York Foundation Trust R&D Unit
SOP
MEDICAGO/S01

Standard Operating Procedure (SOP) Vaccination & Follow Up Visit Safety Procedures In Case of an Emergency MEDICAGO CP-PRO-CoVLP-02

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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Author:	Paula Strider/Kate Howard
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Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	
	Date:	26th April 2021
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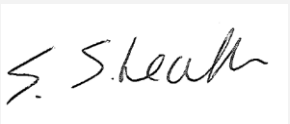
	Signature:	
	Date:	26th April 2021

This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	30th April 2021	

Contents

1 Introduction, Background and Purpose

MEDICAGO CP-PRO-CoVLP-021 will be vaccinating participants with a Coronavirus-Like Particle COVID-19 Vaccine.

The Phase 3 portion is an event-driven, randomized, observer blinded, placebo-controlled, 2-way cross-over design that will evaluate the efficacy and safety of the CoVLP formulation compared to placebo. In the Study Populations, subjects will be enrolled in a 1:1 ratio to receive the CoVLP formulation or placebo.

Period 1 CoVLP formulation or Placebo

Period 2 Placebo or CoVLP formulation

In the 2-way cross-over design, subjects who receive the CoVLP formulation in Period 1 will receive the placebo in Period 2, while subjects who receive the placebo in Period 1 will receive the CoVLP formulation in Period 2.

This SOP covers safety aspects of the vaccination trial process and the process to follow in the event of any unexpected emergencies including anaphylaxis and cardiac arrest.

2 Who Should Use This SOP

Clinical and other study investigators involved in the MEDICAGO study.

3 When this SOP Should be Used

This SOP should be used during the MEDICAGO clinical study at vaccination and any other onsite visits.

4 Procedure(s)

4.1 Visit timings

Staff briefing 0845hrs finish approximately 1700hrs depending on role.

Participants to arrive from 09.00am.

Post vaccination observation period: A minimum of 30 minutes in seated observation area.

4.2 Staff advice

- Report to the Vaccination Clinic Shift Lead on arrival, for introductions, and briefing.

- Maintain social distancing as per local COVID policy where possible.
- Wear appropriate PPE and follow hand hygiene and surface cleaning as per COVID guidelines
- Staff dress code: Wear Uniform/Scrubs or appropriate patient facing attire, with bare below the elbows and appropriate PPE.
- Check who is the Clinician in charge, and who is ALS/ILS trained for that shift, in case of an emergency.

4.3 Protocol:

A copy of the MEDICAGO protocol will be available onsite at all times: with the shift lead, as well as being available electronically. Study documentation patient packs and checklist of activities will be provided for each participant, and must be completed in full at each station in the clinic.

Emergency calling plan

Please familiarise yourself with the Anaphylaxis and ALS algorithms (appendix A & B).

- Most likely cause of collapse in our population is either syncope or anaphylactic reaction.
- In all situations ensure crash trolley is obtained which will be located in the corridor outside the clinic room where vaccination occurs. PPE Defibrillator/oxygen and other emergency equipment is available on the crash trolley. **Do not bring into the room**
- Obtain observations trolley to measure vital sign
- The senior clinician present must make an immediate decision if the diagnosis is syncope, anaphylaxis, or other cause of medical collapse
- Syncope is fainting and is common after vaccine injections in young people. The subject slumps, or falls over onto the floor. Breathing is preserved, the pulse is slow and bradycardic, and there may even be some focal twitching of face, arms or legs.
- If syncope, lie the patient flat on couch or the floor and elevate legs if suspected syncope. Carefully give them a glass of cold water to drink without causing choking. Patients with syncope will usually recover rapidly, but should be advised to rest lying down for 30 minutes.
- Anaphylaxis is an immediate allergic reaction to one of the vaccine components. Subjects often have swelling of the lips, and/or face, redness of the face or a blotchy rash. There may be immediate swelling of the oro-

pharynx which can involve the airway. Thus there may be wheezing or audible stridor. This is a serious medical emergency.

- If anaphylaxis, follow Appendix A
- If neither syncope nor anaphylaxis can be definitely diagnosed, then you must presume this is a cardio-respiratory collapse, and follow Appendix B

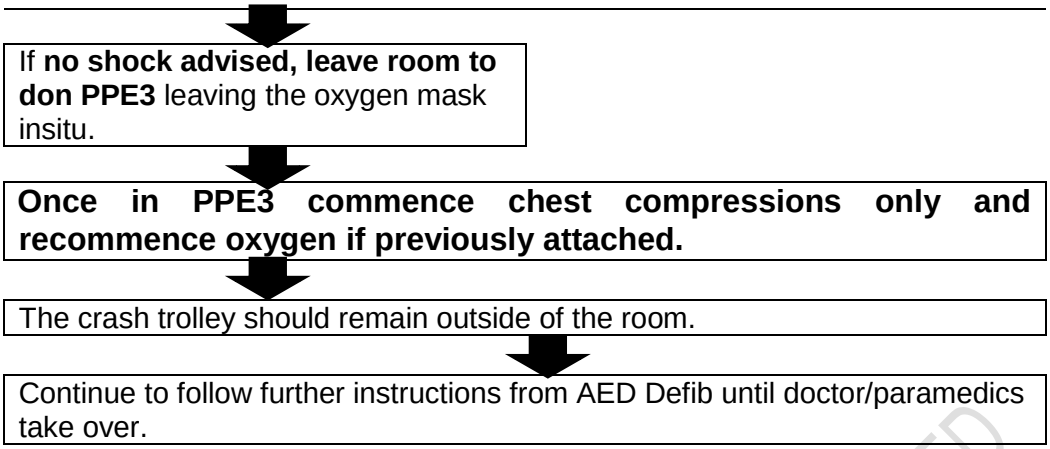
See emergency algorithm below for what to do if situation progresses to sever reaction or cardiac arrest.

Management of medical emergencies and Adult Cardiac Arrests at Vaccination site.

Full PPE3 protection is necessary for all members of the cardiac arrest team when chest compressions start. See Trust guidance on Donning/Doffing and PPE3

Rescuer is the healthcare worker who recognises cardiac arrest
Responder is the healthcare worker who responds to a call for help

Signs of a collapsed patient	
Rescuer	**Responder**
The **rescuer** will shout for help and request for the arrest trolley and that someone calls 999.	**Responder** to get Defib from crash trolley and hand to rescuer in room where participant has collapsed
The **rescuer** will check for the absence of signs of life by feeling for a carotid pulse only. They **must not** listen or feel for breathing. If the patient has been receiving supplemental oxygen via a facemask, this should be left on the patient's face. Flatten trolley.	**Responder** (or other healthcare worker) to activate crash **call alerting doctor** on site and **calling 999.** State Location (James College Q Block – portacabin – Newton Way, Located across from the Student Centre (YUSU) and Roger Kirk Centre Postcode is YO10 5DD) - **and also alert reception staff at Roger Kirk centre to call security on 3333 to direct ambulance to site.**
Attach defib pads to patient's chest, turn on, press analyse.	Don PPE3 from Crash trolley
If **Shock advised,** turn off oxygen and deliver shock. Immediately press analyse again. If shock advised, deliver 2nd shock. Immediately press analyse again. If shock advised deliver 3rd shock. Rescuer then leaves to don PPE3 and return to patient	



Arrival of doctor/paramedic crew

- should be a maximum of 6 personnel in the room with runner outside of room
- On arrival of the doctor/paramedic advanced life support will commence. As per previous recommendations all individuals must wear level 3 PPE if providing chest compressions and airway management. The airway should be secured as soon as possible to reduce any aerosol production. Any equipment used for airway management must be placed in plastic bag. The end of a used yankauer should be placed inside the packet.
- At the end of the resuscitation. All disposable equipment must be disposed of as per Trust guidelines, DEFIB wiped as per equipment cleaning guidelines.

  List of personnel involved must be documented in notes. Immediate debrief if possible.

5 Drug prescribing

This should only be carried out by a clinician, including all simple over-the-counter medication, including paracetamol and oxygen. Hospital prescription pad should be used and the prescription kept in the site file/CRF.

Drugs should be prescribed as follows:

Over-the-counter drugs

Paracetamol 1g four times daily as required

Cetirizine 10mg once daily as required

Ibuprofen 200mg capsules; 1-2 capsules three times daily as required

Chlorphenamine 4mg tablets up to three times daily as required

Oxygen

(0-100 %) and delivery device used – does not need to be prescribed in an emergency situation.

Urgent drugs for use in treatment of an anaphylactic reaction

Adrenaline 500micrograms/0.5ml (1 in 1,000) solution for injection;
500 micrograms, to be injected preferably into the lateral aspect of the middle third of the thigh, doses may be repeated several times if necessary at 5 minute intervals according to blood pressure, pulse, and respiratory function

Chlorphenamine 10mg/1ml solution for injection ampoules; **10mg** to be given either intramuscular injection, or by intravenous injection (maximum 4 doses daily)

Hydrocortisone (as Hydrocortisone sodium phosphate) 100 mg ampoule; **100mg**-300mg to be given by either intravenous injection (preferred) or intramuscular injection **200mgs in 4 mls'** (dilute with Saline).

Emergency drugs for cardiac arrest - As per guidance for non-shockable/ shockable

Adrenaline 1mg (=10ml 1:10,000) pre-filled syringe FOR RESUSCITATION

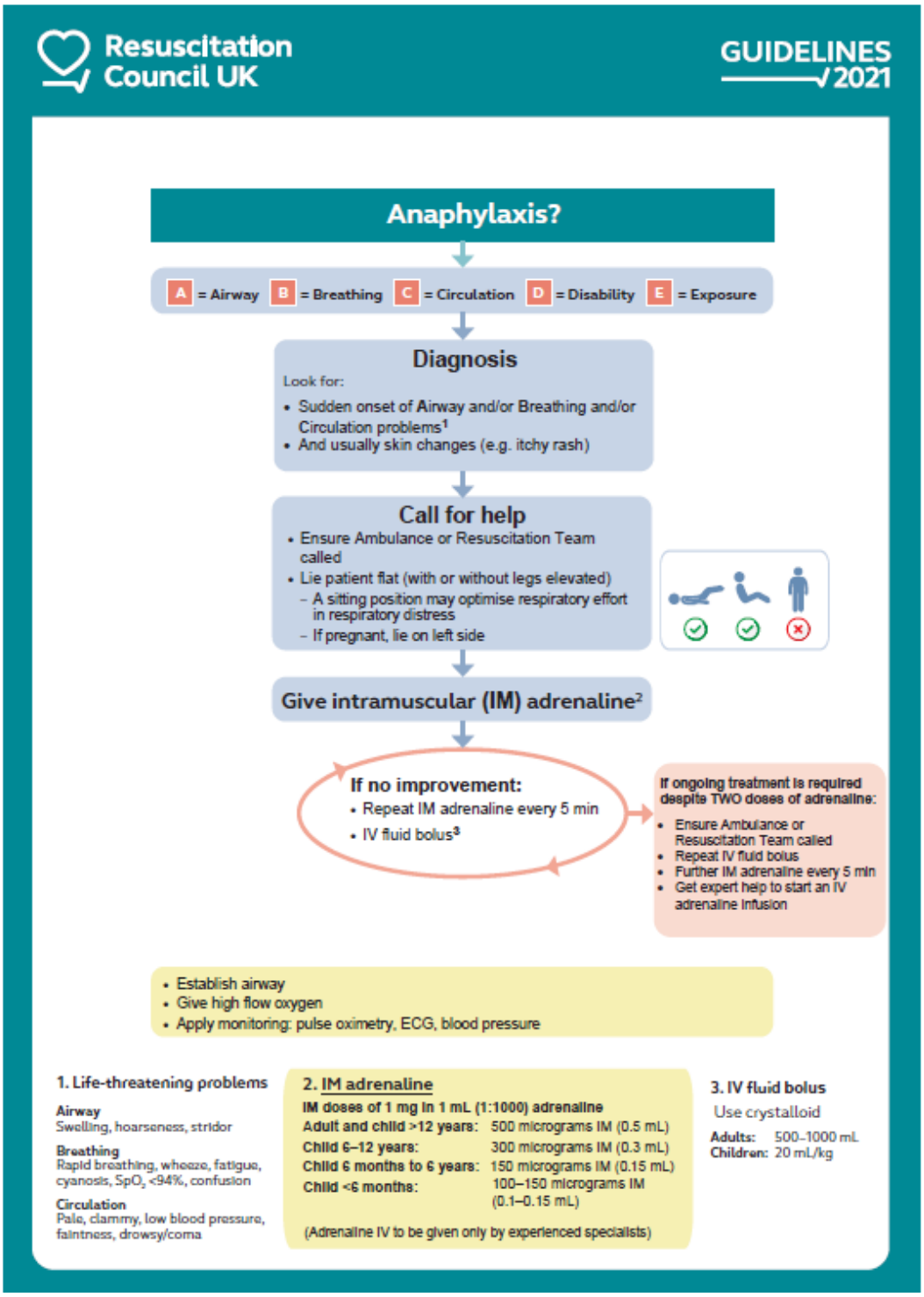
Amiodarone 300mg/10ml solution for injection pre-filled syringes
To be used as per ALS algorithm only

6 Related SOPs and Documents

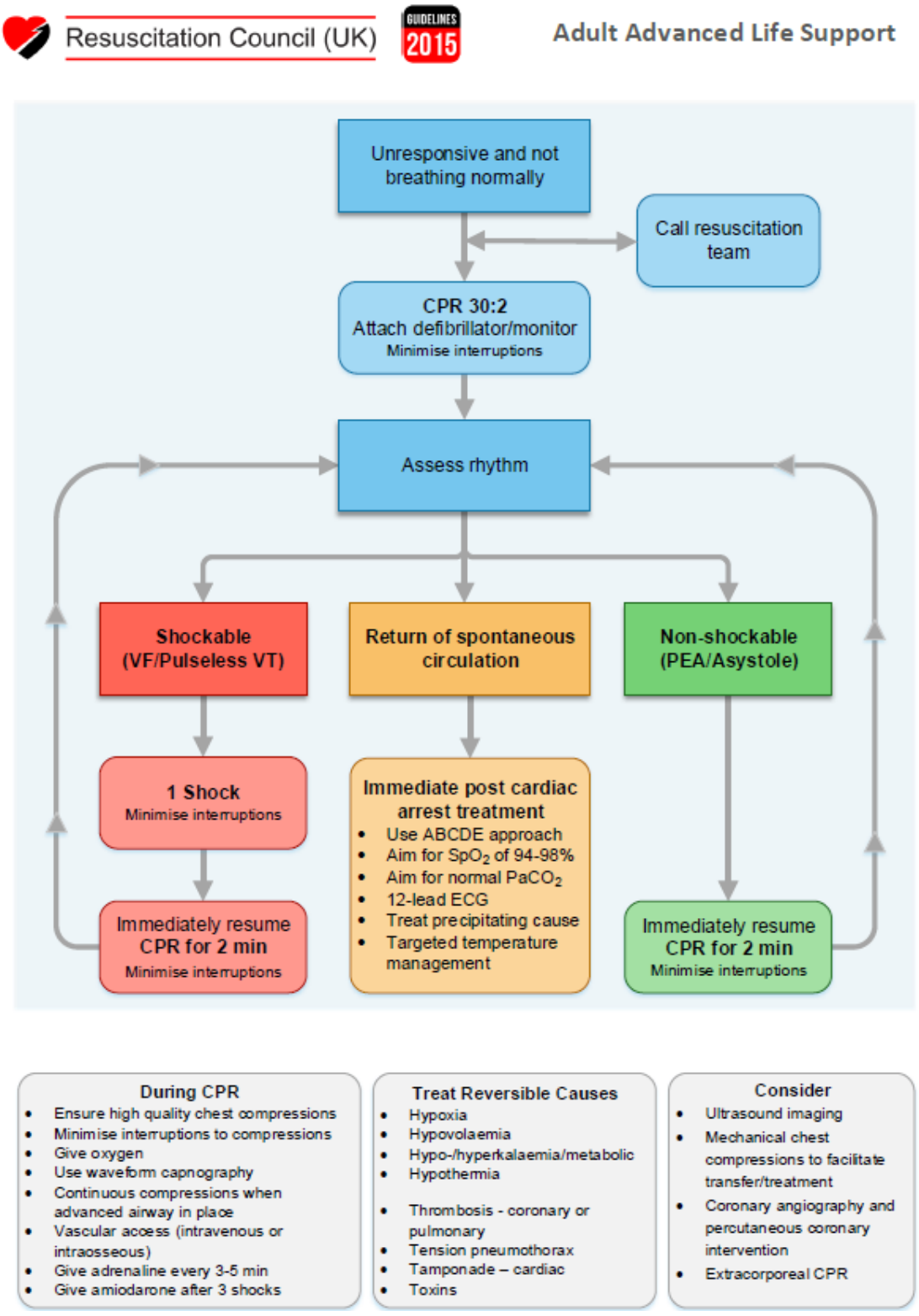
- Emergency procedures SOP
- Case report form: Patient pack will be allocated for each participant.
- Advanced support algorithm including resuscitation and anaphylaxis
- MEDICAGO Protocol

Appendix A

MANAGEMENT OF ANAPHYLAXIS IN THE VACCINATION SETTING



Appendix B


Resuscitation Council (UK)
GUIDELINES 2015
Adult Advanced Life Support
Unresponsive and not breathing normally
Call resuscitation team
CPR 30:2
Attach defibrillator/monitor
Minimise interruptions
Assess rhythm
Shockable (VF/Pulseless VT)
Return of spontaneous circulation
Non-shockable (PEA/Asystole)
1 Shock
Minimise interruptions
Immediately resume CPR for 2 min
Minimise interruptions
Immediate post cardiac arrest treatment
Use ABCDE approach
Aim for SpO2 of 94-98%
Aim for normal PaCO2
12-lead ECG
Treat precipitating cause
Targeted temperature management
Immediately resume CPR for 2 min
Minimise interruptions
During CPR
Ensure high quality chest compressions
Minimise interruptions to compressions
Give oxygen
Use waveform capnography
Continuous compressions when advanced airway in place
Vascular access (intravenous or intraosseous)
Give adrenaline every 3-5 min
Give amiodarone after 3 shocks
Treat Reversible Causes
Hypoxia
Hypovolaemia
Hypo-/hyperkalaemia/metabolic
Hypothermia
Thrombosis - coronary or pulmonary
Tension pneumothorax
Tamponade – cardiac
Toxins
Consider
Ultrasound imaging
Mechanical chest compressions to facilitate transfer/treatment
Coronary angiography and percutaneous coronary intervention
Extracorporeal CPR