

The Importance of Minimum Ages and Intervals in the Vaccine Schedule

How to avoid giving a vaccine too soon, and what to do if you do

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Background

- Healthcare professionals and members of the public can contact IAC by writing to admin@immunize.org.
- We answer ~200–300 such emails each month.
- It appears that more errors are being made (IZ schedule more complex, additional available products, “alternative schedules,” more recommended adult vaccines). In addition, some types of errors that might have gone undetected in the past are now caught by state immunization information systems.

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From January 2015 through December 2017, IAC received questions about approximately **1,180 medical errors** related to vaccination, including errors in vaccine storage and handling, administration, scheduling, and documentation.

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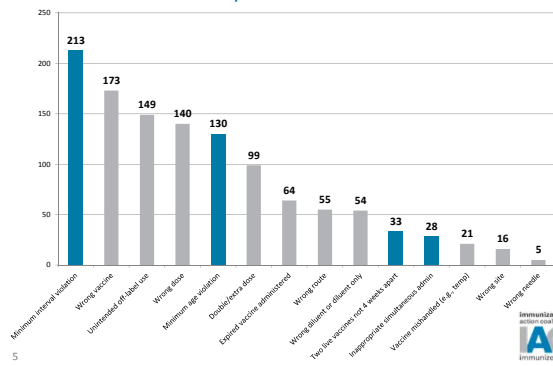


Scheduling errors, including violations of the minimum age and interval rules, giving vaccines simultaneously when not recommended, and administering 2 live virus vaccines not given together less than 4 weeks apart, were the #1 type of error reported to IAC over this 3-year period—**34% of the total**.

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Types of Vaccine Administration Errors Communicated to IAC
January 2015–December 2017



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A CDC study using VAERS data from 2000–13 also found that the most common error group was “**inappropriate schedule**”—5,947 (27%) of the total identified 21,843 errors.

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Vaccination Errors reported to the Vaccine Adverse Event Reporting System, (VAERS) United States, 2000–2013; *Vaccine*, June 22, 2015
<https://www.ncbi.nlm.nih.gov/pubmed/25980429>



What exactly are vaccine minimum ages and intervals?



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Minimum ages and intervals for vaccines

- **Minimum age:** the youngest age group at risk for a disease for whom efficacy and safety of a vaccine have been demonstrated.
- **Minimum interval:** the shortest allowed interval between doses of a series, based on the results of clinical trials for efficacy and safety.



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Minimum ages and intervals for vaccines (cont.)

- Vaccine doses should not be administered at intervals less than the minimum intervals or earlier than the minimum age.*
- Conversely, *increasing* the interval between doses of a multi-dose vaccine does not diminish the effectiveness of the vaccine.

* One exception: ACIP recommends a dose of MMR for infants age 6–11 mos who will be traveling internationally or who are at risk due to a measles outbreak. This dose does not count as dose #1, however.



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IMPORTANT RULE:

Vaccine doses should not be administered at intervals less than the recommended minimum intervals or earlier than the minimum ages.

But there is no maximum interval!
(except for oral typhoid vaccine in some circumstances)



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Doses given even years later than recommended are still valid because the body has “immunologic memory.” The real problem with longer than recommended intervals is not the validity of the doses or their immunologic effect. It is that, until the series is complete, the person may remain susceptible to the associated vaccine-preventable disease.



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What else does ACIP have to say about the use of minimum ages and intervals?



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From ACIP's "General Best Practices Guidelines for Immunization"

- Vaccination providers should adhere as closely as possible to the **recommended vaccination schedules** to provide optimal protection.
- Administration of doses of a vaccine series using intervals that are shorter than recommended might be necessary in certain circumstances, such as impending international travel or when a person is behind schedule but needs rapid protection. You also might choose to seize the opportunity and give vaccines at the minimum intervals when a patient who is in the office is unlikely to return for recommended visits.



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From ACIP's "General Best Practices Guidelines for Immunization" (cont.)

- The accelerated schedule should be used when a child is more than a month behind schedule. Once you have the child back on schedule, use the recommended ages and intervals on the childhood schedule.
- Vaccine doses should not be administered at intervals less than these minimum intervals or at an age that is younger than the minimum age.
- Doses administered too close together or at too young an age can lead to a suboptimal immune response and will be considered invalid.



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From ACIP's "General Best Practices Guidelines for Immunization" (cont.)

- Administering a dose a few days earlier than the minimum interval or age is unlikely to have a substantially negative effect on the immune response to that dose. Therefore, ACIP allows a **4-day grace period** for vaccine doses administered before the minimum interval or age.



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ACIP's "Grace Period"

- Vaccine doses administered up to 4 days before the minimum interval or age can be counted as valid.
- The grace period should be used primarily when reviewing vaccination records.
- The 4-day grace period should not be used when scheduling future vaccination visits and cannot be applied to the 28-day interval between two different live parenteral vaccines not administered at the same visit.
- The grace period cannot be used for rabies vaccine.
- Local or state mandates might supersede this 4-day exemption.



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How to count ages and intervals

- If the interval is **less than 4 months**, it is common to convert months into days or weeks. (*e.g., 1 month = 4 weeks = 28 days*)
- For intervals of **4 months or longer**, you should consider a month a "calendar month" – the interval from one calendar date to the next a month later. (*e.g., 6 months from October 1 is April 1*)
- This convention was introduced on the childhood immunization schedule in 2002.
- Check the exact wording on CDC's immunization schedules.



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What happens when you violate a minimum age or minimum interval rule?



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The result of making such errors can be serious, including:

- harm to the vaccinee from a side effect or vulnerability to disease;
- inconvenience to the parent/patient and perhaps ill will;
- unreimbursed cost to the provider; and
- loss of trust in the provider, with possible negative publicity or even legal action.

Avoiding such errors benefits everyone.



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HELP! “I am a nurse consultant on-call for the state of X. I just received a call from a nurse who tells me she just gave a set of 1-year shots to a 9-month-old—all 6 immunizations.”



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HELP! “I have a patient who got his 1st hep A vaccine on 1/30/17 and his 2nd on 6/13/17. According to our state registry, it is not valid. I am wondering if we have to repeat the 2nd dose or if there is any leeway. The patient is about to enter preschool.”



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HELP! “We have a new patient, a 17-year-old female, who, according to her records, received the MenACWY vaccine three times, at ages 11, 12, and 13. Does she still need a booster at 16?”



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HELP! “While registering her for kindergarten, it was brought to my attention by the school RN that my daughter’s initial MMR vaccine may not be valid. She received this dose 25 days before her first birthday. I do not want to re-administer a 3rd vaccine if it is not necessary. What, if any, steps can I take to avoid re-vaccinating my daughter?”



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HELP! “A nurse in my office accidentally gave flu vaccine to 3-month-old twins. Mom is understandably very upset. Is there any data on the safety or efficacy of this vaccine in babies under 6 months?”



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Common *minimum age* errors

- Giving the 1st dose of MMR, varicella, or hepatitis A vaccine before age 12 mos
- Giving the 4th dose of DTaP before age 12 months (or less than 6 mos after 3rd dose)
- Finishing an infant’s hepatitis B series before age 24 wks
- Giving any vaccine (except hepatitis B) before age 6 wks
- Giving the 2nd dose of MenACWY vaccine before age 16 yrs for a healthy adolescent



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Common *minimum interval* errors

- Giving the 2nd dose of hepatitis A vaccine less than 6 mos after the first dose
- Giving the hepatitis B vaccine series without at least 4 wks between doses 1 and 2; 8 wks between doses 2 and 3; and 16 wks between doses 1 and 3



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Common *minimum interval* errors (cont.)

- Not allowing 6 months between the next-to-last and last dose of IPV
- Giving the 3-dose HPV vaccine series without at least 4 wks between doses 1 and 2; 12 wks between doses 2 and 3; and 5 months between doses 1 and 3
- Giving the 2-dose HPV vaccine series without at least 5 months between the 2 doses



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How to avoid such errors?

- Know the minimum intervals for all vaccine series.
- Keep an easy-to-read immunization schedule handy for clinical staff.
- Train front-office staff to never schedule well-child visits *before* the critical dates (e.g., make sure child will actually be 12 mos old at the “1-year checkup”).
- Attempt to locate old vaccination records by contacting previous healthcare providers and reviewing your state registry.
- If you still aren't sure if a dose will be valid, check with your state immunization program *before* giving it.



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A clinician’s best friend...

CDC’s “Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines”

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



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Vaccine and dose number	Recommended age for this dose	Minimum age for this dose	Recommended interval between doses	Minimum interval between doses
DTaP-IPV	2 months	6 weeks	4 weeks	4 weeks
DTaP-IPV	4 months	10 weeks	4 weeks	4 weeks
DTaP-IPV	6 months	14 weeks	4 weeks	4 weeks
DTaP-IPV	15-18 months	18 months ¹	4 weeks	4 weeks
DTaP-IPV	4-6 years	4 years	4 weeks	4 weeks
DTaP-IPV	11-12 years	11 years	4 weeks	4 weeks
DTaP-IPV	16-18 years	16 years	4 weeks	4 weeks
DTaP-IPV	65 years and older	65 years	4 weeks	4 weeks
DTaP-IPV	70 years and older	70 years	4 weeks	4 weeks
DTaP-IPV	75 years and older	75 years	4 weeks	4 weeks
DTaP-IPV	80 years and older	80 years	4 weeks	4 weeks
DTaP-IPV	85 years and older	85 years	4 weeks	4 weeks
DTaP-IPV	90 years and older	90 years	4 weeks	4 weeks
DTaP-IPV	95 years and older	95 years	4 weeks	4 weeks
DTaP-IPV	100 years and older	100 years	4 weeks	4 weeks
DTaP-IPV	105 years and older	105 years	4 weeks	4 weeks
DTaP-IPV	110 years and older	110 years	4 weeks	4 weeks
DTaP-IPV	115 years and older	115 years	4 weeks	4 weeks
DTaP-IPV	120 years and older	120 years	4 weeks	4 weeks
DTaP-IPV	125 years and older	125 years	4 weeks	4 weeks
DTaP-IPV	130 years and older	130 years	4 weeks	4 weeks
DTaP-IPV	135 years and older	135 years	4 weeks	4 weeks
DTaP-IPV	140 years and older	140 years	4 weeks	4 weeks
DTaP-IPV	145 years and older	145 years	4 weeks	4 weeks
DTaP-IPV	150 years and older	150 years	4 weeks	4 weeks
DTaP-IPV	155 years and older	155 years	4 weeks	4 weeks
DTaP-IPV	160 years and older	160 years	4 weeks	4 weeks
DTaP-IPV	165 years and older	165 years	4 weeks	4 weeks
DTaP-IPV	170 years and older	170 years	4 weeks	4 weeks
DTaP-IPV	175 years and older	175 years	4 weeks	4 weeks
DTaP-IPV	180 years and older	180 years	4 weeks	4 weeks
DTaP-IPV	185 years and older	185 years	4 weeks	4 weeks
DTaP-IPV	190 years and older	190 years	4 weeks	4 weeks
DTaP-IPV	195 years and older	195 years	4 weeks	4 weeks
DTaP-IPV	200 years and older	200 years	4 weeks	4 weeks




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Summary of Recommendations for Child/Teen Immunization (Age birth through 18 years) PAGE 1 OF 4

<p>Immunization schedule for routine vaccination and other guidelines (This schedule can be given with other immunizations.)</p> <p>Immunization schedule for catch-up vaccination (This schedule can be given with other immunizations.)</p> <p>Immunization schedule for special circumstances (This schedule can be given with other immunizations.)</p> <p>Immunization schedule for special circumstances (This schedule can be given with other immunizations.)</p>	<p>Contraindications and precautions (This schedule can be given with other immunizations.)</p> <p>Contraindications and precautions (This schedule can be given with other immunizations.)</p> <p>Contraindications and precautions (This schedule can be given with other immunizations.)</p>
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www.immunize.org/catg.d/p2010.pdf



And/or check with your state immunization registry about when the next dose should be given!




But “stuff” happens!
 What should you do if you inadvertently give a dose at an earlier age or interval than allowed?




Minimum interval violations

- A dose administered 5 or more days earlier than the recommended **minimum interval** between doses is not valid and must be repeated.
- The repeat dose should be spaced after the **INVALID** dose by the recommended minimum interval.




Minimum age violations

- Doses administered 5 or more days before the **minimum age** should be repeated on or after the patient reaches the minimum age. If the vaccine is a live virus vaccine, waiting at least 28 days from the invalid dose is recommended.
- ACIP does not require a minimum interval when an **inactivated vaccine** is given before the minimum age. Once the minimum age is reached, the repeat dose can be given and can be counted. If the vaccine is a **live virus vaccine**, ensuring that a minimum interval of 28 days has elapsed from the invalid dose is recommended.



Minimum age violations (cont.)

- HOWEVER**, some state immunization registries follow a stricter rule, and, when a dose is given before the minimum age, require that the next dose be given after both the minimum age and interval.



ACIP-allowed minimum age/interval exemptions

(besides the 4-day grace period)

- **Hep A** – If 2 doses of hep A vaccine are given without the minimum interval (i.e., after the first *invalid* dose, the HCP doesn't wait the recommended 6 months from that dose to give another dose), another (4th) dose is not needed.
- **Hep B** – The spacing between a 3rd dose of hep B vaccine at 4 months and a 4th dose at 6 months is irrelevant as long as the child is 24 weeks old and it has been at least 16 weeks since the first dose (e.g., infant has received birth dose and then combos).



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ACIP-allowed minimum age/interval exemptions (cont.)

(besides the 4-day grace period)

- **Varicella** – If a child younger than 13 years receives varicella #2 at an interval of 4 weeks or longer from varicella #1, the dose does not need to be repeated.
- **DTaP** – If DTaP #4 is given with at least a 4-month interval after DTaP #3, it does not need to be repeated. However, the minimum age of 12 months for the 4th dose must be met and the 4-day grace period cannot be used here.



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ACIP-allowed minimum age/interval exemptions (cont.)

(besides the 4-day grace period)

- **HPV** – In a 3-dose HPV schedule, the 3rd dose of HPV can be considered to be valid if it was separated from the first dose by at least 5 months (instead of 6 months) and from the second dose by at least 12 weeks.



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ACIP-allowed minimum age/interval exemptions (cont.)

(besides the 4-day grace period)

- **MenB** – The minimum intervals for:
 - *Trumenba 2-dose* are 6 mos between doses 1 and 2*;
 - *Trumenba 3-dose* are 4 wks between doses 1 and 2, 4 mos between doses 2 and 3, and 6 mos between doses 1 and 3;[§]
 - *Bexsero*, 4 wks between doses 1 and 2.[§]

* *Trumenba 2-dose*: If there are less than 6 mos between doses 1 and 2, a 3rd dose is recommended 4 mos after the 2nd dose and at least 6 mos after the 1st dose.

[§] *Trumenba 3-dose and Bexsero*: If these intervals are violated, the doses still count and do not need to be repeated.



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To report errors

The Institute for Safe Medication Practices (ISMP) has a website to report vaccine errors—the [Vaccine Error Reporting Program \(VERP\)](http://verp.ismp.org). <http://verp.ismp.org>

VERP was created to allow healthcare professionals and patients to report vaccine errors confidentially. By collecting and quantifying information about these errors, ISMP will be better able to advocate for changes in vaccine names, labeling, or other appropriate modifications that could reduce the likelihood of vaccine errors in the future.



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In March 2015, ISMP published an excellent guide titled *Recommendations For Practitioners To Prevent Vaccine Errors*

www.ismp.org/newsletters/acutecare/showarticle.aspx?id=104



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To report errors

CDC recommends that healthcare professionals also report vaccine errors to the [Vaccine Adverse Events Reporting System \(VAERS\)](https://vaers.hhs.gov/index). <https://vaers.hhs.gov/index>

If an adverse event occurs following a vaccine administration error, a report should definitely be sent to VAERS. Adverse events should be reported to VAERS regardless of whether a healthcare professional thinks its related to the vaccine or not, as long as it follows administering a dose of vaccine.



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Other scheduling errors

This presentation focuses only on minimum ages and intervals between doses of the same vaccine. There are other types of scheduling errors, including giving vaccines simultaneously when not recommended (such as PCV13 and PPSV23) and administering 2 live virus vaccines not given together less than 4 wks apart.

Some good sources of information follow...



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Resources

- ACIP's *General Best Practice Guidelines for Immunization*
www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- CDC's "Pink Book"
www.cdc.gov/vaccines/pubs/pinkbook/index.html#chapters
- CDC's Immunization Schedules web page
www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html
- IAC's Clinic Resources: Recommendations web page
www.immunize.org/handouts/vaccine-recommendations.asp
- IAC's "Ask the Experts" web section
www.immunize.org/askexperts



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Questions?

- Email CDC's experts: nipinfo@cdc.gov.
- Contact your vaccine representative or call the manufacturer.
- Call your state immunization coordinator (contact information for all state immunization programs can be found at www.vaccineinformation.org/state-immunization-programs).
- Email IAC: admin@immunize.org



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