Global Emerging Pathogens Treatment Consortium

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COVID-19 VACCINE DISTRIBUTION STRATEGY IN AFRICAN COUNTRIES

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VACCINE
Coronavirus

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1.0 Introduction

The devastating global impact of COVID-19 has affected us all, and few will look back on 2020 with fond memories. With over 218 countries and territories affected and around 1.82 million deaths, more than 82 million confirmed cases as of December 31st 2020 and a global economic impact that the World Bank has predicted will trigger the worst recession since World War II and global extreme poverty expected to rise for the first time in more than 20 years1, the COVID-19 pandemic is the biggest global challenge in recorded human history. However, despite the enormous scale of the challenges it has posed, it has also triggered a response that now signals a new era in international cooperation, scientific collaboration, recognition of frontline workers and one which will ultimately play a critical role in bringing this crisis to an end.

The COVID pandemic has proved that it is possible to develop, test, and review multiple safe and effective vaccines against a new disease in less than a year. To have ended up with such encouraging efficacy results from more than one vaccine candidate puts humanity in an extraordinarily promising position, both in terms of ending the COVID-19 pandemic and developing vaccines against other diseases, including future pathogens that could be a source of another pandemic in the future.

Coronavirus vaccines are now being administered in North America, Europe, and few Asian countries, while Africa hopes to start in 2021. Until then, the continent of 54 countries will need to put the necessary logistics in place. Policymakers and governments at the state, national, and regional levels in Africa will have to design and implement the largest vaccination program in history. It will differ from all previous programs both in terms of scale and target populations. The vaccination effort will challenge countries' ability to plan and deliver what will become a basic requirement of global public health and global economic participation.

Africa will need to embark on a massive vaccination program to reconnect to the world economy. Proof of vaccination will become a passport to travel with minimum or no restrictions, reducing the costs in time and money incurred under current PCR testing and quarantine regimes. This will free up business travel and the movement of cargo and freight and will enable international tourism once again.

The African Union has endorsed the need for Africa to develop strategies to actively engage in the development and access to COVID-19 vaccines2. African countries should take steps that will strengthen health systems, improve immunization delivery, and pave the way for the introduction of a COVID-19 vaccine. These include: mobilizing financial resources; strengthening local vaccine manufacturing, and regulatory, supply and distribution systems; building workforce skills and knowledge; enhancing outreach services, and; effective community and stakeholders engagement to counter misinformation3. This document lays out a flexible strategy for the distribution of the intended COVID-19 Vaccine in Africa.

Types of COVID-19 Vaccine

2.0. The different types of COVID-19 Vaccine in development

There has been a miraculous speed in the quest to develop the COVID-19 vaccine. There are more vaccine candidates simultaneously in the pipeline for COVID-19 than ever before for an infectious disease. By mid-December 2020, there are 57 vaccine candidates in clinical research, including 40 in Phase I–II trials and 17 in Phase II–III trials. In Phase III trials, several COVID-19 vaccines demonstrated efficacy as high as 95% in preventing symptomatic COVID-19 infections 4,5. All of them are trying to produce immunity to the virus, and some might also be able to stop transmission. They do so by stimulating an immune response to an antigen, a molecule found on the virus. In the case of COVID-19, the antigen is typically the characteristic spike protein found on the surface of the virus, which it normally uses to help it invade human cells6.

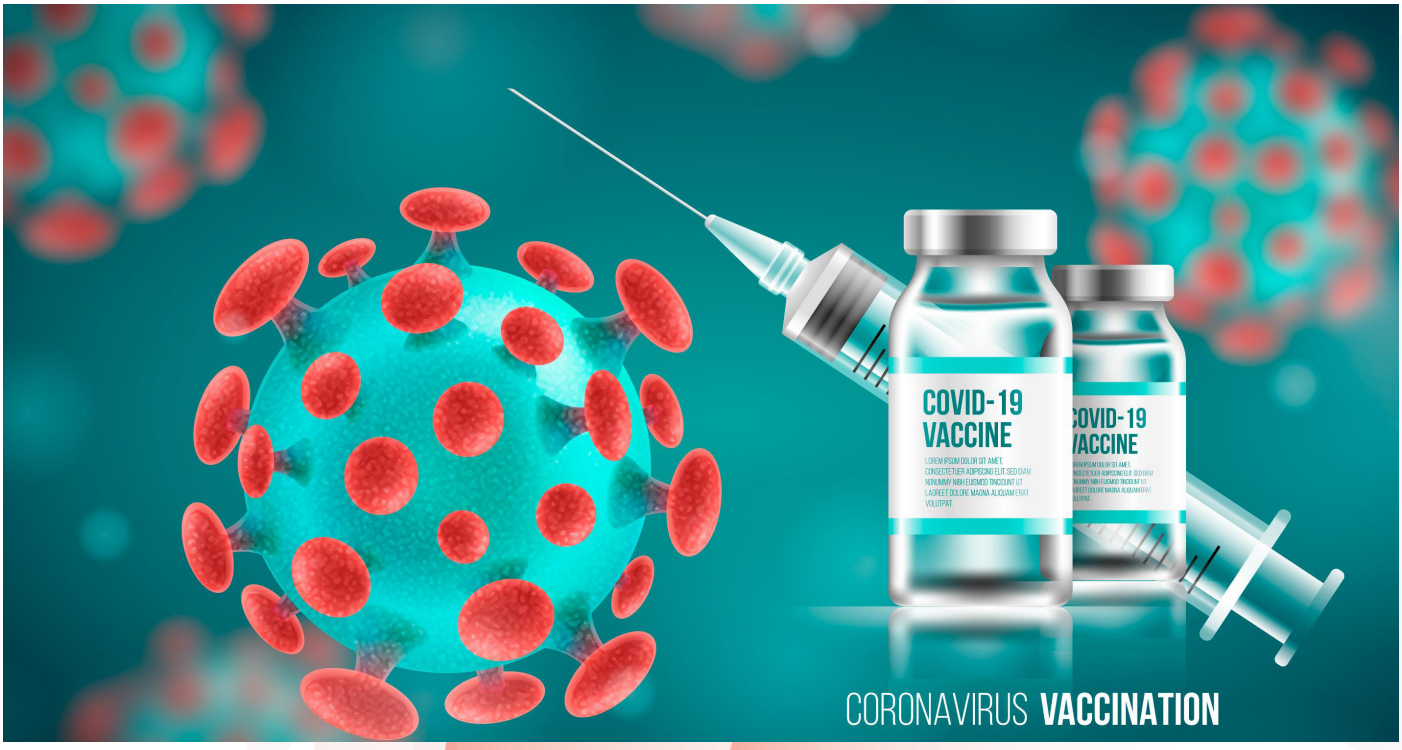
There are four categories of vaccines in clinical trials: Nucleic acid (RNA and DNA), Whole virus, Protein subunit, and Viral vector. Some of them aim at smuggling the antigen into the body; others use the body's cells to make the viral antigen.

1. Nucleic Acid COVID-19 Vaccine

RNA vaccines encode the antigen of interest in messenger RNA (mRNA) or self-amplifying RNA (saRNA). The messenger RNA vaccines developed for COVID-19 are a new type of vaccine to protect against infectious diseases in humans. COVID-19 mRNA vaccines work by giving instructions for our cells to make a harmless piece of what is called the "spike protein."6 The spike protein is found on the surface of the virus that causes COVID-19. Once the instructions (mRNA) are inside the immune cells, the cells use them to make the protein piece. After the protein piece is made, the cell breaks down the instructions and gets rid of them. The cell then displays the protein piece on its surface. Our immune systems recognize that the protein does not belong there, and this triggers an immune response inside our bodies. That immune response, which produces antibodies, is what protects us from getting infected if the real virus enters our bodies.

2. Whole Virus Vaccine:

Whole virus vaccines use a weakened (attenuated) or a dead deactivated form of the pathogen that causes a disease to trigger protective immunity to it6. There are two types of whole virus vaccines. Live attenuated vaccine is the most common traditional method which involves the use of weakened live pathogen which is no longer able to induce infection but able to induce an immune responses and hence mimic features of natural infection. It is capable of inducing both humoral and cellular immune response. These vaccines are popular to induce strong lifelong immune responses within two doses7. These are easy to produce for some viruses but challenging for complex pathogens. World Health Organization reported that as of December 2020, there were7 COVID-19 vaccine candidates in clinical evaluation and 12 candidates in the preclinical evaluation stage developed using this platform8. Inactivated vaccines contain viruses whose genetic material has been destroyed by heat, radiation, or chemicals so they cannot infect cells and replicate, but can still trigger an immune response. On injecting it to the host, inactivated vaccines primarily induce protective antibodies against epitopes



on hemagglutinin glycoprotein on the surface of the virus. These vaccines tend to produce a weaker immune response than live attenuated vaccines, thus adjuvants are required to provide an effective immune response.

3. Protein Subunit Vaccine:

Subunit vaccines (sometimes called acellular vaccines) are composed of protein or glycoprotein components of a pathogen that are capable of inducing a protective immune response and may be produced by conventional biochemical or recombinant DNA technologies8. Recombinant subunit vaccines have distinct advantages over live attenuated and inactivated vaccines since they are efficient in inducing humoral and cell-mediated immunological responses, and the risks associated with handling the pathogen are eliminated, subunit vaccines are considered very safe. However, subunit vaccines may be more expensive and may require a specific adjuvant to enhance the immune response.

4. Viral Vector Vaccine:

Viral vector vaccines work by giving cells genetic instructions to produce antigens. But they differ from nucleic acid vaccines in that they use a harmless virus, different from the one the vaccine is targeting to deliver these instructions into the cell7,8. Viral vector vaccines use part of a different virus, one that has been genetically modified to not be infectious. Viral vector vaccines can mimic natural viral infection and should therefore trigger a strong immune response 10. However, since there is a chance that many people may have already been exposed to the viruses being used as vectors, some may be immune to it, making the vaccine less effective.

Challenges to COVID-19 vaccine production and distribution in Africa

Vaccination is presently the most viable solution for ending the COVID-19 pandemic. The stakes are high and countries all over the world are competing for the available COVID-19 vaccines for their citizens. A well planned and successful vaccination program by African countries will boost economic recovery on the continent and reconnect Africa to the rest of the world.

There can be no vaccination without vaccines. Given Africa's limited capacity to develop and manufacture Covid-19 vaccines, it will have to import them. The challenges Africa countries are likely to encounter in accessing and delivering COVID-19 vaccines will mirror those already experienced by low and middle-income countries since the beginning of the pandemic when global demand for PPE and IPC products like test kits, masks, medicines, and ventilators far exceeded supply. Low and middle-income countries could not get the needed supplies because the world was not producing enough. The same scenario is already playing out in the COVID-19 vaccine distribution. African countries must therefore prepare and be positioned to be actively involved in the COVID-19 global vaccination.

Preparation for the COVID-19 vaccine requires African countries to (i) develop a robust procurement, supply chain, and distribution plan; (ii) have a sustainability plan to ensure continued availability and access to the COVID-19 vaccine; (iii) determine the eligibility criteria - who will be prioritized and why; (iv) develop a robust vaccine distribution strategy; and finally, (v) identify where the vaccine will be administered and by whom (doctors, nurses, etc.).2,9 The challenges most African governments will face in accessing and distributing COVID-19 vaccines include:

1. Cost of available COVID-19 vaccines and possible sources of funding in Africa: If the supply of COVID-19 vaccines is left to the market, African countries will be essentially rationed out of it by the developed countries 10. Africa needs about $9 billion to finance enough COVID-19 vaccines to halt the pandemic on the continent11,12. Afreximbank estimates that Africa will need to spend about $5.8 billion on purchasing vaccines and about $3.3 billion to deliver them to reach the target of vaccinating at least 60% of 1.3 billion Africans beginning in 2021 12. A state like Lagos state in Nigeria with a population of about 20million people will need about $140million for both purchasing and delivery of the vaccine to vaccinate at least 60% of its populace. The current prices of available COVID-19 vaccines are Pfizer $20/dose; Moderna $32-$37/dose; and AstraZeneca- $3-$4/dose. Some funding will come from COVAX, a global alliance co-led by the World Health Organization that aims to secure fair access to COVID-19 vaccines for poor countries13.

2. Miscommunication and lack of trust in government: Long-standing vaccine skepticism and newer COVID-19-specific concerns will produce reluctance towards the use of the COVID-19 vaccine in most African counties. Widespread concern includes the involvement of few Africans in the clinical trials of the vaccines and concerns about the efficacy and safety of the COVID-19 vaccine that seems to have been produced within a very short period of time14. The increased

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speed of vaccine development is most primarily due to improvements in technology as well as unprecedented levels of funding and government cooperation must be clearly communicated to the public. Systemic biases and discrimination present in medicine have also impacted communication surrounding COVID-19 vaccine distribution. 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. Several pools have suggested that Africans might be among those least willing to receive a COVID-19 vaccine due to widespread mistrust in healthcare systems and government fuelled by previous examples of medical racism 14,15.

3. Distribution Logistics and Infrastructure: African countries need effective planning to avoid anticipated difficulties in the storage and distribution of available COVID-19 vaccines. The "cold chain" references the necessity for available COVID-19 vaccines (developed by Pfizer and BioNTech) to be stored at sub-zero temperatures during transport and storage. Often, dry ice is needed in each of these processes, and maintaining the required temperature during storage and distribution may be a significant challenge in most African countries. Pharmaceutical-grade glass vials capable of withstanding sub-zero temperatures might also be in short supply. In most African countries, storage facilities may lack vaccine-qualified refrigerators, potentially greatly affecting the efficacy and storage life of vaccines. Furthermore, proper data monitoring framework is needed to track and evaluate the transport and storage conditions of vaccines distributed widely across countries, regions, and states. We are also facing an 'infodemic' with the surge in rumors and misinformation spread on social media platforms. Misinformation and theories regarding low vaccine efficacy and side-effects fuel anti-vaccine sentiment in the population. Social media is the primary breeding ground of such misinformation, but might also serve as an ideal platform for the proliferation of educational public health communication.

COVID-19 Vaccine Delivery Strategies

Successful implementation of the national COVID-19 vaccination program requires precise coordination across federal, state, and local governments and among many public and private partners. The strength of existing vaccine delivery infrastructure will be explored while leveraging innovative strategies, new public-private partnerships, and robust engagement of state, local, tribal, and territorial health departments to ensure efficient, effective, and equitable access to COVID-19 vaccines.

Most countries have agencies that perform regulatory oversight on the use of medicine in their countries. Nigerian National Agency for Food and Drug Administration and Control (NAFDAC) and the South African Health Products Regulatory Authority (SAHPRA) performs oversight and regulatory checks and approvals for public delivery and use of medicines, packed food and drinks, and other critical health technologies, including vaccines, within Nigeria and South Africa respectively. All vaccines will need to be registered with these agencies, whose job it is to ensure that they meet the necessary standards for safety, quality, and efficacy.

Upon authorization of a vaccine by the relevant agencies, there are key tasks to facilitate easy accessibility

- Engagement with the state, local government, private sector partners, and other stakeholders, as well as the public to communicate public health information, before and after distribution of vaccine. Effective engagement and communication with a stakeholder about the vaccine to enhance vaccine confidence and uptake are particularly important.
- Distribute vaccines immediately upon granting of authorization using a transparently developed, phased allocation strategy.
- Safe administration of the vaccine and availability of administration supplies.
- Monitor necessary data from the vaccination program through an information technology (IT) system capable of supporting and tracking distribution, administration, and other necessary data.

4.1 Vaccine Distribution

A distribution plan must be able to map out strategies for delivery of the approved vaccine to all endpoints, while remaining flexible enough to accommodate a variety of factors, including varying product requirements and manufacturing timelines and volumes.
Any distribution effort must ensure the safety of the vaccine, maintain control and visibility, manage uptake and acceptance, ensure traceability of product, and maximize coverage.

Distribution components can be captured into three stages:

- Partnerships with state and local health departments, territories, tribes, and federal health entities to allocate and distribute vaccines, augmented by direct distribution to commercial health partners.
- Centralized distribution centers in each region or state in the country, with potential for back-up distributors that meet the required storage and handling requirements.
- A flexible, scalable, secure web-based IT vaccine tracking system for ongoing vaccine allocation, ordering, uptake, and management.

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4.1.1 State and Local Partnership

Partnering with federal, state, and local stakeholders will help ensure public health systems are prepared with plans, trained personnel, strategic relationships and partnerships, data systems, and other resources needed for sustaining a successful routine immunization infrastructure, and these plans will be adapted for this vaccine program.

The health stakeholders will develop a "micro plan," based on their existing structures with the help of relevant technical assistance. These micro plans will identify vaccination sites and necessary logistical considerations and layout how the sites will be integrated into the necessary IT system. The micro plans will need to be flexible to allow adaptation as more information about the specific characteristics of the vaccines becomes available. Also, stakeholders will also be responsible for laying the specific groundwork for vaccinating high-risk and prioritized populations through various outreach efforts, including a workgroup or stakeholder groups, and forming a vaccination committee.

4.1.2 Centralized Distribution

Centralized distribution allows the government full visibility, control, and ability to shift assets and use data to optimize vaccine uptake. The government of each country will have to assign a centralized distributor.

This system will be scalable to meet demand. Some vaccines with ultra-cold storage requirements may be shipped directly from the manufacturer to the administration sites, but all distribution will be managed by this centralized system. The COVID-19 pandemic has likely accelerated a trend towards different ways of engaging with the healthcare system, and successful delivery of this vaccine will need to incorporate new types of sites and approaches for vaccine delivery.

5.0 Potential Phased Structure

Upon authorization, initial vaccine doses should be distributed in a fo¬cused manner, to maximize vaccine acceptance and public health protection while minimizing waste and inefficiency. Given the limited availability of the COVID-19 vaccine, especially for developing countries, a gradual allocation plan for each country will need to be rolled out with target groups identified among the population. Vaccination should be done in phases based on the available vaccine and the risk level of citizens. Governments will need to determine the risk profiles of each of the groups that should be vaccinated at each phase. The government may consider the phased vaccination below:

Phase 1: Government may consider vaccinating the health workers and first responders with the first set of available vaccines.

Phase 2: As the volume of available vaccine increases, distribution will expand, and then increasing ac¬cess to the larger population. People over 65 years of age and people under 65 who have underlying high-risk health conditions should be next to receive the vaccine.

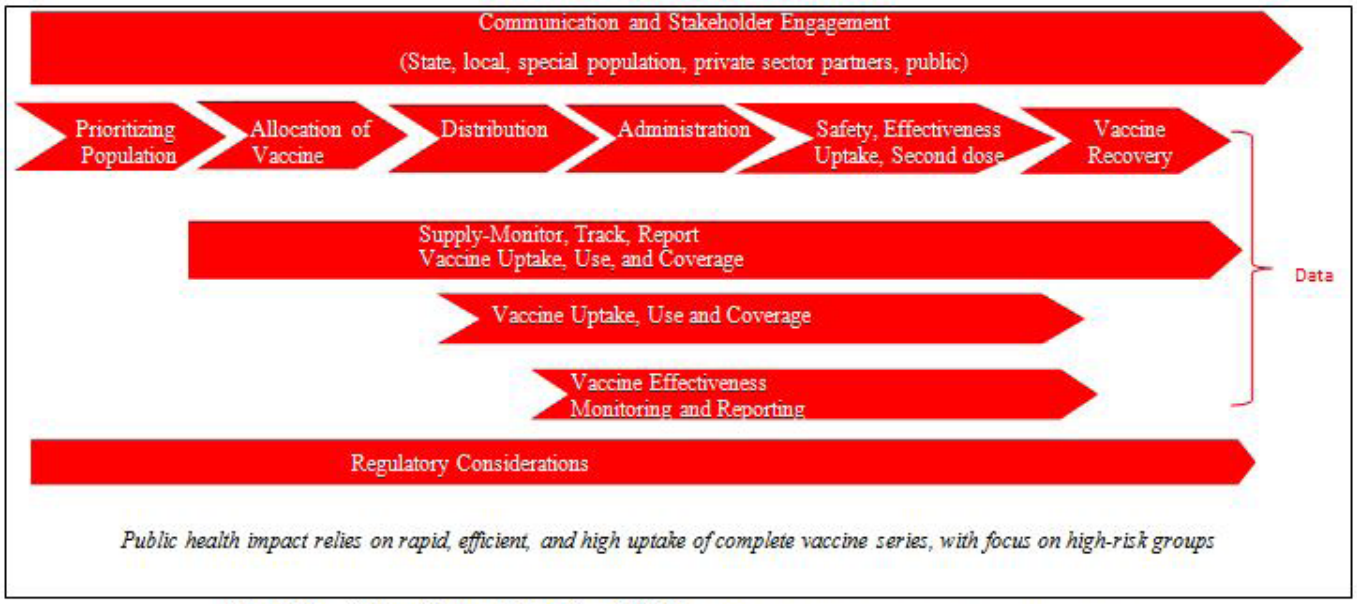
Phase 3: Further priority groups as defined by the country. The risk profiles will need to be re-evaluated periodically as more epidemiological data about the virus becomes known and assessed against any changes to country the context.

Phase 4: If COVID-19 persists such that there remains a public health need for an ongoing vaccination program, COVID-19 vaccines will be integrated into routine vaccination programs, run by both public and private partners.

To implement a phase vaccination program, countries should consider establishing Points of Dispensing (PODs). PODs are places within the communities where dispensation and administration of the vaccine can take place. There are two types of POD: open and closed. Open PODs are public locations such as stadiums, community centers, or schools, operated by local health agencies. Closed

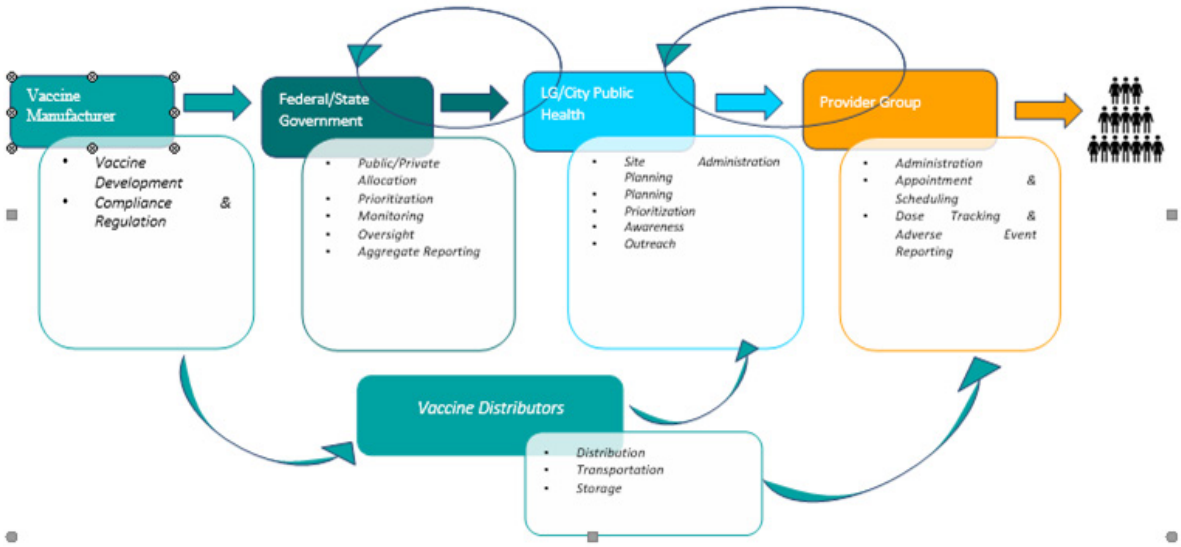
PODs are sites operated by public or private vaccine to their populations.
organizations that dispense and administer a

COMPONENTS OF VACCINE IMPLEMENTATION



Adopted from "From Factory to Frontline, 2019" by U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

VACCINE MANAGEMENT VALUE CHAIN



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Importance of maximizing Technology in COVID-19 distribution

Considering the limited resources available to African countries that will limit their timely access to COVID-19 vaccines, the distribution and allocation of the vaccines must be strategically coordinated across government, private and other stakeholders in the countries. Constant tracking and monitoring of the vaccine distribution pipeline must be achieved through a comprehensive, uniform digital framework. A privacy-focused approach to vaccination and patient follow-up must also be adopted to evaluate the efficacy of the various vaccines and to gather information about vaccination rates and second-dose adherence. An automated system should be set up to coordinate vaccine allocation and distribution. This should be a well-secured, web-based IT system that integrates entire vaccine supply chain from purchasing and ordering through distribution to participating state, local, and federal stakeholders as well as private partners. Through the linkage of several systems, information technology will also help direct people to where to get vaccinated using web-based "finder" systems A digital-based record-keeping system will also be crucial in understanding the long-term effectiveness and side effects of vaccines in diverse population groups.

Tools to monitor the vaccination and health outcomes of individuals 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 to set reminders, schedules, etc. Finally, these tools must be transparent, enabling users to understand the use of their data.

Footnotes

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