Document Type:	Guideline	
Reference Number : **2664**	Version Number: **2**	Next Review Date: **22 December 2023**
Title:	**Preparation of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)Syringes for Administration**	
Document Author:	Accountable Pharmacist (Aseptic Services)	
Applicability:	All NHS Staff Preparing the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) under a Patient Group Direction.	

1. Purpose

This procedure describes the process for preparation of ready to administer syringes of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2).

2. Scope

This procedure covers the process from the removal of vials of thawed vaccine from the outer carton in the refrigerator up until the point of administration. This includes the dilution of the concentrate vial, and the preparation of syringes for administration.This procedure should be used in conjunction with the Trust's Injectable Medicines policy.

3. Responsibility

Staff performing the preparation and administration of the vaccine are responsible for following this procedure.

The Clinical Director - Pharmacy must ensure that appropriate and formal authorisation for vaccine administration is in place such as a Patient Group Direction, protocol or written instruction, and that the staff groups who are supplied with, prepare, and administer the vaccine are those defined as eligible to do so.

4. Procedure

4.1. Removal of vaccines from original carton

4.1.1. Remove a vial of thawed concentrated vaccine, from the original carton in the refrigerator. If there is more than one carton, use the one with the shortest post-thaw expiry. One vial contains sufficient vaccine for 5 syringes /administrations when diluted. Log all the information on Appendix 1 – Vaccine Removal from Fridge.

4.1.2. Once removed from a refrigerator and stored at room temperature, the vials must be:

- diluted within 2 hours

- and then used within 6 hours once diluted.

4.2. Workstation preparation

4.2.1. Confirm the preparation workstation is clear and free from any other vials of vaccine.
4.2.2. Ensure a yellow lidded sharps bin with sufficient free capacity is available.
4.2.3. Ensure indelible pen is available
4.2.4. Put on apron
4.2.5. Clean workstation with a disinfectant wipe and discard into a clinical waste bin.
4.2.6. Clean your hands according to local policy and put on a pair of disposable protective gloves.

4.3. Dilution

4.3.1. Assemble the following materials required to perform dilution:
- Sodium chloride 0.9% ampoule 5mL X 1
- 2mL Syringe X 1
- 21g needle X 1
- Antiseptic swab x2
- Check the expiry dates and that there is no obvious damage to containers or packaging.

4.3.2. Place the single vial of concentrated Pfizer-BioNTech COVID-19 Vaccine into the preparation area.

- Only one vaccine vial must be in use in the preparation workstation at any one time.

4.3.3. Allow the vaccine vial to come to room temperature if immediately removed from the fridge.

4.3.4. Slowly invert the vial 10 times to thoroughly mix the concentrate suspension, DO NOT shake.

4.3.5. Prior to dilution, check the vaccine is an off-white solution with no particulates visible. Discard the vaccine if particulates or discolouration are present.

4.3.6. Remove the vial dust cover and cleanse the vaccine vial stopper with a single use 70% alcohol swab. Discard the swab into a clinical waste bin. Set the concentrated vaccine vial to one side.

4.3.7. Cleanse the top and shoulders of 5mL ampoule of preservative free sodium chloride 0.9% with a single use 70% alcohol swab and discard the swab into a clinical waste bin.

4.3.8. Attach a 21g needle to a 2mL syringe.

4.3.9. Using aseptic technique, snap the top off a 5ml of preservative free sodium chloride 0.9% ampoule and use the 2mL syringe and 21g needle to draw up **1.8 mL** of preservative free sodium chloride 0.9%.

4.3.10. Check the volume of sodium chloride 0.9% drawn up is **1.8mL.**

4.3.11. Dispose of the remainder of the 5ml preservative free sodium chloride 0.9% ampoule into a yellow lidded sharps bin

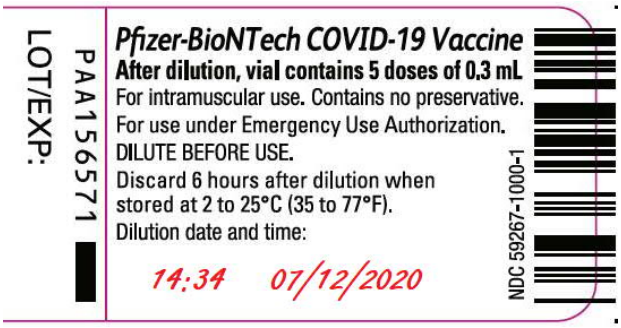
4.3.12. Dilute the concentrate vaccine vial by adding 1.8 mL of preservative free sodium chloride 0.9%. Ensure vial pressure is equalized by withdrawing 1.8 mL air into the empty diluent syringe before removing the needle from the vial.

4.3.13. Dispose of syringe and needle into a yellow lidded sharps bin.

4.3.14. Slowly invert the vial 10 times to mix contents thoroughly, DO NOT shake.

4.3.15. The diluted vaccine should present as an off white solution with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present.

4.3.16. Write the time / date of dilution on the vial label as shown below in red below. Use 24 hour clock format.



4.3.17. The expiry is 6 hours from the point of dilution, but should still be used immediately.

4.3.18. Do not collect another vial of concentrated vaccine from the fridge until the previous vial of diluted vaccine has left the preparation workspace / been discarded.

4.4. **Withdrawal into syringes**

4.4.1. Prepare one syringe at a time for each individual patient.

4.4.2. Clean workstation with a disinfectant wipe and discard into clinical waste bin.

4.4.3. Clean hands according to local policy and put on a pair of disposable protective gloves

4.4.4. Assemble the following materials required to prepare each syringe:

- Diluted Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) vial X 1
- 1x1ml syringe with integrated 23g x 25mm needle
- 1x Single use 70% alcohol swab

4.4.5. Check the vial is within the hand written expiry on the label

4.4.6. Cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.

4.4.7. Using aseptic technique, draw up **0.3mL** of the diluted vaccine using a 1ml syringe with integrated 23g x 25mm needle.
N.B.23g x 38mm needles and 1ml syringes are available for morbidly obese patients.

4.4.8. Adjust to remove air bubbles with the needle still in the vial to avoid loss of diluted vaccine.

4.4.9. Check volume withdrawn is **0.3mL.**

4.4.10. Visually inspect the syringes for particles and leaks. Discard if these are observed.

4.4.11. The newly filled syringe must be used for immediate administration.

4.4.12. Steps 4.4.2 to 4.4.8 may be repeated a further four times to produce a total of five syringes from each diluted vaccine vial. Each time the vial bung is punctured, this should be in a different location to previous points of puncture on the bung.

4.4.13. Once empty, or no longer needed, immediately discard the used vaccine vial into a yellow lidded sharps bin.

4.4.14. At the end of the session discard any part used or unused vials into a yellow lidded sharps bin. Vials must not be stored between sessions or returned to the refrigerator.

4.4.15. Empty outer cartons must be disposed of in a secure manner which prevents theft. Score through label text with a permanent marker and cut the box up into pieces before disposal.

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

Appendices

Appendix 1 – Vaccine Removal from Fridge Log

Appendix 1 – Vaccine Removal from Fridge Log

Date	Time	Number of Vials Removed	Batch Number	New Expiry	Removed By

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 procedure describes the process for preparation of ready to administer syringes of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2).		
Date of issue:	22 December 2020	**Next review date:**	22 December 2023
Version:	2	**Last review date:**	
Author:	Accountable Pharmacist (Aseptic Services)		
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:	16 December 2020		
Links or overlaps with other policies:	Patient Group Direction 2661 version 1.0 Administration of COVID-19 mRNA vaccine BNT162b2 (Pfizer/BioNTech) by Registered Practitioners employed by Torbay and South Devon NHS Foundation Trust. Ref 2661 Trust Injectable Medicines Policy Ref 1923		

Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.	Yes ☐	
	Please select *Yes*	*No*
Does this document have implications regarding the Care Act? *If yes please state:*	☐	☐

Does this document have training implications? *If yes please state:*	☐	☐
Does this document have financial implications? *If yes please state:*	☐	☐
Is this document a direct replacement for another? *If yes please state which documents are being replaced:*	☐	☐

Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
18 December 2020	1	New	Clinical Director – Pharmacy and Prescribing
22 December 2020	2	Minor amendment	Pharmacy Governance Lead and Trust Medication Safety Officer

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.

NHS Devon Clinical Commissioning Group

NHS Torbay and South Devon NHS Foundation Trust

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 ☐	Staff ☐	Other, please state…		☐	
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 ☐ No☐	Gender Reassignment	Yes ☐ No☐	Sexual Orientation	Yes ☐ No☐
Race	Yes ☐ No☐	Disability	Yes ☐ No☐	Religion/Belief (non)	Yes ☐ No☐
Gender	Yes ☐ No☐	Pregnancy/Maternity	Yes ☐ No☐	Marriage/ Civil Partnership	Yes ☐ No☐
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 ☐ No☐
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 ☐ No☐ NA ☐
Are the services outlined in the policy fully accessible[6]?					Yes ☐ No☐ NA ☐
Does the policy encourage individualised and person-centred care?					Yes ☐ No☐ NA ☐
Could there be an adverse impact on an individual's independence or autonomy[7]?					Yes ☐ No☐ NA ☐
EXTERNAL FACTORS					
Is the policy a result of national legislation which cannot be modified in any way?					Yes ☐ No☐
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 ☐	Trade Unions ☐	Protected Groups (including Trust Equality Groups)		☐	
Staff ☐	General Public ☐	Other, please state…		☐	
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 ☐ No☐
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 pfd.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 in 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.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our Data Protection site on the public internet.