

1. What is CDC changing about its temperature guidance for storing refrigerated vaccine?

CDC is adjusting its guidance on the Fahrenheit temperature range for storing refrigerated vaccine from 35°F-46°F to 36°F-46°F. The Celsius temperature range remains 2°C-8°C, as stated in all manufacturers' package inserts for routinely recommended refrigerated vaccines.

2. Why is CDC adjusting the recommended minimum Fahrenheit temperature for refrigerated vaccines from 35°F to 36°F?

The conversion of 2°-8° Celsius equates to 35.6°-46.4° Fahrenheit. Among routinely recommended vaccines, most manufacturers' package inserts note a Fahrenheit temperature range of 36°F-46°F, while some note a temperature range of 35°F-46°F.

The Fahrenheit temperature range of 36°F-46°F aligns with guidance from the United States Pharmacopeia (USP), a scientific organization that sets federally recognized quality standards for food and drugs.

By adjusting CDC's guidance for the Fahrenheit temperature range from 35°F-46°F to 36°F-46°F, CDC is ensuring that its recommended Fahrenheit temperature range does not conflict with the package inserts of any routinely recommended vaccines.

3. Is the 2° -8° Celsius temperature range for storing refrigerated vaccine also changing?

No. CDC's shift to the 36°-46° Fahrenheit temperature reading does not impact the Celsius temperature guidance. The Celsius range remains 2°C-8°C, as stated in all manufacturers' package inserts for routinely recommended vaccines.

4. Are manufacturers of vaccines that indicate a 35°F-46°F storage temperature range in their package inserts changing their temperature range guidance?

No.

5. When does the updated CDC guidance go into effect?

CDC's adjusted guidance first appears in the updated Vaccine Storage and Handling Toolkit, released in June 2016.

6. Do patients who received vaccine previously stored at 35°F need to be revaccinated if that vaccine's package insert recommends storage at 36°F-46°F?

CDC does not recommend revaccinating patients who may have received vaccine stored at 35°F while that vaccine's package insert recommends storage at 36°F-46°F. CDC does not have data to support the need for revaccination.

7. Does vaccine previously stored at 35°F need to be discarded/returned if that vaccine's package insert recommends storage at 36°F-46°F?

CDC does not recommend discarding/returning vaccine previously stored at 35°F if that vaccine's package insert recommends storage at 36°F-46°F. CDC does not have data to support the need to discard/return this vaccine.

8. If I've been storing vaccine at 35°F, is that considered a temperature excursion?

As long as a specific vaccine is stored within the temperature range defined in the manufacturer's package insert, the vaccine is not at risk for a temperature excursion. For vaccines whose manufacturer's package insert indicates a Fahrenheit temperature range of 35°F-46°F, an excursion is defined as a storage temperature below 35°F or above 46°F. Likewise, for vaccines whose Fahrenheit range is listed as 36°F-46°F, an excursion is defined as a storage temperature below 36°F or above 46°F.

9. What is the optimal temperature for storing refrigerated vaccines?

CDC recommends storing refrigerated vaccines at the midpoint of the recommended 2°C-8°C range (36°F-46°F), which is 5°C (40°F).

10. Is there someone I can contact if I have questions about the storage temperature of a specific vaccine?

Contact the manufacturer of that specific vaccine for more information.

For general information about vaccine storage and handling:

Review CDC's Vaccine Storage and Handling Toolkit (released June 2016):
www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

E-mail: CDC at IZcoldchain@cdc.gov

Contact your state or local immunization program

11. Why is CDC adjusting vaccine storage temperature guidance for the Fahrenheit range now?

CDC is making this adjustment in response to issues raised by health care providers about differences in guidance from vaccine storage experts on the Fahrenheit temperature range. Additionally, the June 2016 release of the updated Vaccine Storage and Handling Toolkit provided a timely opportunity to communicate this information in an important CDC resource.

12. When will CDC materials reflect the adjusted guidance?

The updated Vaccine Storage and Handling Toolkit, released in June 2016, is the first CDC resource to reflect the adjusted Fahrenheit temperature range guidance. We will work to update all other related CDC materials as quickly as possible, starting with the CDC website. The website and all online PDFs and program guides will be updated within the next six months.

Educational videos and printed materials will be updated in priority order and as they are scheduled for reprint and reproduction.

13. When are immunization program awardees expected to have their materials updated?

While awardees need to communicate with providers about this change as soon as possible, we recognize that updating all materials will take time. Awardees should develop a roll-out schedule for updating web and printed materials, trainings, etc., that takes into account their available resources for doing so.

14. Should I adjust my digital data logger (DDL) to reflect the updated Fahrenheit temperature range?

Yes. CDC recommends that providers check their DDL's current Fahrenheit temperature range settings. For specific instructions on adjusting your DDL model, contact your DDL's manufacturer.

15. If my immunization information system (IIS)/registry is set up to notify providers about out-of-range temperature settings, should I adjust it?

If your IIS/registry does not allow for vaccine-specific temperature parameters to be set, then CDC recommends setting the Celsius range to 2°C-8°C or the Fahrenheit range to 36°F-46°F, which will not conflict with the package inserts of any routinely recommended vaccines.

16. I am a Vaccines for Children (VFC) Program provider. How will the adjusted Fahrenheit temperature guidance affect my VFC site visit?

During the remaining 2016 site visits, VFC site visit reviewers will be communicating with provider staff about CDC's adjusted Fahrenheit temperature range guidance.

According to VFC Program requirements, vaccines must be stored at all times within the appropriate temperature range, as described in the manufacturers' package inserts.

Beginning in June 2016, when determining whether vaccines are stored within the correct Fahrenheit temperature range, VFC site visit reviewers will follow the adjusted temperature range guidance of 36°F -46°F.

Beginning in January 2017, all VFC Program providers must comply with the adjusted Fahrenheit temperature range of 36°F-46°F for storing refrigerated vaccines.

17. Since the conversion of 2°-8° Celsius equates to 35.6°-46.4° Fahrenheit, why does CDC's adjusted Fahrenheit temperature guidance reflect whole numbers (36°F-46°F) without the decimal point?

None of the manufacturers' package inserts for routinely recommended vaccines include decimal points in the Fahrenheit temperature range recommended for storage. We hope eliminating the decimal points in CDC's guidance will help to avoid any unnecessary confusion about the recommended temperature range.