

Document Type:	Guideline	
Reference Number : <b>2670</b>	Version Number: <b>1</b>	Next Review Date: <b>22 December 2023</b>
Title:	<b>Receipt of Frozen Pfizer-BioNTech Covid-19 Vaccines</b>	
Document Author:	Pharmacy Operations Manager	
Applicability:	All Pharmacy Goods Inwards Staff	

## 1. Purpose

This SOP describes the process of receipt of frozen Pfizer-BioNTech Covid-19 vaccine (BNT162b2), including

- safe handling processes for vaccines supplied at ultra-low temperatures
- recording data attributes needed to provide data for the national vaccination programme.

## 2. Scope

Receipt of Pfizer-BioNTech Covid-19 vaccine.

## 3. Responsibility

Only staff suitably trained and competent in handling dry ice (carbon dioxide) may perform this activity. In addition to the PPE provided, staff must wear clothing that covers their legs and arms, and shoes must be completely enclosed.

**N.B. Part 4.2 of this process will take place simultaneously with storage of the vaccines (See SOP 2665) and must be performed in pairs. One person should lead on performing the tasks in this SOP and the other person on performing SOP 2665.**

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

## 4. Procedure

### 4.1. Accepting Deliveries

4.1.1. Before receiving a vaccine delivery ensure dry-ice handling PPE (gloves/gauntlets and goggles or visor) are readily to hand.

4.1.2. Check:

- The number of shippers (packaging vaccine arrives in containing dry ice (carbon dioxide)) matches the number listed on the delivery note, carrier's receipt or proof-of-delivery device.

- All shippers are in good condition and no damage is evident.
- All shippers are addressed correctly.
- The shipper has not expired

4.1.3. If any part of the delivery is damaged, already opened, missing or otherwise not as expected report without delay to Operations Manager or Procurement Lead.

4.1.4. If the delivery appears to be in order, accept the shipment according to the established acceptance-of-delivery process.

## 4.2. Physical Examination of Delivery

**N.B. This part of the process will take place simultaneously with the unpacking of the delivery. Refer to SOP 2665**

4.2.1. Put on dry-ice handling PPE (gloves/gauntlets and goggles or visor)

4.2.2. Check again that the shipper has not expired

4.2.3. Remove the cartons from the parcel, check tamper evident seal is intact, check for any damage and check identity, batch number, expiry date and quantities against the delivery note.

- If there is any damage or discrepancy, quarantine the stock at the correct storage temperature and report without delay to Operations Lead or Procurement Lead
- If any vials are broken, deal with the spillage following normal SOP for spillages. No special spillage procedures are required for Pfizer-BioNTech Covid-19 (BNT162b2) vaccine.

4.2.4. Replace the lid on the shipper.

4.2.5. Put the vaccines in the correct temperature storage location immediately. Refer to SOP 2665.

4.2.6. Remove the shipper to Goods Inward back corridor. Refer to SOP 2665

## 4.3 Logging Receipts on the Stock Control System

4.3.1 Endorse the delivery note with signature and time/date to indicate

- the correct goods have been received
- the quantities are correct
- batch numbers and expiries on the delivery note are correct

4.3.2 For each purchase order, receive the goods on to the stock control system (Immform and pharmacy stock management system)

4.3.3 Forward completed delivery documentation to Operations Manager or Procurement Lead.

4.3.4 Receipt of vaccine on to the pharmacy stock management system must capture the following product details:

- Date and time received into system (time is automatically captured by the system and not manually entered)
- Supplier
- Purchase order number
- dm+d medicine name (AMP/P) This must be the 'branded' level description
- Pack size and number of vials received
- Batch number (This cannot be scanned and **must** be checked by a second person to ensure the correct information is recorded)
- Expiry of vials

#### **4.4 Dealing with problems and errors on deliveries by Operations Manager or Procurement Lead**

4.4.1 In the event goods arrive

- Damaged
- Expired (either the shipper, or the vials)
- Of a quantity that differs to either the purchase order, delivery note or there are any other discrepancies, report as advised on delivery note.

#### **5 Associated documents**

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

#### **6 References**

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

## 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.*

<b>Ref No:</b>	2670		
<b>Document title:</b>	Receipt of frozen Pfizer-BioNTech Covid-19 Vaccines		
<b>Purpose of document:</b>	This SOP describes the process of receipt of frozen Pfizer-BioNTech Covid-19 vaccine (BNT162b2), including <ul style="list-style-type: none"> <li>• safe handling processes for vaccines supplied at ultra-low temperatures</li> <li>• recording data attributes needed to provide data for the national vaccination programme.</li> </ul>		
<b>Date of issue:</b>	22 December 2020	<b>Next review date:</b>	22 december 2023
<b>Version:</b>	1	<b>Last review date:</b>	
<b>Author:</b>	Pharmacy Operations Manager		
<b>Directorate:</b>	Trustwide		
<b>Equality Impact:</b>	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		
<b>Committee(s) approving the document:</b>	Clinical Director – Pharmacy and Prescribing		
<b>Date approved:</b>	18 December 2020		
<b>Links or overlaps with other policies:</b>			

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

<b>Does this document have financial implications?</b> <i>If yes please state:</i>			<input type="checkbox"/>	<input type="checkbox"/>
<b>Is this document a direct replacement for another?</b> <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 Decemeber 2020	1	New	Clinical Director – Pharmacy and Prescribing

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## 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? <b>PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below</b>			
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 <sup>1</sup> ; travellers <sup>2</sup> ; homeless <sup>3</sup> ; convictions; social isolation <sup>4</sup> ; refugees)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Please provide details for each protected group where you have indicated 'Yes'.			
<b>VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion</b>			
Is inclusive language <sup>5</sup> used throughout?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Are the services outlined in the policy fully accessible <sup>6</sup> ?			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 <sup>7</sup> ?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
<b>EXTERNAL FACTORS</b>			
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? <b>PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below</b>			Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>ACTION PLAN: Please list all actions identified to address any impacts</b>			
Action	Person responsible	Completion date	
<b>AUTHORISATION:</b>			
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](mailto:d-ccg.equalityanddiversity@nhs.net) & [d-ccg.QEIA@nhs.net](mailto:d-ccg.QEIA@nhs.net)

For Torbay and South Devon NHS Trusts, please call 01803 656676 or email [pf.d.sdhct@nhs.net](mailto: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

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

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

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

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

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

<sup>7</sup> 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



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