IMMUNIZATION PROGRAMME

To establish standard procedures on immunization services consistent with the overall policies and strategies of the World Health Organization as well as with the national immunization programmes of the host countries and the Palestinian Authority.

The purpose of this revision is to update the immunization schedule and include provisions on introduction of Haemophilus influenzae type b and combined vaccines.


Applicable in all Fields of UNRWA’s area of operations.

V. INTRODUCTION:

Illness, disability and death of children under 5 years of age from communicable diseases are serious problems in the developing world. The most effective way to prevent childhood illness, death and disability is to provide effective immunization services as an integral part of the maternal and child health care services.

Notwithstanding that vaccine-preventable diseases are generally well under control among Palestine refugees owing to high immunization coverage, nevertheless, this high coverage needs to be sustained if these diseases are to remain well under control/targeted for eradication.

Immunity against infectious diseases develops in response to antigens. Antigens are molecules which are recognized by the immune system and induce an immune response. An antigen stimulates the production of antibodies and/or cellular immune response that will react specifically with that antigen. The antigen may be a soluble substance produced by the microorganism, or a substance present on a bacterium, virus, other cell surface; or in the cell wall. Most antigens are proteins, but some are polysaccharides from bacterial capsules, or glycolipids.

VI. OBJECTIVES:

Consistent with WHO policies and strategies, the objectives of the immunization programme are the following:

To reduce morbidity, disability and mortality from vaccine-preventable diseases by maintaining optimal coverage with all antigens used in the immunization programme for preschool and school children and pregnant women.

To attain the WHO's specific objectives of eradication of poliomyelitis and elimination of neonatal tetanus and measles among Palestine refugees.

To reduce undesirable outcomes of immunization by reinforcing an effective and action-oriented system for surveillance of adverse events following immunization (AEFIs).
Provision of immunization services is an integral part of the comprehensive maternal and child health care. To the extent possible, all health centres/points should adopt the open door policy in respect of immunization where due vaccines should be given at every contact.

All antigens used in the immunization programme are safe when administered simultaneously during the same session but at different sites. If vaccines are not administered in the same session, the main potential problem is interference between two live vaccines, which should be spaced at least 4 weeks apart.

The minimum interval between multiple doses of the same antigen is 4 weeks. There is no maximum interval.

Vaccines should be given by trained nurses/midwives under the close supervision of the senior staff nurse. More than one nurse at each health centre/point should be well trained on administering all types of vaccines including BCG.

During an immunization session, only one vial of each vaccine should be out of the refrigerator at a time and placed in a cold box/vaccine carrier supplied with ice packs far from direct sunlight and away from ice or a heating point.

A freeze-dried vaccine should only be reconstituted with the diluent supplied with it.

One sterile syringe and needle should be used to reconstitute each freeze-dried vaccine.

Mixing different vaccines in the same syringe before injection, or using fluid vaccine for reconstitution of a freeze-dried vaccine should never be attempted.

Opened vials of OPV, DPT, TT, Td, DT and Hepatitis-B may be used in subsequent immunization sessions provided that the expiry date has not passed and that the vaccines are stored under appropriate cold chain conditions (0-8°C).

Vaccine vials which have been taken out of the health centre for school immunization, national immunization campaigns or for use at a health point should be discarded at the end of the day, if opened or exposed to heat.

An opened vial must be discarded immediately if:

- sterile procedures have not been fully observed, or
- there is any suspicion that the opened vial have been contaminated, or
- there is a visible evidence of contamination/deterioration, such as change in appearance or presence of floating particles.

Reconstituted vials of freeze-dried vaccines (BCG, Measles and MMR) should be discarded at the end of the immunization session.
The autodestruct syringe should be used in the administration of all injectable vaccines, except BCG, which is given by the special "one dose" BCG syringe and needle. Immediately after each single use, the needle should be destroyed by the "Needle Destroyer/Terminator" and the syringe and needle should be placed in a safety puncture-resistant box.

All used and partially-used ampoules and vials should be disposed of in the "Safety Box". When the "Safety Box" is full, it must be sealed according to the instructions provided by the manufacturer and placed in the garbage bag. Infection control procedures should be adhered to in accordance with the relevant TIS No. HD/NS/1/95 of August 1995.

In principle, there are no contraindications to vaccination. However, the following conditions require special consideration:

- Children who need hospitalization should be immunized as soon as their general condition improves.
- Live vaccines should not be given to individuals with immune deficiency diseases or to individuals who are immunosuppressed due to malignant disease, therapy with immunosuppressive agents, or irradiation. Children with symptomatic HIV infection should not be immunized with BCG vaccine.
- A severe adverse event following a dose of vaccine (anaphylaxis, collapse or shock, encephalitis/encephalopathy, or non-febrile convulsions) is a true contraindication to immunization. If such an event occurs with DPT vaccine, pertussis component should be omitted and diphtheria and tetanus immunization completed with DT.

16. False contraindications to immunization:

◊ Minor illness such as upper respiratory infections, diarrhoea, mild jaundice, or fever <38.5°C.
◊ Allergy, asthma, or other atopic manifestations, hay fever or “snuffles”.
◊ Prematurity, small-for-date infants.
◊ Malnutrition.
◊ Family history of convulsions (other than the infant itself).
◊ Treatment with antibiotics, low-dose corticosteroids or locally acting (e.g. topical or inhaled) steroids.
◊ Dermatoses, eczema or localized skin infection.
◊ Chronic diseases of the heart, lung, kidney and liver.
◊ Stable neurological conditions, such as cerebral palsy and Down’s syndrome.
◊ History of jaundice after birth.

17. The following steps should be adhered to before administration of a vaccine:

Check the immunization card and the relevant record in order to decide on the type(s) of vaccine to be given and if the vaccine is due. Review the information on the card and the record to ensure that they are complete and accurate.

b. Counsel the mother on:

- Why the child is being immunized?
- Which disease(s) the child is being immunized against?
c. Measure the temperature of the child rectally.
d. Take past history.
   - Febrile or non-febrile (epilepsy) convulsions.
   - Reactions to previous vaccines (anaphylaxis, collapse or shock, encephalitis/encephalopathy, or non-febrile convulsions).

   In such conditions, the pertussis component of DPT should be omitted and diphtheria and tetanus immunization is started/completed with DT. DPT is not given after the age of 6 years; Td is given instead.

e. Take present history:

   If the child has minor illness, reassure the mother and give the vaccine. If the child has severe disease, for example, with high fever, severe jaundice, immune deficiency, etc, seek the opinion of the Medical Officer before giving the immunization. If no contraindications, give the vaccine.
   
   • Check the label on the vial for: type of vaccine, expiry date and dose.
   • Check the vial for deterioration: DPT, TT, DT, Hepatitis-B, IPV and Td vials should be checked for deterioration by shaking the vial through performing the "Shake test". Immediately after shaking, the vaccine that has not been frozen and thawed remains smooth and cloudy. 10-30 minutes later, this vaccine starts to clear with no sediment.

18. After giving the immunization:

   • Record the date of immunization on the Immunization Card and on the relevant record.
   • Give appointment for growth monitoring and/or vaccination and explain to the mother when and why she has to bring the child back to the health centre.
   • Reassure the mother and advise her on the minor/normal reactions that might occur and how to deal with them. (refer to section IX)

VII. IMMUNIZATION SCHEDULE:

The immunization schedules pertinent to each Field are enclosed as annexes I.1-I.4 to this instruction.

IX. VACCINES USED IN EPI:

1. BCG vaccine:

   a. Nature:

   • It is a freeze-dried live attenuated Mycobacterium bovis.
   • It confers good immunity in children against the more severe forms of TB such as meningitis and miliary TB.
   • The diluent and the vaccine must be stored cold in the main compartment of the refrigerator.
   • After reconstitution, the vaccine is easily damaged by sunlight and heat.
   • It should not be shaken after reconstitution, as shaking damages the vaccine.
• Proper mixing of BCG vaccine should be done whenever a dose is drawn in order to ensure proper dosing of vaccine and avoid side effects: withdraw the reconstituted vaccine slowly into the syringe and inject it slowly back into the ampoule or vial. Then draw the required dose and give the injection intradermally in the lateral aspect of the upper part of the left upper arm.
• The reconstituted vial should be discarded at the end of the immunization session.
• There is no need to repeat BCG vaccination if no scar develops.
• There is no need for tuberculin testing before giving BCG.

b. Normal reactions:

• About two weeks after immunization a small tender red swelling (about 10mm in diameter) appears at the vaccination site which may ulcerate and become a scar (about 5mm in diameter) within 3 weeks. The mother should be instructed not to touch the swelling and leave it uncovered.
• If swelling of the lymph nodes draining the injection site occurs, it should be properly investigated as stipulated in Section XI and the attached Annex II on Surveillance of Adverse Events Following Immunization. The child should be referred to the National TB Programme Centre for further evaluation.

2. **Trivalent Oral Poliomyelitis Vaccine (OPV):**

• OPV is composed of the three types (1, 2 and 3) of poliomyelitis virus which are live-attenuated.
• It confers both intestinal and systemic immunity.
• It is damaged very easily by heat and light.
• Neonatal OPV dose is given during the first month after birth. The interval between this dose and the first OPV dose is at least 3 weeks. If the neonatal dose is missed due to late registration, then it will be given with the measles vaccine at 9 months of age and will be considered as the fourth OPV dose. Neonatal OPV dose is not administered in West Bank and Gaza because two doses of IPV are given: the first at registration and the second one month later consistent with the policy of the MOH of the PA.

3. **Inactivated Poliomyelitis Vaccine (IPV):**

a. Nature:

• It is used in West Bank and Gaza Fields if provided by the Palestinian Authority.
• It is a trivalent killed poliomyelitis virus vaccine.
• It confers systemic immunity only.
• It is given subcutaneously in the left upper arm in two doses, 0.5ml each, at first registration and one month after that.
• When used in combination with OPV, it reduces the risk of vaccine-related paralysis.
• IPV is much less sensitive to heat and light than OPV.

b. Normal reaction:

• A mild erythematous reaction of the site of injection may be observed and is accompanied in a few cases by a moderate fever.
4. **Hepatitis-B Vaccine:**

- It contains the virus surface antigen (HbsAg).
- Its efficacy in preventing chronic HBV carriage is high if given to the infant as close to delivery as possible.
- It freezes at -0.5°C.
- Staff who are considered at risk: Doctors, nurses, midwives, laboratory technicians, dental hygienists, dayas and ambulance staff, should receive three doses of the adult HB vaccine according to the manufacturer's instructions.

5. **Diphtheria/Pertussis/Tetanus Vaccine:**

a. **Nature:**

- **Diphtheria** component is a toxoid which is easily damaged by freezing. Its heat stability is high. The potency of the diphtheria component in Td vaccine is around one-fifth of that in DPT or DT.
- **Pertussis** component is killed whole cell pertussis bacteria. It is damaged by heat and is the most easily damaged part of DPT. Pertussis vaccine should not be given to children with history of convulsions and to children older than 6 years. It is effective in preventing serious illness, but does not protect completely against infection with the organism.
- **Tetanus** component is a toxoid which is easily damaged by freezing.

b. **Normal reactions:**

- Mild fever occurring within 24 hours after immunization and lasting for 24 hours or less.
- Pain and swelling at the injection site which resolves within 24 to 48 hours.
- Mild to moderate leg pain during the first two days of immunization.
- Warm dressing at the injection site and paracetamol may be needed to relieve the pain and fever. Advise the mother to keep the child cool and give plenty of fluids.

c. **Adverse events:**

Injection site abscess and neurological symptoms and signs (convulsions, encephalitis, encephalopathy, etc.) should be investigated as stipulated in the attached Annex I on Surveillance of Adverse Events Following Immunization.

6. **Measles Vaccine:**

a. **Nature:**

- It is made from a live attenuated measles virus.
- It is supplied freeze-dried and is not damaged by freezing and re-freezing.
- This vaccine must be reconstituted with the appropriate diluent.
- Once reconstituted, the vaccine loses its potency very quickly and must be used in the same immunization session, then discarded.
- If supplied in single-dose vial, it should not be confused with other vaccines especially BCG.
b. **Normal reactions:**

- Approximately one week after immunization, the child may have a fever and rash for 1-3 days. The rash may be similar to that of measles disease. Such cases should not be reported in the Infectious Diseases Weekly Returns nor a Case Investigation Form filled.
- Mothers should be reassured that these are normal reactions.

7. **Mumps/Measles/Rubella (MMR) Vaccine:**

   a. **Nature:**

   - It is made from a live attenuated combined viruses of measles, mumps and rubella.
   - It is supplied as a freeze-dried triple vaccine.
   - This vaccine must be reconstituted with the appropriate diluent.
   - Once reconstituted, the vaccine loses its potency very quickly and must be used in the same immunization session, then discarded.
   - The vaccine must be stored at temperatures between +2°C to +8°C.
   - The vaccine must be protected from the light at all times even after being reconstituted.
   - Measles and MMR vaccine viruses are propagated in chicken fibroblast and can usually be given to individuals with allergy to egg protein.

   b. **Normal reactions:**

   - The combined vaccine is well tolerated in children.
   - Minor reactions might be observed from the 5th day after injection: mild fever, running nose and mild skin rash.
   - Skin eruption may occur, which consists of small red spots or purplish marks of variable size.

8. **Tetanus Toxoid:**

   It is a formaldehyde-inactivated preparation of tetanus toxin.
   - It is heat stable, but easily damaged by freezing.
   - It induces the formation of specific antitoxin which passes to the foetus across the placenta following active immunization of mothers to prevent neonatal tetanus.
   - Two doses given during the reproductive life, provided that the female had taken all the immunizations in childhood, confers protection during the whole reproductive life.

9. **Haemophilus influenzae type b (Hib) vaccine:**

   a. **Nature**

   - It is an inactivated conjugate polysaccharide vaccine.
   - It is available as liquid or freeze-dried powder (lyophylised). The powder should be reconstituted with the appropriate diluent.
   - It is available as a monovalet vaccine (Hib conjugate vaccine only) or in combination with other routine vaccines (DPT).
   - The vaccine must be stored at temperatures between +2°C to +8°C. Freezing should be avoided.
   - The single dose vial after reconstitution measures 0.5ml, and is administered intramuscularly in the antero-lateral aspect of the thigh.
• It should not be given before 6 weeks of age. It is given in 3 doses with at least 4 weeks between doses.

**b. Normal reactions:**

• Pain and tenderness at the injection site which are mild and transient and spontaneously resolve within two to three days.
• Fever occurs in 2% of cases.
• Warm water dressings at the injection site and paracetamol may be needed for pain and fever.

10. **New combined vaccines:**

• The combined vaccines are currently donated as in-kind contribution from the Ministries of Health of the Host Authorities in SAR and Jordan Fields. DPT is combined with Hib vaccine in Syria and with Hepatitis B vaccine in Jordan.
• Combination of Hib or Hepatitis B vaccine with DPT does not result in a significant difference in safety.

**X. COLD CHAIN AND STORAGE OF VACCINES:**

1. **The vaccine vial monitor**

The vaccine vial monitor (VVM) is supplied with each OPV vial. In the near future, the monitor will be supplied with other vaccines. It is a label made of heat sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time.

The VVM is a circle with a small square inside. The vaccine should not be used when the inner square matches, or is darker than, the colour of the outer ring. However, if the expiry date had passed, the vial should be discarded, irrespective of the colour of the monitor.

<table>
<thead>
<tr>
<th>1 = good OPV</th>
<th>2 = good OPV</th>
<th>3 = bad OPV</th>
<th>4 = bad OPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Use the vaccine)</td>
<td>(Use the vaccine)</td>
<td>(Do not use vaccine)</td>
<td>(Do not use vaccine)</td>
</tr>
</tbody>
</table>

2. **The cold chain monitor**

Each cold chain monitor has a heat-sensitive indicator in the form of a strip with 4 windows stuck to it. The cold chain monitor detects cumulative heat exposures above 10°C and serves as an effective check of the cold chain during shipment by giving the health staff some guidance on whether or not to use the vaccine they receive. One monitor is included with every 3000 doses of vaccine shipments from the manufacturer. It should be kept attached to the particular batch until exhausted. Interpretation of the readings is available on the back of the monitor.
3. The freeze watch indicator

It is a small vial containing red alcohol which is trapped inside a plastic window with a white paper background. When the temperature falls below -5.0 to -6.5 °C, the vial breaks and a bright red stain spreads across the white paper background. If the indicator is stained red, the following vaccines should be destroyed: DPT, DT, Td, TT, Hep-B and IPV. Freeze watch indicator should be available in each vaccine-containing refrigerator.

The cold chain monitor and the freeze watch indicator are available separate or combined as StopWatch.

4. The thermometer

Each refrigerator should have "Min./Max." thermometer (vapour pressure or mercurial) that gives the immediate temperature reading and readings of the highest and lowest temperatures reached since the last reading. All readings should be made at the beginning and at the end of the day and recorded on the “Refrigerator Temperature Monitoring” sheet (Form 2).

5. Storage of vaccine in the Field Pharmacy

a. Oral poliomyelitis and measles vaccines should be stored in freezers. All other vaccines and all diluents should be stored in the cold room/main compartment of refrigerators, but not in freezers. Maximum stock of supplies should only take up to one-half of the total space available in the refrigerator.

The temperature of freezers and refrigerators/cold room should be checked and recorded daily using external thermometer to ensure that optimal storage conditions are maintained. Cold room should be fitted with audible alarm system to warn of high or low storage temperatures (outside predetermined limits) and of power failure to cooling machinery.

6. Distribution of vaccines

Vaccines should be transported from the Field Pharmacy to the health centres in cold boxes or vaccine carriers, which should be packaged properly. Ice packs should be used in transportation. Before packing, ice packs should be left outside the freezer for about 15 minutes to warm up to 0°C, to avoid deterioration of DPT, DT, Td, TT, IPV or Hepatitis-B.

The “previously received” vaccine should be distributed before the “newly received” vaccine. The distribution period depends on the peculiarity of each Field. However, under all circumstances, shortages should be avoided and a maximum of one-month’s requirement should be supplied.

7. Storage of vaccine at the health centre level:

a. Vaccines should be stored exclusively in a separate refrigerator and not with any other biological products, food or drink.
b. Storage in the refrigerator should be arranged in the following manner:
   • **Freezer compartment:** Ice-packs only.
   • **Main compartment:** All vaccines and diluents:
     - **Top shelf:** OPV and measles vaccines,
     - **Middle shelves:** All other vaccines, thermometer, freeze watch
     - **Lower shelf:** Water bottles to preserve the refrigerator temperature.
   • **The door** should be kept free.

c. Vaccines should be stacked carefully so that sufficient air can circulate between them. The maximum stock of vaccine, diluent and water bottles should only take up to one-half of the total space available in the refrigerator.

d. Vaccines should be placed in the refrigerator so that the previously received vaccine will be used first, and the newly received vaccine will be used next.

8. **Handling vaccine vials during the immunization session**

- Only one vial of each vaccine should be withdrawn from the refrigerator at a time.
- Vials of vaccine should be kept in a cold box/vaccine carrier, supplied with ice packs.
- The vaccines should be kept far from direct sunlight and away from a heating point.

XI. **SURVEILLANCE OF ADVERSE EVENTS FOLLOWING IMMUNIZATION**

1. **Definition:**

   An adverse event following immunization (AEFI) is a medical incident that takes place after an immunization, causes concern and is believed to be caused by the immunization. A list of definitions for monitoring AEFI and the way of conducting an investigation of AEFI are available in the attached Annex II, which is considered as an integral part of this Technical Instruction Series.

2. **Trigger Adverse Events:**

   The following medical incidents should be investigated:
   a. all cases of BCG lymphadenitis.
   b. all injection site abscesses.
   c. all deaths that occur within one month of an immunization.

   all cases requiring hospitalization that occur within one month of an immunization.
   all medical events that are believed to have been caused by an immunization and about which people are concerned.

3. **Surveillance:**

   The Medical Officer should immediately inform C/FHP in case of detection of an AEFI. The Medical Officer, under the guidance of FDCO should start the investigation immediately. If the incident is sufficiently serious, as decided by C/FHP, it should be reported to the Director of Health. Serious events needing immediate notification include all hospitalized cases and deaths - where a detailed narrative report is needed. The “Case Investigation Report” form for AEFI (Form 1) should be completed as stipulated in the attached Annex II.
XII. RECORDING AND REPORTING

1. Birth and Immunization Register (Catalogue Number 06.7.693.1)

This register serves as a reference for documentation of the immunization of every child. Where this register is still maintained, it should be updated when the child receives a dose of a vaccine.

2. Child Health Record (Catalogue Numbers 06.7.696.1 for boys, and 06.7.698.1 for girls)

Immunization dates should be recorded against the type of the vaccine on the first page.

3. Maternal Health Record (Catalogue Number 06.7.581.1)

The dates of tetanus toxoid immunizations taken during pregnancies should be recorded in the relevant sections.

4. Immunization Card (Catalogue Number 06.7.691.1)

An immunization card should be issued to every pregnant on first registration at the antenatal clinic. TT immunizations are recorded when administered or if taken during previous pregnancies. After birth, immunizations given to the child are recorded on the same card as they are administered.

5. Clinic Card (Catalogue Number 06.7.658.1)

When the child completes three years of age, the immunizations and their dates should be transferred to the child’s Clinic Card that should be kept in the Family File (Catalogue Number 06.7.679.1) of the child. If the child had had any of the vaccine-preventable diseases, the date of contracting the disease should be transferred as well.

6. Daily Journal of Work - Infant and Child Health Care (Catalogue Number 06.7.716.1)

At the end of every child health care session, the number of doses given from each type of vaccine should be transferred from the daily tally sheet (Catalogue Number 06.7.669.1) to the DJW - Infant and Child Health Care. The numbers are summed up at the end of the month in the total row at the bottom of the report. Doses of vaccine given to children who do not have CHRs at the clinic should not be included in this report.

7. Daily Journal of Work - Maternal Health Care (Catalogue Number 06.7.710.1)

Same as mentioned above for immunizations given to pregnant women.

8. School Health Record (Catalogue Number 06.9.952.1)

Immunizations given to the school child should be inserted in the relevant section on his/her School Health Record.

9. Monthly/Quarterly Report on School Health Services (Catalogue Number 06.7.715.1)

All immunizations given to school-children should be included in the relevant space in the Monthly/Quarterly Report on School Health Services.
10. **Case Investigation Report Form for Suspected AEFI** (Form 1).

See paragraph No. XI-3 above.

11. **Refrigerator Temperature Monitoring Sheet** (Form 2) should be completed daily and always kept on the top of the refrigerator in a special folder.

12. **Epidemiological Reports**

Diagnosis and reporting of vaccine-preventable diseases should be made according to the standard case definitions and on the reporting forms attached to the TIS No. HD/DC/1/98 on Surveillance of Infectious Diseases, including EPI-target Diseases.

**XIII. RESPONSIBILITY:**

1. **Chief, Disease Prevention and Control**

- Keeps abreast with any changes in immunization policies consistent with WHO concepts and strategies.
- Coordinates with Chief, Family Health, all aspects relevant to EPI activities including planning, supervision, evaluation and relevant health services research.
- Coordinates all supply aspects relevant to EPI with Chief, Medical Care Services.
- Maintains regular reporting to WHO/EMRO and WHO/HQ.
- Organizes and follows-up on the training of various health staff on immunization.
- Provides technical advice on immunization polices and procedures.

2. **Head, Health Information System**

- Receives and analyzes all statistical returns and reports on immunization.
- Receives and analyzes the Case Investigation Forms for AEFI.

3. **Field Disease Control Officer**

- In coordination with the Field Family Health Officer and Field Nursing Officer, plans, monitors and evaluates the immunization programme in the Field to which assigned, including work plans, training, reporting and administration.
- Conducts regular supervisory visits to health centres/points and provides technical and administrative support as appropriate.
- Reviews and analyzes the data on immunization reported from the health centres/points in the monthly statistical returns and provides feedback, in coordination with FFHO and FNO.
- Guides and assists in the investigation of AEFIs and mismanagement of cold chain; and reports to CDPC on such events.
- Estimates the Field’s requirements of vaccines and cold chain equipment and ensures their regular supply throughout the Field in coordination with the Field Pharmacist.
- Coordinates with the Education Department the immunization of school children.
- Coordinates with the officials of the Ministries of Health the implementation of NIDs throughout the Field and reports to CDPC accordingly.
4. **Field Nursing Officer**

- Ensures that nursing staff are well acquainted with the various aspects of the immunization programme through participation in training activities especially on counselling, injection techniques, safety precautions, disposal of used syringes and vials and storage of vaccines and materials.
- Ensures that health centre staff are fully acquainted with safety of injections in immunization sessions and the proper and safe disposal of used needles and syringes and used vaccine vials.
- Ensures availability and issuance of Immunization Cards and their updating.
- Ensures that immunizations are recorded in the relevant section of the Child Health Record and transferred to the Clinic Card after the child reaches his/her third birthday.

5. **Field Pharmacist**

- Orders, receives and distributes vaccines, cold chain equipment and syringes.
- Ensures safe storage of vaccines at the Field Pharmacy.

6. **SMO/MO i/c of Health Center/Point**

- Supervises and reports on all aspects relevant to the implementation of the programme at the health centre/point.
- Takes immediate action in case an error or mismanagement within the immunization programme is detected and reports such incidents immediately to FDCO.
- Reviews and analyzes the monthly reports on immunization before sending them to the Field Office.
- Supervises the conduction of NIDs in the catchment area of the Health Centre/point to which assigned.
- Ensures the continued availability of vaccines and syringes and needles at the health centre/point.

7. **Senior Staff Nurse**

- Receives the vaccines and ensures their proper storage at the health centre/point and keeps records of the refrigerator temperature.
- Immediately notifies any error in the cold chain or any unusual incident related to the immunization programme to the SMO/MO i/c of the health centre/point.
- Ensures recording of the immunizations on the Immunization Card and the Child Health Record.
- Ensures that mothers are counselled on issues related to the given vaccines.
- Supervises the administration of vaccines at the health centre/point.
- Ensures that appropriate appointments are given and defaulters are followed-up.
- Ensures proper disposal of the used vaccine vials, syringes and needles.
- Transfers the data on immunization from the Child Health Record to the Clinic Card when the child completes three years of age.
XIV. MONITORING AND EVALUATION:

The comprehensive approach to monitoring and evaluation of all aspects of the immunization programme including implementation of applied policies, schedules, cold chain, safety precautions and surveillance of adverse events following immunization should be an integral part of the duties of senior Health Department staff, each in his/her relevant area during supervisory visits.

The above should be complemented by systematic analysis of the consolidated reports on immunization at the end of every quarter and calendar year to assess the accuracy and completeness of the reported data on vaccination activities at mother and child health care clinics and schools.

Assessment of the coverage of full primary series and booster immunization including coverage of pregnant women with tetanus toxoid will be carried out annually through the rapid assessment technique.

4. Other essential aspects of evaluation should include:

   Periodic assessment of the trends in the incidence of vaccine-preventable diseases.

   Case-fatality rates from vaccine-preventable diseases.

   Assessment of the sensitivity of surveillance activities of specific EPI-target diseases, e.g. AFP.

December 2001

Dr. Fathi Mousa

Director of Health

Mydoc/TIS99/(TISimun01)
REFERENCES


4. Logistcs for Primary Health Care Series. WHO - Expanded Programme on Immunization - WHO/EPI/GEN/96.03. REV. 1.


ANNEX I

IMMUNIZATION SCHEDULES

1. Jordan
2. SAR
3. Lebanon
4. West Bank & Gaza
### Annex 1.1 IMMUNIZATION SCHEDULE - JORDAN

#### CHILDREN BELOW 2 YEARS

<table>
<thead>
<tr>
<th>Age/Category</th>
<th>Vaccine</th>
<th>Course</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>At birth/First</td>
<td>BCG</td>
<td>Single</td>
<td>0.05ml</td>
<td>Intradermal</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>registration</td>
<td>OPV*</td>
<td>Neonatal</td>
<td>(0.1ml after age of 1 year)</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td>2 months</td>
<td>Hepatitis-B + DPT OPV Hib</td>
<td>First primary</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td></td>
<td>First primary</td>
<td>2 drops</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td></td>
<td></td>
<td>First primary</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td>3 months</td>
<td>Hepatitis-B + DPT OPV Hib</td>
<td>Second primary</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Second primary</td>
<td>2 drops</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Second primary</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td>4 months</td>
<td>Hepatitis-B + DPT OPV Hib</td>
<td>Third primary</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Third primary</td>
<td>2 drops</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Third primary</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td>9 months</td>
<td>Measles</td>
<td>Single</td>
<td>0.5ml</td>
<td>Subcutaneous</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>15 months</td>
<td>DPT</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td>OPV</td>
<td>Booster</td>
<td>2 drops</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td></td>
<td>MMR**</td>
<td>Single</td>
<td>0.5ml</td>
<td>Subcutaneous</td>
<td>Left upper arm</td>
</tr>
</tbody>
</table>

#### SCHOOL CHILDREN

<table>
<thead>
<tr>
<th>Age/Category</th>
<th>Vaccine</th>
<th>Course</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 years (school entry)</td>
<td>Td</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>15 years (third</td>
<td>Td</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>preparatory)</td>
<td></td>
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</table>

#### PREGNANT WOMEN

<table>
<thead>
<tr>
<th>Age/Category</th>
<th>Vaccine</th>
<th>Course</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>First pregnancy</td>
<td>TT</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>After five years</td>
<td>TT</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Left upper arm</td>
</tr>
</tbody>
</table>

- As soon as possible after birth but not later than 30 days of age. If neonatal OPV dose is missed, then it should be administered at the age of 9 months with measles vaccine.
- ** Check previous immunization record for measles. If the child is not immunized, give measles vaccine followed by MMR after one month interval.
## IMMUNIZATION SCHEDULE - SYRIAN ARAB REPUBLIC

### CHILDREN BELOW 2 YEARS

<table>
<thead>
<tr>
<th>Age/Category</th>
<th>Vaccine</th>
<th>Course</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>At birth/First registration</td>
<td>BCG</td>
<td>Single dose</td>
<td>0.05ml (&lt;0.1ml after age of 1 year) 2 drops</td>
<td>Intradermal Oral Intramuscular</td>
<td>Left upper arm Mouth Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td>OPV*</td>
<td>Neonatal First dose</td>
<td>0.5ml 2 drops 0.5ml</td>
<td>Oral Intramuscular</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hepatitis-B</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 months</td>
<td>Hib + DPT</td>
<td>First primary</td>
<td>0.5ml 2 drops 0.5ml</td>
<td>Intramuscular Oral Intramuscular</td>
<td>Lateral aspect of thigh Mouth Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td>OPV</td>
<td>Second dose</td>
<td></td>
<td>Oral Intramuscular</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hepatitis - B</td>
<td></td>
<td></td>
<td>Oral Intramuscular</td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>Hib + DPT</td>
<td>Second primary</td>
<td>0.5ml 2 drops</td>
<td>Intramuscular Oral</td>
<td>Lateral aspect of thigh Mouth</td>
</tr>
<tr>
<td></td>
<td>OPV</td>
<td>Second primary</td>
<td></td>
<td>Oral Intramuscular</td>
<td></td>
</tr>
<tr>
<td>4 months</td>
<td>Hib + DPT</td>
<td>Third primary</td>
<td>0.5ml 2 drops</td>
<td>Intramuscular Oral</td>
<td>Lateral aspect of thigh Mouth</td>
</tr>
<tr>
<td></td>
<td>OPV</td>
<td>Third primary</td>
<td></td>
<td>Oral Intramuscular</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>Hepatitis-B</td>
<td>Third dose</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td>9 months</td>
<td>Measles</td>
<td>Single</td>
<td>0.5ml</td>
<td>Subcutaneous</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>15 months</td>
<td>DPT</td>
<td>Booster</td>
<td>0.5ml 2 drops 0.5ml</td>
<td>Intramuscular Oral Subcutaneous</td>
<td>Lateral aspect of thigh Mouth Left upper arm</td>
</tr>
<tr>
<td></td>
<td>OPV</td>
<td>Booster</td>
<td></td>
<td>Oral Subcutaneous</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MMR**</td>
<td>Single</td>
<td></td>
<td>Subcutaneous</td>
<td></td>
</tr>
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</table>

### SCHOOL CHILDREN

<table>
<thead>
<tr>
<th>Age/Category</th>
<th>Vaccine</th>
<th>Course</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 years (school entry)</td>
<td>Td</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>15 years (third preparatory)</td>
<td>Td</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Left upper arm</td>
</tr>
</tbody>
</table>

### PREGNANT WOMEN

<table>
<thead>
<tr>
<th>Age/Category</th>
<th>Vaccine</th>
<th>Course</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>First pregnancy</td>
<td>TT</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>After five years</td>
<td>TT</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Left upper arm</td>
</tr>
</tbody>
</table>

- As soon as possible after birth but not later than 30 days of age. If neonatal OPV dose is missed, then it should be administered at the age of 9 months with measles vaccine.
- Check previous immunization record for measles. If the child is not immunized, give measles vaccine followed by MMR after one month interval.
### IMMUNIZATION SCHEDULE - LEBANON

**Annex 1.3**

<table>
<thead>
<tr>
<th>Age/Category</th>
<th>Vaccine</th>
<th>Course</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CHILDREN BELOW 2 YEARS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At birth/First registration</td>
<td>BCG</td>
<td>Single dose</td>
<td>0.05ml</td>
<td>Intradermal Left upper arm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OPV*</td>
<td>Neaternal First dose</td>
<td>0.05ml</td>
<td>Oral Mouth</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hepatitis-B</td>
<td></td>
<td>0.5ml</td>
<td>Intramuscular Lateral aspect of thigh</td>
<td></td>
</tr>
<tr>
<td>1 month</td>
<td>Hepatitis-B</td>
<td>Second dose</td>
<td>0.5ml</td>
<td>Intramuscular Lateral aspect of thigh</td>
<td></td>
</tr>
<tr>
<td>2 months</td>
<td>DPT</td>
<td>First primary First primary</td>
<td>0.5ml</td>
<td>Intramuscular Lateral aspect of thigh</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OPV</td>
<td></td>
<td>2 drops</td>
<td>Oral Mouth</td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>DPT</td>
<td>Second primary Second primary</td>
<td>0.5ml</td>
<td>Intramuscular Lateral aspect of thigh</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OPV</td>
<td></td>
<td>2 drops</td>
<td>Oral Mouth</td>
<td></td>
</tr>
<tr>
<td>4 months</td>
<td>DPT</td>
<td>Third primary Third primary</td>
<td>0.5ml</td>
<td>Intramuscular Lateral aspect of thigh</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OPV</td>
<td></td>
<td>2 drops</td>
<td>Oral Mouth</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>Hepatitis-B</td>
<td>Third dose</td>
<td>0.5ml</td>
<td>Intramuscular Lateral aspect of thigh</td>
<td></td>
</tr>
<tr>
<td>9 months</td>
<td>Measles</td>
<td>Single</td>
<td>0.5ml</td>
<td>Subcutaneous Left upper arm</td>
<td></td>
</tr>
<tr>
<td>15 months</td>
<td>DPT</td>
<td>Booster Booster</td>
<td>0.5ml</td>
<td>Intramuscular Lateral aspect of thigh</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OPV</td>
<td>Single</td>
<td>2 drops</td>
<td>Oral Mouth</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MMR**</td>
<td></td>
<td>0.5ml</td>
<td>Subcutaneous Left upper arm</td>
<td></td>
</tr>
<tr>
<td><strong>SCHOOL CHILDREN</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 years (school entry)</td>
<td>Td</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular Left upper arm</td>
<td></td>
</tr>
<tr>
<td>15 years (third preparatory)</td>
<td>Td</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular Left upper arm</td>
<td></td>
</tr>
<tr>
<td><strong>PREGNANT WOMEN</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First pregnancy</td>
<td>TT</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular Left upper arm</td>
<td></td>
</tr>
<tr>
<td>After five years</td>
<td>TT</td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular Left upper arm</td>
<td></td>
</tr>
</tbody>
</table>

* As soon as possible after birth but not later than 30 days of age. If neonatal OPV dose is missed, then it should be administered at the age of 9 months with measles vaccine.

** Check previous immunization record for measles. If the child is not immunized, give measles vaccine followed by MMR after one month interval.
## Annex 1.4

### IMMUNIZATION SCHEDULE - WEST BANK & GAZA

<table>
<thead>
<tr>
<th>Age/Category</th>
<th>Vaccine</th>
<th>Course</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CHILDREN BELOW 2 YEARS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At birth/First registration</td>
<td><strong>BCG</strong></td>
<td>Single dose</td>
<td>0.05ml (0.1ml after age of 1 year)</td>
<td>Intradermal</td>
<td>Left upper arm</td>
</tr>
<tr>
<td></td>
<td><strong>Hepatitis-B</strong></td>
<td>First dose</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td><strong>IPV</strong></td>
<td>Second dose</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td></td>
<td>First dose</td>
<td>0.5ml</td>
<td>Subcutaneous</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>1 month</td>
<td><strong>Hepatitis-B</strong></td>
<td>Second dose</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td><strong>IPV</strong></td>
<td>First primary</td>
<td>0.5ml</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td></td>
<td></td>
<td>First primary</td>
<td>2 drops</td>
<td>Subcutaneous</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>2 months</td>
<td><strong>DPT</strong></td>
<td>First primary</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td><strong>OPV</strong></td>
<td>First primary</td>
<td>2 drops</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td></td>
<td><strong>IPV</strong></td>
<td>Second dose</td>
<td>0.5ml</td>
<td>Subcutaneous</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>4 months</td>
<td><strong>DPT</strong></td>
<td>Second primary</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td><strong>OPV</strong></td>
<td>Second primary</td>
<td>2 drops</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td>6 months</td>
<td><strong>DPT</strong></td>
<td>Third primary</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td><strong>OPV</strong></td>
<td>Third primary</td>
<td>2 drops</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td></td>
<td><strong>Hepatitis-B</strong></td>
<td>Third primary</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
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<td></td>
<td></td>
<td>Third primary</td>
<td>2 drops</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td>9 months</td>
<td><strong>Measles</strong></td>
<td>Single</td>
<td>0.5ml</td>
<td>Subcutaneous</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>12 months</td>
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<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Lateral aspect of thigh</td>
</tr>
<tr>
<td></td>
<td><strong>OPV</strong></td>
<td>Booster</td>
<td>2 drops</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td>15 months</td>
<td><strong>MMR</strong>*</td>
<td>Single</td>
<td>0.5ml</td>
<td>Subcutaneous</td>
<td>Left upper arm</td>
</tr>
<tr>
<td><strong>SCHOOL CHILDREN</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 years (school entry)</td>
<td><strong>TD</strong></td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Left upper arm</td>
</tr>
<tr>
<td></td>
<td><strong>OPV</strong></td>
<td>Booster</td>
<td>2 drops</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td>15 years (third preparatory)</td>
<td><strong>Td</strong></td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Left upper arm</td>
</tr>
<tr>
<td><strong>PREGNANT WOMEN</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First pregnancy</td>
<td><strong>TT</strong></td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Left upper arm</td>
</tr>
<tr>
<td>After five years</td>
<td><strong>TT</strong></td>
<td>Booster</td>
<td>0.5ml</td>
<td>Intramuscular</td>
<td>Left upper arm</td>
</tr>
</tbody>
</table>

* Check previous immunization record for measles. If the child is not immunized, give measles vaccine followed by MMR after one month interval.
Annex (II)

Guidelines for Investigation of Suspected AEFI

1. Notes on how to carry out an investigation

These notes should be used to fill in the Case Investigation Report Form for suspected AEFI. Information marked "*" is important to collect but is not included on the case investigation report form. Using the form as a tool will help the investigator to understand why the AEFI occurred. If followed, the form will enable a working hypothesis to be formed which will, in turn, guide decisions about what other investigations and clinical samples are needed to confirm the cause of the AEFI.

1. Demographic details

Ask for

- date of birth (DD MM YY)
- sex
- family name
- first name
- address
- date of notification, date of immunization, and interval to onset of symptoms.

2. Investigate and collect data

Ask about the patient

(a) Type of reaction

- local reaction
- central nervous system
- other adverse events
- other severe or unusual events occurring within 4 weeks after immunization.

(b) Medical*

- immunization history
- history and clinical description of AEFI
- prior history of similar reaction or other allergies
- treatment, whether hospitalized, and outcome.

Ask about the suspected vaccine

- name and dose number of all vaccines given that day e.g. DPT-2.
- lot or batch number, manufacturer’s name and expiry date.
- for vaccines which are reconstituted, the same information is required about diluent.
- length of time the lot has been used*
- list of health centres receiving this lot.
• reports of other centres supplied with the lot and reporting AEFI*
• the conditions under which the vaccine was shipped, its present storage condition, state of vaccine vial monitor, and temperature record of refrigerator*
• storage of vaccine before it arrived at health centre, where it has come from higher up the cold chain, vaccine monitor card*

Ask about local immunization services*

• vaccine storage and distribution
• diluent distribution and storage
• reconstitution (maximum period allowed after reconstitution)
• storage of opened vials
• disposal of used vials
• use and sterilization of syringes and needles
• name of vaccinator(s)
• details of training in immunization practice
• whether there is supervision?
• number of immunizations greater than normal

Observe the service in action*

• what else is stored in the refrigerator?
• what vaccines are stored with other drugs?
• whether any vials have lost their label?
• whether similar containers are stored next to vaccine vials which could be confused with them?
• how reconstitution of vaccine is carried out?
• how and where the diluent is stored?
• how the injections are given?
• how needles and syringes are re-sterilized or disposed of?
• what happens to opened vials?
• whether any open vials look contaminated?

Ask about other people in the area*

• whether others received the same vaccine
• whether others fell ill
• name of health worker(s) who gave immunization which resulted in AEFI.

Formulate a working hypothesis* (so far) as to what was the probable cause of the AEFI. For example:

• Programme related
  - vaccine transportation or storage error
  - reconstitution error
  - unsterile practice
  - incorrect administration technique
• Vaccine-induced
  - vaccine manufacturer error
- vaccine associated (but not manufacturer error)

- Coincidental
- Other
- Unknown

3. Collect and despatch specimens

Once a working hypothesis is arrived at, it should be apparent whether specimens are required to confirm or rule out the suspected cause. If the vaccine is suspected, UNICEF or the MOH should be approached for analysis of vials of the suspected vaccine.

4. Results and conclusions

- Clinical findings
- Laboratory results
- Findings on on-site investigation
- Summary of findings

2. List of Definitions for Monitoring of AEFI

All of the following adverse events should be reported if temporally related to immunization. Unless otherwise specified, this includes all such events occurring within four weeks of a vaccine administration.

1. Local adverse events

**Injection - Site Abscess**

Occurrence of a fluctuant or draining fluid-filled lesion at the site of injection with or without fever.

- Bacterial: Existence of purulence, inflammatory signs, fever, positive Gram stain, positive culture, or finding neutrophil predominance of content will support a bacterial site abscess, but the absence of some of these signs will not rule it out.

- Sterile: There is no evidence of bacterial infection following investigation.

**Lymphadenitis (includes suppurative lymphadenitis)**

Occurrence of either:

- at least one lymph node, 1.5cm in size (one adult finger width) or larger; or
- a draining sinus over a lymph node.

Almost exclusively caused by BCG and then occurring within **2 to 6 months** after receipt of BCG vaccine, on the same side as inoculation (mostly axillary).

**Severe local reaction**

Redness and/or swelling centered at the site of injection and one or more of the following:
• swelling beyond the nearest joint;
• pain, redness and swelling of **more than 3 days** duration; or
• requires hospitalization.

Local reactions of lesser intensity may occur commonly and are generally of little consequence. For monitoring purposes, priority should be given to severe local reactions as defined above.

2. **Central nervous system adverse events**

**Acute Paralysis**

Vaccine-Associated Paralytic Poliomyelitis:

• Acute onset of flaccid paralysis within **4-30 days** of receipt of oral polio-virus vaccine (OPV), or within **4-75 days** after contact with a vaccine recipient, with neurological deficits remaining 60 days after onset, or death.

• Guillain-Barre Syndrome (GBS): Acute onset of rapidly progressive, ascending, symmetrical flaccid paralysis, without fever at onset of paralysis and with sensory loss. Cases are diagnosed by cerebrospinal fluid (CSF) investigation showing dissociation between cellular count and protein content.

  GBS occurring with **30 days** after immunization should be reported.

**Encephalopathy**

Encephalopathy is an acute onset of major illness temporally linked with immunization and characterized by any two of the following three conditions:

• Seizures;
• Severe alteration in level of consciousness lasting for one day or more; and
• Distinct change in behaviour lasting one day or more.

  Cases occurring within **72 hours** after vaccination should be reported.

**Encephalitis**

Encephalitis is characterized by the above mentioned symptoms and signs of cerebral inflammation and, in many cases, CSF pleocytosis and/or virus isolation.

Any encephalitis occurring within **1-4 weeks** following immunization should be reported.
**Meningitis**

Acute onset of major illness with fever, neck stiffness/positive meningeal signs (Kernig, Brudzinski). Symptoms may be subtle to similar to those of encephalitis. CSF examination is the most important diagnostic measure: CSF pleocytosis and/or detection of microorganism (Gram stain or isolation).

**Seizures**

Seizures lasting from several minutes to more than 15 minutes and not accompanied by focal neurological signs or symptoms.

- Febrile Seizures; or
- Afebrile Seizures.

3. **Other adverse events**

**Allergic reaction**

Characterized by one or more of the following:

1. skin manifestations (e.g. hives, eczema);
2. wheezing;
3. facial or generalized oedema

**Anaphylactoid Reaction (acute hypersensitivity reaction)**

Exaggerated acute reaction, occurring within 2 hours after immunization, characterized by one or more of the following:

1. wheezing and shortness of breath due to bronchospasm;
2. laryngospasm/laryngeal oedema;
3. one or more skin manifestations, e.g. hives, facial oedema, or generalized oedema

**Anaphylactic Shock**

Circulatory failure (e.g. alteration of the level of consciousness, low arterial blood pressure, weakness or absence of peripheral pulses, cold extremities secondary to reduced peripheral circulation, flushed face and increased perspiration) with or without bronchospasm and/or laryngospasm/laryngeal oedema leading to respiratory distress occurring immediately after immunization.

**Arthralgia**

Joint pain usually including the small peripheral joints.

- Persistent: Joint pain lasting longer than 10 days.
- Transient: Joint pain lasting up to approximately 10 days.
**Disseminated BCG-itis**

Disseminated infection occurring within **1 to 12 months** after BCG vaccination and confirmed by isolation of Mycobacterium bovis BCG strain.

**Fever**

- **Fever, mild**: Temperature 38°C to 38.9°C (rectal).
- **Fever, high**: Temperature 39°C to 40.4°C (rectal).
- **Fever, extreme (hyperpyrexia)**: Temperature higher than or equal to 40.5°C (rectal).

Only high and extreme fever should be reported.

**Hypotensive-Hyporesponsive Episode (shock collapse)**

Sudden onset of paleness, decreased level or loss of responsiveness, decreased level or loss of muscle tone (occurring within **24 hours** of vaccination). The episode is transient and self-limiting.

**Osteitis/Osteomyelitis**

Inflammation of the bone either due to BCG immunization (occurring within **8 to 16 months** after immunization) or caused by other bacterial infection.

**Persistent Screaming**

Inconsolable continuous crying lasting at least **3 hours** accompanied by high-pitched screaming.

**Sepsis**

Acute onset of severe generalized illness due to bacterial infection and confirmed by positive blood culture.

**Toxic-Shock Syndrome**

Abrupt onset of fever, vomiting and watery diarrhoea within **a few hours** of immunization, often leading to death within 24-48 hours.

**Other severe and unusual events occurring within 4 weeks after immunization and not covered under Nos. 1, 2 or 3.**

Any death of a vaccine recipient temporally linked (within **4 weeks**) to immunization, where no other clear cause of death can be established, should be reported.

In addition, any unusual events should be reported.
## Case Investigation Report Form for Suspected AEFI

<table>
<thead>
<tr>
<th>Field</th>
<th>Health Centre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Name</td>
<td></td>
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<tr>
<td>Address</td>
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<tr>
<td>RC No.</td>
<td>CHR No.</td>
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<tr>
<td>Date of birth</td>
<td>Sex Male [ ] Female [ ]</td>
</tr>
<tr>
<td>Date of notification</td>
<td>Interval to symptoms Days Hours</td>
</tr>
<tr>
<td>Date of immunization</td>
<td>Date of investigation</td>
</tr>
</tbody>
</table>

### Type of AEFI

- **Local**
  - Injection site abscess: Yes No Unknown Anaphylaxis Yes No Unknown
  - BCG lymphadenitis: Yes No Unknown Fever Yes No Unknown
  - Severe local reaction: Yes No Unknown Toxic shock Yes No Unknown

- **Other**
  - Other unusual events (specify): Yes No Unknown

- **CNS**
  - Acute flaccid paralysis: Yes No Unknown
  - Encephalopathy, Encephilitis/Meningitis: Yes No Unknown
  - Seizure: Yes No Unknown

### Suspected vaccine(s)

<table>
<thead>
<tr>
<th>Name of vaccine (BCG, DPT, OPV, Measles, HBV, etc.)</th>
<th>Dose number</th>
<th>Lot/batch number</th>
<th>Manuf. Expiry</th>
<th>Lot. No. Manuf. Expiry</th>
</tr>
</thead>
</table>

### Treatment and follow-up

- Treatment required: Yes* No Unknown
  - If “Yes” specify hospital
- Hospitalized: Yes* No Unknown
  - If “Yes” specify hospital
- Death: Yes* No Unknown

### Specimen Collection and despatch (if any)

<table>
<thead>
<tr>
<th>Specimen type</th>
<th>Date collected</th>
<th>Despatched to</th>
<th>Date of despatch</th>
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* A detailed narrative report, including the management course is expected in case of hospitalization or death.
Refrigerator Temperature Monitoring Sheet

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<th>Day</th>
<th>Morning Temperature (°C)</th>
<th>Afternoon Temperature (°C)</th>
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<td>Time</td>
<td>Minimum</td>
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