Public Health England

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PATIENT GROUP DIRECTION (PGD)

Administration of BCG Vaccine AJV to individuals, from birth to 16 years of age, at increased risk of tuberculosis.

This PGD is for the administration of BCG Vaccine AJV by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	BCG Vaccine AJV PGD
Version no:	v01.00
Valid from:	1 September 2018
Review date:	1 March 2020
Expiry date:	31 August 2020

Public Health England has developed this PGD to facilitate the delivery of publicly funded immunisations in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

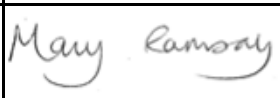
[1] This includes any relevant amendments to legislation (eg 2013 No235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE PGD	23 August 2018

1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		29/08/2018
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		28/08/2018
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		28/08/2018

This PGD has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Colin Campbell	Consultant Epidemiologist, Public Health England
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Vanessa Saliba	Consultant Epidemiologist, Public Health England
Tushar Shah	Pharmacy Advisor, NHS England London Region
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East
Surinder Tamne	Senior Nurse - TB specialist, Public Health England
Sharon Webb	Programme Manager/Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Helen Wilkinson	Principal Pharmacist Bristol, North Somerset & South Gloucestershire Clinical Commissioning Group.

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England Hampshire and Thames Valley (HTV) authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Authorised for use by the following organisations and/or services: All NHS England HTV directly commissioned immunisation services. In addition, the PGD may be adopted by provider organisations (providing NHS immunisation and vaccination services) working within the HTV geography. Where this occurs, provider organisations should have this PGD signed off by their governance lead prior to use. Provider organisation staff will be expected to follow local policies and procedures.
Limitations to authorisation
None stated

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director	**Shahed Ahmad**		**18/9/18**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to england.southcentral-pgd@nhs.net

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be

used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • 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 administering BCG using a correct intradermal injection technique • 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 • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation with BCG and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals from birth to 16 years of age for the prevention of human tuberculosis (TB) in accordance with the national selective immunisation programme and recommendations given in Chapter 32 of Immunisation Against Infectious Disease: "The Green Book".
Criteria for inclusion	Previously unvaccinated individuals living in an area of the UK where the annual incidence of TB is 40/100,000 or greater who: • are aged from birth to 12 months of age Previously unvaccinated individuals, with a parent or grandparent who was born in a country[2] where the annual incidence of TB is 40/100,000 or greater, who: • are aged from birth to 12 months of age • are aged one to five years (these children should be identified at suitable opportunities, and can normally be vaccinated without tuberculin or Interferon Gamma Release Assay (IGRA) testing) • are aged from six years to under 16 years and are tuberculin or IGRA[3] negative (these children should be identified at suitable opportunities, tested and vaccinated if negative) Individuals aged under 16 years who are previously unvaccinated and tuberculin or IGRA[3] negative and who: • are household or equivalent close contacts of cases of sputum smear-positive pulmonary or laryngeal TB • were born in or who have lived for a prolonged period (at least three months) in a country with an annual TB incidence of 40/100,000 or greater Note: Vaccination with BCG for occupational risk or travel (see Chapter 32 for further detail) is not covered by this PGD and individuals should be directed to their occupational health service provider or an appropriate travel health service respectively.
Criteria for exclusion[4] Continued over page	Individuals for whom no valid consent has been received. Individuals who: • have had a confirmed anaphylactic reaction to a component of the vaccine • are 16 years of age or over • have already had a BCG vaccination • have a past history of active or latent TB • are tuberculin positive (ie have an induration of 5mm or more following Mantoux tuberculin skin testing) • have a positive Interferon Gamma Release Assay (IGRA) • are receiving anti-tuberculosis drugs • are less than 2 years of age and in a household where an active TB case is suspected or confirmed, until potential latent TB in the infant/child is excluded from 6 weeks post exposure (see Additional information)

[2] For country information on prevalence see: https://www.gov.uk/government/publications/tuberculosis-tb-by-country-rates-per-100000-people

[3] In the absence of a Mantoux test, persons 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.

[4] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Criteria for exclusion[5] Continued	• are pregnant
	• have a generalised septic skin condition
	• are suffering from malignant conditions (eg lymphoma, leukaemia, Hodgkin's disease or other tumours of the reticulo-endothelial system),
	• have primary or secondary immune-deficiencies or who are HIV positive. Note: Infants born to HIV positive mothers should only be given BCG vaccination when the exclusively formula-fed infant is confirmed HIV uninfected at 12–14 weeks. However, infants considered at low risk of HIV transmission (maternal VL <50 HIV RNA copies/mL at or after 36 weeks' gestation) but with a high risk of tuberculosis exposure may be given BCG at birth.
	• are infants born to a mother who received immunosuppressive biological therapy during her pregnancy or breastfeeding, for as long as a postnatal influence on the immune status of the infant remains possible
	• are receiving or have received in the past 6 months:
	  ○ immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorders
	  ○ immunosuppressive therapy for a solid organ transplant
	• are receiving or have received in the past 12 months:
	  ○ immunosuppressive biological therapy (eg anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab)
	• are receiving or have received in the past 3 months immunosuppressive therapy including:
	  ○ high-dose corticosteroids (>40mg prednisolone per day or >2mg/kg/day in children under 20kg) for more than 1 week
	  ○ lower dose corticosteroids (>20mg prednisolone per day or >1mg/kg/day in children under 20kg) for more than 14 days
	  ○ non-biological oral immune modulating drugs, eg methotrexate, azathioprine or 6-mercaptopurine, except those on low doses, see Chapter 6 of the "Green Book", specialist advice should be sought prior to vaccination
	• 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 Continued over page	In persons whose immune status is in question, BCG vaccination should be postponed until their immune status has been evaluated. If eczema exists, an immunisation site should be chosen that is free from skin lesions. Breast-feeding is not a contraindication to BCG, however if there is any doubt as to whether an infant due to receive BCG vaccine may be immunosuppressed due to the mother's therapy, including exposure through breastfeeding, specialist advice should be sought. It is important that premature infants have their immunisations at the appropriate chronological age, according to the schedule. The potential risk of apnoea and the need for respiratory monitoring for 48-72h should be considered when administering to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

[5] Exclusion under this Patient Group Direction does not necessarily mean the vaccine is contraindicated, but it would be outside its remit and another form of authorisation will be required

Cautions including any relevant action to be taken Continued	Administering the vaccine too deep increases the risk of discharging ulcer, lymphadenitis and abscess formation. 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 patient is excluded	If 16 years of age and over, BCG vaccination is not usually recommended unless the risk of exposure is great (eg those at occupational risk through direct clinical contact with a patient diagnosed with TB or contact with infectious TB materials). Such individuals should be appropriately referred eg to their occupational health service provider. 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 (eg 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 less than 2 years of age in a household where an active TB case is suspected or confirmed should receive chemoprophylaxis and be tuberculin and/or IGRA tested after 6 weeks to exclude latent TB prior to BCG vaccination. BCG vaccination is not recommended during pregnancy and vaccination should be postponed until after the pregnancy. Individuals who may be immunosuppressed through disease or treatment, including those suffering from malignant conditions, primary or secondary immune-deficiencies or who are HIV positive, those on immunosuppressive therapy and infants born to a mother who received immunosuppressive biological therapy should not receive BCG vaccination unless their immune status resolves and they fulfil the criteria for inclusion. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should 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 as required. 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 the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and the decision reached. In a GP practice setting, inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength & formulation of drug	BCG vaccine AJV, *Mycobacterium bovis* BCG (Bacillus Calmette-Guérin), to be diluted with one 1ml of diluted Sauton AJV. This is a multidose container. One vial of reconstituted vaccine contains 1 ml, corresponding to 10 declared doses (of 0.1 ml) for individuals aged 12 months and over or 20 declared doses (of 0.05 ml) for infants under 12 months of age. These are declared number of doses and not the actual number of doses that can be removed in practice. The extractable number of doses that can be removed from the vial of reconstituted BCG Vaccine AJV depends on the specific type of syringe and needle used as well as on the surplus of vaccine removed by the individual vaccine administrator during vaccination. After reconstitution, 1 dose (0.1 ml) for individuals aged 12 months and over contains: • *Mycobacterium bovis* BCG (Bacillus Calmette- Guérin), Danish strain 1331, live attenuated, 2-8 x 10^5 cfu. After reconstitution, 1 dose (0.05 ml) for infants under 12 months of age contains: • *Mycobacterium bovis* BCG (Bacillus Calmette- Guérin), Danish strain 1331, live attenuated, 1-4 x 10^5 cfu.
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	In accordance with the advice in Chapter 32 of the "Green Book", BCG Vaccine AJV may be administered off-label to an infant born to an HIV positive mother only once the exclusively formula-fed infant is confirmed HIV uninfected at 12–14 weeks. Infants considered at low risk of HIV transmission (maternal VL <50 HIV RNA copies/mL at or after 36 weeks' gestation) but with a high risk of tuberculosis exposure may be given BCG Vaccine AJV off-label at birth. Administration of a live vaccine within 4 weeks of BCG Vaccine AJV is off-label but in accordance with the Revised recommendations for the administration of more than one live vaccine (PHE 2015). 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 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.
Route / method of administration Continued over page	BCG Vaccine AJV is administered strictly by the intradermal route, only by those suitably trained and competent to do so (see Section 3 Characteristics of staff). See the "Green Book" Chapter 32 and the manufacturer's SPC for further details on the intradermal administration technique. The multidose vial of BCG Vaccine AJV must be reconstituted prior to administration with 1ml Diluted Sauton AJV in accordance with the manufacturer's instructions.Carefully invert the vial a few times to

Route / method of administration Continued	suspend the lyophilised BCG completely. DO NOT SHAKE. Gently swirl the vial of resuspended vaccine before drawing up each subsequent dose. If the skin is visibly dirty it should be washed with soap and water. The vaccine is administered through either a specific tuberculin syringe or, alternatively, a 1ml graduated syringe fitted with a 26G 10mm (0.45mm x 10mm) short bevelled needle[6] for each individual. The correct dose of BCG vaccine should be drawn into the tuberculin syringe and the 26G short bevelled needle attached to give the injection. The needle must be attached firmly and the intradermal injection administered with the bevel facing up. 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. The vaccine's normal appearance is a white powder in a vial (which might be difficult to see due to the small amount of power 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 vaccine's SPC provides further guidance on administration and is available from http://www.mhra.gov.uk/spc-pil/index.htm?subsName=BCG&pageID=SecondLevel
Dose and frequency of administration	A single intradermal dose of: 0.05ml for infants under 12 months of age 0.1ml for individuals aged 12 months and over
Duration of treatment	A single dose.
Quantity to be supplied / administered	A single dose.
Supplies	Centrally purchased vaccines for individuals at increased risk of tuberculosis can be ordered via ImmForm. Vaccines for use in accordance with this PGD 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).
Storage Continued over page	Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions

[6] The product literature states that a 25G/0.50 mm or 26G/0.45 mm short bevel needle may be used. However, the "Green Book" recommendations are specifically to use a 26G, 10mm (brown) needle.

Storage (continued)	stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to PHE Vaccine Incident Guidance. 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.
Disposal	BCG vaccine waste should be disposed of in accordance with the recommendations for waste classified as potentially cytotoxic / cytostatic (in a purple-lidded container). Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe, 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	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 (PHE 2015). 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. A detailed list of drug interactions is available in the SPC, which is available from http://www.mhra.gov.uk/spc-pil/index.htm?subsName=BCG&pageID=SecondLevel
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 vaccine's SPC, which is available from http://www.mhra.gov.uk/spc-pil/index.htm?subsName=BCG&pageID=SecondLevel

Reporting procedure of adverse reactions	Healthcare professionals and patients/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 Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • Immunisations up to 13 months of age • TB, BCG and your baby leaflet Available from: www.gov.uk/government/collections/immunisation
Patient advice / follow up treatment	Inform the individual/parent/carer of possible side effects and their management. Advise the individual/parent/carer 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/parent/carer 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/parent/carer that other immunisations are not recommended to be given in the same limb for 3 months following BCG vaccination. The individual/parent/carer should be advised to seek medical advice if the lesion looks like it may have become infected. When administration is postponed advise the individual/parent/carer when to return for vaccination.
Special considerations / additional information Continued over page	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of 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. Universal vaccination operates in areas of the country where the TB incidence is 40/100,000 or greater. This is applied for operational

Special considerations / additional information continued	reasons since these geographical areas generally have a high concentration of families who come from regions of the world where the TB incidence is 40/100,000 or greater and therefore a higher potential for transmission events. The decision to introduce universal vaccination in an area is based on geography in order to target vaccination to children who may be at increased risk of TB in an effective way. It does not imply that living in areas that have an incidence of TB 40/100,000 or greater puts children at increased risk of TB infection. This is because most infections of children are likely to occur in household settings. Further, there has been little evidence of TB transmission in schools in the UK. There are few data on the protection afforded by BCG vaccine when it is given to adults (aged 16 years or over), and virtually no data for persons aged 35 years or over. BCG is not usually recommended for people aged over 16 years, unless the risk of exposure is great (eg healthcare or laboratory workers at occupational risk through direct clinical contact with a patient diagnosed with TB or contact with infectious TB materials). Such individuals are not eligible for management under this PGD and should be referred appropriately. 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. Individuals less than two years of age who have contact with a smear-positive case of pulmonary or laryngeal TB should be given chemoprophylaxis immediately, even if their initial tuberculin skin test is negative and then tuberculin tested after six weeks. If the skin test is negative, BCG vaccine should be given. New born babies who are contacts of a non-infectious TB case should be immunised with BCG immediately.
Records Continued over page	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 Patient Group Direction (PGD) Records should be signed and dated (or a password controlled immunisers record on e-records). All records should be clear, legible and contemporaneous.

Records continued	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 Services 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.

6. Key references

Key references	**BCG Vaccine AJV** • Immunisation Against Infectious Disease: The Green Book Chapter 32: Tuberculosis, updated 03 August 2018. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for BCG Vaccine AJV, AJ Vaccines. 22 May 2018. http://www.mhra.gov.uk/spc-pil/index.htm?subsName=BCG&pageID=SecondLevel • NHS public health functions agreement 2017-18, Service specification No.2 Neonatal BCG immunisation programme. April 2017. https://www.england.nhs.uk/publication/public-health-national-service-specifications/ • Revised recommendations for the administration of more than one live vaccine. Public Health England. 24 April 2015 https://www.gov.uk/government/publications/revised-recommendations-for-administering-more-than-1-live-vaccine **General** • 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. January 2014. 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 • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

7. Practitioner authorisation sheet

BCG Vaccine AJV PGD v01.00 Valid from: 01/09/2018 Expiry: 31/08/2020

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	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 England HTV** for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.