**COVID-19 Cold Chain Incident Checklist – for temperature excursions outside all cold-chain systems (refrigerators, cool boxes etc)**

**Please give as much detail as possible when completing this form to enable a more timely response.**

Additional information that can support you completing this form can be found here:

<https://www.sps.nhs.uk/articles/managing-temperature-excursions-for-covid-19-vaccines/>

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| --- | --- | --- | --- | --- |
| **Enquirer and background information** | | | | |
| **Name and job role** |  | | | |
| **Organisation** |  | | | |
| **Email address** |  | | | |
| **Telephone number** |  | | | |
| **Vaccination site name and address** |  | | | |
| **RVOC/CARS reference number** |  | | | |
| **Date and time of incident** |  | | | |
| **Date and time incident form completed** |  | | | |
| **Vaccine information – Include manufacturer, brand name and strength and form of vaccine details** | | | | |
| **Manufacturer, brand name, strength and presentation (e.g. concentrate vial, pre-filled syringe)** | **Batch Number** | | **Expiry date and time** | **Post thaw use by date/time** |
| ***e.g. Pfizer BioNTech Comirnaty 30microgram/dose concentrate vial*** | ***01234*** | | ***4.15pm 28/4/22*** |  |
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|  |  | |  |  |
| *Please append additional pages or lines to this table if there are more affected vaccines.* | | | | |
| **If the vaccine is a concentrate, has it been diluted or is it a ready-diluted preparation?** |  | | | |
| **Date(s) vaccine(s) defrosted** |  | | | |
| **Number of vials affected** |  | | | |
| **Number of doses affected** |  | | | |
| **Were any patients administered affected vaccine? If yes, how many?** |  | | | |
| **Confirmation that the vaccine is currently under correct storage conditions and quarantined.** |  | | | |
| **Temperature excursion information** | | | | |
| **Where did the excursion occur –** in transit between sites, in a fridge/cool box or left out of temperature controlled storage? Give details of the incident. | |  | | |
| **Temperature excursion START time** – what was the date and time of last recorded storage within the designated temperature range? | |  | | |
| **Temperature excursion END time -** when did vaccines return to correct storage temperature conditions? | |  | | |
| **TOTAL DURATION of temperature excursion (include hours/minutes) [If multiple excursions include details of duration for each one]** | |  | | |
| **What were the minimum and maximum temperatures during this excursion?** | |  | | |
| **Date and time temperature excursion was discovered by staff.** | |  | | |
| **You must provide copies of the temperature monitoring records for this excursion:**   1. **a photograph or scan of the max/min and current temperature log; and** 2. **a trace/graph of the recording from the data-logger and/or data-logger raw data in spreadsheet form**   **Ensure all monitoring forms submitted are legible and fully completed with site info etc.** | |  | | |
| **Has the temperature of the refrigerator/validated cool box or storage system returned to within 2-8 deg C? What is the current temperature?** | |  | | |
| **Has the cause of the temperature excursion been rectified? What was it?** (e.g. restocking the refrigerator, incorrectly packed cool box, busy clinic, power failure) | |  | | |
| **When was the min/max thermometer last reset?** | |  | | |
| **Have any of the vaccines involved in this incident previously been exposed to temperatures outside their designated temperature?** | |  | | |
| **Has there been any other incident that might impact on the stability of the vaccine?** For example – have the vaccine vials been dropped, were the vaccine vials not upright when delivered, were the vaccine vials agitated whilst being transported? Give details. | |  | | |
| **Additional questions if the incident involves refrigerator or validated cool box storage** | | | | |
| **Type of refrigerator or cool box**  Medicine/pharmacy or domestic.  Include make/model details if available. |  | | | |
| **Was the medical grade, validated refrigerator/cool box purchased/supplied specifically for temperature controlled storage of medicines?** |  | | | |
| **How old is the refrigerator or cool box?** |  | | | |
| **What alerted you to the temperature excursion/storage event?**  Thermometer out of range; Load probe out of range; Alarming; Data logger; Other |  | | | |
| **Is the refrigerator /cool box overloaded and is there sufficient space for air to circulate?**  Provide picture of loading if uncertain. |  | | | |
| **Is there an alarm fitted on the refrigerator / cool box and if so:**  Confirm the high and low temperature alarm set points? After how long outside of the designated temperature range does the alarm sound? Is it attached to the refrigerator / cool box or a logging system? |  | | | |
| **If the alarm had gone off, what controls are in place to ensure a response? Would anyone have heard it?** (E.g. at night.) |  | | | |
| **What is your preparation process for cool packs** – do you chill or freeze the cool packs prior to use? Do you have an SOP/process to manage this aspect of cool box use? |  | | | |
| **Temperature monitoring system information** | | | | |
| **What type of thermometer(s) used?**  Integral to refrigerator or cool box, Battery operated independent thermometer, Data logger, Load probe. |  | | | |
| **How often are refrigerator/cool box temperatures recorded? (e.g. daily, twice daily, each time its opened, continuous).**  Provide information for each of the thermometers in use. |  | | | |
| **Which thermometer recorded the temperature excursion?** |  | | | |
| **Where is temperature probe positioned in the refrigerator / cool box? E.g. top, middle, bottom of refrigerator; touching the side of the refrigerator; touching an icepack.** |  | | | |
| **Does temperature excursion relate to load probe (probe placed in mock product) or an air probe?** |  | | | |
| **Refrigerator servicing information (if there has been a refrigerator malfunction)** | | | | |
| **When was the refrigerator last serviced?** |  | | | |
| **When was the integral thermometer last calibrated?** |  | | | |
| **Has the refrigerator been temperature mapped?** |  | | | |
| **Has an engineer checked the refrigerator since the incident? What did their report say?** |  | | | |
| **Rectifying steps taken** | | | | |
| **Have steps been taken to prevent the problem recurring?** |  | | | |
| **Have you quarantined the vaccines?** |  | | | |
| **What future actions are planned? When will they be implemented? CARS/NHSE Region will be in contact to discuss further if necessary** |  | | | |

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**Appendix 1**

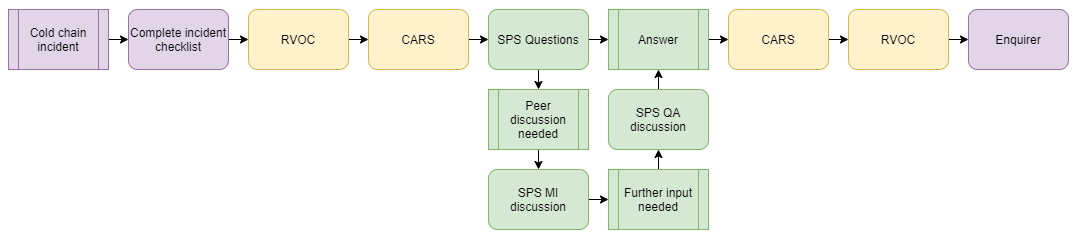
**Managing the cold chain and temperature excursions**

**Useful resources from SPS**

* [Quality Improvement Alert – Cold Chain Management of COVID-19 Vaccines](https://www.sps.nhs.uk/articles/quality-improvement-alert-cold-chain-management-of-covid-19-vaccines/#:~:text=quality%20temp)
* [Managing temperature excursions for COVID-19 vaccines](https://www.sps.nhs.uk/articles/managing-temperature-excursions-for-covid-19-vaccines/)
* [Using fridges appropriately to store COVID-19 vaccines](https://www.sps.nhs.uk/articles/using-fridges-appropriately-to-store-covid-19-vaccines/)
* [Transporting COVID-19 vaccines whilst maintaining the cold chain](https://www.sps.nhs.uk/articles/transporting-covid-19-vaccines-whilst-maintaining-the-cold-chain/)

**Appendix 2**

**Process for reporting temperature excursion incidents**

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