Document Type:	Standard Operating Procedure	
Reference Number : **2663**	Version Number: **1**	Next Review Date: **18 December 2023**
Title:	**Safe and Secure Handling of Covid-19 Vaccine.**	
Document Author:	Governance Pharmacist & Medication Safety Officer	
Applicability:	All NHS staff responsible for planning and managing the COVID-19 vaccination programme in 2020/21, and all NHS Pharmacy staff engaged in supporting and delivering the COVID-19 vaccination programme in 2020/21.	

Contents

1. Introduction 1
2. Purpose 1
3. Definitions 2
4. Duties 3
5. Main Body of Policy 3
6. References and Associated Documentation 6

1. Introduction

The COVID-19 vaccination programme is of the highest priority for the NHS. In order to deliver this programme both safely and effectively, good practice in the handling and management of vaccine is paramount. It is anticipated that a number of COVID-19 vaccines will be introduced during 2020 and 2021, so good governance is essential. Clarity of both the overarching principles and the detailed 'standard operating procedures' are required to enable safe, effective implementation and delivery of the vaccination programme. This document is to be read alongside the Pharmacy Institutional Readiness documents (Guidance for Chief Pharmacists – see references) which focus on the management of each of the individual COVID-19 vaccines, and the aligned Standard Operating Procedures developed for all vaccines and all environments in which the vaccines are handled.

2. Purpose

The document is intended to provide the overarching principles for robust governance of the safe and secure handling and management of COVID-19 vaccines in the end-to-end supply chain for the vaccination programme.

Objectives

- To ensure that all staff involved in the delivery of the vaccination programme are aware of, and adhere to, the correct procedures for the ordering, receipt, storage, supply and administration of the product.
- To ensure that the physical and biochemical integrity and sterility of all vaccines and related medicines are maintained.
- To ensure that all staff involved in the delivery of the vaccination programme are aware of the relevant characteristics of COVID-19 vaccines and the implications this has for vaccine efficacy and patient safety.
- To provide assurance that vaccine safety, sterility and efficacy is protected.
- To define key roles and responsibilities needed to deliver this assurance.
- To ensure that all staff understand their critical roles and responsibilities in delivering these objectives.

3. Definitions

COVID-19 Vaccines

There are a number of COVID-19 vaccines under development and it is anticipated that a range will be utilised in the vaccination programme. None will be authorised at the start of the programme so initially they will come into use under Regulation 174 of the Human Regulations 2012. This regulation enables the Medicines and Healthcare products Regulatory Agency (MHRA) to authorise use of a product on a temporary basis in response to the spread of pathogenic agents.

The characteristics of the different vaccines may vary considerably and will increase in clarity over time. Prior to licensing, the product characteristics are available in the relevant ‘Healthcare Professional Factsheet’ and patient information in the ‘Consumer Factsheet’ (see references). Following award of the Marketing Authorisation this information is available in the Summary of Product Characteristics and Patient Information leaflet respectively.

The first vaccine available requires transport and storage under Ultra-Low Temperature (ULT) conditions (-70 +/- 10 C). This may not be the case for those that follow, but maintaining the cold chain will be critical for all. Use of vaccines that have deviated from recommended storage or transportation conditions risks compromising vaccine efficacy and patient safety. Vaccines that have not been transported or stored correctly may be ineffective or harmful; they would therefore no longer be within the terms of their product authorisation and must not be used. Means of detecting when a temperature excursion has occurred are required. The focus on avoidance of waste should also be of high priority.

Further information concerning COVID-19 vaccines is available in the Public Health England publication ‘COVID-19 vaccination programme Information for healthcare practitioners’: https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners

Legal framework and practice standards.

All activity is to be undertaken in accordance with the Human Medicines Regulations 2012 and Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020.

All activity is also to be aligned with relevant COVID-19 Vaccination Programme NHS policy documents marked as Classification: Official and annotated with a publication approval reference number.

In addition, adherence to national standards of good practice is required including those set by the Care Quality Commission, the National Institute for Health and Care Excellence, Public Health England and the Royal Pharmaceutical Society of Great Britain, as detailed in the references below.

4. Duties

Accountability and responsibility for vaccines, associated medicines and their supply chain

- The Clinical Director - Pharmacy is professionally accountable for the safe and secure handling and management of medicines on all vaccination sites operating within or under the jurisdiction of Torbay and South Devon NHS Foundation Trust. This includes oversight of those elements of practice within vaccination centres and other designated vaccination sites that may impact upon product integrity, from receipt of product to vaccine administration.
- The Specialist Pharmacy Services Regional Quality Assurance Specialists will work with the Clinical Director - Pharmacy to provide specialist pharmaceutical expertise in the development of systems and processes of work to ensure the safe and secure handling of the vaccine.
- The Medicine Governance Committee is to document the above named individuals.
- The Clinical Director - Pharmacy may delegate operational responsibility for oversight of ordering, receipt, storage and safe handling of vaccines and medicines, to a named and suitably trained pharmacy team member on each vaccination site.

5. Main Body of Policy

Handling and management of vaccine and medicines in vaccination sites

The Clinical Director – Pharmacy must ensure that all activities are carried out in accordance with:

- This policy document
- The relevant nationally authored ‘Institutional Readiness’ documents and Standard Operating Procedures (SOPs). See references.
- Relevant local organisational medicines policies
- Standard good practice guidance including aseptic technique
- Relevant Health and Safety guidance
- National Standards including those detailed in the references

Local amendments to this policy

Any amendments to this policy or relevant SOPs must be ratified by the Trust Medicines Governance Committee.

Staff authorisation to be supplied with and administer COVID-19 Vaccines

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 COVID-19 vaccine are those defined as eligible to do so.

Safety and security of vaccines and related medicines

The Clinical Director - Pharmacy must ensure that safe and secure handling and storage of vaccine and medicines are in place in accordance with principles and guidance encompassed in 'Professional guidance on the safe and secure handling of medicines (Royal Pharmaceutical Society of Great Britain)': https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines.

Storage and transportation of vaccines

The 'cold chain' is a term used to describe the cold temperature conditions in which certain products need to be kept during storage and distribution. Maintaining the cold chain ensures that vaccines are transported and stored according to the manufacturer's recommended temperature range until the point of administration. Vaccines must be stored at the correct temperature and transported only in approved and validated packaging, and the temperature of the vaccine carrier and contents monitored and reviewed before use.

The Clinical Director - Pharmacy must ensure that storage and transportation are undertaken in accordance with the relevant SOPs, that cold chain temperatures are monitored correctly and that any 'out of specification' recordings are addressed promptly and appropriately, and that a full audit trail is maintained. Further details are included in the relevant SOPs and in manufacturers' information (see references for relevant SOPs).

Workforce and training

All staff undertaking duties at the vaccination site must meet the necessary training standards and competencies in line with the SOPs and standard trust processes (see references and ICON). A training needs assessment is required for the roles within the vaccination services, with corresponding training materials and assessment process, to enable timely and focussed workforce development.

As detailed in 'Professional guidance on the safe and secure handling of medicines (Royal Pharmaceutical Society of Great Britain)' (see appendix 1) 'the named individual ensures that accountable individuals are competent and supported in their role as it relates to the safe and secure handling of medicines'.

The roles assigned to support the rollout of COVID-19 vaccination need to be in accordance with legislation including that detailed in the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020.

Precautions

Anaphylaxis kits including injections of intramuscular adrenaline 1:1,000 must be in date and readily available at all locations undertaking vaccination.

Any needlestick or other injuries must be addressed in accordance with the policies of Torbay and South Devon NHS Foundation Trust.

Maintenance of records

All records must be maintained in accordance with relevant SOPs (see references). These include the ordering, receipt and issue of vaccines, tracking of product, plus patient focused records including consent and administration.

Any serious adverse reactions are to be escalated for immediate senior clinical input; such situations are to be fully documented following the event and a record kept of relevant product batch numbers. A record of all serious adverse events is to be provided to the Clinical Director - Pharmacy. All incidents must be reported on the Trust incident reporting system and the MHRA Coronavirus Yellow Card reporting site https://coronavirus-yellowcard.mhra.gov.uk/.

Data Protection

All staff have a responsibility to ensure that they do not disclose information about the service, service users, staff members and corporate documentation to unauthorised individuals.

Disposal of vaccines and other waste

Disposal of waste vaccines and any sharps must be undertaken in a safe and secure manner in accordance with relevant SOPs (see references).

Where packaging includes dry ice this must also be disposed of in a safe and secure manner using appropriate personal protective equipment.

Organisational COVID-19 Policy

All NHS Trusts are required to have an operational plan to respond to an outbreak of COVID-19, approved by their Boards. This policy must be adhered to for infection prevention and control measures during the pandemic.

Business Continuity Planning

The responsible Chief Pharmacist will be responsible for establishing an agreed business continuity plan in relation to safe and secure handling of vaccines, and tested in line with the organisational emergency preparedness processes and NHS Core Standards for Emergency Preparedness, Resilience and Response (https://www.england.nhs.uk/ourwork/eprr/gf/). The business continuity plan should detail how the service will respond, recover and manage its services during disruption relating to people, information, security, premises including utilities, facilities particularly ULT and refrigerator failure, supplier, IT and data.

6. References and Associated Documentation

Based on the document prepared by team of the NHSE/I Chief Pharmaceutical Officer; 2.12.20

National Standards

CQC Regulation 12: Safe Care and Treatment
https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment

‘The intention of this regulation is to prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm. Providers must assess the risks to people's health and safety during any care or treatment and make sure that staffs have the qualifications, competence, skills and experience to keep people safe.

- Providers must make sure that the premises and any equipment used is safe and where applicable, available in sufficient quantities. Medicines must be supplied in sufficient quantities, managed safely and administered appropriately to make sure people are safe.
- Providers must prevent and control the spread of infection. Where the responsibility for care and treatment is shared, care planning must be timely to maintain people's health, safety and welfare.

The CQC understands that there may be inherent risks in carrying out care and treatment, and we will not consider it to be unsafe if providers can demonstrate that they have taken all reasonable steps to ensure the health and safety of people using their services and to manage risks that may arise during care and treatment'

NICE Clinical Guideline QS61: Infection Prevention and Control
https://www.nice.org.uk/guidance/qs61
This quality standard covers preventing and controlling infection in adults, young people and children receiving healthcare in primary, community and secondary care settings.

The Green Book - Immunisation against infectious disease (Public Health England)
https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book#the-green-book

The latest information on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK. The COVID-19 vaccine chapter is available on:
https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a

Professional guidance on the safe and secure handling of medicines (Royal Pharmaceutical Society of Great Britain)
Adhere to the documented governance principles and relevant guidance.
Available on https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines

COVID – 19 Associated Documentation

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
https://icon.torbayandsouthdevon.nhs.uk/corp_doc_mgmt/Clinical Effectiveness/G2661.pdf

Pharmacy Institutional Readiness documents (Guidance for Chief Pharmacists).
https://www.sps.nhs.uk/wp-content/uploads/2020/12/V1-Pharmacy-Institutional-Readiness-for-Pfizer-BioNTech-BNT162b2-Vacci....docx

Healthcare Professional Factsheet
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/943417/Information_for_healthcare_professionals.pdf

Consumer Factsheet
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/943249/Information_for_UK_recipients.pdf

Trust SOPs

2673 - Ordering Pfizer-BioNTech COVID-19 Vaccine from Public Health England (PHE) Receipt of frozen Pfizer-BioNTech Covid-19 Vaccines

2663 - Unpacking of frozen Pfizer-BioNTech Covid-19 Vaccines and transfer to fridges to thaw

2668 - Storage and transportation of thawing / defrosted Pfizer-BioNtech Covid-19 vaccines

2664 - Preparation of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)Syringes for Administration

2669 - Administration of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)

2666 - Disposal of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) AND Other Waste

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:	The document is intended to provide the overarching principles for robust governance of the safe and secure handling and management of COVID-19 vaccines in the end-to-end supply chain for the vaccination programme.		
Date of issue:	18 December 2020	**Next review date:**	18 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:	2673 - Ordering Pfizer-BioNTech COVID-19 Vaccine from Public Health England (PHE) Receipt of frozen Pfizer-BioNTech Covid-19 Vaccines 2663 - Unpacking of frozen Pfizer-BioNTech Covid-19 Vaccines and transfer to fridges to thaw 2668 - Storage and transportation of thawing / defrosted Pfizer-BioNtech Covid-19 vaccines 2664 - Preparation of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)Syringes for Administration		

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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

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☐
Race	Yes ☐ No☐	Disability	Yes ☐ No☐
Gender	Yes ☐ No☐	Pregnancy/Maternity	Yes ☐ No☐
Sexual Orientation	Yes ☐ No☐		
Religion/Belief (non)	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.