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This Webinar will be recorded and made available on National Immunisation Pages. Recording will begin at the start of the webinar and end before the question and answer section. No delegate information will be visible on the record

REC

# Primary care immunisation update webinar series

## March 2023: Vaccine ordering, storage and handling

Presenter: Pauline MacDonald

Welcome to the webinar. This webinar will commence at the scheduled time.

Before then please take a moment to read through the tips below



- All delegate's lines are muted throughout the presentation
- If at other times you are in a noisy environment please mute your line by pressing the mute button on your screen
- If you would like to ask a question please use the chat function
- There will be an opportunity for questions at the end – you can unmute to ask your question
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# Webinar Essentials

## Today's webinar

- Trainer is Pauline MacDonald
- 30 minutes Pauline talking with slides
- 15 minutes for questions and answers from delegates

## Access to slides

- Copy of slides will be emailed to delegates
- Underlined text on the slides are hyperlinks – click to go straight to the link

## Following the webinar

- You will be emailed a link to an electronic evaluation (Select Survey)
- Your feedback is essential to support the development of the webinar series
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## March 2023: Vaccine ordering, storage and handling

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# Role of immunisers

Successful immunisation programmes rely on public trust and confidence

This includes trust and confidence in:

- The immunisation programme – including processes such as monitoring safety
- The vaccines being administered
- The immuniser who is knowledgeable and promotes/administers the vaccine/s



This session is an update for currently practising, trained and competent immunisers.  
Foundation immunisation and vaccination training must be completed by all new immunisers

# Learning outcomes

- Consider best practice in vaccine storage, ordering and handling
- Identify any areas for improvement within your own workplace
- Utilise available tools and resources to support best practice

# Storage of vaccines

**Efficacy, safety and quality of vaccines may be adversely affected if they are not stored in the conditions specified in the licence**

- All vaccines must be stored in accordance with manufacturer's instructions:
  - store between +2°C and +8°C
  - do not freeze (miniscule cracks in vials may allow contamination, denatures components)
  - store in original packaging to protect from light, and reduce vaccine choice errors
- Incorrect storage can lead to unnecessary costs and wastage
  - Wastage of ImmForm supplied vaccine in 2019 totalled £5.8 Million
    - <https://www.gov.uk/government/publications/vaccine-update-issue-309-june-2020>
- Always seek advice before disposing of vaccines

# Storage – ‘Cold Chain’

- Medical/Pharmaceutical grade fridge must be used
- The fridge should not be sited in front of a radiator or other electric appliance emitting heat.
- The power supply should be secure so as not to allow the fridge to be inadvertently switched off – isolator switch remotely sited
- Do not overfill the fridge.
- Never allow vaccine to freeze or touch the ‘cold’ panels of the refrigerator.
- The fridge should have **two methods** of measuring temperature. One independent of power source, either a maximum /minimum thermometer or a temperature data logger





# Data Loggers

- Data loggers are not a substitute for twice daily temperature recording (next slide)
  - they should always be used in conjunction with the integral fridge thermometer
- They can be very useful in the event of a cold chain breach
  - Show temperature fluctuations over time
- Useful for working out how long vaccines were stored at out of range temperatures.
- If data loggers are used, the data should be downloaded and checked regularly i.e. weekly.
- There should be a mechanism for monitoring battery life



# Staff responsibilities for vaccines

- Order vaccines little and often (hold max 2 – 4 weeks stock)
- Refrigerate immediately on delivery – ensure all staff know this and responsible staff are identified
  - Check consignment is undamaged and correct on delivery
- Rotate stock
  - put stock with later expiry date to back of fridge - bring existing, earlier expiry date, stock to the front - use stock at front first
- Check fridge temperature twice daily
  - Morning and evening (also before afternoon or evening sessions)
- Keep a daily temperature chart and react if not within range
  - Keep records for 5 years
- Only use validated and service maintained fridges
  - Average quality 'life' of a fridge – 8 years
- Have a contingency plan for fridge failure – as part of business continuity



# Cool Boxes and Transporting vaccines

- Try to maintain same standards as fridges
- Use a validated cool box and cool packs from recognised medical supply company
- Monitor maximum/minimum temperature, recording at regular intervals (e.g hourly if opened and closed frequently)
- Vaccines should be wrapped in bubble wrap or similar insulation material to prevent direct contact with cool packs
- Use insulating material to fill any spaces within the cool box
- Only take enough vaccine for particular session and minimise exposure of the vaccines to room temperatures
- Any unused vaccines, that have been in a cool bag (and kept at 2-8 degrees) for a period of time, can be marked, dated, returned to the fridge and used first next time
  - Don't return vaccines to fridge a second time
- Unopened COVID-19 vaccines can only be returned to the fridge under certain conditions:
  - <https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-roving-and-mobile-models/>



# Preparation prior to administration

- Ensure you only remove vaccines from the fridge/cold chain when patient is present and consent has been obtained
- Use vaccine within the period specified on the SPC, if it is reconstituted
- Minimise the number of vaccines you remove at any one time for large clinics – ideally they should be kept in cool bags or in the fridge
- Do not leave vaccines out of cold chain for just ‘in case’ or opportunistic vaccination (e.g. in flu vaccine clinics) – keep in cool bags in clinicians’ offices
- Do not storing vaccine out of +2°C and +8°C.
  - SPCs or PGDs may give stability data which is outside that range but this does equate to storage requirements.

# BREAK IN THE COLD CHAIN?

- All fridge/cold chain failures resulting in loss of nationally supplied vaccine are to be reported on ImmForm
- If Maximum and Minimum Values remained within 2° - 8°
  - Vaccines OK
  - ASAP Keep at 2° - 8°C
  - Restore power supply or transfer to another fridge/cool bag or box while doing so.
- If temperature is outside 2° - 8°C Range –
  - One off fluctuations of less than 20 minutes OK, but document reason on temp log
- If longer than 20 mins:
  - Quarantine vaccines at 2-8 degrees C – Mark as “do not use”
  - Inform all members of staff of incident
  - Gather information and obtain advice from:
    - Local Imms and Screening team - [england.londonscreening-incidents@nhs.net](mailto:england.londonscreening-incidents@nhs.net)
    - The Vaccine Manufacturers.
- If advised vaccines can still be used get advice in writing
  - May have to use within a certain time period (i.e. shorten expiry date)
  - Their use is classed as ‘off label’ – since they are being used outside the license (see next slides)
- Have an incident meeting/make a contingency plan if you didn’t have one.
- If in doubt - DO NOT USE VACCINE

# Vaccine incident guidance

- <https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors>
- Principles of managing vaccine storage incidents and interruption of the cold chain
  - Vaccine storage incident checklist
- Responding to errors in vaccine preparation and administration
  - Considerations and general principles for revaccination
  - Revaccination tables and advice
- Example letter to patients or carers offering revaccination
- Duty of candour and patient consent



## Vaccine incident guidance

Responding to errors in vaccine storage, handling and administration

Republished 6 July 2022

July 2022



# “Off label” and stored outside temperature vaccine use

## 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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First published as a pdf by Public Health England, November 2014



Public Health  
England



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

A brief guide for  
parents, carers  
and patients



**i**mmunisation  
the safest way to protect your child

<https://www.gov.uk/government/publications/vaccines-stored-outside-the-recommended-temperature-range-leaflet>

# “Off label”



Public Health  
England



## Why is my child being offered an “off label” vaccine?

A guide for parents

Like all medicines, vaccines have to have a license or authorisation before they can be given to members of the public. Sometimes, however, healthcare provider may tell you that the vaccine that your child is being offered is 'off-label'. This leaflet explains what this term means and why it's important that you understand why the vaccine is still recommended.

### How does a vaccine get a licence?

All vaccines used in the UK are authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA). Vaccines will only be submitted to the MHRA after they have been trialed by the manufacturers on their target audience (which can be children or adults) and fully tested to see that they are:

- **acceptably safe** – they do not cause other illnesses or make existing illnesses worse and that any side effects produced are generally tolerable – like pain at the injection site or headaches, nausea and rashes
- **effective** – they offer good protection against the disease they are designed to protect against, and
- **manufactured** to a high standard of quality.

This exhaustive testing process – from the first batch of a vaccine being made in a laboratory to its use in the general population – can take more than ten years.

This leaflet is primarily for parents whose children are being offered an 'off-label' vaccine but the information is relevant for people of all ages.

Only when this information has been reviewed and accepted by the MHRA or EMA, will the vaccine be given a licence and be produced and promoted by the manufacturers for general use. Amongst other things, the license specifies who can receive the vaccine, how many doses are required, what side effects may occur and how the vaccine should be handled and stored.



<https://www.gov.uk/government/publications/off-label-vaccine-leaflets>



Public Health  
England



## Off-label vaccines

An introductory guide for healthcare professionals

Before they can be placed on the market, all medicines, including vaccines, have to have a license (marketing authorisation) for use in humans. Sometimes, however, it is necessary to offer a vaccine that is 'off-label'. This means that, although the vaccine is authorised for use, it's being used in a way that is slightly different from the strict terms laid down in its license. This leaflet describes the circumstances that can lead to vaccines being used 'off-label' and the reasons why this may be recommended.

### How does a vaccine get a licence?

All vaccines have to be authorised by the UK Medicines and Healthcare products Regulatory Agency (MHRA), or the equivalent agency for Europe – the European Medicines Agency (EMA), before they can be placed on the UK market and advertised or promoted for use by the manufacturer. Vaccines are only submitted for licensing to the EMA or MHRA after they have been trialed in the target audience included in the license, which could be children or adults, and fully tested to ensure that they are:

- **acceptably safe**
- **able to provide protection** against the disease they are designed to protect against, and
- **manufactured** to a high standard of quality.

This extensive testing process – from the first batch of a vaccine being made in a laboratory to its use in the general population – can take more than ten years. The detailed information on the results of testing in the laboratory and from clinical trials is then submitted for independent evaluation by the experts at the MHRA or EMA.

Only when these agencies are entirely happy with this information will the company be granted a license to place the product on the market and to advertise or promote its use.

Amongst other things, the license specifies who can receive the vaccine, how many doses are required, what side effects may occur and how the vaccine should be handled and stored.





# Guidance and Training



Public Health England

## Protocol for ordering, storing and handling vaccines

March 2014

<https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines>

Vaccine Storage

Session Overview

Menu Previous 1 / 35 Next

**Description**

This session will provide information to immunisers on the correct procedures to follow for the storage of vaccines. Please note: this session discusses the storage recommendations for the majority of vaccines given in the UK. The COVID-19 vaccines have highly specific storage requirements, some of which may include being stored frozen. Storage requirements for these vaccines have not been included in this session. Please refer to the COVID-19 Vaccination elearning programme to more information about these vaccines. However, the key principles of vaccine storage discussed in this session will apply to the COVID-19 vaccines.

**Authors** Michelle Falconer, Laura Craig

**Duration** 30 min

**Reviewer** Laura Craig

**e-LfH**  
e-Learning for Healthcare

**NHS**  
Health Education England

<https://portal.e-lfh.org.uk/>

## Immunisation against infectious disease


<https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3>




# Summary

- Correct ordering, storage and handling of vaccines is vital to ensure the delivery of safe, successful and trusted immunisation programmes
- Good management reduces vaccine wastage, helping to maintain supply and reducing costs
- Vaccine incidents can be distressing for those involved, and can be complex and time consuming to deal with
- Ensure systems/policies are known by all members of staff and are resilient to changes in vaccine demand and staff availability

# Questions

 Public Health England

**POSTER** 

## Keep your vaccines heal+hy

**When ordering**

- Order when you have two to four weeks' worth of stock left
- You can make weekly orders, so it's best to order smaller amounts regularly
- Some vaccines come in multidose packs – check you order the correct number of doses
- Check Vaccine Update newsletter for latest information

**When receiving your order**

- Check your delivery is correct and undamaged before you sign for it
- Refrigerate the stock as soon as you have checked it off against the order
- Do not over fill the fridge as this restricts the airflow
- Ensure the shortest-dated stock is placed at the front of the fridge

**When stocking your fridge**

- Check expiry dates regularly – never use out of date vaccine
- Keep vaccines in their original packaging in the main part of the fridge, not in drawers
- Keep your fridge door locked at all times
- Keep the opening of the fridge door to a minimum
- Use a maximum-minimum thermometer and keep a daily record of the temperatures
- Have back-up storage for your vaccines in case of power failure
- Position the fridge away from heat sources and mark or tape the fridge plug to avoid it being turned off accidentally
- See Chapter 3 of the Green Book for more information


**Keep a record of your account details**

Our NHS Moviato account number is

We need to place orders before 11:55 am on a

for a delivery on

**Strive for 5°C**




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**Immunisation**  
The safest way to protect your health

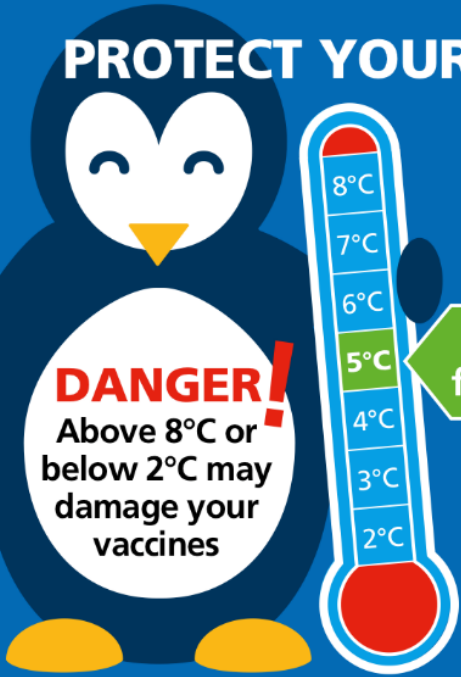
When responding to a vaccine storage incident, please follow the guidance at [www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors](https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors). In the event of vaccine wastage, please record it on the [ImvForm Stock Incident](#) page. If you have any vaccination delivery queries, please call **Moviato** directly on 01234 248632.

## FRIDGE MAGNET

**PROTECT YOUR VACCINES TO PROTECT YOUR PATIENTS** 

**DANGER!**  
Above 8°C or below 2°C may damage your vaccines

**Strive for 5°C**



**READ** minimum and maximum temperatures

**RECORD** temperatures for each one on a log sheet

**RESET** the thermometer after each reading

**REACT** if the temperature is in the danger zone

PHE Product code: CCPVM02

<https://www.gov.uk/government/publications/keep-your-vaccines-healthy-poster>

# Imms queries (London)

For any imms queries please contact the NHSE ICARS team

[london.immunisationqueriescars@nhs.net](mailto:london.immunisationqueriescars@nhs.net)

Primary care  
immunisation update  
webinar series  
2023

February to July

September to  
December

Vaccine ordering, storage &  
handling

Incomplete immunisation  
schedules

Vaccination of individuals with  
underlying medical conditions

Vaccine administration – best  
practice

Child and adolescent  
immunisation update

Addressing concerns around  
vaccines – supporting acceptance

Influenza and Covid-19

Shingles and pneumococcal  
(adult) vaccines

Adverse events following  
immunisation

Current Issues vaccine schedule  
changes. Session to be confirmed

Primary Care Immunisation Update Webinar Series – March to April 2023			
	Date	Start time	Link to register
<b>March 2023</b>		<b>Vaccine ordering, storage and handling</b>	
<b>1</b>	09/03/2023	14:00	<a href="https://March23-Webinar1-VaccineOrderingStorageandHandling.eventbrite.co.uk">https://March23-Webinar1-VaccineOrderingStorageandHandling.eventbrite.co.uk</a>
<b>2</b>	15/03/2023	14:00	<a href="https://March23-Webinar2-VaccineOrderingStorageandHandling.eventbrite.co.uk">https://March23-Webinar2-VaccineOrderingStorageandHandling.eventbrite.co.uk</a>
<b>3</b>	16/03/2023	09:30	<a href="https://March23-Webinar3-VaccineOrderingStorageandHandling.eventbrite.co.uk">https://March23-Webinar3-VaccineOrderingStorageandHandling.eventbrite.co.uk</a>
<b>March 2023</b>		<b>Incomplete immunisation schedules</b>	
<b>1</b>	07/03/2023	09:30	<a href="https://March23-Webinar1-IncompleteImmunisationSchedules.eventbrite.co.uk">https://March23-Webinar1-IncompleteImmunisationSchedules.eventbrite.co.uk</a>
<b>2</b>	07/03/2023	13:00	<a href="https://March23-Webinar2-IncompleteImmunisationSchedules.eventbrite.co.uk">https://March23-Webinar2-IncompleteImmunisationSchedules.eventbrite.co.uk</a>
<b>3</b>	23/03/2023	09:30	<a href="https://March23-Webinar3-IncompleteImmunisationSchedules.eventbrite.co.uk">https://March23-Webinar3-IncompleteImmunisationSchedules.eventbrite.co.uk</a>
<b>April 2023</b>		<b>Vaccination of individuals with underlying medical conditions</b>	
<b>1</b>	05/04/2023	14:00	<a href="https://April23-Webinar1-VaccinationWithUnderlyingConditions.eventbrite.co.uk">https://April23-Webinar1-VaccinationWithUnderlyingConditions.eventbrite.co.uk</a>
<b>2</b>	26/04/2023	09:30	<a href="https://April23-webinar2-vaccinationwithunderlyingmedicalconditions.eventbrite.co.uk">https://April23-webinar2-vaccinationwithunderlyingmedicalconditions.eventbrite.co.uk</a>
<b>3</b>	26/04/2023	14:00	<a href="https://April23-Webinar3-VaccinationWithUnderlyingConditions.eventbrite.co.uk">https://April23-Webinar3-VaccinationWithUnderlyingConditions.eventbrite.co.uk</a>

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