Standard Operating Procedure for the delivery of the COVID-19 vaccination booster & Flu immunisation programme Version 0.1.0

Role	Name	Date
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SOP Approval Group and Date		
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East Suffolk and North Essex NHS Foundation Trust (ESNEFT) will provide Covid-19 vaccines (booster) and seasonal flu vaccine to ESNEFT Staff, NHSP staff and staff from organisations across the ICS (as agreed by the ICS) as per the Joint Committee on Vaccination and Immunisation (JCVI) and national guidance priorities.

This will include immunisations to the following groups:

1. ESNEFT employees
2. OCS employees – Ipswich site
3. CCG employees from North Essex, Ipswich, East Suffolk and West Suffolk
4. Hospice Employees
5. All students on placements at ESNEFT sites
6. Volunteers
7. NHSP Staff undertaking work for ESNEFT

Note: for the purpose of this operational policy and written instructions, employees refers to employees of the authorising organisation (ESNEFT) or employees of another organisation the authorising organisation is commissioned to provide this vaccination service to.

1. Introduction

On 31 December 2019, the World Health Organization (WHO) was informed of a cluster of cases of pneumonia of unknown cause detected in Wuhan City, China.

On 12 January 2020, it was announced that a novel coronavirus was identified as the cause of the illnesses being detected. This virus is referred to as SARS-CoV-2, and the associated disease as COVID-19.

On 30 January 2020, the WHO Emergency Committee agreed that the outbreak met the criteria for a Public Health Emergency of International Concern and on 11 March 2020, the WHO declared COVID-19 as a pandemic.

The aim of the COVID-19 vaccination programme is to protect those who are at most risk from serious illness or death from COVID-19.

Pfizer BioNTech

The Trust is predominantly administering the Pfizer BioNTech COVID-19 mRNA vaccine BNT162b2 which is a mRNA (messenger ribonucleic acid) vaccine.

Pfizer BioNTech contains the genetic sequence (mRNA) for the spike protein which is found on the surface of the SARS-CoV-2 virus, wrapped in a lipid envelope (referred to as a nanoparticle) to enable it to be transported into the cells in the body. When injected, the mRNA is taken up by the host's cells which translate the genetic information and produce the spike proteins.

These are then displayed on the surface of the cell. This stimulates the immune system to produce antibodies and activate T-cells which prepare the immune system to respond to any future exposure to the SARS-CoV-2 virus by binding to and disabling any virus encountered.

As there is no whole or live virus involved, the vaccine cannot cause disease. The mRNA naturally degrades after a few days.

The phase 3 study demonstrated a vaccine efficacy of 95%, with efficacy across age, gender, and ethnicity. The observed efficacy in adults over 65 years of age was 94%

AstraZeneca

From February 2021, the Trust will administer AstraZeneca vaccine for a number of staff and patients in accordance with the national tiered system and for those staff and patients who require AstraZeneca due to the following reasons:

- Members of our staff who cannot have the Pfizer BioNtech vaccine due to contraindications

AstraZeneca Vaccine is a non-replicating viral vector vaccine which uses part of a weakened adenovirus as a carrier to deliver the genetic sequence for the SARS-CoV-2 virus spike protein into cells. The adenovirus has been modified so that it cannot replicate (grow and multiply by making copies of itself) in human cells and therefore cannot cause any disease.

The genes that encode for the spike protein on the SARS-CoV-2 virus have been inserted into the adenovirus's genetic code to make the vaccine. When the vaccine is injected, it enters the host's cells which then manufacture the spike protein. This then stimulates the immune system which reacts by producing antibodies and activating memory T cells to the SARS-CoV-2 virus without causing disease.

The AstraZeneca Vaccine has been evaluated from clinical trials which began in April 2020 and included just under 24,000 participants aged 18 and over from diverse geographical and racial groups in the UK, Brazil and South Africa. In an analysis of over 11,000 patients in the phase 3 study, overall vaccine efficacy against

symptomatic disease was 70.4%. Leaving a longer interval between the two doses has been shown to increase the immune response.

Administration of the Covid19 vaccine will be under the legal framework of the following: Patient Specific Directive (PSD) national Patient Group Directive (PGD) or according to the national protocol as authorised under the Human Medicines Regulations.

The guidance in this operational policy is based on current guidance from the Department of Health and Social Care, Public Health England, NHS England, NHS improvement and the Medicines & Healthcare Products Regulatory Agency (MHRA).

Seasonal Flu Vaccine

In line with the Joint Committee on Vaccination and Immunisation (JCVI) and national guidance priorities, staff will be offered the seasonal influenza vaccine as well as the Covid-19 booster vaccination. Inactivated influenza vaccine is indicated for the immunisation of staff for the prevention of influenza.

During 2020/21, the flu vaccination programme was extended, and more groups were eligible to receive flu vaccine than in previous years.

Although flu activity was low during 2020/21, flu activity during 2021/22 may be high. This is because the non-pharmaceutical interventions to prevent the spread of the coronavirus, such as shielding and social distancing, that were in place during 2020/21 have now been lifted and more of the population may be susceptible to flu this year.

As there may be winter outbreaks of COVID-19, protecting those at high risk of flu, who are also those most vulnerable to hospitalisation as a result of COVID-19, is vitally important. Flu immunisation is one of the most effective interventions immunisers can provide to reduce harm from flu and pressures on health and social care services during the winter.

2. The programme structure and team

The governance and oversight of the programme will sit with the Clinical Reference Group (CRG) under the current level 4 arrangements for the management of the COVID 19 pandemic.

2.1 The Following Team Make up the Programme Management Team:

SRO: Mike Meers

Chief Medical Officer: Angela Tillett

Chief Nurse: Giles Thorpe

Chief Pharmacist: Kevin Purser

Lead Consultants: Peter Phillips (Covid Vaccine) & Jose Sanchez (Seasonal Flu Immunisation)

Lead Nurse: Margaret Grant

Lead Pharmacist: Rawlings Osagie

Project Managers: Alex Osman (Colchester) & Rachel Death (Ipswich)

Training & Education Leads: Sarah Kench & Sharon Wyatt

2.2 Roles and Responsibilities of the Clinical Delivery Team:

Lead Nurse: To ensure the day to day operational management of the vaccination hubs at each site. This includes overall responsibility for ensuring staffing is in place for all shifts on a daily basis, all required checks and assurance documents are completed, all training and education for vaccinators is in date and documented in accordance with the Standard Operating Procedure for the Training of Staff Working on the

Training Vaccination Programme, upkeep of the 'Live register' of vaccinators and attendance at required assurance groups. The Lead Nurse is responsible to ensure their own absence or leave is covered through cross site support or for identification of deputy & escalation if this is not possible. The Lead Nurse is responsible to ensure the medical advice folder is up to date. The Lead Nurse is responsible to ensure no changes to this SOP are made on either site without agreement of the oversight group and mutual discussion prior to the next meeting.

Project Managers: To support the day to day operational management of the vaccination hubs at each site alongside the Lead Nurse. This includes overall responsibility for ensuring all equipment, IT equipment and consumables are stocked, with adequate supplies for weekends. To support the SRO in change management and oversight of the programme of work.

Shift Supervisors: Ensure the management of each session on a day by day basis in accordance with the Vaccine Supervision Checklist. To ensure the reporting and escalation of incidents in accordance with the Trust Incident Management Policy through the Datix system.

Prescribers: Responsible to ensure all relevant eLearning and mandatory education has taken place and familiarization with the PSD. Ensure all elements of the PSD are discussed with the patient and completed, including completing the prescription.

Medical Advisors: Responsible for advice and support for the vaccination hub on a day to day basis in accordance with the Medical Rota.

Vaccine Administrators: Responsible to ensure all relevant eLearning and/or face to face training has taken place in accordance with the Covid-19 vaccine & Seasonal Flu vaccine administration training schedule found in the SOP for the training of staff on the Covid-19 vaccination programme. The Vaccine administrators will complete all documentation in accordance with the PGD or PSD when in use and to escalate any adverse reactions to the Shift Supervisor or Lead Nurse of any adverse reactions.

Pharmacy Support: available on mobile phone to provide support on preparation of the vaccine and maintenance of stocks and relevant equipment in relation to the preparation of the vaccine. Responsible for the safe transportation and ensuring the vaccine preparation room is suitable and secure for the vaccine storage and handling.

Administration Team Leaders: To provide overall leadership and management of the administrative support for the vaccination hub, including oversight of training and schedules and document management. To ensure staff have direct access to NIVS and any other IT systems as required.

Administrative support: Responsible to ensure the day to day bookings have oversight and the smooth running of the hubs through IT and administrative support.

ICT support will be available at all times

Staffing:

Day to day staffing of the vaccination hub is the overall responsibility of the Lead Nurse. Human Resources will provide the day to day direct management of the rosters, with escalation and assurance to the Lead Nurse.

2.3 Legal:

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

All activity covered in this SOP is aligned with relevant Seasonal Flu Immunisation & 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

There are three key requirements from a legal and governance perspective that immunisers need to have in place before a vaccine can be given:

- Consent: Informed consent or best interest declaration from the patient or an appropriate alternative person if the patient cannot legally give consent
- Process for safe medicines administration in accordance with latest PSD, PGD or national protocol
- Knowledge and skills: Immunisers need to have the knowledge and skills to offer information and administer vaccinations
- Support and governance in place to ensure the safe administration of vaccine on a day to day basis, including the daily supervision and debrief session.

Governance:

The Clinical Reference Group (CRG) has responsibility for the clinical review of the Covid-19 Vaccination Booster & Flu Programme and will make recommendations to the Executive Management Committee, which maintains overall responsibility for the Covid-19 vaccination programme.

Due to the rapid pace of delivery of the national vaccination programme a Patient Specific Directive (PSD) & a Patient Group Directive (PGD) have been mandated nationally. The seasonal flu immunisation programme is nationally mandated. Clinical negligence liability will be covered by the Trust's CNST indemnity and relevant individual clinician indemnity cover arrangements. Individual clinician's indemnity cover will be checked and validated by Human Resources team prior to prescribing for this programme.

This SOP should be read in conjunction with the following policies & procedures:

- ESNEFT Vaccine Management policy
- Medication Policy for Healthcare Professionals
- ESNEFT Covid-19 Vaccine Handling and Management Policy 2020/21
- Standard Operational Policy for the training of staff working on the Covid-19 Booster & Flue vaccination programme
- VH8 Preparation of Pfizer-BioNTech Covid-19 Vaccine Syringes for Administration
- VH8.2 Vaccine Supervision Checklist
- AZH3 Preparation of AstraZeneca COVID-19 Vaccine Syringe for Administration
- AZH3.2 AstraZeneca Vaccine Supervision Checklist

Reporting and Assurance

A weekly briefing report will be delivered to CRG with exception reporting to EMC. The Phase 3 – Flu & Covid Booster Group will meet twice weekly and the Complex Patient Group on an ad hoc basis.

3. Delivery arrangements and pharmacy storage of the vaccine

The pharmacy will be responsible for the ordering, inventory management, receipt and storage of the Flu Vaccine & Covid 19 vaccine as per the manufacturer's recommendations. For the Pfizer BioNTech Covid 19 vaccine BNT 162b2 this will include storage in an ultra-low temperature freezer at minus 70 degree.

Covid 19 & Flu vaccines will be supplied to the relevant vaccine hub room as per pharmacy SOPs as listed above.

4 . Prescriber and vaccinator training

All prescribers and peer vaccinators will be required to have completed the online training outlined in the training matrix's for NHS Professionals and for ESNEFT Staff. The online training will be followed by the relevant face-to-face training recommended for each staff group. Where a PSD is used, prescribers need to be medical practitioners, independent nurse or pharmacist prescribers (who are suitably trained with experience in immunisation)

Vaccinators will have completed the required training for the recording of the administration of the vaccine and any further training as deemed a requirement for their staff group and in accordance with the Standard Operational Policy for the training of staff working on the Covid-19 Booster & Seasonal Flu vaccination programme.

Evidence of completed eLearning and relevant face-to-face training will be the responsibility of the individual and this includes the following staff groups: vaccine administrator, pharmacist, prescriber (including Medical staff) and administrative staff. Staff who have already been awarded the C19 Covid 19 Vaccinator Competency (Pfizer) will be listed in the C19 Vaccinator Register – available in MS Teams. Verification of Flu Vaccinator training must be checked by the Shift Supervisor on the day and receipt of any new certificates recorded on the Microsoft Form on Teams. This is automatically submitted daily to the Education Team for recording on OLM. Recording on OLM will be retrospective for ESNEFT Staff only and may take up to 72 hours to be shown on the C19 Vaccinator Register. Staff should be advised to keep certificates with them, until the register reflects their Flu competency. NHSP staff will be recorded on the central training record spreadsheet and stored in the Covid-19 Immunisation central files and a copy sent to NHSP for recording on the individuals NHSP file. Any changes to training will be disseminated through the Lead Nurse who will have responsibility to ensure all staff are aware of the changes and have undertaken any further training.

All staff working in the vaccination hubs must be offered and encouraged to undertake routine lateral flow testing in accordance with Trust policy. Any member of staff testing positive must follow Trust and National guidance for notification, isolation and further testing.

Lateral Flow Testing kits are available in both vaccination hubs for staff which are signed for as per Trust policy.

5. Vaccine collection and distribution to vaccinators

The pharmacy team will ensure sufficient quantities of vaccines will delivered to the vaccination site on an as required basis.

The AstraZeneca COVID-19 Vaccine is stored at 2 to 8 degrees Celsius. Once thawed, the Pfizer BioNtech Covid-19 mRNA Vaccine (Comirnaty) has an expiry of 1 month when kept in a fridge at 2 to 8 degrees Celsius. Details of the safe transfer, storage and transfer of vaccine are included in the ESNEFT Covid-19 Vaccine Handling & Management Policy, AZH3 Preparation of AstraZeneca COVID-19 Vaccine Syringes for Administration, VH8 Preparation of Pfizer-BioNtech Covid-19 Vaccine Syringes for Administration and Summary of Product Characteristics for Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified). Refer to the Summary of Product Characteristics for details on storage and handling for the specific product used for the flu vaccination.

The Shift Supervisor will be responsible for vaccine receipt from the pharmacy team ensuring that batch doses are checked and logged for each session and included on NIVS.

6. Vaccine administration

The prescriber has the responsibility for the prescribing and the administration of the vaccine under the PSD, however the Shift Supervisor will be responsible for oversight of vaccinators on their shift and safe reconstitution (where necessary), handling and administration of the Covid-19 vaccine in accordance with

VH8.2 Pfizer-BioNTech and AZH3.2 AstraZeneca Vaccines Supervision Checklists. The Prescriber should familiarize themselves with the Patient Specific Direction (PSD) for the administration of Pfizer-BioNTech COVID-19 mRNA Vaccine (Comirnaty) and the AstraZeneca COVID-19 Vaccine.

Authorised staff under the national PGD can administer the Pfizer-BioNTech COVID-19 mRNA vaccine (Comirnaty), AstraZeneca COVID-19 Vaccine and Flu vaccine. The staff must be familiar with the latest national guidance for the safe administration of the vaccine including reference to the Green book on immunization and the PHE Covid-19 vaccination programme –information for healthcare practitioners.

The Flu Vaccine will be administered under the written directions (see appendix) as per the Seasonal Flu Vaccination Programme. A Covid-19 booster and flu immunisation will be offered simultaneously.

The Shift Supervisor will ensure that the session checklist is completed and that completed checklists are uploaded to the programme file. The Shift Supervisor has full responsibility to ensure the daily check of the Resuscitation Trolley and any associated equipment in accordance with the Trust Resuscitation Policy. Any patient safety issues or concerns will be escalated to the Shift Supervisor who will escalate further if required to the Programme Lead Nurse.

There will be Medical advice available at all times via telephone.

Identification of staff receiving the vaccine: staff will be asked to bring their ID badge and provide their name and DOB prior to immunisation

Any wasted vaccines should be reported to the shift supervisor and to the pharmacist. The shift supervisor must complete a pharmacy wastage form and this should be scanned to the appropriate file on the central Covid-19 files.

Any unused vaccines are to be returned to the Shift Supervisor at the end of the session. All wasted vaccines should be reported on the daily debrief.

AstraZeneca vaccine administration will be held in separate vaccination hub to Pfizer-BioNTech vaccine, this will be at the outpatient COVID-19 vaccine clinic at each site. Each vaccine has specific syringes which must be held in proximity to the vaccine for which they are suitable. Signs supporting the specific vaccine being prepared or administered should also be in use in the vaccination booths and pharmacy rooms. It is the responsibility of the shift coordinator to fully check the vaccination hub to ensure all un-necessary equipment and signage is appropriate.

Any vaccine not used in the clinic should be removed or locked in the specific fridge used for that vaccine to ensure there is no possibility of the wrong vaccine being administered. Ideally, the vaccine should be removed by pharmacy and returned to the pharmacy, however this may not be possible and therefore the relevant fridge must be kept locked when not in use. It is the shift coordinators responsibility to ensure the vaccine is removed or the fridge locked appropriately.

7. Vaccination Hubs and equipment at Colchester and Ipswich Hospitals

Vaccine Hubs will be situated in Villa 2 at Colchester Hospital and at the Occupational Health Offices at Ipswich Hospital.

The vaccine sites will be open to all eligible groups from the core hours of 9am - 7pm Tuesday through Saturday, being flexible to meet the needs of the national and local programme.

Designated vaccination rooms will have sufficient space for social distancing and appropriate facilities including telephones, computers for accessing health records and e-forms. Equipment for managing anaphylaxis, and resuscitation equipment will be present and is detailed in Appendix 2 & 3.

Vaccination booths will have curtains to maintain dignity, 2 chairs, a small table and a computer on wheels. A trolley will be available in the vaccination hub in the event of a person feeling unwell.

The waiting area will have chairs to ensure social distancing and face coverings/masks must be worn whilst awaiting vaccination.

The Hubs will have an area with seating for use following vaccination, to allow for 15 minutes of rest should the vaccinated person need to drive. A one- way system and markers to encourage social distancing and signage will be placed to aid safe flow.

8. Personal Protective Equipment (PPE)

PPE for all staff in the vaccination area should follow trust guidelines and the shift supervisor will be responsible to ensure adequate PPE is available.

Vaccinators will require the following items of PPE, instructions for donning and doffing can be found on the Trust Intranet on the infection control pages

- Fluid resistant surgical face mask (FRSM) for sessional use
- Gloves, aprons & face visors will be available for use where exposure is likely

There are no specific spillage requirements for the vaccine. Sharps and PPE disposal bins will be available at each vaccinating station.

All persons attending for vaccinations must wear face coverings in accordance with national guidance.

There are handwashing facilities available at both hubs and hand sanitizer available in each vaccination station and on entrance and exit to the vaccination hubs. Vaccinators must use handwashing in preference to hand sanitizer between patients.

9. Emergency and resuscitation procedures and equipment

The vaccination hub has a full Resuscitation trolley including adrenaline for anaphylaxis. It is the Shift Supervisors responsibility to do a daily check of all emergency equipment as per trust policy prior to session commencing.

Should a patient have an anaphylactic reaction then the management of anaphylaxis and /or basic life support should be commenced and staff should call **2222.** A copy of the Resuscitation Council anaphylaxis algorithm in clinical area is available in clinical areas and in appendix 2-4. Should a patient have a cardiac arrest then staff should call “””” and follow appendix 1. A copy is available on the resuscitation trolley.

Switchboard and the resuscitation team have been made aware of the location of each vaccinating hub and individual risk assessment for accessing emergency help and transfer of any unwell patients should be taken on an individual basis for transfer to the main hospital if required.

10. Safety, Incident reporting and evaluation

Any untoward incidents or near misses should be recorded by the shift supervisor at the end of the session on the shift summary checklist and discussed at the end of day debrief. The checklists will be reviewed on a daily basis by the lead pharmacist and lead nurse and any issues escalated to the CMO, CN and Chief Pharmacist. Incident reporting should be undertaken as per ESNEFT Trust policy.

A drop down box for Covid-19 immunisation is available on DATIX. Consideration should be made to report an incident to the MHRA Covid 19 reporting portal https://coronavirus-yellowcard.mhra.gov.uk

A debrief will be undertaken daily to trouble shoot and ensure rapid learning / feedback to vaccinating teams and SIMT.

All ineligible patients will be identified daily and entered on to the NIVS system by the administration team and noted on the daily debrief by the shift supervisor. The Lead Nurse will then escalate these cases to the Clinical Advisory Group for discussion and agreement of any further actions required.

Appendix 4 shows the national incident reporting framework through escalation to the Regional Vaccination Operations Centre (RVOC). RVOC will then liaise with the Clinical Advice Response Service (CARS) to appropriately address the enquiry or incident. Incidents which require notification to the RVOC will be reported by the SRO.

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ovid-19_Vaccination

11. Consent process and booking

For staff being immunised: Staff will be called to book via email. Staff will be asked to complete all information on the COVAC app prior to attending for their vaccination (PGD). Administrative staff will confirm with the member of staff that the form has been completed. The vaccinator will then review the details of the PGD (on COVAC) with the person to be vaccinated, confirming the information given and allowing time to answer further questions. Consent will then be gained, confirming consent and by the vaccintator and this will be confirmed on COVAC. If there is any doubt regarding suitability to receive the vaccine then further advice from Lead Nurse, Shift Supervisor or Medical advisor will be sought.

On arrival at the vaccination area, a further information sheet will be provided.

Vaccinators will need to ensure that the person to be vaccinated has capacity to consent and if in doubt will seek support from the Lead Nurse or Shift Supervisor. Consent processes will follow national guidance and ensure this is informed, voluntary and the person has capacity to consent.

12. Administration teams, Data collection and sharing

Each vaccination session will be supported by 3 administrators who will be responsible for data administration in accordance with local and national guidelines.

Information relating to vaccination will be recorded on National Immunisation Vaccination System (NIVS) via the use of the COVAC app.

13. Security & Cleaning

The Vaccination Hub in Villa 2 Colchester will be unlocked in the morning by the Session Supervisor and locked in the evenings following the final checks by the Session Supervisor.

The Vaccination Hub in the Occupational Health Department at Ipswich will be shared with the Occupational Health Service and the key code will be provided to the session supervisors. The session supervisor will be responsible for ensuring the doors are closed and lock engaged at the end of the session. Vaccine will be returned to main pharmacy if there is no secure storage overnight. The session supervisor will inform pharmacy should a return of vaccine for security reasons be necessary.

Floors, fixtures and fittings will be cleaned daily by the Vaccination Hub's Facilities. Cleaning will take place prior to/at the end of the day. Cleaning of surfaces in waiting area and vaccination booths will be completed by the administrative team and the vaccinators after each service use.

14. Management of Medical Records and Pharmacy Records
Documentation should be securely stored at all times, in adherence to patient confidentiality and Information Governance Requirements.

PGD & PSD: The Chief Pharmacist and Medication Safety Pharmacist will have full oversight of version control and will ensure that following any change to documentation, all old versions are removed from both sites and the most up to date version put in place.

Pharmacy Batch worksheet: Records will be scanned and uploaded to the Covid-19 Trust files by the IT Team upon receipt from the vaccination hubs.

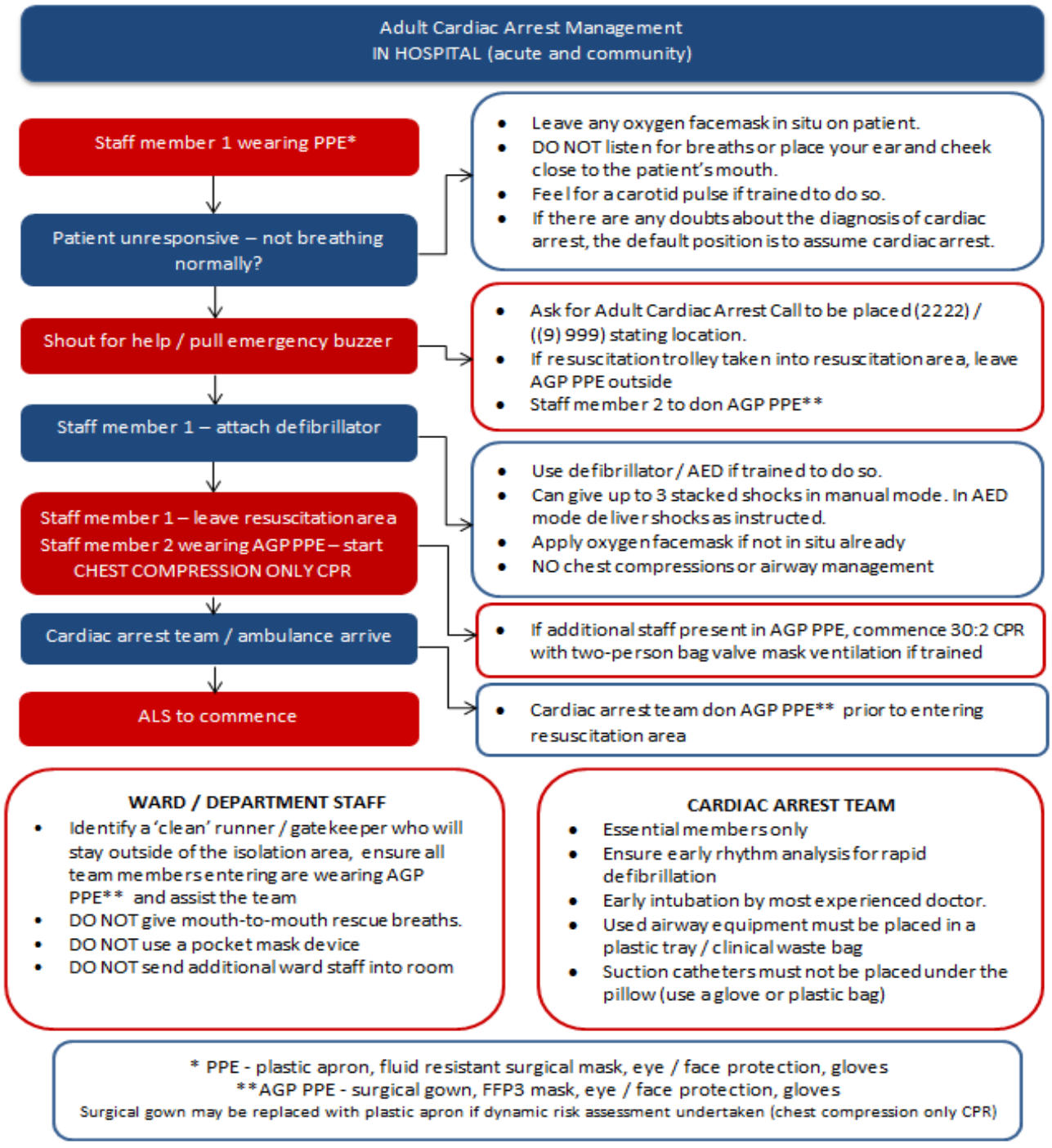
15. Audit Requirements- there will be periodic audit of record keeping compliance and other audits as deemed appropriate by the CRG.

16. Change Management

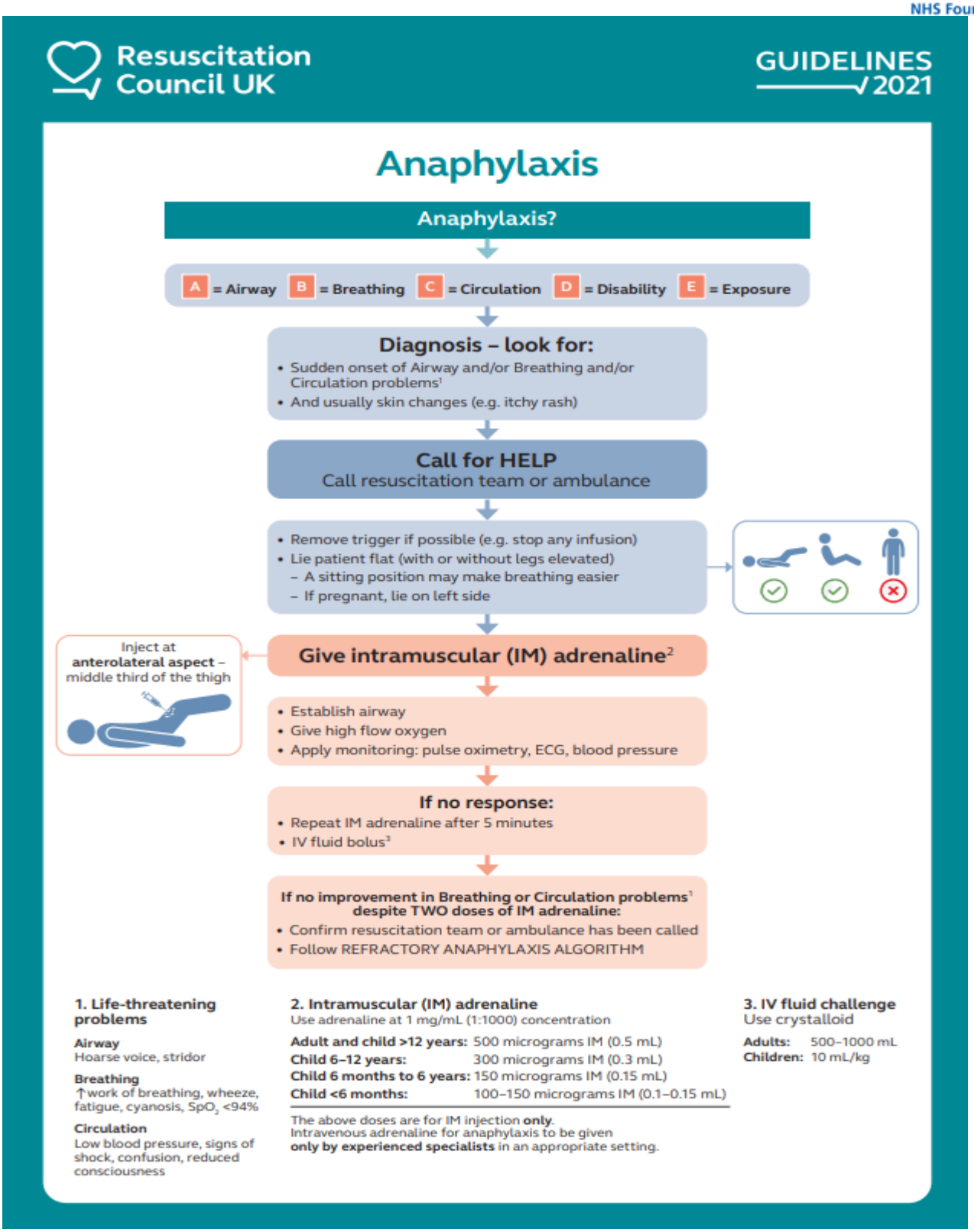
All current and archived versions of all documents related to the Vaccination Programme will be stored in the same central files.

Appendix1

Emergency Protocol



Appendix 2


Resuscitation Council UK
GUIDELINES 2021
Anaphylaxis
Anaphylaxis?
A = Airway
B = Breathing
C = Circulation
D = Disability
E = Exposure
Diagnosis – look for:
• Sudden onset of Airway and/or Breathing and/or Circulation problems[1]
• And usually skin changes (e.g. itchy rash)
Call for HELP
Call resuscitation team or ambulance
• Remove trigger if possible (e.g. stop any infusion)
• Lie patient flat (with or without legs elevated)
– A sitting position may make breathing easier
– If pregnant, lie on left side
Inject at anterolateral aspect – middle third of the thigh
Give intramuscular (IM) adrenaline[2]
• Establish airway
• Give high flow oxygen
• Apply monitoring: pulse oximetry, ECG, blood pressure
If no response:
• Repeat IM adrenaline after 5 minutes
• IV fluid bolus[3]
If no improvement in Breathing or Circulation problems[1] despite TWO doses of IM adrenaline:
• Confirm resuscitation team or ambulance has been called
• Follow REFRACTORY ANAPHYLAXIS ALGORITHM
1. Life-threatening problems
Airway
Hoarse voice, stridor
Breathing
↑work of breathing, wheeze, fatigue, cyanosis, SpO2 <94%
Circulation
Low blood pressure, signs of shock, confusion, reduced consciousness
2. Intramuscular (IM) adrenaline
Use adrenaline at 1 mg/mL (1:1000) concentration
Adult and child >12 years: 500 micrograms IM (0.5 mL)
Child 6–12 years: 300 micrograms IM (0.3 mL)
Child 6 months to 6 years: 150 micrograms IM (0.15 mL)
Child <6 months: 100–150 micrograms IM (0.1–0.15 mL)
The above doses are for IM injection only.
Intravenous adrenaline for anaphylaxis to be given only by experienced specialists in an appropriate setting.
3. IV fluid challenge
Use crystalloid
Adults: 500–1000 mL
Children: 10 mL/kg

Appendix 3

Protocol for the management of medical emergency or cardiac arrest at the Covid-19 vaccination centre
Colchester Hospital Hub

In the event of a medical emergency or cardiac arrest dial 2222 from an internal phone and state:

"Medical emergency / cardiac arrest covid vaccination centre Villa 2, Colchester Hospital"

The vaccination centre will have the following emergency equipment:

ITEM	QUANTITY
Adult resuscitation trolley (defib capable of BP and SpO2 monitoring) with anaphylaxis algorithm present	X1
Stretcher with oxygen cylinder at least ¾ full	X1
Scoop	X1

Emergency equipment must be checked and signed for at the beginning of each day prior to opening.

Staff administering vaccinations are to ensure there is an FFP3 mask available that they have been FIT tested to.

If a patient requires transfer to the Emergency Department / main hospital building a risk assessment will be carried out by the cardiac arrest team to ensure the most appropriate route is taken.

- Patient becomes unresponsive - Responder 1 to check for danger and signs of life.
- Responder 1 to shout for help – if no response and no signs of life, ask for AED and 2222 call
- Responder 2 brings AED and initiates 2222 call – ADULT CARDIAC ARREST, COVID VACCINATION CENTRE, Villa 2, Colchester Hospital"
- Responder 1 to turn on AED and follow instructions, place pads on the patient and deliver shock as necessary –having removed clothes as required.
- Responder 2 to 'don' AGP PPE (FFP3 mask, eye protection, surgical gown (optional) and gloves) to start chest compressions
- Responder 2 returns to patient to start chest compressions once AED is used
- Responder 1 to step away and 'don' AGP PPE and return to patient with Bag/Valve/ mask to deliver 2 breaths
- Carry on 30:2 until Cardiac arrest team arrives with main resuscitation trolley.
- Responder 3 (if present) to move other patients away as quickly and as safely as possible and direct team to area
- Cardiac arrest team to 'don' AGP PPE whilst team continue 30:2

Appendix 4

Protocol for medical emergencies or cardiac arrest in

the Covid Vaccination Centre.
Ipswich Hospital Hub.

In the event of a medical emergency or cardiac arrest dial 2222 from an internal phone and state:

"Cardiac arrest Covid vaccination centre, Occupational Health, North End, 1st Floor

For medical emergencies, fast bleep the medical registrar by calling 4221.

The vaccination centre will have the following emergency equipment:

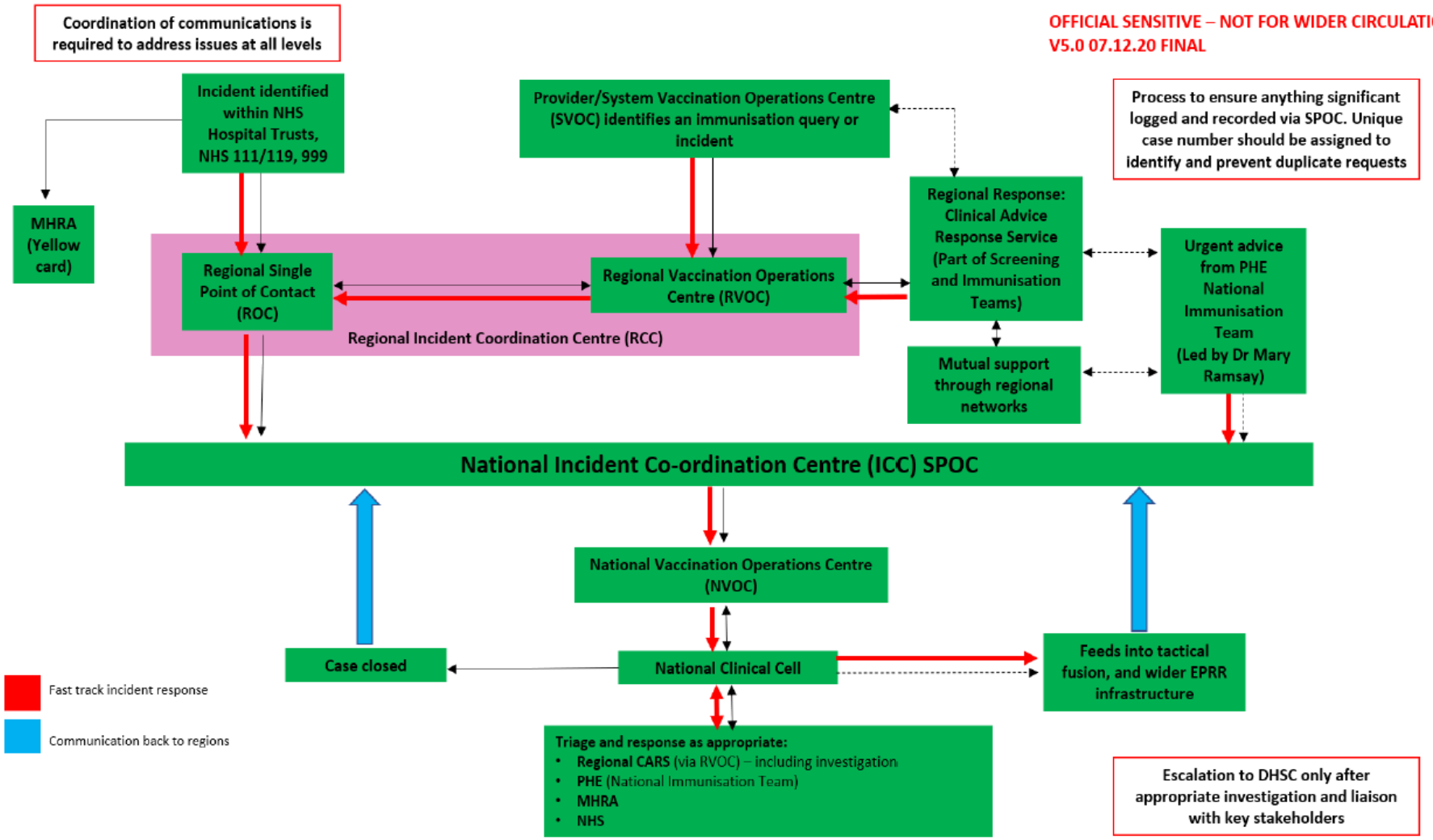
ITEM	QUANTITY
Adult resuscitation trolley (defib capable of BP and SpO2 monitoring) with anaphylaxis algorithm present	X1
Stretcher with oxygen cylinder at least ¾ full	X1
Scoop	X1

Emergency equipment must be checked and signed for at the beginning of each day prior to opening.

Staff administering vaccinations are to ensure there is an FFP3 mask available that they have been FIT tested to. There should be one member of staff FIT tested on each shift, and the relevant PPE available (Mask, Gowns, Gloves, Visors)

- Patient becomes unresponsive - Responder 1 to check for danger and signs of life.
- Responder 1 to shout for help – if no response and no signs of life, ask for AED and 2222 call
- Responder 2 brings AED and initiates 2222 call – ADULT CARDIAC ARREST, COVID VACCINATION CENTRE, Occupational Health, North End of Hospital, 1st Floor
- Responder 1 to turn on AED and follow instructions, place pads on the patient and deliver shock as necessary –having removed clothes as required.
- Responder 2 to 'don' AGP PPE (FFP3 mask, eye protection, surgical gown (optional) and gloves) to start chest compressions
- Responder 2 returns to patient to start chest compressions once AED is used
- Responder 1 to step away and 'don' AGP PPE and return to patient with Bag/Valve/ mask to deliver 2 breaths
- Carry on 30:2 until Cardiac arrest team arrives with main resuscitation trolley.
- Responder 3 (if present) to move other patients away as quickly and as safely as possible and direct team to area
- Cardiac arrest team to 'don' AGP PPE whilst team continue 30:2

Appendix 5


Coordination of communications is required to address issues at all levels
OFFICIAL SENSITIVE – NOT FOR WIDER CIRCULATION
V5.0 07.12.20 FINAL
Incident identified within NHS Hospital Trusts, NHS 111/119, 999
Provider/System Vaccination Operations Centre (SVOC) identifies an immunisation query or incident
Process to ensure anything significant logged and recorded via SPOC. Unique case number should be assigned to identify and prevent duplicate requests
MHRA (Yellow card)
Regional Single Point of Contact (ROC)
Regional Vaccination Operations Centre (RVOC)
Regional Response: Clinical Advice Response Service (Part of Screening and Immunisation Teams)
Urgent advice from PHE National Immunisation Team (Led by Dr Mary Ramsay)
Regional Incident Coordination Centre (RCC)
Mutual support through regional networks
National Incident Co-ordination Centre (ICC) SPOC
National Vaccination Operations Centre (NVOC)
Case closed
National Clinical Cell
Feeds into tactical fusion, and wider EPRR infrastructure
Fast track incident response
Communication back to regions
Triage and response as appropriate:
Regional CARS (via RVOC) – including investigation
PHE (National Immunisation Team)
MHRA
NHS
Escalation to DHSC only after appropriate investigation and liaison with key stakeholders

NHS
East Suffolk and North Essex
NHS Foundation Trust

East of England: Covid VaccinationnRVOC Incident Notification and Reporting Proforma to be completed in line with the below National SOP.

https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/12/C0951-Managing-Covid-19-Vaccination-Incidents-and-Enquiries-SOP-v2-18-December-2020.pdf

Date/ time (DD/MM/YYYY/ HH:MM 24hr)	Organisation Name Address: ODS Code	LVS/HH/VC	Incident type:	Severity of incident / impact assessment (From National Clinical SOP)-	URGENT FAST TRACK
			Actual/Near Miss Clinical/Non-Clinical Delete as required	Limited Moderate Significant Critical Delete as required	Y / N
Description of Incident/Near Miss:					
Mitigation/Action taken:					
Outcome:					

Name of Person completing form:	Contact details:	Further Reporting Required: E.g. MHRA Yellow Card/RIDDOR/HSE	Local SI reporting completed (e.g. Datix):	Entered on Foundry Y/N

Appendix 6

ESNEFT Weekly Vaccination Hub Report

Date of Report	
Week of reporting	
Author	

Vaccination Information

Colchester:

Ipswich:

Total:

Pregnant Women Vaccinated:

Patients unable to be vaccinated, reasons and follow up:

Number of doses wasted and reasons:

Incidents – brief summary of each incident, investigation, actions taken and actions required

Workforce & Staffing

Training & Education

Record Keeping

Infection Control

Appendix 7 - Pathways

The following pathways have been agreed by the Vaccination Governance Group January 26th 2021.

Vaccinees with adverse reaction at time of vaccination

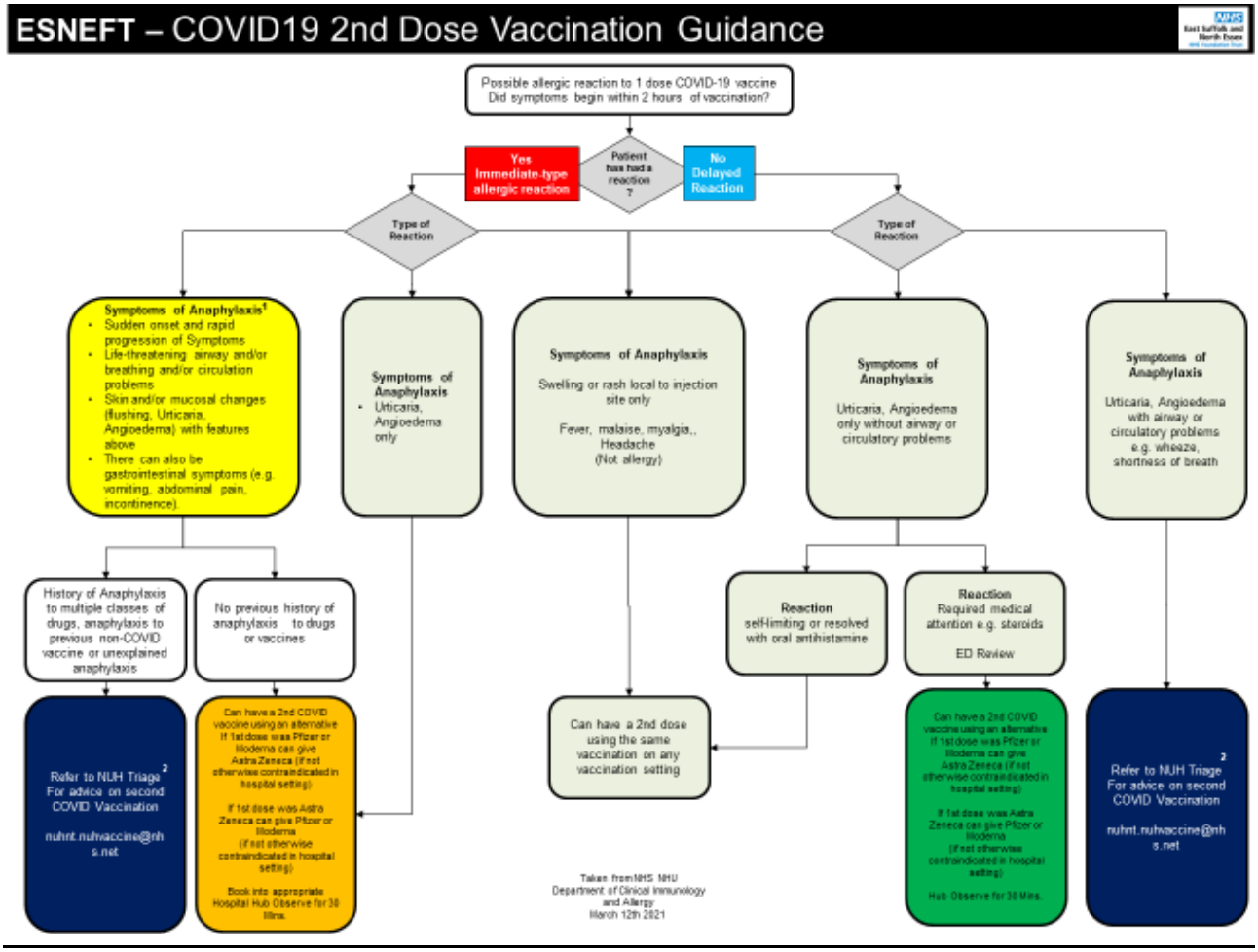
1. Acute event managed appropriately
2. Details of event documented on PGD or PSD. **Every incident reported on Datix by the Shift Coordinator before the end of their shift.**
3. If staff member:
    - Indicate on Datix form that the incident is a member of staff as vaccination incidents will be automatically notified to Occupational Health.
    - Staff member given photocopy of PGD or PSD
    - Occupational Health communicate with staff member if necessary and inform their GP.
4. If non-staff member then shift coordinator gives vaccinee a photocopy of the PGD or PSD detailing incident for them to share with GP in order to maintain records.
5. Report any suspected allergic or anaphylactic reactions as a Yellow Card as per MHRA requirements.
6. Log of any incidents on the daily governance/debrief sheets needs to be kept by the shift coordinator and passed onto the hub Lead Nurse
7. All incidents will be reviewed weekly by the nurse lead, pharmacist and AD Clinical Governance, with clinical support as needed and reported to at the weekly Governance Oversight Group.
8. Decision will be taken either at time or after discussion with governance group as to how vaccinee will receive subsequent doses
9. Log of rejected patients will be kept to provide assurance that these patients receive alternative vaccination; this should be stored in the central Covid Vaccination files.
10. Any persons experiencing anaphylaxis must be referred to the Specialist Allergy Testing Centre at Addenbrookes Hospital for follow up testing by the patients GP on discharge from ED or from an inpatient ward. Tryptase levels must be taken in accordance with guidelines whilst in ED, as an inpatient or advice to the GP as required.
11. Any persons experiencing anaphlylaxis must be sent to the Emergency Department. Tryptase levels will be taken: initial sample as soon as possible after the event, a second sample ideally within 1–2 hours (but no later than 4 hours) and a third sample at 24 hours or in convalescence (for example in a follow up allergy clinic). This provides baseline tryptase levels - some individuals have an elevated baseline level

Simple faints will be reported on Datix, but not reported as a yellow card. If in future simple faints need to be yellow carded the records will be there.

Allergy and second dose guidance

There are very few individuals who cannot receive the Pfizer BioNTech, Moderna or AstraZeneca COVID-19 vaccines. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.

Vaccinees rejected because of allergic reactions will be reviewed each week by the medication safety pharmacist and medical vaccinators at each site on a weekly basis. A decision will be taken as to whether it is safe to vaccinate or whether the vaccinee needs onward referral to a specialist centre. Where a decision is taken to vaccinate this should be undertaken at a session where there is a medical vaccinator present.



Pregnancy

1. Vaccination to be carried out under a PGD Make clear on PGD person is pregnant
2. Informed decision making conversation with vaccine using all available evidence/information. Make sure it is written on PGD that discussion has taken place and vaccine has a copy of and has read government information leaflet
3. Vaccinee needs to also be informed that details will be entered into the vaccination in pregnancy surveillance programme.
4. Vaccinee needs to be given information to take away regarding surveillance programme

   (VIP surveillance has been established for COVID-19 vaccination in pregnancy – PHE guidance issued in April 2021 states that surveillance is now only required in the case of unintentional vaccination). Background information on the medical history of the pregnant women including prior pregnancies is collected at the time of reporting and these are then followed 10 weeks post estimated date of delivery to determine the pregnancy outcome and

initial information for all live births with a final follow up when the baby reaches their first birthday

5. Shift coordinator must scan a copy of the PGD and update the database of persons vaccinated in pregnancy. This is stored in the appropriate file on the Covid 19 Vaccination shared drive.

East Suffolk and North Essex NHS Foundation Trust

Appendix 8 – Flu written instructions

Written instruction to administer inactivated influenza vaccine as part of an NHS Body* or Local Authority occupational health scheme, which may include peer to peer immunisation (2021/22)
For use only by the following: registered nurses, registered midwives, registered nursing associates, registered operating department practitioners, registered paramedics, registered physiotherapists and pharmacists

Organisation name:	East Suffolk and North Essex NHS Foundation Trust (ESNEFT) This can only be an NHS Body* or a Local Authority operating an occupational health scheme
Date of issue:	1st September 2021
Date of review (not to exceed one year from date of issue):	31st August 2022
Reference number:	FLU3
Version number:	1.0
Details of local ratifying committee/governance approval or similar as appropriate:	ESNEFT Patient Group Directions Panel as a sub-group of the ESNEFT Medicines Governance Group

Name and signature of the registered doctor authorising occupational health vaccinators, who declare themselves (in Section 3) to have met the training and competency requirements defined in this written instruction, to operate under this written instruction on behalf of the named organisation.**
Note in the absence of an Occupational Health Service (OHS) physician this can be signed by an organisation's medical director. The Doctor signing this written instruction on behalf of the organisation they are employed by must be working within their own competency when signing.

Name	GMC Registration Number	Job Title	Signature	Date
Dr Jose Sanchez	4245670	Consultant in Occupational Health, ESNEFT		13th August 2021

*** An NHS Body is defined in the Human Medicines Regulations 2012 (HMR 2012) as one of the following:**

- **the Common Services Agency**
- **a health authority**
- **a special health authority**
- **a Clinical Commissioning Group**
- **an NHS trust**
- **an NHS foundation trust**

**** Occupational health vaccinators are defined in Regulations 8 of the HMR 2012, as amended by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020. In accordance with Regulation 8 and Schedule 17 of HMR 2012, occupational health vaccinators employed or engaged by a person operating an occupational health scheme and operating under this written instruction may be: Registered nurses, midwives and nursing associates currently registered with the Nursing and Midwifery Council (NMC); operating**

department practitioners, paramedics and physiotherapists registered in Part 13, 8 or 9 of the Health and Care Professions Council register; Pharmacists registered with the General Pharmaceutical Council.

1. Training requirements

Qualifications and professional registration	Occupational health vaccinators, employed or engaged by a person operating an occupational health scheme, and with one or more of the following professional registrations: • Registered nurses, midwives and nursing associates registered with the Nursing and Midwifery Council (NMC). • Operating department practitioners, paramedics and physiotherapists registered in Part 13, 8 or 9 of the Health and Care Professions Council register. • Pharmacists registered with the General Pharmaceutical Council. **NO OTHER PRACTITIONERS CAN USE THIS WRITTEN INSTRUCTION**
Training and competency	All vaccinators (listed above) must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continuing Professional Development (CPD). All vaccinators (listed above) should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. All vaccinators (listed above) must have undertaken training appropriate to deliver influenza immunisation under this written instruction as required by local policy. This should be informed by the National Minimum Standards and Core Curriculum for Immunisation and tailored to the skills and competencies required for the safe and effective delivery of influenza immunisation services, including peer to peer immunisation. All vaccinators (listed above) must be competent in the handling and storage of vaccines, and management of the cold chain. Training required by ESNEFT: • Yearly training on influenza vaccine administration • Recent CPR training including anaphylaxis training.
Competency assessment	All vaccinators (listed above) operating under this written instruction are personally responsible for ensuring they remain up to date with the use of the vaccine/s included. If any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the Written Instruction and further training provided as required.

	The training undertaken will be recorded on the staff member's OLM training record. This will be checked by the shift supervisor at the start of the staff member's first shift.

2. Details of inactivated influenza vaccine to be administered:

Clinical condition or situation to which this written instruction applies	Inactivated influenza vaccine is indicated for the immunisation of staff for the prevention of influenza. *Note: Staff refers to staff of the authorising organisation or staff members of another organisation the authorising organisation is commissioned to provide this vaccination service to.*
Criteria for inclusion	Inactivated influenza vaccine should be offered to the following staff: • Employees aged 18 years and over including those in clinical at-risk groups. • Employees aged 16-17 years **not** in a clinical at-risk group. • Vaccination also offered to contracted/commissioned staff including site workers, hospitality staff and students.
Criteria for exclusion	Individuals for whom no valid consent has been received (for further information on consent see Chapter 2 of 'The Green Book'). Individuals who: • Are under 16 years of age • Employees aged 16-17 years in a clinical at-risk group – they should be advised to attend their GP surgery to be immunised with LAIV. • Have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process[1] (other than ovalbumin – see Cautions). • Have received a dose of influenza vaccine for the current season • Are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken	Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of administration). Individuals with a severe anaphylaxis to egg which has previously required intensive care can be immunised in any setting using an egg-free vaccine, Flucelvax® Tetra▼ (QIVc),

[1] Residues from the manufacturing process may include beta-propiolactone, cetyltrimethylammonium bromide (CTAB), formaldehyde, gentamicin, hydrocortisone, kanamycin, neomycin, octoxinol-9, octylphenol ethoxylate, polysorbate 80, sodium deoxycholate. Check individual vaccine product SPC for details.

	which is licensed for use in this age group. Individuals with less severe egg allergy can be immunised in any setting using an egg-free vaccine or inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml (equivalent to 0.06 micrograms in a 0.5 ml dose). For details of the influenza vaccines available for the 2021/22 season and their ovalbumin content see Influenza vaccines: 2021 to 2022 flu season. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
Action to be taken if the client is excluded	Where appropriate, such individuals should be referred to the Occupational Health Consultant. In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed. Document the reason for exclusion and any action taken in the individual's vaccine record.
Action to be taken if the client declines treatment	Advise the individual about the protective effects of the vaccine, the risks of infection to themselves, their families and the organisation's service users and potential complications if not immunised. Advise how future immunisation may be accessed if they subsequently decide to receive the inactivated influenza vaccine. Document, in accordance with local policy, advice given and the decision reached.
Arrangements for referral for medical advice	All immunised people to be given the patient information leaflet, which provides guidance on when to seek advice from Occupational Health or their GP.

<table>
<tr><th colspan="2">Description of treatment</th></tr>
<tr><td>Name, strength & formulation of drug</td><td>
Inactivated influenza vaccine suspension in a pre-filled syringe, including:

adjuvanted quadrivalent influenza vaccine (aQIV), Fluad Tetra▼
cell-based quadrivalent influenza vaccine (QIVc), Flucelvax® Tetra▼
egg-grown quadrivalent influenza vaccine (QIVe)
recombinant quadrivalent influenza vaccine (QIVr), Supemtek▼

The vaccines that are available for the 2021 to 2022 influenza immunisation programme are listed here: www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content

Some influenza vaccines are restricted for use in particular age groups. The SPC for individual products should always be referred to.

Summary table of which influenza vaccines to offer (by age)
<table>
<tr><td>16-17 year olds NOT in a clinical at-risk group</td><td>Offer QIVc or QIVr.</td></tr>
<tr><td>18 years to under 65 years</td><td>Offer QIVc or QIVr.
Or, if QIVc or QIVr are not available, offer QIVe.</td></tr>
<tr><td>65 years and over[2]</td><td>Offer aQIV.
Or, if aQIV is not available, offer QIVc or QIVr.
It is recommended that aQIV is offered ‘off-label’ to those who become 65 years of age before 31 March 2022 (see off-label use section).</td></tr>
<tr><td colspan="2">Note – this template does not include high-dose quadrivalent influenza vaccine (QIV-HD) or trivalent influenza vaccines which are not part of the national programme</td></tr>
</table>
</td></tr>
<tr><td>Legal category</td><td>Prescription only medicine (POM).</td></tr>
<tr><td>Black triangle▼</td><td>QIVc, QIVr and aQIV products are black triangle.</td></tr>
</table>

[2] JCVI recommended use of QIV-HD in this age group but this is not currently available in the UK market.

	QIVe vaccine from Viatris (formerly Mylan) is black triangle. This information was accurate at the time of writing. See product SPCs at www.medicines.org.uk for indication of current black triangle status.
Off-label use	The aQIV is licensed for administration to individuals aged 65 years and over. It may be administered under this Written Instruction to 64 year olds turning 65 years of age by 31 March 2022 in accordance with the recommendations for the national influenza immunisation programme for 2021/22. The licensed ages for the 2021/22 season influenza vaccines are: • QIVe are licensed from 6 months of age • QIVc, Flucelvax® Tetra▼, is licensed from 2 years of age • QIVr, Supemtek▼, is licensed from 18 years of age • aQIV, Fluad Tetra▼ is licensed for individuals aged 65 years and over Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this Written Instruction. Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. Note: Different influenza vaccine products are licensed from different ages and should be administered within their licence when working to this written instruction, unless permitted off-label administration is detailed above. Refer to products' SPCs at www.medicines.org.uk and the table of Influenza Vaccines for the 2021 to 2022 season for more information.
Route / method of administration	Administer by intramuscular injection, preferably into deltoid region of the upper arm. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician

	responsible for prescribing or monitoring the individual's anticoagulant therapy. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual should be informed about the risk of haematoma from the injection. Influenza vaccines licensed for both intramuscular or subcutaneous administration may alternatively be administered by the subcutaneous route. Note: QIVc (Flucelvax® Tetra▼), QIVr (Supemtek▼) and aQIV (Fluad Tetra▼) are not licensed for subcutaneous administration so should only be administered intramuscularly under this Written Instruction. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. If aQIV needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs. Shake vaccine before administration. Inspect visually prior to administration and ensure appearance is consistent with the description in the products SPC. The SPCs provide further guidance on administration and are available from the electronic medicines compendium website: www.medicines.org.uk
Dose and frequency of administration	Single 0.5ml dose for the current annual flu season (1 September 2021 to 31 March 2022).
Storage	Store at +2°C to +8°C. Do not freeze. Store in original packaging in order to protect from light.

	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3). In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to PHE Vaccine Incident Guidance and contact the Medicines Information service as follows: Ipswich Hospital site: 01473 703604 Colchester Hospital site: 01206 742161 Alternatively, you can submit your question by email: Medicines.information@esneft.nhs.uk
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Inactivated influenza vaccine may be given at the same time as other vaccines (See Route / method of administration). A detailed list of drug interactions is available in the SPC for each vaccine, which are available from the electronic medicines compendium website: www.medicines.org.uk
Identification & management of adverse reactions	Pain, swelling or redness at the injection site, low-grade fever, malaise, shivering, fatigue, headache, myalgia and arthralgia are among the commonly reported symptoms after intramuscular vaccination. A small painless nodule (induration) may also form at the injection site. These symptoms usually disappear within 1 to 2 days without treatment. Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur. A higher incidence of mild post-immunisation reactions has been reported with adjuvanted compared to non-adjuvanted influenza vaccines.

	The frequency of injection site pain and systemic reactions may be higher in individuals vaccinated concomitantly with inactivated influenza vaccine and pneumococcal polysaccharide vaccine (PPV23) compared to vaccination with influenza vaccine alone and similar to that observed with PPV23 vaccination alone. Influenza vaccine and PPV23 may be administered at the same visit. A detailed list of adverse reactions is available in the SPC for each vaccine, which are available from the electronic medicines compendium website: www.medicines.org.uk
Management of and reporting procedure for adverse reactions	Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. QIVe vaccine from Viatris (formerly Mylan), QIVc, QIVr and aQIV are black triangle. Therefore, any suspected adverse reactions should be reported via the Yellow Card Scheme. Any adverse reaction to a vaccine should be documented in the individual's occupational health record and the individual's GP should be informed.
Written information to be given to client	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
Client advice / follow up treatment	Individuals should be advised regarding adverse reactions to vaccination and reassured that the inactivated vaccine cannot cause influenza. However, the vaccine will not provide protection for about 14 days and does not protect against other respiratory viruses that often circulate during the flu season. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Therefore, consideration should be given to the influenza vaccination of their household contacts. Inform the individual of possible side effects and their management. The individual should be advised when to seek medical advice in the event of an adverse reaction. Individuals in a clinical risk group recommended seasonal influenza vaccine should be encouraged to inform their GP (and midwife if relevant) once they have received influenza vaccine for the current season so their medical records (and maternity records if relevant) can be updated accordingly. Individuals who decline immunisation from their OHS provider and who are immunised elsewhere should be encouraged to inform their employer of their immunisation status

	as per local policy. Resources to share with clients are available at: https://www.gov.uk/government/collections/annual-flu-programme
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination. Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. Staff with learning disabilities may require reasonable adjustments to support vaccination (see https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities). A PSD or referral to another provider may be required if a suitable alternative vaccine is not offered by the OHS.
Records	Record in line with local procedure: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • administered under written instruction Records should be signed and dated (or password-controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. As a wide variety of influenza vaccines are available on the UK market each year, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records. It is important that vaccinations given within Occupational Health settings are recorded according to OH principles and ethics and in a timely manner.

	Local policy should be followed to encourage information sharing with the individual's General Practice where the individual would be eligible for immunisation under the national influenza programme to allow appropriate clinical follow up, improve data capture of vaccination status and to avoid duplicate vaccination. A record of all individuals receiving treatment under this written instruction should also be kept for audit purposes in accordance with local policy.

Key references	**Inactivated influenza vaccination** • Immunisation Against Infectious Disease: The Green Book, Chapter 19. Published 29 October 2020. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Collection: Annual Flu Programme. Updated 29 July 2021. https://www.gov.uk/government/collections/annual-flu-programme • The national flu immunisation programme 2021 to 2022: supporting letter. Published 19 July 2021. https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan • Enhanced Service Specification, Seasonal influenza and vaccination programme 2021/22. https://www.england.nhs.uk/gp/investment/gp-contract/ • Influenza vaccines: 2021 to 2022 flu season. https://www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content • Live attenuated influenza vaccine (LAIV) PGD https://www.gov.uk/government/publications/influenza-vaccine-fluenz-tetra-patient-group-direction-pgd-template • Written instruction for the administration of seasonal 'flu vaccination. NHS Specialist Pharmacy Service. 16 July 2020 https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/ • Summary of Product Characteristics www.medicines.org.uk • Flu immunisation training recommendations. Updated 5 August 2020. https://www.gov.uk/government/publications/flu-immunisation-training-recommendations • Flu Vaccinations: Supporting people with learning disabilities. Updated 25 September 2018.

https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities

- PHE Information for healthcare practitioners https://www.gov.uk/government/publications/inactivated-influenza-vaccine-information-for-healthcare-practitioners

General

- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste
- Immunisation Against Infectious Disease: The Green Book. Chapter 2. Updated 18 June 2021. https://www.gov.uk/government/publications/consent-the-green-book-chapter-2
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources
- Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them
- PHE Guidance on immunisation training during the COVID-19 pandemic. 26 June 2020. https://www.gov.uk/government/publications/immunisation-training-guidance-during-the-covid-19-pandemic/guidance-on-immunisation-training-during-the-covid-19-pandemic
- PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation
- PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors