Trust Policy

University Hospitals Plymouth NHS Trust

COVID-19 Vaccine Handling and Management Policy 2020-21

Issue Date	Review Date	Version
November 2020	November 2022	1.0

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.

Who should read this document?

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.

Key Messages

Objectives

- To ensure that all staff involved in 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 is maintained.
- To ensure that all staff involved in 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.

Core accountabilities	
Owner	Alex Bosley – Interim Deputy Chief Pharmacist
Review	Sally Mayell – Chief Pharmacist
Ratification	Phil Hughes, Medical Director
Dissemination (Raising Awareness)	Sally Mayell – Chief Pharmacist Susan Wilkins – Associate Chief Nurse
Compliance	Medicines Governance Committee

Links to other policies and procedures

Version History

1.0	New Document	Adopted National Policy

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Contents

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) 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 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 is maintained.
- To ensure that all staff involved in 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.
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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'. Following award of the Marketing Authorisation this information is available in the Summary of Product Characteristics and Patient Information leaflet respectively. The first requires transport and

storage under ultra low temperature (ULT) conditions (-70 +/- 10 C). This may not be the case for those that follow, but 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. 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', available on 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 appendix 1 below.

Risk assessment has been undertaken and consideration of the benefit versus the risks mitigated and aligned with the National COVID -19 Pandemic programme.

4 Duties

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

- The Chief Pharmacist is professionally accountable for the safe and secure handling and management of medicines on all vaccination sites operating within or under the jurisdiction of their employing legal entity. This includes oversight of those elements of practice within mass 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 Trust Chief Pharmacist 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 Medicines Governance Committee is to document the above named individuals.

- The Chief Pharmacist may delegate operational responsibility for oversight of ordering, receipt, storage and safe handling of vaccines and medicines, to a named and suitably trained yet to be identified, trained and approved by CP.

5 Main Body of Policy

Handling and management of vaccine and medicines in vaccination sites

The responsible Pharmacist must ensure that all activities are carried out in accordance with:

- This policy document
- The relevant nationally authored 'Institutional Readiness' documents and Standard Operating Procedure (SOP)
- Relevant local organisational medicines policies
- Standard good practice guidance including aseptic technique
- Relevant Health and Safety guidance
- National Standards including those detailed in appendix 1

Local amendments to this policy

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

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

The Chief Pharmacist 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 Chief Pharmacist must ensure that 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)', 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.

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.

The responsible Pharmacist 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.

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. 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 needle stick or other injuries must be addressed in accordance with local policy.

Maintenance of records

All records must be maintained in accordance with relevant SOPs. 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 responsible Pharmacist.

Data Protection

All staff has 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.

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 Overall Responsibility for the Document

Overall responsibility for the document rests with the Chief Pharmacist

7 Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of two years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Medicines Governance Committee and ratified by the Medical Director.

Non-significant amendments to this document may be made, under delegated authority from the Medical Director, by the nominated owner. These must be ratified by the Medical Director.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades that are directly affected by the proposed changes.

8 Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document owner will be responsible for agreeing the training requirements associated with the newly ratified document with the named Medical Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

9 Monitoring Compliance and Effectiveness

The Medicines Governance Committee has the responsibility for reviewing, analysing and proposing changes designed to minimise risks from medicines.

Medicines-related incidents reported via the Trust Incident reporting system are monitored by the pharmacy and reviewed by the Medicines Safety Group on a monthly basis. All medicine related incidents rated as either medium risk or higher are reviewed and monitored by the Medicines Governance Committee. The Medicines Governance Committee will monitor implementation of any identified actions.

Individual training is monitored through the HR workforce and training records by the Workforce Development Team.

10 References and Associated Documentation

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

Annex COVID – 19 Associated Documentation

- **Annex A: Patient-Specific Direction for the administration of Pfizer BioNTech COVID-19 mRNA Vaccine BNT 162b2**
- **Annex B: Pfizer BioNTech COVID-19 mRNA Vaccine BNT 162b2 Patient CONSENT FORM**
- **Annex C: Information for Healthcare Professionals on Pfizer BioNTech COVID-19 Vaccination**
- **Annex D: Information for UK recipients on Pfizer BioNTech COVID-19 vaccine**
- **Annex E: MHRA – Prizer BioNtech Covid-19 Vaccine – Managing Allergic Reactions**

Dissemination Plan and Review Checklist | Appendix 1

Dissemination Plan	
Document Title	COVID-19 Vaccine Handling and Management Policy 2020-21
Date Finalised	4th December 2020
Previous Documents	
Action to retrieve old copies	

Dissemination Plan

Recipient(s)	When	How	Responsibility
All Trust staff		Information Governance StaffNet Page	Information Governance Team

Review Checklist		
Title	Is the title clear and unambiguous?	Y
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Y
	Does the style & format comply?	Y
Rationale	Are reasons for development of the document stated?	Y
Development Process	Is the method described in brief?	Y
	Are people involved in the development identified?	Y
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Y
	Is there evidence of consultation with stakeholders and users?	Y
Content	Is the objective of the document clear?	Y
	Is the target population clear and unambiguous?	Y
	Are the intended outcomes described?	Y
	Are the statements clear and unambiguous?	Y
Evidence Base	Is the type of evidence to support the document identified explicitly?	Y
	Are key references cited and in full?	Y
	Are supporting documents referenced?	Y
Approval	Does the document identify which committee/group will review it?	Y
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A
	Does the document identify which Executive Director will ratify it?	Y
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Y
	Does the plan include the necessary training/support to ensure compliance?	Y
Document Control	Does the document identify where it will be held?	Y
	Have archiving arrangements for superseded documents been addressed?	Y
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Y
	Is there a plan to review or audit compliance with the document?	Y
Review Date	Is the review date identified?	Y
	Is the frequency of review identified? If so is it acceptable?	Y
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Y

Equalities and Human Rights Impact Assessment | Appendix 2

Core Information	
Date	COVID-19 Vaccine Handling and Management Policy 2020-21
Title	4th December 2020
What are the aims, objectives & projected outcomes?	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.
Scope of the assessment	
See names and contributors on page one of the policy	
Collecting data	
Race	N/A
Religion	N/A
Disability	N/A
Sex	N/A
Gender Identity	N/A
Sexual Orientation	N/A
Age	N/A
Socio-Economic	N/A
Human Rights	N/A
What are the overall trends/patterns in the above data?	N/A
Specific issues and data gaps that may need to be addressed through consultation or further research	N/A

Involving and consulting stakeholders	
Internal involvement and consultation	The Medicines Governance Committee Medical Director Deputy Medical Director Interim Chief Pharmacist
External involvement and consultation	No external consultation has been undertaken
Impact Assessment	
Overall assessment and analysis of the evidence	

Action Plan

Action	Owner	Risks	Completion Date	Progress update