



MINISTRY OF HEALTH, MALAYSIA

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# BCG

## PRACTICAL MANUAL

National Tuberculosis  
Control Programme

# PRACTICAL BCG MANUAL

## NATIONAL TUBERCULOSIS CONTROL PROGRAMME

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## ADVISORS

DR. HASSAN ABDUL RAHMAN  
Deputy Director, Communicable Disease Control, MOH

DR. I. KUPPUSAMY  
Director, Institute of Respiratory Medicine

## GROUP CONTRIBUTORS

PN. HJH ZALEHA MOHD  
PN. CHRISTI PHILIPS  
PN. FATIMAH PAWAN  
PN. JEGINDAH KAUR A/P BUTA SINGH  
PN. CHEW SIANG IM  
PN. NANCY GOH HACK YEE  
PN. LIDWINA E AMIR  
PN. CHENG KIANG TOH  
PN. ANISA MOHAMAD  
CIK CHEW GIOK BEE  
PN. ROSLIZA SAAD

## EDITORS

DR. FADZILAH KAMALUDIN  
Principal Assistant Director TB/Leprosy, MOH

For further information, please contact:  
TB/Leprosy Unit, Ministry of Health, Malaysia  
Tel: 03-2540088 Fax: 03-2525667

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## ADVISORS

DR. HASSAN ABDUL RAHMAN  
Deputy Director, Communicable Disease Control, MOH

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Director, Institute of Respiratory Medicine

## GROUP CONTRIBUTORS

TUAN HJ OTHMAN MD HUSSAIN  
ENCIK MUSTAFA KAMIL AZMI OTHMAN  
ENCIK SUBRAMANIAM A/L RAMALOO  
ENCIK MOHD MUSTAZA ABDUL HALIM  
ENCIK ZOHARI MOHAMMAD  
PUAN TAN AYE LIAN  
PUAN ROBIAH AWANG  
PUAN LIM ENG KIM  
PUAN ROHANA MOHD  
PUAN NORAZLINA AHMAD  
PUAN TAN KIM LING

## EDITORS

DR. FADZILAH KAMALUDIN  
Principal Assistant Director TB/Leprosy, MOH

PUAN SOSHILA RAMAYAH  
Microbiologist  
National Public Health Laboratory

For further information, please contact:  
TB/Leprosy Unit, Ministry of Health, Malaysia  
Tel: 03-2540088 Fax: 03-2525667



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## THE OBJECTIVE OF THE BCG MANUAL IS TO PROVIDE:

- ▶ A GUIDELINE FOR ALL HEALTH PERSONAL INVOLVED IN THE BCG VACCINATION PROGRAMME
- ▶ THE STANDARDIZATION OF PROCEDURES AND REPORTING SYSTEMS SO THAT THE SERVICE CAN BE MONITORED, EVALUATED AND MANAGED EFFECTIVELY AND EFFICIENTLY.

## BCG VACCINATION

- ▶ BCG VACCINATION IS A PRIMARY TUBERCULOSIS CONTROL MEASURE IN THE COUNTRY.
- ▶ THE OBJECTIVE OF THE PROGRAMME IS TO PROTECT AT ALL TIMES AT LEAST 95% OF THE SUSCEPTIBLE POPULATION (0 < 20 YEARS).
- ▶ THE PRIORITY POPULATION GROUPS TO BE COVERED ARE AS FOLLOWS:
  1. PRIMARY VACCINATION
    - NEWBORN BABIES
    - ALL OTHERS BELOW 20 YEARS WITHOUT SCARS
  2. REVACCINATION
    - PRIMARY SCHOOL LEAVERS
- ▶ THE PRESENT POLICY IS DIRECT BCG VACCINATION FOR ALL ELIGIBLE POPULATION INCLUDING PRIMARY VACCINATIONS AND REVACCINATIONS.



## INTRODUCTION OF THE BCG VACCINATION PROGRAMME

- 3.1 BCG Vaccination is an extremely valuable weapon for the control of tuberculosis. Its efficacy in providing protection against tuberculosis infection and disease has been well established. As a control measure it constitutes the easiest, most economical and highly effective way of ensuring a significant and substantial reduction in the long term of the tuberculosis problem in the community.

To be effective it must be applied on a country-wide scale with an adequate coverage of the eligible population.

At least 95% of the eligible population should at all times be covered by BCG vaccination before a significant epidemiological impact can be expected on the problem.

- 3.2 The role of BCG vaccination as a control measure is to interrupt the transmission of infection in the community by increasing the resistance of susceptible persons through active immunization. If an adequate number of susceptible persons are protected with BCG vaccination transmission of infection is interrupted to a significant degree despite the presence of infectious sources within the community. Susceptible persons are those who have not yet been naturally infected by tubercle bacilli. The bigger the pool of infectious sources, the greater is the proportion of naturally infected persons in the community. Also the older a person is in such a community, the longer has he been exposed to infection and the greater the chance he has of being naturally infected.



- 3.3 In developing countries which usually have a high prevalence of tuberculosis, most of the adults are already naturally infected and children up to the age of 20 years, constitute the bulk of the susceptible population eligible for and likely to benefit from BCG vaccination. By concentrating on children, an adequate BCG coverage can be achieved of the entire susceptible population

BCG programme in developing countries are, therefore, essentially directed at the child population and the aim is to vaccinate them as early in life as possible, i.e. newborns and infants before natural infection occurs, particularly where infant tuberculosis is a problem.

- 3.4 In Malaysia at the commencement of the control programme 1961, the following priorities were set for BCG vaccination as in order:

- Newborns
- Pre-school children
- Primary school children
- Others below 20 years of age not previously vaccinated.

- 3.5 In 1974 it was decided that revaccination of school children was indicated because:

- Many vaccinations were given at birth and early infancy at which time the immunological response is poor, and it has not been demonstrated that the BCG given to newborns and infants will induce a lasting significant level of protection.
- Young adults are often particularly exposed to infection, are more likely to develop disease soon after infection and they

develop the infectious type of tuberculosis in contrast to infants and young children. Hence, the maintenance of immunity, by revaccination at primary school leaving age, can be expected to yield benefits in terms of disease prevention and also in breaking the chain of transmission.

- 3.6 Commencing from January 1975, revaccination of primary school leavers and secondary school children has been included in the list of priorities.

#### DIRECT BCG VACCINATION

1. Extensive trials conducted in different parts of the world have demonstrated that direct BCG vaccination without prior screening tuberculin test is safe and effective.

Initially direct BCG was given only to newborns and infants under 6 months of age.

In 1966 the age of direct BCG was raised to 6 years

In 1969 it was raised to 20 years.

The current policy since 1969 is direct BCG vaccination for all persons under the age of 20 years who have not been vaccinated previously as shown by the absence of a BCG scar.

In 1975 revaccination was given for those 12-19 years who have one scar.

The reasons for adopting this policy are:

- 1.1 Experience both in Malaysia and in other parts of the world

has shown this to be a safe and effective procedure and that the vaccination of positive reactors did not result in adverse effects that would be of practical importance, whether of a local, regional or generalized nature.

- 1.2 The estimated prevalence of infection in the child population has declined over the years which means that most children can be expected to benefit.
- 1.3 Direct BCG is preferred under almost all circumstances including revaccination because the elimination of prior tuberculin testing reduces cost and improves coverage which can then be maintained because of increased operational facilities.
- 1.4 BCG vaccination can safely be given at the same time with other immunizations.

## BCG VACCINATION SCHEDULE

- ▶ Newborns
- ▶ Pre-school children (without a previous scar)
- ▶ Primary school children
- ▶ Others below 20 years not previously vaccinated.

### 1. PRIMARY VACCINATION

All newborn babies should be given BCG vaccination as soon as possible.

All pre-school children attending MCH clinics/health centres and Standard I pupils should be routinely examined for BCG scars. Those without scars should be vaccinated.

Any person below 20 years of age who does not have BCG scar should also be vaccinated including contacts of known cases and secondary school pupils

### 2. REVACCINATION

All primary school leavers who show only one BCG scar should be revaccinated.

Those who show two or more normal sized scars do not require revaccination.



Children who are prone to keloid/lupoid reaction after primary vaccination should not be revaccinated.

NOTE: BCG Immunisation to infants may be repeated if no BCG scar or Pin point scar is seen after two months from the date of primary vaccination.

## BCG VACCINE

The letters B.C.G. stand for Bacille Calmette-Guerin . Calmette was a bacteriologist and Guerin a veterinarian at Pasteur Institute in Lille, France. For thirteen years they serially cultured 231 passages of a bovine strain of tubercle bacillus originally isolated from a tuberculous cow.

In 1922 they demonstrated that this strain of tubercle bacillus with the passage of time had lost its pathogenicity (power of causing tuberculous disease), but in experiments on animals it was shown to confer a considerable degree of protection against subsequent infection with virulent (disease producing) tubercle bacilli.

BCG is a live vaccine of tubercle bacilli attenuated by prolonged culture in the laboratory. The BCG vaccines that are being produced are all derived from sub- strain of the original strain developed by Calmette and Guerin. It had been shown that some of these strains have become further attenuated and numerous animal experiments indicate that the various BCG strains used nowadays for vaccine production differ markedly in protective efficacy, with some vaccines having a relatively poor immunizing potency.

BCG vaccine can be prepared and presented either as a fresh liquid vaccine or a freeze-dried vaccine. The freeze- dried vaccine is usually preferred because of its superior keeping qualities and heat stability, although its potency is a little reduced when compared to the fresh vaccine prepared from the same batch. As advised by

WHO, the vaccine for use in the country has been freeze-dried vaccine.

The effectiveness (potency) of BCG vaccine depends on the number of viable organisms in it at the time of injection and the aim is to administer the highest dose that is tolerated, i.e. produces a low acceptable rate of local or regional adverse reactions. A potent vaccine when given to a person not previously infected with tubercle bacilli, ensures a substantial degree of protection against tuberculous disease. The protection applies mainly to childhood miliary and meningeal tuberculosis it may last up to 15 years.

## INSTRUCTION FOR RECONSTITUTING FREEZE – DRIED BCG VACCINE

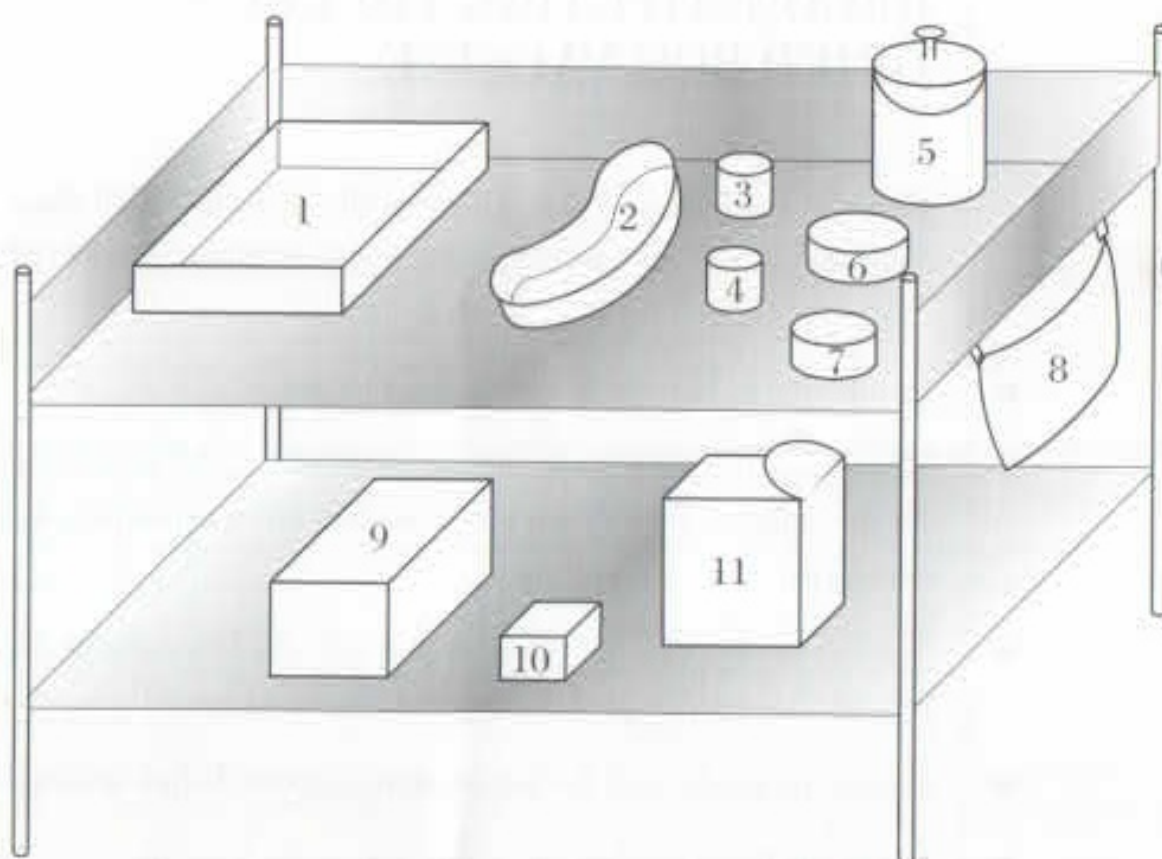
- ▶ Freeze – dried vaccine is supplied mostly in 1 ml. sealed glass ampoule/vial with dry vaccine powder for reconstituting to 1 ml (10 doses).
- ▶ Ensure that the diluent is kept cool before use.
- ▶ When preparing the vaccine for use, it should not be exposed to direct sunlight and every precaution must be taken to prevent contamination.
- ▶ The vaccine must not be contaminated with any antiseptic or detergent.
- ▶ Ensure the powder is at the bottom of the ampoule before opening.
- ▶ Check the Batch number and expiry date of the Vaccine.

### GENERAL INSTRUCTION FOR RECONSTITUTING VACCINE

- ▶ The ampoule should be cleaned with spirit and opened by filing at either 1/3 above the neck of the ampoule or at the neck of the ampoule (according to the manufacturer's instruction).
- ▶ It should be opened with great care as the ampoules are vacuum sealed. When the neck of the ampoule is broken air rushes in and may cause the vaccine powder to be blown out.



► Trolley for BCG vaccination



1. Tray for syringes
2. Kidney dish for dissecting forceps
3. Gallipot with dry swab
4. Gallipot with needle 21G  $\times$   $\frac{1}{2}$ "
5. Vaccine Carrier
6. Container for disposal of vaccine
7. Container with ice cubes for vaccine in use
8. Plastic container
9. Tuberculin syringe 1ml
10. Needles 26G  $\times$   $\frac{1}{2}$ "
11. Sharp Bin

## Instruction For Reconstituting BCG Vaccine

- ▶ A polythene sheet should be wrapped tightly round the file site of the ampoule before it is opened.
- ▶ With a syringe, add the amount of saline diluent (1 ml) into the BCG ampoule.
- ▶ Gently roll the ampoule between the palm of the hands to ensure homogeneity of the suspension before withdrawing the vaccine into the syringe.

Note: Manufacturer's instruction should be followed closely.

- ▶ EVANS (U. K.) DO NOT SHAKE the vial after reconstitution as this causes frothing.
- ▶ Allow to stand for one minute, then draw into the syringe twice to ensure homogeneity.

### HANDLING OF THE RECONSTITUTED VACCINE

- ▶ The ampoule of reconstituted BCG vaccine should be placed in sponge, plastic or glass container and kept in a wide – mouthed thermos flask packed with ice.
- ▶ Ensure the opened ampoule is covered with sterile gauze to prevent contamination.
- ▶ The amount of vaccine drawn into the syringe should be sufficient for a single dose.
- ▶ Once the BCG vaccine is drawn into the BCG syringe it must be used immediately.

► Method: Expulsion Of Excess Vaccine



► BCG Immunisation



- ▶ The reconstituted BCG vaccine should be used within 4 hours after which the opened ampoule should be discarded.

#### TECHNIQUE OF VACCINATION

- ▶ Assemble a Tuberculin syringe and fix a drawing needle size 21G  $\times$   $\frac{3}{4}$ ".
- ▶ Syringe out an adequate amount of vaccine for use.
- ▶ Change the needle to size 26G  $\times$   $\frac{1}{2}$ ".
- ▶ Fix the needle with the bevel facing upward in line with the scale of the syringe.
- ▶ Hold the syringe vertically and move the piston upwards slowly until the solution reaches the tip of the needle.
- ▶ Hold the syringe horizontally and expel one drop of vaccine into the prepared container.
- ▶ Ensure the correct dose is in the syringe.
- ▶ Vaccination for babies – Wrap the baby and expose the left shoulder. Position the baby on the right lateral.
- ▶ The injection site should be the middle of the left deltoid measuring from the line of the armpit.
- ▶ With the thumb and forefingers of your right hand, stretch slightly the skin of the person to be vaccinated.
- ▶ Hold the syringe in between your right index and middle finger with the scale facing upwards.



## Instruction For Reconstituting BCG Vaccine

- ▶ Introduce the needle into the skin with the bevel facing upwards keeping it parallel to the injection site.
- ▶ The injection should be given strictly intradermally.
- ▶ When the correct dose and technique is administered, a slight swelling of the skin (wheal) will appear at the injection site measuring 5–8 mm.

### DISPOSAL OF BCG VACCINE

- ▶ Prepare a container and line it with a polythene bag.
- ▶ Place a piece of gauze soaked in disinfectant at the bottom of the container.
- ▶ During the process of immunization, the Vaccinator is advised to expel any excess vaccine into the prepared container.
- ▶ Any reconstituted vaccine remaining in the BCG vial at the end of the session (maximum 4 hours) should be discarded into this container and sent for disposal (preferably incinerated).

### COURSE OF NORMAL VACCINATION

- ▶ Wheal produced by the injection disappears in a few minutes.
- ▶ After 2–4 weeks, a small nodule develops which gradually increases in size.
- ▶ After 6–8 weeks nodule softens with the formation of pus.
- ▶ At 10–12 weeks the ulcer heals leaving a tiny scar 5–7 mm in size.

## STORAGE

Freeze-dried vaccine, now in use throughout the country, gradually loses its potency (viability) and this loss greatly depends on the temperature at which the vaccine is stored and transported from one place to another.

Under conditions of refrigerated storage and transport all the time the vaccine is extremely stable and has an expiry period of one or two years.

To ensure that the vaccine remains potent it must be kept at temperature of  $2^{\circ}\text{C} - 8^{\circ}\text{C}$  well protected from daylight at all times whether in the clinic, health centre or in the field. This is to ensure that the *Cold Chain* is maintained at all times.

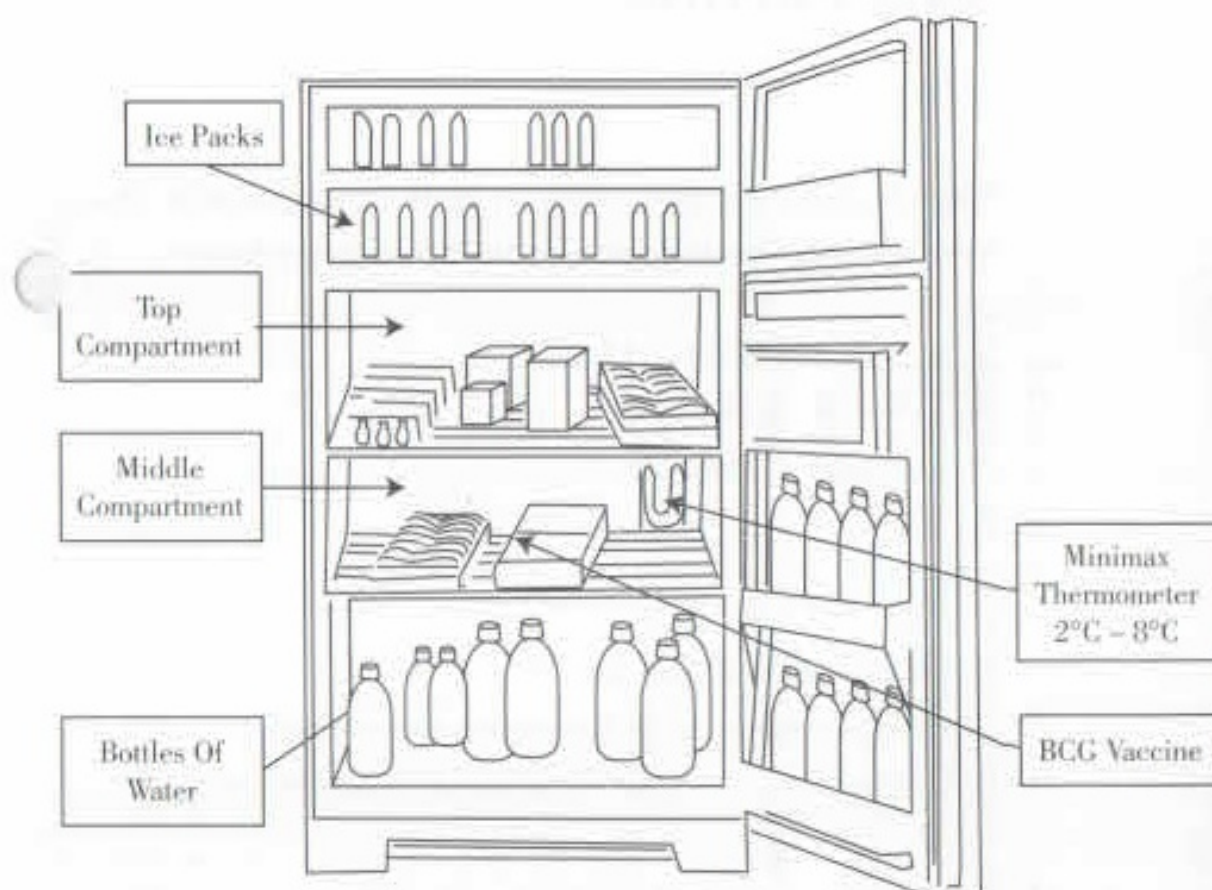
It should be stored in the general part of the refrigerator and not in the freezing compartment or immediately below it.

When in the field it should be kept packed with ice/ice packs.

The production date/expiry date is stated on the printed label of the ampoule.

The vaccine must be used before the expiry date but it must be noted that the expiry date is valid only on condition that the vaccine is stored at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  all the time.

► Vaccine Storage In Refrigerator



## CONTRAINDICATION OF BCG VACCINATION

There is really no contraindication for BCG immunisation. However, immunisation is deferred in the following conditions:

- Birth weight below 1.8 kg
- Neonatal jaundice
- Extensive skin rash
- Fever

**Note:**

Babies born to HIV mothers:

If Asymptomatic – BCG immunisation is given

Symptomatic – BCG immunisation must not be given



## COMPLICATION OF BCG VACCINATION

BCG is now considered to be one of the safest vaccinations in man. Complications after BCG vaccinations are uncommon and are usually local, very rarely general. On the local complications the most frequently observed are the following:

- **Abnormal Evolution Of The Local Vaccination Lesion**

The ulcer which normally develops at the vaccination site after an intradermal injection may reach an abnormal size (more than 10mm diameter). This ulcer will persist for more than 12 weeks causing delay in healing. This is usually due to secondary infection, faulty injection techniques (too deep) or to overdosage.

- **Glandular Enlargement Or Abscess**

The Glandular reaction is normal after BCG vaccination. However noticeable enlargement of the glands in the axilla or at the neck can occur. It usually disappear in 3–4 months but may suppurate, soften and develop into glandular abscess. This complication is generally due to too deep injection or too large a dose. No specific treatment is required. However it is best to aspirate the pus when required. Very rarely treatment such as Isoniazid is necessary.

- **Abnormality Of The Scar**

A tendency for scars to become keloid has been observed in some population whatever the techniques used. As a general rule no specific treatment is required. Other complications like Lupus vulgaris, erythemanodosum, iritis BCG–Osteomyelitis and dissemination in the blood stream are rarely seen.

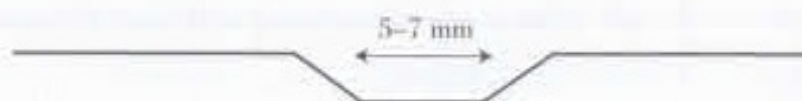
#### EXAMINATION OF BCG SCAR

Both shoulders should be inspected for presence of BCG scar. By applying light pressure on the surrounding skin and directing the pressure towards the scar. The edge of the BCG scar generally sinks in.

## TYPES OF BCG SCAR

### a. Normal BCG Scar

This is normally about 5–7 mm in diameter, has a sharp and shiny and is lower than the surrounding normal skin surface. A well healed scar with an uneven edge is also considered a normal scar.



### b. Pinpoint Scar

This is smaller than the normal scar with a diameter of 2 mm and below. This is due to inadequate dosage. In case of a doubtful or pinpoint scar, the person should be given BCG vaccination again.



### c. Hypertrophic Scar

This scar protrudes above the level of the normal surrounding skin surface, it is often slightly larger than a normal scar. It is firm upon palpation and has a smooth surface.



d. Keloid due To BCG Vaccination

This is an elevated hard or elastic mass which outgrows the areas of original skin. A keloid has one or more of the following characteristic:

- a. In the early stages of development there may occasionally be tenderness, itching or pain.
- b. The scar, often irregular margin is steeply elevated above the surrounding skin.
- c. The colour can change with age of the scar from red to pinkish or brown.





## ROLE OF THE BCG ORGANISER

1. Cooperates in the planning and implementation of the Tuberculosis Control Programme for the State.
2. Coordinates in the planning and implementation of the BCG Immunisation Programme for the State.
3. Supervisory visits to all Health Facilities in the State which are involved in the BCG Immunisation Programme to provide technical advice.
4. Organise, coordinate and conduct the Training for paramedics in the BCG Immunisation Programme.
5. Compile and analyse reports on the BCG Immunisation of live births in the State.
6. Compile and analyse reports on the BCG Immunisation of school children in the State.
7. Ensure all reports pertaining to BCG Immunisation in the State are submitted to the Ministry of Health as required.
8. Collect BCG Vaccine for viability tests from the Health Facilities in the State.

## BCG REPORTS AND RETURNS

Daily BCG vaccination with the number of BCG vaccine used should be recorded in the relevant record books i.e. TBC 104 in hospital and KKK 103, 104, 101 in health centres/Klinik Desa. At the end of the month, the figures should be compiled into TBC 205.

The total number of live births in the months is also included in TBC 205.

Monthly school BCG return for Std. 1 & 6 pupils should be submitted in TBC 201. Both TBC 201 and TBC 205 should be sent to the district Sister who will compile the figures for the district. The district returns together with centre returns are then sent to the state BCG organiser who will compile it for the state. She will also analyse and monitor the performance of each vaccination centre.

One copy each of state return for TBC 201 and 205 are to be forwarded to the State Director. One copy of state, district and vaccination centres returns to be sent to Pengarah NTBC.

## BCG VACCINE – VIABILITY TEST

Batch No: \_\_\_\_\_

Expiry Date: \_\_\_\_\_

Name of Manufacturer: \_\_\_\_\_

Number of ampoule/s: \_\_\_\_\_ (c.e. \_\_\_\_\_)

Name of vaccinating unit or centre: \_\_\_\_\_

Storage condition of vaccine at the centre:

- 1) In refrigerator – which compartment?
- 2) In ice container
- 3) Without refrigeration

(Circle appropriate number)

Date taken from the centre or vaccinating unit: \_\_\_\_\_

Signature : \_\_\_\_\_

Date : \_\_\_\_\_

### REPORT

Date: \_\_\_\_\_ Received at the N.T.B.C.

Date inoculated: \_\_\_\_\_

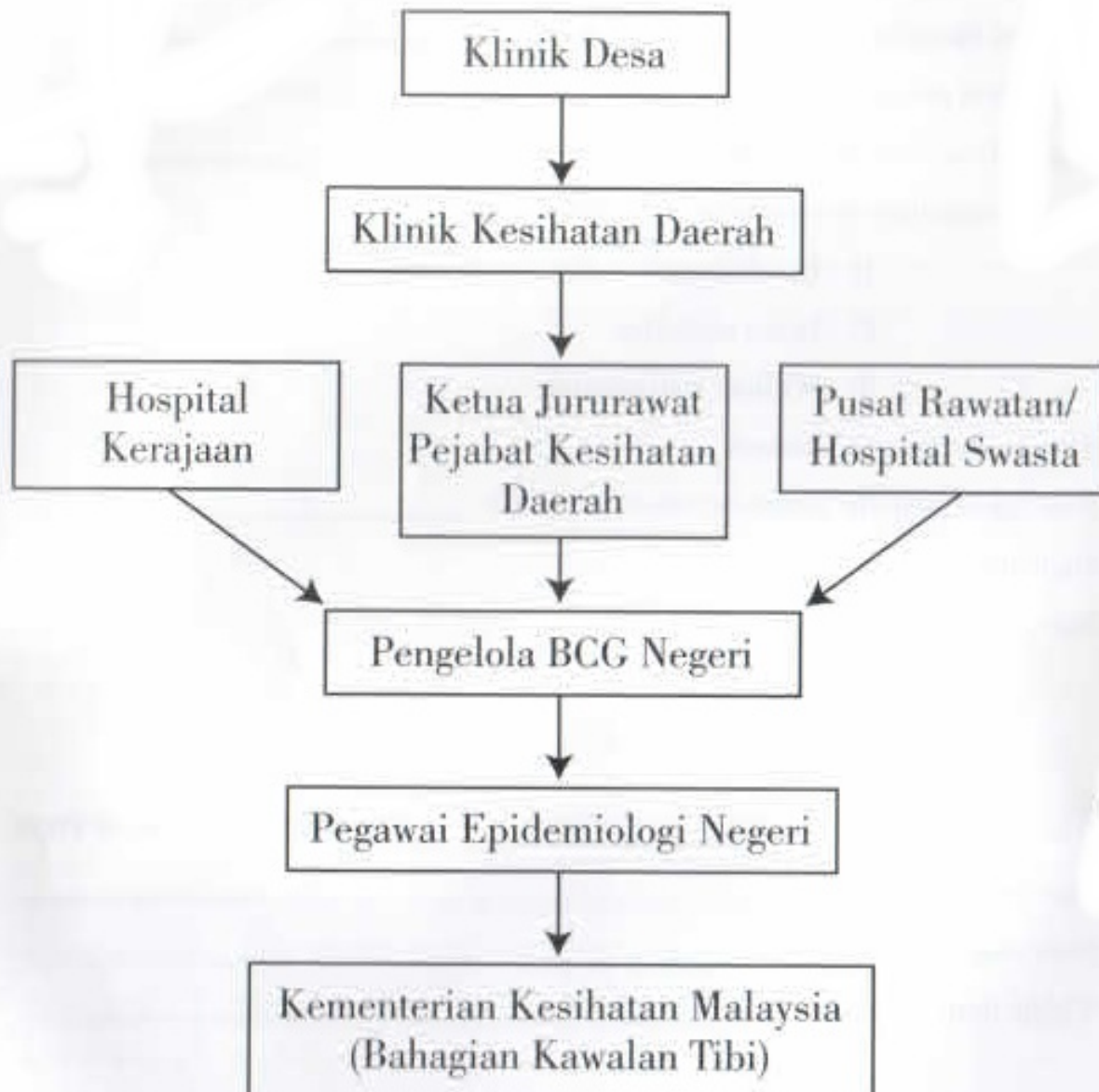
Date read: \_\_\_\_\_

Viable units per ml. \_\_\_\_\_

Signature : \_\_\_\_\_

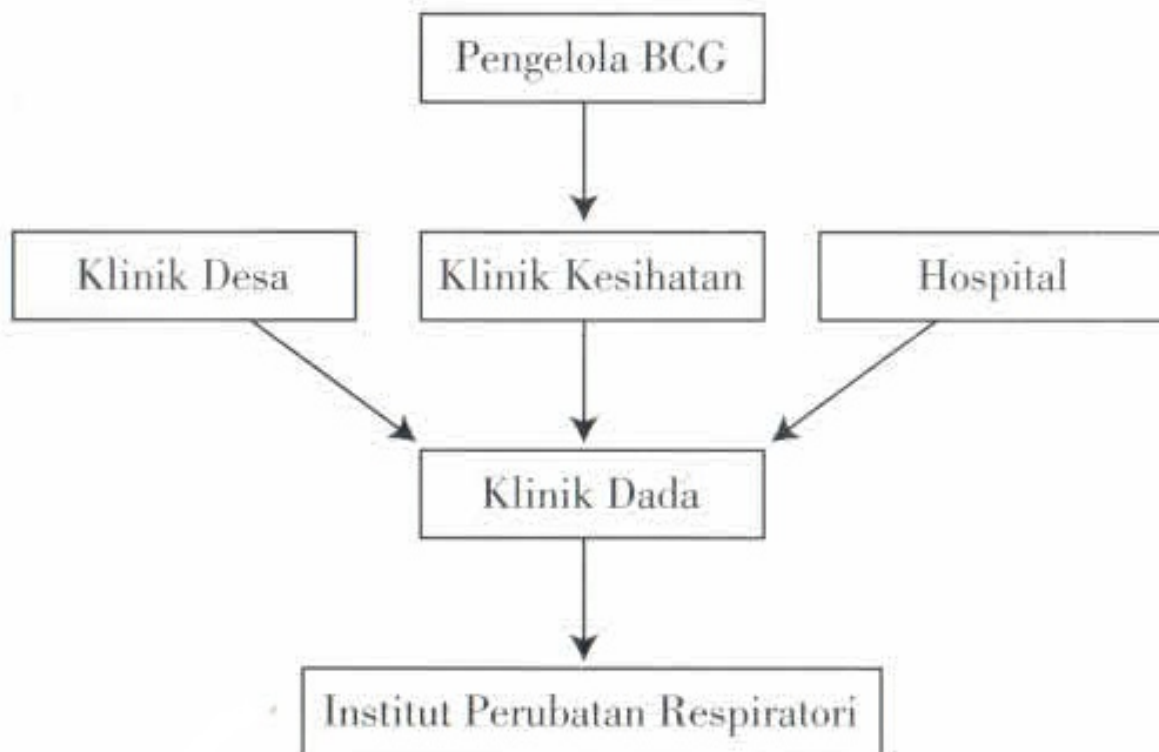
Date : \_\_\_\_\_

## FLOW CHART FOR BCG VACCINE RETURNS





## FLOW CHART FOR BCG VACCINE VIABILITY TEST



- Two vials of BCG vaccine with diluents are taken at random from the vaccination centre.
- The vaccine and diluents must be kept in the vaccine carrier with ice packs to maintain the cold chain.
- Complete 2 copies of viability test formats.
- Send the vaccines and diluents with the completed formats to the Institut Perubatan Respiratori, Jalan Pahang, Kuala Lumpur.

Note: Ensure *Cold Chain* is maintained at all times.

## FLOW CHART OF SUPPLY OF BCG VACCINE TO THE IMMUNISATION CENTRES

