

COVID-19 Vaccinations by Ohio EMS Providers

Ohio Department of Public Safety, Division of EMS



Pfizer®/BioNTech® Edition



Mission

Provision of a foundation of knowledge based upon the Ohio EMS scope of practice and the recommendations from our federal and state public health organizations

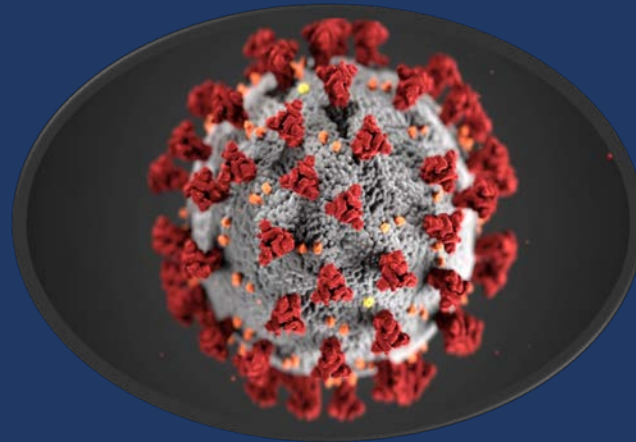
Objectives

- Understand the transmission, signs, and symptoms of Coronavirus Disease 2019 (also known as COVID-19 or SARS-CoV-2)
- Gain knowledge of the types of COVID-19 vaccine available and their respective indications, contraindications, and adverse effects
- Understand the required legal authorization, requirements, limitations, and liability protections regarding administration of immunizations by Ohio EMS providers

Objectives

- Gain knowledge of the need for partnership between with local health departments and EMS agencies during a vaccination campaign and their respective roles and responsibilities
- Gain knowledge of the data to be collected and documented prior to, during, and after the administration of a vaccine to a patient
- Note the need for vaccination of healthcare workers as a measure of disease prevention

Coronavirus Disease 2019 (COVID-19)



- A new strain of Coronavirus never before seen in humans
- Highly contagious
- Causes severe acute respiratory syndrome (SARS)
- Declared a pandemic by the World Health Organization (WHO) on **March 11, 2020**

Burden of Disease

CDC Data	INFLUENZA October 1, 2019 – April 4, 2020 (estimate)	COVID-19 As of December 12, 2020 (One day following FDA approval of the first COVID-19 vaccine)
Illnesses	39 million to 56 million	
Cases		15,718,811
Deaths	24,000 to 62,000	294,535

COVID-19: Symptoms

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

COVID-19: Transmission

- Airborne transmission via respiratory droplets
- Close contact (within 6 feet)
- Direct contact with infected surfaces
- Asymptomatic carriers
- Poorly ventilated or indoor environments

Vaccination Administration by Ohio EMS Providers

- Route of administration is within the Ohio EMS scope of practice for the certificate holder
- Administration is pursuant to medical direction and training on the specific vaccine
- Adherence to the recommendations and instructions of the FDA

Declaration of Emergency by the Governor

- Ohio Administrative Code 4765-6-03
- Defined parameters or restrictions that may include, but are not limited to:
 - Specific pathogen, illness, or other identified threats to public health
 - Age of persons to receive the vaccine
 - Ohio EMS certification levels authorized to participate
 - Duration of declared emergency

Requirements

- Appropriate training for the specified vaccine prior to participating in its administration
- Physician medical direction
- Certified Ohio EMS providers may not exceed the Ohio EMS scope of practice authorized by the EMFTS Board regardless of any training and protocols provided by the local EMS medical director



Liability Protections

- Agent or employee of an Ohio EMS agency
- Organization or employer that is not an Ohio EMS agency
- Federal declaration of emergency
- Medical Reserve Corps (MRC)

Partnership with Public Health

- Local health districts are critical in the determination of:
 - Data collection to identify geographic regions of prevalence and severity of disease
 - Appropriate dosing of vaccines
 - Acquisition and storage of medical records
 - Prioritization of available resources to at-risk populations
 - Points of distribution of the vaccine

COVID-19 Vaccine

- **COVID-19 vaccine is not made from the Coronavirus**
- Created with messenger RNA (mRNA)
- Produced by several manufacturers with varied storage and dosing requirements
- Requires two doses to obtain maximum protection
- Vaccine from other manufacturers are not interchangeable

mRNA COVID-19 Vaccines

Manufacturer	Pfizer®/BioNTech®	Moderna®
Freezer Storage Requirements	Ultracold: -80°C (-122°F)	Normal freezer
Freezer Storage Limit	6 months	6 months
Refrigerator Storage Limit	5 days	7 days
Room Temperature Limit	6 hours	6 hours
Efficacy	95%	94%
Time interval for 2nd Dose	21 days	28 days

COVID-19 Vaccination: Prioritized Populations

- High-risk healthcare workers
- First responders (including EMS personnel)
- Older adults living in congregate or overcrowded settings
- Persons at significantly higher risk due to comorbid or underlying conditions

COVID-19 Vaccine: Considerations

- Pfizer[®]/BioNTech[®] vaccine: Reported adverse reactions in persons with a history of severe allergic reactions
- COVID-19-positive persons: Advised to defer immunization for 90 days
- Immunocompromised patients
- Vaccine safety has not been determined in pregnancy, lactation, and in children less than 16 years of age



COVID-19 Vaccine Preparation and Administration

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Storage/Transport Requirements

- Supplied in multi-dose vials of an undiluted preservative-free suspension
- Delivered frozen in a thermal container from the manufacturer
- Cannot be refrozen once thawed

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Storage/Transport Requirements

- Maintain protection from light until use
- Maintenance of frozen state at ultracold temperatures
 - Ultra-low temperature freezer at -80°C to -60°C (-112°F to -76°F)
 - Temporary storage option: Re-icing with dry ice at -90°C to -60°C (-130°F to -76°F)

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Preparation: Thaw

- Under refrigeration at 2°C to 8°C (35°F to 46°F)
 - Smaller number of vials takes less time to thaw
 - Can be stored in refrigeration up to 5 days (120 hours)
- At room temperature up to 25°C (77°F) for immediate use
 - Can thaw in 30 minutes
 - Storage limit is 2 hours



Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Preparation: Thawed Suspension

- Gently invert the vial 10 times
- Do not shake the vial
- Contents is a white to off-white suspension possibly with white to off-white amorphous crystals
- Discard the vial if contents are discolored or other particles are seen upon inspection

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Preparation: Dilution

- Attach a 21-gauge or smaller needle to a transfer syringe
- Draw up 1.8 mL of 0.9% sodium chloride injection (*non-bacteriostatic normal saline*) using aseptic technique
- This diluent is not supplied by the vaccine manufacturer

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Preparation: Dilution

- Cleanse the vial stopper with a single-use antiseptic swab
- Gently add diluent to the vial
- Prior to removal of the needle, aspirate 1.8 mL of air into the syringe to equalize the pressure inside the vial



Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Preparation: Dilution

- Gently invert the vial 10 times
- Do not shake the vial
- The diluted vaccine is an off-white suspension
- Discard the vial if contents are discolored or contains particulate matter

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Post-Dilution Procedure

- Record the date and time of dilution clearly on the label of the vial
- Store the vial at 2°C to 25°C (35°F to 77°F)
- Discard any unused vaccine 6 hours after dilution



Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Fact Sheet for Recipients and Caregivers

- FDA has authorized the emergency use and this is not an FDA-approved vaccine
- Recipient or their caregiver has the option to accept or refuse the vaccine



Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Fact Sheet for Recipients and Caregivers

- Significant known and potential risks and benefits the vaccine and the extent to which such risks and benefits are unknown
- Information about available alternative vaccines and the risks and benefits of those alternatives

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors whether or not associated with an adverse event
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
- Cases of COVID-19 that result in hospitalization or death

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Vaccine Adverse Event Reporting System (VAERS)

- Serious adverse events (irrespective of attribution to vaccination)
 - Death
 - A life-threatening adverse event
 - Inpatient hospitalization or prolongation of existing hospitalization
 - Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
 - Congenital anomaly/birth defect
 - Important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above



Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®) Infection Control

- Face masks/Surgical masks
- Handwashing procedures
- Gloves
- Needlestick injuries
- Equipment disposal

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Vaccine Dosing and Administration

- A multi-dose vial contains 6 doses of vaccine
- Use low dead-volume syringes and/or needles to extract 6 doses from a single vial

Pfizer[®]/BioNTech[®] COVID-19 Vaccine (Tozinameran[®])

Vaccine Dosing and Administration

- Each dose must contain 0.3 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and contents
- Do not pool excess vaccine from multiple vials

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Vaccine Dosing and Administration

- Needle Gauge: 22-25 gauge
- Needle length
 - ♀ or ♂ < 130 pounds: 5/8 inch to 1 inch
 - ♀ or ♂ 130-152 pounds: 1 inch
 - ♀ 153-200 pounds or ♂ 153-260 pounds: 1 inch to 1½ inch
 - ♀ > 200 pounds or ♂ > 260 pounds: 1½ inch

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Vaccine Dosing and Administration

- Approach #1

 - 3 standard syringes and 3 low/zero dead-volume syringes

- Approach #2

 - 4 standard syringes and 2 low/zero dead-volume syringes

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Vaccine Dosing and Administration

- Cleanse the vial stopper with a single-use antiseptic swab
- Using aseptic technique, withdraw 0.3 mL of vaccine from the vial
- Immediately administer the vaccine intramuscularly

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Contraindications

- Do not administer the vaccine to persons with a known history of a serious allergic reaction or anaphylaxis to the vaccine components
- Components of this vaccine are mRNA, lipids, potassium chloride, monobasic potassium phosphate, sodium chloride (salt), dibasic sodium phosphate dihydrate, sucrose

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Adverse Reactions

- Injection site
 - Pain
 - Swelling
 - Redness
- Fatigue
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Nausea
- Malaise
- Lymphadenopathy

Pfizer®/BioNTech® COVID-19 Vaccine (Tozinameran®)

Post-Vaccination Responsibilities

- Include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system
- Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of the vaccine

COVID-19 Vaccination: **Benefits**

- Provides protection to you via immunity
- Protects the people around you, particularly those at high risk for severe illness from COVID-19
- Effective tool to help stop the COVID-19 pandemic

COVID-19 Pandemic

Impact on the Ohio EMS Workforce

- Stay home if you feel ill or have symptoms of COVID-19
- Don personal protective equipment
- Face mask or surgical mask
- Frequent hand washing
- Social distancing
- ***GET VACCINATED!!!***

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