Immunization Update 2024

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1 VOICE VISION TEAM

Disclosure Statement

- Andrea Kowalski and Rebecca Lahrman have no relevant financial relationship(s) with ineligible companies to disclose.

  and

- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

At the completion of this activity, the participant will be able to:

1. Describe Advisory Committee on Immunization Practices (ACIP) updates, including new vaccine opportunities such as respiratory syncytial virus;
2. Identify best practices in using ImpactSIIS and other tools for clinical decision making; and
3. Review travel vaccine recommendations and patient education to support patient centered goals.

Advisory Committee on Immunization Practices (ACIP) updates

RSV Vaccine Options

RSV Vaccine, Bivalent

- Brand name: Abryxvo ™ by Pfizer
- Indication:
  - Prevention of Lower Respiratory tract disease (LRTD) caused by RSV in individual 60 years and older
  - Prevention of LRTD caused by RSV in infants from birth through 6 months with immunizing pregnant individuals during gestational age 32 to 36 weeks
- Bivalent:
  - Contains preF subunits for A and B

RSV Vaccine, Adjuvanted

- Brand name: Arexvy by GlaxoSmithKline
- Indication:
  - Prevention of Lower Respiratory tract disease (LRTD) caused by RSV in individual 60 years and older
- Adjuvant: AS01E
  - monophosphoryl lipid A (MPL) from Salmonella minnesota
  - QS-21, a saponin purified from plant extract Quillaja Saponaria Molina
  - Zoster Vaccine has AS01B

Quick Comparison

	RSV Vaccine, Bivalent (Abryxvo)	RSV Vaccine, Adjuvanted (Arexvy)
Manufacturer	Pfizer	GlaxoSmithKline
Dose	0.5ml; 120 mcg of RSV stabilized prefusion F proteins (60 mcg RSV preF A and 60 mcg RSV preF B)	0.5ml; 120 mcg of the recombinant RSVPreF3 antigen, 25 mcg of MPL, and 25 mcg of QS-21
Preparation	Comes with a vial, syringe with diluent, and vial adapter	Comes with two vials, one with diluent
Storage	Refrigerated; use within 4 hours after mixing	Refrigerated; use within 4 hours after mixing and protect from light

Older Adults Adverse Events Data

Bivalent

- Common: fatigue, headache, pain at the injection site

Adjuvant

- Common: pain at the injection site, fatigue, myalgia
- Serious: Atrial fibrillation, Guillain-Barre syndrome

V-Safe and
VAERS

RSV Vaccines in Pregnancy

Adverse Effects in Pregnancy

Serious Reactions	RSV Vaccine (CI) N=3,682	Placebo (CI) N=3,675
All Maternal SAE	16.2% (15.1, 17.5)	15.2% (14.0,16.4)
Pre-eclampsia	1.8% (1.4, 2.3)	1.4% (1.1, 1.9)
Gestational hypertension	1.1% (0.8, 1.5)	1.0% (0.7, 1.4)
Premature rupture of membranes	0.4% (0.2, 0.7)	0.4% (0.2, 0.7)

Nirsevimab

- Long-acting monoclonal antibody for the prevention of severe RSV in children younger than 8 months who are born shortly before or during their first RSV season
- Shortage due to demand exceeding supply

More to come on RSV

- NCT05127434
  - mRNA-1345 Vaccine Targeting Respiratory Syncytial Virus (RSV) in Adults ≥60 Years of Age
  - Phase 2/3 trial started November 2021
- Will be discussed further during the June ACIP meeting

Flu

- Timing: Ideal months for administration are September and October
- 2024-25 season may bring trivalent vaccines back with the removal of B/Yamagata
- Estimate for the 2023-24 season is the vaccine prevented about 6 million illnesses, 65,000 hospitalizations, and 3,700 deaths
- Live vaccine: potential removal of contraindication in those with asthma

COVID-19

- Updated 2023-2024 monovalent XBB.1.5 COVID-19 vaccination has provided approximately 54% increase in protection against symptomatic SARS-CoV-2 Infection vs those without the updated strain
- Has shown protection against JN.1 strain which has been the newer circulating strain
- ODH Bridge Access Program through the end of 2024

When will they be combined?

- Moderna has entered a phase 3 study for mRNA-1083 which can protect against flu and COVID-19
  - Estimated study completion may of 2024
  - Single dose
- Pfizer and BioNTech had positive Phase 1/2 studies NCT05596734 and will enter phase three soon
  - Complete phase 1/2 December 2023

Pneumococcal over 65

- No history:
  - PCV15 followed with PPSSV23 a year later or
  - PCV20
- PCV13
  - PCV20 or PPSV23 one year later
- PPSV23:
  - PCV15 or PCV20 one year later
- Received PPSV23 under 65 and a PCV13
  - PCV20 (5 years later) or PPSV23 (see schedule)
- Received PPSV23 after 65 and a PCV13
  - **Shared clinical decision making** PCV20, 5 years later

Adults 19–64 years old with chronic health conditions
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	**PCV20**	**PCV15** → ≥1 year → **PPSV23**
PPSV23 only	≥1 year → **PCV20**	≥1 year → **PCV15**
PCV13† only	≥1 year → **PCV20**	≥1 year → **PPSV23** Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13† and PPSV23	**No vaccines** are recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 65 years old.	
Chronic health conditions	• Alcoholism • Chronic heart disease, including congestive heart failure and cardiomyopathies • Chronic liver disease	• Chronic lung disease, including chronic obstructive pulmonary disease, emphysema, and asthma • Cigarette smoking • Diabetes mellitus

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
† Adults with chronic medical conditions were previously not recommended to receive PCV13

Adults 19–64 years old with specified immunocompromising conditions
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	**PCV20**	**PCV15** → ≥8 weeks → **PPSV23**
PPSV23 only	≥1 year → **PCV20**	≥1 year → **PCV15**
PCV13 only	≥1 year → **PCV20**	≥8 weeks → **PPSV23** → ≥5 years → **PPSV23** Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13 and **1 dose of PPSV23**	≥5 years → **PCV20**	≥5 years† → **PPSV23** Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13 and **2 doses of PPSV23**	≥5 years → **PCV20**	**No vaccines** recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
Immunocompromising conditions	• Chronic renal failure • Congenital or acquired asplenia • Congenital or acquired immunodeficiency§ • Generalized malignancy • HIV infection • Hodgkin disease • Iatrogenic immunosuppression¶ • Leukemia • Lymphoma • Multiple myeloma • Nephrotic syndrome • Sickle cell disease/other hemoglobinopathies • Solid organ transplant	

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
† The minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose
§ Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)
¶ Includes diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy

How many pneumonia vaccines is too many?

- 1984: PPSV23
- 2000: PCV7
  - Routine use in children
- 2010: PCV13 approved in children
  - ACIP recommend PPSV23 two to three doses 5 year apart
- 2011: PCS13 approved in 50 and older (ACIP recommend 65 and above)
- 2014/5: ACIP recommended PCV13 at 65 and PPSV23 a year later
- 2021: PCV15 and PCV 20 approved in adults
- 2022: PCV15 approved for children
- 2023: PCV20 approved for children
- 2024: PCV21?

Tetanus, Diphtheria and Pertussis

- 2020: Production of DT vaccine by Sanofi was discontinued
- 2023: Production of Td vaccine, TdVax, has been discontinued by manufacturer
- MMWR: Ohio Week 8 of 2024 (February 24th)
  - Current cases: 6
  - Previous 52 weeks: 41
  - Year to date: 125
  - Year to date 2023: 68

Meningococcal

- Pentavalent MenABCWY
- Schedule
  - 2 doses 6 months apart
  - Age 1—25 years
  - MenABCWY vaccine can be used only when both MenACWY and MenB vaccines are indicated at the same visit
- CDC also recommends a booster dose for those at increased risk due to an outbreak if 5 or more years have passed since receiving MenACWY.

HPV

- Vaccination prevent more 90% cancers, 9 strains of protection
- Recommended for males and females up through age 26
  - 2 doses 9-14 years is more than 5 months apart
  - 3 doses 15 years and older 0, 1-2 months, 6 months
- Special situations
  - **Shared clinical decision-making** for adults ages 27-45 year
  - Not recommended during pregnancy

Hep A and Hep B

- Hep A
  - Routine 2 or 3 dose series
  - Accelerated schedule for high or intermediate endemic hepatitis A outbreaks/travel
  - Last outbreak in 2022 with 3,770 cases from 2018-2022
- Hep B
  - Titers can be drawn 1-2 months following series

Measles, Mumps, Rubella

2-dose series at least 4 weeks apart if previously did not receive any doses of MMR or 1 dose if previously received 1 dose MMR

- 3rd dose recommended for those at an increased risk of mumps during an outbreak
- First Measles case in Ohio February 3rd
- MMRW: Ohio Week 8 of 2024 measles, mumps
  - Current cases: 2, 0
  - Previous 52 weeks: 1, 2
  - Year to date: 3, 6
  - Year to date 2023: 3 , 5

Mpox vaccine

- Mpox is transmitted with direct contact with an mpox rash
- Two dose vaccine series that is four weeks apart that is administered subcutaneously
- Available through a limited distribution through the ODH

Zoster

- 68% - 91.3% effective in preventing Shingles
- ACIP recommended 50 years and older, two doses 2-6 months apart
- FDA Approval
  - 18 years and older who are or will be at an increased risk of singles due to immunodeficiency or immunosuppression causes by known disease or therapy
- Generally, not offer at ODH

Ohio Department of Health

- Vaccine support for uninsured and underinsured patients through local health departments
- Recommend patient navigation:
  - Call local health department to inquire about availability and access
  - May visit a health department not from home county
- Funding is focused on ACIP recommended vaccines and communicable diseases

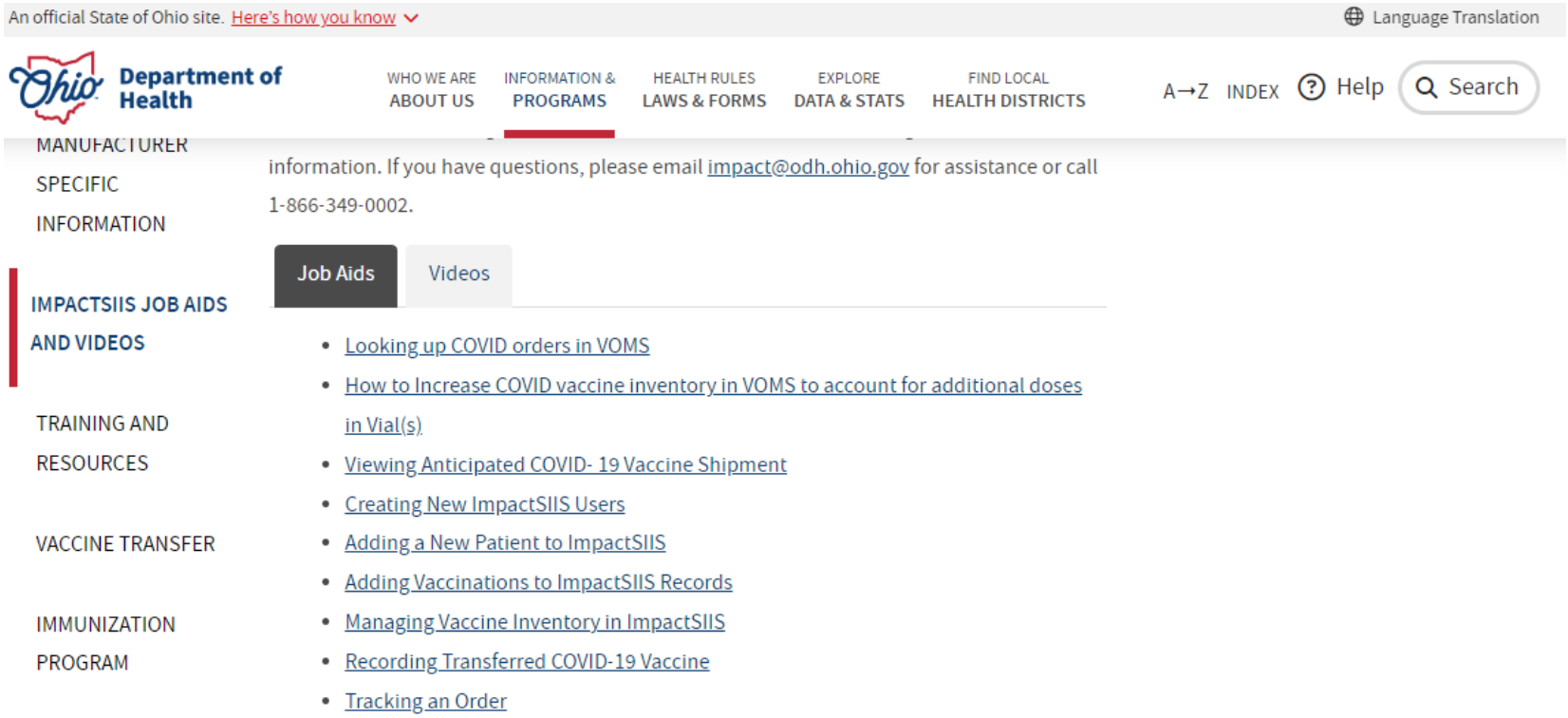
Best practices in clinical decision making

Using ImpactSIIS

- Immunization Information System (ImpactSIIS) features:
  - Vaccine coverage
  - Immunization rates
  - Disease surveillance
- Benefits:
  - Improve data accessibility
  - Enhance surveillance capabilities
  - Support evidence-based decision making

ImpactSIIS resources

- https://odh.ohio.gov/know-our-programs/covid-19-vaccine-provider/impactsiis-job-aids-and-videos

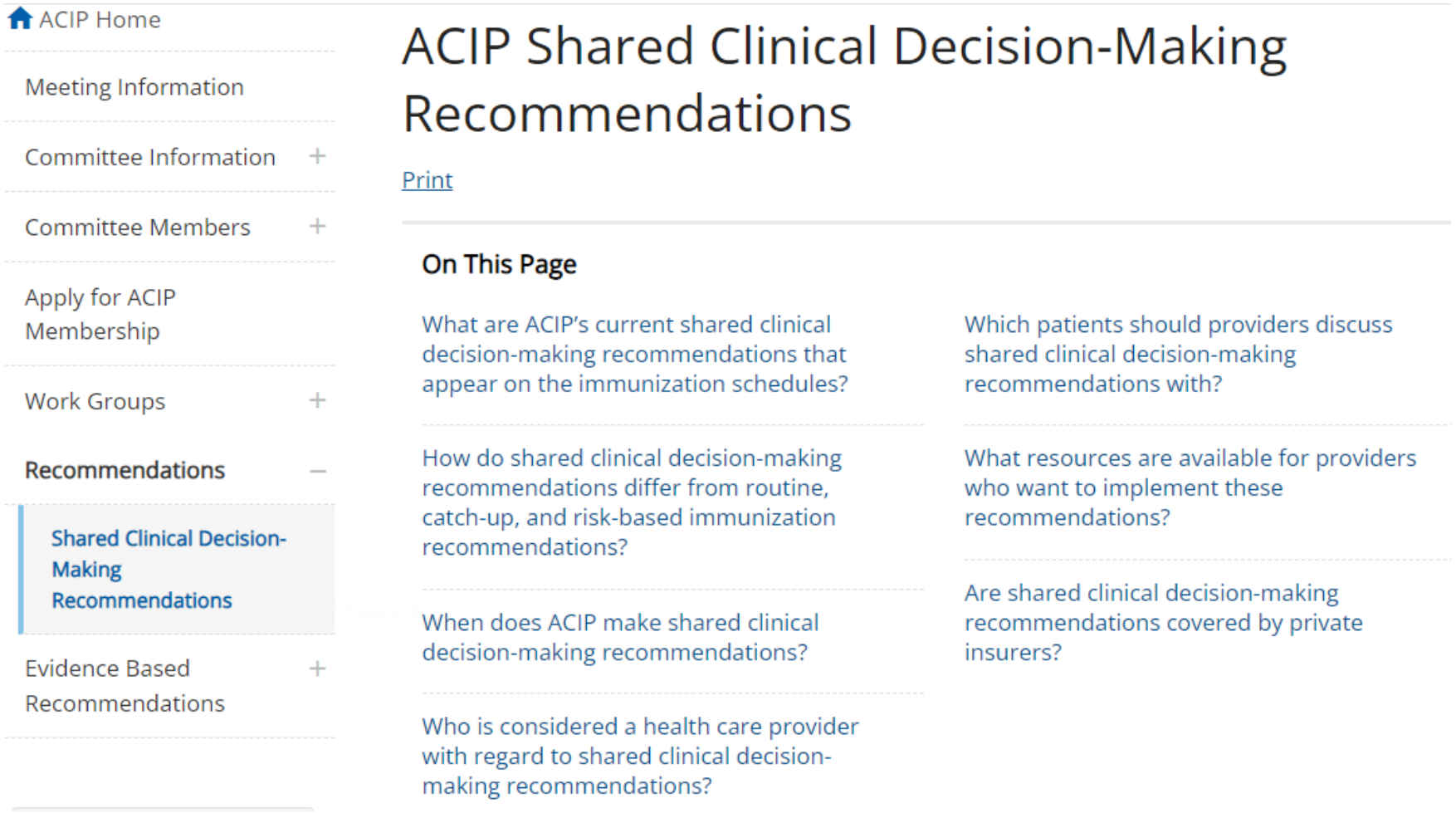


Resource tools and applications

Shared Clinical Decision Making

- Collaborative approach
- Engages patients
- Educates patients
- Considers preferences and values
- Empowers patients

Shared Clinical Decision Making



Shared Clinical Decision Making

- Who is considered a health care provider with regard to shared clinical decision-making recommendations?
  - primary care physicians
  - Specialists
  - physician assistants
  - nurse practitioners
  - registered nurses
  - **pharmacists**

Shared Clinical Decision Making

- What are ACIP's current shared clinical decision-making recommendations that appear on the immunization schedules?
  - 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
  - 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)

Shared Clinical Decision Making

- How do shared clinical decision-making recommendations differ from routine, catch-up, and risk-based immunization recommendations?
  - RSV vaccination for adults aged 60 years and older
    - No default to vaccinate
    - Individually based
    - Informed by discussions between patient and health care provider

Shared Clinical Decision Making

- When does ACIP make shared clinical decision-making recommendations?
  - when individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts.
  - Meningococcal B (MenB) vaccination for adolescents and young adults aged 16–23 years

Shared Clinical Decision Making

- What resources are available for providers who want to implement these recommendations?
  - ACIP resources
    - ACIP Vaccine Recommendations and Guidelines page.
    - *Morbidity and Mortality Weekly Report* (MMWR)
  - CDC resources
    - Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over
    - HPV Vaccination for Adults Aged 27-45 Years
    - Meningococcal B Vaccination
    - PCV20 Vaccination for Adults 65 Years or Older

Shared Clinical Decision Making

- Are shared clinical decision-making recommendations covered by private insurers?
  - Under the ACA, generally required to be covered by group health plans and health insurance
  - Adopted by CDC and are listed on the immunization schedules

Addressing vaccination challenges

- Vaccine fatigue
  - Provide strong recommendation for vaccinations
- Vaccine hesitancy
  - “what else?” tactic

Vaccine confidence resources

- Vaccine confidence
  - CDC website – “Vaccinate with Confidence”
  - APhA- “Vaccine confident”

Motivational Interviewing

- Ask open ended questions
- Reflect on concerns presented
- Show empathy and affirmations
- Summarize key points
- Respectfully share information

travel vaccine recommendations

Navigating the CDC website

- https://wwwnc.cdc.gov/travel/
- Destinations
  - Help determine local vaccine needs for travel to that country
- Travel Notices
  - Contains information about current outbreaks and recommendations for travel
- Advice for Travelers
  - Excellent to refer patients for specific questions

Vaccination Based on travel plans

- Vaccines are listed alphabetically
- Always recommend being up to date on routine vaccines
- Subsequent sections will outline the vaccine use and regionality

Cholera

- Transmission: food and water
- Symptoms:
  - Profuse water diarrhea, vomiting, leg cramps, restlessness, irritability.
  - Concern is severe dehydration
- General locations of concern:
  - Parts of Africa, middle east, Dominican republic and Haiti

Cholera Vaccine

- Name: Vaxchora
- Dosing: reconstitute vaccine
  - Age 4-6: 50 mLs
  - 7-64: 100 mLs
- Avoid eating or drinking for an hour prior and after
- Administer at minimum 10 days prior to exposure
- Live vaccine containing $4x10^8$ to $2x10^9$ CFUS
- No protection against V. cholerae serogroup O139 or other non-O1 serogroups

Cholera Vaccine Safety and Efficacy

- Vaccine efficacy against the occurrence of moderate to severe diarrhea
  - at 10 days postvaccination was 90.3% [95% CI 62.7%, 100.0%]
  - at 3 months post-vaccination was 79.5% [95% CI 49.9%, 100.0%]
  - Similar efficacy against classical Inaba, El tor Inaba, Classica Ogawa and El Tor Ogawa
- It is unknown how long protection lasts beyond 3–6 months after vaccination.
- Adverse effects
  - Tiredness, headache, abdominal pain, nausea/vomiting, diarrhea

Japanese Encephalitis

- Transmission: infected mosquito
- Symptoms:
  - Early signs are headache and vomiting
  - Followed by disorientation, coma and seizures
- General locations of concern:
  - Parts of Asia and the Western Pacific
- Not recommended for travelers planning short-term travel to urban areas or travel to areas with no clear Japanese encephalitis season

Japanese Encephalitis Vaccine

- Name: IXIARO
- Dose: 0.5mls, 2 doses 28 days apart
- Complete the series one week prior to exposure
- A third dose can be given 11 month later for ongoing expose or re-exposure

Japanese Encephalitis Vaccine Safety and Efficacy

- After the final injection, 96% of these people who received both doses of had developed protective levels of antibodies
- Adverse effects:
  - Headache, muscle pain, injection site reactions, nausea, skin rash, fatigue

Rabies

- Transmission: bites or scratches from infected animals, mostly dogs
- Symptoms:
  - Flu like symptoms, pricking/itching at bite site
- General locations of concern:
  - Africa, Asia and parts of Central and South America
  - Rabies in dogs is rare in the United States, Australia, Canada, Japan, and most European countries

Rabies Vaccine

- Names: Imovax and RabAvert
- Pre-exposure prophylaxis
  - 1 ml IM dose administered days 0, 7, 21 or 28
- Post exposure involves the same vaccine products with 5 doses each along with human rabies immune globulin
- Adverse effects
  - Pain, swelling, redness, headache, nausea, muscle aches

Typhoid

- Transmission: bacteria from person to person
- Symptoms:
  - Fevers, weakness, stomach pain, headache, diarrhea, cough and rash.
  - Internal bleeding and death can occur but is rare
- General locations of concern:
  - Eastern and southern Asian, Africa, the Caribbean, central and south America

Typhoid Vaccine

- Typhim VI
  - 0.5mls IM two weeks prior to exposure
  - Reimmunizations recommended every 2 years with continued exposure
- Vivotif
  - Oral live attenuated vaccine
  - Taken on days 1, 3, 5, and 7 one hour prior to a meal with cold or luke-warm water
  - May be repeated every 5 years if continued exposure exists
  - Drug-drug interactions with antimalarials, complete 3~10 days prior to antimalarials

Yellow Fever

- Transmission: mosquitoes
- Symptoms:
  - Most people will only have mild symptoms
  - Symptoms start 3-5 days post bite and have fever chills, headache, muscle aches
  - Serious illness include jaundice, shock, organ failure and potentially death
- General locations of concern:
  - Parts of Africa and Parts of South America
  - Required for travelers ≥1 year old arriving from countries with risk for YF virus transmission.

Yellow Fever Vaccine

- Name: YF-VAX
- Dose: 0.5mls reconstituted subcutaneous vaccine
- Must be administered 10 days prior to travel
- Booster can be given to those received the initial dose with immunocompromising conditions 10 years later
- Adverse effects: injection site reactions, rash, headache, and encephalomyelitis

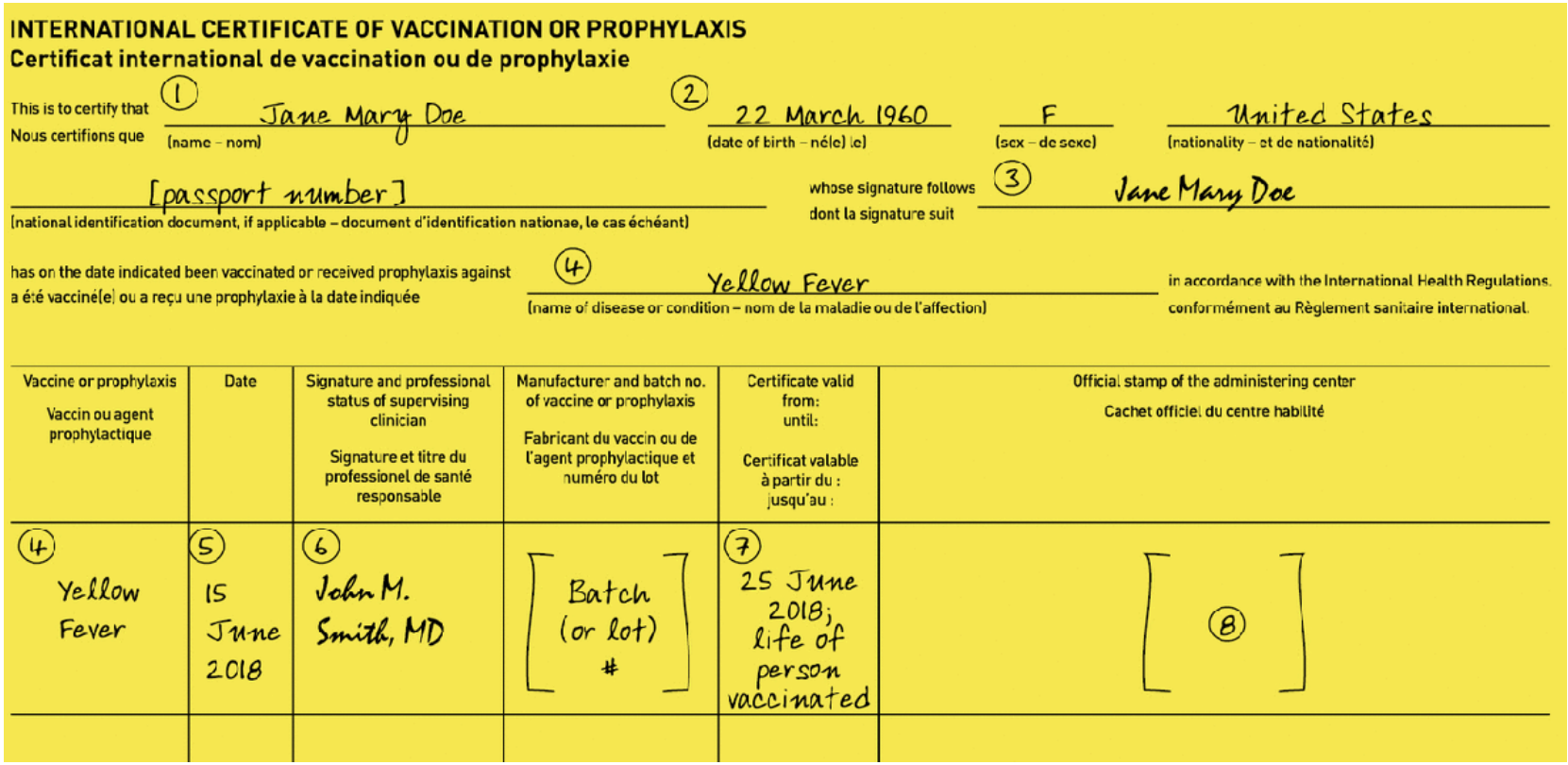
Yellow Fever Distribution

- Sign up with the Ohio Department of Health
- CDC training:
  - http://www.cdc.gov/travel-training/

Antimalarials

- No vaccine opportunity
- Atovaquone/proguanil 250/100mg: one tablet daily, beginning 2 days prior to traveling to the endemic area, once daily while there, and once daily for 7 days following return.
- Doxycycline 100mg: one tablet daily, beginning 2 days prior to traveling to the endemic area, once daily while there, and once daily for 4 weeks upon return.

Vaccine Travel Documentation



INTERNATIONAL CERTIFICATE OF VACCINATION OR PROPHYLAXIS
Certificat international de vaccination ou de prophylaxie

This is to certify that / Nous certifions que (1) Jane Mary Doe (name – nom) (2) 22 March 1960 (date of birth – né(e) le) F (sex – de sexe) United States (nationality – et de nationalité)

[passport number] (national identification document, if applicable – document d'identification nationae, le cas échéant) whose signature follows / dont la signature suit (3) Jane Mary Doe

has on the date indicated been vaccinated or received prophylaxis against / a été vacciné(e) ou a reçu une prophylaxie à la date indiquée (4) Yellow Fever (name of disease or condition – nom de la maladie ou de l'affection) in accordance with the International Health Regulations. / conformément au Règlement sanitaire international.

Vaccine or prophylaxis Vaccin ou agent prophylactique	Date	Signature and professional status of supervising clinician Signature et titre du professionel de santé responsable	Manufacturer and batch no. of vaccine or prophylaxis Fabricant du vaccin ou de l'agent prophylactique et numéro du lot	Certificate valid from: until: Certificat valable à partir du : jusqu'au :	Official stamp of the administering center Cachet officiel du centre habilité
(4) Yellow Fever	(5) 15 June 2018	(6) John M. Smith, MD	[Batch (or lot) #]	(7) 25 June 2018; life of person vaccinated	[(8)]

Patient Assessment

- Travel length
- Locations
  - Countries and rural vs urban areas
- Major airport travel

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