UNIT 7: **IMMUNIZATION PROGRAMME MANAGEMENT, MONITORING AND EVALUATION**

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27. Monitor vaccine use by interpreting Vaccine Vial Monitor and applying the Multi-Dose Vial Policy during immunization sessions.
28. Monitor and reduce the vaccine wastage.
29. **COLD CHAIN AND VACCINE MANAGEMENT**

**Definition.**

* Cold chain is a process of maintaining vaccines in a potent state from the manufacturer to the recipient (child and woman of child bearing age).
* Vaccines lose their potency when exposed to high temperature, sunlight or freezing conditions depending on the type.

**Cold chain system**

* Is a system of ensuring potency and safety of vaccines from the manufacturer to the point of use?
* Entails the supplies of vaccine travel in a cold chain linking from the **manufacturer** to the **central vaccine store** and eventually to the recipient through the **regional** and **countyvaccine depots and finally to the immunizing health facility.**
* An efficient cold chain system requires trained and skilled staff, reliable equipment and adherence to set standards.

**Cold chain equipment**

* The equipments used in maintaining cold chain must meet standards set by the WHO and UNICEF for safe vaccine storage. They vary depending on the level of use. The cold chain equipments currently used in Kenya include:

1. \*Cold rooms and freezer rooms
2. \*Freezer and ice-lined refrigerators
3. \*Gas electric refrigerators
4. \*Solar refrigerators
5. \*Vaccine carriers
6. \*Cold boxes
7. \*Ice packs
8. \*Thermometers
9. **COLD ROOMS AND FREEZER ROOMS**

* Are large rooms, specially constructed for storage of all large quantities of vaccines?
* They have two (2) cooling units; one running while the other one is standby, a 24-hour temperature monitoring system with an alarm, a recorder and a backup generator that turns on automatically when the regular power is interrupted.
* Cold rooms are found at the national and regional levels while freezer rooms are only found at the national level.

1. **Freezers/Ice-lined Refrigerators**

* Are used at Central, Regional and County stores.
* They are used for large storage of antigens and freezing of icepacks at the central, regional, county and sub-county levels.

1. **Gas Electric Refrigerators**

* There are currently 3 major types of gas electric refrigerators used in the country, namely: **Sibir 170GE**, **RCW42EG** and **RCW50EG.**
* **Sibir 170GE**
* Vaccines are placed in shelves in order of sensitivity with the most sensitive to heat (OPV) being on the first shelf below the evaporator (top most shelf/tray).
* TT and Pentavalent being the most sensitive to freezing are placed on the second last shelf from the bottom (since icepacks in the freezing compartment are put at the topmost part of the refrigerator.)
* Vaccines are packed leaving a space of about 5cm in between the packets for air circulation.
* The upper cabinet is used for freezing of icepacks.
* This fridge is used in the county vaccine store and at the immunizing facilities with high target population.

**Diagram 1: Packed upright vaccines in a Sibir 170GE refrigerator**

|  |
| --- |
| ICEPACKS IN THE FREEZING COMPARTMENT (Upper Cabinet) |
| OPV AND MEASLES ON THE TOP TRAY |
| BCG |
| TT, PENTAVALENT AND PNEUMOCOCCAL |
| ICEPACKS |

* **RCW42EG**
* The refrigerator is designed for use at the service delivery point.
* It is operated either on electricity or gas and has top opening door.
* Trays of different colors are used to store each type of vaccine.
* The most sensitive to heat being oral polio vaccine is kept in blue tray that is placed at the bottom most part of the fridge while most sensitive to freezing being Pentavalent is kept in the red tray which is the top tray.
* A sticker is pasted on the front side of the refrigerator to guide on the vaccine arrangement and the arrangement order must be observed at all times.

**Diagram 2: Arrangement of vaccines in RCW42EG**

|  |  |  |
| --- | --- | --- |
| **TRAY COLOUR** | **POSITION** | **VACCINE** |
| Purple | Top | Pneumococcal |
| Red | Second | Pentavalent |
| Orange | Third | Tetanus Toxoid |
| Yellow | Fourth | BCG |
| Green | Fifth | Measles/Yellow fev |
| Blue | Bottom | Polio |

* **RCW50EG**
* This is similar to RCW42EG but has a double vaccine capacity.
* It is suitable for use at places with higher target population or sub county depots.
* It also has higher fuel consumption.

1. **Solar Refrigerator**

* Used in areas with high sun intensity.
* Sun rays are converted into electric energy which is then used to supply the refrigerator.
* Are suitable for use at service delivery points.
* Arrangement of vaccines is similar to RCW.

1. **Vaccine carriers**

* Are used to transport vaccines from county stores to service delivery points (outreach/mobile) and during immunization sessions.
* The cold life in a vaccine carrier is approximately 8 hours.

1. **Cold Boxes**

* Are normally used for transportation of vaccines. They can also be used for temporary storage when a refrigerator breaks down.
* The cold life of a cold box varies depending on the type, the number of openings and the ambient temperature.

1. **Icepacks**

* Are flat rectangular plastic containers filled with water or gel?
* They are used in vaccine carriers, cold boxes or refrigerators to maintain temperatures.
* Always have atleast an extra set of icepacks as a reserve while one set is in use.

1. **Thermometers**

* Different types of thermometers are used to monitor the cold chain temperature.
* These are the dial and alcohol thermometers.
* They indicate the safe operating ranges of temperatures of between +2 degrees C to +8 degrees C for the refrigerators and -15 degrees C to -25 degrees C for freezers.

**HEALTH WORKERS TASKS FOR COLD CHAIN MANAGEMENT**

* These includes following the basic principle of refrigeration and preventive maintenance activities.They include:
* Check temperature twice, in the morning and the evening including public holidays and weekends and chart on the temperature-monitoring chart. Ensure the temperature is between +2 and +8 degrees C.
* Check that the refrigerator is operating.
* Make sure that there is enough gas in the cylinder. Health workers should know how long a cylinder takes when running continuously.
* Ensure that vaccines are well arranged in the refrigerator.
* DO NOT keep any other item in the refrigerator apart from vaccines and diluents.
* Check the ice formation on the evaporator.
* If the ice is thicker than 6mm to 10mm, defrost the refrigerator.
* Check that the refrigerator is level.
* Check that the condenser and the cooling unit are clean.
* Remove any dirt or dust with soft brush or cloth.
* When necessary, clean inside and outside the refrigerator with a damp cloth.
* Clean door gasket and powder it with perfume free talcum
* If solar refrigerator:
* Gently wash the panels with plenty of water and soft cloth, avoid use of detergents.
* Check battery acid level and top up with distilled water when necessary.
* Check battery terminal for tightness and corrosion, lubricate with battery terminal jelly or petroleum jelly.

**WHAT TO DO IF THE REFRIGERATOR IS NOT WORKING PROPERLY**

The refrigerator is not working properly if any of the following happens:

* The refrigerator is not cooling at all
* The refrigerator is not cold enough, above +8 degrees C
* The refrigerator is too cold below +2 degrees C.
* **What to do:**Ensure that all vaccines are transferred into a vaccine carrier or cold box before determining the fault.
* Always start with the first possible fault e.g door sealing (faulty/loose hinges).
* Make sure that a fault does not exist before going to the next one.
* If after checking all the possible faults, the refrigerator is still not working properly, start at the beginning and check everything again.
* If after checking all the possible faults, the refrigerator is not working properly, refer to the county for further action by a trained technician.

**COLD CHAIN EMERGENCIES**

* Emergencies can interrupt immunization services if not planned for.
* Some of the common cold chain emergencies include:

1. Equipment breakdown
2. Electric power failure
3. Shortage of gas
4. Shortage of spare parts

* There should be a warning system for identifying equipments failure and make arrangements in advance for moving vaccines to the nearest health facility or location that has appropriate substitute equipment.
* The county should be notified as soon as possible of such failure.

1. **\*ORDERING VACCINES**

* Steps in ordering vaccines include:

1. Vaccine target setting
2. Defining vaccine supply period
3. Calculating quantities of vaccine for a supply period
4. Calculating the minimum stock level
5. Calculating the maximum stock level
6. Calculating total quantities of vaccine to be ordered.

**Advantages of ordering vaccines**

1. Prevent vaccine stock outs and overstocking
2. Prevent expiry of vaccines during their storage period
3. Ensures that the other appropriate supplies are “bundled” i.e safety boxes, syringes and needles. This implies that none of the components can be considered alone, each component must be considered as part of a bundle that contains the other two. Bundling does not mean that the three items must be packaged together but should be supplied/brought together.

N/B: Remember, long storage periods risk the expiration of vaccines.

1. **Defining vaccine supply period**

After calculating the annual vaccine needs, taking into account the storage capacity and the period of time during which the vaccines will be stored at each specific level. Defining periods of vaccine supply depend on:

* The level operational (county, health facility)
* Status of the cold chain
* Storage space

E.g, a health facility will have a shorter period of vaccine supply (one month) than the county store (three month), where the cold chain is more reliable.

* Avoid overstocking vaccines as this may result in longer storage period which could lead to expiry of vaccines.
* **Calculating the quantities of vaccine for a supply period:**
* The needs for a specific storage or supply period can be calculated as follows:

Vaccines needs for the period= Annual vaccine needs X Supply period (in months)

Number of months in year

Example: The annual BCG vaccine needs for the Kakamega PGH is 18,620 doses. Calculate the vaccines needs for the month of January.

* 18,620 X 1= 1,552 doses

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* **Calculating the minimum stock level**
* The “minimum stock” represents the minimum number of vaccine doses that should be in the refrigerator on the arrival of the next supply consignment. The level of minimum stock is generally fixed at 25% of the total estimate of vaccines needs for a given supply period.
* **Formula is:Minimum stock = Vaccines needs for the period X 25%**
* **Example:** If the BCG vaccines needs for the Kakamega PGH per month is 1,552 doses, calculate the minimum stock:

**Minimum stock = 1,552 X 25/100 =388 doses per month.**

* **Calculating the maximum stock level**
* The maximum stock is the number of vaccine doses that should be found in the refrigerator after a supply.
* Formula is: **Maximum stock = Vaccine needs for the period + Minimum stock**
* **Example:** If the BCG vaccine need per month is 1,552 doses, and the minimum stock is 388 doses, then the maximum stock is:

**1,552 + 388 = 1,164 doses.**

* **Calculating total quantities of vaccine to be ordered**
* Once the order levels are determined, the vaccine quantities to be ordered are calculated on the basis of the balance in stock at hand and the maximum stock.
* The order may be based either on specific supply period (quarterly for counties and monthly for health facilities) irrespective of consumption.
* A stock shortage may occur before the period. It is therefore recommended that an order be placed as soon as the stock of a vaccine reaches the point where an order should be placed.
* **General formula is:**

**Quantity to order = Maximum stock – Stock at hand**

**Example:** The current stock at hand of BCG vaccine at Kakamega PGH is 280 doses. If the maximum stock per month is 1,164 doses, calculate the quantity to order.

* 1,164- 280 =884 doses should be ordered regardless of the period.

**CONTROLLING VACCINE STOCKS**

* The control of vaccine stocks is one of the main tasks of vaccines management. It consists of receiving and accepting vaccines, ensuring the required storing conditions and controlling the distribution of vaccines at all levels (national, regional, and county and health facility) in order to ensure the quality of vaccines for immunization services.

**Receiving Delivered Vaccines and Supplies**

* Vaccines are ordered from the manufacturers once a year and delivered every 3 months. They are later distributed to the regional stores for the County Vaccine Manager to order for their respective health facilities.
* At the county stores usually situated at the county hospital, the staff at the county vaccine store monitor the vaccines in the stores, receive and issue them to the immunizing health facilities within the county.
* The immunizing health facilities receive vaccines from the county vaccine stores and in case of stock out at the facility, they are supposed to collect the vaccines from the county.
* During vaccine delivery at all levels, check for opened and/or damaged packaging, especially where syringes and needles are concerned. Check and compare quantity on the S 11 form with actual ones.
* The S 11 must be signed with all the consistencies recorded. All the inconsistencies must be brought to the attention of the supervisor and the supplier for replacement if necessary.

**Storage, transport and handling of vaccines**

* Vaccines are delicate biological products that lose their effectiveness when they are exposed to incorrect temperatures. Once vaccine effectiveness is lost through heat exposure, it is not possible to restore even if the vaccine is later stored at the required temperatures.
* **Table 1: Vaccine Storage Conditions**

|  |  |  |
| --- | --- | --- |
| VACCINES | NATIONAL AND SUB NATIONAL | PERIPHERAL UP TO 1 MONTH |
| OPV, YF | -15 to -25 | +2 to +8 |
| MEASLES, BCG | +2 to +8 | +2 to +8 |
| PENTA, PCV, TT, Hep B. | +2 to +8 | +2 to +8 |
| DILUENT | Room temp | Room temp. Cool to same temp as vaccine a day before use. |

**Arranging the vaccines in the refrigerator**

* Vaccines should be arranged in such a way as to facilitate air circulation and the reading of their identification and the expiry date.
* Vaccines whose expiry date is close must be used first (First Expired, First Out- FEFO principle). Vaccines whose expiry dates have passed should not be preserved.
* Opened and partially used vials of vaccines that satisfy Multi Dose Vial Policy requirements brought back from an immunization session should be marked and arranged separately to be used first in the next session.
* The refrigerator with vaccines should only be opened in case of necessity. Leaving the refrigerator open for too long must be avoided by all means.
* The arrangement of vaccines in the refrigerator should follow the general storage guidelines given by the county and the sensitivity of vaccines to heat.

**Tools used for vaccine management**

1. **Vaccine order sheet**

* Is a useful tool that helps in ensuring that the min/max stocking policy is adhered to by the health facility placing the orders for vaccines?
* It **should have the following**
* Number of children immunized
* Minimum and maximum stock
* Available stock
* Ordered vaccines

1. **Issue Voucher (S 11)**

* Is a government requisition form which should be issued in two copies (duplicate)?
* The original will be recorded and filled by the vaccine store manager. The copy will be for the facility serve as acknowledgement receipt of the vaccines and other supplies.

1. **Vaccine stock ledgers**

* Is a vaccine management tool used in the store for recording vaccine movements to or from the refrigerator? They should be kept with the vaccines on the same premises. Every vaccine transaction should be recorded thus: received, issued and returned on individual row.

1. **Vaccine physical stock taking**

* Means a total count of quantities of vaccines in stock.
* The physical stock should cover all vaccines stores and should be carried out every month before ordering the supply.
* The stocks balance should be adjusted according to the physical stocks done.
* If the actual quantity is more than the theoretical stock, the difference should be recorded in the vaccine stock ledger and the remarks written as “extra doses”.
* If the actual quantity is less than the theoretical stock, the difference should be recorded under as remarks written as “missing doses”.

**MONITORING THE VACCINE USE: (**MULTIDOSE VIAL POLICY, SHAKE TEST TECHNIQUE AND VACCINE VIAL MONITORS.)

**MULTIDOSE VIAL POLICY**

* An opened Multi-Dose Vial is a vial containing several doses of vaccine from which one or more doses have been taken.
* Initially, any vial opened during an immunization session could be thrown away after the session, irrespective of the type of vaccine and the number of doses remaining.
* To ensure the optimal use of vaccines, WHO and UNICEF issued the directives authorizing the re-use of opened multidose vials of some of the liquid vaccines e.g polio, Pentavalent and TT under certain conditions.
* Reconstituted vaccines (BCG, measles, yellow fever, Hepatitis B and liquid PCV10 are not included in these directives.
* Therefore, the MDVP determines which of the opened vaccine vials may be preserved at the end of an immunization session and used the following days and the conditions under which these vaccines may be stored and re-used without any risk. The MDVP applies only to liquid vaccines ( OPV, liquid Pentavalent and TT)
* In the case of freeze-dried vaccines (BCG, measles, Hib and yellow fever), once they are reconstituted must be discarded after 6 hours or end of immunization session whichever comes first.

**WHO’s REVISED MDVP ON LIQUID VACCINES**

* The vaccine may be preserved and used for subsequent immunization session up to 4 weeks if all the following conditions are met:
* The expiry date has not passed
* The vaccines are stored under appropriate cold chain conditions at all times
* The vaccine vial has not been submerged in water
* Sterile technique has been used to withdraw all doses and
* The VVM if attached has not reached the discard point.

**SHAKE TEST TECHNIQUE**

* This is a test used for testing suspected frozen vaccine vials.
* By shaking the vial, it can be easily established whether vaccines TT, DPT, DT, PCV and Pentavalent are frozen or not.
* When any of these vaccines is suspected to be frozen, it is recommended to apply a shake test as follows:

1. Take a vial you think may be frozen (Test sample)
2. Select another vial of the same type of vaccine that you know has not been frozen (control sample)
3. Hold in one hand and shake vigorously for 10-15 seconds.
4. Allow to stand and leave both vials to rest for 15-30 minutes without touching.
5. Compare both vials against the light to see the sedimentation rate.

**Results**

* If the test sample shows a much slower sedimentation rate same as the control sample, the test sample has not been frozen.
* If the sedimentation rate is faster and a thick sediment forms at the bottom of the vials, the test sample has been damaged by freezing. The supervisor should be notified.

**VACCINE VIAL MONITORS**

* A VVM is a label with a heat-sensitive material, which is placed on a vaccine vial to register cumulative heat exposure over time. The **inner square** is made of heat sensitive material, which is lighter in colour than the outer circle at starting point and becomes **darker with exposure to heat.**
* The combined effects of time and temperature cause the monitor to change colour gradually and irreversibly. A direct relationship exists between the rate of colour change and temperature exposure. As the vial is exposed to more heat, the monitor changes colour more rapidly. After a sufficient amount of heat exposure has occurred, the colour of the monitor will signal that the vaccine in the vial has been exposed to too much heat and is no longer usable. In this case the vial should be discarded.
* Before opening the vial, the status of the vial should be checked to see whether the vaccine has been damaged by heat.

1. **MONITORING THE VACCINE WASTAGE**

* The monitoring of the use of vaccines ensures the quality of immunization services and keeps the vaccine wastage under control.

**Goals of Vaccine Monitoring**

1. To detect management problems and find appropriate solutions during vaccine use.
2. To contribute to the planning by providing data on vaccines needs and vaccines wastage rates.

**Vaccine Wastage**

* Can be categorized into two types, namely:

1. **Wasted Doses**

* The wasted doses are those in unopened vials that have been lost before they could be administered for various reasons:
* Vaccines with expired date
* Damaged vaccines due to freezing
* Doses that have been lost during the administration of vaccines due to lack of skill or knowledge of the vaccinator (overdose, multi-dose vials that are thrown away by either mistake or non-adherance to multidose vial policy)
* Vaccine in vials with Vaccine Vial Monitor (VVM) at discard point or showing excess exposure to heat.

1. **Sacrificed Doses**

* Are the doses of vaccines that have been lost deliberately for the sake of the immunization to take place, thus sacrificed vaccines are:
* The vials containing reconstituted vaccines that have been thrown away at the end of the immunization session in line with the MDVP.
* The vaccines doses that have been administered to persons outside the target population.

**Vaccine Monitoring Indicators: Vaccine Wastage and Use Rates**

* Vaccine management should focus on avoiding losses and minimizing sacrificed doses. This can be achieved only when the use of vaccines is efficiently monitored.

**Vaccine Wastage Rate**

* Represents the quantity of vaccine taken out of the stocks, but not administered to the target population. It is the total amount of wasted and sacrificed doses.
* Vaccine wastage can involve wastage of doses in unopened vials (wastage due to the system) or wastage of doses in opened vials incurred when administering vaccines.
* Differentiation between the various types of wastage rates allows the health worker to take appropriate corrective measures to minimize loss of vaccines and increase and increase the efficiency in immunization session.

**Wastage of Doses in unopened Vials (Wastage due to the system)**

* This wastage depends on the management of, storage and handling conditions of vaccines. The wastage caused by the system is the wastage of doses in **unopened vials.** The causes of such wastages can be due to any of the following:
* Failure of the cold chain: VVM reached discard point, frozen DPT or TT.
* Poor handling: Expired vaccines while in storage, vials without labels, missing as stated by the inventory.
* Accidents: breakages.

**CALCULATIONS OF WASTAGE RATES (ADMINISTERED OR SYSTEMS)**

1. **Wastage (administered) = Used doses – Administered dosesX 100**

**Used doses**

**NOTE:**

* Used doses = Total quantity of doses contained in all the vials opened during the immunization. For each vaccine, the quantity of used dose is equal to the sum of the products of the number of vials and the number of doses in each vial.
* Administered doses = Doses which have been effectively administered to the target population.

**Example:**Kakamega PGH had 200 doses of BCG vaccine in the month of January 2015 and immunized 150 children under one year of age. Calculate the vaccine wastage rate for Kakamega PGH.

Wastage Rate (administered) = Used Doses – Administered dosesX 100

Used doses

= 200 – 150 X100

200

50X 100 = 25%, therefore the wastage rate is 25%

100

N/B: The formula used to calculate the vaccine wastage rate in unopened vials i.e wastage caused by the system is:

Wastage (systems) = Issued doses- used doses X 100.

Issued doses

**Note:**

Issued doses = Total quantity of doses issued from the stock of vaccines. For each vaccine, the quantity of issued doses is equal to the difference between the available quantity of doses of vaccines and the quantity of doses of vaccines at the end of the period.

Used doses= Total quantity of doses contained in all opened vials opened during the immunization.

* The overall wastage is the sum of the wastage due to the system and wastage incurred when administering vaccines.

**DOCUMENTING VACCINE WASTAGE**

* All immunizing facilities should document their vaccine wastage per vaccine. The tool for documenting vaccine wastage in each health facility is the monthly report section B of the EPI immunization and Vitamin A summary sheet. (MOH 710)

**IMMUNISATION SAFETY**

1. **VACCINE DILUENTS**

* Include water, aqueous buffer (e.g buffered saline), alcohols and polyols (e.g glycerol). Vaccines marketed as suspensions or solutions already have the diluent constituted onto the vaccine. Some diluents are provided separately from the lyophilized (freeze-dried) vaccine for reconstitution at the time of use.
* Lyophilized vaccines should only be reconstituted with the diluent provided for this purpose by the manufacturer because diluents are specifically constituted to compliment the particular vaccine in terms of pH and other buffering effects.
* There are no ‘general diluents’ and using a different diluent for a given vaccine may compromise the efficacy of vaccine.

1. **SAFE INJECTION PRACTICES**

* A safe injection is one which does not harm the recipient, nor expose the health worker and the community to any risk.
* An injection is considered safe for:
* The **mother or child**, when a health worker uses a sterile syringe and a sterile needle and appropriate injection technique.
* The **health worker**, when he or she avoids needle-stick injuries
* **Community**, when waste created as a result of used injection equipment is disposed-off correctly and does not cause harmful levels of pollution and injuries.
* An unsafe injection is one that can result in transmission from one patient to another such infectious complications as HIV/AIDS, Hepatitis B and C, and malaria. Transmission from patient to health worker has also been reported in some health care settings.

**COMMON INJECTION PRACTICES THAT CAN CAUSE HARM TO THE RECIPIENT**

* Re-using a syringe or needle
* Changing needle but re-using syringe.
* Loading syringe with multiple vaccines (antigens) and injecting multiple persons.
* Leaving needle on the vial for withdrawal of additional doses
* Touching sterile parts of syringes and needle.
* Applying pressure to bleeding injection site with used materials or dirty fingers
* Keeping freeze-dried vaccines for more than 6 hours after reconstitution.
* Mixing two partially opened vaccines to constitute a dose
* Storing medications and vaccines in the same fridge

**PRACTICES THAT CAN HARM HEALTH WORKER**

* Recapping
* Placing used needles on surfaces or carrying them from point of use for disposal at a designated area.
* Sorting out mixed health care wastes
* Using injection equipment for non-injection purposes.

**PRACTICES THAT HARM THE COMMUNITY**

* Leaving used syringes and needles in unprotected areas where they can be easily accessible to children and grazing animals.
* Community can also be at risk when injection equipment is carelessly disposed-off and because of its commercial value, it can be retrieved, resold and reused.

**STEPS AIMED AT PROMOTING INJECTION SAFETY**

* These include:

1. **Use of Auto-disable(AD) syringes**

* AD syringes are self-locking syringes that can be used only once. They are the recommended equipment for all immunization injections.
* Most AD syringes have fixed needles and there are different AD size syringes for different vaccines e.g BCG etc.
* With AD syringes, the plunger can go back and forward only once, so health workers should not move the plunger unnecessarily as this will disable the syringe.
* Always keep the needle tip in the fluid at all times, making sure to empty the full contents of the vial. To remove air bubbles, hold the syringe upright and tap the barrel. Then carefully push to close the mark.
* When administering the vaccine, push the plunger forward and inject the vaccine. After injection, the plunger will automatically lock and the syringe cannot be re-used. Do not recap the needle after use, dispose it immediately into a safety box.

1. **Pre-filled AD injection devices**

* These are single-dose packets of vaccine with a needle affixed by the manufacturer. They can only be used once and should be disposed immediately at point of use into the safety box.

1. **Re-use prevention needles and syringes**

* These are needles and syringes used for reconstitution of vaccines e.g BCG, measles, Hib, and yellow fever and are disabled to avoid reuse.

1. **Giving the right vaccine safely**

Other than using the injection equipment safely, it is equally important to give the right vaccines that has been kept properly in the cold chain, appropriately reconstituted and safely administered

**Other safety measures include**:

Prevention of needle-stick injuries and infections e.g avoiding recapping of needles, immediate disposal of syringes and needles, feeling the safety boxes three-quarter way full and close it securely.

Hand washing (Infection prevention) prior to giving first immunization and after contact with dirt or blood. Adhere to aseptic technique when handling sterile syringes and needles.

Handling syringes and needles safely to avoid touching the parts that come into contact with the vaccine or the child e.g the needle shaft, bevel, needle adaptor, syringe adaptor, the plunger seal.

Positioning children correctly for injections to avoid unexpected motions at the time of injection that can lead to accidental needle-sticks. Position the child securely before giving the injection. Have the mother sit and place the child on her lap. Make sure the mother’s arm is behind the child’s back, and one of the child’s arms wraps around the mother’s side. The mother may tuck the child’s legs between her own to secure them, or she may hold the child’s legs.

Health worker should avoid holding the child as they require to use both hands to administer the injection.

Always tell the mother when you are about to give the injection.

**ADVERSE EVENTS FOLLOWING IMMUNIZATIONS (AEFI)**

An AEFI is a medical incident that occurs during or after an immunization and is believed to be caused by immunization. Is a reaction that occurs in a client or patient following vaccination that is considered to be related to the vaccine until proved otherwise?

Health workers should detect and report the following events if they occur during or after immunization:

* Anaphylactic shock
* Injection abscesses
* Cases of BCG lymphadenitis
* Cases requiring hospitalization that are thought by health workers, or the public, to be related to immunization.
* Unusual medical incidences that are thought by health workers, or the public, to be related to immunization.
* Death that are thought by health workers, or public, to be related to immunization.

**HOW TO IDENTIFY AEFI**

* **ANAPHYLAXIS**

1. Itchy, urticarial rash
2. Progressive, painless swelling around the mouth face which may be preceded by itchiness, tearing, nasal congestion or facial flushing.
3. Respiratory symptoms e.g sneezing, coughing, wheezing and labored breathing, upper airway swelling possibly causing airway obstruction.
4. Hypotension which generally develops later in the illness and can progress to cause shock and collapse.

**MGT:**

* Place the patient in recumbent position (elevated feet)
* Establish an oral airway if necessary
* Check respiration and pulse
* Promptly administer 0.01ml/kg (maximum 0.5ml) of aqueous epinephrine by Subcutenous or intramuscular injection in the limb to where the vaccination was given. Repeat at 20 minutes interval if necessary.
* Monitor vital signs and reassess the situation frequently to guide medication use.
* Arrange for transfer and refer to an emergency department.
* Since anaphylaxis is rare, epinephrine vials and other emergency supplies should be checked on regular basis and replaced if expired.
* **INJECTION SITE ABSCESSES**
* Signs of injection abscess are swelling or hard nodule at the injection site. That may progress into painful swelling and burst into a wound.

**MGT**

* Reassure the mother/care giver/guardian
* Manage the swelling according to presentation
* **Assess for BCG lymphadenitis and abscess and manage accordingly.**

**POSSIBLE CAUSES OF AEFI**

1. **Programmatic errors:** Usually, they are person based i.e an error in handling, reconstitution, or administration of the vaccine.
2. **Nature of the vaccine (vaccine properties):** or individual response to the vaccine itself.
3. **Coincidental:** Is an event that has no causal association between the immunization and the medical condition of the child or woman.
4. **Unknown cause:** The cause of the event cannot be determined.

**THE KEY ACTION POINTS ON AEFI**

* To increase immunization acceptance and improve the quality of services through the proper surveillance of AEFIs by:
* Detecting and reporting AEFIs as they occur.
* Investigating AEFIs when they occur
* Analyzing reports of AEFIs
* Taking appropriate action following reports of AEFIs.
* Evaluating the reporting systems for AEFIs
* Preventing AEFIs in routine immunization and mass campaigns

**REDUCING INCIDENCES OF AEFI**

Identify the contraindications of the vaccine in the client/patient: Before immunization, ascertain client history for allergies and previous adverse reactions to vaccines. In the case of a possible serious allergy, check with appropriate supervisor before giving the vaccine.

Precautions on allergic reactions previously experienced: Do not give the second or third pentavalent injection to a child who has suffered such a severe anaphylactic reaction to the previous dose.

Programme error: If AEFI was caused by programme error e.g improper handling of vaccines or faulty immunization technique, the actions to be taken will probably include: proper training, supervision and communication.

**IMMUNIZATION WASTE MANAGEMENT**

* Safe handling and disposal of sharps wastes prevents infections to the health workers, waste handlers and the community at large.
* Unsafe disposal can spread some infections e.g HIV/AIDS, hepatitis B and C, which are transmitted through injuries from needles contaminated with human blood.
* Wastes are materials or products made useless for any further use e.g used syringes and needles.

**Terminologies used in waste management**

1. **Segregation of waste:** Is the separation of wastes at points of generation into different and distinct containers or bags according to national colour codes. Segregation should be separated into harmful (hazardous) and non-hazardous waste.
2. **Safety box:** Is a leak proof and puncture proof container that carries 100 syringes and needles when ¾ full. Safety box is filled to ¾ full level to avoid spillage, needle stick injuries and to easy the sealing of safety box and should be stored safely awaiting transportation to the central disposal site.

**Safety box precautions:**

* Do not open used safety boxes or emptied for re-use.
* Do not squeeze or force syringes inside the safety box.

**Colour coding:**

* **Yellow bag:** For hazardous wastes
* **Black bag:** For Non-hazardous wastes
* **Red bag:** For Infectious wastes
* **Sharps:** Disposed all the used sharps into the safety boxes immediately at point of use.

1. **Incinerator:** This is a structure constructed of bricks for the burning of wastes.

**SAFE WASTE DISPOSAL METHODS**

1. **INCENERATION**

* Completely destroys needles and syringes by burning at temperatures above 800 degrees C.
* Produces less air pollution than open burning.
* Some hospitals incinerate on-site while others transport waste to a certain incineration area in the county/division.

1. **OPEN PIT BURNING**
2. **OPEN BURNING**

**DATA MANAGEMENT, MONITORING AND EVALUATION OF IMMUNIZATION PROGRAMME.**

**DEFINITION OF TERMS USED IN DATA MANAGEMENT**

1. **Monitoring:** Is a systematic and continuous process of examining processes, procedures and practices within a program. The focus of monitoring is therefore to identify problems and develop solutions to them. Monitoring is a continuous process thus data used for monitoring is collected, reported, analyzed and used routinely as defined by the program.
2. **Evaluation:** Is a periodic assessment of the overall program performance. An evaluation aims to measure the program performance against its objectives at specific times.
3. **Performance:** Is the level of fulfillment of operational capacity of a person or program.
4. **Indicator:** Is a variable used to compare program performance against its stated objectives.

**ROUTINE IMMUNIZATION MONITORING INDICATORS**

* Indicators usually used in routine immunization are:
* Immunization coverage
* Dropout rates
* Completeness
* Timeliness of reports
* **IMMUNIZATION COVERAGE**
* This is a measure of the extent to which the services being rendered cover the potential need for these services in the community. Is the proportion of vaccinated individuals among the target population?
* It is one of the most important indicators of a successful immunization program.
* Coverage is calculated by dividing the number of individuals vaccinated with a particular vaccine (numerator) by the number of individuals targeted for vaccination with the vaccine (denominator) within the same period. The proportion is then multiplied by 100 to get the percentage coverage.
* **Coverage formula:**

**(Number of individuals vaccinated) X 100**

**(Number of individuals targeted for vaccination)**

* The following coverages are routinely calculated:
* Coverage for each dose
* Coverage for fully immunized child.
* TT2 + coverage

**Example:**During the previous year, Kambiri health centre administered 102 doses of pentavalent vaccine and 73 doses of measles vaccine to the children less than one year of age.

If the target population of children below one year of age in Kambiri health centre is 150, calculate the immunization coverage for both pentavalent and measles vaccines in Kambiri.

**(Number of individuals vaccinated) X 100**

**(Number of individuals targeted for vaccination)**

Pentavalent vaccine coverage= 102X 100 =68%

150

Measles vaccination coverage= 73 X100 = 49%

150

* **DROPOUT RATES**
* Dropout is defined as the number of individuals who start an immunization schedule but fail to get the last dose/antigen on the schedule e.g if a woman brings her child for pentavalent vaccine and OPV1 but does not return for other child hood immunization, her child is considered and ‘DROP OUT’.
* Dropout is calculated by subtracting the number of individuals who completely receive the last antigen/dose in the schedule from the number that started receiving the vaccine (numerator) and dividing the difference by the number of individuals who started the schedule. The proportion is then multiplied by 100 to get a percentage drop out rate.
* For calculating dropout, pentavalent 1 is considered the first vaccine on the schedule and pentavalent 3 the last vaccine dose i.e

DROPOUT RATE FORMULA FOR PENTAVALENT= (DOSES OF PENTA1- DOSES OF PENTA3)

DOSES OF PENTA1

EXAMPLE: During the previous year, dispensary X in Kakamega County administered up to the month of August 91 doses of pentavalent 1, and 76 doses of pentavalent 3 to children less than 1 year of age. Calculate the dropout rate for pentavalent vaccine at dispensary X:

DROPOUT RATE= (91-76) X100

91

16%

* **COMPLETENESS**
* Completeness of the reporting is defined in two different ways depending on the level and functioning reporting unit:

1. At a health facility level, completeness means that all required fields in a report have been filled. How well this is done determines the quality of data being reported.
2. At district and subsequent levels, completeness of reporting for the particular period is defined as the proportion of reports received. This is calculated by dividing the total number of reports received from the reporting units (numerator) by the total number of reporting units (denominator). The result is then multiplied by 100 to make it a percentage.

Completeness formula: Total reports received X 100

Total expected reports

* The health worker should ensure that all monthly reports are sent to the county. Non-reporting of late data affects the overall county and subsequently the national immunization coverage.
* **TIMELINESS**
* Timeless of health reporting is defined as a proportion of reports that are received on time. It is the number of reports received on time (numerator) divided by the total number of reports expected for the period (denominator). The proportion is then divided by 100 to get a percentage.
* **Formula for timeliness:**Total reports received on time X 100

Total reports expected

* Data collected from the tally sheets needs to be summarized, for action at the health facility level and transmitted to the county level by the 5th of the following months. The counties then upload the data to the County Health Information System (CHIS) website.
* When reports are sent and received on time, the possibility of a prompt and effective response is greater. Late data should not be ignored, they must be sent to the county level to update the existing data set at all levels. Not reporting late data affects the overall county coverage and, subsequently, the national immunization coverage. Late reports should be sent together with the next monthly report with explanatory note specifying the month of the data.

**COLLECTING ROUTINE IMMUNIZATION DATA**

* All immunizations must be accurately recorded at the health facility. This will allow accurate calculations of coverage for different vaccines/antigens as well as assist in defaulter tracing where necessary. To monitor immunization activities well, the following tool should be available at each immunizing health facility:

1. **Child health cards/ Mother and child health book:**

* Forms the child’s/woman’s individual immunization record. Brought to the clinic during each visit. The cards/books contain the following information:
* Demographic information about the child/woman.
* The type of vaccine and dose number
* The date the vaccine was given
* The date of the next appointment
* Any adverse event that may have occurred during previous vaccination.

An immunization card serves the following purposes:

* Reminds the caregiver when to return to the clinic
* Assists MCH staff to ascertain the immunization status of the woman/child
* Allows continuity of service when the child/woman moves to another area
* During coverage surveys, the card is used to verify immunization status of the child/woman.

1. **Immunizations and Vitamin A Tally Sheets**

* This is the daily record of immunization activities at a health facility. Each vaccine and dose number is recorded appropriately immediately it is administered.

1. **Immunization and Vitamin A summary sheets**

* An immunization summary sheet is a summary of monthly immunizations given at the health facility. It is completed by summarizing the data from the daily tally sheets for particular month.
* The health worker should ensure that all fields in the monthly immunization summary sheet are filled appropriately before sending to the county level.

1. **Immunization Permanent Register**

* This is the permanent record of individual immunization history at the health facility. Each row represents a single child while each column represents an antigen. Detailed instructions on how to complete the permanent register are at the back of the cover page.
* Once a month, you should go through the register and find the children who should have been immunized that month and were not. Get in contact with the parents and request them to bring the children to the clinic, CHWs can do this.

1. **TT Permanent Register**

* This is a permanent record of a woman’s immunization with tetanus toxoid.
* Each time you administer TT immunization, record them in 3 areas i.e TT antenatal card, tally sheet and the permanent register.

1. **Immunization Monitoring chart**

* Is a graphical presentation of a facility’s performance? It is plotted monthly using data from the monthly immunization summary sheet.

**EPI DOCUMENTATION**

* All vaccinating facilities must keep appropriate up-to-date records of all types of vaccines administered in the above mentioned KEPI records i.e:

1. Mother and child health cards/book
2. Immunization tally sheet
3. Immunization permanent register
4. Immunization and vitamin A summary sheet
5. TT permanent register
6. Immunization monitoring chart.