

How will I know if I or my child is being offered an 'off-label' vaccine?

Your nurse or doctor is obliged to tell you before vaccination because you have to give consent to proceed. So it is your decision whether you or your child has it or not. However, the nurse or doctor would only recommend it to avoid any delay in your child getting protection against a serious infection and if they were sure the vaccine was still safe and effective.

But my friend received a letter telling her that a vaccine she 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, and has a duty to let you know if this has occurred. If the event is not considered to have affected the vaccines, the local NHS experts will advise that no action needs to be taken at all.

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 that have been recommended for use after falling outside this approved temperature range are called 'off-label' vaccines
- Off-label vaccines are still licensed – they are just being used in a different way from that stated in their licence
- Off-label vaccines can still be safe and effective

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

A brief guide for parents, carers and patients

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 to you or your child the best possible protection.

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

For some vaccines, this does not always mean they can no longer be used. If they are used, they are described as being 'off-label' vaccines. If you are told that you or your child is being offered an off-label vaccine there is no cause for concern as the doctor or nurse will have sought expert advice from the manufacturer and/or Public Health England that they are still safe and effective.

This leaflet describes the circumstances under which this situation can arise and what patients or parents need to know if they or their child has been offered or given an 'off-label' vaccine.

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's 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 sometimes fall outside the recommended temperature range. For many vaccines, however, there is good evidence to show that minor 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 given instructions. If they have been inadvertently frozen or have fallen outside the 'cold chain' for a long period they

may weaken more quickly than expected 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 over the weekend are likely to still be usable on the Monday if they are quickly placed back into the recommended cold chain.

Although these small changes do not affect the safety of the vaccine nor the way in which it works, it means the vaccine has to be called 'off-label'.

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

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 this vaccine from information provided by the vaccine manufacturer, World Health Organization and special stability studies, Public Health England 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.