

To:

- Hospital Chief Pharmacists
- Community Trust Chief Pharmacists
- CCG Chief Pharmacists

Skipton House
80 London Road
London
SE1 6LH

cc.

- Regional Chief Pharmacists
- Regional Directors of Commissioning

15 September 2021

Dear colleague

COVID-19 vaccination for secondary school age children: Governance of storage, distribution and preparation arrangements for COVID-19 vaccines by School Aged Immunisation Service (SAIS) teams

First, may I offer my sincere thanks for the immense and continuing efforts made by you and your teams to ensure safe and effective patient care during the pandemic. I recognise that teams are already working hard, including playing their part in recovery, but I must now ask you to again collaboratively lead the pharmaceutical effort for the next and important stage of the vaccination programme, the vaccination of 12-15 year old children.

Many of you will have considerable experience of the pharmaceutical arrangements necessary to maintain the integrity of COVID-19 vaccines so that they remain safe and effective. Some of you may have been less directly involved with the vaccination programme. Please can I ask you once again to come together across local systems to share that experience and support colleagues now asked to play their part in the programme, such as the SAIS teams.

To assist you, drawing on my letters of [4 December 2020](#) and [8 December 2020](#), this letter again sets out the pharmaceutical standards expected to maintain the integrity and, therefore, safety, quality and effectiveness of the COVID-19 vaccines which will be administered by SAIS teams.

Oversight of vaccine processes by senior pharmacists

The Pfizer-BioNTech vaccine (either BNT162b2 approved for emergency use under Regulation 174 or Comirnaty®, which has a Conditional Marketing Authorisation) will be offered to secondary school aged children. Given the fragile nature of the vaccine, pharmaceutical expertise and oversight will be essential to ensure product integrity.

SAIS teams typically but not exclusively operate out of NHS Trusts. In such cases, the Chief Pharmacists of NHS Trusts or NHS Foundation Trusts again hold the lead responsibility for ensuring the safe handling and use of the vaccines in the schools vaccination programme as they do in other vaccination sites. The name of the Lead/Responsible Chief Pharmacist for all school vaccination sites/teams which your trust supports must be identified to your Regional Chief Pharmacist, together with confirmation that the sites are ready to receive the vaccines and deliver vaccinations (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 safe practice in compliance with the technical Standard Operating Procedures (see below).

Where other governance arrangements apply, for example, where the SAIS team operates on behalf of a community enterprise or commercial provider, or where the NHS Trust does not employ a Chief Pharmacist, local NHS systems are expected to work together in conjunction with their NHS England Regional Chief Pharmacist to identify and operationalise suitable oversight arrangements by a Lead/Responsible Chief Pharmacist in line with those of NHS Trusts. CCG chief pharmacists may have a particular role to play here and senior pharmacists across local systems should work collaboratively with other providers of COVID-19 vaccinations.

Confirming readiness to receive COVID-19 vaccines

The Lead/Responsible Chief Pharmacist should use their professional judgement to confirm to their NHS England Regional Chief Pharmacist that the vaccination site or vaccination team is ready to receive the vaccines and deliver a vaccination service. A readiness checklist is provided at Annex A.

Legal basis for supply and administration of the vaccines

It is important that all registered healthcare professionals dealing with the vaccines are familiar with the law underpinning the regulatory authorisation of the vaccine they are using at a particular time whether the Regulation 174 temporarily authorised product or the Comirnaty® branded product which has a Conditional Marketing Authorisation, and the consequential expectations of professional accountability and practice. Dilution of the 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. 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 should use their professional judgement to confirm that the vaccination sites /teams which they support have the appropriate governance systems in place to handle the vaccines safely, whether or not pharmacy professionals will be directly involved in the dilution.

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. These arrangements should already be in place for local vaccination deployment and should now be updated to include new delivery models. Where the SAIS provider is a non-NHS provider, equally robust arrangements are expected to be in place, or be put in place. A model NHS COVID-19 Vaccine handling and management policy 2020/21 is set out at Annex B, 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. In most organisations the COVID-19 vaccination programme has already been approved locally through this process, but approval should be updated to include the new arrangements required for the schools COVID-19 vaccination programme.

Technical Standard Operating Procedures (SOPs)

The characteristics of the Pfizer-BioNTech vaccine make it essential that careful attention is given to its receipt, storage, movement/transportation, and preparation. Handling processes are supported by a suite of technical SOPs which can be found [here](#).

It is also essential that the company's product information on handling instructions is adhered to. This is included in the Summary of Product Characteristics of the Conditional Marketing Authorisation and in the Information for healthcare professionals for the regulation 174 authorisation, both of which have been published by the MHRA and are available [here](#).

Yours sincerely

A handwritten signature in black ink, appearing to read 'K. W. Ridge', with a long horizontal flourish extending to the right.

Dr Keith Ridge CBE
Chief Pharmaceutical Officer for England

Annex A: COVID-19 Vaccination – School vaccination site: Pharmacy Go-Live Checklist

This 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 appropriate Prescribing Committee)
- Clinical oversight identified by lead clinician
- Lead identified for oversight of training for vaccine preparation
- Site Lead/Responsible Chief Pharmacist identified
- SPS RQA approval of plan and that measures to ensure relevant MHRA Good Distribution Practice obligations are in place

Standard Operating Procedures (SOPs)

- SOPs for receipt & safe handling of vaccine delivered at ULT storage, stock control, temperature excursions, record keeping and security in place
- SOPs for preparation of individual doses of vaccine in place
- SOPs for administration of individual doses of vaccine in place
- SOPs for disposal of Dry Ice in place
- SOPs for waste handling in place

Workforce and training

- Appropriately skilled workforce identified for service delivery
- Appropriately skilled pharmacy workforce identified and available for service delivery support
- Standard training material relating to SOPs and service delivery available
- Training delivery plan in place
- Competence assessment in place for appropriate elements

Premises, equipment and supply

- Sufficient validated fridge capacity available, including a dedicated fridge for thawing new stock
- Fridge (automatic temperature monitoring and logging system installed)
- Fridge alarms installed and tested
- Supply of vaccine and non-vaccine consumables determined
- Site Lead/Responsible Pharmacist agreement to vaccination site layout and preparation areas

Sign off

- Lead clinician
- Trust Chief Pharmacist
- Site Lead/Responsible Chief Pharmacist
- Regional Chief Pharmacist

ANNEX B: Model NHS COVID-19 Vaccine handling and management policy 2021-22

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.

Target Audience: Who Should Read This Policy?

All NHS staff responsible for planning and managing the COVID-19 vaccination programme in 2021/22, and all NHS Pharmacy staff engaged in supporting and delivering the COVID-19 vaccination programme in 2021/22.

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 or equivalent 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 Lead/Responsible 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 three COVID-19 vaccines currently in use in the vaccination programme but only the Pfizer product is currently intended to be used for the vaccination of 12-15 year olds.

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, as amended.

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 Lead/Responsible 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 Lead/Responsible 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 Lead/Responsible 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 Lead/Responsible 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 Lead/Responsible Chief 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 Lead/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 Lead/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 and reviewed before use.

The Lead/Responsible Chief 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 amendments made to the Human Medicines Regulations 2012 by S.I. 2020/1125 and 1594.

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 Lead/Responsible Chief 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 Lead/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/epr/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 Annex A.

Document prepared by team of the NHSE/I Chief Pharmaceutical Officer; 14.09.21

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>