

# Simplifying and Demystifying True and False **Contraindications**

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Robert M Jacobson, MD

Medical Director, Primary Care Immunization Program,  
Rochester, Kasson, and Southeast Minnesota

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# Learning Objectives

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- Identify common **false** contraindications
- List the steps in finding the **true** contraindications
- State why the **package inserts** fail as resources



# Definition of Contraindication

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- Condition puts recipient at risk for serious harm
- **Prohibition** against getting a vaccine
- Not subject to clinical judgment
- Basis for malpractice



# A Nearly Universal Contraindication

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- History of a serious allergic reaction or **anaphylaxis**
  - To a previous dose of the vaccine in question
  - To a constituent of the vaccine in question
- Personal history and not family history
- Anaphylaxis harbinger of life-threatening allergy
  - Two or more organ systems
  - Skin, respiratory, cardiologic, or gastrointestinal

# A Related Definition

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- **Precaution**

- Condition calls for provider-patient consideration
  - Might put recipient at risk for serious harm
  - Might cause diagnostic confusion
  - Might compromise response to the vaccine
- Need to weigh individual risks and benefits



# A Nearly Universal Precaution

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- **Acute** moderate to severe illness
  - With fever
  - Without fever
- Moderate = interfere/delay activities of daily living
- Severe = prevent activities of daily living
- Often better to await until acute phase resolves
- Avoids confusing illness with adverse effects
- However, not a contraindication

# The Impact of **False** Contraindications

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- All too often patients go **unvaccinated**
- Healthcare staff often complicit by not addressing
- Misinformation can have a long-lasting impact



## Examples of Universal **False** Contraindications

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- Mild acute illness with or without fever
  - Mild = symptoms do not interfere or prevent
- Mild-to-moderate local reaction after previous dose
- No recent physical exam in well-appearing person
- Fever after previous dose
- Convalescent phase of illness





## More Universal False Contraindications

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- Recent exposure to an infectious disease
- History of penicillin allergy
- History of other non-vaccine allergies
- Relatives with allergies to the vaccine
- Receiving allergen extract immunotherapy



## Nearly Universal False Contraindications

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- Antimicrobial therapy (all but live typhoid vaccine)
- Preterm birth (except HepB vaccine if <2000 g)
- History of Guillain-Barre Syndrome
  - Except\* if within 6 weeks of tetanus vaccine OR
  - Except\* if within 6 weeks of previous flu vaccine

\*Not a contraindication but a precaution

# Where Do We Find True Contraindications

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- Advisory Committee in Immunization Practices
  - **ACIP**
    - Technical Advisor to US Public Health Service
    - Established in 1964
    - Not just recommendations for immunizations
    - Also contraindications and precautions
    - Recommendations published in CDC's *MMWR*



## More on the ACIP

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- **Only** federal source of vaccine recommendations
  - Exception military
  - ACIP and not FDA
  - Recommendations official
- Meet at least three times a year
  - Consider not just licensure data for efficacy, safety
  - Also limits vaccine use by demonstrated need
  - No other licensed drug or device has this standard

# ACIP Recommendations and Immunization Safety

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- FDA requires safety versus placebo at licensure
- FDA monitors post licensure quality of manufacture
- Also **FDA, CDC, & ACIP monitor immunization safety**
  - Passive reports with VAERS
  - Active monitoring with Vaccine Safety Datalink
  - V-safe
  - CISA for adverse events consultation
  - Vaccine pregnancy registries (e.g. COVID)

# Comparison with Other Health Care Products

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Product	Proof of Efficacy by Placebo-Controlled Trials	Proof of Safety by Placebo-Controlled Trials	Proof of Epidemiologic Need in Current US Population	Proof of a Lack of Available Reasonable Alternatives
Vitamins and minerals	No	No	No	No
Probiotics and other nutraceuticals	No	No	No	No
FDA licensed drugs and devices	Yes	Yes	No	No
Vaccines and immunizations	Yes	Yes	Yes	Yes

# The Broadening of the ACIP Reach

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- **Harmonized** recommendations in 1995
  - Centers for Disease Control and Prevention (CDC)
  - Food and Drug Administration or FDA
  - Major independent academic medical academies
- Arbiter of **Vaccines for Children** coverage
- Arbiter for **Affordable Care Act** coverage
  - Immunizations as preventive services
  - First dollar coverage

# Best Source of Contraindications and Precautions

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- Go to [cdc.gov/vaccines](https://www.cdc.gov/vaccines)
- Scroll down to find **For Professionals**
- Click **Healthcare Professionals**
- Scroll down to **ACIP Recommendations** and click it
- Find the left-hand nav bar
- Find **Comprehensive Recommendations & Guidelines**
- Click it







Search

# Vaccines & Immunizations

[Print](#)

**Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2024**

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars. To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Vaccine and other immunizing agents	Birth	1 mo	2 mo	4 mo	6 mo	9 mo	12 mo	15 mo	18 mo	19–25 mo	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Respiratory syncytial virus (RSV) a+b (nirsevimab)	1 dose (depending on maternal RSV vaccination status; See Notes)		1 dose (if through 18 months; See Notes)														
Hepatitis B (HepB)	1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose														
Rotavirus (RV) (RV1 (2-dose series), RV2 (3-dose series))	See Notes																
Diphtheria, tetanus, acellular pertussis (DTaP-4/5)	1 <sup>st</sup> dose, 2 <sup>nd</sup> dose, 3 <sup>rd</sup> dose, 4 <sup>th</sup> dose, 5 <sup>th</sup> dose																
Human papillomavirus type 9 (HPV)	1 <sup>st</sup> dose, 2 <sup>nd</sup> dose (See Notes)																
Pneumococcal conjugate (PCV13, PCV20)	1 <sup>st</sup> dose, 2 <sup>nd</sup> dose, 3 <sup>rd</sup> dose, 4 <sup>th</sup> dose																
Inactivated poliovirus (IPV <18 yrs)	1 <sup>st</sup> dose, 2 <sup>nd</sup> dose, 3 <sup>rd</sup> dose, 4 <sup>th</sup> dose																

**Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2024**

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
COVID-19	1 or more doses of updated (2023–2024 Formula) vaccine (See Notes)			
Influenza inactivated (IIV) or influenza recombinant (RIV)	1 dose annually			
Influenza live, attenuated (LAIV)	1 dose annually			
Respiratory Syncytial Virus (RSV)	Seasonal administration during pregnancy. See Notes.			≥60 years
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes)			
Tetanus, diphtheria, pertussis (Tdap or Td)	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)			For healthcare personnel, see notes
Zoster (ZV)	2 doses (if born in 1988 or later)			
Zoster recombinant (ZvR)	2 doses for immunocompromising conditions (see notes)			
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination and condition			
Pneumococcal (PCV13, PCV20, PPSV23)	1 through 4 doses			
Hepatitis A (HepA)	2, 3, or 4 doses depending on risk			
Hepatitis B (HepB)	2, 3, or 4 doses depending on risk			

## 2024 Immunization Schedules

[Learn More](#)

**COVID-19**

[For](#)  
[an](#)

[For](#)



Children (Birth to 18 Years)



Pregnancy



### Children (Birth to 18 Years)



### Pregnancy and



### Adults (19 and Older)



### Travelers

## For Professionals



Healthcare Professionals



Immunization Managers

## Vaccine Communications

Past Announcements

Newsletters

Immunization MMWRs

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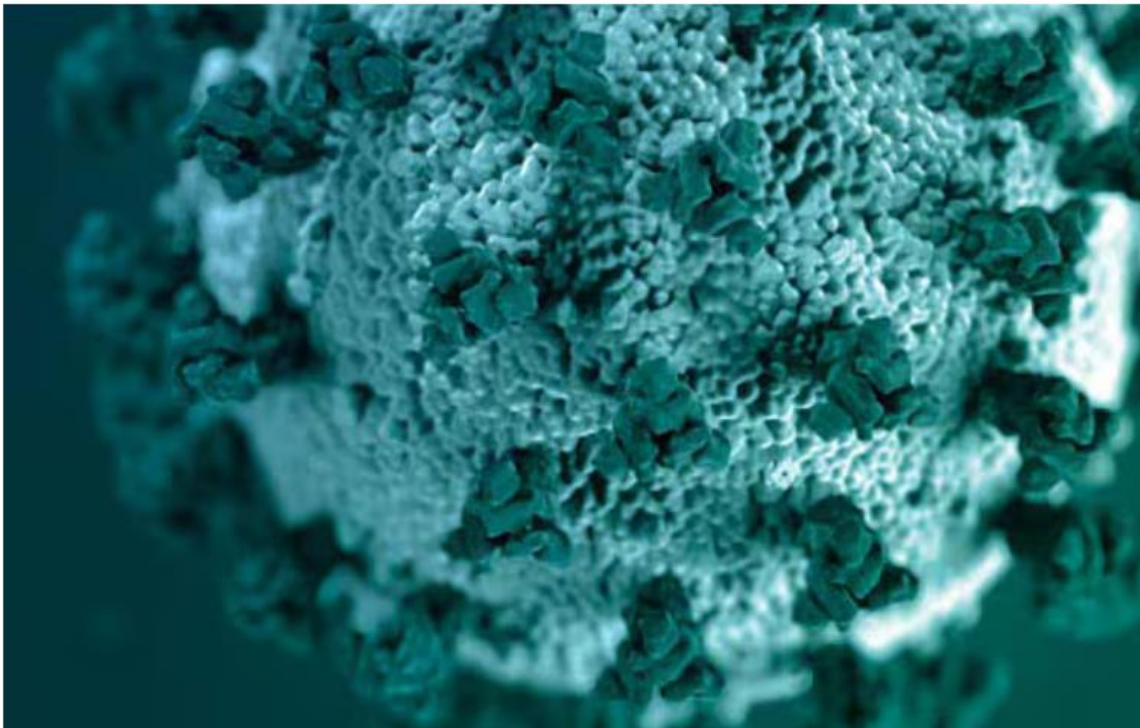
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# Healthcare Providers / Professionals

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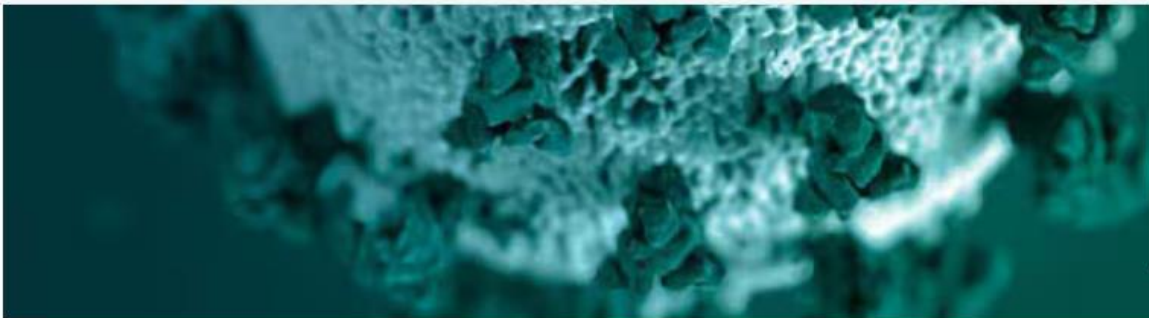
## Preparing Your Practice for COVID-19 Vaccination

Get evidence-based immunization strategies and resources that are critical to implementing a successful vaccination program.

[Get information](#)







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ACIP  
Recommendations



Vaccination  
Schedules



Storage and Handling



V  
A

## Clinical Resources



 Education and Train



# Vaccine Recommendations and Guidelines of the ACIP

ACIP Recs Home

ACIP Recs Home

Vaccine-Specific Recommendations +

Recs Listed by Date

Comprehensive Recommendations and Guidelines +

Archived ACIP Recs

## ACIP Vaccine Recommendations Guidelines

Advisory Committee on Immunization Practices (ACIP)

[Print](#)

### Vaccine-Specific ACIP Recommendations

- [Anthrax](#)
- [Cholera](#)
- [MMRV](#)
- [Meningococcal](#)

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# Vaccine Recommendations and Guidelines of the ACIP

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Vaccine-Specific Recommendations +

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**Comprehensive Recommendations and Guidelines** -

General Best Practice Guidelines +

Archived ACIP Recs

## Comprehensive Recommendation Guidelines

[Print](#)

Advisory Committee on Immunization Practices (ACIP)

- [General Best Practice Guidelines for Immunization](#)
- *MMWR*, November 25, 2011, Vol 60, #RR07  
[Immunization of Health-Care Personnel](#)
  - [Print version](#) [48 pages]

This report updates the previously published summary of recommended immunization practices for health-care personnel (HCP) in the United States (1997). This report su

## Next Steps to Find the Table

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- **General Best Practice Guidelines for Immunization**
- Click it
- Scroll down to **Contraindications and Precautions**
- Click it
- Scroll down to **Table 4-1**
- Organized by vaccine
- Lists contraindications and precautions for each





# Vaccine Recommendations and Guidelines of the ACIP

ACIP Recs Home

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Vaccine-Specific Recommendations +

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# Vaccine Recommendations and Guidelines of the ACIP

[ACIP Recs Home](#) > [Comprehensive Recommendations and Guidelines](#)

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Vaccine-Specific Recommendations +

Recs Listed by Date

Comprehensive Recommendations and Guidelines -

General Best Practice Guidelines -

## General Best Practice Guidelines Immunization

[Print](#)

Updated August 1, 2023

### Best Practices Guidance

*Kroger A, Bahta L, Long S, Sanchez P*

[Printer friendly version](#) 📄 [1.23 MB, 198 pages]

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Introduction

History

Timing and Spacing of Immunobiologics

Contraindications and Precautions

Preventing and Managing Adverse Reactions

Vaccine Administration

Storage and Handling of Immunobiologics

Altered Immunocompetence

Special Situations

Vaccinations Records

## Introduction

Purpose and topics covered in this report...

## History

History of development of: Timing and Spacing, Contraindications and Precautions, Preventing and Managing Adverse Reactions...

## Timing and Spacing of Immunobiologics

Vaccine scheduling, supply and lapsed schedule, spacing of doses, simultaneous and nonsimultaneous administration, licensed combination vaccines, interchangeability of formulations, extra doses, conjugate vaccines...

## Contraindications and Precautions

General principles, standards of valid contraindications and precautions, and conditions incorrectly perceived as contraindications...



# Vaccine Recommendations and Guidelines of the ACIP

ACIP Recs Home > Comprehensive Recommendations and Guidelines > General Best Practice Guidelines

ACIP Recs Home

Vaccine-Specific Recommendations +

Recs Listed by Date

Comprehensive Recommendations and Guidelines -

General Best Practice Guidelines -

## Contraindications and Precaution General Best Practice Guidelines for Immunization

[Print](#)

Updated August 1, 2023

[Printer friendly version](#) [21 pages]

### Updates

Major changes to the best practice guidance in this section include 1) enha



## TABLE 4-1. Contraindications and precautions used vaccines

Vaccine	Citation	Contraindications	Pr
Dengue- ONLY use in persons who have laboratory confirmation of previous dengue infection AND reside in endemic dengue areas <sup>(b)</sup>	(38)	<p>Lack of laboratory evidence of previous dengue infection</p> <p>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</p> <p>Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy<sup>(c)</sup> or patients with HIV infection who are severely immunocompromised)</p>	Pr HI ev im M ill
DT, Td	(4)	Severe allergic reaction (e.g.,	GI

TABLE 4-1. Contraindications and precautions<sup>(a)</sup> to commonly used vaccines

Vaccine	Citation	Contraindications	Precautions
Dengue– ONLY use in persons who have laboratory confirmation of previous dengue infection AND reside in endemic dengue areas <sup>(b)</sup>	(38)	<p>Lack of laboratory evidence of previous dengue infection</p> <p>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</p> <p>Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy<sup>(c)</sup> or patients with HIV infection who are severely immunocompromised)</p>	<p>Pregnancy</p> <p>HIV infection without evidence of severe immunosuppression</p> <p>Moderate or severe acute illness with or without fever</p>
DT, Td	(4)	Severe allergic reaction (e.g.,	GBS <6 weeks after

# Typically

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- **One to three** contraindications
- One to three precautions
- One each for each of the hepatitis A and B vaccines
- Three and four respectively for the MMR vaccine



Hepatitis A	<a href="#">(40)</a>	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	Moderate or severe acute illness with or without fever
Hepatitis B	<a href="#">(41)</a>	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
Hib	<a href="#">(42)</a>	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Age <6 weeks	Moderate or severe acute illness with or without fever
HPV <sup>(d)</sup>	<a href="#">(43)</a>	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component, including yeast	Moderate or severe acute illness with or without fever

# True Contraindications to the Hepatitis B Vaccine

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- Severe allergic reaction (e.g., **anaphylaxis**)
  - After a previous dose
  - Or to a vaccine component
- Hypersensitivity to yeast





# Common **False** Contraindications to the HepB Vaccine

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- Pregnancy
- Autoimmune disease



## True Contraindications to the HPV Vaccine

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- Severe allergic reaction (e.g., anaphylaxis)
  - After a previous dose
  - Or to a vaccine component



# Common **False** Contraindications to the HPV Vaccine

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- Immunosuppression
- Previous equivocal or abnormal Papanicolaou test
- Known HPV infection
- Breastfeeding
- History of genital warts



			<p>Pregnancy</p> <p>Latex sensitivity (MenB-4c)</p>
MMR <sup>(j),(k)</sup>	<u>(1)</u>	<p>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</p> <p>Pregnancy</p> <p>Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy<sup>(c)</sup> or patients with HIV infection who are severely immunocompromised)</p> <p>Family history of altered immunocompetence<sup>(m)</sup></p>	<p>Recent (<math>\leq 11</math> months) receipt of antibody-containing blood product (specific interval depends on product)</p> <p>History of thrombocytopenia or thrombocytopenic purpura</p> <p>Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing<sup>(l)</sup></p> <p>Moderate or severe acute illness with or without fever</p>
MPSV4	<u>(49)</u>	<p>Severe allergic reaction (e.g., anaphylaxis) after a previous dose</p>	<p>Moderate or severe acute illness with or without fever</p>

# True Contraindications to the **MMR** Vaccine

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- Severe allergic reaction (e.g., anaphylaxis)
  - After a previous dose
  - Or to a vaccine component
- Pregnancy
- Known severe immunodeficiency
- Family history of altered immunocompetence<sup>(m)</sup>



# Common **False** Contraindications to the MMR Vaccine

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- Positive tuberculin skin test
- Simultaneous tuberculin skin testing
- Breastfeeding
- Pregnancy of recipient's mother
- Female recipient of child-bearing age
- ...



## More Common False Contraindications

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- ...
- Immunodeficient household contact
- Asymptomatic or mildly symptomatic HIV infection
- Allergy to eggs

...

## Footnotes Are Important with this Table

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- Severe allergic reaction (e.g., anaphylaxis)
  - After a previous dose
  - Or to a vaccine component
- Pregnancy
- Known severe immunodeficiency
- Family history of altered immunocompetence<sup>(m)</sup>

...





## This Specific Footnote

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- Family history of altered immunocompetence<sup>(m)</sup>

<sup>(m)</sup> family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents and siblings), **unless** the immune competence of the potential vaccine recipient has been substantiated clinically or verified by a laboratory



Tdap	<a href="#">(52)</a>	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap	GBS <6 weeks after a previous dose of tetanus-toxoid-containing vaccine Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized  History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid—containing or tetanus-toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid-containing vaccine  Moderate or severe acute illness with or without fever
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# True Contraindications to the **Tdap** Vaccine

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- Severe allergic reaction (e.g., anaphylaxis)
  - After a previous dose
  - Or to a vaccine component
- Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap



# Common **False** Contraindications to the Tdap Vaccine

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- Fever of  $< 40.5$  °C, after a previous dose
- Fussiness or mild drowsiness after a previous dose
- Family history of seizures
- Family history of sudden infant death syndrome
- Family history of an adverse event after a dose
- Stable neurological condition



# COVID-19's Contraindications Listed Elsewhere

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- ACIP recommendations for COVID on **interim pages**
- Start at same starting point: [cdc.gov/vaccines](https://cdc.gov/vaccines)
- Look at special box on upper right
- Click there for recommendations & contraindications
- Click Healthcare Professionals and Jurisdictions
- Then scroll down
- Click Interim Clinical Considerations



# Vaccines & Immunizations

[Print](#)

**Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2024**

**Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2024**

**2024 Immunization Schedules**

[Learn More](#)

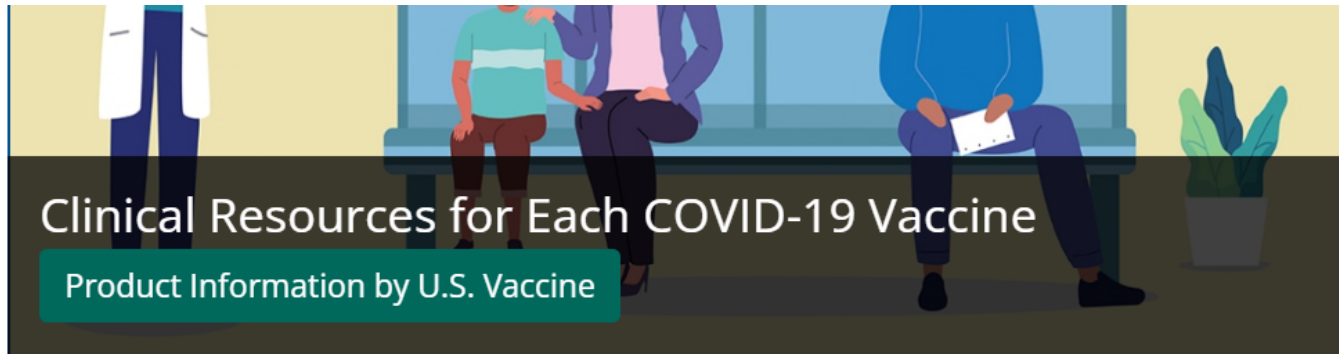
## COVID-19 Vaccination

[For Healthcare Professionals and Jurisdictions](#)

[For You and Your Family](#)

**Children (Birth to 18 Years)**

**Pregnancy and Vaccination**



# Clinical Resources for Each COVID-19 Vaccine

Product Information by U.S. Vaccine


- [6 Things to Know About the COVID-19 Vaccine for Children](#)
- [Resources to Promote COVID-19 Vaccine for Children and Teens](#)




**Enroll as a COVID-19 Vaccine Provider**

Learn More and Enroll

### Interim Clinical Considerations



### Provider Requirements and Support



### Talking with Vaccine Recipients



### COVID-19 Tracking and Reporting Systems



# COVID-19's Contraindications Listed Elsewhere

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- Now scroll to **Safety**
- Click Contraindications and Precautions





Guidance for people who are **not** immunocompromised

## Implementation

Timing, spacing, age transitions, and simultaneous administration

Vaccination and SARS-CoV-2 laboratory testing

Patient counseling

Interchangeability of COVID-19 vaccines

## Safety

Contraindications and precautions

Safety considerations for Novavax COVID-19 Vaccine

Reporting of vaccine adverse events

COVID-19 vaccination and myocarditis and pericarditis

Safety considerations for mRNA COVID-19 vaccines: Moderna and Pfizer-BioNTech

## Special Situations and Populations

**Table 3. Contraindications and precautions to COVID-19 vaccination**

Medical condition or history	Guidance	Recommended action
History of a severe allergic reaction* (e.g., anaphylaxis†) after a previous dose or to a component of the COVID-19 vaccine‡	Contraindication	Do not vaccinate with the same COVID-19 vaccine type. <sup>§</sup>  May administer the alternate COVID-19 vaccine type. <sup>§</sup>  See <a href="#">Considerations for people with a history of allergies and allergic reactions</a> for additional information.
History of a diagnosed non-severe allergy* to a component of the COVID-19 vaccine‡	Precaution	May administer the alternate COVID-19 vaccine type. <sup>§</sup>
History of a non-severe, immediate (onset less than 4 hours) allergic reaction* after administration of a previous dose of one COVID-19 vaccine type <sup>§</sup>	Precaution	For additional information, see <a href="#">Considerations for people with a history of allergies and allergic reactions</a> .
Moderate or severe acute illness, with or without fever	Precaution	<a href="#">Defer vaccination</a> until the illness has improved.
History of MIS-C or MIS-A	Precaution	See <a href="#">COVID-19 vaccination and MIS-C and MIS-A</a> .
History of myocarditis or pericarditis within 3 weeks after a dose of <b>any COVID-19 vaccine</b>	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided.  See <a href="#">COVID-19 vaccination and myocarditis and pericarditis</a> .

**Abbreviations:** MIS-C = multisystem inflammatory syndrome in children; MIS-A = multisystem inflammatory syndrome in adults

\*Allergic reactions in Table 3 are defined as follows:

# One True Contraindication to a Specific COVID Vaccine

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- Severe allergic reaction (e.g., anaphylaxis)
  - After a previous dose to that specific vaccine
  - Or to a vaccine component in that vaccine



# Common **False** Contraindications to COVID Vaccines

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- Other allergies (pets, food, environmental, latex, etc.)
- Recent COVID infection
- Pregnancy
- Prematurity
- Congenital heart disease



# Package Inserts Versus the ACIP Listings

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- Significant **mismatches**
  - Indications versus recommendations
  - Listings of contraindications and precautions
- Package inserts result from Pharma's licensure studies
- The ACIP language result from further deliberation
  - Epidemiology, experience, post-licensure studies
  - Listings here more likely to be updated, corrected



# Further Advantages of ACIP Listings

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- **Harmonized** among the experts
- Subject to **ongoing** review
- Matches **Vaccine Information Statements** content
- For the most part, easily accessed in a single location
  - Start here [cdc.gov/vaccines](https://www.cdc.gov/vaccines)
  - End up at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html#t-01>

# Summary

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- Recognize common **false** contraindications
- Know the steps in finding the **true** contraindications
- Explain why the **package inserts** fail as resources

