East London
NHS Foundation Trust

Stratford Mass Vaccination Hub

Clinical Standard Operating Procedures

January 2021

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Version Control Summary

Version	Date	Author	Status	Comment
1	08-01-2021	Rozi Hamilton and Jennifer Melville		
2	Jan 2021	Indreet Anand/Jo Simms		Medicines safety and incident reporting
3	Jan 2021	Indreet Anand/Jo Simms		Medicines safety and incident reporting
4	Jan 2021	Jennifer Melville Chika Ezeagu		Reviewed, added process flow
5	22-01-21	Jennifer Melville/Janette Clark		Spelling correction, management structure change, removed flu reference
6	25-01-21	Jennifer Melville/Kate Corlett/Angharad Ruttley/Simon Small		Medical emergency detail, dr on-site,
7	26-01-21	Indreet Anand		Datix reporting common side effect
8	08-02-21	Nicola McCoy		Admin training and language line details
9	28-02-21	Jennifer Melville, Duncan Hall Indreet Anand		Supporting pt with health needs Medication Incident/Error Reporting and Adverse Drug Reaction Reporting. Appendix 12 added

Related Policies

- Medicines policy
- SOP for Fridge and Clinical room temperature monitoring for safe storage of medicines Resuscitation Policy
- Anaphylaxis recognition and treatment policy
- Infection prevention and Control Policy Manual
- Covid-19 IPC Policy
- Cardio-pulmonary resuscitation COVID-19 (Exceptional) SOP

1.0 Introduction

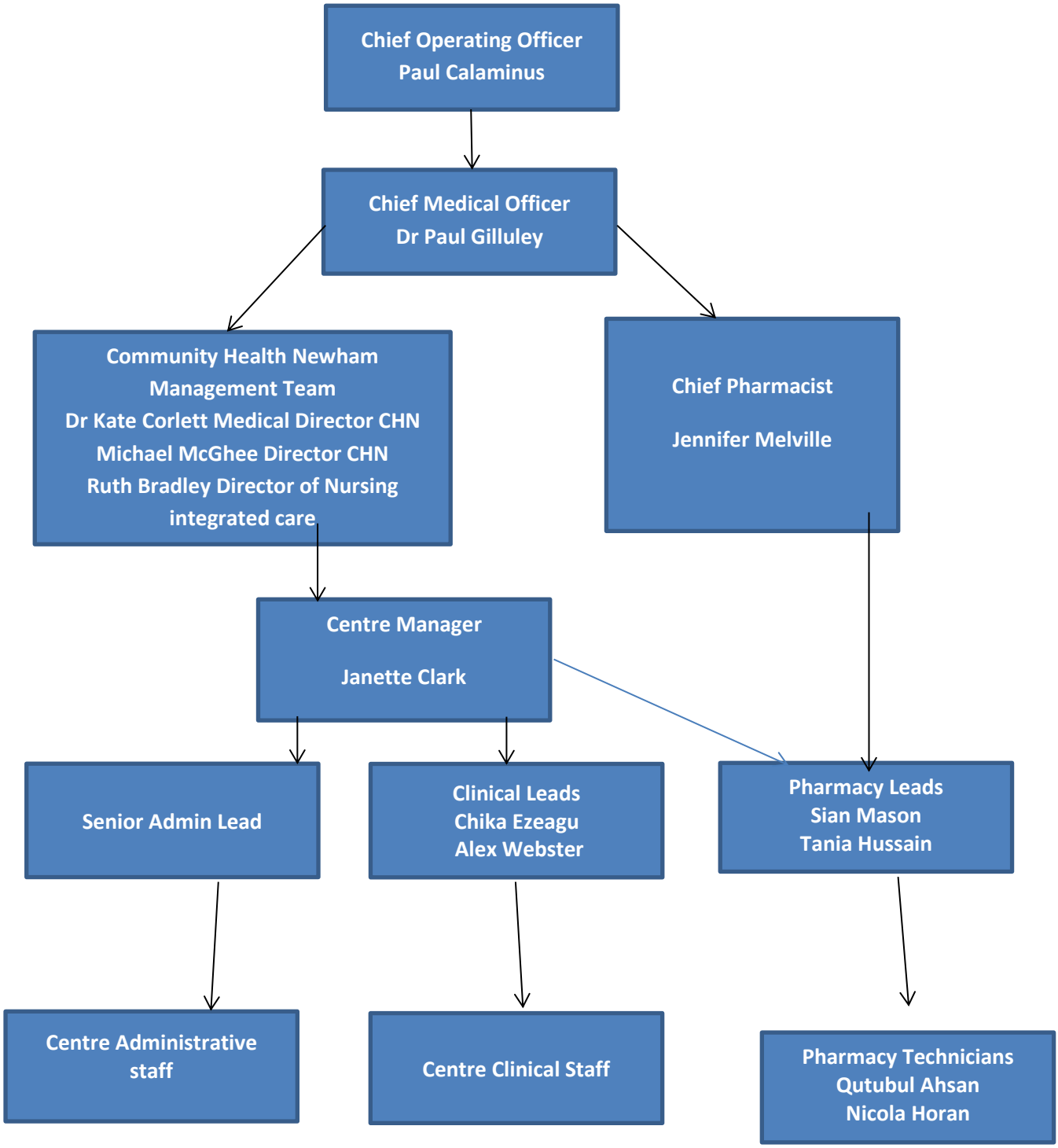
1.1 In response to the global SARS cov-2 pandemic, the United Kingdom Government initiated the Vaccine Task Force. Working alongside NHS England, the National Institute for Health Research, and the Joint Committee on Vaccination and Immunisation (JCVI), the COVID-19 vaccination deployment strategy aims to deliver the SARS CoV-2 vaccines throughout the United Kingdom in order to inhibit the spread of infection and reduce the mortality rate. The Government vaccine taskforce agencies have instructed NHS Trusts to develop and deploy the vaccination programme in readiness for distribution of vaccines once approved by the Medicines and Healthcare products Regulatory Agency (MHRA). East London NHS Trust is responsible for the Stratford Westfield Mass Vaccination Centre which this is the site that this clinical standard operating procedure is for.

2.0 Purpose

2.1 The purpose of this document is to:

- Guide for general management of the vaccine centre, including the process of reconstitution and administration of the COVID-19 vaccine;
- Handling medical emergencies and adverse reactions;
- Overview of vaccination training – See Standard operating procedure for training requirements for COVID-19 vaccination administration for full details of the training requirements.

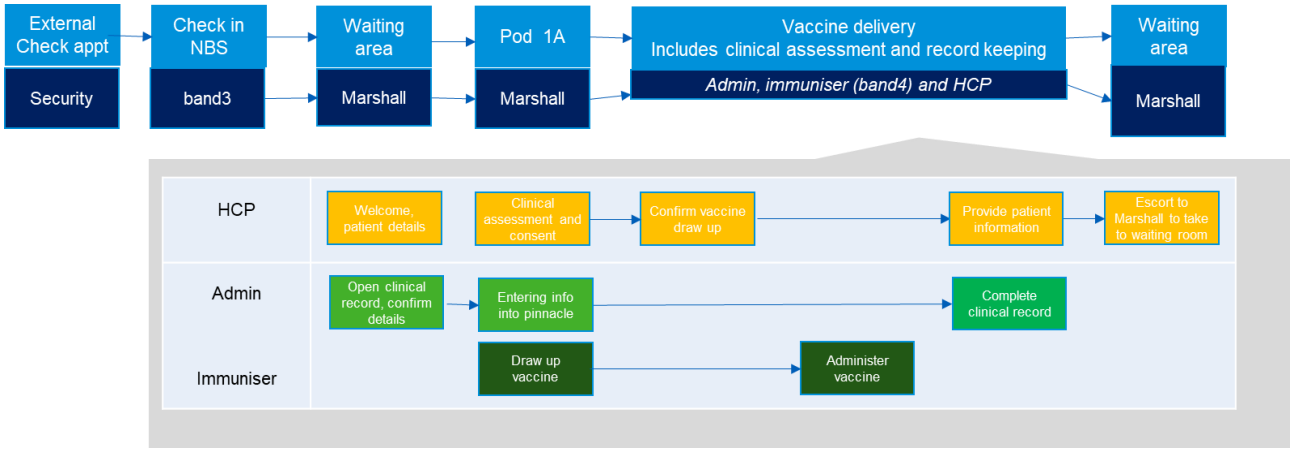
2.2 Vaccination Centre Management Structure



2.3 Definitions

TERM	DEFINITION
COVID-19	Novel coronavirus SARS cov-2
SHIFTPARTNER	Application used to book appointments at the COVID-19 vaccine centre and for correlation of vaccine information.
ELFT	East London NHS Foundation Trust
PPE	Personal Protective Equipment
NIVS	National Immunisation Vaccination System - Information uploaded to this audit tool will be used to support vaccination planning and response activities at both a national and local level.
MHRA	Medicines and Healthcare products Regulatory Agency
PHE	Public Health England
PGD	Patient Group Directive – Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.
PSD	A Patient Specific Direction (PSD) is a written instruction, signed by a prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis. This should not be confused with an FP10 or other written prescription given to the patient for supply from a pharmacy or dispensary

2.4 Vaccination Centre process flow



3.0 Safe Administration of Vaccines

3.1 All staff handling and administering the vaccines must have successfully completed the appropriate training in vaccination or have an existing qualification as a Vaccinator. The vaccination site Clinical Lead will be responsible for ensuring staff have the required training and competencies for the role. The minimum requirements for the role of vaccinator are outlined in appendix 1

3.2 Staff must adhere to all Trust policies in relation to medicines, as well as specific policies/procedures relating to the COVID-19 vaccine Effective immunisation is essential in order to secure individual protection for adults. Healthcare professionals involved in any aspect of immunisation are accountable for their practice and as such have a

responsibility to acquire and maintain the necessary skills. In addition, they must be able to demonstrate their capability to offer safe and effective care.

3.3 All vaccines are Prescription Only Medications (POM). The preferred way for adults to receive medicines is for an appropriately experienced, qualified prescriber to prescribe for an individual on a one-to-one basis. However, in order to facilitate access to vaccines NHSE have issued a Patient Group Direction (PGD) and National Protocol. Specific training, assessment and authorisation will be required to administer under the PGD or National Protocol.

3.1 Staff Responsibilities

3.1.1 Staff must ensure that they adhere to procedures in relation to ordering, delivery, storage and stock checks, including compliance with requirements for maintaining the cold chain standards.

3.1.2 All health professionals working in the vaccination site must:

- Make known immediately to the vaccination site Clinical Lead if they have difficulty or concerns about their ability to manage immunisations;
- Be personally accountable for their clinical practice and for the maintenance and development of their knowledge and competence. Registered practitioners are expected to be familiar with, and to follow at all times, their own professional code of practice;
- Ensure the vaccine is stored and used in accordance with the manufacturer's recommendations and in line with the cold chain standards;
- Monitor and review fridge temperature recordings and document;
- Ensure there is immediate access to Adrenaline (epinephrine) in the event of an anaphylactic reaction, adhering to Trust Anaphylaxis Recognition & Treatment Policy (see, appendix 3);
- Ensure there is a means to call for assistance e.g. telephone, should emergency help be required;
- An interpreter or other suitable person is available (where required) to enable the client to make an informed decision.

3.2 History taking and risk assessment

3.2.1 Prior to administration, the healthcare professional should ensure that:

- There are no contra-indications to the vaccine being given, known drug allergies or previous anaphylaxis.
- They have checked the health status of the patient, for example presenting with a febrile infection.
- They have asked the patient and checked the clinical records and all other relevant information sources, both electronic and paper records, to ensure that the correct vaccine is given.
- They have checked the clinical records and all other relevant information sources, both electronic and paper records, to ensure that the correct vaccine hasn't already been given.
- The patient or carer, is fully informed about the vaccine to be given, has been provided with written information about the vaccine and understands the vaccination procedure.
- They have confirmed with the patient or carer, that the proposed vaccine is the one they are expecting to be given.
- The patient or carer is aware of possible adverse reactions and action to take if they have any concerns.

3.3 Patient Group Direction (PGD)

3.3.1 The vaccine may be administered without a prescription under a patient group direction (PGD) by registered healthcare professionals who have been authorised to use a PGD. Authorised staff must have received the appropriate training and are professionally responsible for ensuring they are familiar with and adhere to the content of the PGD. Administration the vaccine under the PGD must be documented on the NIVS electronic system for healthcare staff or Pinnacle for each patient.

3.3.2 See ELFT trust organisational authorisation.

3.3.3 See https://www.england.nhs.uk/coronavirus/publication/patient-group-direction-for-covid-19-vaccine-astrazeneca-chadox1-s-recombinant/

3.4 National Protocol

3.4.1 The vaccine may be administered without prescription under the national protocol by registered professionals and unregistered trained individuals deemed competent and skilled to undertake the tasks outlined in the protocol. Administration the vaccine under the PGD must be documented on the NIVS electronic system for healthcare staff or Pinnacle for each patient.

3.4.2 See ELFT trust organisational authorisation.

3.4.3 See https://www.gov.uk/government/publications/national-protocol-for-covid-19-vaccine-astrazeneca-chadox1-s-recombinant

3.5 Administration

3.4.1 See SOP AZH3-Preparation of AstraZeneca COVID-19 Vaccine Syringes for Administration

3.4.2 Before administration, staff administering immunisations must ensure that:

- The checklist AZH3.2 Vaccine supervision sessional checklist for Astrazeneca COVID-19 Vaccine v1 is completed;
- The identity of the patient is checked at 2 points including their NHS Number and date of birth;
- Each vaccine is prepared as per manufacturer's instructions and SOP AZH3 and drawn up when required in order to avoid errors and maintain vaccine efficacy and stability;
- Vaccines should not be drawn up in advance of an immunisation session;
- The vaccine does not contain any preservative. Aseptic non-touch technique (ANTT) should be used for withdrawing the dose for administration;
- Follow good practice guidance for the care and storage of the vaccine, checking product details before use and noting the expiry date and batch number;
- Inspect the product visually which should be a colourless to slightly brown, clear to slightly opaque and particle free solution. Discard any product that does not match this description;
- Do not shake the vial;
- Syringe and needle required is a 1ml syringe with integrated 23g (or 25g) x 25mm needle. N.B.23g x 38mm needles and 1ml syringes are available for morbidly obese patients;
- Do not mix with other vaccines in the same syringe;
- Check the route of administration and be familiar and trained in the method of delivery. The COVID-19 Astra Zeneca vaccine is given by intramuscular (IM) injection;
- Vaccines must not be given intravenously or by intradermal injection;
- Ensure the correct sharps bin is available;
- Ensure staff have access to an in-date anaphylaxis kit.

3.4.3 See preparation work plan outlined in SOP AZH3.1 –AstraZeneca COVID-19 Vaccine Preparation Work Instruction.

3.4.4 Recipients should be observed for immediate adverse or anaphylactic reactions in accordance to manufacture guidance. There is no specified monitoring time and patients are not required to remain on site.

3.4.5 Staff should document the below on the vaccination record card and give this to the patient or carer:

- Patient name;
- Name of vaccine given;
- Batch Number;
- Date vaccine given;
- Date next vaccination due (if appropriate),

3.4.6 Patients should also be given the below advice and provided a patient information leaflet:

- Common side effects and action to take to reduce the effects. For example, reducing temperature and care of the injection site
- What to do if there are any adverse effects
- Who to contact in the event of adverse events or concerns

4.0 Resuscitation

4.1 Roles & Responsibilities

4.1.2 The vaccination hub clinical leads are responsible for locally inducting staff to the working environment and the requirements of this SOP. This includes local arrangements for medical emergencies/ resuscitation, the location of equipment and the summoning of specialist help:

- All clinical staff working in the vaccination hub must be trained in cardiopulmonary resuscitation, including Anaphylaxis and defibrillation, appropriate to their discipline;
- All non-clinical staff with frequent, regular patient/ public contact should be trained in basic life support (BLS) with automatic external defibrillation;
- Staff must ensure they are aware of local resuscitation policies and processes and act accordingly.

4.1.3 As a minimum staff must:

- Be able to call for assistance and implement basic life support until qualified assistance arrives.
- Document fully the resuscitation process and the events (if known) that led to resuscitation in the patient record in line with the Lead Trust's clinical record keeping standards & records management policy
- Report all cases of resuscitation as incidents via the DATIX incident reporting system.
- Communicate with the individual and/ or their family/ carers/ significant others in line with East London NHS Foundation Trust Being Open Policy: http://elftintranet/sites/common/private/search_quick21.aspx?q=being%20open&orderby=0&url=ObjectInContext.Show(new%20ObjectInContextUrl(2%2C61443%2C1%2Cnull%2C970%2Cundefined%2Cundefined%2Cundefined%2Cundefined%2Cundefined))%3B

5.0 Consent

5.1 All staff working in the vaccination hub will ensure:

- All adults (aged 18 years and over) consent to their own treatment. If an adult is assessed as lacking capacity to give consent to the administration of a vaccine, this should be referred to their GP for a 'best interest' decision to be made;
- They have maintained a record that a discussion has taken place and the outcomes of the discussion recorded on the PGD;
- Consent has been given freely and voluntarily and has been obtained following an informed discussion about the risks and benefits of any procedure and the potential consequences of declining or refusing the intervention;
- Patients should sign the paper consent form prior administration of the vaccine;
- Any concerns about whether a patient has capacity to consent to the vaccine being given, should be reported to the General Practitioner on site to make a decision on whether to proceed.

6.0 Care of Non English speaking patients

6.1 Patients whose language is not English need to receive the information they need and should be able to communicate appropriately with health and social care staff. Interpreters should be used where it is likely the patient is not going to fully understand what the treatment entails.

6.2 It is not appropriate to use children to interpret for family members; equally, it is not appropriate to use other patients/service users for such support.

6.3 If an appointed interpreter has been used as part of the communication and wider consent process, it is important that the interpreter confirms what was discussed between the patient and the health professional. This will be entered in the clinical record as an accurate account of the consultation. The health professional should ask the interpreter to verify the account and include the name/role and language of the interpreter in the record.

6.4 Interpreter phone service
Newham Dockside I 1000 Dockside Road I London E16 2QU

DDI: 020 3373 4000 I Int: 30739 Lshop.Confirmations@newham.gov.uk

7.0 Supporting service users with physical health/mobile needs

- The Mass Vaccination Centre and staff will ensure an adaptive approach to support those service users with additional physical needs and disabilities;
- The centre will maintain a designated area (the resus area) to provide services to individuals with mobility needs such as wheelchair users to ensure space to maintain social distancing and the safe administration of vaccines.
- The Mass Vaccination Centre and staff will also ensure that individuals with additional physical health needs are not kept waiting unduly and are supported to safely navigate through the process and premises.

8.0 Raising a safeguarding concern/referral

8.1 All staff should, as soon as they become aware of allegations of harm, abuse or neglect (including self-neglect) of an adult should raise this as per the East London NHS Foundation Trust Safeguarding Adults policy.

http://elftintranet/sites/common/private/search_quick21.aspx?q=safeguarding%20policy&orderby=0&url=ObjectInContext.Show(new%20ObjectInContextUrl(2%2C29898%2C1%2Cnull%2C970%2Cundefined%2Cundefined%2Cundefined%2Cundefined%2Cundefined))%3B

9.0 Information governance

9.1 Data quality can affect patient experience; if records are inaccurate or incomplete then future decisions may be wrong and potentially harm the service user. If information is recorded inconsistently, then records are harder to interpret, resulting in delays and possible errors.

9.2 Accurate records of vaccinations given or reason for not giving, are important for patient safety, regular audits, monitoring immunisation uptake and facilitating recall of recipients of vaccines, if required.

9.3 Records are defined as ‘recorded information, in any form, created or received and maintained by the trust in the transaction of its business or conduct of affairs and kept as evidence of such activity compliance with the General Data Protection Regulations and Data Protection Act 2018 and in particular the rights of data subjects such as patients and staff.

9.4 All Staff: have individual responsibility for managing the records they create and handle in accordance with this SOP and keeping appropriate records of their work. Registered

professionals are responsible for complying with their relevant codes and standards of professional practice for record-keeping and for supervision of unqualified members of the team making entries in health records.

10.0 Medicines Management (Vaccine storage and delivery protocols)

10.1 Ordering COVID-19 Vaccine

10.1.1 See SOP AZH1 Ordering AstraZeneca COVID-19 Vaccine from Public Health England (PHE):

- The mass vaccination site pharmacy team will order AstraZeneca COVID-19 vaccines via the Immform platform;
- Westfield orders will be initially received at Mile End hospital pharmacy and locally transported to the Vaccination site;
- Minimum Order Quantity: 400 doses and multiples thereof;
- The product will be delivered with patient factsheets (if paper copies are not available they are available electronically for local printing or access via a QR code);
- The following associated supplies need to be ordered separately on Immform by pharmacy team:
  - Combined needles and syringes for administration;
  - Patient vaccination record card;
  - Anaphylaxis kits.

10.1.2 Patient fact sheets can be found via:

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination/what-to-expect-after-your-covid-19-vaccination

10.2 Receiving vaccine

10.2.1 Vaccine is delivered directly to the Westfield Vaccination Site from supplier Movianto in refrigerated vans. See the following SOPs:

- SOP AZH2b: Receipt of refrigerated AstraZeneca Covid-19 Vaccines (to Westfield Mass Vaccination site);

10.3 Storage

10.3.1 The Astra Zeneca Vaccine is stable at +2°C to +8°C for 6 months.

10.3.2 Vaccine will be delivered at +2°C to +8°C and should be transferred to a refrigerator immediately upon receipt of order.

10.3.3 Packs must be stored upright and cannot be stacked more than 2 high in refrigerators.

10.3.4 No defrosting/thawing required for this vaccine.

10.3.5 Vaccine must be transferred within the 'cold chain' with the use of pharmacy approved validated cool boxes.

10.3.6 Main fridge temperatures must be monitored twice a day according to trust guidance and documented on the 'Temperature Monitoring Chart' attached to fridges. (See SOP AZELFT1- Monitoring Fridge temperature and SOP AZELFT1a Monitoring Minifridge temperatures)

10.3.7 Seealsohttps://www.sps.nhs.uk/wp-content/uploads/2020/12/Refrigerators-for-Covid-19-vaccine-storage-Quick-reference-guide-23.12.20.pdf

10.3.8 Any excursion from the 'cold chain' (+2°C to +8°C), the vaccine must be allocated an expiry date and time (6 hours) and discarded if not used within this time.

10.3.9 Emergency vaccine storage and handling plans which cover actions to be taken in the event of out of range temperature excursions or refrigerator break down refer to Trust SOP for fridge and room temperature monitoring, excursions less than 20 minutes do not require further action apart from reset of thermometer.

10.3.10 Any accidental breach of the cold chain must be reported to the site lead pharmacy team for specific advice

10.3.11 Out of hours any breach of coldchain must be reported to the oncall pharmacist (07508041917) and the out of hours policy followed- SOP AZELFT1b

10.3.12 Information on validated cool pack system and how to pack appropriately:

- Cool boxes https://www.helapet.co.uk/catalog/product.php?CI_ID=355
- Medicool 28 https://www.helapet.co.uk/downloads/Instructions_for_Use_-_VaccinePorter_6.pdf

10.4 **Stock Take**

10.4.1 Stock levels of the vaccine at the Westfield Mass Vaccination service should be checked twice a day and recorded on the 'Temperature Monitoring Chart' in the appropriate section. These are also recorded in the Vaccine reconciliation spreadsheet

10.4.2 Any stock discrepancies should be immediately escalated to the pharmacy team or site manage and a DATIX completed if stock discrepancy cannot be accounted for.

10.4.3 See Medicines SOPs appendix 9.

11 Infection Prevention and Control

11.1 Premises that are administering the covid vaccine should follow the recommended infection prevention and control (IPC) guidance.

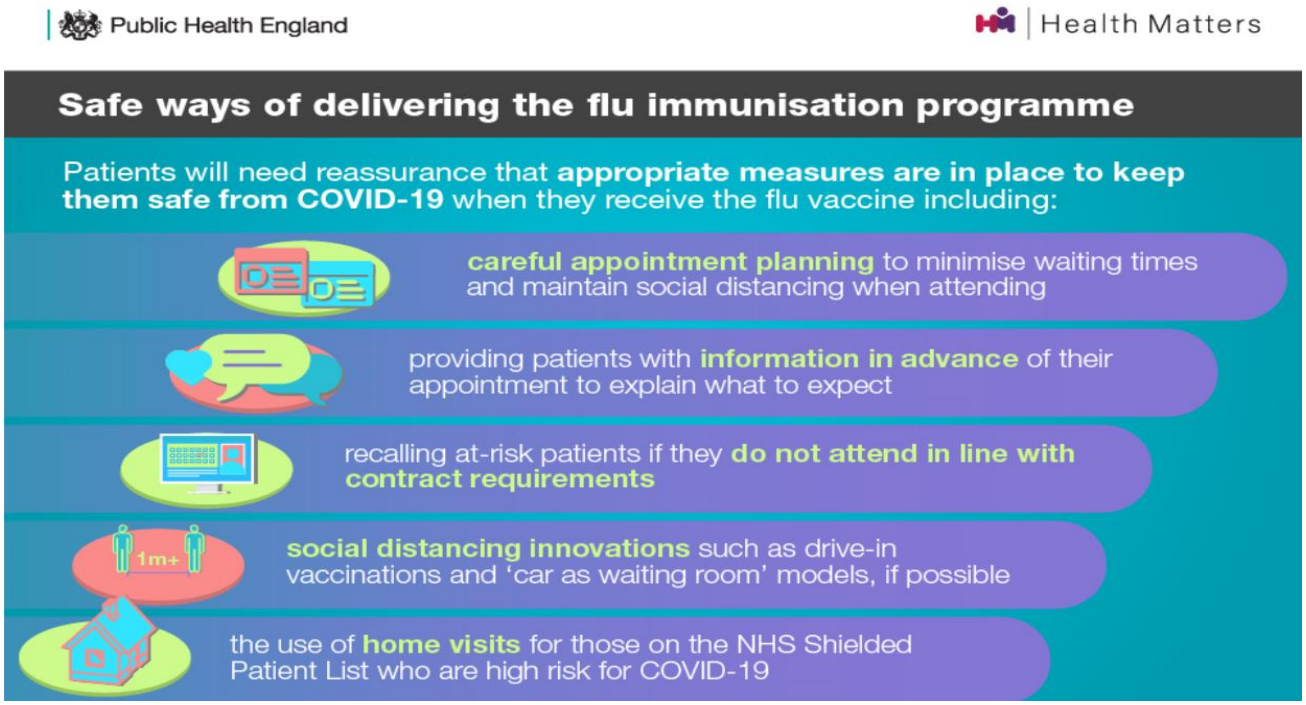
11.2 People who are displaying COVID-19 symptoms or are self-isolating because they are confirmed COVID-19 cases, or contacts of suspected or confirmed COVID-19 cases, should not attend until they have recovered and completed the required isolation period.

11.3 Healthcare professionals who administer the vaccine are required to wear the recommended personal protective equipment (PPE) in line with the government's guidance.

- www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe

11.4 The IPC principles in this guidance apply to all health and care settings, including acute, mental health and learning disabilities, primary care (including community pharmacies) and care homes.

11.5 Further information on IPC measures is provided in the Information for Healthcare Practitioner documents, which will be updated prior to and during the season as required.



11.6 In line with the NHS England and Improvement framework for urgent and planned services infection prevention and control will ensure that the Mass vaccination site has made the following estates alterations to ensure the following is adhered to:

- Reducing movement between different areas, where possible;
- Maintain clear separate entry and exit points to the facility and adequate signage.
- Maintain adequate ventilation in the facility
- Encouraged social distancing 2 metres apart inside and outside vaccination areas e.g. in communal areas;
- To minimise the risk of surface contact transmission, a cleaning operative will be on site from 7am to 8pm daily;
- Cleaning schedules have been issued that mirror NCS 2007 for clinical areas and touch point cleaning is built into these;

- Increasing the frequency of cleaning any shared equipment. Ensure identified hub locations have security arrangements in place;
- Ensure there is sufficient cleaning at each hub. Cleaning of the site is to be carried out in every evening for 6 hours, along with an operative on site from 7am – 8pm carrying out touch point cleaning;
- Adequate levels of PPE to be available in all areas of the hub.

11.7 Infection Prevention and Control measures

11.7.1 All staff are responsible for wearing and using the correct Personal Protective Equipment (PPE) for Contact and Droplet Precautions, in conjunction with other infection control practices (I.E. appropriate hand hygiene).

11.7.2 Roles & Responsibilities

- Staff and visitors are asked to check symptoms prior to entering a site.
- All staff (clinical and non-clinical) should self-check their symptoms prior to attending the workplace. If they are symptomatic, they should:
  - Stay off work or leave work immediately
  - Contact their line manager
  - Arrange aCOVID-19 test via the East London NHS Foundation Trust Intranet
  - Self- isolate as per current guidelines until the test result is available

11.7.3 All staff coming into the vaccination hub must:

- Wash hands immediately on arrival and repeat regularly or use hand gel;
- Soap and water should be used every time where available;
- If using hand gel, hands can become sticky if residue is left so IPC advise that hands should be washed with soap and water after 3 uses of hand gel;
- Avoid touching their eyes, nose, and mouth;
- Adhere to the 2m social distancing rule when moving about the building, including kitchen and toilets;
- Keep sinks and drainers free of all clutter - wash, dry and put away any used crockery and cutlery with the support of cleaning staff;
- Paper towels will be supplied on site;
- Always keep an empty desk or space between you and any other colleague;
- Wipe desks and computer keyboards before starting work and at the end of the day;
- Leave desks completely clear when finished.

11.10 Team/service leads (working with estates and facilities managers):

11.10.1 Adequate quantities of wipes and hand gel must be provided in the centre, in particular in the high traffic areas sufficient stocks of these will be on site and needs to be available for Estates and Facilities staff will distribute during the day when stocks run out.

11.10.2 The following signs/posters will be prominently displayed in the centre:

- Social distancing and hand washing posters;
- Arrows for One way systems;
- Maximum occupancy to be displayed for shared staff spaces and toilets;
- Instructions to wipe down taps and only one person in the urinal area at a time to be displayed in the toilets;

- Sharps poster to be displayed which includes details of occupational health number.

12 Cleaning & Waste Management

12.1.1 Waste management will be provided by East London NHS Foundation Trust for the Stratford site as part of the estates and cleaning contract. The clinician is responsible for cleaning the direct clinical environment they are working in and for disposing of waste safely. A nightly clean of the clinical areas will take place once the hub has closed by cleaning operatives as laid out in cleaning schedules which have been issued to Samsic contractors.

12.2 Stock control, security and monitoring of wastage

- Staff will need to ensure that vaccines are stored securely at all points between receipt and use or disposal.
- All waste must be handled in such a way as to prevent theft and misuse both on site and after removal from the site.
- Waste vaccines due to any reason must be returned to the pharmacy team on site.
- Empty vials must be placed into the clinical or medicinal waste stream according to normal local waste management procedures and SOP AZH3.
- Cartons must have their labels defaced using permanent black marker pens, be destroyed, or placed into a yellow or orange waste sack for incineration, as soon as possible after they become empty.

13 Safe handling and disposal of medicines

13.1 Undertake a Health and Safety risk assessment to ensure medicines risks are adequately controlled.

13.1.1 Spillages on skin/eyes

- See SOP AZELFT4- Handling of spillages
- Staff must be aware of location of handwashing facilities and eyewash kits.
- Spillages on skin should be washed with soap and water.
- If a vaccine is splashed in the eyes, they should be washed with sterile 0.9% sodium chloride solution and medical advice should be sought.

13.1.2 Spillages on surface

- Spillages must be cleared up quickly and gloves should be worn.
- The spillage should be soaked up with paper towels, taking care to avoid skin puncture from glass or needles.
- The area should disinfected with an appropriate antiviral disinfectant
- Gloves, towels, etc. should be sent for incineration

14 Safe handling and disposal of sharps

14.1.1 Incident analysis shows that many sharps incidents occur at the point of disposal. To minimise this risk, staff should:

- Ensure compliance of the statutory Infection Prevention and Control level 2 training in which Sharps management is included;

- Ensure that sharps containers are available at the point of care to enable you to immediately dispose of sharps;
- Dispose of sharps immediately- the person who used the sharp is responsible for the disposal;
- Not place sharps on surfaces for later disposal or for disposal by others;
- Not pass sharps hand to hand; this includes from patient to staff as well as staff to staff;
- Never re-sheath a needle;
- Sharps safety devices should be used if possible.

14.2 Management of Sharps Containers

14.2.1 We can also learn from reported near misses which are mainly due to poor management of sharps containers:

- Do not overfill sharps containers; this results in protruding sharps and increases risk of injury
- Close the temporary closure mechanism when the sharps container is not in use to avoid spillage and overfilling
- Please remember to report all sharps incidents on Datix in addition to contacting the Sharp Line.
- Keep Sharps bins stored off the floor

14.3 Process to follow in the event of a needle stick injury

- In the event of a Sharps injury, staff members must contact the Trust's Occupational Health provider, Team Prevent's Clinical Sharps Line during working hours (Mon-Fri, 08.30-16.30) on 01327 810 777 and on 0800 413 324 during out of hours to report injury. It is very important that staff contact Occupational Health to report the sharps injury. The staff member must complete a Datix reporting form.

- The sharps injury poster must be displayed prominently in the Vaccination Hub (appendix X)

- Following a sharps injury, the infection prevention team will contact you to arrange a clinical support visit in your practice. This is to facilitate shared learning from the incident**.**

15 Training

15.1 Vaccinator training

15.1.1 All vaccinators are to complete the National Vaccination programme prior to attending the local induction:

- https://portal.e-lfh.org.uk/Component/Details/675208 (COVID-19 Vaccination Programme
- https://portal.e-lfh.org.uk/Component/Details/514308 (Immunisation Legal Aspect)
- https://portal.e-lfh.org.uk/Component/Details/514237 (Vaccine storage)
- https://portal.e-lfh.org.uk/Component/Details/514227 (Vaccine Administration)

15.2 A two day virtual face to face induction (see appendix x) will be undertaken which will include statutory and mandatory training, recognition of the deteriorating patient, medicines management and use of the PGD

15.3 Following this staff will have a local induction to the centre (see appendix x)

15.4 All vaccinators will be signed as competent on *the PHE Competency tool for healthcare workers undertaking COVID-19 vaccination (PHE 2020)* prior to working independently (appendix X)

15.5 Administrative Staff Training

15.6 A two day virtual face to face induction will be undertaken which will include statutory and mandatory training

15.7 Following this staff will have a local induction to the centre which also includes Fire Marshal training and will receive user names and passwords for the IT systems prior to their first shift. Admin staff will also have relevant training for the following IT systems:

- Swiftqueue – to register staff members coming for vaccination, check in and understand where relevant information is in the system.
- QFlow – to check in public via the national booking system, understand where data is in order to transfer onto NIVs.
- NIVs – to register the public and staff by using either Swiftqueue or QFlow data.
- National Booking System – staff will be trained to be able to book appointments from walk ins.

16 Clinical Advice Queries

16.1 If there is a clinical/immunisation query, please report this to the site pharmacist or clinical lead/manager or onsite doctor who can either answer this query or if needed escalate this query to the Regional Vaccination Operations Centre (RVOC); england.london-covid19voc@nhs.net. RVOC monitor this email box between the hours of 08:00 to 20:00 seven days a week. For emergencies, outside of these hours, there is automatic email reply set up to advise of a telephone number to contact. The email subject should be marked as “for the attention of the CARS”, or “clinical query”. Please do not include any patient identifiable information.

16.2 RVOC will then liaise with the Clinical Advice Response Service (CARS), as required, to address the enquiry.

17 Medication Incident/Error Reporting and Adverse Drug Reaction Reporting

17.1 *DATIX Reporting* –All incidents and near misses relating to any aspect of the process of end to end deployment of COVID-19 vaccines must be reported on the DATIX system. Within the ‘incident description’ section, the keyword “COVIDVACC” must be included. Site pharmacists and the ELFT Governance and Risk Team should ensure the wording “COVIDVACC” has been included in the incident description when reviewing incidents.

17.2 When Reporting select the following location on the form:

17.3 All errors/incidents should be reported to the clinical lead/manager and site pharmacist. Some errors will require immediate remedial action to ensure patient safety, however they should also be reported on the DATIX system as soon as possible after the incident is realised.

17.5 Examples of incident/errors (**not a fully exhaustive list**):

- *Clinical Adverse Incidents*: patient with fever immunised, staff immunising without appropriate training or deviate from PGD, adverse drug reaction.
- *Delivery Incidents*: e.g. wrong delivery note sent to the wrong vaccination site, a missing/late delivery.
- *Storage Incidents*: vaccines stored outside of recommended temperature, include details of whether any affected vaccines were given to patients.
- *Medication Errors*: Expired vaccine, incorrect dose, wrong route of administration.
- *Consent*: Someone without capacity to consent, immunised without appropriate consent

17.6 The site pharmacist(s) should review all incidents submitted via DATIX daily. For those incidents deemed significant or serious, this should be highlighted to the Trust's Incident Reporting team to assess and escalate whether a 48 hour or Serious Incident (SI) report is required.

17.7 The ELFT Governance and Risk Team will be required to review all COVID-19 vaccination DATIX incidents daily. The Governance and Risk Team should forward/export all DATIX incidents related to the COVID-19 vaccination or vaccination process on to the Regional Vaccination Operations Centre (RVOC); **england.london-covid19voc@nhs.net**. No patient/personal identifiable information should be included. Where RVOC requires patient identifiable information (for example where related to significant or critical adverse events), RVOC will contact ELFT directly using the contact information supplied on the incident form.
See Appendix 12 for 'Incident Escalation Flow Chart'

17.8 *Adverse Drug Reaction* - Suspected adverse reactions following administration of COVID-19 vaccine should be reported on the DATIX and to the MHRA using the specially established Coronavirus Yellow Card reporting scheme (coronavirus-yellowcard.mhra.gov.uk/ or call 0800 731 6789). As a new vaccine product, MHRA have a specific interest in the reporting of adverse drug reactions for the new COVID-19 vaccines.

Known **common/minor** side effects – DO NOT report on DATIX. Please report these to the MHRA via the Coronavirus Yellow Card reporting scheme.

Unknown/**Uncommon/Serious/Significant** side effects - Report to the MHRA via the Coronavirus Yellow Card reporting scheme and then also report onto DATIX and include the MHRA reference number within the DATIX incident description.
Examples include:

- Any side-effect / reaction that is not already noted in the manufacturer's SPC and that the clinician considers to be possibly linked chronologically to the vaccination
- A known side-effect / reaction noted on the SPC but that the clinician considers to be an extreme or severe form of this known side-effect, eg fever that lasts for more than an expected number of days and for which there is no other cause; an urticarial reaction that affects a much larger area than just the injection site etc.

- An acute clinical event linked in time to the vaccination for which the clinician does not consider there to be any other clinical cause.

Unknown/Uncommon/Serious/Significant side effects should be escalated to RVOC by the ELFT Governance and Risk Team. Please also see section 16.11 for information on fast track reporting to RVOC. The clinical lead/manager should assess whether the adverse reaction needs to be reported via the fast track pathway to RVOC.

17.9 *Pregnant women* - COVID-19 vaccine should NOT be administered under the PGD or National Protocol to a pregnant woman. In cases of inadvertent administration under the PGD or National Protocol report this on DATIX. In addition, any administration to a pregnant woman must also be reported to the PHE Immunisation Department (www.gov.uk/ guidance/vaccination-in-pregnancy-vip or telephone: 020 8200 4400).

17.10 *Inadvertent vaccine administration errors* - All errors should be reported onto DATIX, however specific additional information/advice about certain administration errors has been included in the Public Health England Document: COVID-19 vaccination programme. Information for healthcare practitioners (Dec 2020): https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949063/COVID-19_vaccination_programme_guidance_for_healthcare_workers_December_2020_V3.pdf ***(Note: This document may be updated. Please refer to the most up to date version online).***

17.11 Significant Incidents and *Serious Adverse Incidents – Fast Track Reporting to RVOC*

Significant incidents and serious adverse incidents resulting in moderate harm or above (please also refer to the *Trust's Duty of Candour and Being Open Policy*), will require escalation to the RVOC on the same day and where possible **within one hour** of the incident to ensure appropriate escalation, immediate learning and mitigating actions may occur. Such incidents require a fast track response and should be escalated urgently and as a priority through designated fast track pathways. The fast track pathway would require for RVOC (england.london-covid19voc@nhs.net) to be emailed with the incident details (excluding patient identifiable information) and the subject line should begin 'URGENT: ACTION REQUIRED'.

In addition to incidents of moderate harm or above, all **clinical incidents requiring treatment** should be reported as soon as possible after the event using the fast track incident response pathway stated above.

Significant Incident include, but are not limited to:

- Significant adver drug reaction (see 16.8 Adverse Drug Reaction)
- Incidents with significant or critical impact
- Incidents which may impact on the vaccination programme continuing at the affected site
- Incidents with potential for significant vaccine wastage
- Concerns regarding potential defective vaccine(s) or product
- Incidents where there is potential for significant shared learning.

If in any doubt, escalate the incident.

During normal working hours (Monday to Friday, 9am to 5pm), such incidents should be reported on DATIX. In addition, immediately contact the ELFT Governance and Risk Team (please email joanne.sims3@nhs.net **AND** telephone: 07824 561319). Please provide the DATIX ID number and highlight as a serious adverse incident / significant incident that requires escalation to RVOC. The ELFT Governance and Risk Team will escalate the incident to RVOC via the fast track incident response pathway described above.

Outside of normal working hours a DATIX should still be completed, but the clinical lead/manager should be alerted to assess whether the incident requires escalation via the fast track response pathway described above. The clinical lead/manager should then email the incident details directly to RVOC. The email should include the DATIX ID number, incident description (**excluding patient identifiable information**) and cc in the elft.incidentreporting1@nhs.net and joanne.sims3@nhs.net.

Incidents will be reviewed daily by the Governance and Risk Team/ site pharmacists/ clinical leads/ director of nursing in order to identify any incidents which may need to be escalated for review as a 'Serious Incident' or require a 48 hour report in line with the *Trust's Incident Policy*.

17.12 Incidents Relating to Prevention of Vaccine Waste

• If there are concerns about whether vaccine(s) are suitable for use, e.g. a potentially defective vaccine vial, do not discard it. The vaccine should be quarantined in accordance with storage requirements and may need to be sent for further investigation.

• Such incidents/queries should be escalated to RVOC for further advice. If an urgent response is required escalate using the fast track response pathway – see section '16.11 Significant Incidents and Serious Adverse Incidents – Fast Track Reporting to RVOC'

• In deciding whether a vaccine is suitable for use CARS will consult the regional Chief Pharmacist and further advice may be provided by the Regional Quality Assurance Pharmacist and the Specialist Pharmacy Service (SPS).

• If an incident occurs where it is believed that more than 100 doses may need to be discarded, or where the temperature excursion may be ambiguous, this must be urgently escalated to national level for a decision to be made and national authorisation through NVOC is required. This is to minimise any potential vaccine wastage, as further information may be available at a national level or special dispensation may be granted in particular circumstances in conjunction with manufacturers and technical experts. While awaiting a national decision the vaccine must be quarantined in accordance with the storage requirements.

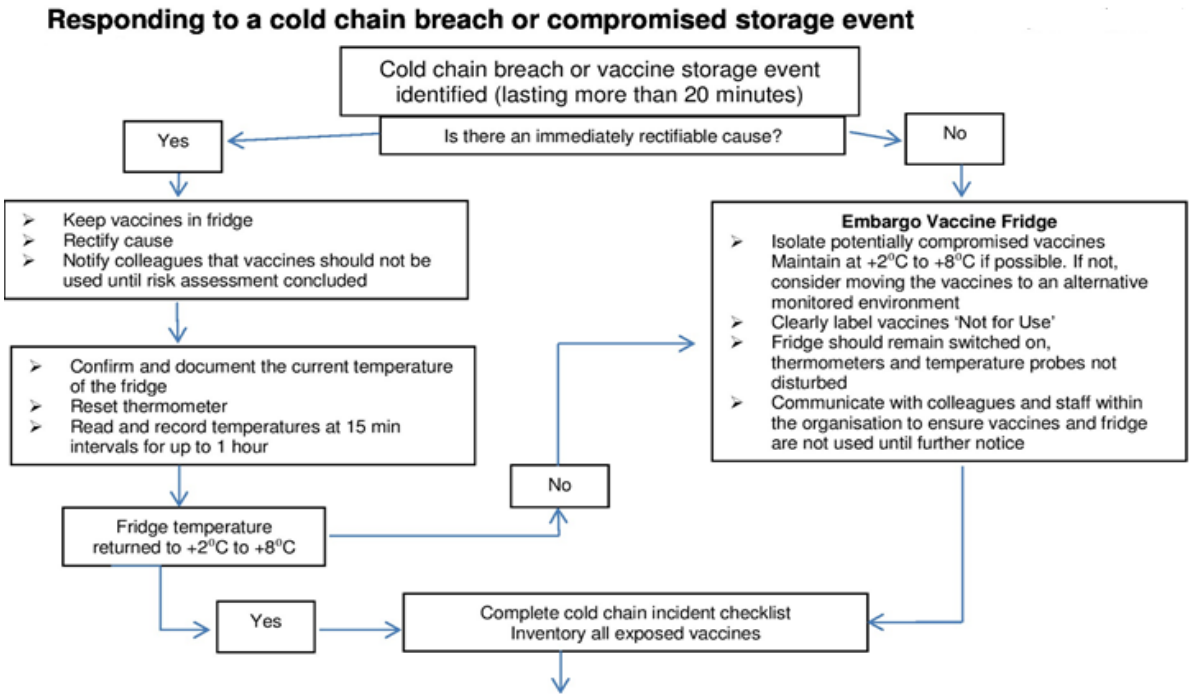
• Incidents that require escalation should include the following information:

- Vaccine type
- Batch number
- Number of vials affected
- Expiry date (fridge and frozen, if applicable).
- Description of current condition and location of the vaccine
- As much detail as possible regarding the incident (including any uncertainty around specific details).

Email **RVOC** (england.london-covid19voc@nhs.net) **ASAP within 1 hour** (Fast-track- subject line should begin 'URGENT: ACTION REQUIRED') & quote vaccine type, batch number, no. of vials affected, expiry date (fridge and frozen, if applicable), description of current condition and location of the vaccine, as much detail as possible regarding the incident (including any uncertainty around specific details).

Report on Datix with "COVIDVACC" in the incident description

17.13 Cold Chain Storage Breach or Compromised Storage Event



17.14*Related Appendices*

Refer to Appendix 11:
'Flow Chart for Medication Incident/Error and Adverse Drug Reaction Reporting'

1. 16.15 *Key Resources*Vaccine Incident Guidance Responding to errors in vaccine storage, handling and administration, Public Health England, Published January 2020 https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors
2. NHS COVID-19 Vaccination Programme, Standard operating procedure: Management of COVID-19 vaccination clinical incidents and enquiries https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-management-of-covid-19-vaccination-clinical-incidents-and-enquiries/

(Note: Above documents may be updated. Please refer to the most up to date version online).

Governance and Risk Team/ site pharmacists/ clinical leads/ director of nursing should refer to relevant national SOPs for more comprehensive information including information on how RVOC escalate/request further information on incidents reported to them.

18 Management of medical emergencies

18.1 Anaphylaxis see appendix 4 for PHE guidance on management of anaphylaxis in vaccination setting

18.2 A doctor will be onsite at all times during opening hours to support medical emergencies.

18.3 All medical emergencies including anaphylaxis should be managed as per BLS training and **emergency services called on 999. State nature of emergency and give the site address: NHS Vaccination Centre, The Street (Unit 1061), Westfield Shopping Centre, London, E20 1EJ. Advise that there is ambulance access via: Westfield Avenue, Pedestrian entrance next to John Lewis, E20 1EJ. (Location using 'What 3 words'= cooks.native.magma**

18.4 Within ELFT, chest compressions and ventilation are both considered as Aerosol Generating Procedures (AGP). As such and as the COVID status of the public attending is unknown, all staff within 2 meters of the patient must be wearing Level 3 AGP PPE when performing CPR *(Cardio-Pulmonary Resuscitation COVID-19 (Exceptional) Standard Operating Procedure, Version 2.2, 1st May 2020).* Defibrillation is not an AGP, therefore staff should prioritise connecting the AED to the patient and the delivery of a shock if indicated, whilst assisting staff don their Level 3 AGP PPE in order to start chest compressions.

18.5 See appendix

Appendix 1: Personal protective equipment

Fluid repellent surgical mask

Fluid-resistant surgical masks (FRSM) provide barrier protection against respiratory droplets reaching the mucosa of the mouth and nose. FRSMs should be well fitted. FRSMs are for single use or single sessional use. Ensure fluid-resistant (blue side) side is facing outwards when wearing. FRSM must be discarded:

- when damp
- is damaged
- is soiled (for example, with secretions, body fluids)
- when uncomfortable.

Disposable gloves

Disposable gloves must be worn when providing direct patient care and when exposure to blood and or other body fluids is anticipated or likely, including during equipment and environmental decontamination. Disposable gloves are subject to single use and must be disposed of immediately after completion of a procedure or task and after each patient contact. This must be followed by hand hygiene.

Disposable Aprons and Gowns

Disposable plastic aprons must be worn to protect staff uniform or clothes from contamination when providing direct patient care and during environmental and equipment decontamination.

Appendix 2:

Public Health England

Putting on personal protective equipment (PPE)

for non-aerosol generating procedures (AGPs)*

Please see donning and doffing video to support this guidance: https://youtu.be/-GncQ_ed-9w

Pre-donning instructions:

- Ensure healthcare worker hydrated
- Tie hair back
- Remove jewellery
- Check PPE in the correct size is available

1. Perform hand hygiene before putting on PPE.

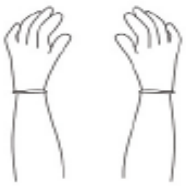
2. Put on apron and tie at waist.

3. Put on facemask – position upper straps on the crown of your head, lower strap at nape of neck.

4. With both hands, mould the metal strap over the bridge of your nose.

5. Don eye protection if required.

6. Put on gloves.



*For the PPE guide for AGPS please see:
www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures

NHS
East London
NHS Foundation Trust

Public Health England

Taking off personal protective equipment (PPE)

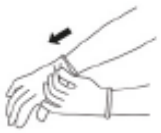
for non-aerosol generating procedures (AGPs)*

Please see donning and doffing video to support this guidance: https://youtu.be/-GncQ_ed-9w

- **PPE should be removed in an order that minimises the risk of self-contamination**
- **Gloves, aprons (and eye protection if used) should be taken off in the patient's room or cohort area**

1 Remove gloves. Grasp the outside of glove with the opposite gloved hand; peel off.

Hold the removed glove in the remaining gloved hand.



Slide the fingers of the un-gloved hand under the remaining glove at the wrist.

Peel the remaining glove off over the first glove and discard.

2 Clean hands.

3 Apron.

Unfasten or break apron ties at the neck and let the apron fold down on itself.

Break ties at waist and fold apron in on itself – do not touch the outside – **this will be contaminated**. Discard.

4 Remove eye protection if worn.

Use both hands to handle the straps by pulling away from face and discard.

5 Clean hands.

6 Remove facemask once your clinical work is completed.

Untie or break bottom ties, followed by top ties or elastic, and remove by handling the ties only. Lean forward slightly. Discard. DO NOT reuse once removed.

7 Clean hands with soap and water.

*For the PPE guide for AGPS please see:
www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures

NHS
East London
NHS Foundation Trust

Appendix 3:

ndix 3: Sharps poster

East London NHS
NHS Foundation Trust

INFORMATION ON SHARPS PROCEDURE

For All Sharps/Splash Contamination Injuries IMMEDIATELY Contact Team Prevent's Clinical Sharps Line:

Monday-Friday (08.30am-16.30pm) – 01327 810 777
Out of Hours – 0800 413 324

SHARP/SPLASH SAFE

1. **FIRST AID:**

   PROCEDURE FOR SHARP/NEEDLE-STICK INCIDENTS
   - ENCOURAGE BLEEDING BY SQUEEZING WHERE SKIN IS PUNCTURED
   - WASH THOROUGHLY WITH SOAP AND WARM WATER, DO NOT USE A SCRUBBING BRUSH

   PROCEDURE FOR SPLASH BY BLOODY OR BODY FLUIDS
   - IF EYES OR BROKEN SKIN AREAS ARE INVOLVED, WASH IMMEDIATELY WITH WATER
   - IF MOUTH IS INVOLVED, RINSE WITH PLENTY OF WATER BUT DO NOT SWALLOW

2. **CONTACT OCCUPATIONAL HEALTH - TEAM PREVENT IMMEDIATELY:**
   - MONDAY-FRIDAY (08.30am-16.30pm) – 01327 810 777
   - OUT OF HOURS – 0800 413 324

3. **MAKE SURE YOU:**
   - INFORM YOUR LINE MANAGER OR DUTY NURSE
   - SUBMIT AN INCIDENT REPORTING FORM ON THE TRUST INTRANET

For staff working within City & Hackney, Forensic Services and Tower Hamlets Directorates:

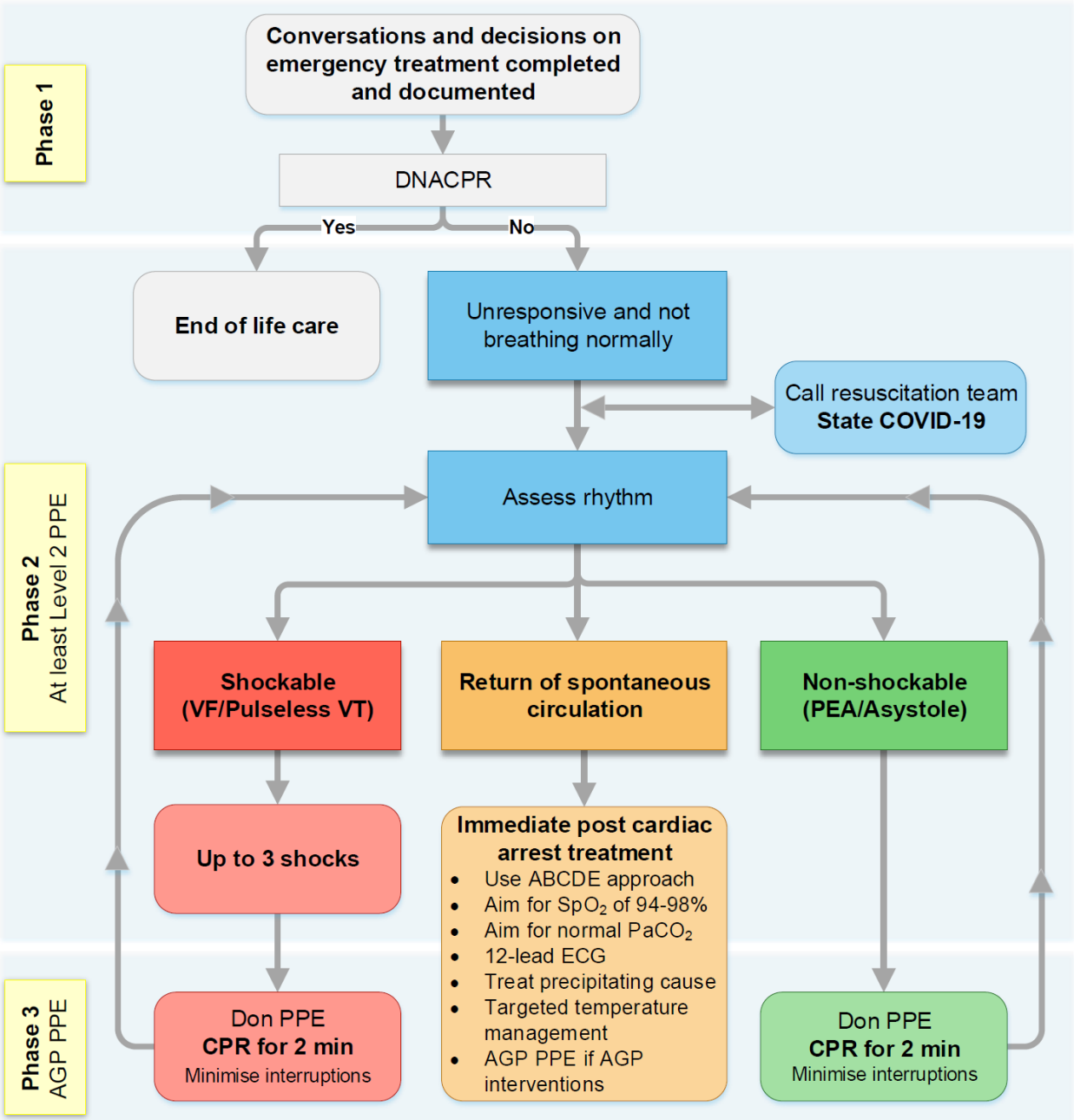
Following the above preliminary process, if staff are advised by OH to seek further assistance, staff should go to the Accident & Emergency Department at the Homerton University Hospital NHS Foundation Trust.

Appendix 4:

NHS East London NHS Foundation Trust

Resuscitation Council UK

Adult Advanced Life Support for COVID-19 patients – Acute hospital settings



During CPR

- Ensure high quality chest compressions
- Minimise interruptions to compressions
- Give oxygen
- Consider reversible causes 4Hs and 4Ts
- Use waveform capnography
- Continuous compressions when advanced airway in place
- Use a viral filter with any ventilation device, including BVM device, SGA or ETtube
- Vascular access (IV or IO)
- Give adrenaline every 3-5 min
- Give amiodarone after 3 shocks

Recommended PPE

Level 2 PPE

- Disposable gloves
- Disposable apron
- Fluid resistant surgical mask
- Eye protection

Level 3 AGP (aerosol generating procedures) PPE

- Disposable gloves
- Disposable gown
- Filtering face piece (FFP3) respirator
- Eye protection

Consider

- Ultrasound imaging
- Mechanical chest compressions to facilitate transfer/ treatment
- Coronary angiography and percutaneous coronary intervention
- Extracorporeal CPR

30/04/2020

MANAGEMENT OF ANAPHYLAXIS IN THE VACCINATION SETTING

Resuscitation Council UK

GUIDELINES 2021

Anaphylaxis?

A = Airway B = Breathing C = Circulation D = Disability E = Exposure

Diagnosis

Look for:

- Sudden onset of **A**irway and/or **B**reathing and/or **C**irculation problems[1]
- And usually skin changes (e.g. itchy rash)

Call for help

- Ensure Ambulance or Resuscitation Team called
- Lie patient flat (with or without legs elevated)
  - A sitting position may optimise respiratory effort in respiratory distress
  - If pregnant, lie on left side

Give intramuscular (IM) adrenaline[2]

If no improvement:

- Repeat IM adrenaline every 5 min
- IV fluid bolus[3]

If ongoing treatment is required despite TWO doses of adrenaline:

- Ensure Ambulance or Resuscitation Team called
- Repeat IV fluid bolus
- Further IM adrenaline every 5 min
- Get expert help to start an IV adrenaline infusion

- Establish airway
- Give high flow oxygen
- Apply monitoring: pulse oximetry, ECG, blood pressure

1. Life-threatening problems

Airway
Swelling, hoarseness, stridor

Breathing
Rapid breathing, wheeze, fatigue, cyanosis, SpO_2 <94%, confusion

Circulation
Pale, clammy, low blood pressure, faintness, drowsy/coma

2. IM adrenaline

IM doses of 1 mg in 1 mL (1:1000) adrenaline

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)

(Adrenaline IV to be given only by experienced specialists)

3. IV fluid bolus

Use crystalloid

Adults: 500–1000 mL
Children: 20 mL/kg

Resuscitation Council UK | BSACI Improving Allergy Care through education, training and research | RCGP Royal College of General Practitioners | Public Health England

Product code: COV2020381 1p 30K DEC (APS)

MANAGEMENT OF ANAPHYLAXIS IN THE VACCINATION SETTING

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Resuscitation Council UK | BSACI Improving Allergy Care through education, training and research | RCGP Royal College of General Practitioners | Public Health England

Product code: COV2020381 1p 30K DEC (APS)

Appendix 5: Minimum training requirement for the role of vaccinator

	COVID-19 elearning programme	Immunisation elearning programme – vaccine storage, administration and legal aspects sessions	Basic Life Support and anaphylaxis training	Any additional statutory and mandatory training required by employer	Face to face training about the COVID-19 vaccine programme which could include webinars or socially distanced classroom-type training	Work-based practical training and assessment of competency
Estimated time required	60-90 minutes for Core Knowledge session. 30 minutes for each vaccine-specific session. 15-30 minutes for knowledge assessments	30 minutes each session	Will depend how the training is undertaken	Will depend on individual roles, local policy and what has already been completed as part of current role requirements	Will depend on what is included	Will depend on how long it takes until vaccinator and assessor agree vaccinator is competent and confident
Workforce group						
Experienced and competent vaccinators (both registered HCPs and unregistered HCSWs) who have vaccinated within the past 12 months	Yes	If update training not undertaken in past year	If no BLS or anaphylaxis training within past year	Yes	Recommended	Competency assessment tool should be used by experienced vaccinators to self-assess and identify if there are any areas where they need to update or further their knowledge
Registered HCPs new to, or returning to vaccination after a prolonged period	Yes	Yes	If no BLS or anaphylaxis training within past year	Yes	Inexperienced vaccinators will benefit from more interactive training where possible. It is strongly recommended that some interactive training which provides the opportunity to ask questions is made available for this group	Yes
Vaccination Support Workers (unregistered healthcare workers new to immunisation with a specific role in vaccine administration only)	Yes	Depending on role	Yes	Yes	This group should not undertake e-learning as their sole means of vaccination training. Interactive training which provides the opportunity to ask questions should be provided for this group.	Yes
Administrative support staff		Storage session if likely to be responsible for cold chain maintenance	Depending on role assigned	Depending on role assigned		

Appendix 6: PHE Competency Assessment Tool

	Competency assessment tool for health care workers administering COVID-19 vaccine	Not applicable to role assigned (NA)	Self-assessment Record: met (M) or needs to improve (NI) (initial & date)	Supervisor review Record: met (M) or needs to improve (NI) (initial & date)	Record action plan for any assessed as 'needs to improve' (as agreed with supervisor)
	Part 1: Knowledge		**Self-Assessment**	**Supervisor review**	
1a	Can provide evidence of completion of the COVID-19 vaccine e-learning programme or attendance at a specific, comprehensive COVID-19 vaccine training course.				
1b	Has successfully completed and passed a knowledge assessment – either the e-learning course assessment or an end of course test.				
1c	Able to access the online Green Book and other relevant COVID-19 vaccine guidance e.g. DHSC/PHE/NHS E&I letters (or Scotland, Wales and Northern Ireland equivalents), Vaccine Update, PHE Information for Healthcare Practitioners on the COVID-19 vaccine programme document, COVID-19 vaccine PGD and Protocol, etc				
1d	Knows who to contact for advice if unsure about issues such as eligibility for vaccination or action to take if a vaccine error occurs.				
1e	Able to explain the basics of how the vaccine works, what it contains and why, how it has been trialled, any contraindications or precautions and possible side effects and how to treat them.				
	Part 2: Core Skills for immunisation	**Not applicable to role**	**Self-Assessment**	**Supervisor review**	**Record action plan for any assessed as 'needs to improve'**
2a	Is up to date with requirements for anaphylaxis and basic life support (BLS) training (has undertaken within past year or as per employers' stipulations).				

2b	Aware of how to respond to an immediate serious adverse event following vaccination and knows the whereabouts of anaphylaxis and emergency care equipment and how and when to use it.				
2c	Can explain incident response and reporting process in case of a procedural error, needlestick injury, breach of infection control measure, etc. as per local protocol.				
2d	Knows how to put on and take off personal protective equipment (PPE) as required and demonstrates good practice in infection prevention and control. Uses aseptic technique when preparing vaccines and handling injection equipment (e.g. syringes, needles) to prevent contamination and infection.				
2e	Disposes of sharps, vaccine syringes and vials and other vaccine equipment safely in line with local protocol.				
2f	Demonstrates knowledge and understanding of the rationale for and importance of maintaining the vaccine cold chain. Familiar with local protocols for cold chain management and the action to be taken in case of cold chain failure and who to contact.				
	Part 3: Clinical process and procedure	**Not applicable to role**	**Self-Assessment**	**Supervisor review**	**Record action plan for any assessed as 'needs to improve' (as agreed with supervisor)**
3a	Checks patient's identity and patient's records prior to vaccination to ascertain suitability for COVID-19 vaccination.				
3b	Able to answer patient/carer questions, referring to leaflets to aid explanations/discussion as appropriate and using interpreter if necessary to ensure patient/carer informed. Knows who to refer to or who to contact if further detail or advice is required.				
3c	Able to clearly and confidently discuss the benefits and risks of COVID-19 vaccination and able to address any concerns patients and/or carers may have.				
3d	Demonstrates knowledge of consent requirements and any relevant issues such as the capacity to consent and Mental Capacity Act. Ensures consent is obtained prior to vaccination and is appropriately documented.				

3e	Demonstrates knowledge and understanding of contraindications and precautions to COVID-19 vaccine and is able to assess appropriately for these, or, if necessary, the need to postpone vaccination.				
3f	Checks that there is an appropriate legal authority to supply and administer the vaccine such as: they are an appropriate prescriber, vaccine has been prescribed to a specific patient via a Patient Specific Direction, or, the vaccinator is authorised to administer the vaccine in accordance with a Patient Group Direction (PGD) or national Protocol.				
3g	Checks the presentation of the COVID-19 vaccine, the expiry date, how it has been stored prior to use and prepares it according to the vaccine manufacturer's instructions.				
3h	Positions patient appropriately and chooses appropriate vaccination site i.e. use of deltoid muscle in upper arm (or anterior lateral aspect of the thigh where there is insufficient muscle mass in deltoid muscle or deltoid muscle is otherwise unsuitable).				
3i	Demonstrates correct intramuscular injection technique.				
3j	Demonstrates an understanding of procedure for the reporting of any vaccine reactions and knows how to report using the MHRA's Coronavirus Yellow Card Scheme.				
3k	Completes all necessary documentation, recording type and product name of vaccine, batch number, expiry date, dose administered, site used, date given and name and signature.				
3l	Demonstrates good record keeping and understands the importance of making sure vaccine information is recorded on relevant data system(s) .				
3m	Advises patient/carer on what to expect after vaccination as appropriate (e.g. local injection site reactions, fever) and management of these. Provides patient/carer with a copy of post-immunisation advice sheet or the product's Patient Information Leaflet if appropriate.				
3n	Understands individual limitations and knows where to refer patients where there may be more complex requirements or a more experienced vaccinator is required.				

Statement of competence	
Name of individual: _____ has the appropriate knowledge, skill and competence to safely administer and/or assess suitability for COVID-19 vaccination. State name(s) of COVID-19 vaccine assessed for: _____ _____	Signature:
Name of supervisor carrying out assessment (or mark as N/A if experienced vaccinator carrying out self-assessment): _____ Role/job title: _____	Signature:

Appendix 7: Local Induction Checklist for Covid-19 Vaccination Site

It is mandatory that all new staff receive a site induction at the start of their placement. In order to ensure an effective induction, both staff and manager are required to complete each topic listed below.

After, completion both you and the manager must also sign and date at the end of the checklist when you both agree that all elements have been adequately covered.

It is expected that the local induction will be completed and returned to xxxxx within two weeks of commencing your placement.

If there are elements of the induction that you have not completed during this time or if you are having any difficulty with having a local induction, then please speak with the site operational lead Janette Clarke

Staff Information:

Full Name	
Start Date	
Job Title	
Band	
Name or Manager / supervisor	

Checklist:

Item of Induction	**Completed (please tick)**
Welcome, Orientation, and Key Information	
Duties, and supervision arrangements clearly explained	
Role clearly explained	
How and where to access support from senior colleagues clearly explained	
Issued with key clinical guidelines and workplace policies	
Introduction to key members of the team including the Clinical Manager/operational lead etc.	
Explanation of what to expect on an average day	
Information given on rotas including, annual leave, sickness reporting, and swapping shifts with peers	
Information on dress code and ID badge	
Given a working understanding of the equipment, including electronic platforms such as National System	
Explanation of how to complete an online Datix Incident form	
Discussed consenting of patients (if applicable)	
Discussed how to raise a concern regarding patient safety	
Discussed escalation process for when a patient is deteriorating	
Discussed and aware of Personal Protective Equipment i.e. masks, gloves etc.	
Aware of oxygen location and storage	

Aware of Patient Group Directive (PGD)	
Has completed all relevant training	
Is up to date with Basic Life Support (inc Anaphylaxis)	
Aware of Health & Safety on site (fire procedure, exits, incident reporting, First Aiders etc.)	
Aware of personal safety at work (including lone working)	
Aware of relevant policies and standard operating policy	

Staff to Complete: I confirm that I have received a full local induction and all areas ticked have been discussed.

Print Name:		
Signed:		
Date:		

Clinical manager / supervisor to Complete: I am satisfied that the above staff has completed all the above elements of their local induction. Print Name: Signed: Date:

Print Name:		
Signed:		
Date:		

Please return to xxxxxx

Appendix 8: Virtual and Classroom Training

Day One (For Clinical and non-Clinical staff)

Training	Time	Method of delivery
Data Security	9:30 – 10:30	Zoom
Infection Control (inc Donning, Doffing and sharps)	10:35 – 11:45	
Incident / Datix	11:45 – 12:15	
LUNCH	12:15 – 13:00	
SGA, MCA & Consent	13:00 – 14:15	
Health and Safety	14:20 – 14:50	
BREAK 14:55 – 15:15		
IM injection	15:15 – 15:50	
Close		

Day Two (For clinical staff only)

Training	Time	Method of delivery
Recognising deteriorating patients including respiratory and sepsis	9:30 – 12:30	Zoom
LUNCH 12:30 – 13:00		
National Protocol, Patient Specific Direction (PSD), Med Safety & History Taking	13:05 – 17:00 Inc 15mins Break)	

Day Three

Training	Time	Method of Delivery
Basic Life Support (inc Anaphylaxis)	9:30 – 12:30 or 13:30 – 16:30	Classroom

Appendix 9: Medicines related SOPs

Policy, SOPs and forms (available at https://www.sps.nhs.uk/home/covid-19-vaccines/astra-zeneca-vaccine/astra-zeneca-vaccine-handling-in-trusts/)

SOP AZH1	Ordering AstraZeneca COVID-19 Vaccine from Public Health England(PHE)
SOP AZH2b	Receipt of refrigerated AstraZeneca Covid-19 Vaccines (Westfield mass vaccination hub)
SOP AZH3	Preparation of AstraZeneca COVID-19 Vaccine Syringes for Administration
Work card AZH3.1	AstraZeneca Vaccine Preparation Work Instruction
Checklist AZH3.2	AstraZeneca Vaccine Supervision Checklist

SOP AZELFT1 Monitoring the main fridges in the pharmacy area at Statford mass vaccination hub

SOP AZELFT1a Monitoring minifridges at Stratford mass vaccination hub

SOP AZELFT2 Stocktaking and Reconciliation of AstraZeneca Covid-19 vaccine at the Stratford mass vaccination hub

SOP AZELFT3 Disposal of damaged, used or expired AstraZeneca Covid-19 vaccine at the Stratford mass vaccination hub

SOP AZELFT4 Handling of Spillages and Breakages of AstraZeneca COVID-19 Vaccine at Stratford Mass Vaccination hub

SOP AZELFT6 Monitoring Clinical Room temperatures

Vaccine Incident Guidance Responding to errors in vaccine storage, handling and administration, Public Health England, Published January 2020

https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

COVID-19 Vaccination Clinical Workstream, Standard operating procedure: Management of COVID-19 vaccination clinical incidents and enquiries
https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-management-of-covid-19-vaccination-clinical-incidents-and-enquiries/

Vaccine Incident Guidance Responding to errors in vaccine storage, handling and administration, Public Health England, Published January 2020

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COVID-19 Vaccination Clinical Workstream, Standard operating procedure: Management of COVID-19 vaccination clinical incidents and enquiries
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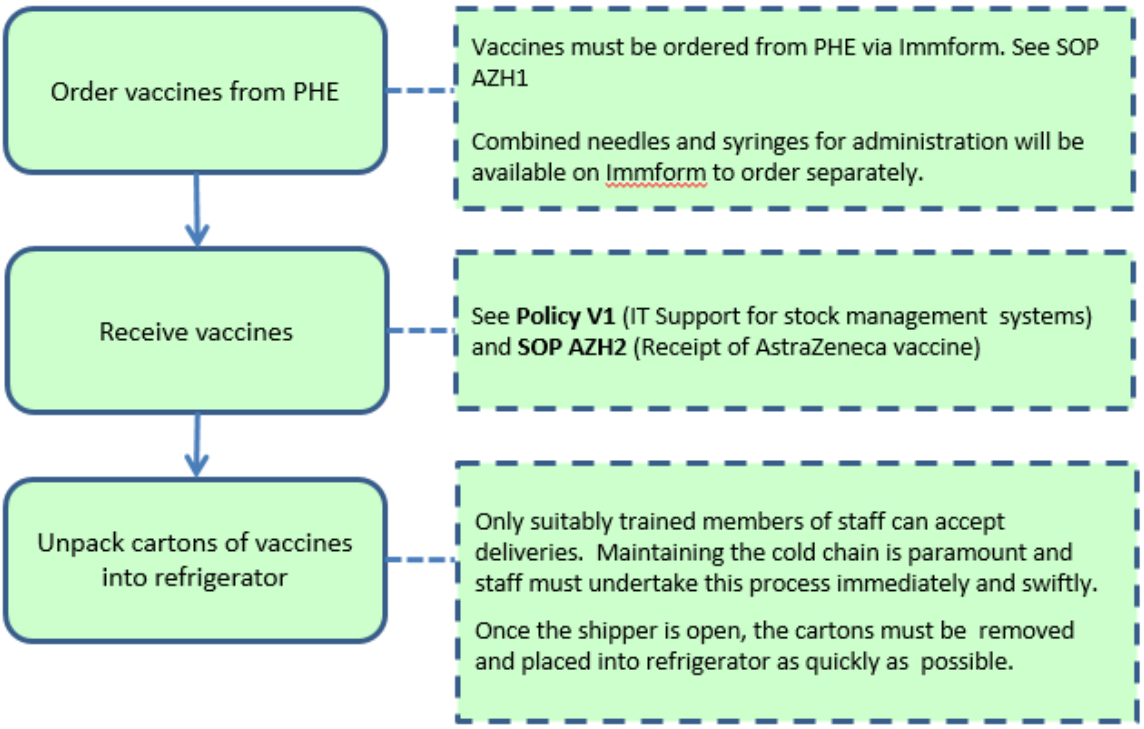
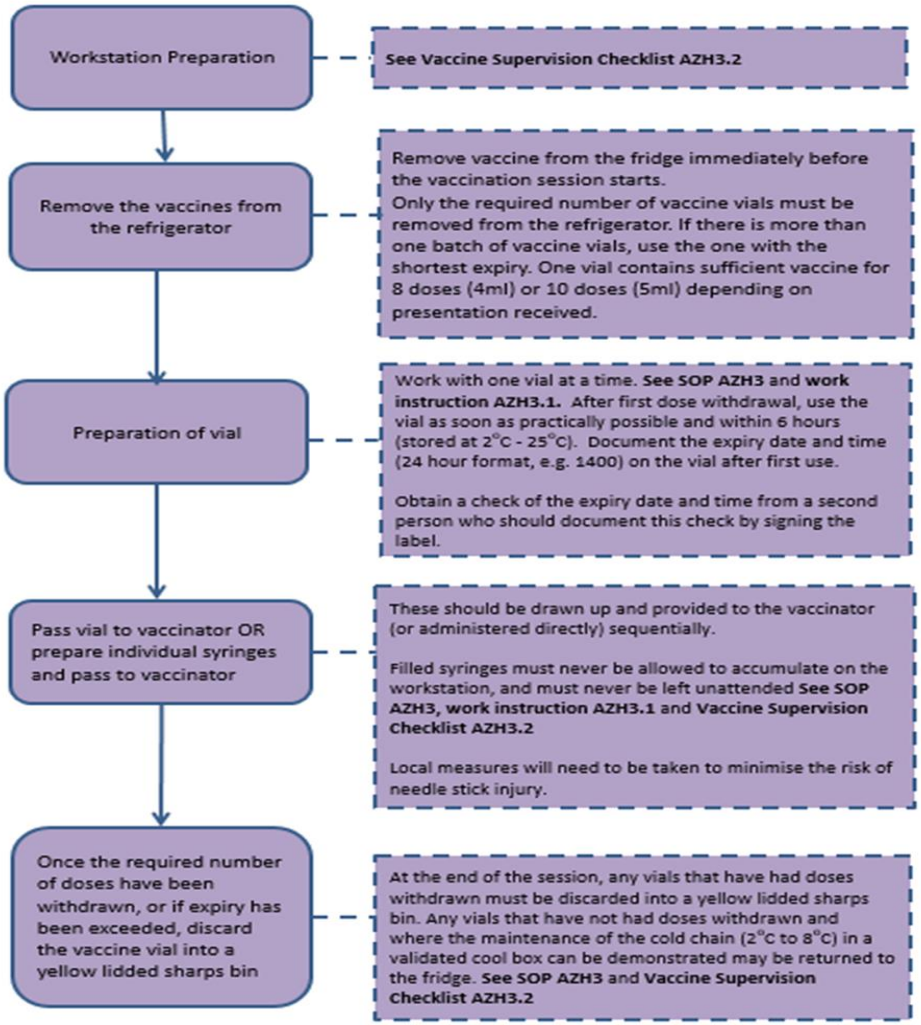
Appendix 10: Process flow 1: Ordering, receipt and storage to maintain cold chain

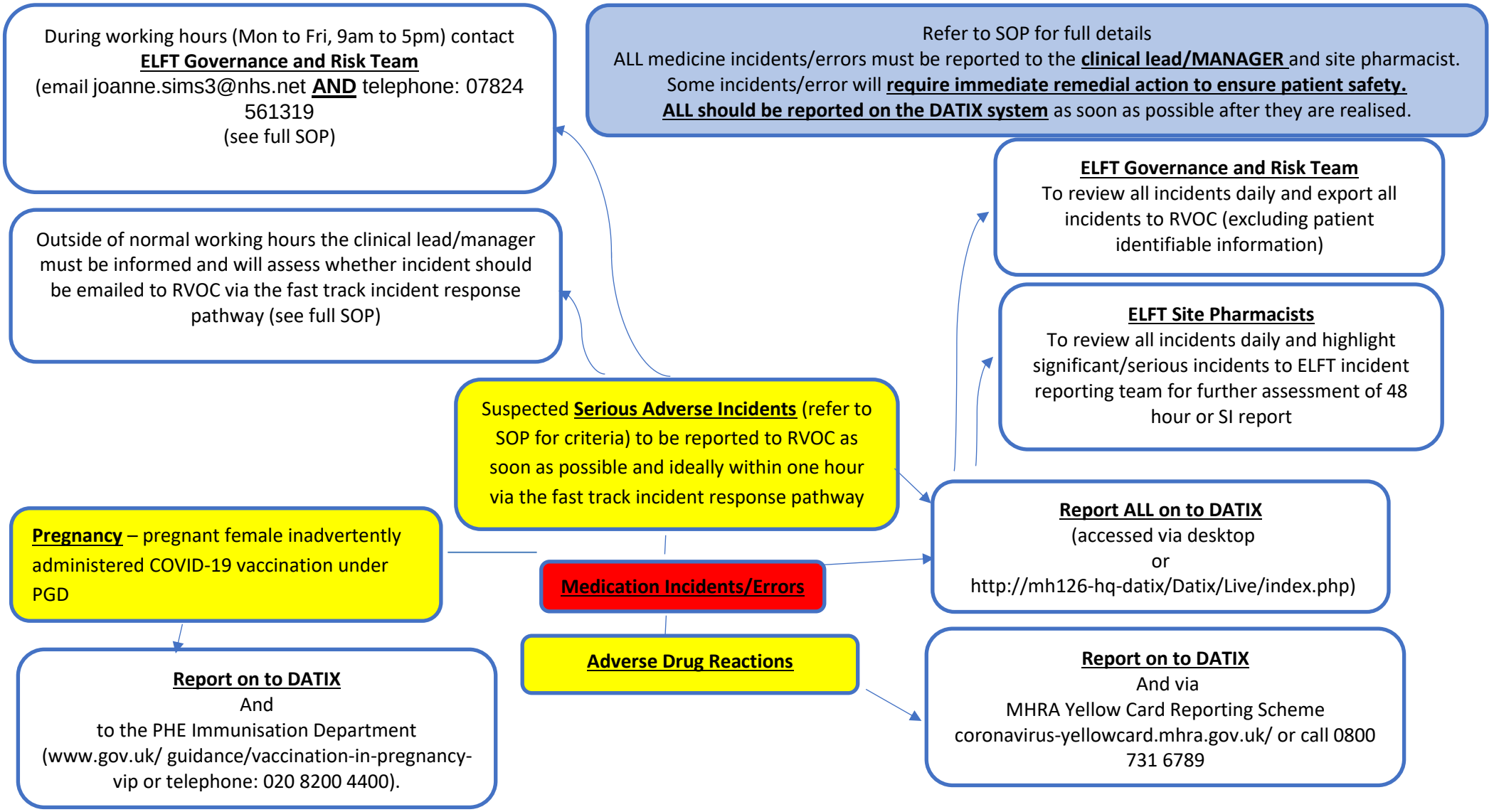


For additional guidance to support the use of fridges and coolboxes in the vaccine cold chain please refer to the SPS document https://www.sps.nhs.uk/articles/guides-to-support-best-practice-for-use-of-fridges-and-coolboxes-in-the-vaccine-cold-chain

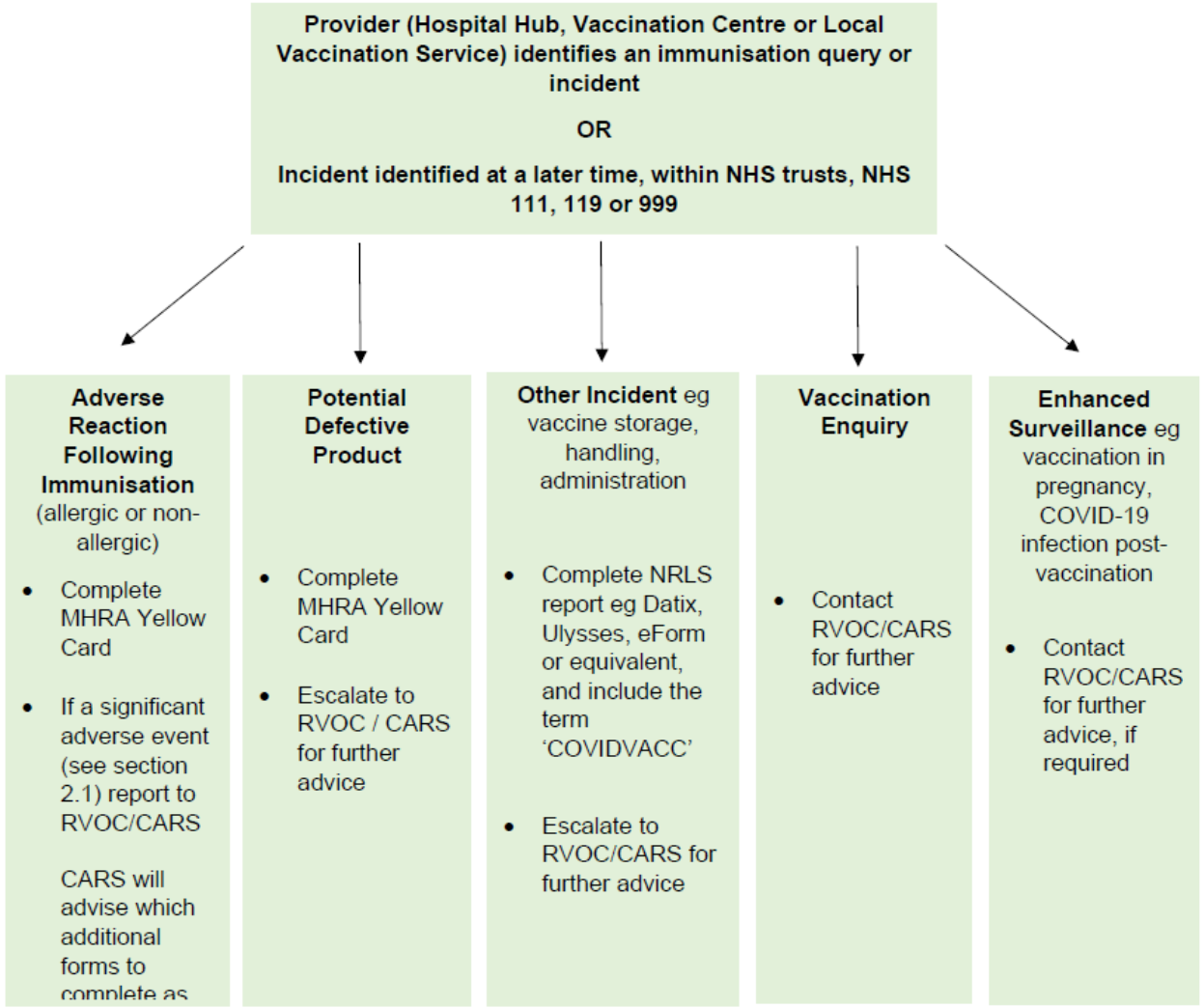
Process flow 3: Vaccine management in support of vaccination session



Appendix 11: Flow Chart for Medication Incident/Error and Adverse Drug Reaction Reporting



Appendix 12: Medication Safety - Incident Escalation Flow Chart



Adopted from:

NHS COVID-19 Vaccination Programme, Standard operating procedure: Management of COVID-19 vaccination clinical incidents and enquiries https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-management-of-covid-19-vaccination-clinical-incidents-and-enquiries/