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Guidelines for Safe Immunization Practices and Monitoring Immunization Programs at the Facility and District Levels in Yemen

First Edition, March 2005

Prepared by:

Ministry of Public Health and
Population of Yemen

With technical support provided by:

Partners for Health Reformplus
WHO/Yemen



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Mission

Partners for Health Reformplus is USAID's flagship project for health policy and health system strengthening in developing and transitional countries. The five-year project (2000-2005) builds on the predecessor Partnerships for Health Reform Project, continuing PHR's focus on health policy, financing, and organization, with new emphasis on community participation, infectious disease surveillance, and information systems that support the management and delivery of appropriate health services. PHRplus will focus on the following results:

- ▲ *Implementation of appropriate health system reform.*
- ▲ *Generation of new financing for health care, as well as more effective use of existing funds.*
- ▲ *Design and implementation of health information systems for disease surveillance.*
- ▲ *Delivery of quality services by health workers.*
- ▲ *Availability and appropriate use of health commodities.*

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Abstract

This is the first edition of *Guidelines for Safe Immunization Practices and Monitoring Immunization Programs at the Facility and District Levels in Yemen*. It is a compendium of revised EPI (Expanded Programme on Immunization) documentation; recordkeeping and reporting requirements of the Ministry of Public Health and Population; current guidelines for immunization data analysis and utilization; and materials for monitoring and evaluating the immunization system and provider performance. The guidelines will be piloted in Amran Governorate in 2005; recommendations based on pilot experience will be incorporated into revised guidelines for use nationwide.

The manual is designed primarily for health personnel who are responsible for the implementation of the immunization program at the facility and district levels. The section on evaluation of the work at facilities can guide both the facilities in doing self-evaluations and district immunization managers in monitoring and supervising facility-level work.

The worksheets contained in this manual for monitoring immunization work are illustrative. A full set of worksheets has been published separately in an immunization workbook for districts.

Table of Contents

Acronyms	ix
Contributors.....	xi
Acknowledgments	xiii
1. Immunization Schedule	1
2. Contraindications to Immunization	3
3. Immunization Safety.....	5
3.1 Safe Injection Practices	5
3.2 Safe Disposal of Injection Equipment.....	6
3.3 Selecting Safe and Effective Vaccines	6
3.4 Reconstituting Vaccines Safely	7
4. Adverse Events Following Immunization	9
5. Record keeping and Reporting Documentation at the Facility Level.....	11
5.1 Defining a Facility’s Catchment Area	11
5.2 Determining Target Populations for Immunization.....	13
5.3 Registration of Routine Immunizations.....	18
5.4 Registration of Immunizations during Mass Campaigns such as National Immunization Days	18
5.5 Routine Monthly Reporting about Immunization Work	19
5.6 Reordering Vaccines and/or Immunization-related Materials.....	21
5.7 Cold Chain Maintenance (safe vaccine storage)	21
5.8 Monitoring of Immunization Performance at the Facility	24
6. Recordkeeping, Reporting and Monitoring at the District Level	27
6.1 Monthly Report on Immunization Practice	27
6.2 Worksheet on Immunization Coverage of Children Under 1 Year by Antigen	30
6.3 Worksheet on Vaccines and Materials Usage in District	32
6.4 Worksheet for the Analysis of Barriers to Immunization in the District.....	35
6.5 Vaccine and Supply Monitoring Register	37
6.6 Cold Chain Equipment Inventory Book	39
6.7 Evaluating Work at Immunization Points	41
7. Information-based Response Matrix.....	43

List of Tables

Table 1. Schedule for Childhood Routine Immunizations, Yemen, 2005	1
Table 2. Schedule for Tetanus Toxoid Immunization.....	2
Table 3. Conditions that are NOT Contraindications for Vaccination.....	3
Table 4. Adverse Events Following Immunization to be Reported Using Form I-1	9
Table 5. Responses to Refrigeration Problems	22
Table 6. Acceptable Wastage Coefficients and Recommended Frequency of Immunization Sessions	32

List of Figures

Figure 1. Planning Strategy for Immunization Service Delivery in a Catchment Area.....	12
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Acronyms

AD	Auto-disable/auto-destruct (syringes)
AFP	Acute Flaccid Paralysis
BCG	Bacille Calmette-Guerin Vaccine
DG	Director General
DPT	Diphtheria, Pertussis and Tetanus Vaccine
EPI	Expanded Programme on Immunization
GIS	Geographic Information Systems
HepB	Hepatitis B Vaccine
Hib	Hemophilus influenza Type B Vaccine
HIS	Health Information Systems
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
IV	Intravenous
MoPH&P	Ministry of Public Health and Population
OPV	Oral Poliovirus Vaccine
Penta-3	Third Dose of Pentavalent Vaccine
PHR<i>plus</i>	Partners for Health Reform <i>plus</i> Project
TT(2+)	Tetanus Toxoid (at least two doses)
UNICEF	United Nations Children’s Fund
USAID	United States Agency for International Development
VVM	Vaccine Vial Monitors
WCBA	Women of Childbearing Age
WHO	World Health Organization

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The immunization records shown in forms in this publication do not refer to real persons and are used for illustrative purposes only.

1. Immunization Schedule

The current (2005) childhood routine immunization schedule in Yemen is outlined in Table 1.

Table 1. Schedule for Childhood Routine Immunizations, Yemen, 2005

Antigens	Age					
	Birth	6wk	10wk	14wk	9 mo	18mo
BCG	X					
OPV	X	X	X	X		
DPT/HepB/Hib (Pentavalent)		X	X	X		
Measles + Vitamin A					X	X

The recommended course of each vaccine should be completed as scheduled. Giving doses too close together (less than the specified interval between doses) should be avoided, and any doses given at less than the recommended interval should not be counted as part of the primary series.

Children may present for immunization later than the exact intervals and times specified. In this case, the child should be given the missed doses immediately, regardless of how large the gap between doses is.

Example: A child was given the first doses of Pentavalent and oral poliovirus vaccine (OPV) 6-12 months ago. At the next health facility visit, this child should be given the second doses of Pentavalent and OPV, as well as any other vaccine(s) for which s/he is due or overdue. The series should then be continued according to the schedule, observing the minimum time interval between doses.

Every attempt must be made to immunize children on time (as per the national Expanded Programme on Immunization [EPI] schedule). Any delay in completing the schedule exposes that child and all others in the community who are not fully immunized to precisely those risks of mortality and morbidity from the target diseases that immunization is designed to avoid. Therefore the statement above about what to do in the case of an interrupted series should NOT be interpreted as an excuse to delay the subsequent doses.

Tetanus toxoid (TT) is given to women of childbearing age (WCBA) (15–45 years) according to the schedule in Table 2. There is no maximum interval between TT doses. However, minimum intervals between doses should be adhered to.

Table 2. Schedule for Tetanus Toxoid Immunization

Dose number	Timing
TT1	At first contact
TT2	4 Weeks After TT1
TT3	6 Months After TT2
TT4	One Year After TT3
TT5	One Year After TT4

Example: A woman who got the first TT dose one year ago presents at the health facility. She should be given the second dose, but the series should not be restarted.

Pregnant women may receive TT immunization at any time during the pregnancy, even in the first trimester.

It is important that every opportunity is used to immunize not only children but also women of childbearing age. For instance, when a woman brings a child for an immunization visit, the health worker should determine the woman's immunization status and offer TT vaccination if necessary.

2. Contraindications to Immunization

A contraindication to immunization is a condition that greatly increases the chances of a serious adverse reaction in a vaccine recipient. That is, if a vaccine is given to a person with a contraindication to the vaccine, then a resulting adverse reaction that harms the vaccine recipient could occur. Therefore, vaccines should not be administered when a contraindication is present. However, it is important to note that there are very few absolute contraindications to EPI vaccines. False contraindications are a major cause of non-immunization or delays in completing the routine immunization schedule. If persons are not immunized due to illnesses that are not true contraindications, then an opportunity for immunization is lost.

Two permanent contraindications to vaccination are:

- ▲ Severe allergy to a vaccine component or severe allergic reaction following a prior dose of a vaccine (e.g., anaphylaxis, collapse/shock, non-febrile convulsions)
- ▲ Encephalopathy within 7 days of pertussis vaccination

Two temporary contraindications to BCG and measles vaccines are:

- ▲ Pregnancy (note: pregnant women may receive TT)
- ▲ Immunosuppression (due to immunodeficiency diseases, malignancies, or chemotherapy).
However, OPV and measles vaccines should be given to people with HIV/AIDS.

Table 3. Conditions that are NOT Contraindications for Vaccination

- | |
|--|
| <ul style="list-style-type: none">▲ Minor illnesses such as upper respiratory infections or diarrhea, with fever less than 38.5°C▲ Allergy, asthma, or other atopic manifestations, hay fever, or "sniffles"▲ Premature, small-for-date infants▲ Malnutrition▲ Child being breastfed▲ Family history of convulsions▲ 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 |
|--|

3. Immunization Safety

3.1 Safe Injection Practices

The World Health Organization (WHO) defines a safe injection as one that:

- ▲ Does no harm to the patient
- ▲ Does not expose the health worker to avoidable risk
- ▲ Does not result in waste that puts other people at risk

Health workers should follow the following procedures when handling syringes and needles:

- ▲ **Use a new needle and syringe** for every injection.
- ▲ Do not use the syringe (or needle) if packaging is open or damaged.
- ▲ Attach the needle **before** removing the needle cap. **Do not attempt to recap the needle before or after injection.**
- ▲ **Do not touch the needle or the rubber cap (septum) of the vaccine vial.** If you touch any of these areas accidentally, discard the contaminated syringe and needle and open a new one(s).
- ▲ If auto-disable (AD) syringes are used, do not pull the piston until you are ready to fill the syringe with vaccine. **Once you pull the piston out, the syringe is disabled; you will not be able to replace the piston and then pull it out again.**
- ▲ Stick the needle into the vaccine vial rubber cap.
- ▲ Gently pull the piston to fill the syringe slightly past the 0.5 ml mark.
- ▲ Gently push the piston to remove excess air if necessary. Stop when you reach the 0.5 ml mark. If air remains in the syringe, discard the syringe and try again. If you expel too much air and no longer have 0.5 ml of vaccine in the syringe, discard the syringe. You should not vaccinate children with less than the full dose.
- ▲ Remove the syringe from the vaccine vial. Do not recap the needle.
- ▲ Inject the dose of vaccine. **Do not use your finger to guide the needle into the injection site.**
- ▲ If the injection site is bleeding, **do not place your finger directly on the injection site to stop the bleeding**; use a cotton swab.

3.2 Safe Disposal of Injection Equipment

1. Place syringes and needles in puncture-proof cardboard or plastic containers (safety boxes) immediately after use. Do not recap syringes before disposal. Do not use your hands to remove the needle from the syringe. Do not use your hands to bend or cut the needle after the injection.
2. Fill the safety box until it is about $\frac{3}{4}$ full (or up to the “Full” line if there is one printed on the box). Do not force too many syringes into the box.
3. Once the safety box is filled, close the lid and seal the box to avoid syringes spilling.
4. Safety boxes should be filled only once, then destroyed immediately or put into a safe storage area and destroyed as soon as possible. This prevents needlestick injuries and exposure to blood and body fluids, which could occur if dumping or reusing containers.
5. When the box is full, dispose of it **by burning**. The compound in which incineration takes place must be secure. Auto-combustion incinerators achieving temperatures above 8000C are preferred, although burning can also be performed in other types of incinerators, for instance, in a pit, drum, or constructed hearth. Open burning is not recommended because it can scatter waste. If safety boxes are placed in an open pit, the pit should not be so deep that people have to crawl down into the pit to start the fire. **Do not bury** safety boxes. If contaminated syringes somehow escape from the box and are carried into streams or fields, people may step on them or children may play with them, or water supplies may be contaminated.



What goes in the safety box?
Disposable syringes, needles,
needles from IV bags, lancets,
other contaminated sharps
Not for the safety box:
Empty vials, cotton pads, gloves,
other plastic materials

3.3 Selecting Safe and Effective Vaccines

- ▲ Check the expiry dates on the vaccine and diluent vials. Discard the vial if the expiry date has passed.
- ▲ If the label has come off, discard the vial.
- ▲ Discard the vial if contamination is suspected, that is, **if**:
 - △ there are leaks or cracks in the vial
 - △ there is a change in appearance or floating particles
 - △ the opened vial has been submerged in water
 - △ the top of the vial has been pierced by a used needle, or a sterile needle on a used syringe
 - △ freeze-dried vaccine has been open for more than 6 hours after reconstitution
 - △ a vial of liquid vaccine has been opened for more than 4 weeks

Do not combine partially opened vials of vaccine:

- ▲ Assess if cold-sensitive vaccines (TT, liquid pentavalent) have been frozen by using the refrigerator log or the “shake test” (see picture). Discard the vials of frozen vaccine.
- ▲ Read the vaccine vial monitors (VVMs) to check that the vaccine has not been exposed to an excessive amount of heat. VVMs show the cumulative irreversible heat exposure to which a vial has been exposed.
 - △ Discard the vial whose inner square is the same color or darker than the outside circle
 - △ Vials with VVMs where the inner square has begun to darken (but is still lighter than the outside circle) should be used before the vials with a lighter inner square



3.4 Reconstituting Vaccines Safely

- ▲ Use **only** diluent recommended by the manufacturer to reconstitute vaccine.
- ▲ Reconstituted vaccines should be kept between 2^o and 8^o C, and away from sunlight, to maintain their potency.
- ▲ Discard reconstituted vaccines at the end of the session or within 6 hours of reconstitution, whichever comes first.
- ▲ Do not reconstitute vaccine until the person needing the vaccine injection is present.
- ▲ Use a new syringe and needle to reconstitute each vial of vaccine. After mixing the diluent and vaccine, discard the syringe and needle.
- ▲ **Do not** leave the mixing needle in the vial, this leaves the vial open to contamination.
- ▲ Withdraw the vaccine from the vial using the same needle and syringe that will be used to inject the vaccine.

4. Adverse Events Following Immunization

Adverse events following immunization are medical incidents that occur at some point after immunization and that are thought to be possibly caused by the immunization.

All of the adverse events following immunization shown in Table 4 should be reported by facilities (using **Form I-1**) immediately to the district immunization manager, who will forward the information to the governorate office, which will decide about the need for investigation.

Table 4. Adverse Events Following Immunization to be Reported Using Form I-1

Local	Central Nervous System	Others
Injection site abscess	Acute paralysis	Death
BCG lymphadenitis	Seizures	Shock/severe hypotension
Severe local reaction	Encephalopathy	Shortness of breath
	Encephalitis	Laryngeal edema
	Meningitis	Generalized edema
		Fever > 39°C

If the adverse event is seen at a vaccination post outside of a health facility, then the patient should be referred immediately and/or transported to the nearest health facility for treatment and completion of **Form I-1**.

Vaccine Adverse Event Reporting Form

Form I-1

Yemen Rep.

MoPH & P

PHC Section

G.D. for Family Health

EPI Programme

Governorate.....

District

Health facility

Date:

Form completed by:

Patient name: _____ **Age:** _____ **DoB:** _____

Address: _____

Date and time of adverse event onset: _____

Date and time of the suspected vaccination: _____

Vaccine administered by: _____ (name) _____ (position)

Name and address of health facility: _____

Enter all vaccines given on and within one week of that day:

Vaccine type	Date of vaccination	Manufacturer	Lot #	Route/Site	No. previous doses

Adverse event type (check as appropriate or provide a description)

LOCAL	CENTRAL NERVOUS SYSTEM	OTHER
<input type="checkbox"/> Injection site abscess?	<input type="checkbox"/> Acute paralysis?	<input type="checkbox"/> Shock/severe hypotension?
<input type="checkbox"/> BCG lymphadenitis?	<input type="checkbox"/> Seizures?	<input type="checkbox"/> Shortness of breath?
<input type="checkbox"/> Severe local reaction?	<input type="checkbox"/> Encephalopathy, encephalitis, meningitis?	<input type="checkbox"/> Laryngeal edema?
Other (describe): _____		<input type="checkbox"/> Generalized edema?
		<input type="checkbox"/> Fever >39°C

Hospitalization required? YES NO Unknown **Specify hospital:** _____

Patient died? YES NO Unknown **When?** _____ **Patient recovered?** YES NO Unknown

Any illness at the time of vaccination (specify): _____

List names and dates of other medications taken on or immediately prior to vaccination date: _____

Pre-existing allergies and medical conditions: _____

Submit one copy of this form immediately to the immunization manager at the district health center (who will forward this information to the Governorate) and keep the other copy filed in the facility.

If you cannot deliver this form to the district within one day, call the district immunization manager to submit this information.

Investigator's comments:

5. Recordkeeping and Reporting Documentation at the Facility Level

This chapter explains the various immunization documentation and reporting requirements that providers of immunization services must complete and file with district health services.

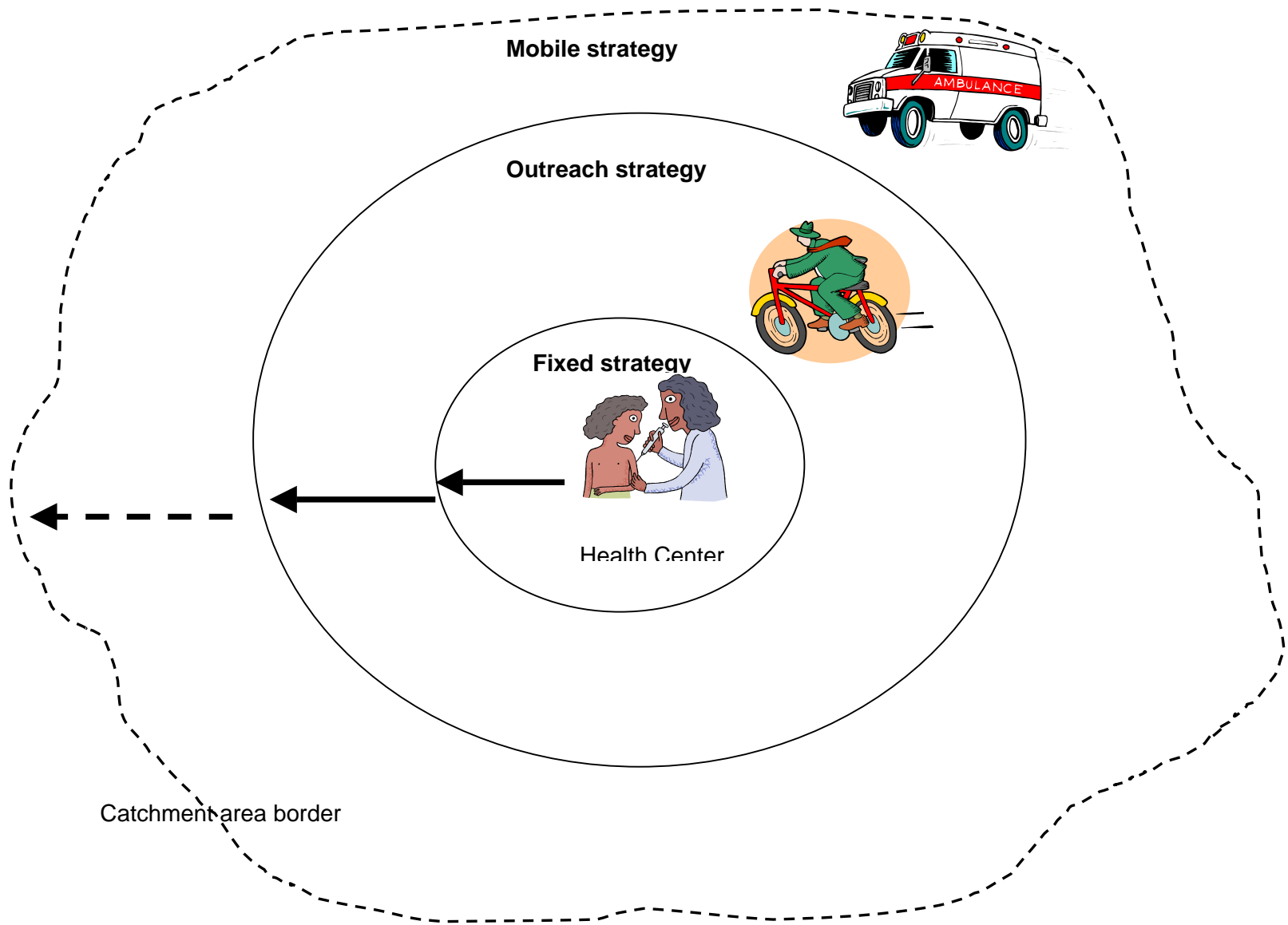
Each section explains how the immunization record book or form should be completed, where data can be found to complete the form, who is responsible for completing it, and when the form should be filed. This reporting documentation applies to health units, health centers, and hospitals (both governmental and private).

5.1 Defining a Facility's Catchment Area

The catchment area is the area in which the population served by the facility resides. The catchment area can be divided into three zones (see Figure 1). The first, which covers the population that can easily access the health facility, uses a fixed-post strategy (that is, children are brought to the facility for immunization). The second zone is too far away for residents to easily access the health facility, but health workers can reach the population on foot to deliver services, and an outreach strategy is used to reach women and children living in this area. The third zone extends to the furthest areas served by the facility, and cars are required to reach these populations (a mobile strategy).

It is important for facilities to work with districts to accurately define their catchment area if they have not done so already.

Figure 1. Planning Strategy for Immunization Service Delivery in a Catchment Area



5.2 Determining Target Populations for Immunization

Every year, preferably in January or February, each health facility is responsible for conducting a house-to-house census of the population eligible for immunization in their catchment area.

The purposes of the annual house-to-house census are to:

- ▲ Determine the denominators for the next year by counting all children born in the previous calendar year (e.g., January–December, 2004) and WCBA
- ▲ Immunize all eligible children and women
- ▲ Provide to women health education based on local needs
- ▲ Update registers of immunizations for children and WCBA

A typical team comprises 2-3 health workers, and it is recommended that at least one of them be female. The team should be equipped with the following materials:

- ▲ Vaccine carriers
- ▲ Vaccines
- ▲ Syringes
- ▲ Safety boxes
- ▲ Immunization registers
- ▲ Immunization cards
- ▲ Tally sheets
- ▲ Household census forms
- ▲ Pens

The census activity includes the following steps:

- ▲ Determine the denominator: Count the number of children born in the previous calendar year and WCBA by completing **Form I-2**.
- ▲ Verify immunization status of children aged <1 year (**Form I-3**) and WCBA (**Form I-4**) by using registers on the following pages.
- ▲ Provide immunizations to eligible children and women and provide them with immunization cards.
- ▲ Update the register and record immunizations given on tally sheets (**Form I-5**).
- ▲ Educate men and women on the safety and importance of immunizations as necessary.

Tally Sheet for Children & Women Vaccination

EPI Programme

Governorate..... District..... Health Facility Name..... Day..... Month..... Year.....

Age group	District	Item	BCG	OPV0	OPV			Penta			Measles + Vit A			Group	District	Item	Tetanus Toxoid Doses					
					1st	2nd	3rd	1st	2nd	3rd <small>(children from my catchment area get one mark in each box)</small>	1st	2nd	Vit A				TT1	TT2	TT3	TT4	TT5	
Under One	Home district	///												Pregnant	Home district	///						
		No.																				
	Other districts	///														Other districts	///					
		No.																				
Above One	All districts	Marks												Non-Pregnant	All districts	Marks						
		///																				
		No.																				
Total														Total								

N.B. Place mark soon after vaccination
 At the end of the work session, calculate the number of vaccinated persons and doses of vaccine used
 *The number of children from the home catchment area getting the 3rd dose of Pentavalent vaccine is used in for coverage monitoring at the facility

Vaccinator's Name..... Signature.....

5.3 Registration of Routine Immunizations

The same record sheets (**Forms I-3 and I-4**) and tally sheet (**Form I-5**) are used to register immunizations given at health facilities. The record and tally sheets are completed immediately upon vaccination. These forms enable vaccinators to separately count children and WCBA who belong to a given facility's catchment area, another facility's catchment area in the same district, or other districts. These data can be analyzed to determine patterns in vaccine-seeking behavior and compute coverage rates specific for a given catchment area or district.

The health worker should record the following information accurately on the forms:

- ▲ The **name** and **age** of the vaccinated person
- ▲ The **date** of vaccination
- ▲ The **accurate and complete address** (district, subdistrict, and village or zone) of the vaccinated person
- ▲ Whether he/she is from the same catchment area of the facility, from another catchment area within the same district, or from another district

In every health facility that provides vaccination services, **the health worker(s) in the vaccination post** of the health facility is/are responsible to give the vaccine and to fill these registration forms.

These immunization registers **should be kept at the immunization post** in the health facility.

5.4 Registration of Immunizations during Mass Campaigns such as National Immunization Days

During mass immunization activities (e.g., polio or measles campaigns), vaccines are administered without regard to previous immunization history and respective doses are **not** counted towards routine immunization schedule. Health workers are only required to complete tally sheets to report about vaccinations performed.

However, during supplementary TT immunization rounds, health workers are required to determine immunization history of women – preferably by examining immunization cards (or in the course of a detailed interview if the card is not available) to assess each woman's eligibility for a TT booster. Tally sheets and campaign registers should be used to record and report the number of vaccinations performed by dose.

TT2+ coverage rates should be calculated separately for campaigns and routine services (they should not be combined because doses received in campaigns are not included in the routine register).
--

5.5 Routine Monthly Reporting about Immunization Work

A health facility worker responsible for immunization is required to submit to the district immunization manager monthly reports about vaccinations performed (**Form I-6**).

Data about targets should come from the annual house-to-house census of population eligible for immunization.

The section on immunizations given should be filled out with the data from routine tally sheets (**Form I-5**).

The number of 3rd doses of pentavalent vaccine (Penta-3) given to children under 1 year in the home catchment area should be indicated separately to enable accurate coverage rate computation for each catchment area.

The section on vaccine use should reflect the flow of vaccine and materials at the facility during the reporting month. It is important to make sure that the balance of vaccines/materials at the beginning of the month equals the balance of respective vaccines/materials at the end of the previous month. The number of doses remaining in an open vial should be estimated based on visual inspection of the vial. Health workers may find it convenient to record the information on the number of doses of vaccines received immediately upon the receipt of vaccines/materials. The information about the balance of vaccines/materials at the end of the month will be accurate **only if** the data are recorded promptly after the end of the month.

Health workers are also required to complete the sections of the report related to obstacles to vaccination during the report month, such as unavailability (even for a single immunization session) of a vaccine or immunization-related material, absence of vaccinators, cold chain problems, a large number of refusals, etc.

Reports should be prepared in duplicate immediately at the end of the month. One copy should be received by the district not later than on the 7th day of the following month. The other copy is retained at the facility. At the time of report submission, the district EPI manager will complete the data accuracy verification checklist at the bottom of the form. Health facility workers are encouraged to review the checklist themselves to ensure the reports they are submitting is as accurate as possible.

Yemen Rep.
MoPH & P
PHC Section
G.D. for Family Health
EPI Programme

Monthly Immunization report

Form I-6

Governorate:
Month:

District:
Year:

Facility:

OBSTACLES TO IMMUNIZATION THIS MONTH? (mark with X)	Vaccinator NOT available?		Describe the problem:	ANNUAL TARGETS (use house-to-house census data where available)		
	Cold chain problem?				Children under 1	
	A lot of parental refusals ?				Women 15-45 yrs old	
	Other? (specify)				Pregnant women	

CHILDREN IMMUNIZATIONS	BCG		OPV						Pentavalent						Penta-3 <small>given to home catchment area children</small>	Measles			Vit A		IMMUNIZATION of WOMEN aged 15-45 yrs	Tetanus Toxoid										
			0		1		2		3		1		2			3		1		2				1		2		3		4		5
UNDER 1 year	HD	OD	HD	OD	HD	OD	HD	OD	HD	OD	HD	OD	HD	OD	HD	OD	HD	OD	2	HD	OD	Pregnant women	HD	OD	HD	OD	HD	OD	HD	OD	HD	OD
	2	1	2	1	2	1	2	1	2	1	2	1	2	1	2	1	2	1	2	2	1			2	1	2	1	2	1	2	1	2
OVER 1 year	ALL DISTRICTS						ALL DISTRICTS						ALL DISTRICTS			ALL DISTR		Non-pregnant women	ALL DISTRICTS													
	1						1						1			1			1													
TOTAL immunizations given	3		15						11						5			4		TOTAL	20											
USE OF VACCINES and MATERIALS	BCG	OPV						Pentavalent						Measles			Vit A		TT	SYRINGES			Safety Boxes	Imm cards								
																					IM	SC		MIX	Children	Women						
Balance at the beginning of the month	1	10						20						15			15		100	15	15	15	15	15	15	15						
No. received	2	5						5						5			5		0	5	5	5	5	5	5	5						
Balance at the end of the month	3	5						8						10			15		70	10	10	10	10	10	10	10						
No. of doses used (including wastage)	4=1+2+3	10						20						10			5		30	10	10	10	10	10	10	10						
Mark X if vaccine or material was not available during one or more sessions		X																	X													

Vaccinator:
Signature:

H.F. Worker
Signature:

HD-home district; OD-other districts

Data accuracy check list (to be used by district EPI managers and for facility workers for self assessment). Correct all mistakes (if any) before accepting the report into the information system

Do targets look realistic?		
Is the no. of OPV-1 and Penta-1, OPV-2 and Penta-2, OPV-3 and Penta-3 vaccinations compatible?		
Is the no. of doses of vaccine used (plus wasted plus destroyed) HIGHER than the number of immunizations given for ALL vaccines?		
Is the no. of Penta-3 vaccinations given to home catchment area children <1y less than or equal to the number of Penta-3 vaccinations given to HD children <1y?		
Does the balance of vaccines/materials at the beginning of a period equal their balance at the end of the previous period?		
Are totals computed correctly?		
Are obstacles to vaccination indicated (if there are any)?		
Are stock-outs of vaccines and materials indicated (if there are any)?		
Are blank spaces in the report explainable (if there any)?		

The health worker should also record the refrigerator temperature on the temperature registration record (**Form I-8**) twice a day, every day. At the end of each month, this form should be signed.

Filling in the temperature registration record (**Form I-8**):

1. The facility must designate one person (usually the health worker responsible for immunization) to be in charge of monitoring and recording the refrigerator temperature twice daily.
2. At the beginning and end of each working day, the designated health worker should check the refrigerator temperature and record that temperature in the appropriate place on **Form I-8**. This form contains the temperature log, by day and by morning/evening, for every month of one calendar year.
3. If the refrigerator is turned off for defrosting, then the health worker should record a “D” in the table for that reading time.
4. If the refrigerator is not working, then the health worker should record an “N” in the table for that reading time.
5. If the refrigerator has been turned off due to a power deficiency, then the health worker should record a “P” in the table for that reading time.
6. At the end of each month, the health facility worker should sign the document in the “signature” column.

Table 5 shows possible scenarios and appropriate responses to refrigeration problems.

Table 5. Responses to Refrigeration Problems

Scenario	Response
Temperature rises steadily over a few days	Compressor may be failing. Immediately notify the district manager.
There are wide variations between morning and afternoon temperature readings	Do not open the door more than necessary. Increase number of ice packs to increase temperature stability.
Morning temperature reading is above 8°C	Cold chain failure. Inform district supervisor promptly.
Morning temperature reading is below 0°C	Cold chain failure. Do not use affected vaccines (e.g., TT, Pentavalent). Dispose of appropriately.

If the cold chain fails:

- ▲ Transfer the vaccines and cold chain monitors to a vaccine carrier or vaccine cold box if the failure is due to lack of power lasting more than 2 hours.
- ▲ Keep the refrigerator door closed – do not open unless absolutely necessary.
- ▲ Contact your district EPI focal point for guidance.

Temperature Registration Record

Form I-8

Year: _____ Responsible person (name)* _____

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Signature		
JAN	morning																																		
	evening																																		
FEB	morning																																		
	evening																																		
MAR	morning																																		
	evening																																		
APR	morning																																		
	evening																																		
MAY	morning																																		
	evening																																		
JUN	morning																																		
	evening																																		
JUL	morning																																		
	evening																																		
AUG	morning																																		
	evening																																		
SEP	morning																																		
	evening																																		
OCT	morning																																		
	evening																																		
NOV	morning																																		
	evening																																		
DEC	morning																																		
	evening																																		

D = refrigerator is turned off for defrosting, N = refrigerator is out of order (not working), P = Refrigerator turned of because of power deficiency.

*Responsible person has to sign the document at the end of each month.

5.8 Monitoring of Immunization Performance at the Facility

Vaccination coverage with 3 doses of pentavalent vaccine (Penta-3) has been chosen as a marker of immunization performance at the facility level.

Instructions for Filling Out Forms

Using the vaccination tally sheet (**Form I-5**) and data from the annual house-to-house census, the health worker responsible for immunization should fill in each month the table at the bottom of the Monitoring of Pentavalent-3 Coverage graph to summarize monthly and cumulative Penta-3 coverage for children aged < 1 year old in the catchment area. Once the Penta-3 coverage cumulative percentage has been calculated every month, a curve reflecting this percentage should be drawn on the graph. After building the curve, health workers will be able to easily compare the district's Penta-3 coverage during the given time period with the target line, reflecting the average percentage of Penta-3 coverage needed to reach the goal by the end of the year.

It is important to make sure that only children residing in the facility's catchment area should be included in the calculations.

In a case where the curve reflecting Penta-3 coverage during the current period of time is below the target line and does not approach it the following month, the health worker should immediately investigate the reasons for the low coverage, which are probably among the following:

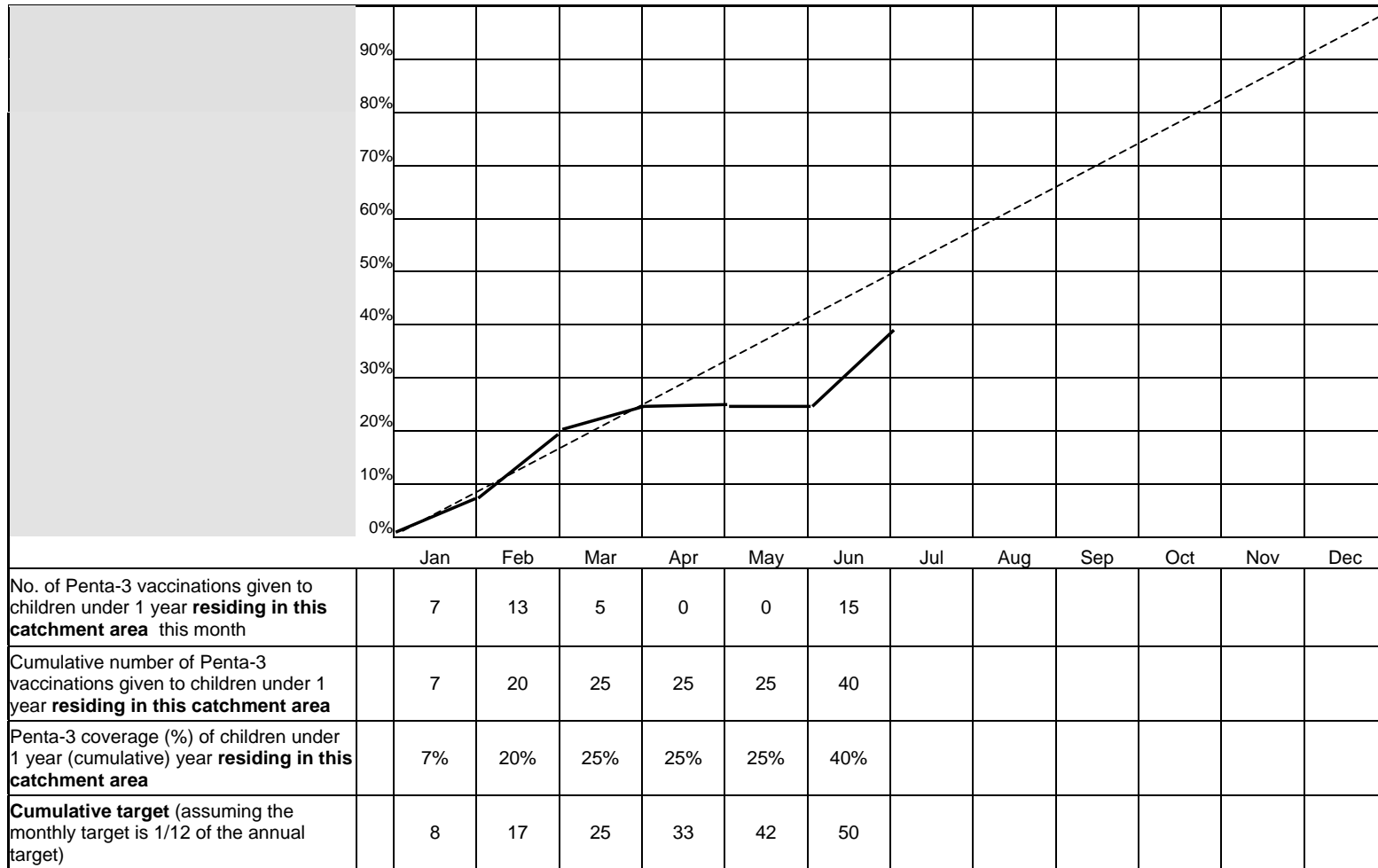
- ▲ Failure to bring children to facility for vaccination (poor access or utilization of services)
- ▲ Cold chain failures
- ▲ Frequent or prolonged shortages of vaccine(s)
- ▲ High proportion of refusals to receive vaccine

The corrective strategy will depend on identifying the appropriate reasons for low coverage. For example, health workers must carry out outreach or conduct health education activities together with local teachers or immediately inform the district manager of refusals, cold chain, or other problems to arrange solutions.

If Penta-3 coverage of children under 1 year is too high (above the target line), the data should be analyzed for data errors: For example, does the numerator include children from outside the catchment area? Was the target population identified correctly during the house-to-house census?

Monitoring of Pentavalent-3 Coverage of Children Under 1 Year in Year 2005

Total number of children in the catchment area – 100



Notes:

Number of children under 1 year is taken from the annual house-to-house census. This record is kept at the facility for monitoring.

6. Recordkeeping, Reporting, and Monitoring at the District Level

District health centers represent the second level of immunization management. This is the level where summaries of reports, analysis of immunization performance, and decisions regarding improving the protection of the population of the service area are made.

6.1 Monthly Report on Immunization Practice

The Summary Report on Immunization Performance (**D-1**) is completed monthly using data from the monthly reports submitted by facilities in the district and using the district's own data on flow of vaccine and materials. It is important to make sure that the data on target populations are derived from facility reports and reflect the findings of the facilities' annual house-to-house census.

Data on immunizations given at each facility must be presented as those given to persons from the home district and those given to persons from other districts to enable accurate calculation of coverage for the district.

At the time of report submission, district EPI managers should perform a **basic verification of health facility reports data accuracy**, namely to verify that:

- ▲ Targets look realistic;
- ▲ Number of OPV-1 and Penta-1, OPV-2 and Penta-2, OPV-3 and Penta-3 vaccinations are compatible;
- ▲ Number of doses of vaccine used (plus wasted plus destroyed) is **higher** than the number of immunizations given for ALL vaccines;
- ▲ Number of Penta-3 vaccinations given to home catchment area children under 1 is less than or equal to the number of Penta-3 vaccinations given to home district children under 1;
- ▲ Balance of vaccines/materials at the beginning of a period equals their balance at the end of the previous period;
- ▲ Totals are computed correctly;
- ▲ Obstacles to vaccination are indicated if there are any;
- ▲ Stock-outs of vaccines and materials are indicated if there are any; and,
- ▲ Blank spaces in the report (if there are any) are explainable.

In general, health facilities should be instructed to put “0” where the number is truly zero and not to leave blank spaces (which may indicate that a health worker forgot to complete that part of a report).

District EPI managers should follow up with facilities at the time of report submission to correct mistakes. They should not accept poor quality data into the system.

Two copies of the report should be prepared. One copy remains at the district level and one is submitted to the governorate before the 15th of the following month.

6.3 Worksheet on Vaccines and Materials Usage in District

District immunization managers should monitor vaccine usage indicators and the balance of available vaccines and materials at every facility as well as in the entire district. The data should come from monthly reports submitted by the facilities (**Form I-6**).

Calculations can be performed electronically (automatically) using the GIS or other software, or manually using the tables in the following format (see example in **Form D-3**). If calculations are performed manually, the vaccine wastage coefficient is calculated by dividing the number of doses used in each facility by the number of vaccinations given for each antigen.

If the usage indicator is too low (< 1), either the data are inaccurate due to improper recording of vaccine usage or the children are not being immunized properly. On the other hand, an indicator of vaccine usage that is too high (see Table 6) may be due to the improper organization of days for immunization, failure to adhere to the temperature storage regimen, or improper recording of vaccine usage. This indicator also allows one to compare the wastage of vaccines of different packing types (vials), which can be used for rational vaccine procurement planning.

Table 6. Acceptable Wastage Coefficients and Recommended Frequency of Immunization Sessions

	Number of children <1 served by facility		
	20-100	101-500	>500
Recommended number of immunization sessions/month	1-3	3-5	As needed
Vaccine	Acceptable wastage coefficients		
2 doses/vial: Pentavalent	1.5	1.3	1.1
10 doses/vial: OPV, TT, measles	2.0	1.5	1.3
20 doses/vial: BCG, OPV	As much as needed		

Wastage that exceeds the numbers in Table 6 points to existence of the above-described problems.

District immunization managers should know how effectively vaccines were used; however, they should be careful when interpreting these data. Higher than average wastage can be justified when doing vaccinations in sparsely populated territories in the absence of mobile teams or when opening large vials to vaccinate children who live in hard-to-reach areas and might remain unvaccinated if the present opportunity is missed. Urgent measures should be taken if the vaccine usage indicator becomes unreasonably high or low.

The major vaccine wastage reduction strategies at the district level are as follows:

- ▲ Better planning of immunization sessions (grouping by days as outlined in the table above)
- ▲ Adherence to the “open vial” recommendations that allow use of open TT vaccine vials for as long as 1 month provided that facilities fully meet cold chain requirements
- ▲ Use of outreach mobile immunization strategies

- ▲ Improved cold chain to avoid exposure of vaccines to heat and freezing
- ▲ Rationalized distribution of vaccines (to use all vaccines before expiration dates and to avoid prolonged storage of unused vaccines where cold chain failure is likely)
- ▲ Training in the use of vaccine vial monitor-equipped vaccines
- ▲ Use of optimal product mix where appropriate (e.g., one- or two-dose vials in villages and 10-dose vials in urban centers)

Vaccine and materials balance

This worksheet also allows immunization managers to ensure uninterrupted functioning of immunization services throughout the district. Immunization managers should monitor the balance of vaccines and materials at every facility every month and take appropriate measures in case they have no or too little vaccine in stock. Such measures may include urgent provision of vaccines and materials or working with facilities to address vaccine supply issues.

A sufficient number of the worksheets are included in the workbook to facilitate the analytical work of district immunization managers.

6.4 Worksheet for the Analysis of Barriers to Immunization in the District

District immunization managers should identify main barriers to immunization in their district using **Form D-4**. Such barriers may include, for example:

- ▲ Unavailability of vaccinators
- ▲ Cold chain failure
- ▲ Vaccines/materials shortages

Data for such analyses come from the routine monthly immunization reports (**Form I-6**) submitted by facilities.

The analyses will allow the district manager not only to map all major obstacles encountered, but also to monitor how effectively the facilities and the district office cooperate towards resolving identified barriers over time and whether an intervention of the governorate or central MoPH&P colleagues may be helpful.

The worksheet should be also used to monitor the performance of facilities with respect to monthly reporting of immunization data.

Upon identifying facilities that do not report on time or at all, district managers should work with them to overcome the obstacles, improve reporting, and therefore ensure completeness of information at the district level.

6.5 Vaccine and Supply Monitoring Register

The vaccine and supply monitoring register (**Form D-5**) is designed to continuously track the supply, distribution, and remaining stock of vaccines, syringes, and safety boxes. Each material (including each type of vaccine) should have its own page (or multiple pages) in the record book.

Vaccine flow is registered in the record book by recording when a vaccine is received, distributed, or written off/destroyed. When registering vaccine flow, one has to indicate the amount of vaccine in doses in all columns.

On each new page of the record book, the name of the item – vaccine, syringe, or safety box – should be written in the second row next to “Item: _____.” The lot number and expiration date are entered in the table, as appropriate to the type of item.

In addition to regularly recording the receipt, issue, and usage of the vaccines, syringes, and safety boxes, the district immunization manager should calculate the balance of remaining vaccines, syringes, and safety boxes in order to be aware at all times (not only at the end of a month) of the type and quantity of materials that are in stock. The manager should be responsible not only for tabulating the quantity of vaccines but also for their proper storage and for ensuring that vaccines with the shortest shelf life are issued first.

At the end of every month the manager should make an inventory of the vaccines left in the refrigerator (cold room) and check whether the amount corresponds to the balance of vaccines in the record book (**Form D-5**). Vaccines that have an expired date, are of bad quality, or are left over must be destroyed/written off according to the existing regulations.

It is important to make sure that a health facility receives, along with new vaccine lots, instructions on the use of those vaccines. It is recommended that health facilities keep such instructions for every type of vaccine.

The “Use of vaccines” section of the Summary Report on Immunization Performance (**Form D-1**) is completed using data from this record book and from the Monthly Immunization Reports (**Form I-6**) submitted by health care facilities.

Vaccine And Supply Monitoring Register

Form D-5

Item:

Unit:

DATE	Permission no.	RECEIVED				GIVEN OUT				DESTROYED / WRITTEN OFF (in doses)	BALANCE (in doses)
		From	Amount (in doses)	Lot #	Exp. date	To	Amount (in doses)	Lot #	Exp. date		
<i>Balance as of 31 Jan</i>										100	
1.02.2005		<i>District XX</i>	600	<i>c-3125</i>	<i>10.2006</i>						700
3.02.2005						<i>Facility A</i>	100	<i>c-3148</i>	<i>10.2005</i>		600
4.02.2005						<i>Facility B</i>	100	<i>c-3125</i>	<i>10.2006</i>		500

This register is kept at the district level and filled out immediately upon receipt or issuance of vaccines and supplies

6.6 Cold Chain Equipment Inventory Book

The Cold Chain Equipment Inventory Book (**Form D-6**) section of the workbook contains information about cold chain equipment at all vaccination points of a district. This section is completed annually (at the beginning of the year) according to the data obtained during scheduled facility visits or through special information requests. The records can be updated during supervisory visits to vaccination points and also upon receipt of new cold chain equipment or when writing off old equipment.

The inventory book is used to monitor the status of the cold chain in the district and to plan purchases of new equipment and repairs of broken equipment.

6.7 Evaluating Work at Immunization Points

The Health Facility Immunization Performance Checklist (**Form D-7**) contains simple questions that district immunization managers can use to monitor and supervise vaccination points or that providers can use to self-monitor their work. The checklist allows for clear and objective evaluations. Periodic monitoring will help health care providers and managers to identify problem areas and plan appropriate interventions to solve the problems.

The person doing the (self-) monitoring should carefully consider each question in the checklist and respond as to whether the condition has been met or not. Where the condition has been met (“Yes”), no further clarification is needed. If a condition has not been met or has been only partially fulfilled (“No”), one should indicate exactly what is wrong and recommend how to correct the problem. Depending on the difficulty of meeting certain conditions, one should decide whether advisory assistance from governorate or central MoPH&P specialists is needed and when the next evaluation will take place. **Form D-8** can facilitate such analysis, by presenting responses in a tabular form.

All facilities should be evaluated at least once a year. The district manager should use the data from the evaluation checklist during subsequent evaluations to monitor progress.

Health Facility Immunization Performance Checklist		Form D-7	
Facility.....		YES	NO
Knowledge of target population			
1	Can the facility correctly define its catchment area?		
2	Are the immunization targets based on the door-to-door population census in the catchment area?		
Organization of records			
3	Has this facility been provided with standard registers, report forms, tally sheets and imm. cards? Observe.		
4	Are copies of ALL monthly reports available for the past 6 months?		
Accuracy and timeliness of monthly reports			
5	Does the reported number of immunizations given (by every type) match the data from tally sheets? (Check randomly.)		
6	Is the reported number of doses used always bigger than the corresponding number of immunizations given?		
7	Was the last monthly report submitted on time?		
Analysis and use of information			
8	Can the health worker show up-to-date coverage rate calculations or monitoring chart(s) for at least Pentavalent vaccine?		
9	Is the numerator is calculated correctly? (It should not include children from other catchment areas.)		
10	Are obstacles to reaching immunization targets reported to the district? (check two last monthly reports)		
11	Are the vaccines and immunization materials ordered timely? (no preventable stockouts in the past 12 months)		
12	Does the health worker manage the existing vaccine stock properly? (no write-offs of expired or frozen vaccine in the past 6 months)		
13	Does the health worker vaccinate eligible women with TT when they bring children for immunizations?		
Knowledge of cold chain and immunization safety procedures			
14	Are vaccines kept in the right temperature (+2)-(+8)C at the time of the supervisory visit?		
15	Does the health worker monitor the temperature daily?		
16	Is the refrigerator used exclusively for vaccines and immunobiologicals?		
17	Does the health worker use the safety boxes correctly?		
18	Does the health worker dispose of safety boxes correctly?		
TOTAL			
Summary of the identified problems and solutions			
PROBLEMS		SOLUTIONS	
1			
2			
3			
4			
Name of the health worker		Date:	
Name and position of the supervisor		Signature _____	

7. Information-based Response Matrix

Problem	TYPICAL RESPONSE ACTIONS	
	Facility Level	District Level
Low vaccination coverage	<ul style="list-style-type: none"> ▲ Identify reasons for low coverage; ▲ Identify where non-immunized children and women live; ▲ Vaccinate those who can be reached with your resources; ▲ Make sure accurate data on immunizations and barriers are reported to the district immunization manager. 	<ul style="list-style-type: none"> ▲ Monitor coverage by catchment area and supervise facilities; ▲ Address the barriers identified by facilities (e.g., replace broken cold chain equipment, assist in health education, provide female vaccinators, etc.); ▲ Provide outreach services to those who cannot be reached by facilities; ▲ Promptly inform the governorate EPI office of outstanding obstacles to reaching full vaccination coverage in the district.
Vaccine/materials stockouts	<ul style="list-style-type: none"> ▲ Prevent stock-outs by monitoring available supplies and reordering them in a timely manner; ▲ In the case of a stock-out, telephone the district EPI office to arrange immediate delivery; ▲ Make sure stockouts are reported on a monthly report form. 	<ul style="list-style-type: none"> ▲ Monitor available supplies at facilities using the data from their monthly reports; ▲ Make sure facility supply requests accurately reflect their needs, make corrections as necessary; ▲ Make sure that sufficient supplies are provided to facilities even if their request does not come on time.
Cold chain failure	<ul style="list-style-type: none"> ▲ Monitor twice a day the temperature of the cold chain equipment; ▲ When cold chain failure is suspected, check vaccines for the signs of exposure to excessive cold or heat and discard damaged vaccines; ▲ If the temperature goes out of the acceptable range, check the electricity supply and temperature settings; ▲ If the equipment breaks, do not open doors frequently and move cold packs from the freezer to the refrigerator, immediately inform the district EPI manager by phone to arrange repairs/replacement. ▲ Indicate cold chain problem on monthly reports if necessary. 	<ul style="list-style-type: none"> ▲ Apply the same rules/procedures for the district cold chain equipment; ▲ Maintain a cold chain register in the district using the data from monthly reports, supervision visits, and special requests for cold chain information. ▲ Repair or replace broken equipment in the district using available resources. ▲ Communicate to the governorate outstanding cold chain needs.

Problem	TYPICAL RESPONSE ACTIONS	
	Facility Level	District Level
High vaccine wastage	<ul style="list-style-type: none"> ▲ Adhere to the “open vial” recommendations that allow use of open Pentavalent and TT vaccine vials for as long as 1 month provided that facilities fully meet cold chain requirements. ▲ Avoid exposure of vaccines to heat and freezing; ▲ Use vaccines with approaching expiry dates first; ▲ Consider reducing the frequency of immunization sessions to more optimally group the target population (this should not result in lower coverage); ▲ Know how to read vaccine vial monitor (VVM); ▲ Accurately report data on vaccine use on monthly reports. 	<ul style="list-style-type: none"> ▲ Monitor vaccine wastage in every facility, and if it appears high work with facilities to implement recommendations indicated in the box to the left; ▲ Monitor vaccine stock and issue vaccines with approaching expiration dates first. ▲ Do not issue too much vaccine to facilities where cold chain failure is likely; ▲ Conduct outreach immunizations in catchment areas of facilities without reliable cold chain; ▲ Train health workers in the use of VVM-equipped vaccines.
Adverse events following immunization	<ul style="list-style-type: none"> ▲ Strictly follow immunization safety instructions outlined in these guidelines; ▲ Should an adverse event following immunization occur, complete the reporting form and promptly (by phone or in person) submit the information to the district EPI manager. 	<ul style="list-style-type: none"> ▲ Carry out training of health workers in immunization safety issues; ▲ Promptly forward the information about the adverse events to the governorate EPI manager; ▲ Participate in investigation of adverse events together with the governorate experts as needed.
Monthly reports not available or late	<ul style="list-style-type: none"> ▲ Make sure monthly reports are submitted on time; ▲ Inform the district EPI manager of any obstacles to timely reporting. 	<ul style="list-style-type: none"> ▲ Monitor whether monthly reports are received from ALL facilities; ▲ Identify poorly reporting facilities, investigate obstacles and work with health facilities on addressing them; ▲ Carry out refresher training as needed or whenever new staff are hired.