

FOI REF: 23/400

18th July 2023

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FREEDOM OF INFORMATION ACT

I am responding to your request for information under the Freedom of Information Act. The answers to your specific questions are as follows:

1) Please provide a copy of the Trust's covid-19 policy in place in July 2021

Please see the attached policies, 'ESHT NHS COVID-19 Vaccine handling and management policy 2020/21' and 'Roadmap to easing of Covid-19 Restrictions from 19/07/21 Policy'.

2) Please provide the waiting lists or timeframes for an urgent vascular assessment following a GP referral for an urgent assessment/consideration for vascular surgery in July 2021.

The following data is based on: -

- Date range – First appointments with an appointment date for July 2021
- Urgent Referrals from GP into Vascular Surgery Specialty
- Average wait time from referral to first assessment appointment – in days

For All Outpatient First Appointments Recorded for July 2021 – Referred as Urgent by GP (whether attended or not)

For All Outpatient First Appointments Recorded for July 2021 – Referred as Urgent by GP (whether attended or not)

Referral Urgency	Nos Appts	Appt Month	Average Wait in Days
Urgent	20	Jul-21	43

For Attended Outpatient First Appointments in July 2021 – Referred as Urgent by GP

Referral Urgency	Nos Appts	Appt Month	Average Wait in Days
Urgent	11	Jul-21	38

If I can be of any further assistance, please do not hesitate to contact me.

Should you be dissatisfied with the Trust's response to your request, you have the right to request an internal review. Please write to the Freedom of Information Department (esh-tr.foi@nhs.net), quoting the above reference, within 40 working days. The Trust is not obliged to accept an internal review after this date.

Should you still be dissatisfied with your FOI request, you have the right of complaint to the Information Commissioner at the following address:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire SK9 5AF

Telephone: 0303 123 1113

Yours sincerely

Linda Thornhill (Mrs)
Corporate Governance Manager
esh-tr.foi@nhs.net

ESHT NHS COVID-19 Vaccine handling and management policy 2020/21

Document ID Number	2133
Version:	V1.1
Ratified by:	Medicines Optimisation Group
Date ratified:	21 st December 2020
Name of author and title:	Simon Badcott Chief Pharmacist Jane Starr Medication Safety Officer
Date originally written:	December 2020
Date current version was completed	December 2020
Name of responsible committee/individual:	Medicines Optimisation Group
Date issued:	15 February 2021
Review date:	December 2021
Target audience:	All ESHT Staff
Compliance with CQC Fundamental Standard	Safe Care and Treatment Good Governance
Compliance with any other external requirements (e.g. Information Governance)	NICE Clinical Guideline QS61: Infection Prevention and Control The Green Book - Immunisation against infectious disease (Public Health England) Professional guidance on the safe and secure handling of medicines (Royal Pharmaceutical Society of Great Britain) COVID-19 vaccination programme Information for healthcare practitioners
Associated Documents:	Medicines Policy Policy for the Management and Administration of Injectable Medicines Procedures for Covid 19 Vaccine VH1- 8.3

Did you print this yourself?

Please be advised the Trust discourages retention of hard copies of the procedural document and can only guarantee that the procedural document on the Trust website is the most up to date version

Version Control Table

Version number and issue number	Date	Author	Reason for Change	Description of Changes Made
1.0	Dec 2020	J Starr/ S Badcott		New Document
1.1	February 2021	J Starr/ S Badcott	Updated to include AstraZeneca vaccine	Extra information and details to include AstraZeneca vaccine as well as Pfizer. Updated allergy info.

Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

Name of Individual or group	Title	Date
Medicines Optimisation Group		Dec 2020
Medicines Optimisation Group		February 2021

This information may be made available in alternative languages and formats, such as large print, upon request. Please contact the document author to discuss.

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1. Introduction

The COVID-19 vaccination programme is of the highest priority for the NHS. In order to deliver this programme both safely and effectively, good practice in the handling and management of vaccine is paramount.

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

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

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

2. Purpose

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

2.1 Rationale

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

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

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

2.2 Principles

- To ensure that all staff involved in delivery of the vaccination programme are aware of, and adhere to, the correct procedures for the ordering, receipt, storage, supply and administration of the product.
- To ensure that all staff involved in the delivery of the vaccination programme are aware of and adhere to the correct pre-vaccination assessment checks and undertake accurate data entry of vaccination activity and details onto that National Immunisations and Vaccination System (NIVS)
- To ensure that the physical and biochemical integrity and sterility of all vaccines and related medicines is maintained.

- To ensure that all staff involved in delivery of the vaccination programme are aware of the relevant characteristics of COVID-19 vaccines and the implications this has for vaccine efficacy and patient safety.
- To provide assurance that vaccine safety, sterility, quality and efficacy is protected.
- To define key roles and responsibilities needed to deliver this assurance.
- To ensure that all staff understand their critical roles and responsibilities in delivering these objectives.

2.3 Scope

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

3. Accountabilities and Responsibilities

3.1. The Chief Executive is the registered person with overall accountability for the safe and secure handling of medicines under regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

3.2. The Medical Director is the Board member with responsibility for the safe and secure handling of medicines. They are responsible for assigning responsibility for clinical and operational oversight

3.3. The Chief Pharmacist is professionally accountable for the safe and secure handling and management of medicines on all vaccination sites operating within or under the jurisdiction of their employing legal entity. This includes oversight of those elements of practice within vaccination centres and other designated vaccination sites that may impact upon product integrity, from receipt of product to vaccine administration.

The Chief Pharmacist may delegate operational responsibility for oversight of ordering, receipt, storage and safe handling of vaccines and medicines, to a named and suitably trained pharmacy team member on each vaccination site.

The Chief Pharmacist must ensure that appropriate and formal authorisation for vaccine administration is in place such as a Patient Group Directions.

The Chief Pharmacist will be responsible for establishing an agreed business continuity plan in relation to safe and secure handling of vaccines, and tested in line with the organisational emergency preparedness processes and NHS Core Standards for Emergency Preparedness, Resilience and Response (<https://www.england.nhs.uk/ourwork/epr/qr/>). The business continuity plan should detail how the service will respond, recover and manage its services during disruption relating to people, information, security, premises including utilities, facilities particularly ULT and refrigerator failure, supplier, IT and data.

3.4. Heads of Nursing or Midwifery, Matrons and Clinical Service Managers are responsible for ensuring:

- Staff working in areas under their control are aware of how to access this policy via the extranet.
- Monitoring and ensuring the policy is implemented in clinical practice by all professionals involved and for reporting any deficits to the Medicines Policy and Procedure group.
- All clinical staff attend appropriate training.

3.5. Pharmacy Staff will ensure procurement, storage and supply arrangements follow national guidance. They will ensure the transport mechanisms are appropriate for maintaining storage temperatures and that temperatures are appropriately monitored during storage.

3.6. All Staff must familiarise themselves with the correct procedures linked to this policy. Individuals must ensure they are competent and supported in their role as it relates to the safe and secure handling of medicines.

3.7 All staff undertaking duties at the vaccination site must meet the necessary training standards and competencies in line with the SOPs and standard trust processes.

4. Process

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

See Separate Standard Operating Procedures:

- Pharmacy SOP for Ordering COVID-19 Vaccine from Public Health England (PHE)
- Pharmacy Receipt of Covid-19 Vaccines
- Unpacking of frozen Pfizer-BioNTech Covid-19 Vaccines and transfer to fridges to thaw
- Preparation of COVID-19 Vaccine Syringes for Administration

4.1 Storage and transportation of vaccines

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

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

4.2 Handling and management of vaccine and medicines in vaccination sites

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

- This policy document
- The relevant nationally authored 'Institutional Readiness' documents and Standard Operating Procedures (SOP)
- ESHT Medicines Policy
- Standard good practice guidance including aseptic technique
- Relevant Health and Safety guidance
- National Standards including those detailed in Reference links (CQC, DH Green book, NICE, PHE Covid-19 vaccination Programme, RPSGB).

4.3 Maintenance of records

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

Any serious adverse reactions are to be escalated for immediate senior clinical input; such situations are to be fully documented following the event and a record kept of relevant product

batch numbers. A record of all serious adverse events is to be provided to the responsible Pharmacist.

4.4 Data Protection

All staff have a responsibility to ensure that they do not disclose information about the service, service users, staff members and corporate documentation to unauthorised individuals.

4.5 Disposal of vaccines and other waste

Disposal of waste vaccines and any sharps must be undertaken in a safe and secure manner in accordance with the [ESHT Policy & Procedure for the Management of Waste](#). Equipment used for vaccination, including used vials, ampoules or syringes, should be disposed of by placing them in a proper, puncture-resistant 'sharps box' according to local authority regulations.

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

5. Special Considerations

5.1 Anaphylaxis/ Adverse reactions to the vaccine

The vaccine should not be given to those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to:

- a previous dose of the same COVID-19 vaccine
- any component (excipient) of the COVID-19 vaccine

The Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 contains polyethylene glycol (PEG). PEGs are a group of known allergens commonly found in medicines, many household products and cosmetics. Known allergy to PEG is very rare but would contraindicate receipt of this vaccine. The AstraZeneca vaccine does not contain PEG and may be used as an alternative. Whether PEG is the cause of reactions in patients with systemic allergic symptoms after the first dose of this vaccine. Pfizer-BioNTech vaccine is unclear; such patients may be considered for a second dose using the AstraZeneca vaccine (see section on incomplete vaccination), and should be observed for 30 minutes following vaccination.

Many biologics/monoclonal preparations contain PEG or related compounds. Individuals who have a history of systemic allergic reactions to biologics should not receive Pfizer vaccine except on the expert advice of an allergy specialist. Patients with undiagnosed PEG allergy may have a history of unexplained anaphylaxis or anaphylaxis to multiple classes of drugs.

The British Society for Allergy and Clinical Immunology (BSACI) has advised that:

- Individuals with a history of immediate onset-anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis should not be vaccinated with the Pfizer BioNTech vaccine. The AstraZeneca vaccine can be used as an alternative (if not otherwise contraindicated)
- Individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in a setting with full resuscitation facilities (e.g. a hospital). If the first dose was with Pfizer vaccine, then AstraZeneca vaccine can be considered (see section on incomplete vaccination) as an alternative (if not otherwise contraindicated) - this could be delivered in a primary care setting but with a 30 minute prolonged observation period
- Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting

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

Vaccine recipients should be monitored for 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment.

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever the Covid-19 vaccine is given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis. Any allergic reactions or adverse effects must be reported to the [MHRA Covid-19 Yellow card site](#)

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

Any needlestick or other injuries must be addressed in accordance with the policies of the relevant employing legal entity and reported via Trust incident monitoring system (Datix).

In the event of trust wide business continuity incident the Trust response plan will be followed; [INCIDENT RESPONSE PLAN \(INCLUDING COMMAND AND CONTROL FRAMEWORK\) OVER-ARCHING PLAN COVERING ALL ASPECTS OF INCIDENT RESPONSE](#).

6. Evidence Base/References

- **CQC Regulation 12: Safe Care and Treatment;** <https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment> (Accessed Dec 2020)
- **NICE Clinical Guideline QS61: Infection Prevention and Control** <https://www.nice.org.uk/guidance/qs61> (Accessed Dec 2020)
- **The Green Book - Immunisation against infectious disease** (Public Health England)
The latest information on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK. The COVID-19 vaccine chapter is available on: <https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a> (Accessed Feb 2021)
- **Professional guidance on the safe and secure handling of medicines** (Royal Pharmaceutical Society of Great Britain)
Adhere to the documented governance principles and relevant guidance. (Accessed Dec 2020)
Available on <https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines>
- **COVID-19 vaccination programme Information for healthcare practitioners:** <https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners> (Accessed Feb 2021)

7. Competencies and Training Requirements

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

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

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

8. Monitoring Arrangements

It is the responsibility of lead practitioners and line managers to ensure that staff involved are trained appropriately. Training records will be held and monitored by Vaccination Leads. Incidents will be monitored reactively through the Trust incident reporting system, with medicine related incidents being reviewed regularly by the Medication Safety Officer and subsequently by the Pharmacy Risk Management Group and Medicines Safety Group.

9. Document Monitoring Table

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Responsible Individual/Group/ Committee for review of results/report	Responsible individual/ group/ committee for acting on recommendations/action plan	Responsible individual/group/ committee for ensuring action plan/lessons learnt are Implemented
Incidents	MSO	Datix incident reporting	Weekly	Medicines Safety Group	Medicines Optimisation Group	Medicines Optimisation Group
Staff training records	Learning and Development	Training records	Annual	Professional Advisory Group	Professional Advisory Group	Professional Advisory Group
PGD procedure	Melanie Adams	Assessment and consent form completion	Monthly	Medicines Optimisation Group	Medicines Optimisation Group	Medicines Optimisation Group

10. Equality and Human Rights Statement

Healthcare Professionals must ensure they consider religious observances, equality, human rights and the promotion of dignity and respect in relation to prescribing, administering and handling medicines. The principles of informed consent and the Mental Capacity Act should be followed. Refer to the full statements within the Medicines Policy.

Appendix A – EHRA Form

A Due Regard, Equality & Human Rights Analysis form must be completed for all procedural documents used by East Sussex Healthcare NHS Trust. Guidance for the form can be found [here on the Equality and Diversity Extranet page](#).

Due Regard, Equality & Human Rights Analysis

Title of document: ESHT NHS COVID-19 Vaccine handling and management policy 2020/21
Who will be affected by this work? Staff, patients, service users, partner organisations
Please include a brief summary of intended outcome: This document is intended to provide the overarching principles for robust governance of the safe and secure handling and management of COVID-19 vaccines

		Yes/No	Comments, Evidence & Link to main content
1.	Does the work affect one group less or more favourably than another on the basis of: (Ensure you comment on any affected characteristic and link to main policy with page/paragraph number)		
	• Age	No	As a Trust policy the document has wide reaching impacts on all groups. The policy interprets current medicines legislation.
	• Disability (including carers)	No	
	• Race	No	
	• Religion & Belief	No	
	• Gender	No	
	• Sexual Orientation (LGBT)	No	
	• Pregnancy & Maternity	No	
	• Marriage & Civil Partnership	No	
	• Gender Reassignment	No	
	• Other Identified Groups	No	
2.	Is there any evidence that some groups are affected differently and what is/are the evidence source(s)?	No	(Ensure you comment and link to main policy with page/paragraph number)
3.	What are the impacts and alternatives of implementing / not implementing the work / policy?	No alternative legislative requirement	
4.	Please evidence how this work / policy seeks to “eliminate unlawful discrimination, harassment and victimisation” as per the Equality Act 2010?	N/A- no one excluded or treated differently	
5.	Please evidence how this work / policy seeks to “advance equality of opportunity between people sharing a protected characteristic and those who do not” as per the Equality Act 2010?	As above	
6.	Please evidence how this work / policy will “Foster good relations between people sharing a protected	As above	

	characteristic and those who do not” as per the Equality Act 2010?	
7.	Has the policy/guidance been assessed in terms of Human Rights to ensure service users, carers and staff are treated in line with the FREDA principles (fairness, respect, equality, dignity and autonomy)	Promotes fairness and equality by opening up the scheme to all patients irrespective of disability, race and sex.
8.	Please evidence how have you engaged stakeholders with an interest in protected characteristics in gathering evidence or testing the evidence available?	N/A
9.	Have you have identified any negative impacts or inequalities on any protected characteristic and others? (Please attach evidence and plan of action ensure this negative impact / inequality is being monitored and addressed).	No

Appendix B:

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

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

Governance and leadership

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

Standard Operating Procedures

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

Workforce and training

	Appropriately skilled pharmacy workforce identified for service delivery including: <ul style="list-style-type: none">▪ Sufficient capacity to provide supervision▪ Enhanced support for go-live to support early continuous improvement
	Standard training material relating to SOPs and service delivery
	Training delivery plan in place
	Competence assessment in place for appropriate elements

Premises, equipment and supply

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

Sign off

	Trust Chief Pharmacist
	Regional Chief Pharmacist

Appendix C- ESHT Process flow map with Risks and proposed Mitigation for Covid 19 Vaccine

	Process	Risks	Mitigation
1	Order vaccine from ImmForm as per procedure.	No stock available	Effective communication on stock availability between NHSE and Hospital hub. Effective communication between pharmacy and vaccination site so appointments not booked unless vaccine supply can be confirmed.
		Stock not ordered	Procurement staff to be aware of the process for ordering and cut off times for orders
2	Receive vaccine from courier by dedicated staff in Pharmacy.	Handling dry ice- injury to staff	Appropriate PPE Procedure for Handling of Dry ice First Aiders available.
		Injury to others	Secure location for the dispersing of the dry ice
		Vials damaged/ missing/ expired	Staff trained in operational SOPs Expiry dates check on delivery/ receipt
3	Unpack vaccine and store at 2-8 degrees Storage of vials in dedicated temperature mapped vaccine in refrigerated unit/ Cold store	Temperature excursion of refrigerated unit/ cold store	Move vials to alternative fridge (already available and temperature mapped).
		Stock not stored correctly upon receipt	SOP for the receipt of stock Trained staff only dealing with the product
4	Dedicated Pharmacy staff to label the thawed vaccine vials with required details as supplied by Pfizer (yellow labels).	Incorrect completion of labels	Second independent check of completion- follow SOP 604 for completion of the labelling requirements. Only trained staff to handle and move the product
		Incorrect shelf life assigned	Clarify that shelf life is assigned from when vaccine starts the thaw process- Second independent check.
		Labels not received from Pfizer	Stock check of labels supplied to be reconciled daily to ensure sufficient labels are available for physical stock held in pharmacy. Contingency label to be developed by pharmacy for this potential situation
5	Pharmacy staff remove required number of vials for the days site from Pharmacy refrigerated unit as per SOP Use suitable trolley and validated cool bag transport the vials to the vaccination site	Breach of cold chain	Vaccination clinics are located in close proximity to the fridge location to reduce the travel time. The vials will be packed in a method to ensure they remain upright to limit movement and not placed on frozen ice blocks (to prevent re-freezing). They will be transported immediately after packing by dedicated and trained pharmacy staff only. The quantity of vials being moved/ transported will be limited to the quantity required for use in preparation at the vaccination sites. Only trained staff to transport vials to vaccination site. Pharmacy will ensure the supply chain requirements (associated PPE and consumables) are also available at the vaccination site before the vaccines have been requested to prevent time out of the fridge (cold chain risk). Limit distance to vaccination site and location of clinics, use of trolley and cool bags.

		Damage to vials on route	Record number of damaged vials and dispose of in sharps bin.
	Process	Risks	Mitigation
6	Place vials in the dedicated vaccination site temperature monitored fridge	Fridge breaks down	Vaccination site fridges to be monitored as per trust Policy. No vaccines allowed to be stored in the fridge overnight. Move vials to an alternative fridge (already available and temperature mapped). 2 dedicated fridges are available at each vaccination site (vaccination areas)
		Temperature excursion in cold store	Move vials to alternative fridge if possible (already available and temperature mapped). Vaccination site fridges to be monitored as per ESHT Trust Policy: Temperature Control for the Storage of Medicines Procedure [Medicines Code]
7	Suitably trained staff to prepare and vaccinate patients as per Preparation Procedure	Poor workflow	Workstation to be prepared with support from Pharmacy aseptic staff (possible POD model). Photos to be taken and displayed showing ideal workstation setup/equipment
		Incorrect/poor dilution	All nursing staff to be observed and signed off by Pharmacist staff Pharmacy staff to be present at all areas of dilution for 1 st week of clinics Pharmacy staff able to challenge any poor techniques of dilution/aseptic technique Chief Pharmacist able to remove any vaccinator from operational tasks if deemed necessary
		Insufficient patients confirmed to utilise all available stock	Trust to contact care home patients or clinically vulnerable shielding patients as part of agreed protocol Trust to request staff to attend for vaccination.
		Health and safety of staff	Integrated needles and sheaths in use to protect vaccinators. Trained nurses will be preparing doses to ensure competence with preparing injectable medicines with oversight from pharmacy aseptic team.
		Lack of pharmacy staff to supervise preparation	Reduce areas for preparation and administration Review staff availability
		Adverse reaction or allergic reaction reported by patient post vaccination	Any person with a history of anaphylaxis to a vaccine, medicine or food should not receive the Pfizer/BioNTech vaccine. A second dose should not be given to anyone who has experienced anaphylaxis following administration of the first dose of this vaccine. Take action according to Trust Policy for drug allergy Report via specific MHRA Yellow card scheme COVID-19 Yellow Card reporting site .

	Process	Risks	Mitigation
8	Vaccination site staff to return unused vaccine vials to pharmacy to enable the completion of documentation for the wastage. Returned vaccine vials will be discarded according to local trust waste processes.	Vials not returned to pharmacy at the end of each session.	No vaccines allowed to be stored in the vaccination site fridge overnight. If vaccines left overnight – these to be disposed of before next delivery To be included on any end of day checklist for vaccination site The pharmacist on duty must return any unused vaccines and complete the required documentation relating to waste.
9	Pharmacy staff reconcile COVID vaccine vials stock daily	Stock levels of vials or labels incorrect	Discrepancies must be investigated and resolved as per departmental procedure daily. Discrepancies must be investigated immediately upon discovery. Only trained staff must be involved in all stages of the stock reconciliation process

Roadmap to easing of Covid-19 Restrictions from 19/07/21 Policy

Document ID Number	2253
Version:	V1
Ratified by:	Incident Management Team
Date ratified:	July 2021
Name of author and title:	Vikki Carruth, Chief Nurse and Director of Infection Prevention and Control
Date originally written:	July 2021
Date current version was completed	July 2021
Name of responsible committee/individual:	Incident Management Team
Date issued:	July 2021
Review date:	July 2022
Target audience:	All Trust staff
Compliance with CQC Fundamental Standard	Safe Care and Treatment
Compliance with any other external requirements (e.g. Information Governance)	National IPC Guidance on Gov.uk website
Associated Documents:	ESHT roadmap visuals (4 pages)

Did you print this yourself?

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Version Control Table

Version number	Date	Author(s)	Reason for Change	Description of Changes Made
1.0	July 2021	Lisa Redmond Vikki Carruth	New Document	N/A

Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

Name of Individual or group	Title	Date
Executive Team Meeting	Executive Team Meeting	July 2021
IMT	IMT	July 2021

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1. Introduction

Within healthcare settings tighter restrictions have been in place to ensure the safety of our patients, protect our staff and avoid outbreaks that could impact our services. The latest Gov.uk guidance states (in July 2021) that:

“Healthcare settings will continue to maintain appropriate infection prevention and control processes as necessary and this will continually be reviewed. Guidance will be updated on the latest clinical evidence this summer”

All staff are required to with hand hygiene, wearing a fluid resistant surgical face mask, maintain social distancing wherever possible and facilitate good ventilation and COVID safe office principles after the planned easing of restrictions on 19th July 2021.

East Sussex Healthcare NHS Trust (ESHT) has produced its own roadmap to help clarify the guidance that is currently in place across Trust sites and when it is due to be reviewed.

2. Purpose

The purpose of this document and road map is to ensure staff understand the guidance and their responsibility to maintain safety.

2.1 Rationale

This document sets out a list of restricted activities that are under constant review with the earliest date they could be eased as decided by the Incident Management Team (IMT) and the COVID ZERO key tests that must be met in order for them to be safely organised.

2.2 Principles

The roadmap will aim to ensure patient, staff and public safety by adherence to the guidance and COVID ZERO principles.

2.3 Scope

This policy is for all Trust staff.

3. Accountabilities and Responsibilities

Incident Management Team – will regularly review current data and information to inform the easing of restrictions when the prevalence of virus is at a level that will maintain patient and staff safety.

Trust staff – must adhere to Trust policy and guidance relating to Covid and the Road map for easing restrictions. They should also support/encourage all patients and visitors to adhere to Trust requirements.

Infection Prevention and Control Team – will ensure that the Trust is updated on all current national guidance and changes that may occur which will affect local implementation and restrictions. They will also provide advice and support in relation to Covid Zero principles and with risk assessments alongside the health and Safety Team.

4. Maintaining a safe environment through COVID ZERO Principles

All patients are required to wear a face mask. This is especially important whilst waiting for an admission COVID test result.

Thereafter, in-patients should be issued with a clean face mask each day (as a minimum) to wear when leaving their bed space/ward for any reason. Visitors and

outpatients must put on a clean surgical face mask on entering the building and clean their hands. Social distancing must also be maintained whenever possible.

If there is a medical exemption to wearing a mask patients must notify the relevant department prior to the visit to enable COVID safe alternative arrangements to be made which may include Lateral Flow Testing.

Due to risk and Health & safety requirements, mask exemption cannot/does not apply to staff who must have a current individual risk assessment. If staff are working in a Covid safe office they may be able to work without a mask but cannot walk around trust buildings without a mask to get to/from their office.

If uncertain and/or if any exceptions staff must discuss this with the divisional Heads of Nursing or equivalent that may need to discuss with Infection Control and/or Health & Safety colleagues.

In addition to mask wearing all staff must:

- maintain regular hand hygiene
- maintain 2 metre social distance
- be aware of the importance of good ventilation and open windows wherever possible and safe to do so
- continue with routine lateral flow test ensuring the result is entered onto the system
- have no Covid symptoms or history of contact with symptomatic or a positive case

The roadmap in appendix 1 provides the details of the requirements as well as the prevalence of virus (and in-hospital prevalence/transmission) and timelines which will guide a review of further easing of restrictions within ESHT.

4.1 Face to Face teaching

In person teaching can only be permitted if deemed essential (e.g. clinical skills simulation) and for small numbers of people. It can only take place if the COVID safe physical requirements can be met.

The COVID safe physical requirements for face to face teachings are:

- Access to a room that is large enough to accommodate 2 metre distancing between each person in the room
- Good natural or mechanical ventilation
- The ability and supplies for cleaning surfaces and shared equipment
- If the room is not required for other essential activity
- There is a requirement for physical interaction with trainer or kit

4.2 Face to Face meetings

Face to face meetings should be avoided whenever possible and staff should aim to use digital meetings. If a meeting is essential, it should be less than 8 people and can occur if the COVID safe physical requirements can be met.

The COVID safe physical requirements for face to face meetings are:

- Access to a room that is large enough to accommodate 2-metre distancing between each person in the room
- Good natural or mechanical ventilation

- The ability and supplies for cleaning surfaces
- The room is not required for other essential activity

4.3 Face to Face interviews

It is strongly advised that digital meetings are used instead of face to face interviews. If a face to face interview is considered essential, then there must be less than 4 people in a room at the same time. It can only take place if the COVID safe physical requirements can be met.

The COVID safe physical requirements for face to face interviews are:

- Access to a room that is large enough to accommodate 2-metre distancing between each person in the room
- Good natural or mechanical ventilation
- The ability and supplies for cleaning surfaces
- The room is not required for other essential activity
- There is a designated seat for a single candidate to wait

In addition to the actions required in the Covid zero principles in section 5.0, the following actions must also be undertaken:

- The candidate must wear a mask on entering/leaving and when moving from the designated seating areas
- There should be evidence of a negative lateral flow test on the day of interview
- Candidates should be managed to avoid multiple people waiting

4.4 External bodies or organisations/Non-ESHT Staff/Company Representatives on site

The only circumstance where this may be necessary is if a representative is deemed to be a critical requirement for a procedure or is supporting essential training/product implementation or updates. It may be necessary for external Auditors or Inspectors to be on site. There must be COVID secure measures in place and the representative must only be on site for the purpose of their visit and must not visit other areas. The time the representative is on site must also be kept to a minimum.

4.5 Volunteers on site

Volunteers can only be on site after agreement directly with the Infection, Prevention and control team.

The Hospital Chaplaincy has recommenced on the low risk wards and the shop trolley has been reintroduced but also on low risk wards with limited contact where possible.

The Pet Therapy will be reintroduced from the 19th July 2021.

There will be no access for any volunteers to Covid high and medium risk areas such as contact positive bays or where Covid status is unknown (e.g. admission areas). There will also be no access to any areas that have been closed due to an outbreak of Covid or other infections.

In addition to the actions required in the Covid zero principles in section 5.0, the following actions must also be undertaken:

- The usual risk assessments for volunteers and ensure mandatory training is up to date
- Volunteers to complete regular lateral flow tests and to inform the Trust of the

result

- Completion of the staff Covid risk assessment
- Encourage vaccination
- Consider contactless payment for the trolley service

4.6 Visiting

The Trust remains committed to compassionate visiting whilst ensuring that patient and staff safety can be maintained. As it may be subject to review and change, current guidance regarding visiting is on the Trust website for the public and the extranet for staff. **Visiting must be pre-booked.**

To support visiting, there should be:

- Good natural or mechanical ventilation with windows open during visiting hours
- Pre booked one hour visiting appointments/slots to prevent overcrowding
- One person from the same household or support bubble (patients may be accompanied if assistance is required)

The following actions must also be undertaken:

- Ensure all visitors wear a mask at all times
- Support visitors with hand hygiene
- Ask all visitors to maintain the 2 metre social distance from other patients and staff
- Ensure there has been a lateral flow test on the day of visiting patients who have isolated prior to admission or who are clinically vulnerable or who are not fully vaccinated for Covid
- Ensure visitors do not have any symptoms of Covid, have not had close contact with someone who has symptoms or who has tested positive.

4.7 Conferences on site

There will be no conferences on site until further notice.

4.8 Team building events

There will be no team building events allowed on site until further notice. There are no restrictions on activities involving staff members from the same team which has been organised in their own time and off site but ensuring national guidance is followed. However, staff are asked to consider the principles of Covid Zero and the risk of impact on the service if an outbreak occurred.

4.9 Unpaid placements

There can be limited unpaid placements on site in particular circumstances but this would need to be agreed by the Infection Prevention and Control Team.

4.10 Staff exercise classes on site

There are currently no staff exercise classes being held indoors.

5. Special Considerations

For reasons of risk and Health & safety, mask exemption cannot/does not apply to staff in clinical and public areas such as corridors and the staff restaurant. All staff must have a current risk assessment. If a staff member has an exemption this must be discussed with their line manager so that reasonable adjustments can be made such as working from home etc. Some staff may be able to remove masks if their office space is formally risk assessed and Covid secure.

6. Evidence Base/References

[Recommended PPE for healthcare workers by secondary care inpatient clinical setting, NHS and independent sector \(publishing.service.gov.uk\)](https://www.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/92122/recommended_ppe_for_healthcare_workers_by_secondary_care_inpatient_clinical_setting_nhs_and_independent_sector.pdf)

7. Competencies and Training Requirements

All relevant staff must be mask fit tested by the Mask Fit Testing team and ensure they wear the specific mask suitable for them.

All staff must be trained in how to don and doff PPE (Personal Protective Equipment).

8. Monitoring Arrangements

Please see overleaf.

Document Monitoring Table

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Responsible Individual/Group/ Committee for review of results/report	Responsible individual/ group/ committee for acting on recommendations/action plan	Responsible individual/group/ committee for ensuring action plan/lessons learnt are Implemented
Compliance with restrictions	IPC Team	Audit and incident data	monthly	Trust Infection Prevention and Control Group	Trust Infection Prevention and Control Group	Trust Infection Prevention and Control Group

9. Equality and Human Rights Statement

An Equality and Human Rights assessment has been completed with the key impact being on people who are unable to wear a mask.

Appendix A: EHRA Form

A Due Regard, Equality and Human Rights Analysis form must be completed for all procedural documents used by East Sussex Healthcare NHS Trust. Guidance for the form can be found on the [Equality and Diversity Extranet page](#).

Due Regard, Equality and Human Rights Analysis

Title of document: Roadmap to easing of Covid-19 Restrictions from 19/07/21 Policy
Who will be affected by this work? Staff, patients, service users, partner organisations, visitors
Please include a brief summary of intended outcome: To maintain safety for all staff, patients and public

		Yes/No	Comments, Evidence and Link to main content
1.	Does the work affect one group less or more favourably than another on the basis of: (Ensure you comment on any affected characteristic and link to main policy with page/paragraph number)		
	<ul style="list-style-type: none"> Age 	No	
	<ul style="list-style-type: none"> Disability (including carers) 	Yes	Mask wearing for staff is mandatory due to risk and H&S. This may adversely affect staff who cannot tolerate a mask. Risk assessments must be undertaken and further discussion will be required with managers re adjustments. See sections 4 and 5. Mask exemption is permitted for patients and the public and compliance cannot be enforced but is expected and recommended.
	<ul style="list-style-type: none"> Race 	No	
	<ul style="list-style-type: none"> Religion & Belief 	No	
	<ul style="list-style-type: none"> Gender 	No	
	<ul style="list-style-type: none"> Sexual Orientation (LGBT) 	No	
	<ul style="list-style-type: none"> Pregnancy & Maternity 	No	
	<ul style="list-style-type: none"> Marriage & Civil Partnership 	No	
	<ul style="list-style-type: none"> Gender Reassignment 	No	
	<ul style="list-style-type: none"> Other Identified Groups 	No	

2.	Is there any evidence that some groups are affected differently and what is/are the evidence source(s)?	Yes	As above re mask exemption for the public and patients.
3.	What are the impacts and alternatives of implementing / not implementing the work policy ?	It will not be possible to ensure the safety of patients, public and staff if all do not follow the guidance.	
4.	Please evidence how this work / policy seeks to “eliminate unlawful discrimination, harassment and victimisation” as per the Equality Act 2010?	This policy is for all staff	
5.	Please evidence how this work / policy seeks to “advance equality of opportunity between people sharing a protected characteristic and those who do not” as per the Equality Act 2010?	This policy is for all staff	
6.	Please evidence how this work / policy will “Foster good relations between people sharing a protected characteristic and those who do not” as per the Equality Act 2010?	This policy is for all staff	
7.	Has the policy/guidance been assessed in terms of Human Rights to ensure service users, carers and staff are treated in line with the FREDA principles (fairness, respect, equality, dignity and autonomy)	This policy is for all staff	
8.	Please evidence how have you engaged stakeholders with an interest in protected characteristics in gathering evidence or testing the evidence available?	No	
9.	Have you have identified any negative impacts or inequalities on any protected characteristic and others? (Please attach evidence and plan of action ensure this negative impact / inequality is being monitored and addressed).	Only where people with disabilities may be affected by the wearing of masks.	

	Current position What the guidance is now	Review date Earliest date restriction will be considered	Physical requirements What needs to be in place to be COVID secure	Prevalence of virus Review of data needed as part of planning activity in COVID secure way	Action required What staff need to do in order to be COVID secure
Face to face teaching	In person teaching is only permitted when essential (e.g. clinical skill simulation) for small numbers of people and when COVID safe physical requirements can be met.	Review by IMT 2/08/2021. Any decision to change the guidance will be communicated as soon as possible afterwards.	Access to a room large enough to support 2-metre distancing. Good natural or mechanical ventilation. Cleaning of surfaces/shared equipment. Room is not required for other essential activity. Requirement for physical interaction with trainer or kit.	Low community prevalence as determined by Clinical Advisory group. No/low in-hospital transmission. No/low prevalence of Variants of Concern (VOC) in community/hospital.	Mask wearing Hand hygiene 2-metre distancing Routine lateral flow testing. No COVID symptoms or history of contact with symptomatic or positive case.
	Avoid whenever possible and aim to use MS Teams. If essential small numbers of people (less than 8) can meet when COVID safe physical requirements can be met.	Week commencing 6 September 2021. Any decision to change the guidance will be communicated as soon as possible afterwards.	Access to a room large enough to support 2-metre distancing. Good natural or mechanical ventilation. Room is not required for other essential activity.	Low community prevalence. No/low in-hospital transmission. No/low numbers of COVID positive inpatients.	Mask wearing. Hand hygiene. 2-metre distancing. Routine lateral flow test. No COVID symptoms or history of contact with symptomatic or positive case.
	Use of MS Teams is advised. If face to face is considered necessary then all COVID safe measures listed must be in place. Suggest less than 4 people in total in a room at the same time.	Any decision to change the guidance will be communicated as soon as possible afterwards.	Access to a room large enough to support 2-metre distancing between each person in the room. Good natural or mechanical ventilation. Open windows. Cleaning of surfaces/shared equipment and door handles between each interview. A designated seat for single candidate to wait. Room is not required for other essential activity.	Low community prevalence. No/low in-hospital transmission. Low numbers of COVID positive inpatients.	Mask wear a mask on entering/leaving and when moving from designated seated area. Hand hygiene 2-metre distancing . Evidence of a negative Lateral flow on day of interview. No COVID symptoms or history of contact with symptomatic or positive case. Manage candidates to avoid multiple people waiting.

Current position What the guidance is now	Review date Earliest date restriction will be considered	Physical requirements What needs to be in place to be COVID secure	Prevalence of virus Review of data needed as part of planning activity in COVID secure way	Action required What staff need to do in order to be COVID secure	
<p>External bodies/ organisations other Non ESHT Staff Company reps On site</p>	<p>If the representative is deemed to be a critical requirement for a procedure (with COVID secure measures in place).</p>	<p>Review by IMT on 6th September 2021. Any decision to change the guidance will be communicated as soon as possible afterwards.</p>	<p>The representative is needed as a critical requirement for a procedure or is supporting essential training/product implementation or updates. The representative must only be on site for the purpose of their visit and not visit other areas. Time on site must be kept to a minimum.</p>	<p>Low community prevalence. No/low in-hospital transmission. Low numbers of COVID positive inpatients.</p>	<p>Mask wearing Hand hygiene 2-metre distancing Evidence of negative Lateral flow on day of visit No symptoms or close contacts with symptoms.</p>
	<p>Volunteers as agreed directly with IP&C Hospital chaplaincy service recommenced on low risk wards. Shop trolley on low risk wards but limit contact where possible. Pet therapy can be re-introduced week commencing 19th July.</p>	<p>Any decision to change the guidance will be communicated as soon as possible.</p>	<p>No access to Covid high and medium risk areas for example, positive or contact bays, COVID status unknown (e.g. admission areas). No access to areas closed due to outbreaks of other infections.</p>	<p>Low community prevalence. Low numbers of COVID positive inpatients. No/low in-hospital transmission.</p>	

	Current position What the guidance is now	Review date Earliest date restriction will be considered	Physical requirements What needs to be in place to be COVID secure	Prevalence of virus Review of data needed as part of planning activity in COVID secure way	Action required What staff need to do in order to be COVID secure
Visiting	<p>Compassionate visiting/End of life in high risk wards.</p> <p>Maternity supporters/partners.</p> <p>One person for 1hr in low risk wards.</p> <p>Elective surgery, oncology or extremely vulnerable patients: One person from the same household or support bubble (may be accompanied if assistance is required).</p> <p>Parent/supporter/guardian of a child.</p> <p>Essential Carer.</p>	<p>Review on Week commencing 11th October 2021.</p> <p>Any decision to change the guidance will be communicated as soon as possible after review date.</p>	<p>Good natural or mechanical ventilation – open windows during visiting hours.</p> <p>Scheduled 1hr appointments slots to prevent overcrowding.</p> <p>One person from the same household or support bubble (may be accompanied if assistance is required).</p>	<p>Low community prevalence.</p> <p>No/low in-hospital transmission.</p> <p>Low numbers of COVID in-patients.</p>	<p>Mask wearing</p> <p>Hand hygiene</p> <p>2-metre distancing from other patients and staff</p> <p>Lateral flow testing on day of visiting patients who have isolated prior to admission or who are clinically vulnerable or who are not fully vaccinated for COVID.</p> <p>No symptoms or close contacts with symptoms</p>
Conferences on site	<p>No on site conferences.</p>	<p>Review by IMT 10 January 2022. Any decision to change the guidance will be communicated as soon as possible after review date</p>	<p>Access to a room large enough to support 2-metre distancing Good natural or mechanical ventilation.</p> <p>Cleaning of surfaces and shared equipment.</p> <p>Room is not required for other essential activity</p>	<p>Low community prevalence.</p> <p>No/low in-hospital transmission.</p> <p>No/low prevalence of Variants of Concern (VOC) in community/hospital.</p> <p>% of staff vaccinated for seasonal flu and COVID.</p>	<p>Mask wearing</p> <p>Hand hygiene</p> <p>2-metre distancing.</p> <p>Lateral flow testing on day of conference</p> <p>No COVID symptoms or history of contact with symptomatic or positive case.</p>

	Current position What the guidance is now	Review date Earliest date restriction will be considered	Physical requirements What needs to be in place to be COVID secure	Prevalence of virus Review of data needed as part of planning activity in COVID secure way	Action required What staff need to do in order to be COVID secure
Team Building Events	No team building events allowed on site. No firm restrictions on activities involving staff members from same team organised in own time off site following national roadmap. However, staff asked to consider principles of Covid Zero and risk of service impact if outbreak occurred.	Review by IMT week commencing 3rd of November 2021.	Good natural or mechanical ventilation Outside if possible Access to a room large enough to support 2-metre distancing. Cleaning of surfaces/shared equipment.	Low community prevalence of COVID. % of staff vaccinated for seasonal flu and COVID.	Mask wearing Hand hygiene 2-metre distancing from other patients and staff . Routine lateral flow testing. No COVID symptoms or history of contact with symptomatic or positive case.
Unpaid placements	Limited unpaid placements on site in particular circumstances as agreed with IP&C.	Review by IP&C Gold Command week commencing 6 September 2021	Risk assess on individual basis for each placement using ESHT approved staff risk assessment tool.	Low community prevalence. No/low in-hospital transmission. No/low prevalence of Variants of Concern (VOC) in community/hospital.	Mask wearing Hand hygiene 2-metre distancing Lateral flow testing No COVID symptoms or history of contact with symptomatic or positive case Encourage vaccination.
Staff exercise classes on site	No staff exercise classes running indoors.	Review by IMT week commencing 6th September 2021.	Access to a space large enough to support 2-metre distancing. Good natural or mechanical ventilation. Cleaning of shared equipment. Safe location that is not required for other essential activity.	Low community prevalence. No/low in-hospital transmission.	Hand hygiene 2-metre distancing Routine lateral flow testing. No COVID symptoms or history of contact with symptomatic or positive case.