

# Rapid Response Report

NPSA/2010/RRR008

From reporting to learning

21 January 2010

## Vaccine cold storage

### Issue

Immunisation is a highly effective way of protecting individuals and communities from infectious disease. However, to remain potent, vaccines must be stored within the temperature range recommended by manufacturers [ $+2^{\circ}\text{C}$  to  $+8^{\circ}\text{C}$ ]. Incorrect storage of vaccines is not only wasteful and costly to the NHS, the failure to store vaccines correctly, particularly at temperatures **below** the manufacturers' recommendations, can reduce vaccine effectiveness and cause vaccine failures. Freezing may also cause hairline cracks in the container, leading to contamination of the contents.

### Patient safety incidents

Between January 2005 and April 2009, about 50 million doses of childhood vaccines were distributed in the UK. During this period the National Patient Safety Agency (NPSA) received 260 reports of incidents from a range of NHS organisations related to vaccination cold storage. Themes identified from these reports include: delay in storage of vaccines (especially after delivery); storage at wrong temperature; fridge switched off or broken; power cut or fridge door left open; no temperature monitoring; inadequate or missing equipment; and inappropriate use of domestic fridges. It is unknown if any of these incidents led to significant harm.

In June 2009, a primary care trust (PCT) audit of vaccine storage in GP practices was shared with the NPSA. A two-year retrospective audit of 96 practices revealed that a significant proportion of vaccines had been stored outside the recommended temperature range. The PCT did further risk assessment to identify which of the vaccines concerned had the greatest potential for harm (such as vaccines rendered ineffective by freezing). As a result, 560 patients from two practices were recalled for repeat vaccination. These local findings, together with incidents reported to the NPSA, suggest scope for improvement in vaccine storage.

**For IMMEDIATE ACTION by all NHS organisations whose departments and providers (including independent contractors) hold vaccines requiring cold storage. Deadline for ACTION COMPLETE is 21 July 2010.**

Actions should be led by the medical director and supported by the chief pharmacist.

### NHS organisations should:

1. Ensure that all departments and providers (including independent contractors) holding vaccine stocks are aware of relevant policy on safe storage (for example, as given in Appendices 3 and 4 of the supporting information). Local policies should include having a designated person and deputy/ies responsible for receipt and storage of vaccines.
2. Have procedures in place to assure themselves that all relevant departments and providers adhere to relevant policy for vaccine cold chain storage. This includes reviewing refrigerator temperature readings in a manner that will identify if vaccines have been stored outside of manufacturers' recommended temperature ranges before they are administered to patients.
3. Have procedures in place for remedial action where vaccines are stored outside manufacturers' recommended temperature ranges, and ensure departments and providers are aware of these. Actions may include initial reference to the UKMi fridge database ([www.ukmi.nhs.uk/applications/fridge](http://www.ukmi.nhs.uk/applications/fridge)) with subsequent advice sought from NHS medicines information services or the vaccine manufacturer.

### Further Information

Supporting information on this Rapid Response Report is available at: [www.nrls.npsa.nhs.uk/alerts](http://www.nrls.npsa.nhs.uk/alerts). Further queries should be directed to: [rrr@npsa.nhs.uk](mailto:rrr@npsa.nhs.uk); telephone 020 7927 9890.

**NPSA has informed:** NHS organisations, the independent sector, commissioners, regulators and relevant professional bodies in England and Wales.

Gateway ref: 13447

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