

Document Type:	Guideline	
Reference Number : 2668	Version Number: 1	Next Review Date: 22 December 2023
Title:	Storage and Transportation of Thawing / Defrosted Pfizer-BioNtech Covid-19 Vaccines	
Document Author:	Pharmacy Operations Manager	
Applicability:	All Pharmacy Staff and Vaccination Centre Staff	

1. Purpose

This SOP describes the safe and secure storage and transportation of Pfizer-BioNTech Covid-19 vaccines in either the Pharmacy Department or Vaccination Centre.

2. Responsibility

Only suitably trained staff should remove the vaccines from refrigeration for transportation or administration. The Pharmacy Manager of the Day or on-call pharmacist (out of hours) is responsible for monitoring the stored vaccine according to the SOP for fridge monitoring. The Clinical Lead for the Vaccination Centre is responsible for monitoring the stored vaccine according to the SOP for fridge monitoring during opening hours, once the stock is at the centre and the on-call pharmacist will monitor remotely out of hours.

3. Procedure

3.1 Storing in Pharmacy Fridge

3.1.1. Once SOP 2665 (Unpacking of Vaccine) is complete the fridge should be locked and only opened when necessary to remove the vaccine for transportation.

3.1.2 The fridge should be monitored according to local SOPs ([Appendix 1](#)) and any out of specifications should be recorded ([Appendix 2](#)), addressed promptly and appropriately, and a full audit trail should be maintained.

3.2 Transportation of the Vaccine

3.2.1. The vaccine should only be transported in approved and validated packaging, and the temperature of the contents and carrier should be monitored.

3.3 Storing in Vaccination Centre

3.3.1. The vaccine should be removed from the transportation packaging immediately on arrival and placed in the fridge, ensuring the fridge is in range and then locked securely.

3.3.2. The fridge should be monitored according to local SOPs and any out of specifications should be addressed promptly and appropriately, and a full audit trail should be maintained.

3.3.3. If an excursion occurs out of hours, the on-call pharmacist is responsible for contacting Clinical Site Managers in order to enter the Horizon Centre and investigate the problem. Clinical Site Managers are only responsible for access and not dealing with the alarm or vaccine. If required, the vaccine will need to be returned in a cool box to a fridge in pharmacy to ensure cold chain is maintained.

3.3.4. Along with remote monitoring, there should also be a twice a day check from the Clinical Lead ensuring safe and secure handling.

4. Associated Documents

[Unpacking of frozen Pfizer-BioNTech Covid 19 Vaccines and transfer to fridges to thaw.](#)

[Preparation of Pfizer-BioNTech COVID-19 Vaccine \(BNT162b2\) Syringes for Administration.](#)

SOP for fridge monitoring (to follow)

[Appendix 1 Recording of fridge temperature at vaccination centre](#)

[Appendix 2 Recording of temperature excursions](#)

Appendix 1 – Recording of Fridge Temperature at Vaccination Centre

The temperature on the Comark monitoring device should be checked and recorded three times a day by either pharmacy or the nurse in charge using the form below.

The device will be attached to the side of the fridge as per picture below.



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 pf.d.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.