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Introduction/Objectives

To ensure that vaccines are ordered, stored and disposed of correctly and in accordance with PHE guidance

Aim to maintain temperatures between 2 and 8 degrees centigrade for optimum efficacy.

To have a protocol in place should the fridge temperature fall out of this range which outlines action to be taken.

Actions

- Both fridges and Treatment Room fridges to be checked daily to ensure in good working condition and temperatures recorded. TeamNet https://teamnet.clarity.co.uk/L81015.
- Fridge temperature, minimum and maximum to be recorded twice daily when possible using the integral fridge thermometer which should be reset twice daily.
- Last nurse to leave the building in the evening to check that all fridge doors are closed and fridges in target range.
- There are vaccine fridges in which the fridge thermometer monitors both the air and the "load" temperatures*. These types of refrigerators usually have the thermometer probe placed within a sealed glycol bottle, which mimics the vaccine liquid. (Load temperature measures more accurately vaccine temperature and is less prone to air temperature variations. Air temperature changes much more rapidly than product or load temperature). Refrigerators that measure "Load" temperature are therefore preferred.
- All vaccines / immunisations should be checked for good condition and continuity of the cold chain prior to being placed in the fridge.
- Where the fridge temperature increases to >8 degrees centigrade or drops below 2 degrees centigrade consult the procedure below.
- Each vaccine fridge has a data logger, measuring the temperature in fridge every 10 minutes. Routinely data logger will be downloaded weekly. However, the data will be downloaded as soon as it's noted that a fridge has gone outside of the 2-8°C recommended temperature range. This will give accurate information on how long the fridge has been out of recommended temperature range. Data logger instructions for use:

Y:\Equipment\Equipment calibration - checks\Fridge Temp Records\Data logger results\Data logger instructions for use.docx

The data logger data will be uploaded to TeamNet.

Persons responsible for vaccine ordering and stock check:



Overall responsibility – Jodie Godfrey and Danielle Townsend, Lead Nurse and Keely Shepherd, Deputy Lead Nurse/Immunisation lead.

Childhood vaccinations – Treatment room nurses (imm form order – allocated individual each week)

Other vaccinations – Admin Asst- Rose Robinson (RJR)

Immunisation lead

Keely Shepherd

Vaccine co-ordinator

Rose Robinson

VACCINE STABILITY

A vaccine stock take and order is done weekly. Expiry dates are checked during this stock check and stock rotated with the shortest expiry date used first.

On receipt of vaccines and before signing for the order reception staff need to check the delivery is for the right health centre and that the box/container is not damaged. If the box is not addressed for CKMP or is damaged then that member of staff must not sign or accept it. Lead nurse to be alerted in this instance.

Once the vaccines have been signed over the box must be placed in the fridge and one of the TRN's or vaccine co-ordinator (RJR) contacted as the vaccines will need to be checked against the order form.

Pharmaceutical distributers and manufacturers will not accept any vaccine for return once it has left their control

Cold chain failure

Fridge outside of temperature range

- 1. If fridge outside of temp range for <20mins and reason known then reset fridge temp only.
- 2. If unknown how long outside of temperature range, quarantine vaccines (clearly label not for use and put in alternate fridge that is in recommended temperature range)
- 3. Download data logger to determine how long out of range. If <20minutes, reset fridge temperatures and data loggers and record on fridge temperature log on teamnet. Return vaccines to fridge. No further action needed.
- 4. If temp is out of range for more than 20 minutes but due to stock check or restock, follow step 5. If unknown why the temperature out of range, follow step 6 and 7.
- 5. If temp is out of range for more than 20 minutes but it was during a fridge stock check or restock, then note min/max and current temps after 1hr of finishing stock check, reset



temps and log on team net. Download data logger results and note that any temperature excursion was due to fridge stock check. A temperature excursion in these circumstances can be excepted and does not need to be logged as a vaccine fridge temperature breach and an incident form does not need to be completed. Attach the following document from PHE to the temperatures logged on teamnet.

Y:\Equipment\Equipment \text{ calibration - checks\Fridge Temp Records\Data logger results\Fridge temp excursion exceptions.docx}

6. In cases where the fridge was out of temperature range for more than 20mins contact the Immunisation and Clinical Advice Response Service(iCARS) for advice, email query to england.swicars@nhs.net. Monday to Friday (9-5). Outside these hours you can contact the health protection team on 03003038162 and press option 1. Please note this is only for section 7A vaccines, any advice regarding adult hep b or travel vaccinations will need to go directly to manufacturer.

Please do not contact the manufacturer until the above has been done. Support from the iCARS team will then be available at investigating and assessing the risk so a full and accurate picture can be obtained before involving the manufacturers.

The Immunisation and Clinical Advice & Response Service(iCARS) will contact the Immform vaccines manufacturers, all the other vaccines (travel vaccines etc not from Immform), CKMP will need to contact the manufacturers for advice if the vaccines can still be used on or off label.

- 7. Complete an incident form on Teamnet, the Immunisation and clinical Advice & Response Service team will send you a form to complete and return, you only need to inform Immform if any of their vaccines need to be destroyed.
- 8. Complete a spreadsheet with the names of the vaccines involved in the excursion on the Y:\Health & Safety\Infection control\Fridges & vaccines in the fridge/vaccine folder along with a copy of team net incident form.
- 9. Label each vaccine involved with the date and time of the excursion if they can still be used.

Power failure

- 1. Quarantine vaccines (clearly label not for use and put in alternate fridge that is in recommended temperature range).
- 2. Place probe of external thermometer in vaccine box in middle of vaccine fridge and monitor fridge temps every 10 minutes. Otherwise, keep fridge shut.
- 3. If temp is out of range for more than 20 minutes follow step 6,7,8,9 above.
- 4. Contact the Immunisation Clinical Advice & Response Service team for advice, email query to england.swicars@nhs.net., Monday to Friday (9-5). Outside these hours you can contact the health protection team on 03003038162 and press option 1.

Y:\Health & Safety\Infection control\Fridges & vaccines\imm-queries.pdf

Please do not contact the manufacturer until the above has been done. Support will then be available at investigating and assessing the risk so a full and accurate picture can be obtained before involving the manufacturers, please document the event and give to nurse manager.



- 5. Unless advised otherwise by PHE, remove the vaccines from the fridge and place in vaccine cool boxes with ice packs (wrapped in bubble wrap or cloth). Place an external thermometer probe in a vaccine box and record the temperatures every 10 mins to ensure stays at recommended 2-8 deg centigrade.
- 6. In cases where the fridge was out of temperature range for more than 20mins, follow 6,7,8,9 in cold chain failure.

Please refer to:

Y:\Health & Safety\Infection control\Fridges & vaccines\Vaccine stability data from National Team-alphabetical list.pdf

NB This is a guide but does not replace contacting the vaccine manufacturers if needed.

Contact Information

Glaxo-Smith-Kline (GSK) 0800 221 441

customercontactuk@gsk.com

www.gsk.com/uk

Sanofi 0800 0352525

uk-medicalinformation@sanofi.com

www.spmsd.co.uk

Novartis 01276 698370

Medinfo.uk@novartic.com

www.novartic.co.uk

Pfizer 01304 616161

vaccines@pfizer.com

www.pfizermwdicalinformation.co.uk

Merck 0208 1548000

medicalinformationuk@msd.com

www.msd-uk.com



Crucell 0844 8003908

medinfo@its.jnj.com

www.crucell.co.uk

Astra-Zeneca 0800 783 0033

www.astrazeneca.com

Disposal of expired/wasted vaccines

- 1. Vaccines due to expire are logged on the stock spreadsheet.
- 2. Once expired all vaccines are disposed of using the yellow lidded sharps box (or purple lidded for live vaccines). Green book chapter 3 refers to local policy to date awaiting response from CCG.
- 3. All expired or wasted vaccines must be recorded on the wastage spreadsheet: Y:\Finance\Stock\Drug Stock\Drug and vaccine wastage.xls . Any vaccines expired or wasted from Immform stock must be logged on Immform as well.

Sources of Information:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_B_ook_Chapter_3_v3_0W.pdf

https://assets.publishing.service.gov.uk/media/62c598188fa8f54e855dfe17/UKHSA-vaccine-incident-guidance-6-july-2022.pdf

https://media.path.org/documents/TS vaccine stability table.pdf? gl=1*1ypqsdt* gcl au*NDM 0MzYwNjg0LjE3MTk5Mjg1MDU.*_ga*NjU1MjczNTl4LjE3MTk5Mjg1MDU.*_ga_YBSE7ZKDQM* MTcxOTkyODUwNC4xLjAuMTcxOTkyODUxMC41NC4wLjA.

CKMP follow the guidance from Public Health England (PHE, 2014) on ordering, storing and handling vaccines: https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

CKMP also follow guidance from Public Health England (PHE, updated 2022) on responding to vaccine and vaccine storage errors:



https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

https://www.sps.nhs.uk/home/tools/refrigerated-medicines-stability-tool/

(Login required-KXS has access)

Version Control

Date	Version	Author	Change Details
June 2022	1.0	L Turner	SOP Created
July 2024	1.1	K Shepherd	Reviewed

