



What to do if issues with vaccine storage management are identified during a Care Quality Commission inspection

This Q&A has been developed to support providers in taking prompt and appropriate action where potential problems have been identified with vaccine storage management following a Care Quality Commission (CQC) inspection.

Q. We've just had our CQC inspection and they raised concerns about the storage of our vaccines – what should we do?

Don't panic! In the event of a breach in the cold chain or concerns regarding the storage and handling of vaccines, it is important to **contact your local screening and immunisation team** in NHS England for further support and advice.

You could also contact the **health protection team at your local public health England centre** for advice.

Q: What should we do if problems with our vaccine storage and management are identified by the CQC?

DO NOT dispose of any vaccines or storage equipment. Label vaccines 'do not use' and quarantine the vaccine fridge. It is important that vaccines remain refrigerated between 2 and 8°C (or in their current storage conditions if these are not between 2 and 8°C), but are not used until a thorough risk assessment has been undertaken.

Q: What if we cannot show temperature records for the past 5 years?

Lack of temperature recording or gaps in temperature records do not necessarily mean that your vaccines have been subject to suboptimal conditions. Evidence about your current stock management system, including stock inventory records, vaccine delivery dates, vaccine turnover, as well as the age, current condition and service history of the fridge, can provide valuable reassurance that unmonitored vaccines have not been poorly stored for prolonged periods of time.

Q: We have no service history for our fridge – what should we do now?

DO NOT dispose of any vaccines or equipment. Arrange for the fridge to be serviced as soon as possible. If there are no indications of obvious problems with the fridge (eg ice on back of fridge or temperature readings outside the 2 to 8°C range), vaccines can continue to be used. If there is any concern about the fridge, the equipment should remain switched on but clearly labelled 'do not use fridge or vaccines' until servicing has taken place. It may also be possible for a data logger to be placed in the fridge for a set time period (eg 48 hours) as an independent check that the fridge is running between 2 and 8°C.

Q: We didn't know our thermometers needed calibration – what should we do now?

DO NOT dispose of any vaccines or equipment. Arrange for the thermometer(s) to be calibrated as soon as possible. If there are no indications of any obvious problems with the thermometer(s) (eg readings are within the 2 to 8°C range), vaccines can continue to be used. It may also be possible for a data logger to be placed in the fridge for a set time period (eg 48 hours) as an independent check to ascertain whether the thermometer is measuring accurately.

Q: What if potentially compromised vaccines have already been given to patients?

Maintaining vaccines within the cold chain recommended temperatures of 2 to 8°C ensures compliance with the manufacturer's license and minimises the risk of compromising the effectiveness of vaccination.

The majority of vaccines, however, are very stable, and any loss of potency following storage above or below the recommended storage temperatures, although irreversible, is not immediate or complete. A failure to adhere to vaccine storage recommendations therefore does not necessarily mean vaccines have been impaired to such an extent as to require recall/revaccination of patients. A thorough risk assessment needs to be carried out to ascertain what action, if any, is necessary.

For further information please see:

ImmForm Helpsheet 18. Fridge failures and stock incidents. Available at:
<https://www.gov.uk/government/publications/fridge-failures-immform-helpsheet-18>

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

Public Health England. Keep your vaccines healthy poster. Available at:
<https://www.gov.uk/government/publications/keep-your-vaccines-healthy-poster>

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