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Dose of Protection: Travel and Non-Respiratory Vaccine Updates Immunization Series Part 2 of 2

NCPA 2024 Annual Convention and Expo Columbus, Ohio

Speaker



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STANFORD UNIVERSITY SCHOOL OF MEDICINE

STANFORD HEALTH CARE



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Disclosure Statement

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Pharmacist and Technician Learning Objectives

- 1. Discuss updates and key considerations for non-seasonal vaccination schedules, including travel vaccines, based on expert consensus guidelines.
- 2. Summarize considerations for use of newly approved agents and agents under consideration.
- 3. Review guidance for storage and administration of travel and non-respiratory vaccines.
- 4. Discuss best practices for documentation, reporting, and referrat of travel and non-respiratory vaccines.



Outline

- Meningococcal
- HPV
- Mpox
- Dengue
- Other Routine Vaccines
 - Tetanus-Containing Vaccines
 - Zoster



Question 1 of 3

Which of the following BEST describes the indications for MenACWY and MenB vaccination in healthy adolescents and young adults?

- a. MenACWY is routinely recommended while MenB is by shared clinical decision making
- b. MenB is routinely recommended while MenACWY is by shared clinical decision making
- c. Both MenACWY and Men B are routinely recommended
- d. Both MenACWY and Men B are recommended only by shared clinical decision making



Question 2 of 3

For which patient would "catch up" (3 doses) instead of the routine 2 doses of HPV vaccine be recommended?

- a. 10-year-old
- b. 12-year-old
- c. 14-year-old
- d. 21-year-old



Question 3 of 3

Which of the following is NOT an appropriate indication for routine mpox vaccination?

- a. Known exposure to someone diagnosed with mpox
- b. MSM with >1 sexual partner
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Meningococcal



Meningococcal Disease in Adults

- Increasing case counts in 2023 (highest since 2014)
 - Large number of outbreaks, affected minorities/disadvantaged populations
- *Serogroup* Y 64% black/AA, majority unvaccinated, 18% HIV



Meningococcal Disease in Adolescents

• Serogroups ACWY disease decreased since routine vaccination introduced but Serogroup B remains similar (no routine vaccination)





College Students at Highest Risk

- Serogroup B risk highest among college students
 - 3.5x higher than non-college students
- Other risk factors: 4-year vs 2-year (5.2x), 1st year students (3.8x), on campus residence (2.9x), Greek life participation (9.8x)







CDC ACIP https://www.cdc.gov/vaccines/acip/meetings/slides-2024-02-28-29.html

Penbraya™

- Meningococcal polysaccharide vaccine
 - Serogroups ACWY + B
- FDA approved September 2024 for ages 10-24 years
- Single dose kit
 - Men B suspension syringe +
 - Men ACWY lyophilized vial
- Storage
 - Refrigerated, Do not freeze
 - Use within 4 hours of reconstitution (fridge or room temp)







ACIP Recommendations

- Quadrivalent (ACWY) (Menveo® and MedQuadfi®)
 - Routinely recommended for all adolescents
 - 2 dose series: 11-12 years and 16 years
 - Menveo® and MenQuadfi® MAY BE interchanged, if needed
- Serogroup B (MenB) (Bexsero® and Trumenba®)
 - Shared clinical decision making
 - 2 dose series: 16-23 years (16-18 preferred)
 - Bexsero[®]: 2 doses 1+ month apart (may be changing)
 - Trumenba®: 2 doses 6+ months apart (3 dose series for high-risk [0, 1, 6 mos])
 - Bexsero[®] and Trumenba[®] are <u>NOT</u> interchangeable
- Pentavalent (ABCWY) (Penbraya®) *NEW*
 - If both ACWY and B indicated at same visit, may be given in place of both vaccines
 - Ideally at age 16
 - Since B-component is Trumenba®, second dose <u>MUST</u> be Trumenba®



Who Should Receive MenB?

- Shared clinical decision making ages 16-23
 - Not everyone at risk
 - Limited efficacy and cost-effectiveness data

Many colleges require MenB vaccination

- See: College websites, Health department websites, Others (American Society of Meningitis Prevention)
- May be predicated on residence/extracurriculars
- Routine for high-risk patients 10+ years...
 - ...with asplenia, complement deficiency, or otherwise immunocompromised
 - ...during a meningococcal serogroup B outbreak
 - ...microbiologists who work with meningococcus
- Ideal to administer at 17-18 years
 - Protection wanes after 1-2 years and highest risk 18-20 years old/first year of college



Bexsero[™] vs. Trumenba[™]

• No preferential recommendation from ACIP

Bexsero™	Trumenba™			
1 month to complete series	6 months to complete series			
2 dose series	2-3 dose series (risk-dependent)			
<u>CANNOT</u> be given after Penbraya®	CAN be given after Penbraya®			
Supplied as pre-filled syringes				
Store refrigerated Do not freeze				

Preparation and Storage

Menveo (ACWY)	MenQuadFi (ACWY)	Bexsero (MenB)	Trumenba (MenB)	Penbraya (ABCWY)
Supplied as one-vial and two-vial product (10 pack)	Single dose vial (1, 5, 10 packs)	Pre-filled syringes (10 pack)	Pre-filled syringes (1, 5, 10 packs)	Vial/Syringe Kit (1, 5, 10 packs)
One vial product does not require reconstitution Two vial product requires reconstitution (use within 8 hours at room temperature)	Does not require reconstitution	Does not require reconstitution	Does not require reconstitution	Requires reconstitution of lyophilized ACWY component (vial) with syringe MenB (syringe) component (use within 4 hours refrigerated or room temporature)
Refrigerated Do not freeze Protect from light	Refrigerated Do not freeze	Refrigerated Do not freeze Protect from light	Refrigerated Do not freeze Protect from light	Refrigerated Do not freeze
				NATIONAL COMMUNITY PHARMACIETS ASSOCIATION

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Changes Coming...

- Bexsero dosing change to mimic Trumenba re: immunogenicity
 - From 2 dose (0, ≥1 mo) → 2 dose (0, 6 mos) or 3 dose (0, 1, 6 mos)
 - FDA approved August 19, 2024

• MenACWY: 11-12 years dose needed?

- Low disease incidence < 15 years
- Reduced carriage of meningococcal disease?

• MenB: Routine for college students?

- Simplification, ease of recommendation/uptake
- Select populations (college students) are reliably high risk

• Pentavalent:

- GSK pentavalent (Menveo® + Bexsero®) in FDA/ACIP review
- Favor 2 dose series at 16 and 17-18 years?
 - Men B protection wanes after 1-2 years







HPV Vaccine Effectiveness

Prevalence of Vaccine-type HPV (HPV 6,11,16,18) in Females, 2015–2018 Compared to Pre-vaccine Era 25 81% Pre-vaccine era, 2003–2006 20 lower 2007-2010 2011-2014 % 2015-2018 Srevalence, 10 18.5 19.9 88% lower 8.8 9.5 5 9.1 7.1 7.2 6.2 3.3 3.3 1.1 0 20-24 years* 14-19 years* 25-29 years 30-34 years

Vaccine Impact among Vaccinated* and Unvaccinated Sexually Experienced Females



CDC ACIP https://www.cdc.gov/vaccines/acip/meetings/slides-2022-06-22-23.html



Cervical Cancer Trends, United States Cancer Statistics



The Scottish Experience

- Routine vaccination in schools in 2008
 - 88% coverage in 2022-23 secondary school (~10th grade)
- Studied 450,000 women born 1988 to 1996
 - 40,000 vaccinated ages 12-13
 - 124,000 vaccinated 14+
 - 300,000 unvaccinated
- Primary outcome:
 - Cases of cervical cancer/100,000 women



Cases per 100K Vax 12-13 years

3.2 Cases per 100K

Vax 14+ years

8.4

Cases per 100K Unvaccinated



ACIP Recommendations Unchanged

- Only One: 9-valent HPV Vaccine (Gardasil-9®)
 - 4- (Gardasil®) and 2-valent (Cervarix®) discontinued in 2017 and 2016

• 2-dose series (Routine, Preferred)

- For adolescents 9-14 years
- First dose 9-14 years (ideally 11-12 years), second 6-12 months later
 - If second dose given <5 months apart give 3rd dose

• "Catch up" 3-dose series (Routine)

- For adolescents/young adults 15-26 years
- 3-dose series: 0, 1-2, and 6 months
- Opportunity if age-limited!



27-45 Year Olds

- 3-dose series via shared clinical decision making (SCDM)
 - May be considered for adults 27-45 years at higher risk new sex partner(s), limited prior sexual exposure
 - 3-dose series: 0, 2, and 6 months
 - Delay if pregnant (not necessarily unsafe but not studied)
- For 27-45, if rec'd bivalent or quadrivalent vaccine previously, may elect to complete series with 9-valent
- Effectiveness of vaccination is better if given earlier (11-12) vs. catch up or later (27-45)
- Prior HPV infection does not obviate vaccination



Increasing Adolescent Vaccination

- Involve all pharmacy staff in identifying patients
- Use age-based targets
 - 11-12 years: HPV, MenACWY (1st dose), Tdap
 - 16 years: MenACWY (2nd dose), "Catch up"
 - 17-18 years: MenB, "Catch up", College vaccines
- Back to school (late summer)
 - Catch up vaccine campaign
 - College readiness vaccine campaign
- Partner with local schools, pediatricians
- Follow up appointments for series (e.g., HPV, MenB)
- Utilize IIS (immunization registries)
- Communication with parents is key!





Communication with Parents and Adolescents



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3Cs Portal - Unity Consortium (unity4teenvax.org)

Vaccine Referral

- Refer to other providers for vaccines you do not provide
 - Make a local list!
 - Examples: Other pharmacies, Health departments, Doctor's offices, Community health clinics, School-based health centers, Travel clinics, Planned Parenthood health centers
- Confirm patient received recommended vaccines at next visit
- Consider providing a written vaccine recommendation

D	
Date	
Vaccines	recommended for you (adults 19 years and older)
	□ Influenza □ Live nasal □ Standard dose, inactivated □ High dose, inactivated □ Intradermal □ Recombinant
R,	 Meningococcal MMR (measles, mumps, and rubella) Pneumococcal polysaccharide (PPSV23) Pneumococcal 13-valent conjugate (PCV13) Td (tetanus and diphtheria only) Tdap (Td plus pertussis, "whooping cough") Zoster (shingles) Hepatitis A Hepatitis B Combination Hepatitis A and B vaccine HPV (Human papillomavirus) Other Vaccine:



CDC https://www.cdc.gov/vaccines/hcp/adults/downloads/standards-immz-practice-referral.pdf

Age 7-18 Limits, By State (non-Influenza/COVID)

Age Range	Prescription Needed	Administration Limitations			
Younger than 18	Georgia, Hawaii*, Iowa (non- HPV)*, North Carolina, South Carolina, West Virginia*				
Younger than 17	Louisiana				
Younger than 14	Texas	Hawaii (non-HPV/Men/Tdap)*			
Younger than 13	Ohio	Minnesota			
Younger than 12		Kansas Washington DC			
Younger than 11	Indiana Iowa (HPV)*	Hawaii (HPV/Men/Tdap)* West Virginia*			
Younger than 9	Kentucky	Massachusetts			

Please also confirm with your state DPH and/or BOP

Washington DC – administration authority excludes MMR, polio, varicella; **Missouri** – prescription needed for Hib, HPV, MMR, varicella regardless of age; **North Carolina** – prescription needed for Hib, MMR, varicella regardless of age Source: NASPA (updated April 2023) - may be outdated, please confirm with your state/local DPH/BOP



RS0 this link is not current. they have updated their resources and updated age information by vaccine is no longer publicly available. Perhaps we delete these slides? Rebecca Snead, 2024-10-17T20:00:02.707

Age 0-18 Limits, By State (Influenza/COVID)

Age No-Rx Req	Influenza Vaccine	COVID-19 Vaccine	
Any Age/6mo+	AL, AK, CA, CO, DE, ID, IA, MI, MS, NE, NV, NH, NM, OK, SD, TN, UT, VA, WA	AL, AK, CA, CO, ID, MI, MS, NE, NV, NH, NM, OK, SD, TN, UT, WA	
2 years +	NY		
3 years +	AZ, AR, MD, NJ, ND	AZ, AR, ME, MD, NJ, ND, VA*	
5-6 years +	PA (5+); KS, MN, WI* (6+)	PA (5+); MN, WI* (6+)	
7 years +	FL, IL, LA*, ME, MO*, MT, OH, OR*, TX*, WY	IL, MT, OH, OR*, WY	
9 years +	KY*, MA, RI (9+); NC (10+), IN (11+)	KY*, MA (9+); NC (10+), IN (11+)	
12 years +	CT, DC*, SC*	DE*, KS	
13-17 years +	GA (13+)*	GA (13+)*, TX (14+)*, LA (17+)*	
18 years +	HI*, VT, WV*	CT, FL, IA*, HI*, NY, RI, VT, WV*	

Please also confirm with your state DPH and/or BOP

*Expanded age range with prescription

Source: NASPA (updated April 2023) - may be outdated, please confirm with your state/local DPH/BOP



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Mpox in the US and World

- Two clades of Mpox: Clade I and II
- Clade II continues to circulate at low levels in US/other countries
- Clade I outbreaks in Democratic Republic of the Congo (DRC) and neighboring countries
- Spread primarily via skin-skin (e.g., close quarters, sexual contact)
 - Secondarily, contaminated items and surfaces and, in West/Central Africa, infected wild animal contact
 - Respiratory spread in real-life outbreaks is unclear/risk very low



Mpox Vaccine Efficacy

- Clade II (US endemic)
 - Mpox incidence <1% with 2 dose JYNNEOS series
 - Effectiveness ~86% with 2 doses and ~75% with 1 dose
 - Protected against severe disease and hospitalization
- Clade I (DRC and neighboring countries outbreak)
 - JYNNEOS is likely to be effective



Guagliardo et al. MMWR 2024 | Dalton et al. MMWR 2023 | Wolff Sagy et al. Nature Medicine 2023 https://www.idsociety.org/globalassets/idsa/public-health/monkeypox/mpox-faq-sept-2024.pdf

Mpox Vaccine Recommendations

- Known exposure to someone diagnosed with mpox
- Gay, bisexual, or other man who has sex with partner who...
 - Has >1 sex partner OR new diagnosis of sexually transmitted disease
- Sex at commercial sex venue or location where mpox transmission is occurring
- Have sex partner with any of the above risks



Accessing Mpox Vaccine

- Strongly consider providing mpox vaccine to your community
 - Register: https://npin.cdc.gov/organization/submit
- Only 1 in 4 eligible patients have received a full series
- Vaccine locators:
 - https://mpoxvaccine.cdc.gov/
 - State/Local Public Health





Common Questions

• Booster dose?

- Not currently recommended, 2 JYNNEOS doses = fully vaccinated
- Healthcare providers?
 - Not currently recommended without risk factors
- Prior mpox infection?
 - Considered fully immune and no further vaccination required
- Access/Coverage?
 - Covered by state Medicaid and Medicare, Most private insurers, Ryan White
 - State/Local health departments for uninsured
- Travel to DRC or neighboring countries? (Next slide)



https://idsociety.org/public-health/Mpox/ | https://www.cdc.gov/mpox/vaccines/index.html https://emergency.cdc.gov/han/2024/han00516.asp

Travel Considerations

- Most travelers: Travel to DRC or other countries with active clade I mpox outbreaks <u>do not</u> require mpox vaccination
- Exception: Those who anticipate <u>sexual exposures</u> while traveling to DRC or other countries with active clade I mpox outbreaks
- Updated September 23, 2024
 - Follow for updates, recommendations may change over time



Question 3 of 3

Which of the following is <u>NOT</u> an appropriate indication for routine mpox vaccination?

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- b. MSM with >1 sexual partner
- c. Sex at a commercial sex venue
- d. Travel to the African continent



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Case Spike in Americas, 2024

Dengue cases in the Americas, 1980–2024

Nearly 10 million cases reported in 2024 as of June 25.



Dengue in US

- Endemic in 6 US Territories and Freely Associated States
- Puerto Rico
- American Samoa
- Marshall Islands
- US Virgin Islands
- Micronesia
- Palau

Puerto Rico declared a public health emergency due to a dengue epidemic in March 2024.



Wong J. CDC ACIP 2024. https://www.cdc.gov/acip/meetings/presentation-slides-june-26-28-2024.html

Dengvaxia Discontinued

- Approved May 2019 for ages 9-16
- Sanofi Pasteur will <u>discontinue</u> production of Dengvaxia[®] due to lack of demand
- Takeda withdrew FDA application for dengue vaccine
- After existing Dengvaxia® supply is used, no FDA-approved will be available in the US





Other Routine Vaccines



Other Routine Vaccines Diphtheria, Tetanus, and Pertussis



ACIP Recommendations Unchanged

- Adults 19+ years: One dose of Tdap regardless of timing from last dose followed by Tdap booster every 10 years
 - **Td shortage:** Tdap should be preferentially used over Td unless contraindication to pertussis component
- Pregnant women: One dose of Tdap each pregnancy at 27-36 weeks
 - Irrespective of prior Tdap/Td vaccination history/timing
- Catch Up (7+ years): 3-dose series (0, 1, 6-12 months)
- Wound Management



Pertussis Cases Spiking in 2024

US Pertussis Cases

as of September 2024



- Four-fold increase vs. same time in 2023
- Reduced mask-wearing
- Increased gathering
- Adult Tdap vaccine coverage remains low (~40%)

Access to OB/GYN Care



Over 35% of US counties are maternity care deserts

Figure 3. Maternity care access designation by county, US and Puerto Rico





https://www.marchofdimes.org/maternity-care-deserts-report

Other Routine Vaccines Zoster



ACIP Recommendations Unchanged

- Adults 50+ Years: 2 doses of Shingrix (0, 2-6 months)
 - Regardless of history of zoster/varicella infection (wait until infection is not active) or Zostavax vaccination (wait 8 weeks)
- Immunocompromised Adults 19+ Years: 2 doses of Shingrix
 - May accelerate second dose if anticipate earlier immunocompromise (as short as 1 month)



Vaccination Delays Dementia?

- Oxford study compared Shingles vs. Zostavax recipients
- 164 additional days without dementia (17% increase)
- Effect greater in women
- Mechanism unclear
- Requires further study but encouraging



nature medicine

Brief Communication

https://doi.org/10.1038/s41591-024-03201-5

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The recombinant shingles vaccine is associated with lower risk of dementia

Paul J. Harrison @ 1.2

Received: 7 June 2024 Accepted: 17 July 2024 Published online: 25 July 2024

There is emerging evidence that the live herpes zoster (shingles) vaccine might protect against dementia. However, the existing data are limited and refer only to the live vaccine, which is now discontinued in the United States and many other countries in favor of a recombinant vaccine. Whether the

Maxime Taquet ¹², Quentin Dercon ³, John A. Todd⁴ &

Questions?



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