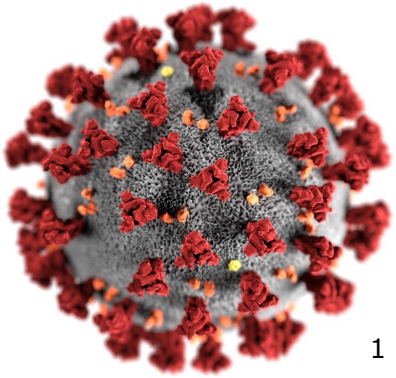
Immunization 101

Laurie Courtney MSN, RN
Immunization Nurse Manager
Massachusetts Department Of Public Health
Immunization Division



Presenter Disclosure Information

I, Laurie Courtney, have been asked to disclose any relevant financial relationships with ACCME-defined commercial entities that are either providing financial support for this program or whose products or services are mentioned during this presentation.

I have no relevant financial relationships to disclose.

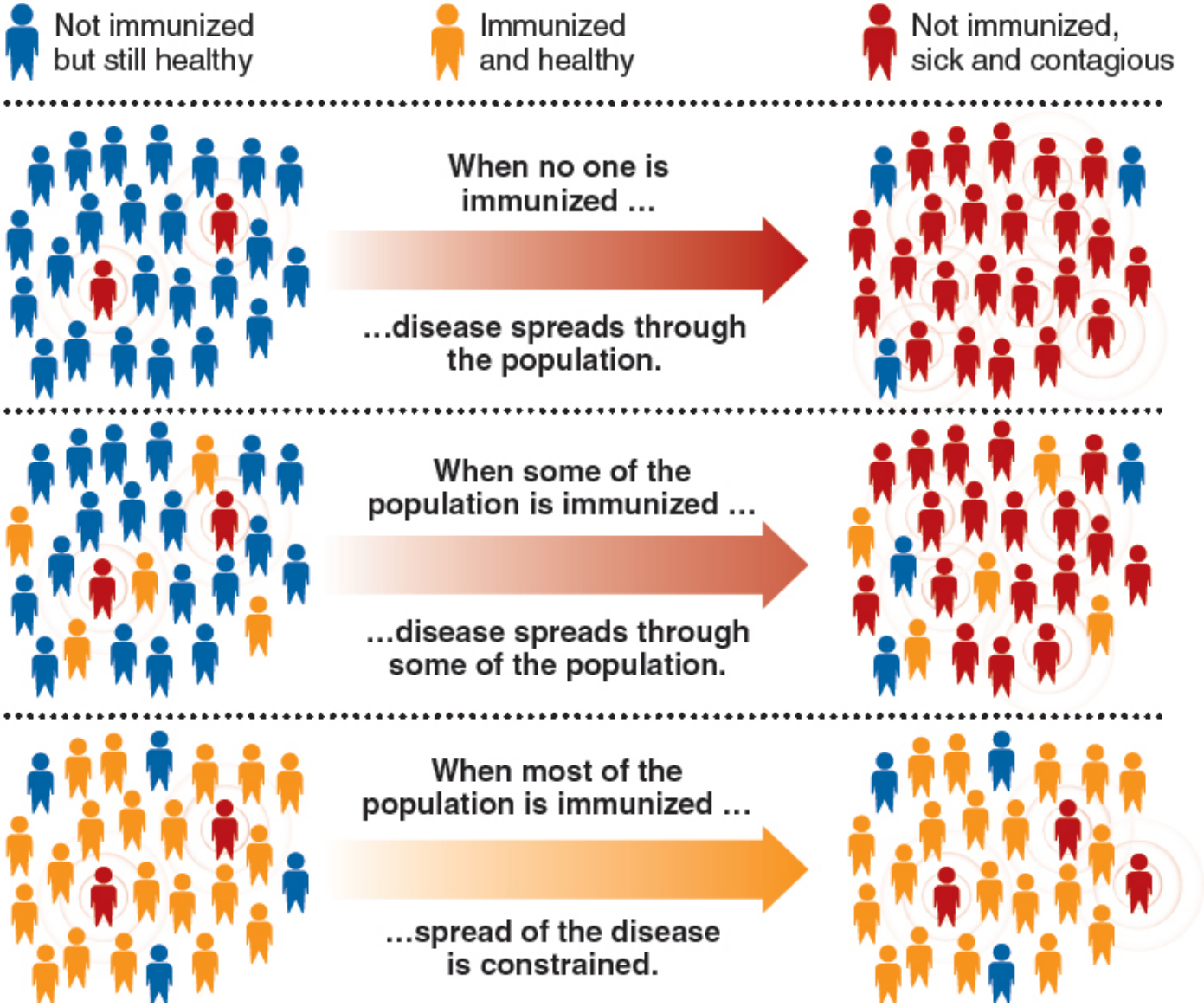
I may discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration, but in accordance with ACIP recommendations

Outline

- Principles of vaccination
- 2021 Immunization schedules
- Vaccination and the COVID-19 pandemic
- Vaccine safety and adverse events reporting
- COVID-19 guidance
- Resources

Principles of vaccination

Community Immunity/Herd Immunity



https://www.mlive.com/news/2014/12/how_do_vaccinations_work_the_s.html

Types of Immunity

- Passive Immunity
  - Produced by one animal or human and transferred to another
  - Immediate, temporary protection
  - Maternal antibodies
  - Blood products, IG, plasma
  - Antitoxin
  - Monoclonal antibodies
- Active Immunity
  - Protection produced by a person's own immune system
  - Lasts for many years, often for a lifetime
  - Survive infection
  - Vaccination

https://www.vaccines.gov/basics/types

Types of Vaccines

- Live-attenuated vaccines
  MMR, LAIV, Varicella, oral polio, rotavirus, BCG
- Inactivated vaccines
  Hep A, IIV, IPV, rabies
- Subunit, recombinant, polysaccharide, and conjugate vaccines
  PPSV23, PCV13, Hep B, MenACWY/B, Shingrix, HPV, Hib, Pertussis
- Toxoid vaccines
  DTaP, Tdap, Td
- Messenger RNA (mRNA) vaccines
  COVID-19
- Viral vector vaccines
  COVID-19

https://www.vaccines.gov/basics/types

Timing and Spacing of Vaccines

- Refer to ACIP General Best Practice Guidelines
  - Guidelines
  - Minimum age and interval tables
  - Table of combination vaccines
  - Spacing of live and inactivated antigens
  - Spacing of antibody-containing products and vaccines

https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Minimum Interval Table

Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines[1,2,3,4]				
Vaccine and dose number	**Recommended age for this dose**	**Minimum age for this dose**	**Recommended interval to next dose**	**Minimum interval to next dose**
Diphtheria-tetanus-acellular pertussis (DTaP)-1[5]	2 months	6 weeks	8 weeks	4 weeks
DTaP-2	4 months	10 weeks	8 weeks	4 weeks
DTaP-3	6 months	14 weeks	6-12 months[6]	6 months[6]
DTaP-4	15-18 months	15 months[6]	3 years	6 months
DTaP-5[7]	4-6 years	4 years	—	—
Haemophilus influenzae type b (Hib)-1[8]	2 months	6 weeks	8 weeks	4 weeks
Hib-2	4 months	10 weeks	8 weeks	4 weeks
Hib-3[9]	6 months	14 weeks	6-9 months	8 weeks
Hib-4	12-15 months	12 months	—	—
Hepatitis A (HepA)-1[5]	12-23 months	12 months	6-18 months	6 months
HepA-2	≥18 months	18 months	—	—
Hepatitis B (HepB)-1[10]	Birth	Birth	4 weeks-4 months	4 weeks
HepB-2	1-2 months	4 weeks	8 weeks-17 months	8 weeks
HepB-3[11]	6-18 months	24 weeks	—	—
Herpes zoster Live (ZVL)[12]	≥60 years	60 years[13]	—	—
Herpes zoster Recombinant (RZV)-1	≥50 years	50 years[14]	2-6 months	4 weeks
RZV-2	≥50 years (+2-6 months)	50 years	—	—
Human papillomavirus (HPV) – Two-Dose Series[15]				
HPV-1	11-12 years	9 years	6 months	5 months
HPV-2	11-12 years (+ 6 months)	9 years (+ 5 months)[16]	—	—

https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval-table.pdf

Timing and Spacing of Vaccines

TABLE 3-3. Guidelines for spacing of live and inactivated antigens

Antigen combination	Recommended minimum interval between doses
Two or more inactivated[a],[b]	May be administered simultaneously or at any interval between doses
Inactivated and live[c]	May be administered simultaneously or at any interval between doses
Two or more live injectable[c]	28 days minimum interval, if not administered simultaneously

(a) Certain experts suggest a 28-day interval between tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine and tetravalent meningococcal conjugate vaccine if they are not administered simultaneously.

(b) In persons with functional or anatomic asplenia, MCV-D and PCV13 should not be administered simultaneously and should be spaced by 4 weeks. Likewise for persons with immunosuppressive high-risk conditions indicated for PCV13 and PPSV23, PCV13 should be administered first, and PPSV23 should be administered no earlier than 8 weeks later. For persons 65 years old or older indicated for PCV13 and PPSV23, PCV13 should be administered first and PPSV23 should be administered 6-12 months later.

(c) The live oral vaccines Ty21a typhoid vaccine and rotavirus vaccine may be administered simultaneously with or at any interval before or after inactivated or live injectable vaccines.

https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Timing and Spacing of COVID-19 Vaccine and Other Vaccines

Spacing of COVID-19 Vaccine and other vaccines

- Alone, with a minimum interval of 14 days before or after administration of any other vaccine
- Shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks, or to avoid barriers/delays
- If administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine

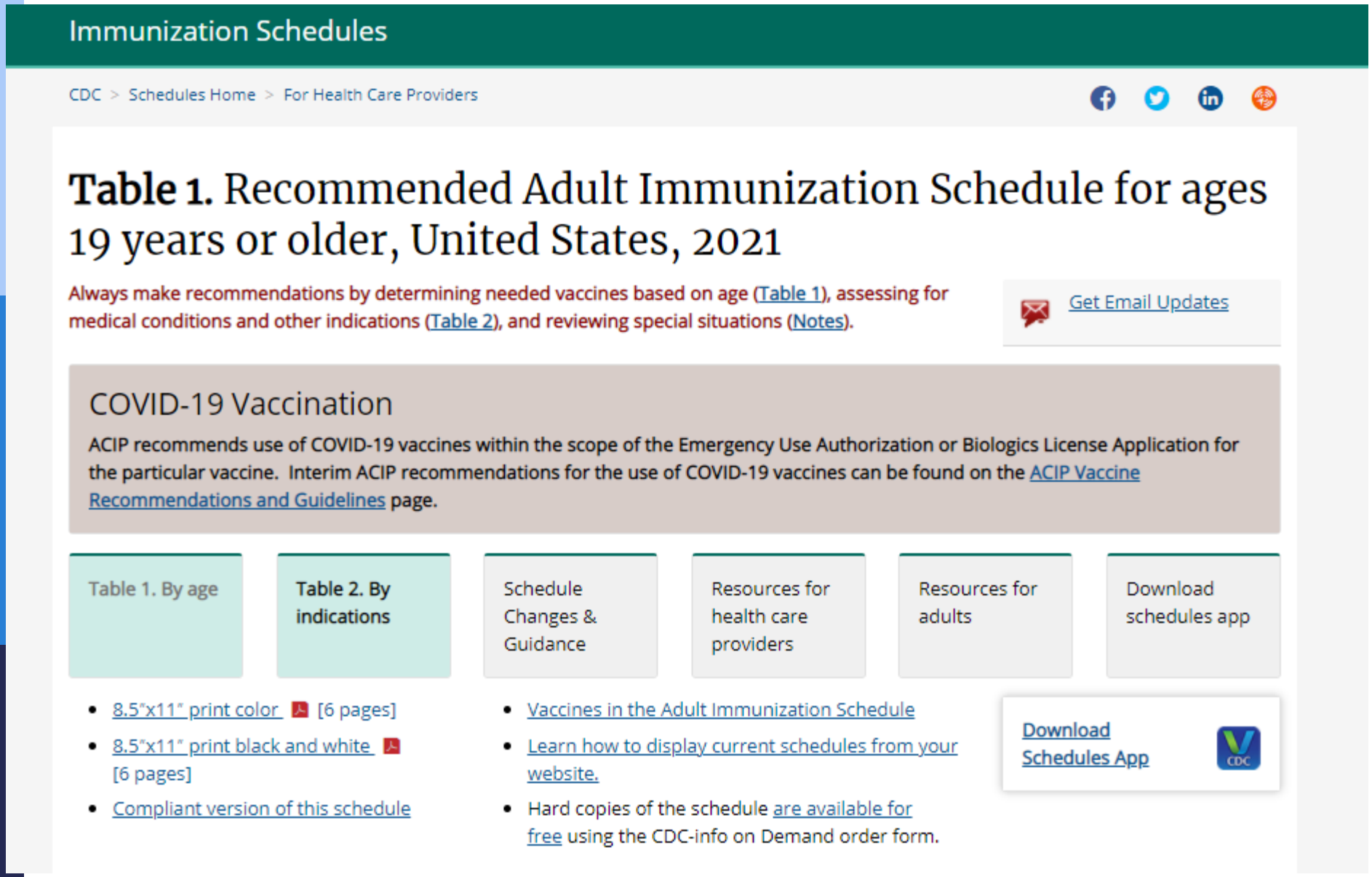
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Immunization schedules

2021 Recommended Adult Immunization Schedules for Persons 19 Years or Older

MMWR Feb 12, 2021: 70(6);193-196

Available at:
https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html (CDC site, schedule with live links)
https://www.cdc.gov/mmwr/volumes/70/wr/mm7006a2.htm
https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7006a2-H.pdf


Immunization Schedules
CDC > Schedules Home > For Health Care Providers
Table 1. Recommended Adult Immunization Schedule for ages 19 years or older, United States, 2021
Always make recommendations by determining needed vaccines based on age (Table 1), assessing for medical conditions and other indications (Table 2), and reviewing special situations (Notes).
Get Email Updates
COVID-19 Vaccination
ACIP recommends use of COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine. Interim ACIP recommendations for the use of COVID-19 vaccines can be found on the ACIP Vaccine Recommendations and Guidelines page.
Table 1. By age
Table 2. By indications
Schedule Changes & Guidance
Resources for health care providers
Resources for adults
Download schedules app
8.5"x11" print color [6 pages]
8.5"x11" print black and white [6 pages]
Compliant version of this schedule
Vaccines in the Adult Immunization Schedule
Learn how to display current schedules from your website.
Hard copies of the schedule are available for free using the CDC-info on Demand order form.
Download Schedules App

Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes)					
	1 dose Tdap, then Td or Tdap booster every 10 years					
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)					
Varicella (VAR)	2 doses (if born in 1980 or later)				2 doses	
Zoster recombinant (RZV)				2 doses		
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years				
Pneumococcal conjugate (PCV13)	1 dose					1 dose
Pneumococcal polysaccharide (PPSV23)	1 or 2 doses depending on indication					1 dose
Hepatitis A (HepA)	2 or 3 doses depending on vaccine					
Hepatitis B (HepB)	2 or 3 doses depending on vaccine					
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, see notes for booster recommendations					
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations					
	19 through 23 years					
Haemophilus influenzae type b (Hib)	1 or 3 doses depending on indication					

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Administer recommended vaccines if vaccination history is incomplete or unknown. Do not restart or add doses to vaccine series if there are extended intervals between doses. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

Recommended Adult Immunization Schedule
for ages 19 years or older

UNITED STATES
2021

How to use the adult immunization schedule

1 Determine recommended vaccinations by age **(Table 1)**

2 Assess need for additional recommended vaccinations by medical condition and other indications **(Table 2)**

3 Review vaccine types, frequencies, and intervals and considerations for special situations **(Notes)**

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/acip) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American College of Physicians (www.acponline.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), American College of Nurse-Midwives (www.midwife.org), and American Academy of Physician Assistants (www.aapa.org).

Vaccines in the Adult Immunization Schedule*

Vaccines	Abbreviations	Trade names
Haemophilus influenzae type b vaccine	Hib	ActHIB® Hiberix® PedvaxHIB®
Hepatitis A vaccine	HepA	Havrix® Vaqta®
Hepatitis A and hepatitis B vaccine	HepA-HepB	Twinrix®
Hepatitis B vaccine	HepB	Engerix-B® Recombivax HB® Heplisav-B®
Human papillomavirus vaccine	HPV	Gardasil 9®
Influenza vaccine (inactivated)	IIV	Many brands
Influenza vaccine (live, attenuated)	LAIV4	FluMist® Quadrivalent
Influenza vaccine (recombinant)	RIV4	Flublok® Quadrivalent
Measles, mumps, and rubella vaccine	MMR	M-M-R II®
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-D MenACWY-CRM MenACWY-TT	Menactra® Menveo® MenQuadfi®
Meningococcal serogroup B vaccine	MenB-4C MenB-FHbp	Bexsero® Trumenba®
Pneumococcal 13-valent conjugate vaccine	PCV13	Prevnar 13®
Pneumococcal 23-valent polysaccharide vaccine	PPSV23	Pneumovax 23®
Tetanus and diphtheria toxoids	Td	Tenivac® Tdvax™
Tetanus and diphtheria toxoids and acellular pertussis vaccine	Tdap	Adacel® Boostrix®
Varicella vaccine	VAR	Varivax®
Zoster vaccine, recombinant	RZV	Shingrix

*Administer recommended vaccines if vaccination history is incomplete or unknown. Do not restart or add doses to vaccine series if there are extended intervals between doses. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to the local or state health department
- Clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System at www.vaers.hhs.gov or 800-822-7967

Injury claims

All vaccines included in the adult immunization schedule except pneumococcal 23-valent polysaccharide (PPSV23) and zoster (RZV) vaccines are covered by the Vaccine Injury Compensation Program. Information on how to file a vaccine injury claim is available at www.hrsa.gov/vaccinecompensation.

Questions or comments

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html.

Helpful information

- *Complete ACIP recommendations:* www.cdc.gov/vaccines/hcp/acip-recs/index.html
- *General Best Practice Guidelines for Immunization* (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/vaccines/pubs/surv-manual
- Travel vaccine recommendations: www.cdc.gov/travel
- Recommended Child and Adolescent Immunization Schedule, United States, 2021: www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html
- ACIP Shared Clinical Decision-Making Recommendations www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CS310021-B

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2021

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
Influenza inactivated (IIV) or **Influenza recombinant** (RIV4)	1 dose annually			
or		or		
Influenza live, attenuated (LAIV4)	1 dose annually			
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes)			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV)			2 doses	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal conjugate (PCV13)	1 dose			1 dose
Pneumococcal polysaccharide (PPSV23)	1 or 2 doses depending on indication			1 dose
Hepatitis A (HepA)	2 or 3 doses depending on vaccine			
Hepatitis B (HepB)	2 or 3 doses depending on vaccine			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, see notes for booster recommendations			
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations			
	19 through 23 years			
***Haemophilus influenzae* type b** (Hib)	1 or 3 doses depending on indication			

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

Recommended vaccination for adults with an additional risk factor or another indication

Recommended vaccination based on shared clinical decision-making

No recommendation/ Not applicable

Table 2 Recommended Adult Immunization Schedule by Medical Condition and Other Indications, United States, 2021

Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count		Asplenia, complement deficiencies	End-stage renal disease; or on hemodialysis	Heart or lung disease, alcoholism[1]	Chronic liver disease	Diabetes	Health care personnel[2]	Men who have sex with men
			<200 mm³	≥200 mm³							
IIV or RIV4	1 dose annually										
or										or	
LAIV4	Not Recommended						Precaution			1 dose annually	
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years									
MMR	Not Recommended*	Not Recommended	1 or 2 doses depending on indication								
VAR	Not Recommended*	Not Recommended		2 doses							
RZV		2 doses at age ≥50 years									
HPV	Not Recommended*	3 doses through age 26 years	2 or 3 doses through age 26 years depending on age at initial vaccination or condition								
PCV13	1 dose										
PPSV23	1, 2, or 3 doses depending on age and indication										
HepA	2 or 3 doses depending on vaccine										
HepB	2, 3, or 4 doses depending on vaccine or condition								<60 years		
									≥60 years		
MenACWY	1 or 2 doses depending on indication, see notes for booster recommendations										
MenB	Precaution	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib		3 doses HSCT[3] recipients only			1 dose						

- Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection
- Recommended vaccination for adults with an additional risk factor or another indication
- Precaution—vaccination might be indicated if benefit of protection outweighs risk of adverse reaction
- Recommended vaccination based on shared clinical decision-making
- Not recommended/ contraindicated—vaccine should not be administered.
- No recommendation/ Not applicable

*Vaccinate after pregnancy.

1. Precaution for LAIV4 does not apply to alcoholism. **2.** See notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations. **3.** Hematopoietic stem cell transplant.

Shared Clinical Decision-Making

- Shared clinical decision-making (SCDM) vaccinations are not recommended for everyone in a particular age group or everyone in an identifiable risk group
- SCDM recommendations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian
- The key distinction between routine, catch-up, and risk-based recommendations and SCDM recommendations is the default decision to vaccinate
- ACIP makes SCDM recommendations when individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts

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

Notes

Recommended Adult Immunization Schedule for ages 19 years or older, United States, 2021

For vaccine recommendations for persons 18 years of age or younger, see the Recommended Child/Adolescent Immunization Schedule.

Additional Information

COVID-19 Vaccination

ACIP recommends use of COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine. Interim ACIP recommendations for the use of COVID-19 vaccines can be found at www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html

Haemophilus influenzae type b vaccination

Special situations

- **Anatomical or functional asplenia (including sickle cell disease):** 1 dose if previously did not receive Hib; if elective splenectomy, 1 dose, preferably at least 14 days before splenectomy
- **Hematopoietic stem cell transplant (HSCT):** 3-dose series 4 weeks apart starting 6–12 months after successful transplant, regardless of Hib vaccination history

Hepatitis A vaccination

Routine vaccination

- **Not at risk but want protection from hepatitis A** (identification of risk factor not required): 2-dose series HepA (Havrix 6–12 months apart or Vaqta 6–18 months apart [minimum interval: 6 months]) or 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 5 months])

Special situations

- **At risk for hepatitis A virus infection:** 2-dose series HepA or 3-dose series HepA-HepB as above
  - **Chronic liver disease** (e.g., persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
  - **HIV infection**
  - **Men who have sex with men**
  - **Injection or noninjection drug use**
  - **Persons experiencing homelessness**
  - **Work with hepatitis A virus** in research laboratory or with nonhuman primates with hepatitis A virus infection
  - **Travel in countries with high or intermediate endemic hepatitis A** (HepA-HepB [Twinrix] may be administered on an accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months)
  - **Close, personal contact with international adoptee** (e.g., household or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A (administer dose 1 as soon as adoption is planned, at least 2 weeks before adoptee's arrival)
  - **Pregnancy** if at risk for infection or severe outcome from infection during pregnancy
  - **Settings for exposure, including** health care settings targeting services to injection or noninjection drug users or group homes and nonresidential day care facilities for developmentally disabled persons (individual risk factor screening not required)

Hepatitis B vaccination

Routine vaccination

- **Not at risk but want protection from hepatitis B** (identification of risk factor not required): 2- or 3-dose series (2-dose series Heplisav-B at least 4 weeks apart [2-dose series HepB only applies when 2 doses of Heplisav-B are used at least 4 weeks apart] or 3-dose series Engerix-B or Recombivax HB at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 8 weeks / dose 1 to dose 3: 16 weeks]) or 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 5 months])

Special situations

- **At risk for hepatitis B virus infection:** 2-dose (Heplisav-B) or 3-dose (Engerix-B, Recombivax HB) series or 3-dose series HepA-HepB (Twinrix) as above
  - **Chronic liver disease** (e.g., persons with hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice upper limit of normal)
  - **HIV infection**
  - **Sexual exposure risk** (e.g., sex partners of hepatitis B surface antigen [HBsAg]-positive persons; sexually active persons not in mutually monogamous relationships; persons seeking evaluation or treatment for a sexually transmitted infection; men who have sex with men)
  - **Current or recent injection drug use**
  - **Percutaneous or mucosal risk for exposure to blood** (e.g., household contacts of HBsAg-positive persons; residents and staff of facilities for developmentally disabled persons; health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids; hemodialysis, peritoneal dialysis, home dialysis, and predialysis patients; persons with diabetes mellitus age younger than 60 years, shared clinical decision-making for persons age 60 years or older)
  - **Incarcerated persons**
  - **Travel in countries with high or intermediate endemic hepatitis B**
  - **Pregnancy** if at risk for infection or severe outcome from infection during pregnancy (Heplisav-B not currently recommended due to lack of safety data in pregnant women)

Human papillomavirus vaccination

Routine vaccination

- **HPV vaccination recommended for all persons through age 26 years:** 2- or 3-dose series depending on age at initial vaccination or condition:
  - **Age 15 years or older at initial vaccination:** 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 12 weeks / dose 1 to dose 3: 5 months; repeat dose if administered too soon)
  - **Age 9–14 years at initial vaccination and received 1 dose or 2 doses less than 5 months apart:** 1 additional dose
  - **Age 9–14 years at initial vaccination and received 2 doses at least 5 months apart:** HPV vaccination series complete, no additional dose needed
- **Interrupted schedules:** If vaccination schedule is interrupted, the series does not need to be restarted
- **No additional dose recommended after completing series with recommended dosing intervals using any HPV vaccine**

Shared clinical decision-making

- **Some adults age 27–45 years: Based on shared clinical decision-making,** 2- or 3-dose series as above

Special situations

- **Age ranges recommended above for routine and catch-up vaccination or shared clinical decision-making also apply in special situations**

2021 Changes

- MenQuadfi added to the list of meningococcal ACWY vaccines; added to relevant sections
- Removed reference to zoster vaccine live (ZVL) - no longer on the market
- American Academy of Physician Assistants (AAPA) now an approving partner
- Added links to FAQs for ACIP Shared Clinical Decision-Making Recommendations
- HepA notes include accelerated Twinrix dosing schedule for travel in countries with high or intermediate endemic hepatitis A
- HepB notes include shared clinical decision-making for HepB vaccines in persons with diabetes 60 years or older
- HPV notes include some clarifying notes
- Influenza notes added clarifying language regarding allergies; a bullet added about LAIV4 and antivirals
- MenB notes: added language about use in outbreak setting
- Pneumococcal notes: updated the link for routine vaccination in persons aged ≥65; bullets on PCV13 and PPSV23 timing
- Tdap notes: updated the information for wound management
- Zoster notes: removed reference to prior receipt of ZVL

https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html#adult

COVID-19 Vaccination Updates (Interim)

Pfizer-BioNTech COVID-19 vaccine

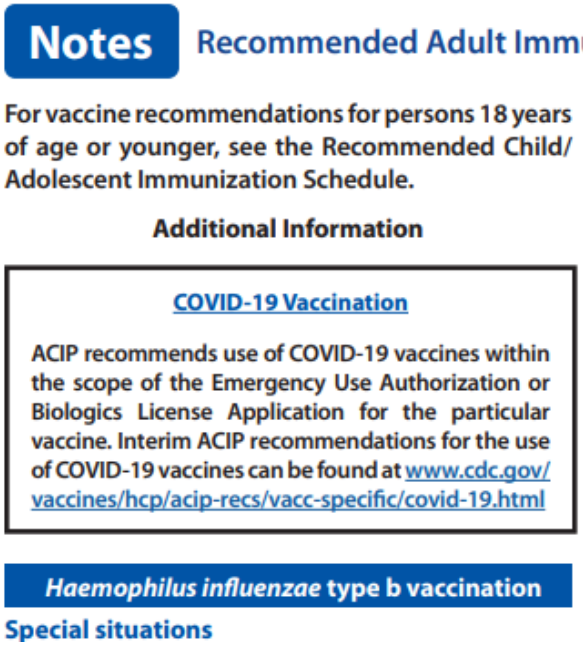
- Interim recommendation for use in persons aged ≥16 years for the prevention of coronavirus disease 2019 (COVID-19)

Moderna COVID-19 vaccine

- Interim recommendation for use in persons aged ≥18 years for the prevention of coronavirus disease 2019 (COVID-19)

Janssen COVID-19 vaccine

- Interim recommendation for use in persons aged ≥18 years for the prevention of coronavirus disease 2019 (COVID-19)



1. Oliver S et al.,The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1922-1924. DOI: http://dx.doi.org/10.15585/mmwr.mm6950e2external icon
2. Oliver S, et al, The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020. *MMWR Morb Mortal Wkly Rep* 2021;69:1653-1656. DOI: http://dx.doi.org/10.15585/mmwr.mm695152e1
3. Oliver SE, Gargano JW, Scobie H, et al, The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021. *MMWR Morb Mortal Wkly Rep*. ePub: 2 March 2021.

https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html

Vaccination and COVID-19 Pandemic

CDC Interim Guidance for Immunization Services During COVID-19 Pandemic

- Vaccination is an essential medical service adolescents, and adults, ideally in the medical home.
- Administer all due or overdue vaccines routine immunization schedule during the same visit.

Picture from: SOTIReport_2021_FINAL.pdf (vaccinateyourfamily.org)

- Implement strategies to catch all patients up on vaccines.
- Includes guidance for the safe delivery of vaccines (e.g., use of personal protective equipment, physical distancing)

https://www.cdc.gov/vaccines/pandemic-guidance/index.html
slide adapted from CDC CIIW 3.3.2021:
https://www2.cdc.gov/vaccines/ed/ciinc/archives/21/downloads/3_3/CDC_Schedule%20Update_Child.Adolescent_Adult.pdf

Routine Immunization During Pandemic

- The COVID-19 pandemic is changing rapidly and requires different strategies to maintain clinical preventive services, including immunization.
- Some public health measures to control the pandemic have resulted in fewer vaccine doses administered.
- Declines in vaccination coverage increase the risk for outbreaks of vaccine-preventable diseases.
- Essential to continue routine immunization during the pandemic:
  - All individuals—children, adolescents, and adults (including pregnant women) need to stay up to date on all recommended vaccines.

Bramer CA et al, Decline in Child Vaccination Coverage During the COVID-19 Pandemic — Michigan Care Improvement Registry, May 2016–May 2020. *MMWR* Morb Mortal Wkly Rep 2020;69:630–631. https://www.cdc.gov/mmwr/volumes/69/wr/mm6920e1.htm#contribAff

Interim Guidance for Routine and Influenza Immunization Services During the COVID-19 Pandemic https://www.cdc.gov/vaccines/pandemic-guidance/index.html

Vaccination Recommendations during the COVID-19 Pandemic https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html

slide adapted from CDC CIIW 3.3.2021:
https://www2.cdc.gov/vaccines/ed/ciinc/archives/21/downloads/3_3/CDC_Schedule%20Update_Child.Adolescent_Adult.pdf

Tips to Increase Immunization Rates

Incorporate measures to improve vaccination rates

- Strong routine recommendation for vaccines
- Presumptive approach
- Reminder/recall
- Standing orders/vaccine only visits
- Speak from personal experience
- Provide information in foreign languages
- Avoid "missed opportunities"

What you say matters.
How you say it matters even more!

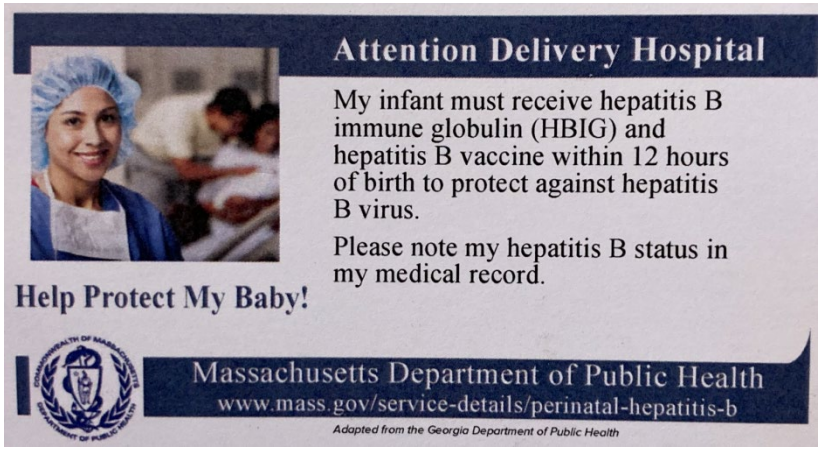
Hepatitis B Birth Dose

- ACIP recommendation for ALL babies, within 24 hours of birth
  - Infants <2,000 grams, born to HBsAg negative mothers: administer 1 dose at chronological age 1 month or hospital discharge (whichever is earlier)
- COVID-19
  - More births by an unplanned provider
  - More births at an unplanned facility
  - Records not always available
- Important safety net!!

https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF

Perinatal Hepatitis B Prevention Program

- Interim guidance to prevent mother-to-child transmission of hepatitis B during the COVID-19 pandemic and related disruptions in services
- OB & pedi staff should prioritize ACIP recommendations for prevention of mother-to-child transmission of HBV infection
- HBIG and hepatitis B vaccine at birth; timely completion of hep B vaccine series; PVST



MAIC 2021

https://www.cdc.gov/vaccines/pandemic-guidance/index.htm
https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm
https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html#adult

Interim Guidance for Routine and Influenza Immunization Services During the COVID-19 Pandemic

The COVID-19 pandemic has caused healthcare providers to change how they operate to continue to provide essential services to patients. Ensuring immunization services are maintained or reinitiated is essential for protecting individuals and communities from vaccine-preventable diseases and outbreaks and reducing the burden of respiratory illness during the upcoming influenza season.

The following are a collection of federal resources designed to guide vaccine planning during the COVID-19 pandemic:

10/20/2020:

- Clarifications added to the "Purpose of the Guidance".
- Paragraphs added to "Additional Considerations for Influenza Vaccination" subsection.
- Updates made to "Vaccination of Persons with Suspected or Confirmed COVID-19 or Persons with a Known Exposure". This section is now titled "Deferring Routine Vaccination Visits for Persons with Suspected or Confirmed COVID-19 Who Are in Isolation or Persons with a Known COVID-19 Exposure Who Are in Quarantine".
- New section added titled, "Additional Considerations for Influenza Vaccination of Persons in Healthcare Facilities and Congregate Settings During the COVID-19 Pandemic"

The COVID-19 pandemic has caused healthcare providers to change how they operate to continue to provide essential services to patients. Ensuring immunization services are maintained or reinitiated is essential for protecting individuals and communities from vaccine-preventable diseases and outbreaks and reducing the burden of respiratory illness during the upcoming influenza season.

The following are a collection of federal resources designed to guide vaccine planning during the COVID-19 pandemic:

COVID-19 Vaccination Provider Requirements and Support

Vaccination providers participating in the COVID-19 Vaccination Program are required to follow the guidance for the safe delivery of vaccination services during the COVID-19 pandemic outlined on this website. Find information about requirements and resources on enrollment, ordering, and data in support of COVID-19 vaccination.

Find requirements & resources

Get Email Updates

To receive email updates about this page, enter your email address:

Email Address

What's this?

Submit

https://www.cdc.gov/vaccines/pandemic-guidance/index.html

Delivering Vaccines Safely During COVID-19 Pandemic

- Assess the vaccination status of all patients across the life span at every health care visit.
- Administer routinely recommended vaccines to children, adolescents, and adults (including pregnant women).
- Delay vaccination for persons with suspected or confirmed COVID-19.
- Follow CDC guidance to prevent the spread of COVID-19 in health care settings
- Implement effective strategies for catch-up vaccination.
- Communicate with patients/families about how they can be safely vaccinated during the pandemic.

https://www.cdc.gov/vaccines/pandemic-guidance/index.html

slide adapted from CDC CIIW 3.3.2021:
https://www2.cdc.gov/vaccines/ed/ciinc/archives/21/downloads/3_3/CDC_Schedule%20Update_Child.Adolescent_Adult.pdf

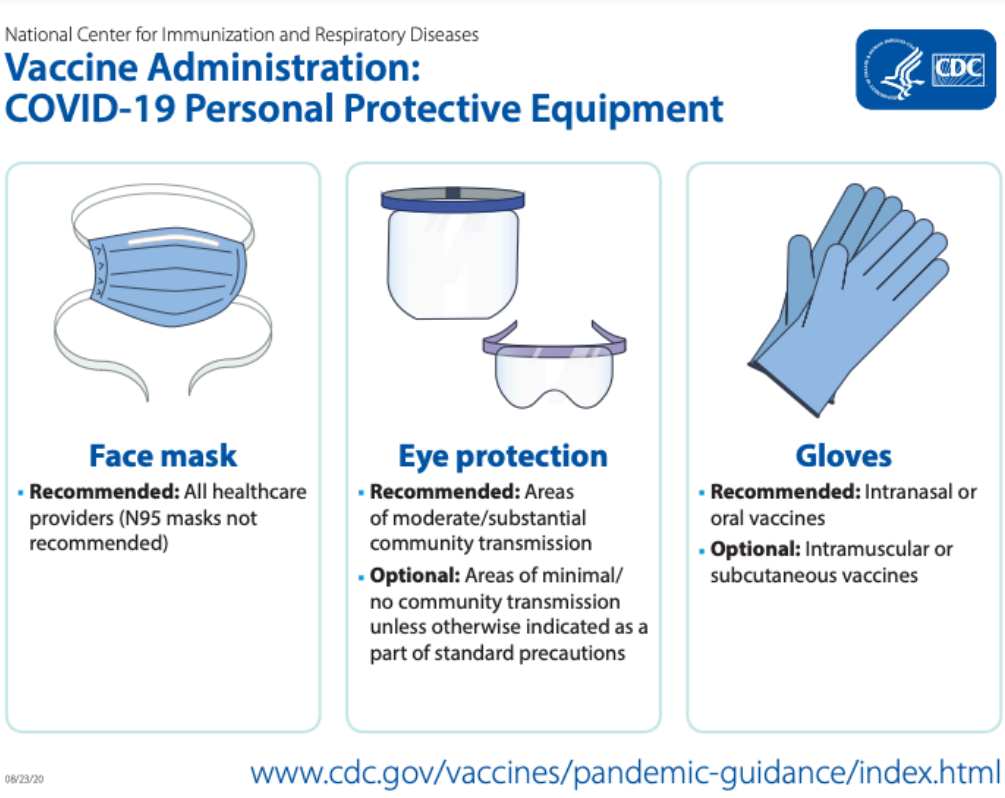
Delivering Vaccines Safely During COVID-19 Pandemic

- Minimize chances for exposures:
  - Screen for COVID-19 exposure and symptoms
  - Limit physical contact with patients at triage
  - Implement use of cloth face coverings in persons >2 years
  - Ensure adherence to respiratory hygiene, cough etiquette, and hand hygiene
- Implement and enforce infection prevention and control procedures:
  - Standard precautions
  - Use of medical face masks
  - Wear gloves when administering intranasal or oral vaccines
  - Eye protection depending on level of community transmission
- Ensure physical distancing:
  - Schedule sick visits and well-child visits during different times of the day
  - Reduce crowding in waiting rooms

https://www.cdc.gov/vaccines/pandemic-guidance/index.html

slide adapted from CDC CIIW 3.3.2021:
https://www2.cdc.gov/vaccines/ed/ciinc/archives/21/downloads/3_3/CDC_Schedule%20Update_Child.Adolescent_Adult.pdf

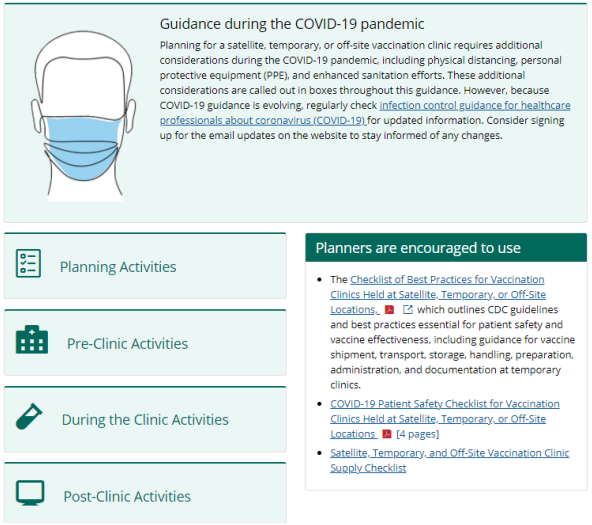
Use Personal Protection Equipment



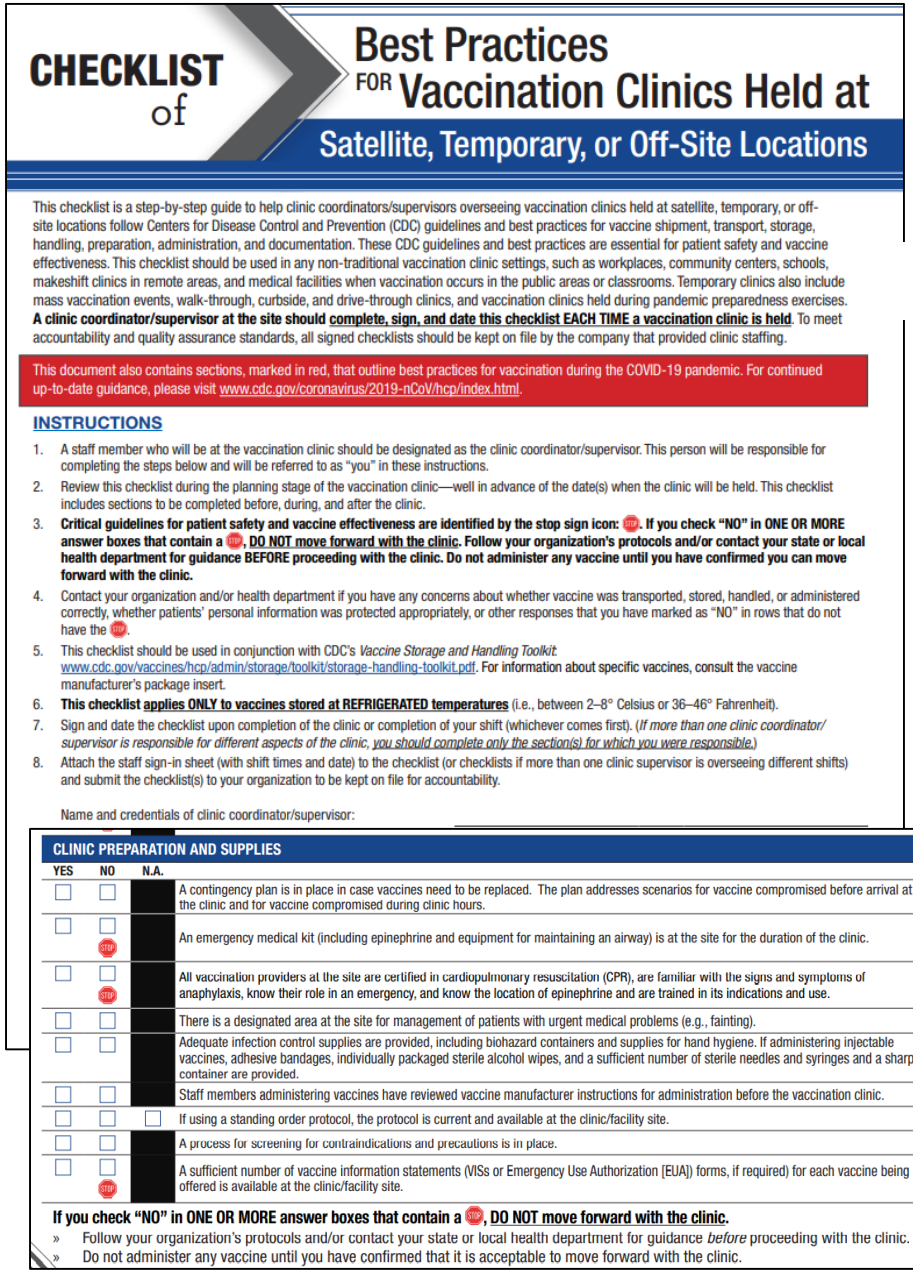
- Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on their hands
- If gloves are worn, they should be changed between patients
- Perform hand hygiene between patients, even if wearing gloves

Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations

- The purpose of the guidance is to assist with jurisdictional planning and implementation of satellite, temporary, or off-site vaccination clinics by public and private vaccination organizations. The guidance also provides information on additional considerations that are required during the COVID-19 pandemic, including physical distancing, PPE, and enhanced sanitation efforts.
- The guidance is broken down into four categories:
  - Planning activities
  - Pre-clinic activities
  - During the clinic activities
  - Post-clinic activities



https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html



CHECKLIST of Best Practices FOR Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations

This checklist is a step-by-step guide to help clinic coordinators/supervisors overseeing vaccination clinics held at satellite, temporary, or off-site locations follow Centers for Disease Control and Prevention (CDC) guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. These CDC guidelines and best practices are essential for patient safety and vaccine effectiveness. This checklist should be used in any non-traditional vaccination clinic settings, such as workplaces, community centers, schools, makeshift clinics in remote areas, and medical facilities when vaccination occurs in the public areas or classrooms. Temporary clinics also include mass vaccination events, walk-through, curbside, and drive-through clinics, and vaccination clinics held during pandemic preparedness exercises. **A clinic coordinator/supervisor at the site should complete, sign, and date this checklist EACH TIME a vaccination clinic is held.** To meet accountability and quality assurance standards, all signed checklists should be kept on file by the company that provided clinic staffing.

This document also contains sections, marked in red, that outline best practices for vaccination during the COVID-19 pandemic. For continued up-to-date guidance, please visit www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html.

INSTRUCTIONS

1. A staff member who will be at the vaccination clinic should be designated as the clinic coordinator/supervisor. This person will be responsible for completing the steps below and will be referred to as "you" in these instructions.
2. Review this checklist during the planning stage of the vaccination clinic—well in advance of the date(s) when the clinic will be held. This checklist includes sections to be completed before, during, and after the clinic.
3. **Critical guidelines for patient safety and vaccine effectiveness are identified by the stop sign icon: STOP. If you check "NO" in ONE OR MORE answer boxes that contain a STOP, DO NOT move forward with the clinic. Follow your organization's protocols and/or contact your state or local health department for guidance BEFORE proceeding with the clinic. Do not administer any vaccine until you have confirmed you can move forward with the clinic.**
4. Contact your organization and/or health department if you have any concerns about whether vaccine was transported, stored, handled, or administered correctly, whether patients' personal information was protected appropriately, or other responses that you have marked as "NO" in rows that do not have the STOP.
5. This checklist should be used in conjunction with CDC's *Vaccine Storage and Handling Toolkit*: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. For information about specific vaccines, consult the vaccine manufacturer's package insert.
6. **This checklist applies ONLY to vaccines stored at REFRIGERATED temperatures** (i.e., between 2–8° Celsius or 36–46° Fahrenheit).
7. Sign and date the checklist upon completion of the clinic or completion of your shift (whichever comes first). (*If more than one clinic coordinator/supervisor is responsible for different aspects of the clinic, you should complete only the section(s) for which you were responsible.*)
8. Attach the staff sign-in sheet (with shift times and date) to the checklist (or checklists if more than one clinic supervisor is overseeing different shifts) and submit the checklist(s) to your organization to be kept on file for accountability.

Name and credentials of clinic coordinator/supervisor: [redacted]

CLINIC PREPARATION AND SUPPLIES

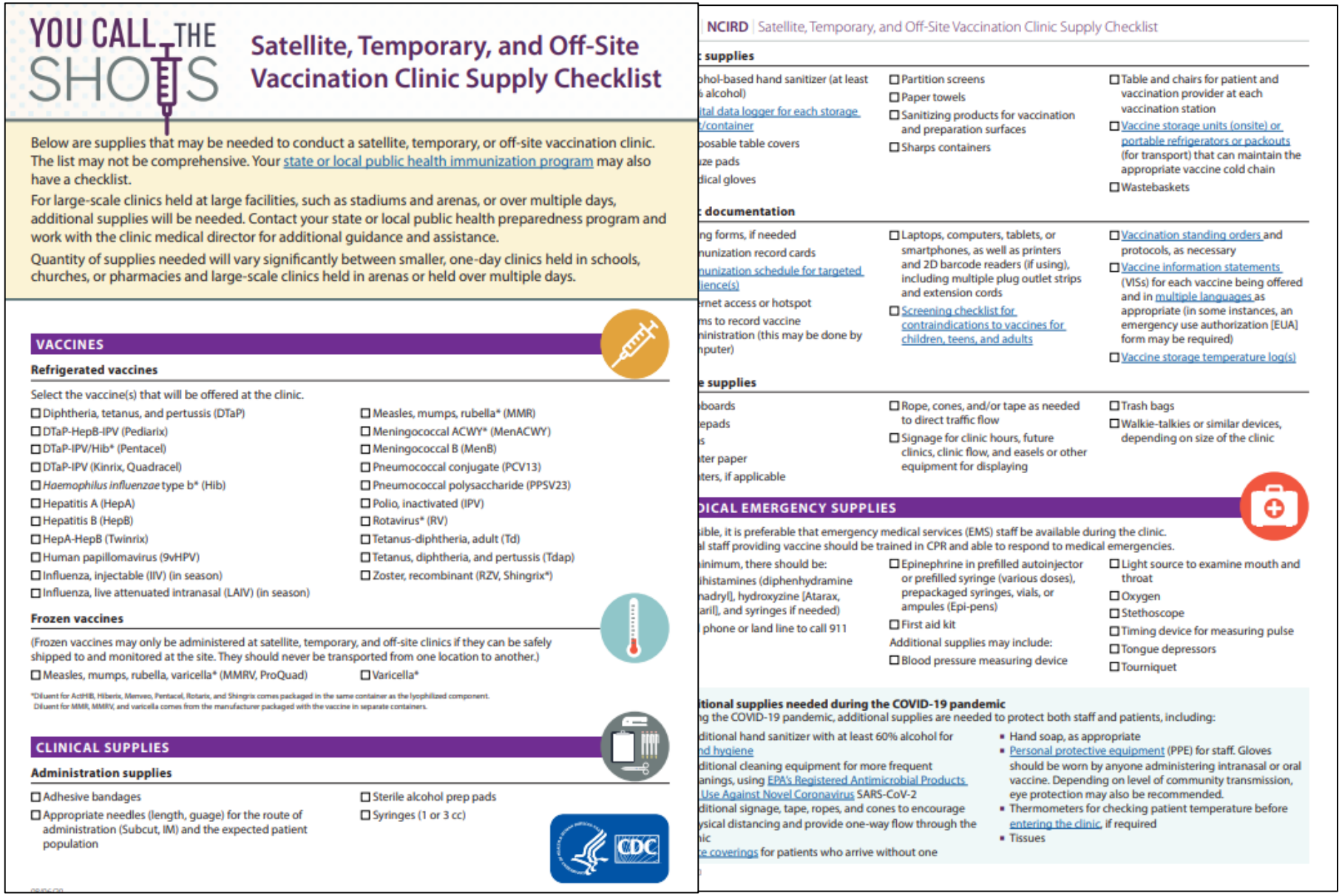
YES	NO	N.A.	
☐	☐	[redacted]	A contingency plan is in place in case vaccines need to be replaced. The plan addresses scenarios for vaccine compromised before arrival at the clinic and for vaccine compromised during clinic hours.
☐	☐ STOP	[redacted]	An emergency medical kit (including epinephrine and equipment for maintaining an airway) is at the site for the duration of the clinic.
☐	☐ STOP	[redacted]	All vaccination providers at the site are certified in cardiopulmonary resuscitation (CPR), are familiar with the signs and symptoms of anaphylaxis, know their role in an emergency, and know the location of epinephrine and are trained in its indications and use.
☐	☐	[redacted]	There is a designated area at the site for management of patients with urgent medical problems (e.g., fainting).
☐	☐	[redacted]	Adequate infection control supplies are provided, including biohazard containers and supplies for hand hygiene. If administering injectable vaccines, adhesive bandages, individually packaged sterile alcohol wipes, and a sufficient number of sterile needles and syringes and a sharps container are provided.
☐	☐	[redacted]	Staff members administering vaccines have reviewed vaccine manufacturer instructions for administration before the vaccination clinic.
☐	☐	☐	If using a standing order protocol, the protocol is current and available at the clinic/facility site.
☐	☐	[redacted]	A process for screening for contraindications and precautions is in place.
☐	☐ STOP	[redacted]	A sufficient number of vaccine information statements (VISs or Emergency Use Authorization [EUA]) forms, if required) for each vaccine being offered is available at the clinic/facility site.

If you check "NO" in ONE OR MORE answer boxes that contain a STOP, DO NOT move forward with the clinic.

» Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.
» Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

- Best Practices Checklist
- Pledge for Organizations Holding Clinics
- Ten Principles for Holding Safe Clinics
- FAQs about checklist and pledge

https://www.cdc.gov/flu/business/hosting-vaccination-clinic.htm
https://www.izsummitpartners.org/content/uploads/2019/02/off-site-vaccination-clinic-checklist.pdf



YOU CALL THE SHOTS

Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist

Below are supplies that may be needed to conduct a satellite, temporary, or off-site vaccination clinic. The list may not be comprehensive. Your state or local public health immunization program may also have a checklist.

For large-scale clinics held at large facilities, such as stadiums and arenas, or over multiple days, additional supplies will be needed. Contact your state or local public health preparedness program and work with the clinic medical director for additional guidance and assistance.

Quantity of supplies needed will vary significantly between smaller, one-day clinics held in schools, churches, or pharmacies and large-scale clinics held in arenas or held over multiple days.

VACCINES

Refrigerated vaccines

Select the vaccine(s) that will be offered at the clinic.

- ☐ Diphtheria, tetanus, and pertussis (DTaP)
- ☐ DTaP-HepB-IPV (Pediarix)
- ☐ DTaP-IPV/Hib* (Pentacel)
- ☐ DTaP-IPV (Kinrix, Quadracel)
- ☐ *Haemophilus influenzae* type b* (Hib)
- ☐ Hepatitis A (HepA)
- ☐ Hepatitis B (HepB)
- ☐ HepA-HepB (Twinrix)
- ☐ Human papillomavirus (9vHPV)
- ☐ Influenza, injectable (IIV) (in season)
- ☐ Influenza, live attenuated intranasal (LAIV) (in season)
- ☐ Measles, mumps, rubella* (MMR)
- ☐ Meningococcal ACWY* (MenACWY)
- ☐ Meningococcal B (MenB)
- ☐ Pneumococcal conjugate (PCV13)
- ☐ Pneumococcal polysaccharide (PPSV23)
- ☐ Polio, inactivated (IPV)
- ☐ Rotavirus* (RV)
- ☐ Tetanus-diphtheria, adult (Td)
- ☐ Tetanus, diphtheria, and pertussis (Tdap)
- ☐ Zoster, recombinant (RZV, Shingrix*)

Frozen vaccines

(Frozen vaccines may only be administered at satellite, temporary, and off-site clinics if they can be safely shipped to and monitored at the site. They should never be transported from one location to another.)

- ☐ Measles, mumps, rubella, varicella* (MMRV, ProQuad)
- ☐ Varicella*

*Diluent for ActHIB, Hiberix, Menveo, Pentacel, Rotarix, and Shingrix comes packaged in the same container as the lyophilized component. Diluent for MMR, MMRV, and varicella comes from the manufacturer packaged with the vaccine in separate containers.

CLINICAL SUPPLIES

Administration supplies

- ☐ Adhesive bandages
- ☐ Appropriate needles (length, guage) for the route of administration (Subcut, IM) and the expected patient population
- ☐ Sterile alcohol prep pads
- ☐ Syringes (1 or 3 cc)

CDC

NCIRD | Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist

supplies

- ☐ Partition screens
- ☐ Paper towels
- ☐ Sanitizing products for vaccination and preparation surfaces
- ☐ Sharps containers
- ☐ Table and chairs for patient and vaccination provider at each vaccination station
- ☐ Vaccine storage units (onsite) or portable refrigerators or packouts (for transport) that can maintain the appropriate vaccine cold chain
- ☐ Wastebaskets

documentation

- ☐ Laptops, computers, tablets, or smartphones, as well as printers and 2D barcode readers (if using), including multiple plug outlet strips and extension cords
- ☐ Screening checklist for contraindications to vaccines for children, teens, and adults
- ☐ Vaccination standing orders and protocols, as necessary
- ☐ Vaccine information statements (VISs) for each vaccine being offered and in multiple languages as appropriate (in some instances, an emergency use authorization [EUA] form may be required)
- ☐ Vaccine storage temperature log(s)

supplies

- ☐ Rope, cones, and/or tape as needed to direct traffic flow
- ☐ Signage for clinic hours, future clinics, clinic flow, and easels or other equipment for displaying
- ☐ Trash bags
- ☐ Walkie-talkies or similar devices, depending on size of the clinic

DICAL EMERGENCY SUPPLIES

ible, it is preferable that emergency medical services (EMS) staff be available during the clinic. l staff providing vaccine should be trained in CPR and able to respond to medical emergencies.

inimum, there should be:

- ☐ Epinephrine in prefilled autoinjector or prefilled syringe (various doses), prepackaged syringes, vials, or ampules (Epi-pens)
- ☐ First aid kit

Additional supplies may include:

- ☐ Blood pressure measuring device
- ☐ Light source to examine mouth and throat
- ☐ Oxygen
- ☐ Stethoscope
- ☐ Timing device for measuring pulse
- ☐ Tongue depressors
- ☐ Tourniquet

tional supplies needed during the COVID-19 pandemic

g the COVID-19 pandemic, additional supplies are needed to protect both staff and patients, including:

- ditional hand sanitizer with at least 60% alcohol for nd hygiene
- ditional cleaning equipment for more frequent anings, using EPA's Registered Antimicrobial Products Use Against Novel Coronavirus SARS-CoV-2
- ditional signage, tape, ropes, and cones to encourage ysical distancing and provide one-way flow through the ic
- e coverings for patients who arrive without one
- Hand soap, as appropriate
- Personal protective equipment (PPE) for staff. Gloves should be worn by anyone administering intranasal or oral vaccine. Depending on level of community transmission, eye protection may also be recommended.
- Thermometers for checking patient temperature before entering the clinic, if required
- Tissues

https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/vaccination-clinic-supply-checklist.html

COVID-19 Vaccine

Patient Safety Checklist for Vaccination Clinics
Held at Satellite, Temporary, or Off-Site Locations

The following checklist is an assessment tool to help clinic coordinators/supervisors prepare for COVID-19 vaccination clinics held at satellite, temporary, or off-site locations. It includes recommended practices that are critical to ensure vaccine recipient safety. Use this checklist before hosting a vaccination clinic to assess clinic staff's competency in each recommended practice.

Note: This checklist highlights minimum practices to maintain patient safety. It is not a step-by-step guide to all activities that should be conducted at an off-site clinic. For a more detailed checklist, see Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations (https://www.izsummitpartners.org/content/uploads/2019/02/off-site-vaccination-clinic-checklist.pdf).

Instructions

1. Review this Patient Safety Checklist with clinic staff.
2. For each recommended practice, select **"yes"** if all staff members responsible for that practice have reviewed the recommended resources and demonstrate competency.
3. For each recommended practice, select **"no"** if all staff members responsible for that practice have NOT reviewed the recommended resources and cannot demonstrate competency.
4. Review the entire checklist when complete. For each practice with **"no"** selected, assign responsible staff to review the recommended resources before proceeding with a vaccination clinic.

Staff Training

YES	NO	RECOMMENDED PRACTICE	RECOMMENDED RESOURCES
☐	☐	Complete training based on core competencies for each vaccine to be provided and for each staff member's role.	• Training and Education https://www.cdc.gov/vaccines/covid-19/training.html • COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers https://www2.cdc.gov/vaccines/ed/covid19/SHVA/index.asp • Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know https://www2.cdc.gov/vaccines/ed/covid19/pfizer/index.asp • Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know https://www2.cdc.gov/vaccines/ed/covid19/moderna/index.asp
☐	☐	Complete training to answer common questions about COVID-19 vaccines (all staff).	• COVID-19 Vaccine FAQs for Healthcare Professionals https://www.cdc.gov/vaccines/covid-19/hcp/faq.html • Questions about Pfizer-BioNTech COVID-19 Vaccine https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/pfizer-bioNTech-faqs.html • Questions about Moderna COVID-19 Vaccine https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/moderna-faqs.html
☐	☐	Complete infection control training (all staff).	• Infection Control Guidance for Healthcare Professionals about Coronavirus (COVID-19) https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html
☐	☐	Complete general training on vaccine storage, handling, preparation, and administration (clinical staff).	• CDC's *Vaccine Storage and Handling Toolkit* https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf • *You Call the Shots*: Vaccine Storage and Handling https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp • *You Call the Shots*: Vaccine Administration https://www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp

COVID-19 Vaccine
ent Safety Checklist for Vaccination Clinics
l at Satellite, Temporary, or Off-Site Locations

ndling (continued)

ECOMMENDED PRACTICE	RECOMMENDED RESOURCES
onitor and record temperatures using a digital ata logger with a buffered probe. If storing in: An on-site refrigerator, then record min/max temperatures at the start and end of the clinic workday A qualified container and packout, then record min/max temperatures every time the container is opened	• CDC's *Vaccine Storage and Handling Toolkit* https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf • Transport Temperature Log https://www.cdc.gov/vaccines/covid-19/downloads/transport-temperature-log.pdf • Refrigerator Storage Temperature Log (Celsius) https://www.cdc.gov/vaccines/covid-19/downloads/refrigerator-storage-logger-celsius.pdf • Refrigerator Storage Temperature Log (Fahrenheit) https://www.cdc.gov/vaccines/covid-19/downloads/refrigerator-storage-logger-fahrenheit.pdf
ake immediate action if a temperature excursion occurs. Label affected vaccines "DO NOT SE," place vaccines in a separate container in the orage unit, complete the vaccine storage troubleshooting record, and immediately contact the accine manufacturer.	• Vaccine Troubleshooting Record https://www.immunize.org/catg.d/p3041.pdf • CDC's *Vaccine Storage and Handling Toolkit* https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

d Administration

ECOMMENDED PRACTICE	RECOMMENDED RESOURCES
creen every patient for contraindications and recautions to determine whether they can ceive COVID-19 vaccine and, if so, follow the commended observation period.	• Prevaccination Checklist for COVID-19 Vaccines https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf • Interim Clinical Considerations https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html • Managing Anaphylaxis https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html
erform hand hygiene before vaccine preparation, etween patients, when changing gloves (if worn), nd any time hands become soiled.	• Hand Hygiene in Healthcare Settings https://www.cdc.gov/handhygiene/providers/index.html
hoose the correct equipment, including the orrect needle size. Use a new, sterile needle for ach injection.	• Vaccine Administration: Needle Gauge and Length https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf
epare vaccine in a designated preparation area sing aseptic technique and as recommended by e manufacturer.	• Pfizer-BioNTech COVID-19 Vaccine Preparation and Administration Summary https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/prep-and-admin-summary.pdf • Moderna COVID-19 Vaccine Preparation and Administration Summary https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/prep-and-admin-summary.pdf • Preparing Vaccines from a Multidose Vial https://www.youtube.com/watch?v=TDcFievcUVs

https://www.cdc.gov/vaccines/covid-19/downloads/patient-safety-checklist-508.pdf

COVID-19 Vaccine

Vaccine Administration Competencies Assessment Form

As COVID-19 vaccines become more widely available, it is crucial that they are safely anc
to as many eligible recipients as possible. This requires knowledgeable, confident, and c
support staff. It is vital that anyone preparing and administering vaccine be properly trai
opportunity to practice these skills (under supervision when needed).

Who can be assessed using this form:

- Experienced vaccinators
- Vaccinators who have not administered vaccines in the past 12 months or longe
- Medical support staff who are not licensed to administer vaccines but assist witl preparation and cold chain management
- Healthcare providers who require documentation of an observation period as p Declaration under the Public Readiness and Emergency Preparation (PREP) Act f Countermeasures Against COVID-19
- Administrative support staff who assist with cold chain management, data repo distribution of required materials to vaccine recipients

For Self-Assessment

Review the competency areas below and the core skills, techniques, and procedures area. Score yourself in the Self-Assessment column. If you check "Needs to Improve," study, practice, or change is needed. If you check "Meets or Exceeds," you indicate tl performing at the expected or higher level of competence.

Supervisors

Use this form to observe staff's readiness to perform assigned functions. Observe th prepare vaccine or administer vaccine to several recipients and score in the Supervis improvement is needed, meet with them to develop a Plan of Action for additional t should undertake to achieve the level of competency you expect. Write desired actic that needs to be addressed. This form may also be used to assist with more formal p

COVID-19 Vaccine

Vaccine Administration Competencies Assessment Form

			Self-Assessment		Supervisor Review		
	Core Skills, Techniques, and Procedures	**N/A**	**Needs to Improve**	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	**Plan of Action***
Vaccine Product Knowledge	1. Completes COVID-19 vaccine training and additional training as needed.[1]						
	2. Understands clinical guidance and can accurately assess and vaccinate based on:						
	• eligibility requirements						
	• vaccination schedule and history						
	• contraindications						
	• precautions						
	• clinical considerations						
	3. Understands post-vaccination clinical guidance, including:						
	• recommended observation times						
	• signs and symptoms of allergic reactions and anaphylaxis						
	4. Explains how the vaccine works, major vaccine components, and side effects.						
Storage and Handling	1. Demonstrates knowledge of proper procedures when managing vaccine shipments, including inspecting, unpacking, accounting, and storing vaccines.						
	2. Explains the cold chain requirement for the specific COVID-19 vaccine product(s) used at the facility, including protocol(s) in case of temperature excursions or cold chain failure.						
	3. Demonstrates use of proper temperature monitoring and recording process for the facility, including the process for handling a temperature excursion.						
	4. Demonstrates understanding of all procedures necessary to prepare and transport vaccine product(s) between facilities.						

https://www.cdc.gov/vaccines/covid-19/downloads/competencies-screening-checklist.pdf

Alternative vaccination site guidance during COVID-19

Follow clinical setting guidance and take additional precautions:

- Select a space large enough to ensure physical distancing.
- Provide specific appointment times and use other strategies to manage patient flow and avoid crowding.
- Set up unidirectional site flow with signs, ropes, or other measures.
- Have a separate vaccination area or separate hours for persons at increased risk for severe illness from COVID-19.

Image credit: Noun Project, CDC

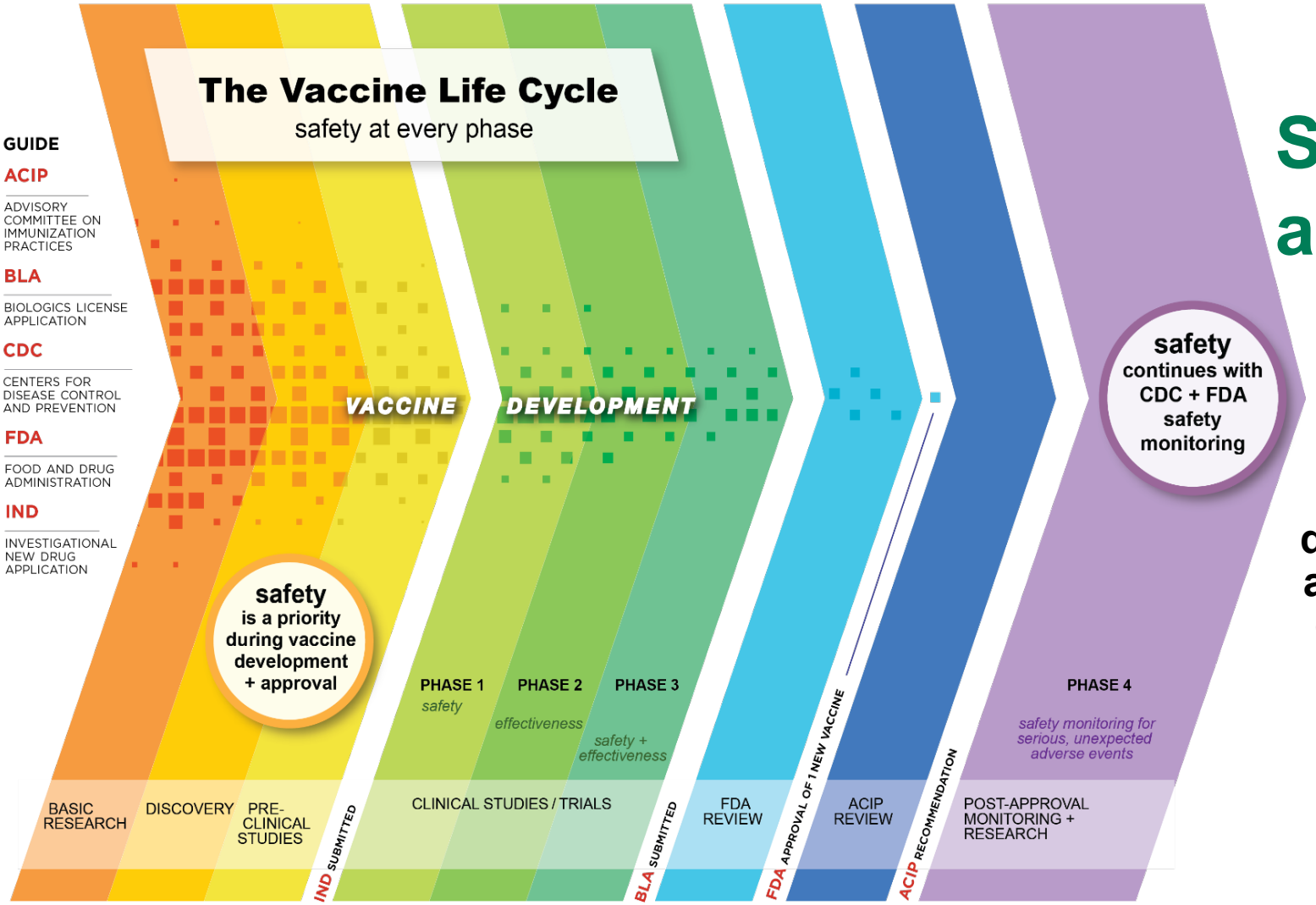
https://www.cdc.gov/vaccines/pandemic-guidance/index.html

Vaccine Safety and Adverse Event Reporting

Importance of Vaccine Safety

Public confidence in vaccine safety critical

- Higher standard of safety is expected of vaccines
- Vaccines generally given to healthy people to prevent disease (vs. ill to treat, for drugs)
- Lower public risk tolerance for adverse reactions, especially in healthy children
- Vaccination universally recommended and mandated



Safety is a priority

during all phases of vaccine development, authorization or approval, and use

https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html#anchor_1593624850886

The Provider's Role

Immunization providers can help to ensure the safety and efficacy of vaccines through proper:

- Communication on benefit and risk, and expected side effects
- Vaccine storage and handling practices
- Accurate timing and spacing of vaccine doses
- Screening for eligibility, contraindications and precautions
- Vaccine preparation and administration, and appropriate observation period
- Being able to recognize early signs and symptoms
- Management of adverse reactions
- Trained in use of emergency equipment
- Reporting to VAERS and any additional COVID specific databases
- Documentation in MIIS and medical record

Seven Rights of Vaccine Administration

- Right Patient
- Right Time
- Right Vaccine (and Diluent)
- Right Dosage
- Right Route, Needle, Technique
- Right Injection Site
- Right Documentation

http://www.immunize.org/technically-speaking/20141101.asp

Administering Vaccines: Dose, Route, Site, and Needle Size

Vaccine	Dose	Route
COVID-19	*Pfizer-BioNTech* ≥16 yrs: 0.3 mL *Moderna; Janssen* ≥18 yrs: 0.5 mL	IM
Diphtheria, Tetanus, Pertussis (DTaP, DT, Tdap, Td)	0.5 mL	IM
***Haemophilus influenzae* type b** (Hib)	0.5 mL	IM
Hepatitis A (HepA)	≤18 yrs: 0.5 mL ≥19 yrs: 1.0 mL	IM
Hepatitis B (HepB) *Persons 11–15 yrs may be given Recombivax HB (Merck) 1.0 mL adult formulation on a 2-dose schedule.*	Engerix-B; Recombivax HB ≤19 yrs: 0.5 mL ≥20 yrs: 1.0 mL Heplisav-B ≥18 yrs: 0.5 mL	IM
Human papillomavirus (HPV)	0.5 mL	IM
Influenza, live attenuated (LAIV)	0.2 mL (0.1 mL in each nostril)	Intranasal spray
Influenza, inactivated (IIV); for ages 6–35 months	Afluria: 0.25 mL Fluzone: 0.25 or 0.5 mL FluLaval; Fluarix: 0.5 mL	IM
Influenza, inactivated (IIV), 3 yrs & older; **recombinant** (RIV), 18 yrs & older; **high-dose** (HD-IIV) 65 yrs & older	0.5 mL FluZone HD: 0.7 mL	IM
Measles, Mumps, Rubella (MMR)	0.5 mL	Subcut
Meningococcal serogroups A, C, W, Y (MenACWY)	0.5 mL	IM
Meningococcal serogroup B (MenB)	0.5 mL	IM
Pneumococcal conjugate (PCV)	0.5 mL	IM
Pneumococcal polysaccharide (PPSV)	0.5 mL	IM or Subcut
Polio, inactivated (IPV)	0.5 mL	IM or Subcut

Injection Site and Needle Size

Subcutaneous (Subcut) injection

Use a 23–25 gauge needle. Choose the injection site that is appropriate to the person's age and body mass.

AGE	NEEDLE LENGTH	INJECTION SITE
Infants (1–12 mos)	5/8"	Fatty tissue over anterolateral thigh muscle
Children 12 mos or older, adolescents, and adults	5/8"	Fatty tissue over anterolateral thigh muscle or fatty tissue over triceps

Intramuscular (IM) injection

Use a 22–25 gauge needle. Choose the injection site and needle length that is appropriate to the person's age and body mass.

AGE	NEEDLE LENGTH	INJECTION SITE
Newborns (1st 28 days)	5/8"[1]	Anterolateral thigh muscle
Infants (1–12 mos)	1"	Anterolateral thigh muscle
Toddlers (1–2 years)	1–1¼"	Anterolateral thigh muscle[2]
	5/8–1"[1]	Deltoid muscle of arm
Children (3–10 years)	5/8–1"[1]	Deltoid muscle of arm[2]
	1–1¼"	Anterolateral thigh muscle
Adolescents and teens (11–18 years)	5/8–1"[1]	Deltoid muscle of arm[2]
	1–1½"	Anterolateral thigh muscle
Adults 19 years or older		
Female or male <130 lbs	5/8–1"[1]	Deltoid muscle of arm
Female or male 130–152 lbs	1"	Deltoid muscle of arm
Female 153–200 lbs Male 153–260 lbs	1–1½"	Deltoid muscle of arm
Female 200+ lbs Male 260+ lbs	1½"	Deltoid muscle of arm

[1] A 5/8" needle may be used in newborns, preterm

NOTE: Always refer to the package insert

Healthcare Provider Documentation Requirements

Providers must ensure that the recipient's permanent medical record (whether paper-based or electronic) contains all of the required vaccine administration documentation, which shall consist of the following:

- Date of administration of the vaccine
- Vaccine manufacturer and lot number of the vaccine
- Name and title of person administering the vaccine
- The address of the facility where the permanent record will reside (if appropriate)
- Date printed on the appropriate VIS
- Date the VIS was given to the vaccine recipient, or the parents/legal representative
- Best practice documentation guidelines also include: the vaccine type, dose, site, route of administration, and vaccine expiration date be documented, and any vaccine refusal (if appropriate).

https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html

COVID-19 Specific Documentation Requirements

- COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration

- Document each recipient's vaccine administration information:
  - Medical record:
    The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
  - Vaccination record card (given to recipient):
    Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional.
  - Immunization information system (IIS):
    Report the vaccination to the appropriate state/local IIS.

https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf

Vaccine Information Statements (VISs) and EUA Factsheet for Vaccine Recipients

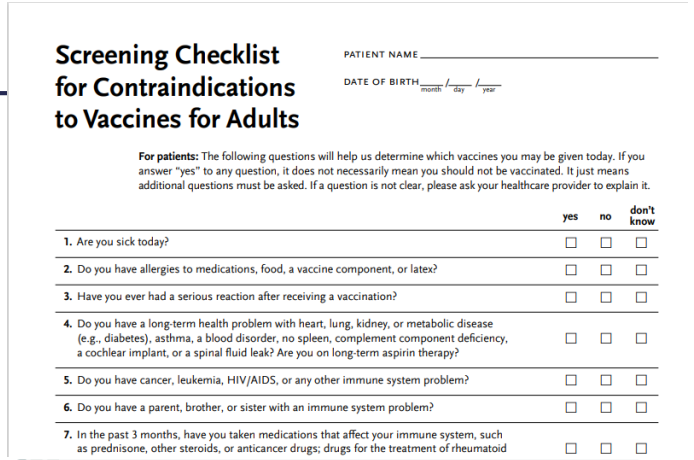
- Give VISs **before** vaccine is administered
- Applies to **every dose** of a vaccine series not just the first dose
- Opportunities for questions should be provided before each vaccination
- Available in multiple languages
- If using a combination vaccine, give VISs for each component of the vaccine, or use the Multi-Vaccine VIS, which covers some of the combination vaccines

- Give EUA **before** vaccine is administered
- Applies to **every dose** of a vaccine series not just the first dose
- Opportunities for questions should be provided before each vaccination
- Available in multiple languages
- Given in lieu of a VIS
- Explains what an EUA is and why it is issued

https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html#give
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

Screening

- Is key to preventing serious adverse reactions
- Specific questions intended to identify contraindications or precautions to vaccination
- Screening must occur at every immunization encounter (not just before the first dose)
- Use of a standardized form will facilitate effective screening
- For COVID-19 vaccine, screening will inform the length of the observation period



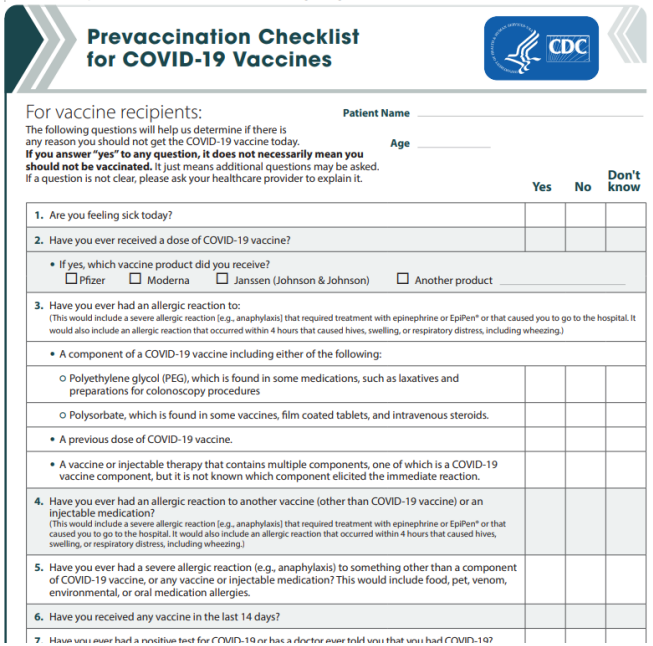
Screening Checklist for Contraindications to Vaccines for Adults

PATIENT NAME _____

DATE OF BIRTH ___ / ___ / ___ (month / day / year)

For patients: The following questions will help us determine which vaccines you may be given today. If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	yes	no	don't know
1. Are you sick today?	☐	☐	☐
2. Do you have allergies to medications, food, a vaccine component, or latex?	☐	☐	☐
3. Have you ever had a serious reaction after receiving a vaccination?	☐	☐	☐
4. Do you have a long-term health problem with heart, lung, kidney, or metabolic disease (e.g., diabetes), asthma, a blood disorder, no spleen, complement component deficiency, a cochlear implant, or a spinal fluid leak? Are you on long-term aspirin therapy?	☐	☐	☐
5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem?	☐	☐	☐
6. Do you have a parent, brother, or sister with an immune system problem?	☐	☐	☐
7. In the past 3 months, have you taken medications that affect your immune system, such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid	☐	☐	☐



Prevaccination Checklist for COVID-19 Vaccines

CDC

For vaccine recipients:

Patient Name _____

Age _____

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. **If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated.** It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

	Yes	No	Don't know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine?			
• If yes, which vaccine product did you receive? ☐ Pfizer ☐ Moderna ☐ Janssen (Johnson & Johnson) ☐ Another product _____			
3. Have you ever had an allergic reaction to: (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)			
• A component of a COVID-19 vaccine including either of the following:			
○ Polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures			
○ Polysorbate, which is found in some vaccines, film coated tablets, and intravenous steroids.			
• A previous dose of COVID-19 vaccine.			
• A vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, but it is not known which component elicited the immediate reaction.			
4. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication? (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)			
5. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, or any vaccine or injectable medication? This would include food, pet, venom, environmental, or oral medication allergies.			
6. Have you received any vaccine in the last 14 days?			
7. Have you ever had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?			

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https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
https://immunize.org/clinic/screening-contraindications.asp
https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf

Contraindication and Precautions

Contraindication

- Conditions in a recipient that increases the risk for a serious adverse reaction.
- A vaccine should not be administered when a contraindication is present.
- Because the majority of contraindications are temporary, vaccinations often can be administered later when the condition leading to a contraindication no longer exists.

Precaution

- A condition in a recipient that might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity.
- In general, vaccinations should be deferred when a precaution is present. However, a vaccination might be indicated in the presence of a precaution if the benefit of protection from the vaccine outweighs the risk for an adverse reaction.

https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html

Contraindications & Precautions

CDC: Table 4.1 in Best Practices
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html

IAC: Guide to Contraindications and Precautions to Commonly Used Vaccines
https://www.immunize.org/catg.d/p3072A.pdf

IAC: Guide to Contraindications and Precautions to Commonly Used Vaccines in Adults
https://immunize.org/catg.d/p3072.pdf

CDC: Interim Clinical Considerations for COVID-19 Vaccines
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Guide to Contraindications and Precautions to Commonly Used Vaccines[1,*]

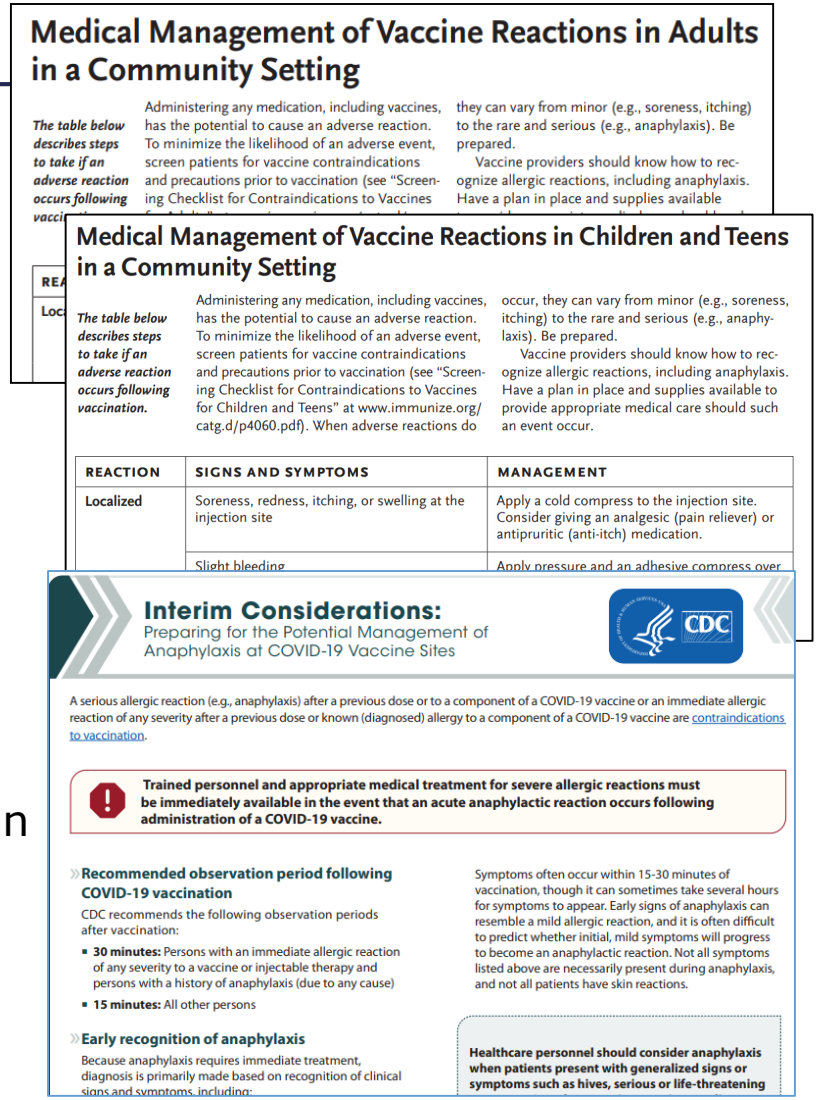
Vaccine	Contraindications[1]	Precautions[1]
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Hypersensitivity to yeast	• Moderate or severe acute illness with or without fever • Infant weighing less than 2000 grams (4 lbs, 6.4 oz)[2]
Rotavirus (RV5 [RotaTeq], RV1 [Rotarix])	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe combined immunodeficiency (SCID) • History of intussusception	• Moderate or severe acute illness with or without fever • Altered immunocompetence other than SCID • Chronic gastrointestinal disease[3] • Spina bifida or bladder exstrophy[3]
Diphtheria, tetanus, pertussis (DTaP) **Tetanus, diphtheria, pertussis (Tdap)** **Tetanus, diphtheria (DT, Td)**	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • For pertussis-containing vaccines: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of a previous dose of DTP or DTaP (for DTaP); or of previous dose of DTP, DTaP, or Tdap (for Tdap)	• Moderate or severe acute illness with or without fever • Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid-containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria- or tetanus toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine • For DTaP and Tdap only: Progressive or unstable neurologic disorder (including infantile spasms for DTaP), uncontrolled seizures, or progressive encephalopathy; defer until a treatment regimen has been established and the condition has stabilized
***Haemophilus influenzae* type b (Hib)**	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Age younger than 6 weeks	• Moderate or severe acute illness with or without fever
Inactivated poliovirus vaccine (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever • Pregnancy

Appendix B: Triage of people presenting for COVID-19 vaccination

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†	Among people without a contraindication, a history of: • Any immediate allergic reaction* to other vaccines or injectable therapies‡ Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#	Among people without a contraindication or precaution, a history of: • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies
Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.†	Actions: • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	Actions: • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

Managing Acute Vaccine Reactions

- Staff must have appropriate training and equipment to manage reactions
- Staff should be familiar with signs and symptoms of hypersensitivity/anaphylaxis
- All vaccination providers should be currently certified in CPR
- Severe reactions are rare
- Screening can help prevent reactions
- There must be a clinic emergency plan for dealing with reactions and you need to ensure that all staff are familiar with that plan
- Have Emergency Treatment Standing Orders signed before the clinic



Medical Management of Vaccine Reactions in Adults in a Community Setting

The table below describes steps to take if an adverse reaction occurs following vacci

Administering any medication, including vaccines, has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination (see "Screening Checklist for Contraindications to Vaccines

they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.

Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available

Medical Management of Vaccine Reactions in Children and Teens in a Community Setting

The table below describes steps to take if an adverse reaction occurs following vaccination.

Administering any medication, including vaccines, has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination (see "Screening Checklist for Contraindications to Vaccines for Children and Teens" at www.immunize.org/catg.d/p4060.pdf). When adverse reactions do occur, they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.

Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available to provide appropriate medical care should such an event occur.

REACTION	SIGNS AND SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply pressure and an adhesive compress over

Interim Considerations:

Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccine Sites

CDC

A serious allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine or an immediate allergic reaction of any severity after a previous dose or known (diagnosed) allergy to a component of a COVID-19 vaccine are contraindications to vaccination.

Trained personnel and appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine.

Recommended observation period following COVID-19 vaccination

CDC recommends the following observation periods after vaccination:

- **30 minutes:** Persons with an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis (due to any cause)
- **15 minutes:** All other persons

Early recognition of anaphylaxis

Because anaphylaxis requires immediate treatment, diagnosis is primarily made based on recognition of clinical signs and symptoms, including:

Symptoms often occur within 15-30 minutes of vaccination, though it can sometimes take several hours for symptoms to appear. Early signs of anaphylaxis can resemble a mild allergic reaction, and it is often difficult to predict whether initial, mild symptoms will progress to become an anaphylactic reaction. Not all symptoms listed above are necessarily present during anaphylaxis, and not all patients have skin reactions.

Healthcare personnel should consider anaphylaxis when patients present with generalized signs or symptoms such as hives, serious or life-threatening

https://www.immunize.org/catg.d/p3082.pdf
https://www.immunize.org/catg.d/p3082a.pdf
https://www.cdc.gov/vaccines/covid-19/downloads/IntermConsid-Anaphylaxis-covid19-vaccine-sites.pdf
https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html

Recommended Meds and Supplies for the Management of Anaphylaxis

Should be available at all sites	If feasible, include at locations
Epinephrine (e.g., prefilled syringe, autoinjector)*	Pulse oximeter
H1 antihistamine (e.g., diphenhydramine, cetirizine)†	Oxygen
Blood pressure monitor‡	Bronchodilator (e.g., albuterol)
Timing device to assess pulse	H2 antihistamine (e.g., famotidine, cimetidine)
	Intravenous fluids
	Intubation kit
	Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation (CPR) mask)

*COVID-19 vaccination locations should have **at least 3 doses** of epinephrine available at all times, and the ability to quickly obtain additional doses to replace supplies after epinephrine is administered to a patient.

People with a history of anaphylaxis who carry an epinephrine autoinjector could be reminded to bring it to their vaccination appointment.

Expired epinephrine or epinephrine that appears to be in unacceptable condition (per the manufacturer's package inserts) should be replaced.

†Antihistamines may be given as adjunctive treatment but should not be used as initial or sole treatment for anaphylaxis. Additionally, caution should be used if oral medications are administered to people with impending airway obstruction.

‡Either an automated or a manual blood pressure monitor, with appropriate cuff sizes, is acceptable. If a manual blood pressure monitor is used, a stethoscope should also be available.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

Recognizing and Responding to Anaphylaxis

How to recognize anaphylaxis

Healthcare personnel should consider anaphylaxis when patients present with generalized signs or symptoms such as **hives, serious or life-threatening symptoms** (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips), or **symptoms that involve more than one body system**.

Respiratory:
- sensation of throat closing
- stridor (high-pitched sound while breathing)
- shortness of breath
- wheeze, cough

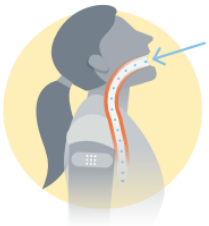
Gastrointestinal:
- nausea
- vomiting
- diarrhea
- abdominal pain

Cardiovascular:
- dizziness
- fainting
- tachycardia (abnormally fast heart rate)
- hypotension (abnormally low blood pressure)

Skin/mucosal:
- generalized hives
- itching
- swelling of lips, face, or throat

Neurological:
- agitation
- convulsions
- acute change in mental status
- sense of impending doom (a feeling that something bad is about to happen)

What to do if you suspect anaphylaxis



Assess airway, breathing, and circulation

Administer epinephrine

Call Emergency Medical Services (EMS)

Place in supine position

Detailed information can be found in the Interim Considerations:
[Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination]

https://www.cdc.gov/vaccines/covid-19/downloads/recognizing-responding-to-anaphylaxis-508.pdf

Key Messages: Preparing for the Potential Management of Anaphylaxis

Early recognition of anaphylaxis symptoms

Prompt treatment with epinephrine

Activation of emergency medical services

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https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

VAERS is the Nation's Early Warning System for Vaccine Safety

- Jointly administered by the CDC & FDA
- Receives ~50,000 reports per year (pre-COVID-19)
- Passive; depends on health care providers and others to report
- Detects:
  - New or rare events
  - Increases in rates of known events after immunization
  - Patient risk factors associated with higher rates of adverse reactions
  - "Signals", possible adverse reactions that may warrant further study
- VAERS cannot establish causality, additional studies would be needed

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

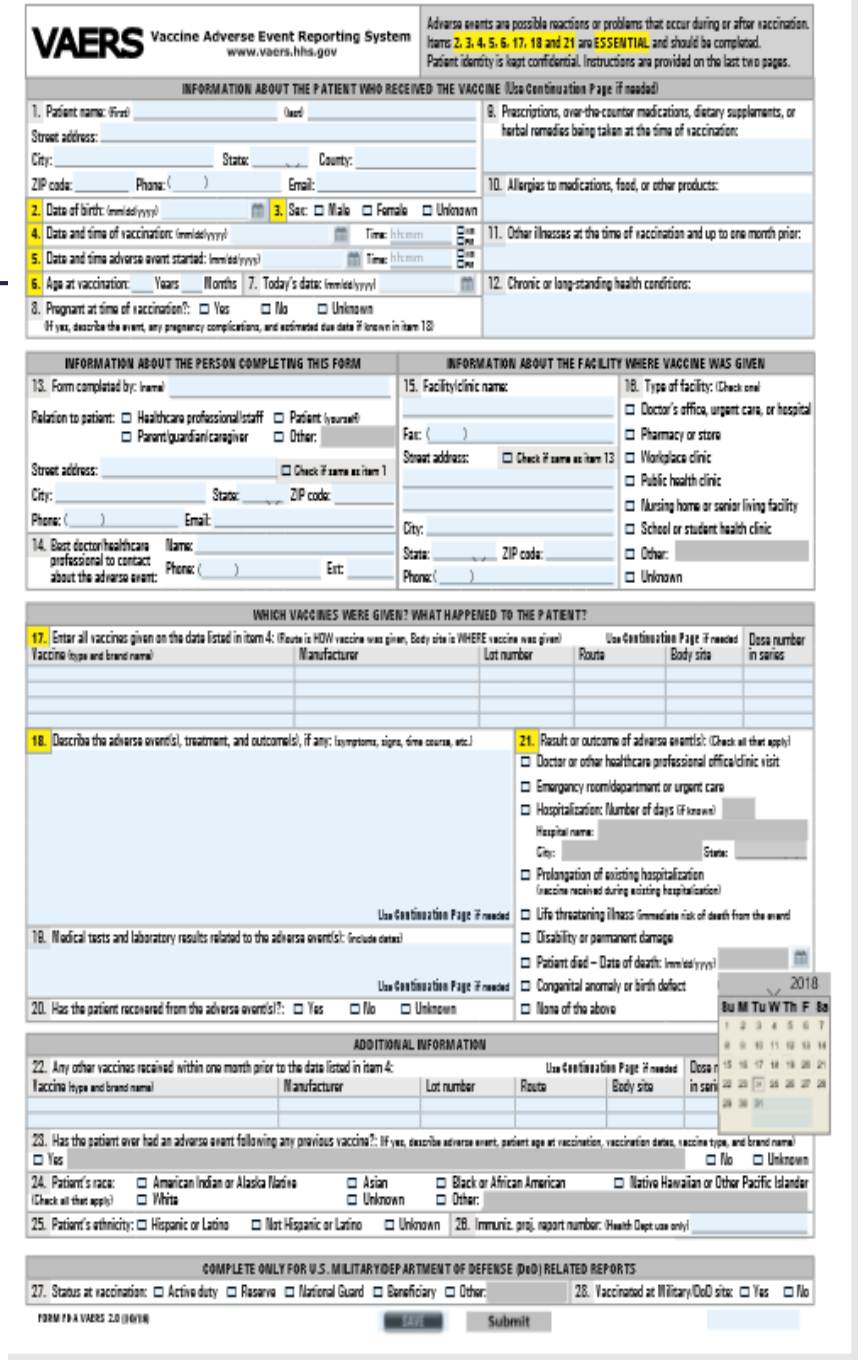
Co-managed by CDC and FDA

http://vaers.hhs.gov

https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html
https://vaers.hhs.gov/about.html

VAERS Form

- One page online form, found at: https://vaers.hhs.gov/
- Asks for information on:
  - Patient
  - Vaccine
  - Adverse event
  - Outcome of adverse event
- For help:
  - Call: 1-800-822-7967
  - Email: info@VAERS.org
  - Video instructions https://youtu.be/sbCWh cQADFE
- If COVID-19 vaccine related:
  - Put "*[brand name]* COVID- 19 Vaccine EUA" in the description


VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items 2, 3, 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed)

1. Patient name: (First) (Last)
Street address:
City: State: County:
ZIP code: Phone: ( ) Email:
2. Date of birth: (mm/dd/yyyy) 3. Sex: ☐ Male ☐ Female ☐ Unknown
4. Date and time of vaccination: (mm/dd/yyyy) Time: (hh:mm)
5. Date and time adverse event started: (mm/dd/yyyy) Time: (hh:mm)
6. Age at vaccination: ___ Years ___ Months 7. Today's date: (mm/dd/yyyy)
8. Pregnant at time of vaccination?: ☐ Yes ☐ No ☐ Unknown
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)
9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
10. Allergies to medications, food, or other products:
11. Other illnesses at the time of vaccination and up to one month prior:
12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to patient: ☐ Healthcare professional/staff ☐ Patient (yourself) ☐ Parent/guardian/caregiver ☐ Other:
Street address: ☐ Check if same as item 1
City: State: ZIP code:
Phone: ( ) Email:
14. Best doctor/healthcare professional to contact about the adverse event: Name: Phone: ( ) Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Fax: ( )
Street address: ☐ Check if same as item 13
City:
State: ZIP code:
Phone: ( )
16. Type of facility: (Check one)
☐ Doctor's office, urgent care, or hospital
☐ Pharmacy or store
☐ Workplace clinic
☐ Public health clinic
☐ Nursing home or senior living facility
☐ School or student health clinic
☐ Other:
☐ Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given) Use Continuation Page if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Use Continuation Page if needed
19. Medical tests and laboratory results related to the adverse event(s): (include dates)
Use Continuation Page if needed
20. Has the patient recovered from the adverse event(s)?: ☐ Yes ☐ No ☐ Unknown
21. Result or outcome of adverse event(s): (Check all that apply)
☐ Doctor or other healthcare professional office/clinic visit
☐ Emergency room/department or urgent care
☐ Hospitalization: Number of days (if known)
Hospital name:
City: State:
☐ Prolongation of existing hospitalization (vaccine received during existing hospitalization)
☐ Life threatening illness (immediate risk of death from the event)
☐ Disability or permanent damage
☐ Patient died – Date of death: (mm/dd/yyyy)
☐ Congenital anomaly or birth defect
☐ None of the above

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4: Use Continuation Page if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose in series

23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name)
☐ Yes ☐ No ☐ Unknown
24. Patient's race: (Check all that apply) ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown ☐ Other:
25. Patient's ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown
26. Immunization proj. report number: (Health Dept use only)

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at vaccination: ☐ Active duty ☐ Reserve ☐ National Guard ☐ Beneficiary ☐ Other:
28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

FORM FDA VAERS 2.0 (08/19)
Print
Submit

What to Report to VAERS

- Providers are required by law to report to VAERS:
  - Any adverse event listed on the VAERS Table of Reportable Events Following Vaccination
  - Any adverse event listed by the vaccine manufacturer as a contraindication to further doses
- Providers are encouraged to report:
  - Any adverse event following the administration of a vaccine, whether or not it is clear the vaccine caused the event
  - Vaccine administration errors
- Manufacturers are required to report:
  - All adverse events that come to their attention

https://vaers.hhs.gov/resources/infoproviders.html
https://vaers.hhs.gov/reportevent.html

COVID-19:What to Report to VAERS

Required to report:

- Vaccine administration errors, whether or not associated with an adverse event
- Cases of COVID-19 that result in hospitalization or death
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
  - Death
  - A life-threatening AE
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - A congenital anomaly/birth defect
  - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome

Encouraged to report:

- Any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event.

https://vaers.hhs.gov/faq.html
https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html

What to Report to VAERS

- Any **clinically significant or medically important** adverse event following immunization even if you are not certain the vaccine caused the event

- Some examples of adverse events to report
  - Local: unusual redness, swelling, pain at injection site
  - Systemic: unusual fever, myalgia, headache
  - Allergic: hives, pruritus, anaphylaxis
  - Vaccination errors (e.g., wrong drug administered)

https://vaers.hhs.gov/reportevent.html
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html

10 Things Healthcare Providers Need to Know about the Vaccine Adverse Event Reporting System (VAERS)

Reporting Adverse Events Following COVID-19 Vaccination

The federal government takes all reports of adverse events following vaccination seriously. Both the U.S. Food and Drug Administration (FDA) and CDC are monitoring the safety of COVID-19 vaccines. CDC uses numerous vaccine safety monitoring systems, including VAERS, to monitor adverse events occurring after vaccination.

1. What is VAERS?

VAERS is the nation's early warning system used by FDA and CDC to collect reports of adverse events after vaccination. VAERS can provide scientists with valuable information to assess possible safety concerns related to vaccines, including new COVID-19 vaccines. VAERS is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might signal a possible safety problem with a vaccine.

2. Who should submit a report to VAERS?

FDA ***requires*** **healthcare providers** to report **certain adverse events** that occur after administering COVID-19 vaccine, but **anyone *can* submit a report to VAERS.** Healthcare professionals, health departments, vaccine manufacturers, vaccine recipients, patients and parents or family members of people who have received a vaccine are encouraged to submit a VAERS report when an adverse event occurs after vaccination.

3. Types of adverse events to report

Healthcare providers are ***encouraged*** to report any adverse event they think is medically important or clinically significant, even if they think the event might not be related to the vaccine. However, healthcare providers are ***required*** to report the following adverse events after COVID-19 vaccines, in accordance with the emergency use authorization (EUA) for COVID-19 vaccines:

- Vaccine administration errors, whether associated with an adverse event or not
- Serious adverse events (as defined by federal law), regardless of causality, including:
  - death
  - a life-threatening event
  - inpatient hospitalization or prolongation of existing hospitalization
  - persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - congenital anomaly/birth defect
  - an important medical event that, based on appropriate medical judgement, may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome (MIS-C or MIS-A)
- Cases of COVID-19 that result in hospitalization or death

Learn more about what to report to VAERS and how to submit a report.

4. How can healthcare providers contact CDC in case of a COVID-19 vaccine safety emergency?

In case of a health emergency, and the patient needs urgent transportation to the hospital, providers should call 911. If the patient does not need transportation to the hospital, providers are encouraged to call the CDC Emergency Operations Center at (770) 488-7100. For complex vaccine safety questions, healthcare providers or health departments in the United States can request a consultation from the Clinical Immunization Safety Assessment (CISA) COVIDvax clinicians. For non-urgent concerns, providers may contact CDC-INFO.

5. What happens after a VAERS report is submitted?

The individual who submitted the VAERS report will receive electronic confirmation that the report was received. Experts from CDC and FDA monitor VAERS reports to identify adverse events that need to be studied further. Vaccine safety experts review all serious reports (those resulting in permanent disability, hospitalization, prolongation of existing hospitalization, life-threatening illness, congenital deformity, or death).

6. Strengths and limitations to VAERS

VAERS is a robust, nationwide reporting system, but it is subject to several important limitations. VAERS is not designed to assess cause and effect so VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. Some reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. Data from VAERS reports should always be interpreted with these limitations in mind.

7. CDC follow-up on VAERS reports

To better understand the circumstances around a particular adverse event, VAERS staff from CDC and FDA request follow-up medical records on reports that are classified as "serious." Serious reports include all adverse events resulting in death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, or congenital anomaly/birth defect. VAERS staff may also request follow-up medical records on adverse events of specific interest, like anaphylaxis.

9. What happens when a death is reported to VAERS

When a death following vaccination is reported to VAERS, CDC requests medical records about the person's death, including an autopsy report (if available) from medical authorities, as well as a death certificate and other relevant medical records. Physicians in the CDC's Immunization Safety Office review all reports of death following COVID-19 vaccination. CDC routinely analyzes death reports in a systematic way to detect unusual or unexpected patterns. This analysis is done through individual report reviews and reviews of records, analysis of automated data, and disproportionality analyses in the VAERS database. VAERS scientists do **not** routinely reach out to the individuals or family members who submitted the report. There is no expectation of state or local health departments to conduct investigations into reported deaths after vaccination.

10. How CDC reports potential vaccine safety issues

CDC regularly presents COVID-19 vaccine safety updates to the Advisory Committee on Immunization Practices (ACIP) and publishes the latest vaccine safety findings in medical literature, including the *Morbidity and Mortality Weekly Report (MMWR)*. You can learn more about COVID-19 vaccine safety monitoring. Also see CDC's clinical resources for COVID-19 vaccines. Additionally, VAERS data with patient identifiers removed are available to the public at HHS VAERS Data.

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https://www.cdc.gov/coronavirus/2019-ncov/downloads/vaccines/10-things-healthcare-providers-need-to-know-about-VAERS.pdf

CDC's Clinical Immunization Safety & Assessment (CISA) Project COVIDvax

- Extension of CDC's CISA* Project's clinical consultation service for U.S. healthcare providers and health departments for complex COVID-19 vaccine safety questions/issues that are**
  - (1) about an individual patient(s) residing in the United States
  - (2) not readily addressed by CDC or ACIP guidelines
- Vaccine safety subject matter expertise in multiple specialties (e.g., infectious diseases, allergy/immunology, neurology, OB/GYN, pediatrics, geriatrics)
- Requests for a CISA consult about COVID-19 vaccine safety:
  - Contact CDC-INFO: 800-CDC-INFO (800-232-4636) or webform
  - Indicate the request is for a "CDC CISA"* consult (no patient identifiers)

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* https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html

**Advice from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management

Shimabukuro, Tom. COVID-19 Vaccine safety Update. ACIP Meeting 1-21-21

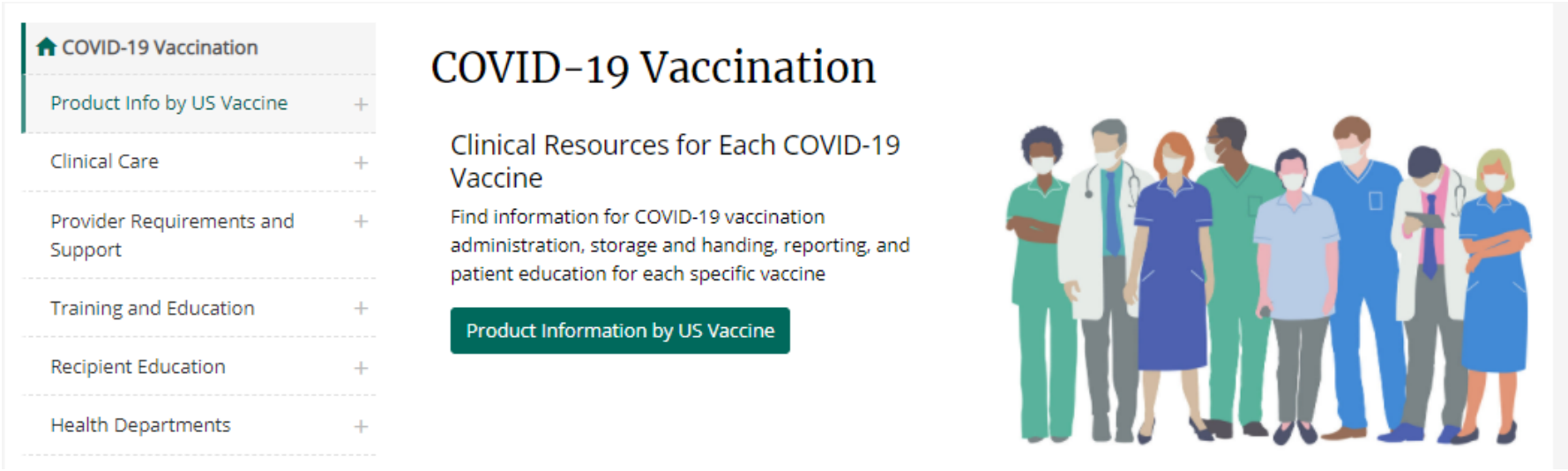
Your Role in Safety

- Recognize, respond, and report anaphylaxis and other adverse events following COVID-19 vaccination to VAERS ✓
- Report adverse events to VAERS in accordance with FDA EUA reporting requirements and CDC guidance ✓
- Participate in CDC's v-safe program yourself when you get vaccinated and encourage patients to participate in v-safe ✓
- Communicate with patients on vaccine safety ✓
- Awareness of Clinical Immunization Safety Assessment (CISA) Project COVID-Vax ✓

COVID-19 Guidance

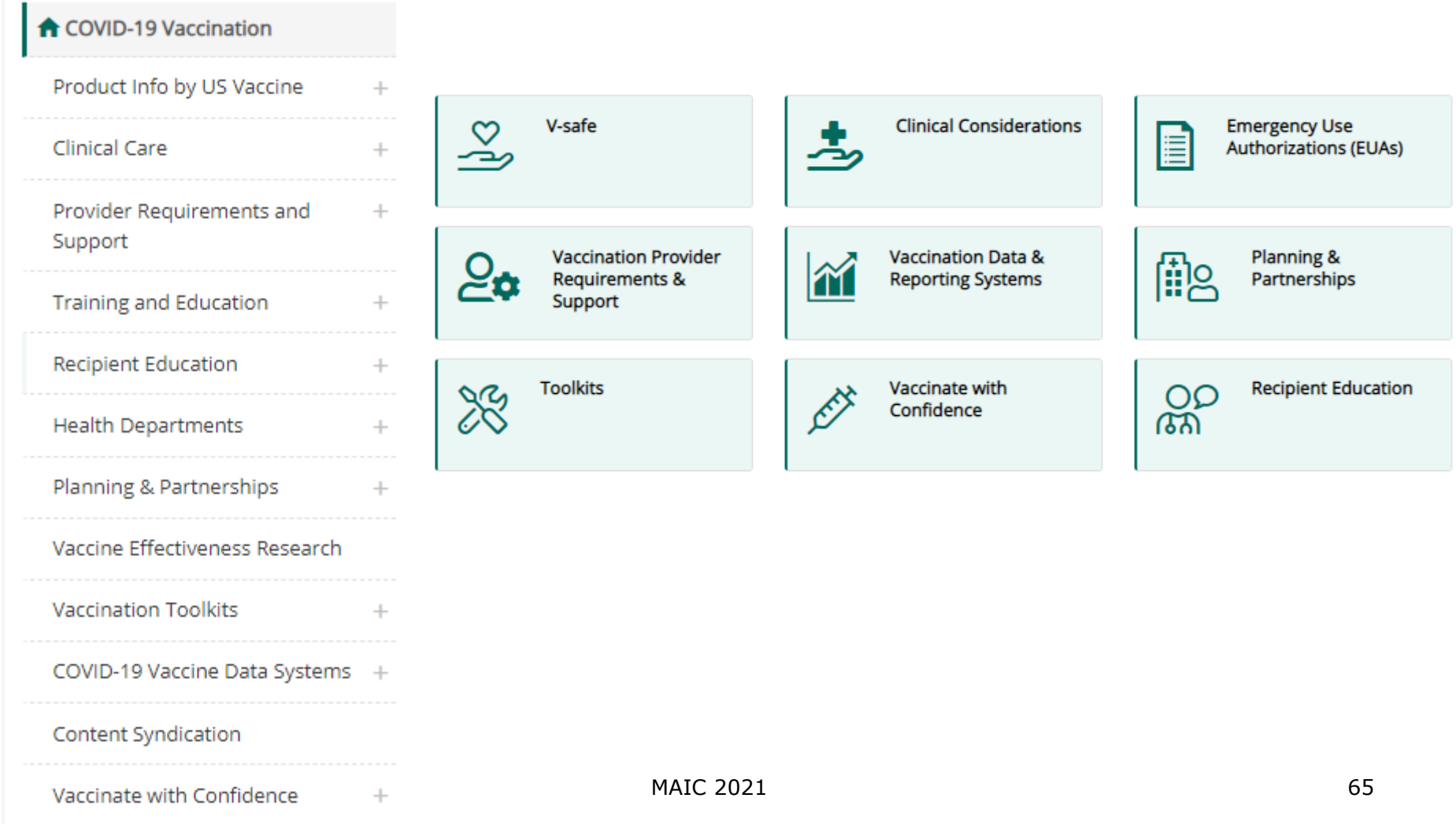
Recommendations are Rapidly Evolving…

Always check the websites for the latest guidance and information



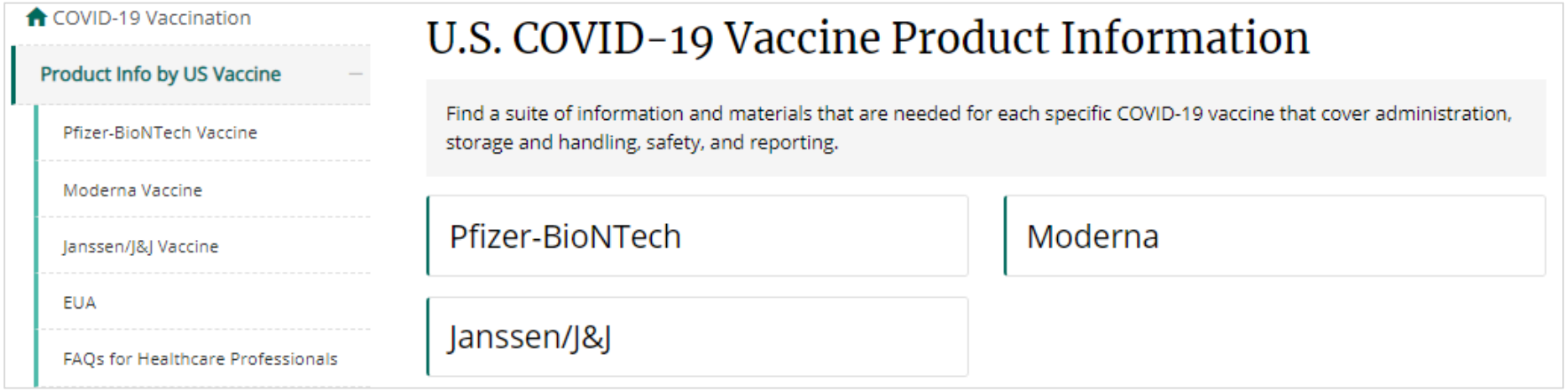
https://www.cdc.gov/vaccines/covid-19/index.html

CDC COVID-19 Vaccination Gateway Page Takes You To…..



https://www.cdc.gov/vaccines/covid-19/index.html

CDC COVID-19 Vaccination Gateway Page Takes You To(2).....



EUA

ACIP Recommendations

Quick Reference Guide

Prep & Admin Summaries

Infographics

Vaccine FAQs

Standing Orders

Screening Form

COVID-19 Vaccine

Quick Reference Guide for Healthcare Professionals

The table below provides basic information on the proper storage, preparation, and administration of the currently authorized COVID-19 vaccine products in the United States. For additional information and detailed clinical guidance go to the manufacturer's and CDC's webpages listed.

		Pfizer	Moderna	Janssen
GENERAL	EUA	www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine	www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine	www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine
	CDC Vaccine Information	www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html	www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html	www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html
	Manufacturer Contact information	**Website:** www.cvdvaccine.com **Medical information:** 800-438-1985 **Customer service:** 800-879-3477	**Website:** www.modernatx.com **Medical Information:** 866-663-3762	**Website:** www.vaxcheck.jnj. **Medical information:** 1-800-565-4008
STORAGE & HANDLING	How supplied	**Multidose vial:** 6 doses	**Multidose vial:** 10 doses	**Multidose vial:** 5 doses
	Diluent	0.9% sodium chloride (preservative-free, normal saline) provided in the ancillary kit. Do NOT use other diluent.	None	None
	Storage Temperatures: Before Puncture	**Between:** -80°C and -60°C (-112°F and -76°F) until the expiration date -25°C and -15°C (-13°F and 5°F) for up to 2 weeks 2°C and 8°C (36°F and 46°F) for up to 120 hours (5 days)	**Between:** -25°C and -15°C (-13°F and 5°F) until the expiration date 2°C and 8°C (36°F and 46°F) for up to 30 days	**Between:** 2°C and 8°C (36°F and 46°F) until the expiration date.
	Storage Temperatures: After puncture	**Between:** 2°C to 25°C (36°F to 77°F) for up to 6 hours. Discard any unused vaccine after 6 hours.	**Between:** 2°C and 25°C [36°F and 77°F] for up to 6 hours. Discard any unused vaccine after 6 hours.	**Between:** 2°C and 8°C (36°F and 46°F) for up to 6 hours. 9°C and 25°C (47°F and 77°F) for up to 2 hours. Discard any unused vaccine after these time frames.
	Transport Temperatures: Before Puncture	**Between:** -80°C and -60°C (-112°F and -76°F) -25°C and -15°C (-13°F and 5°F) 2°C and 8°C (36°F and 46°F)	**Between:** -25°C and -15°C (-13°F and 5°F) 2°C and 8°C (36°F and 46°F) for up to 12 cumulative hours.	**Between:** 2°C and 8°C (36°F and 46°F)
	After Puncture	**Between:** 2°C to 25°C (36°F to 77°F) for up to 6 hours.	**Between:** 2°C and 25°C (36°F and 77°F) for up to 6 hours.	**Between:** 2°C and 8°C (36°F and 46°F) for up to 6 hours
	Type of Vaccine	mRNA	mRNA	Viral vector
	Age Indications	16 years of age and older	18 years of age and older	18 years of age and older
	Schedule	2-doses, separated by 21 days. Both doses must be Pfizer-BioNTech vaccine	2 doses, separated by 28 days. Both doses should be Moderna vaccine	1 dose only
	Dosage	0.3 mL	0.5 mL	0.5 mL
	Needle gauge/length	22–25 gauge, 1 – 1½"	22–25 gauge, 1 – 1½"	22–25 gauge, 1 – 1½"

COVID-19 Vaccine

Quick Reference Guide for Healthcare Professionals

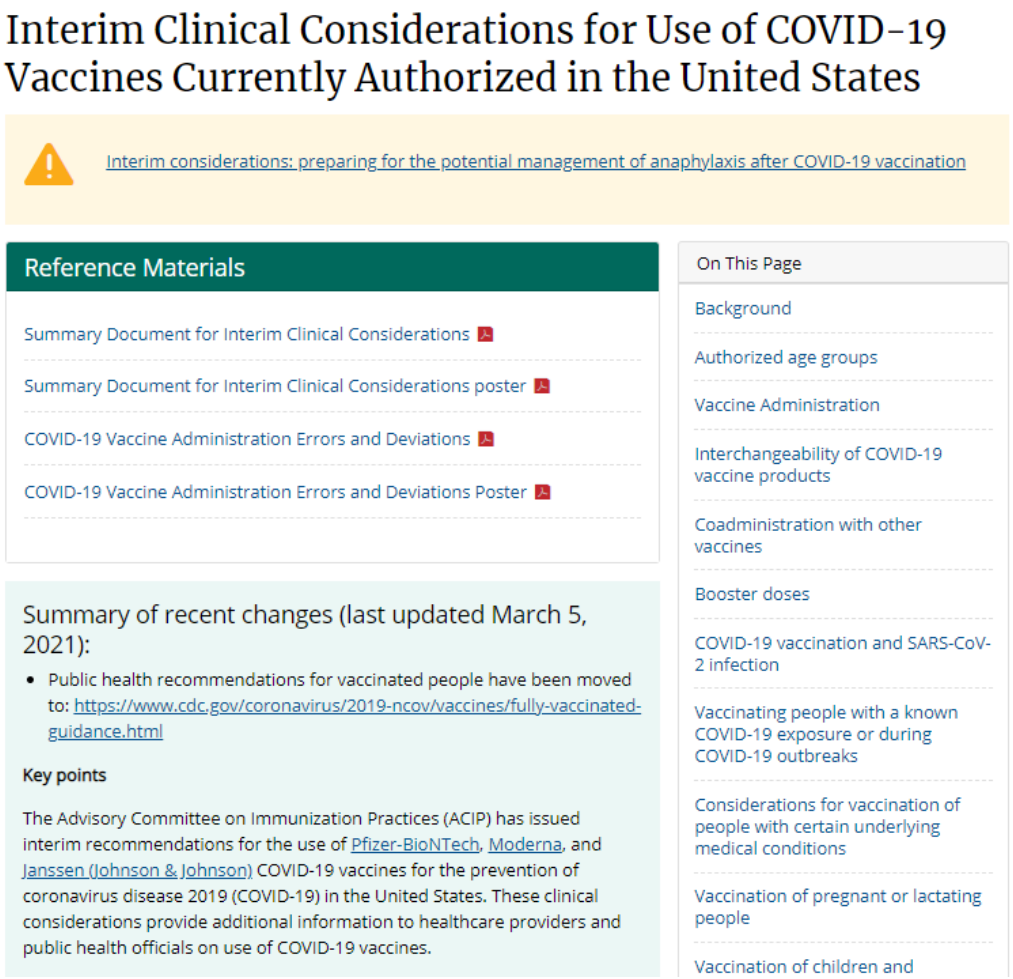
		Pfizer	Moderna	Janssen
VACCINE ADMINISTRATION	Route	Intramuscular (IM) injection	Intramuscular (IM) injection	Intramuscular (IM) injection
	Site	Deltoid	Deltoid	Deltoid
	Thawing Frozen Vaccine	**Between:** 2°C and 8°C (36°F and 46°F) or Room temperature up to 25°C (77°F) **Do NOT** refreeze thawed vaccine.	**Between:** 2°C and 8°C (36°F and 46°F) or 8°C to 25°C (46°F to 77°F) **Do NOT** refreeze thawed vaccine.	N/A
	Mixing Vaccine	Mix vaccine with 1.8 mL of 0.9% sodium chloride (preservative-free, normal saline)	**Do NOT** mix with any diluent	**Do NOT** mix with any diluent
	Contraindications/ Precautions	**Contraindications** • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine • Immediate allergic reaction† of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine **Note:** Persons who have a contraindication to an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 vaccine (see footnote).[a] Persons who have a contraindication to Janssen COVID-19 vaccine may be able to receive an mRNA COVID-19 vaccine (see footnote).[a] **Precautions** • History of an immediate allergic reaction† to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies) » This includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction. • People with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 Vaccine, and vice versa. (see footnote).[a] • Moderate to severe acute illness See Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html		
	Post-Vaccination Observation	**30 minutes:** Persons with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy or a history of anaphylaxis (from any cause) **15 minutes:** All other persons		
	Most common adverse events	**Injection site:** pain, swelling, redness **Systemic:** fatigue, headache, muscle pain, chills, fever, joint pain	**Injection site:** pain, swelling, redness **Systemic:** fatigue, headache, muscle pain, chills, fever, nausea, joint pain	**Injection site:** pain, redness, swelling **Systemic:** fatigue, headache, muscle pain, nausea, fever

†For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms, such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

[a]Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVID vax Project https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose but have a contraindication to a second dose should wait at least 28 days to receive Janssen COVID-19 vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

CDC COVID-19 Vaccination Gateway Page Takes You To(3).....



Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Reference Materials

- Summary Document for Interim Clinical Considerations
- Summary Document for Interim Clinical Considerations poster
- COVID-19 Vaccine Administration Errors and Deviations
- COVID-19 Vaccine Administration Errors and Deviations Poster

Summary of recent changes (last updated March 5, 2021):

- Public health recommendations for vaccinated people have been moved to: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

Key points

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. These clinical considerations provide additional information to healthcare providers and public health officials on use of COVID-19 vaccines.

On This Page

- Background
- Authorized age groups
- Vaccine Administration
- Interchangeability of COVID-19 vaccine products
- Coadministration with other vaccines
- Booster doses
- COVID-19 vaccination and SARS-CoV-2 infection
- Vaccinating people with a known COVID-19 exposure or during COVID-19 outbreaks
- Considerations for vaccination of people with certain underlying medical conditions
- Vaccination of pregnant or lactating people
- Vaccination of children and

Appendix A: Vaccine administration errors and deviations

Appendix B: Triage of people presenting for COVID-19 vaccination

Appendix C: Ingredients included in COVID-19 vaccines

Appendix D: Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

CDC COVID-19 Vaccination Gateway Page Takes You To(4).....

Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination

Summary of recent changes (last updated March 3, 2021)

- Considerations broadened to include use of Janssen (Johnson & Johnson) COVID-19 vaccine.

Key Points

Under the Emergency Use Authorizations for COVID-19 vaccines, appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine. These interim considerations provide information on preparing for the initial assessment and management of anaphylaxis following COVID-19 vaccination.

On This Page

MAIC 2021

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html
pdf of page: https://www.cdc.gov/vaccines/covid-19/downloads/IntermConsid-Anaphylaxis-covid19-vaccine-sites.pdf

CDC COVID-19 Vaccination Gateway Page Takes You To(5).....

Training and Education

Training Required by Professional Qualification

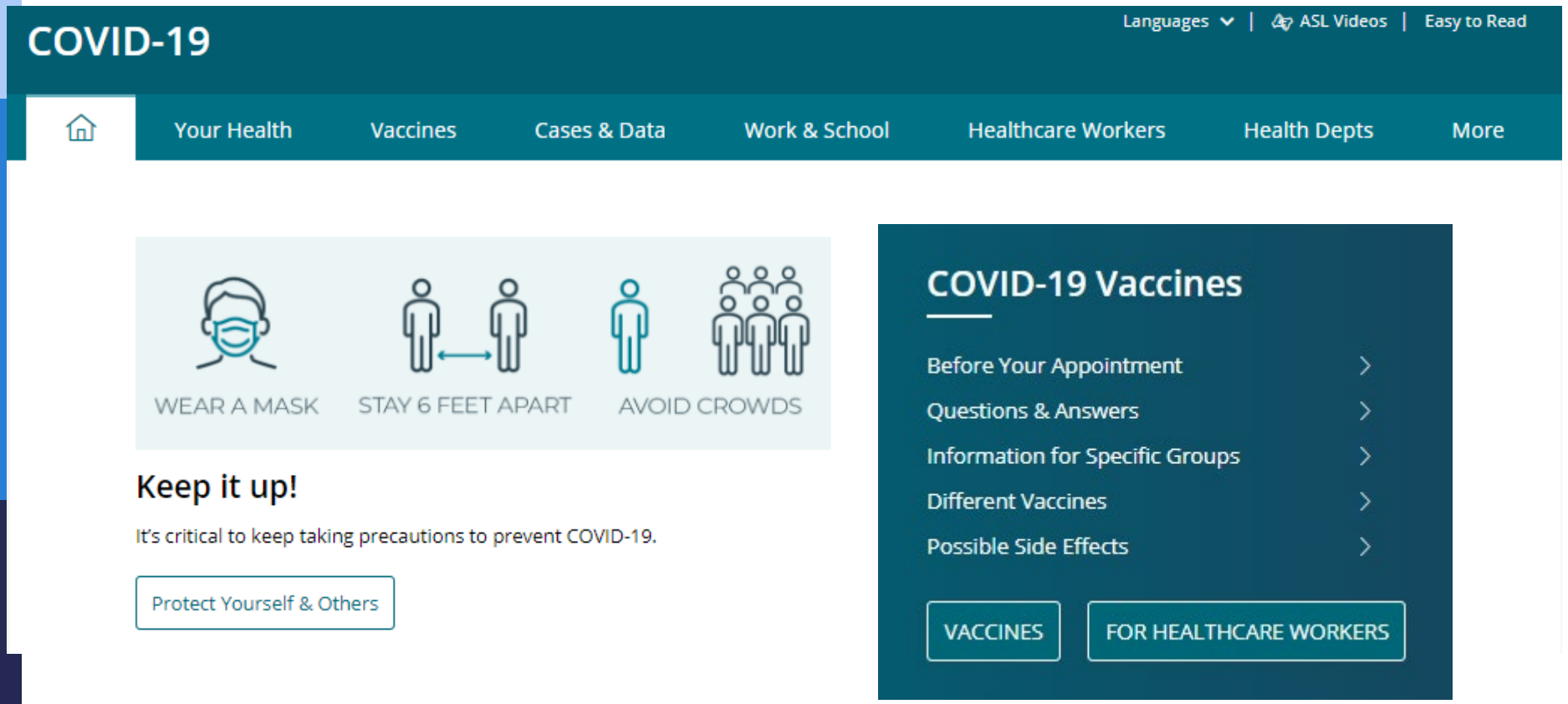
Find the training and core competencies you will need by clicking on your professional qualification below:

- Healthcare professionals who have administered vaccine in the last 12 months
- Healthcare professionals or retired (past 5 years) physicians, nurses, or practical nurses who are licensed/previously licensed to administer COVID-19 vaccine but have not done so in the last 12 months
- Vaccination support workers (not licensed to administer vaccine) qualified to prepare, store, handle, or transport vaccine
- Administration support staff qualified to store, handle, or transport vaccine

- Core Competencies
- Based on Role
- Trainings
- Competencies Assessment Form

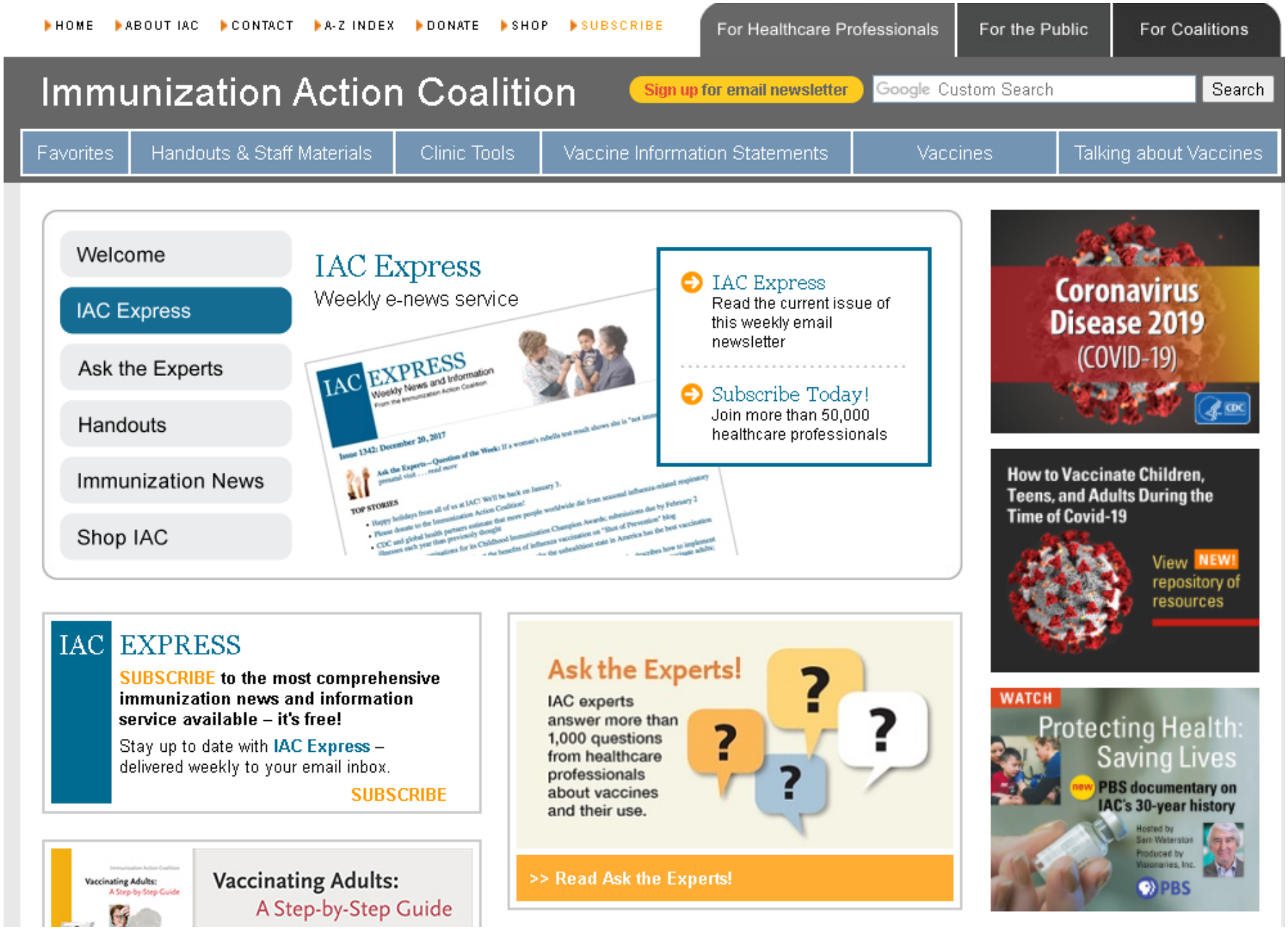
https://www.cdc.gov/vaccines/covid-19/training-education/index.html

CDC COVID-19 Gateway Page Takes You To…..



https://www.cdc.gov/coronavirus/2019-ncov/index.html

Resources



https://immunize.org/

Education Resources

Immunization Education and Training Home Page
https://www.cdc.gov/vaccines/ed/index.html

- You Call the Shots (web-based training course)
  https://www.cdc.gov/vaccines/ed/youcalltheshots.html
- Current Issues in Immunization Webinar (CIIW)
  https://www.cdc.gov/vaccines/ed/ciiw/index.html
- Immunization Courses: Webcasts and Self Study
  https://www.cdc.gov/vaccines/ed/courses.html
- Pink Book Series
  https://www.cdc.gov/vaccines/ed/webinar-epv/index.html

ACIP General Best Practice Guidelines for Immunization
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/

COCA Calls/Webinars
https://emergency.cdc.gov/coca/calls/index.asp

CDC Vaccine Administration webpage
https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html

NFID Webinars
https://www.nfid.org/about-nfid/continuing-medical-education/webinars/

CDC Recommended and Minimum Ages and Intervals Between Vaccine Doses
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html#antibody

https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/age-interval-table.pdf

Immunization Action Coalition
https://www.immunize.org/

MDPH Immunization events/webinars
https://www.mass.gov/service-details/immunization-division-events

MCAAP Immunization Initiative Webinars
http://mcaap.org/immunization-cme/

CHOP Vaccine Education Center
https://www.chop.edu/centers-programs/vaccine-education-center

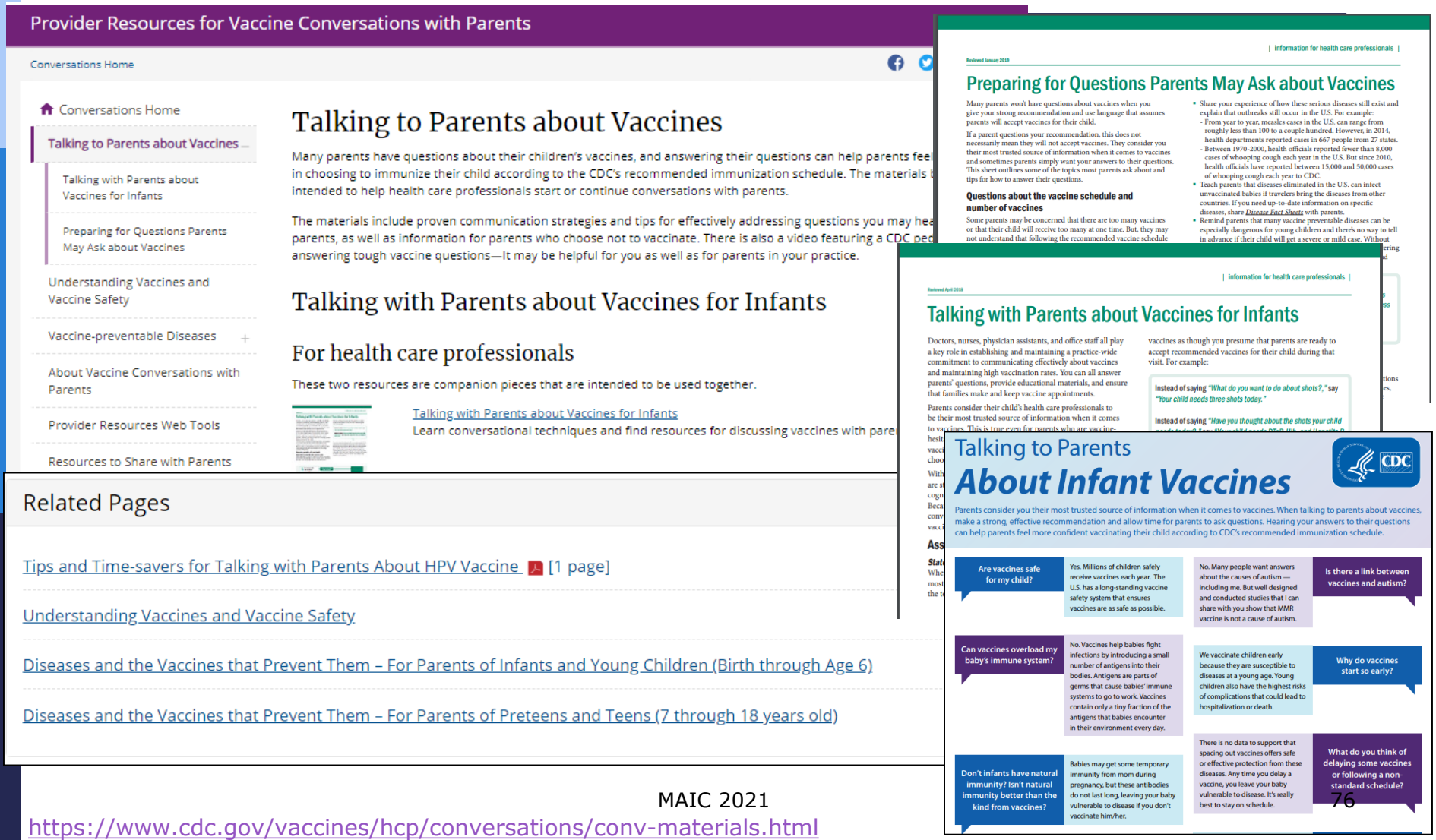
ACIP Recommendations gateway page
https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

https://www.immunize.org/acip/

Storage and Handling Resources

- MDPH Guidelines for Compliance with Federal and State Vaccine Administration Requirements: https://www.mass.gov/doc/guidelines-for-compliance-with-federal-vaccine-administration-requirements/download
- CDC Storage and Handling Toolkit (with COVID-19 addendum): https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
- USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners: https://www.usp.org/covid-19/vaccine-handling-toolkit

CDC Provider Resources for Vaccine Conversations with Parents



https://www.cdc.gov/vaccines/hcp/conversations/conv-materials.html
https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html

Pregnancy Resources

Toolkit for Prenatal Care Providers

Increasing the Use of Maternal Vaccines by Ob-gyns, Nurse-Midwives, and Other Healthcare Professionals

This comprehensive toolkit is intended to help prenatal care providers increase the rates of maternal immunization. Ob-gyns, nurse-midwives, and other healthcare professionals who serve pregnant women can all use this toolkit. The resources here include recommendations from CDC and other relevant details about vaccinating pregnant women.

We want your feedback for this toolkit! What do you find to be most helpful? Is something missing? Your input is important! Please email feedback to adultvaccines@cdc.gov.

Why Maternal Vaccines Are Important

- Tdap (Pertussis) Vaccine
- Rationale: Why Vaccinate Pregnant Women? (Tdap)
- Influenza (Flu) Vaccine and Pregnancy
- ACIP Recommendations and Pregnancy (Flu)

Implementation Resources

- Standards for Adult Immunization Practice
- Strategies for Increasing Adult Vaccination Rates
- Getting Reimbursed for Tdap Vaccination
- Resources for Provider Education

Maternal Vaccination Information

- Guidelines for Vaccinating Pregnant Women
- Recommended Immunization Schedules for Adults
- Maternal Vaccination Coverage
- Resources for Patient Education

Additional Resources for Prenatal Care Providers

Apps for Smartphones and Tablets

- CDC Vaccine Schedules

Podcasts at CDC

- Preventing Flu During Pregnancy

https://www.cdc.gov/vaccines/pregnancy/hcp-toolkit/index.html

COVID-19 Vaccination Resources

CDC COVID-19 Vaccination Home Page
https://www.cdc.gov/vaccines/covid-19/index.html

Product Info by US Vaccine
https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

COVID-19 Vaccine Quick Reference Guide for Healthcare Professionals
https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-quick-reference-guide-2pages.pdf

Interim Clinical Considerations for Use of COVID-19 Vaccine
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Summary Document for Interim Clinical Considerations
https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf

COVID-19 Vaccine Administration Errors and Deviations
https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-errors-deviations.pdf

Managing Anaphylaxis
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

Vaccinating Homebound Persons
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/homebound-persons.html

Training and Education
https://www.cdc.gov/vaccines/covid-19/training-education/index.html

Training and Education Resources
https://www.cdc.gov/vaccines/covid-19/training-education/resources.html

COVID-19 Vaccine Training Modules for Healthcare Providers
https://www2.cdc.gov/vaccines/ed/covid19/

Recipient Education
https://www.cdc.gov/vaccines/covid-19/hcp/index.html

Vaccination Toolkits
https://www.cdc.gov/vaccines/covid-19/toolkits/index.html

Vaccinate with Confidence
https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence.html

COVID-19 Vaccination Resources

USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners
https://www.usp.org/covid-19/vaccine-handling-toolkit

Pfizer
Manufacturer contact information
Customer Service: 800-879-3477
Medical Information: 800-438-1985
Website: https://www.cvdvaccine.com/
EUA
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine

CDC Vaccine Information
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

Moderna
Manufacturer contact information
Medical Information: 866-663-3762
Website: https://www.modernatx.com/
EUA
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine

CDC Vaccine Information
https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html

Janssen
Manufacturer contact information
Medical Information: 800-565-4008
Website: https://vaxcheck.jnj/

EUA
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine

CDC Vaccine Information
https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html

COVID-19 Vaccination Resources

Vaccine Safety

Ensuring COVID-19 Vaccine Safety in the US
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

Safety of COVID-19 Vaccines
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html

COVID-19 Vaccine Reporting Systems
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/reporting-systems.html

Vaccine Adverse Event Reporting System (VAERS)
https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html

10 Things Providers Should Know about VAERS
https://www.cdc.gov/coronavirus/2019-ncov/downloads/vaccines/10-things-healthcare-providers-need-to-know-about-VAERS.pdf

Patient Safety Checklist for Vaccination Clinics
https://www.cdc.gov/vaccines/covid-19/downloads/patient-safety-checklist-508.pdf

COVID-19 Vaccine Monitoring Systems for Pregnant People
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/monitoring-pregnant-people.html

V-SAFE & Vax Text
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe/printresources.html

https://www.cdc.gov/vaccines/covid-19/reporting/vaxtext/

VAERS
https://vaers.hhs.gov/faq.html

https://www.cdc.gov/coronavirus/2019-ncov/downloads/vaccines/10-things-healthcare-providers-need-to-know-about-VAERS.pdf

ACIP
https://www.cdc.gov/vaccines/acip/index.html

COVID-19 Recs (MMWRs)
https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html

FDA COVID-19 Vaccines (EUAs)
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

Vaccine Storage & Handling Toolkit
with Covid-19 Vaccine Addendum
https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

MA COVID-19 Vaccination Resources

COVID-19 Vaccine in MA
https://www.mass.gov/covid-19-vaccine

Main landing page for vaccine providers:
https://www.mass.gov/info-details/massachusetts-covid-19-vaccine-information#guidance-for-health-care-professionals-and-organizations-

MCVP Guidance for Vaccine Providers and Organizations:
https://www.mass.gov/info-details/massachusetts-covid-19-vaccine-program-mcvp-guidance-for-vaccine-providers-and

FAQs for Providers
https://www.mass.gov/info-details/covid-19-vaccine-frequently-asked-questions-vaccine-providers

Weekly Provider Bulletins
https://www.mass.gov/info-details/massachusetts-covid-19-vaccine-program-mcvp-guidance-for-vaccine-providers-and-organizations#weekly-provider-bulletins-

MA COVID-19 vaccination data report
https://www.mass.gov/info-details/covid-19-vaccination-program#weekly-covid-19-vaccination-report-

Stop COVID-19 – Vaccine education and outreach materials
https://www.mass.gov/info-details/stop-covid-19-vaccine-education-and-outreach-materials

COVID-19 Resources

CDC COVID-19 Home Page
https://www.cdc.gov/coronavirus/2019-nCoV/index.html

About COVID-19
https://www.cdc.gov/coronavirus/2019-ncov/your-health/about-covid-19.html

COVID-19 Vaccines
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

Communication Resources
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/resource-center.html

Ensuring COVID-19 Vaccine Safety in the US
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

Cases and Data Tracker
https://covid.cdc.gov/covid-data-tracker/#datatracker-home

Work and School
https://www.cdc.gov/coronavirus/2019-ncov/community/index.html

Link to ASL Videos
https://www.youtube.com/playlist?list=PLvrp9iOILTQatwnqm61jqFrsfUB4RKh6J

Easy to Read Resources
https://www.cdc.gov/coronavirus/2019-ncov/easy-to-read/index.html

Vaccination Clinic Planning Resources

CDC Vaccination Guidance During a Pandemic
https://www.cdc.gov/vaccines/pandemic-guidance/index.html

CDC Guidance for Planning for Vaccination Clinics Held at Satellite, Temporary or Off-Site Locations
https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html

CDC Resources for Hosting a Vaccination Clinic (includes Best Practices)
https://www.cdc.gov/flu/business/hosting-vaccination-clinic.htm

Patient Safety Checklist for Vaccination Clinics
https://www.cdc.gov/vaccines/covid-19/downloads/patient-safety-checklist-508.pdf

COVID-19 Vaccine Administration Competencies Assessment Form
https://www.cdc.gov/vaccines/covid-19/downloads/competencies-screening-checklist.pdf

NAIIS Checklist of Best Practices for Vaccination Clinics
https://www.izsummitpartners.org/content/uploads/2017/02/NAIIS-Vaccination-Clinic-Checklist_v2.pdf

CDC Clinic Supplies Check List
https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/vaccination-clinic-supply-checklist.html
https://www.cdc.gov/vaccines/hcp/admin/downloads/2020-vaccine-clinic-supply-checklist-508.pdf

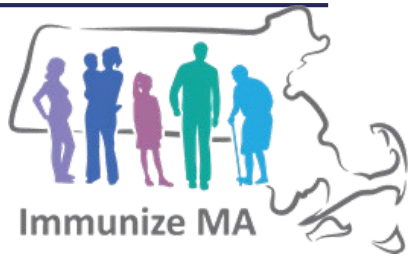
CDC Infection Control Guidance
https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

CDC Considerations for Planning Curbside/Drive-Through Vaccination Clinics
https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/curbside-vaccination-clinics.html

IAC Protective Measures for Vaccinating During a Pandemic
https://www.immunize.org/catg.d/p2009.pdf

IAC COVID Repository of Resources for Maintaining Immunizations during the COVID-19 Pandemic
https://www.immunizationcoalitions.org/resource-repository/

MDPH Immunization Division Contact Information



Immunization Division Main Number

For questions about immunization recommendations, disease reporting, etc.

Phone: 617-983-6800 (24/7 MDPH Epi line)

Fax: 617-983-6840

Website:

https://www.mass.gov/topics/immunization

MIIS Help Desk

Fax: 617-983-4301

Email questions to: miishelpdesk@state.ma.us

Website: https://www.mass.gov/service-details/massachusetts-immunization-information-system-miis

MDPH Vaccine Unit

Phone: 617-983-6828

Email questions to: dph-vaccine-management@massmail.state.ma.us

Website: https://www.mass.gov/service-details/vaccine-management

COVID email box:

COVID-19-Vaccine-Plan-MA@mass.gov

- Who can vaccinate
- Who can get vaccine
- Vaccine prioritization
- Where to get vaccinated
- How ‘x’ group will get vaccinated

MDPH Regional Immunization Nurses

Denise Dillon
Northeast
978-851-7261
denise.dillon@mass.gov

Linda Jacobs
Southeast
508-441-3980
linda.jacobs@mass.gov

Phyllis Schilp
Metro Boston & Central
617-983-6838
phyllis.schilp@mass.gov

Theodora Wohler
Metro West & Western
617-983-6837
theodora.wohler@mass.gov

Laurie Courtney
Nurse Manager
617-983-6811
laurie.a.courtney@mass.gov

THANK YOU!