



# COVID-19 Vaccine Planning

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# OUTLINE

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- Why do we need a vaccine?
- mRNA Vaccines
- SARS-CoV-2 Vaccine Candidates
- Phases of Manufacturing/Distribution Timeline
- Vaccine Priority Groups
- Maryland and Howard County Plans
- Sources of Additional Information and Updates

## WHY WE NEED A VACCINE

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- Pandemic spread of SARS-CoV-2 has had a devastating impact around the world
- Disease caused by the virus, COVID-19, has caused millions of severe illnesses and over 1.4 million deaths
- Spreads easily through populations via respiratory droplets
- Vaccination will be a key element in stopping the pandemic
  - Preventing infection
  - Reducing severity of disease

# MRNA VACCINES

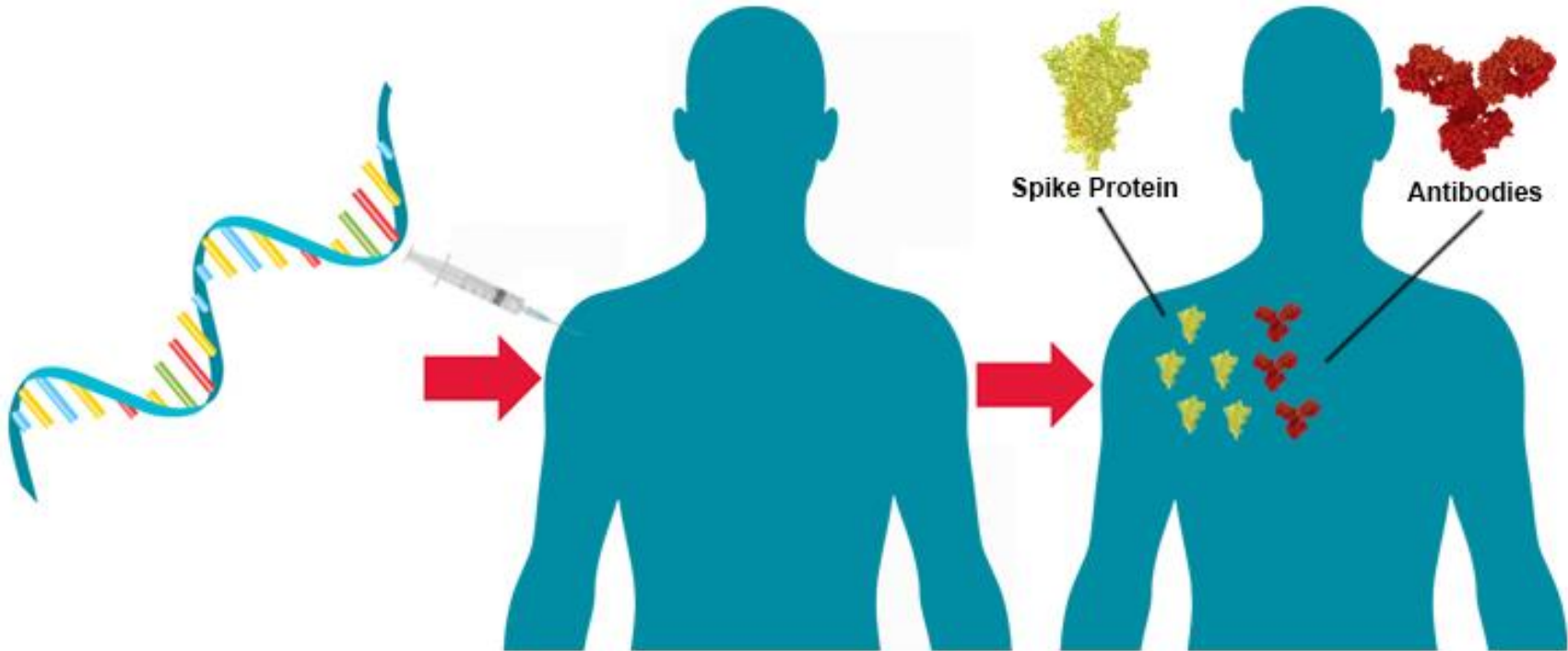
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- New technology making development faster and easier to standardize
- Safety
  - No infectious components used
  - No live virus
  - Does not interact with our DNA
- Efficacy
  - Provides instructions for our cells to make a harmless piece of the spike protein found on the virus surface
  - Injection to upper arm leads muscle cells to make copies of the protein piece
  - Immune system recognizes the protein as not belonging and builds an immune response that protects against future infection

mRNA for spike protein of coronavirus

mRNA is injected into muscle

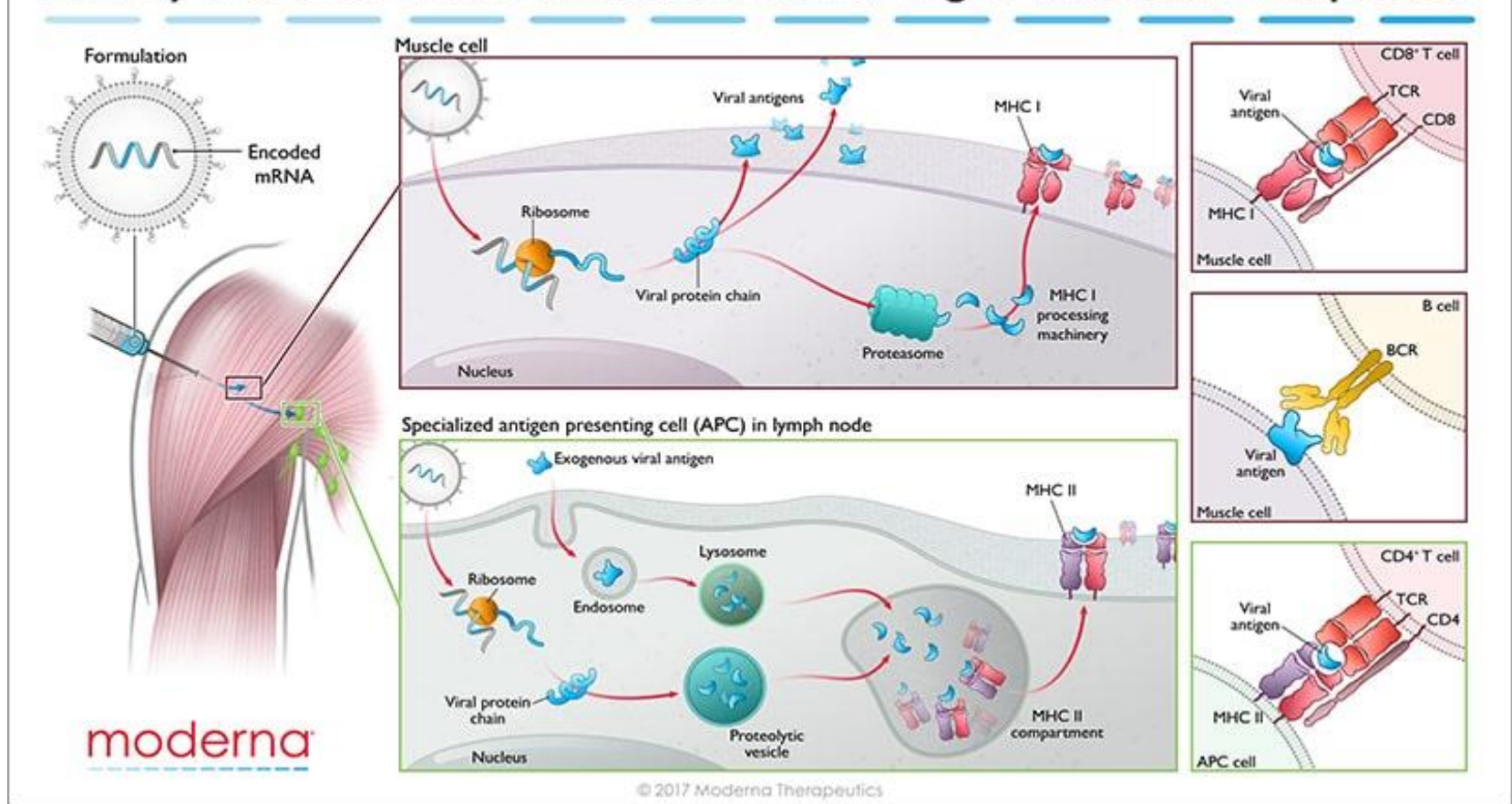
The vaccine triggers production of the spike protein and antibodies specific to it



NIH <https://directorsblog.nih.gov/2020/07/16/researchers-publish-encouraging-early-data-on-covid-19-vaccine/>

# Moderna's mRNA Vaccine Approach

Closely mimics a native viral infection leading to B and T cell responses



Moderna Inc <https://www.modernatx.com/moderna-blog/shedding-light-our-prophylactic-vaccines-moa>

# VACCINE CANDIDATES

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- **Pfizer** (mRNA)
  - 2 doses, 3 weeks apart
  - Ultra cold (-94°F) storage needed, once thawed can be kept in refrigerator 5 days, keeps only 6 hrs once diluted for use
- **Moderna** (mRNA)
  - 2 doses, four weeks apart
  - Stored frozen at -4°F, keeps for a month at refrigerator temp
- **AstraZeneca-Oxford** (Adenovirus vector)
  - 2 doses, one month apart
  - Can be stored at refrigeration temperatures for up to 6 months
- **58 Others in clinical trials:** include Johnson & Johnson (Ad vector, 1 dose); Novavax (recombinant protein, 2 doses), Sanofi (recombinant protein, 2 doses)

# VACCINE CANDIDATES

## Reactogenicity

Data from published Phase I/II trials  
Adults 18–55 years of age

**Moderna<sup>1</sup>**  
  
Symptoms  
greater after  
second dose

100µg	Post-dose 1			Post-dose 2		
N=15	Mild	Moderate	Severe	Mild	Moderate	Severe
Fever	—	—	—	5 (33%)	1 (7%)	—
Headache	4 (27%)	—	—	5 (33%)	4 (27%)	—
Myalgia	1 (7%)	—	—	2 (13%)	6 (40%)	—

**Pfizer<sup>2</sup>**

30µg	Post-dose 1			Post-dose 2		
N=12	Mild	Moderate	Severe	Mild	Moderate	Severe
Fever	1 (8%)	1 (8%)	—	—	2 (17%)	—
Headache	3 (25%)	1 (8%)	2 (17%)	6 (50%)	2 (17%)	—
Myalgia	1 (8%)	1 (8%)	1 (8%)	4 (33%)	3 (25%)	—

<sup>1</sup>Jackson et al. An mRNA Vaccine against SARS-CoV-2- Preliminary report. NEJM 2020;20:1920-1931.

<sup>2</sup>Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14.

# VACCINE CANDIDATES

## Reactogenicity

### Data from published Phase I/II trials

**Moderna<sup>1</sup>** ≥71 years of age Community-dwelling older adults

100µg	Post-dose 1			Post-dose 2		
N=10	Mild	Moderate	Severe	Mild	Moderate	Severe
Any systemic symptom	3 (30%)	—	—	3 (30%)	3 (30%)	1 (10%)*

\*Grade 3 fatigue

**Pfizer<sup>2</sup>** 65-85 years of age

30µg	Post-dose 1			Post-dose 2		
N=12	Mild	Moderate	Severe	Mild	Moderate	Severe
Fever	—	—	—	1 (8%)	—	—
Headache	—	—	—	2 (17%)	1 (8%)	—
Myalgia	—	—	—	2 (17%)	1 (8%)	—

Systemic symptoms lower among older adult population

<sup>1</sup>Anderson et al. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. NEJM 2020; online publication Sept 29

<sup>2</sup>Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14

# PRIORITY GROUPS FOR VACCINATION

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## **Recommended at a meeting of the Advisory Committee on Immunization Practices (ACIP) December 1:**

Once authorized by FDA and recommended by ACIP, vaccination in the initial phase (Phase 1a) should be offered to both:

- Health care personnel
  - paid and unpaid persons serving in healthcare settings with potential for direct or indirect exposure to patients or infectious materials
- Residents of long-term care facilities
  - adults who reside in facilities that provide services, including medical and personal care, to persons unable to live independently

# MARYLAND PLAN FOR COVID-19 VACCINATION

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- MD mass vaccination planning has been underway with federal partners since Spring
- MD Plan, based on CDC COVID-19 Vaccination Interim Playbook, will evolve with more info
- Health care providers are currently registering with the state to administer COVID-19 vaccine
- Local health departments, hospital systems, and pharmacies will also be key partners in administering vaccine

# PLAN COMPONENTS

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- Provider Enrollment
- Vaccine Ordering and Distribution
- Vaccine Administration
- Communication and Outreach

# VACCINE ADMINISTRATION

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- State will work with federal partners, local health systems, local health departments, and pharmacies to administer vaccine to Phase 1 priority groups
- Once vaccine is widely available (Phase 2), Marylanders will be able to receive vaccinations through their health care provider or at a pharmacy (similar to flu shot)
- Health equity considerations are crucial to ensure access across all populations

# COMMUNICATION AND OUTREACH

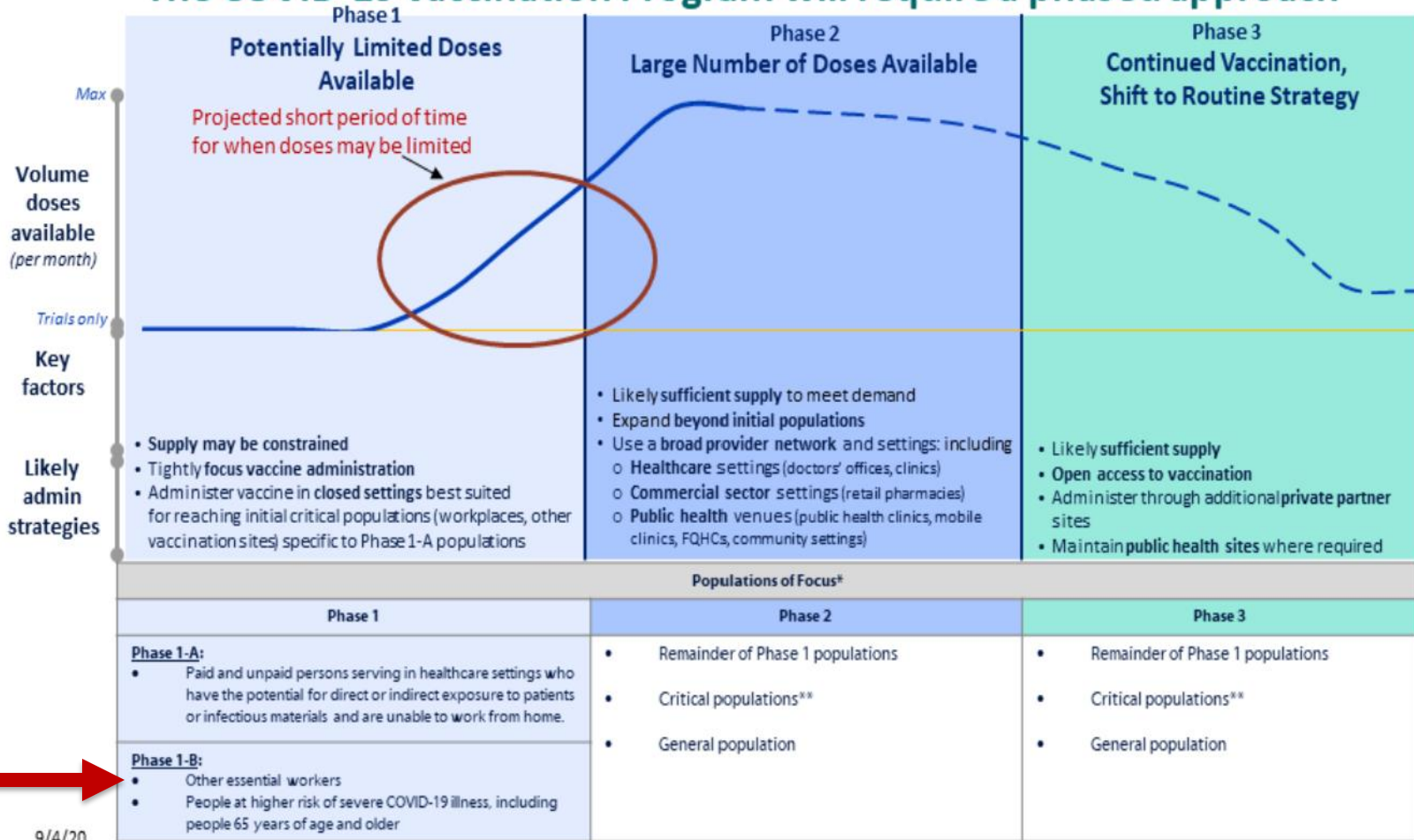
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Communication and sharing of information is crucial

- Some groups may be more hesitant to be vaccinated than others
- Messaging will need to provide facts about the vaccines(s), instill confidence, and encourage vaccination
- Outreach efforts will need to be culturally competent and account for the needs of communities of color and vulnerable populations

# A PHASED APPROACH

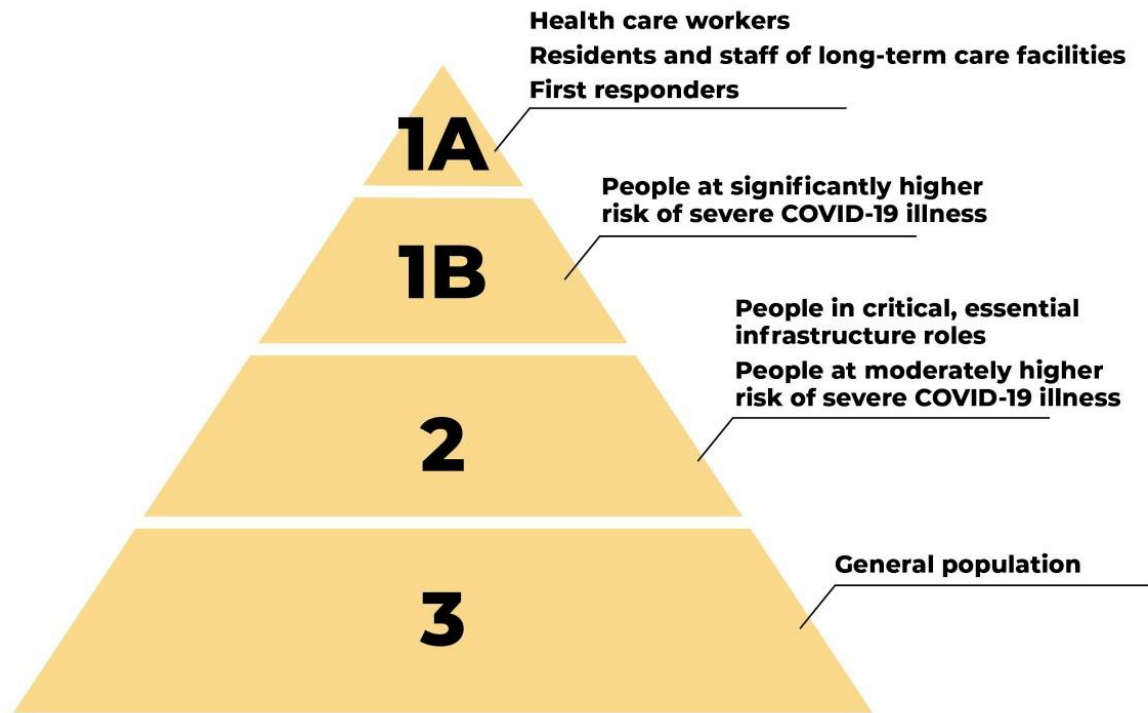
## The COVID-19 Vaccination Program will require a phased approach



9/4/20

# MARYLAND PRIORITY GROUPS

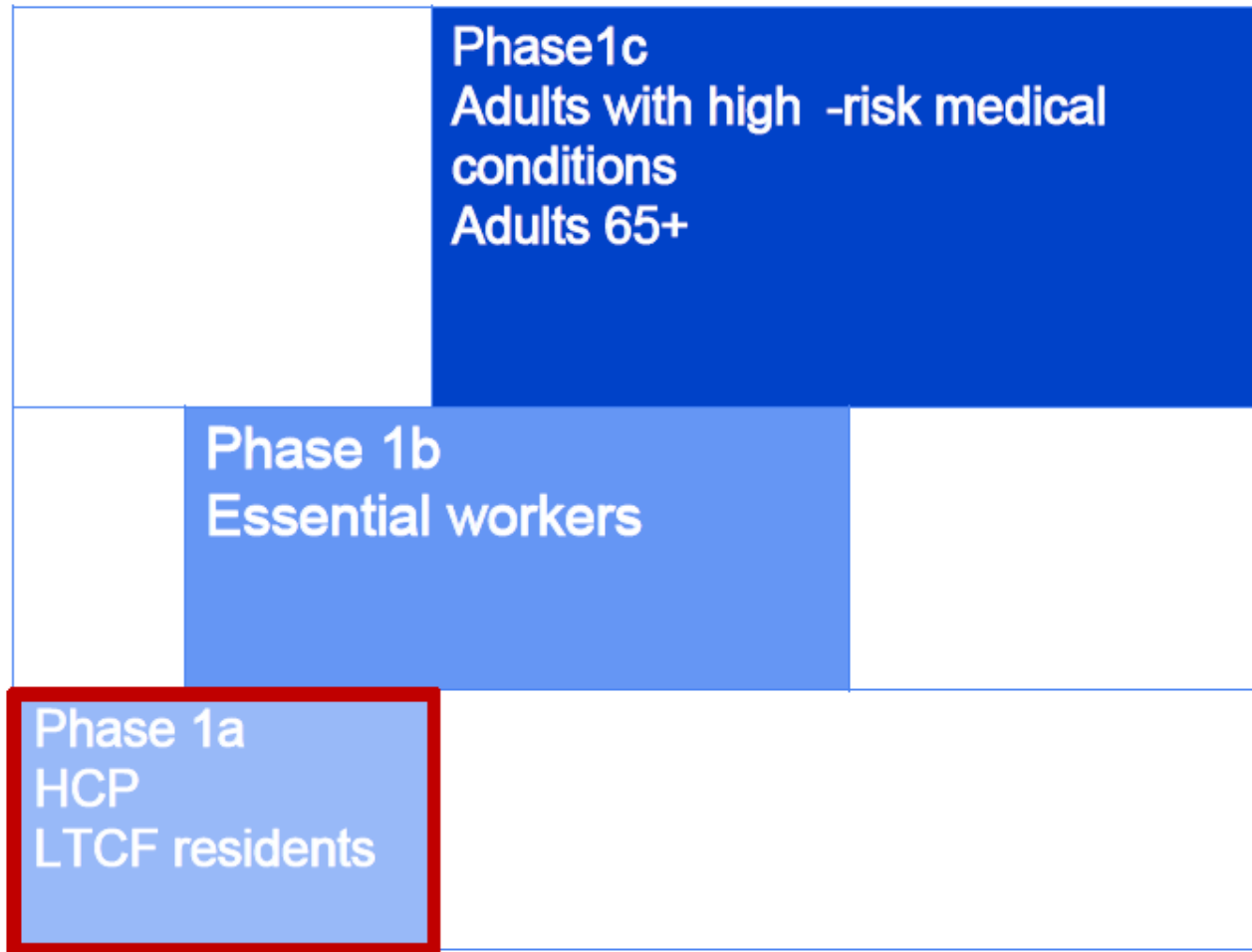
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Vaccine prioritization may be subject to change.

# PHASE 1 – LIMITED SUPPLY OF VACCINE

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# LOGISTICAL CONSIDERATIONS

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- The vaccine comes in two doses and registration will be required
  - Pfizer: Second dose required after three (3) weeks
  - Moderna: Second dose required after four (4) weeks.
- Registration will occur via PrepMod.  
(<https://www.marylandvax.org/>)
- Registration for both doses should be made at the same time.
- Reminder emails will be sent prior to appointments.
- Vaccine doses should be received at the required intervals to be effective.

# EMPLOYER & ESSENTIAL WORKER CONSIDERATIONS

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- Do not recommend vaccinating entire workforce at same time due to potential adverse effects and need for staff sick leave.
- Think about sub-prioritizing employees based upon occupational risk (not personal risk) factors.
- Schedule second dose at time of first appointment for adherence and maximum efficacy. (Pfizer second dose must be administered after 21 – 28 days of first dose.)
- Need guidance on pregnant women.

## HOW TO STAY UPDATED

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- Howard County Health Department [Coronavirus Website](#) or 410-313-6284
- Howard County Government [Coronavirus Updates](#)
- CDC [Coronavirus Vaccines](#)
- FDA [COVID-19 Vaccines](#)

# PROVIDER ENROLLMENT AND DATA SYSTEMS

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- Providers register with ImmuNet (immunization info system)
- MDH is working through partners to encourage providers to enroll
- All Phase 1 vaccinations to be scheduled and tracked per federal guidance
  - PrepMod/Hospital Electronic Health Record system used to schedule appointments and second dose reminders
  - ImmuNet to be used for ordering vaccine, data reporting, and patient record keeping

# VACCINE ORDERING AND DISTRIBUTION

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- Registered providers place vaccine orders in ImmuNet
- Vaccine will be shipped directly to the provider from CDC's distributor
- MDH will work with providers to track inventory and administration of vaccine and to ensure that if two doses are required, people receive the same product each time

# COMMUNITY AND STAKEHOLDER ENGAGEMENT

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State is establishing three advisory groups to provide guidance and recommendations to the state:

- Technical Advisory Group
- Vulnerable Populations Advisory Group
- Stakeholder Advisory Group