Local Resource No 5 Storage and Handling of Vaccines including Cold Chain events

Introduction

An effective and credible programme is dependent on the assurance of vaccine potency and quality. “Substandard handling of vaccines may result in a loss of potency or increased reactogenicity in these vaccines. Individuals immunised with these vaccines may be at greater risk of illness or death from the diseases that the vaccines are intended to prevent.” PHE (2012).
Due to this, the ‘cold chain’ procedure must be adhered to. This will ensure vaccine potency is maintained.

Scope

This guidance applies to all staff (including those managed by a third party e.g. agency staff or contracted domestic staff) staff with any role in ordering, receipt, storage, administration or distribution of refrigerated vaccines or medicines.

This guidance sets out the vaccine storage and cold chain procedures in general practice. All cold chain incidents will be reported through the screening and immunisations team, with full root cause analysis carried out on each incident.

Administration of vaccines

Vaccines should not be prepared in advance of an immunization session as this increases the risk of administering the wrong vaccine and may affect the temperature.

Reconstituted vaccine must be used according to the manufacturer’s recommendations, usually within 1-4 hours.

Vaccines should only be removed from the fridge for the minimum length of time before administration and any opened in error must be discarded.

Oral polio vaccine (OPV) should not be allowed to remain at room temperature awaiting or following an immunisation as this may decrease the potency of the vaccine.

Multi-dose vials may be used for one session only. Any remaining vaccine must be discarded at the end of the session

Skin Preparation

If the skin is socially clean, it is not necessary to disinfect the skin prior to injection. Soap and water is adequate otherwise. If spirit swabs are used ensure the alcohol has evaporated and the skin is dry before administering the vaccine. Some live vaccines may be inactivated by alcohol.

Disposal of vaccines
At the end of a vaccination or immunisation session any prepared or opened vaccines must be destroyed. Place the vaccines in a sharps box, for incineration. Expired vaccines must also be disposed of in a sharps box.

Immunisation training
National standards and a core curriculum have been developed for immunisation training courses. All care workers involved with distribution, handling, storage and administration of vaccines should have received appropriate training.

Cold Chain Lead
There should be a named Cold Chain Lead for the practice supported by the Practice Manager. In addition to the Cold Chain Lead there is a named individual with day to day responsibility for fridges in designated areas:

- Treatment Room
- Dispensary

Ordering, Storing and Handling Vaccines

The ordering, storing and handling of vaccines should be in line with national recommendations as set out in PHE protocol and detailed within the Immunisation of Infectious Diseases (green book):
https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3

Training available by PHE: Protocol for ordering, storing and handling vaccines:
Protocol_for_ordering__storing_and_handling_vaccines_March_2014.pdf

Taking Delivery

- Any medicine requiring refrigeration should be removed from the delivery cool chain protection as soon as possible and placed in the refrigerator.
- A note should be made on the delivery note of time and date delivered and which vaccine fridge they have been put in.

Fridge Maintenance

Specialised refrigerators are available for the storage of pharmaceutical products, and must be used for vaccines and diluents. Ordinary domestic refrigerators must not be used. As the temperatures in these validated fridges are factory set they should never freeze and form ice.

Each fridge should:
- have a unique identifier – e.g. serial number
- be lockable or in a lockable room

- be kept in a well ventilated area away from heat sources
- be serviced and calibrated annually
- have associated records for regular servicing, defrosting, cleaning, calibration and electrical testing
- have a switchless socket to reduce the possibility of accidental disruption to the power supply or the plug should be clearly labelled as the vaccine refrigerator plug
- have sufficient space for air to circulate
- not be overstocked
- have regular stock rotation to ensure vaccines are used in date order
- be kept in a clean condition (refer to cleaning schedule)
- not have build-up of ice. If defrosting is necessary vaccines should be moved to another fridge
- not hold inappropriate items – biological samples and food should not be stored in refrigerators holding medicines
- have a validated vaccine fridge which does not have ice making compartments

Temperature Recording

- Fridge temperature MUST be maintained between 2^{o}C to 8^{o}C for a product to remain in licence. A mid-range of 5 ^{o}C is best practice.
- Minimum and Maximum temperatures should be recorded once each working day first thing in the morning. It should be the first treatment room task for the nurse before the fridge is opened. Temperatures should be recorded on the Fridge Temperature Log – Appendix A
- In the absence of a nurse on any given day the nurse should nominate in advance another qualified team member to read, record and reset
- Temperature check logs should be kept with each fridge
- Fridge temperature logs are to be signed off each month by the Cold Chain Lead
- A thermometer not linked to the power supply should be used in case of interruption to the power supply
- Thermometers should be reset after each check
- Data loggers can be used in addition to but not as a replacement for thermometer checks
- Where data loggers are in place it is advised to download data on a routine basis
- Action should be taken immediately if the temperature reads outside of the range 2^{o}C to 8^{o}C
- Notify the Cold Chain Lead, Practice Manager or a Partner
- When the fridge is opened and out of range due to rotation/restocking/cleaning/auditing record the time and reason on the fridge log sheet, reset after closing the door and recheck in 30 mins to ensure the temperature is back in range, reset again.
- If there is a fridge failure take action according to procedures for Disruption of the Cold Chain (See below)

Transportation

If temperature sensitive medicines are to be transported to patients by vehicle there must be a suitable mechanism for maintaining correct temperature, e.g. validated cool box or refrigerated unit.
A record for vaccines transported by cool box should be kept in the Vaccine Transport Log – An example can be seen in Appendix B.

DISRUPTION OF THE COLD CHAIN/FRIDGE FAILURE

- Seek guidance at: HPA Vaccine Incident Guidance
- Take and record maximum and minimum temperatures as soon as a problem is identified
- Quarantine all affected vaccines in a working vaccine fridge. Label all quarantined vaccines CLEARLY.
- Assess the incident. Establish the last reliable temperature recording and the cause of any temperature fluctuation (e.g. power loss, door left open). This will help to establish if the cold chain has been broken.
- **Contact the Thames Valley Area Team Screening and Immunisation Coordinator at england.tvatpublichealth@nhs.net for advice attaching a Significant Event Reporting Form (Appendix C).**
- Implement any follow up after discussion with the immunisation co-ordinators. This may include identifying and informing or re-immunising patients who have been given unsuitable vaccines as per recommendations in HPA guidance.
- For specific information on individual vaccines contact the manufacturer
  - Sanofi 01628 587 693
  - Wyeth 01628 604 377
  - Novartis 08457 451 500
  - GSK 0800 221 441
  - Baxter 0163 520 6140
  - Crucell 0844 800 3908
  - Pfizer 01737 331111
- Dispose of vaccines considered unsuitable for use. Vaccines that include a needle should go in a yellow sharps bin. Vaccines without a needle should go in the pharmaceutical waste bin.
- Make a list of all vaccines, serial numbers and expiry dates for the Practice Manager.
- Practice needs to report the loss of centrally procured vaccines ordered from Immform via the Immform website
- Call technician who runs annual maintenance testing on all drugs fridges to arrange a service if fridge failure was found to be the cause of the cold chain breach

Waste

Any vaccine waste to be recorded in the Vaccine Waste Log – Example Appendix D.

Stock Check and Audit

- A monthly stock check should be completed on Immform for all centrally procured vaccines.
- The internal practice stock check (example Appendix E) should also be completed every month covering all vaccines.
- Stock checks are to be completed by the responsible Practice Nurse at each surgery.
- The VACCSline Vaccine Storage Audit is to be completed quarterly by the Cold Chain Lead - Appendix E.
  https://www.england.nhs.uk/.../sites/6/2014/08/vacc-storage-audit.doc

Training

- All clinical staff and non-clinical staff with any role in receipt, storage or distribution of refrigerated vaccines or medicines should undertake training suited to the fridge used in the practice.
- All immunisers must attend and evidence Basic Immunisation Training and stay up to date via self-learning/e-learning and self-assessment of competencies including formal external update training at least every 2 year as part of statutory and mandatory training requirements.
- Competencies and training will be reviewed for all staff at annual appraisal.
- Policy and guidance updates will be communicated on an ongoing basis.

Summary of Cold Chain audits and logs

Audit	Frequency	Records
Fridge Temperature Log	Daily	Keep records in Practice
Vaccine Stock Check	Monthly	Keep records in Practice
Vaccine Storage Audit	Annually	Keep records in Practice
Vaccine Transport Log	On receipt or Despatch of vaccines in Cool box	Keep records in Practice
Report of Significant Event or Serious Incident	In event of Cold Chain break	Keep records in Practice & email to TVPHE
Vaccine Waste log	In event of wasted vaccine	Keep records in Practice

Please note that the logs and recording sheets shown in attached appendices are for guidance, they can be adapted to suit the practice's requirements.

Key Contacts

Screening and immunisation team
england.tvatpublichealth@nhs.net

Improving Imms Uptake
scwcsu.improvingimmsuptake@nhs.net

1. References:

PHE (2014) Protocol for ordering storing and handling vaccines
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300304/Protocol_for_ordering__storing_and_handling_vaccines_March_2014.pdf

PHE (2012) Vaccine Incident Guidance; actions to take in response to vaccine errors.
https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

Useful Link

Nigel's surgery 17: Vaccine storage and fridges in GP practices
https://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-17-vaccine-storage-fridges-gp-practices

Falsified Medicines Directive
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/774681/VU_290_January_2019.pdf

Implementing the Falsified Medicines Directive: Safety Features
https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features

This guidance document has been adopted as a policy document by:

Organisation: .....…

Signed: .....

Job Title: .....

Date Adopted: .....

Review Date: .....

Appendices:

Appendix A – Fridge Temperature Log

FRIDGE IDENTIFIER …….

MONTH AND YEAR ……..

The temperature should be between +2ºc and +8ºc. Check each working day.

If the temperature is outside the recommended range, take appropriate action as indicated in the written procedure

Remember: Read, Record, Reset and React.

Date	Time	Current temp	Min temp	Max temp	Checked by (signature)	Thermo-meter reset (tick)	Comments

Monthly Review by: ……..……..(name) ……..(date)

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Appendix B

VACCINE TRANSPORT LOG

Cool Bag ID:	
Date Log Commenced:	

Please record details of vaccines to be transported:

	Date	Vaccine	Supplier	Batch Number	No.	Expiry	Going From	Taken by	Coolbag Out Min/Current/Max	Going to	Rec'd by	Coolbag In Min/Current/Max	Issues Y/N – record below
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													
15													

Date Log Complete:	
Name and Date:	

Issue and action taken or planned: Ref:	
Date Actions Complete:	
Name:	

Issue and action taken or planned: Ref:	
Date Actions Complete:	
Name:	

Issue and action taken or planned: Ref:	
Date Actions Complete:	
Name:	

Issue and action taken or planned: Ref:	
Date Actions Complete:	
Name:	

Issue and action taken or planned: Ref:	
Date Actions Complete:	
Name:	

Oxfordshire
Clinical Commissioning Group

Appendix C

Thames Valley
Report of a Significant Event or Serious Incident
Primary Care

Completed forms should be sent to england.tvatpublichealth@nhs.net

Name of Service/ Practice where the incident occurred		
Contact at the Service/Practice	Name	
	Job Title	
	Tel. No.	
	E-mail	
Reporter details if different from above	Name	
	Job Title	
	Tel. No.	
	E-mail	
Date incident identified		
Time incident identified		
Patient	Date of birth	
	Male/Female	
Type of Incident *(E.g. suicide, death on practice premises, medication error, fall, cold chain break, delayed referral etc.)*		
Description of what happened or what is known about the incident		
Immediate action taken		
Is there any media interest? *(If yes, please add further details)*		

Further information, action being taken, reports awaited, etc.	

Appendix D

VACCINE WASTE LOG

Surgery:	
Date Log Commenced:	

Please provide details of vaccine waste below:

Date	Reason (see list below)	Vaccine	Supplier	Batch Number	Quantity	Centrally Procured?	Stock Incident Reported on Immform	Other Action (expand below)

Reason code:

1. Excess stock ordered in error
2. Fluenz expired before it could be used
3. External power supply problem (I.e. power cut to the building)
4. Fridge door left open in error
5. Fridge equipment failure NOT as a result of loss of power
6. Fridge switched off in error
7. Stock left out of fridge in error
8. Vaccine lost or mislaid
9. Vaccine prepared but damaged before use
10. Vaccine prepared but patient refused
11. Vaccine stolen or damaged during attempted theft
12. Wrong stock ordered in error
13. Faulty stock reported to manufacturer
14. Other - describe

Action taken or planned	
Date Actions Complete:	
Name:	

Action taken or planned	
Date Actions Complete:	
Name:	

Action taken or planned	
Date Actions Complete:	
Name:	

Appendix E

MONTHLY VACCINE STOCK CHECK

Surgery:	
Fridge Location & ID:	
Date of Check:	
Person Completing Audit:	

Please record stock levels at time of stock check:

Vaccine	Supplier	Batch Number	Quantity	Expiry date	Date Delivered

1. Any issues? *e.g. poor stock rotation; out of date stock found; fridge not clean; fridge over filled*

2. Any actions required, by whom and when? *e.g. waste to be reported; order required*	
Date Actions Complete:	
Name:	

Appendix E

Vaccine Storage Audit

Audit procedure

- Work through each of the questions below and tick box, yes or no as appropriate.
- If you have ticked all white boxes then the audit is complete and no further action is needed.
- If you have ticked any boxes that are shaded grey it means that you are not following national cold chain guidance and action must be taken in order to be compliant. See below as where to locate guidance.
- Set a time scale to address the action and then perform the audit again.
- This tool should be used in conjunction with 'Immunisation against Infectious Diseases', (The Green Book 2013), 'Chapter 3, Storage, distribution and disposal of vaccines and the DH Protocol for ordering, storing and handling vaccines'.
- A record of this audit should be kept. Audits should be completed annually unless issues identified require earlier repeat audits.

Policy & Procedures		
1. Does the practice have an up to date cold chain policy (reviewed within the last two years) that is accessible to all staff?	YES	NO
2. Have all staff handling vaccines, from receipt to administration, been trained to follow policies to ensure cold chain compliance?	YES	NO
3. Are there at least two trained people responsible for the ordering, receipt and care of vaccines?	YES	NO
Ordering and monitoring of stock		
4. Are vaccine stocks monitored prior to ordering?	YES	NO
5. Is there more than four weeks supply of vaccine in the refrigerator? (excluding influenza vaccine)	YES	NO
6. Are vaccine stocks audited weekly and records of vaccine stock audited (at least) monthly?	YES	NO
7. Is a routine vaccine management review completed quarterly?	YES	NO
8. Are the expiry dates of vaccines monitored and close to expiry stock clearly labelled?	YES	NO
9. Is out-of-date stock clearly labelled, removed from the refrigerator and destroyed promptly and reported on ImmForm?	YES	NO

Receipt of vaccines		
10. Are vaccines checked against the order for discrepancies and leakage or damage before signing for them?	YES	NO
11. Is there a procedure for recording the date and time at which vaccine types, brands, quantities, batch numbers and expiry dates were received?	YES	NO
12. Are vaccines refrigerated immediately on receipt?	YES	NO
Vaccine refrigerator(s) (if several fridges are used only tick if it applies to all)		
13. Is the refrigerator specialised for the storage of pharmaceutical products?	YES	NO
14. Is the refrigerator of adequate size to store correctly the volume of vaccines required, including during times of increased demand, e.g. annual influenza programme?	YES	NO
15. Is anything other than vaccines stored in the refrigerator (including specimens, food & drink)?	YES	NO
16. Is the refrigerator either both lockable and locked or in a locked room?	YES	NO
17. Is the refrigerator properly ventilated and not located near any heat source, e.g. radiator, window?	YES	NO
18. Is the electricity supply safe, e.g. switchless plugs or cautionary notices in place to prevent accidental unplugging?	YES	NO
19. Are there arrangements in place in the event of a refrigerator failure or power cut including back up facilities?	YES	NO
20. Are there records of regular servicing, defrosting and cleaning as per manufacturers recommendations?	YES	NO
21. Is there an approved cool box with appropriate temperature monitoring or alternative refrigerator available to store vaccines during servicing, defrosting and cleaning?	YES	NO
22. Are vaccines stored in the door, bottom drawers or adjacent to the freezer plate?	YES	NO
Refrigerator thermometers		
23. Is the temperature continually monitored with a maximum– minimum thermometer?	YES	NO
24. Is there a second min/max thermometer independent of mains electricity supply in the fridge?	YES	NO
25. Are the minimum, maximum and actual temperatures in the refrigerator monitored and recorded at least once each working day and acted upon if necessary?	YES	NO
26. Are thermometers reset after being read, according to the manufacturer's guidance?	YES	NO

27. Are temperature records readily accessible and retained until the next audit?	YES	NO
28. Are thermometers calibrated and serviced annually?	YES	NO
Storage of vaccines		
29. Are there systems to minimise refrigerator door opening during immunisation clinics?	YES	NO
30. Are vaccines ever left at room temperature during immunisation clinics?	YES	NO
31. If you need to transport vaccines to outlying clinics, schools etc. do you use validated cool boxes with maximum-minimum thermometers and ice packs? (only complete if applicable)	YES	NO

This audit was completed by

Practice Name:

Person Name:

Date of completion:

If any grey boxes are ticked, date when audit will be reviewed:

Please return this form and queries to: england.screeningandimms@nhs.net

Thank you