University Hospitals of Leicester NHS
NHS Trust

Policy for COVID-19 Vaccination

Approved By:	UHL COVID-19 Tactical Group
Date Approved:	September 2022
Trust Reference:	B43/2021
Version:	3
Supersedes:	version 2, dated 15 Nov 2021
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Latest Review Date:	14 October 2022 – Policy and Guideline Committee
Next Review Date:	October 2025

CONTENTS

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

- Review and update of policy based on experience of vaccination hubs operating.
- Replacement of specific links / embedded documents with direction to where the latest version of these can be found, i.e. to future proof this policy and ensure the latest information in being accessed by staff.
- References added to documents associated with processes related to the use of new vaccines utilised in vaccination clinics.
- Information added about internal transfers of covid vaccinations within the trust and associated documents in pharmacy shared drive.

KEY WORDS

COVID-19, vaccination, vaccine, immunisation

1 INTRODUCTION

The COVID-19 vaccination programme is of a high 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. A number of vaccines are being utilised in the COVID-19 vaccination programme, so good governance is essential.

Several COVID-19 vaccines are in various stages of development. Some have been made using previously used vaccine technology, whilst others have been made using completely new approaches. As with any medicine, vaccines are highly regulated products. A COVID-19 vaccine will only be authorised for use once it has met strict standards of safety, effectiveness and quality through clinical trials and data assessments. The MHRA is the UK's regulator whose role is to ensure medicines, devices and vaccines work effectively and are safe for use. There are checks at every stage in the development and manufacturing process and each COVID-19 vaccine candidate is assessed on a case by case basis.

All COVID-19 vaccines discussed in this document have been authorised for supply in the UK to date. The guidance will be updated as more information about these vaccines becomes available and will include other vaccines as they become available for use. As each vaccine is presented, stored and prepared differently, immunisers must ensure they are familiar with the specific details of the vaccine that they are working with.

The JCVI consider the available epidemiological, microbiological and clinical information on the impact of COVID-19 in the UK and provide the government with advice to support the development of the COVID-19 vaccine strategy. Full details on vaccine eligibility, are included in the Green Book COVID-19 chapter and have therefore not been detailed in this document.
https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a

Authorised COVID-19 vaccines are monitored continuously after roll-out by the MHRA and PHE to ensure that the vaccines perform as expected in routine use and for all population groups. This will help to confirm that the benefit of the vaccines continues to outweigh any risk.

Further information concerning COVID-19 vaccines is available in the Public Health England publication 'COVID-19 vaccination programme Information for healthcare practitioners', available at COVID-19 vaccination: information for healthcare practitioners - GOV.UK (www.gov.uk)

2 POLICY SCOPE

2.1 This policy applies to all staff involved in UHL's COVID-19 vaccination programme.

2.2 The policy 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.

2.3 This policy has the following aims:

2.3.1 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.

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

2.3.3 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.

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

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

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

2.4 Legal framework and practice standards:

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

2.4.2 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.

2.4.3 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

3 DEFINITIONS

3.1 None included in this version.

4 ROLES AND RESPONSIBILITIES

4.1 The executive director responsible for this policy is the **Medical Director**. They are accountable for the clinical care pathways for the provision of the vaccination on all sites operating within or under the jurisdiction of their employing legal entity.

4.2 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 vaccination centres and sites that may impact upon product integrity, from receipt of product to vaccine administration.

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

4.3 **Registered vaccinators (N.B. due to UHL's current operating model, this is limited to those roles permitted within the current Patient Group Direction(s) for the vaccine(s) currently in use)** are responsible for:

4.3.1 Undertaking the training provided to safely reconstitute, draw up and administer the vaccine to patients and staff.

4.3.2 Working under a Patient Specific Direction (PSD) or Patient Group Direction (PGD to safely administer the vaccine

4.4 Non-registered Vaccinators
(**N.B. due to UHL's current operating model, non-registered vaccinators who can work under the national protocol only are not currently able to vaccinate at UHL)**

4.5 **Pharmacy staff** are responsible for:

4.5.1 Ordering of the vaccine via Foundry

4.5.2 Receipt and safe handling of the vaccine maintaining the cold chain storage requirements.

4.5.3 Onward distribution of the vaccine under cold chain storage requirements within the hospital hub (i.e. the same legal entity) from pharmacy department to vaccination location (this includes moving vaccines between sites, to other clinical areas such as wards, and satellite locations as appropriate).

4.6 **Clinical Management Group (CMG) senior management teams** are responsible for:

4.6.1 Ensuring all new and existing staff to whom this is relevant are made aware of this policy.

4.7 Individual Staff are responsible for:

4.7.1 Complying with this policy and the accompanying Standard Operating Procedures as relevant to their role and involvement in UHL's COVID-19 vaccination programme.

4.7.2 Informing relevant managers and clinical leads if there are any implementation or compliance issues with this policy or accompanying Standard Operating Procedures and for participating in any monitoring of compliance as applicable

5 POLICY STATEMENTS

5.1 Ordering of vaccine

UHL has an approved Foundry account to order vaccines together with the necessary syringes and needles for dilution (where required) and administration at the hospital hub. Chief Pharmacist is the named lead individual. The Specialist Pharmacist for Vaccination Hubs and the Deputy Chief Pharmacist Medicines Optimisation are the individuals responsible for ordering and mananging stock. Further information on the use of Foundry may be found on the Future NHS site (login required).

5.2 Medicines Management of vaccines and associated medicines

This section incorporates the following:

- The handling and management of vaccine and associated medicines
- Staff authorisation to be supplied with and administer COVID-19 Vaccines
- Storage and transportation of vaccines and associated medicines
- Safety and security of vaccines and associated medicines

The above will be governed by the documents and National Standards including the following:

- The nationally authored 'Institutional Readiness' documents and Standard Operating Procedures (SOPs) as in the pharmacy shared drive
- Legal mechanisms for administration of the vaccine
- All relevant UHL Medicines Management Policies and Pharmacy SOPs
- Standard good practice guidance including aseptic technique
- Relevant Health and Safety guidance

5.3 Storage and transportation of vaccines

5.3.1 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.

5.3.2 The supervising Pharmacist must ensure that storage and transportation are undertaken in accordance with the relevant SOPs listed in the pharmacy shared drive, that cold chain temperatures are monitored correctly and that any 'out of range' 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.

5.3.3 Transfer of vaccines within an NHS Trust is permitted and instances where one hospital supplies another hospital within its own NHS Trust can continue as with any other medicine, within the terms of the technical SOPs. Internal transfers of vaccine at UHL are sent on the TNT run or with the pathology drivers that also go between sites. By exception, other arrangements may be made for urgent transfers, but this should not be routinely necessary. Guidance for this process and a checklist has been produced and is available on the shared pharmacy drive to ensure cold chain management and a full audit trail.

5.3.4 During use in the vaccination hubs, vials of vaccine should be used as promptly as is practicable and wherever possible part-used vials should not be left unattended. However, it is recognised that this is not always possible due to the need for staff breaks, the flow of patients and appointment fill rate, and other unforeseen circumstances. Safe storage of the vaccine in such situations should be discussed by the lead nurse and pharmacist working in the hub at that time. Further advice on considerations, including based on which vaccine product is being used, are included in the SOP 'Pharmacy processes for working in the uhl vaccination hubs'

5.4 Legal mechanisms to supply the vaccine

The legal mechanisms for supply of the COVID vaccine will vary throughout the vaccination programme. They are as follows:

5.4.1 Written Instruction Administration of influenza or COVID-19 vaccine by an organisation to employees, including peer-to-peer vaccination, is provision of an occupational health service (OHS). Medicines can be supplied or administered in the course of an OHS by a registered nurse acting in accordance with the written and signed instruction of a doctor. **N.B. This mechanism is not currently used for COVID-19 vaccination at UHL.**

5.4.2 Patient Specific Direction (PSD) is an instruction from a prescriber i.e. a doctor, dentist, or independent non-medical prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis

5.4.3 Patient Group Directions (PGDs) are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. They provide a legal framework that allows the supply and/or administration of a specified medicine(s), to a pre-defined group of patients needing

prophylaxis or treatment for a condition described in the PGD, without the need for a prescription or an instruction from a prescriber.

5.4.4 A National Protocol is a new type of instruction that was introduced to support the expanded influenza and COVID-19 Vaccination Campaign. This is a new legal mechanism which has been put in place following amendment of the Human Medicines Regulations 2012 or current medicines regulations. **N.B. This mechanism is not currently used for COVID-19 vaccination at UHL.**

5.5 Workforce and training

5.5.1 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.

5.5.2 As detailed in 'Professional guidance on the safe and secure handling of medicines' (Royal Pharmaceutical Society) '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'.

5.5.3 Vaccinators will be trained in aseptic non-touch technique and vaccine administration and will have read the vaccine specific information (manufacturer information and 'Green Book' chapter) and completed relevant COVID-19 vaccination e-learning.

5.5.4 All vaccinators will be BLS / anaphylaxis trained as per UHL mandatory training requirements. This will include having paediatric BLS trained staff as appropriate for children's clinics and where <18s are vaccinated within JCVI defined cohorts.

5.5.5 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.

5.6 Precautions

5.6.1 Information about anaphylactoid reactions, including in those with previous history of allergy, has evolved as experience with the vaccines has grown. In order to establish the suitability of – and potential choice between – different vaccines in such patients, clinicians should access the latest information available via:

- The latest manufacturer provided information for healthcare professionals (the 'Summary of Product Characteristics' in the case of licensed products); available from either https://emc.medicines.org.uk or https://www.gov.uk/government/collections/covid-19-vaccination-programme
- The COVID-19 chapter of Public Health England's 'Green Book': https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a
- Specialist Pharmacy Services website: https://www.sps.nhs.uk/home/covid-19-vaccines/

Additionally, pharmacy staff working in the vaccination hubs or UHL's Medicines Information service (contactable on extension 1649) can provide further advice.

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

5.6.4 In the event of any life-threatening clinical adverse event (i.e. anaphylaxis, respiratory arrest, cardiac arrest) the resuscitation team should be called as soon as possible.

5.6.5 Any needlestick or other injuries must be addressed in accordance with the UHL Contamination policy.

5.6.6 Suspected adverse reactions to any COVID-19 vaccine should be reported using the MHRA's Yellow Card reporting system.

5.6.7 Any incidents whether they result in harm to patients or not relating to covid vaccination or occurring in the covid vaccination hubs should be reported via the trusts electronic incident reporting system 'DatixWeb'.

5.7 Maintenance of records

5.7.1 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.

5.7.2 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.

5.8 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.

5.9 Disposal of vaccines and other waste

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

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

5.10 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.

5.11 Business Continuity Planning

The Chief Pharmacist will be responsible for business continuity plans in relation to safe and secure handling of vaccines. Existing controls include:

- Use of essential power for refrigerators storing vaccine
- Temperature monitoring
- Other usual pharmacy contingency arrangements

5.12 Patient Consent

5.12.1 Consent for administration of the vaccine is taken verbally by the vaccinator. This includes from the parent / carer where vaccines are being administered to children. The vaccinator must explain the benefits, risks and side-effects of the vaccine so that patients can give informed consent.

5.12.2 For patients who lack capacity, written consent must be taken using the appropriate consent form. A decision must be made in the best interests of the patient and must involve discussion with the patient's relatives, advocates or carers. An independent mental capacity advocate must be involved if the patient has no unpaid carers, friends or relatives to act in their best interests.

5.12.3 Patients must be provided with written information about the vaccine so that they can make an informed decision.

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 It is expected that staff become familiar with the practices expected by reading this policy and would require no additional training.

7. PROCESS FOR MONITORING COMPLIANCE

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements	Lead(s) for acting on recommendations	Change in practice and lessons to be shared
Incidents related to COVID-19 vaccination programme	Medication safety Pharmacist	Datix incident reporting system	Monthly Incident report (plus immediate ad hoc escalation as warranted)	Reported to Medicines Optimisation committee	Medicines Optimisation Committee	As appropriate

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

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

Basic Life Support. Resuscitation Council UK. https://www.resus.org.uk/covid-19-resources/statements-covid-19-coronavirus-primary-care-settings/resuscitation-council-uk

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

The updated version of the Policy will be reviewed every 1 year initially, uploaded and available through INSite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system

Appendix 1: List of Standard Operating Procedures and other supporting documents for safe medicines management of Covid-19 vaccines

This list has been removed in this version of the policy.

UHL specific Standard Operating Procedures and other supporting documents are available in the 'COVID-19 Vaccination Hubs' folder of the pharmacydata shared network drive and/or hosted on the Pharmacy Standard Operating Procedures pages of INSite. Review and version control of these documents will be overseen by the Deputy Chief Pharmacist with responsibility for COVID-19 vaccinations, and staff should ensure they are accessing the latest information for the correct vaccine product.

National documents, most notably the Patient Group Directions for administration of COVID-19 vaccines should be accessed from COVID-19 vaccination programme - GOV.UK (www.gov.uk) . Again, staff should take care to ensure that they are accessing the latest version of these documents and for the correct vaccine product.