

Document Type:	Guideline	
Reference Number : 2669	Version Number: 1	Next Review Date: 22 December 2023
Title:	Administration of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)	
Document Author:	Governance Pharmacist & Medication Safety Officer	
Applicability:	All NHS Staff Administering the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) under a Patient Group Direction.	

1. Purpose

This SOP describes the process for administration of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2).

2. Scope

This procedure covers the process of administering vaccine from the prepared syringes. This procedure should be used in conjunction with the procedure Preparation of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) Syringes for Administration and the Trusts Injectable Medicines policy ([see references](#)).

3. Responsibility

Staff performing the preparation and administration of the vaccine are responsible for following this procedure and complying with the Patient Group Direction (PGD). Individual vaccinators must have been authorised by a senior manager to use the PGD.

4. Procedure

- 4.1. Prepare the syringe as SOP [2664 Preparation of Pfizer-BioNTech COVID-19 Vaccine \(BNT162b2\) Syringes for Administration](#)
- 4.2. Ensure all consent processes have been completed ([Appendix 1](#))
- 4.3. Ensure the individual fits the PGD inclusion criteria and is not excluded (see checklist [Appendix 2](#))

Exclusion criteria includes:

- Any person with a history of immediate-onset anaphylaxis to a vaccine, medicine or food should not receive the Pfizer BioNtech vaccine. A second dose of the Pfizer BioNtech vaccine should not be given to those who have experienced anaphylaxis to the first dose of Pfizer BioNtech vaccination.

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- 4.4. Check volume withdrawn is 0.3ml
 - 4.5. Visually inspect the syringes for particles and leaks. Discard if these are observed
 - 4.6. Check the allergy status of the patient
 - 4.7. Administer the COVID-19 mRNA Vaccine BNT162b2 vaccine intramuscularly in the deltoid muscle as per the PGD
 - 4.8. Do not inject the vaccine intravascularly, subcutaneously or intradermally
 - 4.9. Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment (see PGD)
 - 4.10. Dispose of any waste as SOP [2666 Disposal of Pfizer-BioNTech COVID-19 Vaccine \(BNT162b2\) AND Other Waste.](#)

References:

[Patient Group Direction 2661version 1.0
Administration of COVID-19 mRNA vaccine BNT162b2 \(Pfizer/BioNTech\) by Registered
Practitioners employed by Torbay and South Devon NHS Foundation Trust](#)

[Trust Injectable Medicines Policy](#)



Adults

COVID-19 vaccination consent form

The COVID-19 vaccination will reduce the chance of you suffering from COVID-19 disease. Like all medicines, no vaccine is completely effective and it takes a few weeks for your body to build up protection from the vaccine. Some people may still get COVID-19 despite having a vaccination, but this should lessen the severity of any infection. If you are currently pregnant, planning pregnancy or breastfeeding please read the detailed information at www.nhs.uk/covidvaccination

The vaccine cannot give you COVID-19 infection, and two doses will reduce your chance of becoming seriously ill. You will still need to follow the guidance in your workplace, including wearing the correct personal protection equipment and taking part in any screening programmes. Like all medicines, vaccines can cause side effects. Most of these are mild and short-term, and not everyone gets them.

Please read the product information for more details on the vaccine and possible side effects by searching Coronavirus Yellow Card. You can also report suspected side effects on the same website or by downloading the Yellow Card app. Visit coronavirus-yellowcard.mhra.gov.uk

Full name (first name and surname):	Date of birth:
Home address:	Daytime contact telephone number:
NHS number (if known): 	Ethnicity:
Care home address:	Gender (circle as appropriate): Male Female Prefer not to say
GP name and address:	<input type="checkbox"/> I am a woman of childbearing age and I have read the leaflet on pregnancy and breastfeeding

Consent for a course of COVID-19 vaccination (please complete one box)

I want to receive the full course of COVID-19 vaccination	I do not want to receive the full course of COVID-19 vaccination
Name	Name
Signature	Signature
Date	Date

If, after discussion, you decide that you do not want to have the vaccine, it would be helpful if you would give the reasons for this below/on the back of this form (and return to the provider).

Thank you for completing this form. Please return it as soon as possible.

Office use only

Date of COVID-19 vaccination	Site of injection (please circle)		Batch number/ expiry date	Brand of Vaccine	Immuniser name and signature (please print)	Where administered (care home, home, GP etc)
	L arm	R arm				
First	L arm	R arm				
Second	L arm	R arm				

Appendix 2

Individual Patient Checklist for the administration of Pfizer BioNTech COVID-19 mRNA Vaccine BNT 162b2
To be used in conjunction with PGD 2661

Name		DOB		NHS No	
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Question	First Dose				Second Dose			
	Column 1		Column 2		Column 1		Column 2	
Are you less than 16 years of age?	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>
Are you currently unwell with fever?	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>
Have you had a confirmed anaphylactic reaction to a previous dose of a COVID-19 vaccine?	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>
Have you had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process?	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>
Do you have a history of immediate-onset anaphylaxis to a vaccine, medicine or food?	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>
Are you pregnant or planning to be pregnant in the next 3 months (dose 1) or 2 months (dose 2)?	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>
Are you breast feeding?	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>
Have you had confirmed COVID-19 infection in the preceding 4 weeks?	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>
Are you participating in a clinical trial of COVID-19 vaccines?	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>
Have you received a dose of COVID-19 vaccine in the preceding 21 days?	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>
Have you completed a course of COVID-19 vaccination?	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>
Have you been counselled regarding the vaccine purpose and side effects?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Do you consent to vaccination?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Immuniser details:	Name				Name			
	Signature		Date		Signature		Date	

If any of the boxes in column 2 are ticked, DO NOT administer the vaccine.

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 for administration of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2).		
Date of issue:	22 December 2020	Next review date:	22 December 2023
Version:	1	Last review date:	
Author:	Governance Pharmacist & Medication Safety Officer		
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? <i>If yes please state:</i>	<input type="checkbox"/>	<input type="checkbox"/>

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.