Setting up a Travel Clinic in partnership with Valneva UK Limited

Your Clinic Support Pack

VIP valneva in partnership

valneva TRAVEL HEALTH

Contents

Before you begin

Setting up travel health clinics checklist

Completed

- Register and complete the Neva neva-training.com online travel health training ☐
- Go to VIP via vip.valnevauk.com for extra support ☐
- Ensure PGD provider is sourced or independent prescriber ☐
- Ensure practical immunisation training is up to date ☐
- Upload your clinic details to bewareofthebugs.com website or contact Valneva here to register your clinic on Beware of the Bugs ☐
- Download the Royal College of Physicians and Surgeons of Glasgow's Good Practice Guidance for Providing a Travel Health Service ☐

Source Products and Sundries:

1. Vaccines, antimalarials ☐
2. Clinical/ sharps waste bin ☐
3. Adrenaline ampoules or auto-injectors all strengths: 150mcg, 300mcg, 500mcg ☐
4. 2ml syringes ☐
5. Green and blue needles ☐
6. Cotton wool ☐
7. Spot plasters ☐
8. Resuscitation mask ☐
9. Safe, lockable storage for patient consent forms ☐

- Set up your consultation room ☐
- Identify additional resources and set-up on desktop ☐
- Update SOPs for vaccination services ☐

Completed

- Provide operational guidance for support staff ☐
- Ensure team understand the process for reporting adverse events ☐
- Engage with the extended clinic healthcare team so they understand their role in delivering the travel health service ☐
- Design and develop a vaccination and malaria prophylaxis service price list ☐
- Download your service / disease awareness and marketing materials from the Resources section of the VIP website or alternatively design in-house ☐
- Promote your service in the clinic (e.g. POS, till prompts, leaflets) and on your website. Update your Google Business Profile to reflect your services ☐
- Promote your service within your local community (e.g. GP Practices, mosques, travel agents, schools) ☐
- Look at link selling OTC products (e.g. OTC holiday medicines, suncreams, first aid kits, insect repellent) ☐
- Look at supporting websites and where possible sign up for updates, for example: ☐
  - TravelHealthPro - the website comprising the travel health resources of the Naitonal Travel Health Network anc Centre (NaTHNaC)
  - Immunisation Scotland - numerous leaflets for download in several languages
  - Centers for Disease Control and Prevention - aids to translating foreign immunisation records
  - ISTM - search for reputable clinics abroad
  - RCPSG Faculty of Travel Medicine – clinical diploma
  - The Green Book
  - Monthly government vaccine update

VIP valneva in partnership

Operational, clinical and professional requirements

Operational requirements

- Undertake and successfully complete all relevant training: Neva[1] and any relevant PGD progress training e.g electronic consultations forms (if using).
- Undertake and successfully complete the NaTHNaC Yellow Fever training[2] if planning to offer Yellow Fever vaccinations as part of your service.
- Attend a practical training session which follows National Immunisation Standards[3] covering injection technique, basic life support (BLS) and anaphylaxis – see training requirements by your PGD provider (e.g. NHS or private).
- Administrative staff / clinic assistant to help the HCP as required and to assist the HCP in the occurrence of an adverse event.[4]
- Review your clinic against the Good Practice Guidance for Providing a Travel Health Service.[5]
- Timetable vaccination clinics to be available for both walk-in and pre-booked appointments
  - If vaccinating patients under 16 years of age, undertake and successfully complete an approved Safeguarding Children Course. In England and Wales contact the Centre for Pharmacy Postgraduate Education (CPPE),[6] or elfh training[7] and in Scotland contact NHS Education for Scotland.
- Private PGDs will have different inclusions and exclusions for ages. Read and pay particular attention to the different inclusions and exclusions ages for private PGDs and sign.

References:

1. Neva Training. Available online: https://neva-training.com (Last accessed December 2022).
2. NaTHNac Training. Available online: https://nathnacyfzone.org.uk/become-a-yfvc (Last accessed December 2022).
3. Immunisation training standards for healthcare practitioners. February 2018. Available online: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/679824/Training_standards_and_core_curriculum_immunisation.pdf (Last accessed December 2022).
4. The Green Book: Chapter 8 Vaccine safety and the management of adverse events following immunisation. March 2013. Available online: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/147868/Green-Book-Chapter-8-v4_0.pdf (Last accessed December 2022).
5. Royal College of Physicians and Surgeons of Glasgow. Good Practice Guidance for Providing a Travel Health Service. 2020. Available online: https://rcpsg.ac.uk/documents/publications/1535-tm-guidancedoc-1020-final-hires-singlepages/file (Last accessed December 2022).
6. CPPE. Safeguarding Course. Available online: https://www.cppe.ac.uk/services/safeguarding (Last accessed December 2022).
7. Health Education England. elearning for healthcare (elfh). Available online: https://portal.e-lfh.org.uk/ (Last accessed December 2022).

Operational, clinical and professional requirements

Clinical requirements

ACCESS:

- Reasonable steps have been taken to allow disabled access to the clinic.

STORAGE:

- **In clinic:**[1,2]
  - Vaccine refrigerator with a minimum / maximum thermometer, a maintenance contract and a chart for daily recording of fridge temperature.
  - Storage of vaccines must be between +2 °C and +8 °C.
- **Out of clinic:**
  - Vaccines should be transported to the administration location in a cool box with cool packs and the appropriate insulation to keep the temperature between +2 °C and +8 °C.
  - The vaccines should be kept in their packaging and insulated (e.g. bubble wrap) from the cooling system to avoid the risk of freezing.
  - Vaccines to be stored on site in clinical portable vaccine storage box until required. Any unused vaccines should be returned to clinic fridge as soon as possible (within 8 hours).
  - It is the HCP's responsibility to keep the vaccines stored between +2 °C and +8 °C at all times.

References:
1. Professional Standards Safe and Secure Handling of Medicines, Appendix A A23-A33. Dec 2018. Available online: https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines (Last accessed December 2022).
2. The Green Book: Chapter 3 Storage, distribution and disposal of vaccines. March 2013. Available online: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf (Last accessed December 2022).

VIP valneva in partnership

Operational, clinical and professional requirements

Clinical requirements

CONSULTATION ROOM – IN CLINIC:

The private consultation room for vaccination administration should adhere to Section 2 of the Good Practice Guidance for Providing a Travel Health Service[1] and/or Principle 3 of the General Pharmaceutical Council's Standards for registered pharmacies[2]: the premises where clinic services are provided, and any associated premises, are safe and suitable.

- The premises that clinic services are provided from are safe and properly maintained.
- The size, design and layout of the premises are suitable for the clinic services provided. This includes sufficient space to effectively manage any emergency situations, i.e. undertake cardiopulmonary resuscitation (CPR). The consultation room should be well ventilated and should be temperature maintained; a high ambient temperature can increase likelihood of faints.
- The premises are maintained to an appropriate level of cleanliness and hygiene. No food or drink should be consumed in the area. No smoking.
- The premises are secure and safeguarded from unauthorised access.
- There should be a cleaning and disinfecting rota in place.
- Seating should be provided during vaccination.
- Access to emergency support in the form of a telephone or panic button to summon immediate assistance and 999 backup.
- Clinic audit to be completed and approved by the HCP before the beginning of each clinic (see page 17 for an example of an audit).

References:
1. Royal College of Physicians and Surgeons of Glasgow. Good Practice Guidance for Providing a Travel Health Service. 2020. Available online: https://rcpsg.ac.uk/documents/publications/1535-tm-guidancedoc-1020-final-hires-singlepages/file (Last accessed December 2022).
2. General Pharmaceutical Council (GPhC). Standards for registered pharmacies. June 2018. Available online: https://www.pharmacyregulation.org/sites/default/files/document/standards_for_registered_pharmacies_june_2018_0.pdf (Last accessed December 2022).

Operational, clinical and professional requirements

Clinical requirements

EXTERNAL ROOM – OUT OF CLINIC:

The room provided for the clinics should adhere to consultation room standards and should have access to emergency support (see page 6). For further guidance see PSNC out of clinic guidance[1] and the Good Practice Guidance for Providing a Travel Health Service.[2]

WAITING AREA:

- The patient should be observed for any immediate adverse reaction after any vaccination in sight of clinic staff; this will allow appropriate treatment.[3]
- It should be large enough to permit the patient to lie flat and allow staff access to either side of the patient with enough room to undertake CPR if necessary.
- Seating should be provided. In the event of an adverse reaction the seat could be used to elevate the patient's legs if appropriate.

WASTE DISPOSAL:

- Sharps bin[3] and clinical waste bin must be provided for sharps and clinical waste.
- All sharps bins should be kept out of reach of the public. Also children, even with an accompanying adult, should not be left alone in a consultation room where there is a sharps bin.
- Out of clinic: ensure the car insurance covers carrying clinical and sharps waste. Remember after the clinic the sharps bin must be sealed.
- Any accidental blood contamination is cleaned immediately and the resulting contaminated clinical waste disposed of in the clinical waste.

References:
1. Flu Vaccination – vaccinating outside the consultation room & off-site. Available online: https://psnc.org.uk/national-pharmacy-services/advanced-services/flu-vaccination-service/flu-vaccination-providing-the-service-outside-consultation-rooms-off-site/ (Last accessed December 2022).
2. Royal College of Physicians and Surgeons of Glasgow. Good Practice Guidance for Providing a Travel Health Service. 2020. Available online: https://rcpsg.ac.uk/documents/publications/1535-tm-guidancedoc-1020-final-hires-singlepages/file (Last accessed December 2022).
3. The Green Book: Chapter 4 Immunisation Procedures. March 2013. Available online: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/147915/Green-Book-Chapter-4.pdf (Last accessed December 2022).

Operational, clinical and professional requirements

Clinical requirements

CLINIC DOCUMENTATION – VERY IMPORTANT

- In clinic: clinic audit (see page 17 for an example audit) to be completed and approved by the HCP before starting a vaccination service.
  - Patient Group Directives (PGDs)[1] are used for the supply and administration of vaccines and malaria prophylaxis tablets. These PGDs are for named prescription only medicines in a defined clinical situation to a group of patients that have been individually identified before seeking treatment. The PGD may only be used by the HCP who has been trained in the use of the particular PGD and received any training which is specified within it.
  - By signing the PGD , the HCP is declaring they meet all the criteria and are competent to deliver the service.
- Please note the PGD is the HCP's legal authority to supply and administer. Therefore, the HCP must not operate outside the PGD.
- Access to the most recent online version of the Immunisation Against Infectious Disease – 'The Green Book'[2].

References:
1. Patient group directions (PGDs). Available online: https://www.gov.uk/government/publications/patient-group-directions-pgds (Last accessed December 2022).
2. The Green Book. November 2020. Available online: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book (Last accessed December 2022)

Operational, clinical and professional requirements

Professional requirements

- Vaccination is not considered an exposure prone procedure (defined as a procedure in which there is a risk of injury to a worker which may expose the patient's open tissues to the blood of the worker)[1]. As such, the recipient of a vaccination is not considered 'at-risk' of contracting Hepatitis B from the vaccinator. It is, however, possible for the vaccinator to be infected by the person receiving the vaccination. For this reason it is recommended that all persons delivering the vaccine be immune to Hepatitis B[2].
- Undertake and successfully complete the NaTHNaC Yellow Fever training if planning to offer Yellow Fever vaccinations as part of your service.
- The HCP should consider if they require a Disclosure and Barring Service (DBS) certificate (previously known as a CRB certificate) when vaccinating.[3]

References:
1. Public Health England. Emergency healthcare workers, exposure prone procedures (EPPs) and the exposure prone environment. April 2017. Available online: https://www.gov.uk/government/publications/emergency-healthcare-workers-exposure-prone-procedures (Last accessed December 2022).
2. The Green Book: Chapter 18 Hepatitis B. March 2013. Available online: https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18 (Last accessed December 2022).
3. PSNC DBS checks. Available online: https://psnc.org.uk/quality-and-regulations/Pharmacy-regulation/dbs-checks/ (Last accessed December 2022).

Consultation process

Traveller to complete a full travel health risk assessment document (electronic or paper). Best practice before appointment.

Information required:

- Personal details
- Destinations (if appropriate)
- Risk levels
- Medical history
- Vaccination history
- Allergy confirmation

HCP completes the risk assessment with the traveller online/phone/face to face and gives verbal and written advice (email) on recommended vaccines.

Traveller gives consent for selected vaccines and/or anti-malarials.

If online/ phone HCP clinic staff books the face to face appointment and takes payment from the traveller if possible. Email travel health information.

Traveller arrives at appointed time, HCP reviews risk assessment again and confirms agreed and declined vaccinations. Payment taken if not already taken.

If traveller declines, the HCP should document reason why (if given) alongside advised vaccines and provide to traveller to sign

HCP or trained clinic staff to remove vaccines from fridge. HCP to complete dispensing double-check and prepare vaccines. HCP to administer vaccine in accordance with national immunisation guidelines and reiterate potential side effects.

Provide traveller with any additional Patient Information Leaflets for all vaccines administered and email additional travel health information. Book next appointment, if necessary.

If the traveller is receiving a course of vaccines and pays - attach their name to the remaining vaccines and put aside to ensure stock is available when they return

Consent

You have a professional and legal duty to gain a patient's consent for the professional services, treatment or care you provide, or to use the patient's information.[1]

FOR CONSENT TO BE VALID THE PATIENT MUST:

- Have the capacity to give consent.
- Be acting voluntarily – they must not be under any undue pressure from you or anyone else to make a decision.
- Have sufficient, balanced information to allow them to make an informed decision.
- Be capable of using and weighing up the information provided.

Young people and children

While the capacity to consent depends more on the patient's ability to understand and consider their decision than their age, for the purpose of this vaccination programme, children under 16 years of age can only be vaccinated if the person with parental responsibility has countersigned the e-consultation.

References:
1. Royal College of Physicians and Surgeons of Glasgow. Good Practice Guidance for Providing a Travel Health Service. 2020. Available online: https://rcpsg.ac.uk/documents/publications/1535-tm-guidancedoc-1020-final-hires-singlepages/file (Last accessed December 2022).

Vaccination process

Please note: if the patient is aged under 16 years of age, the person with parental responsibility must be present during the vaccination.

1. Patient to remove outdoor clothing.
2. Seat patient, if preferred, and ask the patient if left or right handed (indicating dominant arm) or ask for patient's preference.
3. Ensure chosen upper arm exposed.
4. Prepare tray with vaccine, a cotton wool ball or small piece of gauze.
5. Wash hands thoroughly. If wearing gloves containing latex, confirm again with the patient that he / she is not allergic to latex.
6. Check arm for preferred site, avoid lesions.
7. In most cases there is no need to clean the skin prior to vaccination. If the skin is dirty, soap and water can be used to clean it and the vaccine given when the skin is dry.
8. Follow the administration instructions in the package information leaflet for the particular vaccine.
    - All injections are intramuscular injections except Yellow Fever which is sub-cutaneous.
    - Check with PGDs about bleeding disorders and sub-cutaneous administration.
    - Intramuscular injections should be given with the needle at a 90° angle to the skin and the skin should be stretched, not bunched. Yellow Fever injections should be given with the needle at a 45° angle to the skin.
    - Refer to the Summary of Product Characteristics, your live practical or Neva[1] online training reconstitution of vaccines.
9. Inject vaccine into patient in a single smooth dart-like action and withdraw needle smoothly from the skin.
10. Apply cotton wool to the vaccination area and ask the patient to press on the cotton wool. Never rub or massage the site.
11. The syringe and used needle should immediately be discarded in a suitable sharps bin. NEVER RE-SHEATH a needle.
12. Apply a plaster if appropriate and if patient is not allergic to plasters.
13. Give patient the package information leaflet contained in the vaccine box(es) or a print out the relevant version from the EMC website.

References:
1. Neva Training. Available online: https://neva-training.com (Last accessed December 2022).

Vaccination process

Guidance on potential anxiety and fainting

Immunisation providers should be aware of the potential for syncope or fainting associated with vaccination, particularly among adolescents. Providers should take appropriate measures to prevent syncope and to readily respond to the patient who feels faint.

HERE ARE SOME THINGS YOU CAN DO TO PREPARE:

- Ensure consultation area is well ventilated, cool and the consultation and vaccination procedure is never rushed.
- Check if the patient has needle phobia or blood phobia.
- Ensure you prepare / reconstitute the vaccine away from patient's sight to reduce anxiety. If space is restricted, turn away from your patient to prepare.
- Make sure the patient is seated at the time of vaccination, or if they know they faint and still want to be vaccinated then discuss sitting on the floor to be vaccinated to prevent falling.
- Ask patient to sit quietly and rest. Observe patient after they are vaccinated for signs and symptoms that precede syncope, such as weakness, dizziness, sweatiness and pallor.
- If patient is experiencing possible signs or symptoms of fainting (looks pale, is clammy, feels dizzy), take the following steps to prevent syncope and injury from falling:
  - Have the patient sit or lie down immediately.
  - Have the patient lie flat or sit with head between knees for several minutes; loosen any tight clothing and maintain an open airway; apply cool, damp cloths to the patient's face and neck.
  - Observe the patient until symptoms completely resolve.

FAQs

Pre-vaccination

Please read before contacting your clinic's medical support line or your PGD provider.

CONCERN	ADVICE
Patient has reduced mental capability	If you have any concerns about a person's ability to consent to the procedure (e.g. under influence of alcohol / drugs), refer the patient to their GP.
Tattoo	If the tattoo is fresh, then proceed with the vaccination using the patient's opposite arm. If the tattoo is long established, proceed with vaccination.
Vaccination site	If the patient insists the injection is to be administered anywhere other than the deltoid (e.g. upper thigh), refer the patient to their GP.
	If there is no access to the necessary injection site, refer the patient to their GP.
Age of child / young person	Refer to your clinic guidelines, PGDs and protocol.
Breastfeeding	Check the Summary of Product Characteristics. If there are any concerns or contraindications, refer the patient to their GP.
Patient would like to have another vaccination at the same time as their travel vaccination	Check the Summary of Product Characteristics for each vaccine. If there is no contraindication to administering a travel vaccination at the same time as any other vaccination proceed with the vaccination. For PGD vaccinations refer to each individual PGD.
Patient is not registered with GP	Proceed with the vaccination.
Recent or prospective blood donor	Refer to latest Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) Donor Selection Guidelines.
Allergies	Check with the Summary of Product Characteristics for each vaccine. If in any doubt, do not proceed with the vaccination(s) and contact the medical support line. For PGD vaccinations refer to each individual PGD.
Medical conditions	
Medications	

FAQs

Post-vaccination

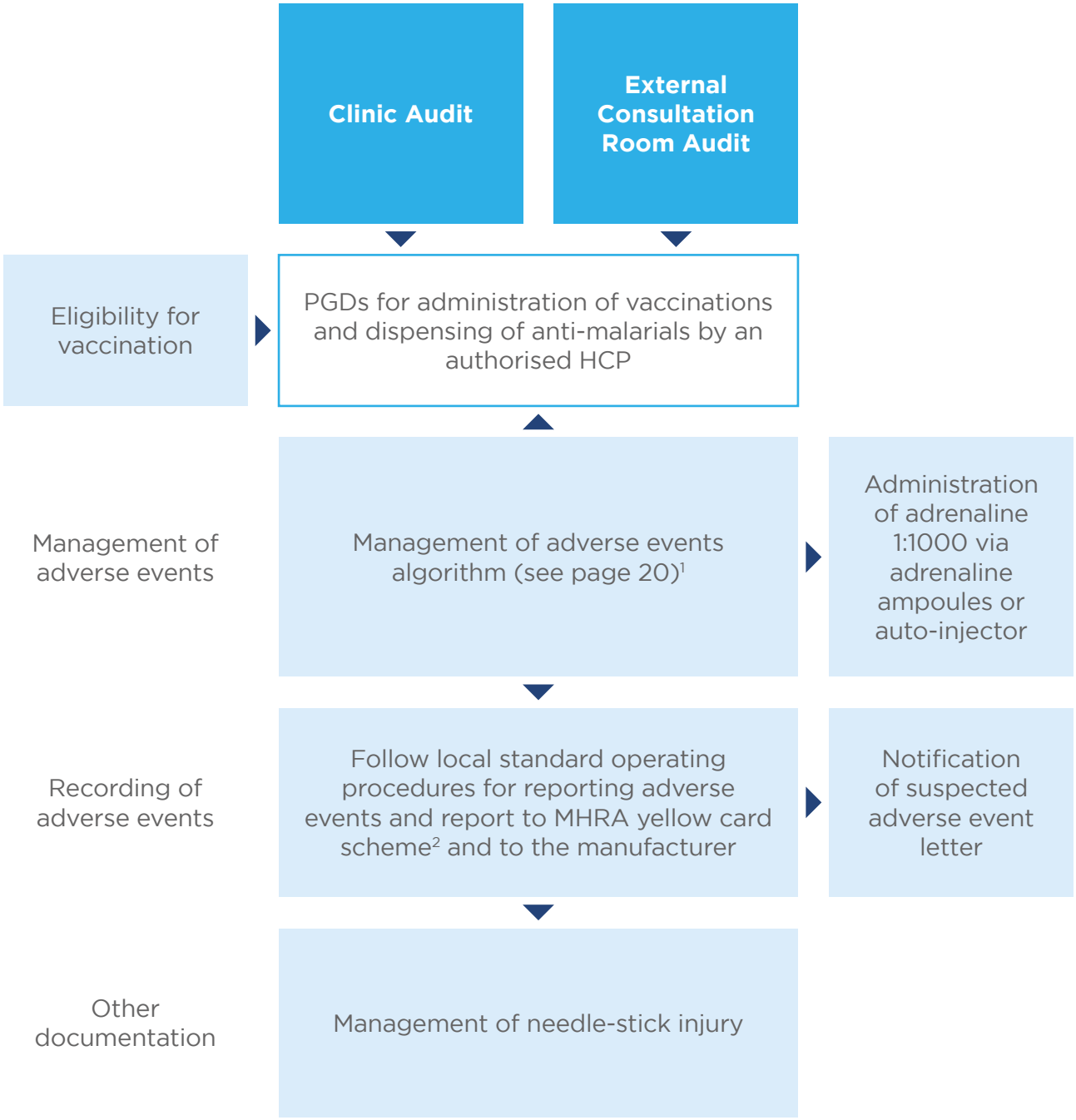
Please read before contacting your clinic's medical support line or your PGD provider.

CONCERN	ADVICE
Bleeding	If the patient's injection site is bleeding, apply pressure using a clean swab until the bleeding subsides. This should not take longer than a couple of minutes. If bleeding continues, seek additional medical assistance.
Fainting	If the patient has fainted, ensure that they are in no imminent danger and if judged necessary, put them in the recovery position. Ensure they are monitored until revived and have returned back to their original state. If the patient's condition worsens, seek additional medical assistance as per algorithm on page 20.
Pain at the injection site	A small amount of localised pain or discomfort may be experienced. If concerned, monitor the patient. If pain doesn't get any worse, offer advice and support e.g. cold compress and simple analgesia. If pain worsens, or an anaphylactic type reaction is suspected, then seek medical help as per algorithm on page 20.
Redness	If there is redness and swelling where you have administered the vaccine, then this is a normal localised inflammatory response. If the redness, and / or swelling worsens, monitor and seek additional medical assistance.

COMMON REACTIONS
For full list of adverse events, please refer to the patient information leaflet. See page 18 for management of adverse events.

Clinical governance framework

Administration of vaccine



References:
1. The Green Book: Chapter 8 Vaccine safety and the management of adverse events following immunisation. March 2013. Available online: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/147868/Green-Book-Chapter-8-v4_0.pdf (Last accessed December 2022).
2. MHRA Yellow Card Reporting. Available online: https://yellowcard.mhra.gov.uk/ (Last accessed December 2022).

Clinic audit

For the administration of vaccination services.

The responsible HCP for the clinic must complete the audit before the first patient is vaccinated.

1. CLINIC DETAILS

Clinic Name: .....

Clinic Address: .....

.....

2. PERSONNEL

Any HCP administering vaccinations in the clinic has completed the relevant training. Yes ☐ No ☐

Clinic support staff identified and appropriately trained / briefed. Yes ☐ No ☐

3. CONSULTATION AREA

Consultation area meets the clinical requirements (see pages 6–7). Yes ☐ No ☐

Immediate access to adrenaline 1:1000 via adrenaline ampoules or auto-injectors. Yes ☐ No ☐

HCP is aware of actions to be taken in the event of a used needle-stick injury. Yes ☐ No ☐

4. PROFESSIONAL STANDARDS AND ETHICS / INDEMNITY

The HCP must ensure they have completed all training for the provision of a clinic vaccination service and has appropriate indemnity insurance for providing vaccination services in clinic and out of clinic (as appropriate). Yes ☐ No ☐

5. YELLOW FEVER

The clinic is a certified Yellow Fever centre for the administration of Yellow Fever vaccinations (If providing Yellow Fever vaccinations). Yes ☐ No ☐

Eligibility to participate in the clinic vaccination services

If your response is Yes to all of the above questions it is appropriate for your clinic to participate in the service.

If your response is No to questions 1-4 it is not appropriate for your clinic to participate until these issues have been resolved.

Clinician name .....

Registration number .....

Signature ..... **Date** .....

Copy to be retained by the responsible person for the premises concerned.

Adverse events and pharmaceutical technical complaints

Adverse events

DEFINITION OF AN ADVERSE EVENT (AE)[1]

Any untoward medical occurrence in a person administered a medicinal product – does not have to be causally related to the treatment.

Any unfavourable and unintended sign (e.g. abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product.

Adverse events following immunisation might include:[2]

- Wrong dose administered
- Use of expired vaccines
- Vaccines used at inappropriate intervals
- Inappropriate method of administration
- Use of incorrectly prepared vaccines
- Injection site reactions
- Systemic reactions such as fever, malaise, myalgia, headache etc.
- Anaphylaxis

Serious adverse events (SAEs) include:[1]

- Fatal
- Life-threatening
- Results in a persistent or significant disability / incapacity
- Results in or prolongs hospitalisation
- Congenital abnormalities and birth defects

ADVERSE EVENT REPORTING

When a patient has shown any adverse reaction following the administration of a vaccine, the adverse event needs to be reported immediately or within 24 hours following the event.

To report an event follow SOPs and also report to MHRA via yellowcard.[3]

When reporting an adverse event please make sure you provide as many details as possible:

- An identifiable patient (e.g. patient initials, gender)
- An identifiable source (e.g. reporter name and address and qualification)
- An identifiable suspected vaccine or medicinal product and date of administration
- An identifiable suspected adverse event or reaction (or interaction or abuse or any other relevant information)
- Batch number and expiry date of vaccine

References:
1. EMA. Clinical safety data management: Definitions and standards for expedited reporting. June 1995. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-15.pdf (Last accessed February 2023).
2. The Green Book: Chapter 8 Vaccine safety and the management of adverse events following immunisation. March 2013. Available online: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/147868/Green-Book-Chapter-8-v4_0.pdf (Last accessed December 2022).
3. MHRA Yellow Card Reporting. Available online: https://yellowcard.mhra.gov.uk/ (Last accessed December 2022).

Adverse events and pharmaceutical technical complaints

Pharmaceutical technical complaint[1]

DEFINITION OF A PHARMACEUTICAL TECHNICAL COMPLAINT (PTC)

A pharmaceutical technical complaint is any fault in quality, any fault of the container or outer packaging, any fault in the labelling or the package insert, any falsification of the product. For example faulty / opened pack, bent needle etc.

Pharmaceutical technical complaints include:

- Any fault in quality
- Any fault of the containers and the outer packages
- Any fault of the labelling and the package insert
- Any falsification of the product
- There must be a named vaccine, with the name and contact details of the reporter.

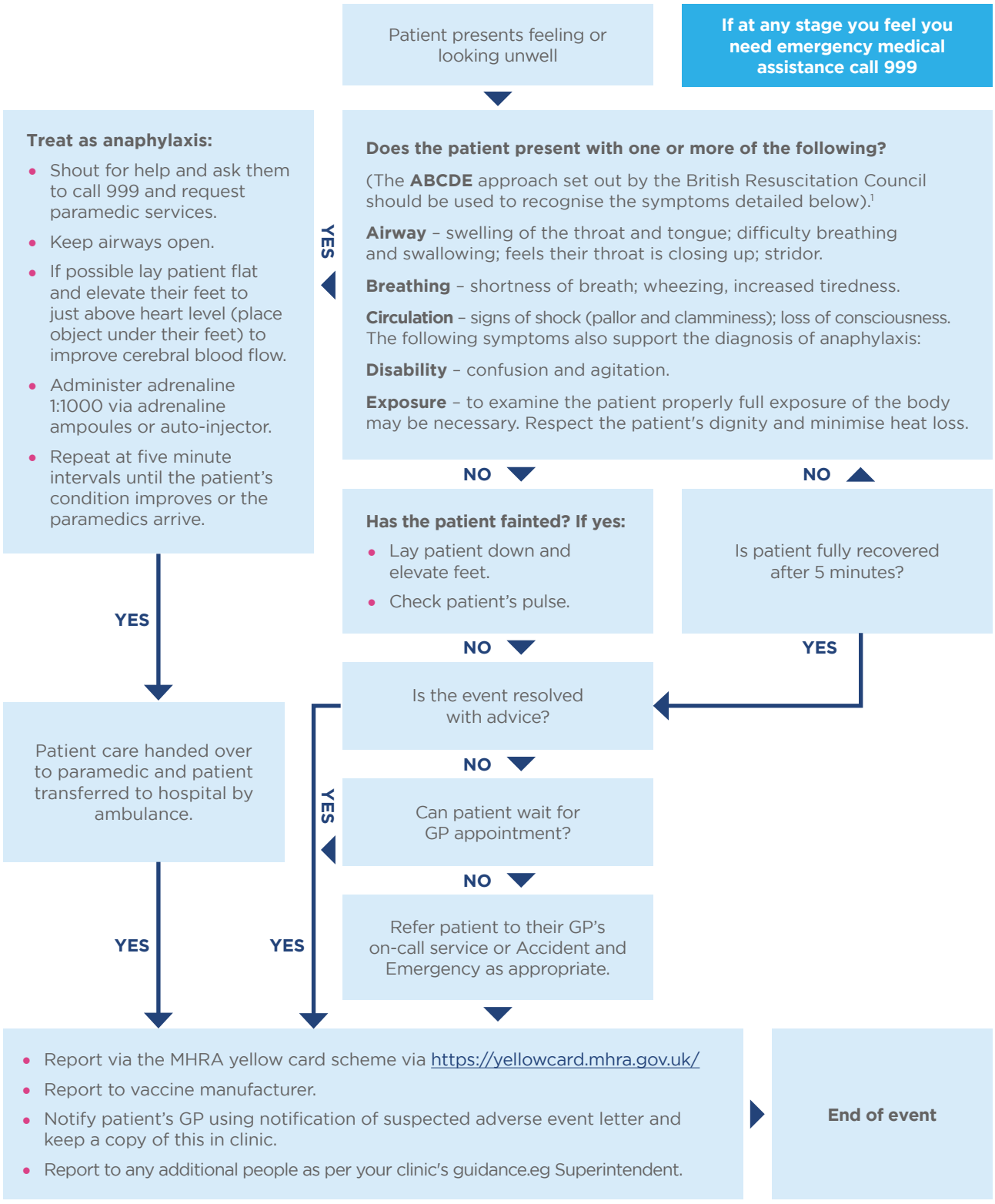
PHARMACEUTICAL TECHNICAL COMPLAINTS REPORTING

Any pharmaceutical technical complaint should be reported to the vaccine manufacturer.

References:
1. MHRA Yellow Card Reporting. Available online: https://yellowcard.mhra.gov.uk/ (Last accessed December 2022).

Management of adverse events algorithm

To be used in conjunction with online / practical training.



Reference:
1. Resuscitation Council (UK). Guidelines and guidance. The ABCDE Approach. Available online: https://www.resus.org.uk/resuscitation-guidelines/abcde-approach/ (Last accessed December 2022)

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Management of needle-stick injury

Clinics should have a needle stick injury procedure in place and all staff involved in the provision of the service should be aware of the contents of the procedure. Template needle stick injury procedures are available from a number of clinic membership organisations.

There is a low risk of transferring infection through needle-stick injury

A needle-stick injury can happen a number of ways:

1. From HCP to patient
2. From patient to HCP / staff

In all cases:[1]

1. Wash the wound with plenty of soap and water
2. Press skin around wound while running under water to encourage bleeding
3. Seek medical help

NB: Accidental injury with an unused needle falls outside this guidance. Should this eventuality arise:

1. Dispose of the unused vaccine as per the clinic protocol
2. Clean and cover the wound appropriately
3. Follow usual in-house accident procedure

Reference:
1. NHS. What should I do if I injure myself with a used needle? Available online: https://www.nhs.uk/common-health-questions/accidents-first-aid-and-treatments/what-should-i-do-if-i-injure-myself-with-a-used-needle/ (Last accessed December 2022)

Immunity to Hepatitis B

INTRODUCTION

Vaccination is not considered an exposure prone procedure (defined as a procedure in which there is a risk of injury to a worker which may expose the patient's open tissues to the blood of the worker)[1]. As such the recipient of a vaccination is not considered 'at-risk' of contracting Hepatitis B from the vaccinator. It is, however, possible for the vaccinator to be infected by the person receiving the vaccination. For this reason it is recommended that all persons delivering the vaccine be immune to Hepatitis B[2].

METHOD

It is recommended that all HCPs who plan to administer vaccines as part of any vaccination service have had Hepatitis B vaccination within 5 years and that following the vaccination course they had a good antibody response or a poor antibody response followed by a booster vaccination.

HEPATITIS B IMMUNISATION[2]

- **Standard immunisation;** a course of three injections at 0, 1 and 6 months; should only be used when accelerated or very rapid immunisation is not required.
- **Accelerated immunisation;** a course of three injections at 0, 1 and 2 months (plus a fourth dose after 12 months, if needed); should be used for most adult risk groups.
- **Very Rapid immunisation;** a course of four injections at 0, 7 and 21 days, and 12 months after the first injection; should be used if a more rapid immunisation is required.
- **All immunisation schedules** should include testing antibody titres 1 to 4 months after completing the primary immunisation course, and require a 5-year booster dose.
- **Vaccines protecting against hepatitis B** contain only inactivated virus particles, which can't cause the disease.

References:
1. Public Health England. Emergency healthcare workers, exposure prone procedures (EPPs) and the exposure prone environment. April 2017. Available online: https://www.gov.uk/government/publications/emergency-healthcare-workers-exposure-prone-procedures (Last accessed December 2022).
2. The Green Book. Chapter 18 Hepatitis B. March 2013. Available online: https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18 (Last accessed December 2022).

RESPONSE TO HEPATITIS B VACCINE[1]

Antibody responses to Hepatitis B vaccine vary widely between individuals. It is preferable to achieve anti-HBs levels above 100mIU/ml, although levels of 10mIU/ml or more are generally accepted as enough to protect against infection.

Poor-responders: around 10-15% of adults fail to respond to three doses of vaccine or respond poorly. Poor-responders to vaccine (anti-HBs between 10 and 100mIU/ml) will be offered one additional dose of vaccine at that time.

In immunocompetent individuals, further assessment of antibody level is not indicated. A reinforcing booster dose should be given at five years, as for good responders.

Non-responders: An antibody level below 10mIU/ml is classified as a non-response to vaccine, and testing for markers of current or past infection is required. In non–responders, a repeat course of vaccine is recommended, followed by re-testing of antibodies 3 months after the second course.

Reference:
1. Patient Info. Hepatitis B Vaccination and Prevention. Available online: https://patient.info/doctor/hepatitis-b-vaccination-and-prevention (Last accessed December 2022).

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