Immunization: It is now time to make it unclear - Reconciling differences between Public Health recommendations and FDA Product Labeling for Vaccines

(Potayto, Potahto? Tomayto, Tomahto?)

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Disclosures

- Dr. Aeschlimann has the following relevant financial relationship to disclose:
  - **Consultant** – F2G, Inc. (Olorofim; an investigational antifungal agent)
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  - Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings

2

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Learning Objectives

- At the conclusion of this CPE activity, participants should be able to:

  1) Compare and contrast the roles & activities of the Center for Biologics Evaluations and Research (CBER), US Food & Drug Administration (FDA), Centers for Disease Control & Prevention (CDC), and the Advisory Committee on Immunization Practices (ACIP) during the development and clinical use of vaccines in the United States.

  2) Describe one specific example where the routine clinical use of a vaccine may differ from FDA-approved product prescribing information due to the following: (a) costs, (b) disease epidemiology, (c) public acceptance, (d) vaccine supplies.

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Pre-Test Time!

- The COVID-19 pandemic and the recent rise of "antivax" cranks, charlatans, and grifters on various social media platforms has increased the public's attention to / scrutiny of government-associated entities involved in vaccine development and use…

- For vaccines, which **ONE** of the following is **NOT** a defined role/responsibility o the Food & Drug Administration (FDA)?

  a) Verifying appropriate vaccine manufacturing processes
  b) Approving advertising for vaccine products
  c) Managing the Vaccine Adverse Event Reporting System (VAERS)
  d) Determining the strategy for public use of vaccines in the U.S.

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Vaccine development, licensing, approval, and use in the United States

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Key Agencies / Organizations for Vaccines

- US Food & Drug Administration (FDA)
- Center for Biologics Evaluations and Research (CBER)
- Vaccines and Related Biological Products Advisory Committee (VRBPAC)
- Centers for Disease Control and Prevention (CDC)
- Advisory Committee on Immunization Practices (ACIP)

https://doi.org/10.1542%2Fpeds.2018-0780

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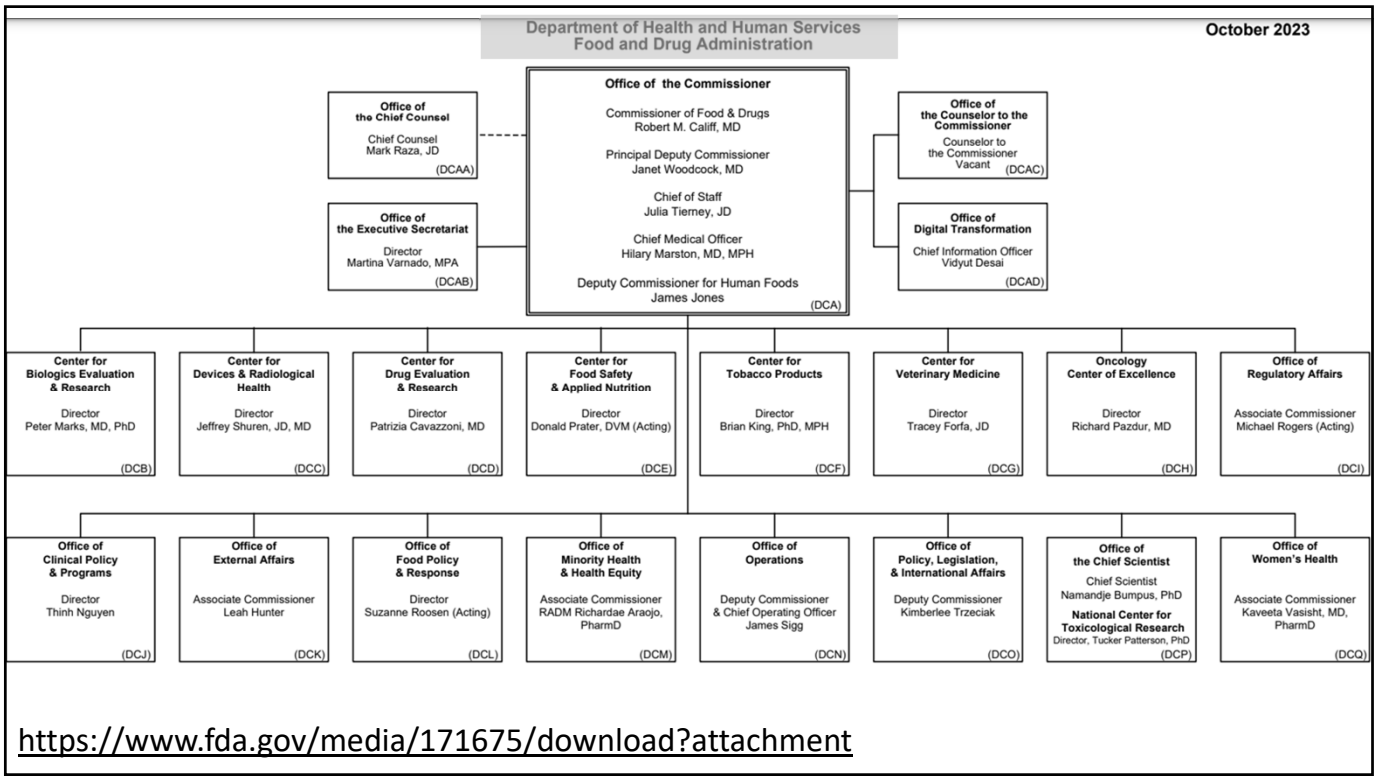

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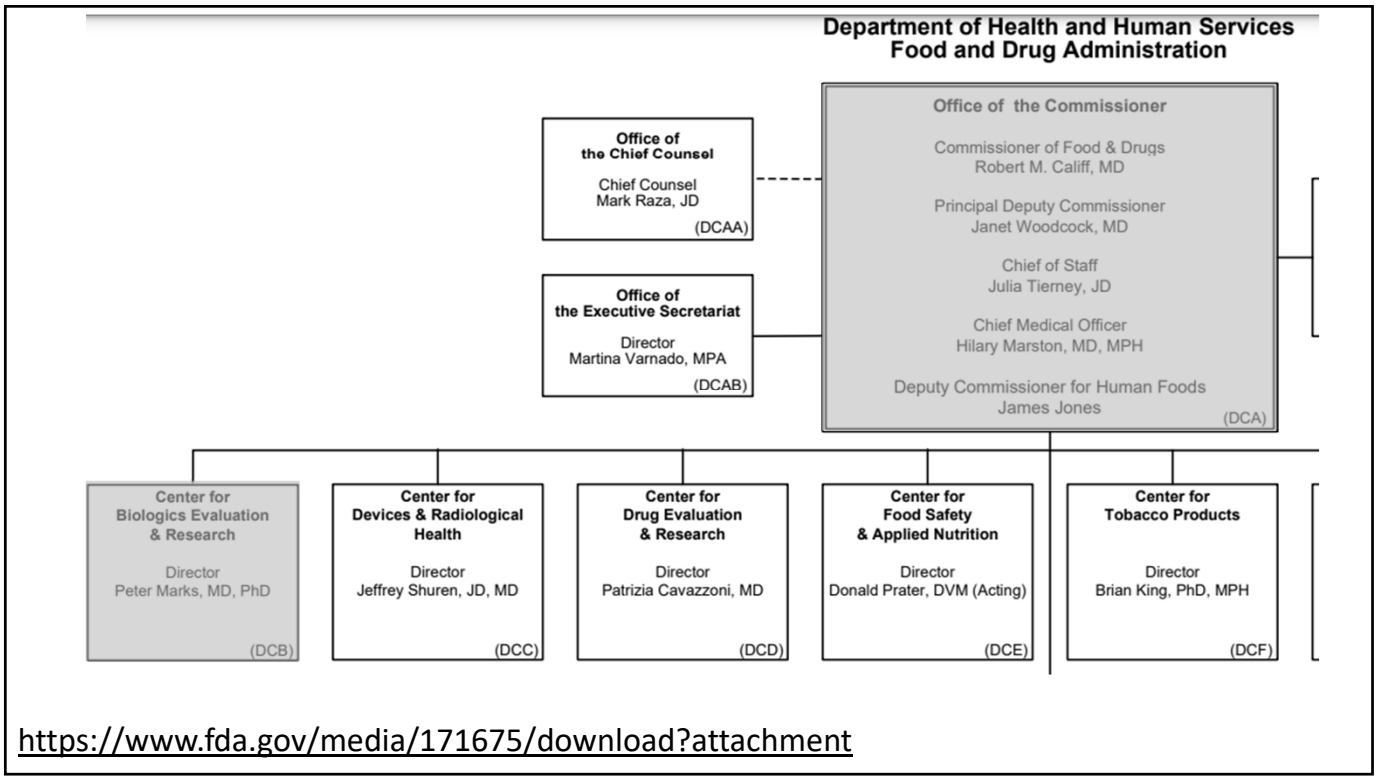

https://www.fda.gov/media/171675/download?attachment

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Roles & Responsibilities of the CBER

- Regulatory oversight of biological products development & licensing
  - Public Health Service Act and the Federal Food, Drug and Cosmetic Act

Mission

The mission of the Center for Biologics Evaluation and Research (CBER) is to ensure the safety, purity, potency, and effectiveness of biological products including vaccines, allergenics, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury. Through our mission, we also seek to protect the public against the threats of emerging infectious diseases and bioterrorism.

https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber

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Vaccines and Related Biological Products Advisory Committee (VRBPAC)

- 15-member Federal advisory committee

The Committee shall consist of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of immunology, molecular biology, rDNA, virology; bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry.

https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber

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Vaccines and Related Biological Products Advisory Committee (VRBPAC)

- 15-member Federal advisory committee

What is an advisory committee?

Advisory committees provide independent expert advice to the FDA on broad scientific topics or on certain products to help the agency make sound decisions based on the available science. Advisory committees make non-binding recommendations to the FDA, which generally follows the recommendations but is not legally bound to do so. Please see, "Advisory Committees Give FDA Critical Advice and the Public a Voice," for more information.

https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber

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FDA/CBER Vaccine Licensing Requirements

- Demonstration of Safety (Risks) & Benefits:
  - What population(s) will be receiving the vaccine?
  - What are the characteristics of the disease(s) the vaccine targets?
    - Infectivity
    - Public health effects
    - Individual morbidity/mortality

https://doi.org/10.1542%2Fpeds.2018-0780
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.126
https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee

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FDA/CBER Vaccine Licensing Requirements

- Vaccine Effectiveness:
  - "Adequate and well-controlled" Randomized controlled trials (RCTs)
    - Endpoints: It depends…
      - Prevention of transmission, reduction of disease severity
  - Immunologic Response [with established correlation to clinical outcomes]
    - Influenza, COVID-19

https://doi.org/10.1542%2Fpeds.2018-0780
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.126
https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee

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FDA-Required Vaccine Prescribing Information ("Product Insert")

- **LOTS** of important information!!!
  - Indications & Usage, Dosage & Administration
  - Contraindications, Warnings, Precautions, Adverse Effects, Interactions
  - Special populations
  - Clinical trial data summaries
  - Storage, handling, preparation
  - Patient counseling information

https://doi.org/10.1542%2Fpeds.2018-0780
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.126

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FDA-Required Vaccine Prescribing Information ("Product Insert")

- What **DOESN'T** get included in the Product Insert???
  - Advice for use in many important detailed population subgroups:
    - Age ranges (≥60y vs. 60-69y/70-79y/80+ y)
    - Chronic illnesses
    - Immunocompromised status
  - Considerations for use in:
    - Outbreak/pandemic situations
    - Other timely public health scenarios
    - Vaccine product shortage situations

https://doi.org/10.1542%2Fpeds.2018-0780
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.126

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Who "weighs in" and provides guidance on these "practical use" items related to vaccines?

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Next Step: Enter the CDC & ACIP…

- **ACIP**: Federal Advisory Committee to the CDC
  - 15 voting-member experts, ~30 non-voting representatives
    - "*…people who are directly employed or have an immediate family member directly employed by a vaccine manufacturer, hold a patent on a vaccine or related product, or serve on a Board of Directors of a vaccine manufacturer are excluded from ACIP membership*."

https://www.cdc.gov/vaccines/acip/committee/role-vaccine-recommendations.html

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Next Step: Enter the CDC & ACIP…

- **ACIP**:
  - Regularly-scheduled meetings (≥3/year) for vaccine recommendations
  - Work groups:
    - New scientific data on FDA-approved vaccines
    - Pre-FDA approval analyses of scientific data for new vaccines

https://www.cdc.gov/vaccines/acip/committee/role-vaccine-recommendations.html

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Next Step: Enter the CDC & ACIP…

- ACIP: Federal Advisory Committee to the CDC
  - "*…ACIP shall provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States*."
  - *"For each vaccine, the Committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended."*
  - *"…provides recommendations on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events."*
  - *"…may provide recommendations that address […] special situations or populations that may warrant modification of the routine recommendations."*

https://www.cdc.gov/vaccines/acip/committee/charter.html

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Next Step: Enter the CDC & ACIP…

- General Process for Vaccine Recommendations:

ACIP recommendations presented to CDC director
↓
CDC Director Approval of Recs
↓
Recs published in CDC's Morbidity and Mortality Weekly Report (MMWR)
↓
Represent the "official" CDC recommendations for immunizations in the United States

https://www.cdc.gov/vaccines/acip/committee/role-vaccine-recommendations.html

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Knowledge Check!

- Which of the following items would you expect to **always/very-commonly** see in the **FDA-Approved product labeling** for a vaccine product?

  a) Instructions for preparation of the product for administration
  b) Comparative effectiveness data for people taking chronic steroid therapy
  c) Recommendations for use of lower doses in case of product shortages
  d) Data on serum antibody titers following receipt of the approved vaccine

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Examples of ACIP / CDC Modifications & Improvements of Vaccine Use…

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ACIP Guidance on Additional Hepatitis B Vaccine doses in High-Risk Health-Care Personnel

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ACIP Guidance on Additional HBV Vaccine doses in High-Risk Health-Care Personnel

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use HEPLISAV-B® safely and effectively. See full prescribing information for HEPLISAV-B.

HEPLISAV-B [Hepatitis B Vaccine (Recombinant), Adjuvanted] Solution for Intramuscular Injection
Initial US Approval: 2017

FULL PRESCRIBING INFORMATION

1 **INDICATIONS AND USAGE**
HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus. HEPLISAV-B is approved for use in adults 18 years of age and older.

2 **DOSAGE AND ADMINISTRATION**
For intramuscular administration.

2.1 **Dose and Regimen**
Administer two doses (0.5 mL each) of HEPLISAV-B one month apart.

https://www.cdc.gov/mmwr/pdf/rr/rr6007.pdf
https://www.fda.gov/media/108745/download

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ACIP Guidance on Additional HBV Vaccine doses in Health-Care Personnel

Immunization of Health-Care Personnel

Recommendations of the Advisory Committee on Immunization Practices (ACIP)

https://www.cdc.gov/mmwr/pdf/rr/rr6007.pdf

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ACIP Guidance on Additional HBV Vaccine doses in Health-Care Personnel

- Vaccine response in healthy adults ≤ 40 y.o.:
  - 30%–55% after 1st dose, 75% after 2nd dose, >90% after 3rd dose
- Post-vaccination serologic testing should be performed for all HCP at high risk for occupational percutaneous or mucosal exposure to blood or body fluids.
- Serologic response testing at 1-2 months:
  - **HCPs with low anti-HBs concentrations (< 10 mIU/mL) should be revaccinated (a 2nd 3-dose series [or 2-dose series])**
  - Re-test & evaluate response after 2nd series complete

https://www.cdc.gov/mmwr/pdf/rr/rr6007.pdf

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ACIP Guidance on 3rd dose of Mumps Virus-Containing Vaccine during outbreaks

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ACIP Guidance on 3rd dose of Mumps Virus-Containing Vaccine during outbreaks

- Current recommended standard: 2-dose MMR or MMRV vaccination schedule

ProQuad®
Measles, Mumps, Rubella and Varicella Virus Vaccine Live
Suspension for intramuscular or subcutaneous injection
Initial U.S. Approval: 2005

1 INDICATIONS AND USAGE

ProQuad is a vaccine indicated for active immunization for the prevention of measles, mumps, rubella, and varicella in children 12 months through 12 years of age.

2 DOSAGE AND ADMINISTRATION

INTRAMUSCULAR OR SUBCUTANEOUS ADMINISTRATION ONLY

2.1 Dose and Schedule

A single dose of ProQuad is approximately 0.5-mL.

The first dose is administered at 12 to 15 months of age but may be given anytime through 12 years of age.

The second dose is administered at 4 to 6 years of age.

At least 1 month should elapse between a dose of a measles-containing vaccine and a dose of ProQuad. At least 3 months should elapse between a dose of varicella-containing vaccine and ProQuad.

https://www.fda.gov/media/147562/download
https://www.cdc.gov/mumps/outbreaks.html

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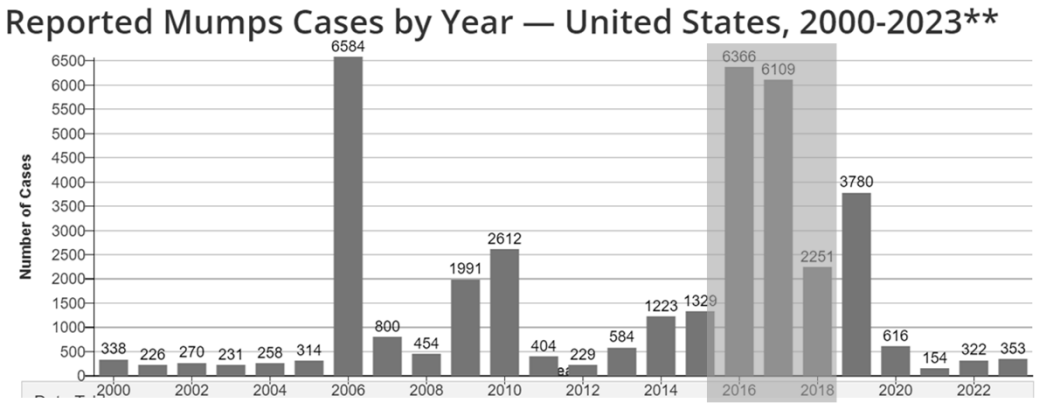
ACIP Guidance on 3rd dose of Mumps Virus-Containing Vaccine during an outbreak

- Since ~2005, occasional outbreaks have occurred in Universities and other close-knit communities



http://dx.doi.org/10.15585/mmwr.mm6701a7
https://www.cdc.gov/mumps/outbreaks.html

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ACIP Guidance on 3rd dose of Mumps Virus-Containing Vaccine during an outbreak

- 2017: ACIP Mumps Work Group:
  - Reviewed available scientific data
  - Developed recommendations for 3rd dose "…*among persons who are at increased risk for acquiring mumps because of an outbreak*."
    - Some evidence for significantly lower mumps attack rates in persons who received a 3rd dose in prior outbreaks…
    - Mumps-specific antibody titers significantly increased within 1 month of 3rd dose
    - No serious adverse events, high safety of product
    - CDC-conducted surveys of stakeholders for values, acceptability, implementation considerations:
      - Survey response rates from students/parents were "very low" (<0.5%) !!!

http://dx.doi.org/10.15585/mmwr.mm6701a7
https://www.cdc.gov/mumps/outbreaks.html

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ACIP Guidance on 3rd dose of Mumps Virus-Containing Vaccine during an outbreak

Recommendation

Persons previously vaccinated with 2 doses of a mumps virus–containing vaccine who are identified by public health authorities as being part of a group or population at increased risk for acquiring mumps because of an outbreak should receive a third dose of a mumps virus–containing vaccine to improve protection against mumps disease and related complications.

http://dx.doi.org/10.15585/mmwr.mm6701a7
https://www.cdc.gov/mumps/outbreaks.html

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ACIP-FDA-NIH-etc Guidance for vaccination during mPox outbreak of 2022 (with limited vaccine supplies)

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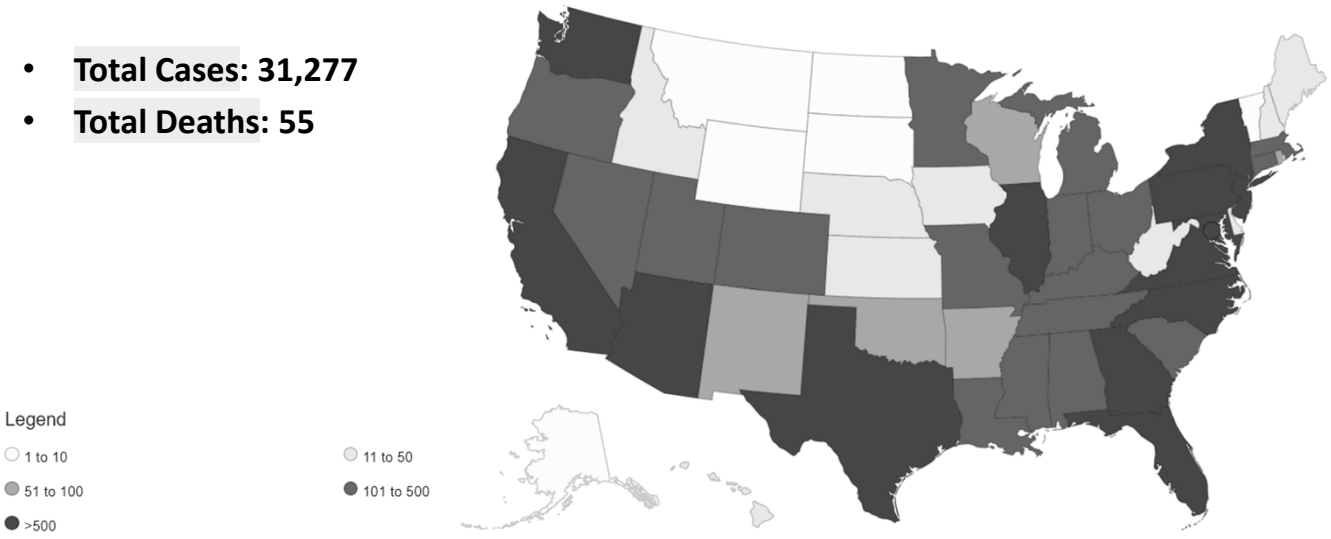
Monkeypox – U.S. Outbreak Epidemiology

- **Total Cases: 31,277**
- **Total Deaths: 55**



https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html (accessed 12/1/23).

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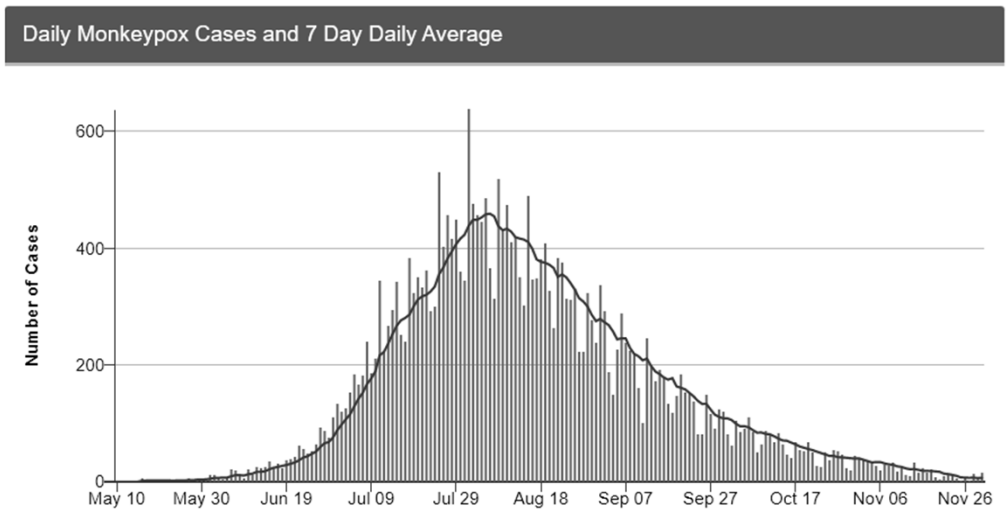
Monkeypox – 2022 U.S. Outbreak Epidemiology



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

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Vaccination Options for Mpox

- **JYNNEOS vaccine:**

1 INDICATIONS AND USAGE

JYNNEOS is a vaccine indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.

2 DOSAGE AND ADMINISTRATION

For subcutaneous injection only.

2.1 Dose and Schedule

Administer two doses (0.5 mL each) of JYNNEOS 4 weeks apart.

  - ACIP/CDC/other Federal agencies: **6/28/2022** national mpox vaccine strategy
    - JYNNEOS vaccine for high-risk individuals
  - EUA issued **8/9/2022** by the FDA 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

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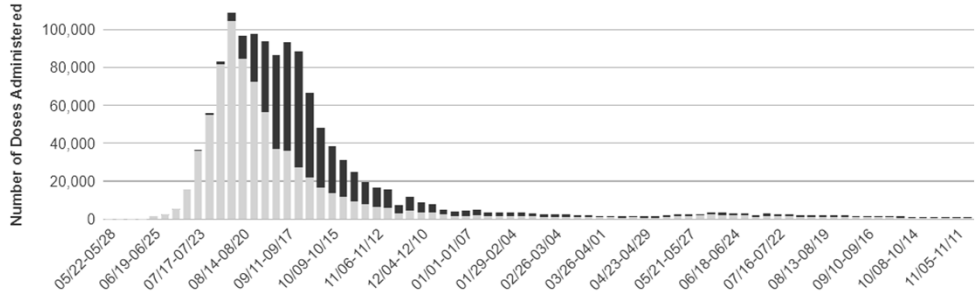
JYNNEOS Vaccine Dosage Administrations in the U.S.

Total Vaccine Doses Administered

1,280,114

Doses Administered in the 57 U.S. Jurisdictions Reporting Data as of November 28 2023 .

Total JYNNEOS Vaccine Second Doses and First Doses Reported to CDC



https://www.cdc.gov/poxvirus/mpox/response/2022/vaccines_data.html

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Knowledge Check!

- Which of the following statements is **FALSE** regarding **ACIP recommendations** for **HBV vaccines, Mumps vaccine** products, and/or **mPox** vaccines?

  a) The JYNNEOS® vaccine was recommended by the CDC for intradermal administration to persons at high risk of mpox in June 2022
  b) HCPs with low anti-HBs concentrations following a standard 2- or 3-dose HBV vaccine series should be given one additional "booster" dose
  c) A "booster" dose of Mumps-containing vaccine products should be given to all students before they head to college

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ACIP Guidance for "Shared Clinical Decision-making" [SCDM] for Vaccines

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ACIP "Shared Clinical Decision-making" Recommendations

- *"…shared clinical decision-making vaccinations are not recommended for everyone in a particular age group or everyone in an identifiable risk group…[they] are **individually based** and **informed by a decision process between the health care provider and the patient or parent/guardian**."*

https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

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ACIP SCDM Recommendations

- All other ACIP vaccination recs: **DEFAULT = VACCINATE**

- SCDM: Consider to vaccinate/not vaccinate based on:
  - best available evidence of who may benefit
  - individual's characteristics, values, and preferences
  - health care provider's clinical discretion
  - characteristics of the vaccine(s) being considered

https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

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ACIP SCDM Recommendations

Who is considered a health care provider with regard to shared clinical decision-making recommendations?

In this context, CDC defines a health care provider as anyone who provides or administers vaccines: primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists.

Which patients should providers discuss shared clinical decision-making recommendations with?

It's up to the provider. Some health care providers may choose to discuss immunizations recommended for shared clinical decision-making with all or most of their patients who could receive it, while some providers may be more selective when discussing these immunizations with their patients. Health care providers should also be receptive to patient-initiated conversations about these immunizations.

https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

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Current Vaccines / Clinical Situations with ACIP SCDM Recommendations

- Respiratory syncytial virus (RSV) vaccination for adults aged 60 years and older
- Meningococcal B (MenB) vaccination for adolescents and young adults aged 16–23 years
- Hepatitis B (HepB) vaccination for adults aged 60 years and older with diabetes mellitus
- Human papillomavirus (HPV) vaccination for adults aged 27–45 years
- Pneumococcal conjugate vaccination (PCV20) for adults aged 65 years and older who have completed the recommended vaccine series with both PCV13 (at any age) and PPSV23 (which was administered at age ≥65 years)

https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

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ACIP SCDM Recommendations: HPV Example

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use GARDASIL 9 safely and effectively. See full prescribing information for GARDASIL 9.

GARDASIL®9
(Human Papillomavirus 9-valent Vaccine, Recombinant)
Suspension for intramuscular injection
Initial U.S. Approval: 2014

https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html
https://www.fda.gov/media/90064/download

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1 INDICATIONS AND USAGE

1.1 Girls and Women

GARDASIL®9 is a vaccine indicated in girls and women 9 through 45 years of age for the prevention of the following diseases:

- Cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers caused by Human Papillomavirus (HPV) types 16, 18, 31, 33, 45, 52, and 58
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11

And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:

- Cervical intraepithelial neoplasia (CIN) grade 2/3 and cervical adenocarcinoma *in situ* (AIS)
- Cervical intraepithelial neoplasia (CIN) grade 1
- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3
- Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3

1.2 Boys and Men

GARDASIL 9 is indicated in boys and men 9 through 45 years of age for the prevention of the following diseases:

- Anal, oropharyngeal and other head and neck cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11

And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:

- Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3

The oropharyngeal and head and neck cancer indication is approved under accelerated approval based on effectiveness in preventing HPV-related anogenital disease *[see Clinical Studies (14.5)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

https://www.cdc.g
https://www.fda.g

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ACIP SCDM Recommendations: HPV Example

- **June 2019:**
  - shared clinical decision-making for HPV vaccination of adults aged 27–45 years

Shared Clinical Decision-Making

HPV Vaccination for Adults Aged 27-45 Years

Vaccine	19-26 years	27-49 years	50-64 years	≥65 years
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		

https://www.cdc.gov/vaccines/hcp/admin/downloads/isd-job-aid-scdm-hpv-shared-clinical-decision-making-hpv.pdf

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ACIP SCDM Recommendations: HPV Example

HPV vaccination does not need to be discussed with most adults in this age group.
If you do decide to discuss HPV vaccination with an adult patient:

Remember:

- Most HPV infections clear on their own within a year or two, but persistent infections can lead to development of precancers or cancers, usually after several decades.
- HPV vaccination is not routinely recommended for adults 27-45 years of age.
- HPV vaccine effectiveness is highest in people who have never had sex.
- HPV vaccination prevents new HPV infection, it does not treat existing HPV infection or disease.
- Most adults who have had sex have been exposed to HPV before.
- HPV vaccine effectiveness might be low among people with more risk factors for HPV, such as having had sex with more than one person or having certain immunocompromising conditions.

https://www.cdc.gov/vaccines/hcp/admin/downloads/isd-job-aid-scdm-hpv-shared-clinical-decision-making-hpv.pdf

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ACIP SCDM Recommendations: HPV Example

Consider:

- At any age, having a new sex partner is a risk factor for getting a new HPV infection. However, this is only one possible consideration for SCDM.
- Adults with more HPV risk factors (for example, multiple previous sex partners or certain immunocompromising conditions) might have been infected with HPV in the past, so might have a lower chance of getting a new HPV infection in the future.
- Adults with fewer HPV risk factors (for example, few or no previous sex partners) might not have been infected with HPV in the past, so might have a higher chance of getting a new HPV infection from a new sex partner in the future.

If you vaccinate:

- If you and your previously unvaccinated adult patient decide to initiate HPV vaccination, offer a 3-dose series of HPV vaccine at 0, 2, and 6 months.
- If your patient is pregnant, delay HPV vaccination until after pregnancy.
- HPV vaccination is safe, unless a patient had a severe allergic reaction after a previous dose or to a vaccine component.

https://www.cdc.gov/vaccines/hcp/admin/downloads/isd-job-aid-scdm-hpv-shared-clinical-decision-making-hpv.pdf

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ACIP SCDM Recommendations: RSV Example

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ABRYSVO safely and effectively. See full prescribing information for ABRYSVO.

ABRYSVO™ (Respiratory Syncytial Virus Vaccine) solution for intramuscular injection
Initial U.S. Approval: 2023

1 INDICATIONS AND USAGE

1.1 Immunization of Pregnant Individuals

ABRYSVO is a vaccine indicated for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.

1.2 Immunization of Individuals 60 Years of Age and Older

ABRYSVO is a vaccine indicated for active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

https://www.fda.gov/media/168889/download?attachment
https://www.cdc.gov/vaccines/vpd/rsv/hcp/older-adults.html

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ACIP SCDM Recommendations: RSV Example

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use AREXVY safely and effectively. See full prescribing information for AREXVY.

AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted) suspension for intramuscular injection

Initial U.S. Approval: 2023

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AREXVY is indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in individuals 60 years of age and older.

https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Arexvy/pdf/AREXVY.PDF
https://www.cdc.gov/vaccines/vpd/rsv/hcp/older-adults.html

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ACIP SCDM Recommendations: RSV Example

Vaccine	19-26 years	27-49 years	50-64 years	≥65 years
Respiratory Syncytial Virus (RSV)	Seasonal administration during pregnancy. (See notes)			≥60 years

- **Decision to vaccinate may be informed by:**
  - The patient's health status
  - Their risk of severe RSV disease
  - The health care provider's clinical judgment
  - The patient's preferences
  - The safety profile of the RSV vaccine products

https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

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ACIP SCDM Recommendations: RSV Example

Shared Clinical Decision-Making (SCDM)

RSV Vaccination for Adults 60 Years and Older

- Respiratory syncytial virus (RSV) is a cause of severe respiratory illness across the lifespan. Each year in the United States, RSV leads to approximately 60,000-160,000 hospitalizations and 6,000-10,000 deaths among adults 65 years and older.
- Adults 60 years of age and older now have the option to receive one dose of RSV vaccine based on a SCDM process between a patient and their health care provider.
- Consider multiple factors when discussing RSV vaccination with your patients. SCDM recommendations are optional and are informed by whether the patient has any risk factors for severe RSV disease; a patient's risk of exposure to RSV; a patient's preferences for RSV vaccination; and the clinical discretion of the health care provider.

https://www.cdc.gov/vaccines/vpd/rsv/downloads/provider-job-aid-for-older-adults-508.pdf

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ACIP SCDM Recommendations: RSV Example

Underlying medical conditions associated with increased risk for severe RSV disease include:


Chronic lung disease (e.g., COPD and asthma)


Chronic kidney disease


Moderate or severe immunocompromise


Chronic cardiovascular disease (e.g., CHF and CAD)


Chronic liver disease


Chronic hematologic disorders


Chronic or progressive neurologic or neuromuscular conditions


Diabetes Mellitus


Any underlying *condition* that a provider determines might increase the risk of severe RSV disease

https://www.cdc.gov/vaccines/vpd/rsv/downloads/provider-job-aid-for-older-adults-508.pdf

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ACIP SCDM Recommendations: RSV Example

Other factors associated with **increased** risk for severe RSV disease include:

Frailty or advanced age, as determined by the healthcare provider

Residence in a nursing home or other long-term care facility

Any underlying *factor* a provider determines might increase the risk of severe RSV disease

Other points to **consider**:

- Serious neurologic conditions, including Guillain-Barré syndrome (GBS), have been reported after RSV vaccination in clinical trials. However, it is unclear whether the vaccine caused these events.
- Persons with history of severe allergic reaction (e.g., anaphylaxis) to any component of RSV vaccine should not receive the vaccine.

https://www.cdc.gov/vaccines/vpd/rsv/downloads/provider-job-aid-for-older-adults-508.pdf

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Let's "SCDM" some example patient cases together…

- The following people come into your pharmacy and inquire about getting the new "*RSV vaccine that they saw advertised on TV the other night during an episode of Jeopardy*…"
- What are some SCDM thoughts / opinions / questions / advice you have for:

1. A 70-year-old female (she/her) in very good health (other than osteopenia) who volunteers once a week at a local nursing home
2. A 61 year old male (he/him) with extreme obesity, COPD, diabetes, hypertension, hyperlipidemia, and atrial fibrillation
3. A 50-year female (she/her) who has had a kidney transplant and who is on two potent immunosuppressive medications

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ACIP SCDM Recommendations: Show me the Money???

Under the Affordable Care Act and its implementing regulations, ACIP recommendations that have been adopted by CDC "with respect to the individual involved" and are "listed on the Immunization Schedules of the Centers for Disease Control and Prevention" generally are required to be covered by group health plans and health insurance issuers offering group or individual health insurance coverage without imposing any cost-sharing requirements (such as a copayment, coinsurance, or deductible).[1] This coverage requirement includes shared clinical decision-making recommendations when they have been adopted by CDC and are listed on the immunization schedules.

https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

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Conclusions & Final Thoughts…

- The FDA & CDC (and associated agencies/committees) play complementary roles in vaccine approval and optimal use in the United States
- The use of many vaccines can be complex!
  - FDA – provides foundational guidance
  - CDC/ACIP – provides timely granular/nuanced advice
- If you can't find info for your specific patient in the product insert, chances are the CDC/ACIP can help!

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Thank you!!!

- Questions?

SESSION CODE

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