

## What if I don't want to have a vaccine that has been stored outside of the recommended temperature range?

Your healthcare professional will only provide a vaccine if they know it is still safe and effective. The decision to use the vaccine will have been based on studies of how stable the vaccine is at different temperatures and they will have taken advice from local or national experts.

This may be the only way the vaccine is available at your appointment and refusal may delay you or your child becoming protected against serious infections.

## My friend received a letter telling them that a vaccine they had already received had been stored incorrectly. Why did this happen?

This can happen occasionally because the interruption in the 'cold chain' has only been noticed after the vaccination has been given.

Often you will not need to do anything but, if needed, public health experts in the local NHS area team will write to you telling you about the problem and recommending what actions you should take.

The NHS takes breaches of medicines storage very seriously. If the event is not considered to have affected the vaccines, the local NHS experts will advise that no action needs to be taken.

## Isn't using off-label vaccines just a way of saving money?

No, it would be a waste of public money to throw away expensive vaccines unnecessarily. It's also better to use the vaccines readily available in the surgery than to delay vaccinating you or your child who might be at risk of a serious infection, or to run out of vaccine for another patient.

### Summary

- ❄ It is recommended that vaccines are kept between +2°C and +8°C to maintain their effectiveness
- ❄ If a vaccine is stored outside this recommended temperature range, it doesn't mean it can't be used
- ❄ Vaccines temporarily stored outside the recommended temperature range are only recommended for use if still considered safe and effective
- ❄ Vaccines that have been recommended for use after falling outside this approved temperature range are called 'off-label' vaccines
- ❄ Off-label vaccines can still be used – they are just being used in a different way from that stated in their licence



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## The use of vaccines that have been temporarily stored outside the recommended temperature range

A brief guide for  
parents, carers  
and patients



mmunisation  
the safest way to protect your child

As part of the manufacturer's licensing conditions, it is recommended that vaccines are kept cool at all stages of their production, distribution and storage. This helps to ensure that they work as well as they can to offer you or your child the best possible protection.

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**Sometimes however, this 'cold chain' as it is called, is interrupted and the vaccines may get warmer or colder than recommended.**

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Some vaccines are not affected by a short interruption and can still be used. If they are used, they are described as being 'off-label' vaccines. If you or your child are offered an off-label vaccine, there is no cause for concern as the healthcare professional will have sought expert advice from the manufacturer and/or UKHSA that the vaccine is still safe and effective.

This leaflet describes what it means if a vaccine is stored outside the recommended temperature range.



### **Why are vaccines kept under controlled temperature conditions?**

Vaccines are made in very carefully controlled laboratory conditions. They are complex mixtures of different substances, including bacteria or viruses. In order to maintain their effectiveness, it is recommended that vaccines are stored between +2°C and +8°C from production right up until they are given to the patient.

Following production, vaccines are transported in refrigerated containers to surgeries and local vaccine storage facilities where they are then stored in special vaccine fridges. Keeping the vaccines within the +2°C and +8°C temperature range throughout this process is called 'maintaining the cold chain'.

The 'cold chain' can be interrupted at any of these stages and vaccines may sometimes fall outside the recommended temperature range. For many vaccines, however, there is good evidence that minor or short term temperature changes do not affect how well the vaccine works. So, as long as the vaccine is used within its shelf life, it will still be effective.

### **What are 'off-label' vaccines? Can they still be used?**

Vaccines, like all medicines, should always be stored in accordance with the manufacturer's instructions. If they have been inadvertently frozen or have fallen outside the 'cold chain' for a long period they may not be as effective and so should not be used. Sometimes however, the storage temperature has varied only a little and most vaccines can tolerate being above the recommended range for a short period of time.

For example, vaccines in a fridge that breaks down during the night are likely to still be usable the following day if they are quickly placed back into the recommended cold chain temperature range.

Although small temporary changes are not likely to affect the safety of the vaccine, nor the way in which it works, it means the vaccine is referred to as being used 'off-label' because it has been stored in a way other than that described in its licence.

### **Who decides if the vaccines can still be used 'off-label'?**

This depends on how long the vaccines were outside the cold chain and what temperatures they were stored at.

Based on what is known about the vaccine from information provided by the vaccine manufacturer, World Health Organization and special stability studies, UKHSA and/or the vaccine manufacturer will advise on whether the vaccine can still be used.

You can be assured that the decision to allow the vaccine to be used 'off-label' will only be taken if the vaccine is still considered to be safe and effective.

