**Cold Chain Management of COVID-19 Vaccines – Assuring Vaccine Quality and Reducing the Risk of Wastage**

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| **Date of issue** | 13/05/2021 |

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| **Who is this alert for?** |
| This alert is for all NHS vaccination centres engaged in the delivery of the COVID-19 immunisation programme. Implementation should be co-ordinated by a Chief Pharmacist or equivalent within the organisation and supported by relevant clinical leaders. |

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| **Medicines quality issue identified** |
| This quality improvement alert has been produced to share learning from SPS experiences in supporting NHS vaccination centres with COVID-19 vaccine cold chain temperature excursions.  Due the nature of their temporary authorisation, COVID-19 vaccines must be stored in accordance with strict conditions of use and may only be stored at room temperature for relatively short periods of time. There is no data to support their use outside of these conditions. It is essential to set up and use fridges and monitoring systems correctly to ensure the cold chain is maintained, and to facilitate investigation of excursions and their impact on vaccines.  Whilst overall vaccine waste since the start of the immunisation programme has been low, a review of incidents reported to SPS has identified the following common themes which present the opportunity to improve cold chain resilience and reduce the potential for vaccine waste:   * Reliance on a single in-built temperature sensor. These are dependent on the fridge power supply and so are unable to provide useful information in the event of power failure. They are also unable to indicate length of time out of range. * Infrequent formal recording of max/min readings * Lack of informal checks of temperatures during use, leading to missed opportunities to prevent an excursion * Errors in recording the max/min/current readings in the correct column on the log * Failure to re-set the max/min thermometer after use leading to a gap in monitoring data * Excursions linked to fridge doors being left ajar   **Vaccination centres should immediately undertake the following actions**: |

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| **Required Actions** |  |  |
| 1. Install a data logger (independent of the fridge and the local power supply) which monitors the temperature continuously. This should have a probe placed inside a mocked up product to simulate the effect of excursions on the vaccine. 2. Until a datalogger is installed, increase the frequency at which min/max thermometers are recorded and reset to an interval linked to the vaccines’ pre-puncture room temperature shelf lives. 3. There should be SOPs to cover the setting up, monitoring and use of fridges, and managing temperature excursions. 4. Systems must be in place to ensure alarms are acted upon immediately to prevent excursions, and excursions are managed and investigated without delay to minimise the impact on the vaccines. 5. Complete the best practice checklist below for the setup, monitoring and use of refrigerators for storage of COVID-19 vaccines 6. Identify and address any areas of non-compliance | | |
| **Fridge Set Up** | **Check By** | **Date Complete** |
| The fridge is a pharmacy fridge designed for storing medicines (not a domestic one). |  |  |
| The fridge has been installed in accordance with the manufacturer’s instructions. |  |  |
| The fridge temperature set point should be 5OC unless in-house temperature mapping indicates a different set point is appropriate. |  |  |
| The plug is clearly labelled to identify its purpose so that it is not accidentally switched off or unplugged. |  |  |
| There is evidence the fridge is functioning correctly before use. This may include temperature mapping, or as a minimum ensuring the temperature is monitored and stable for 24-48 hours prior to use. |  |  |
| **Fridge Use** | **Check By** | **Date Complete** |
| Ensure the fridge is not over filled and is loaded in a manner which allows for sufficient air to circulate. |  |  |
| **Fridge Monitoring** | **Check By** | **Date Complete** |
| The fridge contains a data logger, independent of the fridge and the local power supply, which monitors the temperature continuously. The probe is placed inside a mocked up product to simulate the effect of excursions on the vaccine. |  |  |
| The fridge has an inbuilt sensor measuring air temperature with a digital display of the max, min & current temperatures. |  |  |
| The inbuilt sensor is linked to an audible alarm. |  |  |
| The low temperature alarm is set no lower than 2°C and the high temperature alarm is set no higher than 8°C, and the alarm delay is no longer than 20 minutes (if adjustment is possible). |  |  |
| There are approved written procedures which cover the following points:   * Max, min & current temperatures are formally recorded at least twice a day at a frequency linked to the room temperature shelf life of the vaccine. Readings are recorded and signed for on a standard format log, and the log is checked daily by a supervisor. * After reading, the max/min thermometers are reset. * Max/min and current temperatures are checked each time the fridge is opened. * The datalogger is downloaded and reviewed periodically (at least weekly). |  |  |
| All temperature probes have been calibrated to within +/- 0.5°C accuracy within the past 12 months. |  |  |
| There is a system in place to ensure the fridge door is always closed correctly and end-of-session housekeeping checks include checking the fridge door is closed, the power is on and the temperatures are within range. |  |  |
| **Response to incidents** | **Check By** | **Date Complete** |
| There is an approved written procedure which cover the following points:   * Alarms are responded to immediately and escalated to senior staff. * Stock is quarantined at the correct temperature without delay, and clearly labelled as not for use until an investigation has been completed. * An assessment is made to determine the impact of the excursion on the vaccine. * Use of an approved checklist for gathering information on the excursion. An [SPS template checklist](https://www.sps.nhs.uk/articles/managing-temperature-excursions-for-covid-19-vaccines/) is available. * Max/min thermometers are re-set after the fridge returns within range. |  |  |
| **Training** | **Check By** | **Date Complete** |
| Ensure all staff are trained in use and monitoring of the refrigerator and there is a formal record of training. |  |  |
| **Actions Required** | | |
| **Approved By: Date:** | | |

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| Supporting Resources |
| 1. The Green book – Chapter 3 (Storage distribution and disposal of vaccines)   <https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3>   1. SPS website – Use of fridges to appropriately store COVID-19 vaccine.   <https://www.sps.nhs.uk/articles/using-fridges-appropriately-to-store-covid-19-vaccines/>   1. Public Health England (PHE) – Responding to Vaccine Incidents Guidance   <https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors> |

To provide feedback on this quality improvement recommendation please contact us via email at [LNWH-tr.spsquestions@nhs.net](mailto:LNWH-tr.spsquestions@nhs.net)