MONKEYPOX VACCINATION FRAMEWORK

Pennsylvania Department of Health
2022 Monkeypox Outbreak

Version 5.0
Revised September 12, 2022

1. Overarching Strategy

The Pennsylvania Department of Health (Department) has developed this framework to ensure rapid and equitable distribution and utilization of vaccines for the current outbreak of Monkeypox impacting Pennsylvania. This includes prioritizing utilization for post exposure prophylaxis (PEP), but also maximizing the impact of vaccine for enhanced PEP (also known as PEP++) and pre-exposure prophylaxis (PrEP).

a. Planning Assumptions

This plan is developed with the following assumptions:

- Vaccine distributed under this framework will constitute the primary source of vaccine for monkeypox response. Currently monkeypox vaccine is not commercially available and the U.S. Strategic National Stockpile (SNS) is the source for vaccine.
- All providers (Points of Vaccination) will be onboarded and known to the Bureau of Communicable Diseases (either through the Immunization program or through the STD and/or HIV program). A majority of providers are already working with the department via COVID Vax, VFC, or other vaccine programs. Those needing truly "new" connections to our systems and programs will take longer to onboard; however, we are ready and able to work through that process with them.
- Philadelphia is, as of Phase 2a, treated as a standalone vaccine jurisdiction by CDC and HHS for this initiative. However, the Department and certain contacts will be copied on important correspondence with federal partners. The Pennsylvania and Philadelphia programs have and will work closely together.
- Jynneos will be the primary vaccine used under this initiative; ACAM2000 may be requested in addition in limited cases. ACAM2000 can only be ordered by working through the Department, and after consultation on the risk/benefits of utilizing this product.
- There is currently a limited supply of Jynneos with more doses anticipated to be made available through the remainder of the summer and early fall. There is a plentiful supply of ACAM2000.
- Monkeypox treatment (TPOXX [tecovirimat]) will remain available for those who have a confirmed or suspected case of Monkeypox; requests for this product will continue in the current practice of going through the Department and coordinating with the CDC.

b. Plan Implementation

This plan will be implemented as part of an organized Department response that includes input from the following Bureaus/Offices:

- Bureau of Epidemiology
- Bureau of Communicable Diseases
- Bureau of Community Health Systems
- Bureau of Emergency Preparedness and Response

- Bureau of Laboratories
- Office of Communications
- Office of Legal Counsel
- Office of Intergovernmental Affairs
- Executive Office

Each Bureau/Office may have an operational role in the development and execution of this plan, and coordination between entities will occur through routine coordination, and may involve an activation of the Department's Incident Management System.

Additionally, this plan relies on the participation and support of additional partners, including County and Municipal Health Departments and other healthcare providers (including, but not limited to STD/HIV clinics, FQHCs).

2. Distribution Framework

The Department will be the primary Pennsylvania entity responsible for ordering and managing the distribution of Monkeypox vaccines; and, in Phase 1 this included managing vaccine allocations for the City of Philadelphia. Currently, the Department is planning only for the JYNNEOS vaccine, but will also consider requesting ACAM2000 on an ad-hoc basis.

a. Prioritization of Vaccine

As of the date of this document, the current prioritization of the JYNNEOS vaccine is recommended to prioritize first those needing Post Exposure Prophylaxis (PEP), then those needing enhanced PEP. Due to the limited quantity of vaccine available, pre-exposure prophylaxis (PrEP) is recommended in limited situations specifically for individuals meeting the criteria described below.

- **Priority 1 - PEP:** High or Intermediate-risk case contacts identified by public health via case investigation, contact tracing, and risk exposure assessments (this may include sexual partners, household contacts, and healthcare workers) ***[Note: This would include contacts named by the case during an investigation or individuals coming forward and reporting to public health high or intermediate risk contact with a known monkeypox case]***
- **Priority 2 – Enhanced PEP:**
    - Individuals who report having a sex partner or other direct contact (e.g., unprotected contact between a person's skin or mucous membranes and the skin, lesions, or bodily fluids) in the past 14 days with an individual showing symptoms consistent with monkeypox, such as a rash or sores; **OR**
    - Gay, bisexual, or other men who have sex with men, and/or transgender, gender non-conforming, or gender non-binary persons who have had multiple (2+) or anonymous sex partners in the past 14 days **AND meet one of the following criteria:**
        - Have knowledge/suspicion that they may have been exposed to monkeypox or another STI in the past 14 days

        - Have had any newly diagnosed STI in the past 3 months, including gonorrhea, chlamydia, early syphilis, or HIV
        - Have attended an event (e.g., rave, sex party, sauna/bathhouse or other social venue), met sex partner(s) through online apps or social media platforms, or exchanged money or other goods/services for sex
        - Have a condition that may increase their risk for severe disease if infected with monkeypox virus, such as HIV or another condition that weakens their immune system, or they have a history of atopic dermatitis or eczema
        - Are on HIV pre-exposure prophylaxis (PrEP)
    - Individuals who report being a member of an exposed cohort (e.g., participated in activities associated with risk of transmission in a setting where multiple cases occurred)
    - Sex workers of any sexual orientation or gender identity
- **Priority 3- PrEP:** Any individual not meeting the above criteria could be considered for PrEP. While the current vaccine supply does not allow for widespread vaccine use for PrEP, as demand for PEP and enhanced PEP has slowed down, administration of PrEP to reach individuals who may be at higher risk for acquiring monkeypox, utilizing the following criteria is recommended. To reduce vaccine wastage, PrEP may be considered for other individuals (see details in vaccine administration section). As additional supply become available, further expansion of vaccine for PrEP will be considered.

    - Gay, bisexual, or other men who have sex with men; transgender or gender diverse persons who have sex with men; and women who have sex with men who have sex with men AND one of the following:

        - have multiple (2+) or anonymous sex partners
        - may be at high risk for severe disease if exposed to monkeypox, such as individuals living with HIV or another immunocompromising condition
        - are on HIV PrEP
        - have had any newly diagnosed STI in the past 12 months, including gonorrhea, chlamydia, or syphilis
        - have recently (i.e., in the past 30 days) attended or plan to attend any venue where anonymous sex or sex with multiple partners will occur (e.g., saunas, bathhouses, sex clubs, sex parties, campgrounds) in the next 30 days
        - have met recent (i.e., in the past 30 days) partners with whom they had sexual or other intimate contact, or plan to meet partners with whom they will have sexual or other intimate contact in the in the next 30 days through social media platforms (such as Grindr, Tinder

or Scruff), or at venues such as clubs, raves, sex parties, saunas, campgrounds etc.
- are experiencing homelessness or housing insecurity
- has been determined to be at high risk by a healthcare provider or public health official

[Note: The Pennsylvania Department of Health has developed screening criteria for administration of enhanced PEP and PrEP. If providers have patients who they believe are eligible under these criteria (but are not a current vaccination site), they are encouraged to call (or have their patients call) 877-PA-HEALTH for evaluation and referral to a site for vaccine administration]

Providers should prioritize and schedule second doses at the time of the first dose whenever possible. Providers should also contact individuals who received their first dose but do not have a second dose appointment scheduled in order to schedule one within the recommended interval. If an individual is beyond the recommended interval, a second dose should be scheduled as soon as possible, noting that if a person received one dose, a second dose can be administered without having to restart the series, even if the second dose is given after the minimum interval of four weeks. Providers are responsible for managing first and second doses from their supply and should not rely on a future shipment to accommodate second doses.

According to the U.S. Food and Drug Administration (FDA), Jynneos is indicated for prevention of smallpox and monkeypox disease in adults. However, since no vaccine is 100 percent effective, it is important for individuals to reduce their risk of potential exposures to monkeypox both before and after being vaccinated. We encourage vaccine providers to discuss prevention strategies with patients at the time of vaccination.

b. Allocation

As the federal government expands access to vaccine, including direct shipment of vaccine to providers, the Department is shifting its allocation processes.

Allocation of vaccine to sites will be determined by the Department to maximize access and availability based on metrics such as monkeypox case counts and other important data relating to the populations disproportionately impacted in the current outbreak, such as sexually transmitted disease (STD) and HIV data. Current vaccine on hand and administration data will also be considered when making allocations.

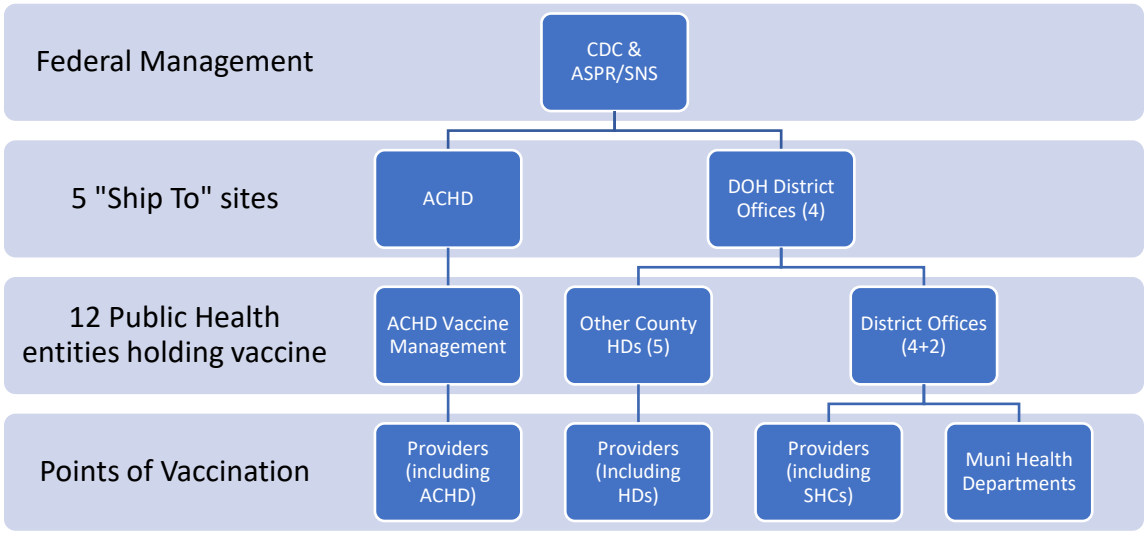
c. Redistribution

Previously, a CDC requirement had been enacted requiring the Department to have only 5 designated “Ship-to” sites, from which the Department distributed to other “Points of Vaccination” (POVs). The federal government through CDC and ASPR are now expanding the number of “ship-to” sites that jurisdictions can utilize. This may mean that more POVs will receive direct shipments from the federal government based on the Department’s orders. Other POVs may continue to receive shipments from a DOH “ship-to” site. All POVs will be recruited by the HIV/STD and Immunizations programs and

onboarded per Division of Immunizations guidance to provide vaccine to affected populations per the prioritization guidelines above. POVs will be provided an allocation (minimum of 20 vials at a time, based on the likely demand of the facility), but will be allowed to request additional doses once previously provided doses have been utilized. Throughout this process, transfers should be tracked, inventory reconciled at both locations, and administration reporting must be accomplished per the directives below and following the Secretary's order.

The Bureau of Emergency Preparedness and Response and the Bureau of Community Health Systems will support the timely movement of vaccines to providers in the Department's jurisdiction. County Health Departments may also be responsible for coordinating with providers in their jurisdictions to distribute and deploy vaccine.

It is anticipated that the majority of individuals needing PEP, enhanced PEP or PrEP will present themselves to a provider site that is already a POV. Otherwise, the Department will maintain a list of POV sites, and will make appropriate referrals to a POV location (such as when a potential patient calls the Department for consultation on vaccine access).



3. Reporting

CDC is now utilizing the HPOP (Health Partner Ordering Portal) and Tiberius systems for vaccine ordering and tracking. Currently, the Department will take the lead for placing orders for providers based on the allocation strategy defined in this document.

Additionally, all administrations of monkeypox vaccine from providers outside of Philadelphia must be recorded in PA-SIIS, following normal reporting requirements. All administrations of monkeypox vaccine from providers within Philadelphia must be recorded in PhilaVax. This reporting is required per the Secretary's order.

A supplemental form has been created to assist the Department in tracking utilization of vaccine, and to collect additional data points that may be required by CDC. This form should be filled out within 48 hours of vaccine administration and can be found at https://bit.ly/PA-MPXvax.

4. Utilization of Vaccine

Utilization of the vaccine by providers must be accomplished in conjunction with current CDC requirements, including all storage and handling guidelines. A few items of note include:

- Requests for vaccine doses to providers outside of a County Health jurisdiction should be sent to the Department who will take the lead on approving and coordinating vaccine transport.
    - Providers within county health departments should coordinate with that health department and the Department for vaccine access
- Jynneos is shipped at -20°C and requires cold chain management.
    - When stored frozen at -20°C, vials have a considerably longer shelf life. Lots currently in use have an expiration of August 2023, when they remain frozen.
    - Expiration dates are found on the carton but not on the vial itself. Expiration dates may also be found at: Monkeypox (hhs.gov)
    - When thawed and refrigerated at 2-8°C temperature, unopened vials can be used for up to 8 weeks based on information provided directly by the manufacturer (this differs from the package insert).
    - Punctured vials may be stored continuously in the refrigerator for up to 8 hours, after which time they should be properly disposed of
    - Unpunctured vials may be held at room temperature (between 8°C and 25°C) for up to 6 cumulative hours.
    - Once thawed, product CANNOT be refrozen.
    - Use beyond-use date labels for this vaccine to track storage times.
- Jynneos is **not** shipped from the SNS with ancillary supplies (syringes/needles); however, the Department will supply these through a separate process, unless the provider opts out.
- Jynneos is licensed as a series of two doses administered 28 days (4 weeks) apart.
    - The standard regimen for Jynneos involves a subcutaneous route of administration with an injection volume of 0.5mL. The standard regimen is the FDA-approved dosing regimen for individuals over the age of 18. Since August 9, 2022, the standard regimen has been authorized for people aged <18 years under an Emergency Use Authorization.
    - In the context of the current national Public Health Emergency, and to stretch the limited resources, an alternative regimen should be used for people age ≥18 years under an Emergency Use Authorization beginning August 9, 2022. The authorized alternative regimen involves an intradermal (ID) route of administration with an injection volume of 0.1mL. CDC has noted that intradermal is the expected route of administration at this time, noting that

some individuals should not receive the vaccine intradermally, such as those who have a history of developing keloid scars.

- The second dose of Jynneos vaccine should be given 28 days after the first dose; however, based on available clinical study data and ACIP general best practices, the second dose may be administered up to four days before the minimum interval of 28 days and up to seven days later than the minimum interval or as soon as possible.
- When necessary, a person aged 18 years or older who received one Jynneos vaccine dose with the standard subcutaneous regimen may receive a second dose with the alternative intradermal regimen at the recommended interval (i.e., 28 days) to complete the vaccination series. For example, a person who received only one dose of the standard regimen before the date of initial Emergency Use Authorization for the alternative regimen (August 9, 2022), may receive one dose with the alternative regimen to complete the series. Also, a person whose 18th birthday occurs between their first and second dose may complete the series with the alternative regimen.
- More information for providers is available and should be referenced in the CDC's Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak | Monkeypox | Poxvirus | CDC for more information regarding vaccine considerations and many related resources including:
  - Jynneos Package Insert
  - Jynneos Vaccine Information Statement (when given subcutaneously a VIS should be given to recipients; when given intradermally, a copy of the EUA should be given)
  - Jynneos Storage and Handling Summary
  - Jynneos Standing Orders (Standard and Alternative Regimen)
  - Jynneos Preparation and Administration Summary (Standard and Alternative Regimen)
  - Video and images for Administering Jynneos Intradermally
  - FDA EUA Fact Sheets for Providers and for Patients/Caregivers
  - Intradermal administration teaching tools.
- Healthcare providers are strongly encouraged, and in some cases required to report adverse events related to vaccine administration to the Vaccine Adverse Event Reporting System (VAERS) (hhs.gov)

The Department encourages strategies to minimize wastage of vaccine, understanding that this may not be possible in all circumstances, and opportunities to vaccinate someone who needs it should not be missed. Some examples of such strategies to maximize the use of thawed vials, or doses per vial, include but are not limited to:

1) coordinating the scheduling of several individuals for second dose appointments on the same day, which may mean scheduling clients up to four days before the recommended 28-day interval, or up to seven days (or as soon as possible) after the 28-day interval

2) maintaining a cancelation or waiting list and calling those clients to come in when an appointment opens up
3) when doses would otherwise go to waste, offering them to individuals who may not meet current eligibility criteria for PEP, enhanced PEP or PrEP, but may benefit from vaccination (e.g., health care workers involved in testing/treating patients suspected to have MPX)

5. Vaccine Strategy

The Department is committed to incorporating health equity principles as a foundation of this framework. Anyone can acquire monkeypox through close personal, often skin-to skin contact with someone who has monkeypox, however in this current outbreak, most (94%) reported U.S. cases have occurred among gay, bisexual, or other men who have sex with men, or transgender and nonbinary people who have sex with men. A substantial proportion of cases (41%) occurred among people living with HIV infection. Health disparities by race and ethnicity have also been reported, with a disproportionate number of cases among people who are Black and Hispanic. The Department has engaged diverse and trusted partners, providers and venues that already serve these communities, including but not limited to sexual health or STD clinics, LGBTQIA+ health clinics, local/state public health clinics, specialty medical providers (i.e., infectious disease, HIV) and federally qualified health centers (FQHC), noting that some FQHCs will receive vaccine directly from the federal government.

At this time, the Department is not considering mass vaccination for all individuals or for all sexually active people. On a limited basis, we are working with some providers to conduct smaller scale clinics, offering enhanced PEP. As supplies have become more plentiful, and it appears the needs for PEP and enhanced PEP are being sufficiently met, the Department is recommending PrEP for individuals at increased risk of monkeypox from non-occupational exposure (see criteria above in 2a), as part of a larger prevention effort to reach the most impacted communities and to ensure equitable access, including bringing vaccine to the community through outreach.

6. Communication

The Department will ensure communication to the provider community through routine email communication, as well as regular monkeypox stakeholder calls with key partners (such as County and Municipal Health Departments).

The Division of Immunizations has set up a resource account, RA-DHMPX_VAX@pa.gov, to receive, triage and respond to inquiries specifically on the monkeypox vaccine from onboarded and potential POV providers and the public.

The Department may also make periodic public announcements about this vaccine campaign; however (especially when supplies are significantly constrained), the talking points will be limited to:

- Limited supply of vaccine
- Prioritization of PEP first, enhanced PEP, then PrEP where most appropriate/for highest vulnerability populations

- Equitable distribution to District Offices and County Health Departments to ensure products are used in accordance with CDC recommendations

The Department is required by law to limit the public release of data around personal health information, including data relevant to this vaccination campaign. It is the Department's intention to follow legal requirements to protect personal health information, especially given the sensitivities of the population being vaccinated and the limited numbers of individuals likely to receive vaccine.