This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, *Haemophilus influenzae* type b and hepatitis B (DTaP/IPV/Hib/HepB) vaccine to

By registered health care professionals for

Individuals from 6 weeks (routinely 8 weeks) to under 10 years of age in accordance with the national immunisation programme

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 85

1. Change History

Version number	Change Details	Date
V01.00	New PHE PGD template	03/07/2017

V02.00	PHE DTAP/IPV/Hib/HepB PGD v01.00 reviewed and amended to: • include additional healthcare practitioners in Section 3 • remove reference to using pentavalent DTaP/IPV/Hib vaccine • refer to vaccine incident guidelines in off-label and storage sections • review wording regarding use of prophylactic paracetamol • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	19/07/2019
V03.00	PHE DTAP/IPV/Hib/HepB PGD v02.00 reviewed and amended to: • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs and updated references • addition of Vaxelis® suspension • addition of stability data	28/07/2021
V04.00	UKHSA DTAP/IPV/Hib/HepB PGD v03.00 reviewed and amended to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 • add management of cases and contacts in an outbreak of polio in accordance with the national guidelines and recommendations from the local health protection teams • add information for vaccinating individuals with family history of seizures as per Green Book Chapter 26 and SPCs in the special consideration and additional information section.	25/07/2022

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Pre Signatures			
Job Title	**Name**	**Signature**	**Date**
Pharmaceutical Adviser			
Head of Ambulance Services			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)	N/A	N/A	N/A
Final signatures			
Medical Director	Dr Marina Hudson		
Director of Nursing	Paul Moore		

5. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy Additionally practitioners: • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the 'cold chain' • must be competent in the recognition and management of anaphylaxis Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

6. Clinical Conditions

Clinical condition or situation to which this PGD applies	• the active immunisation of individuals from 6 weeks (routinely 8 weeks) to under 10 years of age for the prevention of diphtheria, tetanus, pertussis, poliomyelitis, Haemophilus influenzae type b and hepatitis B in accordance with the national immunisation programme and recommendations given in Chapter 15, Chapter 16, Chapter 18, Chapter 24, Chapter 26, and Chapter 30 of Immunisation Against Infectious Disease: 'The Green Book'. • individuals who require immunisation in response to an outbreak of polio in accordance with the National polio guidelines: Local and regional services guidelines and recommendations from the local health protection team.
Inclusion criteria	Individuals from 6 weeks to under 10 years of age who: • require a primary course of immunisation against diphtheria, tetanus, pertussis, poliomyelitis, Haemophilus influenzae type b and hepatitis B (including those who do not have a complete or reliable vaccination history, see Special considerations / additional information section) • have a tetanus prone injury and primary immunisation is considered incomplete or immunisation status is not known or uncertain (see 'The Green Book' Chapter 30) • require vaccination in line with the management of cases and contacts of polio in an outbreak in accordance with the National polio guidelines: Local and regional services guidelines and recommendations from the local health protection team
Exclusion criteria	Individuals for whom no valid consent has been received. Individuals who: • are less than 6 weeks of age • are aged 10 years and over • have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis, poliomyelitis, Haemophilus influenzae type b or hepatitis B containing vaccine, including any conjugate vaccines where diphtheria or tetanus toxoid is used in the conjugate • have had a confirmed anaphylactic reaction to any component of the vaccine or residual products from manufacture (see Name, strength and formulation plus relevant SPC) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

Cautions (including any relevant action to be taken)	• 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 preventable infection. Vaccination should be promptly given once the diagnosis and/or expected course of the condition becomes clear. • If a child has experienced encephalopathy or encephalitis within 7 days of a previous immunisation with a pertussis-containing vaccine, it is unlikely these conditions will have been caused by the vaccine and they should have been investigated by a specialist. • If a cause was identified or the child recovered within 7 days, immunisation should proceed as recommended. In children where no underlying cause was found and the child did not recover completely within 7 days, immunisation should be deferred until the condition has stabilized or the expected course of the condition becomes clear. • If the child has not been investigated by a specialist, then immunisation should be deferred until a specialist opinion is obtained. • If a seizure associated with a fever occurred within 72 hours of a previous immunisation with any component of the vaccine, immunisation should continue as recommended if a cause is identified or the child recovers within 24 hours. However, if no underlying cause has been found and the child did not recover completely within 24 hours, further immunisation should be deferred until the condition is stable. • The immunogenicity of the vaccine could be reduced in immunosuppressed subjects; however vaccination is still recommended. • Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hrs when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hrs.
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment

Action to be taken if patient excluded	• If aged less than 6 weeks advise to return for routine immunisation when the child is 8 weeks of age or over and give an appropriate appointment. Immunisation can be administered to infants from 6 weeks of age if required, for instance if travelling to an endemic country or at increased risk of hepatitis B virus and dose of HepB vaccine is due. • If aged 10 years or over assess for immunisation with Td/IPV as appropriate. • In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. • Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician when a vaccine is indicated outside the remit of this PGD rather than delay immunisation. • The risk to the individual of not being immunised must be taken into account • Document the reason for exclusion and any action taken in the individual's clinical records • Inform or refer to the GP or a prescriber as appropriate
Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so (see the Manx Care Policy for Capacity, Best Interests Decisions and Deprivation of Liberty) • Where appropriate care should be escalated • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration

7. Details of the medicine

Name, form and strength of medicine	Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated), *Haemophilus influenzae* type b (conjugate) and hepatitis B (rDNA) vaccine (adsorbed), DTaP/IPV/Hib/HepB: • Infanrix®-hexa, powder (Hib) in vial and suspension (DTaP/IPV/HepB) for suspension for injection in a pre-filled syringe or vial The vaccine may contain traces of formaldehyde, neomycin and polymyxin • Vaxelis® suspension for injection in a pre-filled syringe The vaccine may contain traces of glutaraldehyde, formaldehyde, neomycin, streptomycin, polymyxin B and bovine serum albumin
Legal category	Prescription only medicine (POM)

Black triangle▼	No
Indicate any off-label use (if relevant)	• Administration of Infanrix®-hexa to individuals born before 24 weeks of gestational age or to individuals who are over 36 months of age is off-label but is indicated until 10 years of age under this PGD in accordance with national recommendations for the vaccination of individuals with uncertain or incomplete immunisation status guidance and the relevant chapters of 'The Green Book'. • Administration of Vaxelis® to individuals who are over 15 months of age is off-label but is indicated until 10 years of age under this PGD in accordance with national guidance recommendations for the vaccination of individuals with uncertain or incomplete immunisation status and the relevant chapters of 'The Green Book'. • Administration of DTaP/IPV/Hib/HepB to individuals who experienced an encephalopathy of unknown cause occurring within 7 days following previous vaccination with pertussis-containing vaccine is off-label. Individuals may be vaccinated under this PGD once the condition has stabilized or the expected course of the condition becomes clear (see Cautions), in line with the recommendations in the associated chapters of 'The Green Book'. • Administration of Infanrix®-hexa by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 of 'The Green Book'. Do not administer Vaxelis® by deep subcutaneous injection. • The vaccine product SPCs do not make reference to use of DTaP/IPV/Hib/HepB for the management of outbreak, cases or contacts but do include use of the vaccine as a booster and state that the vaccine should be administered in accordance with official recommendations. Vaccination is therefore recommended under this PGD in accordance with the relevant chapters of the Green Book and the National polio guidelines: Local and regional services guidelines. • Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD • Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

Route/method of administration *(continued) …*	• Infanrix®-hexa is presented in two parts, as DTaP/IPV/HepB suspension for injection and Hib powder, which must be reconstituted in accordance with the manufacturer's instructions prior to administration. • Vaxelis® is presented as a suspension for injection in a pre-filled syringe. • Administer by intramuscular injection, preferably into the anterolateral aspect of the thigh in infants under 1 year of age. The deltoid region of the upper arm may be used in individuals over 1 year of age. • When administering at the same time as other vaccines, care should be taken to ensure 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 vaccine was given should be noted in the individual's records. • For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see "The Green Book" Chapter 4).However, the SPC for Vaxelis® specifically states to not administer by intravascular, intradermal or subcutaneous injection. Therefore, where a deep subcutaneous injection is required, use Infanrix®-hexa. • If the only available vaccine is Vaxelis®, individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/parent/carer should be informed about the risk of haematoma from the injection. • Infanrix®-hexa: the normal appearance is a white, slightly milky liquid, which may sediment during storage. Shake the DTaP/IPV/HepB suspension for injection well to uniformly distribute the suspension prior to reconstitution of the vial containing the powder (Hib) and before administering the vaccine. The reconstituted vaccine appears as a slightly more cloudy suspension than the liquid component alone.

Route/method of administration *… (continued)*	• The vaccine should be inspected prior to and after reconstitution and should not be used if discoloured or foreign particles are present. • Vaxelis®: shake the pre-filled syringe gently prior to administration to obtain a homogeneous, whitish, cloudy suspension. • The suspension should be inspected, prior to administration, for foreign particulate matter and/or variation of physical appearance. If either is observed, discard the pre-filled syringe. • The SPCs provide further guidance on administration and are available from the electronic Medicines Compendium website.
Dose and frequency *(continued) …*	Single 0.5ml dose per administration **Routine Childhood Immunisation Schedule** The national recommendation for infants is for a 3-dose primary course of DTaP/IPV/Hib/HepB to be administered at 4-week intervals* routinely starting at 8 weeks of age (and no earlier than 6 weeks* of age). DTaP/IPV/Hib/HepB 0.5ml should ideally be given at the: • first primary immunisation visit (usually at age 8 weeks) • second primary immunisation visit (usually at age 12 weeks) • third primary immunisation visit (usually at age 16 weeks) *Note: immunisation may be brought forward to commence no earlier than 6 weeks of age, and an interval of not less than 3 weeks (for 1 dose only) when required, for instance due to impending travel to an endemic country. **Vaccination of individuals with incomplete immunisation status** When primary vaccination has been delayed the individual should be immunised at the earliest opportunity. If the primary course is interrupted it should be resumed but not repeated, allowing an interval of 4 weeks between remaining doses. If a course was commenced but not completed with pentavalent vaccine (DTaP/IPV/Hib), it can be completed with hexavalent vaccine (DTaP/IPV/Hib/HepB). DTaP/IPV/Hib/HepB can be given to eligible individuals until 10 years of age in accordance with the vaccination of individuals with uncertain or incomplete immunisation status guidance. **Management of tetanus prone wound** Individuals with incomplete or uncertain history of tetanus immunisation should be vaccinated in accordance with the recommendations in the 'The Green Book' Chapter 30 Table 30.1. Individuals may also require human tetanus immunoglobulin (see 'The Green Book' Chapter 30). This PGD does not cover the administration of immunoglobulin.

Dose and frequency *… (continued)*	**Immunisation of infants at risk of hepatitis B** Infants born to hepatitis B infected mothers should receive monovalent hepatitis B (HepB) vaccine (see HepB PGD) at birth and 4 weeks of age and then 3 doses of DTaP/IPV/Hib/HepB vaccine at 8, 12 and 16 weeks of age. They should receive a booster dose of monovalent HepB vaccine (see HepB PGD) at 12 months of age, at which time they should also have a blood test to check for hepatitis B infection. Where such infants have received doses of monovalent hepatitis B vaccine scheduled for 0 and 4 weeks late, but before 6 weeks of age, routine primary immunisations should still continue to be scheduled at 8 weeks of age, irrespective of the timing of the late monovalent hepatitis B vaccine dose. This is necessary in order not to delay protection against the other infections. If an infant born to a hepatitis B infected mother attends after the age of 6 weeks for their first or second dose of hepatitis B vaccine, DTaP/IPV/Hib/HepB should be administered along with the primary immunisation series, with subsequent immunisation visits scheduled at 4-week intervals. In this situation it is very important that the child is tested, at 12 months of age, to check whether they were infected early in life as they missed an early dose of HepB vaccine.
Quantity to be administered	Single 0.5ml dose per administration
Maximum or minimum treatment period	• The primary course usually consists of 3 doses with an interval of 1 month between each dose • Stability data indicate that for Infanrix®-hexa the vaccine components are stable at temperatures up to 25°C for 72 hours. After reconstitution the vaccine should be used immediately. However, stability has been demonstrated for 8 hours at 21°C after reconstitution • For Vaxelis® stability data indicate the vaccine is stable at temperatures up to 25°C for 150 hours • These data are intended to guide healthcare professionals in case of temporary inadvertent temperature excursion only. At the end of these periods the vaccines should be used or discarded.Other diphtheria, tetanus, pertussis and polio containing vaccines are routinely recommended for subsequent boosters to complete immunisation in accordance with national recommendations

Storage	• Store at +2°C to +8°C • Store in original packaging to protect from light • Do not freeze • Stability data indicate that for Infanrix®-hexa the vaccine components are stable at temperatures up to 25°C for 72 hours. After reconstitution the vaccine should be used immediately. However, stability has been demonstrated for 8 hours at 21°C after reconstitution • For Vaxelis® stability data indicate the vaccine is stable at temperatures up to 25°C for 150 hours • These data are intended to guide healthcare professionals in case of temporary inadvertent temperature excursion only. At the end of these periods the vaccines should be used or discarded.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, refer to PHE Vaccine Incident Guidance
Adverse effects *(continued) …*	• When hepatitis B vaccine is added to DTaP/IPV/Hib vaccine the frequency and type of adverse reactions experienced remain similar • Prophylactic paracetamol is routinely recommended with co-administered infant doses of DTaP/IPV/Hib/HepB and 4CMenB (see the information about MenB vaccine and paracetamol and the What to expect after vaccinations leaflet on the PHE Immunisation webpage for more information) • Increased reporting rates of convulsions (with or without fever) and hypotonic hyporesponsive episode (HHE) were observed with concomitant administration of DTaP/IPV/Hib/HepB and PCV13 • Prophylactic administration of paracetamol is not routinely recommended where PCV13 and DTaP/IPV/Hib/HepB are co-administered in the absence of 4CMenB. Administration of paracetamol concomitantly with PCV13 vaccination may reduce the immune response to some pneumococcal serotypes in PCV13 in infancy, although this reduction is unlikely to be clinically significant; this effect is not seen when also co-administered with the 4CMenB vaccine. If post immunisation fever does occur after any vaccination visit, then symptoms may be managed with paracetamol • Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. A small painless nodule may form at the injection site • Other common adverse reactions include fever, abnormal crying, irritability, restlessness, appetite loss, fatigue, diarrhoea, vomiting and nervousness • Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare

Adverse effects *… (continued)*	• A detailed list of adverse reactions is available in the SPCs, which are available from the electronic Medicines Compendium website: www.medicines.org.uk **Reporting procedure of adverse reactions** Healthcare professionals and individuals/parents/carers are encouraged to 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Records to be kept	• The administration of any medication given under a PGD must be recorded within the patients' medical records • Please see Appendix C for more details.

8. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request Immunisation promotional material may be provided as appropriate: • A guide to immunisations for babies up to 13 months of age • A quick guide to childhood immunisation for the parents of premature babies • What to expect after vaccinations • Using paracetamol to prevent and treat fever after MenB vaccination Available from:www.gov.uk/government/collections/immunisation
Follow-up advice to be given to patient or carer	• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately • When administration is postponed advise the individual/carer/parent when to return for vaccination • Inform the individual/parent/carer of possible side effects and their management • Give advice regarding normal reaction to the injection, for example redness and pain at the injection site • Advise the parent/carer about administering prophylactic paracetamol with routine immunisations scheduled at 8 weeks and 16 weeks of age when DTaP/IPV/Hib/HepB is co-administered with MenB vaccine (see Identification and management of adverse reactions) • The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction.

9. Appendix A

References

1. British National Formulary (BNF) available online: https://bnf.nice.org.uk
2. Nursing and Midwifery "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. Electronic medicines compendium available online: https://www.medicines.org.uk
6. Manx Care Policy for Capacity, Best Interests Decisions and Deprivation of Liberty http://edrmgi/sites/hospital/Clinical%20Policies%20and%20Procedures/Policy%20for%20Capacity,%20Best%20Interests%20Decisions%20and%20Deprivation%20of%20Liberty.pdf#search=deprivation

DTaP/IPV/Hib/HepB vaccine

- Immunisation Against Infectious Disease: The Green Book Chapter 15, Chapter 16 and Chapter 26 last updated 19 April 2013; Chapter 30, last updated 22 January 2020; Chapter 24, last updated 7 April 2016; and Chapter 18, last updated 28 November 2019 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Summary of Product Characteristic for Infanrix®-hexa, GlaxoSmithKline. Last updated on eMC 01 January 2021 https://www.medicines.org.uk/emc/product/2586/smpc
- Summary of Product Characteristics for Vaxelis® 01 January 2021 https://www.medicines.org.uk/emc/product/12264
- Annex: public health functions (section 7A) agreement 2020 to 2021 – services to be provided https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2020-to-2021/annex-public-health-functions-section-7a-agreement-2020-to-2021-services-to-be-provided
- The hexavalent DTaP/IPV/Hib/HepB combination vaccine information for healthcare practitioners https://www.gov.uk/government/publications/hexavalent-combination-vaccine-programme-guidance
- Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status

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- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017 https://www.nice.org.uk/guidance/mpg2/resources
- PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation
- PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

10. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

11. Appendix C

Special considerations/ additional information	• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. • 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. A family history of seizures is not a contraindication to immunisation. (see Green Book Chapter 26 and SPCs).When there is a personal or family history of febrile seizures, there is an increased risk of these occurring after any fever, including that caused by immunisation. Seizures associated with fever are rare in the first six months of life and most common in the second year of life. After this age the frequency falls and they are rare after five years of age (see Green Book Chapter 26). • Children coming to the UK who have a history of completing immunisation in their country of origin may not have been offered protection against all the antigens currently used in the UK. They may not have received Hib-containing vaccines in their country of origin. • Children coming from developing countries, from areas of conflict, or from hard-to-reach population groups may not have been fully immunised. • Where there is no reliable history of previous immunisation, it should be assumed that individuals are unimmunised and the full UK recommendations should be followed. • Un- or incompletely immunised children require 1 dose of Hib over the age of 1 year. It does not matter if the child receives additional Hib at subsequent appointments if the DTaP/IPV/Hib/HepB vaccine is given. • If an individual has received vaccination for a tetanus-prone wound with the same vaccine as due for routine immunisation and it was administered at an appropriate interval then the routine immunisation is not required; refer to advice in 'The Green Book' Chapter 30. • Tetanus vaccine given at the time of a tetanus-prone injury may not boost immunity early enough to give additional protection within the incubation period of tetanus. Therefore, tetanus vaccine is not considered adequate for treating a tetanus-prone wound. However, this provides an opportunity to ensure the individual is protected against future exposure. Individuals may also require human tetanus immunoglobulin which is not covered by this PGD (see 'The Green Book' Chapter 30).

Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013)
Drug interactions	• Immunological response may be diminished in those receiving immunosuppressive treatment. This is not a reason to withhold vaccinatio but the individual/parent/carer should be advised • May be given at the same time as other vaccines (Identification and management of adverse reactions – see below) • A detailed list of interactions is available in the SPCs, which are available from the electronic Medicines Compendium website: www.medicines.org.uk
Supplies	Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3).
Records	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and 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 • supplied via PGD • Records should be signed and dated (or a password-controlled immuniser's record on e-records) • All records should be clear, legible and contemporaneous. • This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed • The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement • A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy