إدارة اللقاحات و سلسلة التبريد
في المؤسسات الصحية

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Introduction

When it comes to the field of vaccination, Iraq is one of the leading and developed countries. It is one of the first Eastern Mediterranean countries that run the expanded program of immunization. This program is continuously evolving since its start in 1985 to cope with the scientific development in the field of vaccination and modern logistic tools, the program has made a noticeable improvement to serve the community.

This guide was prepared by the staff of immunization division at public health department. To be a guide for the staff working in the field to run the vaccination and cold chain, and perform vaccination activities, due to the great importance that these activities represent to provide effective and safe vaccines in sufficient quantities and appropriate time to reach the required community immunity. This scientific guide includes five chapters that covers vaccination management and cold chain. The first chapter covered an introduction about the concept of cold chain and the equipment it involves, the second chapter covered the vaccine storage methodology, and the third chapter covered vaccination temperature monitoring. The fourth chapter is dedicated to cover storage capacity and method by which it’s calculated and how to convert vaccination doses into volumes. Finally the fifth chapter was about estimating the vaccination need, the factors that affect it, the method to calculate this need and calculation of vaccine waste.

We hope for this guide to fulfill the required purpose, to improve technical expertise to accomplish the required aim of eradicating childhood communicable deadly diseases and prevent the return of epidemic. We pray for God Almighty to keep our children safe and gives them health and prosperity and make us succeed in our deed.
Chapter One

Vaccine Cold Chain
Vaccine Cold Chain

The accurate definition of **vaccination cold chain** is summarized as (the system that ensures preserving the vaccines safe and effective from manufacturing moment to the use of vaccine. Thereby the basic elements of cold chain are the equipment used (in storing and transportation) and the personnel in charge of receiving, transporting, storing, distribution and delivering vaccines during different stages that vaccines pass through, this is called vaccine cold chain.

Cold chain is considered the main pillar in the expanded program of immunization and the guarantee for delivering affective vaccines to the targeted sector in a correct way, since vaccine exposure to heat of freezing influence the efficacy of the vaccine and thereby the required immunity would not be satisfied, exposing the community to the risk of contacting preventable diseases.

The figure below shows a comprehensive diagram of cold chain:

![Cold Chain Diagram](image)

**Vaccination and soda:**
Someone may ask: why cold soda are available in far areas while vaccination are not.
We confirm that soda is a profitable product, it does not require continuous cooling, but only require to be cold on demand, on the other hand vaccines lose its efficacy when heated (or frozen in some types)

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**The levels of cold chain and equipment used:**

The different levels of primary health care require different equipment to transport and store vaccines and solvents in the appropriate temperature to preserve each vaccine.

The vaccine is stored on arrival from the factory in the main warehouse, until the end of specific test, to be distributed at the level of province warehouse, and therefrom to the warehouses of health district and primary health care centers (PHCCs).

- **The central main warehouse:** Require cold rooms, freezing rooms and freezers, refrigerated vehicles and portable insulated containers (for transport).

- **Branch warehouses:** Require cold rooms, refrigerators, freezers for ice blocks, refrigerated vehicles and portable insulated containers (for transport and emergency cases).
• **District warehouses:** Require freezers for ice-blocks, refrigerators and cold boxes, (for transport and emergency cases).

• **Primary health Care Clinics:** Require refrigerators, freezers for ice-blocks, cold boxes (to preserve the vaccine during transport or emergency) and vaccine carrier.

• **Primary Health Care sub-clinics:** Require refrigerators, freezers for ice-blocks, cold boxes (to preserve the vaccine during transport or emergency) and vaccine carrier.

**Instruction of work in the cold room and freezing room:**

The vaccine store officer is the first person and the watching eye to follow the status of the cold rooms and freezer rooms dedicated for vaccines, thereby he is one of the maintenance team. The instructions that workers in the cold rooms and freezing rooms should follow are the following:

1. **Daily actions, these are the following:**
   - Watch and document temperature twice daily, temperature must be between (+2°C - 8°C) for cold rooms and (-15 °C - 25°C) for freezer room, the cold rooms and freezer room should maintain this temperature range at all the time.
   - Listen to the sound, the cooling or freezing unit produce during work, if you notice any strange or unusual sound report to the maintenance team.
   - Inside the room check the following:
     - Cold air flow as usual from the internal cooling unit with the absences of malfunction in the internal cooling unit fans.
     - Ensure the absence of water on the floor of the cold room, the. Presence of water may indicate blockage in the water drain pipe connected to the cooling unit.
   - Outside the room do the following:
     - Make sure there is no traces of mice and rats near the electricity unit of the cold rooms or freezing rooms.
     - Supervise the cleaning of the floor on which the cold rooms and freezer rooms are installed twice weekly, with the removal of all dirt and vaccines shipping derbies.
   - At the end of the day make sure of:
     - You turned off the interior lighting of cold or freezer rooms.
     - No one is inside the room before locking it.
     - That you closed and locked the cold room and freezer room.

2. **Weekly actions:**
   - During the week make sure the cooling and freezing units are working alternatively and regularly.
   - In addition to daily follow up make sure that vaccines are well organized according to the expiratory date, light sensitivity and freezing.
   - Check carefully "liquid sight glasses" near the compressor, if you noticed any air bubbles this may indicate presence of leak of refrigerant from the system, inform the maintenance staff.
   - Regarding electric generator you should check:
     - The level of oil in the engine and level of fuel in the fuel tank.
     - The battery terminals are well connected and check the level of acid in the battery.
3. Monthly actions:
   - Ensure the absence of cracks or opening between the units forming the cold/freezing room.
   - Check that the insulator tape at the door of the room is in good shape.
   - Do inventory for the vaccine and solvents stock and compare it to the stock card.
   - Make sure that the vaccine are placed to ensure that the near expire vaccine dispensed first.
   - Make sure there is enough fuel for one month.

Cold chain equipment used in the primary health care clinics (PHCC):

Refrigerators:
The refrigerators used in the PHCCs rely on electricity, gas, kerosene and solar energy. The electric refrigerator are considered the one with the least cost and easiest to maintain, provided that electricity is always available in the PHCC. Ice lined refrigerators are considered the most appropriate when electricity is not always available in the PHCCS and branch warehouses, these refrigerators maintain temperature for certain period depending on the weather temperature. Below is a table demonstrates the time temperature is maintained when electricity is off at weather temperature between (+32 - 43°C) for the refrigerators used in Iraq:

<table>
<thead>
<tr>
<th>Refrigerator model/ Vestfrost</th>
<th>Weather temperature +32 °C</th>
<th>Weather temperature +43 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>MK 204</td>
<td>46 hours</td>
<td>More than 20 hours</td>
</tr>
<tr>
<td>MK 304</td>
<td>49 hours</td>
<td>15 hours</td>
</tr>
</tbody>
</table>

Refrigerators have different storage capacity to store vaccines, so the refrigerator must contain enough space to store:
1. One month share of vaccines and solvents.
2. One week share as an additional stock, that represent 25% of monthly need.
3. Distance between vaccines must be enough to allow air flow between vaccines and diluents.

Vaccine transport equipment:
All vaccine transport equipment used in cold chain must be capable of protecting vaccine from heat and light, even in winter when temperature below zero centigrade. That’s why cold box and vaccine carrier box where designed.
The term “cold life" means the number of hours during which the vaccine is preserved at appropriate temperature and according to WHO definition is the number of hours the box or vaccine carrier can maintain temperature less than 10°C, before its frozen packs are replaced. The cold life varies from one box to another and from one vaccine carrier to another depending on the following:

- Type of cold box or vaccine carrier, insulating material, thickness and design.
- Frequency and duration during which the cover of the box or carrier is opened.
- Air temperature.

**Cold Boxes:**

The cold box is an insulated box where icepacks (already prepared) can be arranged within in order to preserve vaccines and solvents within appropriate temperature.

Cold boxes are used in the PHCC to transport vaccines monthly from branch warehouses it is also used to store vaccines in the PHCC when refrigerator is not available or broken (in cases of emergency).

There are different types of cold boxes with different storage capacity. The PHCC (in which ice lined refrigerator is not available) requires one or more cold box that can accommodate:

- The PHCC’s monthly share of vaccines and diluent.
- One or two week’s remaining share of vaccines and diluent.

The table below shows some examples of cold boxes and their cold life in different air temperature:

<table>
<thead>
<tr>
<th>TYPE OF COLD BOX</th>
<th>“COLD LIFE” AT 32 °C</th>
<th>“COLD LIFE” AT 32 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrolux RCW 25</td>
<td>226 hours</td>
<td>181 hours</td>
</tr>
<tr>
<td>“IGLOO” 20 liters</td>
<td>Not tested</td>
<td>84 hours</td>
</tr>
<tr>
<td>“IGLOO” 4.4 liters</td>
<td>Not tested</td>
<td>50 hours</td>
</tr>
<tr>
<td>THERMOS 1.7 liters</td>
<td>40 hours</td>
<td>33 hours</td>
</tr>
</tbody>
</table>
The figure above shows how to arrange ice packs and put the vaccine inside the cold box.

1. Put the ice packs in bottom of the box
2. & 3. Put the ice packs on the sides
4. Put the vaccine in the cold box
5. Put the ice packs over the vaccine

The figure above shows how to arrange ice packs and put the vaccine inside the cold box.
**Vaccine Carriers:**

As in the case of cold box, vaccine carrier is a heat insulating container where ice packs are put adjacent to the walls to keep vaccines and diluent cold. It is usually smaller than cold box, and very easy to carry but the duration it keeps the vaccine is 24-72 hours.

Vaccine carrier can be used during vaccination campaign for the mobile teams. Also for the monthly transport of vaccine to small PHCCs.

There different types of vaccine carriers that are used in the PHCC that varies according to the number of vaccine bottles, diluent, icepacks, the duration it keeps vaccine at appropriate temperature and method of transport.

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**Sponge cover:** is a thin piece of sponge put at the neck of vaccine carrier, there are openings in the sponge cover where vaccines bottles are placed, its benefit is to keep vaccines cold, ensure that it will into be contaminated through mixing with opened vaccine bottles, in addition protect it from sunlight.

**Important note:** the sponge cover must be kept clean and replaced at least once weekly. It can be provided from local markets and cut it according to the shape of the vaccine carrier.
**Ice Packs:**

Regular shape plastic bag filled with water, and available in different sizes. Two main sizes are:
- 0.4 L used in vaccine carrier.
- 0.6 L used in cold boxes.

The purpose of using ice-packs is to keep temperature between +2 to +8°C inside cold boxes and vaccine carriers during storage and transport.

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**Preparing ice Packs:**

Ice pack preparation require approximately 48 hours, as follow:
- Fill the bag with cold relatively cold water and close the lid tightly.
- Carry each icepack and turn it upside down and squeeze to ensure there is no leak.
- Arrange ice packs as in the figure above.
- Keep it for 48 hours in the freezer for the water to freeze.

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**Remember:**

- After taking ice packs out of the freezer it must not be used till it melt and the sound of water is audible when shaken, these melt pack are helpful to transport freezing sensitive vaccines (hepatitis B, pentavalent, DTP, DT and Tetanus toxoid).
- It is not required to refill the ice pack after each use, use the same water several times.
- When refreezing the ice pack after use in the field, it must be put in the freezer sequentially, since this affect the temperature of the freezer.
- Always keep enough quantity of require icepacks in the freezer, to be used in daily work and during vaccination campaigns and emergencies.
Chapter Two

Vaccines Storage
Vaccination Storage

Each vaccine contains biological materials that can lose efficacy, that is to say lose the ability to develop immunity against disease with time. The rate increases when the vaccine is exposed to high temperature (or low according to the vaccine, to preserve the vaccine it must be kept continuously at appropriate temperature from the time of manufacture to time of use cause when vaccine lose efficacy this cannot be reversed by correcting storage method.

Cold chain preserve vaccine at all stages, it include sequential stages of storage, transport of the vaccine to keep the vaccine at appropriate temperature until it reach the user, below is a typical diagram of cold chain:

![Diagram of Cold Chain]

- **International shipping**
  - Vaccines
  - Airport
- Storage facilitation in idle time (+2 °C to +8 °C)
  - Cold rooms (+2 °C to +8 °C), freezing rooms (-15 °C to -25 °C)
  - Cold rooms (+2 °C to +8 °C), freezing rooms (-15 °C to -25 °C)
- Refrigerators (+2 °C to +8 °C), freezers (-15 °C to -25 °C)
- Refrigerators (+2 °C to +8 °C), vaccine boxes
- Refrigerators (+2 °C to +8 °C), vaccine boxes, vaccine carriers
- **Vaccines main warehouse**
- **Vaccines branch warehouse (In the province)**
- **Vaccines branch warehouse (In the District)**
- **PHCC**
- **PHC sub-clinic, vaccination teams**
- Child or mother

Transported by refrigerated cars and/or vaccine carriers for vaccination teams
Method of Vaccination Storage

All vaccines are considered heat sensitive, but they have different range of heat sensitivity, the vaccines can be arranged according to heat sensitivity in the following way:

The following chart illustrates all freezing-sensitive vaccines (that get damaged when exposed to freezing), they can be classified from the most sensitive to the least sensitive vaccines as follows:

Always remember:
- All vaccines freeze below zero centigrade.
- Hepatitis B vaccines freezes at 0.5o C thereby it is the most heat sensitive vaccines.
- Vaccines becomes more sensitive after being reconstituted with its specific diluent, BCG, Measles and MMR vaccines should never be frozen after being reconstituted.
### Vaccine storage and distribution chart

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Main warehouse</th>
<th>Branch warehouses</th>
<th>PHCC</th>
<th>PHC sub-clinic or vaccination teams</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Province warehouse</td>
<td>District warehouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPV</td>
<td>-15 °C to -25 °C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BCG</td>
<td>According to WHO regulations it is not necessary to store these vaccines at (-15 °C to -25 °C) even if it is possible to do so, but to be stored at (+2 °C to +8 °C)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measles</td>
<td>+2 °C to +8 °C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR</td>
<td>+2 °C to +8 °C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hep B</td>
<td>+2 °C to +8 °C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTP-HepB-Hib</td>
<td>+2 °C to +8 °C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTP+Hib</td>
<td>+2 °C to +8 °C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rota</td>
<td>+2 °C to +8 °C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DT</td>
<td>+2 °C to +8 °C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TT</td>
<td>+2 °C to +8 °C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Td</td>
<td>+2 °C to +8 °C</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When diluent are supplied with freeze dried vaccines in the same package, both vaccines and diluent must be kept at (+2 °C to +8 °C), when vaccine is supplied in separate package form diluent the diluent should be preserved at (+2 °C to +8 °C) at the level of PHCC (when there is no enough space in the PHCC refrigerator then only weekly reserved can be kept and the remaining to be stored out of the cold chain) at the level of main and branch warehouse it is not necessary to keep the diluent in the cold chain.

Note: WHO recommends that the 6 month storage period referred to above is the longest storage period at the level of main warehouse, this period should cover the time required for customs clearance, storage and distribution in the main warehouse.

Vaccines that are suitable for use are stored in the cold chain, any vaccine that is expired or spoiled due to heat exposure should not be stored in the cold rooms and refrigerator (out of the cold chain) and to be marked as not suitable for use.

On the other hand it must be avoided to use freeze dried vaccines without its specific diluent, because one vaccine should not be reconstituted with another vaccines diluent, example measles vaccine diluent cannot be used to reconstitute BCG vaccine, diluent can be kept out of the cold chain it is separate from the vaccine, but it must be stored within the cold chain to be used to reconstitute vaccine for no less than 24 hours.
**Light sensitive vaccines:**

Some vaccines are sensitive **to intense light**, where light exposure reduce its efficacy, thereby it should not be exposed to sunlight or fluorescent light or any other source of light. These include BCG, measles, MMR vaccines (these vaccines are also heat sensitive) usually these vaccines are supplied in dark colored bottles to provide partial protection from damage due to light exposure. Even though care must be taken when handling these vaccines by keeping it covered and away from light all time as possible.

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![Vaccines sensitivity diagram](image_url)

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**Vaccines that are more sensitive to light**

- BCG
- Measles
- Rubella

**Vaccines that are less sensitive to light**
Vaccines arrangement chart

The process of arranging vaccines in the horizontal ice lined refrigerator is one of the important issues that workers in the field of vaccination should know and consider, from detailed point and diagrams we will learn in this chapter ho to arrange vaccines:

The figure above shows the typical diagram for vaccine storage in horizontal ice lined refrigerator, in case the vertical one is used the vaccine arrangement would be the reverence for that in the horizontal refrigerator. OPV, BCG Rota, measles and MMR vaccines are placed in upper shelves the other (freeze sensitive vaccines) vaccines pentavalent, quadruple, TT, Hep B are placed in the lower shelves and water is placed below in the refrigerator.
Regulations of vaccine arrangement and storage in the refrigerator:

- Put enough unfrozen ice packs low down in the horizontal refrigerator, to keep the refrigerator cold when electricity is shut down.
- The BCG, OPV, Rota measles and MMR are saved below in the refrigerator (lower baskets of the refrigerator)
- The TT, Hep B, pentavalent and quadruple vaccines are kept above in the refrigerator (upper basket of the refrigerator)
- Put electronic thermometer with freezing monitor in the upper and middle baskets in a visible place to detect mean temperature degree inside the refrigerator and we can detect occurrence of freezing.
- Put the unopened, sealed vaccines vials that was taken out of the refrigerator for use and put back in a clear place in front of other vaccines to have priority in disposal, the name of the returned vaccine is marked for these bottles to be used in the next session.
- Destroy any reconstituted vaccine six hours after the time of reconstitution.
- Check temperature twice daily, to be between (+2 °C to +8 °C) a document it with date and day in temperature chart.
- Take any expired vaccine out of the refrigerator and isolate it in separate place and mark any information related to that vaccine.
- Get rid of expired vaccine according to the due procedures and the formal vaccine destruction contexts.
- Don’t put any food, drink, or drug in vaccine refrigerator.
- Avoid opening the refrigerator door more than twice daily:
  - Plan and determine what you are going to do before opening the refrigerator door.
  - Cut short the time required to arrange and prepare vaccine to the minimum.
Chapter Three

Monitoring temperature
Monitoring and documentation of vaccine temperature:

Monitoring temperature is done through reading the thermometer in the refrigerator twice daily, (beginning and end of work) and follow up during Fridays and holidays. Document the temperature and write the date and time on temperature table and keep that table is special folder.

If the temperature inside the refrigerator is more or less than the safe temperature to keep vaccines then apply emergency plan (for example transport the vaccines to the cold box, and try to modify temperature using the thermostat inside the refrigerator, after temperature stabilize return the vaccines to the refrigerator).

The example below show the temperature documentation table that was previously used, it does not contain a column for notes that can occur during the month and required to be referred to:

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
<th>16</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>E</td>
<td>B</td>
<td>E</td>
<td>B</td>
<td>E</td>
<td>B</td>
<td>E</td>
<td>B</td>
<td>E</td>
<td>B</td>
<td>E</td>
<td>B</td>
<td>E</td>
<td>B</td>
<td>E</td>
</tr>
</tbody>
</table>

Note:
- Beginning of the day = B
- End of the day = E

Always remember:
- Document temperature at least twice daily.
- Put an alternative plan to store vaccines for emergencies, (refrigerator malfunction, electricity shut down for long period, natural disasters, etc.) it is necessary to consider monitoring temperature during long holidays.
- Be accurate when reading thermometer of different types (avoid reading mistakes, decimals for example)
Instructions to fill temperature monitoring tables (temperature chart):

Below is the certified standard model for the monthly temperature monitoring table (temperature chart) for all levels of vaccination storage below re the instruction to fill this table:

1. Set the number of the col room or vaccine refrigerator in the health institute, in case there are more than one cold room or refrigerator
2. Set the type of cold room or vaccine refrigerator used (example Ice Lined MK 204)
3. Check and document temperature twice daily (at the beginning and end of working day)
4. Check and document the status of freezing monitor. (X or OK)
5. Document the highest and lowest temperature recorded during the day and the status of fridge tag (OK or Alarm) by pressing the button (Read) in the fridge tag.
6. Sign twice daily at the bottom of the table after doing the steps above
7. Document all the unusual event in the Note column and as in the example below:
   • Monday 20/1/2014 after noon the cooling system issued loud sound
   • Tuesday 21/1/2014 morning the cooling system is not functioning, the heat sensitive vaccines were transferred to vaccine storage refrigerator number (3) the remaining vaccines were transferred to the cold box, maintenance team have been contacted.
   • Wednesday 22/1/2014 maintenance work is finished at 4:30 PM.
8. Show the table to the manager of the institute to document his note and keep a copy for the previous month in special folder.

Knowing that this table (chart) contains all the requirement to document and monitor temperature and according to WHO recommendations.
Types of vaccination temperature monitors used in Iraq:

**Vaccine vial monitor VVM:**

Vaccine vial monitor is a patch put on the vaccine vial that contain heat sensitive material aim to mark the accumulation of temperature with time. The combined effect of time and temperature cause grading of color of the internal square of the VVM from snow white into dark in an irreversible way. The degree of color change increase with temperature exposure. Color change rate increases with exposure to heat.

Vaccine vial monitor is placed either on the top of the vaccine vial or inside the inner box of the vaccine vial monitor, which is made of heat-sensitive material, pure white in the beginning and the gradually gets darker when exposed to heat.

Rules of reading a vaccine vial monitor are summarized as shown below:

- Inner box is bright white compared to the outer circle and the vaccine is still valid, **use** the vaccine
- Over the time, the inner box color gradually gets darker, but still brighter than the outer circle, if the vaccine is still valid, **use** the vaccine
- Inner box color is identical to the outer circle color, **do not use** the vaccine regardless of exp. date
- Inner box color is darker than the outer circle color, **do not use** the vaccine regardless of exp. date
**Fridge-Tag®**

This thermometer was adopted to monitor the temperatures in all primary health care centers during 2013 instead of disc thermometer, it records temperatures for the past 30 days and alerts in case there's any increase or decrease in the desired temperature for vaccines storage (+2 to +8) centigrade.

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**How to activate the electronic thermometer**

When you receive the thermometer, the screen will not show any number. In order to activate it you must press the READ button and the SET button at the same time for more than two seconds, four zeros will appear on the screen, the first zero blinks on and off.

**Time setting**

For time setting, use the READ button. Every time you press the READ button the blinking digit will increase one number. For example, if you want to set the time to 13:47 you must do the following steps:

1. The first zero blinks on and off. Press the button READ one time, it will show the number "1", then press SET button to save
2. Second zero blinks on and off, press the button READ three times, it will show the number "3" as the second digit of the screen, then press SET button to save
3. Third zero blinks on and off, press the button READ four times, it will show the number "4" as the third digit of the screen, then press SET button to save
4. Fourth zero blinks on and off, press the button READ seven times, it will show the number "7" as the fourth digit of the screen, then press SET button to save
If you press the button READ during the previous process more than required, continue pressing it until reaching the desired number and then press the SET button to save.

**Set Temperature unit**
When you complete the time setting, the mark "°C" will appear downright the screen, you should then click on the button SET to save. Thus activating the thermometer has been completed and it will start recording.
Note / then, pressing the READ button will change temperature unit from Celsius to Fahrenheit. Then press the SET button to save and continue, noting that we use Celsius degrees so it's best not to change it.

Once the process of activating the electronic thermometer ends, the word "Ok" will appear as well as the current temperature.

**Change time setting**
If you make a mistake in time setting it can be reset. To reset the time setting after the process of activating the electronic thermometer you should press the SET button and then the READ button a few time, and then you must apply what described above in paragraph "time setting". The reset process is confined to reset the time and temperature unit between Celsius and Fahrenheit.

**Temperature limits exceeded**
Electronic thermometer Fridge-Tag® has two levels of temperature warning: high and low. In temperature limits exceeded the mark "Ok" will change into "ALARM".

High temperature alarm is given when the thermometer is exposed to temperatures above +8 °C for more than 10 hours continuously, while low temperature alarm appears when the thermometer is exposed to less than -0.5 °C for 60 minutes continuously.

Sometimes temperatures may get high or low but for less than the above periods, so the "ALARM" will not be given. This can be found when checking the temperature record for the previous days.
How to read the temperatures that have been recorded

The Fridge-Tag® electronic thermometer records temperatures continuously and shows warning sign "ALARM" on the screen in the event of any limit exceeded for the periods specified. These information can be found for the last thirty days.

Even if the thermometer wasn't exposed to over-limit temperatures and the "OK" sign still appears on the screen, it is possible to see the lowest and highest average temperature the thermometer has been exposed to for the last thirty days as well as for how long the thermometer was exposed to these temperatures.

By pressing the button READ once the highest temperature and the cumulative time of that degree will appear (hours: minutes) the thermometer was exposed to today when the temperature is higher than the +8 °C.

And pressing the READ button for the second time will show the least temperature and cumulative time of that degree (hour: minutes) the thermometer was exposed to today when the temperature is lower than -0.5 °C.

If you continuously press the button READ it will show you the details of the previous days respectively. During this process, the arrow indicates increase and decrease in temperature of the previous days.

The following example shows that there were three alarms in the past days; the first and second days there was (high temperature alarm) and on the fifth day (low temperature alarm).

As previously explained, you should press the READ button to enter to the information of increase and decrease temperatures recorded in addition to the period of exposure for higher/lower the limits. The following example shows exposure to higher than +8 °C temperature for 12 hours and 15 minutes in the second day to +25 °C as the highest temperature recorded.
The following example shows exposure to less than -0.5 °C temperature for 2 hours and 45 minutes on the fifth day and to -5.7 °C as the lowest temperature registered.

**Cold Chain Monitor CCM:**

The cold chain monitor consists of information fields and windows A, B, C, D, which are temperature-sensitive indicators that change color according to the temperature. It is a cumulative and permanent change (irreversible) as window color transformed from white to blue.

Cold chain monitor is used in factories, main and branch warehouses and in vaccine transportation. One card is attached for each three thousand doses. Upon vaccine arrival, the vaccine official at the main, branch warehouse or the PHCC shall check the cold chain monitor card A, B, C, D to determine if there has been any change in the color of the windows to blue in order to take the appropriate action, and the warehouse manager shall write down the following information on the card:

- Vaccine batch Input and output dates
- Windows Color A, B, C, and D.
- Name of the warehouse
- Types of vaccines and Lot Numbers.
Instructions for using the cold chain monitor card:

- If all the windows A, B, C, D are white, all vaccines could be used normally.
- If window A color changed from white to blue while windows B, C and D colors are still white color, the OPV should be dispensed within 3 months, while the rest of the vaccines used normally.
- If windows A, B color changed to blue while windows C, D color is still white, OPV cannot be used and measles, MMR, quadruple and pentavalent vaccines must be used within three months while the rest of the vaccines used normally.
- If windows A, B, C color changed to blue while window D color is still white, OPV, measles MMR, quadruple and pentavalent vaccines cannot be used, while DPT can still be used (preventive vaccine against tuberculosis) within three months. The rest of the vaccines used naturally, noting that reaching this status means that the vaccines are exposed to higher than +10 °C and lower than 34 °C temperature for a period ranging between 11 to 14 days.
- If all the windows A, B, C, D color changed from white to blue, all the vaccines cannot be used, the administrator must be informed and the vaccines must be reserved until discarded according to the instructions, noting that this condition occurs if vaccines exposed to a temperature of 34 °C or more for at least two hours.
Freezing Index

Freeze-tag, used to monitor freezing-sensitive vaccines where the ✓ mark appears on the electronic screen in the mark As long as freezing index was not exposed, otherwise it shows to mark ✗ and the side figure illustrates the Freeze-tag.

Disc thermometer

There are multiple types of disc thermometers used at all levels (main and branch warehouses and PHC clinics) and also in vaccine transportation. Disc thermometer should always be placed in the middle shelves of the refrigerator and freezer rooms so we get an accurate reading.
Shake test

Shake test helps to know whether the vaccine was exposed to freezing that led to damage. The test is performed for all freezing-sensitive vaccines which were exposed to below zero temperature for an hour or more (quadruple, pentavalent, tetanus toxoid, DT, Td, hepatitis B for children and adults)

Freezing exposure guide

If temperature dropped below zero centigrade in the freezer or refrigerator room, you'll notice that temperature monitors are as follows:

How to do shake test

If you found a temperature decrease inside the vaccine refrigerator or freezer room by observing the freezing index, do the following:

1. Stop using all freezing-sensitive vaccines mentioned above if found in that refrigerator/freezer room.
2. Freeze (i.e. discard) one vaccine vial of each freezing-sensitive vaccines found inside the refrigerator/cold room by placing them in the freezer for at least 10 hours.
3. Take out the vaccine from the freezer and leave it to melt completely (Don't apply a heat source; leave it melts at room temperature)
4. Write "Damaged" on that vaccine to be recognized from other suspected vaccines inside the refrigerator/cold room.
5. Start shaking the two vaccine vials of the same batch for no more than 20 ~ 30 seconds.
6. Put the two vials on a level surface in a place with adequate lighting after shaking.
7. Start comparing the two vials.
   - If the two vaccines precipitated at the same, it means that the suspected vaccine is damaged.
   - If the suspected vaccine precipitated faster than the vaccine you discarded, it means that the suspected vaccines are damaged.
   - If the suspected vaccine precipitated slower than the vaccine you discarded, it means that the suspected vaccine is still valid and usable.
Note:
Shake test must be performed for all freezing-sensitive vaccines found inside the refrigerator/cold room and for each Batch No. of the same vaccine. For example, suppose there's tetanus toxoid vaccine which has 3 batch numbers in a refrigerator where temperature decreased below zero and the mark X was shown in the freezing indicator, here 3 vials (3 batch numbers) must be taken and frozen and shake test is performed as previously explained.

Shake test chart
Chapter Four

Vaccines Storage Capacity
Vaccines Storage Capacity:

Vaccine management system relies primarily on providing storage capacity for vaccines to maintain good quantities of vaccine stocks to ensure the continuation of immunization activities (routine immunization and campaigns) throughout the year, so it is very important to know the storage capacity at all levels, starting from the main vaccines warehouse down to PHCCs that provide services of the Expanded Program on Immunization.

**Vaccine storage capacity is classified into two parts:**

1. Vaccine storage capacity at freezing temperature degrees (-15 to -25) centigrade.
2. Vaccine storage capacity at cold degrees (+2 to +8) centigrade.

It is not possible to combine them to extract the total storage capacity.

**Mechanism to calculate Vaccine Storage Capacity:**

- **Cold rooms, freezing rooms**

Storing vaccines in the refrigerators cold rooms requires the following:

1. Don't store vaccines on the refrigerator/cold room floor.
2. Allow spaces between the vaccines for ventilation.
3. Don't store freezing-sensitive vaccines close to the condenser.

**Calculation is done through:**

1. There are usually many shelves in the cold room that could be fixed or movable.
2. Measure the dimensions of shelves; length, width space between shelves in addition to the number of shelves.

**Example 1:**
To calculate vaccines storage capacity in a cold room containing metal restraints with 6 shelves, i.e. the cold room has 6 pieces like in the side figure:

- Each piece contains (4) shelves as shown
- The dimensions are: 170 cm length of the shelf, width 50 cm, space between shelves is 60 cm
- Calculating the total storage capacity of the cold room shelves:

One shelf width X one shelf length X space between shelves X number of shelves in each piece X number of pieces in the cold room.
Total Storage Capacity =
50 cm × 170 cm × 60 cm × 4 × 6 = 12240000 cm³

Actual storage capacity = two-thirds of the total storage capacity
= 12240000 × 2 \ 3
= 8160000 cm³ = 8.16 m³
= 8160 liters

Example 2:
How much the storage capacity of the cold room shown in figure No. ( ), which contains fixed shelves, noting that the room has four shelves?

1. Measure the actual dimensions of the shelves as follows:
   - Each shelf consists of two side shelves, each shelf’s length = 110 cm, width = 50 cm
   - Front shelf length = 300 cm, width = 50 cm
   - Space between shelves = 45 cm
2. Calculating total storage capacity of the cold room shelves is as follows:
(Side shelf length × side shelf width) × 2) + (front shelf length × front shelf width) × space between the shelves × total number of shelves

**Total storage capacity =**

\[
\left(110 \text{ cm} \times 50 \text{ cm}\right) \times 2 + \left(300 \text{ cm} \times 50 \text{ cm}\right) \times 45 \text{ cm} \times 4 \\
= 468000 \text{ cm}^3
\]

**Actual storage capacity = two-thirds of the total storage capacity**

\[
= 468000 \text{ cm}^3 \\
= 468000 \text{ cm}^3 \times \frac{2}{3} \\
= 3120000 \text{ cm}^3 \\
= 3.12 \text{ Cu m} \\
= 3120 \text{ liters}
\]

**Important note:**

When calculating the actual vaccine storage capacity, there should be spaces between the vaccines for cold air circulation between vaccines. This space is approximately one-third of the total volume calculated and thus:

**Actual storage capacity = total storage capacity × \frac{2}{3}**

---

**Refrigerators and Freezers**

The following is a table showing vaccine storage capacity in the ice lined, ordinary and Kerosene refrigerators and freezers used to keep the vaccines by our warehouses, PHC Districts and PHCCs

**Ice lined refrigerators**

<table>
<thead>
<tr>
<th>#</th>
<th>Manufacturer</th>
<th>Refrigerator Model</th>
<th>Vaccine storage capacity to in liters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Vest frost</td>
<td>MK 204</td>
<td>63</td>
</tr>
<tr>
<td>2</td>
<td>Vest frost</td>
<td>MK 304</td>
<td>108</td>
</tr>
<tr>
<td>3</td>
<td>Vest frost</td>
<td>MK 074</td>
<td>20</td>
</tr>
<tr>
<td>4</td>
<td>Vest frost</td>
<td>MK 144</td>
<td>45</td>
</tr>
<tr>
<td>5</td>
<td>Electrolux</td>
<td>TCW 1990</td>
<td>37,5</td>
</tr>
<tr>
<td>6</td>
<td>Electrolux</td>
<td>TCW 1152</td>
<td>169</td>
</tr>
<tr>
<td>7</td>
<td>Electrolux</td>
<td>RCW 50/EG/CF</td>
<td>24</td>
</tr>
</tbody>
</table>

**Freezers**

<table>
<thead>
<tr>
<th>#</th>
<th>Manufacturer</th>
<th>Refrigerator Model</th>
<th>Vaccine storage capacity to in liters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Vest frost</td>
<td>MF 114</td>
<td>72</td>
</tr>
<tr>
<td>2</td>
<td>Vest frost</td>
<td>MF 214</td>
<td>192</td>
</tr>
<tr>
<td>3</td>
<td>Vest frost</td>
<td>MF 314</td>
<td>264</td>
</tr>
</tbody>
</table>
Ordinary vertical electric and Kerosene refrigerators

<table>
<thead>
<tr>
<th>#</th>
<th>Manufacturer</th>
<th>Refrigerator Model</th>
<th>Vaccine storage capacity to in liters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SIBIR</td>
<td>V170 KE</td>
<td>55</td>
</tr>
<tr>
<td>2</td>
<td>SIBIR</td>
<td>V 240 KE/CE</td>
<td>55</td>
</tr>
<tr>
<td>3</td>
<td>Ordinary electric vertical refrigerators in general</td>
<td>55</td>
<td></td>
</tr>
</tbody>
</table>

Notes:
- For the ice lined refrigerators, vaccine storage capacity is calculated including the vaccine baskets.
- As for Freezers, they are dedicated to keeping ice packs, but they can be used to keep vaccines that require freezing at the main warehouse and province levels.

Calculating the volume of vaccines

In order to make sure that storage capacity calculated is enough to store the vaccines received while maintaining stocks of (25% to 50%), the actual volume occupied by the vaccine should be known in order to compare it with the calculated storage capacity. Calculating the volume occupied by the vaccine depends on a mathematical calculation through which the number of vaccine doses can be converted into volume.
**Mechanism to convert vaccine doses into volume:**
Below we include a table of doses volumes for most serums, vaccines and solvents used in Iraq:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dosage</th>
<th>Volume</th>
<th>Quantity</th>
<th>Order</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTP liquid + Hib freeze-dried</td>
<td></td>
<td></td>
<td>10</td>
<td>13.20</td>
<td>Quadruple vaccine</td>
</tr>
<tr>
<td>DTP-HepB-Hib liquid</td>
<td></td>
<td></td>
<td>1</td>
<td>15.50</td>
<td>Pentavalent vaccine</td>
</tr>
<tr>
<td>Rota vaccine</td>
<td></td>
<td></td>
<td>1</td>
<td>85.00</td>
<td>Rotavirus vaccine</td>
</tr>
<tr>
<td>Polio</td>
<td>OPV</td>
<td>Liquid</td>
<td>20</td>
<td>0.65</td>
<td>OPV</td>
</tr>
<tr>
<td>BCG</td>
<td>BCG</td>
<td>Lyophilized</td>
<td>20</td>
<td>0.80</td>
<td>0.7 BCG vaccine</td>
</tr>
<tr>
<td>Tetanus Toxoid</td>
<td>TT</td>
<td>Liquid</td>
<td>10</td>
<td>3.00</td>
<td>Tetanus toxoid vaccine</td>
</tr>
<tr>
<td>Measles</td>
<td>Measles</td>
<td>Lyophilized</td>
<td>10</td>
<td>3.00</td>
<td>3.0 Measles vaccine</td>
</tr>
<tr>
<td>Measles-Mumps-Rubella freeze dried</td>
<td>MMR</td>
<td>Lyophilized</td>
<td>10</td>
<td>3.00</td>
<td>3.0 MMR vaccine</td>
</tr>
<tr>
<td>Diphtheria-Tetanus</td>
<td>DT</td>
<td>Liquid</td>
<td>10</td>
<td>3.00</td>
<td>DT vaccine for children</td>
</tr>
<tr>
<td>Tetanus-Diphtheria</td>
<td>Td</td>
<td>Liquid</td>
<td>10</td>
<td>3.00</td>
<td>Td vaccine for adults</td>
</tr>
<tr>
<td>Hepatitis B child</td>
<td>HepB</td>
<td>Liquid</td>
<td>10</td>
<td>3.00</td>
<td>Hepatitis B vaccine or children</td>
</tr>
<tr>
<td>Hepatitis B adult</td>
<td>HepB</td>
<td>Liquid</td>
<td>1</td>
<td>17.00</td>
<td>Hepatitis B vaccine or adults</td>
</tr>
<tr>
<td>Hepatitis A adult</td>
<td>HepA</td>
<td>Liquid</td>
<td>1</td>
<td>105.00</td>
<td>Hepatitis A vaccine or adults</td>
</tr>
<tr>
<td>Hepatitis A child</td>
<td>HepA</td>
<td></td>
<td></td>
<td>105.00</td>
<td>Hepatitis A vaccine or children</td>
</tr>
<tr>
<td>Typhoid vaccine</td>
<td>Typhed</td>
<td>Liquid</td>
<td>2</td>
<td>2.00</td>
<td>Typhoid vaccine</td>
</tr>
<tr>
<td>Influenza A vaccine</td>
<td>FluaRix</td>
<td>Liquid</td>
<td>1</td>
<td>135.00</td>
<td>Seasonal flu vaccine</td>
</tr>
<tr>
<td>Meningococcal A/C/W/Y</td>
<td>MV_A/C/W/Y</td>
<td>Lyophilized</td>
<td>22.75</td>
<td></td>
<td>Meningococcal conjugate vaccine</td>
</tr>
<tr>
<td>Pneumococcal polysaccharide</td>
<td>PNEUMO 23</td>
<td>Liquid</td>
<td>1</td>
<td>105.00</td>
<td>Pneumococcal vaccine</td>
</tr>
<tr>
<td>Rabies vaccine</td>
<td>Rabies</td>
<td>Lyophilized</td>
<td>1</td>
<td>170.40</td>
<td>Rabies vaccine</td>
</tr>
<tr>
<td>Tetanus immunoglobulin</td>
<td></td>
<td>Lyophilized</td>
<td>1</td>
<td>33.40</td>
<td>Tetanus human serum</td>
</tr>
<tr>
<td>Rabies human immunoglobulin</td>
<td>Rabies</td>
<td></td>
<td></td>
<td>21.00</td>
<td>Rabies serum</td>
</tr>
<tr>
<td>Anti-Venom</td>
<td>FAVIREPT</td>
<td></td>
<td>10</td>
<td>60.00</td>
<td>Snake antivenum</td>
</tr>
</tbody>
</table>
Example/ The following table represents the monthly need of vaccines (including the backup balance) of a given PHCC:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polio</td>
<td>2500</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>450</td>
</tr>
<tr>
<td>Quadruple</td>
<td>1430</td>
</tr>
<tr>
<td>Measles</td>
<td>500</td>
</tr>
<tr>
<td>MMR</td>
<td>900</td>
</tr>
<tr>
<td>BCG</td>
<td>730</td>
</tr>
<tr>
<td>Pentavalent</td>
<td>700</td>
</tr>
<tr>
<td>Tetanus toxoid</td>
<td>450</td>
</tr>
<tr>
<td>Rotavirus vaccine</td>
<td>700</td>
</tr>
</tbody>
</table>

Calculating volume of all the vaccine is as follows:
From the table of vaccine doses volumes we can extract the volume of each vaccine doses and multiply it by the number of doses of each vaccine then combine volumes of all vaccines doses as illustrated in the following table:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Needed quantity in doses</th>
<th>Volume of each vaccine dose in cm³ (from the table)</th>
<th>Volume of each solvent dose in cm³ (from the table)</th>
<th>Volume of each vaccine dose in cm³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polio</td>
<td>2500</td>
<td>0.65</td>
<td></td>
<td>1625</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>450</td>
<td>3</td>
<td></td>
<td>1350</td>
</tr>
<tr>
<td>Quadruple</td>
<td>1430</td>
<td>13.2</td>
<td></td>
<td>18876</td>
</tr>
<tr>
<td>Measles</td>
<td>500</td>
<td>3</td>
<td>3</td>
<td>3000</td>
</tr>
<tr>
<td>MMR</td>
<td>900</td>
<td>3</td>
<td>3</td>
<td>5400</td>
</tr>
<tr>
<td>BCG</td>
<td>730</td>
<td>0.8</td>
<td>0.7</td>
<td>1095</td>
</tr>
<tr>
<td>Pentavalent</td>
<td>700</td>
<td>15.5</td>
<td></td>
<td>10850</td>
</tr>
<tr>
<td>Tetanus toxoid</td>
<td>450</td>
<td>3</td>
<td></td>
<td>1350</td>
</tr>
<tr>
<td>Rotavirus vaccine</td>
<td>700</td>
<td>85</td>
<td></td>
<td>59500</td>
</tr>
<tr>
<td>The total volume of all doses of vaccines in cm³</td>
<td></td>
<td></td>
<td></td>
<td>103046</td>
</tr>
</tbody>
</table>

The total volume of vaccines in that PHCC = 103046 cm³ which is equivalent to almost 104 liters.
Thus, this PHCC needs an ice lined refrigerator that has bigger capacity than the figure resulted from the calculations, and if we know that the refrigerator Model MK 304 capacity is more than 108 liters so one refrigerator of this model will be enough to accommodate the PHCC monthly need along with the backup balance.
Chapter Five

Vaccine Management
Vaccine needs assessment

The provision of sufficient quantities of vaccines for immunization sessions and campaigns is considered a major factor and an urgent need for the success of the immunization program, so making vaccines need assessment on annual basis is one of the pillars of the sustainability of the program, which in turn is based mainly on the knowledge and awareness of policy and plans set to achieve routine coverage, types and volumes of vaccines used, determine the size of the target group and find out how much stockpile available and calculate of backup quantities, taking into account the amount of wastage which is one of the important factors in assessing the need.

Using modern scientific methods and statistical data in calculating the need is the basis for accurate monthly and annual need of vaccines, taking into consideration any community events developed.
Factors affecting the needs assessment

1. Calculate the target population.
2. The number of doses required in the routine vaccination schedule.
3. Expected rates of coverage for each vaccine in the routine vaccination schedule.
4. Reserve balance rates needed.
5. Wastage factor of each vaccine.
6. Available (initial) balance

First: Target group

Accuracy in calculating the target group is a key factor for need assessment and coverage calculation, which is to be modified no annual basis, and there are factors that affect calculation of the target coverage like immigration and non-noticeable changes in birth rates.
Second: The number of doses required in the routine vaccination schedule
And is determined depending on the national vaccination schedule which shows the doses of each vaccine type to be given.

Third: Expected coverage rates for each vaccine
Coverage rate can be defined as the percentage of the number of people in a certain group who have been given a certain vaccine to the total population of that group. For example, polio vaccine coverage achieved for under-5 children can be calculated as follows:

\[
\text{Number of people vaccinated with polio vaccine in immunization activities (routine sessions or campaigns of which coverage is to be calculated) who are under–5 children} \times 100
\]

\[
\text{Total number of under–5 children}
\]

By calculating the vaccine coverage achieved we can know the following:
- Calculate population number of a certain group who have protection against communicable diseases out of the total population.
- Determine communities or areas where coverage is below the required level, then inspect reasons of low coverage there.
- Monitoring the coverage achieved in different periods of time contributes in assessing the effectiveness of immunization programs adopted and the progress made towards the desired goals.

While the the target coverage rates are the ratios Ministry of Health intends to achieve for each vaccine according to its strategic plans. It is important to achieve high rates of coverage and vaccinate the highest possible number of target groups because it means protecting them from communicable diseases, and most importantly, it eventually leads to protect everyone. When reaching high rates of coverage of a certain infection's vaccine, that infection cannot be endemic even if it appears again in the community, and it could be unable to affect the adequate number of people to spread.

Fourth: Backup Stockpile (safety stock):
Is the quantity of vaccine that can be used if the new batch of the vaccine was late or there has been a sudden growing demand for the vaccine (as happens in epidemic waves and emergency campaigns). Health facilities should keep a backup stocks of vaccine, which is usually 25% of the need of those facilities.
**Fifth: Vaccine usage and wastage**

Vaccine Wastage can be defined as the loss of the vaccine during use, expiry, breaks and others. Wastage can be known by calculating vaccine use rate which is the rate of actually used vaccines to the rate of vaccines supplied.

**Types of wastage**

- Wastage of unopened vials, and this happens at all levels of vaccine supply system (warehouses and transportation)
- Wastage of opened vials (opened to be used), it happens during and after the vaccination session as in the following table:

<table>
<thead>
<tr>
<th>Wastage of unopened vaccine vials</th>
<th>Wastage of opened vaccine vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiry</td>
<td>In addition to what mentioned in the right column:</td>
</tr>
<tr>
<td>Inner box and outer circle colors are matched (VVM).</td>
<td>Discard doses remnants at the end of the session.</td>
</tr>
<tr>
<td>Exposure to high temperature</td>
<td>Inability to withdraw the number of doses specified in the vaccine vial label.</td>
</tr>
<tr>
<td>Freezing.</td>
<td>Mixing the vaccine with the wrong amount of solvent or in a wrong way.</td>
</tr>
<tr>
<td>Breakage.</td>
<td>Opened vials submerged in water.</td>
</tr>
<tr>
<td>Damage of the vaccine label</td>
<td>Exposure to pollution</td>
</tr>
<tr>
<td>Theft.</td>
<td>Sudden movement of children, which may require re-vaccination.</td>
</tr>
</tbody>
</table>

- Valid vaccines should not be kept with those invalid in the cold chain; they should be quarantined until finalizing all due processes to be discarded.
Mechanism of calculating vaccine usage and wastage rates:

- **In vaccine warehouses** where there is open vials (i.e. vaccine stored in various storage levels: Main warehouses, District warehouses, PHCC pharmacy, wastage rates will be as follows)

  Number of damaged or wasted doses includes all doses in the unopened vials and damaged due to expiry, vaccine vial monitor, exposure to high temperature, breaking, freezing or theft. This equation is used to calculate wastage in vaccine warehouses and District drugstore.

- **In PHCCs**: and they are of two types (immunization session and PHCC)
  1. **In immunization sessions or campaigns**, wastage rate is calculated as follows:

  Number of doses wasted in a given period of time
  
  Vaccine wastage rate = \[
  \frac{\text{Number of damaged doses (wasted)}}{\text{Primary balance + the number of doses received}}\] \times 100

  2. **In the PHCC pharmacy** where the vaccine is stored before giving it to the immunization sessions in their refrigerators, wastage is calculated as follows:

  Number of valid doses + number of doses received - number of usable doses - number of doses used
  
  For use at the beginning of a period of time during that period in the balance at the end of the period in that period
  
  Vaccine wastage rate = \[
  \frac{\text{Number of valid doses + number of doses received} - \text{number of usable doses} - \text{number of doses used}}{\text{Number of valid doses + number of doses received}} \] \times 100

  Number of valid doses + number of doses received - number of usable doses for use at the beginning of a period of time during that period in the balance at the end of the period

  
  Vaccine usage rate = 100 - vaccine wastage rate (wastage rate of certain place, like vaccination session or PHCC pharmacy, should be calculated to extract the usage rate of the same place)
- **Wastage factor**: Wastage factor is used to predict the quantities of vaccine to be added to the actual need, specifically in the equation of needs assessment. It is calculated in a particular place through wastage or usage rates of that place in the cold chain, as follows:

  - **Wastage factor in immunization sessions**, as follows:

    | Wastage factor = | Total number of doses supplied by the pharmacy in a given period of time |
    |------------------|-------------------------------------------------------------------------------------------------|
    |                  | Total number of people vaccinated in that same period                                          |

  - **Wastage factor in the main and district warehouse or the PHCC pharmacy**. First, wastage rate is calculated through the equation (usage percentage = 100 - wastage percentage)

    | Wastage factor = | Percentage of vaccine usage |
    |-----------------|-----------------------------|
    |                 | Percentage of vaccine usage |
Now, some applied examples of calculating usage and wastage rates and wastage factor:

1. In the vaccine warehouse of a given district, the balance at the beginning of the month was 1000 doses of BCG, and more 500 doses were received from pharmacy department, and 40 doses damaged due to breaking, calculate wastage rate and wastage factor.

   **Answer:**

   Wastage rate = number of damaged doses / (primary balance + number of doses received) x 100 = 40 / (1000 + 500) x 100 = 40/1500 X 100 = **(2.67%)** is the wastage percentage

   Wastage factor = 100/ (100 - wastage rate) = 100 / (100-2.67) = 100 / 97.33 = (1.027) is the wastage factor

2. In a given PHCC, initial balance of the valid toxoid tetanus vaccine at the beginning of the month was 400 doses, and more 200 doses of the same vaccine were received, vaccination sessions were provided with 250 doses, usable doses at the end of the month were 350 doses, number of women vaccinated was 210, calculate wastage rate and wastage factor of the **PHCC pharmacy**

   **Answer:**

   Vaccine wastage rate = \[
   \frac{\text{Number of valid doses + number of doses received - number of usable doses - number of doses given}}{\text{For use at the beginning of the month during the month in the balance at the end of the month}} \times 100
   \]

   \[
   = \frac{(400 + 200-350-210)}{(400 + 200-350)} \times 100%
   \]

   \[
   = 40/250 \times 100\% = (16\%) \text{ is the percentage of waste}
   \]
Wastage factor = 100 / usage rate or 100 / (100 - wastage rate) and apply the first law
= 84/100 = 1.19 is the wastage factor.

Wastage factor varies from vaccine to another as it is bigger with the vaccines of multiple doses or those discarded after 6 hours of being dissolved, and in the one–dose vaccines to a lesser extent.

Fifth: Available Balance
It is necessary to calculate and know the available balance of each vaccine type at all levels of usage and storage, and adopt it in the need assessment process before requesting any more quantities of the vaccine.
Needs Assessment process:
As we already mentioned, predicting the vaccine needed quantity requires knowing the number of target population, target coverage, supply scheduling and wastage factor. There are several ways universally adopted in assessing the need for the vaccine, such as estimation depending on the consumed quantity in the past few years, or depending on the number of vaccine sessions. And the most appropriate way to calculate the vaccine is to depend on the target group size according to the following equation that determines the monthly need for the PHCCs:

\[
\text{Actual need} = \text{monthly need} - \text{the remaining balance}
\]

To calculate the monthly need, apply the following equation:

\[
\text{Monthly need} = (\text{number of monthly targeted group} \times \text{desired coverage rate} \times \text{number of doses of each vaccine of the vaccination schedule} \times \text{wastage factor}) + \text{backup balance} - \text{remaining balance}
\]

- Monthly need: It is the needed quantity of each type of vaccines in monthly doses. In the case of annual need, calculate the target group of one year.
- Number of target group: The total population \(\times\) percentage of annual of births
- Coverage rate required According to the annual plans (which are 95\% for each vaccine except for the rotavirus vaccine 80\% and tetanus toxoid 85\%)
- Number of doses of each vaccine in the vaccination schedule: It is based on the national vaccination schedule.
- Wastage factor: Already discussed.
- Backup balance: Represents 25\% of the actual need for a certain period, as minimum for PHCCs. As for the districts and branch warehouses, it is determined according to the storage capacity and number of receipts provided that it is no less than 25\% of the actual need.
- The remaining balance of is a specific vaccine that was available in the warehouse in the beginning when need assessment is conducted.
Merits of this method are as follows:

1. Facilitates effective and precise planning for vaccine need.
2. Helps in monitoring vaccine wastage rates over time.

Example: Calculate the monthly need for vaccines in a PHCC, noting that the number of population it serves 30,000, assuming that:
The annual percentage rate of births is 3.7%
The desired coverage rate for all vaccines is 95%
Number of doses for each targeted in the national vaccination schedule, wastage factor, remaining balance of each vaccine at the end of the month, number of doses for each vaccine vials is as follows:

<table>
<thead>
<tr>
<th>#</th>
<th>Vaccine</th>
<th>The number of doses for each target in the national vaccination schedule</th>
<th>The number of doses per vial</th>
<th>Suppose wastage factor</th>
<th>Coverage rate required</th>
<th>The remaining balance of each vaccine type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Polio vaccine</td>
<td>6</td>
<td>20</td>
<td>1.3</td>
<td>95%</td>
<td>400</td>
</tr>
<tr>
<td></td>
<td>Quadruple vaccine</td>
<td>2</td>
<td>10</td>
<td>1.3</td>
<td>95%</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>Pentavalent vaccine</td>
<td>2</td>
<td>One dose</td>
<td>1.05</td>
<td>95%</td>
<td>232</td>
</tr>
</tbody>
</table>

Steps of solution/

1. We calculate the number of target group as follows:
The number of the target group annually = population x percentage of annual births.
   = 30000 x 3.7% = 1110 is the size of the target group annually.
   Number of target group per month = 1110/12 = 93

2. Required coverage rate must be known, we notice here that coverage required for each vaccine as in the example is 95%.

3. Wastage factor of each vaccine type must be identified (as previously mentioned in wastage section). In the example is supposed stated in the table above.

4. Backup balance is 25% of the need for each period of time (month or year).

5. Remaining balance of each vaccine in the warehouse should be known to be subtracted from the monthly need later.
Then we start applying the equation of need assessment for each vaccine type separately:

- **Actual need of polio vaccine** = \((\text{number of monthly targeted group} \times \text{desired coverage rate} \times \text{number of doses of each vaccine of the vaccination schedule} \times \text{wastage factor}) + \text{backup balance} - \text{remaining balance})\).

\[
\begin{align*}
= & \left(93 \times 95\% \times 6 \times 1.3 \right) + 25\% \left(93 \times 95\% \times 6 \times 1.3\right) - 400 \\
= & 689 + 172 - 400 \\
= & 689 + 172 - 400 \\
= & 860 - 400 \\
= & 461 \text{ dose, i.e. } 460 \text{ dose, representing the need of the next month for polio vaccine in the PHCC of the example above.}
\end{align*}
\]

- **Quadruple vaccine need**

\[
\begin{align*}
= & \left(93 \times 95\% \times 2 \times 1.3 \right) + 25\% \left(93 \times 95\% \times 2 \times 1.3\right) - 200 \\
= & 230 + 58 - 200 \\
= & 288 - 200 \\
= & 88 \text{ dose, i.e. } 90 \text{ dose, representing the need of the next month for quadruple vaccine in the PHCC of the example above.}
\end{align*}
\]

- **Pentavalent vaccine need**

\[
\begin{align*}
= & \left(93 \times 95\% \times 2 \times 1.05 \right) + 25\% \left(93 \times 95\% \times 2 \times 1.05\right) - 232 \\
= & 186 + 46 - 232 \\
= & 232 - 232 \\
= & 0 \text{ dose, meaning that the balance available of pentavalent vaccine in the PHCC covers the monthly need with a backup balance, thus it is not requested for the next month.}
\end{align*}
\]

Then a monthly schedule of needs should be prepared as follows:

<table>
<thead>
<tr>
<th>#</th>
<th>Vaccine</th>
<th>Monthly need in doses:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Polio vaccine</td>
<td>460</td>
</tr>
<tr>
<td>2</td>
<td>Quadruple vaccine</td>
<td>90</td>
</tr>
<tr>
<td>3</td>
<td>Pentavalent vaccine</td>
<td>Zero</td>
</tr>
</tbody>
</table>
It is preferable to provide the vaccine supplier warehouse with the remaining balances for organizational purposes, so the PHCC order for the example above will be as follows:

**PHCC "S"
Monthly target group 93**

<table>
<thead>
<tr>
<th>#</th>
<th>Vaccine</th>
<th>Monthly need with the backup balance</th>
<th>The remaining balance of each vaccine type</th>
<th>Required quantity/doses</th>
<th>Quantity supplied</th>
<th>Notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Polio vaccine</td>
<td>860</td>
<td>400</td>
<td>460</td>
<td>460</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quadruple vaccine</td>
<td>288</td>
<td>200</td>
<td>90</td>
<td>50</td>
<td>Shortage in the warehouse at present</td>
</tr>
<tr>
<td></td>
<td>Pentavalent vaccine</td>
<td>232</td>
<td>232</td>
<td>Zero</td>
<td>Zero</td>
<td></td>
</tr>
</tbody>
</table>

- The field of quantity supplied and comments is for the immunization official at the District or the DoH in consultation with the vaccines storekeeper.
Number of receipts during the year or month (supply scheduling)

Determining the number of receipts to be adopted at each level and is determined depending on:
- Availability of transportation equipment and its storage capacity
- Storage capacity available in the health facility
- Quality and consistency of power supply

And the following table identifies the ideal supply periods for the vaccine according to the different levels:

<table>
<thead>
<tr>
<th>Level</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>National vaccine warehouse</td>
<td>6 months</td>
</tr>
<tr>
<td>DoH warehouse</td>
<td>3 months</td>
</tr>
<tr>
<td>District warehouse</td>
<td>1 month</td>
</tr>
<tr>
<td>PHCC warehouse</td>
<td>1 month</td>
</tr>
<tr>
<td>PHC sub-clinic or health houses</td>
<td>1 week</td>
</tr>
</tbody>
</table>
Stock Management

One of the important considerations in vaccine management is stock management at each of vaccine storage levels. Access to the vaccine stocks must be exclusive to the authorized staffs who are trained on how to handle and move the vaccines to keep them effective all the time.

To ensure the effective management of the stocks the immunization official at the PHCC should know:

1. Quantities and types of vaccines and solvents received.
2. Quantities and types of vaccines and solvents dispensed, wasted, and damaged.
3. Quantities and types of vaccines and solvents currently available in the warehouse.
4. Which vaccines and solvents must be used first.
5. Which vaccines and solvents were expired and must be taken away from the rest of stocks.
6. Quantities and types of vaccines and solvents that must be requested.

The weekly inventory form is used in the PHCCs. It includes quantities of available vaccines, expiry dates, batch numbers and receipt date. It aims to:

- Control the vaccine stocks in the refrigerator, and particularly the arrangement of vaccines in a way that ensures dispensing the first to expire vaccines first.
- Follow-up vaccines expiry dates and batch numbers of the stocks.
- Facilitate refrigerator maintenance and sustainable cleanliness by arranging the vaccines.

(Sample) form of stocks in the vaccine refrigerator

<table>
<thead>
<tr>
<th>#</th>
<th>Vaccine</th>
<th>Quantity</th>
<th>Expire date</th>
<th>Patch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BCG</td>
<td>100</td>
<td>10/2/2014</td>
<td>T56544</td>
</tr>
<tr>
<td></td>
<td>BCG</td>
<td>200</td>
<td>10/5/2014</td>
<td>6566j</td>
</tr>
<tr>
<td>2</td>
<td>Measles</td>
<td>300</td>
<td>20/8/2014</td>
<td>5478</td>
</tr>
<tr>
<td>3</td>
<td>MMR</td>
<td>400</td>
<td>22/4/2014</td>
<td>U4557</td>
</tr>
<tr>
<td></td>
<td>MMR</td>
<td>1000</td>
<td>15/10/2014</td>
<td>U4558</td>
</tr>
<tr>
<td>4</td>
<td>Measles solvent</td>
<td>300</td>
<td>5/12/2015</td>
<td>H5684</td>
</tr>
<tr>
<td></td>
<td>Etc...</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Note:** The from must be inventoried and updated at least on weekly basis, and fixed above the vaccine refrigerator or in a visible place on top of the refrigerator.

To organize vaccine orders, the responsible staff must determine the backup balance quantity (safety balance), re-request balance and the maximum quantity that can be stored in the health facility for each vaccine.

- **Maximum balance that can be stored in the health facility:** The maximum number of doses of a given vaccine the health facility can store based on the storage capacity available.
- **Re-demand balance:** This level represents the balance at which there should start a vaccine order to avoid using the backup balance. And here the period of time between the request preparation and receipt should be taken into account.

The figure below shows the relationship between the backup balance and the re-request level and the maximum possible storage on one hand and scheduling supply time on the other hand:

- The level of backup balance represents 25% of the need for the supply scheduling duration which is usually one months for PHCCs.
- Numbers in the figure above are only illustrative examples. Level of the backup balance, re-request balance and the maximum balance that can be stored from one facility to another.
- Re-request balance will be explained (re-request level) in the next example.
In a given PHCC the maximum balance of the polio vaccine was determined by the immunization official to be 1250 doses based on the monthly need and storage capacity in the same PHCC. which is 1000 doses of actual need and 250 doses of backup balance (25%), the vaccine's daily dispense was 40 doses per day, and the required period of time starting from preparing the order papers and obtaining the approvals until the receipt is 3 days for example.

What is the re-request level of vaccine at which the regular need of vaccine shall be requested?

Answer/ steps are as follows:

1. In any case, backup balance level should be maintained, which is 250 doses in the example above throughout the year. And not to be used only in emergency situations (emergency campaigns, epidemiological wave ... etc.).
2. The period required for the organization of the order is 3 days as mentioned as an example and it may be different from one facility to another.
3. Provide balance adequate for 3 days during which there are vaccination sessions that give 40 doses a day, meaning 40 x 3 = 120 doses.
4. Add the result of step 3 to the backup balance and the outcome will be as follows: 120 + 250 = 370 doses is the balance level at which the vaccine order must be started. If the data are as mentioned in the example.

Notes:

❖ Numbers in the example above are just examples to illustrate the process and they vary from one facility to another.
❖ Order days may coincide with an official holiday, so it must be taken into account not to calculate the required quantity for that day, and the outcome for the example above will be 2 x 40 = 80 doses of vaccine, combined with the balance (250) dose to be = 330 doses.
❖ Process above belongs to the routine order of the vaccine, it is not used in the national and emergency campaigns.
❖ Backup stock should be circulated with farther expiry date batches. And newly received too.
❖ Supply scheduling varies from one facility to another depending on the availability of transportation, storage capacity, and dispense of vaccine in each health facility.
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Revision Committee:

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