University Hospitals of Derby and Burton NHS Foundation Trust

Written instruction for Occupational Health Services

Registered Nurses ONLY

BACILLUS CALMETTE-GUERIN MULTIDOSE VACCINE (BCG VACCINE - AJV)

Documentation details

Reference no:	UHDB089
Version no:	V1.0
Valid from:	27/04/2021
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Expiry date:	26/04/2024

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 written instruction is to be approved by a chief pharmacist (or nominated deputy) and senior OH nurse (or nominated deputy).

Pharmacist designation:		
Name	Signature	Date
James Hooley		27/04/2021
Nursing designation:	Nurse Consultant	88E1197E
Name	Signature	Date
Lucy Kenyon		1/5/2021

Name and signature of the registered doctor authorising registered nurses, who declare themselves (in Section 3) to have met the training and competency requirements defined in this written instruction, to operate under this written instruction on behalf of the named organisation.

Name	GMC Registration Number	Job Title	Signature	Date
Ilias Macheridis	6138922	AdvDipOccMed DDAM, MScPH OHP		28.04.2021

Local enquiries regarding the use of this Written Instruction 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 Written Instruction.

Change history

Version number	Change details	Date
1	Changed from PGD to Written Instructions	22/04/2021

28.04.2021

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 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. The registered nurse must have undertaken training appropriate to deliver BCG immunisation under this written instruction 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 BCG immunisation. Successful completion of the Trust written Drug Assessment & any essential to role Medicines Management/Safety training. 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 the Written Instructions 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	BCG vaccination 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 written instruction are personally responsible for ensuring they remain up to date with the use of the products included. If any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the Written Instruction and further training provided as required.

2. Clinical condition or situation to which this Written Instruction applies:

Clinical condition or situation to which this written instruction applies	BCG Vaccination for active immunisation against tuberculosis for individuals working in a healthcare setting with direct / indirect patient contact or pathology workers who are handling clinical specimens. Other at risk occupational groups - those working with animals susceptible to TB; those working with prisoners; those working in care homes for the elderly or hostels for the homeless, refugees or asylum seekers, who have no evidence of BCG vaccination from documentation or scar and are tuberculin negative. *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	Adults (16 years and over) meeting the above criteria for occupational protection, who have no evidence of BCG vaccination from documentation or scar and have a negative tuberculin skin test (Mantoux) prior to receiving BCG vaccination. **All individuals should receive a Tuberculin skin Test (Mantoux) prior to BCG vaccination.** • UHDB HCWs / non-clinical and laboratory workers as detailed above. • Individuals needing protection for occupational purposes who are working in organisations where Occupational Health are contracted / commissioned to provide a service.
Criteria for exclusion	• Consent not gained (for further information on consent see DH Reference guide to consent for examination or treatment) • Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics • Pregnancy • Suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • Have a primary or acquired immunodeficiency state (see the 'Green Book' Chapter 6 for more detail) • Suffering from malignant conditions (such as lymphoma, leukaemia, Hodgkin's disease or other tumours of the reticulo-endothelial system) • Current or recent high dose immunosuppressive treatment, corticosteroid or biological therapy - (inhaled steroids are not a contraindication) (see the 'Green Book' Chapter 6 for more detail) • BCG is absolutely contraindicated in HIV positive individuals, including those suspected, regardless of CD4 cell count, ART use, viral load and clinical status. • Have already had a BCG vaccination (evidence includes documentary evidence, a clear reliable history of vaccination or a characteristic scar) • Have a past history of active or latent TB - positive Interferon Gamma Release Assay (IGRA)

	• Tuberculin positive - having an induration of 5mm or more following Mantoux tuberculin skin testing • Receiving anti-tuberculosis drugs • Those with generalised septic skin conditions. If eczema exists an immunisation site should be chosen that is free from skin lesions.
Cautions including any relevant action to be taken	If an individual is acutely unwell, immunisation should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. Previous severe reaction to vaccination. Clarify nature of reaction and seek further advice. If eczema exists, an immunisation site should be chosen that is free from skin lesions. Although no harmful effects to the breastfed child have been associated with BCG Vaccine AJV, vaccination of the mother is not recommended during lactation. However, in areas with high risk of tuberculosis infection, BCG Vaccine AJV may be given during lactation if the benefit of vaccination outweighs the risk. Specialist advice should be sought. BCG cannot be given without a prior Mantoux Test or IGRA Test All those with a Mantoux test reading – diameter of induration 5 mm or more – will need to have an IGRA test. All those with a positive IGRA test – should be referred to TB Nurse specialist for further assessment. BCG must be given within 3 months of a negative tuberculin skin test or negative IGRA test. Will need to be repeated if not given within this timeframe. Although anaphylaxis is rare, facilities for its management should always be available during vaccination. Whenever possible, patients should be observed for an allergic reaction for up to 15-20 minutes after receiving immunisation. 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	• 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.

	• Individuals excluded for health reasons or who have had a confirmed anaphylactic reaction to any components of the vaccine should be referred to a Senior Clinician for specialist advice and appropriate management. • Individuals with a past history of active or latent TB, prior BCG vaccination, a positive Mantoux test (induration of 5mm or more) or a positive IGRA result do not require BCG vaccination as there is an increased risk of adverse reactions and there is no evidence that repeat BCG offers additional protection. • Individuals receiving anti-tuberculosis drugs (such as for chemoprophylaxis) should have vaccination postponed until latent TB infection is excluded. Note: BCG vaccination is contraindicated in individuals with TB or a past history of TB. • Individuals who have a primary or acquired immunodeficiency state or who are currently, or were recently, on high dose immunosuppressive or biological therapy (see Chapter 6): consult appropriate specialist regarding the individual's immune status and suitability for receiving live varicella vaccine. • BCG vaccination is not recommended during pregnancy and vaccination should be postponed until after the pregnancy. • Inform manager in writing if the individual's occupation places them at risk through exposure.
Action to be taken if the client or carer declines treatment	• Document advice given and the decision reached • Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. • Inform manager in writing if the individual's occupation places them at risk through exposure. • Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.
Arrangements for referral for medical advice	Inform and seek advice from the Senior Occupational Health Clinician as appropriate. In case of allergies or specialist treatment refer individual to their GP or Specialist Clinician.

3. Description of treatment

Name, strength & formulation of drug	BCG Vaccine AJV, powder and solvent for suspension for injection BCG vaccine contains a live attenuated strain derived from M. bovis. BCG Vaccine AJV (AJ Vaccines) is the only licensed vaccine in the UK. It contains the Danish strain 1331.
Legal category	POM - Prescription only medicine

Route / method of administration	• BCG Vaccine AJV is administered strictly intradermally in the arm (usually the left), over the distal insertion of the deltoid muscle onto the humerus. • Should only be administered by Registered Nurses suitably trained and competent to do so. • BCG Vaccine AJV is a multidose product which require reconstitution with the solvent provided (Sauton AJV solvent). This provides 1ml of reconstituted solution (i.e. up to 10 x 0.1ml adult doses per vial) • Carefully invert the vial a few times to resuspend the lyophilised BCG completely. DO NOT SHAKE. Gently swirl the vial of re-suspended vaccine before drawing up each subsequent dose. • The vaccine's normal appearance is a white powder in a vial (which might be difficult to see due to the small amount of powder in the vial) and a clear colourless solvent in a vial without any visible particles. Following reconstitution the vaccine is a colourless, slightly opaque, homogenous suspension. • 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. • The upper arm should be positioned approximately 45˚ to the body. This can be achieved if the hand is placed on the hip with the arm abducted from the body, • If the skin is visibly dirty it should be washed with soap and water. The vaccine should be administered using a specific tuberculin syringe. The correct dose of BCG vaccine should be drawn into the tuberculin syringe and the intradermal injection administered with the bevel facing up. The immuniser should stretch the skin between the thumb and forefinger of one hand and with the other slowly insert the needle, with the bevel upwards, • BCG vaccine must be administered strictly by intradermal injection, normally into the lateral aspect of the left upper arm at the level of the insertion of the deltoid muscle (just above the middle of the left upper arm – the left arm is recommended by WHO). Sites higher on the arm, and particularly the tip of the shoulder, are more likely to lead to keloid formation and should be avoided. • A correctly given intradermal injection results in a tense, blanched, raised bleb, and considerable resistance is felt when the fluid is being injected. A bleb is typically of 7mm diameter following a 0.1ml intradermal injection.

	• When administering at the same 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 in different arms. The site at which each was given should be noted in the individual's records.
Indicate any off-label use (if relevant)	Administration of a live vaccine within 4 weeks of BCG Vaccine AJV is off-label but in accordance with the recommended intervals between vaccines in Chapter 11 of the 'Green Book'. 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 PHE 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 drug is recommended off-label consider, as part of the consent process, informing the individual that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	Adults – 0.1ml once only **NB. BCG can be given within 3 months of a negative tuberculin skin test**
Obtaining supplies	Vaccine supplies will be ordered from Pharmacy Stores using the stock list protocol set up by pharmacy
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. BCG Vaccine AJV should be reconstituted with the diluent supplied by the manufacturer (Diluted Sauton AJV) and used immediately. Reconstituted vaccine may be used for up to four hours at room temperature, after which any unused reconstituted vaccine should be 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.
Drug interactions	The following interactions have been identified and should be considered where it is known a client is on the following medicines: • May be given at the same time as other vaccines, including other live vaccines which can also be administered at any time before

	or after BCG vaccination • Other vaccines to be given at the same time as BCG Vaccine AJV should not be given into the same arm. It is advisable not to give further vaccination in the arm used for BCG vaccination for 3 months because of the risk of regional lymphadenitis. • BCG vaccine should not be given to patients taking anti-tuberculosis medicines. (SPC) Please refer to the relevant SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	The expected reaction to successful vaccination with BCG Vaccine AJV includes induration at the injection site followed by a local lesion that may ulcerate some weeks later and heal over some months leaving a small, flat scar. A local site reaction may include erythema and tenderness. It also may include enlargement of a regional lymph node to less than 1 cm. Other side-effects are uncommon but may include headache and fever. An excessive response to the BCG Vaccine AJV may result in a discharging ulcer. This may be attributable to inadvertent subcutaneous injection or to excessive dosage. The ulcer should be encouraged to dry and abrasion (by tight clothes, for example) should be avoided. Expert advice should be sought regarding the appropriate treatment regimen for the management of systemic infections or persistent local infections following vaccination with BCG Vaccine AJV. Hypersensitivity reactions (including anaphylactic reactions), more severe local reactions such as abscess formation, and disseminated BCG complications (such as osteitis or osteomyelitis) are rare and should be managed by a specialist. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Management of and reporting procedure for adverse reactions	• Healthcare professionals and clients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual occupational health record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use. • If anaphylaxis management may be required ensure immediate access to blue Anaphylaxis box for treatment of Anaphylaxis

	(Follow algorithm in Anaphylaxis box).
Written information to be given to client or carer	Offer marketing authorisation holder's patient information leaflet (PIL) if available in the pack and any relevant OH leaflet.
Client advice / follow up treatment	Inform the individual of possible side effects and their management, including the normal reaction to the injection and about caring for the vaccination site. Read the vaccination information checklist covering risks / side-effects supplied before taking the medicine. Advise the individual of the expected site reaction to successful BCG vaccination which includes: • a slight swelling, redness and tenderness at the injection site followed by a local lesion • some weeks later this lesion evolves into a small ulcer • after some months this ulcer will heal leaving a small, flat scar • a slight swelling of the lymph nodes in the armpit may be experienced Advise the individual that it is not necessary to protect the site from becoming wet during washing and bathing. The injection site is best left uncovered to facilitate healing. The ulcer should be encouraged to dry, and abrasion (by tight clothes, for example) should be avoided. Should any oozing occur a temporary dry dressing may be used until a scab forms. It is essential that air is not excluded. If absolutely essential (eg to permit swimming), an impervious dressing may be used but it should be applied only for a short period as it may delay healing and cause a larger scar. Inform the individual that other immunisations are not recommended to be given in the same limb for 3 months following BCG vaccination. Read the patient information leaflet covering risks / side-effects supplied before taking the medicine The individual should be advised to seek medical advice in the event of an adverse reaction. When administration is postponed advise the individual when to return for vaccination.
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. If the individual is undergoing immunosuppressant therapy the effect of the vaccination may be diminished. Advice needs to be sought prior to Mantoux testing or administering BCG vaccination. The vaccine stopper must not be wiped with any antiseptic or detergent. If alcohol is used to swab the rubber stopper of the vial, it must be allowed to evaporate before the stopper is penetrated with the syringe needle. Likewise the injection site should be clean and dry. If the skin is visibly

	dirty it should be washed with soap and water. If antiseptics (such as alcohol) are applied to swab the skin, they should be allowed to evaporate completely before the injection is made. Evidence of a previous BCG vaccination includes: documentary evidence; a clear, reliable history of vaccination; or evidence of a characteristic scar. Individuals with an uncertain history of prior BCG vaccination should be tuberculin or IGRA tested before being given BCG vaccine. In the absence of a Mantoux test, individuals with negative IGRA results should only be given BCG in the absence of a BCG scar and in the absence of a reliable history of BCG vaccination. Although anaphylaxis is rare, facilities for its management should always be available during vaccination. Whenever possible, patients should be observed for an allergic reaction for up to 15-20 minutes after receiving immunisation.
Records	Record in line with local procedure: • that valid informed consent was given • name of individual, address, date of birth • name of registered nurse operating under this instruction • name and brand of product • date of administration • dose, form and route of administration • quantity administered • batch number and expiry date • anatomical site of administration • when next dose is due (if applicable) • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • Clarify it was administered under 'written instruction' 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.

4. Key references

Key references	• Summary of Product Characteristic for BCG Vaccine AJV, AJ Vaccines. 19 June 2020. https://www.medicines.org.uk/emc/product/9890

	• Electronic BNF https://bnf.nice.org.uk/ • PHE BCG Vaccine AJV PGD https://www.gov.uk/government/publications/bcg-patient-group-direction-pgd-template • Immunisation Against Infectious Disease: The Green Book Chapter 32: Tuberculosis, updated 03 August 2018 https://www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32 • 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 • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

5. Practitioner authorisation sheet – BCG Vaccine

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) who are authorised and willing to administer the vaccine in accordance with this written instruction as part of the named organisation's occupational health scheme, which may include peer to peer immunisation:

Name	Profession and Professional Registration Number	Signature	Date	Clinical Supervisor/Line manager name	Clinical supervisor/line manager signature	Date