Responding to Vaccine Pharmaceutical Incidents (non-clinical)

Standard Operating Procedure.

Document Reference No:	PTHB / MMP444	
Version No:	4	
Issue Date:	May 2024	
Review Date:	May 2027	
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Document Owner:	Chief Pharmacist	
Accountable Executive:	Medical Director	
Approved By:	Approved by Vaccination & Immunisation Operational Development Group	
Approval Date:	06/06/2024	
Document Type:	Standard Operating Procedure	Non-clinical
Scope:	PTHB	

The latest approved version of this document is online.
If the review date has passed, please contact the Author for advice.

Powys Teaching Health Board is the operational name of Powys Teaching Local Health Board
Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

Version Control:

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue MMT SOP 0125	14/01/2021
1.1	Wording updated for more clarity	05/09/2022
1.2	Updated to indicate that this SOP does not include reporting clinical vaccine incidents	19/03/2023
4	MMT SOP 0125 moved to PTHB SOP template	20/05/2024

Engagement & Consultation

Key Individuals/Groups Involved in Developing this Document

Role / Designation
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Circulated to the following for Consultation

Date	Role / Designation
11/03/2024	Vaccination Centres Clinical Lead
11/03/2024	Vaccination Centre Lead Nurse

1 Introduction

It is essential that staff are aware of how they should respond to pharmaceutical incidents in order for them to be investigated, documented and reported accurately and consistently.

This process is following compliance with current legislative requirements and good practice guidance.

2. Objective

To clearly establish any actions which must be taken when responding to pharmaceutical incidents, involving vaccines, including how to report an Adverse Drug Reaction (ADR). Note, this SOP does not cover responding to clinical incidents.

3. Definitions

- **PTHB** – Powys Teaching Health Board
- **GPhC** – The General Pharmaceutical Council are the regulatory body for pharmacists, pharmacy technicians and pharmacies in Great Britain.
- **GDP** – Good Distribution Practice requires that medicines are obtained from the licensed supply chain and are consistently stored, transported and handled under suitable conditions, as required by the product specification.
- **WIS** – Welsh Immunisation System
- **Cold chain** – is the system of transporting and storing medicines within the recommended temperature range of +2°C to +8°C from the place of manufacturer to the point of administration to a patient.
- **Temperature deviation/excursion** – any incident where the recorded Labcold™ portable vaccine carrier temperature is outside of the recommended range of +2°C to +8°C.
- **Vaccine** – a suspension of attenuated or killed microorganisms (viruses, bacteria or rickettsia) or of antigenic proteins derived from them, administered for prevention, amelioration or treatment of infectious disease.

- **ADR** – Adverse Drug Reaction is a response to a medicinal product which is noxious or unintended.

4. Role / Responsibilities

4.1 Senior Pharmacy Technician, Vaccination/Immunisation, Therapies & Pharmacy Stores

The senior pharmacy technician for immunisation / vaccination is responsible for:

- Ensuring that Vaccination Centre (VC) pharmacy support staff are trained and competent to perform the duties required of them in accordance to GPhC standards Standards | General Pharmaceutical Council (pharmacyregulation.org)
- Arranging regular review to monitor compliance with this procedure.
- Providing advice and support on how to respond to pharmaceutical incidents.
- Providing advice and support on the documentation process when responding to pharmaceutical incidents.
- Informing staff of the outcome of investigations into pharmaceutical incidents.

4.2 Senior Clinical Lead for Immunisation/Vaccination /Clinical Lead for Vaccination Centres / Lead Nurses

The senior clinical lead for immunisation / vaccination, clinical lead for vaccination centres (VC) and lead nurses (in collaboration with the senior pharmacy technician for immunisation/vaccination) are responsible for:

- Ensuring that staff for whom they have responsibility within the VCs are trained and competent to perform pharmacy support duties in accordance with GPhC standards Standards | General Pharmaceutical Council (pharmacyregulation.org).
- Ensuring that they understand how to respond to pharmaceutical incidents i.e. that they are documented and reported immediately to the senior pharmacy technician for immunisation/vaccination via Info.MedicinesManagement.Powys@wales.nhs.uk and by emailing nikki.mathers@wales.nhs.uk and where appropriate reported via DATIX.

4.4 Other Staff

- All VC pharmacy support staff are responsible for undertaking cold chain training, Good Distribution Practice (GDP) training, adhering to this SOP, maintaining competence, and appropriately reporting and reacting to pharmaceutical incidents. Evidence of competencies must be made available on request from the Medicines Management Team.

5. Process for Reporting Vaccine Pharmaceutical Incidents

5.1 Cold Chain – Temperature Deviation / Excursion

If there is a disruption of the cold chain (i.e. outside of +2 ^{o}C to +8^{o}C), immediate action must be taken (i.e. reporting to the senior pharmacy technician for immunisation/vaccination and pharmacy store technician, recording on the disruption of cold chain form and reporting via DATIX). These tasks may be delegated to appropriately trained individuals to ensure a swift response to the temperature excursion but overall management to the response to the disruption of the cold chain is jointly held between the clinical lead / nurse in charge on site and the senior pharmacy technician for immunisation/vaccination.

Please see MMP 427 - Safe and Secure Management of Refrigerated Medicines and Vaccines for detailed instruction of responding to cold chain incidents.

5.2 Reporting Vaccine Waste

Any vaccine waste i.e., expired stock, vaccine spillage, unused doses of covid vaccine etc. must be recorded via the Welsh Immunisation System (WIS). Where WIS does not support vaccine waste recording i.e. MMR vaccine then this waste must be recorded on the relevant pharmacy stock management system. NB Any unusual levels of waste i.e. large quantities of vaccine must be reported immediately to the senior pharmacy technician for immunisation/vaccination.

The senior pharmacy technician immunisation/vaccination or pharmacy stores technician will report waste via ImmForm where applicable and will inform the Vaccination Programme Delivery Unit of unexpected large volumes of waste.

Please see MMP 429 - Safe & Secure Stock Management, Handling and Preparation of Vaccines for reporting vaccine waste.

5.4 Vaccine Spillage

Spillages on skin/eyes

- Staff must be aware of the location of handwashing facilities and eyewash kits.
- Spillages on skin should be washed with soap and water.
- If a vaccine is splashed in the eyes, a sterile 0.9% sodium chloride solution must be used to irrigate the eyes and medical advice should be sought.

Spillages on surfaces

- Warn others that there has been a spill.
- Assess the spillage: if this procedure cannot be followed or there are any other concerns about safety, escalate to the clinical lead on site.
- Put on a pair of disposable gloves.
- Carefully absorb the spill onto paper towels or wipes, taking care with broken glass.
- Scoop up the spillage and place everything, including the disposable gloves, into an appropriate waste container.

Clean down the area:

- with any available detergent and water
- Wash hands after clean down.

Reporting

- Report the spill to clinical lead on site.
- Where the spill is to skin/eyes the individual must be monitored and any adverse effects reported.
- Record the number of broken or contaminated vials as discarded stock on WIS, or report to pharmacy stores team for stock requiring recording on ImmForm.
- When the above procedure cannot be followed or there are any concerns about the safety of personnel this must be escalated to the clinical lead on site. In turn they should inform senior pharmacy technician for immunisation/vaccination or PTHB Chief Pharmacist.

5.6 Adverse Drug Reactions (ADRs)

Any Suspected ADRs should be reported via the 'Yellow Card Scheme'.

Covid vaccine ADRs can be reported either online via the specific Coronovirus Yellow Card Website: https://coronavirus-yellowcard.mhra.gov.uk or via the paper form available in the back of the BNF.

Only serious ADRs should be reported for established vaccines, however all ADRs should be reported for new vaccines (BNF black triangle).

All ADRs in children should be reported.

6. Monitoring Compliance / Audit / Review

Compliance with this SOP will be audited during annual pharmacy audits.

This SOP will be reviewed every three years or earlier should changes to legislation or to practice indicate otherwise.

7. References

PTHB MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines Medicines Management - SOPs - All Documents (sharepoint.com)

SOP-HCV-7-Dealing-with-spillages-of-COVID-19-vaccines-V1.1-27.03.23.docx (live.com) accessed 11/03/2024