Current Thinking on Vaccine Production, Distribution, and Acceptance

Prepared by Kenan Institute Research Services, September 2020

Summary

Overall it seems that in general the public has been focusing on the wrong question. The question should not have been if we get a vaccine, but should have been will be able to get the vaccine out the door (do we have vials, syringes, needles, bottle stoppers). As things stand now, it seems that we will have a vaccine approved by the FDA by the end of the year (give or take a couple of months), but we may not be able to package all of the vaccines due to supply shortages (e.g. glass vials, etc.) and potential storage issues. Finally, state and local health departments, which have been tasked with distributing the vaccine to their communities, are underequipped to meet the demand. In essence, while we were so enamored by the heroic efforts of the medical community and the drama surrounding the vaccine development, we have become like the fated son of Zeus, Tantulus, banished to the underworld and unable to reach the lush fruit trees growing above him to quench his unyielding hunger and thirst.

Additionally, public perception of the safety of a vaccine will be important to a successful distribution of the vaccine. Currently, a recent Pew Research poll found that 49% of Americans would "probably not" or "would not" get the vaccine, up from 27% in May (). Right now, doctors estimate the 60-70% of the population need antibodies in order to reach herd immunity.

As for who should get the vaccine first – there are two primary models: (1) providing vaccines to healthcare workers and the most vulnerable; and, (2) distributing based on population. Many public health academics and economists are thinking about global distribution, rather than a U.S.-specific strategy, arguing a global pandemic need a global response. However, the United States has declined to join the WHO's global efforts for vaccine development and distribution.

U.S. Government Vaccine Development & Distribution Planning

- Operation Warp Speed, collaboration between DoD and HHS:
  - Info graphic on the distribution process
  - Manufacturing of the vaccine being done concurrently with clinical trials
  - Allocation of initial/limited doses will be based on CDC prioritization models
  - CDC - COVID-19 vaccine prioritization: Work Group considerations Report (August 26, 2020):
- Health and Human Services Distribution Strategy (developed with DoD and CDC):
  - Strategy document
  - CDC is working with state and local health departments to prepare for vaccine distribution and administration; CARES money was allocated to help prepare immunization programs; and there are five pilot jurisdictions (CA, FL, MN, ND, and Philadelphia). Each pilot develops its own "microplan"

- In a letter to State governors, CDC Director Redfield told them to be prepared to start distributing vaccines by November 1 – in particular, "CDC urgently requests your assistance in expediting applications for these distribution facilities and, if necessary, asks that you consider waiving requirements that would prevent these facilities from becoming fully operational by November 1, 2020." - https://apnews.com/71e616bb423c6d3e97fbaa7a97bca7e7
    - CDC Memo to State Governments on making preparations:
- Distributor chosen – McKesson:
    - Existing contract options with McKesson
    - Also distributed H1N1 vaccine in 2009-10
- Pre-COVID-19 CDC Guidance on vaccine distribution during a pandemic

Will State and Local Health Departments Be Ready?

- "But health departments that have been underfunded for decades say they currently lack the staff, money and tools to educate people about vaccines and then to distribute, administer and track doses to some 330 million people. Nor do they know when, or if, they'll get federal aid to do that." – Kaiser Health News
- There has not been a specific allocation of Federal funds to health departments for vaccine distribution. However, they can use some of the recent emergency funding for vaccine distribution, many have been overtaxed by testing and contact tracing, or they have been waiting for funds to arrive, and they'll likely need an infusion of funding for vaccine distribution (see summary article).
- Pharmacists in local drug stores/grocery stores/ etc. (e.g. CVS, Walgreens, Walmart) may be an important factor in vaccine distribution. The CDC recently allowed all children's vaccine to be given by a licensed pharmacists (rather than a doctor). A move that comes ahead of preparing for a covid vaccine. (see summary article)

Who Should Get the Vaccine First?

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- Two primary Models:
    - (1) Some experts have argued that health care workers and high-risk populations, such as people over 65, should be immunized first. (see John Hopkins framework below)
    - (2) The WHO suggests countries receive doses proportional to their populations.
        - COVAX Facility link1; link2:
        - COVAX is co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO. Its aim is to accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world.
- Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States, Center for Health Security (John Hopkins)
    - "It is important to emphasize that we are not providing a set of definitive recommendations about who should be prioritized for vaccination. Rather, based on our ethics framework, we have identified candidate groups that should be given serious consideration as priority groups."

    - Tier 1: Those most essential in sustaining the ongoing COVID-19 response; Those at greatest risk of severe illness and death, and their caregivers; Those most essential to maintaining core societal functions
    - Tier 2: Those involved in broader health provision; who face greater barriers to access care if they become seriously ill; Those contributing to maintenance of core societal functions; Those whose living or working conditions give them elevated risk of infection, even if they have lesser or unknown risk of severe illness and death
- Fair Priority Model – "An ethical framework for global vaccine allocation"
    - Led by Ezekiel Emanual from Penn
    - Who Should Get the COVID-19 Vaccine First? Penn-Led Team Lays Groundwork for Fair Distribution:
        - https://radioadvisory.advisory.com/35
        - "In their proposal, the authors point to three fundamental values that must be considered when distributing a COVID-19 vaccine among countries: Benefiting people and limiting harm, prioritizing the disadvantaged, and giving equal moral concern for all individuals. The Fair Priority Model addresses these values by focusing on mitigating three types of harms caused by COVID-19: death and permanent organ damage, indirect health consequences, such as health care system strain and stress, as well as economic destruction."
- In an NYT Op-Ed, economists from Stanford and Harvard argued for an Advance Market Commitments (AMC) model for COVID-19 vaccination distribution worldwide,
    - Learn more about AMC:

Potential Supply Chain Challenges

This article from Bloomberg does a nice summing up some of the supply chain issues specifically with the supplies needed to administer a vaccine: Without Vials and Needles, a Virus Vaccine Is Just a Formula https://www.bloomberg.com/features/2020-covid-vaccine-manufacturing-essentials/

- There is a global shortage on glass vials used to bottle the vaccine:
    - https://www.pharmaceuticalprocessingworld.com/could-honeywells-glass-bottles-alternative-help-covid-19-vaccine-distribution/
    - https://www.wsj.com/articles/coronavirus-vaccine-makers-are-hunting-for-vital-equipment-glass-vials-11592317525
    - CEO of AstraZeneca said: "The challenge is not so much to make the vaccine itself, it's to fill vials" and ""There's not enough vials in the world." They are looking to see if they can fit 5 to 10 does in a vial.
    - **Government contracts:** Government contract didn't happen until June for more vials.
    - Flurry of deals: https://www.bloomberg.com/news/articles/2020-06-25/fear-of-vial-shortage-for-covid-vaccines-prompts-flurry-of-deals
- Other supply issues: syringes, stoppers, etc.
- **Storage for vaccines could be an issue**. Moderna and Pfizer's vaccines need to be stored in very low temperatures:
    - CDC briefed on the issue

Trust and vaccine confidence: Will people take the vaccine?

- According to Pew Research, the share of Americans who said they would get vaccinated when the vaccine is ready has declined from earlier this year
- There is a lot of confusion at the federal level who is making decisions, causing mass concerns over vaccine safety
- Center for Health Security at John Hopkins released a report with recommendations, titled "
- The Public's Role in COVID-19 Vaccination: Planning Recommendations Informed by Design Thinking and the Social, Behavioral, and Communication Sciences.
    - Their list of recommendations (including an independent oversight committee, and programs to combat misinformation):
- Determinants of COVID-19 vaccine acceptance in the US
    - Abstract: The COVID-19 pandemic continues to adversely affect the U.S., which leads globally in total cases and deaths. As COVID-19 vaccines are under development, public health officials and policymakers need to create strategic vaccine-acceptance messaging to effectively control the pandemic and prevent thousands of additional deaths.
- One Brookings Fellow makes the argument that you should pay people to take the vaccine ; and it should come in two installments – one when you get the vaccine, and one when the U.S. reaches herd immunity. It's like we all get a pizza party for good behavior.
    - "Want herd immunity? Pay people to take the vaccine."
- Bloomberg opinion article on what would make it easier for people to get vaccinated (and trust getting):
- Social solidarity and widespread public trust needed to boost vaccine confidence during COVID-19: