Ripping Your Hair Out: How to Roll Out Vaccine X

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COVID Background

- Global pandemic.
- Novel virus with no readily available vaccine.
- Health departments had months to prepare for vaccine, but no clear deadline until days before vaccine arrived.
- Unexpected rollout leadership (Operation Warp Speed).
- Guidance on who was to be vaccinated immediately was changed rapidly.
- Cadence of vaccine delivery was unknown at first.

COVID Vaccine Challenges

- Vaccine product was a "new" type (mRNA).
- Vaccine required specialized storage and handling to maximize expiration dates.
- Vaccine product initially came in very large quantity packages.
- Messaging going to public at the same time as program.
- Demand outstripped supply.
- By the time supply was ample, demand was dropping.

COVID Vaccine Successes

- Strong focus on equitable distribution.
- Increased funding to programs allowed for new partnerships which we hope to maintain long term.
- Public/Private partnerships helped to create and distribute large amounts of vaccine quickly.
- COVID Vaccines have saved an estimated 3 million lives in the U.S. and over \$1 Trillion in healthcare costs.
- Staff have gotten a large amount of experience and subject matter expertise during a high pressure and compressed amount of time.

Mpox Background

- Relatively rare disease, spread through person-to-person contact.
- Symptoms include rash on hands, feet, chest, face, mouth, or on or near genitals.
- Other symptoms include fever, chills, exhaustion, muscle aches, cold symptoms.
- In spring 2022, increase in cases were being reported in the U.S.
- Cases were primarily affecting men who have sex with men.
- While previously called Monkeypox the name was changed to Mpox to help avoid stigma.

Mpox Vaccine Challenges

- Vaccine existed, but not originally recommended.
- No mass production.
- Only available through Strategic National Stockpile (SNS).
- Different ordering system.
- Limited recommendation to subpopulation.
- Many cooks in the kitchen (CDC, ASPR, Etc.).
- Changes to administration type (IM to ID) midstream (and almost too late), ID left marks on a community that is already isolated (stigma).
- Extremely limited distribution.

Mpox Vaccine Successes

- Vaccine already existed, just needed to be recommended.
- Partnerships established during COVID were leveraged to assist with vaccine distribution.
- Collaboration with STD and HIV partners which allowed use of their existing networks.
- Strong partnerships among state and local health departments, including the Pennsylvania and Philadelphia departments and their immunization programs.
- Vaccinations lead to declining case counts.

RSV Background

- Respiratory Syncytial Virus (RSV) is a common respiratory virus that infects the nose, throat, lungs and breathing passages.
- RSV can be serious for infants, toddlers, and adults over 60.
- In children <1, annually it leads to about 2.1 million outpatient visits, 58,000-80,000 hospitalizations, and about 100-300 deaths in children younger than 5.
- Additionally in adults over 65, it leads to about 6,000-10,000 deaths annually
- Prior to the 2023/2024 season there were no vaccines, and the only monoclonal antibody was only recommended to high-risk babies (and it was expensive)

Nirsevimab Challenges

- New monoclonal antibody for neonates and young babies entering their first RSV season approved in 2024.
- Target providers not enrolled in VFC Program everywhere.
- Not enough product for demand due to typical new product algorithm used by manufacturers.
- No ordering caps upfront from CDC, so disproportionate ordering occurred across the country.
- CDC "borrowing" messaging was confusing and often conflicted with local policy.
- New MAB rolled out at the same time as new vaccines for older adults/pregnant persons which caused confusion and some incorrect administrations.

Nirsevimab Successes

- VFC Program enrollment by birthing hospitals increased equitable access.
- White House involvement helped increase production.
- Nirsevimab is shown to be 90% effective at preventing RSVassociated hospitalization in infants during their first RSV season.
- This first season of having an immunization product available has been a great learning experience and improvements will be implemented for 2024-2025 season and beyond.
- This will include additional nirsevimab being available to meet demand.

Explanation and Transition to Tabletop Scenarios