Protocol to support Patient Specific Direction (PSD) for Occupational Health Registered Nurses ONLY

Tuberculin PPD for Mantoux Testing

Documentation details

Reference no:	UHDB082
Version no:	V2.0
Valid from:	02/04/2024
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Expiry date:	01/04/2027

Organisation name:	University Hospitals of Derby & Burton NHS Foundation Trust All UHDB sites plus any external sites where UHDB OH deliver their services.
Review Date	3 years from approval
Details of local ratifying committee/governance approval or similar as appropriate:	In addition to the physician in occupational health services, this Protocol is to be approved by a chief pharmacist (or nominated deputy) and senior OH nurse (or nominated deputy).

Pharmacist designation:	Medicines Safety Officer	
Name	Signature	Date
James Hooley	Signed copy held in Pharmacy	02/04/2024
Nursing designation:	OH Clinical Nurse Manager	
Name	Signature	Date
Carolyn Freeman	Signed copy held in Pharmacy	25/03/2024

Name and signature of the registered doctor authorising registered nurses, who declare themselves (in Section 5) to have met the training and competency requirements defined in this document, to operate under this protocol in accordance with a signed PSD (Patient Specific Direction).

Name	GMC Registration Number	Job Title	Signature	Date
Dr Ilias Macheridis	6138922	Occupational Health physician	Signed copy held in Pharmacy	25/03/2024

Local enquiries regarding the use of this Protocol may be directed to UHDB.PGDgovernance@nhs.net

Section 5 provides a registered health professional authorisation sheet. Individual professionals must have signed this declaration prior to practising under this Protocol.

Change history

Version number	Change details	Date
V1.0	Converted from old Protocol format	21/04/21
2	Reviewed by Carolyn Freeman (OH Nurse manager), Nina Woolhouse (OH Nurse Advisor), Dominic Moore (Deputy Chief Pharmacist – clinical review), Ilias Macheridis (OH Physician)	15/02/2024

1. Training requirements

Qualifications and professional registration	Nurses currently registered with the Nursing and Midwifery Council (NMC).
Training and competency	The registered nurse must be familiar with the vaccine or product and alert to changes in the Summary of Product Characteristics (SPC) and online Immunisation Against Infectious Disease ('The Green Book'). The registered nurse must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continuing Professional Development (CPD). The registered nurse should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. Successful completion of the Trust written Drug Assessment & any essential to role Medicines Management/Safety training. The registered nurse must have undertaken training appropriate to deliver Mantoux testing under this protocol as required by local policy. This should be informed by the National Minimum Standards and Core Curriculum for Immunisation and tailored to the skills and competencies required for the safe and effective delivery of Mantoux testing immunisation services. The registered nurse must be competent: • to undertake immunisation and to discuss issues related to immunisation • in the handling and storage of vaccines, and management of the 'cold chain' • in the recognition and management of anaphylaxis • must have access to this Protocol and any associated online resources. Annual attendance at Trust BLS training including anaphylaxis and AED training. Annual immunisation and vaccination update training by face to face taught sessions or e-learning via link below: https://www.e-lfh.org.uk/programmes/immunisation/
Competency assessment	The test should only be performed by Registered General Nurses who have received specialist immunisation training in the intradermal injection technique and Mantoux reading/interpretation and have been assessed as clinically competent. Registered nurses operating under this Protocol are personally responsible for ensuring they remain up to date with the use of the product/s included. If any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the Protocol and further training provided as required.

2. Details of Tuberculin PPD for Mantoux Testing to be administered:

Clinical condition or situation to which this protocol applies	The Mantoux Test is performed for two main reasons: 1) An investigation aid for screening/diagnostic purposes 2) To assess an individual's sensitivity to tuberculin protein for HCWs requiring BCG vaccination. *Note: Includes staff of the authorising organisation or staff members of another organisation the authorising organisation is commissioned to provide this vaccination service to.*
Criteria for inclusion	**All HCWs in regular contact with patients and pathology workers handling specimens which may contain tuberculous material will require a Mantoux Test if BCG vaccination is needed.** • UHDB employees as detailed above, including HCWs working in organisations where Occupational Health are contracted to provide services will be included.
Criteria for exclusion	• Have received a live viral vaccine in the previous 4 weeks • Have previously experienced a severe skin reaction to Tuberculin products • History of travel to a country with a high TB incidence - wait at least 6 weeks to avoid any false negative results. • Known history of TB contact, in this instance IGRA testing should be carried out. • Known hypersensitivity to any component of the medicinal product • Have not provided valid consent (for further information on consent see DH Reference guide to consent for examination or treatment) • Suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication)
Cautions including any relevant action to be taken	**BCG vaccine cannot be given without a prior and valid Mantoux Test**. Advice to be sought for individuals who are acutely unwell or have an infectious illness. Advice to be sought for immunocompromised individuals. If the patient is undergoing immunosuppressant therapy the result may be inaccurate. Advice needs to be sought prior to Mantoux testing or administering BCG vaccination. Previous severe reaction to vaccination. Clarify nature of reaction and seek further advice. **The following factors may affect the test result:** -Glandular Fever -Viral infections such as measles and varicella zoster (chickenpox) but NOT upper respiratory tract infections or gastroenteritis.

	-Testing within 4 weeks of having received a live vaccine -Sarcoidosis -Corticosteroid therapy - Immunocompromised or HIV+ve patients. 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 to be taken if the client is excluded	Re-appoint individuals who have received a live vaccine within the last 4 weeks In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed. Document the reason for exclusion and any action taken in the individual's Occupational Health records. If excluded from testing for health reasons explain reasons and seek advice from Senior Occupational Health Clinician / TB Nurse Specialists. Inform manager in writing if the individual's occupation places them at risk through exposure to tuberculosis.
Action to be taken if the client declines treatment	Document, in accordance with local policy, advice given and the decision reached. For those who decline ensure explanation of the reason for Mantoux Testing to allow informed decision making. Advise the individual about the protective effects of the vaccine, the risks of infection to themselves, their families and the organisation's service users and potential complications if not immunised. Advise how future immunisation may be accessed if they subsequently decide to receive the Tuberculin PPD. Inform manager in writing if the individual's occupation places then at risk through exposure to tuberculosis. Explain that a BCG cannot be given without a prior and valid Mantoux Test in individuals 6 years of age and over.
Arrangements for referral for medical advice	Inform and seek advice from the Senior Occupational Health Clinician / TB Nurse Specialists as appropriate. In case of allergies or specialist treatment refer individual to the GP or specialist clinician.

3. Description of treatment

Name, strength & formulation of drug	Mantoux test using: 2TU/0.1ml tuberculin PPD (Purified Protein Derivative), solution for injection.
Legal category	POM - Prescription only medicine (Unlicensed)
Black triangle▼	No
Indicate any off-label use (if relevant)	Unlicensed therefore administered only following Patient Specific Direction as per Appendix 1. Product 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 PHE Vaccine Incident Guidance. Where product is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration.
Route / method of administration	Intradermal injection. Preferred site is the flexor surface of the left forearm at the junction of the upper third with the lower two-thirds.
Dose and frequency of administration	The strength 2 T.U./0.1ml is recommended Pre-BCG/TB Contacts/New Entrants/Health Care Worker: Dose is 0.1ml (2 T.U.) on any single occasion. Mantoux test may be repeated if necessary, but the site of the test should be altered to avoid the risk of local hypersensitivity. If the HCW fails to return for Mantoux reading within 3 days then a further test may be performed. Where the first Mantoux test (PPD 2TU) is negative (less than 5 mm in diameter) and a retest is considered appropriate for clinical purposes (e.g. in immunocompromised HCWs / contacts where the Mantoux test response is considered less than reliable), PHE recommends using Interferon Gamma Release Assay (IGRA) testing together with a Mantoux test using PPD 2TU.
Obtaining supplies	Vaccine supplies will be ordered from Pharmacy Stores using the stock list protocol set up by pharmacy
Storage	Store at +2°C to +8°C. Store in original packaging to protect from light. Do not freeze. In the event of an inadvertent or unavoidable deviation of these conditions, product 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 and consult local pharmacy team for further advice.

Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment, corticosteroid therapy, recent live viral vaccines (past 4 weeks), glandular fever, sarcoidosis and viral infections including those of the upper respiratory tract, but it is important to still immunise this group. Tuberculin PPD for mantoux testing may be given at the same time as other inactivated vaccines. Live viral vaccines can suppress the tuberculin response, and therefore testing should not be carried out within four weeks of having received an injectable live viral vaccine such as MMR. (See Route / method of administration). HCWs who have a negative test but who may have had a significant infection (such as measles, varicella zoster (chickenpox), scarlet fever, glandular fever) at the time of testing or at the time of reading should be re-tested two to three weeks after clinical recovery before being given BCG. If a second tuberculin test is necessary it should be carried out on the other arm: repeat testing at one site may alter the reactivity by hyper-sensitising the skin, and a changed response may reflect local changes in skin sensitivity only.
Identification & management of adverse reactions	Pain, irritation or discomfort at the injection site immediately after the injection. Headache, fever, Enlargement of regional lymph node There is a potential for anaphylactic reactions Document signs and symptoms reported by individual in their OH records. Inform the Senior Clinician / TB Nurse Specialists of any reported serious reactions. Serious reactions are to be reported to MHRA via Yellow card or reported online www.yellowcard.gov.uk.
Management of and reporting procedure for adverse reactions	Healthcare professionals and individuals 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 Any adverse reaction to a vaccine or medicinal product should be documented in the individual's occupational health record and the individual's GP should be informed.
Written information to be given to client	HCW will be given Occupational Health information showing care of the site and possible side effects following mantoux test. Offer patient information leaflet (PIL) if provided with the product and/or offer unlicensed medicines leaflet (See Unlicensed medicines policy on Koha)
Client advice / follow up treatment	Read the patient information leaflet / Mantoux checklist covering contraindications, risks / side-effects before taking the medicine. Verbal advice on why product administered, action of the tuberculin and subsequent management of condition. Inform individual that the

	product is unlicensed but administered in accordance with national guidance. Wash site normally, do not cover, do not apply perfumes/lotions to site; try not to scratch the site if becomes itchy. HCWs should be re-called for follow-up within 48-72 hours following the test for Mantoux reading and interpretation (although a valid reading can be obtained up to 96 hours later) Inform the individual of possible side effects and their management. The individual should be advised to seek medical advice in the event of an adverse reaction. When administration is postponed advise the individual how future vaccination may be accessed.
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. Pregnancy – skin tests may be done, but as BCG cannot be done at follow-up, it may be better to postpone the test. As an unlicensed product the signature of a medical practitioner will be required prior to the clinic, see form in Appendix one.
Records	Record in line with local procedure: • 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 product • date of administration • dose, form and route of administration of product • 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 • administered via PSD (patient specific direction) Records should be signed and dated (or password-controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous and recorded on the occupational health database. Additionally for this product the PSD (appendix 1) should be signed/dated and retained in the department for 5 years.

4. Key references

Key references	**Tuberculin PPD for Mantoux Testing** Immunisation Against Infectious Disease. The Green Book, Chapter 32 Tuberculosis (updated on line August 2018): https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/731848/_Greenbook_chapter_32_Tuberculosis_.pdf The Mantoux test – administration, reading and interpretation' DOH. https://www.up.ac.za/media/shared/Legacy/sitefiles/file/45/1335/877/mantouxflipchart.pdf Tuberculosis. NICE guidelines (NG33) Published date: January 2016 http://www.nice.org.uk/guidance/ng33 British National Formulary www.bnf.org MHRA Yellow Card Scheme http://yellowcard.mhra.gov.uk/ **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. NHS England 2022 Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste (england.nhs.uk) • 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 • Reference guide to consent for examination or treatment, Department of Health, published 4 August 2009. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

5. Practitioner authorisation sheet – Tuberculin PPD for Mantoux Testing

Details of registered Nurses working for University Hospitals of Derby & Burton NHS Foundation Trust who have completed the required training and been assessed as competent (as detailed in Section 2 and confirmed by line manager/clinical supervisor signing below). Once signed, these staff are permitted to administer Tuberculin PPD for Mantoux Testing in accordance with this Protocol and Patient Specific Direction as part of the named organisation's occupational health scheme, which may include peer to peer immunisation:

Name	NMC Registration Number	Signature	Date	Clinical Supervisor/Line manager name	Clinical supervisor/line manager signature	Date

Appendix 1 – Patient Specific Direction - HCWs receiving a Mantoux test

The names of the HCWs need to be placed on the list and the OH doctor must sign the completed form prior to administration during the clinic. **Retain document within OH department for 5 years**

Occupational Health Physician providing Patient Specific Direction for the OH Nurses to administer this unlicensed medicine to the named patients below in accordance with UHDB Unlicensed Medicines Policy		
Doctors Name:	Doctors Signature:	Date signed:

Name of Recipient	DOB	Job Role of recipient	Administration session use	
			Signature of Nurse administering	Date