



Giving Safe Injections: Using Auto-Disable Syringes for Immunization

September 2001

Introduction

Who should use this manual

This manual is for health workers who inject vaccines. Each of the five chapters covers a different lesson related to the safe injection of vaccine.

These chapters discuss the ways to give injectable vaccines without harming the recipient, the health worker, or the general population. Chapter 1 discusses how health workers can unknowingly spread diseases with injections contaminated by germs present in the blood, skin, and environment. Chapters 2 and 3 review special issues in the safe selection of and reconstitution of vaccines. Chapter 4 discusses how to arrange work stations and syringe disposal to prevent needlestick injuries to health workers and communities. Chapter 5 introduces auto-disable syringes.

How to use this manual

The manual can be presented by a trainer and/or reviewed by health workers alone or in groups. To gain the maximum benefit from the manual, it is important to thoroughly read the material, complete the practical exercises, and take the quizzes. The case studies are provided to reinforce the information and as tools for discussion, if in a group setting. The answers to the practical exercises, quizzes, and case studies can be found in the back of the manual.

Trainer Supplement

In the back of this manual is a section designed to help trainers understand the objectives of each chapter and effectively plan a training schedule. Also included are important recommendations for presenting the material. We encourage trainers to read the manual prior to conducting the lessons.

Acknowledgements

This document was produced by Program for Appropriate Technology in Health (PATH) with funding from BD and from USAID under the HealthTech (Technologies for Health) program, Cooperative Agreement #HRN-A-00-96-90007. The opinions expressed within are those of the authors and do not necessarily reflect the views of the sponsors or WHO.

PATH gratefully acknowledges:

- WHO and WHO illustrators- Ivanson Kayaii, Janet Moore, Daphne Paley Smith, and Beth Rogers;
- AVSC International, for permission to reprint material from “Online Infection Prevention Course,” <http://www.avsc.org>, May 2000;
- Bader, BD, Star Syringe Ltd., and Terumo Europe N.V. for technical assistance with syringe instructions; and
- The following reviewers for their very helpful comments and suggestions- R. Araya, Boi-Betty Betts, A. Chweya, Philippe Duclos, W. Githitu, Yvan Hutin, Bertrand Jacquet, A. Jurua, K. Kagaruki, Deborah Lans, W. Msirikale, M. Mulenga, Francis Mutumbisha, L. Pierre, Zeil Rosenberg, A. Saleh, Y. Sanyang, Fred Simiyu, Jeffrey Spieler, E. Taylor, Elly Tumwine, Alasdair Wylie, and P. Zaninka.

This document may be reproduced or adapted to meet local needs with permission from PATH, provided the parts reproduced are distributed free or at cost and not for profit. Please contact PATH before beginning any translation or adaptation. PATH may be able to supply original Adobe PageMaker or Adobe Acrobat computer files on CD-ROM as well as instructions for adapting the manual. PATH requests that a copy of all materials, in which any part from this manual has been adapted, be sent to the address below.

path Program for Appropriate Technology in Health
4 Nickerson Street, Seattle, Washington 98109-1699, U.S.A.

Tel: 206-285-3500

Fax: 206-285-6619

Web site: www.path.org

E-mail: info@path.org

Available online at [Http://path.org/resources/safe-inj-pdf.htm](http://path.org/resources/safe-inj-pdf.htm).

Copyright 2000 Program for Appropriate Technology in Health (PATH)
Immunization version 2, September 2001

Table of Contents

Chapter 1	The Health Impact of Unsafe Injections	1
	Key Points	8
	Quiz Questions	9
Chapter 2	Selecting Safe and Effective Vaccines	11
	Key Points	16
	Quiz Questions	17
	Practical Exercise #1 “How to Read Vaccine Vial Monitors (VVMs)”	18
	Case Study#1 “The Unlabelled Vaccines in the Vaccine Carrier”	20
Chapter 3	Reconstituting Vaccines Safely	21
	Key Points	24
	Quiz Questions	25
	Practical Exercise #2 “Selecting Vaccines from the Vaccine Carrier”	26
Chapter 4	Safe Handling and Disposal of Sharps	31
	Key Points	40
	Quiz Questions	41
	Case Study#2 “The Recapping Quandary”	42
	Case Study#3 “The Pile of Debris”	43
	Case Study#4 “The Pit at the Turtle Clinic”	44
	Case Study#5 “The Missing Syringe Barrels”	45
Chapter 5	Using Auto-Disable Syringes	47
	Key Points	67
	Guidelines for Use of AD Syringes	68
	Comparing Different AD Syringes	69
	Quiz Questions	70
	Case Study#6 “Wrong-way Kudzu”	71
Answer Section		73
Trainer Supplement		90
References		93

Chapter

The Health Impact of Unsafe Injections

This chapter reviews the impact of unsafe injections and discusses the responsibility of health workers to prevent disease and injuries caused by unsafe injections.

1

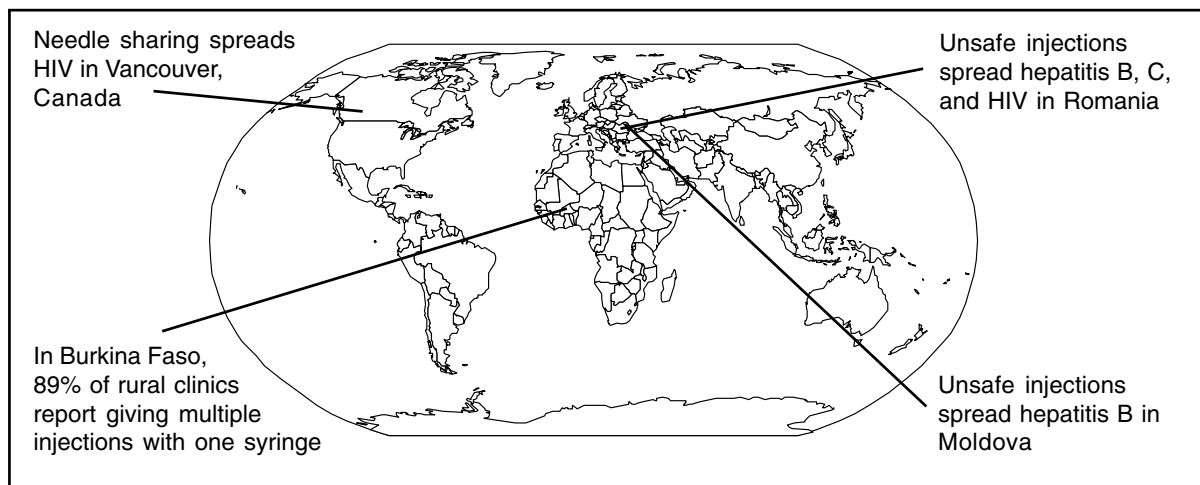
Unsafe Injections Cause Infections, Injuries, and Drug-Related Problems

The World Health Organization (WHO) estimates that at least 50 percent of the developing world's 12 billion injections administered each year are unsafe—posing serious health risks to recipients, health workers, and the public. Most injections are given for therapeutic purposes, rather than for immunizations. However, most of the injections given may be unnecessary, ineffective, or inappropriate (see Simonsen, 1999).

The most common, serious infections transmitted by unsafe injections are hepatitis B, hepatitis C, and HIV. WHO estimates that unsafe injections transmit 8-16 million hepatitis B virus infections, 2.3-4.7 million hepatitis C virus infections, and between 80,000-160,000 HIV infections each year. Unsafe injections can also transmit parasitic (malaria), fungal, bacterial, and other types of infections. Some infections, such as abscesses, may appear relatively quickly; however, other infections spread by used syringes may not be obvious for years or decades.

Poorly administered injections can also cause injuries or drug toxicities when the wrong injection site, drug, diluent, or dose are used.

Figure 1. Unsafe injection practices are a worldwide problem.



What is an Unsafe Injection?

Figure 2 lists some of the common injection practices that can cause harm.

Figure 2. Specific examples of unsafe injection practices.

Practices that can harm recipients:

- Re-using a syringe or needle
- Sterilization without supervision or monitoring with time, steam, and temperature indicators
- Changing the needle but re-using the syringe
- Giving an injection when there are safer alternatives
- Keeping freeze-dried vaccine more than 6 hours after reconstitution
- Attempting to sterilize injection equipment without prior cleaning
- Attempting to sterilize and re-use disposable syringes
- Boiling injection equipment in an open pan
- Using only disinfectants on contaminated syringes and needles to prepare them for re-use
- Loading syringes with multiple doses and injecting multiple persons
- Applying pressure to bleeding sites with used material or a finger
- Vaccinating infants in the buttocks
- Leaving a needle in the vial to withdraw additional doses
- Mixing (decanting) two partially opened vials of vaccine
- Flaming needles
- Mixing 10-dose vials of vaccine with a single-dose of diluent
- Using a jet injector with a re-usable nozzle
- Storing medication and vaccine in the same refrigerator
- Touching the needle

Practices that can harm health-care workers:

- Recapping needles
- Placing needles on a surface or carrying them any distance prior to disposal
- Sharpening blunt or blocked needles for re-use
- Reaching into a mass of used syringes or needles (for cleaning or sorting waste)

Practices that can harm the community:

- Leaving used syringes in areas where children can play with them
- Giving or selling used syringes to vendors who will resell them
- Leaving used syringes in areas accessible to the public

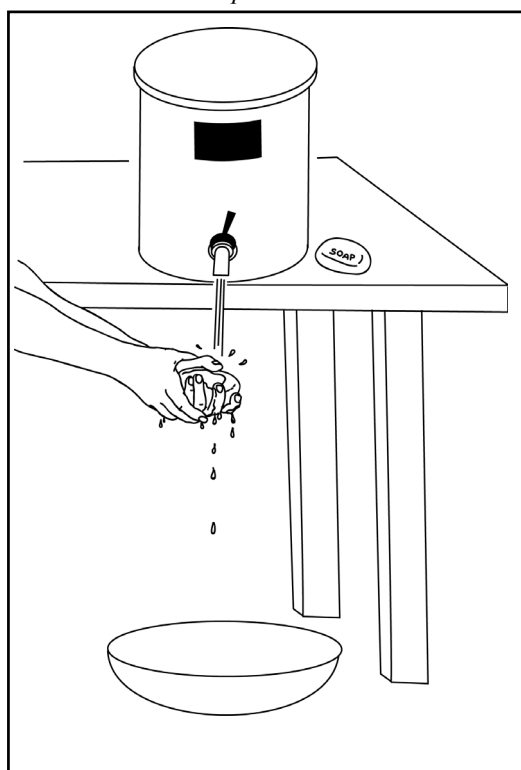
Assume All Body Fluids Contain Pathogens

In this manual, *pathogens* and *germs* refer to microorganisms that can cause disease. The term *body fluids* or *body substances* refers to secretions such as blood, saliva, vomit, mucous, sputum, feces, urine, semen, vaginal secretions, pus, sweat, or tears.

To give injections safely, health workers should understand that any body substance may contain pathogens that spread disease. Some body substances contain more germs than others—one can assume that feces contain more germs than tears. Other substances may vary from day to day in the presence and quantity of germs they contain. Blood from an individual may be sterile one day (i.e., contain no organisms) but swarm with millions of pathogens days later, if the person is sick.

Because our eyes cannot see who is carrying dangerous, infectious germs, health workers should treat all blood and body substances as if they contained pathogens. At a minimum, this means health workers should never use any item that has come into contact with blood or other body fluids. Health workers should wash their hands carefully after touching body fluids by using water from a tap or water poured from a pitcher, soap if available, and scrubbing thoroughly until all visible dirt is gone.

Figure 3. Washing hands—a simple act to protect health workers and patients



Adapted with permission from *Immunization in Practice*. WHO/EPI/TRAM/98.12

The body substances of animals also contain germs. For example, hepatitis E is a newly identified virus that can live in infected pigs, sheep, goats, rodents, cattle, and monkeys. When it has caused disease in humans, it has killed up to 10% of pregnant women who were infected. This infection can spread if fingers or objects that touch the virus are then placed in the mouth, and it is likely that injected viruses could cause infection as well.

Some vaccination campaigns try to attract crowds by offering immunizations to both people and their animals. Outreach efforts that vaccinate humans and animals at the same time must strictly separate syringes, needles, personnel, sterilizers, and supply containers to avoid spreading pathogens from animals to humans and vice versa.

Assume the Skin and the Environment Contain Germs

In addition to body fluids, hands tend to be highly contaminated with germs. Prior to arriving at work, a health worker may have placed his fingers on small, bleeding cuts acquired during the morning shave or haircut, blown his nose, shaken hands to greet a sick aunt, wiped a small child's bottom, slaughtered an animal, or handed money to the bus driver. These small tasks all can transfer unseen but infectious pathogens. When the health worker arrives at the immunization clinic and opens vials or separates cotton into cotton balls, the germs on his or her hands may be transferred to the tops of vaccine vials, or to the injection site via fingers or cotton. The needle can easily pick up these germs, push them into a vial, or carry them from the skin onto the needle and deposit them beneath the skin.

Unsafe Injections Can Spread Pathogens More Efficiently than Breathing, Swallowing, or Sex

Humans survive in environments full of germs because the skin is an excellent outer barrier, and the immune system is an excellent inner barrier. The body has many mechanisms that prevent germs from passing through the lungs, the skin, reproductive organs, mouth, or stomach. But injections can carry germs directly past these protective barriers. They do so when germs are:

- transferred from fingers or objects to the needle;
- present on the skin, picked up by a needle, and carried under the skin;
- in the medication to be injected; or are
- inside the syringe barrels or needles that were previously used, inadequately cleaned, or incompletely sterilized.

Injections can carry large numbers of pathogens into sterile parts of the body. Diseases that normally are spread when one person coughs germs out and another breathes them in, when one swallows

germs, or when fingers carry pathogens to the nose, can almost always be spread more efficiently by injection. **Remember: injections can carry pathogens from body fluids or from the environment into the body. Unsafe injections can kill.**

This manual is written at a time in history when millions of persons have weakened immune systems. It is a time when water is increasingly scarce to clean hands, clean equipment, and sterilize injection devices. Billions of injections are given each year with increasing numbers given by parents, salesmen, street children, and folk practitioners who give injections with no understanding of the dangers involved. In our lifetimes, dozens of new pathogens have been recognized. It is a time in history when more and more injections are given in worsening conditions to weakened individuals. The stage is set for unsafe injections to cause epidemics of both established and emerging infections.

This manual has been developed to remind health workers to take simple steps to prevent these complex tragedies. These chapters guide workers to abide by WHO principles for safe injections: give injections that harm neither the recipient, the care-giver, nor the community.

Responsibilities of the Health Worker: First, Do No Harm

Health workers should not cause harm through their actions. Patients depend on them to make themselves and their children healthier, not sicker. For example, health workers should:

- Give only necessary injections.
- Use a sterile syringe and sterile needle for every immunization, or do not immunize.
- Arrange the workspace and disposal practices to prevent needlesticks.

Give only necessary injections.

Most vaccinators give curative injections as well as immunizations. While immunizations are necessary, most curative injections, unfortunately, are not. For example, routine injections should not be used to give multivitamins or to treat conditions like colds, influenza, or diarrhea.

Reduce unnecessary injections.

Review the clinic registry to see what injections are given in your clinic for the most common symptoms and diagnoses. Ask your supervisor to find the national recommendations for treatment for those conditions. Discuss as a team whether avoidable injections are being given in your clinic and how to reduce them.

Why unnecessary injections are sometimes given.

- Patients and health workers may not know when problems can be treated more effectively and safely with oral medications or other therapies.
- Health workers or patients may falsely believe that injections are necessary, and may mistakenly believe that injections are always more effective than oral medications.
- Some health workers may think that patients want an injection, even when they don't.
- Some patients may demand injections, even against the advice of their health care providers.
- Some clinics make more money if they give an injection than if they give a pill.

These pressures to give injections can cause harm without anyone intending to do so. The more injections a patient receives, the more likely it is that some of them will be unsafe. Health staff can prevent problems by giving injections only when they are necessary. If a health worker gives an injection when it is not necessary, the health worker may give a patient an incurable, fatal disease; may waste money; and may make a patient expect injections at every visit.

Use a sterile syringe and sterile needle for every immunization—or do not immunize.

Infections, including hepatitis B, hepatitis C, and less commonly, HIV, can be spread when needles and syringes are re-used without sterilization. Effective sterilization in field settings requires first, cleaning the equipment to remove all visible dirt or blood, and second, using indicators to monitor temperature, steam, and time. These indicators (for example, TST Control Spots) ensure that the conditions necessary to sterilize have been met. Boiling, on the other hand, does not sterilize. Another common practice, changing the needle but re-using the syringe, is also unsafe.

Widespread problems ensuring the use of sterile needles and syringes led to the WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes. It states that the auto-disable syringe is the equipment of choice for administering vaccines, both in routine immunization and mass campaigns.

Why re-use of non-sterile syringes and needles sometimes occurs.

Re-use of contaminated injection equipment occurs (1) when there is an inadequate supply of injection equipment, (2) when health workers do not understand the dangers of re-using equipment, (3) when sterilization is unmonitored or injection technique is unsupervised, and (4) when disposal and distribution practices allow public access to injection equipment.

Arrange the workspace and disposal process to prevent needlesticks.

Needlesticks (also called needlepricks) transmit fewer infections than does the use of contaminated equipment, but prevention of needlesticks is still important. Health workers who use, carry, or recap needles; who manually disassemble or clean needles; or who dispose of needles are at risk of disease through needlesticks. Minimize handling of injection equipment to reduce the risk of needlestick injuries. More information on this topic can be found in Chapter 4.

The public may also receive needlesticks if syringes are dumped in open public areas. It is important to dispose of used syringes and needles and other medical supplies in areas protected from people and animals, both to prevent injuries and to prevent scavenging of needles that can lead to re-use.

Key Points

- Unsafe and unnecessary injections spread disease.
- Over half of all injections in resource-poor countries are unsafe.
- Health workers can prevent unsafe injections by **reducing the unnecessary use** of injectable medications.
- Re-use of syringes and needles can spread blood-borne diseases, including hepatitis B, hepatitis C, and HIV.
- Common examples of unsafe injections or situations that can lead to unsafe injections (See Figure 2, page 2):
 - giving an injection when it is not necessary,
 - lacking sufficient injection supplies for the number of persons requiring injections,
 - sterilizing disposable syringes for re-use, and
 - changing the needle on a used syringe and re-using the syringe.
- Most importantly, health workers have a professional commitment to **first, do no harm**.

Quiz Questions

1. What is an unsafe injection?
2. What types of infections can be caused by unsafe injections?
3. What are some common examples of unsafe injection practices?
4. What are two ways that health workers can improve injection safety?
5. Why is it so important to eliminate unnecessary injections?
6. What is an important responsibility of the health worker?
7. What type of syringe does WHO, UNICEF, and UNFPA recommend for immunization?
8. Indicate the level of risk for each of the following practices:

	Very Dangerous	Some Risk	Good Practice
Allowing the public access to discarded syringes			
Holding cotton wool on the bleeding injection site			
Not washing hands between injections			
Re-using needles and syringes after the last sterile syringe has been used in an immunization campaign			
Changing the needle and re-using the syringe in an immunization campaign			

9. Please discuss how each of the following practices can be improved:
 - A doctor washes his hands by dipping them in a basin of water before examining a patient.
 - Staff wash their hands by thoroughly scrubbing hard-to-reach areas for 10 to 15 seconds at the end of an immunization session.

Answers are provided on page 73.

Notes:

Chapter

2

Selecting Safe and Effective Vaccines

Vaccines are very sensitive. Age, heat, sunlight, cold, or use of the wrong diluent can make vaccines ineffective. In some cases, the use of contaminated vaccine can be lethal. An important aspect of injection safety is ensuring the use of safe and effective vaccines and medications. In this chapter, we will review the procedures for checking vaccine vials and labels.

Read the Labels on the Vaccine and Diluent Vials: Check the Expiry Date

Before you use any vaccine or diluent, check the following information:

- Is the label still attached to the vial?
- Is it the right vaccine and its specific diluent?
- Has the vaccine or diluent passed its expiry date?

Assess for Contamination

If contamination is suspected, discard the vial. Germs can be present in lethal quantities long before they are visible.

- Check the vial to be sure there are no leaks or cracks.
- Check the solution for a change in appearance or floating particles.
- If an opened vial has been submerged in water, assume the vial is contaminated and discard it.
- If the top of the vial has been pierced with a used (non-sterile) needle or a sterile needle on a used syringe, assume the contents are contaminated and discard it.
- If a needle has been left in the rubber stopper of a vial, assume the vial is contaminated and discard it.
- If a vaccine has been reconstituted for more than 6 hours, assume that it is contaminated and discard the vial (also see Chapter 3, Reconstituting Vaccines Safely).

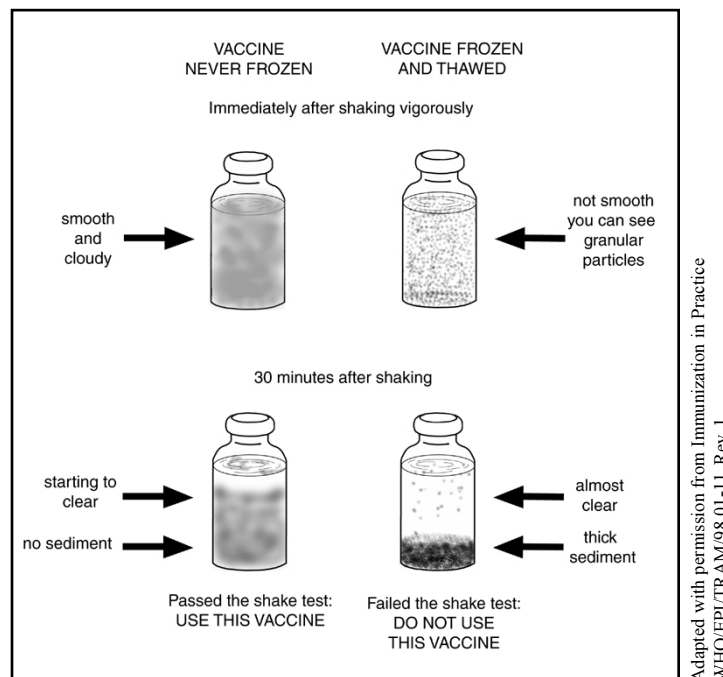
These vials must be discarded. Remember: “*When in doubt, throw it out.*”

Assess if Cold-Sensitive Vaccine Has Been Frozen

Confirm that cold-sensitive vaccines and their diluents have not been frozen.

- Discard vials of DTP, DT, Td, TT, hepatitis B vaccine, Hib vaccine, and diluents if it is certain or highly probable that they have frozen.
- If the refrigerator log shows subfreezing temperatures, the “shake test” can be used to determine if vials of DTP, DT, Td, or TT may have been frozen (see Figure 4).

Figure 4. The shake test



When vaccinators shake a possibly frozen and an unfrozen vaccine vial of the same type from the same manufacturer, the frozen vaccine will have sediment separate from the liquid more rapidly, and will eventually have sediment at the bottom of the vial. Vials containing an aluminum hydroxide adjuvant, such as DTP, TT, DT, or Td, that fail the “shake test” should not be used.

However, the shake test is not perfect. It is subjective, requires experience, and does not reliably identify all of the vials of DTP, DT, TT, and Td which may have been damaged by freezing. Instructions for the shake test are available from WHO in the poster “Has your DTP or TT Vaccine Been Frozen?” Specify order number CCPS/02 [4001] when ordering.

- Hepatitis B and Hib vaccine vials should be discarded if frozen or suspected of freezing. It is not currently known if the “shake test” works on these vaccines.
- Diluents should not be frozen because the vials may crack, allowing contaminants like pathogens and dirt to enter.

Assess Exposure to Heat: Read the Vaccine Vial Monitors

A vaccine vial monitor (VVM) is a label made of heat-sensitive material that is placed on a vaccine vial to show cumulative heat exposure over time. Health workers can use VVMs to:

- help ensure that only good vaccine is used, and
- reduce wastage of good vaccine.

Check that the vaccine has not been exposed to an excessive amount of heat.

- If the vial has a VVM, refer to the VVM since it shows the heat exposure for that particular vial. Check to see if the inner square is lighter than the outside circle. Discard the vial if the inner square is the same color or darker than the outside circle.
- If the vial does not have a VVM, check the temperature log and the cold-chain monitoring card. If the vial has been exposed to temperatures above 8°C, follow the instructions on the cold-chain monitoring card. If no card is available, discard the vial.

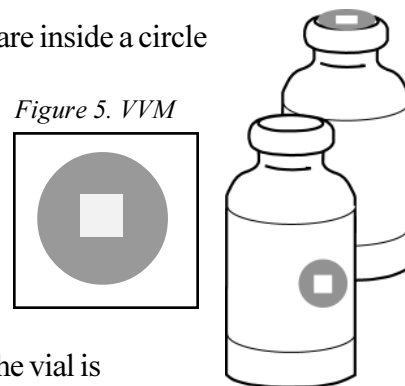
Reading Vaccine Vial Monitors

The VVM is printed on the vial label or cap. It looks like a square inside a circle (see Figure 5).

Starting in the year 2001, VVMs will begin to appear on all vaccines purchased by UNICEF.

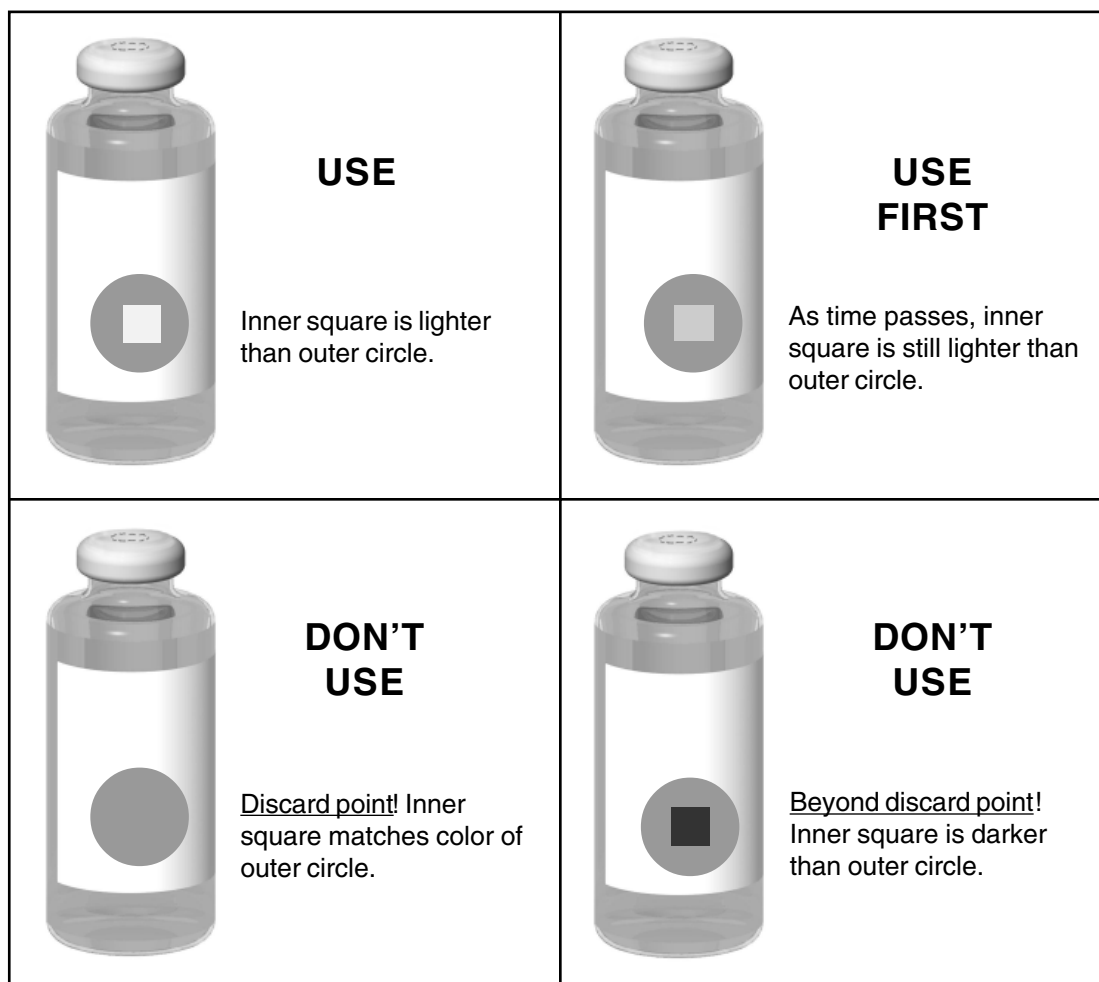
VVMs show the cumulative, irreversible heat exposure to which a vial has been exposed. The VVM is tailored to the specific heat stability of the vaccine to which it is attached. As the vial is exposed to more heat, the square becomes darker and darker. Use only vials of vaccine in which the inner square on the VVM is lighter than the outside circle.

Figure 5. VVM



By looking at the VVMs, health workers can determine which vials of vaccine are still usable, and which have been exposed to more heat than others. **Vials with VVMs where the inner square has begun to darken (but is still lighter than the outer circle) should be used before the vials with a lighter inner square.** In this way, health workers can minimize the number of vials that have to be discarded. In countries where the WHO policy on multi-dose vials has been adopted, VVMs help countries to save liquid vaccines (DTP, DT, TT, Td, OPV, hepatitis B, and liquid Hib) for subsequent sessions. This will decrease the wastage of vaccine in opened vials.

Figure 6. Instructions for reading VVMs



Other Tips to Keep Vaccines Safe

Fill the syringe only when the patient is ready to receive an injection.

Manually prefilled syringes are likely to become contaminated.

Do not combine partially opened vials of vaccine.

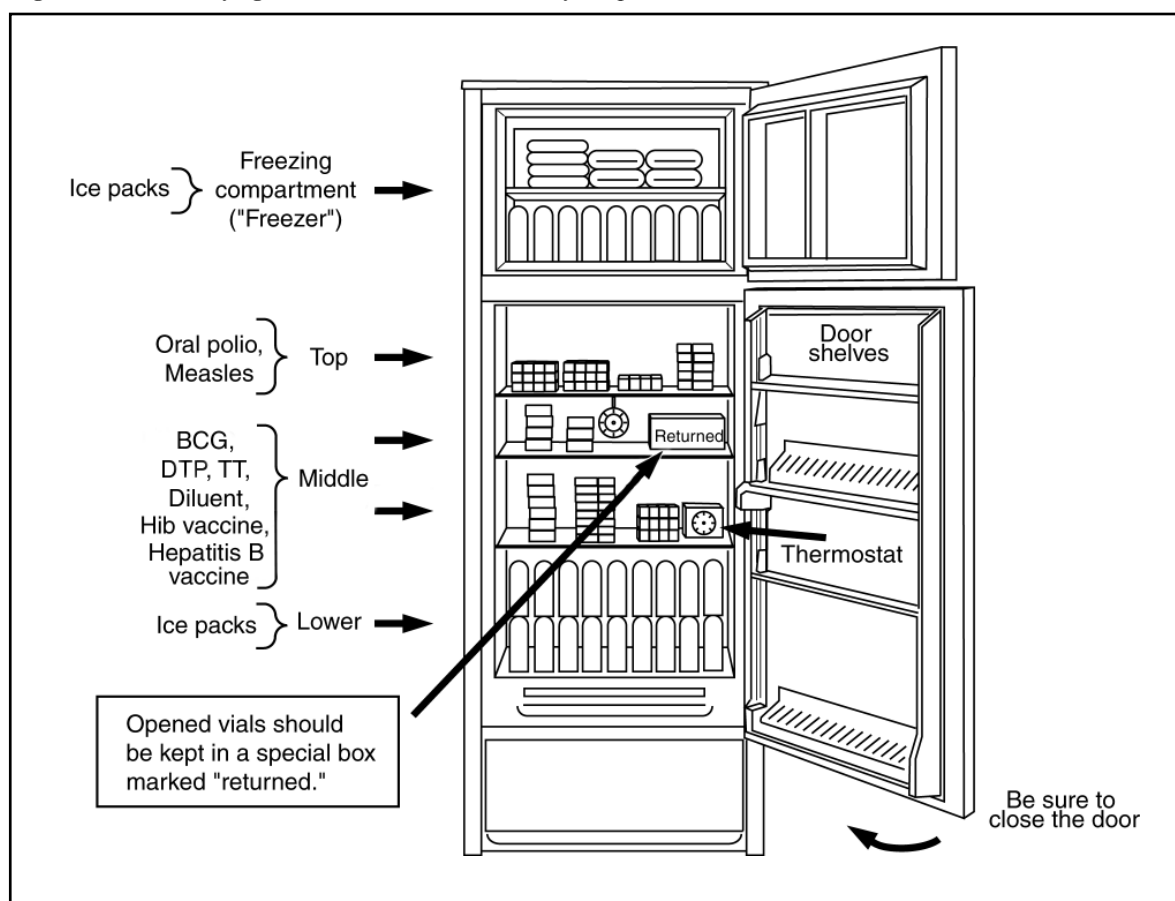
Combining partially opened vials of vaccine into another vial contaminates the vaccine.

Do not save opened vials of liquid vaccine for more than 4 weeks.

Opened vials of liquid vaccine should be kept in a special box in the refrigerator marked “returned.”

If your work site saves opened vials of OPV, DTP, DT, TT, Td, hepatitis B, and liquid Hib, these vials should be put in a box marked “returned” in the refrigerator and used before unopened vials during the next session (see Figure 7). **Remember: reconstituted vaccines must be used within 6 hours after reconstitution. The “returned” box should never contain opened vials of measles, yellow fever, BCG, or reconstituted Hib vaccines.**

Figure 7. Vaccine refrigerator with “returned” box for opened vials



Adapted with permission from *Immunization in Practice*. WHO/EPI/TRAM/98.12

Key Points

- Check vaccine vials for expiration, contamination, and signs of exposure to excessive heat or excessive cold before use.
- Fill the syringe only when the patient is ready to receive an injection.
- Do not combine partially opened vials of vaccine.
- Assume a vial is contaminated if:
 - there are leaks or cracks in the vial; **OR**
 - there is a change in appearance or floating particles; **OR**
 - the opened vial has been submerged in water; **OR**
 - the top of the vial has been pierced by a used needle, or a sterile needle on a used syringe; **OR**
 - freeze-dried vaccine has been opened for more than 6 hours after reconstitution; **OR**
 - a vial of liquid vaccine has been opened for more than 4 weeks.
- If the label has come off, discard the vial.
- If the vaccine's expiry date has passed, discard the vial. Vaccines must never be used past their expiry date.
- VVMs show cumulative heat exposure. The vial has not been heat damaged if the inner square is lighter than the outside circle.
- Vials with VVMs whose inner square has begun to darken but is still lighter than the outer circle should be used before vials whose squares are lighter.

Quiz Questions

1. Name four things that a health worker must check before filling a syringe from a vial.
2. Is the following statement true or false? “The syringe should be filled only when the patient is ready to receive an injection.”
3. Name five situations in which you should assume vaccine is contaminated.
4. Why use vaccine vial monitors (VVMs)?
5. What should be done when the inner square of the VVM is the same color or darker than the outside circle?
6. True or false? “Vials with VVMs that have just started to change color should be used before vials whose VVMs have not changed color.”
7. For each vial shown in the VVM Illustration on page 19, state whether or not the vial can be used.

Answers are provided on page 76.

Practical Exercise #1

How to Read Vaccine Vial Monitors (VVMs)

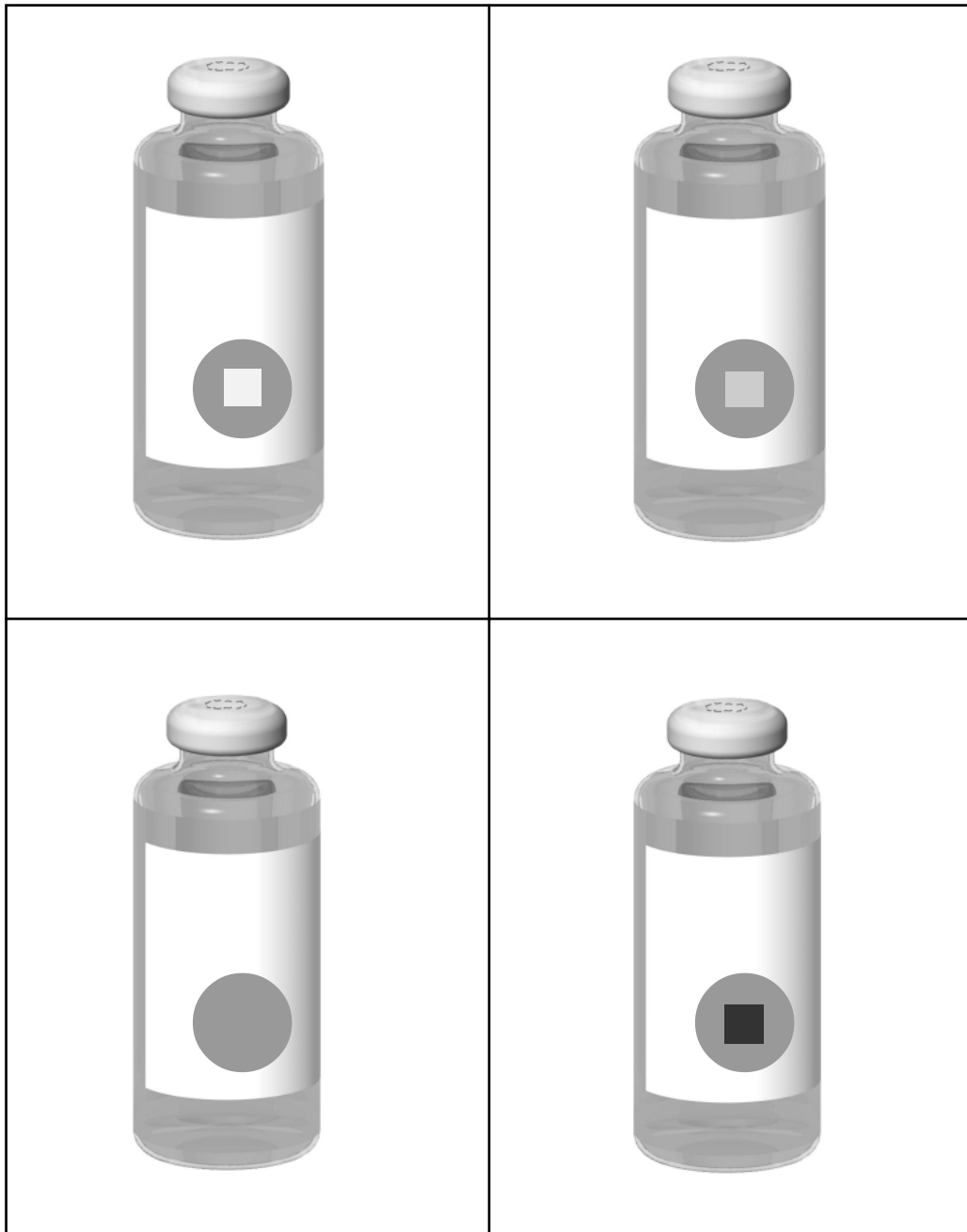
Review the illustration on page 19 to answer the following questions:

1. Which vial has been exposed to the most heat?
2. Which vial has been exposed to the least heat?
3. Which vial should be used first?
4. Which vials should be discarded?

Answers are provided on page 78.

Practical Exercise #1

VVM Illustration



NOTE: photocopying may change the appearance of VVMs. Before using photocopies, check that the top two vials have VVMs with squares lighter than the surrounding circles.

Case Study #1

The Unlabelled Vaccines in the Vaccine Carrier

When Nurse Santina opens the vaccine carrier during an outreach session to take out some DTP vaccine, she sees a lot of water in the carrier. Earlier in the day, she had not been able to find any ice packs, so she had filled the container with loose ice instead. Apparently, the lid had not been closed and the ice melted. Now everything is wet. Nurse Santina finds that the water has washed the labels off of some of the vials.

She says to herself, “I think those vials are DTP. All our DTP was new last week. These people have come a long way for their DTP immunizations, and I don’t want to disappoint them.”

She gives four babies an injection of 0.5 ml of liquid from one of the vials. Thirty minutes later, the babies’ mothers rush back to the health center. They are frightened and angry because their children became unconscious.

Later, a senior nursing officer comes to discuss what has happened. She says: “It appears that when the vaccine carrier was packed, someone gave you the insulin that had been stored in the refrigerator. You gave injections of insulin instead of vaccine.”

Questions for Review

1. What was Nurse Santina’s mistake?
2. What should she do to avoid making this mistake again?

Answers are provided on page 79.

Adapted with permission from *Immunization in Practice*. WHO/EPI/TRAM/98.12

Chapter

3

Reconstituting Vaccines Safely

Reconstitution affects both the safety and the effectiveness of vaccines. This chapter reviews the procedures involved in the safe reconstitution of vaccines.

Correct reconstitution of vaccines is critical to safe injection practices. Safe and effective use of reconstituted vaccines requires storage of vaccines and diluents at appropriate temperatures, mixing of vaccines only with specific diluents, the ability to identify contaminated vaccines, and the knowledge of when to discard vaccines. Review these issues in Chapter 3 carefully, because incorrect use of reconstituted vaccines can be fatal.

Reconstituting Vaccines Correctly

Errors in reconstituting vaccines commonly occur when:

- vial labels are missing, making correct identification of the vial impossible;
- health workers believe that diluents are interchangeable;
- diluents for different vaccines are mixed together in the refrigerator; and
- medication is stored in the same refrigerator where a busy health worker can mistakenly choose the wrong vial.

These errors are dangerous and must be avoided.

Use ONLY diluent recommended by the manufacturer to reconstitute vaccine.

It is important to reconstitute vaccine using only the diluent provided by the manufacturer for each specific vaccine. Diluents may contain stabilizers that affect heat stability, bactericides to maintain sterility, chemicals to assist in dissolving, and/or buffers to ensure the correct pH of the reconstituted vaccine. Diluents are not interchangeable.

Using the wrong diluent, substituting normal saline, or using sterile water makes the vaccine ineffective and less able to provide protection against disease. Deaths have resulted when vaccines were incorrectly mixed with medications other than diluents specifically approved for use with specific vaccines by the manufacturer.

Vaccines Need Specific Diluents

A partial list of vaccines that need specific diluents includes:

- BCG vaccines
- Measles-containing vaccines
- Freeze-dried *Haemophilus influenza* type b (Hib) vaccines
- Yellow fever vaccines

Reconstituted vaccines should be kept cool, and away from sunlight.

Keeping reconstituted vaccines **between 2° to 8°C** helps to maintain their potency. Place them in slits made in a foam piece that sits in the top of the vaccine carrier. This also keeps the vials out of direct sunlight.

Discard reconstituted vaccines after 6 hours.

BCG vaccines, measles-containing vaccines, yellow fever vaccines, and freeze-dried Hib vaccines do not have preservatives that limit the growth of microorganisms. As a result, microorganisms that enter the vial during reconstitution can multiply rapidly. **Reconstituted vaccines must be discarded at the end of the session or within 6 hours after reconstitution, whichever comes first.** Deaths have resulted when children received injections of reconstituted vaccines that were not discarded after 6 hours.

If possible, store only vaccines in the refrigerator with other vaccines.

Vaccines accidentally reconstituted with other medications such as insulin or anesthetics have resulted in deaths. It is safer to keep vaccines and diluents separate from other medication vials to avoid confusion and mistakes.

Do not reconstitute vaccine until the person needing the vaccine injection is present.

Remember that reconstituted vaccines are sensitive, must be kept cool after reconstitution, and must be discarded after 6 hours. For these reasons, the vaccine should not be reconstituted until the person needing the immunization is present.

Use a new syringe and needle to reconstitute each vial of vaccine. After mixing the diluent and vaccine, discard the syringe and needle.

Follow the steps below to safely reconstitute vaccines:

1. Read the label on the diluent vial to be sure that it is the diluent provided by the manufacturer for that specific vaccine and vial size.
2. Cool the diluent to 2-8°C prior to use to avoid thermal shock to the vaccine. **Make sure that you allow enough time for sufficient cooling.**
3. Check to make sure the expiry date of the vaccine and diluent vials has not passed, and that the VVM shows that the vaccine can be used. The VVM is located on the cap of vaccine vials that must be reconstituted.
4. Open the vaccine vial and discard the VVM with the vial cap.
5. Open the diluent vial and draw the entire contents of the diluent vial into the mixing syringe.
6. Empty the entire contents of diluent into the vaccine vial.
7. Discard the used mixing syringe and needle.
8. Do not leave the mixing needle in the vial; this is a common mistake that leaves the vial open to contamination.
9. Roll the vial between your fingers to mix the contents until all of the vaccine powder has dissolved. If necessary, note the date and time the vial was mixed.
10. Keep the reconstituted vaccine cool by placing the vaccine inside slits cut in the top of a foam pad that has been cut to fit a vaccine carrier. WHO recommends this technique to keep vaccine cold and protected from sunlight. Other techniques for keeping the vaccine cold—such as placing the vial inside a cup of ice—can damage or remove the vaccine vial label.
11. **Discard all reconstituted vaccine 6 hours after reconstitution, or at the end of the session, whichever comes first.**
12. Withdraw the vaccine from the vial using the same needle and syringe that will be used to inject the vaccine.

DANGER

BCG

Measles

*freeze-dried
Hib Vaccine*



Yellow Fever

*Must be discarded 6 hours
after reconstitution*

Adapted from poster CCPS/21, (4031) Freeze-dried Vaccine, World Health Organization (WHO)

Key Points

- Using the wrong diluent or another medication to reconstitute a vaccine can make the vaccine ineffective or dangerous.
- Use ONLY the diluent approved by the manufacturer to reconstitute the specific type of freeze-dried vaccine.
- Do not reconstitute the vaccine until the person needing that particular vaccine is present.
- Discard reconstituted vaccines within 6 hours of reconstitution, or at the end of the session, whichever comes first.
- Use a sterile syringe and needle to mix each vial of freeze-dried vaccine.
- Do not leave a needle in the top of the vial.
- Use the same syringe and needle to draw up the dose and to inject.

Quiz Questions

1. What are some common mistakes that lead health workers to use the wrong diluent to reconstitute vaccines?
2. Why is it important to reconstitute vaccine using the diluent prepared by the manufacturer for their specific vaccine?
3. When should reconstituted vaccines be discarded?
4. Name the vaccines that must be discarded within 6 hours of reconstitution.
 - A. BCG vaccines
 - B. Freeze-dried Hib vaccines
 - C. Yellow fever vaccines
 - D. Measles-containing vaccines
 - E. All of the above
5. What may happen if reconstituted vaccines are stored longer than 6 hours after reconstitution?
6. What are some major safety concerns related to reconstituted vaccines?

Answers are provided on page 80.

Practical Exercise #2

Selecting Vaccines from the Vaccine Carrier

1. Review the VVM cards on pages 27-30.
2. Assume you are an immunizer taking vials out of a vaccine carrier at the beginning of a campaign. The vials were taken from the refrigerator and placed in the vaccine carrier an hour earlier. Assume reconstituted vaccines were mixed the day before. Assume no vials have been opened today.
3. Which vials would you USE, and which vials would you NOT USE.
4. Keep in mind the following hints:

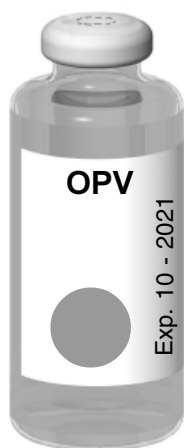
The vial is not usable if it:

- has expired or has no label;
 - **is suspected to be contaminated** (for example, if there are leaks or cracks in the vial; **OR** there is a change in appearance or floating particles; **OR** the opened vial has been submerged in water; **OR** the top of the vial is pierced with a used needle or a sterile needle on a used syringe; **OR** reconstituted vaccine has been opened for more than 6 hours after reconstitution);
 - was exposed to excessive heat, as indicated by the VVM.
5. **The answers are printed on the back of each illustrated card.**

Practical Exercise #2, cont.

VVM Cards Front

Unopened



1

Unopened



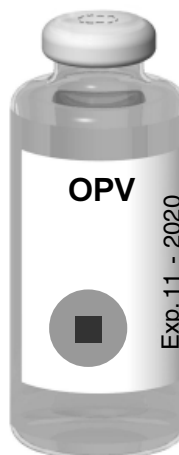
2

Opened



3

Unopened



4

Practical Exercise #2, cont.

VVM Cards Back


Answer:
DISCARD

Because:

- No label on vial.

2

Unopened Vial of OPV




Answer:
DISCARD

Because:

- The VVM has reached the discard point.

1

Unopened Vial of OPV



Answer:
DISCARD

Because:

- The VVM is beyond the discard point.

4

Opened Vial of Vaccine Diluent

Answer:
DISCARD

Because:

- The entire volume of the diluent vial should have been mixed to ensure correct vaccine concentration. Diluents usually do not contain preservatives and should be mixed immediately upon opening.

3

Practical Exercise #2, cont.

VVM Cards Front

Reconstituted



5

Unopened



6

Unopened



7

Unopened



8

Practical Exercise #2, cont.

VVM Cards Back

**Unopened Vial of
Measles Vaccine**

Answer:
USE

6

**Reconstituted Vial of
Measles Vaccine**

Answer:
DISCARD

Because:

- Reconstituted vaccines should be used as soon as possible after mixing and discarded within 6 hours.

5

**Unopened Vial of
Yellow Fever Vaccine**



Answer:
USE

8

**Unopened Vial of
Measles Vaccine**



Answer:
DISCARD

Because:

- The VVM is beyond the discard point.

7

Chapter

4

Safe Handling and Disposal of Sharps

Preventing Needlestick Injuries

Needles frequently injure health workers and can inject small but dangerous amounts of blood infected with hepatitis B, hepatitis C, HIV, or other germs. Needlestick injuries that occur immediately after an injection are more likely to spread disease caused by blood-borne pathogens, but needlesticks from trash piles may cause injury and infection from germs in the environment. Needlesticks may occur through recapping or carrying used syringes and needles, through insecure positioning of the patient—particularly children—and through disposal practices that leave syringes and needles accessible to the public or to grazing animals. In this chapter we will review ways to prevent needlestick injuries.

Minimize Handling of Needles and Syringes

Needlestick injuries can occur at any time, but they occur most frequently during and immediately after the injection. In general, the more that used or contaminated equipment is recapped, handled, or carried, the greater the risk of needlesticks. However, needlesticks are preventable, and there are simple steps health workers can follow to reduce the risk of needlesticks.

Minimizing handling of injection equipment is key to preventing injuries; however, it is often overlooked. Tips to minimize handling:

- Place a sharps disposal container at the immunization work area of every immunizer to permit immediate disposal of used syringes and needles.
- Do not manually remove the contaminated needle from the syringe.
- Do not walk around the immunization area or work site carrying used syringes.
- Do not recap syringes.
- Put the needle and syringe in the vial, in the patient, and in the sharps disposal container without setting it down in between steps.
- Do not manually sort medical waste.

Most of the injections given in curative care are unnecessary. Therefore, the most important way to prevent blood-borne infections in the workplace is to stop unnecessary injections.

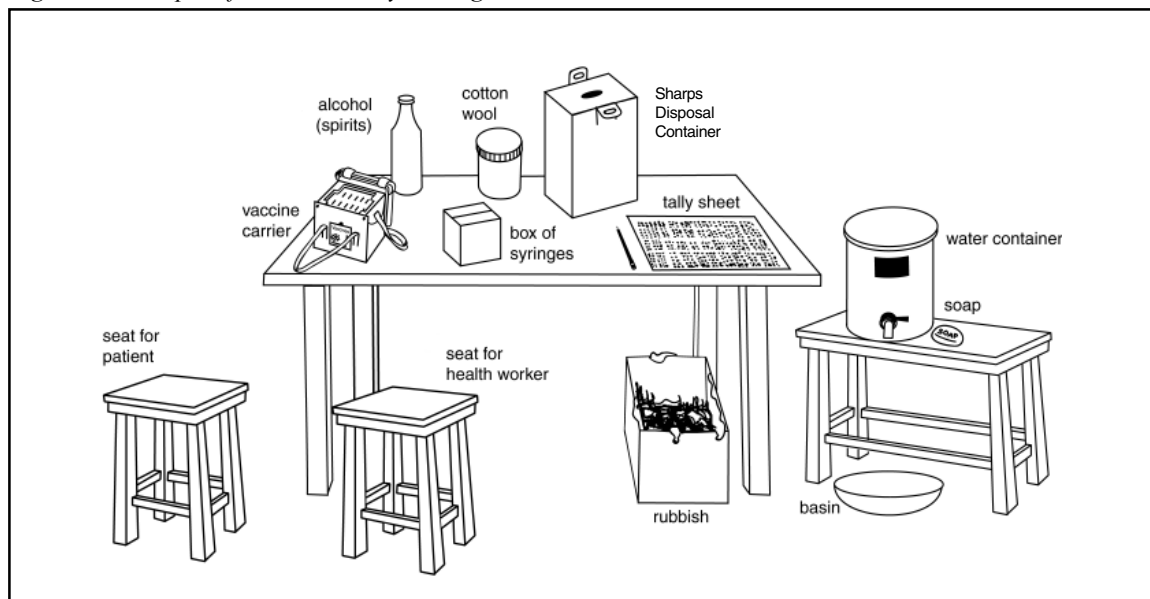
Physical Layout of the Vaccination Work Area

Health workers should plan the layout of their work space so that:

- the vaccine carrier is in the shade of a roof or under a table;
- the immunizer is between the child and all needles or sharp objects;
- the immunizer can see the entrance hole of the sharps disposal container and avoid pricks when disposing of needles. Some individuals may stand when giving immunizations. Those who sit may want to place the sharps disposal container on the floor.
- the worker can dispose of used needles without setting them down or taking a step;
- only one child at a time is at her/his work space; and
- each immunizer should have her/his own sharps disposal container at busy sites.

Note that in Figure 8, handwashing equipment is nearby. Research has shown that busy health workers do not wash their hands unless soap and water are immediately available.

Figure 8. Example of a conveniently arranged, indoor immunization table



Modified with permission from *Immunization in Practice*.
WHO/EPI/TRAM/98.12

Needlesticks can be prevented by setting up the work area carefully so that syringes can be immediately disposed of at the point of use, needles are not recapped, and no used injection equipment needs to be put down or picked up prior to disposal.

Remember: Reduced handling of needles and syringes means fewer needlesticks.

Part of setting up the clinic involves planning the patient flow. For an efficient clinic, keep the following guidelines in mind:

- Patients should enter in one area and exit in another (See Figure 9).
- For campaigns, separate registration tables from injection tables to help keep children calm.
- Try to arrange a shaded working space and a patient waiting area out of the hot sun.

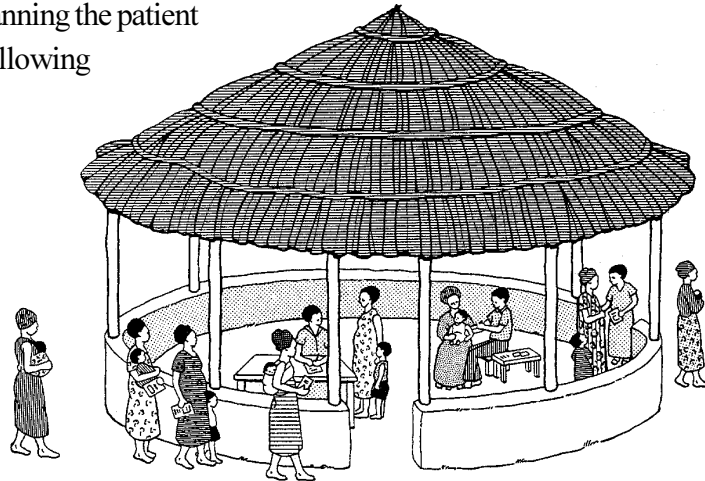


Figure 9. Separating entrances and exits to minimize crowding

Reprinted with permission from *Immunization in Practice*. WHO/EPI/TRAM/98.12

Other Tips that Help Prevent Needlesticks

Positioning children for injections

Unexpected motion at the time of injection can lead to accidental needlesticks. To prevent this, ***position the child securely*** before giving the injection. Have the adult sit and place the child on the lap with one arm behind the adult's back. Adults may tuck the child's legs between theirs to secure them, or hold the child's legs as shown in Figures 10 and 11. The adult should also hold the child's free arm (see Figure 12). Health workers cannot hold the child because they need both hands for the injection. Even though the child is securely positioned, ***always tell him/her when you are about to give them an injection.***

Figure 10. Dividing the thigh into three parts to choose the middle part of the upper, outer thigh for an intramuscular injection

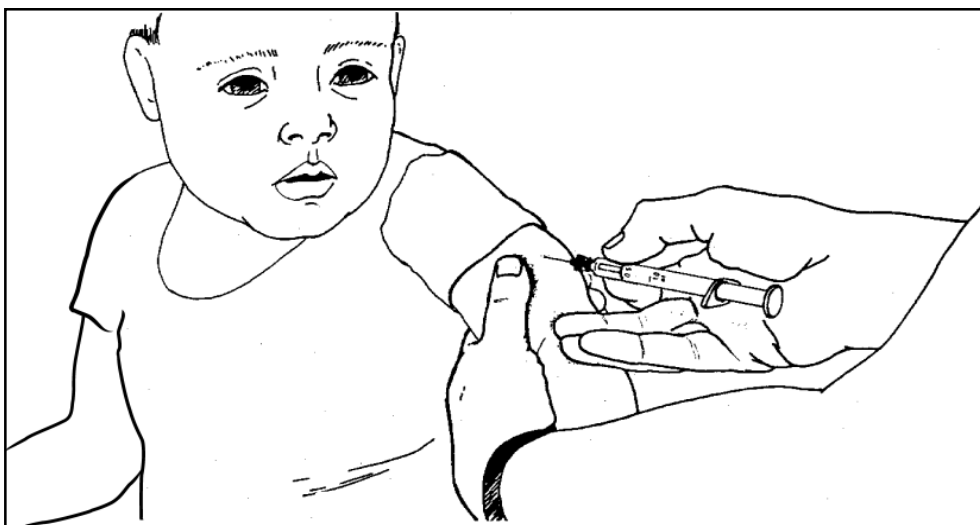


Figure 11. Giving an intramuscular injection: example of a securely positioned child



Reprinted with permission from *Immunization in Practice*. WHO/EPI/TRAM/98.12

Figure 12. Example of good subcutaneous injection technique but poor positioning
The child could reach around with his free hand to grab the needle.



Adapted with permission from *Immunization in Practice*. WHO/EPI/TRAM/98.12

After an injection

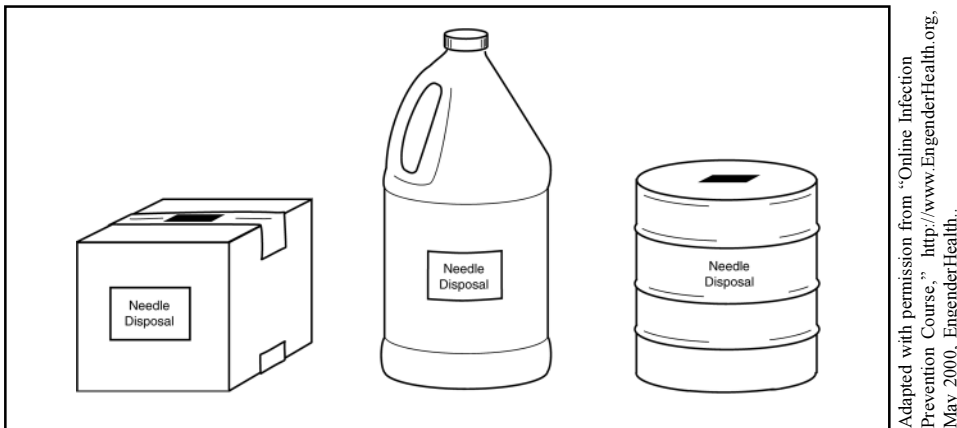
Health workers sometimes recap, bend, or manually remove the needle from the syringe after use because they think that these practices are safe. These are well-meaning—but dangerous—practices that place the health worker at risk of accidental needlestick injury. ***Never recap, bend, or manually remove the needle from a used syringe.***

One-handed methods to remove and contain the needle could reduce the volume of sharps waste. Several approaches are now being explored. Evidence of their effectiveness is sought from groups experienced with their use.

Safe Disposal of Injection Equipment and Other Sharps

To further prevent needlesticks after use, syringes, needles, and other contaminated sharps should be immediately placed in a leak-proof, puncture-proof container. These containers are called *needle-disposal boxes*, *sharps disposal containers*, or *safety boxes*. Medical waste that might cut or puncture the skin should be separated from paper and other waste and placed inside the sharps disposal container. For example, after use, needles and syringes, broken vaccine vials, lancets, and broken ampules should be placed inside the sharps container that is located within reach of the health worker. These containers should be used only once. The practice of opening them to reach inside and pull out syringes is dangerous.

Figure 13. Sharps disposal containers



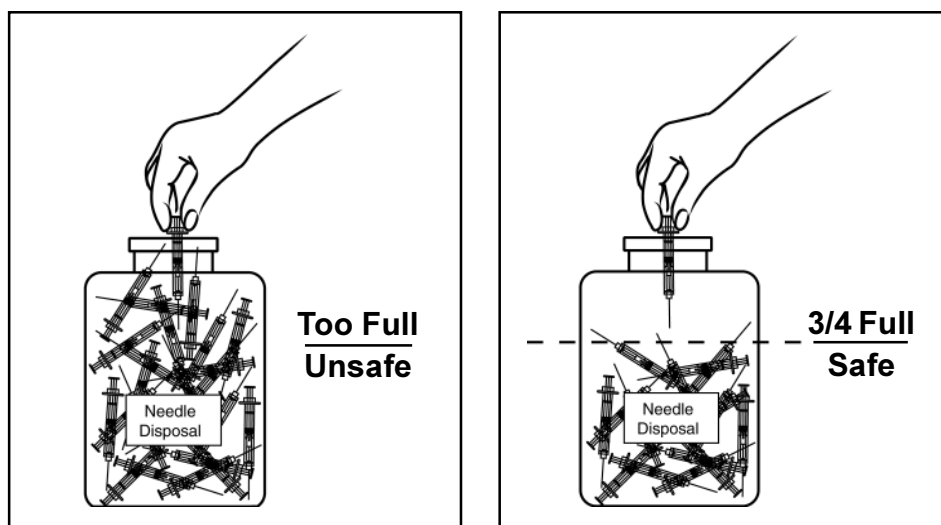
To prevent needlesticks during transport or storage, sharps disposal containers should be:

- puncture proof and leak proof,
- labeled with a warning that can be understood by local people, and
- sealed so they remain closed when stacked.

Do not fill sharps disposal containers completely full.

When only three-quarters full, sharps disposal containers should be sealed and discarded to prevent needlesticks that occur when the lid is pushed down against an overly-full box, or when people must put their hands too close to the points of contaminated needles. Sharps disposal containers should be filled only once and discarded immediately to minimize risk of needlesticks by workers who empty them.

Figure 14. Filling sharps disposal containers more than three-quarters full may cause needlesticks



Transporting contaminated waste

Transporting contaminated waste can expose others to disease and injury. Consider the following points when transporting waste:

- Delays in the disposal of contaminated needles may increase the occurrence of accidents. Containers should be collected for incineration or other forms of destruction (burn and bury) as soon as possible at the end of the immunization session.
- Contaminated needles should not be transferred from container to container.

- If containers are transported in a vehicle and the containers leak, the vehicle should be disinfected with a bleach/water solution (1 to 100 ratio) before being used for other purposes. This solution should be prepared the day of use because bleach (sodium hypochlorite) is rapidly inactivated.
- Do not allow people to sit on top of sharps disposal containers during transport. The containers may break open under their weight and turn the sitter into a pin cushion!

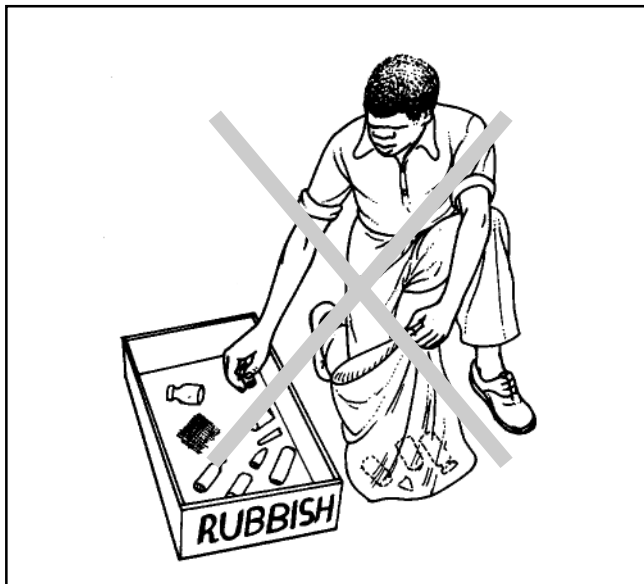
Health Workers' Responsibility for Cleaning the Outreach Site

If health workers are giving immunizations at an outreach clinic or site, they should not leave any materials behind that could harm people or animals. Health workers should never save used syringes to count later in order to estimate the number of children immunized.

Before leaving the immunization outreach site, health workers should:

- Remove all empty or discarded vials from the immunization work site.
- Remove all syringes or needles at the immunization work site.
- Make sure all single-use injection equipment is disposed of in sharps disposal containers that are sealed and taken to the holding site for destruction by burning, incineration, or burial.

Figure 15. Never sort broken vials and medical waste by hand



Modified with permission from *Immunization in Practice: Module 9*.
WHO/EPI/TRAM/98.12

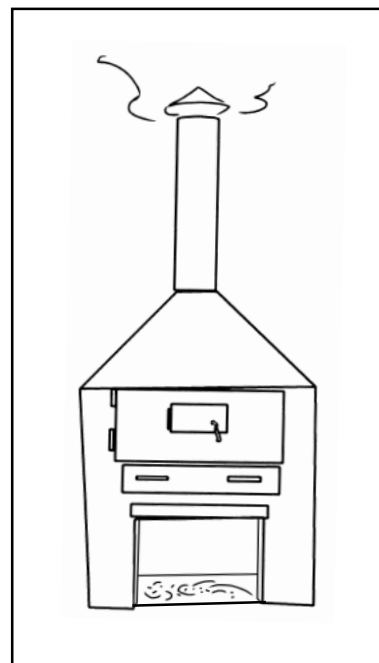
Destroying syringes: no easy options, no good solutions

Unfortunately, there are no easy, non-polluting methods that destroy syringes or needles. Injection equipment can be decontaminated by placing it in bleach and water prior to burial. Decontamination removes blood-borne pathogens. However, once the material is buried, it will be contaminated by other germs. People who step on needles will remain at risk for injury and other infections such as tetanus. Two other options that destroy syringes and needles after disposal are incineration and burning.

Incineration

Incineration can completely destroy needles and syringes by burning at temperatures above 800°Celsius. The high temperatures kill microorganisms and reduce the volume of waste to a minimum. Properly functioning incinerators ensure the most complete destruction of syringes and needles, and produce less air pollution than burning at lower temperatures. Because they require special facilities and personnel, some hospitals use incinerators at other facilities, such as cement factories, to destroy their wastes. Sharps disposal containers can sometimes be destroyed by commercial or public incinerators.

Figure 16. Incinerator

**Burning**

“Burning” refers to the combustion of injection equipment at lower temperatures that may or may not completely destroy them. Adding kerosene and igniting medical waste is an example of burning. Burning is commonly done in an open field or in a protected hearth.

To facilitate burning, some cardboard or fiberboard sharps containers instruct persons to open holes in the cardboard at specially marked sites when the box is assembled. Do this before sharps are placed in the box. These holes allow air to get inside the box during burning and aid the destruction of the syringes.

Open burning

Open burning of contaminated sharps in a pit is the least preferred, most toxic option. Open burning is not recommended, because it scatters waste. If waste is placed in an open pit, the pit should not be so deep that people have to crawl down into the pit to start the fire. They could be pricked by the remaining stubs of needles.

However, if open burning must be done, health workers should:

- fence off and clear the area in which open burning takes place;
- warn people to stay away and avoid smoke and fumes from the fire;
- carry the waste to the site just before burning;
- burn the waste in small, designated areas;
- prevent animals or people from accessing the site;
- make sure the fire is completely out before leaving the site; and
- prevent waste from scattering and littering the surrounding areas.

Burning in metal drum or hearth

This is another way to dispose of used injection equipment and contaminated needles. Sharps disposal containers can be placed in a metal container. When the container is three-quarters full, fuel can be poured in, the waste ignited, and the materials burned until the fire goes out on its own. The remains should then be buried.

Burying debris after burning or incineration.

The remains of injection equipment and sharps disposal containers should be buried after burning. Bury debris in a pit at least one meter deep, in a controlled area for burying waste, or a similar location where people do not have access and will not dig to plant crops or establish latrines.

Some people recommend covering the site with concrete when the pit is full to prevent digging at the site in the future.

Key Points

- Needlestick injuries can occur at any time during an injection, but they occur most frequently during and immediately after the injection.
- Always prepare and position young children securely before giving an injection so they do not grab needles, or kick unexpectedly.
- Always tell patients when you are about to give them an injection.
- Do not recap, bend, or break needles before disposal. Do not manually remove the needle from the syringe.
- After injections, discard syringes and needles at the point of use; do not walk around with used equipment.
- Sharps disposal containers should be closed, sealed, and labeled when they are three-quarters full.
- Sharps disposal containers should be puncture-proof and used only once.
- Burning is one way to destroy sharps disposal containers.
- Well-functioning incinerators that burn above 800°C ensure the most complete destruction of syringes and needles. Burning at high temperatures can produce less air pollution than burning at lower temperatures.

Quiz Questions

1. Why is it important for an adult to hold a child securely for an injection?
2. Is the following statement true or false? “Everyone who handles used, contaminated injection equipment is at risk of infection and injury.”
3. Is the following statement true or false? “If injection equipment and other sharps need to be stored at a facility before they are burned, they should be placed in a big pile behind the clinic.”
4. Proper disposal of injection equipment and other sharps:
 - A. Minimizes the spread of infections.
 - B. Reduces the risk of injury from needlesticks.
 - C. Improves the appearance of a facility.
 - D. All of the above.
5. Proper disposal of used syringes, needles, and other sharps includes:
 - A. Always breaking or bending the needle before disposal to prevent re-use.
 - B. Placing the needle and attached syringe in a puncture-proof container.
 - C. Waiting until sharps containers are full before throwing them away.
 - D. Removing the needle from the syringe with two hands.
 - E. None of the above.
6. The biggest reduction in transmission of blood-borne infections through unsafe injections can be achieved through:
 - A. Eliminating unnecessary injections.
 - B. Burning syringes completely to the point of destruction.
 - C. Using only sterile needles and syringes in immunization programs.
7. What steps can make open burning safer?
8. Describe the procedures for burning injection equipment and other sharps in a metal container.

Answers are provided on page 82.

Case Study #2

The Recapping Quandary

Your clinic has a special container for disposing of needles and syringes. The container is located in the vaccination room, since that is where most injections are given. Occasionally, patients need to be given injections in the treatment room, which is down the hall from the vaccination room. When this occurs, the nurses recap the hypodermic needles, carry them down the hall to the vaccination room, and deposit them in the sharps disposal container.

Question for Review

What should be done differently to reduce the risk of infections at your clinic?

Answer is provided on page 84.

Reprinted with permission from “Online Infection Prevention Course,” <http://www.engenderhealth.org/ip/index.html>, May 2000, EngenderHealth.

Case Study #3

The Pile of Debris

All waste from the district hospital is gathered and thrown into piles behind the main hospital building. Every six months, the hospital director hires some laborers to shovel the waste into trucks and cart it off to the closest dump, which is located in a neighboring town. Frequently, people pick through the waste looking for items that they can use or sell. Children also play near the waste, and dogs commonly are seen poking their noses in the piles.

Questions for Review

1. Who is at risk of infection from these practices?
2. How can the waste-disposal problems here be solved?

Answers are provided on page 85.

Reprinted with permission from "Online Infection Prevention Course," <http://www.engenderhealth.org/ip/index.html>, May 2000, EngenderHealth.

Case Study #4

The Pit at the Turtle Clinic

Ms. Gomez is a new district supervisor making her first visit to the Turtle Clinic. The night guard asks to speak with her to explain his concerns about waste disposal. Upon visiting the waste-disposal site, Ms. Gomez finds a large pit that is less than half full, with a layer of leaves and other garden debris visible. While talking to the night guard, she sees a gardener dump a wheelbarrow full of branches, leaves, and other debris into the pit. Then, against the outside of the fence, she finds a pile of what looks like recently dumped medical waste, complete with bloody dressings and exposed needles attached to IV tubing.

Questions for Review

1. What are the waste-disposal issues here?
2. What should be done about this situation?

Answers are provided on page 86.

Reprinted with permission from “Online Infection Prevention Course,” <http://www.engenderhealth.org/ip/index.html>, May 2000, EngenderHealth.

Case Study #5

The Missing Syringe Barrels

Ms. Oludara is a nurse-midwife at the Yaro Clinic, a small but busy maternal/child health clinic. She recently attended an infection-prevention training course where she realized that she did not know where medical waste was disposed of at her clinic. Upon returning to the clinic, Ms. Oludara discovers that the area designated for waste disposal is a shallow pit among the trees behind the clinic. She notices that there are many plungers for the syringes but not the barrels. She questions the doctors, midwives, and housekeeping staff, but no one can explain what is happening to the syringe barrels. The providers say that after using the syringes and needles, they manually remove the needles, place them in empty bottles, and throw the syringes in the trash can. Ms. Oludara then asks the man who collects and disposes of the medical waste about the barrels. He tells her that he once saw some teenage girls who lived near the clinic collecting the syringe barrels to use as rollers for their hair. He had thought it was a clever idea.

Questions for Review

1. What are the waste-disposal issues here? Who is at risk of infection or injury, and why?
2. What should be done about this situation?

Answers are provided on page 87.

Reprinted with permission from “Online Infection Prevention Course,” <http://www.engenderhealth.org/ip/index.html>, May 2000, EngenderHealth.

Notes:

Chapter

5

Using Auto-Disable Syringes

Auto-Disable Syringes

Re-use of injection equipment is responsible for most of the infections that result from immunization. Fortunately, several new types of syringes have been designed to prevent re-use: auto-disable (AD) syringes automatically become disabled after one use. WHO and UNICEF now recommend that auto-disable syringes be used for administering vaccines—particularly in mass immunization programs.

Auto-disable syringes are designed for use with little or no instruction. However, an initial practice session with the new syringes may help workers understand how to use them more quickly, may help them appreciate the benefits of auto-disable syringes, and may assist workers to switch between different types of syringes without wasting them.

Auto-Disable Syringe Designs

This chapter will review the following AD syringe designs, and will discuss their use and relative advantages. Some designs are produced by several different manufacturers, so you may need to refer to the syringe description and illustration to identify the design.

New types of auto-disable syringes:

- Soloshot™* and Soloshot™* FX syringes
- K1™* syringes
- Destroject®* syringe
- Univec™* syringe
- Uniject™* prefill injection device

*SoloShot and SoloShot FX, and Uniject are trademarks of BD; K1 is a trademark of Star Syringe, Ltd.; Destroject is a registered trademark of Bader and Partner Vertriebsgesellschaft mbH; Univec is a trademark of Univec, Inc.

BD SoloShot™ and SoloShot™ FX Auto-Disable Syringes

Syringe Description

The SoloShot and SoloShot FX syringes are single-use, disposable, auto-disable syringes with a metal clip that locks the plunger after a single use. The SoloShot syringe has a fixed needle and is packaged with plastic caps to keep the needle and plunger sterile before use. In contrast, the SoloShot FX syringe currently comes with a detachable needle that is packaged together with the syringe in a sterile paper package. **The SoloShot FX detachable needle can only be attached to the SoloShot FX syringe barrel.** This prevents the needle from being re-used with other syringes.

Figure 17. SoloShot FX

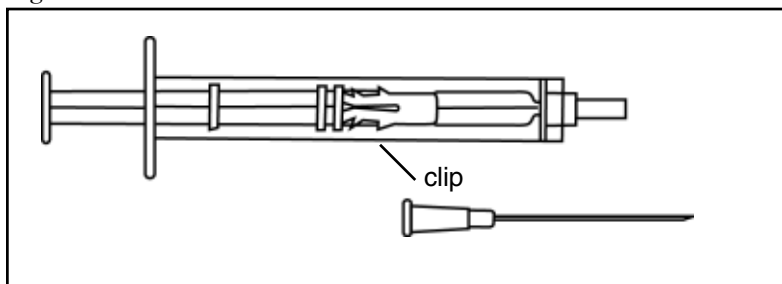
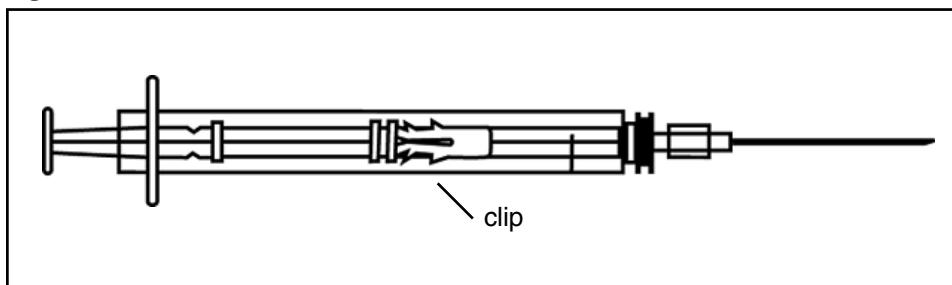


Figure 18. SoloShot



Change in injection technique required

Because the plunger can go back and forward only once, health workers should NOT draw up air to inject it into the vial. In addition, the locking mechanism decreases the distance that the plunger can move if the health care workers aspirate for blood when giving an injection. It is still possible to aspirate, but the plunger will travel only a short distance.

Advantages of the SoloShot AD syringes

- SoloShot is designed to prevent the re-use of non-sterile syringes.
- The longer syringe length makes it less tiring to use when immunizing large groups of people.
- The fixed-needle design reduces the dead space in the syringe that wastes vaccine or medicine.

Advantages of the SoloShot FX AD syringes

- SoloShot FX is designed to prevent the re-use of non-sterile syringes.
- The shorter length reduces the volume of material to be shipped and destroyed after use.
- Elimination of the black rubber seal on the plunger reduces the harmful by-products produced by incinerating syringes.

For more details about the SoloShot and SoloShot FX, or other BD immunization devices, please contact:

BD

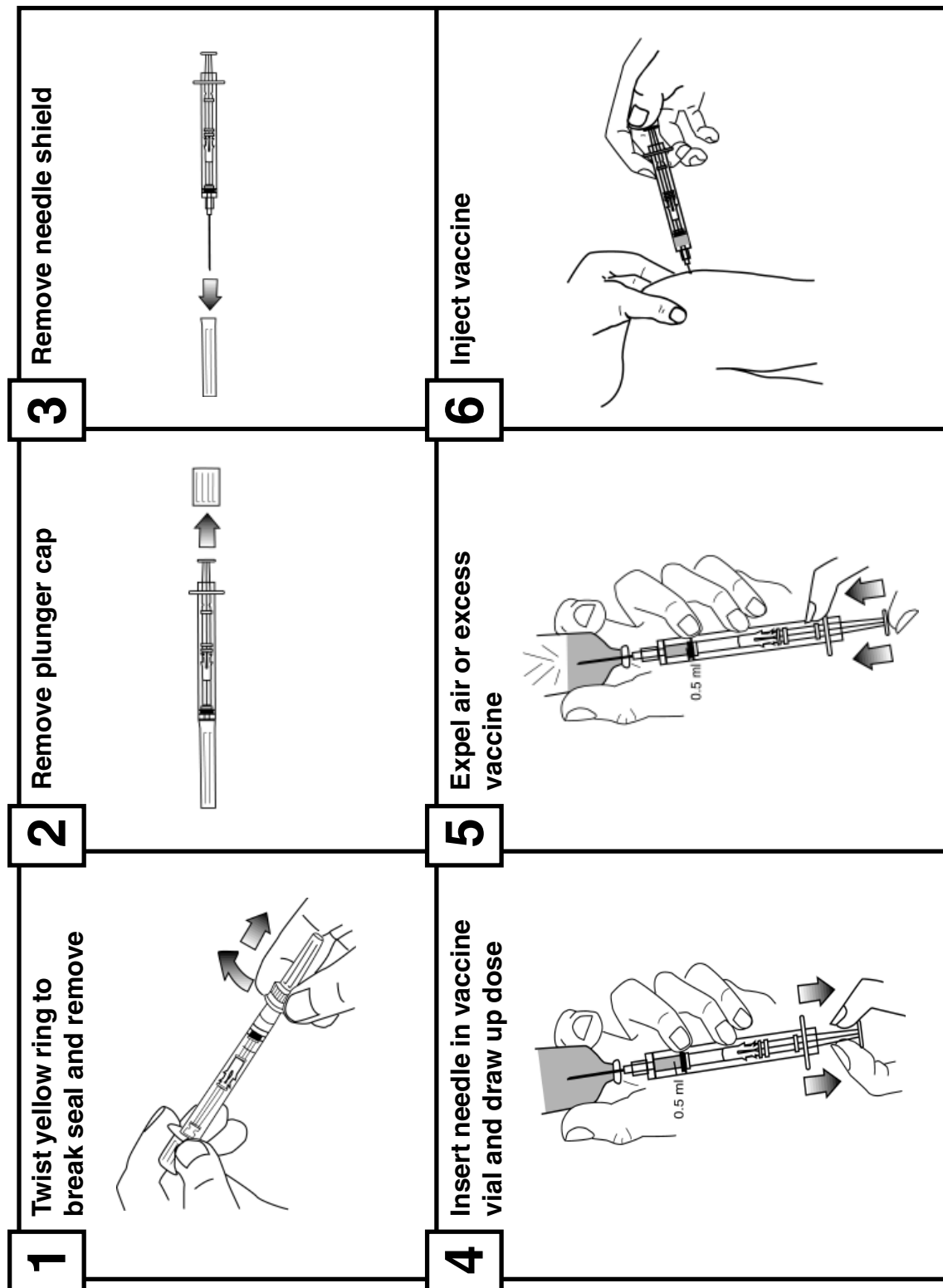
1 Becton Drive
Franklin Lakes, NJ 07417
U.S.A.

Phone: (201) 847-6800

Fax: (201) 847-4845

Web site: www.bd.com/immunization/

SoloShot Syringe Instructions



Adapted with permission from BD.

SoloShot FX Syringe Instructions

1 Peel open sterile wrapper	2 Attach needle	3 Remove needle shield	6 Inject vaccine
4 Insert needle in vaccine vial and draw up dose	5 Expel air or excess vaccine		

Adapted with permission from BD.

K1™ Auto-Disable Syringes*

Syringe description

The K1 syringe is a single-use, disposable, auto-disable syringe with a safety plunger that breaks off after a single use. The K1 syringe can be purchased with a fixed needle or a detachable needle. The detachable needle supplied with the syringe cannot be used with standard disposable syringes. A BCG syringe with a 0.05 ml dose line is available. Production of a BCG syringe with a 0.05 ml and 0.1 ml line is under discussion.

Figure 19. K1 Syringe with twist tab

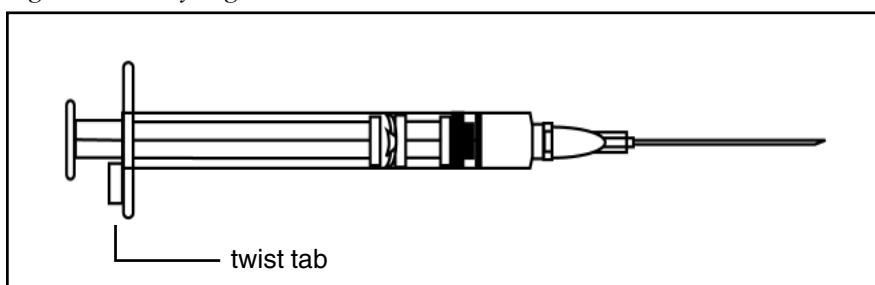
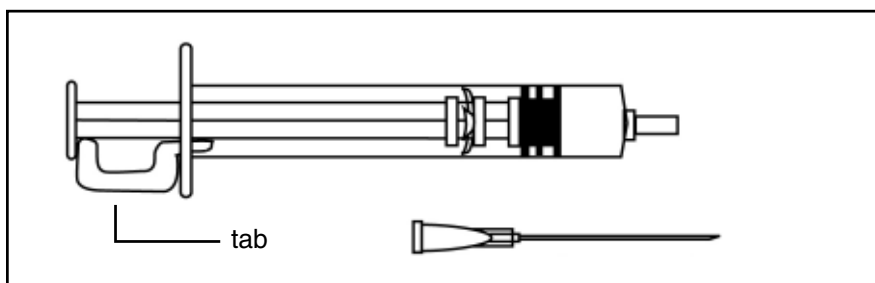


Figure 20. K1 Syringe with tab to pull off



Change in injection technique required

The K1 syringe differs from the other AD syringes discussed in this manual because it must be activated before use. The K1 syringes either have a small, plastic tab that must be removed, or 1 or 2 small twist tabs. Both measures provide assurance that the syringe has not been used before.

To use these syringes, first look at the K1 syringe to see whether the syringe has a twist tab at the end of the barrel, or whether there is a rectangular tab holding the plunger to the barrel. Instructions are illustrated on page 54.

*Manufacturers known to make this design for immunization as of September 2001 include: Tyco International (www.kendallhq.com), and Hindustan Medical Devices (www.hmdhealthcare.com).

If the syringe has a twist tab:

Twist the plunger slightly—about $\frac{1}{4}$ of a turn—to break the seal connecting the plunger and the barrel.

Caution: if the barrel is twisted too far, the plunger will detach and the syringe will be disabled.

If the syringe has a small rectangular tab on the plunger:

Pull the plunger back slightly and pull the tab off.

Then, regardless of the type of K1 syringe, the same technique used with standard syringes or AD syringes can be used to draw up and inject the dose.

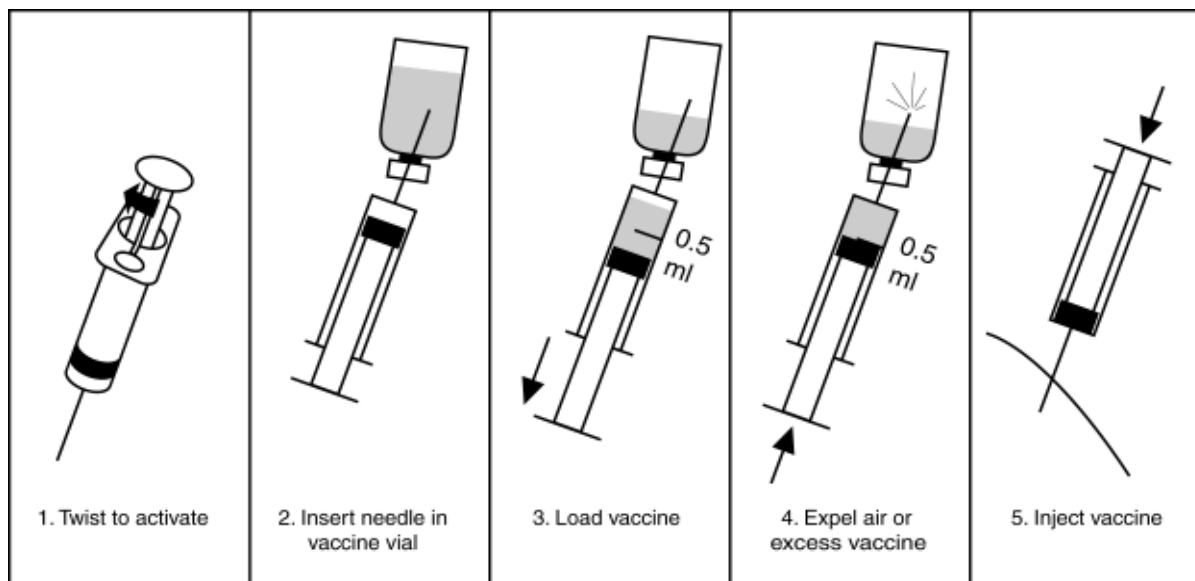
Advantages of K1 AD syringes

- K1 syringes are designed to prevent the re-use of non-sterile syringes.
- The smaller barrel reduces the volume of material to be shipped and destroyed after use.
- The fixed-needle design reduces the dead space in the syringe that wastes vaccine or medicine.
- The design allows some air to be injected into vials to equalize the pressure that develops when doses are withdrawn from a multi-dose vial.

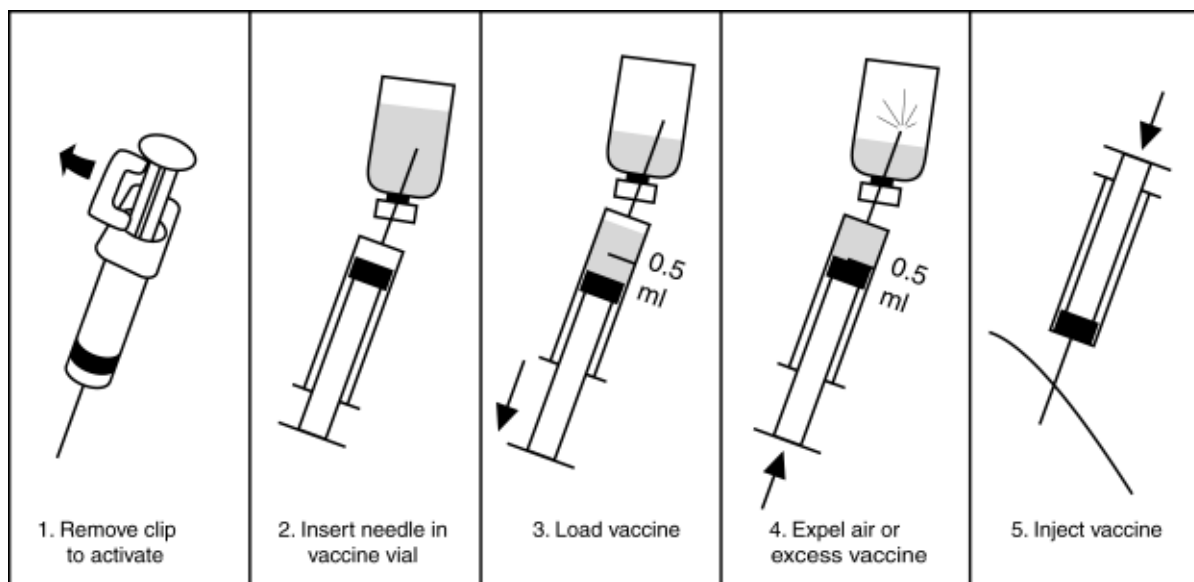
For more details about the K1 devices, please contact:
Star Syringe Ltd.
Gossard House
7-8 Savile Row
London, England W1X 1AF
Phone: (44) 20 7292 0800
Fax: (44) 20 7292 0801
Email: mkoska@starsyringe.co.uk
Web site: www.k1.adsyringes.com

K1 Syringe Instructions

Type One: K1 Syringe with twist tab—twist to activate



Type Two: K1 Syringe with tab—remove tab to activate



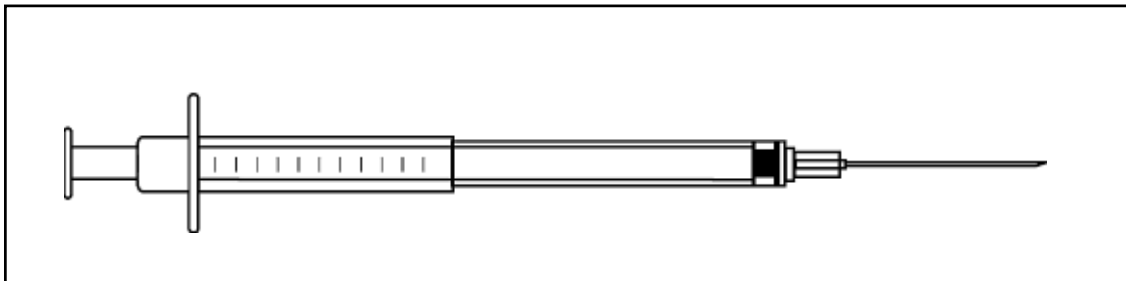
Instructions from Star Syringe Ltd., 1999-2000 (www.kl.adsyringes.com/products/htm); modified with permission.

Destroject® Auto-Disable Syringe

Syringe description

The Destroject single-use, disposable, auto-disable syringe comes with a fixed needle. The sterile packaging includes a plunger cap and needle shield. The plunger locks once it is depressed. This syringe is available in a 0.5 ml size.

Figure 21. Destroject syringe



Change in injection technique required

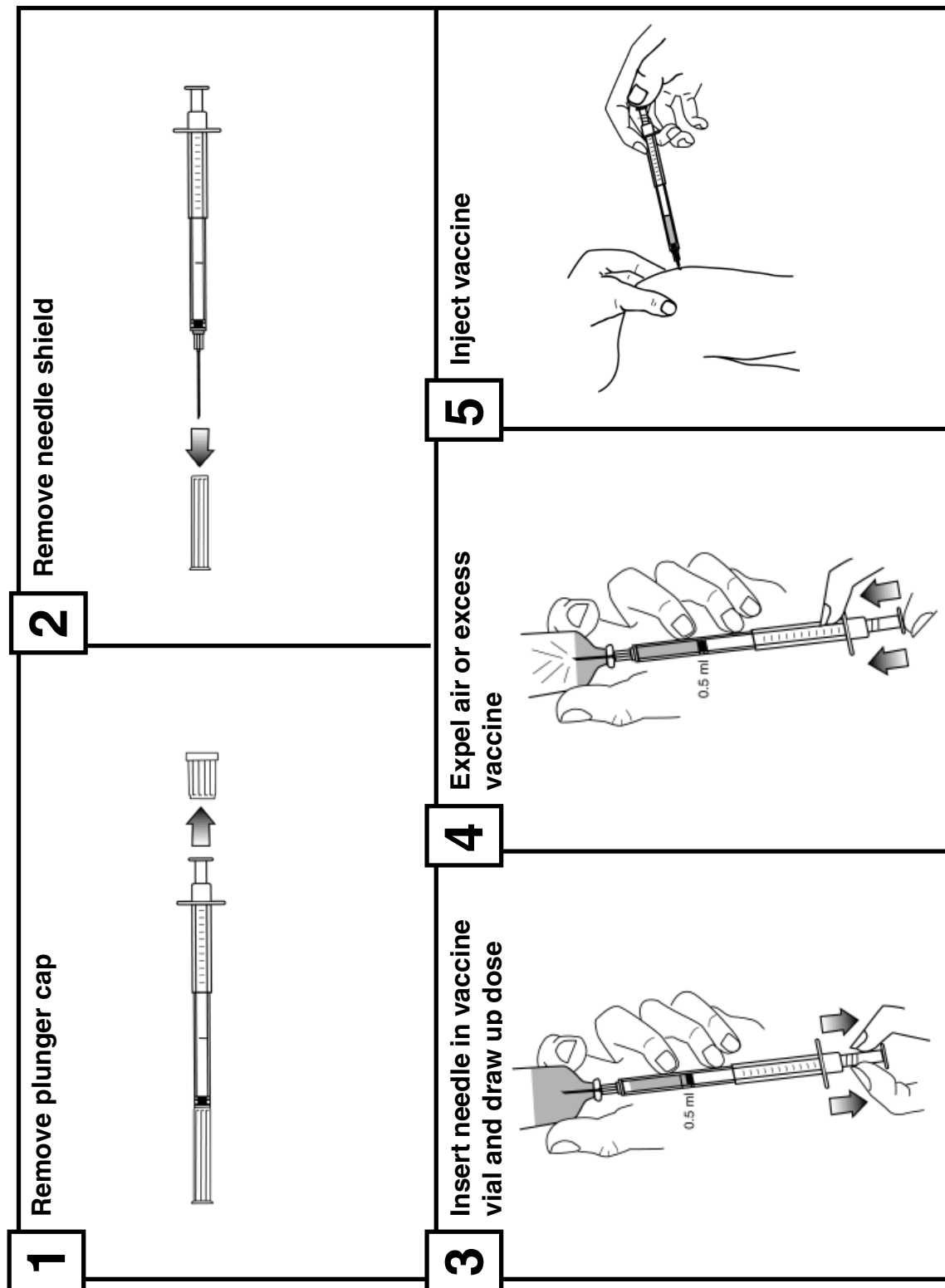
Like the SoloShot syringes, the plunger of this syringe can be pushed in only once. Users should not draw the plunger back to inject air into the vial prior to drawing up a dose. It is not possible to aspirate for blood when using this syringe.

Advantages of Destroject AD syringes

- Destroject is designed to prevent the re-use of non-sterile syringes.
- The longer syringe length makes it less tiring to use when immunizing large groups of people.
- The fixed-needle design reduces the dead space in the syringe that wastes vaccine or medicine.

For more details about the Destroject device, please contact:
GmbH Medical Devices
Havelstrasse 1-3
24539 Neumünster
Germany
Phone: (49) 43 2188 0088
Fax: (49) 43 218 1855
Email: info@destroject.de
Web Site: www.destroject.de

Destroject Syringe Instructions



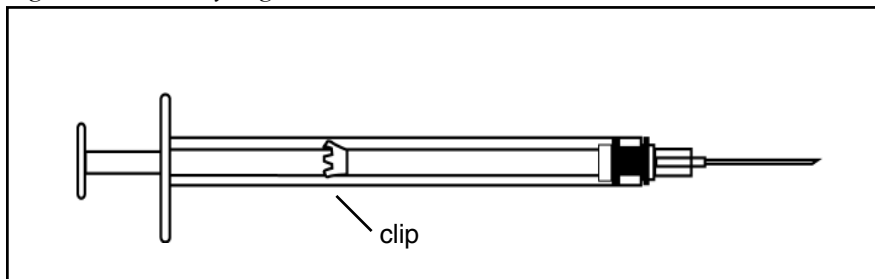
Modified with permission from GmbH Medical Devices.

Univec™ Auto-Disable Syringe*

Syringe description

The Univec syringe is a 0.5 ml syringe which comes with a fixed needle or detachable needle. The syringes are individually packed in sterile paper packaging. The plunger locks once it is depressed, but can be withdrawn a short distance to aspirate for blood when checking the needle position. A BCG syringe with a 0.05 ml dose line is available.

Figure 22. Univec syringe



Change in injection technique required

Like the SoloShot and DestroJect syringes, the plunger of this syringe can be pushed in only once. Users should not draw the plunger back to inject air into the vial prior to drawing up a dose.

Advantages of Univec AD syringes

- Univec is designed to prevent the re-use of non-sterile syringes.
- The longer syringe length makes it less tiring to use when immunizing large groups.
- The fixed-needle design reduces dead space in the syringe that wastes vaccine or medicine.
- The plunger has some limited back and forth motion that can assist in removing air from the syringe.

For more details about the Univec device, please contact:

Univec

22 Dubon Court
Farmingdale, NY 11735
U.S.A.

Phone: (631) 777-2000

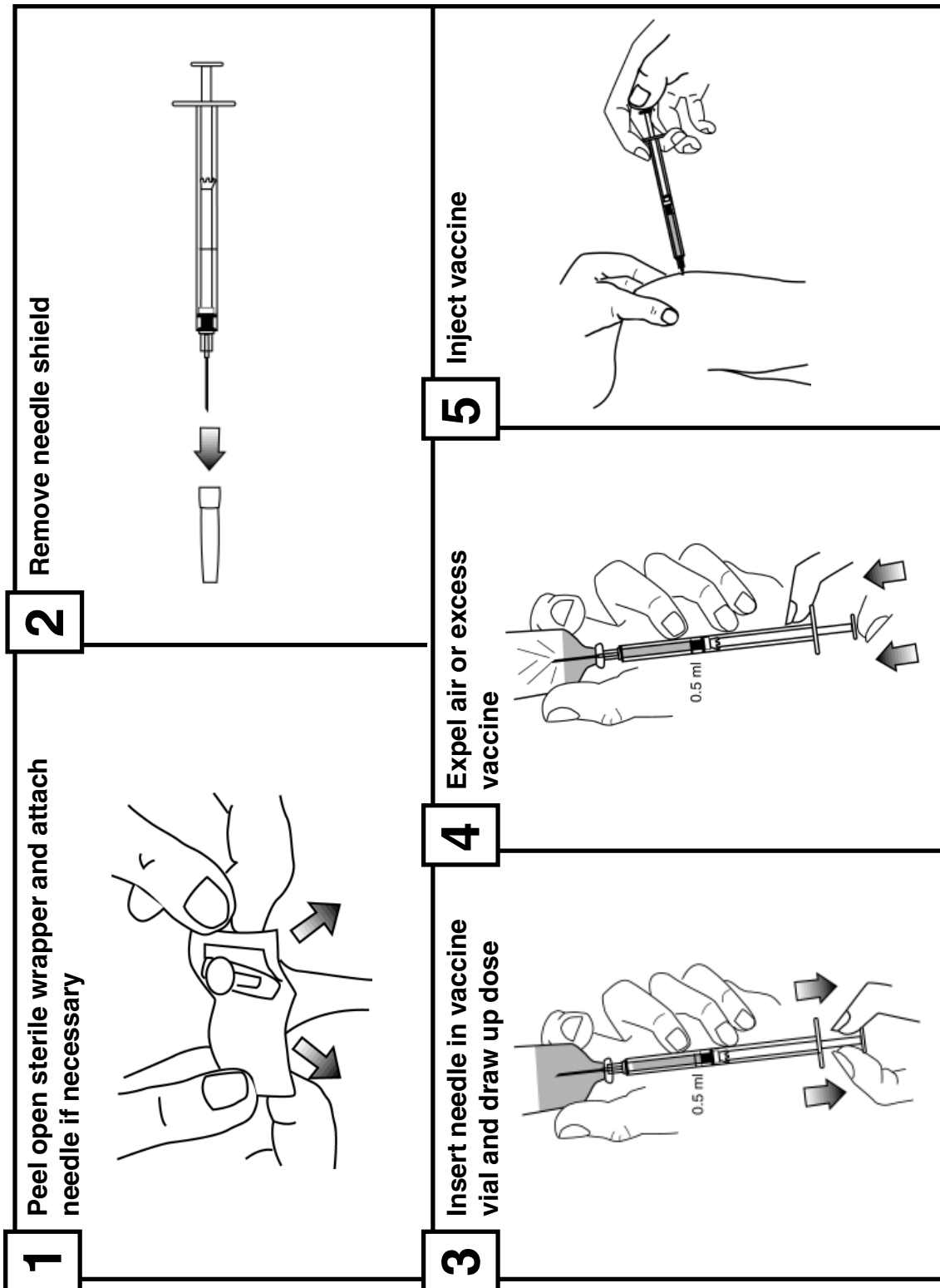
Fax: (631) 777-2786

Email: univec@univec.com

Web Site: www.univec.com

*Manufacturers known to make this design for immunization as of September 2001 include: Terumo (www.terumo-europe.com), and Univec.

Univec Syringe Instructions



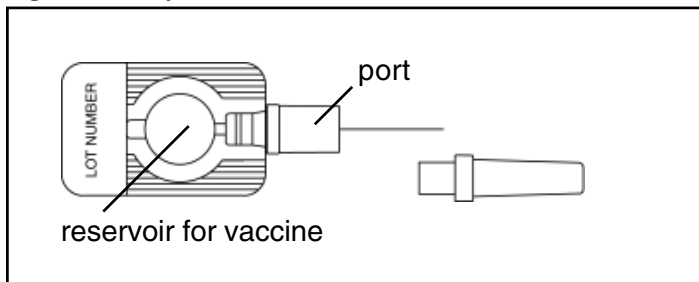
Adapted with permission from Univec, Inc.

BD Uniject™ Prefill Injection Device

Device description

The Uniject is a single-use, disposable, auto-disable injection device that contains one dose of vaccine or medicine. Currently, each dose is individually wrapped in a foil envelope. Because the dose cannot be separated from the injection device, use of Unijects can increase the volume of cold storage required, particularly at central levels of the cold chain.

Figure 23 . Uniject



For more details about the Uniject devices, please contact:

BD

1 Becton Drive
Franklin Lakes, NJ 07417
U.S.A.

Phone: (201) 847-6800

Fax: (201) 847-4845

Web site: www.bd.com/immunization/

Change in injection technique required

The device needs to be activated by pressing the needle shield into the port. This opens the canal that allows medication or vaccine to flow into the needle. The health worker then removes the needle shield. While holding the Uniject by the hard plastic port, the health worker inserts the needle into the patient and squeezes the bubble-like reservoir until the entire dose has been injected.

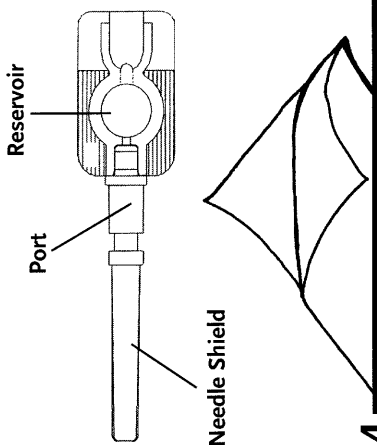
Advantages of Uniject injection device

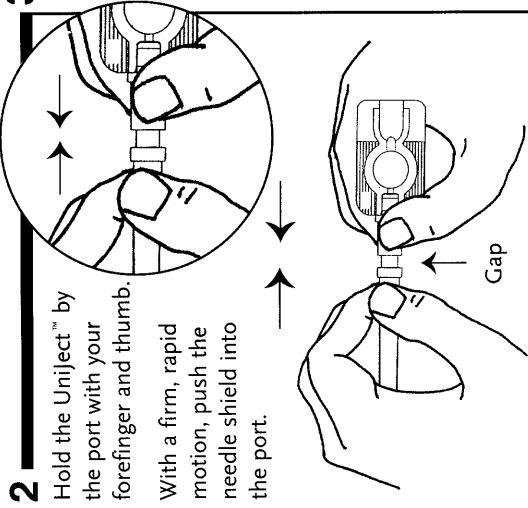
- Uniject can only be used once.
- The prefilled device ensures an accurate dose.
- The syringe and vaccine can be ordered with a single request.
- Vaccine and syringes will always be available in the necessary ratios: one dose of vaccine and one syringe.
- The device contains less plastic than a syringe, so the volume of waste is reduced.
- The unit-dose device reduces the vaccine wastage that occurs when health workers use open multi-dose vials.
- Use of VVMs on the Uniject outer packaging may allow flexible storage procedures for heat-stable vaccines.

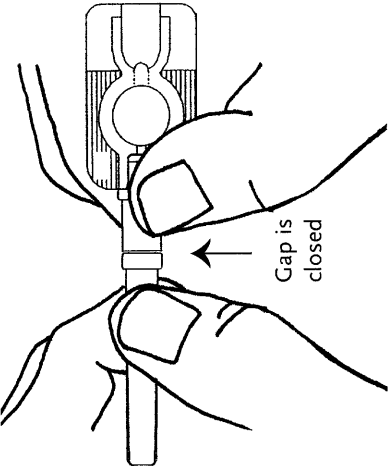
Uniject™ Device Instructions

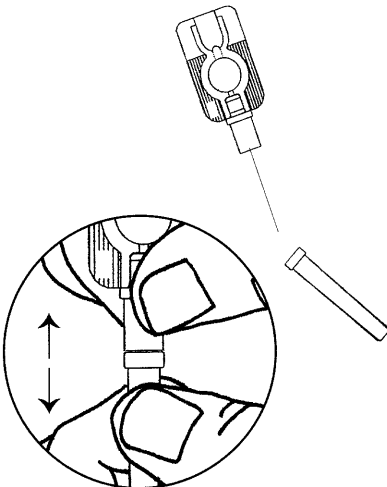
Uniject™ Activation and Use

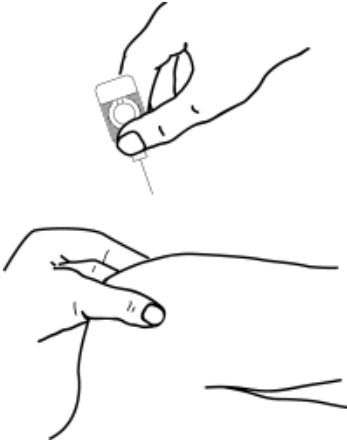
- 1** Open the foil pouch and remove the Uniject™.

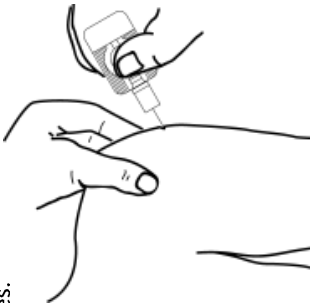

- 2** Hold the Uniject™ by the port with your forefinger and thumb. With a firm, rapid motion, push the needle shield into the port.


- 3** As Uniject™ activates, you will feel a click. Continue to push firmly until you close the gap between the needle shield and port.


- 4** Remove the needle shield.


- 5** Continue to hold the Uniject™ by the port and insert the needle into the patient.


- 6** Squeeze the reservoir firmly to inject. After the reservoir completely collapses, remove the Uniject™. Do not re-shield used Uniject™. Discard the used Uniject™ according to established medical waste disposal procedures.



Reprinted with permission from BD.

Is Aspiration Necessary?

Some of the new designs of AD syringes do not permit health workers to aspirate for blood when they place the needle in the injection site. The inability to aspirate with AD syringes has led workers to wonder whether it is necessary to aspirate when giving immunizations.

It is not necessary to aspirate for blood for routine immunizations.

AD syringes were used without aspirating in campaigns where millions of intra-muscular immunizations were given. No problems were documented related to lack of aspiration. There is also no evidence to justify the need to aspirate when giving subcutaneous or intradermal vaccinations. Many health workers have been taught to aspirate for blood to see if the needle is in a blood vessel. However, the injection sites used for immunization (e.g., the center of the deltoid muscle; the subcutaneous fat of the upper arm; and the middle portion of the upper, outer thigh) do not have large blood vessels.

It is also important to note that blood oozing from the injection site after the needle is removed does not indicate that the needle was in a blood vessel, does not indicate poor technique, and can occur with injections given by experts. After considering the way vaccines act in the body (pharmacokinetics), the historic experience with vaccines, and the fact that injection sites do not have large, accessible vessels, WHO does not require that immunizers aspirate for blood when injecting vaccines into these sites. While the plunger of some AD syringes can be drawn enough to aspirate, it is not necessary to do so for routine immunizations and should not be given as a reason to delay adoption of auto-disable syringes.

Injection Practices to Continue

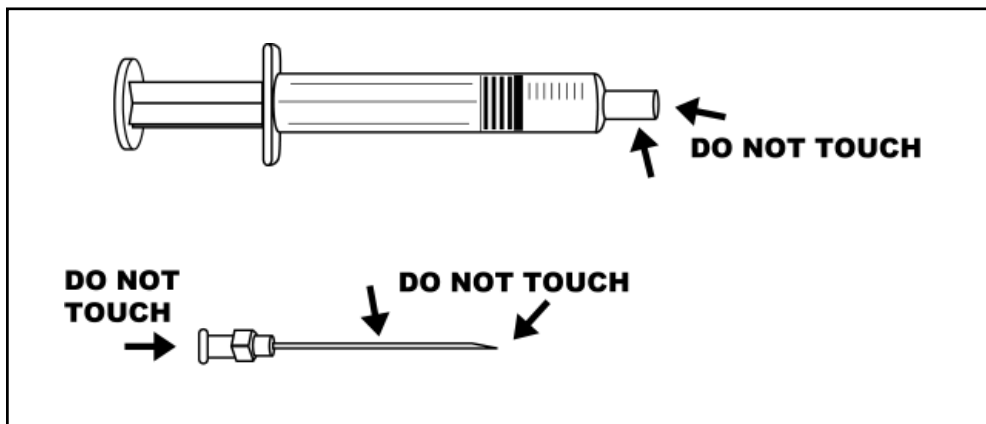
While some practices change with the use of AD syringes, others are important and should be continued.

Keep the needle and syringe sterile.

Because any part of the syringe that you touch becomes contaminated, you should NOT touch parts that come into contact with the injectable vaccine. If you touch any of these parts by accident, the syringe and needle are not sterile. Discard them immediately and replace them with a sterile syringe and needle.

Never touch the needle with your fingers.

Figure 24. The “do not touch” areas of a syringe and needle



Health workers sometimes place their fingers on the needle to help guide it in when pushing through the skin. Touching the needle with your fingers contaminates the needle.

Should the injection site be cleaned?

The WHO Expanded Programme on Immunization does not require that injection sites be cleaned prior to giving an injection. Several large U.S. studies showed that persons receiving injections into uncleaned skin had no significant problems.

Despite the lack of evidence that it is necessary to clean injection sites, wiping the site with 70% alcohol remains the standard of practice in many settings. It does no harm if clean cotton and uncontaminated alcohol are used. It will decrease the number of organisms present on the skin, and thus may help reduce the risk of abscesses, as was shown in a study for drug users. Disinfectants other than alcohol may not be beneficial. Pathogens can grow in many other disinfectants, and can grow well on moist cotton. Contamination can occur when containers for disinfectant or cotton are refilled again and again without cleaning, when cotton is torn with the hands, and when cotton is moistened and stored.

In a survey of more than 1,000 intravenous drug users, 173 reported always cleaning their skin prior to injection. These persons had fewer abscesses. (See Vlahov 1992)

Avoid touching the injection site with your fingers.

After an injection, health workers sometimes apply pressure to the injection site with their fingers or a piece of cotton wool to reduce bleeding. It is a better practice to ask the patient or the adult accompanying small children to hold the cotton on the injection site. If the nurse

contaminates his or her fingers with blood, he or she can transmit pathogens from one patient's injection site to another.

Other injection practices that remain the same when using AD Syringes.

- **DO NOT re-use syringes that have been used before, including mixing syringes.** Used, disposable syringes cannot be sterilized and eventually change shape at temperatures necessary for sterilization. Health workers who try to decontaminate, clean, and sterilize disposable equipment are at risk of accidental needlestick injuries. Re-using syringes and needles can also transmit infections between patients.
- **NEVER leave a needle inserted in the vial cap to withdraw multiple doses.** This provides a direct route for microorganisms to enter the vial and contaminate the vaccine. The needle used to withdraw the vaccine from the vial should also be used to administer the dose.
- **ALWAYS use a new needle and a new syringe every time an injection is given.** The practice of loading multiple doses in a syringe and then injecting several children is dangerous and never justifiable.
- **ALWAYS use a sterile needle and sterile syringe to mix each vial of freeze-dried vaccine.** Then, discard the mixing syringe and sharps in the sharps disposal container.
- **ALWAYS use a new needle and a new syringe each time vaccine is withdrawn from a multi-dose vial.** Re-using the same syringe to give injections to several patients—even if the needle is changed—is a dangerous practice. It allows pathogens to contaminate the multi-dose vial and then be transmitted from patient to patient both by the contaminated vaccine and the syringe.

Ensuring Adequate Supplies of Injection Equipment

If you need to order injection equipment, the following pages will help you calculate the number of syringes and sharps disposal containers to order for routine immunization or campaigns. Figure 25 provides the basic formulas and Figure 26 shows examples of how these formulas are used. The formulas presented are consistent with current GAVI guidelines, but adjustments should be made to reflect the needs and wastage rates of individual sites. Order quantities must also be rounded up to match the case or box size available from the supplier.

Ordering auto-disable syringes

It is essential that each injection is delivered with a sterile syringe and needle. Managers must therefore ensure that they order and distribute adequate quantities of syringes for the target population to be immunized, including an allowance for wastage. Wastage can occur when auto-disable syringes get disabled prematurely, break, or become contaminated. Managers can measure their site's wastage rate using the first formula in Figure 25. If this is not possible, then a 10% syringe wastage rate should be used.

The syringe wastage rate is converted into a wastage factor in order to calculate the quantity of syringes to order. The second formula in Figure 25 shows how to calculate the wastage factor, which is 1.11 for a wastage rate of 10%.

If managers are ordering auto-disable syringes for the first time, they should establish reserve stock to ensure that when demand varies or supplies arrive late, syringes will still be available for immunization. UNICEF and WHO estimate that a 25% reserve stock should be ordered, in addition to the syringes to be used and those that will be wasted. The third formula in Figure 25 shows the calculation of syringes to be ordered for the first time, including use of the 1.25 factor for reserve stock.

If managers are re-ordering auto-disable syringes, then the quantity of remaining syringes in stock should be subtracted from the total quantity of syringes needed, taking into account the target population, the wastage and the reserve stock. The fourth formula in Figure 25 shows how to calculate the quantity of syringes to be re-ordered.

Figure 25. Calculating injection equipment needs (Syringe example)

$$\begin{aligned}
 1) \text{ Wastage rate} &= \frac{(\text{number of syringes used} - \text{number of persons immunized})}{\text{number of syringes used}} \times 100 \\
 2) \text{ Wastage factor} &= \frac{100}{100 - \text{wastage rate}} \\
 3) \text{ Number of syringes to order (first time order)} &= \text{target population} \times \frac{\text{number of injections}}{\text{per person}} \times \text{wastage factor} \times 1.25 \\
 4) \text{ Number of syringes to re-order} &= (\text{target population} \times \frac{\text{number of injections}}{\text{per person}} \times \text{wastage factor} \times 1.25) - \text{remaining in stock}^*
 \end{aligned}$$

* Estimate the number of syringes that will be in stock when the new order arrives.

Ordering mixing syringes

It is also essential that each vial of freeze-dried vaccine is reconstituted with a sterile mixing (or reconstitution) syringe. The following formula can be used to calculate the number of mixing syringes to order for each type of freeze-dried vaccine :

$$\text{Number of mixing syringes to order} = \left(\frac{\text{doses of freeze dried vaccine requested}}{\text{doses per vial}} \times \text{wastage factor} \times 1.25 \right) - \text{number of mixing syringes in stock}$$

Ordering sharps disposal containers

Adequate quantities of sharps containers should be ordered to contain all used auto-disable and mixing syringes and ensure that the containers are available at each immunization site. The following formula can be used to calculate the number of sharps containers to order. This formula assumes that each sharps container can hold 100 used syringes.

$$\text{Number of sharps containers to order} = \frac{\text{number of AD and mixing syringes ordered}}{100} - \text{sharps containers in stock}$$

Since sharps disposal containers are relatively inexpensive and can be used for disposal of other sharps, larger quantities should be ordered whenever the budget allows.

Rotating Stock

Remember to rotate syringe supplies on a “First In, First Out” (FIFO) basis so that the oldest syringes are used first. Storage facilities should be organized and labeled to facilitate stock rotation.

Figure 26. Calculating order quantities of injection equipment: 3 examples

Calculating the number of auto-disable syringes to order

Community	Number of People to be Immunized	Number of Injections Per Person	Total Number of Injections	AD Syringe Wastage Factor	Subtotal	Reserve Stock Factor	Subtotal	AD Syringes in Stock	Minimum Number of AD Syringes to Order
A	1000	1	1000	1.11	1110	1.25	1388	0	1388
B	5000	1	5000	1.11	5550	1.25	6938	900	6038
C	1260	3	3780	1.11	4196	1.25	5245	1200	4045

Calculating the number of mixing syringes to order

Community	Number of Doses of Freeze-dried Vaccine to Order	Number of Doses Per Vial	Number of Vials	Wastage Factor	Subtotal	Reserve Stock Factor	Subtotal	Mixing Syringes in Stock	Minimum Number of Mixing Syringes to Order
A	1400	10	140	1.11	155	1.25	194	25	169
B	6000	20	300	1.11	333	1.25	416	83	333
C	4200	80	53	1.11	59	1.25	74	62	12

Calculating the number of sharps containers to order

Community	Number of AD Syringes to Order	+	Number of Mixing Syringes to Order	=	Total Syringes (÷ 100)	Subtotal	Sharps Containers in Stock	−	Minimum Number of Sharps Containers to Order
A	2100		200		2300	23	0		23
B	7500		400		7900	79	10		69
C	4800		100		4900	49	0		49

Key Points

- New syringe designs can prevent re-use of syringes. Purchase of auto-disable syringes can reduce re-use.
- Do not draw back on the plunger to put air into a vial when using SoloShot, SoloShot FX, Univec, or Destroyject syringes. The plunger will move back and forth only once!
- NEVER leave a needle inserted in the vial cap.
- ALWAYS use a new needle and a new syringe **every time** an injection is given.
- Syringes designed to prevent re-use do not automatically prevent needlesticks.
- Order adequate quantities of auto-disable syringes, mixing syringes, and sharps disposal containers.

Guidelines for Use of Auto-Disable Syringes

Persons giving injections should:

- ☐ Verify the medication, the dose, the patient, the site, and the route of administration.
- ☐ Check the sterile pack's expiry date; if the expiry date has passed, it should be discarded.
- ☐ Check whether the sterile pack is damaged or punctured. If damaged or punctured, it should be discarded.
- ☐ For syringes wrapped in sterile (blister) paper packaging,
 - ☐ Peel open the package without touching the needle hub or syringe tip.
 - ☐ If the syringe has a detachable needle, attach the syringe firmly to the needle and twist.
- ☐ Activate the syringe, if necessary.
- ☐ Remove the protective caps on the plunger and the needle, if present.
- ☐ Remove the needle cap or shield.
- ☐ Insert needle into the vial, keeping the needle in the fluid until a complete dose is drawn up.
- ☐ Remove air bubbles by tapping the barrel and pushing the plunger to the correct dose mark, while the needle remains in the vial.
- ☐ Check that the dose is correct.
- ☐ Inject the entire dose.
- ☐ After injection, place the syringe immediately in a sharps container box.

Persons giving injections should handle the syringes safely after use.






The health worker should NOT:

- ☐ Recap the needle.
- ☐ Set the needle down before disposal.
- ☐ Carry the syringe from the area where the immunization was given.

The health worker should:

- ☐ Discard the used, uncapped syringe in a sharps disposal container at the point of use.

Comparing Different AD Syringes

Type of AD Syringe	Packaging	Requires Activation	Disabled by	Available with Fixed Needle (as of August 2001)
SoloShot 	Bulk packed with plunger caps	No	Metal clip	Yes
SoloShot FX 	Individual paper package	No	Metal clip	No
K1 	Individual paper or plastic package	Remove tab or twist plunger (depending on style)	Plunger breaks off	Fixed or detachable needle available
Destroject 	Bulk packed with plunger caps	No	Ratchets on plunger	Yes
Univec 	Individual paper package	No	Metal clip and ratchets on plunger	Fixed or detachable needle available
Uniject 	Prefilled, single dose: individual foil package	Push port into needle shield	Reservoir (bubble) can not be refilled	Yes

Quiz Questions

1. What are some advantages of auto-disable syringes?
2. How are auto-disable syringes different from other syringes?
3. When is it acceptable to re-use contaminated single-use syringes?
4. Which syringes have the lowest risk of re-use?
5. What changes in technique are necessary when using an auto-disable syringe?
6. What must you do if you accidentally touch the “do not touch” parts of the syringe or needle (page 62)?
7. Which of the following can be used to clean the injection site?
 - A. It is not necessary to clean the injection site, but 70% alcohol (rubbing alcohol or spirits) can be used
 - B. Soap and water
 - C. Water only
 - D. Any of the above

Answers are provided on page 88.

Case Study #6

Wrong-way Kudzu

Kudzu, the vaccinator, arrives at the outreach site late and many children are waiting. He has been on a crowded bus for two hours and wants a cigarette to calm his nerves. He smokes while preparing for the immunization session.

The community has given him a table to use during the session. He places it in the sun, because the clients are sitting in the only shady place—under a mango tree.

Before he starts giving the immunizations, Kudzu takes out two vials of each kind of vaccine, two ampules of diluent for BCG, and two ampules of diluent for measles vaccine. He reconstitutes the BCG and measles vaccines. He then puts the vaccines in the slits of the foam pad on top of the open vaccine carrier.

In his rush to get ready, Kudzu drops his only mixing syringe with the needle-point first, onto the ground. He washes his hands thoroughly, then decides to reconstitute vaccine with the other type of syringes. He holds the syringes and needles by their adapters when assembling them, thinking that this is satisfactory as long as he does not touch the other parts.

Finally, he loads a syringe with 2 ml of measles vaccine, puts it inside the vaccine carrier to keep it cool, and begins immunizing.

Kudzu is giving the fourth injection with the same syringe and needle when a supervisor passes by and whispers in his ear to “please stop the session.”

Questions for Review

1. Is the supervisor right to stop the session?
2. What reasons does she have for stopping the session?

Answers are provided on page 89.

Case Study was adapted with permission from *Immunization in Practice*. WHO/EPI/TRAM/98.12

Notes:

Answer Section

Quiz Answers for Chapter 1

1. What is an unsafe injection?

An unsafe injection is an injection that harms the recipient, the provider, or that results in waste that is dangerous for other people. Unsafe injections can cause disease, injury, and death.

2. What types of infections can be caused by unsafe injections?

Unsafe injections can transmit infections including hepatitis B, hepatitis C, and HIV. They can also cause abscesses at the injection site, parasitic infections (malaria), fungal infections, bacterial infections, and many other types of infections.

3. What are some common examples of unsafe injection practices?

- *Giving an injection when it is not necessary.*
- *Lacking sufficient injection supplies for the number of persons requiring injections.*
- *Re-using single use, disposable syringes and needles.*
- *Sterilizing equipment without first cleansing it.*
- *Changing needles on a used syringe and re-using the syringe.*

(See Figure 2 on page 2 for additional examples.)

4. What are two ways that health workers can improve injection safety?

Health workers can improve injection safety by: (1) reducing unnecessary injections (not using injectable vitamins, not using injections when an oral medication is available, not giving injections for viral conditions like colds and the flu); and (2) educating patients about the risks of unsafe injection practices and the necessary precautions required for safe injection.

5. Why is it so important to eliminate unnecessary injections?

Most of the injections given in the world are unnecessary. An unnecessary injection does no good and may cause harm to the patient. The more injections a patient receives, the more likely it is that some of them will be unsafe. Unnecessary injections also are expensive to the clinic and the patient.

6. What is an important responsibility of the health worker?

An important responsibility of the health worker is to first, do no harm. No health worker should bring harm to another person through his or her actions.

7. What type of syringe does WHO, UNICEF, and UNFPA recommend for immunization?

The auto-disable syringe, since it is designed to prevent re-use of injection equipment.

8. Indicate the level of risk for each of the following practices:

	Very Dangerous	Some Risk	Good Practice
Allowing public access to discarded syringes • <i>This encourages re-use.</i>	X		
Holding cotton wool on the bleeding injection site • <i>This has some risk because blood from one child can be transmitted on a health worker's finger to the open site of another child. It's best to have parents or older children hold cotton wool with their own fingers.</i>		X	
Not washing hands between injections • <i>Hands should be washed periodically during the session, as hands can easily become contaminated.</i>		X	
Re-using needles and syringes after the last sterile syringe has been used in an immunization campaign • <i>This is an extremely dangerous practice and cannot be justified.</i>	X		
Changing the needle and re-using the syringe in an immunization campaign • <i>This is an extremely dangerous practice and cannot be justified.</i>	X		

9. Please discuss how each of the following practices can be improved:

- A doctor washes his hands by dipping them in a basin of water before examining a patient.

Hands can be contaminated when dipped into a basin of water. Standing water can easily become contaminated, even if antiseptic is added. In the absence of running water at a clinic, a staff member should pour water over another's hands to rinse. The rinse water should be discarded.

- Staff wash their hands by thoroughly scrubbing hard-to-reach areas for 10 to 15 seconds at the end of an immunization session.

Staff could also wash their hands prior to beginning work and often during work time when hands are contaminated.

Quiz Answers for Chapter 2

1. Name four things that a health worker must check before filling a syringe from a vial.

Examples:

- *Check that the patient is ready to receive the injection.*
- *Check for a label on the vial.*
- *Check the expiry date of the vial.*
- *Check for signs of contamination.*
- *Check to make sure that freeze-sensitive vaccines and diluents have not been frozen.*
- *Check to make sure that the vaccine has not been exposed to excessive heat.*

2. Is the following statement true or false? “The syringe should be filled only when the patient is ready to receive an injection.”

True.

3. Name five situations in which you should assume the vaccine vial is contaminated.

- *There are leaks or cracks in the vial; **OR***
- *There is a change in appearance or floating particles; **OR***
- *The top of the opened vial has been submerged in water; **OR***
- *The top of the vial has been pierced with a used needle, or a sterile needle on a used syringe; **OR***
- *Freeze-dried vaccine has been opened for more than 6 hours after reconstitution (see Chapter 3, Reconstituting Vaccines Safely); **OR***
- *The vial has been opened for more than 4 weeks.*

4. Why use vaccine vial monitors (VVMs)?

VVMs help health workers determine whether vaccines have been damaged by exposure to too much heat. In addition, VVMs reduce vaccine wastage during cold-chain breakdowns. If vials have VVMs with an inner square that is the same color or darker than the outside circle, health workers should discard the vials. In countries where the WHO policy on multi-dose vials has been adopted, VVMs help workers to save liquid vaccines (DTP, OPV, DT, TT, Td, hepatitis B, and liquid Hib) for subsequent sessions.

5. What should be done when the inner square of the VVM is the same color or darker than the outside circle?

The vaccine vial should be discarded.

6. Is the following statement true or false? “Vials with VVMs that have just started to change color should be used before vials whose VVMs have not changed color.”

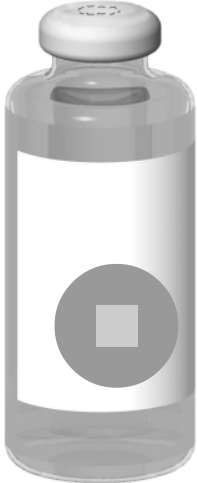
True, if the inner square is still lighter than the outer circle.

7. For each vial shown in the VVM Illustration, page 19 , indicate whether or not the vial can be used.

- *The inner square is lighter than the outside circle. **USE the vaccine.***
- *The inner square has darkened slightly, but still is lighter than the outside circle. **USE this vaccine first.***
- *The inner square matches the color of the outside circle. **DO NOT use the vaccine.***
- *The inner square is darker than the outside circle. **DO NOT use the vaccine.***

Answers for Practical Exercise #1

How to Read Vaccine Vial Monitors (VVMs)

 <p>USE</p> <p>Inner square is lighter than outer circle.</p>	 <p>USE FIRST</p> <p>As time passes, inner square is still lighter than outer circle.</p>
 <p>DON'T USE</p> <p><u>Discard point!</u> Inner square matches color of outer circle.</p>	 <p>DON'T USE</p> <p><u>Beyond discard point!</u> Inner square is darker than outer circle.</p>

Answers for Case Study #1

The Unlabelled Vaccines in the Vaccine Carrier

1. What was Nurse Santana's mistake?

Nurse Santana's mistake was giving an injection from a vial without a label.

2. What should she do to avoid making this mistake again?

She should discard vials without labels.

Quiz Answers for Chapter 3

1. What are some common mistakes that lead health workers to use the wrong diluent to reconstitute vaccines?
 - *Saving vials with missing labels, making correct identification of vial contents impossible.*
 - *Storing diluents for different vaccines mixed together in the refrigerator.*
 - *Believing that diluents are interchangeable.*
 - *Storing other medications in the refrigerator where a busy health worker can mistakenly choose them.*

2. Why is it important to reconstitute vaccine using the diluent prepared by the manufacturer for their specific vaccine?

Manufacturers specifically prepare and test each vaccine diluent for the particular formulation of each vaccine. Using other substances may make the vaccine ineffective, or may result in overdose.

3. When should reconstituted vaccines be discarded?

WHO recommends that reconstituted BCG vaccines, measles-containing vaccines, yellow fever vaccines, and freeze-dried Hib vaccines be discarded within 6 hours of reconstitution, or at the end of the session, whichever comes first.

4. Name the vaccines that must be discarded within 6 hours of reconstitution.

E. All of the above

5. What may happen if reconstituted vaccines are stored longer than 6 hours after reconstitution?

Because freeze-dried vaccines do not have preservatives that limit the growth of microorganisms, microorganisms that enter the vial during reconstitution can multiply. Reconstituted vaccine saved longer than 6 hours after mixing may have high numbers of bacteria so must be considered contaminated and discarded immediately. Deaths have resulted from toxic shock when children received injections of reconstituted vaccines that had been mixed for longer than 6 hours.

-
6. What are some major safety concerns related to reconstituted vaccines?
- *Reconstituted vaccines should be used within 6 hours of reconstitution. After 6 hours, discard them.*
 - *Vaccines accidentally reconstituted using insulin and anesthetics stored in the same refrigerator have resulted in death.*
 - *Using a diluent intended for another vaccine or medication to reconstitute vaccine may render the vaccine ineffective, or may cause overdose. When reconstituting vaccines, use ONLY the diluent recommended by the manufacturer for that particular vaccine.*
 - *Reconstituted vaccines should be kept cool (stored between 2° to 8°C) once reconstituted. This helps maintain the efficacy of the vaccine and helps slow the growth of organisms inside the vial.*

Quiz Answers for Chapter 4

1. Why is it important for an adult to hold a child securely for an injection?

A child must be held securely to prevent unexpected movements that could cause accidental needlesticks. Children often kick or try to grab the needle and, thus, prick themselves or contaminate the needle.

2. Is the following statement true or false? “Everyone who handles used, contaminated injection equipment is at risk of infection and injury.”

True.

3. Is the following statement true or false? “If injection equipment and other sharps need to be stored at a facility before they are burned, they should be placed in a big pile behind the clinic.”

False. Place waste in a container in a closed area that is protected from the public.

4. Proper disposal of injection equipment and other sharps:

D. All of the above.

5. Proper disposal of used syringes, needles, and other sharps includes:

B. Placing the needle and attached syringe in a puncture-proof container.

6. The biggest reduction in transmission of blood-borne infections through unsafe injections can be achieved through:

A. Eliminating unnecessary injections.

While all three practices are important, the greatest number of infections will be prevented by eliminating unnecessary injections (see Chapter 1 for more information).

-
7. What steps can make open burning safer?

Open burning is not recommended because it scatters waste and is dangerous. However, if open burning must be done, carry the waste to the site just before burning, and burn it in a small, designated area. Avoid smoke and fumes from the fire, and make sure the fire is completely out before leaving the site. Any remains should be buried in the dirt after burning, in a location where people cannot access them.

8. Describe the procedures for burning injection equipment and other sharps in a metal container.

Sharps disposal containers can be placed in a metal container. When the metal container is three-quarters full, fuel can be poured on it, then ignited, and the materials burned until the fire goes out on its own. The remains should then be buried.

Answer to Case Study #2

The Recapping Quandry

What should be done differently to reduce the risk of infections at your clinic?

Recapping causes more needlesticks than any other single procedure. It must be avoided.

- *To reduce the risk of infection to health workers, needles should not be recapped before disposal.*
- *Puncture-proof sharps disposal containers should be placed at every point where needles and syringes are used. The uncapped needle and syringe should be immediately disposed of in a puncture-proof container.*

Answers to Case Study #3

The Pile of Debris

1. Who is at risk of infection from these practices?

The staff who dispose of the waste, the laborers who cart the waste away, and members of the community in the neighboring town who scavenge or play in the waste are all at risk. The animals also are at risk for some infections, as are those who slaughter or eat the animals.

2. How can the waste-disposal problems here be solved?

The waste-disposal problems here can be reduced by:

- Having health care workers dispose of contaminated needles and medical waste separately from general waste to reduce the amount of waste requiring special handling, and to eliminate dangerous manual handling later on.*
- Building an incinerator or digging a pit to burn or bury the medical waste.*
- Reducing the number of unnecessary injections.*
- Ensuring that people and animals do not have access to the waste while it is stored at the hospital, and removing it more often than every six months.*

Answers to Case Study #4

The Pit at the Turtle Clinic

1. What are the waste-disposal issues here?

The incorrect waste-disposal practices here are:

- *dumping medical waste outside of the fence instead of in the pit; and*
- *dumping needles and syringes with other waste.*

2. What should be done about this situation?

Ms. Gomez should discuss the problem with the night guard and work with the clinic physicians, other staff, and community members to make waste disposal safer and to follow up to make sure the new practices are maintained.

Answers to Case Study #5

The Missing Syringe Barrels

1. What are the waste-disposal issues here? Who is at risk of infection or injury, and why?

The incorrect practices here are:

- *the manual removal of needles from contaminated syringes;*
- *the disposal of medical waste in a shallow pit and garbage cans that are easily accessible to the community; and*
- *the use of blood-containing devices for beauty aids.*

The clinic staff and members of the community (including the teenage girls who scavenge in the pit and the people to whom they give the syringe barrels) are at risk of infection if they come into contact with pathogenic organisms.

2. What should be done about this situation?

Ms. Oludara should inform the staff of the situation and discuss the safe use and disposal of needles and syringes. The clinic should then develop a plan to:

- *improve the waste-disposal site so that it is not accessible to members of the community;*
- *appropriately incinerate, burn, or bury the needles and syringes so that both the needles and syringes are no longer usable;*
- *explain to scavengers why they are restricting access to the medical waste.*

Quiz Answers for Chapter 5

1. What are the advantages of auto-disable equipment?

- *They prevent re-use.*
- *They improve dose accuracy.*
- *They produce less toxic smoke when burned.*
- *They can reduce the volume of medical waste when compared to other disposable syringes.*

2. How are auto-disable syringes different from other syringes?

Some auto-disable syringes have plungers that lock after a single use. This prevents the syringe from being used a second time. It is important not to pull back the plunger to inject air into a vial before drawing up a dose. Uniject, a pre-filled, auto-disable injection device, has no plunger, and cannot be re-used.

3. When is it acceptable to re-use a contaminated single-use syringe?

NEVER.

4. Which syringes have the lowest risk of re-use?

Auto-disable syringes.

5. What changes in technique are necessary when using an auto-disable syringe?

Do not inject air into the vial; draw back the plunger only once, it is not necessary to aspirate when injecting EPI vaccines.

6. What must you do if you accidentally touch the “do not touch” parts of the syringe or needle?

Discard the syringe and needle immediately and replace them with a sterile syringe and needle.

7. Which of the following can be used to clean the injection site?

A. It is not necessary to clean the injection site, but using 70% alcohol remains the standard of practice in many settings and does no harm if clean cotton and uncontaminated alcohol are used.

Answers to Case Study #6

Wrong-way Kudzu

1. Is the supervisor right to stop the session?

Yes, it is the supervisor's duty because Kudzu is harming the children he is vaccinating. Stopping the session may be embarrassing for Kudzu and may raise concern among the clients, but the health worker's first responsibility is to prevent harm. It is worse to put people at risk for abscesses, hepatitis B, hepatitis C, HIV, or other illnesses than to face embarrassment.

2. What reasons does she have for stopping the session?

The most dangerous mistake Kudzu made was:

- *He used the same syringe for four children by loading more than one dose into a syringe.*

Other areas for improvement:

- *He arrives late.*
- *He smokes while working.*
- *He puts the vaccination table in a sunny place.*
- *He takes two vials of each vaccine out of the vaccine carrier.*
- *He reconstitutes vials of BCG and measles vaccines before he has the children who need them.*
- *He touches the adapter of the syringe that must remain sterile.*
- *He loads a syringe before he has a client needing the particular vaccine.*
- *He puts a loaded syringe into the vaccine carrier where it will get contaminated.*

The supervisor should privately talk with Kudzu to see if he has any safe vaccine and sterile syringes. If not, the supervisor could try to find a new supply of vaccine, sterile syringes, and needles; otherwise, the supervisor could help explain to the crowd that they will reschedule a new clinic session because they have run out of sterile needles and syringes.

The supervisor should follow up to see if Kudzu needs additional training or extra supervision.

Trainer Supplement

Notes to Trainers

Each chapter covers one topic and may be taught separately or given together in a one-day course. We recommend that trainers study the material ahead of time. In our pretest sessions, groups led by trainers unfamiliar with the material often read the chapter aloud, and consequently, were unable to cover the material in the time suggested.

We encourage trainers to follow these recommendations when presenting the material in this manual.

- Review each chapter in advance.
- If the resources are available, the trainer should photocopy the trainer's aids and hand them out to the participants before beginning the instruction for the relevant chapter.
- At the end of each chapter, review the Key Points with the participants.
- Give the quizzes orally to stimulate classroom discussion. After the discussion for each question, repeat the correct answer (found in the Answer Section, pages 73-89).
- At the end of the quiz, review each chapter's Key Points again (located at the end of each chapter).

To aid in planning the training sessions, the objectives for each chapter are included below with the estimated time to complete the lesson. The trainer's aids are pages from within the manual that are helpful to display visually during the lesson, or to photocopy and hand out to each participant.

Chapter 1

Objectives: After completing this chapter, participants will be able to:

- describe why injections can be harmful;
- name the common ways injections create health risks;
- name three common blood-borne diseases transmitted by unsafe injections;
- explain why reducing unnecessary injections is key to improving injection safety;
- describe the responsibilities of health workers in improving injection safety;
- explain the importance of routine handwashing.

Time: 30 minutes

Chapter 2

Objectives: After completing this chapter, participants will be able to check vials for:

- expiry dates;
- signs of contamination;
- signs of exposure to freezing;
- signs of exposure to too much heat; and
- correct diluent for reconstitution.

Time: 1 hour

Trainer's Aid: VVM Illustration (from Practical Exercise #1), page 19

Chapter 3

Objectives: After completing this chapter, participants will be able to:

- explain the importance of using the specific diluent when reconstituting vaccines;
- describe the safe procedures for reconstituting vaccines; and
- describe major safety concerns related to reconstituted vaccines.

Time: 1 hour

Trainer's Aid: VVM Cards Front and Back (from Practical Exercise #2), pages 27-30

Chapter 4

Objectives: After completing this chapter, participants will be able to:

- describe high-risk practices that contribute to needlesticks;
- design the equipment layout and patient flow for the immunization campaign sites that can decrease the risk of needlesticks; and
- discuss ways to dispose of medical waste that minimize needlestick injuries.

Time: 2 hours

Chapter 5

Objectives: After completing this chapter, participants will be able to:

- name several kinds of auto-disable syringes;
- change their injection technique to use auto-disable syringes; and
- describe the injection practices to continue when using auto-disable syringes.

Time: 1 hour

Trainer's Aids: Syringe Instructions, pages 50, 51, 54, 56, 58, and 60
Guidelines for Use of Auto-Disable Syringes, page 68
Comparing Different AD Syringes, page 69
Auto-Disable syringe samples, if available
Small containers of water for “mock” injections

Additional Practical Exercise for Chapter 5

If extra auto-disable syringe samples are available, the following exercise should be included.

Note: The trainer will distribute AD syringes, a photocopy of the applicable Syringe Instructions, and a photocopy of the Guidelines for Use of Auto-Disable Syringes to the participants before proceeding with the exercise.

Practice Use of Auto-Disable Syringes and Devices

1. The trainer demonstrates the use of the auto-disable syringe or syringes that the participants will be using, and reviews the instructions and observation guidelines.
2. The trainer divides the group into pairs.
3. The pairs take turns being an “immunizer” and an “observer.” The immunizer tries to fill the syringe with a full dose of water and then ejects the dose. The observer helps by reading the steps on the instruction sheet. After trying 1-2 syringes, the immunizer should then pretend to give a safe injection. The observer follows the steps listed on the Guidelines for Use of Auto-Disable Syringes to ensure that routine safety precautions necessary for any injection are being demonstrated.

References

PATH gratefully acknowledges several extremely useful sources of information on safe injection issues. Following is a list of these resources and the areas in which they specifically contributed to the development of this manual:

EngenderHealth. Infection Prevention Online course (Accessed December 1999). Available online at <http://www.engenderhealth.org/ip/index2.html>.

Battersby A, Feilden R, and Stilwell B. *Vital to Health? A Briefing Document for Senior Decision Makers* [Draft]. (September 16, 1998). Available online at http://www.childrensvaccine.org/Vital_to_Health.pdf.

Catlin M. Dipping syringes in wine: comparing safe injection practices [Draft]. Seattle: PATH (1999).

Catlin M, Muller N. The physician's role in improving injection safety. *Africa Health* 22(1):12-14 (November 1999).

Dicko M et al. Safety of immunization injections in Africa: not simply a problem of logistics. *Bulletin of the World Health Organization* 78(2):163-169 (2000).

Hutin YJ. Injections given in healthcare settings as a major source of acute hepatitis B in Moldova. *International Journal of Epidemiology* 28(4):782-786 (August 1999).

Kane AJ et al. Transmission of hepatitis B, hepatitis C and human immunodeficiency viruses through unsafe injections in the developing world: model-based regional estimates. *Bulletin of the World Health Organization* 77(10):801-807 (1999). Available online at <http://www.childrensvaccine.org/kane.pdf>.

MMWR. Frequency of vaccine-related and therapeutic injections—Romania, 1998. *Morbidity and Mortality Weekly Report* 48(13):271-274 (April 9, 1999).

Nelson CM et al. Use of SoloShot autodestruct syringes compared with disposable syringes, in a national immunization campaign in Indonesia. *Bulletin of the World Health Organization* 77(1):29-32 (1999).

Simonsen L et al. Unsafe injections in the developing world and transmission of bloodborne pathogens: a review. *Bulletin of the World Health Organization* 77(10):789- (1999).

Steinglass R et al. Safety, effectiveness and ease of use of a non-reusable syringe in a developing country immunization programme. *Bulletin of the World Health Organization* 73(1):57-63 (1995).

Strathdee SA et al. Needle exchange is not enough: lessons from the Vancouver injecting drug study. *AIDS* 11(8):F59-65 (July 1997).

Vlahov D et al. Bacterial infections and skin cleaning prior to injection among intravenous drug users. *Public Health Reports* 107(5):595-598 (September-October 1992).

World Health Organization (WHO). *Reducing the Risk of Unsafe Injections in Immunization Programmes: The Role of Injection Equipment*. WHO/EPI/LHIS/94.2 (Adapted version). Geneva: WHO Expanded Programme on Immunization (1994).

WHO. *Immunization in Practice*. Geneva: WHO Global Programme for Vaccines and Immunization (1998). Available online at <http://www.who.int/gpv-documents/DoxTrng/H4IIP.html>.

WHO. *Safety of Injections in Immunization Programmes: WHO Recommended Policy* [Draft]. WHO/EPI/LHIS/96.05 Rev.1. Geneva: Global Programme for Vaccines and Immunization (October 1998). Available online at <http://www.who.int/gpv-documents/DocsPDF/www9665.pdf>.

WHO. *Safety of injections—A brief background*. Fact Sheet No. 231. Geneva: WHO (October 1999). Available online at <http://www.who.int/inf-fs/en/fact231.html>.

WHO. *Safety of injections—A glossary*. Fact Sheet No. 233. Geneva: WHO (October 1999). Available online at <http://www.who.int/inf-fs/en/fact233.html>.

WHO. *Safety of injections: Questions and answers*. Fact Sheet No. 234. Geneva: WHO (October 1999). Available online at <http://www.who.int/inf-fs/en/fact234.html>.

WHO. *Safety of injections: WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services*. WHO/V&B/99.25. Geneva: WHO Department of Vaccines and Biologicals (1999). Available online at <http://www.who.int/vaccines-documents/DocsPDF99/www9948.pdf>.