CONTROLLED DOCUMENT

University Hospitals Birmingham NHS Foundation Trust

COVID-19 Vaccine Handling and Management Operational Policy 2020/21

CATEGORY:	Operational Policy
CLASSIFICATION:	Governance & Clinical
PURPOSE	To implement good governance in the context of the safe and secure handling and management of COVID-19 vaccines
Controlled Document Number:	1278
Version Number:	Version 1.0
Controlled Document Sponsor:	Chief Executive
Controlled Document Lead:	Chief Pharmacist
Will this Controlled Document impact upon any contracts held by the Trust?	No
Approved By:	Medicines Management Advisory Group (MMAG)
On:	8th December 2020
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Distribution: • **Essential Reading for:** • **Information for:**	• All NHS Pharmacy staff engaged in supporting and delivering the COVID-19 vaccination programme in 2020/21 • All NHS staff responsible for planning and managing the COVID-19 vaccination programme in 2020/21

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1. Policy Statement

1.1 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.

1.2 To ensure that the physical and biochemical integrity and sterility of all vaccines and related medicines is maintained.

1.3 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.

1.4 To provide assurance that vaccine safety, sterility, quality and efficacy is protected.

1.5 To define key roles and responsibilities needed to deliver this assurance.

1.6 To ensure that all staff understand their critical roles and responsibilities in delivering these objectives.

2. 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.

3. Scope

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.

This policy document enables corporate and professional governance for use of the COVID-19 vaccines, with the expectation that all areas detailed are addressed locally and that standard NHS medicines governance arrangements are in place.

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.

This policy applies to all areas and activities of the Trust and to all individuals employed by the Trust including contractors, volunteers, students, locum and agency staff and staff employed on honorary contracts.

4. 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 and 174a 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 available vaccine 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 (possibly) 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

5. Legal framework and practice standards

All activity is to be undertaken in accordance with the Human Medicines Regulations 2012 and Human Medicines (Coronavirus) 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 Section 9.

The Chief Pharmacist shall approve all procedural documents associated with this policy, and any amendments to documents, and is responsible for ensuring that such documents are compliant with this policy.

6. Overarching Governance Statement

All governance arrangements have been developed in collaboration between relevant departments and are supported by the Chief Executive, Chair of MMAG and the Chief Pharmacist.

This Policy sets out the governance and assurances put in place to maintain integrity and, therefore, safety, quality and effectiveness of the COVID-19 vaccines.

- Staff seconded to support the UHB COVID-19 vaccination programme will receive appropriate training and competency assessment. All staff will comply with national training made available both for the delivery of the COVID-19 vaccination programme and to ensure health and safety guidelines are adhered to.
- The introduction of the vaccine will undergo due diligence processes including approval from MMAG. All related governance documents such as Patient Group Directions, written instruction and Patient Specific Directions will also be approved by MMAG before implementation.
- Pharmacy will ensure compliance with national guidance and SOPs for the management of COVID-19 vaccines.
- Administration of COVID-19 vaccine will comply with legal mechanisms and have associated documentation and approval in place.
- Clinic set-up has been assessed by Infection Prevention & Control, Health & Safety.

7. Roles and responsibilities under this policy

The Trust will assign responsibility for clinical and operational oversight. Executive Director oversight should be in place and the responsibilities should include the Chief Pharmacist as accountable for the safe and secure handling and management of the COVID-19 vaccine and related medicines.

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

7.1.1 Trust 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 vaccination centres and other designated vaccination sites that may impact upon product integrity, from receipt of product to vaccine administration.

7.1.2 The Specialist Pharmacy Services Regional Quality Assurance Specialist 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.

7.1.3 MMAG will document the above named individuals.

7.1.4 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 pharmacy team member on each vaccination site.

7.2 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 Section 9.

7.3 Amendments to this policy

Any amendments to this policy or relevant SOPs will be ratified by MMAG.

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

The Chief Pharmacist will 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.

7.5 Safety and security of vaccines and related medicines

The Chief Pharmacist will 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.

7.5 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 Chief Pharmacist will have oversight to 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.

7.6 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 Section 9) '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) Regulations 2020.

7.7 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 the policies of the relevant employing legal entity.

7.8 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. All adverse drug reactions should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) via the COVID-19 Yellow-card interface (https://coronavirus-yellowcard.mhra.gov.uk/).

7.9 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.

7.10 Disposal of vaccines and other waste

Disposal of waste vaccines and any sharps will be undertaken in a safe and secure manner in accordance with relevant Trust Waste procedures.

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

7.11 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 will 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.

8. Implementation and Monitoring

8.1 Implementation

8.1.1 This policy will be available on the Trust's Intranet Site. The policy will also be disseminated through the management structure within the Trust;

8.1.2 All NHS Pharmacy staff engaged in supporting and delivering the COVID-19 vaccination programme in 2020/21. All NHS staff responsible for planning and managing the COVID-19 vaccination programme in 2020/21.

8.2 Monitoring

Appendix A provides full details on how the policy will be monitored by the Trust.

9. Associated Policy and Procedural Documentation

9.1 Links to relevant National Standards

9.1.1 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.

- The Trust 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.

- The Trust 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'

9.1.2 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.

9.1.3 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

9.1.4 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

Appendix A Monitoring Matrix

MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
Compliance with this policy	Chief Pharmacist	Chief Executive	Review of processes as the landscape of Covid-19 changes will be carried out.	Annually