Phased vaccine allocation

Distribution will adjust as volume of vaccine doses increases

- **Limited Doses Available**
  - Constrained supply
  - Highly targeted administration required to achieve coverage in priority populations

- **Large Number of Doses Available**
  - Likely sufficient supply to meet demand
  - Supply increases access
  - Broad administration network required, including surge capacity

- **Continued Vaccination, Shift to Routine Strategy**
  - Likely excess supply
  - Broad administration network for increased access

**Example populations**
- **HCPs First responders**
- **People with high-risk conditions**
- **Non-healthcare critical workers**
- **Young adults**
- **All others in the US who did not have access in previous phases**
New vaccine technology

mRNA vaccine
SARS-CoV-2 virus

mRNA packaged in lipid nanoparticles
Vaccine delivered as injection

mRNA released into cell

Host cell
mRNA used to make viral proteins

Spike protein
mRNA is made with instructions 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 2\textsuperscript{nd} dose (28 days after initiate vaccine)
- No serious adverse events, but more than half had fatigue, chills, headache, muscle aches after 2\textsuperscript{nd} 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
Fact Sheet for Vaccine Recipients and Caregivers

- Similar to Vaccine Information Statement (VIS) for licensed vaccines
- Will provide specific information about each COVID-19 vaccine, including:
  - Basic information on COVID-19, symptoms, and what to discuss with a healthcare professional before vaccination
  - Who should and should not receive the vaccine
  - That recipients have the choice to receive the vaccine
  - Vaccine series information
  - Risks and benefits of the vaccine, including common side effects
  - Information on reporting side effects to VAERS
  - An explanation of what an EUA is and why it is issued
  - Any approved available alternatives for preventing COVID-19
  - Additional resources

- Written informed consent is not required under EUA
- Translations anticipated to be available
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 2\textsuperscript{nd} 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 1\textsuperscript{st} dose than 2\textsuperscript{nd}
• More than half had mild-moderate fatigue, chills, headache, muscle aches after 2\textsuperscript{nd} dose
• Mild-moderate pain at the injection site
  • 1\textsuperscript{st} dose \sim 60-80\% mild 10\% moderate
  • 2\textsuperscript{nd} dose \sim 60-75\% mild, up to 25\% moderate)
• Up to 3\% severe headache, up to 2\% severe fatigue after 2\textsuperscript{nd} 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
Table 1. Ranking of COVID-19 among the leading causes of mortality this week, assuming uniform deaths of non-COVID causes throughout the year

<table>
<thead>
<tr>
<th>Cause name</th>
<th>Weekly deaths</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19</td>
<td>173</td>
<td>1</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>172</td>
<td>2</td>
</tr>
<tr>
<td>Tracheal, bronchus, and lung cancer</td>
<td>75</td>
<td>3</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>73</td>
<td>4</td>
</tr>
<tr>
<td>Stroke</td>
<td>73</td>
<td>5</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>39</td>
<td>6</td>
</tr>
<tr>
<td>Alzheimer’s disease and other dementias</td>
<td>36</td>
<td>7</td>
</tr>
<tr>
<td>Colon and rectum cancer</td>
<td>28</td>
<td>8</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>27</td>
<td>9</td>
</tr>
<tr>
<td>Lower respiratory infections</td>
<td>25</td>
<td>10</td>
</tr>
</tbody>
</table>
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.*

<table>
<thead>
<tr>
<th>Race</th>
<th>Death Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>3.2</td>
</tr>
<tr>
<td>Latino</td>
<td>3.2</td>
</tr>
<tr>
<td>Indigenous</td>
<td>3.1</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>2.4</td>
</tr>
<tr>
<td>Asian</td>
<td>1.2</td>
</tr>
<tr>
<td>White</td>
<td>1.0</td>
</tr>
</tbody>
</table>

*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 2\textsuperscript{nd} dose? No – example Pfizer vaccine

<table>
<thead>
<tr>
<th>1\textsuperscript{st} week</th>
<th>2nd week</th>
<th>3\textsuperscript{rd} week</th>
<th>4\textsuperscript{th} week (21 days after 1\textsuperscript{st} week)</th>
<th>5\textsuperscript{th} week (21 days after 2\textsuperscript{nd} week)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>200 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>200 doses</td>
<td></td>
<td></td>
<td></td>
<td>200 doses + 1000 booster for Week 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200 doses + 200 booster for Week 2</td>
<td></td>
</tr>
</tbody>
</table>
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 vaccine 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](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.

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

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

**VAERS call center**

**Healthcare workers, essential workers, etc.**