VACCINES:

How to create a successful vaccine program

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- Nothing to disclose and no conflicts of interest

Overview

- Vaccine Overview
- Vaccine Guidelines
- Purchasing: Supply, Manufacturers, Storage, Returns
- Reimbursement
  - Codes
  - Billing Assistance
  - Commercial
  - Medicare

Brief History of the Vaccine

- Edward Jenner credited as Father of Immunology
- Observed milkmaids who contracted cowpox (variolae vaccinae) did not develop smallpox (variola major and minor).
- Vacca is Latin for from cows, Varius is Latin for spotted
- Took pus from a milkmaid, Sarah Nelmes, and inoculated James Phipps
- Phipps develops cowpox
- Jenner then inoculates Phipps with pus from smallpox scabs
- Phipps does not develop disease
- Vaccination invented, possibly greatest advancement in medicine

Figures 1 and 2 should be read with the footnotes that contain important general information and considerations for special populations.

Figure 1. Recommended immunization schedule for adults aged 19 years or older by age group, United States, 2017

Vaccine	19–21 years	22–26 years	27–59 years	60–64 years	≥ 65 years
Influenza[1]	1 dose annually				
Td/Tdap[2]	Substitute Tdap for Td once, then Td booster every 10 yrs				
MMR[3]	1 or 2 doses depending on indication				
VAR[4]	2 doses				
HZV[5]				1 dose	
HPV–Female[6]	3 doses				
HPV–Male[6]	3 doses				
PCV13[7]	1 dose				
PPSV23[7]	1 or 2 doses depending on indication				1 dose
HepA[8]	2 or 3 doses depending on vaccine				
HepB[9]	3 doses				
MenACWY or MPSV4[10]	1 or more doses depending on indication				
MenB[10]	2 or 3 doses depending on vaccine				
Hib[11]	1 or 3 doses depending on indication				

Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection

Recommended for adults with additional medical conditions or other indications

No recommendation

Figure 2. Recommended immunization schedule for adults aged 19 years or older by medical condition and other indications, United States, 2017

Vaccine	Pregnancy[1-4,9]	Immuno-compromised (excluding HIV infection)[3-7,11]	HIV infection CD4+ count (cells/μL)[3-7,9-11]		Asplenia, persistent complement deficiencies[7,10,11]	Kidney failure, end-stage renal disease, on hemodialysis[7,9]	Heart or lung disease, chronic alcoholism[7]	Chronic liver disease[7-9]	Diabetes[7,9]	Healthcare personnel[2,4,9]	Men who have sex with men[6,8,9]
			< 200	≥ 200							
Influenza[1]	1 dose annually										
Td/Tdap[2]	1 dose Tdap each pregnancy	Substitute Tdap for Td once, then Td booster every 10 yrs									
MMR[3]	contraindicated	1 or 2 doses depending on indication									
VAR[4]	contraindicated	2 doses									
HZV[5]	contraindicated			1 dose							
HPV–Female[6]		3 doses through age 26 yrs									
HPV–Male[6]		3 doses through age 26 yrs			3 doses through age 21 yrs						3 doses through age 26 yrs
PCV13[7]		1 dose									
PPSV23[7]		1, 2, or 3 doses depending on indication									
HepA[8]	2 or 3 doses depending on vaccine										
HepB[9]	3 doses										
MenACWY or MPSV4[10]	1 or more doses depending on indication										
MenB[10]	2 or 3 doses depending on vaccine										
Hib[11]	3 doses post-HSCT recipients only	1 dose									

Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection

Recommended for adults with additional medical conditions or other indications

Contraindicated

No recommendation

Pneumonia

- 2 vaccines available, Prevnar-13 and Penumovax-23
- Total of 1 dose of Prevnar-13 and 2 doses of Pneumvoax-23
- Initially give Prevnar-13 when indicated, a year later Pneumovax-23 and 5 years later repeat Pneumovax-23
- If already received Pneumovax-23 then give Prevnar-13 and follow up with Pneumovax-23 5 years after Pneumovax-23
- Special category of immunocompromised conditions, asplenia, cochlear implant of CSF leak should receive Prevnar-13 followed by Pneumovax-23 at 8 week interval

Pneumonia Vaccine Indications

- All adults age 65 and up
- All adults 19 and up with specific medical conditions
  - Diabetes
  - Congestive Heart Failure, Cardiomyopathy, Chronic Heart Disease
  - Chronic Lung Disease, Chronic Obstructive Pulmonary Disease, Asthma
  - Chronic Liver Disease, Cirrhosis, Alcoholism
  - Cigarette Smokers
  - Congenital or Functional Asplenia, sickle cell disease, hemoglobinopathies, splenectomy
  - Immunocompromised conditions, HIV, Combined B or T lymphocyte deficiency, acquired immunodeficiency, complement and phagocytic disease, radiation therapy, long term corticosteroids
  - Chronic Renal Failure, Nephrotic Syndrome
  - Leukemia, lymphoma, malignancy, multiple myeloma, organ transplant
  - Cochlear Implant and CSF leak

Influenza

- All adults should receive yearly Flu vaccine
- Nasal live vaccine not advised
- Egg allergy is only a contraindication if angioedema, respiratory distress or severe illness
- Hives from eggs is not a contraindication
- Recombinant vaccine available for egg allergy
- Trivalent and Quadravalent available
- High dose available for over age 65

Tetanus, diphtheria, pertussis (Tdap)

- One dose after age 19
- Resume dT every 10 years
- Pregnant women should receive Tdap in third trimester of each pregnancy
- Vaccination helps to protect newborns before age 6 months who can not be vaccinated
- Create a circle of protection

Zostavax

- 1 in 3 people develop shingles
- Vaccine reduces incidence by 70%
- All adults age 60 should receive vaccine
- Do not need to check prior varicella status
- Live vaccine contraindicated in immunosuppression
  - Medication induce e.g. biologics
  - Chronic immunosuppression
  - Bone marrow and lymphatic system suppression
  - HIV with CD 4 + <200

Shingrix

- 1 in 3 people develop shingles
- Vaccine reduces incidence by 90%
- All adults age 50 should receive vaccine
- Do not need to check prior varicella status
- Recombinant Vaccine
- CDC Recommendations
  - Shingrix for all immunocompetent adults aged 50 years and older (14-1 vote)
  - For immunocompetent adults who previously received Zostavax (12-3) vote
  - Shingrix preferred over Zostavax (8-7 vote)

Hepatitis A

- 2 doses at 0 and 6 months or Hep A/B combination at 0, 1, 6 months
- Any adult who wishes Hep A protection
- Chronic liver disease
- Receiving clotting factor concentrates
- Men who have sex with men
- Drug Use
- Research lab setting
- Travel risk

Hepatitis B

- 3 doses at 0, 1, 6 months
- Indicated for adults seeking protection from Hep B
- Men who have sex with men, any adult with multiple sex partners
- Living in house with Hep B infected individuals
- Healthcare workers or anyone exposed to blood
- IV drug uses
- Liver disease including Hep C, cirrhosis, alcoholic liver disease, fatty liver disease, autoimmune hepatitis, AST and ALT twice normal
- End state renal disease, hemodialysis
- HIV
- Diabetes
- Pregnant women exposed to Hep B
- At risk travelers

Meningitis

- 2 types of vaccines
  - Menactra for A,C, W, Y
  - Bexsero or Trumenba for Type B
- Menactra 1 dose every 5 years while at risk
- Bexsero 2 doses, 4 weeks apart every 5 years while at risk
- Trumenba 3 doses at 0, 1-2, 6 months every 5 years while at risk
- At risk includes
  - College students
  - Military Recruits
  - Microbiologists who work with Neisseria
  - Travel exposure
- Special categories
  - Asplenia and complement deficiencies should receive Menactra 2 doses at 8 week interval and Bexsero 2 doses at 4 week interval each every 5 years
  - HIV infected should received Menactra 2 dose series at 8 week interval and then every 5 years
- Bexsero and Trumenba are not interchangeable

Gardasil

- Human Papillomavirus
- Prevention of cervical, anal, penile and throat cancer
- 3 dose series at 0, 1-2, 6 months
- All female ages 9-26
- All males age 9-21
- Males age 21-26 if male having sex with male
- Immunocompromised conditions including B and T lymphocyte deficiency, malignancy, transplantation, autoimmune disease and immunosuppressive therapy

Supply side

- Buy direct from manufacturer
  - Merck, Aventis, Pfizer, Glaxo, etc.
- Group purchasing organization e.g. Atlantic Health Partners, et. al.
- Buy multiple vaccines for discount
- Defer paying invoice for several months
- Pay promptly on due date for further discounts
- Order what is needed to avoid vaccine loss from expiration
- Many manufactures will take back unused vaccines and credit account

Manufacturers and Vaccines

- Merck: www.merckvaccines.com
  - Gardasil-9
  - Zostavax
  - Pneumovax-23
  - Hepatitis A (Vaqta)
  - Hepatitis B (Recombivax)
- Aventis (Sanofi-Pasteur): www.vaccineshoppe.com
  - Adacel (Tdap)
  - Menactra (Meningitis A, C, Y, W-135)
  - Fluzone, Quadrivalent and High Dose
  - Yellow Fever
  - Typhim
- Pfizer: www.pfizerprime.com
  - Prevnar-13
  - Trumemba (Meningitis B 3 dose)
- Glaxo Smith Kline" www.gskdirect.com
  - Bexsero (Meningitis B 2 dose)
  - Energix-B (Hepatitis B)
  - Havrix (Hepatitis B)
  - Fluarix and Flulaval (Influenza quadrivalent)
  - Tdap (Boostrix)
  - Shingrix

Storage Best Practices for Refrigerated Vaccines–Fahrenheit (F)

1 Unpack vaccines immediately

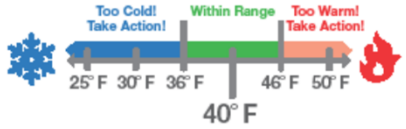
1. Place the vaccines in trays or uncovered containers for proper air flow.
2. Put vaccines that are first to expire in front.
3. Keep vaccines in original boxes with lids closed to prevent exposure to light.
4. Separate and label by vaccine type and VFC/public or private vaccine.

2 Store vaccine at ideal temperature: 40°F

Never freeze refrigerated vaccine!

Exception: MMR can be stored in fridge or freezer

Refrigerated Vaccine



Report out-of-range temperatures immediately!

3 Use vaccine storage best practices

DO

- Do make sure the refrigerator door is shut!
- Do replace crisper bins with water bottles to help maintain consistent temperature.
- Do label water bottles "Do Not Drink".
- Do leave 2-3 inches between all vaccine containers and refrigerator walls.
- Do post "Do Not Unplug" signs on refrigerator and near electrical outlet.

DON'T

- Don't use dormitory-style refrigerator.
- Don't use top shelf for vaccine storage.
- Don't put food or beverages in refrigerator.
- Don't put vaccines or diluents in doors or on floor of refrigerator.
- Don't drink from or remove water bottles.

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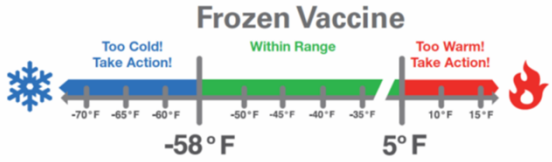
Visit www.cdc.gov/vaccines/SandH or contact your state health department for more information.

Vaccine Storage Best Practices for Frozen Vaccines–Fahrenheit (F)

1 Unpack vaccines immediately

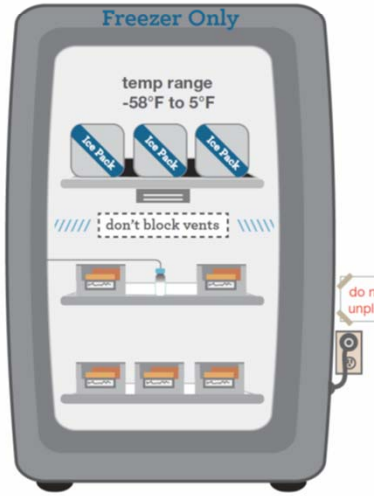
1. Place the vaccines in trays or uncovered containers for proper air flow.
2. Put vaccines that are first to expire in front.
3. Keep vaccines in original boxes with lid closed to prevent light exposure.
4. Separate and label by vaccine type and VFC/Public or private vaccine.

2 Store vaccine at ideal temperature range: -58°F to 5°F



Report out of range temperatures immediately!

3 Use vaccine storage best practices



DO

- Do make sure the freezer door is shut!
- Do use ice packs to help maintain consistent temperature
- Do leave 2 to 3 inches between all vaccines and freezer walls
- Do post "Do Not Unplug" signs on freezer and by electrical outlet

DON'T

- Don't use dormitory-style refrigerator/freezer
- Don't use combo fridge/freezer unit
- Don't put food in freezer
- Don't store vaccines in doors

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Visit www.cdc.gov/vaccines/SandH for more information, or your state health department.

Using Standing Orders for Administering Vaccines: What You Should Know

The use of standing orders for vaccination facilitates the delivery of immunization services to patients in clinics, hospitals, and community settings.

Standing orders have been shown to increase vaccination coverage rates.

▼
Go to **www.immunize.org/standing-orders** for the most current versions of sample standing orders.

What are standing orders?

Standing orders authorize nurses, pharmacists, and other appropriately trained healthcare personnel, where allowed by state law, to assess a patient's immunization status and administer vaccinations according to a protocol approved by an institution, physician, or other authorized practitioner. Standing orders work by enabling assessment and vaccination of the patient without the need for clinician examination or direct order from the attending provider at the time of the interaction. Standing orders can be established for the administration of one or more specific vaccines to a broad or narrow set of patients in healthcare settings such as clinics, hospitals, pharmacies, and long-term care facilities.

Who recommends standing orders for vaccination?

The Community Preventive Services Task Force (Task Force): The Task Force[1] recommends standing orders for vaccinations based on strong evidence of effectiveness in improving vaccination rates:

1. in adults and children,
2. when used alone or when combined with additional interventions, and
3. across a range of settings and populations.

Read the full Task Force Finding and Rationale Statement at www.thecommunityguide.org/vaccines/standingorders.html.

The Centers for Disease Control and Prevention (CDC): CDC's Advisory Committee on Immunization Practices (ACIP) specifically recommends standing orders for influenza and pneumococcal vaccinations and several other vaccines (e.g., hepatitis B, varicella). See *Use of Standing Orders Programs to Increase Adult Vaccination Rates: Recommendations of the ACIP. MMWR* 2000;49 (No. RR-1) at www.cdc.gov/mmwr/preview/mmwrhtml/rr4901a2.htm.

What are the elements of a standing order?

A comprehensive standing order should include the following elements:

1. Who is targeted to receive the vaccine;
2. How to determine if a patient needs or should receive a particular vaccination (e.g., indications, contraindications, and precautions);
3. Procedures for administering the vaccine (e.g., vaccine name, schedule for vaccination, appropriate needle size, vaccine dosage, route of administration);
4. Provision of any federally required information (e.g., Vaccine Information Statement);
5. How to document vaccination in the patient record;
6. A protocol for the management of any medical emergency related to the administration of the vaccine; and
7. How to report possible adverse events occurring after vaccination.

Who is authorized to administer vaccines under standing orders?

Each of the 50 states separately regulates physicians, nurses, pharmacists, and other health-related practitioners. For further information about who can carry out standing orders in your state, contact your state immunization program or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Who is authorized to sign the standing order?

In general, standing orders are approved by an institution, physician, or authorized practitioner. State law or regulatory agency might authorize other healthcare professionals to sign standing orders.

What should be done with the standing orders after they have been signed?

Signed standing orders should be kept with all other signed medical procedures and protocols that are operational in one's clinic setting. A copy should also be readily available for clinic staff who operate under those standing orders.

Do standing orders need to be renewed (e.g., yearly)?

Generally, standing orders will include an implementation date as well as an expiration date. Periodic review of standing orders is important, because vaccine recommendations may change over time.

Where can I find sample standing orders?

The Immunization Action Coalition has developed templates of standing orders for vaccines that are routinely recommended to children and adults. They are updated as needed and reviewed for technical accuracy by immunization experts at CDC. The most current versions can be accessed by going to www.immunize.org/standing-orders.

FOOTNOTE

1 The Task Force was established in 1996 by the U.S. Department of Health and Human Services to identify population health interventions that are scientifically proven to save lives, increase lifespans, and improve quality of life. The Task Force produces recommendations (and identifies evidence gaps) to help inform the decision making of federal, state, and local health departments, other government agencies, communities, healthcare providers, employers, schools, and research organizations. For more information, see www.thecommunityguide.org/index.html.

Technical content reviewed by the Centers for Disease Control and Prevention

Immunization Action Coalition
Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

www.immunize.org/catg.d/p3066.pdf • Item #P3066 (8/15)

Coding-Vaccines

Vaccine	CPT code	Average Reimbursement
Pneumovax-23	90732	$89.95
Prevnar-13	90670	$181.06
Influenza Quadrivalent	90686	$19.03
Influenza High Dose	90662	$42.72
Zostavax	90736	$214.20
Hepatitis A	90632	$63.88
Hepatitis B	90746	$61.48
Menactra	90734	$126.83
Bexsero	90620	$180.01
Gardasil-9	90651	$216.87
Tdap	90715	$47.00
Yellow Fever	90717	$148.31
Typhim	90691	$99.21

Administration	CPT code	Average Reimbursement
Administration 1st dose	90471	$21.86
Administration 2nd dose	90472	$11.29
Flu Medicare	G0008	$25.72
Pneumonia Medicare	G0009	$25.72
Hep B Medicare	G0010	$25.72

Coding-Vaccines

Vaccine	Average Cost	Average Reimbursement	Average Admin Reimbursement	Profit
Pneumovax-23	$84.11	$89.95	$20	$25.84
Prevnar-13	$158.83	$181.06	$20	$42.23
Influenza Quadrivalent	$16.37	$19.03	$20	$22.66
Influenza High Dose	$41.22	$42.72	$20	$21.50
Zostavax	$202.46	$214.20	$20	$31.64
Hepatitis A	$57.36	$63.88	$20	$26.52
Hepatitis B	$40.43	$61.48	$20	$41.05
Menactra	$101.51	$126.83	$20	$45.32
Bexsero	$152.86	$180.01	$20	$47.41
Gardasil-9	$187.09	$216.87	$20	$49.58
Tdap	$30.65	$47.00	$20	$36.35
Yellow Fever	$140.66	$148.31	$20	$27.65
Typhim	$92.76	$99.21	$20	$26.45

Reimbursement tips for Commercial and Medicare

- Dx code for all vaccines Z23
- Know the CPT for each vaccines, check with manufacturer
- All vaccines need a specific CPT code for the vaccine and an administration code
- First administration code is 90471 for commercial, subsequent injection on same visit is 90472 x number of units
- Medicare vaccines for flu (G0008), pneumonia-23and prevnar-13 (G0009), and Hepatitis B (G0010), use G code as first dose administration
- If given on the same day as visit then use modifier 25 on EM code with modifier 59 for vaccines and administration code
- All vaccines for commercial submitted through normal claims process
- Medicare part B vaccines (Flu, Pneumonia, Hepatitis B) submitted through normal claims process
- Zostavax, Tdap, Hep A for Medicare submitted through 3rd party vendor

Medicare part D

- Certain vaccines are considered Drugs and covered under part D
- To bill Medicare part D use www.mytransactRX.com
- Allows to check coverage of patients, print out proof, and submit claim through portal and then direct deposit to account
- Check for Zostavax, Tdap, Hep A
- Limited if patient not covered under drug plan or information not up to date
- Advisable to use Advanced Beneficiary Notice for vaccines such as Prevnar, Tdap Hep A and Zostavax.
- Medicare strict on coverage guidelines and if patient has received vaccine but does not remember then claim will not be paid, ABN protects provider and can allow reimbursement from patient

Zostavax commercial

- Checkcoveragenow.com
- Similar to transactRX
- Can look at benefits and show to patient
- Submit through normal claims process

Billing examples

- Patient comes in only for high dose flu shot, Medicare or Medicare advantage
  - No physician visit
  - Bill 90662 and G0008
- If see physician for visit then bill:
  - E/M code appropriate level such as 99213-25 G0008-59 and 90662-59
  - Do not use 99211 and vaccines unless patient is specifically having a separate service such as blood pressure adjustment etc

More examples

- Patient comes in for Flu, Hep B and Pneumonia with Medicare
  - G0008,90662,G0009,90732,G0010,90746
- If commercial then bill:
  - 90471,90686(quadrivalent),90472 for 2 units, 90732,90746
- Again if with E/M then modifier 25 on E/M and modifier 59 on each administration and each vaccine

More examples

- Flu, pneumonia and hep B with other vaccines
  - Patient with pneumonia and zostavax
  - Medicare G0009,90732,90472,90736
  - Commercial 99471,90472,90732,90736
- Flu, pneumonia and zostavax
  - Medicare G0008,90662,G0009,90732,90472,90736
  - Commercial 90471,90472 2 units,90732,90736,90685

Questions?

MOC question

- A 62 year old male, has never been vaccinated, presents to your office in October with a history of HIV, diabetes, heart disease, and COPD. He actively smokes and is planning to visit his daughter who gave birth to a healthy baby girl, currently 3 months old. He reports allergy to eggs and only develops mild hives. What vaccines would you advise him to receive?
  - A. No vaccines because he has no risk factors
  - B. Tdap, Prevnar, Hep A, Hep B, Zostavax, Menactra, and annual Influenza
  - C. Prevnar only
  - D. Influenza only
  - E. Bexsero only

MOC answer

- Correct Answer: B
- The patient has multiple indications and risk factors for multiple vaccines, which can be given at the same visit. Given the patients age, he should receive the zostavax. The patient has HIV which is an indication for Menactra, Hepatitis A and B, and pneumonia. Bexsero has not been indicated for HIV infection as only serotype A,C, W, Y have been seen as increased risk in HIV population, not type B. The patient also has heart and lung disease, which also suggests the need for pneumonia vaccine and the first dose should be Prevnar-13 with Pneumovax-23 the following year and 5 years after. The patient has Diabetes which is an indication for Hepatitis B, and Pneumonia vaccine. Tdap is indicated for all adults, especially if potential exposure to a newborn. Annual flu shot is indicated for all patients and hives from eggs is not a contraindication to the vaccine.
- Citation: CDC vaccine schedule