

VACCINE DEVELOPMENT, MANUFACTURING AND DISTRIBUTION DURING A PANDEMIC

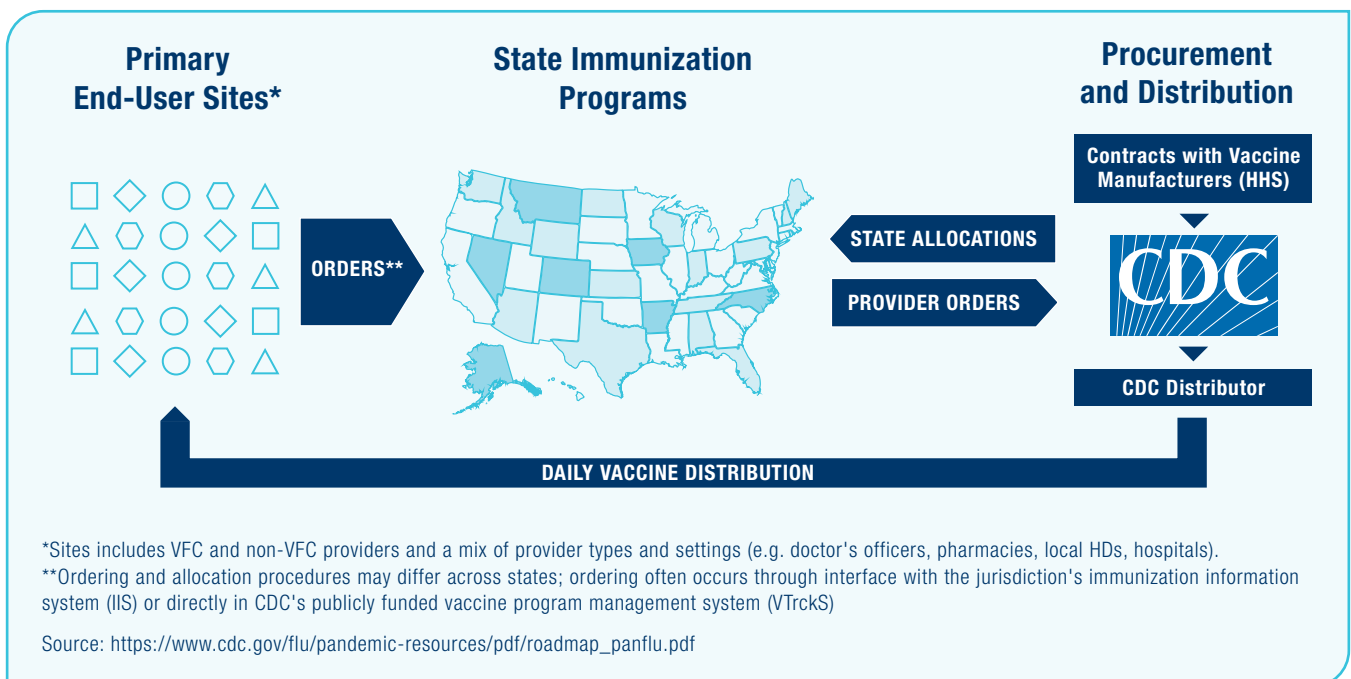
How would a COVID-19 vaccine be procured and distributed during the public health emergency?

Medical countermeasures (MCMs) – vaccines, therapeutics, and diagnostics – for biological threats resulting from a deliberate attack, laboratory accident, emerging infectious disease, or pandemic pathogen are developed through co-funded public-private partnerships between the U.S. government and biopharmaceutical companies.



Procurement of a COVID-19 vaccine, when available, may require multiple emergency supplementals to ensure an adequate supply of vaccines for all Americans. For our longer term preparedness against future biological threats, it is critical that Congress replenish and continue to fully fund BARDA, the Project BioShield SRF, and the SNS.

Over the past two decades, the federal government has developed plans for the distribution of a pandemic vaccine. The H1N1 pandemic vaccine was procured using supplemental funding and distributed according to these plans. Given the declaration of a public health emergency, COVID-19 vaccines will most likely be distributed in the same way.



How Public-Private Partnerships Fuel Response to Global Outbreaks

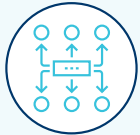
Ebola is an excellent example of the importance of public-private partnerships in responding to a potential global outbreak. **The partnership that came together to advance Merck's Ebola vaccine during two outbreaks was unprecedented in speed, scale, and diversity.**



Partnerships with WHO, national government research institutes and public health agencies, and NGOs are critical throughout the development process.



Industry partners invest significant human and financial resources for clinical development and licensure and building the capacity to manufacture the licensed doses needed to meet global demand.



Size, location, and timing of demand can be unpredictable and uncertain, even when a stockpile is the goal."



Company investments include building full-scale manufacturing capacity, often without a clear idea of global demand. Manufacturing is time-intensive and complex and cannot be turned on and off quickly.



The use of internal funds and resources for response to an emerging infectious disease results in significant opportunity costs as resources are diverted from ongoing R&D and manufacturing efforts aimed at tackling other critical unmet medical needs.



Capacity – people, licensed facilities, supply chains – must be maintained and sustained, even after an outbreak subsides

WHO: World Health Organization NGO: Non-Governmental Organization

To best ensure long-term broad global access to products for public health emergencies, industry participation must be sustainable. This includes the ability to recover investments, sustain manufacturing in the face of uncertain or highly variable demand, and re-invest funds into supporting the post-market clinical, regulatory, and manufacturing lifecycle management activities required for these products.