of their data. In each of these aspects, digital solutions can be more effective and secure than the use of traditional paper methods for user engagement and follow-up.

6 Communication

Communication is perhaps as important a tool as vaccination itself in combating the COVID-19 pandemic. Fears surrounding a "COVID theater" of political communication in which certain public leaders might appear to take stances on issues without substantive action, have resulted in the proliferation of misinformation and uncertainty. The public must be made thoroughly and transparently aware of both the importance of vaccination, as well as the fact that vaccines are only a part of the continued public health framework of social distancing and mask-wearing that must be put in place to overcome COVID-19.

6.1 Challenges

6.1.1 Political Communication

Proper governance is integral to successful reduction in disease prevalence. Political leaders who downplay the pandemic or disregard the opinions of health care experts and scientists in an attempt to manufacture good news to the public can stifle a nation's trajectory towards recovery [11, 12]. In the United States, the presidential administration has been criticized for mixed stances on mask-wearing and the use of hydroxychloroquine for COVID-19 treatment [36]. These messages have oftentimes conflicted with the stances of the national scientists including Dr. Anthony Fauci, potentially undermining public trust in public health policies [25]. A lack of consistent messaging across a country's top executive and scientific officials creates ideal conditions for the spread of false information and mistrust.

It is imperative to note that even if all vaccines developed for COVID-19 are highly efficacious, it is possible that these vaccines may not prevent infection with COVID-19 at high rates [23]. As evidenced by the recent Pfizer and Moderna vaccines, efficacy has been assessed based upon primary endpoints of clinically apparent disease, while asymptomatic infection and spread has gone mostly unmonitored [23]. It is critical that this is accurately and thoroughly communicated to individuals in order to ensure that proper public health protocols remain in place following widespread vaccination.

6.1.2 Coordination in Vaccine Distribution

Thorough distribution of a vaccine in both developed and developing nations will require varying levels of coordination between multiple levels of government, private companies, and nonprofit organizations. Within developed countries, collaboration between national health authorities and authorities at state, district, and county levels will be required to assess vaccination needs and plan distribution of vaccines accordingly. Developing countries will often require collaborations with NGOs or organizations such as the WHO, GAVI, etc. to procure and distribute vaccines. [76] In either case, communication between a wide array of governmental, corporate, and nonprofit organizations will be crucial for successful vaccine dissemination.

6.1.3 Miscommunication and Trust

The majority of the American population is divided in the acceptance of vaccines. Both long-standing anti-vaxxer sentiment and newer COVID-19-specific concerns produce reluctance towards use of COVID-19 vaccine. One widespread concern involves the efficacy and safety of COVID-19 vaccines that appear to have been produced far faster than previous vaccines [50]. However, it has been demonstrated that the increased speed of vaccine development is most primarily due to improvements in technology as well as the unprecedented levels of funding and government cooperation leveraged for COVID-19 vaccine production [23]. Furthermore, there is larger widespread support for full FDA approval rather than emergency use authorizations (EUAs). Previously, data for EUA decisions were not publicly available, but the FDA has recently agreed to make this data public [24]. These misconceptions have not been well-communicated to the public and form the basis for many rumors and misconceptions regarding vaccine safety.

Systemic biases and discrimination present in medicine have also impacted communication surrounding COVID-19 vaccine distribution. [49] For instance, plans to distribute COVID-19 vaccines to marginalized populations first have sparked fears that such a policy would be viewed as experimentation of the vaccine on minority populations [62].

6.1.4 Misinformation Shared on Social Media

We are facing an 'infodemic' with the surge in rumors and misinformation spread on social media platforms [54]. Rumors regarding cures for COVID-19 have led to death and hospitalizations [52, 54], and have also prompted individuals to be lax in mask-wearing and social distancing. A popular conspiracy theory [5] claims that COVID-19 vaccines may be utilized by Bill Gates to implant individuals with microchips. Obviously, these rumors and theories fuel anti-vaccine sentiment in the population. Social media is the primary breeding ground of such misinformation [15].

6.2 Consequences

Unaddressed, challenges in communication threaten the very foundation of widespread vaccination. Miscommunication whether intentional or unintentional has the power to sway individual and societal understandings of vaccine efficacy and safety. Below we outline key effects of miscommunication.

6.2.1 Disease Spread

The effect of miscommunication on individual and societal behavior is the primary way in which it will tend to affect disease spread. Miscommunication can reduce vaccination rates, adherence to public health policies, etc., thereby resulting in higher disease prevalence and spread.

6.2.2 Individual Behavior

Improper or inadequate communication by the government can have dramatic implications for an individual's likelihood to adhere to precautionary measures in the pandemic. Misinformation that downplays or underestimates the severity of COVID-19 can de-incentivize people from seeking vaccines. The same effect is produced if vaccine trials and efficacy are not properly and thoroughly explained to the public. Skepticism, doubt, and mistrust can act even more dramatically, causing individuals to actively reject vaccines, further compounding beliefs that the COVID-19 pandemic is "fake news". Proper communication and education surrounding the need for two-dose vaccination regimes is also critical in properly providing vaccine coverage to the population.

6.2.3 Societal Impact

In America, already inflamed public tensions can become further exacerbated in populations that believe that their own source of information regarding COVID-19 is absolute fact. In the setting of contradicting or unclear messaging from multiple government and scientific sources, groups might be easily turned against one another as they rely on their own personal source of information. This will engender a positive feedback cycle of mistrust and further antagonism between groups at odds with one another. An illustrative example lies in the use of masks; even some physicians in the US have described their belief in the inefficacy of masks, furnishing groups in society with backing for anti-masker views [6].

6.2.4 Economic Impact

Miscommunication can cause multiple sources of economic loss. Small businesses can be affected by miscommunicated policy guidelines and difficulty enforcing policies that are not believed by the public to be necessary, as in the case of wearing masks in some areas. Miscommunication can also result in improper allocation of resources or goods; for instance the advertisement of false COVID-19 therapies can result in wasted resources in obtaining ineffective treatments.

6.2.5 Security/Bad Actors

Miscommunication and the spread of false information is one of the primary ways in which bad actors can influence behavior in the setting of the pandemic. If governments are not explicit about vaccination procedures, it is possible for bad actors to provide disingenuous information in order to perform fraud or other malicious actions. For instance, if long term monitoring is introduced for vaccinated individuals, false apps or websites as were observed in the setting of contact tracing might appear in attempts to steal user information [40]. These same security breaches can occur at every intersection of user interaction with government protocol if guidelines are not explicitly and transparently communicated to individuals.

6.3 Need for Technology Solutions

Technological advances have the potential to greatly augment effective communication efforts during COVID-19 vaccine distribution. Large social network companies are in positions to take bigger steps to eliminate the spread of misleading information (that could potentially discourage vaccine adoption) through their platforms.

Social media platforms also are uniquely situated to disseminate accurate educational information concerning vaccine development and distribution. Furthermore, advances in machine learning-based fake news detection [54, 68] can help automate the process of removing misinformation. Finally, it is critical that governments have intense security built around their technological solutions to prevent unwanted influence from bad actors.

7 Discussion and Conclusion

The initial step in overcoming the many challenges associated with vaccination in the COVID-19 pandemic is the proper identification of each potential issue. In this early draft, we have presented challenges spanning the logistics, health outcomes, user-centric issues, and communication surrounding COVID-19 vaccine development and distribution. We explicitly connect these challenges to consequences in disease spread, individual behavior, societal impact, economic impact, and data security. Our work is intended to succinctly compile these findings for governments, organizations, and individuals as they navigate the unprecedented landscape of mass vaccine distribution. This is not intended to be an exhaustive enumeration of every challenge likely to be faced in this setting, but we hope to address those challenges with the most potential to negatively impact society should they remain unaddressed.

Many challenges remain unaddressed by current vaccination strategies and guidelines, and, in some cases, no easy solutions exist. Nevertheless it is crucial that governments, organizations, academics, and individuals begin to develop the frameworks and approaches necessary to prevail over these challenges.

Future work will seek to better identify the solutions and frameworks already developed to meet these challenges, in addition to proposing privacy-minded digital solutions to many of the obstacles demonstrated in this work.

Advances in technology and global cooperation have brought about the development of incredibly efficacious vaccine candidates. The same forces must be harnessed in a transparent, privacy-minded manner in order to ensure the equitable and effective distribution of COVID-19 vaccines.

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

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