Storage and Handling of the COVID-19 Vaccines

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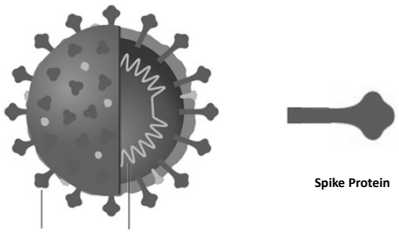


Pfizer COVID-19 Vaccine

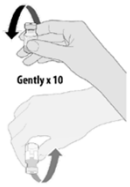
- Storage: -76° to -112° F
  - Temporary storage in dry ice
  - Cannot refreeze thawed vials
- Thawing:
  - In refrigerator: 35° to 46° F for 2-3 hours
    - Can store in refrigerator up to 5 days
    - Must use within 6 hours of dilution
  - Room temperature: 77° F for 30 minutes
    - Must use within 2 hours

Pfizer COVID-19 Vaccine

- Dilution:
  - Thaw vial
  - Invert vial ***gently*** 10 times
  - Add 1.8 ml 0.9% sodium chloride injection USP
    - NOT bacteriostatic sodium chloride injection
- Each vial contains 6 doses, 0.3 ml each
- Administer intramuscularly

1

2



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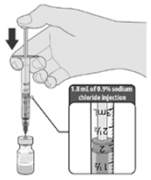

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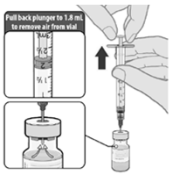

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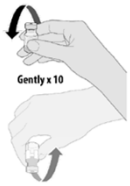

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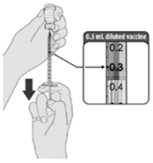
Store at 35° to 77° F
for up to 6 hours

7



Do not pool vaccine from multiple vials for any single injection

Pfizer COVID-19 Vaccine: What's in the vial?

- Lipids
- Polyethylene glycol
- Cholesterol
- Potassium chloride
- Potassium phosphate
- Sodium chloride
- Sucrose
- 30 mcg mRNA to the spike glycoprotein
- Vial stopper does **NOT** contain natural rubber latex
- Vaccine is preservative-free

Moderna COVID-19 Vaccine

- Storage: -13° to 5° F
  - DO NOT store in dry ice or below -40° F
  - Can store refrigerated 36° to 46° F for 30 days
  - Cannot refreeze thawed vials
- Unpunctured vials 46° to 77° F for 12 hours
- Punctured vials 36° to 77° F for 6 hours

Moderna COVID-19 Vaccine

- Thaw in refrigerator 2 hours 30 minutes
  - After thawing, let stand 15 minutes at room temperature
- Alternatively thaw at room temperature 1 hour

Moderna COVID-19 Vaccine

- Swirl gently
  - **DO NOT** shake
- Each dose = 0.5 ml
- Vials contain 10 doses
- Administer intramuscularly
- FDA-approved for 18 years and older

Moderna COVID-19 Vaccine: What's in the vial?

- Lipids
- Polyethylene glycol
- Cholesterol
- Tromethamine
- Acetic acid
- Sodium acetate
- Sucrose
- 100 mcg mRNA to the spike glycoprotein
- Vial stopper does **NOT** contain natural rubber latex
- Vaccine is preservative-free

Vaccine Administration Logisitics

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Our First Doses Administered

Assembling the Teams

- Vaccine Prioritization: Dr. Nick Kman & Dr. Ryan Nash
  - Goal: Defining and Implementing the Prioritization of Vaccine
  - Met 3x week
- Vaccine Administration: Dr. Crystal Tubbs & Ryan Haley
  - Goals: Managing Supply Chain & Administration Process
  - Met 2x week but had multiple subgroups
- Vaccine Education: Beth Necamp
  - Goals: Developing education for internal and external groups
  - Established later in the process

Assembling the Workforce

- Vaccine Administration Roles
  - Manager
  - Scheduling (Call Center)
  - Pharmacist Station
  - Check-In / Registration Staff
  - Runner/Navigator
  - Vaccinator
  - Physician
  - Campus Police
- Indirect Support
  - IT
  - Marketing
  - Legal Services
  - Revenue Cycle
  - Volunteer / Staffing Management

The Vaccine Administration Process

- Before the Visit
  - Invitations / Notifications
  - Scheduling (Online vs Phone) w/screening questions
  - Reminders
- Day of the Visit
  - Arrival / Check-In
  - Review of Screening Questions
  - **Vaccine Administration**
  - Post-vax monitoring (15 min vs 30 min)
  - Full registration
  - Scheduling of 2nd visit
- After the Visit
  - Billing for Service
  - Post-vax Nurse Line
  - Vsafe reporting

Safety

- Universal masking
- Physical distancing both in lines and at the vaccine stations
- Visual indicators to demonstrate whether vaccine station is clean or dirty
- One way traffic flow
- Vaccine screening questions
- Vaccine manufacturer double checks

Supply Chain / Schedule Management

- Managing the extreme variability of weekly supply (ranging from 975 in a week to 8850)
- Balancing allocated supply with specific number of appointment slots (how much risk do you take?)
- Multiple manufacturers
- 1st Dose vs 2nd Dose
- Visit Type by Manufacturer
- Goal to get all shipments out within 7 days or less of receipt
- ZERO DOSES WASTED from overdraws

Communication / education

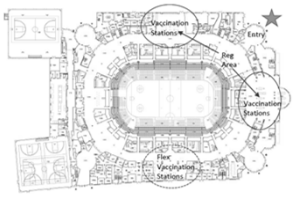
- Town halls
- eLearning
- HealthBeat Hub FAQs
- Daily updates from chancellor
- Vaccine email address

OSUWMC's Vaccine Hours Locations

- Initially used 3 different locations on campus
  - Biomedical Research Tower (capacity 900 patients per day)
  - East Hopsital Conference Room (capacity 450 patients per day)
  - Ackerman Administrative Building (capacity 1100 patients per day)
- Days and Hours – somewhat dependent upon demand
  - M-F 7a-7p (12 hours, w/10.5 hours of vaccine uptime)
  - Saturdays 7a-3p (8 hours, w/7 hours of vaccine uptime)

Scaling Up: Shots at the Schott

- Schottenstein Center
  - 2 Concourses (~150-160 vaccine stations)
  - Max capacity in 12 hour shift ~ 3K
  - Goal of 2 table turns per hour



Schottenstein Center Pictures

Schottenstein Center Pictures

Schottenstein Center Pictures

mRNA COVID-19 Vaccines

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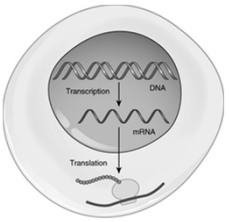
Traditional Vaccines

Type of Vaccine	Mechanism of Action	Examples
Live-attenuated	Weakened virus that infects cells and induces immune response.	Measles, Mumps, Rubella Variola (Smallpox) Varicella (Chickenpox) Yellow Fever Influenza (intranasal)
Inactivated	Virus is inactivated. Not pathogenic to host, but can induce an immune response.	Hepatitis A Rabies Influenza (IM)
Subunit (recombinant, polysaccharide, conjugate)	Antigenic material (sugar, protein, etc) that are components of the organism are used to induce an immune response	*Haemophilus influenzae* type b Hepatitis B HPV Pneumococcus Meningococcus
Toxoid	Toxin produced by the organism is inactivated and used to induce an immune response.	Diphtheria Tetanus

Nucleic Acid Vaccines

- Nucleic acid that encodes the desired antigenic protein is inserted into the cell.
- The cell uses its own machinery to transcribe and/or translate the nucleic acid into the protein.
  - DNA Plasmid
    - Examples: Zika, influenza
  - Viral Vector
    - Examples: Zika, HIV, Ebola, SARS-CoV-2
  - mRNA Vaccines



Source: https://cnx.org/contents/FPtK1zmh@8.25:fEI3C8Ot@10/Preface

mRNA Vaccine Research

- 1990 - 1st successful use in animal model of mRNA was injected into mice and protein production was detected
- Very promising technology for vaccines against infectious agents, cancer therapies, and protein replacement therapies.

Early Barriers	**Advancements**
Rapid mRNA degradation	Development of cationic lipid/polymer molecules to usher the mRNA in the cell
Inefficient *in vivo* delivery into the cell	
High innate immunogenicity	Immunogenicity can be down-regulated

Parti et al. Nature Reviews. 2018.

Types of mRNA Vaccines

	Delivery Method	Pathogens Studied
1. Self-Amplifying	Complex to lipid nanoparticle and injected into host	RSV, influenza, CMV, HCV, rabies, HIV, Ebola, Zika *Toxoplasma gondii* Group A Strep, Group B Strep
2. Non-replicating	*Ex vivo* loading of DC, then infusion into host	HIV, CMV
	Complex to lipid nanoparticle and injected into host	***Influenza***, rabies, HIV, ***Zika***

Parti et al. Nature Reviews. 2018.
Feldman et al. Vaccine. 2019 May 31;37(25):3326-3334.

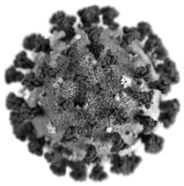
mRNA - promising alternative to traditional vaccine methodologies

- Safety
  - No potential risk of infection
  - Non-integrating platform
  - Degraded by normal cellular processes
  - High innate immunogenicity can be down-regulated
- Efficacy
  - mRNA can be modified to be more stable and highly translatable
  - Carrier/delivery molecules have been developed to efficiently deliver the mRNA into the cytoplasm before degradation can occur
- Production
  - Able to implement rapid, inexpensive, scalable manufacturing

Parti et al. Nature Reviews. 2018.

SARS-CoV-2 Vaccine Candidates in Phase 3 Trials

Type of Vaccine	Sponsor
mRNA	Pfizer Moderna
Viral Vector	Astra Zeneca/Oxford Janssen (J&J) CanSino
Recombinant Protein	Novavaxx
Inactivated	Sinovac Wuhan Institute of Biological Products



This media comes from the Centers for Disease Control and Prevention's Public Health Image Library (PHIL), with identification number **#23312**.
https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines/

Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine

- Published in NEJM December 2020
- Multinational, placebo-controlled, observer-blinded efficacy trial
- 16 and older
- 1:1 randomization of placebo vs BNT162b2 vaccine candidate
  - Lipid nanoparticle-formulated, nucleoside-modified RNA vaccine that encodes the SARS-CoV-2 full-length spike protein

Polack et al. NEJM 2020;383:2603-15.

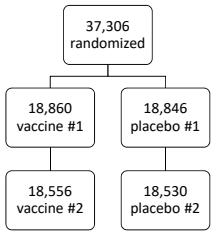
Primary Endpoints

- Efficacy
  - Confirmed COVID-19 at least 7 days after 2nd dose in subjects with no history of infection
  - Confirmed COVID-19 in all subjects regardless of past infection
- Safety
  - Solicited adverse events and use of antipyretics within 7 days of injection
  - Unsolicited adverse events through 1 month after 2nd dose and serious adverse events through 6 months after 2nd dose

Confirmed COVID-19 = at least 1 symptom + positive NAAT test

Polack et al. NEJM 2020;383:2603-15.

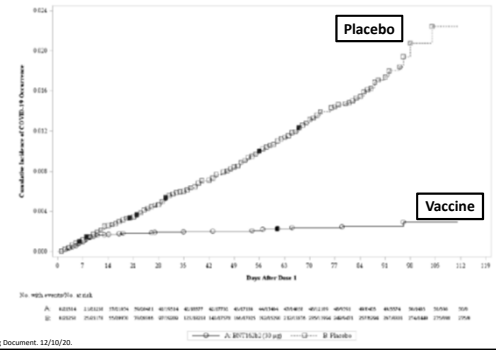
Interim Analysis 10/9/20



Male	50.6%
White Black Asian Hispanic	82.9% 9.3% 4.3% 28.0%
Median Age 16-55 years >55 years	52.0 years (16-91) 57.8% 42.2%
BMI >30 ≥1 Co-morbidity	35.1% 21%
Argentina Brazil South Africa US	15.3% 6.1% 2.0% 76.7%

Polack et al. NEJM 2020;383:2603-15.

Pfizer-BioNTech COVID-19 Vaccine



Pfizer & BioNTech. FDA Briefing Document. 12/10/20.

Primary and Secondary Endpoints

	# cases BNT162b2	# cases Placebo	Vaccine Efficacy, % (95% credible interval)
COVID-19 at least 7 days after 2nd dose in subjects without evidence of past infection (n = 36,523)	8	162	95.0% (90.3-97.6)
COVID-19 at least 7 days after 2nd dose in subjects with and without evidence of past infection (n = 40,137)	9	169	94.6% (89.9-97.3)
Severe COVID-19 (n=10)	1	9	

Polack et al. NEJM 2020;383:2603-15.

Vaccine Efficacy by Subgroup

	# cases BNT162b2	# cases Placebo	Vaccine Efficacy, %
16-55 years	5	114	95.6%
>55 years	3	48	93.7%
≥65 years	1	19	94.7%
≥75 years	0	5	100.0%
Male	3	81	96.4%
Female	5	81	93.7%
White	7	146	95.2%
Black	0	7	100.0%
All others	1	9	89.3%
Hispanic	3	53	94.4%
Non-Hispanic	5	109	95.4%

Between Dose #1-#2 = 52%

1st 7 days after Dose #2 = 91%

mRNA-1272 – Moderna Vaccine

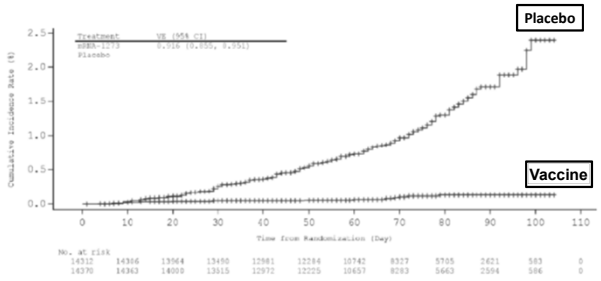
- 27,817 participants
- 82% of subjects considered at occupational risk for exposure
  - 25.4% were HCW
- 22.3% with at least 1 risk factor for severe disease

mRNA-1272 – Moderna Vaccine

	# cases nRNA-1272	# cases Placebo	Vaccine Efficacy, % (95% credible interval)
COVID-19 at least 14 days after 2nd dose in subjects without evidence of past infection (n = 27,817)	5	90	94.5% (86.5-97.8)
18-64 years (n = 20,791) ≥65 years (n = 7026)	5 0	75 15	93.4% (83.7-97.3%) 100%
Severe COVID-19 (n= 11)	0	11	

After Dose #1 = 80.2%

Moderna COVID-19 Vaccine



Take home points:

- mRNA vaccines have been researched for years with significant recent advancements.
- 2 currently available vaccines with excellent and nearly identical efficacy and safety profiles.

Remaining questions:

- What is the efficacy for asymptomatic transmission?
- How long dose immunity last?
- When will children be vaccinated?

COVID-19 Vaccine Safety

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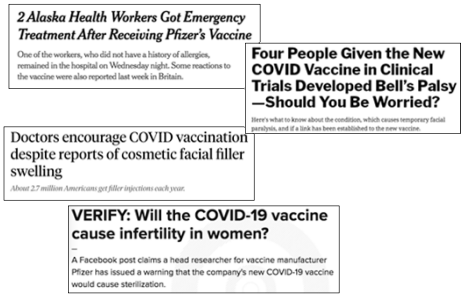
Adverse drug reactions in the news



2 Alaska Health Workers Got Emergency Treatment After Receiving Pfizer's Vaccine

One of the workers, who did not have a history of allergies, remained in the hospital on Wednesday night. Some reactions to the vaccine were also reported last week in Britain.

Four People Given the New COVID Vaccine in Clinical Trials Developed Bell's Palsy —Should You Be Worried?

Here's what to know about the condition, which causes temporary facial paralysis, and if a link has been established to the new vaccine.

Doctors encourage COVID vaccination despite reports of cosmetic facial filler swelling

About 2.7 million Americans get filler injections each year.

VERIFY: Will the COVID-19 vaccine cause infertility in women?

A Facebook post claims a head researcher for vaccine manufacturer Pfizer has issued a warning that the company's new COVID-19 vaccine would cause sterilization.

Adverse drug reactions in clinical trials

Adverse Event	Moderna (n=15,185)	Pfizer (n=21,621)
All	1242 (8.2%)	4484 (20.7%)
Serious	6 (<0.1%)	4 (<0.1%)
Fatal	0	0
Medically-attended	140 (0.9%)	Not assessed
Leading to study discontinuation after 1st dose	18 (0.1%)	Not assessed
Leading to study withdrawal after either dose	0	37 (0.2%)
Severe	71 (0.5%)	240 (1.1%)

Baden LR. *N Engl J Med.* Forthcoming 2021. doi 10.1056/NEJMoa2035389
Polack FP. *N Engl J Med.* 2020;383:2603-15.

Adverse drug reactions in clinical trials

- Minor local (e.g., injection site pain) and systemic (e.g., fatigue, headache) side effects were common
  - Onset usually within first 24-48 hours
  - Mean duration 2-3 days

Baden LR. *N Engl J Med.* Forthcoming 2021. doi 10.1056/NEJMoa2035389
Polack FP. *N Engl J Med.* 2020;383:2603-15.
Castells MC. *N Engl J Med.* Forthcoming 2021. DOI 10.1056/NEJMra2035343.

Serious reactions in trials: Moderna

- Occurred in 1.5% of Moderna vaccine recipients vs 1.1% placebo
  - Injection site rash, injection site urticaria
  - 1 anaphylactic reaction in each group
  - Facial swelling in 2 patients with history of dermatological fillers (onset 1 and 2 days after vaccination)
- 3 reports of Bell's palsy in Moderna vaccine group
  - Onset: 22, 28, and 32 days after vaccination
  - Insufficient information to determine causal relationship with the vaccine

Baden LR. *N Engl J Med*. Forthcoming 2021. doi 10.1056/NEJMoa2035389

Serious reactions in trials: Pfizer

- 4 serious reactions related to Pfizer vaccine reported:
  - Shoulder injury related to vaccine administration
  - Right axillary lymphadenopathy
  - Paroxysmal ventricular arrhythmia
  - Right leg paresthesia

Polack FP. *N Engl J Med*. 2020;383:2603-15.

Anaphylactic reactions in practice

- 3 cases of anaphylaxis reported within first 24 hours after mass vaccination began in UK and US (Pfizer)
  - 2 females in UK with known food/drug allergies
  - 1 female in US with no known allergies
- Several more cases associated with Pfizer vaccine reported in US
  - Incidence ~1 in 100,000
  - Known stable incidence of anaphylaxis with other vaccines: ~1 in 1,000,000
- Too soon to identify similar potential signal with Moderna vaccine
  - Cases have been reported

Castells MC. *N Engl J Med*. Forthcoming 2021. DOI 10.1056/NEJMra2035343.

Facial Fillers

- 3 patients with history of cosmetic filler injections reported facial swelling after receiving Moderna vaccine
  - Fillers injected 2 weeks, 6 months, and unknown period of time prior to COVID-19 vaccine
  - Onset 1-2 days after vaccination
  - All resolved

https://emergency.cdc.gov/coca/ppt/2020/dec-30-coca-call.pdf

Safe Vaccine Administration: CDC Recommendations

CDC Recommendations

Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine.

- Vaccinated persons should be monitored
  - 30 minutes: history of immediate allergic reaction of any severity to a vaccine or injectable therapy OR anaphylaxis due to any cause
  - 15 minutes: all others

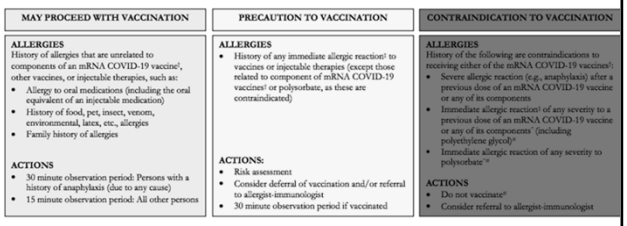
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

Vaccination in Special Populations

System	Signs/Symptoms
Immuno-compromised	may administer if not otherwise contraindicated, but counsel about lack of data and potential for reduced immune response.
Autoimmune conditions	administer if not otherwise contraindicated.
History of Guillain-Barré	administer if not otherwise contraindicated.
History of Bell's palsy	Cases observed in mRNA vaccine clinical trials, but no causality; frequency similar to that expected in general population. Administer if not otherwise contraindicated.
Pregnancy	No safety concerns in animal models but lack of human data; may administer vaccine if patient wishes (risk/benefit discussion recommended).
Lactation	No data available; may administer vaccine if patient wishes.

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Prevention: Triaging of mRNA Vaccine



MAY PROCEED WITH VACCINATION

ALLERGIES
History of allergies that are unrelated to components of an mRNA COVID-19 vaccine[1], other vaccines, or injectable therapies, such as:
- Allergy to oral medications (including the oral equivalent of an injectable medication)
- History of food, pet, insect, venom, environmental, latex, etc., allergies
- Family history of allergies

ACTIONS
- 30 minute observation period: Persons with a history of anaphylaxis (due to any cause)
- 15 minute observation period: All other persons

PRECAUTION TO VACCINATION

ALLERGIES
- History of any immediate allergic reaction[2] to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines[3] or polysorbate, as these are contraindicated)

ACTIONS:
- Risk assessment
- Consider deferral of vaccination and/or referral to allergist-immunologist
- 30 minute observation period if vaccinated

CONTRAINDICATION TO VACCINATION

ALLERGIES
History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines[3]:
- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction[2] of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components[4] (including polyethylene glycol)[5]
- Immediate allergic reaction of any severity to polysorbate[5,6]

ACTIONS
- Do not vaccinate[6]
- Consider referral to allergist-immunologist

https://emergency.cdc.gov/coca/ppt/2020/dec-30-coca-call.pdf

Mandatory Reporting to Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors
- Serious (irrespective of attribution to vaccination)
  - Death
  - Life-threatening adverse drug event
  - Inpatient hospitalization or prolongation of existing hospitalization
  - Persistent or significant incapacity or substantial disruption of ability to conduct normal life functions
  - Congenital anomaly/birth defect
- Cases of COVID-19 that result in hospitalization or death

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html