The Monkeypox Crisis: Knowledge, Skills and Tools that OEM Physicians Can Rapidly Deploy to Protect Healthcare Workers

- The epidemic, its pattern of spread and distinct clinical characteristics.
- Addressing exposures in healthcare settings, collaborative strategies to ensure appropriate contact tracing, monitoring and delivery of prophylaxis.
- The orthopoxvirus vaccines: PEP, PEP++ and PrEP.
- Discussion

Monkeypox 2022: The Epidemic, Considerations for Clinicians

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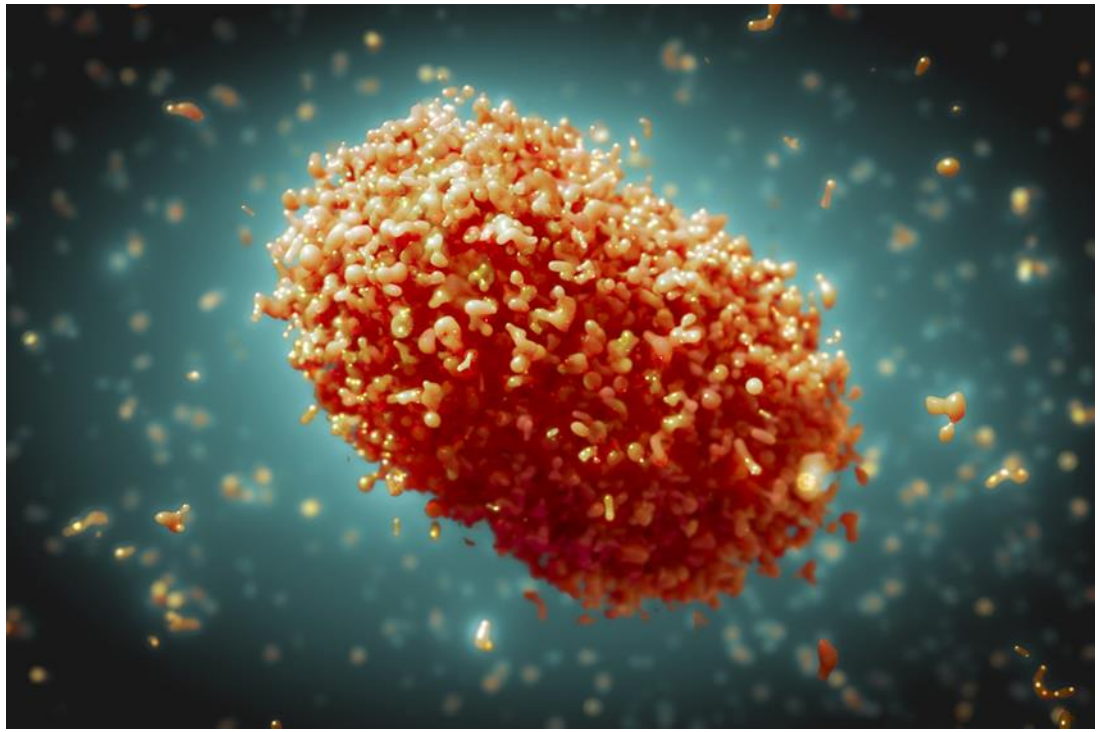
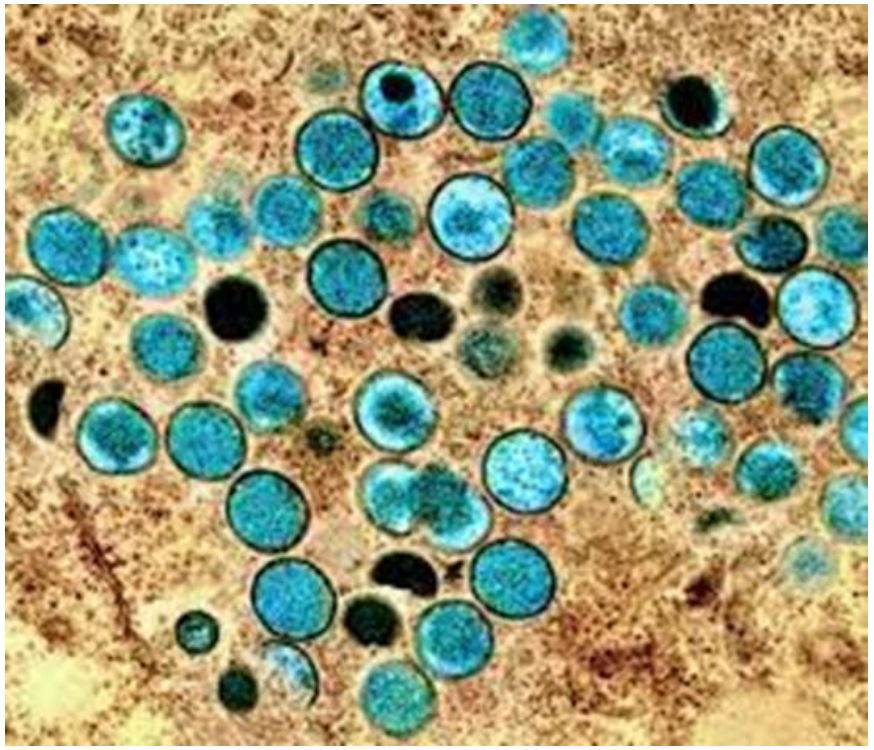
How it began

- April 29: British resident develops rash while visiting Nigeria
- May 6: Test is positive for monkeypox, West African clade. Contact tracing initiated.
- May 12: UK Health Security Agency confirms two new cases, no link to first case, no foreign travel.
- May 17: Four new cases confirmed in UK, no links to prior three cases.
- May 18: Portugal reports 14 cases, Spain reports 7, US reports first case.
- May 19: Italy, Sweden, Belgium report cases.
- May 20: Germany, France, the Netherlands, Australia report cases.
- June 10: UKHSA review of 314 cases. 311 are men, all who complete sexual practice questionnaire report MSM.



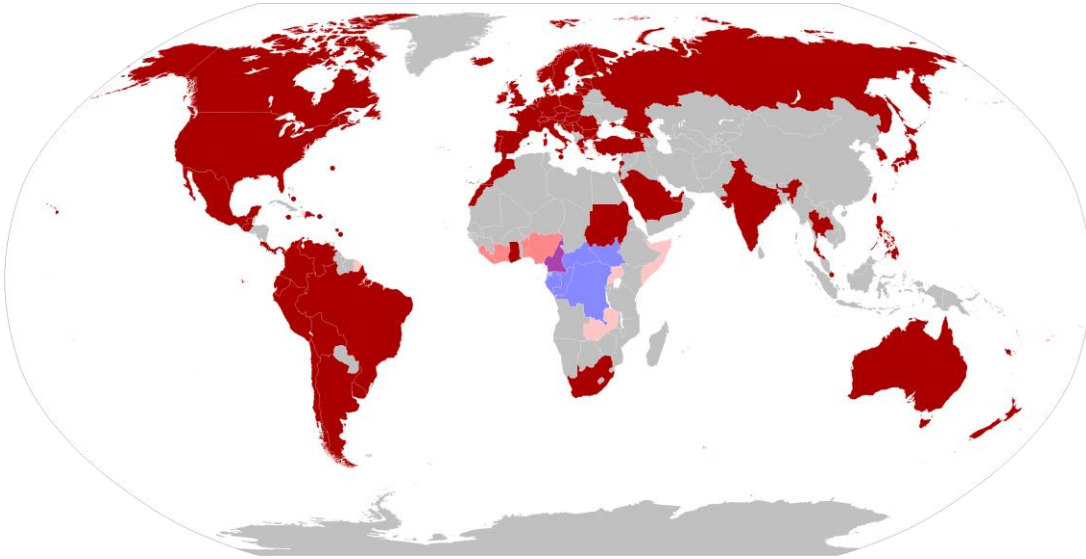
How it is transmitted

- Close skin-to-skin contact
- Linked to sexual activity, activity with multiple partners
- Role of actual sexual transmission beyond skin-skin contact uncertain
- Role of respiratory transmission uncertain
- Bed linens, fomites



How widely it has spread

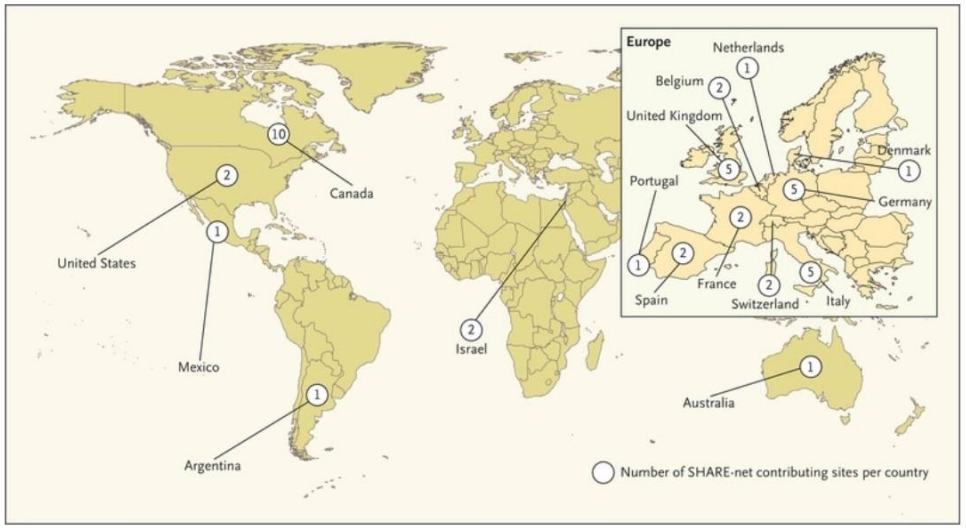
- US: 8933
- Spain: 4942
- Germany: 2916
- UK: 2859
- France: 2423
- Brazil: 1721
- CDC: 88 countries, 30,189 cases as of 5 PM, August 8, 2022.



Clinical characteristics

- Thornhill et al, NEJM, July 21, 2022: Case series from international collaborative group of physicians
- 528 infections diagnosed April 27-June 24 from 43 sites in 16 countries

Figure 1.



Global Distribution of SHARE-net Contributing Sites.

Table 1. Demographic and Clinical Characteristics of the Persons with Monkeypox.*

Characteristic	All Persons (N = 528)
Median age (range) — yr	38 (18–68)
Sex or gender — no. (%)	
Male	527 (>99)
Female	0
Trans or nonbinary	1 (<1)
Sexual orientation — no. (%)†	
Heterosexual	9 (2)
Homosexual	509 (96)
Bisexual	10 (2)
Race or ethnic group — no. (%)†	
White	398 (75)
Black	25 (5)
Mixed race	19 (4)
Latinx	66 (12)
Other or unknown	20 (4)
HIV positive — no. (%)	218 (41)
HIV negative or status unknown — no. (%)	310 (59)
Use of preexposure prophylaxis against HIV — no./total no. (%)	176/310 (57)
Foreign travel in month before diagnosis — no. (%)‡	147 (28)
Continent of travel — no./total no. (%)	
Europe	132/147 (90)
North America	9/147 (6)
Australasia	0/147
Africa and Middle East	2/147 (1)
Central and South America	2/147 (1)
Not stated	2/147 (1)
Known to have undergone STI screening — no. (%)	377 (71)
Microbiologically confirmed concomitant STI present — no./total no. screened (%)	109/377 (29)
Gonorrhea	32/377 (8)
Chlamydia	20/377 (5)
Syphilis	33/377 (9)
Herpes simplex virus infection	3/377 (1)
Lymphogranuloma venereum	2/377 (1)
Chlamydia and gonorrhea	5/377 (1)
Other or not stated	14/377 (4)
HIV test taken — no./total no. with previously unknown or negative HIV status (%)	122/310 (39)
New HIV infection diagnosis — no./total no. (%)	3/122 (2)
Sexual history not known — no. (%)	122/528 (23)
Median no. of sex partners in previous 3 months (IQR)	5 (3–15)
"Chemsex" reported in the previous month — no. (%)	106 (20)
Reported attendance at a sex-on-site event in the previous month — no. (%)	169 (32)
Known hepatitis infection — no. (%)	
Hepatitis B virus surface antigen positive	6 (1)
Hepatitis C virus antibody positive	30 (6)
Hepatitis C virus RNA positive	8 (2)
Reported history of smallpox vaccination — no. (%)	49 (9)

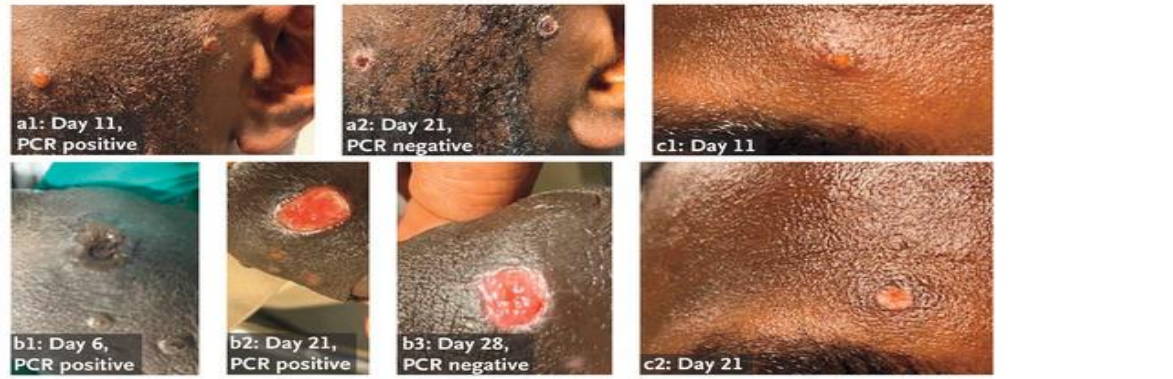
* Percentages may not total 100 because of rounding. HIV denotes human immunodeficiency virus, IQR interquartile range, and STI sexually transmitted infection.
† Sexual orientation and race or ethnic group were reported by the persons.
‡ Travel from the country of residence in the month before the positive monkeypox virus polymerase-chain-reaction (PCR) result is shown.

Table 3. Diagnosis and Clinical Characteristics of Monkeypox in the Case Series.*

Characteristic	All Persons (N = 528)
Medical setting of presentation — no. (%)	
Sexual health clinic	120 (23)
Emergency department	106 (20)
Primary care	20 (4)
Dermatology clinic	38 (7)
HIV clinic	154 (29)
Other hospital clinic	30 (6)
Private clinics or other	60 (11)
Suspected route of transmission — no. (%)	
Sexual close contact	504 (95)
Nonsexual close contact	4 (1)
Other or unknown	17 (3)
Household contact	3 (1)
Contact with person known to have monkeypox — no. (%)	135 (26)
Reported clinical features — no. (%)	
Rash or skin lesions	500 (95)
Fever	330 (62)
Lymphadenopathy	295 (56)
Pharyngitis	113 (21)
Headache	145 (27)
Lethargy or exhaustion	216 (41)
Myalgia	165 (31)
Low mood	54 (10)
Proctitis or anorectal pain	75 (14)
Site of positive monkeypox viral PCR — no. (%)†	
Skin or anogenital lesion	512 (97)
Nose or throat swab	138 (26)
Blood	35 (7)
Urine	14 (3)
Semen	29 (5)
Site of skin lesions — no. (%)‡	
Anogenital area	383 (73)
Face	134 (25)
Trunk or limbs	292 (55)
Palms or soles	51 (10)
Description of rash — no./total no. with rash reported (%)	
Vesiculopustular	291/500 (58)
Macular	19/500 (4)
Single ulcer	54/500 (11)
Multiple ulcers	95/500 (19)
Other	41/500 (8)
No rash	28
No. of skin lesions — no. (%)	
<5	207 (39)
5–10	131 (25)
11–20	112 (21)
>20	56 (11)
No lesions or missing data	22 (4)
Mucosal lesions present — no. (%)	217 (41)
Site of mucosal lesions — no./total no. (%)	
Anogenital only	148/217 (68)
Oropharyngeal only	50/217 (23)
Anogenital and oral	16/217 (7)
Nasal and eye	3/217 (1)
Medical care setting — no. (%)	
Inpatient	70 (13)
Outpatient	458 (87)
Received monkeypox-specific treatment — no. (%)	25 (5)
Treatment used — no. (%)	
Cidofovir	12 (2)
Tecovirimat	8 (2)
Vaccinia immune globulin	1 (<1)
Other	2 (<1)

* Percentages may not total 100 because of rounding.
† Some persons underwent testing from multiple sites, and not all sites were tested for all persons.
‡ More than one site per person may have been reported.

A Evolution of Cutaneous Lesions



Day −4
Condomless sexual contact in MSM

Day 0
Single genital lesion treated with IM penicillin as suspected syphilis

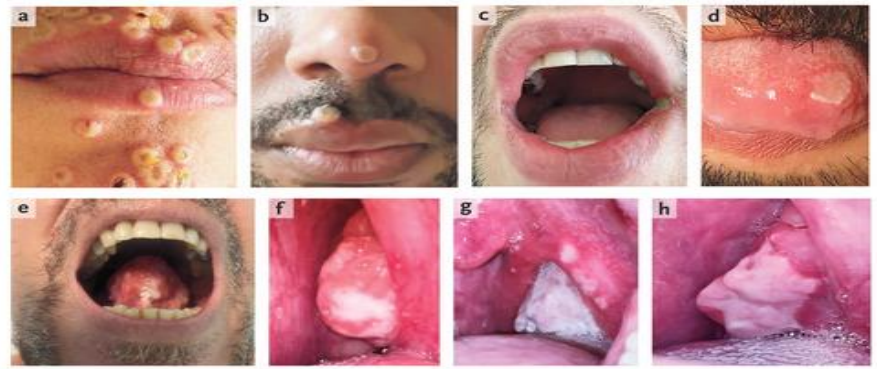
Days 4–6
Feeling unwell; additional lesions develop

Day 11
Confirmed monkeypox: facial and genital lesions PCR positive

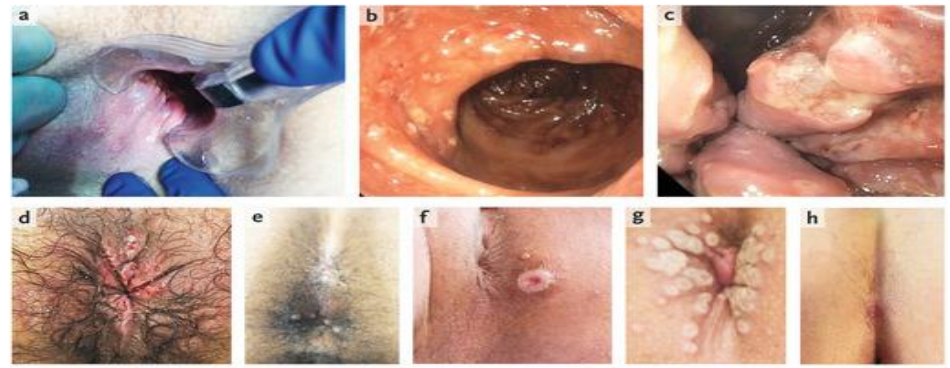
Day 21
Follow-up 1: facial lesions PCR negative, genital lesions PCR positive

Day 28
Follow-up 2: genital lesions PCR negative

B Oral and Perioral Lesions



C Perianal, Anal, and Rectal Lesions



What we're not seeing…

- Transmissions on planes, buses, trains
- Transmissions during public events
- Transmissions from casual contact
- Transmission in well resourced healthcare settings appears to be exceedingly rare.

Transmission to healthcare workers

- ICHE article by Zachary and Shenoy, online published June 9, 2022.
- Review of literature from 2000-2022, outside of endemic areas.
- (Of note, there are rare reports of transmission in resource limited healthcare settings within endemic areas.)
- 12 papers met study criteria: descriptions included the 2003 US prairie dog outbreak, as well as outbreaks between 2018 and 2021 in UK, Israel, Singapore, US involving travelers returning from endemic areas.

Year	Country	Description	Definition of HCP Exposure	Methods to Assess for Monkeypox Infection Following Exposure	Outcomes, Including Risk Assessment, Nosocomial Transmission, and Administration of Postexposure Prophylaxis (PEP)	Reference
2003	United States, Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin	Describes exposure investigation after 3 monkeypox patients identified as part of the 2003 prairie dog outbreak were admitted to hospital	HCP entered 2 m radius of the patient	Symptom monitoring; serology	81 HCP exposed; 57 (70%) participated; 40 of 57 (70%) had ≥ 1 unprotected exposure defined as not using gloves, gown, and either surgical mask or N95 respirator; no symptoms reported; 31 (54%) of 57 reported some history of prior smallpox vaccination; 1 HCP had antiorthopoxvirus IgM detected and had been vaccinated <6 mo prior; no transmissions reported.	Fleischauer et al[8]
		Summary of the 2003 prairie dog outbreak with a total of 71 cases (suspected and confirmed), including use of pre-exposure prophylaxis and PEP in HCP	Not provided	Not provided	Details of patient to HCP exposures not provided; among 30 individuals (HCP and non-HCP) in whom smallpox vaccine was administered, 2 HCP received vaccine as part of pre-exposure prophylaxis, and 10 HCP as PEP; no transmissions reported.	Gross[9] *MMWR* update[10]
2018	United Kingdom	Two travel-related cases; case 1 initially presented to general practitioner and later admitted to hospital; case 2 presented to an ED and was admitted to hospital	Different criteria used for case 1 (southwest England) and case 2 (northwest England)	Symptom monitoring; HCP who developed symptoms were directed to phone their designated public health and to stop working until they were assessed by the imported fever service (IFS).	High risk: 5 (5 received PEP); intermediate risk: 125 (84 received PEP); low risk: 158 (0 received PEP); 1 HCP in high-risk category developed infection; HCP described as having changed bedding without respiratory protection during period when monkeypox patient had active lesions prior to isolation; received PEP with attenuated nonreplicating vaccinia vaccine >4 d after exposure	Vaughan et al[4] Vaughan et al[11]
2018	Israel	Travel-related case; patient presented to an ED and admitted to hospital	Not provided	No details provided; only that all contacts were followed up for 21 d; no transmission was detected	11 HCP identified as exposed without details; all offered PEP with one HCP vaccinated; no transmissions reported.	Erez et al[12]
2019	Singapore	Travel-related case; patient presented to an ED and admitted to hospital	Due to up front suspicion for monkeypox, all HCP were wearing PPE; Ambulance HCP: N95 respirator, gown, gloves, no eye protection; HCP at hospital: N95 respirator, gown, gloves, eye protection); patient placed in AIIR	Symptom monitoring	No HCP were exposed; all asymptomatic; no transmissions; 27 HCP identified, but all with appropriate PPE.[13] Contact tracing of community exposures including 23 "close contacts" within 2 m of the patient for >30 min or had physical contact with patient or surfaces or materials contaminated by secretions (19 individuals who attended the same conference and 4 hotel staff) and 8 lower risk without definition of lower risk; 14 of 22 close contacts (1 of 23 had left the country) received PEP with with live, attenuated vaccinia virus (2 had contraindications and 6 declined)	Kyaw et al[13] Ng et al[14] Yong et al[15]
2021	United States, Texas	Travel-related case; patient presented to the ED and admitted to hospital	High, intermediate, low/uncertain, no risk; reports on mostly nonhealthcare exposures; based on CDC published exposure guidelines (since updated)	Symptom monitoring	High: 0; intermediate: 31 non HCF; 3 lab; low/uncertain: 146 non HCF; 43 HCP (care with gown, gloves, eye protection, N95 respirator or equivalent); no transmissions reported.	Rao et al[16]
2021	United States, Maryland	Travel-related case; patient presented to the ED and admitted to hospital	High, intermediate, low/uncertain, no risk; reports on mostly nonhealthcare exposures; based on CDC published exposure guidelines (since updated)	Symptom monitoring	40 HCP identified as contacts; none in high-risk group according to contemporary CDC guidelines; no PEP administered; no transmissions reported.	Costello et al[17]
2021	United Kingdom	Travel-related case resulting secondary transmission to 2 family members; case 1 presented to an ED and was initially discharged but then admitted to hospital the next day; entire household eventually admitted for observation after case 2 (child) developed symptoms; case 3 (adult member of family) was admitted at the time of symptom onset per above	High (direct contact with skin/mucous membranes; no FFP3 respirator), intermediate (not specified), low (physical contact with appropriate PPE)	Symptom monitoring; low risk: passive surveillance; intermediate or high risk: active surveillance daily	No. of exposed HCP not provided; no transmissions outside the household were reported.	Hobson et al[18]

Where will it go…

- Current vaccine supply inadequate to meet demand, FDA considering leveraging intradermal administration.
- PEP/PEP++/PrEP dependent upon supply.
- Reduction in risk behaviors.
- Expansion beyond current risk groups.
- Animal host reservoirs.

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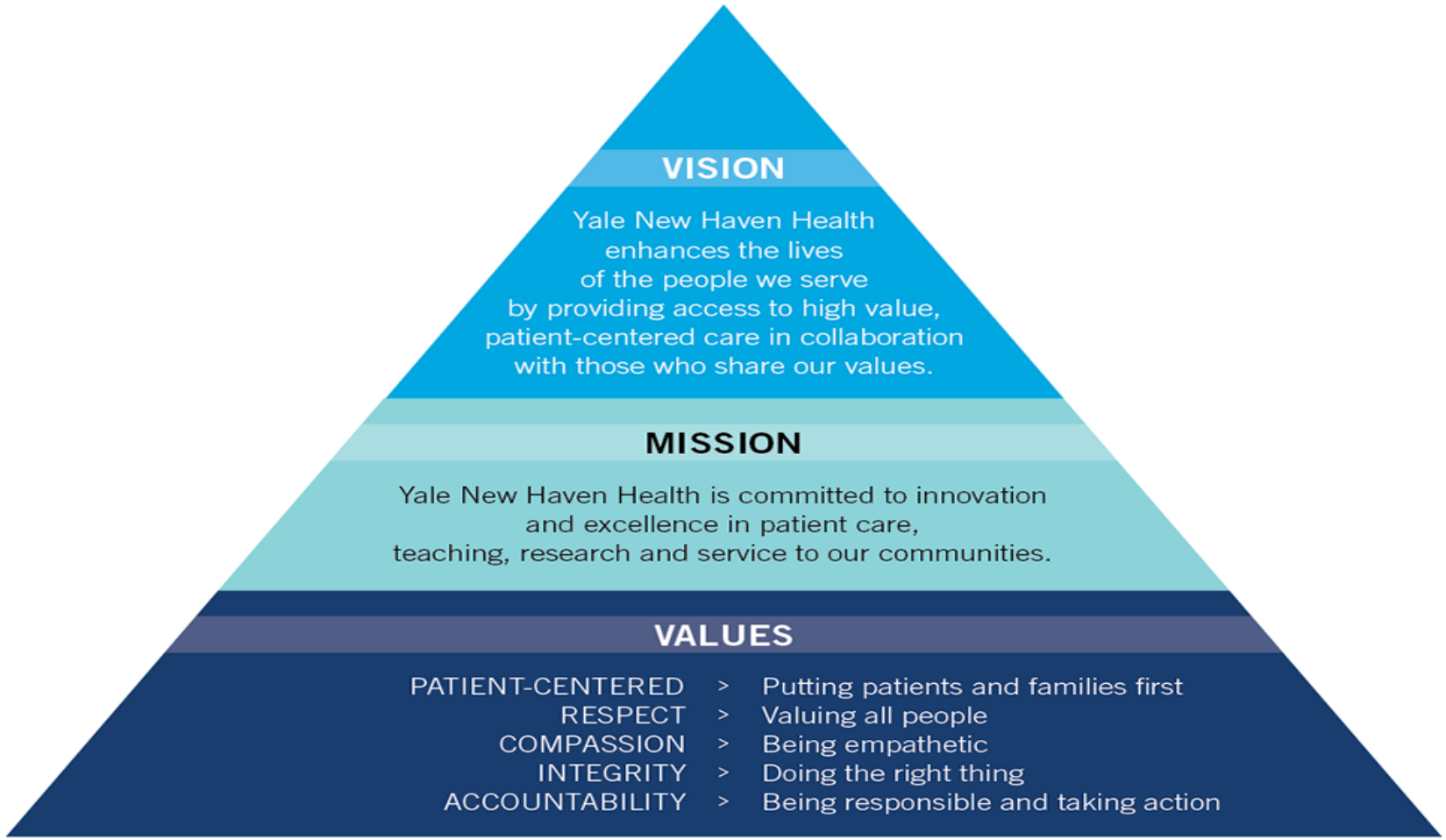
Monkeypox Exposure Risk Assessment, Vaccination and Self-Monitoring Plans

Craig D. Thorne, M.D., MPH, MBA, FACP, FACOEM

August 10, 2022

VISION, MISSION AND VALUES



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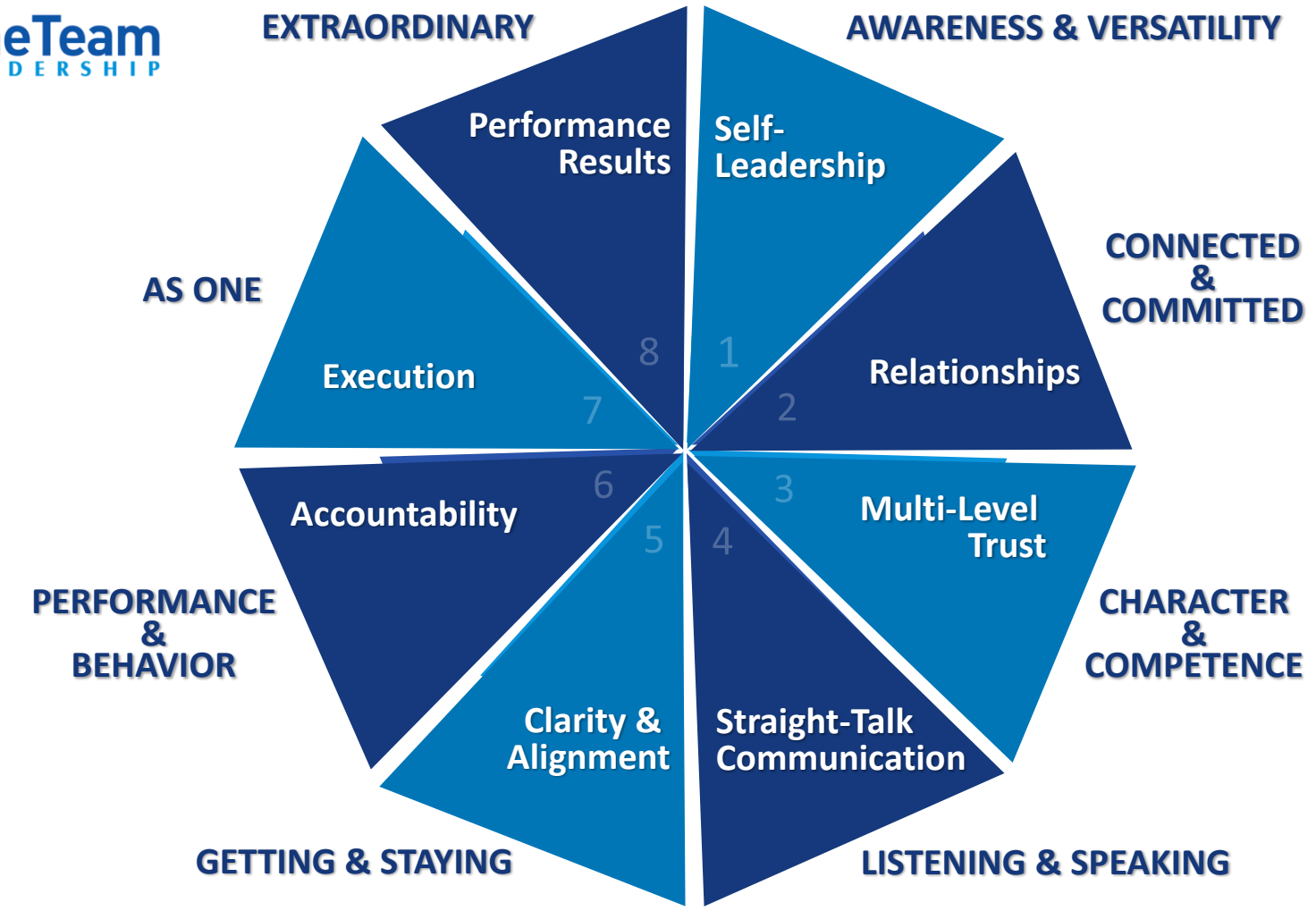
Bridgeport Hospital | Greenwich Hospital | Lawrence + Memorial Hospital | Westerly Hospital | Yale New Haven Hospital | Northeast Medical Group



Exposure Risk Assessment

- Per NIOSH: Occupational risk assessment is a method for estimating health risks from exposure to various levels of a workplace hazard.
- The aim of a risk assessment is to answer three basic questions:
  1. What can happen?
  2. How likely is it to happen?
  3. What are the consequences if it does happen?
- Understanding how much exposure to a hazard poses health risks to workers is important to appropriately eliminate, control, and reduce those risks.

Case Definition, Process and Contact Information

CASE DEFINITION of infectious Source Patient

- Monkeypox Source Patient's infectious period starts with onset of the following symptoms: fever ≥ 100.4 degree F, chills, new rash, and/or new lymphadenopathy (periauricular, axillary, cervical, or inguinal).

Exposure and Notification Process:

- Staff member(s) notifies Supervising Manager of possible exposure to a positive monkeypox source patient
- Supervising Manager(s), in collaboration with Infection Prevention, will confirm the source patient's diagnosis and level of exposure outlined per the Monkeypox Exposure Risk Table

Infection Prevention contact numbers M-F 8am-4:30pm

- GH: 203-863-3269
- BH: 475-248-6263
- YNHH: 203-688-4634
- LMH: 860-271-4904
- WH: 401-348-3574
- Ambulatory areas: 203-214-3935

- Evenings and weekends: On-call Infection Prevention: 203-444-6579

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STEP 1: **Determine HCW PPE and Contact Setting with Monkeypox Source**	**STEP 2:** **Determine Risk level**
HCW PPE and Type of Contact with Monkeypox Source	**Exposure Level**
Meets one or more of the following: ☐ Unprotected contact between a HCW skin or mucous membranes and the Source Patient's skin, lesions, or bodily fluids (e.g., inadvertent splashes of patient saliva to the eyes or oral cavity of a person, ungloved contact with patient), or contaminated materials (e.g., linens, clothing) ☐ Being in the patient's room during any procedure that may create aerosols oral secretions, skin lesions, or re-suspension of dried exudates (e.g., shaking of soiled linens) **while NOT wearing both an N95 or equivalent respirator AND eye protection**	**HIGH RISK**
Meets one or more of the following: ☐ Being within 6 feet of an unmasked patient for **greater than or equal to 3 hours** while NOT wearing a facemask or N95/equivalent respirator ☐ Activities resulting in contact between sleeves and other parts of an individual's clothing and the patient's skin lesions or bodily fluids, or their soiled linens or dressings (e.g., turning, bathing, or assisting with transfer) while wearing gloves but not wearing a gown.	**INTERMEDIATE RISK**
Meets one or more of the following: ☐ Entered the patient's room one or more times without eye protection REGARDLESS of duration** ☐ Wore gown, gloves, eye protection, and at minimum, a facemask during one or more entries in the patient care area or room, but not an N95 or equivalent respirator** ☐ Was within 6 feet of an unmasked patient for less than 3 hours while NOT wearing a facemask ***If an aerosol-generating procedure was performed in the room while the employee was not wearing an N95 or equivalent respirator, refer to the "High Risk" criteria*	**LOW RISK** **---** **UNCERTAIN RISK**

Step 3: Implement Action Measures	
Exposed Asymptomatic Employees	**Symptomatic Employees**

• Employee may continue to work
• Employee must check for fever (temp greater than or equal to 100.4 F) twice per day, once before a work shift
• Employee must actively self-monitor for **symptoms*** for 21 days from the 1st date of exposure
 	
*** Symptoms to be monitored include**:
• Fever (temp > 100.4 F) or Chills
• New Rash
• New Lymph Node Swelling
 	
• HCW should notify their supervisor that they are fever and symptom free prior to work shift.
• If "High" or "Intermediate Risk," employee may be offered the Monkeypox vaccine
  • *Employees with "Low Risk" exposures are not eligible for the Monkeypox vaccine at this time*
	• Immediately remove employee from work
	• Contact Occupational Health at the Employee Resource Center: 1-844-543-2147 (Option 2)
	
	• Contact Infection Prevention
	  ○ **(M-F 8am-4:30pm)**
	  ▪ GH: 203-863-3269
	  ▪ BH: 475-248-6263
	  ▪ YNHH: 203-688-4634
	  ▪ LMH: 860-271-4904
	  ▪ WH: 401-348-3574
	  ▪ Ambulatory areas: 203-214-3935
	  ○ **Evenings, weekends, and holidays:** 203-444-6579

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Documents available for your use

1. Monkeypox Exposure Risk Table and Responsibilities

2. Monkeypox Exposure Spreadsheet

3. Employee Instructions After Monkeypox Exposure

Exposed Employee's Responsibilities

- Follow Infection Prevention guidelines
- Notify Supervising Manager of possible exposure
- If asymptomatic, continue with work but monitor for symptoms and await for Occupational Health outreach about the availability of monkeypox vaccine availability and indications if deemed to be at high or intermediate risk
- If becomes symptomatic, remain home and contact Occupational Health at the Employee Resource Center (844) 543-2147; Option # 2)

Infection Prevention Responsibilities

- Investigate and confirm monkeypox positive source patient
- Initiate contact tracing for exposed staff and patients
- Work with supervising manager and reference the Monkeypox Exposure Risk Table to determine high, intermediate, and low/uncertain risk staff
- Update the Monkeypox Exposure Spreadsheet with the exposed employee's name, preferred phone number, and date of birth
- Advise the Supervising Manager to provide the Employee Instructions After Monkeypox Exposure handout to low/uncertain risk employees and instruct them to self-monitor twice daily for 21 days from the date of exposure
- Apply any lessons learned including PPE use and other control measures

Supervising Manager's Responsibilities

- Educate staff on Infection Prevention guidelines and the Monkeypox Exposure Risk Table
- Encourage staff to report possible unprotected exposure(s)
- Contact Infection Prevention about any possible exposure(s) or with questions
- Advise Low Exposure Level Staff to continue to work but self-monitor for symptoms for 21 days since the exposure date using the Employee Instructions after Monkeypox Exposure handout

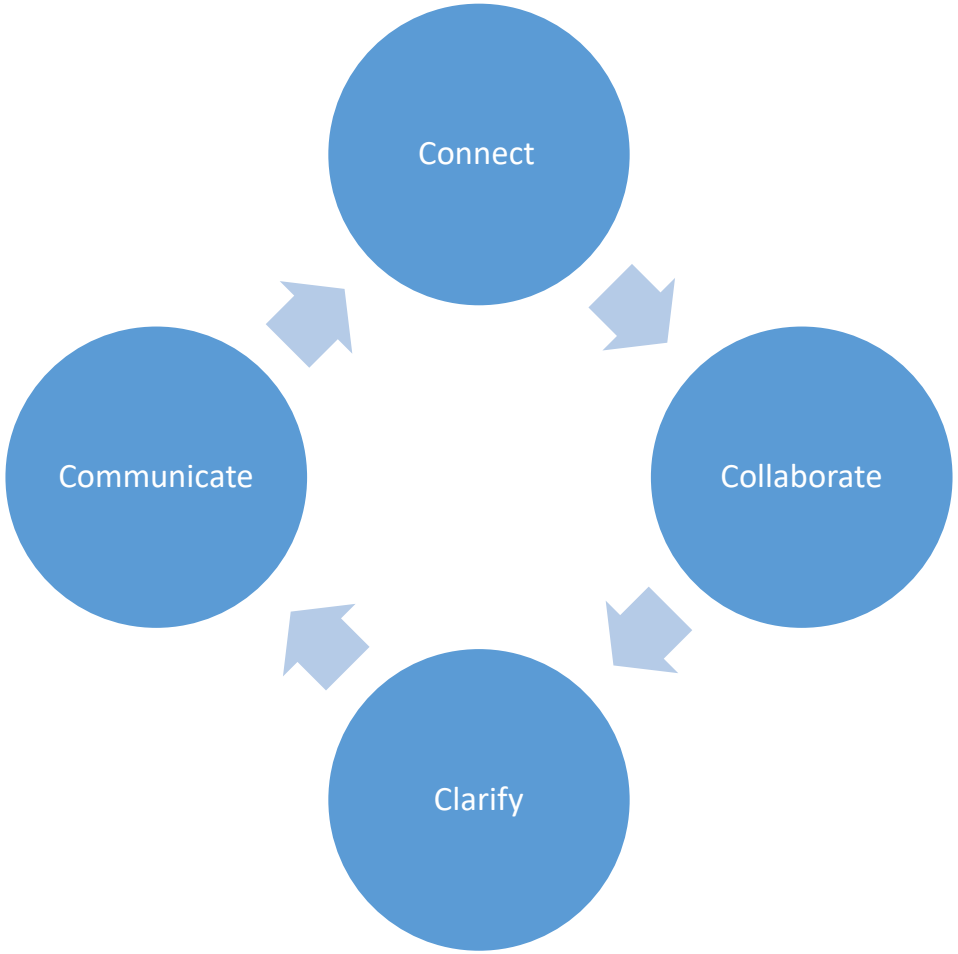
Occupational Heath Responsibilities (done virtually through Employee Resource Center)

- Designated clinician will track and update the Monkeypox Exposure Spreadsheet in the shared drive; will highlight the exposed staff members who consent to PEP vaccine
- Report back to the Occupational Health Nurse Coordinator and primary Infection Preventionist the names and contact information for the exposed staff who consent to PEP vaccination
- Occupational Health Nurse Coordinator (or designee) will coordinate vaccine appointments at local Occupational Health clinics or ED (both 1st and 2nd doses) and request vaccines from Central Pharmacy

Central Pharmacy's Responsibilities

- Request and manage the receipt and storage of the vaccine through the Health Department
- Coordinate with Occupational Health Nurse Coordinator the transport of the vaccine and local storage for eligible employees who have consented to receive it

Summary of Leadership Principles Used to Ensure Success: Four C's



Orthopoxvirus vaccine for monkeypox, smallpox and vaccinia

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Medical Director, Physician Health Center
Associate Medical Director, Occupational Health Service
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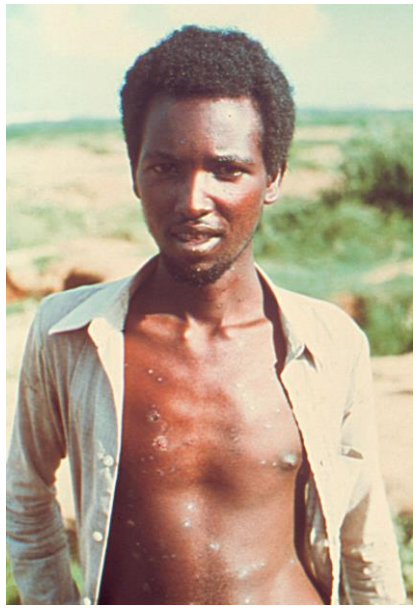
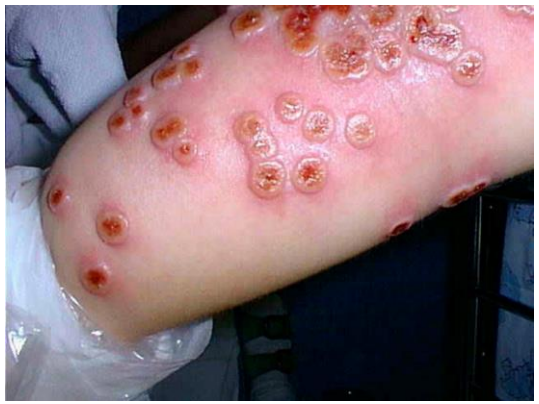
Orthopoxviruses

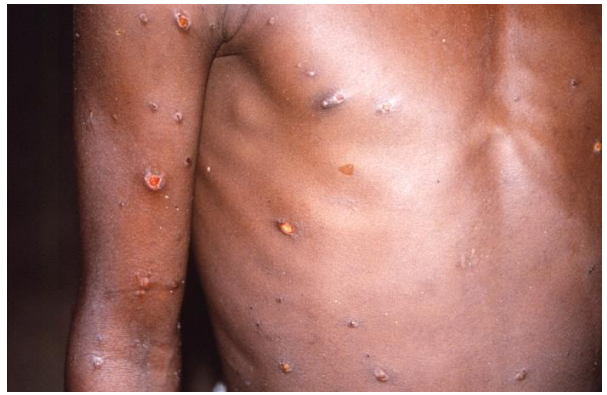
Variola major



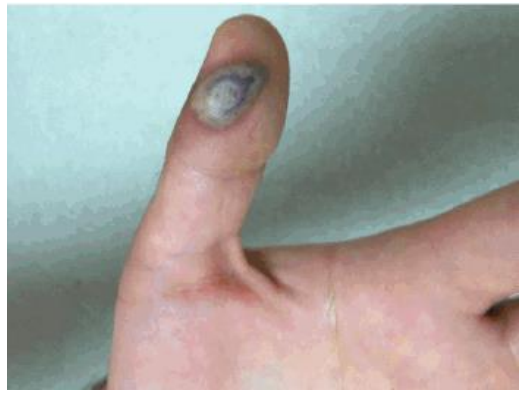
Variola minor



Cowpox



Monkeypox



Vaccinia

Vaccinia virus Ankara strain
(Turkish Vaccine Institute)

University of Munich

x 516

- Modified Vaccinia Ankara (MVA)
- Loss of cytopathic effects
- Incapable of replication in mammalian cells
- Retains cross-immunogenicity for orthopoxviruses

ACAM2000 vs Jynneos

	ACAM2000	JYNNEOS
Vaccine virus	Replication-competent, virulent	Replication-deficient, avirulent
“Take”	“Take” blister/scab occurs	No “take” to observe
Risk of inadvertent inoculation and autoinoculation	Yes	No
Serious adverse events	Risk exists	None expected
Cardiac adverse events	Myopericarditis 5/7 per 1,000	Not quantified, appears lower and subclinical in clinical trials
Effectiveness	Estimated over 90% for 3 years	Comparable to ACAM2000, duration 2 years
Administration	Percutaneous by multiple punctures with bifurcated needle	Subcutaneous in 2 doses, spaced 28 days apart

Contraindications and precautions

Condition	ACAM2000	JYNNEOS
Eczema/atopic dermatitis	Contraindicated	OK
Household member with eczema	Contraindicated (or separation)	OK
Immunocompromised	Contraindicated	OK (but may not have optimal immune response)
Pregnant	Contraindicated	OK if risk of disease is high (e.g. high risk exposure). No studies in humans. Safe in animal studies.
Breastfeeding	Not known if transmitted in breast milk; infants at high risk of serious complications from live vaccinia	OK if risk of disease is high (e.g. high risk exposure). Not known if transmitted in breast milk. Virus cannot replicate in mammals; risk low to infant.
Heart disease or multiple cardiac risk factors	Contraindicated	OK. Monitor for cardiac symptoms and report if noted.
Use of ocular steroids	Contraindicated	OK

Jynneos Vaccine Side Effects

- Injection site reactions are common:
  - Pain
  - Redness
  - Swelling
  - Itching
- Systemic reactions (no prior smallpox vaccine/previous vaccine)
  - Fatigue – 30.4%/33.5% (placebo 20.5%)
  - Headache – 34.8%/27.6% (placebo 25.6%)
  - Muscle aches – 42.8%/21.5% (placebo 17.6%)
  - Fever – 1.7%/0.5% (placebo 0.9%)
  - Cardiac adverse events – 1.3%/2.1% (placebo 0.2%)
    - Driven by asymptomatic elevation of troponin
    - Clinical significance unknown
    - None of the cardiac AEs were considered serious

PEP, PEP++ and PrEP

- **PEP** – Post exposure prophylactic vaccination after an identified high-risk exposure, ideally within 4 days (up to 14)
- **PEP++** (Expanded PEP) presumptive vaccination of individuals more likely to have recently been exposed.
  - Does not require documented exposure.
  - *Current monkeypox outbreak response strategy.*

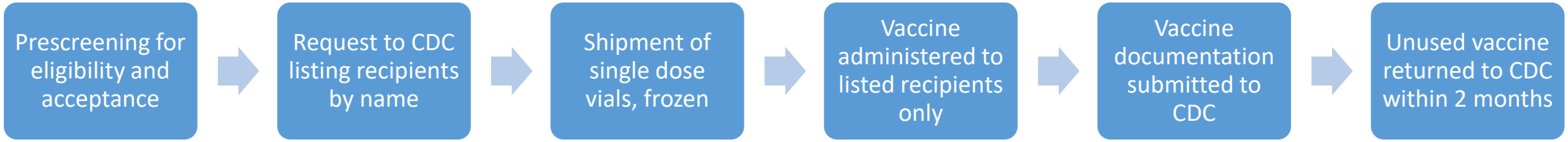
Vaccine allocation from Strategic National Stockpile to states: https://aspr.hhs.gov/SNS/Pages/JYNNEOS-Distribution.aspx

- ~1 million doses allocated to states, 617,693 requested and shipped as of 8/8/22
- 6.9 million doses anticipated in US supply by mid-2023

- **PrEP** - preexposure prophylaxis for individuals at high risk
  - Primary use of occupational vaccination
  - Laboratorians handling orthopoxvirus, or samples known/suspected to contain orthopoxvirus
  - Special pathogen healthcare teams – theoretical smallpox risk outweighed by monkeypox outbreak

Separate allocation and distribution process via CDC drug service.

Jynneos **preexposure** occupational vaccination procedure



- REQUEST FORM REQUIRES PRINCIPAL INVESTIGATOR AND RECEIVING PHYSICIAN
- DOSE 2 IN 28 DAYS
- BOOSTER EVERY 2 YEARS IF RISK REMAINS (10 YEARS FOR VACCINIA WORK ONLY)
- NO LAB TEST FOR IMMUNITY AT THIS TIME