Group-4

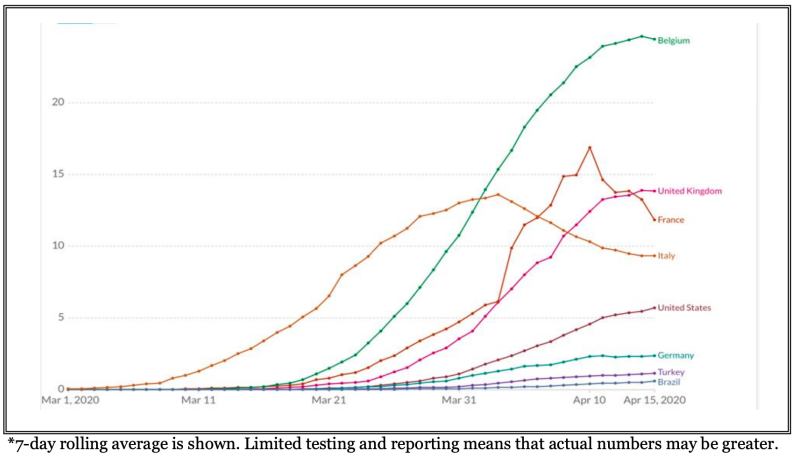
Building the Supply Chain for COVID-19 Vaccines

Executive Summary

Introduction

This in-depth examination of the "Building the Supply Chain for COVID-19 Vaccines" report explores the complex challenges encountered during the COVID-19 pandemic, with a specific emphasis on the worldwide effort to create, produce, and distribute vaccines. Originating in Wuhan, China, in December 2019, the pandemic quickly escalated into a global emergency, prompting a swift and cooperative reaction from nations across the globe.

Exhibit 1 *Daily New Confirmed COVID-19 Deaths per Million People**



*7-day rolling average is shown. Limited testing and reporting means that actual numbers may be greater.

Source: Our World in Data, COVID-19 Dataset 2020.

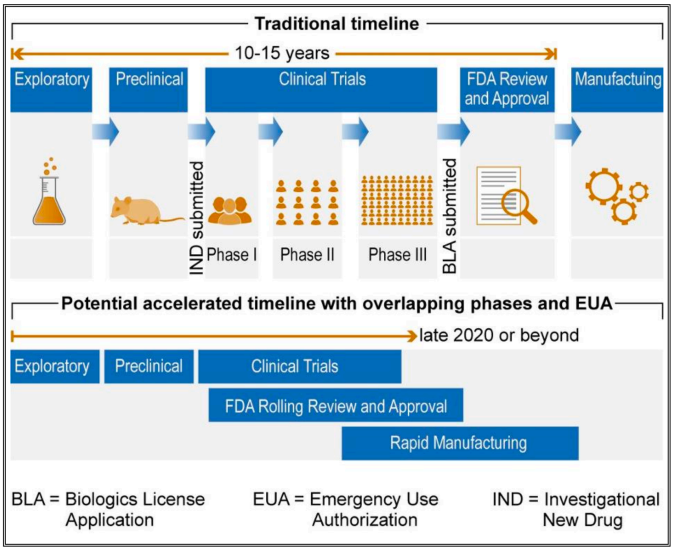
This analysis consolidates crucial data points and perspectives to offer a comprehensive grasp of the immense endeavors and intricate logistics associated with vaccine distribution. It scrutinizes the evolution of the pandemic, the united global effort in vaccine development, and the unparalleled challenges encountered in achieving fair access and effective distribution. Moreover, this summary not only accentuates the pivotal elements of the supply chain but also emphasizes the insights gained and strategic suggestions for future pandemic readiness and healthcare strategies.

Vaccine Development Efforts

Efforts in developing COVID-19 vaccines, following the WHO's declaration of a global pandemic on March 11, 2020, witnessed an unprecedented acceleration in research and collaboration. Governments, international organizations, and private sectors pooled resources, resulting in 137

vaccine candidates in pre-clinical trials and 46 in human trials by October 2020. This rapid advancement was propelled by innovative vaccine technologies and adaptations in conventional clinical trial methodologies, often bypassing or amalgamating Phase II trials with larger ones. However, this rapid progress encountered hurdles, notably in clinical trials due to the unique characteristics of the coronavirus. The complexity arose from limited initial understanding of the virus, further compounded by public health measures such as social distancing. Additionally, political pressures in several countries raised concerns regarding premature vaccine approvals.

Exhibit 4 *Vaccine Development Process*



Source: GAO analysis of GAO-20-215SP, FDA, HHS, and Pharmaceutical Research and Manufacturers of America (PhRMA) documentation. GEO-20-583SP.

The global vaccination endeavor witnessed a diversification in technology application, although apprehensions regarding politically motivated exclusions and financial biases towards specific candidates surfaced. The COVAX initiative played a pivotal role in ensuring equitable global vaccine access, with a goal to secure two billion doses by the conclusion of 2021. Simultaneously, the U.S. initiated Operation Warp Speed, dedicating substantial funds to vaccine development.

Experts cautioned that initial vaccines might provide only partial protection, emphasizing the necessity for sustained investment in second-generation vaccines for comprehensive resolution of the crisis. This continuous development, alongside essential public health measures, underscored an ongoing global commitment extending beyond the initial vaccine deployment phase.

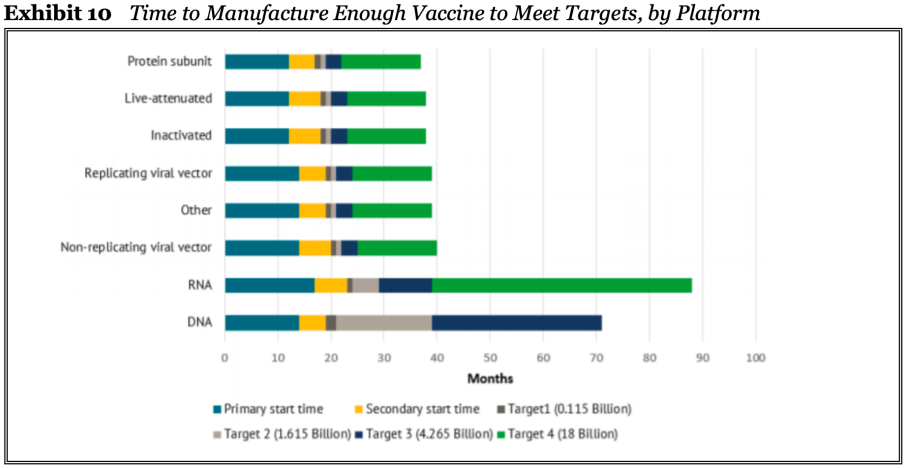
Vaccine Manufacturing: A Complex Process

Manufacturing Capacity and Investment Risks

Traditionally, investment in manufacturing capacity for vaccines begins after Phase III trials. However, due to the urgent nature of the pandemic, manufacturing capacity had to be

developed concurrently with clinical trials, leading to significant financial risks. To address this, governments and organizations like COVAX provided grants and advance purchase commitments to incentivize vaccine developers.

Exhibit 10 *Time to Manufacture Enough Vaccine to Meet Targets, by Platform*



Source: McDonnell et al., 2020.

Production Stages

Vaccine production involves two main stages: drug substance production and drug product manufacture. Key steps include raw material preparation, active ingredient manufacturing, and formulation. Bioreactors, although crucial, posed potential bottlenecks due to their cost and capacity constraints.

Vaccine Technologies and Portfolio Diversification

The global portfolio of COVID-19 vaccines encompassed diverse technology platforms, ranging from traditional to novel ones like DNA and mRNA vaccines. Each technology necessitated different manufacturing processes, potentially requiring new or significantly modified facilities.

Production Sites and Economic Geography

Decisions on vaccine production locations were influenced by factors such as cost, domestic demand, and policy incentives. Political and nationalistic pressures also played a role, impacting global vaccine availability.

Financing and Incentives

Advance Market Commitments (AMCs) played a crucial role in encouraging manufacturers to build capacity for COVID-19 vaccines, despite the risk of unused capacity post-pandemic. These commitments involved purchasing large quantities of vaccines regardless of trial outcomes.

Raw Material and Component Supply

Securing sufficient quantities of ingredients and packaging materials posed challenges, slowing down vaccine production. Efficient allocation of these scarce resources was vital for timely vaccine availability.

Scaling Risks and Strategies
Scaling up production carried significant risks due to variability in raw material quality. Options included scaling up existing facilities and contracting production to third parties, each with associated challenges and risks.

Agile Capacity
Planning for potential switchovers to new systems and manufacturing process flexibility was crucial. Investments in manufacturing capacity had to be carefully planned to mitigate risks associated with vaccine candidate failure in clinical trials.

Challenges in Distributing COVID-19 Vaccines

- **Global Distribution Challenges:** The task of distributing vaccines to the global population of around 7.8 billion people presented obstacles related to transportation, perishable product delivery, and ensuring fair international distribution.

- **Equitable International Distribution:** Early global collaboration encountered hurdles stemming from increasing economic and political tensions. This led to two main distribution approaches: multilateral cooperation, spearheaded by the COVAX Facility, and bilateral agreements between individual countries and pharmaceutical companies. COVAX aimed to secure lower prices and access for lower-income nations, proposing a "fair allocation" mechanism based on population size and urgency.

- **Bilateral Agreements and Vaccine Nationalism:** Certain countries opted for parallel bilateral agreements due to doubts about the efficiency of COVAX. Examples include the US' Operation Warp Speed, targeting the delivery of 300 million doses, and similar endeavors by France and Germany.

- **Domestic Distribution Considerations:** In the US, the CDC unveiled a phased distribution strategy focusing on high-risk individuals and essential workers. A consensus study recommended a four-phased equitable allocation framework.

- **Vaccine Hesitancy:** Doubts and reluctance regarding vaccination emerged as significant barriers. Surveys indicated varying degrees of willingness to receive vaccines, influenced by apprehensions about safety, effectiveness, and inadequate information.

- **Transportation and Storage Challenges:** Ensuring stringent temperature controls during vaccine transportation posed significant challenges, with approximately half of all vaccines globally wasted annually due to temperature and logistical issues. Notably, the Pfizer-BioNTech vaccine necessitated ultra-cold storage (-112F/-80C), further complicating logistics.

- **Infrastructure and Capacity Constraints:** Many less developed countries lacked the requisite infrastructure for cold chain distribution, especially for vaccines requiring ultra-cold storage. Private entities like UPS undertook initiatives to construct additional cold storage facilities to address these needs.

- **Volume of Shipments:** Distributing roughly 10 billion COVID-19 vaccine doses entailed a monumental logistical endeavor, demanding meticulous planning and coordination throughout the supply chain. This encompassed substantial quantities of pallet shippers, flights, cooling boxes, and other logistical resources.

Conclusion

The "Building the Supply Chain for COVID-19 Vaccines" report offers an in-depth understanding of the unparalleled global task of creating, producing, and disseminating COVID-19 vaccines. It emphasizes the remarkable speed of vaccine development propelled by innovative scientific cooperation and substantial financial backing. Moreover, the report illuminates the complexities of manufacturing and the logistical challenges of distribution to guarantee fair access globally. It highlights the issues of vaccine nationalism, stresses the importance of transparent and fair distribution strategies, and addresses the logistical obstacles in vaccine transportation and storage.

Future Considerations

- Enhanced Global Collaboration: The pandemic has underscored the urgent need for increased global cooperation, not only in vaccine development but also in ensuring fair distribution. Future endeavors should prioritize strengthening international collaboration mechanisms like COVAX.

- Supply Chain Management and Flexibility: Establishing more adaptable and flexible supply chains capable of swiftly adjusting to evolving needs and circumstances, such as emerging virus variants, is imperative. This involves more efficient management of raw material supplies and manufacturing capacity.

- Investment in Novel Technologies: Continuous investment in innovative vaccine technologies and manufacturing processes is vital. This should be accompanied by strategic planning to facilitate rapid scalability.

- Preparedness for Future Pandemics: The lessons learned from the COVID-19 experience should serve as a blueprint for addressing future pandemics. This entails learning from both the challenges and successes of the current response, particularly in the realms of rapid vaccine development and deployment.

- Addressing Vaccine Hesitancy: Efforts must be directed towards understanding and mitigating vaccine hesitancy through effective communication strategies aimed at building public trust in vaccine safety and efficacy.

- Policy and Ethical Considerations: Policymakers need to strike a balance between the urgency of vaccine development and ethical considerations, ensuring that shortcuts in clinical trials or manufacturing processes do not compromise vaccine safety and efficacy.

- Adapting to Climate Change and Globalization: As the world becomes increasingly interconnected and as climate change continues to impact global health, strategies must be devised to mitigate the heightened risk of pandemics. This includes enhancing surveillance, implementing rapid response systems, and fortifying global health infrastructure.