Worcestershire Acute Hospitals NHS Trust

COVID-19 VACCINE HANDLING & MANAGEMENT POLICY

(Policy on the Purchasing, Prescribing, Supply, Storage, Administration and Control of Covid-19 vaccine)

Department / Service:	Pharmacy
Originator:	Associate Director - Medicines Optimisation and Director of Pharmacy
Accountable Director:	Chief Medical Officer
Approved by:	Medicines Safety Committee
Date of approval:	4th October 2023
Next Revision Due:	4th October 2026
Target Organisation(s):	Worcestershire Acute Hospitals NHS Trust
Target Departments:	All departments/sites involved with the handling & management of Covid vaccine
Target staff categories:	All staff undertaking tasks related to the handling & management of the Covid vaccine

Policy Overview

Worcestershire Acute Hospitals NHS Trust is committed to the safe and secure handling of medicines to protect its patients, staff and visitors, and its financial resources.

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 document is supported by the safe and secure handling of medicines principles described in the Trust Medicines Policy and its associated standard operating procedures

Key amendments to this document

Date	Amendment	By
Dec 2020	New WHAT-CG-840 V1.0	Tania Carruthers Director of Pharmacy
14/12/2020	Further to feedback from Regional Quality Assurance Pharmacist: 4.2 Removed reference to Unlicensed Medicines Policy	Tania Carruthers Director of Pharmacy

	5.1 Added links to the Reg 174 Information for UK Healthcare Professionals and Reg 174 Information for UK Recipients Minor wording changes to the legal status section relating to Reg 174 and Temporary Authorisations	
March 2022	Section 1: Introduction: minor updates to reflect national vaccination programme. Section 5: Principles of Covid-19 Vaccine Use – updated to reflect use of the licensed vaccine Comirnaty in the Trust. Added link to access information on the handling of this vaccine in adults and adolescents Section 5.1: added link to the HWICS Vaccination Guidance Section 5.4: updated to reflect administration of vaccine is via nationally approved patient group direction Section 5.9: added the link for reporting adverse drug events to MHRA via yellow card scheme	Tania Carruthers Director of Pharmacy
Sept 2022	Genericised the document to reflect site approval for Comirnaty and Spikevax Bivalent vaccines Included reference to Nuvaxovid Covid vaccine Added link to updated reference document containing summary information produced by HWICS Updated link to Specialised Pharmacy Service website which hosts useful and up to date information on Covid-19 vaccines Updated monitoring table Updated EIA	Tania Carruthers Director of Pharmacy
Sept 2023	P.7 Removed reference to Autumn 2022 campaign P.7 Referred to approved SOP for immunising patients referred from PCN allergy clinic. Section 9.1 – removed reference to 2 years to recent years to reflect 'recent' experience	

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1. Introduction

The aim of the COVID-19 vaccination programme is to protect those who are at highest risk from serious illness or death from COVID-19 or at risk of transmitting infection to multiple vulnerable persons or other staff in a health or social care environment. 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. 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.

This policy and associated Standard Operating Procedures have been developed such that the Trust can deliver the vaccine service in accordance with the requirements of a hospital hub.

2. Scope of this document

- 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.

3. Local Amendments to this Policy

Any amendments to this policy or relevant SOPs must be ratified by the Medicines Safety Committee or *Trust Command and Control Structure*

4. Responsibilities and Duties

The Chief Executive has overall responsibility for Medicines Optimisation in the Trust. The Chief Medical Officer oversight is in place for medicines, and responsibilities of the Director of Pharmacy as accountable for the safe and secure handling and management of the COVID-19 vaccine and related medicines.

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

- The Director of Pharmacy is professionally accountable for the safe and secure handling and management of medicines on all vaccination sites operating within or under the jurisdiction of Worcestershire Acute Hospitals NHS Trust. This includes oversight of those elements of practice within vaccination centres and other designated vaccination sites that may impact upon product integrity, from receipt of product to vaccine administration.

- The Specialist Pharmacy Services Regional Quality Assurance Specialists will work with the Trust Director of Pharmacy to provide specialist pharmaceutical expertise in the development of systems and processes of work to ensure the safe and secure handling of the vaccine.

- The Medicines Safety Committee (or equivalent) is chaired by the Chief Medical Officer, with the Director of Pharmacy acting as professional secretary. Where the MSC is paused, the approval process is assumed by the Trust Command and Control Structure.

- The Director of Pharmacy may delegate operational responsibility for oversight of ordering, receipt, storage and safe handling of vaccines and medicines, to a named and suitably trained pharmacy team member on each vaccination site.

4.2 Handling and management of vaccine and medicines in vaccination sites

The Director of Pharmacy will 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:
  Such policies and procedures may include:
  - Medicines Policy
  - Injectables Medicines Policy
- Standard good practice guidance including aseptic technique
- Relevant Health and Safety guidance
- National Standards including those detailed in appendix 1

5. Covid-19 Vaccine Policy

5.1 Principles for Covid-19 Vaccine Use

There are a number of Covid-19 vaccines which have been licensed for use in the UK. 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. This document refers to the Covid-19 vaccine and related procedures which the Regional Quality Assurance pharmacist has authorised the Trust to deliver.

The Covid-19 vaccine authorised for use in the Trust is the COVID-19 Vaccine Comirnaty 30 micrograms/dose (Pfizer) and Spikevax Bivalent (Moderna). Nuvaxovid vaccine will be reserved for those patients who are allergic to mRNA vaccines.
Details of the storage and preparation of the COVID-19 Vaccines is available in the Summary of Product Characteristics.
Information relating to Covid-19 vaccines is available via the following link: https://www.sps.nhs.uk/home/covid-19-vaccines/ and includes the pharmaceutical processes for safe handling of the Covid-19 vaccines from initial ordering through to administration for PCNs and Trusts. These vaccines require special transport and storage and the cold chain will be critical. 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

Information on the Herefordshire and Worcestershire ICS Covid-19 vaccination programme is summarised in the following document and contains very helpful resources:
HWICS COVID-19 Vaccination Programme: Schedule Summary and Key Document Links v1.0

5.2 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.

5.3 Technical Standard Operating Procedures

A series of technical SOPs have been produced for Chief Pharmacists to ensure careful attention is given to receipt, storage, movement/transportation, and preparation. These have been adapted locally by the pharmacy team for use within the pharmacy and where procedures impact on other individuals such as preparation those details have been included in the latest version of the Trust's Staff Covid-19 SOP. A separate SOP has been produced to enable immunisation of those patients referred from the ICB allergy clinics.

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

Staff will be authorised to supply and administer COVID-19 vaccine by appropriate and formal authorisation for vaccine administration such as a Patient Group Direction and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so.

Patient Group Direction (PGD)
A PGD is a written instruction for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. They should be reserved for those situations where they offer an advantage for patient care (without compromising patient safety) and where they are consistent with appropriate professional relationships and accountability. The Trust will utilise the nationally approved PGD, with on-going updates noted at the Medicines Safety Committee (or Command and Control Structure) and then published on the Trust's PGD database.

Patient Specific Direction (PSD)
A Patient Specific Direction will be used for the Nuvaxovid vaccine and delivered under a prescriber led model for patients who are allergic to mRNA vaccines.

5.5 Safety and security of vaccines and related medicines

Safe and secure handling and storage of vaccine and medicines arrangements 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.
This guidance has been incorporated into the latest version of the Trust Medicines Policy (WAHT-CG-580).

5.6 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.

Storage and transportation must be 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.

5.7 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 has been undertaken 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.

5.8 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.

5.9 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. This may be via a national software platform.

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. Suspected adverse events should be reported on a yellow card to the MHRA via https://coronavirus-yellowcard.mhra.gov.uk/.

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

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.

5.12 Business Continuity Planning

The Director of Pharmacy will ensure business continuity in relation to safe and secure handling of vaccines. At the time of writing this policy, this has not been 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. Implementation

Plan for dissemination

This Policy and associated procedures will be published on the Trust intranet, in accordance with the Trust's 'Policy for the development, approval and management of key documents'.

7. Monitoring and Compliance

The Director of Pharmacy together with the Medicines Safety Committee is responsible for monitoring compliance with the Covid-19 Vaccine Policy as described in Appendix 2

8. Policy Review

The policy will be reviewed in 12 months due to the evolving developments associated with the Covid-19 vaccine programme plans. Interim amendments, corrections and changes to the policy will be considered by the Medicines Safety Committee or through the *Trust's Command and Control Structure e.g.* for example in response to incidents and internal / external initiatives and new vaccines.

9. Background

9.1 Consultation

This key document was originally circulated to the following individuals for consultation:

The Trust Covid-19 Task and Finish Group
Bronze and Silver Tactical Command
Associate Director for Medicines Commissioning for H & W CCG
This document has been updated in accordance with knowledge acquired through implementation of the programme over recent years and the national updated reference document:
https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners

9.2 Approval Process

This policy will be approved by the Trust Command and Control Structure which includes the Trust Chief Medical Officer or the Medicines Safety Committee subject to which is in operation at the time of the updates.

9.3 Equality Requirements

Details of the Equality Impact Assessment can be found in Supporting Document 1

9.4 Financial Risk Assessments

Details of the Financial Risk Assessment can be found in Supporting Document 2

Appendix 1: Links to relevant National Standards

CQC Regulation 12: Safe Care and Treatment
https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment
'The intention of this regulation is to prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm. Providers must assess the risks to people's health and safety during any care or treatment and make sure that staffs have the qualifications, competence, skills and experience to keep people safe.
• Providers must make sure that the premises and any equipment used is safe and where applicable, available in sufficient quantities. Medicines must be supplied in sufficient quantities, managed safely and administered appropriately to make sure people are safe.
• Providers must prevent and control the spread of infection. Where the responsibility for care and treatment is shared, care planning must be timely to maintain people's health, safety and welfare.
The CQC understands that there may be inherent risks in carrying out care and treatment, and we will not consider it to be unsafe if providers can demonstrate that they have taken all reasonable steps to ensure the health and safety of people using their services and to manage risks that may arise during care and treatment'

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

The Green Book - Immunisation against infectious disease (Public Health England)
https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book#the-green-book
The latest information on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK. The COVID-19 vaccine chapter is available on:
https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a

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

APPENDIX 2 COVID-19 VACCINE HANDLING & MANAGEMENT POLICY PROCESS FOR MONITORING COMPLIANCE

Key Control	Where the check will be carried out	Checks to be carried out to confirm compliance:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to:	Frequency of Reporting
WHAT?	WHERE?	HOW?	WHEN?	WHO?	WHERE?	WHEN?
Safe and secure handling, purchasing, storage and supply of medicines	Designated Clinic (may be off-site)	Pharmacist supervision assessment	For first few days of clinic sessions and ad hoc thereafter	Supervising pharmacist/chief technician	Medicines Safety Committee Clinical Governance Group	Quarterly Quarterly
	Pharmacy dept	Pharmacy Dept Audit checklist (WM)	Annual	Lead Operational Pharmacist and/or Chief Technician	Pharmacy Governance Committee Medicines Safety Committee Clinical Governance Committee	Annual
Vaccine & medicines related incidents	Designated Clinics Hospital Pharmacy	Datix (or similar) incident reports	On-going	Pharmacist/technician Nurse/midwife/doctor Other Healthcare professional	Medicines Safety Committee Clinical Governance Group	Quarterly Quarterly

Supporting Document 1 - Equality Impact Assessment Tool

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form

Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	x	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	Tania Carruthers Associate Director - Medicines Optimisation and Director of Pharmacy

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Tania Carruthers	Associate Director - Medicines Optimisation and Director of Pharmacy	Tania.carruthers@nhs.net
Date assessment completed	**6/3/2022** **Reassessed 8/9/2022** **Reassessed 19/9/2023**		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title: Covid-19 Vaccine Policy**			
What is the aim, purpose and/or intended outcomes of this Activity?	The Covid-19 Vaccine Policy describes the Trust's control measures for reducing medicine-related risks (including Handling, Purchasing, Prescribing, Supply, Storage, and Administration of Covid-19 vaccines) within a framework provided by legislation and official guidance and must support Clinical Governance within the Trust.			
Who will be affected by the development & implementation of this activity?	❑	Service User	x	Staff
	x	Patient	❑	Communities
	❑	Carers	❑	Other
	❑	Visitors	❑	_____
Is this:	x Updated content based on updated advice and guidance and local experience of using the vaccine since April 2022			
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	Information arising from monitoring of compliance with the policy (Appendix 1) Information arising from Incidents, Risks and Complaints			
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	The Covid-19 Vaccine Policy describes the Trust's control measures for reducing medicine-related risks within a framework provided by legislation and official guidance for the Covid-19 vaccine. The content will be reviewed within 12 months due to the changing landscape for vaccine planning and introduction of new vaccines and services. Changes may arise with input from representatives of staff required to follow it), and as required where safety or other issues are identified.			
Summary of relevant findings	No equality issues identified.			

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	**Potential positive impact**	**Potential neutral impact**	**Potential negative impact**	**Please explain your reasons for any potential positive, neutral or negative impact identified**
Age		x		Note that implementation of the vaccine will be prioritised based on age based on national advice.
Disability		x		Note that implementation of the vaccine will be prioritised in accordance with clinical vulnerability. National advice.
Gender Reassignment		x		
Marriage & Civil Partnerships		x		
Pregnancy & Maternity		x		
Race including Traveling Communities		x		
Religion & Belief		x		
Sex		x		

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Sexual Orientation		x		
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		x		Those people living in residential/care homes may be prioritised in accordance with national directives.
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		x		

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
	None	.		
How will you monitor these actions?	**N/A**			

When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	**In 12 months as part of the Policy Review**

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Tania Carruthers
Date signed	19/9/2023
Comments:	N/A
Signature of person the Leader Person for this activity	Tania Carruthers
Date signed	19/9/2023
Comments:	N/A

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	no
2.	Does the implementation of this document require additional revenue	no
3.	Does the implementation of this document require additional manpower	no
4.	Does the implementation of this document release any manpower costs through a change in practice	no
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	no
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval