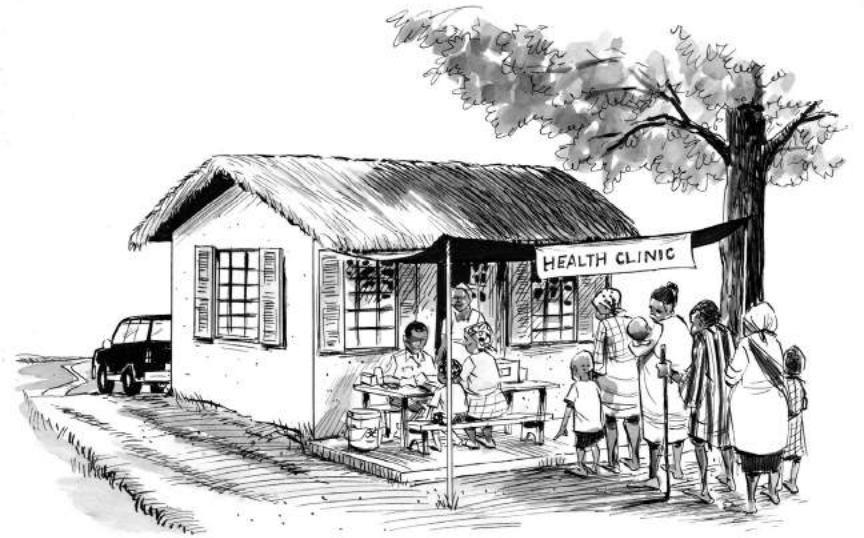
Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests in Health Clinics



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USAID | DELIVER PROJECT, TASK ORDER 3

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The Foundation for Innovative New Diagnostics (FIND) is a Product Development and Implementation Partnership (PDIP) devoted to developing and implementing diagnostic tools for poverty-related diseases. An independent non-profit Swiss foundation based in Geneva, FIND focuses on a disease portfolio covering tuberculosis, malaria and human African trypanosomiasis. In its commitment to develop technologies that can be used as near as possible to where patients seek care, FIND has accumulated an impressive pipeline of new improved diagnostic tests that are expected to be deployed in the next few years.

CITATION

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ABSTRACT

The publication is intended for staff at health clinics that use malaria rapid diagnostic tests (RDTs). It describes the basic principles for management and storage of RDT stock, and it outlines practical solutions for protecting RDTs against high temperatures during storage and transport. It also describes how to manage waste generated from RDT use.

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INTRODUCTION

Rapid diagnostic tests (RDTs) for malaria are providing much-needed access to diagnosis in remote areas where laboratories are not available. However, RDTs are sensitive to high temperatures, which can damage the tests and reduce the shelf life. The recommended storage temperature for most RDTs is 2°C–30°C (35°F–86°F), although it is higher for some products. The various measures discussed in this manual to control exposure to high temperature will depend on your local climate and the storage specifications for the specific RDT. You may need to take similar measures when you store other diagnostics and medicines.

In many remote locations, where air conditioning is unavailable, it is a challenge to control the storage temperature. RDTs are frequently stored at remote health facilities for long periods because stock is delivered infrequently. Under these conditions, diagnostic tests are especially vulnerable.

In tropical climates, by planning carefully and taking simple steps, you can improve the storage conditions and help preserve the tests.

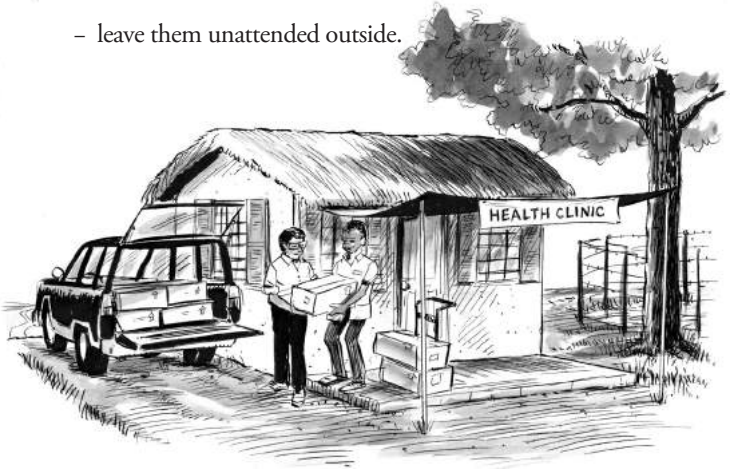
RECEIVING RDTS

Before you receive the RDTs, make sure you have sufficient clean storage space inside the building where they will be stored.

General Guidelines

Follow these guidelines when you receive a shipment of RDTs:

- Count the number of tests you receive and compare this number with the quantity ordered.
- Immediately after you receive the RDTs, place them inside the building.
  - If this is not possible, place them in the shade—under a tree or, preferably, in a shelter—until you can move them into the building.
- For the RDTs, **DO NOT**—
  - leave them directly in the sun or inside a vehicle parked in the sun
  - store them in a freezer
  - leave them unattended outside.

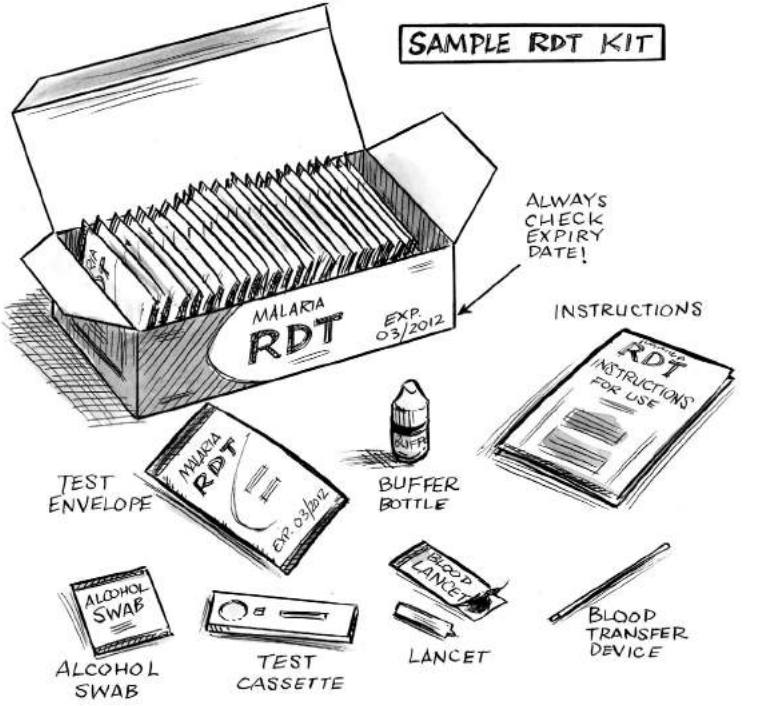


Inspecting

For each lot or type of RDTs you receive, do the following:

- Check—
  - the quantity and expiry date
  - the manufacturer's recommended storage temperatures
  - that all original boxes are unopened and in good condition.
- Open two or three kit boxes; ensure that the individual packaging (test envelope) is intact.
- For tests that arrive in kits with one buffer bottle, make sure that the buffer bottle is full.

The components shown may vary depending on the RDT product or brand.



If any RDTs have expired or if the tests are damaged (e.g., buffer bottle leaked or individual packaging is broken), notify the sending institution and return the tests.

Do not use expired or damaged tests.

STORING RDTS

Ensure that the storage area is protected against theft at all times (e.g., barred windows, padlocked doors). Take precautions to prevent harmful insects and rodents from entering the area.

During long-term storage, keep RDTs in the coolest part of the health facility, but never freeze them. They do not need refrigeration.

If air conditioning is not available, take the following steps to protect RDTs from excessive heat:

- Store away from direct sunlight.
- Do not store close to a wall or ceiling, as both absorb heat during the day.
  - Store a minimum of 30 cm away from walls and ceiling.
- Do not store directly on the ground.
  - To reduce damage from moisture, water, and pests, store on a shelving unit or shelf, if possible.
- If used outdoors or transported to a different location, keep the tests in the shade as much as possible (see Transporting RDTs on page 18).

Choose the Best Storage Location

To store RDTs in the coolest place available, consider the following:

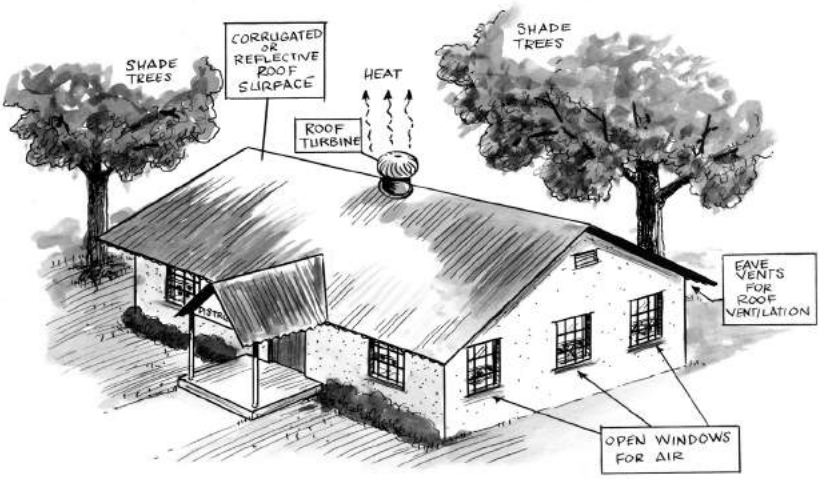
- A thatch roof may be cooler than an iron or tin roof.
- Stone/clay or wood/clay materials may be cooler than concrete or brick.
- Large shade trees may be cooler than small or no trees.

Control Storage Temperatures

You can take simple measures to lower the temperature in the building where you store the RDTs.

- ***Protect from sunlight:*** Shade the windows or install curtains to prevent direct sunlight from entering the building.
- ***Provide natural ventilation:***
  - In a hot, dry climate with significantly different day and night temperatures: Open windows at night to release heat and draw in the cooler night air; close windows on hot days to keep the building cool.
  - In a hot, humid climate with little difference between day and night temperature: Keep windows and air vents open at all times to allow air to circulate.
- ***Prevent high-ceiling temperatures:***
  - Use a reflective roof surface.
  - Ensure adequate ventilation for the loft space. You can install a ventilation turbine on the roof to remove hot air.

- ***Plant shade trees:*** Plant trees around the building to lower indoor temperatures.



COOL STORAGE

Simple, cheap solutions will also help protect RDTs from high ambient temperatures during long-term storage.

In-Ground Storage

Ground temperatures fluctuate very little; they remain well below mid-day air temperatures. In hot climates, if well constructed, you can use an in-ground cavity to store RDTs.

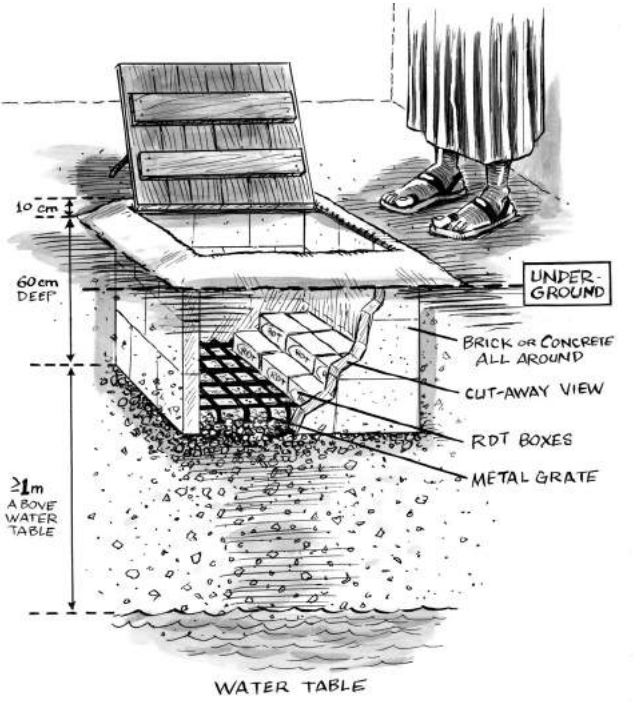
In-ground storage is a simple cavity in the ground lined with bricks or other material to strengthen the walls and to keep the inside dry and clean—the size of the cavity depends on the need. Contain the cavity completely within a shaded structure or building. You can build the storage into the clinic floor.

Construct the in-ground storage to prevent water from entering the storage area from underneath or from entering during rain or flooding.

- Ensure that the edge of the cavity is at least 10 cm above the ground.
- Ensure that the bottom of the cavity construction is at least 1 m above the water table (groundwater level). Remember—the groundwater level may be higher during the rainy season.

Keep the storage area covered at all times. Use a strong wood or metal cover as a lid; to improve insulation, line the inside with polystyrene. To protect the tests from moisture, place them on top of a grate or on boards at the bottom of the cavity.

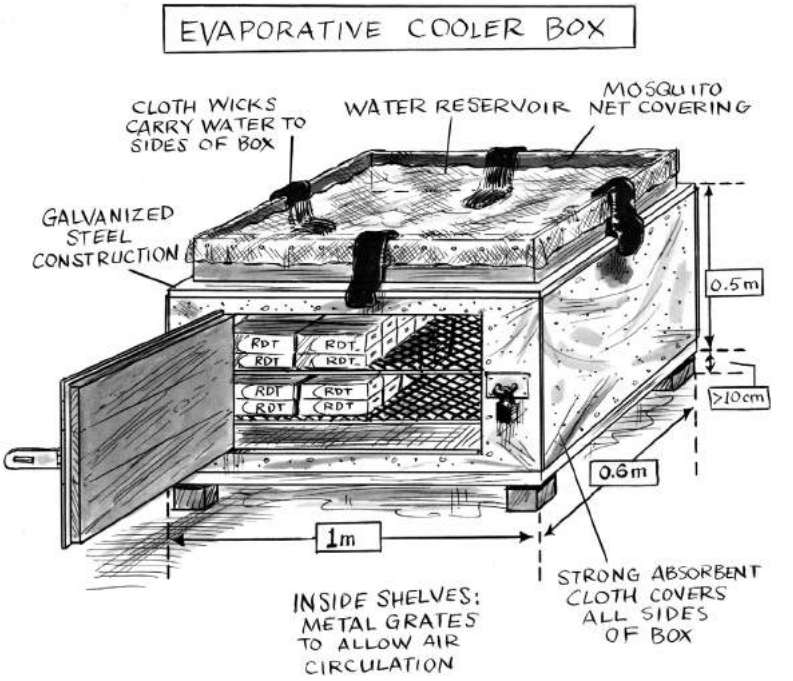
Never let the RDTs touch the sides of the cavity or ground.



EVAPORATIVE COOLER BOX STORAGE

An evaporative cooler box is another simple way to protect RDTs and other health commodities from temperatures above the manufacturers' recommended storage specifications. The boxes are cheap and can be made locally.

You have many choices in the design of an evaporative cooler box, but for all boxes, the principle is the same.



Example of an evaporative cooler box

You can construct the box of galvanized steel that you cover with a strong absorbent fabric—often a sacking cloth; and add a hinged door. Mount a tray with water on top of the cooler box. At all times, keep the wicks that connect the cloth and the water tray wet.

As the water evaporates from the cloth, the temperature inside the cooler box decreases. This same principle also keeps the water cool in an unglazed clay pot. Evaporative cooling works best in areas with high temperatures and low humidity.

Cover the screen over the water tray to prevent mosquitoes from using the tray as a breeding place.

TRANSPORTING RDTS

RDTs are very vulnerable to damage from heat during any type of transport. Protect them during loading, transport, and delivery; always arrange for uninterrupted transport and avoid extended stops or other preventable delays. Also, protect the shipment from theft, damage, and loss.

By Car or Truck

Safeguards for transporting RDTs in cars:

- Load the vehicle in the shade.
- Place the boxes close to the bottom of the load.
- Create an airspace between the top of the load and the roof.
- During breaks, park the vehicle in the shade.
- If the vehicle—
  - does not have air conditioning, keep windows open to allow air circulation
  - has an open-top, cover the boxes with a waterproof sheet—white or light-colored, if possible—to reflect heat from the sun.
- Park the vehicle out of the sun—unless the air conditioning is on.

By Boat

Safeguards for transporting RDTs on boats:

- Before and during transit—
  - Keep in waterproof boxes, if possible
  - Protect against direct sunlight
  - Keep in the shade or in a shelter.
- If transported in an open boat with no shelter, cover the boxes to keep them as cool as possible (e.g., with freshly cut leaves or tree branches).

By Foot, Bicycle, and Motorbike

Safeguards for transporting RDTs on foot, bicycle, or motorbike:

- If possible, transport early in the morning or evening to avoid high temperatures and exposure to the sun.
- If you are traveling over a long distance and it is hot, stop frequently in the shade; open the box to release the hot air.
- Tie fresh leaves or small branches lightly to the top and sides of the box to keep the inner part of the boxes cool.
- Always keep products out of direct sunlight.

Delivery

Follow these guidelines for RDTs when you make deliveries:

- Ensure that you notify the receiving site in advance about the delivery.
- Place the product inside the building immediately after delivery. If stored outside, keep products in the shade (e.g., under a tree or, preferably, in a shelter).
- **DO NOT—**
  - leave unattended
  - leave in the sun or rain
  - place in a freezer.

MANAGING RDT STOCK

If you practice good stock management, you will minimize waste and the time it takes to estimate future needs. You will be ready to reorder RDTs on time.

Rotate Stock

Follow these guidelines to improve management of RDTs.

- Remember the first-to-expire first-out (FEFO) procedure: Use the RDTs first that will expire first.
  - The RDTs most recently delivered may expire before RDTs delivered earlier. Reorganize RDT stocks accordingly, if necessary.
- Never use RDTs after they have expired; they may not result in a reliable test.

Monitor the Use

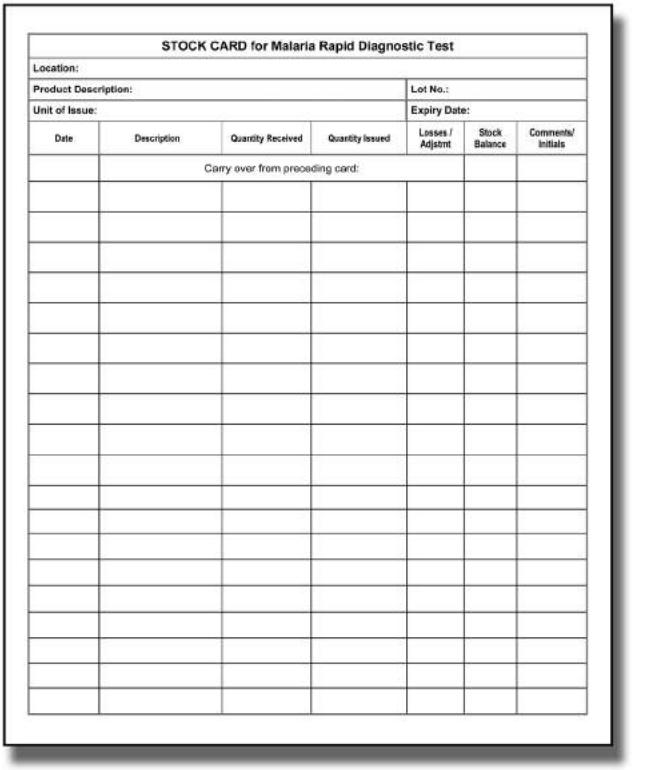
Use a stock record book to track the monthly consumption of RDTs in the health facility and to plan orders for new stock. Update the records at least once a month.

- Record these details when you receive new stock:
  - name of product and the expiry date
  - number of tests received.
- At the end of every month, record the number of RDTs used that month (using the patient register book, calculate the number of

people tested with RDTs). Use this number to determine how many RDTs remain in stock. If your health facility only has a small stock, estimate the quantity left by counting the number of unopened kit boxes.

- Whether you dispose of expired or damaged RDTs, or return them to the sending institution, record the quantity.

If a stock card is not available, every month record the number of RDTs left in stock on a separate sheet or in the patient register book.



STOCK CARD for Malaria Rapid Diagnostic Test

Location:						
Product Description:				**Lot No.:**		
Unit of Issue:				**Expiry Date:**		
Date	**Description**	**Quantity Received**	**Quantity Issued**	**Losses / Adjstmt**	**Stock Balance**	**Comments/ Initials**
	Carry over from preceding card:					

Order New Supplies

You must keep supplies of RDTs and antimalarial medicines in stock. If supplies are often stocked out, patients may lose confidence in the service and stop visiting the health facility. It may be difficult to predict how many RDTs will be used in the coming months, but good stock management will make it easier, over time, to quantify the consumption.

To avoid running out of stock, consider two factors: (1) the number of patients to be tested in the coming months or season and (2) the time lag between placing the order and receiving the shipment (delivery time).

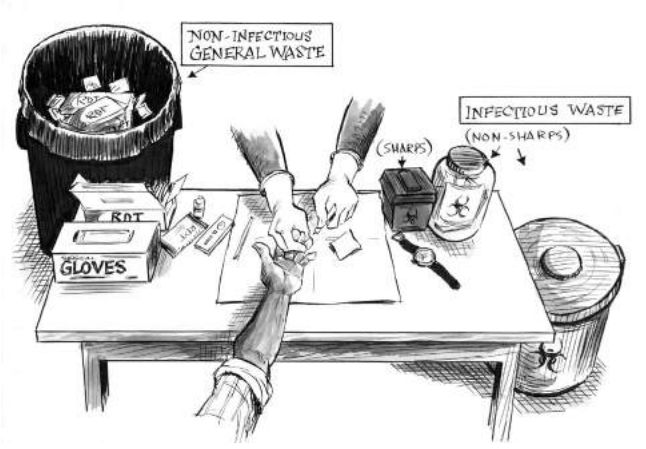
- The number of patients tested for malaria varies, depending on the season. Use the number of malaria consultations from the previous year to estimate the quantity of RDTs to be used in the coming months.
- Delivery can take days, weeks, or months, depending on many factors: road conditions, work load at the issuing store, and available stock at the store. Always order RDTs on time, especially if your health facility is hard to reach during the rainy season.

Plan ahead. Always order new supplies well before the RDT stock will run out or expire; always keep at least three months of stock in the health facility, especially in remote areas.

MANAGING WASTE

Some waste generated from RDT use can be infectious. Used sharps (lancets and needles) can cause serious injury or illness. If sharps are contaminated with blood or other body fluids, they can cause infection with hepatitis B, hepatitis C, and HIV. To protect health personnel, waste handlers, and the community against potential injury, you must establish safe, environmentally sound ways to handle and dispose of waste.

This section includes general recommendations for handling infectious waste from RDT use. If national guidelines and policies are available, you must follow them. If they are not available, follow the general recommendations below.



Types of Waste

Two types of waste are generated from RDT use: *infectious waste* (sharps and other potentially infectious waste) and *non-infectious general waste*:

INFECTIOUS WASTE

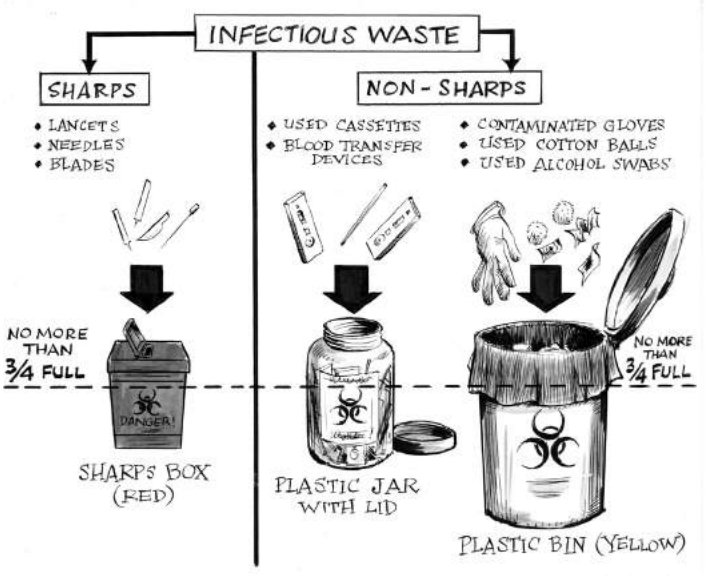
- Infectious waste, all waste and instruments that may have been in contact with blood or other body fluids:
  - sharps (lancets, needles, scalpel blades)
  - RDTs; blood collection devices like tubes, straws, or loops; gloves; swabs; and cotton.

NON-INFECTIOUS GENERAL WASTE

- Non-infectious general waste—
  - RDT packaging (envelope), desiccant, buffer, unused RDTs, and carton boxes
  - unused, expired, or damaged RDTs.

Segregate Waste

Immediately segregate all waste from RDTs, including other health care waste, into the appropriate container. Use different colored bags: for example, *red bags* for infectious and potentially



infectious waste and *black bags* for non-infectious general waste.

INFECTIOUS WASTE—SHARPS:

- Collect sharps (lancets, needles, scalpels) separately in plastic or cardboard sharps containers fitted with covers. If containers are not available, use thick puncture-resistant plastic bottles, glass jars with a lid, or small, strong cardboard boxes.
- Store the containers in a safe place, out of the reach of children and stray animals.
- When the sharps container is three-fourths full, transfer the contents to special sharps barrels or a sharps pit for final

disposal (see Dispose of Infectious Waste).

- Never over-fill a sharps container, or try to force sharps through a blocked entry hole.
- While wearing gloves, disinfect reusable sharps containers with household bleach.

OTHER INFECTIOUS WASTE—NON-SHARPS:

- Collect infectious waste (used RDTs, blood collection devices, swabs, gloves) in a strong, leak-resistant plastic bag placed in a metal or plastic bin with a lid.
- Store the bin in a safe place, out of the reach of children and stray animals.
- When the plastic bag is ¾ full, seal it and remove it from the bin. Safely dispose of the waste—for example, in a burial pit (see Dispose of Infectious Waste).
- While wearing gloves, disinfect the bin with household bleach before putting in a new plastic bag.

NON-INFECTIOUS GENERAL WASTE:

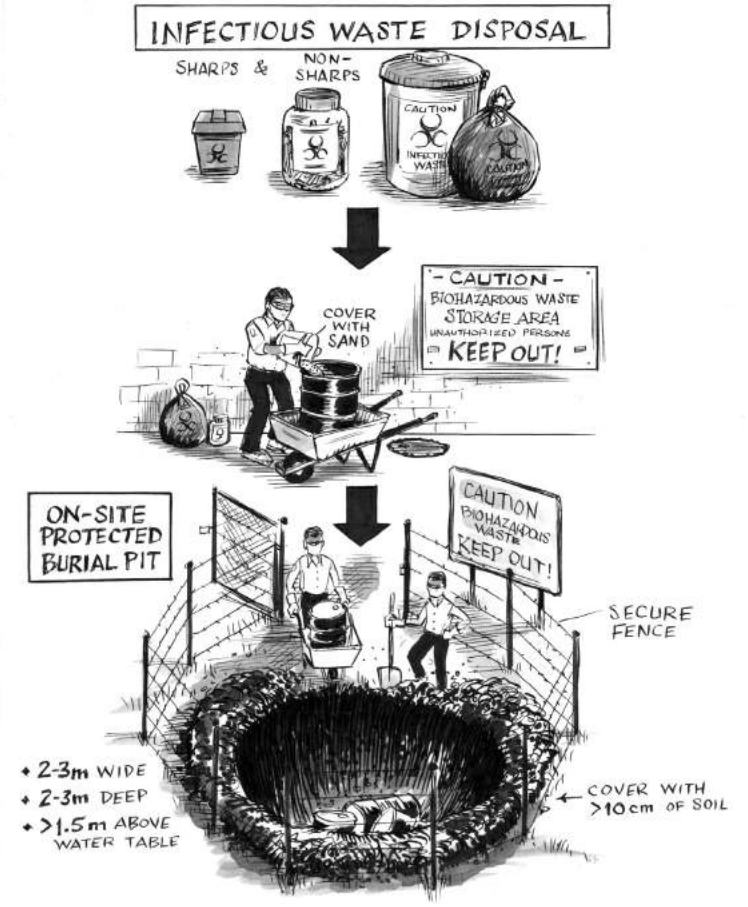
- You can treat non-infectious general waste (e.g., packaging, desiccant, and buffer) as regular solid household waste; dispose of it in a burial pit on site or send it to a waste disposal location off-site.

Store Infectious Waste before Final Disposal

- Do not mix infectious waste with non-infectious general waste.
- Store contaminated water and general waste in separate areas.
- Clearly mark storage area for infectious waste (for example, **Caution: Infectious Waste Storage Area. Unauthorized Persons Keep Out.**).
- Never store infectious waste in patient's rooms, laboratories, function room, or any public access area.

Dispose of Infectious Waste

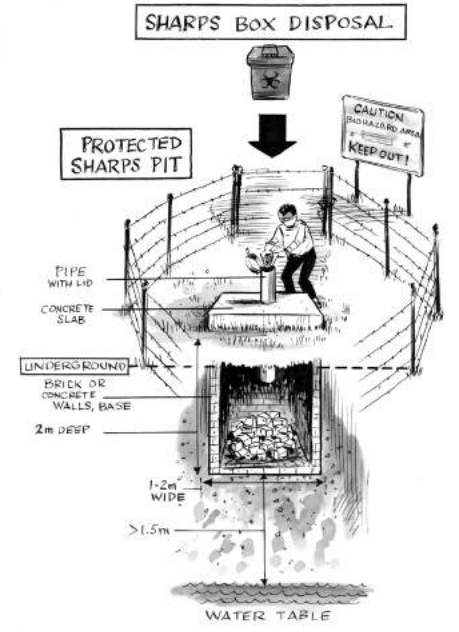
The best way to dispose of infectious waste depends on your local conditions and regulations. This section describes several on-site disposal options. You can send infectious waste to regional facilities for destruction or disposal but, for small amounts, on-site disposal is usually best.



SHARPS:

Protected sharps barrel: You can use a simple, safe protected drum or barrel (e.g., 44-gallon) to dispose of sharps waste. Place the drum or barrel of solid plastic or metal in a secure, convenient site. Fit a funnel into a hole on top of the barrel. When the barrel is three-fourths full, remove the funnel and fill the barrel with concrete. Dispose of the container in a deep burial pit, in a landfill, or store it for later destruction at a different site.

Protected sharps pit: You can also use a deep hole in the ground, with the floor and sides lined with clay, bricks, or cement; or a hole constructed with cement pipes. Make sure the pit has a concrete cover with a narrow cylinder, through which you drop sharps into the pit. When the pit is full, fill it (encapsulate) with concrete or other immobilizing material and seal it off. Keep the pit fenced off or secured when it is in use.



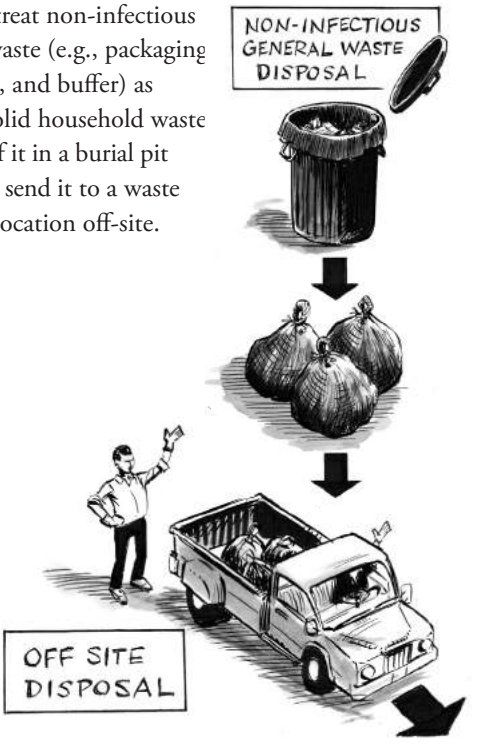
OTHER HAZARDOUS WASTE (NON-SHARPS):

Burial pit: Bury infectious waste in a deep pit with the bottom at least 1.5 meters above the water table and 2–5 meters deep; line it with a low-permeability material, such as clay. Add a layer of soil or sawdust after each layer of waste. Allow only authorized personnel access to the site. When you construct the pit, to prevent flooding, consider rainfall and the level of groundwater. Do not locate disposal pits near water supply sources like water courses or wells.

Drum and pit burning: Avoid burning waste, if possible. However, if unavoidable, burn infectious waste in simple drum incinerators or in burial pits. These inexpensive methods can greatly reduce the volume of waste. Because burning waste can generate harmful smoke and particles, only burn in areas with a low population or in rural areas. Always bury the remaining residue—ashes and unburned glass and metals—in a safe place, covered with soil.

Dispose of General Waste

You can treat non-infectious general waste (e.g., packaging desiccant, and buffer) as regular solid household waste dispose of it in a burial pit on site or send it to a waste disposal location off-site.



Always—

- wear gloves when handling infectious waste
- handle sharps carefully to avoid injury and potential infections.

Do not—

- reuse sharps (lancets, needles, scalpels)
- open sharps containers or empty the contents, unless transferring contents to a protected sharps barrel or pit
- deposit or scatter sharps and other infectious material on the ground
- burn plastic that contains polyvinylchloride (PVC).

FINDING RESOURCES ON WASTE MANAGEMENT

The World Health Organization (WHO) website on Healthcare Waste Management (HCWM):

http://www.healthcarewaste.org/en/650_tech_small.html.

The WHO decision-making guide: Management of solid health-care waste at primary health-care centres: A decision-making guide.

http://www.who.int/water_sanitation_health/medicalwaste/decisionmguide_rev_oct06.pdf.

World Health Organization

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