

NHS Covid-19 Vaccine Handling and Management Policy (M-028)

Version Number:	1.2
Author (name & job title)	Leanne Bloor, Chief Technician
Executive Lead (name & job title):	Dr Kwame Fofie, Executive Medical Director
Name of approving body:	Quality Committee
Date full policy approved:	7 April 2021 (V1.0)
Date Ratified at Trust Board:	11 January 2024
Next Full Review date:	January 2027

<i>Minor amendments made prior to full review date above (see appended document control sheet for details)</i>	
<i>Date approved by Lead Director:</i>	<i>QPAS – 11 January 2024</i>
<i>Date EMT as approving body notified for information:</i>	<i>January 2024</i>

Please note - This policy follows the national NHS template

Policies should be accessed via the Trust intranet to ensure the current version is used

Contents

1	Purpose / Legal Requirements / Background	4
2	Policy / Procedure / Guideline details	5
3	Process for monitoring compliance.....	8
4	References.....	9
	Appendix 1 - Links to relevant National Standards	10
	Appendix 2 - NHS Trust Hospital Hub & Vaccination Site Pharmacy Go-Live Checklist.....	11
	Appendix 3 - Document Control Sheet	13
	Appendix 4 - Equality Impact Assessment (EIA)	14

Humber Teaching NHS Foundation Trust

NHS COVID-19 Vaccine handling and management policy

Broad Recommendations / Summary

Document definition:

This model policy document enables HTFT to implement good governance in the context of the safe and secure handling and management of COVID-19 vaccines.

Target Audience: Who Should Read This Policy?

All NHS staff responsible for planning and managing the COVID-19 vaccination programme, and all NHS Pharmacy staff engaged in supporting and delivering the COVID-19 vaccination programme.

Purpose

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. It is anticipated that the Drug and Therapeutic Group agrees this policy, and that it is authorised as soon as possible by the Chief Pharmacist, chair of the committee and the local chief pharmacist.

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.

Model NHS COVID-19 Vaccine handling and management policy

1 Purpose / Legal Requirements / Background

Document definition:

This is a model policy document to enable local organisations to implement good governance in the context of the safe and secure handling and management of COVID-19 vaccines.

Introduction

The COVID-19 vaccination programme is of the highest priority for the NHS. In order to deliver this programme both safely and effectively, good practice in the handling and management of vaccine is paramount. It is anticipated that a number of COVID-19 vaccines will be introduced, 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.

Purpose

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. It is anticipated that the Drug and Therapeutic Group agrees this policy, and that it is authorised as soon as possible by the Chief Pharmacist, chair of the committee and the local chief pharmacist.

The document is intended to provide the overarching principles for robust governance of the safe and secure handling and management of COVID-19 vaccines in the end-to-end supply chain for the vaccination programme.

Objectives

- To ensure that all staff involved in delivery of the vaccination programme are aware of, and adhere to, the correct procedures for the ordering, receipt, storage, supply and administration of the product.
- To ensure that the physical and biochemical integrity and sterility of all vaccines and related medicines is maintained.
- To ensure that all staff involved in delivery of the vaccination programme are aware of the relevant characteristics of COVID-19 vaccines and the implications this has for vaccine efficacy and patient safety.
- 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.

2 Policy / Procedure / Guideline details

Target Audience: Who Should Read This Policy?

All NHS staff responsible for planning and managing the COVID-19 vaccination programme, and all NHS Pharmacy staff engaged in supporting and delivering the COVID-19 vaccination programme.

COVID-19 Vaccines

There are a number of COVID-19 vaccines under development and it is anticipated that a range will be utilised in the vaccination programme.

The characteristics of the different vaccines vary. Information is available in the Summary of Product Characteristics and Patient Information leaflet respectively. Use of vaccines that have deviated from recommended storage or transportation conditions risks compromising vaccine efficacy and patient safety. Vaccines that have not been transported or stored correctly may be ineffective or harmful; they would therefore no longer be within the terms of their product authorisation and must not be used. The focus on avoidance of waste should also be of high priority.

Further information concerning COVID-19 vaccines is available in the Public Health England publication 'COVID-19 vaccination programme Information for healthcare practitioners', available on <https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners>

Legal framework and practice standards.

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

All activity is also to be aligned with relevant COVID-19 Vaccination Programme NHS policy documents marked as Classification: Official and annotated with a publication approval reference number.

In addition, adherence to national standards of good practice is required including those set by the Care Quality Commission, the National Institute for Health and Care Excellence, Public Health England and the Royal Pharmaceutical Society of Great Britain, as detailed in the appendix 1 below.

Roles and responsibilities under this policy

The legal entity responsible for operating the vaccination site is to assign responsibility for clinical and operational oversight. Executive Director oversight should be in place, and the responsibilities should include the relevant Chief Pharmacist as accountable for the safe and secure handling and management of the COVID-19 vaccine and related medicines.

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

- The relevant Provider Trust Chief Pharmacist is professionally accountable for the safe and secure handling and management of medicines on all vaccination sites operating within or under the jurisdiction of their employing legal entity. This includes oversight of those elements of practice within mass vaccination centres and other designated vaccination sites that may impact upon product integrity, from receipt of product to vaccine administration.
- The Specialist Pharmacy Services Regional Quality Assurance Specialists will work with the Trust Chief Pharmacist (Weeliat Chong) 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 Drug and Therapeutic Group is to document the above named individuals.
- The Chief Pharmacist may delegate operational responsibility for oversight of ordering, receipt, storage and safe handling of vaccines and medicines, to a named and suitably trained pharmacy team member on each vaccination site.

Handling and management of vaccine and medicines in vaccination sites

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

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

Local amendments to this policy

Any amendments to this policy or relevant SOPs must be ratified by the Drug and Therapeutic Group of the legal entity responsible for operating the vaccination site.

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

The responsible Chief Pharmacist must ensure that appropriate and formal authorisation for vaccine administration is in place such as a Patient Group Direction, protocol or written instruction, and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so.

Safety and security of vaccines and related medicines

The responsible Chief Pharmacist must ensure that that safe and secure handling and storage of vaccine and medicines are in place in accordance with principles and guidance encompassed in 'Professional guidance on the safe and secure handling of medicines (Royal Pharmaceutical Society of Great Britain)', available on <https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines>.

Storage and transportation of vaccines

The 'cold chain' is a term used to describe the cold temperature conditions in which certain products need to be kept during storage and distribution. Maintaining the cold chain ensures that vaccines are transported and stored according to the manufacturer's recommended temperature range until the point of administration. Vaccines must be stored at the correct temperature and transported only in approved and validated packaging, and the temperature of the vaccine carrier and contents monitored.

The responsible Pharmacist must ensure that storage and transportation are undertaken in accordance with the relevant SOPs, that cold chain temperatures are monitored correctly and that any 'out of specification' recordings are addressed promptly and appropriately, and that a full audit trail is maintained. Further details are included in the relevant SOPs and in manufacturers' information.

Workforce and training

All staff undertaking duties at the vaccination site must meet the necessary training standards and competencies in line with the SOPs and standard trust processes. A training needs assessment is required for the roles within the vaccination services, with corresponding training materials and assessment process, to enable timely and focussed workforce development.

As detailed in 'Professional guidance on the safe and secure handling of medicines (Royal Pharmaceutical Society of Great Britain)' (see appendix 1) 'the named individual ensures that accountable individuals are competent and supported in their role as it relates to the safe and secure handling of medicines'.

The roles assigned to support the rollout of COVID-19 vaccination need to be in accordance with legislation including that detailed in the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020.

Precautions

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

Any needlestick or other injuries must be addressed in accordance with the policies of the relevant employing legal entity

Maintenance of records

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

Any serious adverse reactions are to be escalated for immediate senior clinical input; such situations are to be fully documented following the event and a record kept of relevant product batch numbers. A record of all serious adverse events is to be provided to the responsible Pharmacist and recorded on Datix.

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.

Disposal of vaccines and other waste

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

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

Organisational COVID-19 Policy

All NHS Trusts are required to have an operational plan to respond to an outbreak of COVID-19, approved by their Boards. This policy must be adhered to for infection prevention and control measures during the pandemic.

Business Continuity Planning

The responsible Chief Pharmacist will be responsible for establishing an agreed business continuity plan in relation to safe and secure handling of vaccines, and tested in line with the organisational emergency preparedness processes and NHS Core Standards for Emergency Preparedness, Resilience and Response (<https://www.england.nhs.uk/ourwork/eprp/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.

Go-live checklist

A proposed NHS Trust & Large Vaccination Site Pharmacy Go-Live Checklist is provided in appendix 2.

Process for distribution and dissemination – by Trust corporate e-mail and available on the intranet.

Who to contact for support in complying with the policy –

Weelait Chong, Chief Pharmacist.

3 Process for monitoring compliance

Compliance with this policy will be monitored by the Pharmacy Department and Drug and Therapeutic Group, utilising the Trust Datix error reporting system in relation to medication errors.

4 References

NHSE/I - URGENT IMPORTANT: COVID-19 vaccination: Governance, handling and preparation of vaccines in Hospital Hubs and Vaccination Centres (4 December 2020)
<https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/12/C0926-COVID-19-vaccination-Governance-handling-and-preparation-of-vaccines-in-Hospital-Hubs-and-Vaccination-Ce.pdf>

PHE - COVID-19 vaccination guidance for healthcare practitioners (December 2020 Version 02.00)
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1155194/COVID-19-vaccination-information-for-IHCP-v6.0-May2023.pdf

Appendix 1 - Links to relevant National Standards

Links to relevant National Standards (Appendix 1 in National template document)

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 - NHS Trust Hospital Hub & Vaccination Site Pharmacy Go-Live Checklist

The following list provides an indication of the specific items for consideration in providing assurance that the pharmacy and medicines handling requirements for the vaccination programme have been met. It is by no means definitive and is subject to change.

Governance and leadership

- Approval of local policy to assure safe and secure handling of the vaccine from receipt to administration (via D&T or similar)
- Responsible chief pharmacist identified
- Pharmacy Aseptic and Senior Nurse lead(s) identified for oversight of training for vaccine preparation SPS RQA review of plan
- SPS RQA approval that relevant MHRA Good Distribution Practice obligations are in place

Standard Operating Procedures

- Ordering of vaccine
- Ordering of anaphylaxis kits and other related medicines
- Receipt, storage, stock control, temperature excursions, record keeping and security
- Thaw process
- Supply chain from vaccine receipt to administration assurance
- Preparation of individual doses
- Administration of individual doses

Waste handling

Workforce and training

- Appropriately skilled pharmacy workforce identified for service delivery including:
 - Sufficient capacity to provide supervision
 - Enhanced support for go-live to support early continuous improvement
- Standard training material relating to SOPs and service delivery
- Training delivery plan in place
- Competence assessment in place for appropriate elements

Premises, equipment and supply

- Sufficient validated fridge and, where appropriate, freezer capacity available
- Fridge and freezer automatic temperature monitoring and logging system installed
- Fridge and freezer alarms installed and tested
- Supply of vaccine and non-vaccine consumables determined
- Chief Pharmacist agreement to vaccination site layout and preparation areas

Sign off

- Trust Chief Pharmacist
- Regional Chief Pharmacist

Appendix 3 - Document Control Sheet

This document control sheet, when presented to an approving committee must be completed in full to provide assurance to the approving committee.

Document Type	Policy		
Document Purpose	Covid 19 Vaccination handling and management policy (National template)		
Consultation/ Peer Review:	Date:	Group / Individual	
<i>list in right hand columns consultation groups and dates - ></i>	DTG	30 November 2023	
Approving Body:	QPAS	Date of Approval:	11 January 2024
Ratified at:	Trust Board	Date of Ratification:	April 2021 (v1.0)
Training Needs Analysis: <i>(please indicate training required and the timescale for providing assurance to the approving committee that this has been delivered)</i>		Financial Resource Impact	
Equality Impact Assessment undertaken?	Yes []	No []	N/A [] Rationale:
Publication and Dissemination	Intranet []	Internet []	Staff Email []
Master version held by:	Author []	HealthAssure []	
Implementation:	<i>Describe implementation plans below - to be delivered by the Author:</i>		
	As per national guidance•		
Monitoring and Compliance:	Compliance with this policy will be monitored by the Pharmacy Department and Drug and Therapeutic Group, utilising the Trust Datix error reporting system in relation to medication errors.		

Document Change History:			
Version Number / Name of procedural document this supersedes	Type of Change i.e. Review / Legislation	Date	Details of Change and approving group or Executive Lead (if done outside of the formal revision process)
V1.0	New Document	Dec-20	New policy in line with National NHS template Approved at DTG in line with Covid national guidance Approved at DTG December 2021, QPAS 4 March 2021 Quality Committee 7 April 2021
V1.1	Review	Jan-22	General / minor updates to be in line with the latest National COVID-19 vaccination programme Approved 27 January 2022 DTG. QPAS 17 January 2022
V1.2	Review	Oct -23	Minor updated to be in line with vaccines available. Approved at DTG (30 Nov 2023) and then at QPAS (11 January 2024).

Appendix 4 - Equality Impact Assessment (EIA)

For strategies, policies, procedures, processes, guidelines, protocols, tenders, services

NHS COVID-19 Vaccine handling and management policy

Main Aims of the Document, Process or Service

This model policy document enables HTFT to implement good governance in the context of the safe and secure handling and management of COVID-19 vaccines.

Please indicate in the table that follows whether the document or process has the potential to impact adversely, intentionally or unwittingly on the equality target groups contained in the pro forma

Equality Target Group 1. Age 2. Disability 3. Sex 4. Marriage/Civil Partnership 5. Pregnancy/Maternity 6. Race 7. Religion/Belief 8. Sexual Orientation 9. Gender re-assignment	Is the document or process likely to have a potential or actual differential impact with regards to the equality target groups listed? Equality Impact Score Low = Little or No evidence or concern (Green) Medium = some evidence or concern (Amber) High = significant evidence or concern (Red)	How have you arrived at the equality impact score? a) who have you consulted with b) what have they said c) what information or data have you used d) where are the gaps in your analysis e) how will your document/process or service promote equality and diversity good practice
---	---	--

Equality Target Group	Definitions	Equality Impact Score	Evidence to support Equality Impact Score
Age	Including specific ages and age groups: Older people, Young people, Children, Early years	Low	There are no factors in this Policy that are likely to have a differential impact on this target group.
Disability	Where the impairment has a substantial and long term adverse effect on the ability of the person to carry out their day to day activities: Sensory, Physical, Learning, Mental Health (and including cancer, HIV, multiple sclerosis)	Low	There are no factors in this Policy that are likely to have a differential impact on this target group.
Sex	Men/Male Women/Female	Low	There are no factors in this Policy that are likely to have a differential impact on this target group.
Marriage/Civil Partnership		Low	There are no factors in this Policy that are likely to have a differential impact on this target group.
Pregnancy/ Maternity		Low	There are no factors in this Policy that are likely to have a differential impact on this target group.

Race	Colour Nationality Ethnic/national origins	Low	There are no factors in this Policy that are likely to have a differential impact on this target group.
Religion or Belief	All Religions Including lack of religion or belief and where belief includes any religious or philosophical belief	Low	There are no factors in this Policy that are likely to have a differential impact on this target group.
Sexual Orientation	Lesbian Gay Men Bisexual	Low	There are no factors in this Policy that are likely to have a differential impact on this target group.
Gender Re-assignment	Where people are proposing to undergo, or have undergone a process (or part of a process) for the purpose of reassigning the person's sex by changing physiological or other attribute of sex	Low	There are no factors in this Policy that are likely to have a differential impact on this target group.

Summary

Please describe the main points/actions arising from your assessment that supports your decision above:

There are no factors in the NHS COVID-19 Vaccine handling and management policy which are likely to have a differential impact on any of the Equality Target Groups

EIA Reviewer – Weeliat Chong

Date completed: 30.11.2023

Signature *W Chong*