

Document Type:	Guideline	
Reference Number : 2665	Version Number: 1	Next Review Date: 22 December 2023
Title:	Unpacking of Frozen Pfizer-BioNTech Covid-19 Vaccines and Transfer to Fridges to Thaw	
Document Author:	Pharmacy Operations Manager	
Applicability:	All Pharmacy Goods Inwards Staff	

1. Purpose

This SOP describes the process of unpacking frozen Pfizer-BioNTech Covid-19 vaccine (BNT162b2) and transfer into a fridge to thaw.

2. Scope

Unpacking of Covid-19 vaccines from shippers containing dry ice (carbon dioxide) and storage in fridges, expiry reduction, and safe disposal of the dry ice.

3. Responsibility

Only staff suitably trained and competent in handling dry ice (carbon dioxide) and the allocation of new expiry dates may perform this activity.

A second check is required at point 5.10. This person must also be trained and competent in handling dry ice and the allocation of new expiry dates.

N.B. This process will take place simultaneously with receipt checks (See SOP 2670 Receipt of Pfizer-BioNTech Covid-19 Vaccines) and must be performed in pairs. One person should lead on performing the tasks in this SOP and the other person on performing SOP 2670.

When working in pairs, it is the responsibility of both people to continue to observe all local Covid-19 precautions.

4. Health and Safety rules for handling dry ice

- Dry ice may cause cold burns, and carbon dioxide gas may cause asphyxiation if it is not allowed to escape into the atmosphere
- Always work in pairs when unpacking deliveries from dry ice.
- In addition to the PPE provided (mid-length gauntlets, goggles or face shield and apron), staff must wear clothing that covers their legs and arms, and shoes must be completely enclosed.
- Always ensure good ventilation:

- Never move shippers containing dry ice in a lift
- Never place shippers containing dry ice in a cold store or fridge, or other unventilated areas
- Always leave the dry ice in the shipper
- First aid for dry ice burns is the same as for heat burns: treat with tepid running water and seek medical attention.

5. Procedure

- 5.1. Collect dry-ice handling PPE (mid-length gauntlets, goggles or face shield and apron), disposable gloves to wear under the gauntlets, a trolley, a roll of Pfizer thaw labels (see [appendix 1](#)) for expiry reduction, and a pair of tweezers for removal of the labels from their backing.
- 5.2. Work in the designated well-ventilated area, as close as possible to the fridge.
- 5.3. Check the temperature display on the fridge to ensure it is between 2 and 8°C. If it is not, do not proceed and follow local SOP for fridge temperature excursions.
- 5.4. Check that the shipper is within its expiry date.
- 5.5. Put on the PPE.
- 5.6. Remove the cartons from the shipper and place them onto the trolley or a bench immediately adjacent to the fridge. If there is any distance to travel between the shipper and the fridge use the trolley instead of carrying the cartons.
- 5.7. Allow the other person to perform receipt checks according to SOP 2670 (Receipt of Pfizer-BioNTech Covid-19 Vaccines)
- 5.8. Replace the inner lid on the shipper to contain the dry ice.
- 5.9. Complete one Pfizer thaw label for each carton detailing
 - Time and date removed from the shipper
 - Time and date of expiry i.e. 120 hours (exactly 5 days) from removal from the shipper
 - Batch number
 - Signature of person completing the label
- 5.10. Ask the other person to
 - check the thawed expiry date and time calculation
 - check the batch number
 - check that there are exactly the same number of completed Pfizer thaw labels as there are cartons
 - sign the labels to confirm the check is complete.

- 5.11. Attach one Pfizer thaw label to each of the cartons, ensuring no part of the original carton label is covered. It may be necessary to use tweezers or ask the other person to peel the label off its backing if this cannot be done while wearing gauntlets.
- 5.12. Transfer the cartons into the fridge.
- 5.13. Close the shipper box and use the trolley to remove it to Goods Inward back corridor ensuring the area is well ventilated. Keep on all PPE, except gauntlets if it is essential to remove them e.g. to open a locked door.
- 5.14. Put gauntlets back on again (if removed) and position the shipper box with lid ajar. Write the date and time on the box so that there is a record of when it is safe to discard.
- 5.15. Secure the location and leave to allow the carbon dioxide to turn to gas (sublime) for at least 24 hours.
- 5.16. Remove PPE and store in a designated clean, dry location. If the goggles or visor may be worn by someone else, wash in soapy water or wipe them down with a bactericidal wipe and leave to dry.
- 5.17. Remove and discard the disposable gloves according to local waste disposal practices and wash your hands.
- 5.18. Once the carbon dioxide has completely sublimed, discard the shippers with general and cardboard waste following normal Trust procedures.

4 Associated documents

[Receipt of frozen Pfizer-BioNTech Covid-19 Vaccine](#)

5 References

<https://www.sps.nhs.uk/articles/handling-dry-ice-and-vapour-phase-nitrogen-shippers-advice-for-hospital-pharmacies/>

Appendix 1

Pfizer Thaw label (approx. actual size):

COVID-19 mRNA Vaccine BNT162b2
Thawed product can be kept for 120 hours (5 days) at 2-8°C.

In refrigerator at 2-8°C: DD / MM / YY At HH : MM	Batch number:
↓ 120h (5 days) ↓	
Discard after: DD / MM / YY At HH : MM	Signed: _____ Checked: _____

PP-CVV-GBR-0034, November 2020

Document Control Information

This is a controlled document and should not be altered in any way without the express permission of the author or their representative.

Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.

If printed, this document is only valid for the day of printing.

This guidance has been registered with the Trust. The interpretation and application of guidance will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using clinical guidance after the review date, or outside of the Trust.

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Purpose of document:	This SOP describes the process of unpacking frozen Pfizer-BioNTech Covid-19 vaccine (BNT162b2) and transfer into a fridge to thaw.		
Date of issue:	22 December 2020	Next review date:	22 December 2023
Version:	1	Last review date:	
Author:	Pharmacy Operations Manager		
Directorate:	Trustwide		
Equality Impact:	The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief		
Committee(s) approving the document:	Clinical Director – Pharmacy and Prescribing		
Date approved:	18 December 2020		
Links or overlaps with other policies:			

Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.	Yes <input type="checkbox"/>	
	Please select Yes No	
Does this document have implications regarding the Care Act? <i>If yes please state:</i>	<input type="checkbox"/>	<input type="checkbox"/>
Does this document have training implications? <i>If yes please state:</i>	<input type="checkbox"/>	<input type="checkbox"/>
Does this document have financial implications?	<input type="checkbox"/>	<input type="checkbox"/>

<i>If yes please state:</i>		
Is this document a direct replacement for another? <i>If yes please state which documents are being replaced:</i>	<input type="checkbox"/>	<input type="checkbox"/>

Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
22 December 2020	1	New	Clinical Director – Pharmacy and Prescribing

The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

“The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves”. (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on ICON.

<https://icon.torbayandsouthdevon.nhs.uk/areas/mental-capacity-act/Pages/default.aspx>

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

Rapid (E)quality Impact Assessment (EqIA) *(for use when writing policies)*

Policy Title (and number)		Version and Date	
Policy Author			
An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.			
Who may be affected by this document?			
Patients/ Service Users	<input type="checkbox"/>	Staff	<input type="checkbox"/>
Other, please state...		<input type="checkbox"/>	
Could the policy treat people from protected groups less favourably than the general population? PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below			
Age	Yes <input type="checkbox"/> No <input type="checkbox"/>	Gender Reassignment	Yes <input type="checkbox"/> No <input type="checkbox"/>
Race	Yes <input type="checkbox"/> No <input type="checkbox"/>	Disability	Yes <input type="checkbox"/> No <input type="checkbox"/>
Gender	Yes <input type="checkbox"/> No <input type="checkbox"/>	Pregnancy/Maternity	Yes <input type="checkbox"/> No <input type="checkbox"/>
Sexual Orientation			Yes <input type="checkbox"/> No <input type="checkbox"/>
Religion/Belief (non)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Marriage/ Civil Partnership			Yes <input type="checkbox"/> No <input type="checkbox"/>
Is it likely that the policy could affect particular 'Inclusion Health' groups less favourably than the general population? (substance misuse; teenage mums; carers ¹ ; travellers ² ; homeless ³ ; convictions; social isolation ⁴ ; refugees)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Please provide details for each protected group where you have indicated 'Yes'.			
VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion			
Is inclusive language ⁵ used throughout?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Are the services outlined in the policy fully accessible ⁶ ?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Does the policy encourage individualised and person-centred care?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Could there be an adverse impact on an individual's independence or autonomy ⁷ ?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
EXTERNAL FACTORS			
Is the policy a result of national legislation which cannot be modified in any way?			Yes <input type="checkbox"/> No <input type="checkbox"/>
What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)			
Who was consulted when drafting this policy?			
Patients/ Service Users	<input type="checkbox"/>	Trade Unions	<input type="checkbox"/>
Protected Groups (including Trust Equality Groups)		<input type="checkbox"/>	
Staff	<input type="checkbox"/>	General Public	<input type="checkbox"/>
Other, please state...		<input type="checkbox"/>	
What were the recommendations/suggestions?			
Does this document require a service redesign or substantial amendments to an existing process? PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below			Yes <input type="checkbox"/> No <input type="checkbox"/>
ACTION PLAN: Please list all actions identified to address any impacts			
Action	Person responsible	Completion date	
AUTHORISATION:			
By signing below, I confirm that the named person responsible above is aware of the actions assigned to them			
Name of person completing the form		Signature	
Validated by (line manager)		Signature	

Please contact the Equalities team for guidance:

For Devon CCG, please email d-ccg.equalityanddiversity@nhs.net & d-ccg.QEIA@nhs.net

For Torbay and South Devon NHS Trusts, please call 01803 656676 or email pdf.sdhct@nhs.net

This form should be published with the policy and a signed copy sent to your relevant organisation

Consider any additional needs of carers/ parents/ advocates etc, in addition to the service user

² Travelers may not be registered with a GP - consider how they may access/ be aware of services available to them

³ Consider any provisions for those with no fixed abode, particularly relating to impact on discharge

⁴ Consider how someone will be aware of (or access) a service if socially or geographically isolated

⁵ Language must be relevant and appropriate, for example referring to partners, not husbands or wives

⁶ Consider both physical access to services and how information/ communication is available in an accessible format

⁷ Example: a telephone-based service may discriminate against people who are d/Deaf. Whilst someone may be able to act on their behalf, this does not promote independence or autonomy

Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes No

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our [GDPR](#) page on ICON (intranet)

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdf@nhs.net,
- See TSDFT's [Data Protection & Access Policy](#),
- Visit our [Data Protection](#) site on the public internet.