Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Pharmacy Risk Assessment Example - Medicine Shipments received in Electric (VIA Capsule™) Shippers

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Notes for completion

A – Complete for your department altering fields as necessary

B – Some Advanced Therapy Medicinal Products (ATMPs) may be potentially infectious e.g. in vivo gene therapy using viral vectors

C – Consider installing an anchor point to secure shipper. A shipper containing a medicinal or therapeutic product must remain in the custody of a trained healthcare professional, or be stored securely in a locked medicines storage area. Consider addition of a tamper evident security tag as the original tag will have been removed when checking the contents (include all steps in SOP and receipt checklist documentation).

D – Keep shipper upright at all times, the validated storage time depends on this. The shipper is easily manoeuvrable but wheels should be locked at all times unless being moved manually.

E – Ensure SOP is detailed and explains what to do with the medication and shipper as well as procedure for spillage of the contents of the shipper and return of the shipper. If the shipper is stored in the pharmacy/clinical area ensure that the SOP covers plugging in the shipper if necessary, checking the temperature at specified intervals and procedure if shipper is increasing in temperature or near to the maximum storage time. The shipper may need to be returned to the supplier or contents relocated (with company/sponsor approval).

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Example SOP: Procurement of Advanced Therapeutic Medicinal Products (ATMPs) – CAR-T cells

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Hospital:	e.g. Hospital name	**Location of Risk:**	e.g. Pharmacy stores
Directorate:	e.g. Pharmacy and Medicines Management	**Date Form Completed:**	28/9/2020

Risk Title
Electric VIA Capsule Shipper Risks

Description of Risk:

Explain risk

Some Advanced therapy medicinal products (ATMPs) may be received into the hospital pharmacy 'goods in' area and moved around the hospital in an electric VIA capsule shipper to maintain cryogenic temperature (below -120°C). Pharmacy have not had experience of these shippers before, however we are expecting a delivery in a shipper approximately once a month. A number of staff members are usually in the pharmacy goods in area and staff will be rarely if ever working alone.

There is a risk that staff can be harmed in a number of ways if they handle the shipper incorrectly. There may also be risk of infection to staff or environment if contents are infectious or genetically modified. There is a risk to the therapeutic product if it is handled incorrectly or if the validated storage time is exceeded or acceptable temperature limit is breached.

Cause / Source / Event

Due to the manual handling risk, extreme cold (causing burns, or causing materials to be brittle and shatter) and potentially infectious contents (see note B) ATMPs are very sensitive to changes in temperature and brittle when frozen, they must be handled very carefully and at constantly monitored temperatures.

Impact / Consequence

Physical injury, cold burns, infection, damage to medicine, therapeutic failure.

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Score Risk without Current Controls (Initial Risk Score)					
Consequence	4	X Likelihood	5	= Risk Rating	20

Controls in Place:
1.Staff training – Shippers look different to other deliveries and staff know not to undertake tasks that they are not trained for and will ask for help if encounter shipper.

Score Risk without Current Controls (Initial Risk Score)					
Consequence	4	X Likelihood	3	= Initial Risk Rating	12

Likelihood					
Consequence	1 Rare	2 Unlikely	3 Possible	4 Likely	5 Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

	1-3	Low Risk
	4-6	Moderate Risk
	8-12	High Risk
	15-25	Extreme Risk

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Gaps in Controls:
1. Training in handling shippers and contents.
2. There are some deficiencies in personal protective equipment available in the department.
3. SOPs not yet available for process.

Assurances:

Gaps in Assurance:

Actions Required to reduce risk rating:	Action Lead	Target Completion Date
1. All staff transporting (see note D) or unpacking shippers must undertake formal training see https://portal.e lfh.org.uk/Component/Details/648764 this should be included in staff induction and rolled out to current staff. A template competency assessment tool is available from the Specialist Pharmacy Service website to guide assessment and recording of staff competency to work with dry shippers (https://www.sps.nhs.uk/wp-content/uploads/2020/10/Handling-Dry-Ice-and-Vapour-Phase-Nitrogen-Shippers.pdf).		
2. First aiders in the department should be trained in cold burns		
3. Ensure people store and open shippers in designated areas. Safe custody of medications policy must always be adhered to and access to the medication must be restricted to trained staff only. SOPs must be written to cover receipt, storage, transport, and opening of the shippers (see notes C and E).		
4. Purchase temperature resistant gloves, goggles and lab coat or coverall to be worn when removing products from the shipper (suitable shoes as per uniform policy; arms and legs should be covered).		
5. Establish procedure for return to the company of empty shipper, or if necessary of shipper containing therapeutic product.		

Notepad

Put any supporting relevant information here that does not sensibly fit in the other sections but you feel is useful.

Consider the final destination of the medication and consider implication of moving a shipper around the hospital if this is required. If it does need to be moved it should be done by trained operators only.

For more information see https://www.cytivalifesciences.com/en/gb/shop/cell-therapy/systems/via-capsule-system-p-24018#related

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Considering all of the information you have on the controls and assurances how would you rate the risk when the actions are completed (Target Risk Score):					
Consequence	**4**	**X Likelihood**	**1**	**= Target Risk Rating**	**4**

Main Risk Type: *please tick one only*				
Clinical Care/Quality	Communication/ PR	Compliance with Standards	Corporate Governance	Estates
Financial	Health & Safety	Information Governance	Infection Control	Legal
Safeguarding	Security	Social Care	Strategic	

Signature of Assessor	
Date of Assessment	
Risk Owner	
Signature of Clinical Board Director	
Date	

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