



Responding to cold chain failures involving the live attenuated intra-nasal influenza vaccine (LAIV)

Introduction

This information sheet is to assist providers in taking prompt and appropriate action in the handling of live attenuated influenza vaccine (LAIV) (Fluenz Tetra®/Flumist®) that has been stored outside the recommended temperature range.

What should we do if our LAIV stock has been exposed to temperatures outside of those recommended for storage? (2-8°C)

1. DO NOT DISPOSE OF ANY VACCINES OR STORAGE EQUIPMENT
2. Isolate potentially compromised vaccines clearly labelling '**not for use**'. These vaccines should be maintained at 2-8°C
3. ENSURE the vaccine fridge involved remains switched on at the main electrical supply and that thermometers and temperatures probes are undisturbed
4. Complete the cold chain incident checklist questions attached
5. Contact your **local** NHS England **screening and immunisation team** for further support and advice
(see www.nhs.uk/servicedirectories/Pages/AreaTeamListing.aspx)

Stability of live attenuated intra-nasal influenza vaccine

Maintaining LAIV within the recommended temperature range of 2-8°C ensures compliance with the manufacturer's license and maintains the vaccine's potency. However, a failure to adhere to vaccine storage recommendations does not necessarily mean that LAIV has been rendered unusable.

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Several studies¹ have demonstrated that LAIV potency is maintained after exposure to temperatures outside the recommended storage range. Specifically these studies have shown that LAIV is likely to maintain acceptable potency following:

- a one-off freezing event
- exposure to room temperature for up to 12 hours
- exposures between 8°C and 15°C degrees for up to 72 hours

On return to recommended storage temperatures (2-8°C) the vaccine could be expected to remain potent to the end of its shelf life.

This information may not bring the vaccine back within the terms of its product licence, but where a full risk assessment has been made and advice taken from the screening and immunisation team, health protection team or other expert, off-label use of the product may still be in line with good clinical practice.

So can the vaccine be stored outside cold chain?

No! Maintaining cold chain standards is essential to the success of immunisation programmes and providers should do all that they can to prevent breaks in the cold chain. This can be achieved by adhering to national policy recommendations for the storage, and administrations of vaccines as laid out in the **Green Book**.²

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Incident checklist

Date and time of breach	
What were the temperature readings when the breach was noticed? (eg current/minimum/maximum)	
How long was the temperature outside 2-8°C or when was the cold chain last guaranteed?	
What alerted you to the cold chain breach/storage event? (eg thermometer out of range, fridge alarming, temperature log)	
Has the cause of the breach been rectified and/or steps taken to prevent the problem recurring?	
Has anybody been vaccinated with potentially affected vaccines?	
How often are fridge temperatures usually recorded?	
When was the thermometer last reset?	
When was the thermometer last calibrated?	
How would you describe the current stock level of the fridge (eg less than 10% full, 25%, 50%, 75%, full, very full or over stocked)	
Are vaccines stored in their original packaging?	
Are there any obvious signs of freezing (eg frosting on sides or back of the fridge, wet or damaged vaccine boxes)?	
Have any vaccines been pushed up against the cooling plate or cold air inlet?	
What is the expiry date of the vaccines?	
Have any of the vaccines involved in this incident previously been exposed to temperatures outside 2-8°C? (ie involved in previous cold chain incident)	
When was your fridge last serviced?	

More information

Fluenz Tetra Summary of Product Characteristics. Available at:
<http://www.medicines.org.uk>

Health Protection Agency. Vaccine incident guidance: responding to vaccine errors.
Available at: www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

ImmForm Helpsheet 18. Fridge failures and stock incidents. Available at:
www.gov.uk/government/uploads/system/uploads/attachment_data/file/346028/ImmForm_Helpsheet18_FridgeFailures_StockIncidents_acc2.pdf

NHS Off-label vaccines: a guide for parents.
Available at: www.gov.uk/government/collections/immunisation

NHS. The use of vaccines that have been temporarily stored outside the recommended temperature range.
Available at: www.gov.uk/government/collections/immunisation

Public Health England. Protocol for ordering, storing and handling vaccines.
Available at:
www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

References

1. Toback et al. Clinical Guidance on the Use of Live Attenuated Influenza Vaccine After Inadvertent Freezing and Warming. *Journal of Pediatric Nursing* (2012) 27, 163–167
2. Public Health England. Immunisation against infectious diseases: storage, distribution and disposal of vaccines. The Green Book Chapter 3.
<https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3>

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