

Immunization: Is Winter Here? An Update on Monkey Pox and Covid Vaccines



Jeffrey R. Aeschlimann, Pharm.D
Associate Professor, UConn School of Pharmacy
Adjunct Associate Professor, UConn School of Medicine



1

Disclosures

- Dr. Aeschlimann has no financial relationships with ineligible companies.
- This activity may contain discussion of unlabeled/unapproved use of drugs.
 - The content and views presented in this educational program are those of the faculty and do not necessarily represent those of the University of Connecticut School of Pharmacy.
- Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings

2

Disclosures, Part 2

- The use of public-domain materials found on the CDC and its Advisory Committee on Immunization Practices (ACIP) websites does not imply endorsement by CDC, ACIP, ATSDR, HHS or the United States Government of Dr. Aeschlimann, UConn, and/or UConn School of Pharmacy
- Additionally, any reference to specific commercial products, manufacturers, companies, or trademarks does not constitute its endorsement or recommendation by the U.S. Government, Department of Health and Human Services, or Centers for Disease Control and Prevention
- The public-domain materials presented have not been substantively changed, and all of the source materials are available on the agency's website for no charge.

3

Disclosures, Part 3

- The contents of the FDA website (www.fda.gov) — both text and graphics — are not copyrighted. They are in the public domain and may be republished, reprinted and otherwise used freely by anyone without the need to obtain permission from FDA. Credit to the U.S. Food and Drug Administration as the source is appreciated but not required
- Additionally, any reference to specific commercial products, manufacturers, companies, or trademarks does not constitute its endorsement or recommendation by the U.S. Government, Department of Health and Human Services, or Centers for Disease Control and Prevention

4

Learning Objectives

- At the conclusion of this CPE activity, participants should be able to:
 - 1) Discuss trends in the epidemiology of the COVID-19 pandemic and Monkeypox outbreak.
 - 2) Discuss current clinical data on the safety and effectiveness of (i) the bivalent COVID-19 booster vaccines and (ii) the JYNNEOS or ACAM2000 vaccines for Monkeypox.
 - 3) Explain whether a person would be eligible for receipt of (i) the bivalent COVID-19 booster vaccines and/or (ii) the JYNNEOS or ACAM2000 vaccines for Monkeypox

5

Let's get started

Monkeypox is the name and name-changing is the game. What has the World Health organization decided to call this infection and why?

- a. It will be "monk's disease," which will remove some of the stigmatizing language and remind people to live like a monk until the lesions disappear.
- b. It will be "mpox," which is intended to dissuade people from using racist and stigmatizing language to describe people infected with this virus.
- c. It will be "var-vac-human," reflecting its similarity to variola (smallpox) and vaccinia (viral vaccine for smallpox) and its mostly non-zoonotic transmission.

6

Monkeypox (Mpx)

World Health Organization | Health Topics | Countries | Newsroom | Emergencies

WHO recommends new name for monkeypox disease

28 November 2022 | News release | Geneva, Switzerland | Reading time: 3 min (781 words)

Following a series of consultations with global experts, WHO will begin using a new preferred term "mpox" as a synonym for monkeypox. Both names will be used simultaneously for one year while "monkeypox" is phased out.

When the outbreak of monkeypox expanded earlier this year, racist and stigmatizing language online, in other settings and in some communities was observed and reported to WHO. In several meetings, public and private, a number of individuals and countries raised concerns and asked WHO to propose a way forward to change the name.

Assigning names to new and, very exceptionally, to existing diseases is the responsibility of WHO under the International Classification of Diseases (ICD) and the WHO Family of International Health Related Classifications through a consultative process which includes WHO Member States.

<https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease> (accessed 11/29/22)

7

Monkeypox – Background & Basics


- Orthopoxvirus
- DNA virus, large and fairly stable genome
- Similar to Variola (smallpox virus) & Vaccinia (viral vaccine for smallpox)
- **Clade 1**: mortality up to 12%, more virulence/immunomodulating genes
- **Clade 2**: less-severe infections (mortality <0.1%)

[https://doi.org/10.1016/S0140-6736\(22\)02075-X](https://doi.org/10.1016/S0140-6736(22)02075-X)

8

Monkeypox – Background & Basics

- Zoonotic viral infection
- First described in primates in 1958
 - monkeys shipped from Singapore to Denmark
- First human infection in 1970 (D.R.C.)
 - Child < 1 year old without smallpox vaccination
- “Clade 1” Mpx outbreaks throughout west/central Africa 1970-2020
 - Higher case fatality rates (>10%)
- **U.S. outbreak in 2003**: ~70 cases related to imported mammals (mostly rodents)



[https://doi.org/10.1016/S0140-6736\(22\)02075-X](https://doi.org/10.1016/S0140-6736(22)02075-X) https://en.wikipedia.org/wiki/Congo_rope_squirrel
<https://southafrica.co.za/african-ajant-pouched-rat.html>

9

Monkeypox – U.S. Outbreak Epidemiology (as of 12/1/22)

- **Total Cases: 29,607**
- **Total Deaths: 17**

Legend:
 1 to 10
 11 to 50
 51 to 100
 101 to 500
 >500

<https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html> (accessed 12/1/22)

10

Monkeypox – U.S. Outbreak Epidemiology (as of 12/1/22)

- **As of 12/1/22**

<https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html> (accessed 12/1/22)

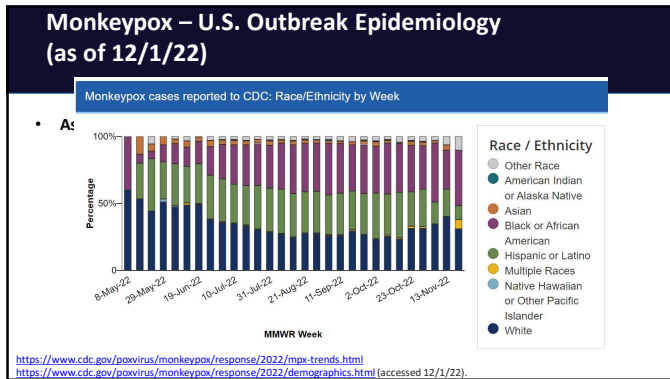
11

Monkeypox – U.S. Outbreak Epidemiology (as of 12/1/22)

Monkeypox cases reported to CDC: Age and Gender

<https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html>
<https://www.cdc.gov/poxvirus/monkeypox/response/2022/demographics.html> (accessed 12/1/22)

12



13

Characteristics of the 2022 Mpox Outbreak: Transmission

- Mostly via close, intimate (usually sexual) contact w/**symptomatic** people
- Majority among men during male-to-male sexual contact
- **Occasional:**
 - Heterosexual
 - To children via close non-sexual skin-to-skin contact w/ caregiver(s)
 - Needlestick
 - Piercing/Tattooing

<https://www.cdc.gov/poxvirus/monkeypox/about/science-behind-transmission.html>

14

Exposure source	Monkeypox virus DNA detected by PCR	Replication-competent virus detected/isolated	Epidemiologically supported source of infection
Skin	Yes	Yes	Yes
Oropharynx and saliva	Yes*	Yes	Yes
Anorectum	Yes	Yes	Yes*
Semen	Yes*	Yes	Insufficient data
Urine/urethra	Yes	Yes	Insufficient data
Conjunctiva or ocular fluid	Yes	Yes	Insufficient data
Blood/plasma/serum	Yes	Insufficient data	Insufficient data
Feces	Yes	Insufficient data	Insufficient data
Vaginal fluid	Insufficient data	Insufficient data	Insufficient data
Breastmilk	Insufficient data	Insufficient data	Insufficient data
Contaminated sharp†	Insufficient data	Insufficient data	Yes

• **XXX**

<https://www.cdc.gov/poxvirus/monkeypox/about/science-behind-transmission.html#table>

15

Characteristics of the 2022 Mpox Outbreak: Symptoms/Clinical Findings

- Rash with anogenital or oropharyngeal/perioral lesions
 - Commonly as first noticeable symptom
- Fevers, chills
- Headache
- Lymphadenopathy

<https://www.cdc.gov/poxvirus/monkeypox/about/science-behind-transmission.html>
<https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html>
<https://www.cdc.gov/poxvirus/monkeypox/response/2022/demographics.html>

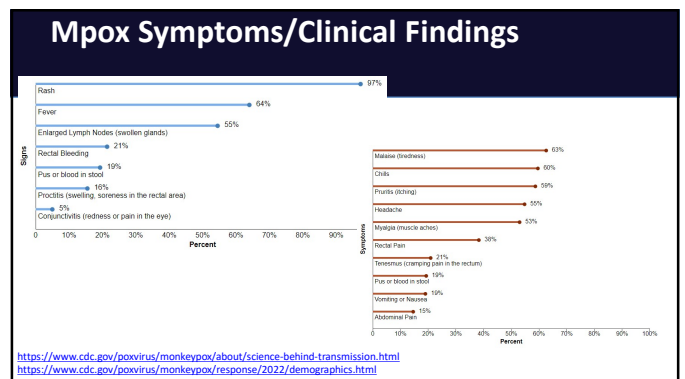
16

Enanthem Through the Scab Stage

Stage	Stage Duration	Characteristics
Enanthem		• Sometimes, lesions first form on the tongue and in the mouth.
Macules	1–2 days	• Macular lesions appear.
Papules	1–2 days	• Lesions typically progress from macular (flat) to papular (raised).
Vesicles	1–2 days	• Lesions then typically become vesicular (raised and filled with clear fluid).
Pustules	5–7 days	• Lesions then typically become pustular (filled with opaque fluid) – sharply raised, usually round, and firm to the touch (deep seated). • Finally, lesions typically develop a depression in the center (umbilication). • The pustules will remain for approximately 5 to 7 days before beginning to crust.
Scabs	7–14 days	• By the end of the second week, pustules have crusted and scabbed over. • Scabs will remain for about a week before beginning to fall off.

<https://www.cdc.gov/poxvirus/monkeypox/about/science-behind-transmission.html>
<https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html>
<https://www.cdc.gov/poxvirus/monkeypox/response/2022/demographics.html>

17



18

Who Should Get Vaccinated

In the current outbreak, you may want to get vaccinated if:

- You might have **already been exposed** to monkeypox if:
 - You have been identified as a close contact of someone with monkeypox.
 - You learn that one of your sex partners in the past 2 weeks has been diagnosed with monkeypox.
 - You are a man who has had sex with other men, or if you are a transgender or nonbinary person, and in the past 2 weeks you have had:
 - Sex with multiple partners or group sex.
 - Sex at a commercial sex venue (like a sex club or bathhouse).
 - Sex at an event, venue, or in an area where monkeypox transmission is occurring.

<https://www.cdc.gov/poxvirus/monkeypox/vaccines/vaccine-basics.html> <https://www.cdc.gov/poxvirus/monkeypox/clinicians/faq.html>

19

Who Should Get Vaccinated

In the current outbreak, you may want to get vaccinated if:

- You **might be exposed** to monkeypox in the future, if:
 - You are a man who has sex with other men, or if you are a transgender or nonbinary person and in the past 6 months have had any of the following:
 - A new diagnosis of one or more sexually transmitted diseases including acute HIV, chancroid, chlamydia, gonorrhea, or syphilis.
 - More than one sex partner.
 - You are a person who in the past 6 months has had any of the following:
 - Sex at a commercial sex venue (like a sex club or bathhouse)
 - Sex at an event, venue, or in an area where monkeypox transmission is occurring.
 - You are a person whose sexual partner identifies with any of the above scenarios.
 - You are a person who anticipates experiencing any of the above scenarios.

<https://www.cdc.gov/poxvirus/monkeypox/vaccines/vaccine-basics.html> <https://www.cdc.gov/poxvirus/monkeypox/clinicians/faq.html>

20

Quick Question!

What is eczema vaccinatum?

- a. A complication of the ACAM2000 vaccination that can occur in patients who have eczema/atopic dermatitis, in which vaccinia virus disseminates to cause an extensive rash and systemic illness.
- b. A complication of the JYNNEOS vaccination that can occur in patients who have eczema/atopic dermatitis, in which vaccinia virus disseminates to cause an extensive rash and systemic illness.
- c. A complication of the ACAM2000 vaccination that can occur in patients who have any chronic skin condition, in which vaccinia virus disseminates to cause an extensive rash and systemic illness.

21

Vaccination Options for Mpox

- **ACAM2000 vaccine:**
 - **FDA Approved** for prevention of smallpox (percutaneous administration)
 - Very limited data on effectiveness for mpox
 - Available for use during mpox outbreak via **Expanded-access IND protocol**
 - Significant/substantial toxicity concerns:
 - Myocarditis, pericarditis
 - Encephalitis, eczema vaccinatum

<https://www.cdc.gov/poxvirus/monkeypox/clinicians/vaccines/vaccine-considerations.html>

22

Vaccination Options for Mpox

- **JYNNEOS vaccine:**
 - **FDA Approved** for prevention of mpox & smallpox in persons >18 y.o
 - EUA issued **8/2022** for:
 - Subcutaneous use in persons <18 y.o.
 - Intradermal use in persons >18 y.o.

<https://www.cdc.gov/poxvirus/monkeypox/clinicians/vaccines/vaccine-considerations.html>

23

JYNNEOS Vaccine for Mpox

- **Standard Regimen:**
 - Subcutaneous (SQ) administration (0.5mL volume)
 - Two-dose series, 28 days apart
- **EUA Regimen:**
 - Intradermal (ID) administration (0.1mL volume)
 - Two-dose series, 28 days apart

<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#resources>
<https://www.sciencedirect.com/science/article/pii/S0264410X15008762?via%3Dihj>

24

Intradermal JYNNEOS Vaccine for Mpx

- Based on Phase II comparative evaluation of in ~500 non-pregnant persons:
 - Strategic National Stockpile context (for smallpox vaccination)
 - ≥ 18 y.o. with no history of smallpox vaccination
- **Local reactogenicity:**
 - **Any:** 100% for ID, ~85% for SQ
 - **Severe (>30mm):** 95% for ID, 58% for SQ
 - Duration >30 days, nodules and/or skin discoloration:
 - **67% for ID, 25% for SQ**

<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#resources>
<https://www.sciencedirect.com/science/article/pii/S0264410X15008762?via%3Dihub>

25

Intradermal JYNNEOS Vaccine for Mpx

- Immunogenicity Response (via 4 assay evaluations):

BN-ELISA
 — Lymphoblast-IRVAMALINE SC
 — Liquid IRVAMALINE SC
 — Liquid IRVAMALINE ID
 — Positive Titration

b Per protocol Non-inferiority Evaluation Liquid-SC vs. Liquid-ID

<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#resources>
<https://www.sciencedirect.com/science/article/pii/S0264410X15008762?via%3Dihub>

26

JYNNEOS Vaccine for Mpx: Intradermal Administration

Video Link ↓

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally

STEP 1

Locate and clean a site for injection in the inner (volar) surface of the forearm.

www.cdc.gov/monkeypox

<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#resources>

27

JYNNEOS Vaccine for Mpx: Intradermal Administration

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally

STEP 2

While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5- to 15-degree angle into the dermis.

www.cdc.gov/monkeypox

<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#resources>

28

JYNNEOS Vaccine for Mpx: Intradermal Administration

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally

STEP 2

While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5- to 15-degree angle into the dermis.

www.cdc.gov/monkeypox

<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#resources>

29

JYNNEOS Vaccine for Mpx: Intradermal Administration

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally

STEP 3

Slowly inject 0.1mL intradermally. This should produce a noticeable pale elevation of the skin (wheal).

www.cdc.gov/monkeypox


<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#resources>

30

JYNNEOS Vaccine for Mpx: Intradermal Administration

MONKEYPOX
How to administer a JYNNEOS vaccine intradermally

STEP 4
Observe patients for 15 minutes after vaccination or 30 minutes if they have a history of anaphylaxis to gentamicin, ciprofloxacin, chicken or egg protein.



www.cdc.gov/monkeypox

<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#resources>

31

JYNNEOS Vaccine for Mpx: Clinical Pearls

- Data supports the 2nd dose can be given up to 35 days after the 1st dose
- Not recommended to restart series if beyond 35 days
- No data on earlier administration (< 28 days after 1st dose)
 - ACIP Best-practices for any vaccination: 4 day "grace period"

<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#resources>
<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4567089/>

32

Another question!

Andi is a person living with HIV infection who also is prone to keloids. This patient wants the JYNNEOS vaccination for mpx. What is the best course of action?

- Administer the vaccine intradermally
- Administer the vaccine subcutaneously
- Recommend using ACAM2000 instead

33

JYNNEOS Vaccine for Mpx: Clinical Pearls

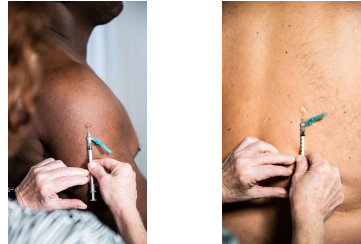
- Persons living with HIV Infection (PLWH):
 - ~40% of 2022 Mpx cases worldwide occurred in PLWH
 - Proven immunogenicity of JYNNEOS (SQ administration) based on prior study
 - Responses to ID and SQ influenza vaccines are similar in PLWH
- People of any age who have a history of developing keloid scars:
 - Administer via **SQ route**

<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#resources>
<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4567089/>

34

JYNNEOS Vaccine for Mpx: Clinical Pearls

- Intradermal administration can occur on inner forearm, upper arm, or upper back (below scapula)
- *IMPORTANT CONSIDERATION FOR REDUCING POTENTIAL STIGMA***

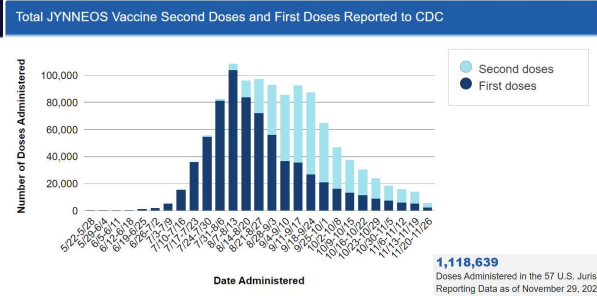


<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#resources>

35

Vaccination Efforts for Mpx in the U.S.

Total JYNNEOS Vaccine Second Doses and First Doses Reported to CDC



1,118,639
Doses Administered in the 57 U.S. Jurisdictions Reporting Data as of November 29, 2022.

https://www.cdc.gov/poxvirus/monkeypox/response/2022/vaccines_data.html (accessed 12/2/22)

36

Estimating the Effectiveness of Vaccination for Mpox

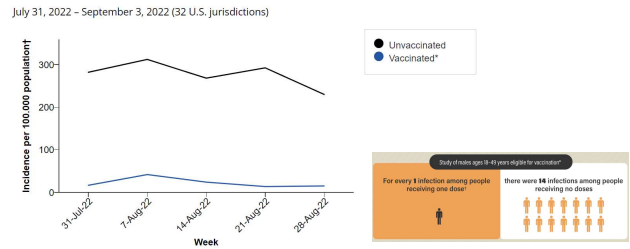
- Current epidemiologic data has **many limitations** due to:
 - Reporting differences amongst states/jurisdictions
 - Imperfect definitions/estimations of population(s) at risk
 - Testing differences amongst population(s) at risk
 - Potential behavioral differences for vaccinated/unvaccinated

<https://www.cdc.gov/poxvirus/monkeypox/cases-data/mpx-vaccine-effectiveness.html>

37

Effectiveness of Vaccination for Mpox

Rates of Monkeypox Cases by 1st Dose Vaccination Status



<https://www.cdc.gov/poxvirus/monkeypox/cases-data/mpx-vaccine-effectiveness.html>
https://www.cdc.gov/mmwr/volumes/71/wr/mm7140a3.htm?_cdd=mm7140a3_w

38

COVID-19 Infection



39

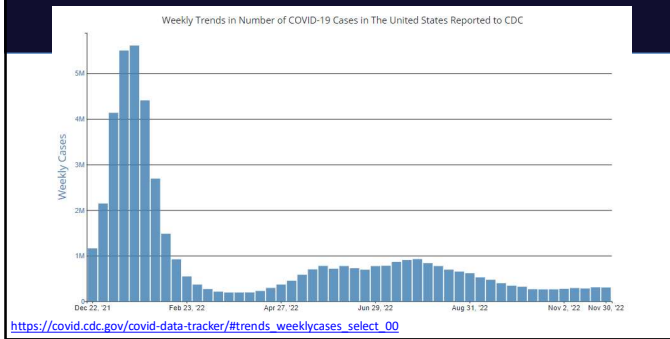
What about COVID?

Good news! News reporters and Internet sites are began announcing in the spring and summer of 2022 that the global pandemic had ended. What do you think of that?

- YAY! Science prevailed and we obliterated that bad boy and sent it away!
- FAKE NEWS. Approximately 2,000 Americans still die each week from COVID.
- CORRECT, but COVID is still a major concern in our socially inclined young adults.

40

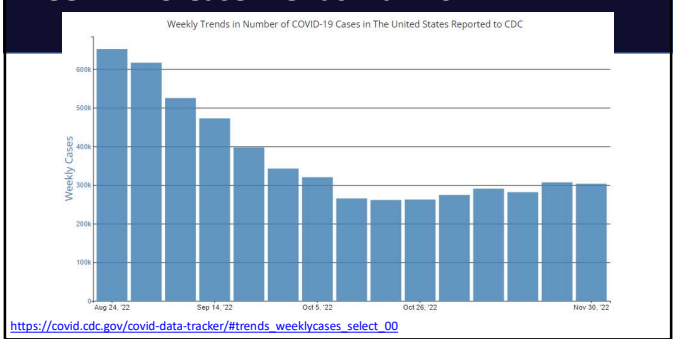
COVID-19 U.S. Case Trends since we last met.....



https://covid.cdc.gov/covid-data-tracker/#trends_weeklycases_select_00

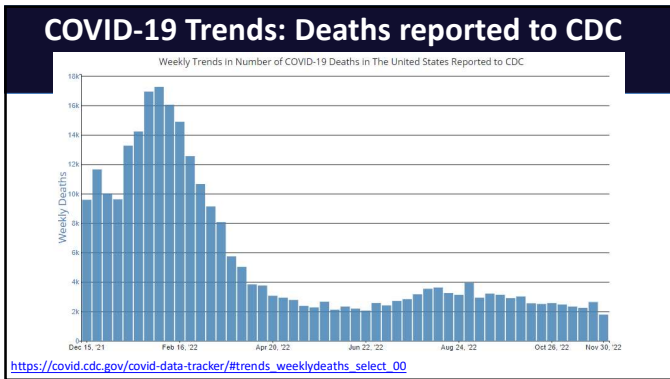
41

COVID-19 Case Trends: Fall 2022

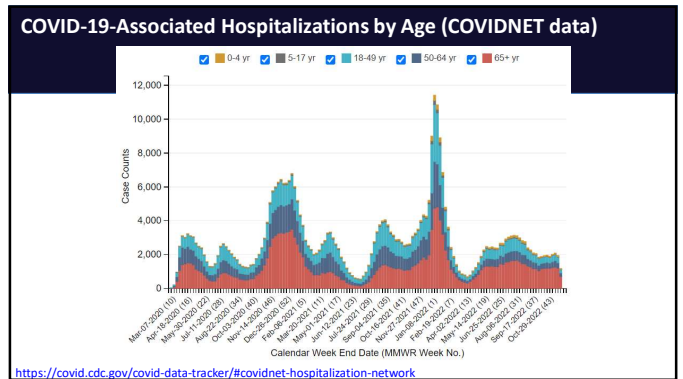


https://covid.cdc.gov/covid-data-tracker/#trends_weeklycases_select_00

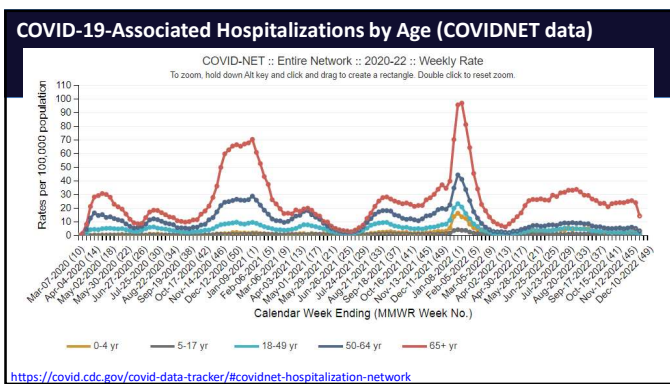
42



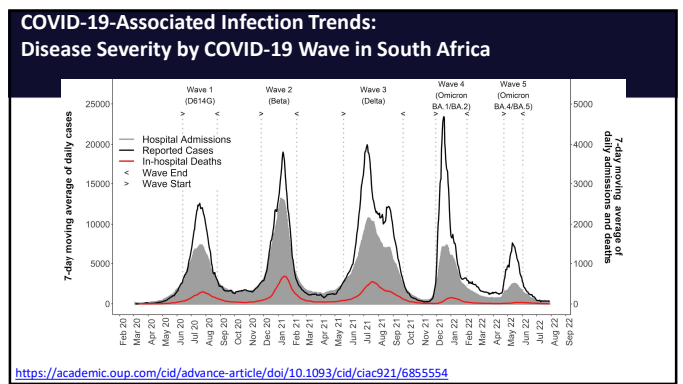
43



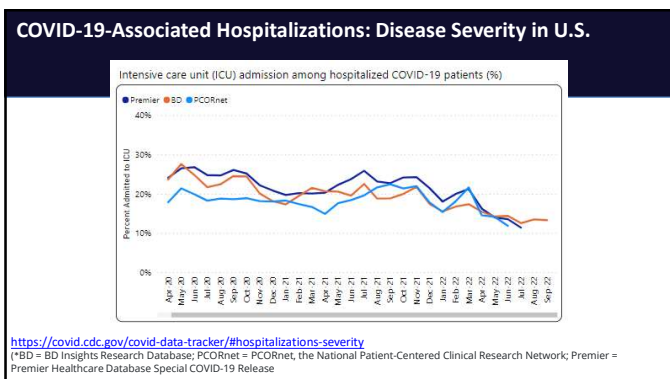
44



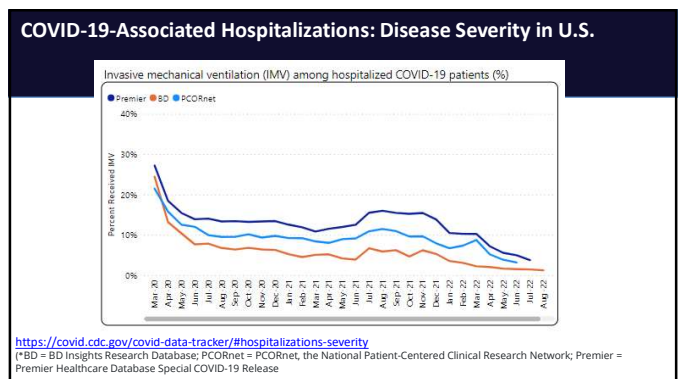
45



46

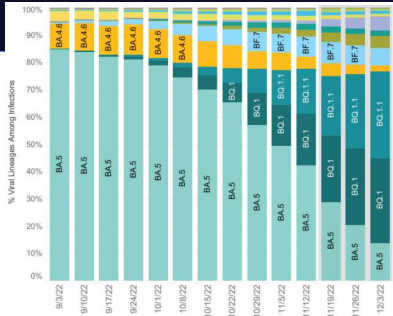


47



48

Recent Trends in COVID-19 Variant Proportions in the U.S.



***Trends in Variant Proportions in CT & New England are similar...

<https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

49

COVID-19 Infection Vaccination Basics

- Vaccination is recommended for all persons aged 6 months and over
- Type(s) of approved vaccines varies based on the age of the person
- mRNA vaccines generally preferred:
 - Limited roles for viral vector ("Janssen") and protein derivative (Novavax) vaccines at this time
 - Myocarditis/pericarditis are rare w/ mRNA vaccines
 - risks are important to consider (esp. males ages 12–39 years)
- Vaccination / booster doses are recommended even in persons with a recent history of COVID-19 infection
 - Usually delay administration by ~2-3 months

50

Quick Question!

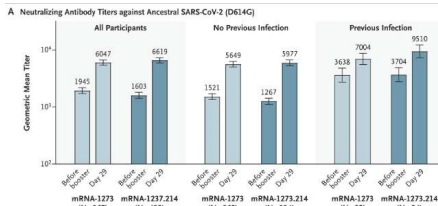
What does the data say about adverse effects associated with the bivalent COVID-19 boosters?

- The most common adverse effects are systemic (fever, chills, fatigue)
- The most common adverse effects are central (headache, mental fogginess)
- The most common adverse effects are local (pain, erythema, swelling)

51

What data are there on Vaccine Effectiveness/Activity against Trending COVID-19 Variants?

- Phase 2/3 comparative study of Moderna mRNA-1273.214 bivalent vaccine
- Antibody Titer Responses:

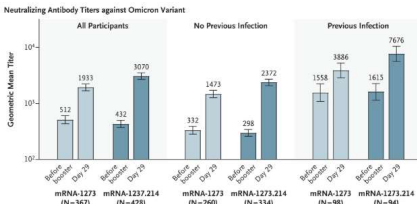


<https://www.nejm.org/doi/full/10.1056/NEJMoa2208343>

52

What data are there on Vaccine Effectiveness/Activity against Trending COVID-19 Variants?

- Phase 2/3 comparative study of Moderna mRNA-1273.214 bivalent vaccine
- Antibody Titer Responses:

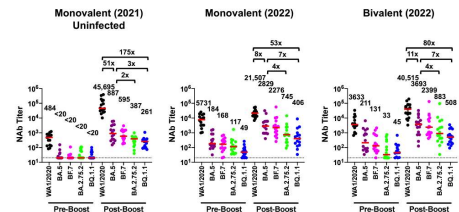


<https://www.nejm.org/doi/full/10.1056/NEJMoa2208343>

53

What data are there on Vaccine Effectiveness/Activity against Trending COVID-19 Variants?

- Recent pre-print on Pfizer mRNA mono-/bivalent vaccine
- Neutralizing antibody titer responses (pseudovirus assay):



<https://www.biorxiv.org/content/10.1101/2022.11.01.514722v1>

54

What data are there on Vaccine Effectiveness/Activity against Trending COVID-19 Variants?

- Recent pre-print on mRNA mono-/bivalent vaccine & booster responses
- Neutralizing antibody titer responses (live virus assay):

<https://www.biorxiv.org/content/10.1101/2022.10.31.514636v1>

55

Data on Safety of Bivalent COVID-19 Boosters

- Phase 2/3 comparative study of Moderna mRNA-1273.214 bivalent vaccine

Local	Event	mRNA-1273	mRNA-1273.214
Local	Any	79.5	79.4
	Pain	75.6	77.3
	Erythema	3.7	6.9
	Swelling	6.6	6.9
	Axillary Swelling or Tenderness	15.4	17.4

<https://www.nejm.org/doi/full/10.1056/NEJMoa2208343>

56

Data on Safety of Bivalent COVID-19 Boosters

- Phase 2/3 comparative study of Moderna mRNA-1273.214 bivalent vaccine

Systemic	Event	mRNA-1273	mRNA-1273.214
Systemic	Any	66.1	73.3
	Fever	3.4	4.4
	Headache	41.1	43.9
	Fatigue	51.4	54.9
	Myalgia	38.6	39.6
	Arthralgia	31.7	31.1
	Nausea or Vomiting	10.0	10.3
	Chills	21.1	23.8

<https://www.nejm.org/doi/full/10.1056/NEJMoa2208343>

57

Summary of Approach to COVID-19 Vaccinations: Fall/Winter 2022-23 – Pfizer/BioNTech vaccine (Comirnaty®)

Ages: 6 months through 4 years (Maroon capped vial and bordered label)	Ages: 5 through 11 years (Orange capped vial and bordered label)	Ages: 12 and older (Gray capped vial and bordered label)
MONOVALENT Primary Series	MONOVALENT Primary Series, BIVALENT Booster Dose	MONOVALENT Primary Series, BIVALENT Booster Dose (Single-dose and Multidose Vials)
Vial cap color: Monovalent Maroon Cap	Monovalent Orange Cap, Bivalent Orange Cap	Monovalent Gray Cap, Bivalent Gray Cap
Ages: 6 months through 4 years	5 through 11 years	12 years and older
Supplied in: MDV: 10 doses per vial, Requires diluent	MDV: 10 doses per vial, Requires diluent	MDV: 10 doses per vial, Requires diluent; MDV: 6 doses per vial, No diluent; MDV: 6 doses per vial, SDV: 1 dose, No diluent

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>

58

Summary of Approach to COVID-19 Vaccinations: Fall/Winter 2022-23 – Pfizer/BioNTech vaccine (Comirnaty®)

For Most Persons

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>

59

Summary of Approach to COVID-19 Vaccinations: Fall/Winter 2022-23 – Pfizer/BioNTech vaccine (Comirnaty®)

For Moderately or Severely Immunocompromised Persons

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>

60

Summary of Approach to COVID-19 Vaccinations: Fall/Winter 2022-23 – Moderna vaccine (Spikevax®)

<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/administration.html>

61

Summary of Approach to COVID-19 Vaccinations: Fall/Winter 2022-23 – Moderna vaccine (Spikevax®)

For Moderately or Severely Immunocompromised Persons

<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/administration.html>

62

Summary of Approach to COVID-19 Vaccinations: Fall/Winter 2022-23 – Novavax vaccine

- U.S. EUAs issued:
 - July, August (use for primary series in 12+ y.o.)
 - October (booster after a mRNA primary series in >18 y.o. for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate and in individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine)
- Protein subunit vaccine
- Adjuvant: *Quillaja saponaria* Molina extract
- Other ingredients:
 - Lipids (cholesterol, phosphatidylcholine)
 - Salts, sugars, acids (polysorbate-80, sodium/potassium chlorides & phosphates)

<https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/administration.html>
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/overview-COVID-19-vaccines.html#protein-subunit>

63

Summary of Approach to COVID-19 Vaccinations: Fall/Winter 2022-23 – Novavax vaccine

- Storage: refrigerate between 2° to 8°C (36° to 46°F)
- 10-dose vial, but must **discard remaining contents 6h after 1st puncture**
- Warnings/Precautions:
 - Myocarditis/pericarditis has occurred after administration
- Solicited adverse effects:
 - injection site pain/tenderness (82.2%), fatigue/malaise (62.0%), muscle pain (54.1%), headache (52.9%), joint pain (25.4%), nausea/vomiting (15.6%), injection site redness (7.0%), injection site swelling (6.3%), and fever (6.0%)

<https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/administration.html>
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/overview-COVID-19-vaccines.html#protein-subunit>

64

Summary of Approach to COVID-19 Vaccinations: Fall/Winter 2022-23 – Novavax vaccine

Type	Recipient Age	Product ^a	For Most People		Those Who ARE Moderately or Severely Immunocompromised	
			Doses	Interval Between Doses ^b	Doses	Interval Between Doses
Protein subunit vaccine	12 years and older	MONOVALENT Novavax <small>mRNA (Moderna, Pfizer-BioNTech) should be used for the booster dose.</small>	Primary series: Monovalent			
			Dose 1 to 2	At least 3-8 weeks ^c	Dose 1 to 2	At least 3 weeks
			Booster dose: Bivalent			
			Dose 2 to 3	At least 8 weeks (2 months)	Dose 2 to 3	At least 8 weeks (2 months)
Protein subunit vaccine	18 years and older	MONOVALENT Novavax <small>Moderna or Pfizer-BioNTech bivalent COVID-19 vaccine should be used for the booster dose.</small>	Primary series: Monovalent			
			Dose 1 to 2	At least 3-8 weeks ^c	Dose 1 to 2	At least 3 weeks
			Booster dose ^b : Bivalent			
			Dose 2 to 3	At least 8 weeks (2 months)	Dose 2 to 3	At least 8 weeks (2 months)

<https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/administration.html>
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/overview-COVID-19-vaccines.html#protein-subunit>

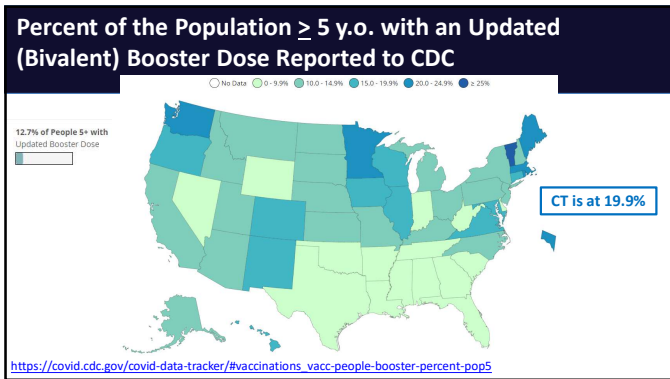
65

Last question!

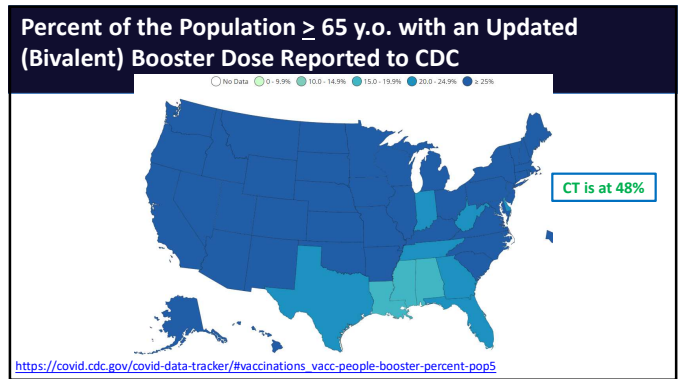
Based on current vaccination statistics about populations that have the poorest booster coverage for COVID-19, which of the following population should pharmacists be encouraging to GET VACCINATED!?!?

- Children age 5 or younger in the Great Lakes regions
- People older than 65 in the Pacific northwest
- Everybody everywhere

66



67



68

Thank you!!!

- Questions?

SESSION CODE

69