PROCEDURE AND AUDIT CHECKLIST

Vaccine storage and cold chain checklist

Source anchors

- UKHSA Green Book chapter 3, storage, distribution and disposal of vaccines
- CQC GP mythbuster 17, vaccine storage and fridges in GP practices
- CQC Regulation 12, safe care and treatment
- CQC Regulation 17, good governance

How to use this checklist

Use this checklist to audit whether the service can evidence safe vaccine storage and cold-chain governance. It can be used monthly, before a high-volume vaccination clinic, after a cold-chain incident, or before an inspection-readiness review.

For each row, record:

- **Met:** evidence is current and complete.
- **Part met:** evidence exists but has a gap or needs follow-up.
- **Not met:** evidence is absent or the control is not working.
- **Not applicable:** the service does not carry out this activity.

Every `Part met` or `Not met` item should create an action with an owner and due date.

The PDF is designed for printing, or for completing on screen with a PDF viewer's Fill & Sign, Markup or comment tools. Use those tools to tick boxes and type into the lines.

Service details

SERVICE NAME	LOCATION
DATE COMPLETED	COMPLETED BY
REGISTERED MANAGER	COLD CHAIN LEAD
FRIDGE ASSET IDENTIFIER	PERIOD REVIEWED

1. Governance and ownership

CHECK AND EVIDENCE	STATUS	OWNER	DUE
1 **Cold Chain Lead is named.** **Evidence:** Procedure, role list, governance record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
2 **Cold Chain Deputy is named.** **Evidence:** Procedure, rota, absence cover record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
3 **Staff know who to contact if there is a cold-chain concern.** **Evidence:** Staff interview, induction record, procedure.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
4 **Current cold-chain procedure is available to staff.** **Evidence:** Procedure location, staff briefing record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
5 **Procedure has been reviewed against current UKHSA and CQC source material.** **Evidence:** Review date, source check, governance minute.	☐ Met ☐ Part met ☐ Not met ☐ N/A		

2. Fridge and equipment

CHECK AND EVIDENCE	STATUS	OWNER	DUE
1 **Vaccines are stored in a dedicated vaccine or pharmaceutical fridge.** **Evidence:** Physical check, asset record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
2 **Domestic fridge is not used for vaccines.** **Evidence:** Physical check, equipment record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
3 **Fridge is secure and access is controlled.** **Evidence:** Physical check, key/access process.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
4 **Fridge is clean, free of ice build-up and not overfilled.** **Evidence:** Physical check, cleaning record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
5 **Vaccines are kept in original packaging and away from fridge walls and door.** **Evidence:** Physical check.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
6 **Power supply is protected from accidental switch-off where reasonably practicable.** **Evidence:** Physical check, socket label or equivalent control.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
7 **Servicing, maintenance or calibration evidence is current.** **Evidence:** Service record, calibration record, asset log.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
8 **A backup plan exists for fridge failure or power failure.** **Evidence:** Business continuity plan, cold-chain procedure.	☐ Met ☐ Part met ☐ Not met ☐ N/A		

3. Temperature monitoring

CHECK AND EVIDENCE	STATUS	OWNER	DUE
1 **Temperature record covers every required day in the review period.** **Evidence:** Temperature log.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
2 **Current temperature is recorded.** **Evidence:** Temperature log.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
3 **Minimum and maximum temperatures are recorded.** **Evidence:** Temperature log.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
4 **Staff name or initials are recorded.** **Evidence:** Temperature log.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
5 **Thermometer reset is recorded where required by local procedure.** **Evidence:** Temperature log.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
6 **Out-of-range readings are clearly escalated.** **Evidence:** Temperature log, incident record, advice record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
7 **Data logger use does not replace required routine readings.** **Evidence:** Data logger record, temperature log.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
8 **Temperature records are reviewed by the Cold Chain Lead.** **Evidence:** Review signature, governance note.	☐ Met ☐ Part met ☐ Not met ☐ N/A		

4. Stock control

CHECK AND EVIDENCE	STATUS	OWNER	DUE
1 **Current stock list is accurate.** **Evidence:** Stock record, physical stock check.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
2 **Batch numbers and expiry dates are recorded.** **Evidence:** Stock record, delivery record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
3 **Shortest expiry stock is used first.** **Evidence:** Physical layout, stock rotation record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
4 **Expired or damaged vaccines are removed from usable stock.** **Evidence:** Physical check, disposal record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
5 **Stock levels are proportionate to clinic need and fridge capacity.** **Evidence:** Stock record, clinic schedule, ordering record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
6 **Repeated waste or expiry has been reviewed.** **Evidence:** Audit record, incident/action log.	☐ Met ☐ Part met ☐ Not met ☐ N/A		

5. Ordering, receipt and transport

CHECK AND EVIDENCE	STATUS	OWNER	DUE
1 **Vaccine deliveries are recorded on receipt.** **Evidence:** Delivery record, stock record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
2 **Delivery condition concerns are escalated before use.** **Evidence:** Delivery note, incident record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
3 **Vaccines are moved into the fridge without avoidable delay.** **Evidence:** Receipt process, staff interview.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
4 **Transport outside the fridge is approved and recorded.** **Evidence:** Transport record, cold-chain procedure.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
5 **Transport records identify vaccine, batch, destination and time out of fridge.** **Evidence:** Transport record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
6 **Temperature assurance during transport is recorded where required.** **Evidence:** Transport record, container validation evidence.	☐ Met ☐ Part met ☐ Not met ☐ N/A		

6. Cold-chain excursion response

CHECK AND EVIDENCE	STATUS	OWNER	DUE
1 **Affected vaccines are labelled and kept separate from usable stock.** **Evidence:** Physical check, incident record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
2 **Affected stock is not used until advice and decision are recorded.** **Evidence:** Quarantine record, advice record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
3 **Excursion duration and temperature range are recorded where known.** **Evidence:** Temperature log, incident record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
4 **Affected vaccines, batches, expiry dates and quantities are identified.** **Evidence:** Incident record, stock record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
5 **Advice route is documented.** **Evidence:** Advice record, email, call note.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
6 **Final decision is recorded for each affected vaccine.** **Evidence:** Advice record, disposal record, stock release record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
7 **Patient impact has been assessed if affected vaccine was administered.** **Evidence:** Clinical review, patient contact record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		

CHECK AND EVIDENCE	STATUS	OWNER	DUE
8 **Duty of candour and external reporting were considered where relevant.** **Evidence:** Incident review, governance note.	☐ Met ☐ Part met ☐ Not met ☐ N/A		

7. Incidents, learning and improvement

CHECK AND EVIDENCE	STATUS	OWNER	DUE
1 **Cold-chain excursions are recorded as incidents.** **Evidence:** Incident register.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
2 **Vaccine errors are recorded and clinically reviewed.** **Evidence:** Incident record, clinical review.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
3 **Adverse-event reporting route is considered where relevant.** **Evidence:** Incident record, Yellow Card decision record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
4 **Root cause is identified for significant or repeated failures.** **Evidence:** Investigation record.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
5 **Corrective actions have owners and due dates.** **Evidence:** Action log.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
6 **Actions are closed only when completion evidence exists.** **Evidence:** Action record, evidence.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
7 **Learning is shared with relevant staff.** **Evidence:** Team briefing, supervision, training update.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
8 **Repeated issues are added to the risk register or governance agenda.** **Evidence:** Risk register, governance minutes.	☐ Met ☐ Part met ☐ Not met ☐ N/A		

8. Staff training and competence

CHECK AND EVIDENCE	STATUS	OWNER	DUE
1 **Staff handling vaccines have role-appropriate cold-chain training.** **Evidence:** Training matrix.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
2 **Staff know the breach procedure.** **Evidence:** Staff interview, supervision note.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
3 **Staff know not to use quarantined or uncertain stock.** **Evidence:** Staff interview, procedure.	☐ Met ☐ Part met ☐ Not met ☐ N/A		

CHECK AND EVIDENCE	STATUS	OWNER	DUE
4 **Reception or administrative staff know what to do with deliveries.** **Evidence:** Induction record, staff interview.	☐ Met ☐ Part met ☐ Not met ☐ N/A		
5 **Training is refreshed after incidents or process changes.** **Evidence:** Training record, incident action.	☐ Met ☐ Part met ☐ Not met ☐ N/A		

9. Summary judgement

Is the cold-chain system safe today? _____

Are any vaccines currently quarantined or uncertain? _____

Are any actions overdue? _____

Is the risk register up to date? _____

Does the Registered Manager need to review this immediately? _____

10. Action log

Action	Source check	Owner	Due date	Completion evidence

11. Completion

Sign-off	Name	Date
Completed by		
Reviewed by Registered Manager		

This checklist is a working tool. It does not replace clinical judgement, product-specific storage requirements, live regulator guidance or the service's own governance decision.

Related reading

- Article: Vaccine storage and cold chain compliance: what CQC-ready evidence looks like
- Sample policy: GP vaccination and cold chain