

## 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

January 2020 • Item #S8025



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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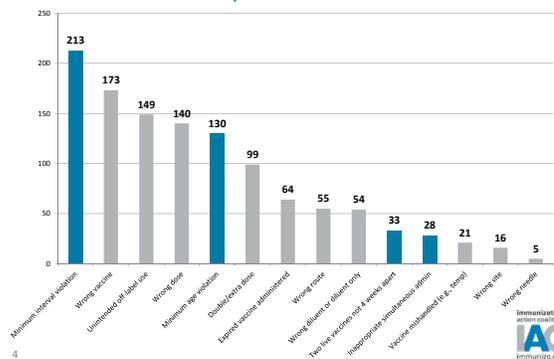


**Scheduling errors**, including violations of the minimum age and interval rules, giving vaccines simultaneously when not recommended, and administering 2 live virus vaccines not given together less than 4 weeks apart, were the #1 type of error reported to IAC over this 3-year period—**34% of the total**.

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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 1<sup>st</sup> hep A vaccine on 1/30/17 and his 2<sup>nd</sup> on 6/13/17. According to our state registry, it is not valid. I am wondering if we have to repeat the 2<sup>nd</sup> 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 3<sup>rd</sup> 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 1<sup>st</sup> dose of MMR, varicella, or hepatitis A vaccine before age 12 mos
- Giving the 4<sup>th</sup> dose of DTaP before age 12 months (or less than 6 mos after 3<sup>rd</sup> dose)
- Finishing an infant's hepatitis B series before age 24 wks
- Giving any vaccine (except hepatitis B) before age 6 wks
- Giving the 2<sup>nd</sup> dose of MenACWY vaccine before age 16 yrs for a healthy adolescent



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



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



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### 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.



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### 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.



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### 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.



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### 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 (4<sup>th</sup>) dose is not needed.
- **Hep B** – The spacing between a 3<sup>rd</sup> dose of hep B vaccine at 4 months and a 4<sup>th</sup> 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;<sup>§</sup>
  - **Bexsero**, 4 wks between doses 1 and 2.<sup>§</sup>

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

<sup>§</sup> **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](http://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](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html)
- CDC's "Pink Book"  
[www.cdc.gov/vaccines/pubs/pinkbook/index.html#chapters](http://www.cdc.gov/vaccines/pubs/pinkbook/index.html#chapters)
- CDC's Immunization Schedules web page  
[www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html](http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html)
- IAC's Clinic Resources: Recommendations web page  
[www.immunize.org/handouts/vaccine-recommendations.asp](http://www.immunize.org/handouts/vaccine-recommendations.asp)
- IAC's "Ask the Experts" web section  
[www.immunize.org/askexperts](http://www.immunize.org/askexperts)



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## Questions?

- Email CDC's experts: [nipinfo@cdc.gov](mailto: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](http://www.vaccineinformation.org/state-immunization-programs)).



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