Classification: Official

Publication approval reference: 001559

Dr Keith Ridge CBE

NHS England and NHS Improvement
Skipton House
80 London Road
London
SE1 6LH

To: NHS Trust hospital chief pharmacists

CC: NHS Trust Chief Executives

4 December 2020

Dear Colleagues,

URGENT IMPORTANT: COVID-19 vaccination: Governance, handling and preparation of vaccines in Hospital Hubs and Vaccination Centres

The purpose of this letter is to set out the principles and expectations necessary to maintain integrity and, therefore, safety, quality and effectiveness of the COVID-19 vaccines.

Local COVID-19 vaccines policy

Corporate and professional governance for use of the vaccines should be through normal NHS medicines governance arrangements, via the Trust Drug and Therapeutic (D&T) Committees (or equivalent). A model *NHS COVID-19 Vaccine handling and management policy 2020/21* is set out at Annex A, and this should be agreed as soon as possible by the Medical Director, chair of the D&T committee and the Trust Chief Pharmacist on behalf of the local NHS organisation responsible for the administration of the vaccines.

Technical Standard Operating Procedures (SOP)

The novel characteristics of the first vaccine (*Covid-19 mRNA vaccine BNT 162b2*) which is temporarily authorised for supply by the Medicines and Healthcare products Regulatory Agency (MHRA) make it essential that very careful attention is given to its receipt, storage, movement/transportation, and preparation. These and other processes are supported by a suite of technical Standard Operating Procedures (SOPs) which can be found at SPS Guidance for Chief Pharmacists (please note that you will need to be a registered user and signed in to access this website). Information for healthcare professionals has also been published by the MHRA and is available here: HCP Information

Further technical SOPs, if required, will be provided as additional vaccines become available.

Oversight of vaccine processes by senior pharmacists

In the first period of COVID vaccination, there are likely to be three delivery models for the vaccines: (a) NHS Hospital Hubs; (b) Vaccination Centres; and (c) Local Vaccination Services. This letter focuses on models (a) and (b).

Given the novel nature of the vaccines, pharmaceutical expertise and oversight will be essential to ensure integrity of the vaccines. Chief Pharmacists of NHS Trusts/ Foundation Trusts will hold the lead responsibility for ensuring the safe handling and use of the vaccines at Hospital hubs or at Vaccination centres. The name of the Lead Responsible Chief Pharmacist must be identified to your Regional Chief Pharmacist, together with confirmation that the Hub is ready to receive the vaccines (see below). The Lead Responsible Chief Pharmacist should also identify senior pharmacy team members with significant experience of the delivery of, and training related to, aseptic preparation or a senior nurse with experience in Aseptic non-touch technique (ANTT) training in order to ensure compliance with the technical SOPs. The NHS Specialist Pharmacy Service, which has led the development of the technical SOPs, will allocate expert pharmacy quality assurance staff to each NHS Trust Hospital Hub to help each Lead Responsible Chief Pharmacist familiarise themselves with the technical SOPs, and will also be on hand to answer any queries as they arise.

Confirming readiness to receive COVID-19 vaccines

The Lead Responsible Chief Pharmacist should use their professional judgement to confirm to their Regional Chief Pharmacist that the Hospital Hub or Vaccination Centre is ready to receive the vaccines. A readiness checklist is provided at Annex A (Appendix 2).

Legal basis and expectations of HMR regulation 174 (temporary) authorisation for supply of the vaccine products

It is important that all registered healthcare professionals dealing with the vaccines are familiar with the law underpinning any regulatory authorisation of the vaccines and the consequential expectations of professional accountability and practice.

The UK medicines regulatory framework empowers the licensing authority (the UK and NI Health Ministers) to temporarily authorise the supply or distribution of unlicensed medicinal products in response to certain public health events, for example a pandemic. The specific legislation is set out in regulation 174 and 174A of the Human Medicines Regulations 2012, as amended. Regulation 174A provides for

conditions to be attached to the temporary authorisation, which will generally be done in order to assure the safety, quality and efficacy of the specific medicine. Ministers would consider the temporary authorisation of a medicine after taking advice of the independent expert advisory committee for medicines, the Commission on Human Medicines. Supply and administration of the medicine (Covid vaccine in this case) must comply with the conditions. These conditions will be in addition to the normal regulatory requirements for control of manufacture, distribution, compliance with appropriate good practices, monitoring and reporting of adverse reactions etc.

Healthcare organisations and healthcare professionals are also subject to legislation and good governance requirements. The Medicines Act 1968, section 10, sets out the professional exemption for pharmacists, within which they must operate for preparation and assembly of products, underpinned by professional good practice requirements and governance.

In practice, the professional expectations are as follows:

Hospital Hubs: different exemptions may be relied on in terms of administration of the vaccine (the occupational health exemptions rather than the Patient Group Direction or immunisation protocol exemptions). If it is deemed there is essentially an upscaling of a normal in-house vaccination programme for influenza, it may be nurse led in the usual way. However, final dilution of the *Covid-19 mRNA vaccine BNT 162b2* vaccine is a skilled operation, and both individual health care professionals and the governance systems within which they operate have to be satisfied it is being done by people acting within their professional competence. Typically, these skills are ones which are normally found amongst pharmacy professionals. As part of their declaration of readiness to receive vaccines, the Lead Responsible Chief Pharmacist, as part of their overarching responsibility for ensuring the safe and effective supply of medicines at the Hospital Hub should use their professional judgement to confirm that the Hospital Hub has the appropriate governance systems in place to administer the vaccines, whether or not pharmacy professionals will be involved in the final dilution of the products.

Vaccination centres: these will become temporary hospital premises listed as the temporary responsibility of a particular NHS Trust. The expectation is that those vaccines requiring final dilution to be done at those premises will be done under section 10 of the Medicines Act 1968, i.e. by or under the supervision of a pharmacist, unless the vaccine characteristics do not warrant this. Pharmacists may supervise other health professionals doing the final dilution, but again it should only be done by registered health care professionals acting within their professional

competence. The ordinary expectation is that it will be pharmacy professionals and staff, but the pharmacist could be supervising, for example, nurses who possess the relevant skills. Again, part of their declaration of readiness to receive vaccines, the Lead Responsible Chief Pharmacist, as part of their overarching responsibility for ensuring the safe and effective supply of medicines for the Vaccination centre, should use their professional judgement to confirm to their Regional Chief Pharmacist that the Vaccination Centre has the appropriate governance systems in place to administer the vaccines.

Yours sincerely

Dr Keith Ridge CBE
Chief Pharmaceutical Officer for England

ANNEX A: Model NHS COVID-19 Vaccine handling and management policy 2020/21

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.

Who should read this policy?

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

Introduction

The COVID-19 vaccination programme is of the highest priority for the NHS. In order to deliver this programme both safely and effectively, good practice in the handling and management of vaccine is paramount. It is anticipated that a number of COVID-19 vaccines will be introduced during 2020 and 2021, so good governance is essential. Clarity of both the overarching principles and the detailed 'standard operating procedures' are required to enable safe, effective implementation and delivery of the vaccination programme. This document is to be read alongside the Pharmacy Institutional Readiness documents (Guidance for Chief Pharmacists) which focus on the management of each of the individual COVID-19 vaccines, and the aligned Standard Operating Procedures developed for all vaccines and all environments in which the vaccines are handled.

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 Therapeutics Committee (or equivalent) agrees this policy, and that it is authorised as soon as possible by the Medical Director, 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, quality 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.

COVID-19 Vaccines

There are a number of COVID-19 vaccines under development and it is anticipated that a range will be utilised in the vaccination programme. None will be authorised at the start of the programme so initially they will come into use under Regulation 174 of the Human Regulations 2012. This regulation enables the Medicines and Healthcare products Regulatory Agency (MHRA) to authorise use of a product on a temporary basis in response to the spread of pathogenic agents.

The characteristics of the different vaccines may vary considerably and will increase in clarity over time. Prior to licensing the product characteristics are available in the relevant 'Healthcare Professional Factsheet' and patient information in the 'Consumer Factsheet'. Following award of the Marketing Authorisation this information is available in the Summary of Product Characteristics and Patient Information leaflet respectively. The first requires transport and storage under ULT conditions (-70 +/- 10 C). This may not be the case for those that follow, but cold chain will be critical for all. Use of vaccines that have deviated from recommended storage or transportation conditions risks compromising vaccine efficacy and patient safety. Vaccines that have not been transported or stored correctly may be ineffective or harmful; they would therefore no longer be within the terms of their product authorisation and must not be used. Means of detecting when a temperature excursion has occurred are required. The focus on avoidance of waste should also be of high priority.

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

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 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 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 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 Committee (or equivalent) 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 Drugs and Therapeutics Committee (or equivalent) 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 safe and secure handling and storage of vaccine and medicines are in place in accordance with principles and guidance encompassed in 'Professional guidance on the safe and secure handling of medicines (Royal Pharmaceutical Society of Great Britain)': https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines.

Storage and transportation of vaccines

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

The 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.

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/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.

Go-live checklist

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

Document prepared by team of the NHSE/I Chief Pharmaceutical Officer; 2.12.20

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: 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