North East London
Clinical Commissioning Group

BHR ICB Cold Chain guidance

Out of Range Vaccine Fridge Temperature

The aim of the guidance is to:

- Provide a consistent approach to considering the appropriate action in response to vaccine storage and administration errors and signpost for support and advice.
- Ensure vaccines are appropriately handled following compromised storage incidents, thus reducing vaccine wastage
- Minimise the recall and unnecessary revaccination of patients by assisting providers to make an accurate assessment as to whether vaccine safety or efficacy have been compromised and to inform a proportionate response to incidents
- Encourage immunisation providers to recognise the need to report vaccine errors and incidents and use the lessons learned to improve future practice.

The following Public Health England guidance on "vaccine incident guidance: Responding to errors in vaccine storage, handling and administration" is intended to be used by a wide range of healthcare professionals, with a role in delivering immunisation programmes, in the investigation and management of vaccine storage or administration incidents.

PHE_vaccine_incident_guidance_July2021.pd

This document is available to help support decision making following an incident where a vaccine fridge temperature range has deviated outside the recommended +2 to +8^{0}C range. Within this document there are some very helpful Appendices which covers:

Appendix A:

1. Responding to a cold chain breach or compromised storage event.
2. Managing a cold chain incident where compromised vaccines have been administered to patients

Appendix B: is a vaccine storage incident checklist which can be used when dealing with cold chain incidents
Appendix C: is an example letter to patients or carers offering re-vaccination
Appendix D: has re-vaccination recommendations for people who have received compromised vaccines

To report a vaccine incident, please contact england.londonscreening-incidents@nhs.net . As new vaccines are incorporated into the schedule, vaccine manufacturers have provided additional 'on label' stability data as part of the product licensure and this is detailed in the

SPC or product monographs. This data is intended to guide healthcare professionals in making a clinical decision following temporary temperature excursions only. The manufacturer's medical departments can and should be contacted for specific advice about their products when explicit incident details are provided. Vaccines should not be disposed of until this has been discussed and agreed with the Local Screening and Immunisation (SIT) team.

Supply of cold chain breached vaccine under a Patient Group Direction (PGD)
Current medicines legislation does not prevent the use of, or necessitate amendment to PGDs to deliver vaccine that has been assessed as suitable for use following a temperature excursion. However, NICE Medicines Practice Guideline (MPG2) recommendation 1.1.7 (11) advises that off-label use under a PGD should be supported by best clinical practice. Whilst best practice would always be to store vaccines according to the manufacturer's instructions (for example, +2°C to +8°C), providing the advice from the manufacturer and/or risk assessment indicated that continued use of the vaccine is considered to be appropriate clinical practice, supply and/or administration may continue under a PGD. Such circumstances do not necessitate a Patient Specific Direction (PSD)

Useful resources:

WHO temperature sensitivity of vaccines guidance:

https://apps.who.int/iris/handle/10665/69387

NHS England and NHS improvement London - Immunisation

https://www.england.nhs.uk/london/our-work/immunis-team/

EMC weblink for obtaining manufacturer contact details:

https://www.medicines.org.uk/emc