

# **Bacille Calmette-Guérin (BCG) Immunization Protocol for the Freeze – Dried Glutamate BCG Vaccine (Japan)**

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# Bacille Calmette-Guérin (BCG) Immunization Protocol for the Freeze – Dried Glutamate BCG Vaccine (Japan)

<b>Purpose</b>	To provide information and guidance for the Bacille Calmette-Guérin (BCG) immunization program in Nunavut. Always refer to the product monograph or insert for specific information.
<b>Objective</b>	To protect infants and young children from serious complications of Tuberculosis (TB) infection in Nunavut. Although it does not provide permanent or absolute protection against TB, the BCG vaccine does have a protective effect against TB meningitis and disseminated disease.
<b>Indication</b>	Nunavut's publicly funded program is offered to all newborn infants on a routine basis. The vaccine should be administered as soon after birth as possible for maximum protection.
<b>Product</b>	Freeze-Dried Glutamate BCG Vaccine (Japan)
Vaccine Type	Live vaccine derived from an attenuated strain of <i>Mycobacterium bovis</i> .
Manufacturer	Japan BCG Laboratory
Route of Administration	Intradermal (ID) injection over the outer lower aspect of the deltoid region on the right arm. It is administered in a syringe with a 26-gauge needle, the bevel facing upwards.
Dose Series	Single dose of <b>0.1mL*</b> of reconstituted vaccine for infants. The vaccine should be administered as soon after birth as possible for maximum protection. See Appendix A. <b>*Dose alert</b>
Eligibility	Only infants up to 12 months of age living in Nunavut. Infants born outside of Nunavut who did not already receive the BCG vaccine are eligible to receive it upon their return to the Territory.
Special Instruction	<ul style="list-style-type: none"> <li>- Since BCG is a live vaccine given intradermally and may squirt during administration, it is likely prudent to protect the eyes of the infant, their caregiver and the vaccine provider. However, there is no known evidence or incidences of eye injuries.</li> <li>- The BCG glass ampoule requires scoring with supplied file prior to snapping off the top (scoring not necessary for diluent ampoule) See Appendix B.</li> <li>- Using an incorrect diluent may result in damage to the vaccine and/or serious reactions to those receiving the vaccine.</li> <li>- The skin at the site of injection should be cleansed with an alcohol swab and allowed to dry prior to vaccination.</li> <li>- BCG can be given with another live vaccine simultaneously, or at least 4 weeks apart.</li> <li>- A Tuberculin Skin Test (TST) is indicated prior to BCG vaccine administration depending on the age of the infant as follows: <ul style="list-style-type: none"> <li>• Infants &lt;2 months of age do not require a tuberculin skin test (TST) before receiving BCG vaccine, since reactivity does not develop before this age.</li> <li>• Infants between 2 – 6 months of age should be assessed on an individual basis for risk-benefit of having a TST prior to vaccination. A TST at this age may result in a false negative reading. Based on the outcome of the risk-benefit assessment either:</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ Administer a one-step TST before BCG vaccine if there is a high risk of prior TB exposure <b>OR</b></li> <li>○ Administer BCG vaccine without prior TST if the infant may not return after TST for BCG vaccine</li> </ul> <ul style="list-style-type: none"> <li>● Infants &gt; 6 months of age require a TST. Proceed with BCG vaccine on infants with a negative TST reading of &lt; 5mm. For TST readings ≥ 5mm contact your RCDC for further recommendations and do not give the BCG vaccine.</li> </ul> <p>- BCG immunization will not prevent the development of active TB in individuals who are already infected with <i>M. tuberculosis</i>.</p> <p>- Maternal HTLV-1 (human T-cell lymphotropic virus type 1) infection and possible neonatal HTLV-1 infection are not a contraindication to BCG, as neonatal HTLV-1 infection does not result in significant immune suppression in the child</p> <p>- Inadvertent subcutaneous injection may produce abscess formation. Incision or drainage of the abscess is not recommended.</p>
Booster Dose	Not Applicable
Vaccine Interchangeability	Not Applicable
Contraindications	<ul style="list-style-type: none"> <li>- Anaphylactic allergy to the vaccine or its components.</li> <li>- Any person with a condition resulting in impaired cell-mediated immune response, including HIV infection, altered immune status due to malignant disease, and impaired immune function secondary to treatment with corticosteroids or radiation.</li> <li>- Infants born of HIV positive mothers, or if HIV status of mother is unknown, the infant should NOT be vaccinated.</li> <li>- Family history of immunodeficiency including severe combined immunodeficiency syndrome (SCIDS).</li> <li>- A positive TST result and/or a history of TB</li> <li>- Extensive skin disease or burns</li> <li>- If an infant has received Immune Globulin or Blood products, the BCG vaccine should be held until further consultation with regional CDC.</li> </ul>
Vaccine Composition	<p>Live Bacteria of Calmette and Guerin (0.5mg/ampoule)</p> <p>Sodium Glutamate (2.0mg/ampoule)</p>
Precautions and Additional Notes	<ul style="list-style-type: none"> <li>- Administration of BCG vaccine should be postponed in persons with moderate or severe acute illness (including neonates with suspected sepsis). Infants with minor acute illness (with or without fever) may be vaccinated.</li> <li>- A history of receiving the BCG Vaccine may result in a positive TST in the future.</li> <li>- An abscess at the site of the BCG should never be lanced or drained.</li> </ul>
Formats available	Consists of a BCG ampoule and diluent. Follow package insert instructions for reconstitution. One reconstituted ampoule contains 10 (0.1mL) doses.
Storage	<p>BCG vaccine and diluent should be stored in a monitored vaccine refrigerator between 2°C and 8°C and should be protected from light.</p> <p>If doing a catch-up or mass immunization <u>by a single provider</u>, reconstituted BCG vaccine may be kept up to 6 hrs (stored at 2 to 8 degrees C and protected from light). Unused vaccine must be discarded after 6 hrs. In all other cases, excess reconstituted vaccine should preferably be discarded after single use.</p> <p>Doses of the BCG vaccine should be drawn up into a syringe only when the vaccine is to be</p>

	<p>given, as storing the vaccine in syringes for extended periods of time may decrease the efficacy of the vaccine and could lead to medication errors. In order to maintain sterility, reconstituted ampoules for mass immunizations may be stored in sterile specimen containers (stored at 2 to 8 degrees C and protected from light). If sterility of the reconstituted vaccine cannot be maintained and ensured, the remaining doses should be discarded.</p> <p>In case of a cold chain event, segregate damaged product keeping the cold chain protocol and inform RCDC and regional pharmacy.</p>
<b>Vaccine Supply and Distribution</b>	Regional pharmacy is responsible for territorial vaccine supply and distribution. Vaccine should be ordered and distributed in accordance with recommended practice.
<b>Consent</b>	Consent form must be reviewed and signed by the client or parent/guardian prior to vaccination.
<b>Anaphylaxis</b>	Review the principles of the emergency management of anaphylaxis, as found in <i>Anaphylaxis: Initial Management in the Non-Hospital Setting</i> , found in the Canadian Immunization Guide.
<b>Side Effects</b>	<p>A local reaction is normal and expected after BCG. A small tender red swelling may appear at the site of the injection, which gradually changes to a small vesicle and then an ulcer in 2-4 weeks. This resolves within 2 to 5 months often leaving a scar 2- 10 mm in diameter. Rarely, the nodule may persist and ulcerate. It is not recommended to use antibiotic ointment or to cover with occlusive bandage (including Telfa) at the site. (expected)</p> <p>All the following side effects require reporting using the Adverse Events Following Immunization (AEFI) Form.</p> <ul style="list-style-type: none"> <li>- Abscess formation may occur. Incision or drainage of the abscess is not recommended. (moderate)</li> <li>- Occasionally, enlargement of axillary lymph nodes may appear in 2-4 months following immunization. (moderate)</li> <li>- Very rarely, enlarged lymph nodes can suppurate. (moderate)</li> <li>- Disseminated BCG disease (frequency &lt; 1:1,000,000) may occur in infants who are immunocompromised, and is a life threatening condition. (severe)</li> </ul>
<b>Reportable Adverse Events/Side Effects</b>	<p>Report all <u>moderate</u> or <u>severe</u> adverse events listed above and as well as any unusual/unexpected events using the Public Health Agency of Canada (PHAC) <i>Adverse Events Following Immunization (AEFI) Form</i>, (also available online at: <a href="http://www.phac-aspc.gc.ca/im/ae-fi-form-eng.php">http://www.phac-aspc.gc.ca/im/ae-fi-form-eng.php</a>).</p> <p>Fax to RCDC:</p> <p>Baffin: 867-975-4833; Kitikmeot 867-983-4088; Kivalliq: 867-645-8272</p> <p>The Nunavut policy is:</p> <ul style="list-style-type: none"> <li>• AEFI forms are <b>only</b> for the reporting of serious adverse events following immunization.</li> <li>• Refer to the <i>Nunavut Community Health Nursing Administration Manual</i>, Policy 05-004 for the reporting of medication errors and other events.</li> </ul> <p>If there is an AEFI <b>and</b> a vaccination error, both forms should be completed.</p>
<b>Vaccine</b>	Vaccine coverage data are essential for monitoring the vaccine uptake, impact of immunization strategies, and policy.

<b>Coverage and Reporting</b>	The BCG Vaccine Reporting Form must be filled out <b>for every ampoule</b> . Each vaccine dose given or wasted must be accounted for to meet the requirements of the Special Access Program (SAP) for Health Canada. Fax completed forms to regional CDC.
<b>Materials and Resources</b>	<p>BCG Vaccine Fact Sheet</p> <p>BCG Consent Form</p> <p>BCG Vaccine Reporting Form</p> <p>Appendix A – BCG Japanese Product Insert</p> <p>Appendix B - BCG Reconstitution, Administration and Reporting Directions</p> <p>Adverse Events Following Immunization (AEFI) Form</p>
<b>References</b>	<ol style="list-style-type: none"> <li>1. Freeze-Dried Glutamate BCG Vaccine (Japan) Product Monograph. Japan BCG Laboratory.</li> <li>2. Public Health Agency of Canada. (2012). <i>Canadian Immunization Guide</i>. (8<sup>th</sup> ed.). Part 4 – BCG Vaccine (embargo)</li> <li>3. Public Health Agency of Canada and Canadian Lung Association/Canadian Thoracic Society. (2007). <i>Canadian Tuberculosis Standards</i>. (6th ed.). Ottawa Source: <a href="http://www.phac-aspc.gc.ca/tbpc-latb/pubs/tbstand07-eng.php">http://www.phac-aspc.gc.ca/tbpc-latb/pubs/tbstand07-eng.php</a></li> <li>4. Government of Nunavut. <i>Nunavut TB Control and Elimination Manual</i>.</li> </ol>



# Bacille Calmette-Guérin (BCG) Vaccine Consent Form

## Freeze – Dried Glutamate BCG Vaccine (Japan)

### (for ID Injection)

House/Building #: \_\_\_\_\_  
 P.O. Box #: \_\_\_\_\_  
 Parent/Guardian Information: \_\_\_\_\_  
     Phone # (cell/home/work/other): \_\_\_\_\_  
     Phone # (cell/home/work/other): \_\_\_\_\_  
     Phone # (cell/home/work/other): \_\_\_\_\_  
 Work/School: \_\_\_\_\_

Please fill in OR addressograph/affix label:  
 Last Name: \_\_\_\_\_  
 First Name: \_\_\_\_\_  
 Sex (M/F): \_\_\_\_\_  
 DOB (dd/mm/yyyy): \_\_\_\_\_  
 Chart #: \_\_\_\_\_  
 HCP #: \_\_\_\_\_  
 Community of Residence: \_\_\_\_\_

**Please Answer:**

1	Does the child have any medical condition that decreases their ability to fight off infections, or are they on any medications that suppress their immune system?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2	Is there anyone in the child's family who has Severe Combined Immunodeficiency Syndrome (SCIDS)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3	Is the birth mother of the child HIV+ or is the HIV status of mother unknown?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4	Is the child sick with a serious illness at this time?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5	Has the child been exposed to anyone who has active Tuberculosis or is the child on TB medications?	<input type="checkbox"/> Yes <input type="checkbox"/> No

\*\*\* If **Yes** was answered to any of the above questions, the BCG vaccine **should not** be given at this time

The Japan BCG Laboratory vaccine is not licensed in Canada, but is approved for use in Canada under Health Canada's Special Access Programme and has been used in other parts of the world for 25 years.

**CONSENT:**

I have read or had explained to me the *Bacille Calmette-Guerin (BCG) Vaccine Fact Sheet* and have asked questions which were answered to my satisfaction. I understand the benefits and risks of the vaccine.

I consent to receiving the BCG vaccine for:  My Child or  My Dependant/Ward

Print Name

Signature of Client or Parent/Legal Guardian (if applicable)

Date (dd/mm/yyyy)

**INDICATIONS FOR TUBERCULIN SKIN TEST PRIOR TO BCG VACCINE – VACCINE ADMINISTRATOR TO COMPLETE IF APPLICABLE**

Child's age	Tuberculin Skin Test Requirements
<input type="checkbox"/> < 2 months	TST is not necessary prior to BCG immunization
<input type="checkbox"/> 2 – 6 months	Administer a one-step TST before BCG vaccine if there is a high risk of prior TB exposure <b>OR</b> administer BCG vaccine without prior TST if the infant may not return after TST for BCG vaccine.
<input type="checkbox"/> > 6 months	TST is required prior to BCG immunization

TST required for this child?  Yes - Continue to box below  No - BCG may be given at this time

Date TST administered: \_\_\_\_\_ Date TST read: \_\_\_\_\_ Result \_\_\_\_\_ mm

TST Result < 5mm - BCG vaccine may be given  TST Result ≥5mm – **DO NOT** give BCG vaccine and consult RCDC.

**Section below must be completed by vaccine administrator**

**Ampoule #** \_\_\_\_\_ **BCG Lot # 1449 Given:** \_\_\_\_\_  
**Diluent Lot # 1-1353** \_\_\_\_\_ **dd/mm/yyyy)** \_\_\_\_\_  
**(Name and Designation)**

# Bacille Calmette-Guerin (BCG) Vaccine Fact Sheet



## Tuberculosis

- Tuberculosis (TB) is an infection that can cause coughing, fever, and difficulty breathing.
- It spreads through the air when a person coughs.
- TB is most often an infection of the lungs, but it can also affect other parts of the body.

## Benefits of the BCG Vaccine

- Helps prevent children from getting very sick from TB.
- Does not prevent all types of TB but it helps prevent serious types of TB (meningitis, miliary TB) that can make children very sick.

## Possible side effects of the BCG Vaccine

- *Swollen lymph node* (raised lump) in the armpit or above collarbone 2-4 months after the vaccine. This usually goes away on its own.
- Very rarely the swollen lymph nodes get infected and need to be treated medically. If you find a lump, talk to your health care provider.
- Future positive Tuberculin Skin Test (TST).

## Normal Reaction to the BCG Vaccine

- Small blister where the vaccine was given.
- Small raised red bump that can swell and leak fluid 2 - 4 weeks after the vaccine, this usually heals within 2 - 5 months and may leave a small scar.

## Care after the BCG Vaccine

- Wash your baby's arm normally.
- Put a cool damp cloth over any swelling.
- If the sore is draining, cover it with gauze or a light cotton T-shirt.
- Do NOT:
  - massage the arm
  - put cream or ointment on it
  - put a band aid on the sore
  - pop or scratch the bump

If you are concerned about a reaction with the vaccine, talk with your health care provider.

## Your baby should not have vaccine if:

- Has Immune system difficulties such as:
  - taking medications that affect immune system.
  - HIV positive.
  - born to HIV positive or unknown HIV status mother.
  - has a family member diagnosed with Severe Combined Immunodeficiency Syndrome (SCIDS).
- Positive TST or Active TB disease
- Is allergic to the vaccine or its components
- Has burns or other serious skin problems

With all vaccines, there is a small chance of an allergic reaction called *anaphylaxis*.

Anaphylaxis appears as hives, rash, swelling of the mouth, difficulty breathing.

This reaction usually occurs within 15 minutes of receiving a vaccine and is the reason it is recommended you stay in the clinic for 15 minutes after getting a vaccine.

Anaphylaxis can be treated and your nurse or doctor is trained to treat it.

**Special Note:** The Japan BCG Laboratory vaccine is not licensed in Canada, but is approved for use in Canada under Health Canada's Special Access Programme and has been used in other parts of the world for 25 years





# Bacille Calmette-Guerin Aaniarut (BCG-mik) naitumik taivagaat Kapukhiqtunut titiraqtauhimayut Naunaitkutikhaq



## Puvallunniq

- Puvallunniq aaniarut taima qallakhulikpaktun, kitjalikhutik, ayukhalikpaktun aniqhaagiangatlu.
- Hiमितiqtaaqtuq aniqhaaqnikkut aniqnimi taima inuk kituliqaak qallakhuraangat.
- Puvallunniq aaniarut puvaknut, taimalu aaniaqtitivaktuqlu allanunt timimut.

## Pitjutikhat talvanga BCG-mik Kapukhiqnirmin

- Ikayuutigivaktuq nuttaqqanut aaniaqnaitumik tapfuminga puvallunnirmin.
- Ayunaitilimaituq tamaat aaniarutingnin TB-nik kihimi ikayutiniaqtuq ayuknautiqaqyuagtunik TB-nik taimaitunin (qaritauyaqmi aaniarut, uvinirlungnir TB-ngit) taima nuttaqqanut aaniaqiyuagtupagain.

## Ayuknautiit Naunairutilgit tapkuninga BCG-mik Kapuktaugumik

- *Puvitniaqtuq qiliqhinat* (pulinganiaqtun) uvinim ataani qullaaniluuniit qupturaqmi taima 2nik 4nik tatqikhiutinik kapukhiikihimaliqan. Una tamaqpaliaaniaqtuq inmikkut.
- Qiliqhinat puviluayuttugaluit aaniarutmik taima havautinik havauhiqtauvaktun. Nalvaaqhiguvit puvingayumik, munarhingnut uqaqtau yakhat.
- Hivunirmi TB-nik Aaniarutiqangmangt Uvinirni Ihivriuqtau yukhaq.

## Naunaituq Tautungnaqniaqtuq BCG-mik Kapukhiruvit

- Mikanuanik maqiaqniaqtuq kapukhiknirmi.
- Mikanuanik puvingngayunik aupayaaqtunik puviqaaqniaqtun maqiniaqtunlu taima 2nik – 4nik havainirnik aulaniaqtun kapukhiguiruvit, taima mamianiaqtuq 2nik – 5nikluuniit tatqikhiutingnik taimalu mikiumik qiligualiqniaqtuq.

## Munaginir BCG-nik Kapukhiguiruvit

- Ualugit biipinuat aingit ubluk tamaat.
- Uagutmik kinipayumik niglaumayumik ilugaklugu puvingnganinganiituni.
- Taima ulluguaqtuq maqiinaliqan, matuhiqlugu matutingnik ilupaakhaqnikluuniit.
- Imaliuktailutin:
  - Hugiinaqtailugu tallit
  - Nanuqtiqtailugu nanuutingnik
  - Matuhiqtailugu ulluguanirni
  - Qagaqtitailugu kumiktailugu puvingnganik

Ihumaluutigungni qanuriliunianga kapukhigungni, uqaqatigilugu munarhingit.

## Biibinnuaq kapuqhiqtughaungittuq havauhiqtuqtauhimayunik imaa:

- Taima ayungnautiqaqanik imaitunik:
  - Havautituqhimaagumik taima ayuknautiqaqniaqtun inuuhiani
  - HIV-qaligumi
  - Inuugumik HIV-qaligumik taimaluuniit nallunaqtunikluuniit HIV-qaligumi maamanga
  - Taima ilangit ilitugiyauligumik imaitumik aanniarutmik Severe Combined Immunodeficiency Syndrome-mik (SCIDS)
- TST-qaqqan taimaluuniit TB-nik aanniarutiqaqumi.
- Ayungnautiqagumilu kapuutinik taimaluuniit aatjikiivayaktunik tapkuninga kapuutinik.
- Taima utingniqaqqan taimaluuniit allanik uviningniklukumi.

Talvuuna tamaita kapuutingnik, taima ikituq ayuknautiqaqniaqtun taima taivagaat uuminga *anaphylaxis*.

Anaphylaxis-ni tautuktuurutiqaqtun puvingnganinuanik, uvinirlungniklu, puvikniqaliqtuqlu qaniqmi, ayukhaliqlunilu aniqhaagiangat. Una ayuknautit

tautungnaqhivaktuq taima 15 minits nik qangiutikpan kapukhiknirmi taima talvanitquyavaktun munarhitkuni 15 minitsnik kapukhiraangamik.

Anaphylaxis-mi ihuaqhaiyutiqaqiaqtaat munarhit taimaluuniit taakti ilihaiyagiikihimalirumiuk ihuaqhaitjutikhangit.

**Naunaitkuti:** Taamna Japan-mi BCG Laboratory havaut laisiqangittuq Kanadami, kihimi angiqtauhimayuq Kanadami ataani Health Canada'p Aallangayumi Piyaarnikkut Pinahuarutimi atuqtauhimavaktuqlu ahini nunaryaumi avaqtuhihayuni 25ni ukiuni.

# Fiche de renseignements sur le vaccin Bacille Calmette-Guérin (BCG)



## Tuberculose

- La tuberculose est une infection qui peut causer la toux, la fièvre et des difficultés respiratoires.
- La tuberculose se propage dans l'air ambiant quand une personne tousse.
- La tuberculose est le plus souvent une infection des poumons, mais elle peut aussi affecter d'autres parties du corps.

## Avantages du vaccin BCG

- Aide à empêcher qu'un enfant soit très malade à cause de la tuberculose.
- Ne prévient pas tous les types de tuberculose, mais il aide à prévenir des types graves (méningites, tuberculose militaire) qui peuvent rendre les enfants très malades.

## Effets secondaires du vaccin BCG

- *Ganglion lymphatique enflé* (enflure) dans l'aisselle ou au-dessus de la clavicule de 2 à 4 mois après la vaccination. L'enflure disparaît habituellement par elle-même.
- Il est très rare que le ganglion enflé s'infecte et nécessite un traitement médical. Si vous observez une enflure, parlez-en à votre infirmière ou à votre médecin.
- Le prochain test cutané à la tuberculine (TST) sera positif.

## Réactions normales au vaccin BCG

- Petite cloque au point d'injection du vaccin.
- Petite bosse rouge qui peut enfler et laisser échapper du liquide de 2 à 4 semaines après le vaccin, qui guérit habituellement dans les 2 à 5 mois et peut laisser une petite cicatrice.

## Soins à apporter après le vaccin BCG

- Laver le bras du bébé normalement.
- Poser une compresse froide sur toute enflure.
- Si la plaie coule, il faut la couvrir avec de la gaze ou un coton léger.
- NE PAS :
  - masser le bras
  - appliquer de crème ou d'onguent
  - appliquer de pansement adhésif sur la plaie
  - crever ou gratter l'enflure

Si une réaction au vaccin vous préoccupe, parlez-en à votre infirmière ou à votre médecin.

## Votre bébé ne doit pas recevoir le vaccin si :

- A des problèmes liés au système immunitaire tels que :
  - prise de médicaments qui affectent le système immunitaire
  - est séropositif pour le VIH
  - est né séropositif pour le VIH ou son statut pour le VIH est inconnu mère
  - un membre de sa famille qui a un diagnostic de syndrome d'immunodéficience combinée aiguë (SCIDS)
- Est positif au TST ou est atteint de tuberculose active.
- Est allergique au vaccin ou à ses composants.
- A des brûlures ou d'autres problèmes cutanés graves.

Dans le cas de tous les vaccins, il y a une faible possibilité d'une réaction allergique appelée *anaphylaxie*.

Voici certains symptômes de l'anaphylaxie : urticaire, éruption cutanée, enflure de la bouche, difficultés respiratoires.

Cette réaction se produit habituellement dans les 15 minutes suivant la vaccination et c'est pourquoi il est recommandé de rester à la clinique 15 minutes après l'injection.

L'anaphylaxie se traite et votre infirmière ou votre médecin saura la traiter.

**Note spéciale :** Le vaccin du *Japan BCG Laboratory* n'a pas obtenu sa licence au Canada, mais son utilisation au Canada a été approuvée en vertu du Programme d'accès spécial de Santé Canada et il est utilisé dans d'autres parties du monde depuis 25 ans.



# **BCG Vaccine Reporting Form**

**Please complete one form per ampoule of Freeze Dried  
Glutamate BCG vaccine (Japan) used.  
All doses must be accounted for under the Special Access  
Program**

Health Center/QGH: \_\_\_\_\_  
 Contact Person: \_\_\_\_\_  
 Telephone: \_\_\_\_\_  
 Fax: \_\_\_\_\_

**Fax Form to your Regional Communicable  
Disease Coordinator:**  
 For Kitikmeot region: 867-983-4088  
 For Kivalliq region: 867-645-8272  
 For Baffin region: 867-975-4833  
 Date Faxed to RCDC \_\_\_\_\_  
(dd/mm/yyyy)  
**\*Keep Copy on File\***

**Ampoule #** \_\_\_\_\_ **BCG Lot # 1449** **Diluent Lot # 1-1353**  
**Date of immunization:** \_\_\_\_\_  
(dd/mm/yyyy)

	HCP # OR Chart #	Surname	Given Name	DOB (dd/mm/yyyy)	Sex	Community
1					M / F	
2					M / F	
3					M / F	
4					M / F	
5					M / F	
6					M / F	
7					M / F	
8					M / F	
9					M / F	
10					M / F	

**Number of doses wasted for this ampoule:** \_\_\_\_\_

## Appendix A

(For The Medical Profession)

# FREEZE-DRIED GLUTAMATE BCG VACCINE (JAPAN) FOR INTRADERMAL USE

### DESCRIPTION

It is a live freeze-dried vaccine made from an attenuated strain of *Mycobacterium bovis*. It is used for the prevention of tuberculosis. The vaccine fulfils WHO requirements for BCG vaccine.

### COMPOSITION OF VACCINE

a) Live Bacteria of Calmette and Guerin (as approximately 70% moist bacteria) ..... 0.5mg/ampoule  
b) Sodium Glutamate (as a stabilizer) ..... 2.0mg/ampoule

### ADMINISTRATION

The recommended dose of the reconstituted vaccine is 0.1ml for each child regardless of age, given by intradermal injection. Special syringes allow administration of the exact dose. A sterile syringe and a sterile needle should be used for each injection. The skin should not be cleaned with antiseptic. Special care is needed in opening the ampoule so that the vaccine is not blown out. Because of sensitivity to ultraviolet light, the vaccine must be protected from sunlight. If not used immediately after reconstitution, the vaccine should be kept on ice to maintain its temperature between +2°C and +8°C. Any opened container remaining at the end of a session (within six hours of reconstitution) must be discarded.

The diluent supplied is specially designed for use with this vaccine. Only this diluent may be used to reconstitute the vaccine. Do not use diluents from other types of vaccine or from other manufacturers. Water for injection may NOT be used for this purpose. Using an incorrect diluent may result in damage to the vaccine and/or serious reactions to those receiving the vaccine. Diluent must not be frozen but must be cooled between +2°C and +8°C before reconstitution.

Skin testing with tuberculin is not generally carried out before giving BCG, but when performed, those who are found to be positive reactors need not be immunized.

### RECONSTITUTION AND VACCINATION

File the neck part of the BCG ampoule with the file provided with the pack for cutting the ampoule. Wrap the filed site with the sheet provided with the pack to prevent the vaccine from blowing out of the ampoule as the interior of the ampoule is kept vacuum, and then snap to break off the ampoule at the filed site. With a syringe, add the whole amount of saline diluent into the BCG ampoule (A file is not needed to break off the diluent ampoule). Give a few gentle shakes to the ampoule to ensure homogeneity of the suspension. A homogeneous suspension in a concentration of 0.5mg per ml is now obtained. The vaccination site is about half way down the outer aspect of the upper arm. Do not vaccinate at the shoulder, nor revaccinate at a previously vaccinated site. Any volume of vaccine remaining in the container must be discarded.

### IMMUNIZATION SCHEDULE

BCG should be given routinely to all infants at risk of early exposure to the disease. For maximum protection, this vaccine should be given as soon after birth as possible. It can be given at the same time as DTP, measles, polio (OPV and IPV), hepatitis B, Haemophilus influenzae type b, and yellow fever vaccines and vitamin A supplementation. Many countries still recommend not to give BCG within 4 weeks of another live vaccine.

### SIDE EFFECTS

A local reaction is normal after BCG. A small tender red swelling appears at the site of the injection, which gradually changes to a small vesicle and then an ulcer in 2-4 weeks. The reaction usually subsides within two to five months and in practically all children leaves a superficial scar 2-10 mm in diameter. Rarely, the nodule may persist and ulcerate. Occasionally, enlargement of axillary lymph nodes may appear in 2-4 months following immunization. Very rarely, enlarged lymph nodes can suppurate. Inadvertent subcutaneous injection may produce abscess formation and may lead to scarring.

### CONTRAINDICATIONS

Keloid and lupoid reactions may also occur at the site of injection and children experiencing such reactions should not be revaccinated.

Do not give in pregnancy.

### Immune deficiency

The vaccine is contraindicated in individuals with cell-mediated immune deficiency.

Individuals known to be infected with human immunodeficiency virus (HIV), either non-symptomatic or symptomatic, should **NOT** receive BCG vaccine.

### STORAGE

BCG vaccine should be stored and transported between +2°C and +8°C. It is even more stable if stored in temperatures as low as -20°C. The diluent should not be frozen. The vaccine should be protected from the light. Vaccine ampoules and diluents should be transported together. The expiry is specified on the BCG ampoule label.

### PRESENTATION

The vaccine comes in boxes of 100 ampoules each containing 0.5 mg BCG (moisture weight).

The diluent in boxes of 100 ampoules each containing 1.0ml physiological saline accompanies all orders.

### REFERENCES

1. Quality Control of freeze-dried BCG vaccine from Japan BCG Laboratory, Tokyo, Japan, 1994/1995, Dr. J. Milstien, WHO Vaccine Supply and Quality, 1996.
- 2 The Thermostability of Different BCG Products, K.Bunch-Christensen, Chief, BCG Department, Statens Serum Institut, Copenhagen, WHO Collaborating Centre for BCG Vaccine; WHO/TB/81.118, 1981.

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## APPENDIX B

### Reconstitution, Administration and Reporting Directions for the Freeze-Dried Glutamate BCG Vaccine (Japan)

#### Equipment

- Brown glass ampoule containing freeze-dried glutamate BCG.
- Clear glass ampoule containing specialized normal saline BCG diluent.
- Small, heart shaped file to score BCG ampoule, and plastic sleeve for breaking ampoules (please keep in plastic pill container to avoid losing).
- 3 cc syringe for reconstituting
- 0.5 cc or 1.0 cc tuberculin syringe with 26 or 27 gauge needle for vaccine administration.
- Alcohol swabs.

#### Storage and Handling

- Store numbered BCG vaccine and specialized diluent ampoules together in the refrigerator between 2 and 8 degrees Celsius. Protect from sunlight.
- Use vaccine immediately after reconstitution. For catch up clinics only, a single vaccine provider may store their own reconstituted vaccine up to 6 hours (e.g. in a sterile specimen container, wrapped in gauze), protected from light and kept at 2 to 8 degrees Celsius. Unused vaccine must be discarded after 6 hrs. In all other cases, excess reconstituted vaccine should preferably be discarded after reconstitution and single use.
- Drawing up and storing multiple syringes of reconstituted vaccine is not recommended (avoids increased risk of contamination, drug error, and drug molecules may adhere to the inside barrel of the syringe affecting dose accuracy).
- After 6 hours discard all remaining vaccine doses.

#### Reconstitution

- Select and use the numbered BCG ampoules in sequence.
- Cleanse the tops of the BCG and diluent ampoules with an alcohol swab. Grasping the tip of the heart shaped file, hold it horizontally against the neck of the BCG ampoule. Pressing the 'lobes' of the heart against the ampoule neck, score a line fully around the ampoule.
- Slip the plastic sleeve (or other clean barrier e.g. 4x4, alcohol swab wrapper) over the scored BCG ampoule and snap the top of the ampoule away from you.
- Repeat this with the diluent ampoule, snapping the top off away from you. The diluent ampoule does not require scoring.
- Using a 3 cc syringe draw up all of the saline diluent and inject it into the BCG containing ampoule. Swirl gently to create a homogenous suspension (= 0.5 mg/ml)

## Administration

- Using a sterile 0.5 cc or 1.0 cc, 27 or 26 gauge tuberculin syringe draw up **0.1 ml** of reconstituted BCG vaccine (dose alert).
- Cleanse the site (outer, lower aspect of the right arm, deltoid area). Allow the skin to dry.
- Holding the syringe and needle parallel to the skin surface, inject the vaccine intradermally (bevel up) into the site. Inject slowly, creating a distinct bleb.
- Do not vaccinate at the shoulder. Do not administer subcutaneously.
- Since BCG is a live vaccine, and may squirt during administration, it may be prudent to protect the eyes of the infant, their caregiver and the vaccine provider. However there is no known evidence or incidences of eye injuries.
- Dispose of all sharps in the sharps container.

## Documentation and Reporting

- As per Health Canada's Special Access Program (SAP) requirements, every BCG ampoule and each vaccine dose given and wasted must be accounted for.
- Please see the **BCG Vaccine Reporting Form** for recording and accounting for each numbered ampoule, and each dose given and wasted.
- Fax the Reporting Form to the Regional CDC per every ampoule used. Contact your Regional CDC with any questions:  
**Baffin Region fax: 867-975-4833**  
**Kitikmeot Region fax: 867-983-4088**  
**Kivalliq Region fax: 867-645-8272**

## Resources

- Bacille-Calmette (BCG) Immunization Protocol for Freeze-Dried Glutamate Protocol
- BCG related pictures from the Nunavut TB Control and Elimination Manual.

