Patient Group Direction (PGD)

Administration of Japanese encephalitis vaccine

Publication date: 01 February 2022

Version 1.0
Effective from: 01 February 2022
Review date: 31 January 2024

Version history

Version	Date	Summary of changes
1.0	01/02/22	Version 1.0 new PGD

Contents

Authorisation

PGD Japanese encephalitis vaccine

This Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS boards. NHS Borders has ensured that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer Japanese encephalitis vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/summary of product characteristics (SPC) for all vaccines administered in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS Borders by:

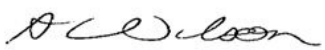
Doctor ….Dr Tim Patterson…….... **Signature** 

Pharmacist ….Adrian Mackenzie…… **Signature** 

Nurse ……Jill Madden…… **Signature** 

Approved on behalf of NHS Borders by:

Medical Director ……Dr Lynn McCallum…… **Signature** 

Director of Pharmacy/
Senior Pharmacist ……Alison Wilson…… **Signature** 

Clinical Governance Lead …Sarah Horan…… **Signature** 

Date approved: 21/02/2022

Effective from: 01/02/2022 **Review date:** 31/01/2024

Clinical situation

Category	Description
Indication	Active immunisation of individuals who are deemed to be at risk from exposure to Japanese encephalitis virus.
Inclusion criteria	• Valid consent has been given to receive the vaccine. Individuals aged 2 months and older who: • intend to travel to or reside in countries where Japanese encephalitis vaccination is currently recommended for travel in accordance with national recommendations issued by TRAVAX **www.travax.nhs.uk/destinations/** the risk of exposure should be determined after careful risk assessment of an individual's itinerary, season of travel, duration of stay, planned activities and medical history.
Exclusion criteria	Individuals for whom no valid consent has been received. Individuals who: • are under two months of age • have had a confirmed anaphylactic reaction to a previous dose of any Japanese encephalitis containing vaccine or to any components of the vaccine including the residues protamine sulphate, formaldehyde, bovine serum albumin, host cell DNA, sodium metabisulphite (refer to relevant SPC) • have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions/need for further advice/ circumstances when further advice should be sought from a doctor	The Green Book advises there are very few individuals who cannot receive Japanese encephalitis containing vaccines. When there is doubt, appropriate advice should be sought from the lead clinician rather than withholding the vaccine. As a precautionary measure, administration of Japanese encephalitis vaccine during pregnancy or lactation should be avoided. However, travellers and their medical advisers must make a risk assessment of the theoretical risks of Japanese encephalitis vaccine in pregnancy against the potential risk of acquiring Japanese encephalitis. Miscarriage has been associated with Japanese encephalitis virus infection when

Category	Description
	acquired in the first two trimesters of pregnancy (Green Book) Individuals with immunosuppression can be given Japanese encephalitis containing vaccines although these individuals may not make a full antibody response. The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
Action if excluded	Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in accordance with local procedures. Inform or refer to the lead clinician in charge. Advise the individual on other preventative measures that may be implemented such as mosquito bite avoidance. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Individuals who have had a confirmed anaphylactic reaction to a previous dose of a Japanese encephalitis containing vaccine or any components of the vaccines should be referred to a clinician for specialist advice and appropriate management.
Action if patient declines	Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease. Advise how future immunisation may be accessed if they subsequently decide to receive

Category	Description
	the vaccine. Advise the individual on other preventative measures that may be implemented such as mosquito bite avoidance. Document advice given and decision reached. Inform or refer to the lead clinician in charge.

Description of treatment

Category	Description
Name of medicine/Form/strength	Japanese encephalitis vaccine (inactivated, absorbed) available as IXIARO® suspension for injection, 0.5ml
Route of administration	Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm or the anterolateral area of the thigh muscle in small children. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the 'Green Book' **Chapter 4** The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.
Dosage	Children aged two months to under 3 years – 0.25ml Children three years and over, and adults – 0.5ml
Frequency	**Primary pre-exposure immunisation:** Children from two months and adults: **Standard schedule**: • First dose on day 0 • Second dose on day 28 **Rapid schedule***

Category	Description
	• First dose on day 0 • Second dose on day 7 **licensed for adults aged 18-64 years of age. For age 2 months to 17 years and adults 65 years of age and older, the rapid schedule can be used (off label) in circumstances where there is genuinely insufficient time to complete the standard schedule prior to travel (see'* Is the use out with the SPC' section of this PGD). **With both schedules, primary immunisation should ideally be completed at least one week prior to potential exposure** but can be given up to the day of departure. Travellers should be reminded that optimum protection will not be immediate and should practice mosquito bite avoidance measures. **Reinforcing Immunisation:** First booster *Children (from two months) and adults:* Individuals who remain at risk of exposure should be given a booster dose 12 months after primary immunisation. Second booster Adults 18-64 years of age: A second booster dose (4th dose) should be offered at 10 years from the first booster to those who remain at risk or prior to potential re-exposure to Japanese Encephalitis. Children <18 years and adults 65 years of age and older: The length of protection following the first booster dose is not known. Refer to lead clinician. IXIARO® may be used as a booster for those who received Green Cross vaccine or Biken vaccine previously
Duration of treatment	As above
Maximum or minimum treatment period	As above
Quantity to supply/administer	One dose per occasion
▼ black triangle medicines	No

Category	Description
Legal category	Prescription Only Medicine (POM)
Is the use out with the SPC?	The rapid schedule administered at days 0 and 7 is 'off label' for age 2 months to 17 years and adults 65 years of age and older. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines or national vaccine incident guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.
Storage requirements	Vaccine should be stored at a temperature of +2° to +8°C. Store in the original packaging to protect from light. Do not freeze. NHS board guidance on Storage and Handling of vaccines should be observed. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal.
Additional information	Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. Immunological response may be diminished in those receiving immunosuppressive treatment. ~~As a precautionary measure, administration of Japanese encephalitis vaccine during pregnancy or lactation should be avoided. However, travellers and their medical advisers must make a risk assessment of the theoretical risks of Japanese encephalitis vaccine in pregnancy against the potential risk of acquiring Japanese encephalitis. Miscarriage has been associated with Japanese encephalitis virus infection when acquired in the first two trimesters of pregnancy (Green Book)~~ Japanese encephalitis vaccine can be given at the same time as other vaccines, including other travel vaccines. When administering at the same

Category	Description
	time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each was given should be noted in the individual's records.

Adverse reactions

Category	Description
Warnings including possible adverse reactions and management of these	For full details/information on possible side effects, refer to the marketing authorisation holder's SPC. Localised reactions such as redness, swelling or pain at the site of injection within 24 to 48 hours of administration. Other reactions commonly reported are headache, myalgia, erythema, hardening, swelling and itching at the injection site, influenza-like illness, pyrexia and fatigue. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. In the event of severe adverse reaction individual should be advised to seek medical advice.
Reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **http://yellowcard.mhra.gov.uk/** Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.
Advice to patient or carer including written information	Written information to be given to individuals: • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. Individual advice / follow up treatment: • Inform the individual/carer of possible side effects and their management. • Advise the individual on other preventative measures that may be

Category	Description
	implemented such as mosquito bite avoidance. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk/ • When applicable, advise individual/parent/carer when the subsequent dose is due.
Observation following vaccination	Following immunisation, patients remain under observation in line with NHS board policy.
Follow up	As above
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular 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.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer vaccines: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council.
Specialist competencies or qualifications	Persons must only work under this PGD where they are competent to do so. All persons operating this PGD: • must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it • must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information, • must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent • must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine • must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy Employer: The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD. As a minimum, competence requirements stipulated in the PGD must be adhered to.

Category	Description
Continuing education and training	All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

Audit trail

Name	Description
Record/ audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of person that undertook assessment of individual's clinical suitability for vaccine • name of person that administered the vaccine • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • batch number • where possible expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • administered under PGD Records should be kept in line with local procedures. Local policy should be followed to encourage information sharing with the individual's General Practice. All records should be clear, legible and contemporaneous and in an easily retrievable format.

Additional references

Name	Description
Additional references	Immunisation against Infectious Disease [Green Book] **https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book** Immunisation against Infectious Disease [Green Book] chapter 20 **GreenBook chapter 20 - Japanese encephalitis (publishing.service.gov.uk)** Current edition of British National Formulary. Marketing authorisation holder's Summary of Product Characteristics. Professional Guidance on the Administration of Medicines in Healthcare Settings 2019 **https://www.rpharms.com/Portals/0/RPS document library/Open access/Professional standards/SSHM Admin/Admin Meds prof guidance.pdf/ver=2019-01-23-145026-567** Professional Guidance on the Safe and Secure Handling of Medicines **https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines** NHSGGC Japanese encephalitis vaccine PGD ref no: 2020/2072

PGD for administration of Japanese encephalitis vaccine v1.0 Valid from: 01/02/2022 Expiry: 31/01/2024 - authorisation

Practitioner

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's summary of product characteristics for all vaccines administered in accordance with this PGD.

By signing this Patient Group Direction you are indicating that you agree to its contents and that you will work within it. I agree to administer the Japanese encephalitis vaccine only in accordance with this PGD.

Name of professional	Signature	Date

Authorising Manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **NHS Borders** for the above named health care professionals who have signed the PGD to work under it.

Lead clinician for the service area

Name ……..

Signature ……..

Date ……

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation. This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.