



South Carolina Department of Health and Environmental Control

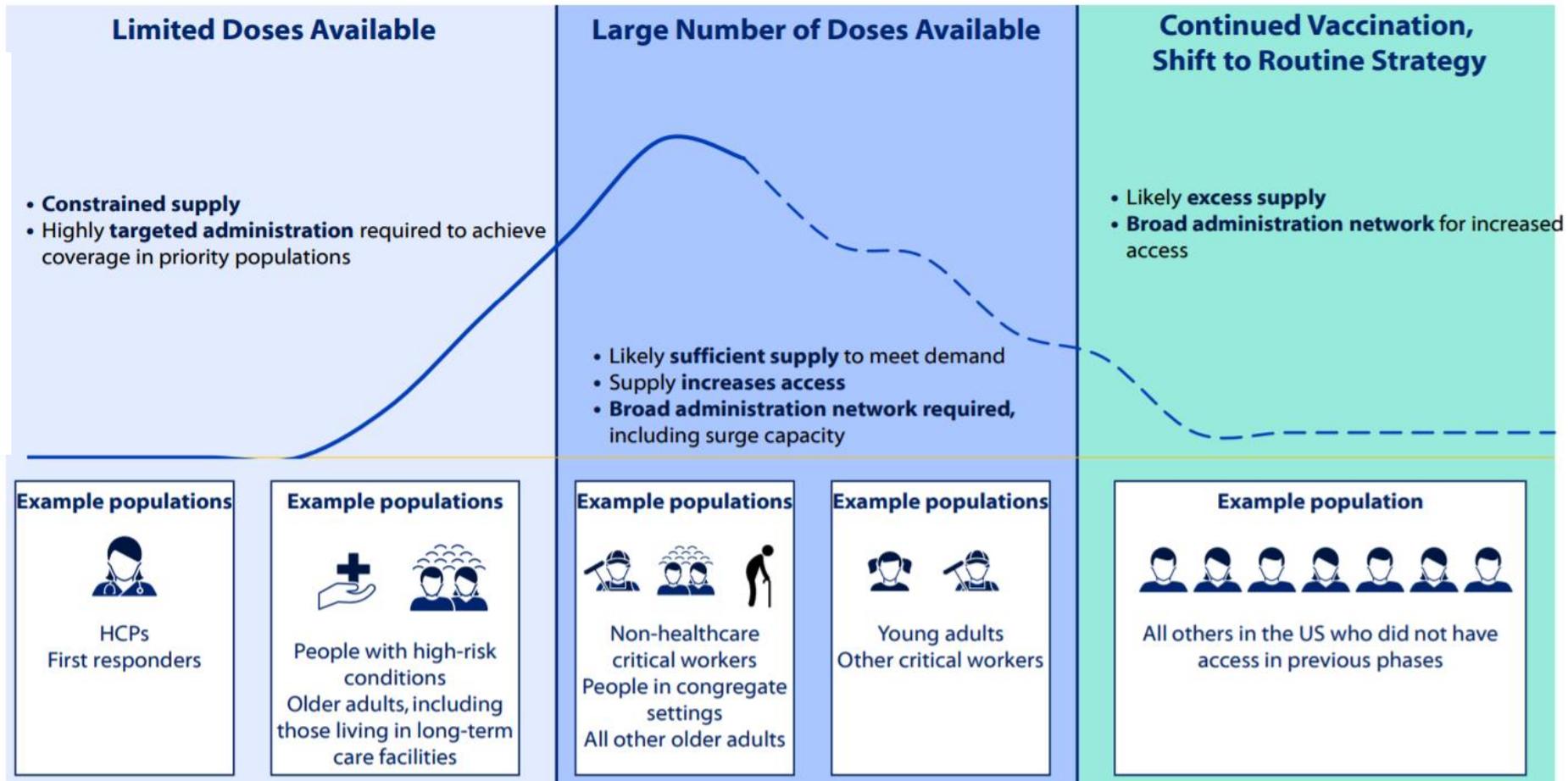
COVID-19 Vaccine Update

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SC DHEC
December 08, 2020



Phased vaccine allocation

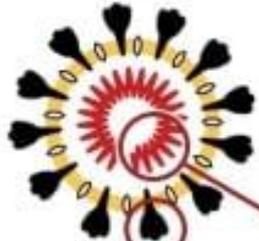
Distribution will adjust as volume of vaccine doses increases



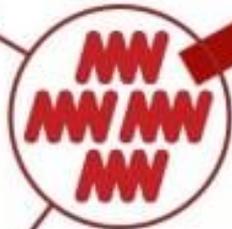
New vaccine technology

mRNA vaccine

SARS-CoV-2 virus

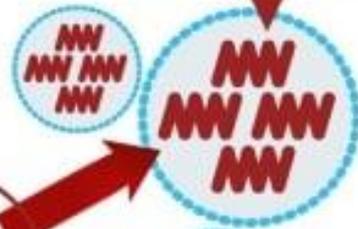


Spike protein

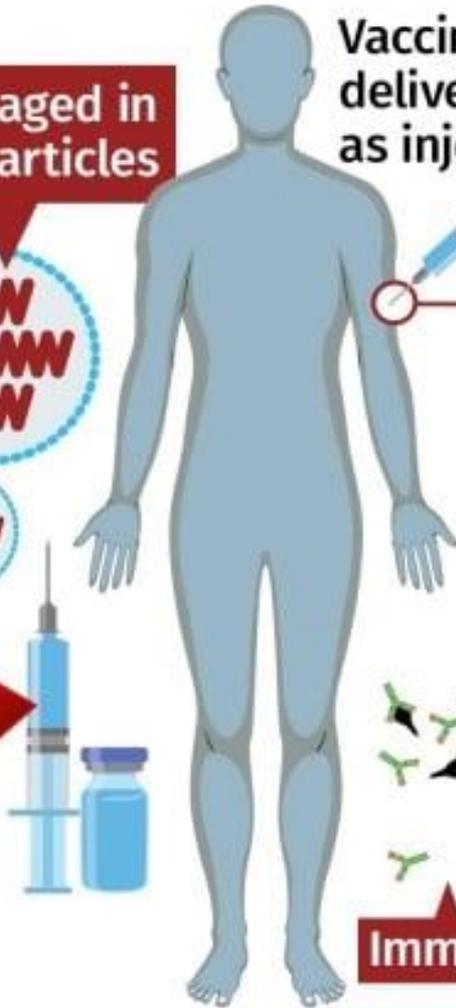


mRNA is made with instructions to make viral proteins

mRNA packaged in lipid nanoparticles



Vaccine delivered as injection



mRNA released into cell



Host cell

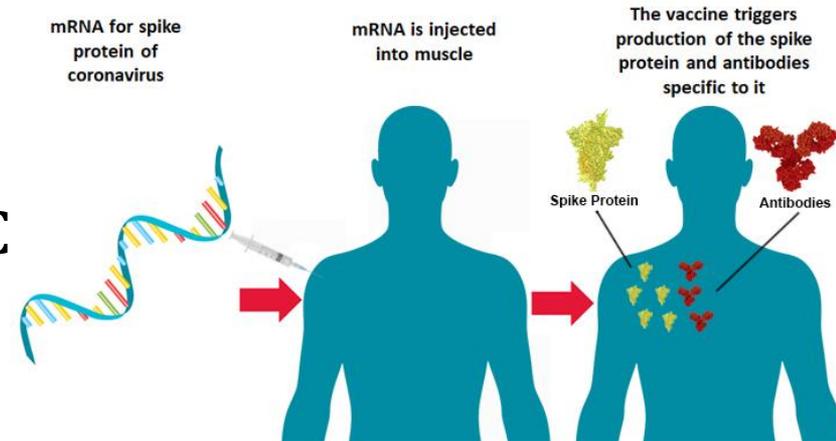
mRNA used to make viral proteins



Immune response

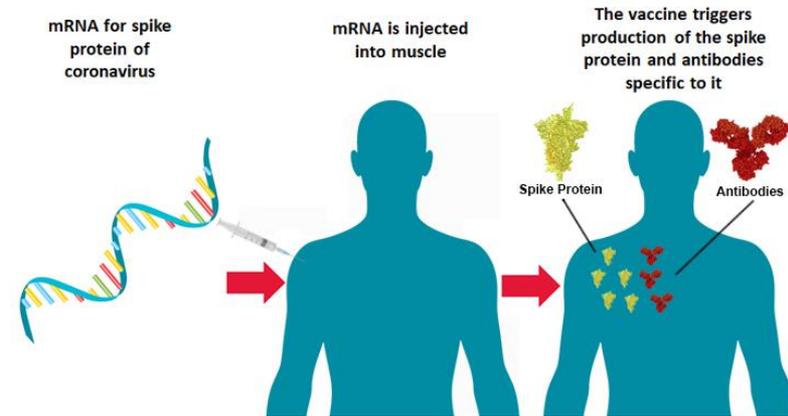
Moderna

- New technology, store at -20°C
- Refrigerate up to 30 days
- 2 injections 28 days apart
- Phase 3 study, >30,000 people
 - 94% efficacious: 196 w/ symptoms & tested positive for COVID
 - 185 placebo (30 severe disease), 11 vaccine (0 severe)
 - Immunity 14 days after 2nd dose (43 days after 1st dose)
- No serious adverse events, but more than half had fatigue, myalgias, chills, headache after second dose
- Mild-moderate pain at the injection site in almost all
- Cannot mix and match Pfizer and Moderna vaccines; 1st and 2nd dose must be of the same vaccine brand

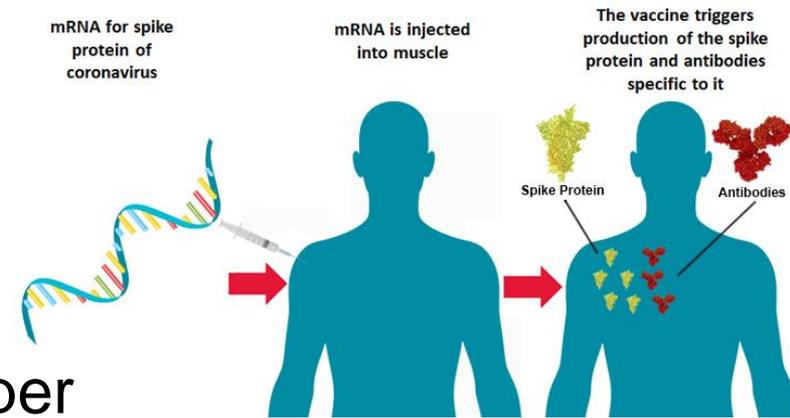


Pfizer

- New technology, store at -70°C
- 2 injections 21 days apart
- Phase 3 study in 42,000 people
 - 95% efficacious: 170 w/symptoms & tested positive for COVID
 - 162 placebo (9 severe disease), 8 vaccine (1 severe)
 - Immunity 7 days after 2nd dose (28 days after initiate vaccine)
- No serious adverse events, but more than half had fatigue, chills, headache, muscle aches after 2nd dose
- Mild-moderate pain at the injection site in almost all
- Likely authorized for emergency use after FDA and ACIP reviews 12/11/2020
- Special requirements to maintain cold chain



Pfizer



- Vaccine sent via a thermal shipper
- Three options for storage:
 - Ultra-low-temperature freezers
 - Pfizer thermal shippers can be used as temporary storage units by refilling with dry ice every five days for up to 30 days of storage.
 - Refrigeration units that are commonly available in hospitals
 - Once thawed, vaccine can be stored for five days at refrigerated 2-8°C conditions

Emergency Use Authorization (EUA)

- EUA issued only after safety and efficacy standards are met
- Determination that the known and potential benefits of the investigational product outweigh its known and potential risks
- Use of an investigational vaccine under an EUA is not subject to informed consent requirements; rather a Fact Sheet is provided

Vaccine Allocation

- CDC has indicated SC's anticipated allocation will be ~200,000 to 300,000 doses by the end 2020
- Those amounts are subject to change
- We won't know exact amount until doses received
- Current plan is weekly shipments as manufacturing increases
- Initially sending Pfizer vaccine to 5 secure locations capable of storing vaccine at ultra-cold temperatures
- From those 5 secure locations, vaccine will be distributed to licensed vaccine providers
- At this time, we have nearly 200 licensed vaccine providers across the state who have completed their enrollment to administer COVID-19 vaccine

Next Steps

- DHEC and the Vaccine Advisory Committee have draft plans for vaccine allocation for 1a and later phases
- Awaiting opportunity to review the ACIP recommendations on Dec. 11, 2020 before finalizing plans for Phase 1b, 2 and 3

Phase 1a Vaccination

- ACIP recommendations: “Health care personnel defined as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials”
- **Initial supply of vaccine will be limited; sub-prioritization is necessary**
- DHEC recommends vaccinating frontline workers in a healthcare setting that are at highest risk of contracting COVID-19 and who are essential to preventing mortality among confirmed COVID-19 cases
- Protecting the individual workers but also protecting the health care system

Phase 1a Vaccination

- Persons performing direct medical care to suspected and/or confirmed COVID-19 patients
- Ancillary staff directly interacting with suspected and/or confirmed COVID-19 patients
- Emergency room staff at high risk of exposure to suspected and/or confirmed COVID-19 patients
- Paid and volunteer medical first responders (EMS, paramedics, fire department personnel who provide emergency medical services) and hospital transport personnel in direct contact with suspected and/or confirmed COVID-19 patients

Phase 1a Vaccination

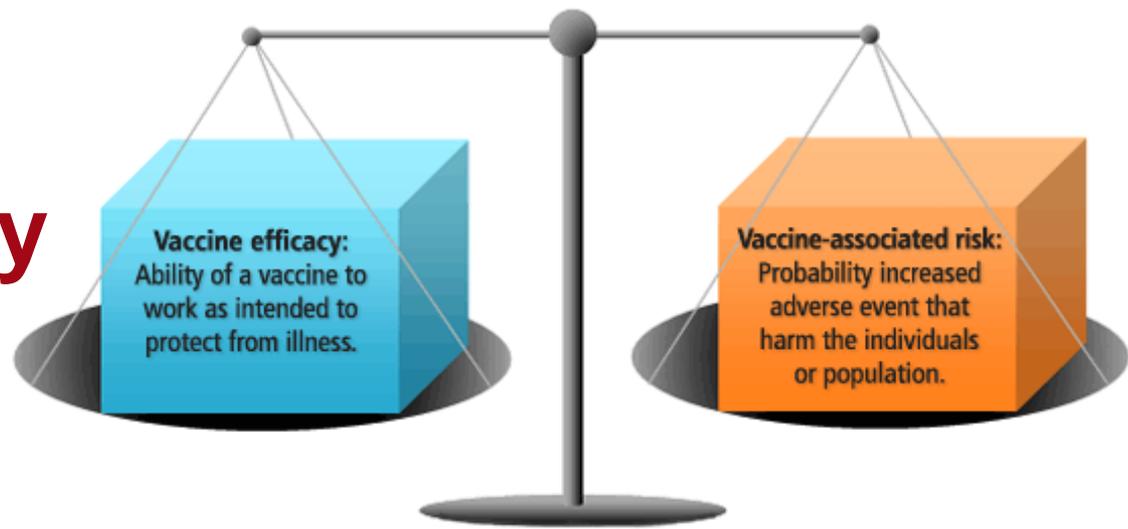
Persons providing direct medical care in

- Correctional facilities
- Long-term care facilities
- Dialysis and infusion centers
- Outpatient medical settings treating persons with suspected or confirmed COVID-19 infection
- Settings where monoclonal antibodies for COVID-19 infusions were given
- Home health and Hospice workers

Phase 1a Vaccination

- Residents and staff in long-term care facilities
- DHEC will provide guidance on sub-prioritization of HCP when vaccine supply is limited initially
- Guidance on scheduling to avoid potential clustering of worker absenteeism related to systemic reactions associated especially with the 2nd dose of vaccine
- DHEC will not require vaccination though individual facilities may as a condition for employment (similar to influenza vaccine)

Safety and Reactogenicity



- Generally want to minimize reactogenicity
 - Public perception of “flu” from influenza vaccine (i.e., innate immune response)
- Sometimes a reactogenic vaccine is better
 - New shingles vaccine (97% vs 51%)
- Patient’s perceived benefit vs. risk impacts willingness to receive vaccine

What symptoms may occur?

Moderna and Pfizer vaccines

(Results from limited number of people from Phase 1/2 studies)

- No serious adverse events
- Fewer and milder symptoms with the 1st dose than 2nd
- More than half had mild-moderate fatigue, chills, headache, muscle aches after 2nd dose
- Mild-moderate pain at the injection site
 - 1st dose ~60-80% mild 10% moderate
 - 2nd dose ~60-75% mild, up to 25% moderate)
- Up to 3% severe headache, up to 2% severe fatigue after 2nd dose

Discussing the facts around vaccine including side effects

- You, as a health care professional, are a trusted voice
- People need to know ahead of time about **possible local and systemic symptoms** (so they are not surprised!)
- Avoid the term “side effects”
- Use “temporary symptoms”
- Explain the symptoms are a sign that the vaccine is working; the immune system is responding

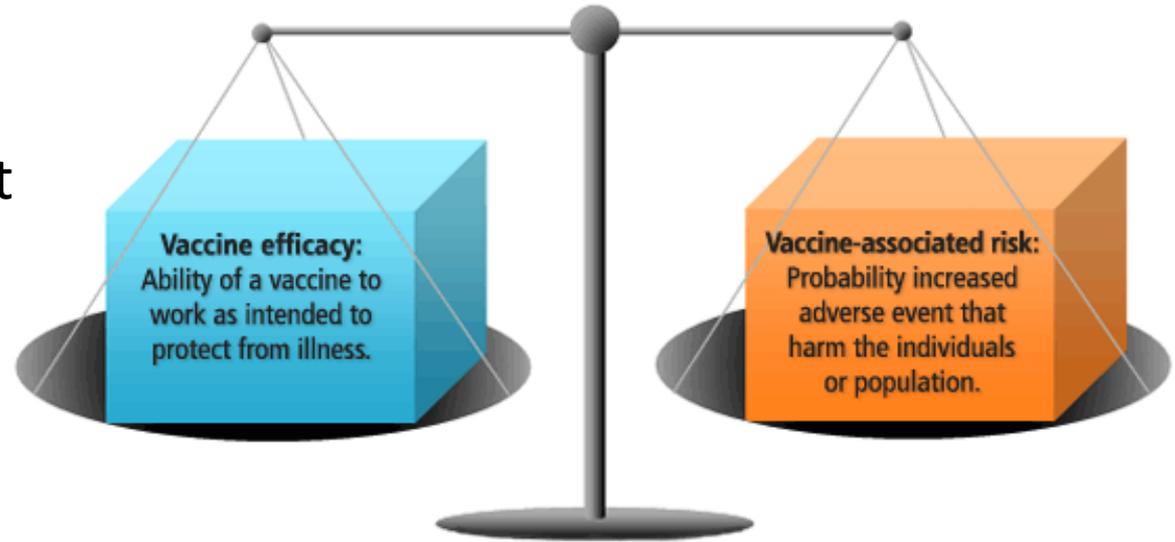


What should I tell people?

- Severe symptoms are rare, but mild-moderate ones are common, with the COVID-19 vaccines
- Consider the shingles vaccine analogy
 - Which would you prefer: the old shingles vaccine that causes fewer symptoms but only works half the time, or the new one that is 97% efficacious but may give you fever, myalgias, and fatigue for a couple of days?
 - Risks of vaccine vs. risk of COVID-19 disease
 - Don't forget you can take acetaminophen
- Workers might consider getting vaccinated when they have 1-2 days off following vaccination, especially after the second dose

What about long-term or rare side effects?

- Might not know about rare or long-term side effects until millions are vaccinated



- FDA and CDC will collect safety data from those vaccinated
- Will also have safety data from other countries (e.g., England)
- Each of us must weigh risk/benefit ratio:
 - Benefit of vaccine (with 95% efficacy) protecting from COVID-19 now vs.
 - Symptoms with vaccination and unknown rare or long-term risks

Institute for Health Metrics and Evaluation, SC, 12.06.2020

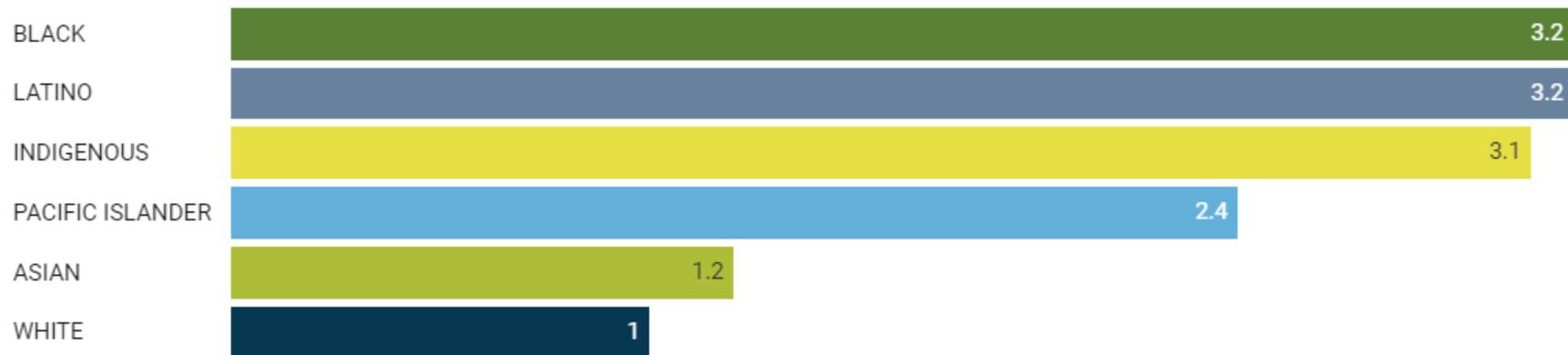
Table 1. Ranking of COVID-19 among the leading causes of mortality this week, assuming uniform deaths of non-COVID causes throughout the year

Cause name	Weekly deaths	Ranking
→ COVID-19	173	1
Ischemic heart disease	172	2
Tracheal, bronchus, and lung cancer	75	3
Chronic obstructive pulmonary disease	73	4
Stroke	73	5
Chronic kidney disease	39	6
Alzheimer's disease and other dementias	36	7
Colon and rectum cancer	28	8
Diabetes mellitus	27	9
Lower respiratory infections	25	10

Death rates for COVID-19

Adjusted for age, other racial groups are this many times more likely to have died of COVID-19 than White Americans

Reflects mortality rates calculated through Oct. 13.



Indirect age-adjustment has been used.

Source: [APM Research Lab](#) • [Get the data](#) • Created with [Datawrapper](#)

Vaccines don't save lives; vaccinations do!

- **Timeline not definite**
- USG contracted for 100M doses from each company
- CDC has indicated SC allocation will be ~200K-300K doses by the end of 2020 (subject to change)
- We won't know exact amount until doses are received
- DHEC anticipates this will be enough for medical first responders, frontline workers in medical settings at highest risk for COVID-19, residents/staff in LTCF
- Need to stagger vaccinations (don't vaccinate entire team at same time!), and not everyone in the first week
- As more vaccine becomes available early 2021, will expand vaccination program

Which facilities will receive vaccine first?

- **DHEC cannot publicly release this information**
- There are already threats and attempts of people trying to access the ultra-cold storage sites for cyber terrorism.
- Concern about a rush for vaccine
- Once vaccine becomes more readily available, likely sometime in 2021, we will release location sites to promote access.



Do I need to save and store the 2nd dose? No – example Pfizer vaccine

1 st week	2 nd week	3 rd week	4 th week (21 days after 1 st week)	5 th week (21 days after 2 nd week)
1000 doses				
	200 doses			
		200 doses		
			200 doses + 1000 booster for Week 1	
				200 doses + 200 booster for Week 2

Preventing disease vs. Preventing infection

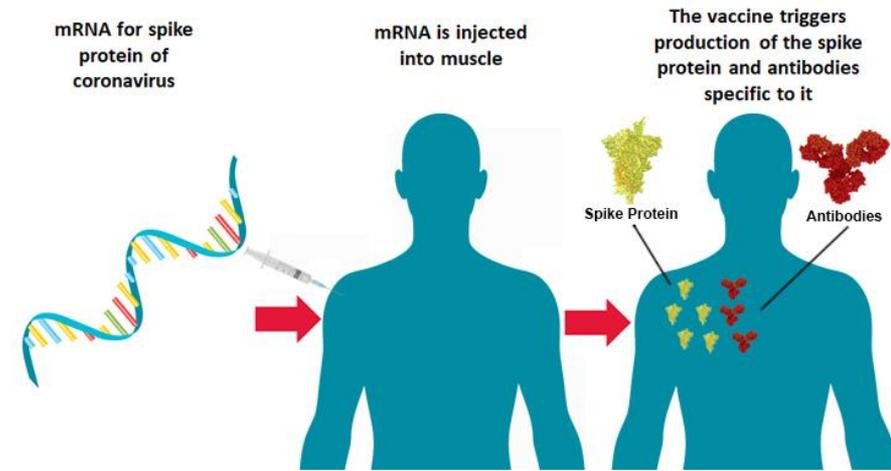


IPV



OPV

COVID-19 Vaccine Questions



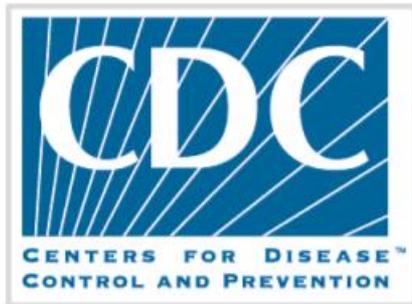
- Are the mRNA vaccines like IPV or OPV?
- Reduce infection and transmission or reduce symptomatic disease only?
- In HIV terms, U = U (undetectable = untransmittable)
- Does vaccinating me protect you?
- Do I have to wear a mask after vaccination?
 - Yes! Until we find out if V = U or we have a vast majority vaccinated
- Safe in immunocompromised? Organ transplant patients?

Safety in Pregnancy

- Pregnant women are excluded from vaccine trials
- mRNA vaccines do not contain a live virus but rather induce humoral and cellular immune response through the use of viral mRNA
- The theoretical risk of fetal harm from mRNA vaccines is very low
- As data emerge, counseling will likely shift, as some vaccines (e.g., AstraZeneca adenovirus vector) may be more suitable for pregnant women
- The Society for Fetal and Maternal Medicine recommends that healthcare workers, who are considered prioritized for vaccination, be offered the vaccine if pregnant
- <https://www.smfm.org/covidclinical>

Active safety follow-up (in addition to VAERS)

Vaccine safety assessment for essential workers (V-SAFE)



1. Text messages or email from CDC with follow-up – daily 1st week post-vaccination and weekly thereafter out to 6 weeks

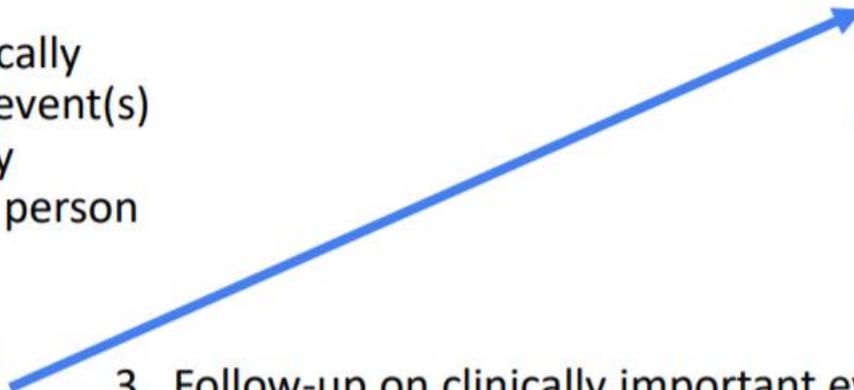


Healthcare workers, essential workers, etc.

2. Any clinically important event(s) reported by vaccinated person



VAERS call center



3. Follow-up on clinically important event, complete a VAERS report if appropriate

