CME Pre-Training Assessment

If you are seeking 1 credit of CME for participating in this session, PLEASE FOLLOW THE LINK BELOW (also noted in Zoom chat box), to take the required pre-test.

THIS IS NOT REQUIRED for those seeking CPE (pharmacy continual education credit). CPE information will be available at the end of the presentation.

https://ndstate.co1.qualtrics.com/jfe/form/SV_8dLAKDiM4ldvs5n
Polling Questions
What is your professional designation? N=244

- RN, LPN: 34%
- PharmD, RPh: 25%
- Student: 17%
- Other: 9%
- MD, DO: 7%
- Public Health Professional: 5%
- PA, NP: 3%
- PhD: <1%
PRE-presentation: If the FDA authorized a vaccine to prevent COVID-19 today, at no cost under Emergency Use Authorization, would you agree to be vaccinated? N=249

- Yes: 49%
- No: 13%
- Unsure: 38%
What would be the absolute lowest possible rate of severe adverse events, also referred to as SAE (e.g. an event following vaccination which was life-threatening or requires hospitalization) in a COVID-19 vaccine that you find acceptable? N=241
What do you think is the relative risk of acute respiratory distress syndrome (ARDS) in a laboratory-confirmed COVID-19 case compared to a patient with influenza? N=247

- 10% of Participants think the same
- 34% think it is 2x higher
- 51% think it is 13x higher

Correct Answer: 19x higher
If someone becomes sick from COVID-19, what do you think is their overall chance of being hospitalized? N=252

- 31% believe the chance is less than 1%
- 48% believe the chance is 5%
- 18% believe the chance is 14%
- 3% believe the chance is 36%

Correct Answer: 14%
Learning Objectives

1. Describe the virology and epidemiology of the SARS-CoV-2 virus.

2. Describe the development, licensure, approval, and possible distribution of the COVID-19 vaccine.

3. Accurately and confidently address patient concerns with the COVID-19 vaccine.

4. Describe North Dakota’s role in planning for the pilot distribution of COVID-19 vaccine.
Coronaviruses are a large family of viruses - some cause illness in people, and others only infect animals.

Common coronaviruses (NL63, 229E, OC43, HKU1) cause mild upper-respiratory illnesses, like the common cold.

Some coronaviruses infect animals then spread to people, and then spread person to person such as:

- Middle East Respiratory Syndrome (MERS)
- Severe Acute Respiratory Syndrome (SARS)
- SARS-CoV-2 (COVID-19)
Drop in share of Americans who say they would get a COVID-19 vaccine if it were available to them today

<table>
<thead>
<tr>
<th>Would get the vaccine</th>
<th>May '20</th>
<th>Sept '20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitely</td>
<td>42%</td>
<td>21%</td>
</tr>
<tr>
<td>Probably</td>
<td>30%</td>
<td>30%</td>
</tr>
<tr>
<td>Probably</td>
<td>16%</td>
<td>25%</td>
</tr>
<tr>
<td>Definitely</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>Would NOT get the vaccine</td>
<td>27%</td>
<td>24%</td>
</tr>
</tbody>
</table>

Pew Research Center
Vaccine

RISK

BENEFIT
Tend to use (less accurate) quick rule of thumb calculations of risk

Do no harm: bad outcome from inaction more tolerable than bad outcome from action

Ambiguity: more comfortable with known than unknown risks

Availability bias: we conflate things that we remember easier

Compression: we overestimate rare risks and underestimate common risks, especially as they become more familiar
United States

Coronavirus Cases: 8,827,932

Deaths: 230,068
Prevalence of Any Underlying Medical Conditions for Severe COVID-19 Outcomes

Median County Prevalence for Any Medical Condition

47%
Where Does COVID-19 Fit Amongst Our Pandemic Influenza Outbreaks?

![Graph showing severity categories](image-url)

- **Low Severity**: 2011-12
- **Seasonal range**: 2011-12
- **High Severity**: 2009 pandemic
- **Very High Severity**: 1918 pandemic, 1957 pandemic, 1968 pandemic
- **COVID-19**
### Worst Case Scenario?

<table>
<thead>
<tr>
<th>Calculation</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Population x % Susceptible x IFR = Total Mortality</td>
<td>328 million x 50-90% x 0.6% = 164-295 million</td>
</tr>
<tr>
<td>Total Mortality</td>
<td>984,000 – 1.8 million</td>
</tr>
</tbody>
</table>
Aren’t You Just Kicking the Can Down the Road?

Vaccines And Treatments!
The Odds an American Will…

Develop shingles in one’s lifetime
1 in 3

Die of COVID-19
1 in 300

Die of choking on food
1 in 2,696

Die of flu*
1 in 4084

Die of lightning strike
1 in 161,856

Develop Guillain-Barre Syndrome or anaphylaxis from vaccination
1-2 in 1,000,000

*Based on flu deaths in the United States during the 2017-2018 flu season

Table taken from:
## Risk of COVID-19 Infection for Hospitalization or Death

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Hospitalization / 100k</th>
<th>Death / 100k</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-9</td>
<td>50</td>
<td>2</td>
</tr>
<tr>
<td>10-19</td>
<td>150</td>
<td>6</td>
</tr>
<tr>
<td>20-29</td>
<td>600</td>
<td>30</td>
</tr>
<tr>
<td>30-39</td>
<td>1,600</td>
<td>80</td>
</tr>
<tr>
<td>40-49</td>
<td>2,500</td>
<td>150</td>
</tr>
<tr>
<td>50-59</td>
<td>5,100</td>
<td>600</td>
</tr>
<tr>
<td>60-69</td>
<td>8,300</td>
<td>2,200</td>
</tr>
<tr>
<td>70-79</td>
<td>12,100</td>
<td>5,100</td>
</tr>
<tr>
<td>80+</td>
<td>13,600</td>
<td>9,300</td>
</tr>
</tbody>
</table>

Adapted from Verity R et al. Lancet Inf Dis, 2020

### Adverse Reactions

- **Anaphylaxis - all vaccines**: 0.1 : 100k
- **RRV – Intussusception**: 1 : 100k
- **MMR ITP**: 2.5 : 100k
- **Yellow Fever Vaccine**: 0.4 : 100k
- **Smallpox – Encephalitis**: 1.2 : 100,000
Herd Immunity = $1 - \frac{1}{R_0}$

50% - 67%

% Immune = \% Vaccinated \times \% VE
Where FDA Has Set the Bar for Efficacy

50%
### Sample Size Needed to Detect an Adverse Event Greater than the Background Rate

<table>
<thead>
<tr>
<th>Background rate in general population</th>
<th>Rate in Vaccinated Population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5-fold higher</td>
</tr>
<tr>
<td>1 in 10,000</td>
<td>16,000</td>
</tr>
<tr>
<td>1 in 100,000</td>
<td>160,000</td>
</tr>
<tr>
<td>1 in 1,000,000</td>
<td>1,599,000</td>
</tr>
</tbody>
</table>

Assumes 5% risk of Type I error and power of 90%

## Comparing Clinical Trial Sizes of Vaccine Series

<table>
<thead>
<tr>
<th>Vaccine or Developer</th>
<th>Type of Vaccine</th>
<th>Protects Against</th>
<th>Approval Year</th>
<th>Doses</th>
<th>Phase II n</th>
<th>Phase III n</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPOL</td>
<td>Inactivated</td>
<td>Polio</td>
<td>2000</td>
<td>4</td>
<td>361</td>
<td>2,358</td>
</tr>
<tr>
<td>Daptacel</td>
<td>Combination</td>
<td>Diphtheria,</td>
<td>2002</td>
<td>5</td>
<td>7,471</td>
<td>10,575</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tetanus, Pertussis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gardasil</td>
<td>Subunit</td>
<td>HPV</td>
<td>2006</td>
<td>3</td>
<td>4,047</td>
<td>22,938</td>
</tr>
<tr>
<td>Prevnar 13</td>
<td>Inactivated</td>
<td>Pneumococcal</td>
<td>2010</td>
<td>4</td>
<td>1,478</td>
<td>49,296</td>
</tr>
<tr>
<td></td>
<td></td>
<td>disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderna/NIH</td>
<td>mRNA</td>
<td>COVID-19</td>
<td>-</td>
<td>2</td>
<td>600*</td>
<td>30,000</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>Viral vector</td>
<td>COVID-19</td>
<td>-</td>
<td>2</td>
<td>394*</td>
<td>60,000</td>
</tr>
<tr>
<td>BioNTech/Pfizer</td>
<td>mRNA</td>
<td>COVID-19</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>43,000†</td>
</tr>
</tbody>
</table>

*combined phase I and phase II trial
†combined phase II and phase III trial

Reference:
I need to see the long-term results before I’ll take any vaccine!
- Ambiguity: more comfortable with known than unknown risks
- Do no harm: bad outcome from inaction more tolerable than bad outcome from action
- Compression: overestimate rare risks and underestimate common risks
Post-Discharge Symptoms at 4 mos

- Fatigue – 55%
- Dyspnea – 42%
- Memory loss – 34%

Garrigues E. J Infect – Sept 2020
Evidence of Myocarditis and Myocardial Injury in Athletes Recovered from COVID-19

- Assessed 26 athletes from 5 sports after COVID-19 quarantine (11-53 days) with cardiac MRI
- 73% had been asymptomatic, 27% mild sx
- 15% met criteria for myocarditis, additional 31% had LGE T2 elevation (sign of prior myocardial injury)

Rajpal S, et al. JAMA Cardiology, Jul 2020
Vaccines and Immune Response
SARS-CoV-2 Spike Protein: Viral Entry

corona = crown or circle of light

Spike Protein

Viral membrane

Antibody Responses in Patients with COVID-19 vs Several Controls

Caturegli. Ann Int Med, 2020
Rapid Decay of Antibody Levels After SARS-CoV-2 Infection

Antibody Half Life = 36 days

Ibarrondo FJ. NEJM 2020
Declining Ab Levels 8 Weeks After Infection

Long Q. Nature 2020
Seropositivity in Icelanders 4 mos After Infection

Gudbjartsson et al. NEJM 2020

N = 1215

91.1%
Antibody vs T-Cell Responses to SARS-CoV-2 in Sweden

Sekine T et al. Cell, Aug 2020
T-Cell Response to Moderna mRNA Vaccine in Rhesus Macaque Monkeys

Good Th1 and Interleukin-21 Response, particularly at higher dose

Corbett KS. NEJM Jul 2020
## Evidence for and Against Durable Immunity

<table>
<thead>
<tr>
<th>Against</th>
<th>For</th>
</tr>
</thead>
<tbody>
<tr>
<td>No durable immunity against 3/4 seasonal coronaviruses (reinfection common)</td>
<td>Durable T-cell immunity demonstrated in MERS and SARS CoV-1</td>
</tr>
<tr>
<td>Select Ab studies show waning as early as 3-4 mos</td>
<td>Durable Ab response shown (Iceland – 4 mos) when Pan-IgG Abs studied</td>
</tr>
<tr>
<td>SARS CoV-2 reinfection documented</td>
<td>Several vaccine candidates shown to induce both B and T-cell responses (including memory T-cells)</td>
</tr>
<tr>
<td>Asymptomatic and mild infection mounts lower immune response</td>
<td>Vaccine and natural infection protective in Rhesus macaques</td>
</tr>
</tbody>
</table>
### The New York Times

**Coronavirus Vaccine Tracker**

<table>
<thead>
<tr>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>LIMITED</th>
<th>APPROVED</th>
</tr>
</thead>
<tbody>
<tr>
<td>35</td>
<td>14</td>
<td>11</td>
<td>6</td>
<td>0</td>
</tr>
</tbody>
</table>

- Vaccines testing safety and dosage
- Vaccines in expanded safety trials
- Vaccines in large-scale efficacy tests
- Vaccines approved for early or limited use
- Vaccines approved for full use

SARS-CoV-2 Vaccine Strategies

- mRNA
- DNA
- Replication defective viral vectors
- Replicating viral vectors
- Whole killed virus
- Live attenuated virus
- Purified viral protein
Vaccines That Use Our Cells to Make the Viral Antigens

- mRNA
- DNA
- Replication defective viral vectors
- Replicating viral vectors
- Live attenuated virus
- Whole killed virus
- Purified viral protein
Front-Running Vaccine Platforms That Use Our Cells to Make the Viral Antigens

- mRNA
- DNA
- Replication defective viral vectors
- Replicating viral vectors
- Live attenuated virus
- Whole killed virus
- Purified viral protein
mRNA and DNA Vaccine Platforms

- mRNA
- DNA
- Replication defective viral vectors
- Replicating viral vectors
- Whole killed virus
- Live attenuated virus
- Purified viral protein
mRNA Vaccines in Phase III

PharmaLive.com

MODERNA COMPLETES ENROLLMENT IN LARGE COVID-19 VACCINE STUDY

PHASE 2  PHASE 3  COMBINED PHASES

BIONTECH  Pfizer  FOSUN PHARMA
Pfizer Update on Phase III Enrollment – Oct 22

- 37,864 out of planned 44,000 participants – 31,062 have received 2\textsuperscript{nd} dose

<table>
<thead>
<tr>
<th>Subject Characteristics</th>
<th>Percent of Enrolled Subjects in U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>10%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>13%</td>
</tr>
<tr>
<td>Native American</td>
<td>0.8%</td>
</tr>
<tr>
<td>Asian</td>
<td>5%</td>
</tr>
<tr>
<td>Age 56-85</td>
<td>47%</td>
</tr>
</tbody>
</table>
## Pros and Cons of mRNA Vaccine Platform

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can be produced quickly</td>
<td>Novel – no approved RNA vaccines, but some clinical testing for other viruses (rabies and influenza)</td>
</tr>
<tr>
<td>Low production cost (vs. protein vaccines)</td>
<td>Instability of single stranded mRNA</td>
</tr>
<tr>
<td>No adjuvants</td>
<td>Inflammatory reaction possible</td>
</tr>
<tr>
<td>Non-Infectious</td>
<td>Potential difficulty of intracellular delivery</td>
</tr>
<tr>
<td>Synthesize by in vitro transcription</td>
<td>Development of additional technologies for storage and administration</td>
</tr>
<tr>
<td>Free of microbial molecules</td>
<td>Most formulations require deep cold chain for longevity and stability</td>
</tr>
<tr>
<td>Non-integrating (vs. DNA vaccines)</td>
<td>Low immunogenicity – require multiple doses</td>
</tr>
<tr>
<td>Induction of T and B cell immune response</td>
<td></td>
</tr>
</tbody>
</table>

**References:**
SARS-CoV-2 Vaccine Strategies

- mRNA
- DNA
- Replication defective viral vectors
- Replicating viral vectors
- Whole killed virus
- Live attenuated virus
- Purified viral protein
SARS-CoV-2 Vaccine Strategies

- mRNA
- DNA
- Replication defective viral vectors
- Replicating viral vectors
- Whole killed virus
- Live attenuated virus
- Purified viral protein

Inovio’s Electroporation
<table>
<thead>
<tr>
<th>Pros and Cons of DNA Vaccine Platform</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advantages</strong></td>
</tr>
<tr>
<td>• Can be produced quickly</td>
</tr>
<tr>
<td>• Low production cost (vs. protein vaccines)</td>
</tr>
<tr>
<td>• Long-term stability (vs. mRNA vaccines)</td>
</tr>
<tr>
<td>• Non-Infectious</td>
</tr>
<tr>
<td>• Stimulation of innate immune response</td>
</tr>
<tr>
<td>• Cell and Egg Free</td>
</tr>
<tr>
<td>• Can be used in immunocompromised subjects</td>
</tr>
</tbody>
</table>

References:
SARS-CoV-2 Vaccine Strategies

- mRNA
- DNA
- Replication defective viral vectors
- Replicating viral vectors
- Whole killed virus
- Live attenuated virus
- Purified viral protein
Replication-defective adenovirus vectors

(a) Wild-type replication-competent virus
- Gene(s) that are essential for viral replication
- Adhesion of virus to target cell and entry
- Viral DNA replication
- Viral protein synthesis
- Virion assembly
- Infection of other cells

(b) Recombinant replication-defective viral vector
- Viral replication genes replaced with transgene and its promoter
- Transduction of target cell and vector entry
- Viral DNA replication
- Transgene protein synthesis
- Transport (and secretion) of transgene-encoded protein
- No infectious virus produced

Construction of a typical replication-defective recombinant virus

Expert Reviews in Molecular Medicine © 1999 Cambridge University Press
Replication-Defective Virus Vector Vaccines
# Pros and Cons of Viral Vector Vaccines

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Amplify antigen production</td>
<td>• Cross-reactive Ad antibodies may decrease effectiveness</td>
</tr>
<tr>
<td>• More immunogenic – good T-cell</td>
<td>• Ab’s to the Adenovirus may make future booster doses less effective</td>
</tr>
<tr>
<td>• Th1 biased immune response</td>
<td>• Grown in cell-cultures derived from past aborted fetus</td>
</tr>
<tr>
<td>• May only require 1 dose</td>
<td></td>
</tr>
<tr>
<td>• Refrigeration, not frozen</td>
<td></td>
</tr>
<tr>
<td>• Track record – fairly safe</td>
<td></td>
</tr>
</tbody>
</table>

References:
SARS-CoV-2 Vaccine Strategies

- mRNA
- DNA
- Replication defective viral vectors
- Replicating viral vectors
- Whole killed virus
- Live attenuated virus
- Purified viral protein
VSV-Ebola vaccine (VSV) against Ebola virus

The current Ebola outbreak is caused by the "Zaire" type of the virus. Ebola virus attacks human cells by attaching to them with an anchor protein (GP) covering the surface of the virus. It then enters the cells and forces them to produce new viruses. The GP protein is then massively produced by infected cells and enters the bloodstream, where it is toxic to the blood vessels' walls, causing the bleeding and hemorrhages which are the hallmark of the disease.

To be protected against the Ebola virus, a person must produce antibodies that neutralize the GP protein. This requires the body to come into contact with GP protein, but without the risk of developing the disease. This is precisely the role of the VSV-Ebola vaccine. The idea is to bring the GP protein into the bloodstream, but carried by another virus – the vesicular stomatitis virus (VSV) – selected for its ability to stimulate the immune system of a person, without becoming life-threatening. Known for infecting cattle, in humans the VSV virus causes symptoms no worse than those of a flu.

To make the vaccine, Canadian researchers took the gene of the GP protein from the Ebola virus and transferred it into the VSV virus (thus replacing the VSV surface protein gene). They also weakened the VSV virus to make it even safer for humans.
SARS-CoV-2 Vaccine Strategies

- mRNA
- DNA
- Replication defective viral vectors
- Replicating viral vectors
- Whole killed virus
- Live attenuated virus
- Purified viral protein
Baculovirus-based influenza antigen manufacturing processes (cell culture)
Protein Sciences, subunit rHA

- Engineer baculovirus with the gene of interest (e.g. Hemagglutinin)
- Baculoviruses highly specific to insect cells
- Powerful promoter generates high yield of protein of interest
- Culture expression of insect cells in a fermenter
- Infect cells with engineered virus
- Incubate infection for ~48 - 72 hours
- Protein forms rosettes
- Purify protein to > 90% into final product
- Formulate with PBS into vaccine

Sanofi

Flublok® Approval → Validation
Traditional vs Accelerated Vaccine Pipeline

90% Failure Rate
- 50% in Phase III
What’s the “Warp Speed”?

Traditional timeline:
- Exploratory
- Preclinical
- Clinical Trials
- FDA Review and Approval
- Manufacturing

10–15 years

Exploratory
- Preclinical
- Clinical Trials
- FDA Review and Approval
- Manufacturing

IND submitted
- Phase I
- Phase II
- Phase III
- BLA submitted

20–100
- 100s
- 1000s

Potential accelerated timeline with overlapping phases and EUA:
- 1–2 years
- late 2020 or beyond

Exploratory
- Clinical
- Clinical Trials
- FDA Rolling Review and Approval
- Rapid Manufacturing
Halted clinical trials put focus on COVID-19 vaccine transparency

BY NATHANIEL WEIXEL - 10/14/20 06:28 PM EDT

36 SHARES

Just In...

- Transverse myelitis in UK
- Death in Brazil
- Trial restarted in U.S.

? What
- Trial restarting in U.S.
Serious Adverse Events – Transverse Myelitis in Astra-Zeneca Trial

- Trials aim to enroll ~ “N” about size of Minot

- Expected incidence 1.3-4.6 per million
  - 1 every 5 years in city like Minot

- If include MS, ~ 25/million
  - 1 case per year in city like Minot
Emergency Use Authorization Process

1. Confirm Public Health Emergency
   - Determination of a domestic, military, or public health emergency.

2. Declaration of an Emergency
   - Formal declaration that there is a public health emergency.

3. Pre-EUA Submission
   - A pre-meeting will facilitate a rapid and more complete submission.

4. Submission of EUA
   - Submission of an EUA request and review by the FDA.

5. Approve/Reject EUA
   - FDA issues a formal approval or rejection of the EUA application.

6. EUA Termination
   - EUA terminates after emergency is ended.
Vaccine and Related Biological Product Advisory Committee (VRBPAC)

Reference:
1. FDA. Vaccines and Related Biological Products Advisory Committee. Available at: https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee
## Comparison of BLA to EUA

<table>
<thead>
<tr>
<th>BLA</th>
<th>EUA</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Can take up to a year to acquire</td>
<td>• FDA authorization of unlicensed product</td>
</tr>
<tr>
<td>• Multidisciplinary FDA review team</td>
<td>• Faster to obtain</td>
</tr>
<tr>
<td>• Inspection of vaccine’s manufacturing plant</td>
<td>• Vaccine data will be reviewed by VRBPAC</td>
</tr>
<tr>
<td>• Presented to VRBPAC</td>
<td></td>
</tr>
</tbody>
</table>

Reference:
90% of serious adverse events are detected in 1st 6 weeks after vaccination
ND Role in CDC Pilot Project

- 1 of 4 states chosen to be part of pilot project
  - Partnership with CDC/DOD

- Plan for distribution of COVID-19 vaccine
  - NOT a vaccine clinical trial

- North Dakota chosen for:
  - Rural nature
  - Tribal relationships

ND Goals in CDC Pilot Project

- Vaccine shipment to North Dakota
- How to **safely** and **effectively** transport, store, and distribute vaccine within the state
  - Temperature: thermostability
  - Administration: multidose vials
- Tracking distribution
- Who administers vaccine

## COVID-19 vaccine priority group comparison

<table>
<thead>
<tr>
<th>Group</th>
<th>Johns Hopkins</th>
<th>National Academies</th>
<th>WHO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare personnel</td>
<td><strong>Tier 1</strong>: Frontline healthcare personnel including LTCF providers; EMS</td>
<td><strong>Phase 1a</strong>: Frontline healthcare personnel including LTCF providers; EMS</td>
<td>Priority groups unranked</td>
</tr>
<tr>
<td></td>
<td><strong>Tier 2</strong>: HCP &amp; staff with direct, non-COVID patient contact; pharmacy workers</td>
<td><strong>Phase 2</strong>: Other healthcare personnel</td>
<td></td>
</tr>
<tr>
<td>Other essential workers</td>
<td><strong>Tier 1</strong>: Public transport, food supply workers; teachers &amp; school workers</td>
<td><strong>Phase 1a</strong>: Police, fire</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Workers necessary for pandemic support: (e.g. vaccine manufacturers; public health workers/support)</td>
<td><strong>Phase 2</strong>: Critical infrastructure at risk of exposure; teachers and school staff incl childcare workers</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Tier 2</strong>: Frontline infrastructure; warehouse/delivery/postal; deployed military; police &amp; fire; TSA and border security; high-density or high-contact jobs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underlying medical conditions</td>
<td><strong>Tier 1</strong>: Those with elevated risk of serious disease; members of social groups experiencing disproportionately high fatality rates</td>
<td><strong>Phase 1b</strong>: Significantly higher risk (≥2 CDC designated conditions)</td>
<td></td>
</tr>
<tr>
<td>Adults ≥65 years of age</td>
<td><strong>Tier 1</strong>: Adults ≥65 years including those living with or providing care to them</td>
<td><strong>Phase 2</strong>: Moderately higher risk (1 CDC condition)</td>
<td><strong>Phase 1b</strong>: Older adults in congregate settings</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Phase 2</strong>: All older adults not in Phase 1</td>
<td><strong>Phase 2</strong>: All older adults not in Phase 1</td>
</tr>
</tbody>
</table>
Possible groups for Phase 1 vaccination

**August ACIP meeting**
- Phase 1a:
  - HCP
- Phase 1b:
  - Essential Workers
  - High Risk Med Conditions
  - Adults ≥ 65 years old

**September ACIP meeting**
- Explore groups for phase 1b
  - Risk for COVID-19
  - Overlap between groups
  - Racial and ethnic composition
  - Summary of Work Group considerations

- High Risk Medical Conditions
  - >100M

- Essential workers
  - ~80M

- Healthcare personnel
  - ~20M

- Adults ≥ 65 years old
  - ~53M
Overlap: Essential Worker & High-Risk Medical Conditions

- COPD
- CKD
- Cancer
- CVD
- Diabetes
- Essential workers (3%)
- ~4%
- ~2%
- ~4%
- ~7%
- Obesity (BMI > 30) (~30%)
New Safety System for Essential Workers - COVID
Presented by Tom Shimabukuro, CDC/NCIRD to the ACIP

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.

CDC

VAERS call center

Healthcare workers, essential workers, etc.

FDA
### Estimates of Priority Groups in ND

#### Possible groups for Phase 1

<table>
<thead>
<tr>
<th>Stage</th>
<th>Priority Populations</th>
</tr>
</thead>
</table>
| Phase 1A | HCW  
LTC providers & residents  
Direct care public health workers                                      |
| Phase 1B | Tribes  
High priority infrastructure  
Ancillary HCW  
High Risk Med Conditions  
Adults ≥65yoa                              |

CME Post-Training Assessment

If you are seeking 1 credit of CME for participating in this session, PLEASE FOLLOW THE LINK BELOW (also noted in Zoom chat box), to take the required post-test & evaluation. THIS IS NOT REQUIRED for those seeking CPE (pharmacy continual education credit). CPE information in next slide.

https://ndstate.co1.qualtrics.com/jfe/form/SV_0OioNehunRjs9yB
Obtaining CPE Credit for Pharmacists

Continuing Pharmacy Education (CPE) for SARS-COV-2: Virology to Vaccine, what YOU need to know! Has been accredited by Ceimpact, an ACPE-accredited provider of continuing pharmacy education.

Although you attended the live session, you MUST complete the online requirements to obtain your CPE Credit (link in chat box).

The deadline for obtaining your CPE credit is: November 28, 2020

This deadline is non-negotiable due to the CPE Monitoring reporting timelines.

*If this is the first time you have utilized the Ceimpact Learning Management System (LMS) you will need to create an account.

Questions? team@ceimpact.com
Polling Questions
POST-presentation: If the FDA authorized a vaccine to prevent COVID-19 today, at no cost under Emergency Use Authorization, would you agree to be vaccinated? N=362

An 18% increase in “yes” from pre-presentation response
Comparison of Pre and Post-Presentation Response: If the FDA authorized a vaccine to prevent COVID-19 today, at no cost under Emergency Use Authorization, would you agree to be vaccinated? N=362

- **Yes**: 49% Pre-Presentation, 67% Post-Presentation (An 18% increase in “yes” from pre-presentation response)
- **No**: 13% Pre-Presentation, 9% Post-Presentation
- **Unsure**: 38% Pre-Presentation, 24% Post-Presentation