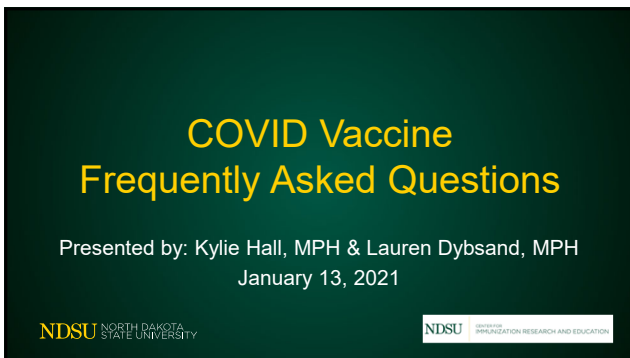




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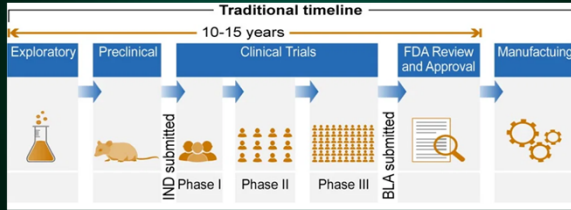


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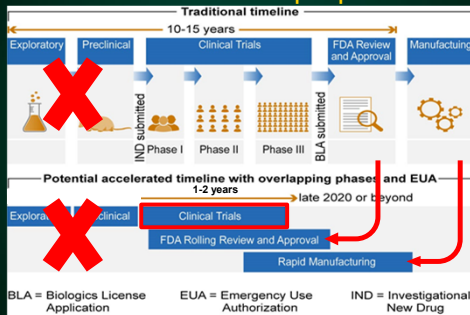
Clinical Trials



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4

What is the "Warp Speed"



5

How did we develop a COVID-19 vaccine so fast?


- Utilizing existing technology
- Quickly deciphered SARS-Cov-2 genome
- Able to determine efficacy quickly
- Financing for development and manufacturing
- FDA rolling reviews
- Support efforts

– Operation Warp Speed
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6

2. How do we know the COVID-19 vaccines are safe?



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7

How do we know the COVID-19 vaccines are safe?

- Clinical trials studied in the vaccines in large groups of people
- FDA set standards for safety and efficacy
- Vaccines will continue to be monitored after FDA approval

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8

Comparing Sample Size of Vaccine Clinical Trials

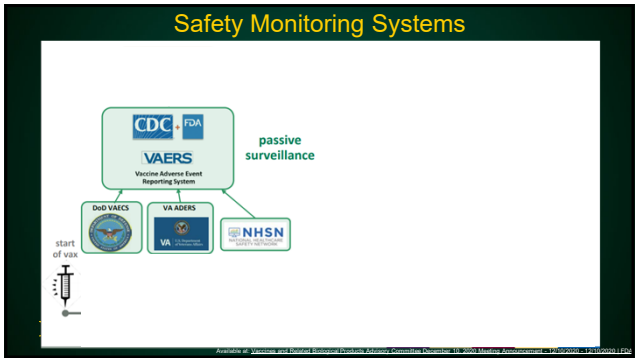
Vaccine or Developer	Type of Vaccine	Protects Against	Approval Year	Doses	Phase II n	Phase III n
IPOL	Inactivated	Polio	2000	4	361	2,358
Daptacel	Combination	Diphtheria, Tetanus, & Pertussis	2002	5	7,471	10,575
Gardasil	Subunit	HPV	2006	3	4,047	22,938
Pneumovax 13	Inactivated	Pneumococcal disease	2010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

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

Reference: Weinberg SE, et al. Size of clinical trials and introductory prices of prophylactic vaccine series. Human Vaccines & Immunotherapeutics. 2012;8(3):106-20. PMID: 22474000. Available at: <https://pubs.rsos.royalsocietypublishing.org/doi/10.1098/rsos.120000>

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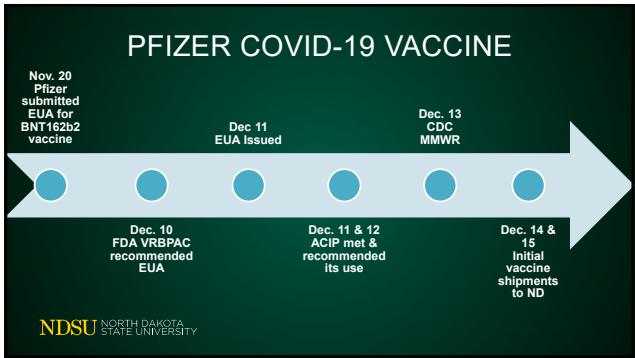


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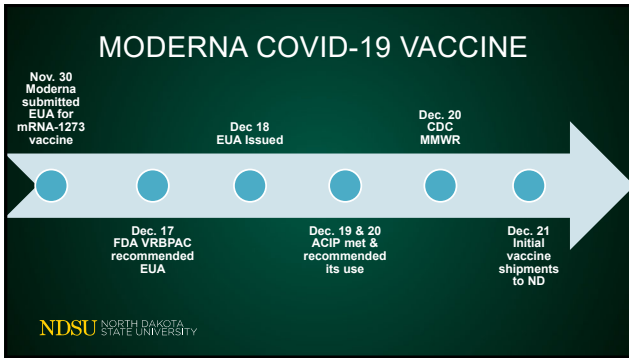
3. What COVID-19 vaccines are currently available in the U.S.?

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11



12



13

Currently Available COVID-19 Vaccines

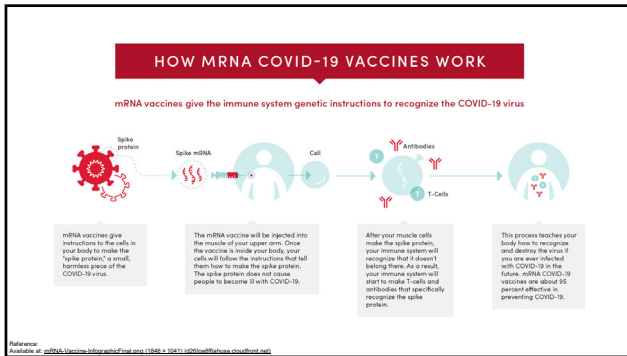
	Pfizer	Moderna
Type	mRNA vaccine	mRNA vaccine
# of Doses Required	2	2
Time Between Doses	3 weeks	4 weeks
Reported Efficacy	95%	94.1%
Storage	-94 degrees F	-4 degrees F
Age Indication	16 years of age and older	18 years of age and older
Vaccine Side Effects	Most common side effects reported include: <ul style="list-style-type: none"> Fever, chills, fatigue, headache, and muscle and joint aches Side effects more common after 2 nd dose	
U.S. Distribution	27 million (as of January 12, 2021). Information updated regularly at CDC COVID Data Tracker .	
Cost of Vaccine	Free - Healthcare providers may charge administration fees (covered by insurance), but those unable to pay can't be turned away.	

Reference: [Pfizer and Moderna COVID-19 vaccine information](#)

14



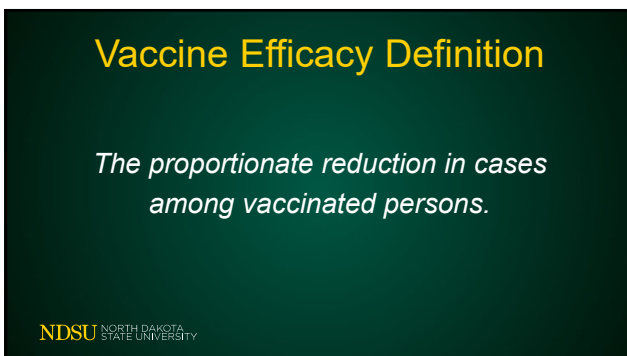
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16



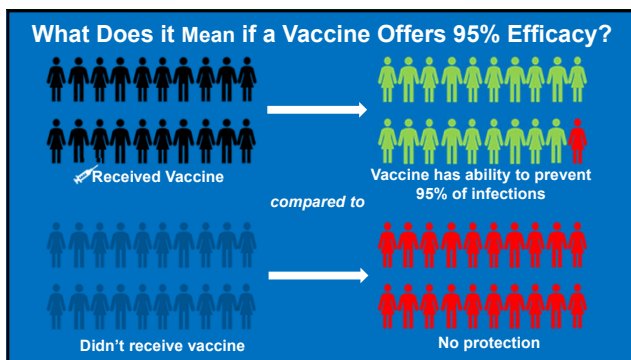
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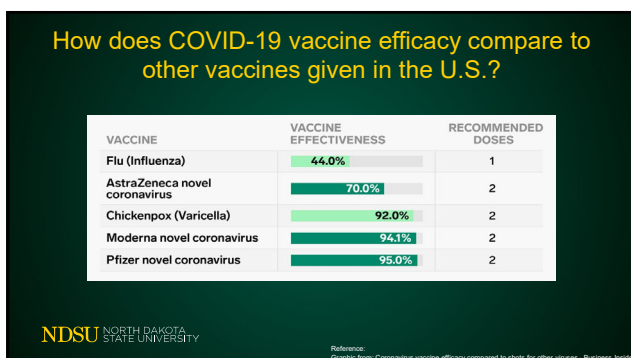
18



19




20



21

6. What groups are prioritized for COVID-19 vaccine in ND?

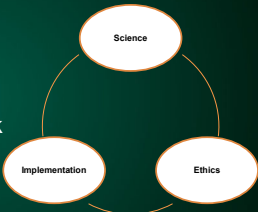


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22

What are ND's priority groups?

- Vaccine supply is currently limited and needs to be prioritized
- Prioritize those at higher risk of COVID-19 morbidity and mortality



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Reference: Available at: [How are States Prioritizing Who Will Get the COVID-19 Vaccine First? | NEP](#); [How CDC is Making COVID-19 Vaccine Recommendations | CDC](#); [Current Allocation of COVID-19 Vaccine | CDC.gov](#)

23

Who determines priority groups?

Nationally

- National Academy for Sciences, Engineering and Medicine
 - Created framework for equitable allocation
- ACIP
 - Formal priority group recommendations

North Dakota

- ND Advisory Committee on COVID-19 Vaccination Ethics
 - Creates state recommendations on:
 - Priority Groups
 - Sub-priority groups
 - Allocating doses

Guides →

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Reference: Available at: [How are States Prioritizing Who Will Get the COVID-19 Vaccine First? | NEP](#); [How CDC is Making COVID-19 Vaccine Recommendations | CDC](#); [Current Allocation of COVID-19 Vaccine | CDC.gov](#)

24

What are ND's priority groups?

COVID-19 VACCINE Priority Groups

Phase 1a

In Order of Priority

- Health care workers in direct contact with COVID-19 in hospitals
- Long-term care residents and staff

Phase 1b

In Order of Priority

- Ages 75 and older
- Ages 65-74 with 2+ underlying conditions
- Other care facility residents & staff & 2+ underlying conditions
- Ages 65-74 with 1+ underlying condition
- Ages 65 and older who are not in a care facility
- People of any age with 2+ underlying conditions
- Healthcare workers in non-hospital settings
- Resident care in 12-15 skilled nursing

Phase 1c

In Order of Priority

- Essential workers not personally covered
- General public
- COVID-19 vaccine breakthrough studies 1A
- People caring for others in their homes
- People caring for others in long-term care facilities
- People caring for others in the first and second school years
- People aged 18-64 with 1+ underlying condition
- People aged 18-64 with 2+ underlying conditions
- All other residents in nursing homes, retirement & independent living communities
- All other residents in assisted living communities & independent living communities
- People aged 18-64 unable to work from home

Phase 2

General Public


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Reference: Available at: [Grand Forks Public Health Services Issues for 18 priority groups | Grand Forks Health | COVID-19 Vaccine Priority Groups | Department of Health and Aging](https://www.dakotahealth.org/COVID-19-Vaccine-Priority-Groups)

[illegible]

25

7. What is considered an underlying condition for COVID-19?

An illustration on a dark green background. A nurse in a white coat and red cap holds a large red syringe. Several red, spiky virus particles are scattered around. A large red question mark is positioned to the right of the nurse.

26

Underlying Conditions for COVID-19 Vaccination Eligibility

- Cancer
- Pregnancy
- Chronic kidney disease
- COPD
- Down Syndrome
- Heart conditions (e.g. heart failure, coronary artery disease, or cardiomyopathies)
- Immunocompromised state from solid organ transplant
- Obesity (BMI of 30 kg/m² or higher)
- Sickle cell disease
- Smoking
- Type 2 diabetes mellitus

Reference:
Centers for Disease Control and Prevention. (2020, July 16). <https://www.cdc.gov/media/releases/2020/s0716-covid-vax-eligibility.html>

27

The list may not include every condition that might increase one's risk for developing severe illness from COVID-19, such as those for which evidence may be limited (e.g., rare conditions). Individuals with any underlying medical condition (including those conditions that are NOT on the current list) should consult with their healthcare providers about personal risk factors and circumstances to determine whether extra precautions are warranted.


-CDC Website

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Reference:
Available at: [Certain Medical Conditions and Risk for Severe COVID-19 Illness | CDC](#)

28

8. What is the protocol regarding extra doses of COVID-19 vaccine in multi-dose vials?



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FDA statement:


At this time, given the public health emergency, it is acceptable to use every full dose obtainable from each vial.


However, since these are preservative free vials, it is critical to note that any further remaining liquid that does not constitute a full dose should not be administered or pooled from multiple vials to create a full dose.

Reference:
Available at: [COVID-19 Vaccine, FDA, Health_Care_Workers.pdf \(fda.gov\)](#)

30

9. How will North Dakotans be notified when they're eligible for vaccine?






31

How will North Dakotans be notified when they're eligible for vaccine?

- Updates on NDDoH website and social media pages
- Locally:
 - Local Public Health
 - Local Media
 - Health Systems (ex. EMR notifications or patient portals)
- ND COVID-19 Vaccine Locator

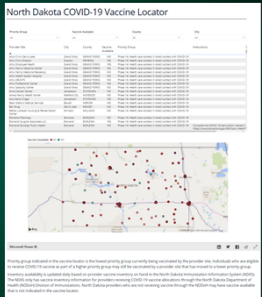


Reference:
Available at: [COVID-19 Vaccine FAQ: Health Care Workers.pdf \(nd.gov\)](#)


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North Dakota COVID-19 Vaccine Locator

- Available 1/13/2021 at 11 a.m.
- Helps the general public see:
 - Which ND provider sites have enrolled to receive/administer COVID vaccine
 - Where COVID vaccine is available
 - Which priority group enrolled providers are currently vaccinating
 - How to contact their local provider and/or express interest in receiving COVID vaccine



North Dakota COVID-19 Vaccine Locator



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Updates on Vaccine Allocation

- Second doses will no longer be held back
- Continue to provide second doses to those who have had first dose
- Urged states to offer vaccine to anyone ≤ 65

The Washington Post
Trump administration reverses stance, will no longer hold back second shots of coronavirus vaccine

Change comes several days after President Donald Trump said he planned to release nearly all available doses to senior government and military personnel.

By Sarah K. Lee and Laurie R. King
 Jan. 12, 2021 at 12:45 a.m. EST

RELATED ARTICLES

The Washington Post is providing this important information about the coronavirus for free. For more free coverage of the coronavirus pandemic, sign up for our [Coronavirus Update newsletter](#) where all stories are free to read.

The Trump administration will announce sweeping changes to its vaccination rollout on Tuesday, including making many more doses of the coronavirus vaccine available and urging states to provide shots to anyone 65 and older. The move was an effort to speed up what has been a delayed and disjointed effort.

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Reference: [Trump administration reverses stance, will no longer hold back second shots of coronavirus vaccine](#), The Washington Post

34

10. I heard there is a new strain of COVID-19 circulating globally. Will COVID-19 vaccines provide protection against it?

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What we know about variant strains:

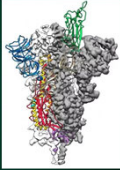
- Spread more easily than the original virus, but no evidence they cause:
 - More severe illness
 - Increase risk of death
- Variants/new strains found in:
 - U.K.
 - South Africa
 - Nigeria
 - U.S.

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Variant Strains and the Vaccine

- Body will make antibodies against *multiple sections of the COVID-19 spike protein*
 - Single mutation unlikely to change effectiveness of COVID-19 vaccines
- Data suggests that Pfizer vaccine still produces neutralizing antibodies to new strains
 - Similar findings expected to be found from research on Moderna's vaccine




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Reference: Available at: [COVID-19 Vaccine FAQs: Health Care Workers and the Public](#). Reevaluation of North Carolina SARS-CoV-2 IgG seroprevalence among health care workers. [https://www.ncdhhs.gov/newsroom/press-releases/2021/01/08/covid-19-vaccine-faqs-health-care-workers-and-the-public](#)

37

11. Should I get vaccinated if I have already had COVID-19?



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YES!!

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Why get vaccinated if you've had a previous COVID-19 infection?

- Might offer protection from reinfection
- Can wait 90 days after your diagnosis to get vaccinated
- Anyone currently infected:
 - Wait to get vaccinated until illness has resolved & met criteria to discontinue isolation



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Reference:
Available at: [COVID-19 Vaccine FAQ: Health Care Workers and Infected](#)
Commonly Asked questions about COVID-19 Vaccination | CDC

40

12. If a vaccine recipient has tested positive since their 1st dose, should they get their 2nd dose?



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YES!!


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- For people who have received 1 dose of COVID-19 vaccine and subsequently test positive before receiving dose #2, they should complete the series as soon as:
 - *They have met the minimum interval for vaccination*
 - AND
 - *They have completed their isolation period*

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Reference: Available at: COVID-19 Vaccine FAQ Health_Care_Workers.pdf (nd.gov) Frequently Asked Questions about COVID-19 Vaccination | CDC

43


13. Will the COVID-19 vaccine give you COVID-19?



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44

Will the COVID-19 vaccine give you COVID-19?




NO!!

Reference: Available at: COVID-19 Vaccine FAQ Health_Care_Workers.pdf (nd.gov) Facts about COVID-19 Vaccines (cdc.gov)

45

Will the
COVID-19
vaccine give
you COVID-
19?



Here's why not:

- Authorized & recommended COVID-19 vaccines *do not* contain live virus that causes COVID-19
- Vaccines can cause side effects (e.g. fever & body ached)
 - This is NOT COVID-19
 - Sign body is building immunity

Reference:
Available at: COVID-19 Vaccine FAQ Health Care Workers.pdf (nd.gov)
Fact about COVID-19 Vaccines (nd.gov)


46

14. Will the COVID-19
vaccine alter your
DNA?



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"Will the new COVID-19 mRNA vaccine alter your DNA essentially making you a genetically modified human being!?"

NO!!

48

"Will the new COVID-19 mRNA vaccine alter your DNA essentially making you a genetically modified human being!?"

Here's why not:

- They *can't* alter DNA
- The mRNA doesn't integrate into the cell nucleus of its recipients:
 - Thus, *genetic modification isn't possible*

Reference:
Available at: www.who.int/news-room/qa-questions-and-answers Learn About the New COVID-19 Vaccine

49

15. Will the COVID-19 vaccine make you test positive for COVID-19?

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50

Will the vaccine make you test positive for COVID-19?

- Simple answer: No
- Vaccine doesn't contain components nor produce components in the body that would be detected by currently used diagnostic tests:
 - RT-PCR test (PCR test)
 - Rapid antigen test (e.g. Abbott BinaxNOW test)

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Reference:
Available at: www.who.int/news-room/qa-questions-and-answers Frequently Asked Questions about COVID-19 Vaccines | CDC

51

16. Is there anyone who shouldn't get a COVID-19 vaccine?

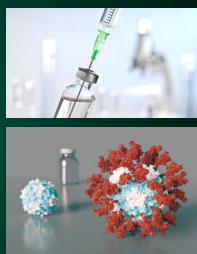


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Do not administer COVID-19 vaccine to individuals:

- With known history of severe allergic reaction (e.g. anaphylaxis) or immediate allergic reaction to:
 - Previous dose of COVID-19 vaccine
 - Any component of COVID-19 vaccine
- Children under 16 years of age




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Reference:
Available at: [covid19_Vaccine_FAQ_General_Public_use](https://www.fda.gov/covid19/vaccine-faq-general-public-use) (nd.gov) Get the facts about COVID-19 vaccines - Mayo Clinic

53

17. Should I be concerned about an allergic response from the COVID-19 vaccine?

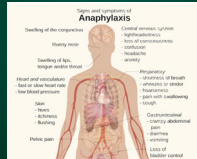


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54

What is anaphylaxis?

An acute and potentially life-threatening serious allergic reaction that rarely follows vaccination



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Reference:
Available at: [COVID-19 Vaccine FAQ Health Care Workers.pdf \(nd.gov\)](#), [Get the facts about COVID-19 vaccines - Mayo Clinic](#)

55

What we know so far regarding anaphylaxis and COVID-19 vaccination:

- During December 14-23, 2020 monitoring by VAERS:
 - 21 cases of anaphylaxis were reported after 1,893,360 first doses of Pfizer's COVID-19 vaccine
 - E.g., 11.1 cases per 1,000,000 doses
- 71% of these occurred within 15 minutes of vaccination



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Reference:
Available at: [COVID-19 Vaccine, FAO Health Care Workers.pdf \(nrt.gov\)](#), [Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020 | MMWR \(cdc.gov\)](#)

56

What are the FDA & CDC guidelines regarding allergic reactions and administering COVID-19 vaccine?

- **Additional guidance:**
 - Screen recipients for contraindications and precautions
 - Those with severe allergic reaction to any vaccine or injectable therapy:
 - Must be counseled about the unknown risks of developing severe allergic reaction and balance risk against the benefit of vaccination
 - Should be observed for 30 minutes following vaccination for potential adverse reaction (versus standard 15 minutes)
- **Healthcare providers should be prepared to manage acute anaphylactic reactions:**
 - Recommended supplies and medication
 - Properly trained staff

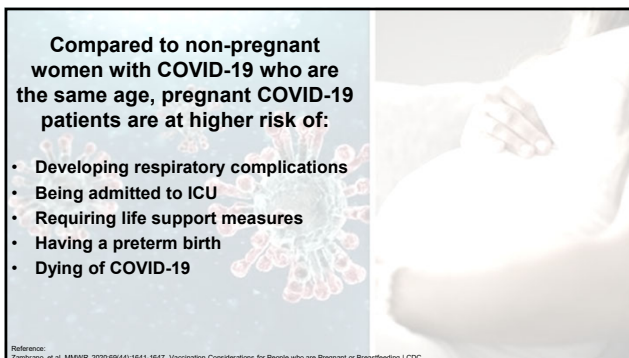
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Reference:
Available at: [COVID-19 Vaccine FAQ Health Care Workers.pdf \(nd.gov\)](#), [Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020 | MMWR \(cdc.gov\)](#)

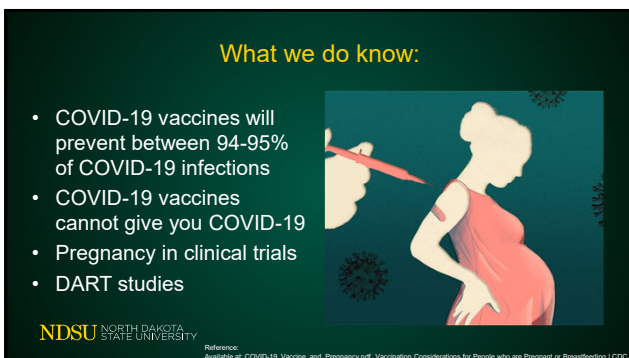
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Experience of a Local North Dakota OBGYN with pregnancy and COVID-19 vaccination



"The vaccine hasn't been studied in pregnant women. So, the decision is all in weighing the risks vs benefits, my risk of exposure to COVID working in the hospital remains high."

Dr. Jessica Sedevie
KFYR Interview 12/21/2020

Reference:
Available at: [Sanford OBGYN decides to get COVID vaccine while pregnant \(KFYR news\)](#)

61

It is important to look at every patient's unique situation, and look at their risk:

Patient is at *lower* risk if:

- Always able to wear a mask
- You and those you live with can socially distance for your whole pregnancy
- Community doesn't have high/increasing rate of COVID-19 being reported

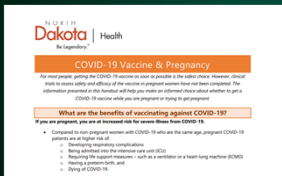
Patient is at *increased* risk if:

- 35 yoa+
- Underlying health conditions
- Smoker
- Are a healthcare worker
- Have contact with people outside the household who don't wear masks
- Community has high rate of COVID-19 infection

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NDDoH Handout on COVID-19 Vaccine and Pregnancy



- **Reviews:**
 - Benefits and risks of COVID-19 vaccination during pregnancy
 - How to best make an informed decision on vaccinating

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Reference:
Available at: [COVID-19 Vaccine FAQ: Health Care Workers.pdf \(nd.gov\)](#) [COVID-19 Vaccine and Pregnancy.pdf](#)

63

What about breastfeeding?



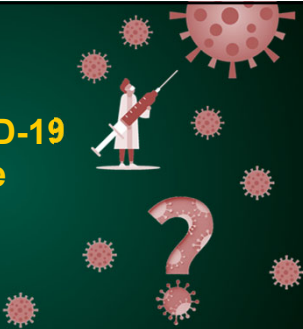
- No data on safety of COVID-19 vaccines in lactating women or effects of mRNA vaccines on:
 - Breastfed infants
 - Milk production/excretion
- *MRNA vaccines are not thought to be risk to breast feeding infants*
- Lactating women may choose to be vaccinated

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Reference:
Available at: COVID-19 Vaccine FAQ Health Care Workers.pdf (nd.gov)
COVID-19 Vaccines and Recommendations for Vaccination Recommendations for People who are Pregnant or Breastfeeding | CDC

64

19. Can the COVID-19 vaccine cause infertility?



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"I have heard the vaccine could cause female infertility? Is this true?"

INFERTILITY

THIS IS FALSE!!

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The Facts:

Experts say there is *no evidence* that the COVID-19 vaccines would result in infertility of women

- During the Pfizer clinical trial, 12 women in the vaccine group became pregnant *during the trial*
- If this theory was true, you'd expect infertility to occur from natural infections
 - *We are not seeing this after ~70 million COVID-19 infections in the U.S.*

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Reference:
Available at: COVID-19 Vaccine FAQ Health Care Workers.pdf (nd.gov) No Signs COVID-19 Vaccine Causes Infertility - COVID-19 Featured Health Topics - Rockswold, Meridian Health

67

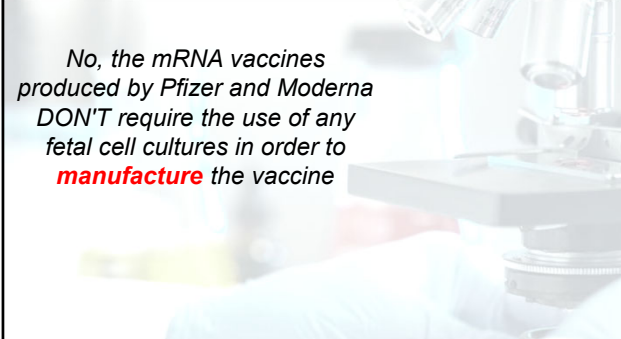
20. Was the COVID-19 vaccine manufactured using fetal cells?



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*No, the mRNA vaccines produced by Pfizer and Moderna **DON'T** require the use of any fetal cell cultures in order to **manufacture** the vaccine*



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The following organizations assert that the mRNA COVID-19 vaccines are *ethically uncontroversial*:

- National Catholic Bioethics Center
- The Vatican – Congregation for the Doctrine of the Faith
- Charlotte Lozier Institute
- North Dakota Catholic Conference

CHARLOTTE LOZIER INSTITUTE

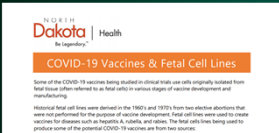
NBCBC

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Reference: Available at: COVID-19 Vaccine FAQ Health Care Workers.pdf (nd.gov) COVID-19 Vaccine Fetal Cell Handout.pdf

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The NDDOH COVID-19 Vaccines & Fetal Cell Lines Handout



COVID-19 Vaccines & Fetal Cell Lines

Some of the COVID-19 vaccines being studied in clinical trials use cells originally isolated from fetal tissue after referred to as fetal cells in various stages of vaccine development and manufacturing.

Historical fetal cell lines were derived in the 1960s and 1970s from two elective abortions that were not performed for the purpose of vaccine development. Fetal cell lines were used to create vaccines for diseases such as hepatitis A, measles, and others. The fetal cell lines being used to produce some of the potential COVID-19 vaccines are from two sources.


- Contains greater detail on:
 - Why fetal cells are used in vaccine research, development, & manufacturing
 - Which COVID-19 vaccines use fetal cell lines
 - Where you can find more information on the topic

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Reference: Available at: COVID-19 Vaccine FAQ Health Care Workers.pdf (nd.gov) COVID-19 Vaccine Fetal Cell Handout.pdf

71

21. Why do we have to continue to mask and socially distance following COVID-19 vaccination?

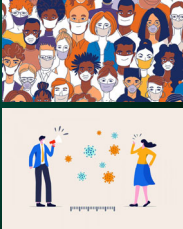


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To effectively contain this pandemic, vaccinating campaigns *and* reducing exposure to the virus must continue. The facts...

- Vaccination doesn't provide immediate immunity
- We don't yet know whether vaccines prevent transmission of COVID-19
- We don't know how much protection COVID-19 vaccines will provide under real-life conditions
- Herd immunity threshold for COVID-19 is unknown
- It will be impossible to know who is/isn't vaccinated
- We don't know the duration of vaccine protection



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Reference: COVID-19 Vaccine: FAQs, Health, Policy, Ethics and Safety. Frequently Asked Questions about COVID-19 Vaccination. CDC

73

22. Why should we vaccinate against COVID-19?



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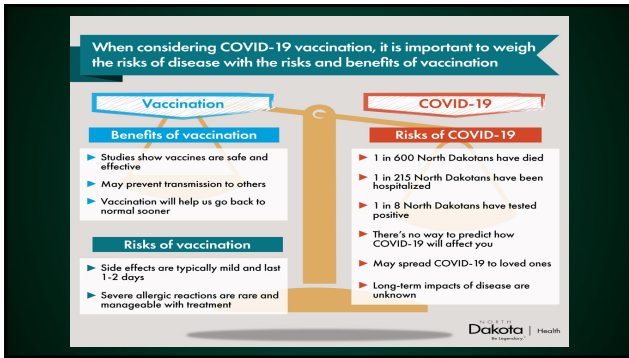
Why should we vaccinate against COVID-19?

Weigh the benefits against the risks...



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How to Manage COVID-19 Vaccine Decliners

- Assess *why* an individual is refusing
- Have a one-on-one conversation
- Address concerns and questions
 - Use open questions
- Have decliners review and sign a declination form

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Reference:
Accelerate or COVID-19 Vaccine FAQ: Health Care Workers and Staff, COVID-19 Vaccine Best Practices, 4/20/21 and 1/13/21

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NDDoH Declination of COVID-19 Vaccination for Healthcare Personnel Handout

- Check out the NDDoH COVID-19 vaccine declination form
- Available as Word document that can be tailored with your own logo

Optional form that may be used by healthcare and long-term care facilities. Facilities may change and/or add your own logo.

Declination of COVID-19 Vaccination For Healthcare Personnel

Employee's Name: _____ Employer's ID#: _____

I have been advised that I am eligible to receive the COVID-19 vaccine to protect myself and the patients I serve. I have read the FDA's [Emergency Use Authorization Fact Sheet](#) and North Dakota Department of Health's [COVID-19 Vaccine: Frequently Asked Questions \(handout\)](#) explaining the vaccine and the disease it prevents. I have had the opportunity to discuss the fact sheet and have my questions answered by a healthcare provider.

I am aware of the following facts (please read and check each box):

Reference:
Available at: [COVID-19 Vaccine: Frequently Asked Questions.pdf \(nd.gov\)](#) [https://www.health.nd.gov/newsroom/COVID-19-vaccine-best-practices-ltcf.pdf \(nd.gov\)](#)

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NDDoH Resources for LTCFs

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Best Practices for Addressing COVID-19 Vaccination in Long-Term Care Facilities

It is not easy, but the act of vaccinating, that goes into safe and effective vaccine against COVID-19. Best practices have been developed, but if the vaccine can't get out and under the needle, then the effort and money spent are daunting. There is a report to build confidence and provide clear and evidence based information on COVID-19 vaccine to residents, staff and families to make informed and educated decisions regarding vaccination.

Prepare Staff for COVID-19 Vaccination

Emphasize the benefits of vaccinating against COVID-19. It is important to clearly weigh the benefits of vaccinating against COVID-19 and the risks associated with COVID-19 infection.


- Check out the NDDoH website for handout which addresses:
 - How to prepare staff for COVID-19 vaccination
 - How to address staff COVID-19 vaccine refusal

Reference:
Available at: [COVID-19 Vaccine: Frequently Asked Questions.pdf \(nd.gov\)](#) [COVID-19 Vaccine: Best Practices: LTCF.pdf \(nd.gov\)](#)

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24. How should winter travelers be counseled on COVID-19 vaccine?




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Winter Travel and COVID-19 Vaccine

- Advise travelers to:
 - Be aware that priority groups in state of destination may differ from ND
 - Contact local public health in area for more information
- For those who have received 1st dose in ND:
 - Be aware of differing priority groups by state
 - Remind them to keep Vaccination Record Card in a safe and easily accessible place



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Reference:
Available at: [COVID-19 Vaccine FAQs Health Care Workers.pdf \(nd.gov\)](#)
Essentially Answer questions about COVID-19 Vaccination Logic

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25. Where can I find high quality resources on COVID-19 vaccine?



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Where to find more information on COVID-19 vaccines

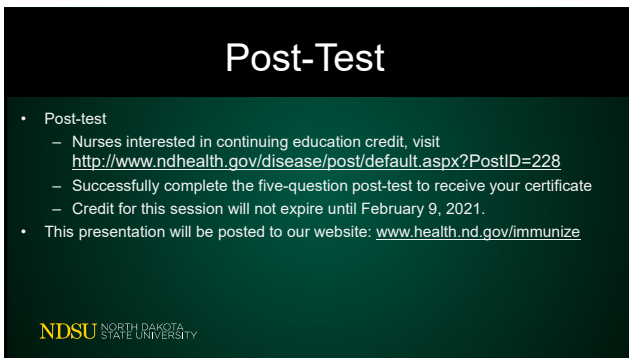
- The NDDoH website: COVID-19 Vaccine Information
- The CDC website: COVID-19 Vaccination
- The FDA website: COVID-19 Vaccines
- Pfizer website: www.cvdvaccine-us.com
- Moderna website: www.modernatx.com

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