COVID-19 | Vaccine Update

Live webinar held 11/13/20; slides updated 12/03/20
Welcome & Introductions

Special thanks to Emily Singleton, PharmD for content assistance
COVID-19 Bad News, Good News

Good News

- Better understanding of disease progression and mitigation strategies
- Transmission related to school attendance
- EUA approval of treatments (convalescent plasma and monoclonal antibodies)
- Early data from Pfizer and BioNTech vaccine is promising
- Moderna results anticipated within weeks

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Average # of New Cases the Last 7 & 14 Days Between School Ages (5‒18) & All Ages


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The effective reproduction number (or transmission rate) \((R_t)\) by county measures the effective number of people infected by each infected individual at time \(t\) under local conditions and practices. Each data point is a 14-day weighted moving average. A transmission rate above a rate of 1.0 signals a spread; a rate below 1.0 signals the spread is slowing.


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Vaccination Facts

INFLUENZA VACCINATION IS STILL IMPORTANT

Influenza Vaccine

CDC burden of influenza averted by vaccination last season showed it prevented:
• 7.5 million flu illnesses
• 3.7 million flu medical visits
• 105,000 flu hospitalizations
• 6,300 flu deaths

2019–2020 vaccination coverage among those 6 months and older increased from last season to nearly 52%

COVID-19 Vaccine

COVID-19 Vaccination availability per DOD briefing on Operation Warp Speed
• 10s of millions by the end of December
• 100s millions by January or February

You can receive the influenza & COVID-19 vaccine in the same visit

References:
Estimated Influenza Illnesses, Medical visits, Hospitalizations, and Deaths in the United States 2019-2020 Influenza Season. Available at: https://www.cdc.gov/flu/about/burden-averted/2019-2020.htm

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Operation Warp Speed (OWS)

Goal

• Deliver 300 million doses of safe & effective vaccines available by January 2021

Partnership

• Health & Human Services (HHS)
• Centers for Disease Control & Prevention (CDC)
• National Institutes of Health (NIH)
• Biomedical Advanced Research & Development Authority (BARDA)
• Department of Defense (DoD)

Payment

• ~$10B in federal funding has been dispersed to vaccine developers
• $6.5B for countermeasure development through BARDA
• $3B for NIH research
• All product produced through the OWS process will be given to the American people at no cost


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Historical vs. OWS Vaccine Development Process

**OPERATION WARP SPEED**
**ACCELERATED VACCINE PROCESS**

**MISSION:** Deliver 300 million doses of safe and effective vaccine by 1 January 2021.

**TYPICAL PROCESS**
- 3 MONTHS
- 5 MONTHS
- 21 MONTHS
- 3 MONTHS
- 15 MONTHS
- 6 MONTHS
- 73 MONTHS TO COMPLETION

**ACCELERATED PROCESS**
- 5 MONTHS
- 6 MONTHS
- 3 MONTHS
- 14 MONTHS TO COMPLETION

1. A typical 8-month process is accelerated by:
   - Creating vaccine candidates immediately after viral genome sequencing is available.
   - Using vaccine platforms developed for other diseases.

2. A typical 42-month process is accelerated by:
   - Large-scale Phase III clinical trials of 30,000+ volunteers allowing for rapid collection and earlier analysis of safety and efficacy data from large, demographically diverse populations by the FDA, reducing the typical 12-month approval process to three months.
   - Two promising candidates began Phase III clinical trials in July, with others to follow quickly in coming months. Before beginning Phase III, candidates must show safety data from animal and human studies.
   - The U.S. Government funding at-risk, large-scale manufacturing of the most promising vaccine candidates during Phase III clinical trials to ensure any vaccine proves to be safe and effective is available immediately upon FDA Emergency Use Authorization (EUA) approval or licensure.

3. A typical 6-month process is accelerated by:
   - A new approach based on CDC recommended allocation methodology used as part of pandemic planning.
   - Planning for infrastructure and distribution before the vaccines are approved or authorized.
   - CDC's leading distribution planning, with DoD augmentation.

4. A typical 15-month process is accelerated by:
   - Providing continuous safety and efficacy data collected in large Phase III clinical trials.

5. A typical 12-month FDA review for EUA approval or licensure is accelerated by:
   - R&D + Preclinical Trials: Vaccine Candidate Identified
   - Phase I Clinical Trials
   - Phase II Clinical Trials
   - Manufacturing
   - Distribution

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## Vaccine Candidates

### COVID-19 Candidates in Phase 3 in the U.S.

<table>
<thead>
<tr>
<th></th>
<th>BNT162b2</th>
<th>mRNA-1273</th>
<th>AZD1222</th>
<th>Ad26.COV2.S</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
<td>Pfizer &amp; BioNTech</td>
<td>Moderna</td>
<td>AstraZeneca &amp; University of Oxford</td>
<td>Janssen</td>
</tr>
<tr>
<td><strong>Platform</strong></td>
<td>mRNA</td>
<td>mRNA</td>
<td>Non-Replicating Viral Vector</td>
<td>Non-Replicating Viral Vector</td>
</tr>
</tbody>
</table>
| **Phase 3 Study Population** | • 43,538 participants enrolled  
• Age 12-85 years | • 30,000 participants enrolled  
• Age ≥18 years | • ~30,000 participants planned  
• Age ≥18 years | • ~60,000 participants planned  
• Age ≥18 years |
| **Dosing**         | 30 mcg/0.3 mL IM,  
2 doses 21 days apart  | 100 mcg/0.5 mL IM,  
2 doses 28 days apart | 5 × 10^{10} vp/0.5 mL IM,  
2 doses 28 days apart | 5 × 10^{10} vp/0.5 mL IM,  
1 dose |
| **How Supplied**   | Solution for dilution in 5-dose vial  | Solution in 10-dose vial  | Solution in 10-dose vial  | Solution in 5-dose vial |
| **Storage & Stability** | • 6 months in ultra-low temp freezer at -60 to -80°C  
• 30 days in thermal shipper at -60 to -80°C  
• 5 days in fridge at 2-8°C  
• After dilution, 6 hours at room temperature | • 6 months in freezer at -20°C  
• 30 days in fridge at 2-8°C  
• 12 hours at room temperature  
• Once entered, 6 hours at room temperature | • In fridge at 2-8°C  
• 4 hours at room temperature | • 3 months in fridge at 2-8°C  
• Once entered, 6 hours in fridge at 2-8°C |
| **Timeline**       | Expect to have data required for EUA by 3rd week of November then submit for EUA | Expect to have data required for EUA in 2nd half of November then submit for EUA | Expect to have data later this year | To be determined |

[https://clinicaltrials.gov](https://clinicaltrials.gov)
Vaccine Candidates’ Differing Approaches

U.S. COVID-19 Candidates in Phase 3

**SARS-CoV-2**

Spike Protein

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**mRNA**

Pfizer / Moderna

NUCLEIC-ACID VACCINES

- DNA vaccine
  - Electroporation
  - DNA
  - Coronavirus spike gene
  - A process called electroporation creates pores in membranes to increase uptake of DNA into a cell
  - Antigen-presenting cell
  - Coronavirus spike peptide
  - Immune response
  - Viral proteins
  - mRNA

RNA vaccine

- RNA is often encased in a lipid coat so it can enter cells

**Non-Replicating Viral Vector**

AstraZeneca / Janssen

VIRAL-VECTOR VACCINES

- Replicating viral vector (such as weakened measles)
  - The newly approved Ebola vaccine is an example of a viral-vector vaccine that replicates within cells. Such vaccines tend to be safe and provoke a strong immune response. Existing immunity to the vector could blunt the vaccine’s effectiveness, however.

- Non-replicating viral vector (such as adenovirus)
  - No licensed vaccines use this method, but they have a long history in gene therapy. Booster shots can be needed to induce long-lasting immunity. US-based drug giant Johnson & Johnson is working on this approach.

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https://www.nature.com/articles/s41563-020-0746-0
https://www.nature.com/articles/d41586-020-01221-y
Distribution in a Phased Approach

Phase 1: Potentially Limited Doses Available
- Projected short period of time for when doses may be limited

- Supply may be constrained
- Tightly focus vaccine administration
- Administer vaccine in settings best suited for reaching initial critical populations (workplaces, other vaccinations sites specific to Phase 1-A populations)

Phase 2: Large Number of Doses Available
- Likely sufficient supply to meet demand
- Expand beyond initial populations
- Use a broad provider network and settings including:
  - Healthcare settings (doctors' offices, clinics)
  - Commercial sector settings (retail pharmacies)
  - Public health venues (public health clinics, mobile clinics, FQHCs, community settings)

Phase 3: Continued Vaccination, Shift to Routine Strategy
- Likely sufficient supply
- Open access to vaccination
- Administer through additional private partner sites
- Maintain public health sites where required

Populations of Focus:

Phase 1
- Phase 1-A: Paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home.
- Phase 1-B: Other essential workers
- People at higher risk of severe COVID-19 illness, including people 65 years of age and older

Phase 2
- Remainder of Phase 1 populations
- Critical populations**
- General population

Phase 3
- Remainder of Phase 1 populations
- Critical populations**
- General population

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COVID-19 Vaccine Allocation Decision Framework

The NIH & CDC requested that the National Academies of Sciences, Engineering & Medicine & the National Academy of Medicine (NAM) develop a framework to assist policymakers’ plan for equitable allocation of COVID-19 vaccines.

NAM findings from Sept. 1 were shared with the CDC’s Advisory Committee on Immunization Practices (ACIP).

ACIP will review & incorporate epidemiology, vaccine safety, efficacy, quality & implementation issues.


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<th></th>
<th></th>
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<tbody>
<tr>
<td>1a</td>
<td>High-risk health workers</td>
<td>H</td>
<td>M</td>
<td>H</td>
<td>H</td>
<td>Adequate access to personal protective equipment. Workplace management of exposure.</td>
</tr>
<tr>
<td>1a</td>
<td>First responders</td>
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<td>M</td>
<td>H</td>
<td>H</td>
<td>Adequate access to personal protective equipment. Workplace management of exposure.</td>
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<td>1b</td>
<td>People with significant comorbid conditions (defined as having two or more)</td>
<td>M</td>
<td>H</td>
<td>M</td>
<td>M</td>
<td>Ability to maintain social distance and isolate.</td>
</tr>
<tr>
<td>1b</td>
<td>Older adults in congregate or overcrowded settings</td>
<td>H</td>
<td>H</td>
<td>L</td>
<td>M</td>
<td>Effective institutional management of exposure.</td>
</tr>
<tr>
<td>2</td>
<td>K-12 teachers and school staff and child care workers</td>
<td>H</td>
<td>M</td>
<td>H</td>
<td>H</td>
<td>Online schooling, especially for lower grades, recognizing educational and social impacts.</td>
</tr>
<tr>
<td>2</td>
<td>Critical workers in high-risk settings</td>
<td>H</td>
<td>M</td>
<td>H</td>
<td>M</td>
<td>Adequate access to personal protective equipment. Workplace management of exposure.</td>
</tr>
<tr>
<td>2</td>
<td>People with moderate comorbid conditions</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>Ability to maintain social distance and isolate.</td>
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<tr>
<td>2</td>
<td>People in homeless shelters or group homes and staff</td>
<td>H</td>
<td>H</td>
<td>L</td>
<td>H</td>
<td>Adequate access to personal protective equipment. Effective institutional/workplace management of exposure.</td>
</tr>
<tr>
<td>2</td>
<td>Incarcerated/detained people and staff</td>
<td>H</td>
<td>M</td>
<td>L</td>
<td>H</td>
<td>Adequate access to personal protective equipment. Effective institutional/workplace management of exposure.</td>
</tr>
<tr>
<td>2</td>
<td>All older adults</td>
<td>M</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>Ability to maintain social distance and isolate.</td>
</tr>
<tr>
<td>3</td>
<td>Young adults</td>
<td>H</td>
<td>L</td>
<td>M</td>
<td>H</td>
<td>Ability to maintain social distance and isolate. Closure of congregate settings (e.g., bars).</td>
</tr>
<tr>
<td>3</td>
<td>Children</td>
<td>M</td>
<td>L</td>
<td>M</td>
<td>M</td>
<td>Ability to participate in online schooling.</td>
</tr>
<tr>
<td>3</td>
<td>Workers in industries important to the functioning of society</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>Adequate access to personal protective equipment. Effective institutional/workplace management of exposure.</td>
</tr>
</tbody>
</table>
COVID-19 Vaccine Distribution: A Logistical Challenge

- McKesson will be the sole distributor for all COVID-19 vaccines with the exception of Pfizer.
- Pfizer vaccines will come direct from Pfizer to administration sites.
- Ancillary kits will be supplied separately but shipped to match vaccine delivery schedule.
- Partner depots (i.e., FedEx, UPS) have freezer farms to hold shipments.
- Ultra cold chain and two-shot vaccination series complicate the scenarios.

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[Diagram showing the overview of distribution and administration]

Vaccine Administration Supplies

**Administration Ancillary Kits**
- 105 Needles
  - Pediatric (25-gauge 1")
  - Adult (22-25-gauge 1-1.5")
- 105 Syringes (1-3mL)
- 100 vaccination record cards
- 1 Vaccine Needle Guide
- 210 Alcohol Prep Pads
- 4 Surgical Masks
- 2 Face Shields

**Diluent Kits & Timing of Delivery**
- **McKesson Distributed Vaccines**
  - For vaccines requiring a diluent to mix, a separate kit with needles, syringes & alcohol pads will be automatically ordered
  - May be delivered in separate package from vaccine, but arrive on or before vaccine delivery
- **Pfizer Distributed Vaccines**
  - Combined kit of administration supplies, mixing supplies & vials of diluent will ship together

**Additional Supplies Needed**
- For all vaccine administration:
  - Sharps containers
  - Exam gloves
  - Bandages
  - Additional PPE required by hospital policy
- For Pfizer vaccine:
  - Cryogenic gloves
  - Dry ice shovel / scoop
  - Eye protection

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Pfizer Candidate: How Supplied

1 Vial = 5 doses
1 Tray = 195 vials = 975 doses
1 Thermal Shipper = 5 trays = 975 vials = 4,875 doses

https://www.pfizer.com

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Pfizer Candidate: Storage & Stability

**DISTRIBUTION**

- Distribute in Thermal Shipper (-60 to -80°C)

**STORAGE**

- Store in Refrigerator (2-8°C) for ≤5 days
- Store in Thermal Shipper (-60 to -80°C) for ≤10 days if:
  - Unopened
  - Dry ice not replenished
- Store in Thermal Shipper (-60 to -80°C) for ≤30 days if:
  - Opened ≤2 times/day
  - Dry ice replenished within 24 hrs of delivery & every 5 days
- Store in Ultra-Cold Temp Freezer (-60 to -80°C) for ≤6 months

**PREPARATION**

- Thaw at Room Temperature (20-25°C) for 30 minutes to 2 hours
- Dilute
- Store in vial or syringe at Room Temperature (20-25°C) for ≤6 hours
- Administer
**Moderna Candidate: How Supplied & Storage & Stability**

- **Distribute at**: Freezing Temperature (-20°C)
  - In cartons of 10 vials with 10 doses per vial
- **Store in Freezer (-20°C)**
  - For ≤6 months
- **Store in Refrigerator (2-8°C)**
  - For 2 hours to ≤30 days
- **Thaw at Room Temperature (20-25°C)**
  - For 1 hour
- **Store at Room Temperature (20-25°C)**
  - For ≤12 hours total
  - For ≤6 hours once entered
- **Administer**

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[https://www.modernatx.com](https://www.modernatx.com)
How We Have Expedited Development

• Prior knowledge of coronaviruses (SARS, MERS)
• Improvement in gene sequencing
• Advancements in bioengineering tech
  – Weakened virus (Flu shots) – expensive & time-consuming
  – Spike Proteins (Sanofi, AZ)
  – Viral vector (J&J)
  – Genetic code (Inovio, Pfizer, Moderna) – first in class
• Government support & funding
  – $10 Billion in funding
  – Allows for parallel testing to occur without risk of losing millions
• Shortened testing timeline
  – Cells
  – Animals
  – Human
    ✓ Phase 1, 2 and 3 done in parallel
    ✓ Very costly – but government funded

Phase One  Phase Two  Phase Three

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COVID-19 Vaccine Safety & Efficacy

Pre-approval 5 checkpoints
1. Independent Safety Board
   • Data Safety and Monitoring Board (DSMB)
   • Independent interim analyses and pivotal role in pausing and resuming trials with unexpected results

2. Manufacturer Independent Safety Board
   • Teams of 4–10 with extensive experience in infectious disease and vaccine safety
   • 2–5 interim analyses may take place during their phase 3 trials

3. FDA Submission & Review
   • Evaluates safety, efficacy, immunogenicity, study design and other clinical factors
   • Evaluates the manufacturing rigor deployed and assesses quality of process

4. FDA Advisory Committee (VRBPAC)
   • Existing advisory committee meets to discuss safety, efficacy and manufacturing of vaccines (public)
   • Augmented advisory committee with leading Coronavirus experts

5. FDA Career Scientist
   • Ultimate decision-makers on EUA approval
   • Employees of the FDA that consist of physicians, scientists, pharmacists and statisticians

Post-approval safety monitoring
• Vaccine Adverse Event Reporting System
• Vaccine Safety Datalink
• Clinical Immunization Safety Assessment Project
• FDA and The Centers for Medicare and Medicaid Services
• FDA Biologics Effectiveness and Safety System
• FDA: Sentinel Initiative
• Department of Defense
• Department of Veterans Affairs
• Indian Health Service

Expanded safety monitoring
• CDC: V-SAFE
• CDC National Healthcare Safety Network
• FDA: Other large insurer/payer databases

References:
https://www.fda.gov/media/139638/download

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Program Planning – Getting Started

Connect with your jurisdiction

• Jurisdictions consist of:
  – 50 states
  – 6 cities (Chicago, Houston, Philadelphia, District of Columbia, New York City & San Antonio)
  – 8 territories (American Samoa, Guam, Marshall Islands, Micronesia, N. Mariana Islands, Palau, Puerto Rico, U.S. Virgin Islands)
  – 1 federal entity – Indian Health Services

• Each jurisdiction developed, and submitted for approval, its COVID-19 Vaccination Plan, based on the guidance from the CDC

• Access to executive summaries of these plans is available [here](https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html)

• The HealthTrust Vaccination Checklist

Each location wishing to receive/administer COVID-19 vaccine (point of dispensing) must work with its jurisdiction to complete the Vaccination Provider Enrollment & the CDC COVID-19 Vaccination Provider Profile form for each location where the vaccine will be administered.

References: [https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html](https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html)

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Consider Current Processes for Influenza Vaccination During COVID-19

**SIMILARITIES**

- Appropriate PPE for vaccine administrators
- Schedule appointments
- Screen for COVID-19 symptoms
- Call from car prior to entering
- Ensure patient flow to avoid congestion prior to and after vaccination
- Maintain social distancing and universal masking

**DIFFERENCES**

- Ordering
- Distribution
- Storage
- Reactogenicity
- Education

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Ordering & Distribution

Influenza Vaccine Pull With Open Dispensing

- Order vaccine and it is delivered to the site
- Points of dispensing (POD) are open
- Vaccine can be administered to any patient
- Vaccine is accessible in multiple locations

COVID-19 Vaccination Push/Closed Distribution

Initial Phases (I/II) of vaccination

- Vaccine is ordered by the jurisdiction through the VTrkS System
- The vaccine is pushed to the jurisdictions as it becomes available
- The jurisdiction allocates the vaccine to predetermined points of dispensing based on specific criteria
  - Jurisdiction Vaccination Plan
  - Advisory Committee for Immunization Practices
  - Sites ability to vaccinate target population
  - POD must file appropriate documents with the jurisdiction
- Vaccine is distributed to a defined population within the POD (closed dispensing)

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Storage

Risk of improper storage & security risk

- Each of the COVID-19 vaccines has different storage requirements
- Concerns have been voiced regarding security risk
- Delivery locations should have availability of 24-hour delivery with two points of contact for each location
- Review of standard operating procedures for vaccine delivery and security is recommended
- Ensure all staff are educated as to proper delivery and security procedures
- Staff must be educated on proper storage and handling of each vaccine
  - Dry ice management
  - Viability of vaccine once thawed


CDC Vaccine Storage and Handling Toolkit Available at: [https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)

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Reactogenicity – Body’s Local & Systemic Response to Vaccine

Safe vaccines can have significant reactogenicity. Note: all injections are likely to cause local pain & tenderness.

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Systemic Reaction Type (mild to moderate)</th>
<th>Timing of Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Messenger RNA Vaccine</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pfizer mRNA</td>
<td>Fever, chills, HA, myalgia, nausea</td>
<td>More significant after second dose</td>
</tr>
<tr>
<td>Moderna mRNA</td>
<td>Chills, HA, myalgia, fatigue</td>
<td>More significant after second dose</td>
</tr>
<tr>
<td><strong>Viral Vectored Vaccine</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AstraZeneca ChAd Spike</td>
<td>Chills, feverish, HA, malaise, muscle ache</td>
<td>More significant after first dose</td>
</tr>
<tr>
<td>Janssen Ad26 Spike</td>
<td>Fatigue, HA, myalgia, fever</td>
<td>More significant after first dose (within 2 days, lasting 2 days)</td>
</tr>
<tr>
<td><strong>SS-Protein Based</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Novavax</td>
<td>Systemic: Fatigue, HA, myalgia, malaise</td>
<td>Single dose vaccine</td>
</tr>
</tbody>
</table>

MHJ Lifesciences COVID-19 Race for a Vaccine webinar October 27, 2020
Available at: https://www.mjhlifesciences.com/covid/race-for-vaccine

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Staff Education

CDC recommended education

• Different vaccines: Storage, administration
• Vaccine development and safety
• Who will receive the vaccine when (Phase Ia, Ib, II, III)
• Currently no vaccination dosages for pediatric patients
• Who is considered a high-risk patient
• Vaccine administration record
• Vaccine adverse event reporting system (VAERS)
• Use of **vaccine finder**
• Necessary patient education:
  • Vaccine development and safety
  • Vaccinate even if previously COVID-19 positive
  • Two vaccines 21–28 days apart
  • Process for reminder notification
  • EUA process and paperwork
  • Potential side effects


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COVID-19 Vaccine Coordinator

Responsible for all vaccine management activities, including an in-depth understanding of the jurisdiction’s plan for vaccination.

**Responsibilities**

- Receive, process and maintain records of inventory
- Ensure acceptable temperature ranges have been maintained during transport
- Maintain proper vaccine storage & monitoring
- Request new inventory
- Maintain list of ordering and vaccinating providers with credentials
- Ensure proper education of staff


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For more COVID-19 Vaccine Resources

https://education.healthtrustpg.com/covid-19-resources/#vaccine-information

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Upcoming COVID-19 Vaccine Podcast & COVID-19 Collaborative Community

December 2020 – COVID-19 Vaccine Podcast
• Dr. John Young, CMO, HealthTrust and Dr. Kelly Moore, Founder and President of The Vaccine Advisor, discuss vaccine distribution planning, vaccine prioritization and programs.
• Join our Candid Conversations mailing list for podcast news and updates

COVID-19 Collaborative Community (HealthTrust Members Only)
• Directly connect with peers for collaborative learning in real-time to learn best practices
• Quick and easy access to HealthTrust COVID resources
• Awareness of HealthTrust educational events

Join our mailing list or Collaborative Community

Contact Elle Petty
Elle.Petty@healthtrustpg.com