



**Patient Group Direction for the Administration of  
Bacillus Calmette-Guerin (freeze dried live attenuated) vaccine (BCG)  
to identified 'at risk of TB' patients attending BCG Clinics**

**This document authorises the administration of Bacillus Calmette-Guerin (freeze dried live attenuated) vaccine by Registered Nurses to at risk patients who meet the criteria for inclusion under the terms of the document**

**The registered nurses seeking to administer Bacillus Calmette-Guerin (freeze dried live attenuated) vaccine must ensure that all clients have been screened and meet the criteria before supply takes place**

**The purpose of this Patient Group Direction is to ensure access to BCG vaccine in a timely fashion**

**PGD previously approved: March 2011**

**This direction was authorised on: August 2012**

**The direction will be reviewed by: August 2014**

**Clinician Responsible for Review: Health Protection Nurse Specialist**

**PGD reviewed by: Chris Faldon, Tim Patterson, Mark Clark**



**Patient Group Direction for the Administration of Bacillus Calmette-Guerin Vaccine without a Prescription for a Named Individual by Registered Nurses employed by NHS Borders**

**1. This Patient Group Direction relates to the following specific Vaccine preparation:**

Name of Vaccine	Bacillus Calmette-Guerin (freeze dried live attenuated) vaccine
Legal status	POM (Prescription only medicine)
Storage	+2°C - +8°C in a refrigerator Protect from light. Do not freeze Store diluent below 25°C Use within four hours of reconstitution Discard any partly used vials at the end of the vaccination session NB - Disposal should be by placing the vial in a disposable sharps container for later incineration.
Dose	0.1ml (infants under 12 months 0.05ml)
Route/method	<ul style="list-style-type: none"> <li>• Strictly <b>intra-dermal injection</b> over the distal insertion of the deltoid muscle onto the humerus (approx. one third down the left upper arm and avoiding tattoos). Must only be administered by persons trained in the technique.</li> <li>• Individuals with generalised septic skin conditions should not be vaccinated. If eczema exists, an immunisation site should be chosen that is free from skin lesions.</li> <li>• Administer using a 0.5 or 1 ml insulin syringe with 30G needle or a 1ml graduated syringe fitted with a short bevel 25G or 26G needle. The intra-dermal injection is administered with the bevel of the needle uppermost. A correctly given intra-dermal injection results in a tense, blanched, raised bleb and considerable resistance is felt when the vaccine is being injected. If little resistance is felt when injecting and a diffuse swelling</li> </ul>

	<p>occurs as opposed to a tense blanched bleb, the needle is too deep.</p> <ul style="list-style-type: none"> <li>The needle should be withdrawn and reinserted intradermally before the remainder of the dose of vaccine is given. <b>DO NOT</b> repeat the dose under any circumstances.</li> </ul>
Frequency	Single dose
Total dose number	One
Advice	<p>The expected reaction to successful BCG vaccination, seen in 90 to 95% of recipients, is induration at the injection site followed by a local lesion which starts as a papule two or more weeks after vaccination. It may ulcerate and then slowly subside over several weeks or months to heal, leaving a small, flat scar. It may also include enlargement of a regional lymph node to less than 1cm.</p> <p>It is not necessary to protect the site from becoming wet during washing and bathing, but should any oozing occur, a temporary dry dressing (not a plaster) may be used until a scab forms. Do not exclude air. If absolutely essential (e.g. 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.</p>
Relevant Warnings	<ul style="list-style-type: none"> <li>Vertigo and dizziness occur occasionally</li> <li>More severe reactions, contact GP</li> <li>No further immunisation should be given in the arm used for BCG immunisation for at least three months because of the risk of regional lymphadenitis.</li> </ul>
Follow up Arrangements	Ask patient to remain on the premises where they can be observed for 10 minutes following vaccination.

## 2. Clinical condition

Clinical Condition to be treated	<ul style="list-style-type: none"> <li>To protect against human tuberculosis (TB) in persons with demonstrable lack of immunity by previous tuberculin testing</li> <li>Vaccination confers a variable degree of protection to infection with <i>Mycobacterium tuberculosis</i></li> </ul>
Criteria for inclusion	Adults and children up to age 16 years eligible for

	<p>immunisation deemed at higher risk of tuberculosis Previously unvaccinated with BCG <b>and</b> tested tuberculin negative within the last 3 months <b>if</b> one of the following criteria is fulfilled:</p> <ul style="list-style-type: none"> <li>• Children with a parent or grandparent who was born in a country where the incidence of TB is 40/100,000 or greater <b>and</b> there is continued contact with residents of this country</li> <li>• New entrants who 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</li> <li>• Previously unvaccinated contacts of those with active tuberculosis</li> <li>• Those under 16 years who are going to live or work with local people for more than one month in a country where the annual incidence of TB is 40/100,000 or greater</li> <li>• Adults requesting it for travel purposes (private vaccine)</li> </ul> <p><i>Note: testing is unnecessary for children under 6 years who <b>are not</b> TB contacts or <b>have not</b> lived in a in a country for at least three months where the incidence of TB is 40/100,000 or greater. Such children who are in school but under 6 years old can therefore proceed straight to a BCG. Pre-school children will be seen at the Borders General Ambulatory Care Clinic</i></p>
Criteria for exclusion	<ul style="list-style-type: none"> <li>• No valid consent</li> <li>• Had previous BCG immunisation (evidenced by the presence of a characteristic scar) When history is uncertain should only be re-immunised if tuberculin negative and benefits are judged to outweigh risks, especially in an occupational setting</li> <li>• Patients with a positive tuberculin skin test</li> <li>• Patients with current acute illness (minor infections without systemic upset or fever, are not reasons to postpone immunisation)</li> <li>• Patients receiving corticosteroid or other immunosuppressive treatment (Inhaled steroids are not a contraindication)</li> <li>• Patient suffering from a malignant condition</li> <li>• HIV positive individuals</li> <li>• Patients with generalised septic skin</li> </ul>

	<p>conditions</p> <ul style="list-style-type: none"> <li>• Pregnancy and lactation. It is wise to avoid immunisation until after delivery or breast feeding if possible</li> <li>• Patients who have received another live vaccine within the past four weeks</li> <li>• Patients known to be hypersensitive to any component of the vaccine</li> </ul>
Action if excluded	Information about when patient may have vaccine if appropriate
Action if declines	Record in patients' notes. Advise of risks
Interactions with other medicaments and other forms of interaction	BCG vaccine may be given <b>concurrently</b> with another live vaccine. If they are not given at the same time, an interval of four weeks is normally recommended between two live vaccines. BCG need not delay primary childhood immunisations.

### 3. Records: As appropriate for Patient location

#### a) The following records should be kept (either paper or computer based)

- The GP practice
- The patient name and CHI number
- The medicine name, dose, route, time of dose(s), and where appropriate, start date, number of doses and or period of time, for which the medicine is to be supplied or administered
- Drug batch number and expiry
- The signature and printed name of the approved healthcare professional who supplied or administered the medicine
- The patient group direction title and/or number
- Whether patient met the inclusion criteria and whether the exclusion criteria were assessed
- Quantity supplied / received

#### b) The patient information record must be forwarded to Public Health for database updating

#### c) Preparation, audit trail, data collection and reconciliation

Stock balances should be reconcilable with receipts, administration, records and disposals on a patient by patient basis.

### 4. Professional Responsibility

- ❖ All Health Professionals will ensure he/she has the relevant training and is competent in all aspects of medication, including contra-indications and the recognition and treatment of adverse effects. He/she will attend training updates as appropriate. For

those involved in immunisation, regular anaphylaxis updates are mandatory.

- ❖ Nurses will have due regard for the NMC Code of Professional Conduct, standards for conduct, performance and ethics (2008) and NMC Standards for Medicines Management (2008)

## 5. References

- ❖ British National Formulary (BNF) current edition  
<http://bnf.org/bnf/index.htm>
- ❖ Department of Health (2006) Immunisation against infectious disease (The Green Book). The Stationary Office. Updated 5<sup>th</sup> Nov 2007 at  
[http://www.dh.gov.uk/prod\\_consum\\_dh/idcplg?IdcService=GET\\_FILE&dID=153344&Rendition=Web](http://www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=153344&Rendition=Web)
- ❖ SPC for BCG vaccine (ImmuCyst® 81 mg)  
<http://www.medicines.org.uk/EMC/medicine/7779/SPC/ImmuCyst+81mg/>



## Appendix

### Informed consent for BCG

Name	Date of Birth
Address	
Phone	GP

You should not have the BCG vaccination if any of the following

apply:

- Previous confirmed allergic reaction to a component of the vaccine
- Have had tuberculosis
- Have a positive Mantoux skin test (induration of 6mm or more)
- Are immunocompromised by virtue of disease or treatment (including corticosteroids or immunosuppressive agents)
- Had a vaccination with a live virus vaccine within the last four weeks
- Had a previous BCG vaccination (unless specifically advised)
- During pregnancy or breastfeeding (unless considered essential by a doctor)
- Have a generalised septic skin condition

I HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND CONSENT FOR THE BCG VACCINE TO BE GIVEN TODAY.

Patient receiving vaccine  Parent/Guardian  (Please tick correct box)

Signature \_\_\_\_\_ Date \_\_\_\_\_

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BCG vaccine 0.1 ml given ID

Manufacturer	Lot #	Exp. Date
Site	Given by (Print)	Signature