Pfizer-BioNTech COVID-19 Vaccine

- Vaccine initiates production of antibodies to mRNA encoding spike protein
    - Spike protein facilitates entry of the virus into cells
    - Antibodies block entry of the virus into cells, preventing infection
    - mRNA technology is new, but not unknown
        - This technology has it has been studied for more than a decade
        - It does not affect or interact with a person's DNA
- It is NOT a live virus and therefore will not infect those administered
- FDA issued an Emergency Use Authorization for those 16-years-old and older
- 2 dose series, 3 weeks apart
    - Day 21 is the preferred date for the 2nd dose but there is a 4-day grace period (day 17-21)
    - If >21 days, 2nd dose should be administered at the earliest opportunity
        - No doses need to be repeated
    - Single dose efficacy has not been evaluated
    - Two dose efficacy – 95%
- Series needs to be completed with the same producer
    - Pfizer not interchangeable
- Should be administered alone with a minimum of 14 days before or after any other vaccines
    - If inadvertently administered within 14 days, doses of either vaccine do not need to be repeated
- History of infection
    - Vaccination should be offered to persons regardless of history or prior symptomatic or asymptomatic infection
- Current infection
    - Vaccination should be deferred until recovered from current, active infection and out of isolation
    - No minimal interval between infection and vaccination
- Antibody therapy
    - Vaccination deferred at least 90 days in persons who received monoclonal antibodies or convalescent plasma for COVID-19 treatment
- Exposure in outpatient setting
    - Defer vaccine until quarantine period has ended (to avoid exposure of others)
- Special populations
    - Underlying Medical Conditions – Vaccine may be administered to those with no contraindications to vaccination
    - Immunocompromised – Data not available to establish safety and efficacy of vaccine
        - May still receive vaccine unless otherwise contraindicated with proper counseling
    - Pregnancy – No data on the safety of vaccination in pregnant women
        - mRNA vaccines – not live, don't enter the nucleus cell but might increase the risk of adverse pregnancy outcomes, such as preterm birth
    - Breastfeeding – No data on the safety of COVID-19 vaccine or effects of mRNA vaccines
        - Since mRNA isn't live, not thought to be a risk to infant

CDC: https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf
Last Updated 12/13/2020

Complete Pfizer-BioNTech COVID-19 Vaccine Fact Sheet Available at: https://www.fda.gov/media/144414/download