NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
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Commissioner

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Dear Colleague:

The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech vaccine against COVID-19 on December 11, and the Advisory Committee on Immunization Practices (ACIP) voted to approve use of this vaccine on December 12. Vaccine efficacy, estimated at 95%, was consistent across age, race/ethnicity, and gender demographics. The two-dose vaccine is authorized for use in individuals ages 16 years and older. The purpose of this letter is to summarize ACIP recommendations regarding the vaccine, describe the initial population prioritized for receipt of vaccine, and remind providers of the need to report to the Citywide Immunization Registry (CIR) all administered doses of the COVID-19 vaccine. Future correspondence will delve into these subjects in greater detail and will also inform you when you can order vaccine for your population.

The ACIP has released recommendations regarding vaccine allocation and use. ACIP recommendations are based on evidence related to SARS-CoV-2 epidemiology, vaccination program implementation and ethical principles.

Vaccine Allocation
COVID-19 vaccine will become available in three phases. During the current first phase, limited amounts of vaccine are available. In the second phase, there will be greater availability of vaccine for the general public. In the third phase, there will be a shift to routine vaccination.

We are currently in the first phase of the vaccination program, and ACIP recommends that vaccines be provided to specific populations in three sub-phases. Phase 1a recommends vaccination of health care personnel[1] at high risk for transmitting or becoming infected with SARS-CoV-2 and residents and staff of long-term care facilities. ACIP intends to make recommendations for Phase 1b and 1c in the near future.

COVID-19 vaccine is now being distributed to hospitals for administration to health care personnel at the greatest risk of exposure to COVID-19 (such as those working in emergency departments or intensive care units). Distribution to additional health care facilities and providers has started, for example, to health care personnel at Federally Qualified Health Centers (FQHCs). Distribution will continue and be based on vaccine supply, populations prioritized for vaccination, and vaccine storage and handling capacity. Vaccines will be distributed in a transparent way that adheres to national and New York State guidance and ensures equitable access to New York City (NYC) residents.

[1] Health care personnel include all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials.

The NYC Department of Health and Mental Hygiene (NYC Health Department) is now enrolling private practices, independent pharmacies and other facilities that will immunize individuals in the NYC COVID-19 Vaccination Program. Enrollment in the program is required for COVID-19 vaccine delivery. If your facility chooses to participate, you will need to complete the COVID-19 Vaccination Program Provider Agreement in the online CIR. Access to the Provider Agreement is now available and instructions may be found in the provider enrollment letter.

Recommendation for use of Pfizer-BioNTech COVID-19 vaccine:
The Pfizer-BioNTech COVID-19 vaccine is recommended for people ages 16 and older in the United States (U.S.) under the EUA. The vaccine is administered intramuscularly as a series of two doses (0.3 mL) three weeks apart. Administration of the second dose within a four-day grace period (i.e. Day 17 to21) is considered valid; however, if the second dose is administered earlier than day 17, it does not need to be repeated. If more than 21 days have passed since the first dose, the second dose should be administered at the earliest opportunity (the series does not need to be restarted).

The Pfizer-BioNTech COVID-19 vaccine is not interchangeable with other COVID-19 vaccines. Individuals who have received one dose of Pfizer-BioNTech COVID-19 vaccine should receive a second dose of Pfizer-BioNTech vaccine to complete the vaccination series. However, **i**f one dose each of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.

Special Populations

Individuals with underlying medical conditions
Vaccines may be administered to individuals with underlying medical conditions who have no contraindications to vaccination. Phase 2 and 3 clinical trials demonstrate similar safety and efficacy profiles in people with underlying medical conditions, such as obesity and diabetes, compared to individuals without comorbidities.

Immunocompromised individuals
Data are not currently available to establish the safety and efficacy of vaccine in individuals with immunocompromising conditions. These individuals may still receive COVID-19 vaccination unless otherwise contraindicated. They should be counseled about the unknown vaccine safety and efficacy profiles in immunocompromised individuals and the potential for a reduced immune response to the vaccine. They should continue to follow all current guidance to protect themselves against COVID-19.

People who are pregnant
There are no available data on the safety of COVID-19 vaccines in people who are pregnant. Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk for people who are pregnant. People who are pregnant that are members of a group recommended to receive COVID-19 vaccine may choose to be vaccinated. Discussion and shared decision-making with a health care provider may be helpful prior to vaccination. Considerations for discussion are presented in the Centers for Disease Control and Prevention (CDC)'s Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine. People

who are pregnant that experience fever following vaccination should be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes. Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is not recommended. Those who are trying to become pregnant do not need to avoid pregnancy after Pfizer-BioNTech COVID-19 vaccination.

People who are breastfeeding or lactating

There are no data on the safety of COVID-19 vaccines in people who are lactating or the effects of mRNA vaccines on an infant being breastfed or on milk production and excretion. However, mRNA vaccines are not live virus vaccines and are not thought to be a risk to an infant that is being breastfed. People who are lactating and are members of a group recommended to receive COVID-19 vaccination may choose to be vaccinated.

Adolescents

Adolescents ages 16 to 17 who are part of a group recommended to receive a COVID-19 vaccine may be vaccinated, with appropriate assent and parental consent. While vaccine safety and efficacy data in this age group are limited, there is no evidence that safety and efficacy profiles are different than those observed in individuals 18 and older.

Individuals with current COVID-19 or who had COVID-19 within the last 90 days

Vaccination should be deferred in individuals with current symptomatic or asymptomatic SARS-CoV-2 infection until criteria have been met to discontinue isolation. Because evidence suggests that reinfection is uncommon in the 90 days after initial infection, individuals with documented acute SARS-CoV-2 infection in the preceding 90 days may be vaccinated or may choose to delay vaccination until near the end of this period.

Persons with a known SARS-CoV-2 exposure

For individuals with a known SARS-CoV-2 exposure, vaccination should be deferred until the quarantine period has ended unless the person resides in a congregate residential setting. Residents of congregate settings with a known SARS-CoV-2 exposure may be vaccinated but precautions should be taken to limit mixing of these individuals with other residents or staff.

Individuals with history of COVID-19

Previous SARS-CoV-2 infection, whether symptomatic or asymptomatic, is not considered a contraindication to vaccination. Data from phase 2 and 3 clinical trials suggest that vaccination is safe and likely efficacious in these individuals. Viral or serologic testing is not recommended for the purpose of vaccine decision-making. See “Individuals with current COVID-19” above for recommendations on those whose history of COVID-19 was within the last 90 days.

Individuals who received passive antibody therapy for COVID-19

There is currently no data on the safety or efficacy of vaccination in individuals who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Vaccination should be deferred for at least 90 days in these individuals to avoid interference of the treatment with vaccine-induced immune responses.

Coadministration with other vaccines
The Pfizer-BioNTech COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration of any other vaccines because there is a lack of data on the safety and efficacy of this vaccine administered simultaneously with other vaccines. If the Pfizer-BioNTech COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, doses of either vaccine do not to be repeated. The second dose of the Pfizer/BioNtech vaccine (if not already given) should be administered 21 days after the first dose.

Reactogenicity
Before vaccination, providers should counsel vaccine recipients about expected local post vaccination symptoms (e.g., pain, swelling, erythema at the injection site) and systemic post-vaccination symptoms (e.g., fever, fatigue, headache, chills, myalgia, arthralgia). Data from phase 2 and 3 clinical trials demonstrate that 85% of individuals who were vaccinated developed at least one local injection site symptom and 77% developed at least one systemic symptom following vaccination. Most systemic post-vaccination symptoms are mild to moderate in severity, occur within the first three days of vaccination, and resolve within one to two days of onset. Generally, these symptoms were more common and more prominent after the second dose than after the first dose and in participants who were younger (ages 18 to 55) compared to participants who were older (ages 55 and above). Unless a person develops a contraindication to vaccination, they should be encouraged to complete the series even if they develop post-vaccination symptoms in order to optimize protection against COVID-19. Antipyretic or analgesic medications may be taken for treatment of post-vaccination symptoms. Routine prophylaxis to prevent symptoms is not recommended due to the lack of information on the impact of prophylaxis on vaccine-induced antibody responses.

Some systemic signs and symptoms such as cough, shortness of breath, rhinorrhea, sore throat, and loss of taste or smell are not typical for post-vaccination signs and symptoms. Individuals with these symptoms should be excluded from work pending evaluation for possible etiologies, including SARS-CoV-2 infection. The CDC provides additional guidance for managing systemic signs and symptoms following COVID-19 vaccination in health care personnel and long-term care facility residents.

Adverse Effects
No serious safety concerns have been identified thus far from the ongoing phase 3 clinical trial. The FDA requires that providers report vaccination administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine to the Vaccine Adverse Event Reporting System (VAERS). Reports may be submitted online. Assistance is available by calling 1-800-822-7967. Providers should also encourage vaccine recipients to enroll in the CDC's V-Safe program, a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after receipt of a COVID-19 vaccination. Personal information collected by V-safe will be kept confidential.

Contraindications and precautions
The Pfizer-BioNTech COVID-19 vaccine is contraindicated in individuals with a history of severe allergy to any of the vaccine components. The Pfizer BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

Because of reports of anaphylactic reactions among persons vaccinated outside of clinical trials, a history of severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous or subcutaneous) is a precaution to vaccination at this time but is not a contraindication. A risk assessment should be conducted to determine type of reaction and certainty of information, and the individual should receive counseling about the unknown risks of developing a severe allergic reaction, balancing these risks against the benefits of vaccination. Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions. Individuals with a history of anaphylaxis due to any cause should be observed for 30 minutes and all other persons should be observed for 15 minutes. Providers should ensure that appropriate medical treatment used to manage immediate allergic reactions is immediately available in the event an acute anaphylactic reaction occurs.

SARS-CoV-2 testing in individuals previously vaccinated
Prior receipt of the Pfizer-BioNTech COVID-19 vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests. Positive results on serologic tests that assess antibodies to the SARS-CoV-2 spike protein may indicate either prior infection or vaccination. To evaluate for evidence of prior infection in an individual with a history of Pfizer-BioNTech COVID-19 vaccination, a test specifically evaluating antibodies to the nucleocapsid protein should be used.

Public health recommendations for vaccinated persons
Vaccine recipients should be informed that protection from the vaccine is not immediate; the vaccine is a two-dose series and it will take one to two weeks following the second dose to be considered fully vaccinated. Moreover, no vaccine is 100% effective. Individuals who are vaccinated must continue to follow all current guidance to protect themselves and others, including wearing a mask when outside the home, staying at least 6 feet from others, and washing hands frequently. Individuals who are vaccinated should also follow quarantine guidance following a recent exposure or travel.

Reporting to the CIR
Reporting of all administered COVID-19 vaccine doses to the CIR is required within 24 hours of administration. See the "Prepare to Report COVID-19 Vaccinations to the CIR" section in our vaccine enrollment letter. New York State Executive Order 202.82 removes the requirement that adults must consent to have their immunization information reported to the CIR.

COVID-19 vaccine communication resources

- CDC: Engaging in Effective COVID-19 Vaccine Conversations
- CDC: Toolkit for Medical Centers, Clinics, and Clinicians

The NYC Health Department will continue to release information as it becomes available to help providers plan for allocation, distribution, and administration of COVID-19 vaccine.

Sincerely,

Jane R. Zucker, MD, MSc
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Bureau of Immunizations