Leicestershire Partnership NHS Trust

COVID-19 Vaccination Policy

This policy describes the overarching principals for the management of COVID vaccines within Leicestershire Partnership NHS Trust or at vaccination centres listed as temporary responsibility of Leicestershire Partnership NHS Trust

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Type of Policy	Clinical √	Non-clinical √
Which Relevant CQC Fundamental Standards?		

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Version Control and Summary of Changes

Version number	Date	Comments (description change and amendments)
Version 1	21st December 2020	Produced from amalgamation of UHL's Policy for COVID Vaccination and model policy contained in the urgent correspondence from Dr Keith Ridge (publication approval reference 001559 – dated 4th December 2020). National SOPs adapted and adopted for use within LPT.
Version 1.2	12th January 2021	Uploaded updated PGD (v2), amendment to
Version 1.3	20th January 2021	Changes to document following regional quality assurance review: 1. Addition to Version Control on each national SOP 2. Addition of 5.8.3 – reporting quality concerns with the vaccines
Version 1.4	02/03/2021	Addition of SOP AVH7 - Transporting Astra Zeneca COVID-19 Vaccine for Inpatient Vaccination. Addition of 5.6 (Mutual aid and other forms of distribution) Changed 'pharmacist' to 'staff' in appendix 3 and 4.
Version 1.5	23/03/2021	Version 2 of the Astra Zeneca PGD and version 3 of the Pfizer PGD incorporated.
Version 1.6	21/04/2021	Reorganisation of section 5.8. Addition of supporting document for Moderna vaccine in appendix 1. Minor changes to Astra Zeneca SOPs to bring them all in line. New version of AZ workstation logs embedded Version 3 of the Astra Zeneca PGD incorporated
Version 1.7	31/05/2021	Version 4 of the Astra Zeneca PGD incorporated Astra Zeneca national protocol updated to version 3 Inserted Moderna National Protocol (Version 1) Vaccine Tally updated to include tabs for Moderna and Pfizer
Version 1.8	21/06/2021	Addition of Pfizer SOP VH2(a) – Receipt of Thawed Pfizer-BioNTec Covid-19 vaccines
Version 1.9	07/07/2021	Pfizer SOP VH4 updated (now V 2.0). Pfizer SOP PVH7 (V 1.0) inserted.
Version 2.0	10/08/2021	Version 4 of the Pfizer PGD incorporated
Version 2.1	17/08/2021	Version 4 of the Pfizer national protocol incorporated. Expiration date extended

3.0	12/09/2021	SPC for Comirnaty (Pfizer) and Spikevax (formally Moderna) incorporated. Comirnaty National Protocol V1.0 and PGD V2.0 incorporated. Pfizer BioNTech PGD updated to V5.0. ALL Pfizer SOPs updated to include Comirnaty, associated changes due to this product and other updates. Moderna SOPs' review dates and issue dates changed. Minor change to SOP MDH4. Rest of Moderna SOPs changed to extend review date in line with rest of policy. All Astra Zeneca SOPs changed to extend review date in line with rest of policy. Insertion of Management of Pfizer / Comirnaty for School Aged Immunisation Programme.
3.1	22/11/2021	SOP PVH7 updated based on latest SPS version. SOP now covers movement of Comirnaty to other designated sites.
3.2	30/11/2021	Addition of MVH7 (Transporting Moderna (Spikevax)) and MDH-4b (Preparation of the Moderna (Spikevax) booster dose) Added updated Comirnaty PGD (v3.0) and Spikevax (Moderna) PGD (v2.0)
3.3	15/12/2021	Added updated Comirnaty PGD (v4.0) and National Protocol (v4.0) Added updated Spikevax (Moderna) PGD (v3.0) and National Protocol (v3.0)
3.4	22/12/2021	Added updated Comirnaty PGD (v5.0) and National Protocol (v5.0) Added updated Spikevax (Moderna) PGD (v4.0) and National Protocol (v4.0) Added updated Astra Zeneca PGD (v5.0) and National Protocol (v5.0)
3.5	14/01/2022	Added updated Comirnaty PGD (v6.0) and National Protocol (v6.0)
3.6	04/02/2022	Updated page numbers in Content section. Added section 5.15 – Managing Multiple Vaccines Inserted supporting documents (CVH1, CVH2, CVH2.1 and CVH2.2) for Comirnaty for children (5-11 years) into its own table. Inserted Comirnaty (for children) PGD (v1.0) and national protocol (v1.0) Added updated Spikevax (Moderna) PGD (v5.0) and National Protocol (v5.0)
3.7	25/02/2022	Added updated Astra Zeneca PGD (v6.0) and National Protocol (v6.0). Updated number in Contents page.
4.0	05/04/2022	Incorporating latest versions of all the SPS SOPs, PGDs and national protocol. Some updates to the main body of the policy in line with changes to practice.

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Equality Statement
Leicestershire Partnership NHS Trust (LPT) aims to design and implement policy documents that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.
It takes into account the provisions of the Equality Act 2010 and promotes equal opportunities for all.

This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity.

In carrying out its functions, LPT must have due regard to the different needs of different protected equality groups in their area.

This applies to all the activities for which LPT is responsible, including policy development and review.

Due Regard

LPT must have **due regard** to the aims of eliminating discrimination and promoting equality when policies are being developed (**see section 2 of the template for further information)**

1 INTRODUCTION

1.1 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 as named in appendix 1.

1.2 There are a few COVID-19 vaccines available and further development may also be taking place. Some of these vaccines may 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.

1.3 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 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.

1.4 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

2 POLICY SCOPE

2.1 This policy applies to all staff involved in LPT'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 of Great Britain, as detailed in the appendix 1 below.

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

4.3 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.

4.4 **Director of Nursing, AHPs and Quality** is responsible for ensuring there is a robust training and competency assessment arrangement in place for staff, in accordance with this Policy and the accompanying standard operating procedures.

4.5 **Non-registered Vaccine Administrators** are responsible for undertaking the training provided to safely administer the vaccine to patients and staff under the supervision of a doctor, nurse or pharmacist.

4.6 **Pharmacy / site staff** are responsible for:

4.6.1 Ordering of the vaccine through appropriate platform.
4.6.2 Receipt and safe and secure handling of the vaccines
4.6.3 Maintaining the cold chain storage requirements
4.6.4 Onward distribution of the vaccine under cold chain storage requirements between vaccination sites (or roving team) within the same legal entity

4.7 **The directorate senior management teams** are responsible for:
4.7.1 Ensuring all new and existing staff to whom this is relevant are made aware of this policy.

4.7.2 Ensuring that all staff have undertaken the training and assessed as competent.

4.8 **Individual Staff are responsible for:**

4.8.1 Complying with this policy and the accompanying standard operating procedures as relevant to their role and involvement in LPT's COVID-19 vaccination programme.

4.8.2 Working under a Patient Specific Direction (PSD) / Written Instruction OR Patient Group Direction (PGD) OR national protocol to safely administer the vaccine.

4.8.3 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

LPT has (or with sufficient notice can extend) access to the appropriate ordering platform (e.g. ImmForm / Foundry) to order vaccines for administration at the hospital hub or vaccination centre. Chief Pharmacist is the lead individual, but may delegate this responsibility.

Anaphylaxis kits and other related medicines may be provided with the vaccine. If this is not the case or further supply is needed, it can be ordered from Leicestershire Partnership NHS Trust pharmacy department by emailing lpt.pharmacyorders@nhs.net stating location, name of medicine, quantity, professional registration number and best contact number.

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 as listed in appendix 1
- Legal mechanisms for administration of the vaccine
- All relevant LPT 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 responsible pharmacist / staff must ensure that storage and transportation are undertaken in accordance with the relevant standard operating procedures listed in appendix 1, 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 standard operating procedures and in manufacturers' information.

5.4 Security of Vaccines, Associated Medicines and Keys

5.4.1 COVID vaccine, accompanying diluent solution and emergency medicines are POMs, therefore, they need to be stored securely.

5.4.2 The refrigerators will be lockable and stored inside a designated locked room. If access is via keypad combination, this must be changed immediately upon first use of the non-NHS premises and only disclosed to authorised people. During regular use and staff presence, it is permissiable to keep the refrigerator door unlocked as long as the room door is locked by the last person leaving. The suitably secure medicines cabinet should be fixed to the wall or floor, located in the same room and kept locked. The key will be kept in the key cabinet. A reasonable quantity of diluent can be taken out of the medicines cabinet and placed on a stable surface to negate the need to keep opening and closing the medicines cabinet or leaving it unlocked.

5.4.3 Keys to the room door and key cabinet will be kept by the responsible pharmacist / authorised staff but can be delegated to another suitable member of staff.

5.4.4 The key cabinet is the central place that holds all the keys to receptacles storing medicines. This needs to be located in a secure place and kept locked at all times. When the hub is not being used for vaccinations, the

refrigerators, medicines cabinet and key cabinet must all be locked. Keys to the key cabinet and room must be kept in a safe location.

5.4.5 Keys should not be taken home.

5.4.6 COVID vaccines and diluent will be issued to manned work stations during vaccination sessions. Emergency medicines will also be provided to some work stations. Each individual is responsible for the security of the medicines on their work station. If they leave the work station for any period (up to 5-10 minutes), they must ensure the responsible pharmacist, staff or adjoining person with a natural and unobstructed view to the work station is notified so that the stock can be supervised in their absence. They must also store it discretely such that it is not visible to passersby.

5.5 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:

5.5.1 Whilst a Written Instruction could be used, NHS and Social Care Staff will be included as a patient cohort so can be vaccinated under a PGD or National Protocol. A written instruction wouldn't be required for receiving the COVID vaccine.

5.5.2 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.

5.5.3 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.

5.5.4 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 Medicines Regulations.

5.6 Mutual aid and other forms of distribution

5.6.1 In certain circumstances, vaccines can be distributed from an LPT operated location (e.g. vaccination centre) to other LPT sites. Distribution to PCNs can occur via a mutual aid arrangement (please refer to the Midlands Policy on Mutual Aid for more details).

5.6.2 Regardless of the recipient, the following principals must be adhered to when distributing:

1. Request for vaccines must be made at least 24 hours in advance to the donor (person / location supplying the vaccine), ideally in writing (such as email or completion of a mutual aid document). The request needs to detail quantity required, name of individual collecting (if known), name of organisation and rough date and time of collection.

2. The person distributing the vaccines must check that the person collecting is legitimate and has valid identification.

3. Consumables (syringes, appointment cards and patient information) need to be offered too.

4. Only provide the vaccines once you are satisfied with the cool bag arrangement - make a record of the the temperature at the point vaccines are given.

5.7 Workforce and training

5.7.1 All staff undertaking duties at the vaccination site must meet the necessary training standards and competencies in line with the standard operating procedures and processes (see appendix 1). 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.

5.7.2 As detailed in ‘Professional guidance on the safe and secure handling of medicines’ (Royal Pharmaceutical Society of Great Britain) ‘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’.

5.7.3 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 the COVID-19 vaccination training package.

5.7.4 All vaccinators will be BLS / anaphylaxis trained as per LPT mandatory training requirements.

5.7.5 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.

5.8 Precautions

5.8.1 The MHRA issued an advisory note on 9 Dec 2020 regarding the Pfizer vaccine as follows:

5.8.1.1Background

There have been two cases of anaphylactoid reactions in individuals with a strong past history of allergic reactions both of whom carried an adrenaline auto injector. These individuals developed symptoms of anaphylactoid reaction shortly after receiving the vaccine. Both recovered after appropriate treatment. We are seeking further information and will issue further advice following investigation.

Please report any suspected adverse reactions via the Yellow Card scheme. To make a report or find out more about the Yellow Card COVID-19 reporting site please visit: Coronavirus Yellow Card reporting site.

5.8.1.2All patients should be advised that they need to be observed for 15 minutes post-vaccination.

5.8.1.3Anaphylaxis kits including injections of intramuscular adrenaline 1:1,000 must be in date and readily available at all locations undertaking vaccination.

5.8.1.4In the event of any life-threatening clinical adverse event (i.e. anaphylaxis, respiratory arrest, cardiac arrest) the ambulance should be called as soon as possible.

5.8.2 Latest advice can be found in chapter 14a of the green book;

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948757/Greenbook_chapter_14a_v4.pdf

5.8.3 Any needle stick or other injuries must be addressed in accordance with the relevant LPT policy.

5.8.4 Report all adverse drug reactions thought to be due to Covid vaccine to the MHRA via their on line yellow card reporting system: https://coronavirus-yellowcard.mhra.gov.uk/

5.9 Maintenance of records

5.9.1 All records must be maintained in accordance with relevant standard operating procedures. These include the ordering, receipt and issue of vaccines, tracking of product, plus patient focused records including consent and administration.

5.9.2 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.

5.9.3 Any quality concerns with vaccines (e.g. unusual colour or particles) must be reported to the pharmacist or lead clinician on duty who can report via the yellow card reporting site (see link above in 5.7.1.

5.9.4 Workstation logs must be kept for each workstation. At the end of the day, they must be filed away and can be discarded after one week if no longer needed.

5.10 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.

5.11 Disposal of vaccines and other waste

5.11.1 Disposal of waste vaccines and any sharps must be undertaken in a safe and secure manner in accordance with relevant standard operating procedures.

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

5.12 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.

5.13 Business Continuity Planning

5.13.1 The responsible Chief Pharmacist will be responsible for business continuity plans in relation to safe and secure handling of vaccines and temperature excursions. The precise details will need to be worked through depending on the facilities available in each vaccination centre location, however, below are principals that can be followed.

5.13.2 If there is a malfunction with a refridgerator, quickly check that the power has not been accidently turned off. If there is no obvious and rectifiable reason, immediately place the vaccines in the affected refrigerator into a clear plastic bag, label it as 'quarantined stock – DO NOT USE' and move to another functioning refrigertor. Quickly document the minimum, current and maximum tempertures of the affected refrigerator and log this in the temperature monitoring log for that refrigerator. Notify the accountable pharmacist / staff for advice before supplying the vaccines.

5.13.3 If there is a total power failure, immediately check with the site manager what the arrangements are in the event of power failure. If the power failure is said to be brief (10-15 minutes) or a generator can be utilised within this time, it is sufficient to leave the vaccines in the refrigerator and monitor the (out) temperature every 5 minutes using the portable thermometer without opening the refrigerator door. Record this in the temperature monitoring log. In the event of total power failure that is likely to last more than 15 minutes, and a back up generator is not available, business continuity planning will need to be implemented. The responsible pharmacist / staff will need to act quickly. Whilst the responsible pharmacist / staff are on site, this is likely to be identified quickly due to other lighting or electrical equipment failing or refrigerator alarm sounding.

5.13.4 Upon encountering this situation, the responsible pharmacist / staff on site will need to do the following:

1. Get one orange cool bag (located in the same room as the refrigerators) and collect all the ice packs from the freezer.
2. Bring the orange cool bag back to the room housing the refrigerators. Place 5 ice packs inside as per image below.
3. Place a portable thermometer probe inside the orange cool bag, being careful that it doesn't touch the ice packs, and quickly zip up the lid shut. Wait for the temperature inside the cool bag to reach 5˚C,

4. Quickly remove the COVID vaccines from the refrigerators (in its original box where possible) and place them in the cool bag in the space opposite the ice pack. Zip the cool bag firmly shut and do not open it unless absolutely necessary.
5. Reset the minimum and maximum temperatures of the portable thermometer. Monitor the current, mimimum and maximum temperatures in the cool bag using the portable thermometer (out temperature reading) every 30 minutes and document in Log for business continuity plan (appendix 5).
6. If the temperature reaches 6˚C inside the cool bag, add an additional ice pack away from the probe.
7. Repeat step 6 until the refrigerator is functioning again and its temperature has reached in range (i.e. +2˚C to +8˚C).
8. Place the items in a clear plastic bag with a note saying 'Quarantined stock – DO NOT USE' along with the date and time the vaccine was taken out of the refrigerator and place back in the functioning refrigerator. Notify the accountable pharmacist for advice before supplying the vaccines. They will need to review the log for business continuity plan.

5.14 Patient Consent

5.14.1 Consent for administration of the vaccine is taken verbally by the vaccinator. The vaccinator must explain the benefits, risks and side-effects of the vaccine so that patients can give informed consent.

5.14.2 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.

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

5.15 Managing Multiple Vaccines

5.15.1 Delivering multiple vaccines in the same location has become common practise. In doing so, it must be acknowledged that there is a risk of medication error in a busy immunisation session.

5.15.2 Risks can be minimised through careful planning and operationalisation. Each location must ensure that care and attention is given to mitigate against the risks. Strategies can include segregating vaccines in refrigerators, separating session times/days, partitioning rooms and patient flow. Additional measures such as use of colour receptacles, double checks and restricting access can also help.

5.15.3 Each location must complete the assurance framework.

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 Pertinent elements of this Policy will be included in the LPT training and competency assessment package.

6.2 Staff are required to undertake the LPT training and be competency assessed in order to deliver the COVID vaccination programme.

6.3 Staff are required to familiarise themselves with the relevant standard operating procedures, Patient Group Direction and future published documents.

7 MONITORING COMPLIANCE AND EFFECTIVENESS

Ref	Minimum Requirements	Evidence for Self-assessment	Process for Monitoring	Responsible Individual / Group	Frequency of monitoring
5.2	Full compliance	Completion of daily check list (appendix 3) & in-session	Inspection	Lead professional on site	Daily / once weekly

Ref	Minimum Requirements	Evidence for Self-assessment	Process for Monitoring	Responsible Individual / Group	Frequency of monitoring
		check (appendix 4)			
5.4	Full compliance	Signed PGD / PSD / protocol	Inspection	Lead professional on site	Start of each shift

8 STANDARDS/PERFORMANCE INDICATORS

See appendix 3 and 4.

9 REFERENCE AND BIBLIOGRAPHY

Policy was drafted with reference to the following:

LPT Maintaining Cold Chain of Medicines Policy
UHL COVID-19 Policy V1
COVID-19 Vaccination: Governance, handling and preparation of vaccines in Hospital Hubs and Vaccination Centres; NHS Publication; 4th December 2020; Reference 001559; DoH.

Immunisation Against Infectious Diseases – "The Green Book"; accessed from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/943663/Greenbook_chapter_14a_v3.pdf

The Safe and Secure Handling of Medicines: A Team Approach; accessed from; http://www.rpsgb.org.uk/pdfs/safsechandmeds.pdf

Vaccine Cold Storage; NPSA Rapid Response Report 008; accessed from: http://www.nrls.npsa.nhs.uk/resources/?entryid45=66111

Leicestershire Medicines Code; accessed from: https://www.lmsg.nhs.uk/guidelines/secondary-care/medicines-code/

Reporting and Management of Incidents Policy (2020)

Appendix 1

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

Pfizer-BioNTech (Comirnaty) COVID-19 Vaccine for adults and adolescents 12 years plus

SOP relating to task / responsibility	Detail	Policy link / attachment
Ordering of vaccine	VH1 procedure retired.	Order via UKHSA ImmForm portal
Receipt of goods / booking in	VH2–Receipt of frozen of Pfizer-BioNTech (Comirnaty) COVID-19 Vaccine	VH2-Receipt-of-froze n-Comirnaty-concentı
	VH2(a) –Receipt of Thawed Pfizer-BioNTec (Comirnaty) COVID-19 vaccines	VH2(a) Receipt of Thawed Pfizer Vaccine
Unpacking and transfer to fridge	VH4-Unpacking of frozen Pfizer-BioNTech (Comirnaty) COVID-19 Vaccines and transfer to fridges to thaw COSHH Risk Assessment to be agreed once location of receipt confirmed	VH4-Unpacking-froz en-Comirnaty-concen
	Process flow for moving stock	Process flow - Packing thawed vials
Preparation of the vaccine	VH8-Preparation of Pfizer-BioNTech (Comirnaty) COVID-19 Vaccine Syringes for Administration	VH8-Preparation-of-Pfizer-BioNTech-COV
	VH 8.1-Work instruction for Preparation of Pfizer BioNTech (Comirnaty) COVID-19 Vaccine syringes (starting from Refrigerator)	VH8.1-Preparation-of -0.3mL-syringes-usin
	VH 8.2-Vaccine Supervision Checklist for Pfizer Comirnaty COVID-19 Vaccine	VH8.2 Vaccine Supervision Checklist
	PVH7-Transporting Pfizer-BioNTech (Comirnaty) COVID-19 Vaccine to end user locations	PVH7-Transporting-C omirnaty-concentrate
	Management of Pfizer / Comirnaty for School Aged Immunisation Programme	Management of Pfizer for School Age

SOP relating to task / responsibility	Detail	Policy link / attachment
	Workstation log	Workstation log for Pfizer.xlsx
Technical information for the vaccine [relevant for COVID-19 mRNA Vaccine BNT162b2]	Equivalent to an SPC for temporary authorisation to supply medicine by the MHRA	https://www.medicines.org.uk/emc/product/12740/smpc#gref
LPT Patient Group Direction	Legal framework for the administration of Comirnaty COVID-19 Vaccine under Patient Group Direction	C1618-patient-group-direction-for-comirn
LPT Patient Specific Direction	Legal framework for the administration of Pfizer-BioNTech COVID-19 Vaccine under a Patient Specific Direction	Patient-Specific-Direction-Covid-19-mRNA-
National Protocol	Legal framework for the administration of Comirnaty under a National Protocol	Comirnaty30microgramsProtocolV07.00.d

Pfizer-BioNTech (Comirnaty) COVID-19 Vaccine for children 5-11 years

SOP relating to task / responsibility	Detail	Policy link / attachment
Ordering of vaccine	VH1 procedure retired	Order via NHS Foundry
Receipt of goods / booking in	CVH1 – Receipt of Thawed Comirnaty concentrate for children 5-11 years	CVH1 - Receipt of thawed Comirnaty co
Preparation of the vaccine	CVH2 – Preparation of 0.2ml syringes using Comirnaty concentrate for Children 5-11 years	CVH2-Preparation-of -0.2mL-syringes-usin
	CVH2.1-Preparation-of-0.2mL-syringes-using-Comirnaty-concentrate-for-Children-5-11-years-Work-Instruction	CVH2.1-Preparation-of-0.2mL-syringes-us
	CVH2.2-Vaccine-Supervision-Checklist-for-Comirnaty-concentrate-for-Children-5-11-years	CVH2.2-Vaccine-Supervision-Checklist-for
LPT Patient Group Direction	Legal framework for the administration of Comirnaty 10micrograms/dose COVID-19 Vaccine under Patient Group Direction	C1617-patient-group-direction-for-comirna
National Protocol	Legal framework for the administration of Comirnaty 10micrograms/dose COVID-19 Vaccine under a National Protocol	Comirnaty10PaedCovid-19VaccineProtocc

Astra Zeneca COVID-19 Vaccine

SOP relating to task / responsibility	Detail	Policy link / attachment
Ordering of vaccine	AZH1-Ordering-AstraZeneca-COVID-19-Vaccine-from-Public-Health-England-PHE	AZH1-Ordering-Astra Zeneca-COVID-19-Va
Receipt of goods / booking in	AZH2-Receipt-of-refrigerated-AstraZeneca-Covid-19-Vaccines	AZH2 - Receipt of AstraZeneca COVID -1
Preparation of vaccine	AZH3-Preparation-of-AstraZeneca-COVID-19-Vaccine-Syringes-for-Admin-Issue	AZH3 - Preparation of AstraZeneca COVIL
	AZH3.1-AstraZeneca-Vaccine-Preparation-Work-Instruction	AZH3.1 –AstraZeneca COVID-19 Vaccine Pre
	AZH3.2-AstraZeneca-Vaccine-Supervision-Checklist	AZH3.2 Vaccine Supervision Sessional
	AVH7 – Transporting Astra Zeneca COVID-19 Vaccine for Inpatient Vaccination	AVH7- Transporting AstraZeneca COVID-1
	AstraZeneca Vaccine and Temperature Log	Vaccine and Temperature Log.doc
	Workstation log for 8 dose vial	ASTRA ZENECA Workstation log_8 do
	Workstation log for 10 dose vial	ASTRA ZENECA Workstation log_10 d
Technical information for the vaccine [relevant to Astra Zeneca COVID-19 Vaccine]	Equivalent to an SPC for temporary authorisation to supply medicine by the MHRA	https://www.medicines.org.uk/emc/product/12333
LPT Patient Group Direction	Legal framework for the administration of Astra Zeneca COVID-19 Vaccine	C1622-patient-group -direction-for-astrazel
LPT Patient Specific Direction	Legal framework for the administration of Astra Zeneca COVID-19 Vaccine under a Patient Specific Direction	Patient-Specific-Direction-Covid-19-ChAdO

SOP relating to task / responsibility	Detail	Policy link / attachment
National Protocol	Legal framework for the administration of AstraZeneca COVID-19 Vaccine under a National Protocol	ProtocolCovid-19VaccineAstraZenecaV07.0

Spikevax (Moderna) COVID 19 Vaccine

SOP relating to task / responsibility	Detail	Policy link / attachment
Ordering of vaccine	MDH1 – Ordering Moderna COVID-19 Vaccine from Public Health England	MDH-1-Ordering-Moderna-COVID-19-Vac
Receipt of goods / booking in	MDH2 – Receipt of frozen Moderna COVID-19 vaccine	MDH-2-Receipt-of-frozen-Moderna-Spikev
Unpacking and thawing in refrigerator	MDH3 – Unpacking of frozen Moderna COVID-19 vaccine and transfer to fridges to thaw	MDH-3-Unpacking-of-frozen-Moderna-Spi
Preparation	MDH4a – Preparation of Moderna COVID-19 vaccine syringes (Primary Course Dose) for administration	MDH-4a-Preparation-of-Moderna-Spikeva
	MDH-4b-Preparation of Moderna (Spikevax)-COVID-19 vaccine (booster dose)	MDH-4b-Preparation-of-Moderna-Spikeva
	MDH 4.1a - Vaccine preparation work instruction for Moderna COVID-19 vaccine (primary course dose)	MDH4.1a Moderna COVID-19 Vaccine (Sp
	MDH 4.1b - Vaccine preparation work instruction for Moderna COVID-19 vaccine (booster dose)	MDH4.1b Moderna COVID-19 Vaccine (Sp
Checklist	MDH4.2 - Vaccine Supervision Sessional Checklist for Moderna COVID-19 vaccine	MDH4.2 Vaccine Supervision Sessional
	MVH7 - Transporting Moderna COVID-19 Vaccine to end user locations within the Trust	MVH7- Transporting Moderna Spikevax® (
	Summary of product characteristics for SpikeVax COVID-19 vaccine	https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna/information-for-healthcare-professionals-on-covid-19-vaccine-moderna
	Workstation Log	Moderna Worksheet for Vaccination Statio
National Protocol	Legal framework for the administration of SpikeVax COVID-19 Vaccine under a National Protocol	SpikevaxCovid19VaccineProtocolv06.00[re

LPT Patient Group Direction	Legal framework for the administration of Spikevax (Moderna) COVID-19 vaccine	C1619-patient-group -direction-for-spikeva

Pharmacy

SOP relating to task / responsibility	Detail	Policy link / attachment
5.8 Maintenance of records	Vaccine Distribution Log	COVID-19 Vaccine Distribution Log.xlsx
	Vaccine Tally	Combined Vaccine Tally.xlsx

Appendix 2

Temperature Monitoring Log

Name of Location: **Description of Refrigerator:**

Date	Time	Current Temp (˚C)	Min. Temp (˚C)	Max Temp (˚C)	Thermometer reset (tick)	Initial	Print Name	Comments

Appendix 3

Daily Check List (to be completed by the duty staff)

Name of Location: **Date:**

Start of the Day

Item	Initial (when complete)	Comments (if needed)
Designated room locked on arrival		
Key cabinet locked at start of day		
Key cabinet contains all the keys (usually two for each refrigerator and and medicines cabinet)		
All refrigerators locked on arrival		
Medicine cabinet locked on arrival		
Refrigerator temperatures checked and in range		
Diluent and COVID vaccine stock check done and tallies		
Emergency medicine stock check done and tallies		
Ascertain patient numbers for the next two working days and email: [ ] before 11am		

Before the session

Item	Initial (when complete)	Comments (if needed)
Emergency drugs in date		
Emergency drugs distributed to work stations		

End of Session

Item	Initial (when complete)	Comments (if needed)
Retrieve all opaque containers (two for each active workstation)		
Diluent and COVID vaccine stock check done and tallies		
Emergency medicine stock check done and tallies		
Refrigerator temperatures checked and in range		
Sharps bins secured in a locked room		
Sweep of the vaccination hall to ensure no medicines or restricted items left		
All refrigerators and medicines cabinet locked		
All keys returned to key cabinet		
Key cabinet locked		
Designated room locked		
Key to key cabinet and designated room handed to site manager		Name:

Name of Staff:

Signature of Staff:

Appendix 4

In-session Check

Name of Location: **Date:**

Ref	Section of Policy	Yes	No	N/A	Comments/Detail Stations Checked
4.7.1	Staff have undertaken the necessary mandatory training and either assessed as competent or working towards this (if new).	☐	☐	☐	
4.8	Individual staff authorised to use PGD or there is a PSD or national protocol	☐	☐	☐	
SOP	At the workstation, vaccine vials are stored in a plastic bag inside an opaque container	☐	☐	☐	
SOP	Plastic bag has a completed 'Concentrate room temperature bag expiry' label	☐	☐	☐	
SOP	Workstation is neat	☐	☐	☐	
SOP	Only one vial in use at a time	☐	☐	☐	
SOP	Label of vial in use is fully completed once diluted	☐	☐	☐	
SOP	Workstation record is up-to-date	☐	☐	☐	
		☐	☐	☐	
		☐	☐	☐	
		☐	☐	☐	

Name of Staff:

Signature of Staff:

Appendix 5

Log for Business Continuity Plan

Date:	**Out temp. of cool bag at start:** ˚C
Min/max temp. reset: Yes No	**Time vaccines placed in cool bag:**

Time	Current (Out) Temp (˚C)	Extra gel pack added (tick)	Staff name and signature

Time vaccines placed in cool bag:	**Out temp. of cool bag at start (Out):** ˚C
Minimum out temp: ˚C	**Maximum out temp:** ˚C

PLEASE INFORM LEAD PHARAMCIST BEFORE USING STOCK

Appendix 6

PRIVACY IMPACT ASSESSMENT SCREENING

Privacy impact assessment (PIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet individual's expectations of privacy. The first step in the PIA process is identifying the need for an assessment. **The following screening questions will help decide whether a PIA is necessary. Answering 'yes' to any of these questions is an indication that a PIA would be a useful exercise and requires senior management support, at this stage the Head of Data Privacy must be involved.**			
Name of Document:	**COVID-19 Vaccination Policy**		
Completed by:	**Tejas Khatau**		
Job title	**Lead Pharmacist - FYPC**	**Date**	**21/12/2020**
			Yes / No
1. Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document.			**No**
2. Will the process described in the document compel individuals to provide information about themselves? This is information in excess of what is required to carry out the process described within the document.			**No**
3. Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information as part of the process described in this document?			**Yes**
4. Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?			**No**
5. Does the process outlined in this document involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics.			**No**
6. Will the process outlined in this document result in decisions being made or action taken against individuals in ways which can have a significant impact on them?			**No**
7. As part of the process outlined in this document, is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or other information that people would consider to be particularly private.			**No**
8. Will the process require you to contact individuals in ways which they may find intrusive?			**No**
If the answer to any of these questions is 'Yes' please contact the Head of Data Privacy Tel: 0116 2950997 Mobile: 07825 947786 **Lpt-dataprivacy@leicspart.secure.nhs.uk** **In this case, adoption n of a procedural document will not take place until approved by the Head of Data Privacy.**			
IG Manager approval name:			
Date of approval			

Acknowledgement: Princess Alexandra Hospital NHS Trust