

# Safe Injection and Waste Management

*Reference for Logistics  
Advisors*

la Nersesian  
essa Cesarz  
son Cochran  
hifer Mboyane  
e Schmidt



**DELIVER**

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# Safe Injection and Waste Management

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*A Reference for Logistics Advisors*

Paula Nersesian  
Vanessa Cesarz  
Allison Cochran  
Jennifer Mboyane  
Katie Schmidt

2004



## **DELIVER**

DELIVER, a five-year worldwide technical assistance support contract, is funded by the Commodities Security and Logistics Division (CSL) of the Office of Population and Reproductive Health of the Bureau for Global Health (GH) of the U.S. Agency for International Development (USAID).

Implemented by John Snow, Inc. (JSI) (contract no. HRN-C-00-00-00010-00), and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], Social Sectors Development Strategies, Inc., and Synaxis, Inc.), DELIVER strengthens the supply chains of health and family planning programs in developing countries to ensure the availability of critical health products for customers. DELIVER also provides technical support to USAID's central contraceptive procurement and management, and analysis of USAID's central commodity management information system (NEWVERN).

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## **Recommended Citation**

Nersesian, Paula V., Vanessa Cesarz, Allison Cochran, Jennifer Mboyane, and Katie Schmidt. 2004 *Safe Injection and Waste Management: A Reference for Logistics Advisors*. Arlington, Va.: John Snow, Inc./DELIVER, for the U.S. Agency for International Development.

## **Abstract**

*Safe Injection and Waste Management: A Reference for Logistics Advisors* was developed as a reference for logistics advisors as they face the challenge of designing and supporting programs to improve injection safety and injection waste management. The reader will find useful information and tools, as well as discussions of important issues, including those related to commodity security for safe injection devices (i.e., injection device security) and the development of a safe injection and waste management policy. Available in this reference guide are assessment tools for safe injection and waste management, and references to more detailed articles about specific issues related to safe injection and waste management.

The information in this reference was taken from a variety of reliable sources, including the World Health Organization, peer-reviewed journals, and USAID-supported projects. It includes a table of organizations involved in safe injection work and a list of journal articles on a variety of topics related to safe injection and waste management.



## **DELIVER**

John Snow, Inc.  
1616 North Fort Myer Drive, 11th Floor  
Arlington, VA 22209 USA  
Phone: 703-528-7474  
Fax: 703-528-7480  
Email: [deliver\\_project@jsi.com](mailto:deliver_project@jsi.com)  
Internet: [deliver.jsi.com](http://deliver.jsi.com)

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# Acronyms

AD	auto-disable
AIDS	acquired immunodeficiency syndrome
CBD	community-based distributors
CD	compact disc
CSL	Commodities Security and Logistics Division
DMPA	depot medroxyprogesterone acetate
GAVI	Global Alliance for Vaccines and Immunization
HBV	hepatitis B virus
HCV	hepatitis C virus
HCW	health care waste
HCWM	health care waste management
HIV	human immunodeficiency virus
HSR	health sector reform
IPC	infection prevention and control
ISO	International Standards Organization
JSI	John Snow, Inc.
PATH	Program for Appropriate Technology in Health
SIGN	Safe Injection Global Network
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UP	universal precautions
USAID	United States Agency for International Development
WHO	World Health Organization



# Acknowledgements

The authors thank the DELIVER staff members and colleagues from John Snow, Inc. (JSI) and other organizations, particularly colleagues at the Safe Injection Global Network (SIGN) Secretariat and the World Health Organization (WHO). These groups and individuals have helped move the important issues of safe injection and waste management to the forefront of concern within the public health community. Without their contributions, this document would not be possible. In addition, we thank everyone who reviewed the manuscript and those who supported the process of making this resource available.

As always, we are grateful to the DELIVER communications team and other DELIVER staff for their contributions in editing, formatting, and making this document readable and usable.



# Introduction

## 1. Background

Unsterile injection practices and improper disposal of health care waste are major problems that occur widely in many developing countries. According to the World Health Organization (WHO), 16 billion injections are given each year, making injections one of the most common medical procedures. Unsafe injections can transmit blood-borne pathogens, such as hepatitis B (HBV), hepatitis C (HCV), and the human immunodeficiency virus (HIV). More than ninety percent of injections are for therapeutic purposes, and most of these are unnecessary. Very few situations warrant an injection. Nevertheless, even when equivalent oral preparations are available, which are far safer and just as effective, they are often not used. This places clients at risk of contracting highly infectious diseases through unnecessary exposure to injections.

The WHO defines a safe injection as one that does not harm the recipient, expose the health care worker to any avoidable risks, or result in any dangerous waste for the community (WHO 2001). When a patient receives an injection, it should be given because the patient needs it (i.e., there is no other treatment clinically appropriate treatment). It should be given by a trained health care provider using a sterile needle and syringe that will not or cannot be reused (if the syringe has a reuse prevention feature). Immediately after the injection, the syringe must be discarded in a puncture-proof receptacle that will not fall apart if it gets wet (i.e., a safety box). When the safety box is full, it must be kept in a secure, locked location until it can be safely destroyed in an environmentally-responsible manner by a health facility worker properly trained in health care waste management.

Health care waste (HCW) includes sharps (e.g., needles, scalpel blades, trocars), chemicals, medical devices, pharmaceuticals, blood, body parts, pressurized containers, and radioactive waste. Improper disposal of health care waste can harm clients, health care workers, and community members, and contaminate the environment. Developing countries face many obstacles to correct effective health care waste management (HCWM) including—

- lack of policies addressing HCWM
- lack of knowledge about the health risks posed by improper HCW disposal
- insufficient financial and human resources to support HCWM
- poor access to information about technological solutions as well as devices for HCWM (e.g., incinerators, burn and bury pits, needle pullers)

- limited access to training for health care workers on HCWM
- low status often ascribed to health facility workers designated to manage HCW.

To effectively address the problem of unsafe injections and waste disposal, the following three-pronged strategy is recommended by WHO and the Safe Injection Global Network (SIGN).<sup>1</sup>

1. Change behavior of health care workers and patients.
2. Ensure availability of equipment and supplies.
3. Manage waste safely and appropriately.

Because safe injection and waste management is a multidimensional problem, all three elements of the strategy must receive attention from policymakers and health care providers. Community members can also contribute by actively requesting non-injection treatment and advocating for proper waste disposal in their community.

WHO has developed aide-mémoires on injection safety, health care waste management, health care worker safety, and infection control. These aide-mémoires are available on the WHO website as part of the SIGN toolbox. They are also included as annexes A, B, C, and D at the end of this document.

- Annex A: Injection Safety: Aide-Mémoire for a National Strategy for the Safe and Appropriate Use of Injections (WHO 1999).

*[http://www.who.int/injection\\_safety/about/country/en/AMENG.pdf](http://www.who.int/injection_safety/about/country/en/AMENG.pdf)*

- Annex B: Safe Health Care Waste Management: Aide-Mémoire for a National Strategy for Health Care Waste Management (WHO 2000).

*[http://www.who.int/injection\\_safety/toolbox/en/AM\\_HCWaste.pdf](http://www.who.int/injection_safety/toolbox/en/AM_HCWaste.pdf)*

- Annex C: Health Care Worker Safety: Aide-Mémoire for a Strategy to Protect Health Workers from Infection with Bloodborne Viruses (WHO 2003).

This aide-mémoire describes the key elements of universal precautions and a checklist and guidelines for universal precautions policies.

*[http://www.who.int/injection\\_safety/toolbox/en/AM\\_HCW\\_Safety\\_EN.pdf](http://www.who.int/injection_safety/toolbox/en/AM_HCW_Safety_EN.pdf)*

- Annex D : Infection Control: Aide-Mémoire for Infection Prevention and Control in a Health Care Facility (WHO 2004).

This aide-mémoire identifies and describes the key elements of infection prevention and control and lists the core interventions for health facilities with associated target groups, required supplies, and indicators.

*[http://www.who.int/injection\\_safety/toolbox/docs/en/AideMemoireInfectionControl.pdf](http://www.who.int/injection_safety/toolbox/docs/en/AideMemoireInfectionControl.pdf)*

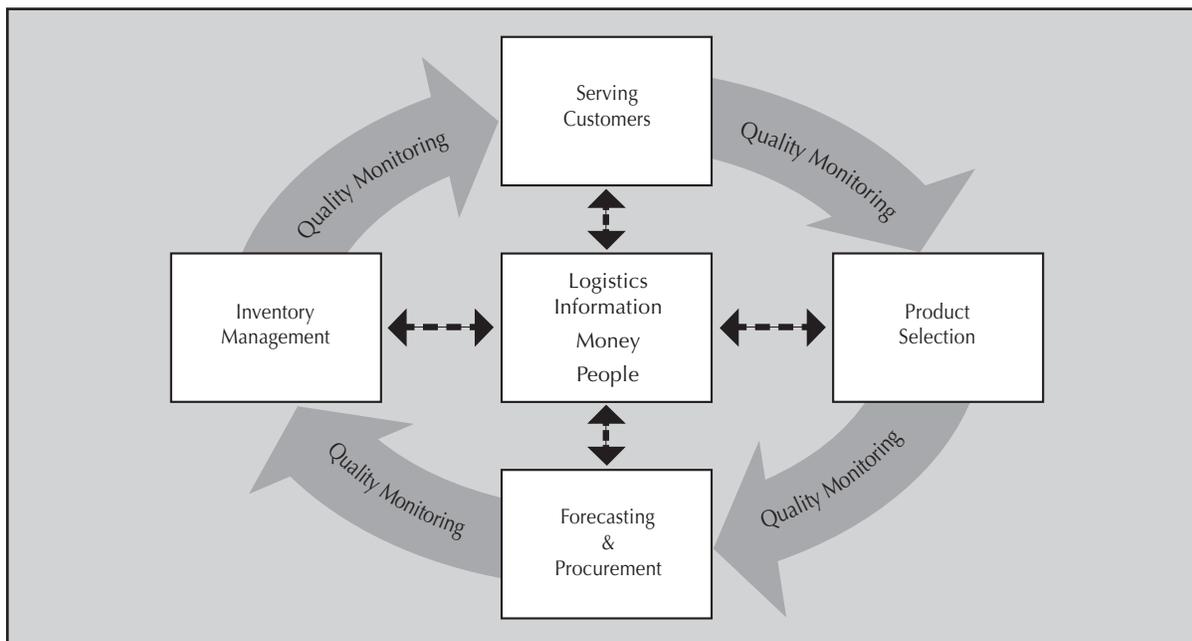
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1. "First, do no harm" Introducing auto-disable syringes and ensuring injection safety in immunization systems of developing countries (WHO 2002).

## 2. Logistics Considerations

Figure 1 depicts the logistics cycle and shows how the supply chain helps make essential products available to users. The customers' needs must be considered in the first step of *product selection*. After the list of products is finalized, short- and long-term product needs must be *quantified*. Then, the products in the correct quantities have to be *procured* and cleared through customs and quality control checks. Next, products are tracked by an *inventory management system* and *distributed* through the health care system, which includes transport and storage at several levels. After the products arrive at service delivery points, the products are prescribed and dispensed, and used or administered to clients. To ensure injection safety, health care providers must use the injection devices and injectable preparations correctly. The process is then repeated. Finally, there must be a *supportive policy and legal framework* to ensure that the cycle is completed.

**Figure 1**  
**The Logistics Cycle**



Products for safe injection are treated the same as any other health commodity that is required in full supply. When products are held in full supply, it means the health commodity or product should never be out of stock at a health facility (it is always available). To achieve a full supply of an essential health commodity, all functions of the logistics cycle must be addressed. This document includes a number of tools to help logistics advisors understand issues related to the products required for safe injection, particularly single-use injection devices and safety boxes.

As with all health commodities, logistics should always focus on serving the customer. Injections are seriously overused in many countries, but when an injection is required it is imperative that appropriate injection

devices and supplies are available to ensure that no harm is done to the patient, care provider, or community. Therefore, customer service for safe injections includes not only the patient, but also the health care provider and members of the community, because everyone benefits when injections are administered safely and devices are disposed of properly.

### 3. How to Use This Reference

You may decide to read this document from cover to cover. However, it was written as a reference for logistics advisors as they face the challenges of designing or supporting programs for safe injection and injection waste disposal. You will find a discussion of issues related to commodity security for safe injection devices (i.e., injection device security); tools for introducing and assessing safe injection and waste management; and references to more detailed articles about specific safe injection issues.

Please note that although we mentioned health care waste management broadly in the introductory section, this document focuses on sharps waste management. However, the authors main purpose is to give logistics advisors the information and tools they need to safely administer injections and properly dispose of the used injection devices. General resources concerning HCWM are listed in this resource.

This document includes many useful references, and most have an Internet link. For readers without easy Internet access, several complete documents are included. Additionally, most of the documents cited are available on the SIGN Toolbox website—

*([http://www.who.int/injection\\_safety/toolbox/en/](http://www.who.int/injection_safety/toolbox/en/))*

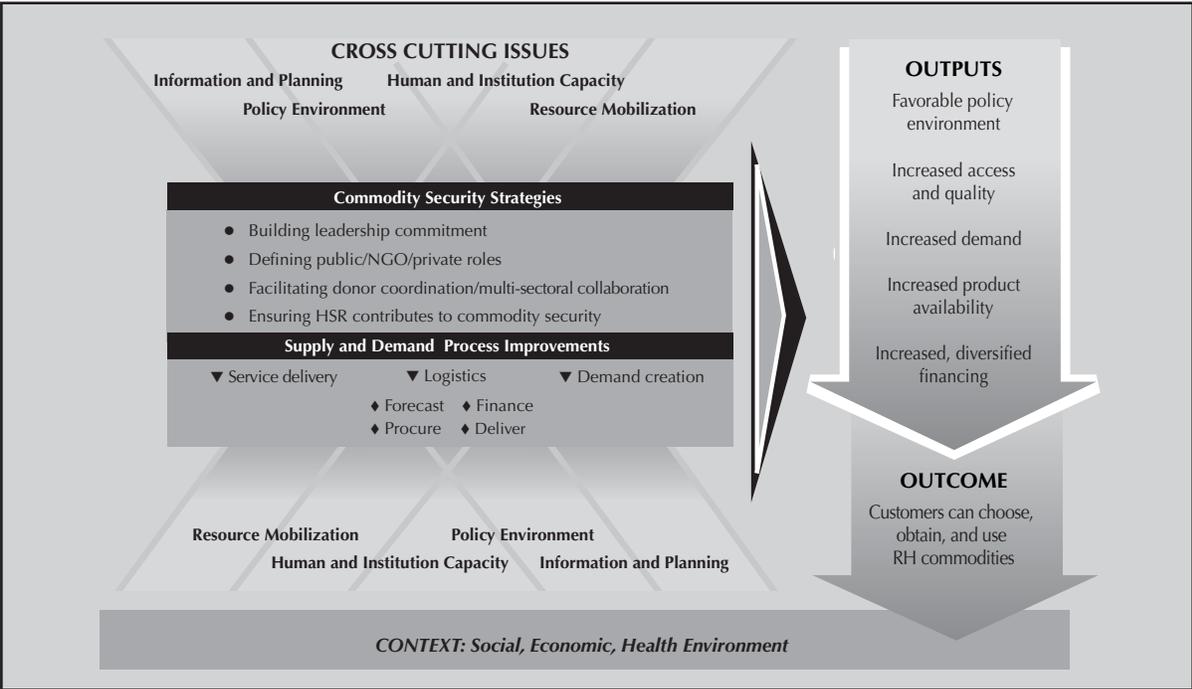
—and compact disc (CD), which is available through the SIGN secretariat at the WHO for little or no charge. Please note that several documents were published after the SIGN Toolbox CD was completed.

# Injection Device Security

## 1. Introduction and Background— Commodity Security

DELIVER’s Model for Health Commodity Security encompasses a range of issues, strategies, and supply and demand process improvements that will result in outputs and outcomes. These enable customers, clients, and patients to choose, obtain, and use health commodities within specific social, economic, and health environments. The primary logistics elements for commodity security for safe injection devices or injection device security includes forecasting, financing, procuring, and delivering products (see figure 2).

**Figure 2**  
*DELIVER’s Model for Health Commodity Security*



Note: Health sector reform (HSR) refers to health sector reform activities currently underway in the country.

### 1.1. Forecasting Injection Device Needs

Effective forecasting for injection devices requires an estimate of the number of anticipated injections to be administered. The number of doses of injectable preparations procured provides an estimate of the number of

needles and syringes to procure since providers should generally have the same number of devices as doses for injection administration. Additional needles and syringes are also needed for reconstitution, which some injectable preparations require.

Consumption data also informs forecasts because provider variation may alter the quantity and distribution of sizes of syringes needed. Consumption data is also useful information as programs begin to establish a full-supply of injection devices, particularly when logistics systems for essential drugs and medical devices are managed in separate systems.

To estimate the number of safety boxes, you need to know the number of injections to be administered. (This number is the number of doses of injectable preparations procured or forecasted.)

For example, if you are procuring safety boxes with a capacity of 100 syringes (with needles attached) and 1,000 doses of injectables, you need a minimum of 10 safety boxes.

Health facilities may not receive a box every time they place an order for injectable preparations because they may order fewer than 100 doses. This means that distribution facilities must keep extra stock to ensure the boxes are available when facilities request one. Also, some facilities, such as surgical facilities and laboratories, fill their boxes more quickly if they generate a significant amount of other sharps waste.

Additional needs must also be considered when estimating how many boxes to procure. The types of boxes to be procured must also be identified based on the types of services provided. For example, if injectable contraceptives are administered by community-based distributors (CBD), smaller safety boxes must be selected in addition to the 100-capacity boxes because CBD workers must be able to easily transport the boxes into the field. Laboratories, on the other hand, may select boxes with a larger capacity than 100 syringes, depending on how much sharps waste they generate.

Additional methodologies for quantifying need based on consumption and morbidity estimates are described in WHO's *Procuring Single-Use Injection Equipment and Safety Boxes* (see annex F). However, it is important to remember that consumption data may not be reliable if injection devices have not been held in full supply; this would cause an underestimation. And, the morbidity method of forecasting need may be unreliable if the health information system is not well developed or if morbidity statistics are not reliably reported. Morbidity-based forecasting may also be difficult in circumstances where many treatment modalities are employed. In this case, substitution of treatments makes it particularly difficult to estimate injection devices.

### **1.2. Identifying Financing**

Another critical logistics element for ensuring commodity security is securing sufficient *financing*. WHO's *Guiding Principles to Ensure Injection Device Security* (WHO 2003) calls on "all donors and lenders who finance injectable products to also finance appropriate quantities of single-use injection devices, single dose diluents, safety boxes and the cost of sharps

waste management.” You should pay attention to advocacy for sustainability of financing mechanisms for injection safety-related commodities for preventive services—particularly immunization and family planning—as they are heavily donor-dependent in many countries (supplied by the Global Alliance for Vaccines and Immunization [GAVI], U.S. Agency for International Development [USAID], United Nations Population Fund [UNFPA], and others). To expand the discussion of commodity security for injection devices provided by donors, you should raise questions about long-term financing.

Consider government financing of injection devices equally because, in most countries, the government pays directly for injection devices for therapeutic and, in many cases, preventive services. Given the current budget constraints within the health sector, it is critical to secure financing for injection devices since they must be held in full supply.

### **1.3. Procuring Injection Devices**

WHO adopted the current global safe injection strategy that calls for single-use injection devices and safety boxes for every injection administered. One of the most important elements in supporting this strategy is coordinated procurement, which means procuring quantities of single-use injection devices to match the number of doses of injectable preparations procured. It also means procuring the corresponding number of safety boxes. The issue of coordinated procurement is crucial to supporting commodity security for injection safety. Advisors can find specific advice on procuring safe injection devices in the following section.

### **1.4. Supply Management for Injection Devices**

Finally, a critically important issue to consider about *supply management (including delivering)* for safe injection devices is how to provide the supplies in complementary quantities, also called *bundling*. Bundling usually refers to distributing injectable products with an appropriate number of syringes, diluent (if needed), and safety boxes, to ensure that every injection is given safely and the used syringe is disposed of safely. This term can be confusing because it may be equated with physically shipping products in the same box or carton. Physically bundling products is not necessary if the same quantity of products are provided to health facilities. Depo-Provera®, donated by USAID, is an example of a physically bundled product. Each shipped carton contains 400 single-dose vials of Depo-Provera, 400 auto-disable syringes with attached needles, and four safety boxes with 100 syringe capacity each. Although these products are provided in complementary quantities within the cartons, the distribution managers must continue to provide complementary quantities of products all the way to the service delivery point. Problems can arise when facilities receive fewer than 100 doses of Depo-Provera because only one safety box is provided for every 100 doses. Local solutions can be found for sharps waste disposal. Logistics advisors can help lower-level facilities locate puncture-proof, leak-proof, disposable containers with a small opening until safety boxes are routinely provided.

It is important for you to recognize that injection devices typically flow through existing supply management systems within countries. Logistics advisors helping to strengthen the system and develop effective supply management for injection devices must understand how those systems operate and they must understand their strengths and weaknesses.

**Annex E: Guiding Principles to Ensure Injection Device Security (WHO December 2003)**

This document applies the commodity security framework to the security of equipment and supplies for injection safety (single-use injection devices for injection and reconstitution, appropriate single-dose diluents, and safety boxes). The entire document is available as annex E and the link is provided below.

*[http://www.who.int/injection\\_safety/toolbox/docs/en/Guiding\\_Principle\\_Inj.pdf](http://www.who.int/injection_safety/toolbox/docs/en/Guiding_Principle_Inj.pdf)*

## **2. Procurement**

The following two documents provide guidance for effective procurement of safe injection devices, including quantification methodologies that use consumption data and morbidity data. We suggest that you review the section in this document, “Forecasting Injection Device Needs,” before selecting the best methodology for quantifying need.

The first document discusses safe injection needs for health services in general; the second document is tailored for immunization programs. You should note there is a great deal of information about how to ensure safe injection in immunization programs. The section in this document titled “Immunization Contributions to Safe Injection and Waste Management Practices” provides additional resources and tools related to safe injection for immunization programs, including routine services and campaigns.

This reference manual contains the complete procurement guidance document for injection devices developed by WHO, because it contains useful tools to support procurement of injection devices (see annex F). In the annex you will find a description of the procurement cycle, including detailed descriptions of the tasks that should be undertaken during each phase of procurement. You will find information about the prequalification of injection device suppliers, criteria for evaluating suppliers, and a list of suppliers. The glossary at the end of this document includes terms commonly used in the procurement of injection devices, tables describing the characteristics of the devices you may need to procure, and a table of International Standards Organization (ISO) standards.

**Annex F: Procuring Single-Use Injection Equipment and Safety Boxes (WHO, 5 May 2003).**

The link is available below, but the entire document is available as an annex.

*[http://www.who.int/injection\\_safety/toolbox/docs/en/Procurement.pdf](http://www.who.int/injection_safety/toolbox/docs/en/Procurement.pdf)*

Procurement of vaccines for public-sector programmes (WHO, May 1999).

[http://www.who.int/vaccines-access/procurement/PDF\\_Proc\\_Manual/](http://www.who.int/vaccines-access/procurement/PDF_Proc_Manual/)

### 3. Safe Injection Supplies

A small number of supplies are needed to effectively provide safe injections:

- single-dose diluents (when needed)
- single-use injection devices for injection administration and reconstitution of the injectable preparation
- single-use hypodermic needles (when not integrated with a syringe)
- safety boxes.

Although additional supplies are needed to ensure that infection control practices can be implemented, a limited number of supplies are needed to ensure injection safety. The best practices for injection safety are outlined in the document cited below.

#### Best Infection Control Practices for Skin-Piercing Intradermal, Subcutaneous, and Intramuscular Needle Injections (WHO, November 2001)

These best practices are measures that have been determined through scientific evidence or expert consensus to effectively protect patients, health care providers, and communities.

[http://www.who.int/injection\\_safety/toolbox/en/LeafletBestPracticesPrinter.pdf](http://www.who.int/injection_safety/toolbox/en/LeafletBestPracticesPrinter.pdf)

#### 3.1. Universal Precautions

Although the focus of this document is injection safety, you should understand that it is only one part of universal precautions. The list of supplies required to ensure that universal precautions can be practiced in health care settings is understandably longer than the list of safe injection supplies. This document treats universal precautions minimally because, as a much broader topic, it is treated extensively in other references. The following paragraph, taken from WHO's aide-mémoire on health care worker safety (WHO 2003), is the definition of universal precautions and the interventions required to achieve it.

Universal Precautions are a simple set of effective practices designed to protect health care workers and patients from infection with a range of pathogens including blood-borne viruses. These practices are used when caring for all patients regardless of diagnosis. They are applied universally. It is not feasible, effective or cost-effective to test all patients for all pathogens prior to giving care in order to identify those who are infected and take precautions only with them. Knowing a patient is infected does not prevent occupational exposure to blood. Thus, decisions regarding the level of precautions to use are based on the nature of the procedure and not on the actual or assumed serological status of the patient. It is not safe to take precautions only with those from so-called risk groups for infection with blood-borne pathogens as many people belonging to risk groups

are not infected and many infected people do not belong to risk groups. In practice, the implementation of Universal Precautions includes the following interventions:

- Washing hands after any direct contact with patients.
- Preventing two-handed recapping of needles.
- Collecting and disposing of needles safely (hypodermic and suture) and sharps (scalpel blades, lancets, razors, scissors) with required puncture- and leak-proof safety boxes in each patient care area.
- Wearing gloves for contact with body fluids, non-intact skin, and mucous membranes.
- Wearing a mask, eye protection, and a gown (sometimes a plastic apron) if blood or other body fluids might splash.
- Covering all cuts and abrasions with a waterproof dressing.
- Promptly and carefully cleaning up spilt blood and other body fluids.
- Using a safe system for health care waste management and disposal.

Key practices outlined in WHO's aide-mémoire are complementary to the description of universal precautions contained in the document prepared by the United States Government's National Institute of Environmental Health Sciences of the National Institutes of Health:<sup>2</sup>

- *Barrier protection* should be used at all times to prevent skin and mucous membrane contamination with blood, body fluids containing visible blood, or other body fluids (cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids, semen, and vaginal secretions). Use of barrier protection is included in the following procedures.
- Wear gloves when you may have hand or skin contact with blood, other potentially infectious material, or contaminated items and surfaces.
- Wear face protection (face shield) during procedures when you are likely to generate droplets of blood or body fluid; this will prevent exposure to mucous membranes of the mouth, nose, and eyes.
- Wear protective body clothing (disposable laboratory coats [Tyvek]) when there is a potential for splashing of blood or body fluids.
- Wash hands or other skin surfaces thoroughly and immediately with soap if you are contaminated with blood, body fluids containing visible blood, or other body fluids
- Place in puncture resistant containers, marked with a biohazard symbol (see figure 3) for disposal, all used needles, disposable syringes, scalpel blades, pipettes, and other sharp items.

**Figure 3**  
**Biohazard Symbol**



2. National Institute of Environmental Health Sciences, National Institutes of Health, Bethesda, Md. 2001.

### 3.2. Product-Specific References for Procurement and Quality Assurance

The following references may be useful when you develop tender specifications and other procurement documentation related to quality of products for tender.

**Annex G: WHO Template Procurement Specifications for Sterile Hypodermic Syringes for Single-Use Including a Reuse-prevention Feature (WHO, 8 November 2002).**

This two-page document contains procurement specifications for single-use syringes for general purpose and those that have a feature preventing reuse. The link is available below; the entire document is also available as annex H.

[http://www.who.int/injection\\_safety/toolbox/docs/en/SpecCurativeAD%20BCT.02.12.pdf](http://www.who.int/injection_safety/toolbox/docs/en/SpecCurativeAD%20BCT.02.12.pdf)

**Annex H: A Guide for the Quality Assurance of Single-Use Injection Equipment (WHO, 17 February 2003).**

This document outlines the suggested standards, regulatory requirements, and marketing clearances necessary to consider when you procure single-use injection technologies. It includes a checklist for essential information on proposed products and a flow-chart to guide decision making on product quality. The link is below; the entire document is also available as annex H.

[http://www.who.int/injection\\_safety/toolbox/docs/en/InjEquQuality-Guiden.pdf](http://www.who.int/injection_safety/toolbox/docs/en/InjEquQuality-Guiden.pdf)

**Product Information Sheets, 2000 Edition. (WHO 2000).**

You can obtain pricing and manufacturer information for safe injection-related products for immunization programs from WHO Product Information Sheets.

<http://www.who.int/vaccines-documents/DocsPDF00/www518.pdf>

## 4. Storage

**Guidelines for the Storage of Essential Medicines and Other Health Commodities (DELIVER 2004).**

Contains guidelines for storage of health commodities, and includes a chapter devoted to the management of waste for health care facilities.

[http://www.deliver.jsi.com/pdf/g&h/storage\\_pocketguide.pdf](http://www.deliver.jsi.com/pdf/g&h/storage_pocketguide.pdf)

**Guide to Good Storage Practices for Pharmaceuticals (WHO Technical Report Series 908, Annex 9, 2003).**

Contains guidelines for the storage of pharmaceutical products applicable to manufacturers of medicinal products, pharmaceutical contractors, wholesalers, and community and hospital pharmacies.

<http://www.who.int/medicines/library/qsm/trs908/trs908.pdf>



# Developing Policies for Injection Safety and Injection Waste Management

One strategy you can use to effect change in safe injection practices is to establish a national policy that either focuses directly on safe injection and waste management issues or updates and enhances the policies that already exist. A number of countries have successfully followed this strategic process, including Burkina Faso, Cambodia, Guinea, Senegal, and Uganda. Additional countries are now working on policies for safe injection and waste management as a result of increased funding under the President's Emergency Plan for HIV/AIDS Relief.

## 1. Introduction

### Assessing injection practices

To effectively inform policy work, a preliminary study is undertaken to determine the injection practices currently employed by health care workers and health facility staff. The WHO/BASICS-developed *Tool for the Assessment of Injection Safety* is also known as “Tool C.”

*Tool for the Assessment of Injection Safety*. (WHO 2001).

[http://www.who.int/injection\\_safety/toolbox/en/InjectionSafetyAssessment-Tool.pdf](http://www.who.int/injection_safety/toolbox/en/InjectionSafetyAssessment-Tool.pdf)

Another tool developed by WHO and BASICS:

*Injection Practices: Rapid Assessment and Response Guide* (WHO, 1 October 2002).

This guide was designed as a framework for partners to examine injection practices and their determinants and consequences, and to eventually formulate an action plan.

[http://www.who.int/injection\\_safety/toolbox/en/RARG.pdf](http://www.who.int/injection_safety/toolbox/en/RARG.pdf)

## 2. Guidelines for Developing National Safe Injection and Waste Management Policies

This section briefly explores how standard tools can be used to help develop national guidelines, policy, and an action plan for safe injection and waste disposal.

A critical step in the policy development or enhancement process is engaging key stakeholders in the country and obtaining their support. Given the multifaceted nature of injection safety, the stakeholders will represent diverse governmental and nongovernmental organizations.

- Stakeholders from within the government should represent clinical services and environmental health.
- Academic institutions doing research on HIV transmission through unsafe injections should be involved in this process.
- Community-based organizations that may be able to influence behavior change around injection overuse are key partners in the policy change process.
- Environmental groups advocating for cleaner technologies for health care waste management should be invited to participate.
- International organizations, including the United Nations partners, can offer critical input to the technical content of policies.
- It is important for organizations with expertise in supply chain management and logistics to also be involved in the policy change process because of the need to ensure continuous availability of injection devices.

Although this list is not exhaustive, it does provide some information about what groups or individuals to seek out and why. After key stakeholders are identified and buy-in is obtained, representatives from the various organizations and entities are assembled into a national safe injection group to identify what changes are needed in existing policy and guidelines (or develop new policy if none exists), and to create an action plan to move the issue forward. The WHO tool cited below outlines how to initiate the policy change process for injection safety; the tool also helps track progress toward implementation of the policy to ensure that it is enacted and implemented.

**Managing an Injection Safety Policy (WHO, 14 March 2003).**

This WHO-developed tool can assist in the policy development, implementation, and monitoring processes. The objective of the document is to “assist in benchmarking, assessing, planning, implementing and evaluation of a national strategy for the safe and appropriate use of injections.”

*[http://www.who.int/injection\\_safety/toolbox/en/ManagingInjectionSafety.pdf](http://www.who.int/injection_safety/toolbox/en/ManagingInjectionSafety.pdf)*

# Implementing Safe Injection and Waste Management Practices

## 1. Improving Safe Injection Practices

Since the development of single-use syringes with a reuse prevention feature, efforts have been underway to use the syringes in public health sector services, primarily in immunization programs. However, recent efforts have included them in family planning services, as well. This section provides general information and resources on single-use syringes and single-use syringes with a reuse prevention feature for general purpose, which prevents subsequent reuse after the injection is given.

Single-use syringes should only be used once, but the reality is that they are often reused, often without proper cleaning and sterilization. Auto-disable (AD) syringes have a design feature that prevents their reuse. However, because the used needle remains exposed after use, these devices do not always protect the health care provider, client, or community from unintentional needle sticks. Newer designs of auto-disable syringes incorporate a retraction device enabling the used needle to enter the barrel of the syringe after use, which protects all parties from accidental needle stick injuries. However, these used devices must still be kept in a secure location after use to avoid tampering until they can be disposed of safely. Other devices designed to protect health providers and others from accidental needle sticks include those that require the health provider to manually shield or cover the used needle after use.

Regardless of the device used, it is imperative that sufficient supplies of needles and syringes are available to ensure that every injection can be administered with a new sterile needle and syringe.

Cost implications will obviously influence which devices can be obtained. Cost analysis is not a simple issue, however, because the cost of the syringe, needle, and disposal mechanism must all be considered, as well as the potential cost saving over subsequent years if transmission of blood-borne diseases are prevented. In looking only at the cost of the devices, at present, standard single-use disposable syringes and needles are the least expensive option; syringes with a reuse prevention feature only are the next most costly. Devices with a needle-stick prevention feature and a reuse prevention feature are even more costly. Of course, this is general information; you must obtain specific cost information directly from manufacturers and suppliers. The WHO document cited earlier in this resource, *Procuring Single-Use Injection Equipment and Safety Boxes*, includes a list of potential suppliers. You can also find pricing and manufacturer information on the WHO Product Information Sheets cited earlier.

## **1.1 Introduction and Use of Single-Use Syringes in Immunization and Family Planning Programs**

Immunization programs were usually the first to introduce AD syringe technology into public sector services in resource-constrained settings. Many tools and resources were developed to support the introduction of this new technology and several are cited below. Later, some family planning programs began incorporating AD syringe technology into their injectable contraceptive services. Tools for immunization were adapted to help introduce this technology to family planning service providers, although many of the providers were already familiar with the technology because of their responsibilities for immunization services.

The following three resources were designed by the Program for Appropriate Technology for Health (PATH) and USAID, with input from the Safe Injection Task Force (no longer a functional working group), to help countries receiving USAID-provided Depo-Provera® introduce the new injection technology. The last document listed in this collection, *Giving Safe Injections: Introducing Auto-Disable Syringes*, is a useful companion to the first two documents. It was designed as a training manual for immunization programs, and it can also be adapted to family planning programs using Depo-Provera and AD syringes.

### **Introducing Auto-Disable Syringes and Sharps Disposal Containers with DMPA. (PATH, July 19, 2001).**

The following description of the document was taken from PATH's website (<http://www.path.org/resources/safe-inj-pdf.htm>), and it provides the links to this document in English, French, and Spanish.

This document is designed to help introduce AD syringes and sharps containers into family planning programs that will receive USAID-supplied depot medroxyprogesterone acetate (DMPA). The document provides guidance on points to consider when introducing these technologies, and key training messages to help health workers use the new syringes and sharps containers safely and effectively. Guidelines for disposal of contaminated waste and used syringes are also provided.

*[http://www.path.org/files/SI\\_CNVP15904\\_English.pdf](http://www.path.org/files/SI_CNVP15904_English.pdf)*

### **Introducing Auto-Disable Syringes with DMPA (depot medroxyprogesterone acetate) (PATH 2001).**

This companion piece to the document referenced above is a one-page job aid for health care providers using AD syringes with Depo-Provera. It provides step-by-step instructions on how to use the device and includes useful tips.

*[http://www.path.org/files/SI\\_Job%20Aide\\_English.pdf](http://www.path.org/files/SI_Job%20Aide_English.pdf)*

### ***Giving Safe Injections: Using the Auto-Disable Syringes for Immunization (Training Manual) (PATH, September 2001).***

This training manual can be adapted to country-specific and program-specific circumstances. Although the document was originally designed for training health care providers working in immunization programs, it has

since been used for training health care providers who will be using AD syringes in family planning programs. As described on PATH's webpage (<http://www.path.org/resources/safe-inj-pdf.htm>), “As a training aid, it discusses current policies and practices for the delivery of safe injections, and includes specific instructions for each of the currently available WHO-approved auto-disable syringes. This is particularly important, since each new design requires some variation in technique.” The site includes links to this document in English, French, and Russian.

[http://www.path.org/files/SI\\_Giving\\_Safe\\_Injections\\_complete.pdf](http://www.path.org/files/SI_Giving_Safe_Injections_complete.pdf)

This following WHO-developed document is specific to immunizations; it also contains concepts and information that may be useful for curative services.

**“First, do no harm” Introducing auto-disable syringes and ensuring injection safety in immunization systems of developing countries (WHO 2002).**

This detailed resource provides programmatic guidance for implementing safe injection practices in immunization programs. Although the document addresses issues specific to immunization programs, many of the concepts, tables, figures, and information can be applied to other health programs. It is an easy-to-use online resource.

<http://www.who.int/vaccines-documents/DocsPDF02/www704.pdf>

## 2. Improving Health Care Waste Management Practices

Although many improvements have been made in the availability of safe injection devices in developing countries, the improvements in HCWM have not kept pace. A number of technological devices are available to handle HCW: incinerators, autoclaves, shredders, and needle removers. Their availability, however, is inconsistent. Where some devices exist, particularly incinerators, they are not always the type that minimize environmental contamination or achieve effective combustion. In addition, more technologically advanced devices—effective, large-scale environmentally sound autoclaves and shredders—are often financially prohibitive for municipalities and national governments. Finally, even if technologically advanced devices were available in developing countries, ways to transport wastes to the devices have not been developed. There have been no breakthroughs with the development of so-called *reverse logistics systems*, which have been discussed in electronic forums such as SIGNPost. Establishing transportation options for moving biohazardous waste to facilities with safe and appropriate disposal mechanisms creates many challenges, including—

- limited transportation resources overall (e.g., vehicles, drivers, and funding for per diem)
- lack of storage mechanisms to contain the waste within the vehicle during transport

- potential for contamination of medical supplies if transported with biohazardous waste or in a vehicle that has been used to transport biohazardous waste
- difficulties in implementing safe and effective disinfection practices for vehicles
- lack of policies in most countries to regulate the transportation of biohazardous waste
- insufficient storage space at health facilities to securely store biohazardous waste prior to transport
- addition of transport into the life cycle of waste increases the number of individuals that need to be trained in safety procedures.

The documents listed in this section will provide you with background information about the various options for HCWM that are appropriate at various levels in the health system.

## **2.1. Guidelines**

### **Safe Management of Wastes from Health Care Activities (WHO 1999).**

This handbook provides comprehensive guidance on safe, efficient, and environmentally sound methods for handling and disposing of health care wastes. It describes the various categories for health care waste and stresses the careful planning that is essential for the success of waste management. Most of the text is devoted to the collection, segregation, storage, transport, and disposal of wastes. Technologies more suitable for use in limited resource settings for treatment of waste and disposal of final residues are discussed at length.

*[http://www.who.int/water\\_sanitation\\_health/medicalwaste/wastemanag/en/](http://www.who.int/water_sanitation_health/medicalwaste/wastemanag/en/)*

### **Teacher's Guide: Management of wastes from health care activities (WHO 1998).**

This teacher's guide provides teaching materials and recommendations for a three-day training course, designed mainly for managers of health care facilities, public health professionals, and policymakers.

*[http://www.who.int/water\\_sanitation\\_health/medicalwaste/wsh9806/en/](http://www.who.int/water_sanitation_health/medicalwaste/wsh9806/en/)*

### **Health Care Waste Management: at a glance (WHO June 2003).**

This four-page reference has useful information, including a table describing types of HCW, a reference list, **Do's and Don'ts**, a graphic depiction of the HCWM project cycle, and a table identifying factors that influence the effectiveness of treatment technologies. It also briefly treats the issue of procurement, as well as human resources issues.

<http://www.healthcarewaste.org/linked/onlinedocs/WW08383.pdf>

### **Guidelines for the Storage of Essential Medicines and Other Health Commodities (DELIVER 2004).**

Contains guidelines for storage of health commodities, and includes a chapter devoted to management of waste from health care facilities.

[http://www.deliver.jsi.com/pdf/g&h/storage\\_pocketguide.pdf](http://www.deliver.jsi.com/pdf/g&h/storage_pocketguide.pdf)

**Safe Health Care Waste Management: Aide-Mémoire for a National Strategy for Health Care Waste Management (WHO, September 2000).**

Outlines key components when planning a national strategy on health care waste management, including a checklist for action at the national and local levels. Available as annex B.

[http://www.who.int/injection\\_safety/toolbox/en/AM\\_HCWaste.pdf](http://www.who.int/injection_safety/toolbox/en/AM_HCWaste.pdf)

## **2.2. Overview of Waste Treatment Options**

The following table summarizes information about the various methods of waste disposal and their inherent strengths and weaknesses.

**“First, do no harm”** Introducing auto-disable syringes and ensuring injection safety in immunization systems of developing countries (WHO 2001).

## **2.3. Other Resources**

**Wastes from health care activities. (Fact Sheet No. 253) (WHO, October 2000).**

The following brief WHO document discusses the various types of waste; health impacts of HCW particularly related to sharps, vaccines, and radioactive wastes; issues around management of waste, including risks associated with waste management activities; and WHO’s response to these challenges.

<http://www.who.int/mediacentre/factsheets/fs253/en/>

### **Health Care Waste Management Working Group Technical Options Database**

The Health Care Waste Management Working Group promotes the safe management of health care waste through a coalition of organizations committed to this issue. Their website is operated by WHO and contains a number of useful resources. Of special interest is the technical options database that contains details of many different waste management techniques specific to the various stages in the waste stream (i.e., handling to final disposal). It includes detailed schematic plans, applicability to resource-poor settings, and information on the environmental considerations of various solutions. Technologies reviewed include, among others, incinerator models (from industrial models to locally built models), encapsulation, and needle pullers.

To access the Health Care Waste Management Working Group Technical Options Database, go to the home page of the working group and click on databases on the left side navigation bar. [www.healthcarewaste.org](http://www.healthcarewaste.org) .

**Table 1. Comparison of Various Methods for Processing and Disposing of Immunization Waste**

Method	Strengths	Weaknesses
Waste burial pit/cement	<ul style="list-style-type: none"> <li>Simple.</li> <li>Inexpensive.</li> <li>Low tech.</li> </ul>	<ul style="list-style-type: none"> <li>Potential of being unburied (if pit is only soil covered and waste is not encapsulated).</li> <li>No volume reduction.</li> </ul>
Encapsulation or other immobilizing	<ul style="list-style-type: none"> <li>Prevents unsafe needle and syringe reuse.</li> <li>Prevents sharp related infections/injuries to waste handlers/scavengers.</li> </ul>	<ul style="list-style-type: none"> <li>No disinfection of wastes.</li> <li>Pit will fill quickly during campaigns.</li> <li>Not recommended for non-sharp infectious wastes.</li> </ul>
Agent (sand, plaster)		<ul style="list-style-type: none"> <li>Presents a danger to community if not correctly buried.</li> <li>Inappropriate in areas of heavy rain or if water table is near the surface.</li> <li>Inexpensive.</li> <li>Low tech.</li> <li>Prevents unsafe needle and syringe reuse.</li> <li>Prevents sharp related infections/injuries to waste handlers/scavengers.</li> </ul>
Burning (<400o C)	<ul style="list-style-type: none"> <li>Relatively inexpensive.</li> <li>Reduction in waste volume.</li> <li>Reduction in infectious material.</li> </ul>	<ul style="list-style-type: none"> <li>Incomplete combustion.</li> <li>May not be completely sterilized.</li> <li>Results in heavy smoke &amp; potential fire hazard.</li> <li>May require fuel, dry waste to start burning.</li> <li>Toxic air emissions (i.e., heavy metals, dioxins, furans, fly ash) that may violate environmental or health regulations.</li> <li>Production of hazardous ash containing leachable metals, dioxins, and furans.</li> <li>Potential for needle-stick injuries because needles are not destroyed.</li> </ul>
Medium Temperature Incineration (800–1000° C)	<ul style="list-style-type: none"> <li>Less expensive than high-temperature incinerators.</li> <li>Reduction in waste volume.</li> <li>Reduction in infectious material.</li> </ul>	<ul style="list-style-type: none"> <li>Incomplete combustion.</li> <li>Potential for heavy smoke.</li> <li>May require fuel and dry waste to start up and maintain high temperatures.</li> <li>Requires trained personnel to operate.</li> <li>Potential emission of toxic air pollutants to some low level (i.e., heavy metals, dioxins, furans, fly ash) which may violate environmental or health regulations in particular settings.</li> <li>Production of hazardous ash containing variable amounts of leachable metals, dioxins, and furans.</li> <li>Potential for needle stick injuries because some needles may not be destroyed.</li> <li>Needs constant attention during operation and regular maintenance throughout year.</li> </ul>

**Table 1. Comparison of Various Methods for Processing and Disposing of Immunization Waste (cont'd)**

Method	Strengths	Weaknesses
High Temperature Incineration(>1000° C)	<ul style="list-style-type: none"> <li>• Almost complete combustion and sterilization of used injection equipment.</li> <li>• Further reduces toxic emissions if pollution control devices are installed.</li> <li>• Greatly reduces volume of immunization waste.</li> </ul>	<ul style="list-style-type: none"> <li>• Expensive to build, operate, and maintain.</li> <li>• Requires electricity, fuel, and trained personnel to operate.</li> <li>• Toxic air emissions (i.e., metals, dioxins, furans, fly ash) may still be released unless pollution control devices are installed.</li> <li>• May still produce hazardous ash containing variable amounts of leachable metals, dioxins, and furans.</li> </ul>
Needle removal/needle destruction <i>(Models range from simple manual and battery operated to more complex electrical units)</i>	<ul style="list-style-type: none"> <li>• Prevents needle reuse.</li> <li>• Reduces occupational risks to waste handlers and scavengers.</li> <li>• In some instances, plastic may be recycled for other uses after treatment.</li> <li>• Manual or battery operated models available.</li> </ul>	<ul style="list-style-type: none"> <li>• Fluid splashes may contaminate work area and/or operator.</li> <li>• Fluid splash back and used needle manipulation may result in disease transmission in some cases.</li> <li>• Used needles/syringes need further treatment for disposal in some cases.</li> <li>• Safety profile is not established.</li> </ul>
Melting syringes	<ul style="list-style-type: none"> <li>• Greatly reduces volume of immunization waste.</li> <li>• Prevents reuse.</li> </ul>	<ul style="list-style-type: none"> <li>• Emission of potentially toxic gases.</li> <li>• Electricity required.</li> <li>• Safety profile not established.</li> </ul>
Steam sterilization (autoclaving or hydroclaving), microwaving (with shredding)	<ul style="list-style-type: none"> <li>• Successfully used for decades to treat sharps and non-immunization health care wastes (hospital staff may be familiar with autoclave technology).</li> <li>• Range of models (simple to complex) and capacities available.</li> <li>• Sterilizes used injection equipment.</li> <li>• Less hazardous air emissions (no dioxins or heavy metals) than burning or incinerating.</li> <li>• Reduced waste volume when used with shredder.</li> <li>• Plastic may be recycled for other uses after separation.</li> </ul>	<ul style="list-style-type: none"> <li>• High capital cost (but may be less than high temperature incinerators with pollution control devices).</li> <li>• Requires electricity and water.</li> <li>• High operational costs.</li> <li>• High maintenance.</li> <li>• May emit volatile organics in steam during depressurization and opening of chamber.</li> <li>• Requires further treatment to avoid reuse (e.g., shredding).</li> <li>• Resulting sterile waste still needs to be disposed.</li> </ul>

### **3. Immunization Contributions to Safe Injection and Waste Disposal Practices**

#### **3.1 Introduction**

Many of the significant contributions to improved safe injection practices in developing countries are attributable to immunization programs. Both national governments and donors, such as those participating in the Global Alliance for Vaccines and Immunization (GAVI), recognized the necessity of ensuring that the injections delivered through immunization programs were safe. The use of auto-disable syringes and safety boxes was largely introduced to the health sector through immunization programs. USAID-supported family planning programs are now following suit by providing these important commodities with donated Depo-Provera®.

#### **3.2. Immunization Services and Injection Safety**

WHO has taken a leading role in defining issues around injection safety in immunization programs. It has developed a number of documents to guide national immunization programs in developing policies and guidelines for health workers that incorporate single-use injection technology into their practice.

##### **3.2.1. Policy Statement**

**Safety of injections: WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services (WHO 2003).**

The key United Nations agencies involved in immunization programs (i.e., WHO, United Nations Children’s Fund [UNICEF], and UNFPA) set as a goal the exclusive use of AD syringes in immunization programs by the end of 2003. Although this goal was not fully achieved, the number of immunization programs administering vaccines with devices that employ a reuse prevention feature has increased significantly since those agencies released the Joint Statement.

*<http://www.who.int/vaccines-documents/DocsPDF99/www9948.pdf>*

##### **3.2.2. Injection Safety in Routine Immunization Services**

**“First, do no harm” Introducing auto-disable syringes and ensuring injection safety in immunization systems of developing countries (WHO 2002).**

This detailed resource provides programmatic guidance for implementing safe injection practices in immunization programs. Although the document addresses issues specific to immunization programs, many of the concepts—tables, figures, and information—can be applied to other health programs. It is an easy-to-use online resource.

*<http://www.who.int/vaccines-documents/DocsPDF02/www704.pdf>*

**Designing Safe Syringe Disposal Systems for Immunization Services  
(Children's Vaccine Program/PATH, October 2003)**

This document provides step-by-step guidance for planning a safe syringe waste management system for routine immunization services.

*[http://childredivaccine.org/files/CVP\\_Sharps\\_waste\\_planning\\_guide.pdf](http://childredivaccine.org/files/CVP_Sharps_waste_planning_guide.pdf)*

**3.2.3. Injection Safety in Immunization Campaigns**

**Aide-Mémoire: Safety of Mass Immunization Campaigns (WHO 2002).**

This aide-mémoire outlines safety issues around mass immunization campaigns, including vaccine safety, safe administration of the vaccine, management of sharps waste, and monitoring for adverse events following immunization.

*[http://www.who.int/injection\\_safety/toolbox/en/AM\\_SafetyCampaigns.pdf](http://www.who.int/injection_safety/toolbox/en/AM_SafetyCampaigns.pdf)*

**Management of Wastes from Immunisation Campaign Activities: Practical Guidelines for Planners and Managers (WHO 2004).**

This job aid, for use in conjunction with immunization campaigns, provides practical information on improving waste management planning and coordination at the central level, as well as improving local level waste management practices during mass immunization campaigns.

*[http://www.who.int/water\\_sanitation\\_health/medicalwaste/en/HCWM.pdf](http://www.who.int/water_sanitation_health/medicalwaste/en/HCWM.pdf)*



# Tools: Introducing and Assessing Safe Injection and Health Care Waste Management

## 1. WHO Tools

The World Health Organization and SIGN have developed a toolbox that includes resources to assist in the management and development of national safe injection policies. Below are links to just a few useful tools. See the following link for the complete toolbox.

[http://www.who.int/injection\\_safety/toolbox/en/](http://www.who.int/injection_safety/toolbox/en/)

### 1.1. Policy Management Tools

1. The injection safety policy planner: A framework to assess, plan, implement, and evaluate a national policy for the safe and appropriate use of injections.

[http://www.who.int/injection\\_safety/toolbox/InjectionSafetyPlanner.pdf](http://www.who.int/injection_safety/toolbox/InjectionSafetyPlanner.pdf)

2. A behaviour change strategy to promote the safe and appropriate use of injections.

[http://www.who.int/injection\\_safety/toolbox/en/BehaviourChangeStrategy.pdf](http://www.who.int/injection_safety/toolbox/en/BehaviourChangeStrategy.pdf)

3. Best infection control practices for skin-piercing intradermal, subcutaneous, and intramuscular needle injections.

[http://www.who.int/injection\\_safety/toolbox/InjectionBestPractices.pdf](http://www.who.int/injection_safety/toolbox/InjectionBestPractices.pdf)

4. Injection Practices: Rapid Assessment and Response Guide

[http://www.who.int/injection\\_safety/toolbox/RARG.pdf](http://www.who.int/injection_safety/toolbox/RARG.pdf)

### 1.2. Assessment Tools

1. Tool for the assessment of injection safety

<http://www.who.int/vaccines-documents/DocsPDF01/www576.pdf>

2. Health care waste management Rapid Assessment Tool

[http://www.who.int/injection\\_safety/toolbox/en/](http://www.who.int/injection_safety/toolbox/en/) follow link under Technical Tools

### 1.3. Aide-Mémoires

1. Injection Safety: Aide-Mémoire for a National Strategy for the Safe and Appropriate Use of Injections

[http://www.who.int/injection\\_safety/about/country/en/AMENG.pdf](http://www.who.int/injection_safety/about/country/en/AMENG.pdf)

2. Health Care Worker Safety: Aide-Mémoire for a Strategy to Protect Health Care Workers from Infection with Blood-borne Viruses  
[http://www.who.int/injection\\_safety/toolbox/en/AM\\_HCW\\_Safety\\_EN.pdf](http://www.who.int/injection_safety/toolbox/en/AM_HCW_Safety_EN.pdf)
3. Safe Health Care Waste Management: Aide-Mémoire for a National Strategy for Health Care Waste Management  
[http://www.who.int/injection\\_safety/toolbox/en/AM\\_HCWaste.pdf](http://www.who.int/injection_safety/toolbox/en/AM_HCWaste.pdf)
4. Safe Medical Devices: Aide-Mémoire for National Medical Device Administrations  
[http://www.who.int/bct/Main\\_areas\\_of\\_work/Resource\\_Centre/Aide-M%e9moires/Devices\\_AM/AM\\_Safe\\_Devices.pdf](http://www.who.int/bct/Main_areas_of_work/Resource_Centre/Aide-M%e9moires/Devices_AM/AM_Safe_Devices.pdf)
5. Infection control: Aide-Mémoire for Infection Prevention and Control in a Health Care Facility  
[http://www.who.int/injection\\_safety/toolbox/docs/en/AideMemoireInfectionControl.pdf](http://www.who.int/injection_safety/toolbox/docs/en/AideMemoireInfectionControl.pdf)

## 2. Other Tools

### 2.1. USAID Safe Injection Bundling for Donated Depo-Provera<sup>®</sup>

When USAID committed to providing AD syringes and safety boxes (also known as sharps disposal containers) with their donated Depo-Provera, they employed PATH and other USAID partners to develop materials to facilitate the smooth transition from single-use disposable needles and syringes to AD syringes, with the addition of safety boxes. The two documents below are available from USAID through the DELIVER project for distribution to USAID missions and other partners that might welcome the information.

#### Program for Appropriate Technology for Health (PATH). 2001. **Introducing Auto-Disable Syringes and Sharps Disposal Containers with DMPA.**

This document provides information on the following topics:

- descriptions of—
  - the AD syringes and safety boxes
  - the difference between a single-use disposable needle and syringe and an AD syringe
  - how to use the safety box properly and with safe disposal concepts
  - injection practices to use during administration of the DMPA
  - pictorial for using the AD syringe with DMPA
- considerations when introducing AD syringes and safety boxes
- shipping specifications.

Unfortunately, some of the information provided in this document is out-of-date because Becton-Dickinson is currently providing Solo-Shot IX AD syringes instead of the FX model shown in the document. The two models differ: the FX model packaged the needle and syringe together but not connected, while the IX connects the needle to the syringe.

*[http://www.path.org/files/SI\\_CNVP15904\\_English.pdf](http://www.path.org/files/SI_CNVP15904_English.pdf)*

**Job Aid for Introducing Auto-Disable Syringes and Sharps Disposal Containers with DMPA (depot medroxyprogesterone acetate) (PATH 2001).**

This job aid lists the key behaviors required when administering DMPA with an AD syringe.

*[http://www.path.org/files/SI\\_Job%20Aide\\_English.pdf](http://www.path.org/files/SI_Job%20Aide_English.pdf)*



# Related Topics

## 1. Blood Safety

**Blood Safety: Aide-Mémoire for National Blood Programmes**  
(WHO 2002).

*[http://www.who.int/bct/Main\\_areas\\_of\\_work/BTS/aide%20memoire.PDF](http://www.who.int/bct/Main_areas_of_work/BTS/aide%20memoire.PDF)*

**Blood Products and Related Biologicals: Aide Mémoire—Quality and safety of blood products and related substances** (WHO 2002).

*[http://www.who.int/bct/Main\\_areas\\_of\\_work/Resource\\_Centre/QSD/AM\\_Blood\\_Products\\_E.pdf](http://www.who.int/bct/Main_areas_of_work/Resource_Centre/QSD/AM_Blood_Products_E.pdf)*

**Quality Systems for Blood Safety: Aide-Mémoire for National Blood Programmes** (WHO 2002).

*[http://www.who.int/bct/Main\\_areas\\_of\\_work/Resource\\_Centre/Aide-M%e9moires/BTS\\_AM/Quality\\_Aide-Mem\\_Final.pdf](http://www.who.int/bct/Main_areas_of_work/Resource_Centre/Aide-M%e9moires/BTS_AM/Quality_Aide-Mem_Final.pdf)*

## 2. Infection Prevention and Control

Although we have discussed issues specifically related to safe injection in this document, it is important to remember that safe injection practices are part of the larger concerns of a health system that is related to infection prevention and control (IPC). Effective IPC interventions help ensure health care quality and help create a safe environment for the delivery of health care services for patients, their families, as well as health care providers.

A key element of infection prevention and control is universal precautions (UP). When health workers follow UP, they make the assumption that all blood and body fluids are potentially infectious and take necessary actions (precautions) to ensure that they, the health workers, are not exposed to blood and body fluids, and that patients are not exposed to pathogens. Although there is currently heightened awareness around HIV transmission in health care settings, the application of universal precautions, and IPC practices in general, contributes to reducing the risk of transmission of other blood-borne pathogens, such as hepatitis, at even higher levels. Other elements of IPC include, for example, ensuring that instruments and devices are effectively sterilized or disinfected between patients; managing the supplies and systems designed to ensure safe health care, including waste management; supervising staff to ensure they can and do practice safely; ensuring that injections are administered safely; and maintaining equipment needed for IPC.

WHO/AFRO and partners recently undertook a study (WHO/AFRO. April 2004. “WHO/AFRO Supports Infection Prevention and Control”) to look at IPC practices, and they found the following:

- non-compliance with standard (i.e., universal) precautions
- poor hospital-based sanitation and management
- unsafe injection practices
- unsafe injection waste disposal
- unsafe sterilization and disinfection practices
- poor management practices by IPC staff, where they exist
- insufficient supplies to implement IPC
- poor maintenance of equipment.

WHO/AFRO has made a commitment to support countries in developing countries and to enhance their infection prevention strategies and practices, in collaboration with the public and private sectors. As part of their commitment, they have developed generic regional guidelines and a training curriculum that can be adapted to country-specific circumstances. These materials are available through WHO/AFRO.

See also annex D on Infection Control or  
*[http://www.who.int/injection\\_safety/toolbox/docs/en/AideMemoireInfectionControl.pdf](http://www.who.int/injection_safety/toolbox/docs/en/AideMemoireInfectionControl.pdf)*.

# Additional Resources

## 1. Organizations Involved in Safe Injection and Health Care Waste Management

**Table 2. Organizations Involved in Safe Injection and Health Care Waste Management**

Organization	Website	Description
Safe Injection Global Network (SIGN)	<a href="http://www.who.int/injection_safety/en/">http://www.who.int/injection_safety/en/</a>	SIGN, a voluntary coalition of stakeholders, work to achieve safe, appropriate use of injections throughout the world. The Blood Safety and Clinical Technology (BCT) department of the World Health Organization (WHO) provides the secretariat for the network. The WHO Injection Safety website has links to useful policy and implementation tools.
WHO Department of Blood Safety and Clinical Technology	<a href="http://www.who.int/injection_safety/en/">http://www.who.int/injection_safety/en/</a>	Department of Blood Safety and Clinical Technology, established in 1998, is part of the cluster on Health Technology and Pharmaceuticals (HTP). They promote the safety, quality, and adequacy of blood and blood products, and selection of appropriate and cost-effective diagnostic and therapeutic procedures essential to providing health care.
Health Care Waste Working Group (Secretariat: WHO)	<a href="http://www.healthcarewaste.org/">http://www.healthcarewaste.org/</a>	This working group, a voluntary coalition, promotes safe management of HCW and works to find sustainable solutions. Department of Protection of the Human Environment (PHE) of the WHO provides the secretariat for the working group. Their website's goal is to support primarily developing countries in implementing safe health care waste management systems.
Water, Engineering and Development Centre (WEDC)	<a href="http://www.lboro.ac.uk/wedc/">http://www.lboro.ac.uk/wedc/</a>	The management of solid waste is an essential service for improving the health and well being of communities. WEDC is concerned with seeking solutions to serious problems associated with inadequate collection and poor disposal of waste in low- and middle-income countries where indiscriminate dumping of waste is common.
Program for Appropriate Technology in Health (PATH)	<a href="http://www.path.org/resources/safe-inj-pdf.htm">http://www.path.org/resources/safe-inj-pdf.htm</a>	PATH identifies, develops, and applies appropriate, innovative solutions to public health problems. For injection safety, PATH has helped develop single-use injection technologies and other technologies to increase the safety of injections and sharps waste management, including needle removers and other devices.

## 2. Journal Articles for Further Reading

Hutin, Y. J. F., A. M. Hauri, and G. L. Armstrong. 2003. "Use of injections in health care settings worldwide, 2000: literature review and regional estimates." *British Medical Journal* 327: 1075.

A review of the literature that describes the frequency and safety of injection practices worldwide. They cite overuse of injections and unsafe injection practices as a still common occurrence in developing and transitional countries. This document provides regional estimates and policy recommendations.

Kane, A., Lloyd, J., Zaffran, M., Simonsen, L., Kane, M 1999. "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.

Reports global and regional estimates in the developing world on the number of hepatitis B (HBV), hepatitis C (HCV), and HIV infections that may be caused by unsafe injections. Using a simple mass-action model comprising data on unsafe injection practices, transmissibility of the various pathogens, prevalence of the infections, and rates of injection use obtained from the literature, the authors estimate that unsafe injection practices cause approximately 8–16 million HBV, 2.3–4.7 million HCV, and 80,000–160,000 HIV infections.

Drucker, E., P. G. Alcabes, and P. A. Marx. 2001. "The injection century: massive unsterile injections and the emergence of human pathogens." *The Lancet* 358: 1989–92.

Provides a historical perspective on injection practices, disease transmission, and the impact on public health.

Brody, S., D. Gisselquist, J. J. Potterat, and E. Drucker. 2003. "Evidence of iatrogenic HIV transmission in children in South Africa." *International Journal of Obstetrics and Gynaecology* 110: 450–452.

Brief summary of the controversial position first put forward by Gisselquist in March 2003 in the *International Journal of STD and AIDS*. The authors contend that the research to date on HIV transmission routes has largely ignored unsafe injection and other medically-related transmission routes, and they suggest that as much as 30 percent of HIV infections in sub-Saharan Africa are due to unsafe injections and other medical procedures.

Crabb, C. 2003. "Contaminated needles and the spread of HIV in Africa." *AIDS* 17(13): N9.

Briefly presents evidence to refute Gisselquist claims, pointing out that hepatitis C virus is far more transmissible by needles. They contend that if the HIV burden were largely due to unsafe injections, one would expect an accompanying surge in hepatitis C (HCV) infections, which is not the case.

Kallestrup, P., Zinyama, R., Gomo, E., Dickmeiss, E., Platz, P., Gerstoft, J., Ullum, H. 2003. “Low prevalence of hepatitis C virus antibodies in HIV-endemic area of Zimbabwe support sexual transmission as the major route of HIV transmission in Africa.” *AIDS* 17(9): 1400–1402.

More in-depth article that cites the comparison of HIV and HCV rates to refute Gisselquist claims that injections play a major role in transmission of HIV.

Hutin, Y., A. Hauri, L. Chiarello, M. Catlin, B. Stilwell, T. Ghebrehiwet, J. Garner, and Members of the Injection Safety Best Practices Development Group. 2003. “Best infection control practices for intradermal, subcutaneous, and intramuscular needle injections.” *Bulletin of the World Health Organization* 81(7): 491–500.

Summarizes evidence-based best practices for preventing injection-associated infections in resource-poor settings.

Drain, P. K., J. S. Ralaivao, A. Rakotonandrasana, and M. A. Cantrell. 2003. “Introducing auto-disable syringes to the national immunization programme in Madagascar.” *Bulletin of the World Health Organization* 81(8): 553–560.

Small randomized controlled trial to evaluate the introduction of auto-disable (AD) syringes into Madagascar’s immunization program. Compares clinics using AD syringes for all vaccinations, a mix of AD syringes for non-routine immunizations and sterilizable syringes for routine immunization sessions, and clinics using only sterilizable syringes for all immunizations. The study found that, although they are more expensive, AD syringes can be introduced into a country’s immunization program and will improve both safety and coverage rates.

Drain, P. K., C. M. Nelson, and J. S. Lloyd. 2003. “Single-dose versus multi-dose vaccine vials for immunization programmes in developing countries.” *Bulletin of the World Health Organization* 81(10): 726–731.

Compares the programmatic and economic considerations associated with multi-dose versus single-dose vials for vaccines, as well as single-dose pre-filled auto-disable syringes. Discusses implications for injection safety, cold chain storage requirements, wastage rates, and cost.

Ekwueme, D. U., B. G. Weniger, and R. T. Chen. 2002. “Model-based estimates of risks of disease transmission and economic costs of seven injection devices in sub-Saharan Africa.” *Bulletin of the World Health Organization* 80(11): 859–874.

Assesses and compares seven different injection technologies (resterilizable syringes, disposable syringes, disposable-cartridge jet injectors, manual needle-shielding syringes, automatic needle-shielding syringes, reusable-nozzle jet injectors, and auto-disable syringes) in terms of their risk of iatrogenic infection and economic costs.

Dziekan, G., D. Chisholm, B. Johns, J. Rovira, and Y. Hutin. 2003. "The cost-effectiveness of policies for the safe and appropriate use of injection in health care settings." *Bulletin of the World Health Organization* 81(4): 277–285.

Examines the cost-effectiveness of various interventions for injection safety, including national and district level planning workshops; behavior change strategies for providers and patients; provision of single-use injection technologies; and combinations of these approaches.

# Glossary

**auto-disable (AD) syringes.** A specially modified plastic syringe with a fixed needle that is automatically disabled after a single use.

**bundling.** Providing safe injection devices (syringes, diluent when necessary, and safety boxes) in the same quantities as the doses of injectable preparations issued to health facilities. The goal is to ensure that every injection that is administered is done safely and the used syringe is disposed of safely. This term can be confusing because it is often equated with physically shipping products in the same box or carton. Physically bundling products is not necessary if the appropriate number of products is provided.

**disposable syringes.** Syringes intended for single-use and immediate disposal that may or may not have engineered features for prevention of reuse and/or needle-stick injury. Usually refers to single-use devices without engineered features.

**disposal.** Collection, storage, and subsequent destruction of all syringes and needles to avoid needle-stick injury.

**full supply.** Products that are always available at health facilities and are never out of stock. Products in full supply must never be rationed or procured at less than their calculated need.

**health care waste.** Waste that results from health care, including sharps (e.g., needles, scalpel blades, trocars), chemicals, medical devices, pharmaceuticals, blood, body parts, pressurized containers, and radioactive waste.

**injectable preparations.** Any substance injected into a patient or client, includingm for example, vaccines, contraceptives, and medicines.

**injection.** Administration of a substance into the skin, subcutaneous tissue, and muscle tissue or veins.

**ISO standards.** The International Standards Organization has established standards of general quality assurance that are documented agreements of technical specifications or other precise criteria. They are to be used consistently as rules, guidelines, or definitions of characteristics to ensure that materials, products, processes, and services are fit for their purpose. They are unofficial standards and are voluntary unless a government adopts them as part of regulatory legislation.

**needle pullers.** A device used to remove needles from syringes after use; it disables the syringe and will contain the used sharp device.

**reconstitution.** Adding a liquid (often sterile water) to a powder or other product to create an injectable solution.

**reuse prevention feature.** An engineered feature of an auto-disable syringe that inactivates the device after one use to prevent reuse.

**safe injection.** An injection that does not harm the recipient, expose the health care worker to any avoidable risks, or result in any dangerous waste for the community.

**safety box.** Safety boxes, also known as sharps containers, are puncture-proof, impermeable containers for the safe and convenient disposal of used syringes and needles, and other contaminated sharps. Safety boxes are filled once only, then collected safely, and destroyed. When used consistently, the boxes can help prevent needle-stick injuries.

**safety syringe.** A single-use syringe with a needle-stick prevention feature.

**sharps box.** *See safety box.*

**sharps waste.** Used medical devices, including needles, scalpel blades, trocars, capillary tubes, and lancets, that can puncture skin and potentially be contaminated with infectious agents.

**sterile.** Free from living microorganisms; aseptic.

**sterilizable syringe.** Either all plastic or all glass syringe with steel needle. This type is designed for reuse after proper cleaning and sterilization in a steam sterilizer or autoclave.

**universal precautions.** A simple set of effective practices to protect health care workers and patients from infection caused by a range of pathogens, including blood-borne viruses. These precautions are used when caring for all patients, regardless of diagnosis.

# Injection Safety

*Aide-Mémoire for a National Strategy for the  
Safe and Appropriate Use of Injections*

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WORLD HEALTH ORGANIZATION

# Injection Safety

## AIDE-MEMOIRE

### *for a national strategy for the safe and appropriate use of injections*

A safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in any waste that is dangerous for other people.

Worldwide, each year, the overuse of injections and unsafe injection practices combine to cause an estimated 8 to 16 million hepatitis B virus infections, 2.3 to 4.7 million hepatitis C virus infections and 80,000 to 160,000 HIV infections\*. Among unsafe practices, the re-use of syringes and/or needles without sterilization is of particular concern.

Injection-associated transmission of bloodborne pathogens can be prevented through the development of a strategy to reduce injection overuse and achieve injection safety and its implementation by a national coalition, with the assistance of a coordinator.

The three elements of a strategy for the safe and appropriate use of injections are described in detail overleaf:

- Behaviour change among patients and healthcare workers to decrease injection overuse and achieve injection safety
- The availability of necessary equipment and supplies
- The management of sharps waste.

### Words of advice

- **Conduct an initial assessment**
- **Secure government commitment and support for the safe and appropriate use of injections**
- **Establish a national injection safety coalition, coordinated by the Ministry of Health**
- **Develop a national policy and plan**
- **Develop a systematic strategy for behaviour change among patients and healthcare workers to decrease injection overuse and achieve injection safety**
- **Ensure the continuous availability of injection equipment and infection control supplies**
- **Set up a waste management system for the safe disposal of sharps**
- **Monitor the impact of activities on injection frequency, injection safety and injection-associated infections**



### Checklist

#### National policy on the safe and appropriate use of injections

- Assessment of injection practices
- Coordination of injection safety
- Multidisciplinary national coalition
- National policy and plan
- Costing, budgeting, and financing
- Three-point strategy for the prevention of unsafe injection practices
- Monitoring and evaluation

#### Behaviour change

- National behaviour change strategy
- National standards for injection safety
- Incorporation of safe injection practices into minimum standards of care
- Promotion of safe technologies
- Promotion of rational use of injections
- Other components of behaviour change

#### Equipment and supplies

- Auto-disable (AD) syringes for immunization
- Appropriate types of syringes and needles for curative care
- Norms and standards for equipment
- Central bulk procurement, including safety boxes
- Central management of storage
- Efficient distribution system

#### Management of sharps waste

- Policy for sharps waste
- Assessment of waste management system
- Selection of appropriate waste disposal systems
- Regulatory framework
- Adequate resources
- Implementation of waste management system
- Training and supervision

\* Kane A et al. Bull World Health Organ 1999; 77: 801-807.

# Key elements

## National policy on the safe and appropriate use of injections

It is the responsibility of governments to ensure the safe and appropriate use of injections.

The achievement of this goal requires the establishment of a national multidisciplinary coalition involving different departments of the Ministry of Health and other stakeholders, such as non-governmental organizations and associations, and private healthcare providers.

The coalition should be coordinated by a Ministry of Health team and should receive political support, adequate funding and trained staff.

Important activities include:

- Initial assessment of injection frequency, breaks in injection safety and adverse events

associated with injections, including a behavioural and systems analysis

- Establishment of an injection safety unit to coordinate departments of the Ministry of Health, including health promotion, immunization, family planning, essential drugs programmes, healthcare service delivery, nosocomial infections, blood transfusion service and waste management
- Establishment of a national coalition, including WHO, universities, non-governmental organizations, behaviour change specialists and associations (e.g. consumers, public and private healthcare workers, traditional practitioners)

- Development of a national policy and plan (including costing, budgeting, and financing) by the national coalition, within the Ministry of Health's overall plan of action
- Prevention through behaviour change to reduce injection overuse and achieve injection safety; provision of sufficient quantities of injection equipment and infection control supplies; and management of sharps waste
- Monitoring of the impact through process indicators (injection frequency and injection safety) and outcome indicators (incidence of injection-associated infections, rational use of injections)

### Behaviour change

The foundation for the safe and appropriate use of injections is a behaviour change strategy targeting consumers as well as public, private and lay healthcare workers.

Important activities include:

- Development of a national communication and behaviour change strategy on the basis of behaviour and systems analysis
- Definition of national standards for safe injection practices
- Incorporation of injection safety into minimum standards of care
- Promotion of safe technologies
- Promotion of the rational use of injections within essential drug programmes (e.g. restriction of unnecessary injectable drugs) and with the private sector
- Addressing issues that may lead to poor injection practices, including attitudes, emotions, incentives, beliefs, power relationship, norms and systems

### Equipment and supplies

Eradication of the re-use of syringes and needles without sterilization requires the continuous, sufficient availability of injection equipment and infection control supplies in all healthcare facilities.

Important activities include:

- Adoption of auto-disable (AD) syringes for immunization
- Selection of appropriate types of syringes and needles for curative care (sterilizable, disposable or auto-disable)
- Enforcement of international norms and standards by the national regulatory authority
- Central bulk procurement of injection equipment and infection control supplies, including safety boxes
- Central management of storage
- Efficient distribution system to ensure continuous, sufficient availability in all healthcare facilities nationally

### Management of sharps waste

The efficient, safe and environmentally-friendly management of sharps waste is the only means of ensuring that disposable syringes and needles are not re-used and do not lead to accidental needlestick injuries.

Important activities include:

- Formulation of a policy stating that disposal is part of the syringe lifecycle and that healthcare services have a duty to manage sharps waste
- Assessment of the waste management system, including expressed and real needs
- Selection of appropriate waste disposal systems for all levels of healthcare facilities
- Implementation of a regulatory framework
- Identification of human and financial resources required
- Implementation of a waste management system
- Training and supervision

Additional information on the safe and appropriate use of injections can be obtained on the World-Wide Web at [www.injectionsafety.org](http://www.injectionsafety.org) and on the Safe Injection Global Network internet forum at [sign@who.int](mailto:sign@who.int)

# Safe Health Care Waste Management

*Aide-Mémoire for a National Strategy for  
Health Care Waste Management*

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## AIDE-MEMOIRE

### *for a national strategy for health-care waste management*

Health-care waste is a by-product of health care that includes sharps, non-sharps, blood, body parts, chemicals, pharmaceuticals, medical devices and radioactive materials. Poor management of health-care waste exposes health-care workers, waste handlers and the community to infections, toxic effects and injuries. It may also damage the environment. In addition, it creates opportunities for the collection of disposable medical equipment (particularly syringes), its re-sale and potential re-use without sterilisation, which causes an important burden of disease worldwide.

The most important principles underlying effective programmes for the management of health-care waste include, firstly, the assignment of legal and financial responsibility for safe management to the waste producer; and, secondly, the responsibility of duty of care. Precaution should be applied whenever risks are uncertain.

It is essential that everyone concerned by health-care waste should understand that health-care waste management is an integral part of health care, and that creating harm through inadequate waste management reduces the overall benefits of health care.

Policies and plans for the safe management of health-care waste should address the following three elements:

- 1 The establishment of a comprehensive system of health-care waste management, from the generation of waste to its disposal – to be implemented gradually.
- 2 The training of all those involved and increasing awareness.
- 3 The selection of safe and environment-friendly options for the management of health-care waste.

#### Words of advice

- **Secure government commitment and support for safe health-care waste management**
- **Conduct an initial assessment of the situation of potential harms from health-care waste**
- **Manage waste comprehensively, addressing responsibilities, resources, waste minimization, handling and disposal**
- **Raise awareness among those responsible for regulating, generating and handling waste and provide training in safe practices**
- **Select safe, environment-friendly and sustainable waste management options**
- **Monitor and evaluate waste management activities and their impact**



#### Checklist

for action at national and local level

##### National policy for safe health-care waste management

- Designation of responsible authority
- Regulatory framework and guidelines
- Initial assessment
- Integration into overall waste management plan
- Monitoring and evaluation

##### Comprehensive system of health-care waste management

- Assignment of waste management responsibilities to personnel
- Allocation of resources
- Minimization of waste
- Segregation of waste
- Safe collection, handling and storage
- Safe treatment and disposal

##### Awareness and training

- Inclusion of waste management in the curricula of health-care personnel
- National training package
- Train the trainers programme
- Education on health risks
- Education on safe practices

##### Selection of options for the management of health-care waste

- Review of available options
- Checks of safety and environment-friendliness
- Ensure workers' safety
- Evaluation of sustainability
- Assessment of acceptability
- Monitoring of safety and efficiency

# Key elements

## National policy for safe health-care waste management

It is the responsibility of governments to create a framework for the safe management of health-care waste and to ensure that health-care facility managers take their share of responsibility to manage wastes safely.

This requires a national coordinating mechanism involving the Ministry of Health and other stakeholders. It is important that a designated authority coordinates these efforts and receives sufficient political support, funding and trained staff.

Important activities for a national strategy to achieve safe health-care waste management include:

- Identification of key partners, including but not necessarily limited to: Ministry of Health, Environment Agency, non-governmental organizations, waste producers and waste disposal companies or services

- Designation of the responsible authority for policy formulation, implementation and evaluation
- Initial assessment and analysis of problems leading to unsafe handling or disposal
- Development of a national policy framework stating that the management of waste is part of the health-care system, and that health-care services should be assigned legal and financial responsibility for safe waste management and should manage their waste with duty of care
- Development of a regulatory framework and national guidelines, based on a comprehensive approach, including training, occupational health and safety issues and sound choices of waste management options, according to local circumstances

- Development of an enforcement mechanism
- Setting of practical targets or objectives over a specified time period
- Establishment of a national and regional infrastructure for health-care waste disposal
- Support of regional and municipal authorities in implementation
- Integration of waste minimization into national purchasing policies
- Routine monitoring of impact through process indicators (number of health-care establishments with safe waste management systems) and outcome indicators (e.g. number of accidents involving health-care waste).

### Comprehensive system

Facilities that generate health-care waste should set up a comprehensive waste management system based on the most appropriate means of achieving the safe, environment-friendly management of waste. The system should start with basic measures and then gradually be improved. First steps should include the segregation and safe handling, treatment and disposal of sharps.

Important activities include:

- Assignment of responsibilities for waste management
- Allocation of sufficient human and financial resources
- Waste minimization, including purchasing policies and stock management practices
- Segregation of waste into harmful and non-harmful categories
- Implementation of safe handling, storage, transportation, treatment and disposal options
- Monitoring of waste production and waste destination.

### Awareness and training

Awareness of the risks related to health-care waste and training in safe practices is essential in obtaining both commitment and behaviour change by all involved in the management of health-care waste.

Important activities include:

- Advocacy targeting policy makers and health-care facility managers regarding the risks and responsibilities related to health-care waste
- Inclusion of health-care waste management into the training curricula of nurses, doctors and health-care managers
- Development of a national training package, adapted to various professional categories
- Development of a 'train-the-trainers' programme
- Education of health-care and waste workers and the community on the risks associated with health-care waste and safe management practices.

### Selection of options

Waste management options should be efficient, safe and environment-friendly to protect people from voluntary and accidental exposure to waste when collecting, handling, storing, transporting, treating or disposing of waste.

Important activities include:

- Identification of available centralized waste management and disposal resources
- Choice of sustainable management and disposal options, according to:
  - Affordability
  - Environment-friendliness
  - Efficiency
  - Workers' safety
  - Prevention of the re-use of disposable medical equipment (e.g. syringes)
  - Social acceptability
- Identification of appropriate options for all levels of health-care facilities
- Monitoring and evaluation of safety and efficiency.

Related documents and additional information on health-care waste management can be obtained on the World-Wide Web at [www.healthcarewaste.org](http://www.healthcarewaste.org)

# Health Care Worker Safety

*Aide-Mémoire for a Strategy to Protect Health  
Workers from Infection with Bloodborne  
Viruses*

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## AIDE-MEMOIRE

### *for a strategy to protect health workers from infection with bloodborne viruses*

Health workers are exposed to blood and other body fluids in the course of their work. Consequently, they are at risk of infection with bloodborne viruses including human immunodeficiency virus (HIV), hepatitis B (HBV) and hepatitis C (HCV). The risk of infection for health workers depends on the prevalence of disease in the patient population and the nature and frequency of exposures. Occupational exposure to blood can result from percutaneous injury (needle-stick or other sharps injury), mucocutaneous injury (splash of blood or other body fluids into the eyes, nose or mouth) or blood contact with non-intact skin. The most common form of occupational exposure to blood and the most likely to result in infection, is needle-stick injury. The most common causes of needle-stick injury are two-handed recapping and the unsafe collection and disposal of sharps waste. Health workers in areas such as operating, delivery and emergency rooms and laboratories have an enhanced risk of exposure. Cleaners, waste collectors and others whose duties involve handling blood-contaminated items are also at risk.

Among the 35 million health workers worldwide, about 3 million receive percutaneous exposures to bloodborne pathogens each year; two million of those to HBV, 0.9 million to HCV and 170 000 to HIV. These injuries may result in 15 000 HCV, 70 000 HBV and 500 HIV infections. More than 90% of these infections occur in developing countries.

Most blood exposures in health settings are preventable. Strategies to protect health workers include implementation of Universal Precautions, immunization against hepatitis B, provision of personal, protective equipment and the management of exposures. Successful implementation of these strategies requires an effective infection control committee with support from the health setting management team.

### Words of advice

- **Set up and empower an Infection Control Committee**
- **Use surveillance to identify risk situations and procedures and modify them wherever possible**
- **Achieve compliance with universal precautions through ongoing commitment, training of all staff members and provision of supplies**
- **Immunize health care workers against hepatitis B early in their career**
- **Ensure availability of personal protective equipment**
- **Manage cases of exposure to blood and body fluids**
- **Enforce safe practices through monitoring and supervision**



### Checklist

#### Universal precautions

- Hand washing after any direct contact with patients
- Safe collection and disposal of sharps
- Gloves for contact with body fluids, non-intact skin and mucous membranes
- Wearing a mask, eye protection and a gown if blood or other body fluids might splash
- Covering cuts and abrasions
- Cleaning up spills of blood and other body fluids
- Safe system for hospital waste management and disposal

#### Hepatitis B immunization

- Immunize early in the career
- Pre-vaccination serological testing is unnecessary
- Use 0, 1 and 6 months schedule
- If possible, conduct post-vaccination testing
- Do not administer boosters routinely

#### Personal protective equipment

- Ensure adequate supplies
- Involve staff in the selection of personal protective equipment
- Train staff in correct use
- Use influential senior staff as role models
- Monitor compliance and inappropriate use
- Dispose safely

#### Post-exposure management

- Guidelines outlining all procedures
- Dissemination of guidelines
- Information, education and communication
- Support and counselling
- Where possible, provision of post-exposure prophylactic medication for high-risk exposures
- Analyze surveillance data

# Key elements

## Universal Precautions

Universal Precautions are a simple set of effective practices designed to protect health workers and patients from infection with a range of pathogens including bloodborne viruses. These practices are used when caring for all patients regardless of diagnosis. They are applied universally. It is not feasible, effective or cost-effective to test all patients for all pathogens prior to giving care in order to identify those who are infected and take precautions only with them. Knowing a patient is infected does not prevent occupational exposure to blood. Thus, decisions regarding the level of precautions to use are based on the nature of the procedure and not on the actual or assumed serological status of the patient. It is not safe to take precautions only with those from so-called risk groups for infection with bloodborne pathogens as many people belonging to risk groups are not infected and many infected people do not belong to risk groups. In practice, the implementation of Universal Precautions includes the following interventions:

- Hand washing after any direct contact with patients
- Safe collection and disposal of needles (hypodermic and suture) and sharps (scalpel blades, lancets, razors, scissors), with required puncture- and liquid- proof safety boxes in each patient care area
- Wearing gloves for contact with body fluids, non-intact skin and mucous membranes
- Wearing a mask, eye protection and a gown (and sometimes a plastic apron) if blood or other body fluids might splash
- Covering all cuts and abrasions with a waterproof dressing
- Promptly and carefully cleaning up spills of blood and other body fluids
- Using a safe system for hospital waste management and disposal

### Hepatitis B immunization

Routine immunization of health workers against infection with HBV is an effective way to protect them. HBV is the most infectious bloodborne virus and in many parts of the world, the most prevalent. The long-term sequelae of HBV infection include cirrhosis and hepatocellular carcinoma. Hepatitis B vaccine is effective, cost-effective relatively inexpensive (less than US\$ 0.5 a dose) and widely available.

- Immunize health care workers early in their career
- Pre-vaccination serological testing is unnecessary but may save resources if feasible and if prevalence of immunity is high
- Use a 0, 1 and 6 months schedule of three injections
- If possible, control antibody levels between two to six months after the last dose
- Do not administer boosters routinely as protection is lifelong

### Personal protective equipment

Personal protective equipment includes gloves, goggles or glasses, masks, gowns and plastic aprons.

- Ensure adequate supplies of personal protective equipment in all areas
- Involve staff in the selection of personal protective equipment as equipment that is of poor quality or uncomfortable to wear will not be used
- Train staff in the correct use of personal protective equipment
- Use influential senior staff as role models to promote personal protective equipment
- Monitor compliance and inappropriate use. Inappropriate glove use wastes resources and compliance eye protection often requires additional effort
- Dispose of used personal protective equipment safely

### Post-exposure management

The risk of infection following a needle-stick injury with needle from an infected source patient is ~ 0.3% for HIV, 3% for hepatitis C and 6-30% for hepatitis B. An effective response to occupational exposure to blood or other body fluids involves the following:

- Development guidelines outlining the first aid required, reporting mechanism and procedure to be followed for post-exposure prophylaxis and follow-up testing
- Dissemination of guidelines
- Information, education and communication
- Provision of support and counselling
- Where possible and indicated, provision of post-exposure prophylactic medication
- Analyze reported cases of exposure to improve practices

Additional information on the safe and appropriate use of injections can be obtained on the World-Wide Web at [www.injectionsafety.org](http://www.injectionsafety.org) and on the Safe Injection Global Network internet forum at [sign@who.int](mailto:sign@who.int).

# Infection Control

*Aide-Mémoire for Infection Prevention and  
Control in a Health Care Facility*

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## AIDE-MEMOIRE

### *For infection prevention and control in a health care facility*

Health care-associated infections lead to death, disability and excess medical costs. Introduction of new technologies, in the absence of infrastructure to use them safely, may lead to adverse events. Infection prevention and control maximize patient outcomes and are part of the government's responsibility to provide effective, efficient and quality health services. They must be achieved through collaboration with the public and private sectors. Health care facilities must execute infection prevention and control policies supported by institutional management. An overall approach to an infection prevention and control policy at the health care facility level is based upon:

- Management;
- Information, Education and Communication (IEC);
- Continuous availability of essential equipment and supplies;
- Surveillance.

Examples of core infection prevention and control interventions are listed overleaf. In addition, specific activities include:

- Health care worker protection;
- Isolation protocols for specific infectious diseases (e.g., tuberculosis, SARS) and high-risk settings (e.g., dialysis);
- Rational use of anti-microbials;
- Safe and appropriate use of injections and infusions;
- Safe and appropriate use of blood and blood products;
- Hospital sanitation.

### Words of advice

- **Conduct an initial assessment**
- **Establish an infection prevention and control committee coordinated by the infection prevention and control officer**
- **Formulate an Action Plan, with costing, budgeting and financing**
- **Develop an IEC strategy for health care workers and strengthen supervision**
- **Ensure the continuous availability of supplies and equipment for patient care management**
- **Surveillance**
- **Confirm value through monitoring, providing data and measuring the impact of interventions**



### Checklist

#### Management

- Infection prevention and control policy, with committee and officer
- Initial infection control assessment
- Assignment of responsibilities
- Choice of appropriate technologies
- Costing, budgeting and financing
- Quality standards
- Monitoring & supervision
- Performance assessment

#### Information, Education and Communication (IEC)

- Adoption of best practices standards
- Standard precautions
- Pre-service training
- In-service training

#### Equipment and supply

- Establishment of a list of essential infection control equipment and supplies
- Forecasting of needs
- Costing, budgeting and financing
- Procurement
- Inventory control and stock management
- Maintenance

#### Surveillance

- Surveillance
- Feedback
- Outbreak investigation
- Evaluation using indicators of:
  - Structure
  - Process (practices)
  - Outcomes (incidence of infections)

## Core infection prevention and control interventions for health care facilities at a glance

Specific interventions	Target groups	Equipment and supply needs *	Critical process indicators for monitoring
<b>Hand hygiene</b>	<ul style="list-style-type: none"> <li>All health care workers †</li> <li>Visitors</li> <li>Patients</li> </ul>	<ul style="list-style-type: none"> <li>Clean running water</li> <li>Soap (mounted preferable)</li> <li>Sinks or basins</li> <li>Towels</li> <li>Alcohol-based solutions</li> </ul>	<ul style="list-style-type: none"> <li>Proportion of staff observed performing hand hygiene before attending patients</li> </ul>
<b>Personal protective equipment</b>	<ul style="list-style-type: none"> <li>All health care workers †</li> </ul>	<ul style="list-style-type: none"> <li>Gloves</li> <li>Gowns</li> </ul>	<ul style="list-style-type: none"> <li>Proportion of staff observed wearing gloves when exposure to blood or body fluids is anticipated</li> </ul>
<b>Isolation precautions</b>	<ul style="list-style-type: none"> <li>Nurses</li> <li>Physicians</li> <li>Nursing aids</li> <li>Other</li> </ul>	<ul style="list-style-type: none"> <li>Gloves</li> <li>Gowns</li> <li>Masks</li> <li>Eye protection</li> </ul>	<ul style="list-style-type: none"> <li>Average time between admission and isolation for tuberculosis patients</li> </ul>
<b>Aseptic technique</b>	<ul style="list-style-type: none"> <li>Nurses</li> <li>Physicians</li> <li>Laboratory technicians</li> <li>Dental surgeons</li> </ul>	<ul style="list-style-type: none"> <li>Antiseptics</li> <li>Sterile gloves</li> <li>Sterile devices and instruments</li> <li>Sterile barrier devices</li> </ul>	<ul style="list-style-type: none"> <li>Proportion of intravenous lines inserted using aseptic technique</li> </ul>
<b>Cleaning and disinfection</b>	<ul style="list-style-type: none"> <li>Nurses</li> <li>Nursing aids</li> <li>Housekeeping staff</li> <li>Laboratory staff</li> </ul>	<ul style="list-style-type: none"> <li>Cleaning fluids</li> <li>Cleaning equipment</li> <li>Disinfectant</li> </ul>	<ul style="list-style-type: none"> <li>Proportion of rooms appropriately disinfected after patients' discharge</li> </ul>
<b>Sterilization</b>	<ul style="list-style-type: none"> <li>Sterilization staff</li> <li>Nurses</li> <li>Laboratory technicians</li> <li>Dental surgeons</li> </ul>	<ul style="list-style-type: none"> <li>Autoclaves and steam sterilizers</li> <li>Test strips</li> <li>Chemicals</li> </ul>	<ul style="list-style-type: none"> <li>Proportion of sterilized devices whose sterility is documented with test strips</li> </ul>
<b>Waste management</b>	<ul style="list-style-type: none"> <li>Health care workers</li> <li>Waste handlers</li> <li>Logisticians</li> </ul>	<ul style="list-style-type: none"> <li>Sharps boxes and other collection containers</li> <li>Storage space and container for interim storage</li> <li>Final disposal options</li> <li>Personal protection equipment for waste handlers</li> </ul>	<ul style="list-style-type: none"> <li>Presence of health care waste in the surroundings of the health care facility</li> </ul>
<b>Antibiotic use protocol</b>	<ul style="list-style-type: none"> <li>Physicians</li> </ul>	<ul style="list-style-type: none"> <li>Essential list of antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>Proportion of prescriptions including an antibiotic</li> </ul>
<b>Immunization and exposure management</b>	<ul style="list-style-type: none"> <li>All health care workers †</li> </ul>	<ul style="list-style-type: none"> <li>Hepatitis B vaccine and other appropriate vaccines</li> </ul>	<ul style="list-style-type: none"> <li>Three-dose hepatitis B vaccine coverage among nurses, physicians and laboratory technicians</li> </ul>

\* Key indicator: Proportion of essential supplies stocked out.

† Include nursing staff, physicians, dental staff, laboratory staff, housekeeping staff, waste management staff and morgue staff.

# Guiding Principles to Ensure Injection Device Security

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## Annex E



# GUIDING PRINCIPLES TO ENSURE INJECTION DEVICE SECURITY

WORLD HEALTH ORGANIZATION

## BACKGROUND



Injections are the most common health care procedure worldwide. In developing and transitional countries alone, some 16 thousand million injections are administered each year.<sup>1</sup> Most injections, more than 90%, are given for therapeutic purposes while 5 to 10% are given for preventive services, including immunization and family planning. The majority of therapeutic injections in developing and transitional countries are unnecessary.

A safe injection does not harm the recipient, does not expose the health care worker to any avoidable risk and does not result in waste that is dangerous for the community.<sup>2</sup> When injections are medically indicated they should be administered safely. Unsafe injections place patients at risk of disability and death. Reuse of injection devices without sterilization is of particular concern as it may transmit hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV), accounting for 30%, 41% and 5% of new infections in 2000, respectively.<sup>3</sup> In addition, inappropriate and unhygienic use of multi-dose vials may transmit bloodborne pathogens.<sup>2</sup>

Best infection control practices for intradermal, subcutaneous and intramuscular injections recommend the use of a new, single use injection device for each injection and for the reconstitution of each unit of medication.<sup>4</sup> Sterile single use injection devices are widely available at low cost. The international retail price for a single use syringe and needle set ranges from 3 US cents (sterile hypodermic syringe 2 ml) to 6 US cents (auto-disable syringe 0.5 ml). Failure to systematically fund sufficient supplies of injection devices was identified as a key determinant of widespread reuse of syringes and needles in the absence of sterilization in immunization services.<sup>5</sup> Interventions to increase the availability of injection devices in curative services have improved injection safety.<sup>6</sup> Interventions to prevent infections with bloodborne pathogens through provision of single use devices are a very cost-effective investment in health.<sup>7</sup>

Sterile, single use injection devices include sterile hypodermic syringes, sterile hypodermic needles, auto-disable syringes for immunization purposes, syringes with a reuse-prevention feature for general purposes and syringes with needle-stick prevention features (e.g., safety syringes) for general purposes. WHO is strengthening its collaboration with national regulatory authorities to ensure the quality and safety of injection devices through: (1) the enforcement of national regulations based upon international standards for injection devices<sup>3</sup> and (2) reliance on internationally accepted certifying bodies that provide the ISO certification and carry out the auditing function.<sup>8</sup>

The safe collection and disposal of used sharps (e.g., needles, syringes with fixed needles) is an integral part of the life cycle of injection devices. The collection of sharps waste in safety containers (e.g., safety boxes) at the point of use and their safe and environmentally-responsible disposal protect health care workers and the general public from needle-stick injuries. Interventions to reduce injection overuse reduce waste thereby facilitating its management. Management choices and technology options will depend on many considerations, including workers' safety, sustainability and acceptability. Low-cost, effective waste treatment options are available.

## INJECTION DEVICE SECURITY

In curative and preventive services, ensuring injection device security implies appropriate forecasting, financing, procurement and supply management so that the following items are available in adequate quantities:<sup>12</sup>

- Injectable products;
- Appropriate single dose diluents;
- Single use injection devices for injection and reconstitution;
- Safety boxes.

This procurement policy does not imply that items mentioned above must be physically packaged together, but ultimately these items should be available in a timely manner in health care facilities in adequate quantities. Suppliers and shipping routes may differ for injectable products, injection devices and other infection control supplies. The application and success of this policy is dependent on a reliable distribution system for health products.

UNFPA, UNICEF and WHO have reaffirmed the current policy stating that by the end of the year 2003, all countries should be using only auto-disable syringes in immunization services. Auto-disable syringes and safety boxes should be supplied in adequate quantities with all consignments of vaccines.<sup>9</sup>

## RECOMMENDATION

**WHO RECOMMENDS THAT INJECTION DEVICE SECURITY IS ENSURED IN ALL HEALTH CARE FACILITIES, INCLUDING THERAPEUTIC SERVICES (SEE BOX), SO THAT INJECTABLE MEDICINES, DILUENTS, SINGLE USE INJECTION DEVICES AND SAFETY BOXES ARE SUPPLIED IN A TIMELY MANNER IN ADEQUATE QUANTITIES.**



## IN PRACTICE

- WHO reaffirms the need to ensure access to single use injection devices and safety boxes of good quality. Sterile, single use injection devices for injection and reconstitution and safety boxes must be available in every health care facility in sufficient quantities for the number of injections administered;
- While the use of sterilizable injection devices is being phased out worldwide, WHO urges that all countries use only single use injection devices for therapeutic injections. Syringes with a reuse-prevention feature offer the highest level of safety for injection recipients. They should be considered for use for therapeutic injections where local data indicate that unsafe practices are particularly common;
- WHO urges that by 2005 all injectable medications are supplied with matching quantities of single use injection devices, appropriate diluents and safety boxes through essential medicine programmes and other health programme supply mechanisms;
- To prevent injection overuse, national drug policies should promote the rational use of therapeutic injections. This may include removing unnecessary injectable medicines from the national essential medicines list;
- Health care services must manage sharps waste as part of the duty of care in a safe and environmentally responsible way, within a broader policy of health care waste management. Awareness and training for appropriate sharps waste management are required. Sharps waste disposal management should be costed, budgeted and funded.
- WHO requests all donors and lenders who finance injectable products (i.e., vaccines, contraceptives and medications) to also finance appropriate quantities of single use injection devices, single dose diluents, safety boxes and the cost of sharps waste management. All organizations involved in medicine donations should also ensure that they are following this recommendation.

## STRATEGY

WHO developed a strategy to ensure that special attention is paid to the safe administration of all types of injections in health care services. A set of tools are available to support the assessment, planning, implementation and evaluation of national injection safety policies for preventive and curative services.<sup>10,11</sup> Ministries of health, donors, lenders and partners who are active in the health sector, including in essential medicines programmes, are invited to endorse these recommendations. More information on injection safety is accessible on the WHO Injection Safety internet site ([www.injectionsafety.org](http://www.injectionsafety.org)) which includes a toolbox of resources to assist in the management of national safe and appropriate use of injection policies.

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### SAFE INJECTION GLOBAL NETWORK (SIGN) SECRETARIAT

Department of Essential Health Technologies

World Health Organization

E-mail: [sign@who.int](mailto:sign@who.int)

Fax: + 41 (22) 791 4836

# Procuring Single-use Injection Equipment and Safety Boxes

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# Procuring Single-use Injection Equipment and Safety Boxes



***A Practical Guide for Pharmacists, Physicians,  
Procurement Staff and Programme Managers***

5 May 2003

## Acknowledgements

WHO wishes to thank all who provided comments and suggestions to aid in the development of this guide. These contributors include: Katinka Aanjesen (UNICEF Supply Division/Immunization team), Paul Acriviadis (WHO/Procurement Services), Michael Cheng (Medical devices consultant, Canada), William Dierick (International Association of Safe Injection Technology and The European Medical Technology Industry Association), Richard Duncan (Procurement consultant, Australia), Peter Evans (Global TB drug Facility), Marthe Everard (WHO/Essential Drugs and Medicines Policy), Michael Free (Program for Appropriate Technology in Health /USA), Bonnie Fundafunda (ECHO International Health Services Limited/UK), Fiona Garin (International Association of Safe Injection Technology), Kathy Holloway (WHO/Essential Drugs and Medicines Policy), Yvan Hutin (WHO/Blood Safety and Clinical Technology), Marjolein Jacobs (WHO/Safe Injection Global Network project), Fabienne Jouberton (WHO/Stop TB), Manjit Kaur (ECHO International Health Services Limited/UK), Corinne Lejeune (Médecins Sans Frontières Logistique/France), John Lloyd (Program for Appropriate Technology in Health /USA), Rosalie Maikere (Transfer/Belgium), Tom Moore (WHO/Stop TB and Global TB drug Facility), Rasjiv Nath (International Association for Safe Injection Technology), Carib Nelson (Program for Appropriate Technology in Health/USA), Craig Shapiro (Centers for Disease Control and Prevention, China), Joel Shoenfeld (International Association of Safe Injection Technology), Bernd Simon (International Association of Safe Injection Technology), Monique Supiot (UNICEF Supply Division/Technical Service Centre), Janet Vail (Program for Appropriate Technology in Health /USA), Andre Van Zyl (WHO/Essential Drugs and Medicines Policy), Gerald Verollet (WHO/Blood Safety and Clinical Technology), Stacey Walter (Program for Appropriate Technology in Health /USA).

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## **EXECUTIVE SUMMARY**

### **Background**

Ensuring sufficient and continuous access to single-use injection equipment is a key element of any strategy to achieve the safe and appropriate use of injections. Experience from immunization and general services indicates that increased access to injection equipment improves practices. Thus, in April 2002, the 12th Expert Committee on the selection and use of essential medicines recommended that "when injectable medicines are being supplied, the necessary equipment for sterile injections should be supplied." This recommendation can be achieved through the existing drug supply delivery system.

### **Objective**

The objective of this guide is to accompany pharmacists, physicians, procurement staff and programme managers through the process of procuring single-use injection equipment and safety boxes of assured quality, on a national or international market, at reasonable prices.

### **Procurement procedures**

International organizations have established standardized procurement procedures for medicines and medical devices. This guide describes how these procedures can be used to ensure the procurement of injection equipment and safety boxes.

### **Ensuring the quality of injection equipment**

Institutions procuring injection equipment need to develop a list of manufacturers that are pre-qualified on the basis of certain criteria which include international quality standards. This guide provides steps and tools for procurement, including a pre-qualification procedure of injection equipment for purchase. Developing a monitoring system for supplier performance will improve and safeguard the quality of injection equipment selected and prevent or eliminate unreliable suppliers.

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## ***Objective of the guide***

The objective of this guide is to facilitate the procurement of single-use injection equipment and safety boxes of appropriate quality and to develop practical competence through a step-by-step approach, by:

- Defining the characteristics and current quality standards of injection equipment and safety boxes;
- Describing a comprehensive procurement procedure that ensures quality and responds to a variety of operational needs;
- Identifying the challenges and constraints when estimating injection equipment and safety boxes requirements for health care services.

## ***Who should use this guide?***

This procurement manual was prepared to assist pharmacists, physicians and procurement officers at the national level who wish to purchase single-use injection equipment and safety boxes on the national or international market.

This guide may also be used by:

- National programme officers and managers who have the responsibility of setting programme needs in terms of quantity and type of injection equipment;
- Wholesalers of medicines and medical devices;
- Programme officers and procurement units of international agencies (e.g., United Nations procurement agencies including WHO, UNFPA, UNAIDS and UNICEF);
- Nongovernmental organizations (NGOs) active in the health care sector;
- Bilateral donors;
- International low-cost procurement agencies.

## **Background**

### **Poor injection practices spread bloodborne pathogens**

An estimated 16 thousand million injections are administered worldwide each year, with more than 90% of these injections administered for curative purpose. A safe injection is one that does not harm the recipient, does not expose the health care worker to any avoidable risks and does not result in any waste that is dangerous for the community.<sup>1</sup> However, unsafe injections occur worldwide with up to 70% of injections administered with syringes and needles reused in the absence of sterilization.<sup>2</sup> Each year, unsafe injections may account for 30% of new hepatitis B virus (HBV) infections, 40% of new hepatitis C virus (HCV) infections and 5% of new human immunodeficiency virus (HIV) infections throughout the world.<sup>2</sup>

### **Safe and appropriate use of injections requires a multi-disciplinary approach**

To prevent injection-associated infections, safe injection practices are required and injection overuse must be reduced. Firstly, patients and health care workers need to move away from unsafe and/or unnecessary injections and toward oral medications. Secondly, single-use injection equipment must be available continuously in sufficient quantities to eliminate the reuse of syringes and needles in the absence of sterilization. Thirdly, sharps waste must be managed to eliminate the risks of reuse of dirty needles and needle-stick injuries. Guidance to multidisciplinary national safe and appropriate use of injection policies are provided in detail in the WHO injection safety planner.<sup>3</sup>

### **Improving access to injection equipment to improve injection safety**

Increased access to single-use injection equipment improves injection practices in immunization<sup>4</sup> and general services.<sup>5</sup> The 12<sup>th</sup> WHO Expert Committee on the selection and use of essential medicines in April 2002 recommended that “when injectable medications are being supplied, the necessary equipment for sterile injections should be supplied.”<sup>6</sup> To ensure best practices, this implies that single-use syringes and needles, appropriate diluents and safety boxes<sup>1</sup> be supplied along with injectable medications. The WHO department of HIV/AIDS also stated that “by all 2005, all injectable medications and vaccines will be supplied with single-use injection equipment.”<sup>7</sup> The incremental cost of ensuring availability of injection equipment is not high. In Burkina Faso, the cost of single-use injection equipment was estimated to account for 2.2% of the essential drug expenses in primary health care facilities (WHO unpublished data, 2001). In addition, investing in single-use injection equipment and safety boxes is a cost-effective way to prevent infections with bloodborne pathogens.<sup>8</sup>

For immunization services, in 2000 a joint Statement by WHO, the United Nations Children’s fund (UNICEF), the United Nations Population Fund (UNFPA) and the International Federation of Red Cross and Red Crescent (IFRC) recommended that sufficient syringes and safety boxes be “bundled” with consignments of vaccines.<sup>9</sup> Because Auto-Disable (AD) syringes offer a high level of protection against reuse and are available in sizes that allow their use for immunization, the WHO/UNICEF/UNFPA “bundling” policy called for the exclusive use of AD syringes for the administration of all vaccines by the year 2003.

This guide follows a step-by-step approach to assist stakeholders in the introduction and purchasing of single-use injection equipment and safety boxes that are needed to make injections safe in health care services.

## ***Planning policy changes***

In countries where sterilizable injection equipment is still in use, it will also ensure a smooth transition to single-use injection equipment.

### **Phase A: Describe current**

Make an inventory of all injection equipment and safety boxes currently procured and used, including types and volumes of syringes, size of needles, purchase prices and quantities procured.

### **Phase B: Develop a national policy on injection equipment and safety boxes**

Key policy issues include:

- Adopting of auto-disable equipment for immunization;
- Adopting single-use equipment for curative and preventive care (including syringes with a reuse-prevention feature and safety syringe);
- Securing the financial resources for injection equipment, including safety boxes;
- Adopting international quality standards for syringes and needles and for quality systems as the basis for national regulation;
- Procuring injection equipment and safety boxes in bulk, centrally, at all levels;
- Managing injection equipment and safety boxes storage, centrally, at all levels;
- Distributing effectively to ensure continuous and sufficient availability of single-use syringes, needles and safety boxes in all health care facilities;
- Coordinating with general health care services and programmes that make use of injections to ensure that an appropriate and environmentally-friendly sharps waste disposal system is in place for all levels of care.

### **Phase C: Develop a national plan of action to introduce the new policy on the change to new single-use injection equipment**

A plan of action with timeline and budget, identifies the actions required to implement the procurement, including training of the procurement staff, and distribution of the single-use injection equipment. Implementation in a phased manner, according to the operational structure and budget resources, will facilitate transition (e.g., on a region by region and/or programme by programme basis).

### **Additional supporting policy components**

#### ***Rational use of injectable medicines***

A national strategy for the rational use of injectable medicines will limit the needs of injection equipment and safety boxes and reduce overall costs. Approaches include training of health care workers, and information, education and communication (IEC) activities. Monitoring and supervision increase effectiveness and may be used to forecast injection equipment quantities.

#### ***Sharps waste collection and management***

Sharps waste management is an important part of a policy for the safe and appropriate use of injections (Appendix 1). Ensuring that safety boxes are provided by the procurement system assists broader waste management plans managed by general health services.

## ***Managing procurement***

### **The procurement cycle**

Products that will need to be procured are (1) injection equipment (i.e., single-use syringes and needles) and (2) safety boxes.

### **Organization of procurement services**

Procurement of injection equipment and safety boxes is based on the four strategic objectives for good pharmaceutical procurement<sup>10</sup>:

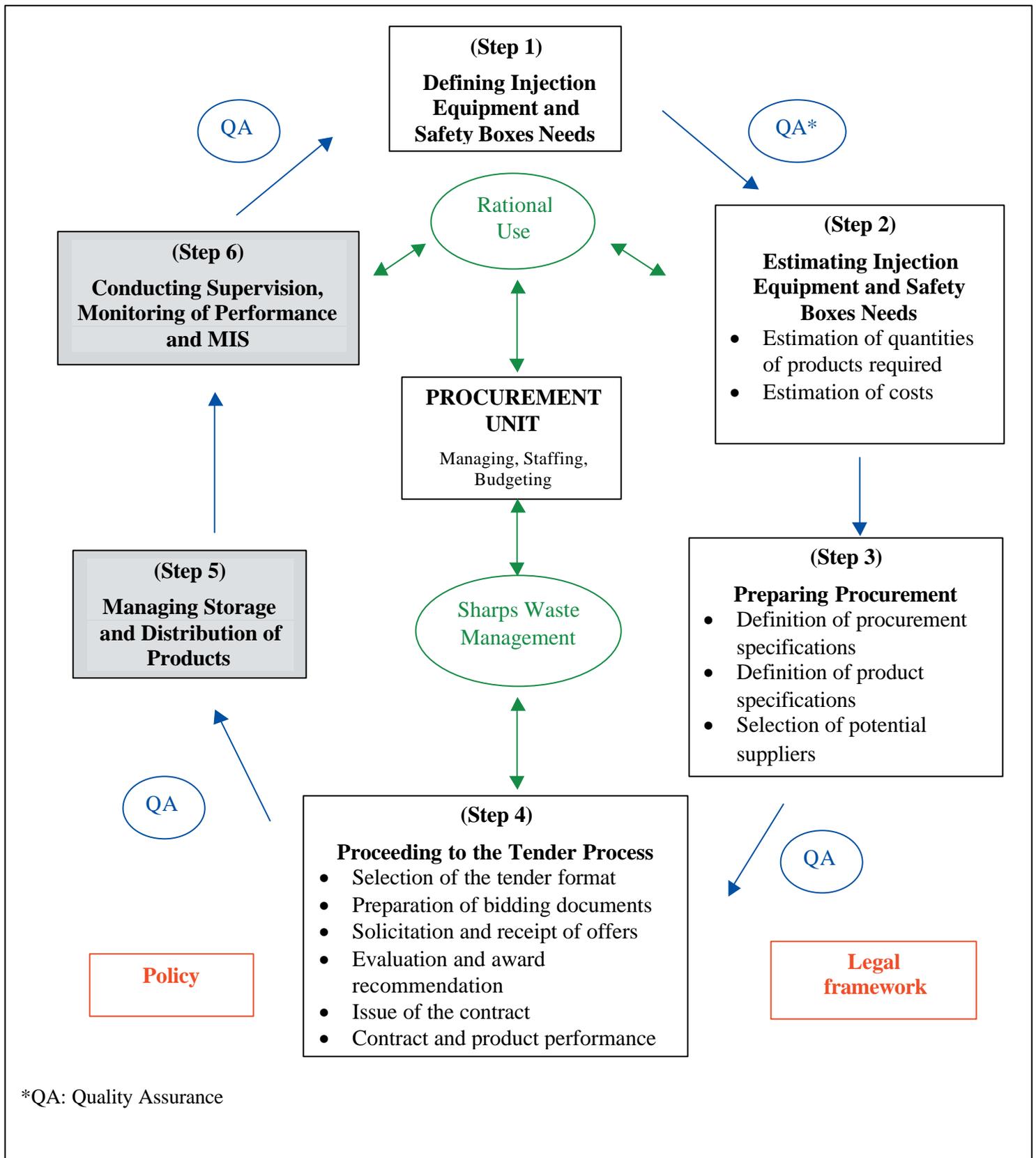
- Procure the most cost-effective safe products in appropriate quantities;
- Pre-qualify reliable suppliers of assured quality products;
- Ensure timely delivery;
- Achieve the lowest possible total cost for a good quality product and meeting the needs over the appropriate period of time.

Procurement can be thought of as a cycle (Figure 1) that includes six steps. No matter what model is used to manage the procurement and distribution system, efficient procedures in place will assist in:

1. Defining the required performance of injection equipment and safety boxes to be procured;
2. Estimating the quantity of injection equipment and safety boxes needed and their costs;
3. Preparing procurement;
4. Proceeding to the tender;
5. Managing the storage and distribution of products;
6. Conducting the supervision, the monitoring of performance of products and suppliers and the management of the information system (MIS).

Quality assurance of injection equipment and safety boxes procured is an ongoing process throughout the whole procurement cycle and is not limited to sample testing in a quality control laboratory.

**Figure 1: The procurement cycle for injection equipment and safety boxes**



## A step-by-step approach of procurement

The different steps of the procurement process from product definition to the product and contract performance are reviewed in Table 4 and described in greater detail below:

### *Step 1- Defining injection equipment and safety boxes needs*

The rational selection of injection equipment and safety boxes has three advantages:

- It allows cost-saving through bulk procurement;
- It standardizes quality;
- It simplifies inventory requirements and makes ordering easier.

Considerations for the selection of injection equipment and safety boxes include:

- The national injection safety policy (e.g., recommended syringe types, syringe types currently used);
- The list of injectable medications included in the national formulary or the national essential drug list and identify which injection equipment is needed to administer these medicines (e.g. needles, syringes, reconstitution syringes, IV giving sets)
- The intended area of use for the injection equipment (e.g., immunization, general curative care, specific disease or other);
- Financial resources available.

### **Box A: Guidance to develop a list of injection equipment and safety boxes needed in curative services:**

A list of injection equipment may be based on the range of medicines used in the national formulary.

1. Identify injectable medicines in the national formulary. This list would include items such as injectable antibiotics, IV fluids, narcotics, etc.
2. Identify which injection equipment is needed to administer these medicines (e.g. needle, syringes, reconstitution syringes, IV placement unit, butterfly needles, etc.) and which safety boxes are needed to collect injection equipment (Appendix 2, Appendix 3). The sizes of injection equipment required are determined by the volume of each identified injectable medicine and the route of administration.
3. Rationalize the amount of different injection equipment and safety boxes in the list if possible. A list of injection equipment and safety boxes can be developed as proposed below according to the intended use:

#### Selection of needles:

- 26G needle for intradermal injection;
- 23G needle for subcutaneous injection and intramuscular for children;
- 21G needle for intramuscular injection for adults;
- 19G needle for intravenous injection and reconstitution.

#### Selection of syringes:

- 2 ml, 5ml, 10ml, 20ml syringe;
- Specific syringes for immunization and insulin.

#### Selection of safety boxes:

- 5L safety boxes for health care facilities.

### *Step 2 - Estimating injection equipment and safety boxes needs*

Forecasting injection equipment and safety boxes requirements consists of (1) estimating the quantities of products required and (2) estimating the amount of products that can be procured with the available financial resources.

## **Step 2. 1. Estimation of the quantities of products required**

In general services, two methods used to estimate medicines requirements can be applied to estimate injection equipment and safety boxes needs.

- The **consumption method**. This uses data on past utilization (adjusted for stock-outs and projected changes in injectable medicines utilization) to estimate future needs. This is likely to be the most reliable method providing that supply has been consistent and usage records are accurately kept. It does not require detailed morbidity data or standard treatment guidelines.
- The **morbidity method**. This uses estimates on the number of health care contacts, common disease incidences and current standard treatment guidelines (see example for a specific programme in Table 1). This method is based on rational prescribing and requires good morbidity data. It is most appropriate for calculating injection safety needs according to injectable medicines needs in new programmes and for comparing actual use with theoretical needs.

In practice, the best approach may include a combination of the consumption and morbidity methods. The consumption method may be used first to improve quantification in the short run and then the morbidity method could be applied progressively for each type of service, to allow prescribing standards to be reviewed and improved. Alternatively initial estimates might be made by the morbidity method, to establish a base from which to start, and once this is assured the consumption method can be introduced. The general approach is to calculate enough injection equipment according to each injectable medicine to be supplied for 12 months. An appropriate buffer stock at the central level will ensure that supplies can be maintained if usage increases or orders are delayed.

**Table 1: Estimated quantities and costs for injection equipment and safety boxes for a curative programme “P” (use one table per injectable medicine)**

		Formula	Total units needed	Unit price	Total cost
A	Number of patients for a programme “P”	#			
B	Number of injections for an injectable medicine “M” per patient for one course of treatment or for X months of need	#			
C	Number of injectable doses	A x B			
D	<b>Number of syringes + needles *</b>	C			
E	<b>Number of safety boxes (+10% of extra need<sup>†</sup>)</b>	D x 1.11/Y <sup>‡</sup>			
F	Total costs	C+D+ E			

\* As the estimation of injectable medicines already includes a buffer stock, a buffer stock for injection equipment is not suggested in this table. Usually buffer stocks are estimated according to national means of transport, time of delivery, and distribution system.

<sup>†</sup> 10% of extra need is an indicative figure that may be adapted on the basis of country experience.

<sup>‡</sup> Y denotes the capacity of a safety box, Y is estimated at 80 to 100 syringes per 5 L box according to the size and volume of the syringes. This estimate can be adapted according to manufacturers’ instructions and experience.

**In immunization services**, vaccine requirements are based on population figures (targeted population, expected coverage and number of doses required per client, with an adjustment for a wastage factor, Table 2). Injection safety requirements are calculated according to the number of children/women expected to be vaccinated, with an allowance made for syringe/safety box wastage.

**Table 2 : Estimated quantities and costs for immunization injection equipment for vaccination a vaccine “V” (use one table for each vaccine)**

		Formula	Total units needed	Unit price	Total cost
A	Number of children for “V” vaccinations (for Tetanus Toxoid (TT) target of women)	#			
B	Number of doses per child (per woman for TT)	#			
C	Estimated wastage factor	#			
D	Number of “V” doses	$A \times B \times C$			
E	Vaccines buffer stock *	$D \times 0.25$			
F	Total vaccine doses	$D + E$			
G	AD syringes (+10% * wastage)	$A \times B \times 1.11$			
H	AD syringes buffer stock †	$G \times 0.25$			
I	Total AD syringes	$G + H$			
J	Number of doses per vial	#			
K	Number of single-use syringes for reconstitution ‡ (+10% wastage)	$F \times 1.11 / J$			
L	Number of safety boxes § (+10% of extra need)	$(I + K) \times 1.11 / 100$			
M	Total costs	$F+I+K+L$			

**Estimating the quantity of safety boxes needed** will assist in safe sharps waste collection in all services. These may be estimated according to the quantities of injectable equipment ordered and the estimated capacity of the boxes. \*\* The appropriate use of safety boxes recommend to not overfill the boxes (1) to prevent needlesticks that occur when health workers stuff needles and syringes into full sharps containers and prick themselves with needles already inside the boxes and (2) to facilitate the complete combustion during the incineration of the safety boxes once filled with used syringes and needles.

\* 10% wastage is an indicative figure that may be adapted on the basis of country experience.

† The buffer stocks for vaccines and AD syringes are set at 25%. This is calculated with the first stock of doses required to introduce the vaccination in any given geographic area. Then the country would aim to gradually reduce to 15% by the third year. For vaccine in single or two-dose vials the maximum wastage suggested is 5%.

‡ Only for lyophilized vaccines. Use zero for other vaccines.

§ The capacity of a safety box is estimated at 100 AD syringes for immunization per 5L box. This estimate can be adapted according to manufacturers’ instructions and experience. The capacity of a box depends on the design of the injection equipment. Recent developed designs of AD syringes increase the capacity of a box up to 300 pieces.

\*\* Removing needles is not recommended according to WHO best infection control practices for injections. <sup>1</sup> Estimates of syringes number are based on syringes with fixed needles.

## **Step 2.2. Estimation of costs**

After a quantification has been completed it may be still necessary to adjust the quantities that can be procured according to the funds available. In any case, the adjustment must keep the balance between injectable medicines and single-use injection equipment ordered. Freight cost is an important element to consider both in estimating and comparing the landed cost of different solutions as injection equipment are bulky products and to include in the planning for in-country distribution. Insurance is another element to consider in the global cost.

The accurate costing of injection equipment and safety boxes requirements is needed also to avoid stock-outs or overstocks. In addition, if suppliers believe the estimated procurement quantities are accurate, they are more willing to offer the lowest competitive price on an estimated quantity supply contract.

Price information on injection equipment and safety boxes can be obtained from various sources, including Internet sites and price catalogues from commercial companies, non-commercial organizations, NGOs and international procurement agencies (Appendix 4). Prices from catalogues give an indication but they may vary significantly according to quantities ordered. The cost of safety boxes is incorporated into the total required budget.

## ***Step 3- Preparing procurement***

### **Step 3.1. Definition of procurement specifications**

The tender committee will elaborate the procurement specifications, based on the product specifications and tender requirements, e.g. transport, time of delivery, port of entrance.

### **Step 3.2. Definition of product specifications**

Expert and users' committees define the required characteristics of the product that is needed (Appendix 2, Appendix 3).

### **Step 3.3. Selection of potential suppliers**

Quality is the most important selection criterion when choosing injection equipment and safety boxes suppliers. Criteria used to assess potential suppliers and monitor already selected suppliers include:

- Product quality;
- Service reliability;
- On-time delivery performance;
- Financial viability.

Service reliability includes quality assurance policy and service, goods return and recall policy and freight service. In addition, the credentials of vendors who introduce themselves as representatives of manufacturers may also be checked. Pre-qualification procedures before the bidding process or post-qualification procedures after the bidding process will help to eliminate substandard suppliers.

There are two main options to select suppliers. First, the pre-qualification, also known as the procedure for assessing the acceptability, in principle, of a product and suppliers, is used for restricted tender. Second, the post-qualification procedure is used for open tender. Monitoring suppliers' performance is also an important component of supplier selection.

## Pre-qualification procedure

The procedure for assessing the acceptability of injection equipment or safety boxes and suppliers is the formal procedure for the screening of potential bidders prior to invitation to bid. It is a process to ensure that invitations to bid are extended only to those who have adequate capabilities and resources. Substantial time may be required to establish an initial list of pre-qualified suppliers meeting pre-determined norms and standards. However, once this is completed it will allow the lowest acceptable bidder for each product to be deemed qualified and to expedite adjudication and contract award. International agencies (e.g., WHO, UNICEF, UNFPA) and the World Bank highly recommend and support the pre-qualification of potential suppliers according to set procedures to ensure product quality and consistent supply. WHO is currently developing procedure for the pre-qualification of single-use injection equipment named: “Procedure for assessing the acceptability, in principle, of injection equipment for purchase by United Nations agencies”.

### Box B: Pre-qualification: Objectives and tools

#### *Objectives*

1. Develop a list of potential suppliers and manufacturers of injection equipment and safety boxes meeting specifications and standards by a procurement committee in collaboration with the national regulatory authority;
2. Purchase acceptable quality products while maintaining a competitive procurement process to obtain best possible prices.

#### *Tools for the quality assessment of manufacturers/suppliers<sup>11</sup>*

The manufacturer has to demonstrate the production of medical equipment according to quality standards:

##### a. International standards:

- International standards (ISO standards) are available for injection equipment and cover both product standards and quality systems (Appendix 5). The use of international standards is recommended above the use of national standards.
- There are no ISO standards for safety boxes and some national standards are too stringent for developing countries. Thus, WHO procurement specifications and standard test procedures are used by default.<sup>20</sup>

##### b. Control of compliance to international standards:

- Laboratory quality testing is performed to assess conformity to ISO standards and/or WHO procurement specifications;
- The manufacturer has to register its products at the national regulatory authority of the country of import.

#### *Mechanism to assess manufacturers/suppliers*

The programme/technical bodies will determine which standards and specifications to use for injection equipment and safety boxes and how compliance to these standards and specifications will be verified. The decision to purchase or to reject proposed injection equipment will be based upon (1) information provided by manufacturers or vendors and (2) an algorithm to use this information to accept or reject the product (Appendix 6, Appendix 7).

## **Post-qualification procedure**

Post-qualification evaluates suppliers to be selected after bids have been received, according to the same criteria of quality as those requested in the pre-qualification process. The disadvantage of this procedure is that if there are numerous offers from unknown suppliers there may be long delays in awarding contracts, as it will be necessary to validate suppliers' capacity to supply assured quality products.

## **Monitoring supplier performance**

In addition to using pre-qualification procedures, good supplier performance is ensured through a formal monitoring system that tracks:

- Product-specific performance indicators:
  - Quality of injection supply items received;
  - Remaining shelf-life;
  - Compliance with packaging;
  - Labelling instructions and other specifications.
  
- A file for each supplier with commercial indicators:
  - Lead times;
  - Compliance with contract terms;
  - Partial shipments;
  - Management of supply problems;
  - Number and value of tender contracts awarded and the value of total purchases from the supplier by year and performance for each tender.

A more detailed list of criteria for evaluating suppliers is given in Appendix 8.

If procurement officers already monitor supplier performance for other items, injection equipment and safety boxes can be incorporated into this monitoring system. The procurement office will keep a database of all past procurement reports and contract history, to assist in the selection of suppliers for coming tenders. This will make the procurement process more efficient, especially suppliers selection procedures and collation of tender offers for adjudication. Information collected will be kept in general procurement records (Table 3).

**Table 3: Information kept in general procurement records \***

Report name	Contents
Product records	Lists of specifications
Records related to tendering and ordering	Files of invitations to tender Adjudication reports Tender award lists
List of pre-qualified suppliers	Files of assessment reports per supplier
Quality assurance records	Quality assurance testing Reporting of product problems from prescribers, dispensers and consumers
Records to monitor supplier performance	Monitor performance and compliance with contractual terms by suppliers and per contract <ul style="list-style-type: none"> <li>• Monitor suppliers' lead time</li> <li>• Delivery status</li> <li>• Compliance with commercial terms and conditions</li> <li>• Remaining shelf life</li> <li>• Compliance with packaging and labelling</li> </ul>
	Elaborate a file on each supplier containing copies <ul style="list-style-type: none"> <li>• All registration papers</li> <li>• References</li> <li>• Correspondence</li> <li>• Complaints, reporting of problems</li> <li>• Value of tender contracts awarded</li> <li>• Other information</li> </ul>

#### ***Step 4- Proceeding to the tender***

The tender process covers:

1. Selection of the tender format.
2. Preparation of bidding documents for selective tender.
3. Solicitation and receipt of offers for selective tender.
4. Evaluation and award recommendation.
5. Issue of the contract.
6. Performance of the contract and the product.

The two first actions (selection of the tender format and preparation of bidding documents for selective tender) are detailed below. The four others are generic to all procurement procedures and are outlined in Table 4.

\* The list of procurement reports proposed in the table is generic and not exhaustive.

#### **Step 4.1. Selection of the tender format**

Most established procurement systems use restricted tenders with pre-qualification procedures that solicit bids only from pre-qualified suppliers. The most appropriate tender format for the procurement of injection equipment and safety boxes is the “Limited International Bidding” (LIB) combined with an pre-qualification procedure. Continuous efforts to seek out potential new suppliers maintain the competitiveness of the procurement process. Other procurement methods, including the “Request for Quotations” (RFQ) may be appropriate for emergency supply situations or when small volumes of supplies are required.<sup>12</sup>

#### **Step 4.2. Preparing bidding documents for selective tender**

International organizations, including United Nations agencies and the World Bank, have developed guidelines for procurement procedures that can be applied to the procurement of injection equipment.<sup>13,14,15</sup> Key elements of these procedures are summarized in Table 4. Sources of templates that can be used to develop bidding documents are provided in Appendix 9.

The specific characteristics of single-use injection equipment and safety boxes will be clearly stated in the tender document.

For injectable equipment, these include:

- Type and volume of syringe (Appendix 2);
- Syringe without needle, with integrated needle or with non-integrated (attachable) needle;
- Type, size and length of needles (Appendix 2);
- Packaging;
- Remaining shelf life for single-use injection equipment after delivery (maximum life time for sterile injection equipment is five years).

For safety boxes, these include:

- Type and size of safety boxes (Appendix 3);
- Packaging.

In addition to the above, the normal tender requirements specify and include:

- Method of transport: Freight mode (Incoterms 2000);<sup>16</sup>
- Insurance for goods;
- Realistic delivery time;
- Location of the delivery: Point of receipt of goods in the recipient’s country.

#### ***Step 5 - Managing storage and distribution of products and Step 6 - Conducting supervision and monitoring of performance.***

Step 5 (Managing storage and distribution of products) and Step 6 (Conducting supervision and monitoring of performance) of the procurement cycle are managed according to the same rules that apply for the procurement of pharmaceuticals and medical devices.

The focus of this guide is to describe specific features of the procurement of single-use injection equipment and safety boxes, therefore only the first four steps of the procurement cycle are discussed.

**Table 4: Applying general procurement procedures to the procurement of injection equipment and safety boxes**

Steps	Objectives	Tasks
<p><b>(Step1)</b>  <b>Defining injection equipment and safety boxes needs</b></p>	<p>Define products (Appendix 2 and 3)</p>	<p>Define the type of single-use injection equipment required according to the purpose of use:</p> <ul style="list-style-type: none"> <li>• Type of syringes</li> <li>• Volume of syringes</li> <li>• Syringes with integrated or non-integrated (attachable) needles</li> <li>• Diameter and length of needles</li> <li>• Type of safety boxes</li> <li>• Volume of safety boxes</li> </ul>
<p><b>(Step2)</b>  <b>Estimating injection equipment and safety boxes</b></p>	<p>Estimate injection equipment and safety boxes needs (Information available at national or provincial level)</p> <p>Quantify injection equipment and safety boxes:                      Estimate funds required</p>	<p>Estimate needs in preventive and curative services according to:</p> <ul style="list-style-type: none"> <li>• Orders of vaccines and injectable medicines</li> <li>• Consumption of syringes and needles, needles for reconstitution for medicines that required reconstitution, syringes and vials, including multi-dose vials</li> <li>• Wastage (e.g., 10% in immunization)</li> <li>• Buffer stock at the central level</li> <li>• Principle of matching quantities of injectable medicines to quantities of syringes and safety boxes</li> </ul> <p>Calculate costs using international indicator prices or from other sources (e.g. past prices paid)</p>

## Applying general procurement procedures to the procurement of injection equipment and safety boxes

Steps	Objectives	Tasks
<p><b>(Step3)</b> <b>Preparing procurement</b></p>	<p>Define procurement or tender specifications</p> <p>Specify injection equipment and safety boxes specifications (Appendix 2)</p> <p>Prepare bidding documents (Appendix 9)</p> <p>Select potential suppliers</p>	<ul style="list-style-type: none"> <li>• Specific: attributes and features of the product needed</li> <li>• Non specific: Agreed transport, delivery time and location. (port of entrance)</li> </ul> <p>Specify injection equipment characteristics:</p> <ul style="list-style-type: none"> <li>• Type and volume of syringes</li> <li>• Type of needles (integrated or non-integrated)</li> <li>• Size and length of needles (Gauze)</li> <li>• Packaging (number of unit per package)</li> <li>• Labelling (refer to ISO standards)</li> <li>• Remaining shelf life after delivery (minimum of 2/3 of the life time of the product)</li> </ul> <p>Specify safety boxes characteristics:</p> <ul style="list-style-type: none"> <li>• Type and volume of boxes</li> <li>• Labelling (refer to the WHO specifications)</li> <li>• Packaging (unfolded)</li> </ul> <ul style="list-style-type: none"> <li>• Product specifications</li> <li>• Checklist form for vendors and product information</li> <li>• Tender specifications</li> <li>• Financial arrangements</li> </ul> <p>Choose potential suppliers from a list of pre-qualified suppliers</p>

## Applying general procurement procedures to the procurement of injection equipment and safety boxes

Steps	Objectives	Tasks
Selection of the tender format	Choose a tender format	Appropriate methods of procurement for injection equipment: <ul style="list-style-type: none"> <li>Limited International Bidding (LIB)</li> <li>Request For Quotation (RFQ)</li> </ul>
<b>Preparation of bidding documents for selective tender</b>	List documentation to be presented by the bidder	Elaborate the list of documentation: <ul style="list-style-type: none"> <li>Eligibility documentation</li> <li>Specification documentation</li> <li>Pre-shipment procedures</li> <li>Importation procedure</li> </ul>
<b>(Step 4) Proceeding to the tender</b>	Draft document for bid package “ <i>Invitation to Bid</i> ”	<ul style="list-style-type: none"> <li>Draft model of a tender documentation</li> </ul>
<b>Solicitation and receipt of offers for selective tender</b>	Draft selection criteria for selected tender bidders	<ul style="list-style-type: none"> <li>Define selection criteria</li> <li>Describe evaluation methods</li> </ul>
<b>Evaluation and award recommendation</b>	Send invitation to bid and bidding documents	<ul style="list-style-type: none"> <li>Issue the bidder’s list</li> </ul>
	Open bids on date specified on the bid document	<ul style="list-style-type: none"> <li>Receive and open offers</li> <li>Record bid opening</li> </ul>
	Comparison of the bids	<ul style="list-style-type: none"> <li>Elaborate adjudication worksheet</li> </ul>
	Collate offers for adjudication by the tender review committee	<ul style="list-style-type: none"> <li>Summary cover sheet</li> </ul>
	Select known or new pre-qualified supplier(s) according to checklist Evaluate supplier(s)	<ul style="list-style-type: none"> <li>Gather tender committee review panel</li> <li>Choose best bid on the basis of price and other elements of the offers</li> <li>Finalize award process</li> <li>Notify successful bidder</li> </ul>
	Award supplier contract(s)	<ul style="list-style-type: none"> <li>Transmit official award letter</li> </ul>

## Applying general procurement procedures to the procurement of injection equipment and safety boxes

Steps		Objectives	Tasks
<b>(Step 4) Proceeding to the tender</b>	<b>Contract issue</b>	Draft final purchase order	<ul style="list-style-type: none"> <li>Approve and sign</li> <li>Submit to the supplier for signature</li> <li>Advise unsuccessful bidders</li> </ul>
		Financial arrangements	<ul style="list-style-type: none"> <li>Collaborate with the finance unit,</li> <li>Organize the arrangement for release of funds</li> <li>Notify the supplier and the purchaser of responsibilities for contract performance</li> </ul>
		Make delivery	<ul style="list-style-type: none"> <li>Receive and inspect goods, control batches.</li> <li>Report deficiencies as necessary</li> </ul>
		Monitor performance of supplier	<ul style="list-style-type: none"> <li>Assess compliance with contract terms by suppliers for this current contract</li> </ul>
		Closeout activities	<ul style="list-style-type: none"> <li>Maintain warranty records</li> </ul>
		Monitor performance of injection equipment	<ul style="list-style-type: none"> <li>Detect performance problems in the field and provide feedback to the supplier and the National Regulatory Authority (NRA) monitors</li> </ul>
	<b>Supplier performance</b>		
	<b>Product performance</b>		



## ***Glossary and abbreviations***

**Auto-Disable syringes (AD):** AD syringes are single-use syringes that inactivate themselves after one use. AD syringes reduce the risk of injection-associated infections because they can not be reused. AD syringes are now widely available at low cost (less than a 20% increase over the cost of a standard single-use syringes). AD syringes are the recommended equipment for administration of vaccines, both in routine immunization and mass campaigns.

**Bundling:** "Bundling" refers to the inclusion of the costs of AD syringes and safety sharps boxes in the costs of good quality vaccines provided by donors and lenders as described in the WHO/UNICEF/UNFPA/IFRC 1999 policy statement. "Bundling" has no physical connotation and does not imply that items must be "packaged" together.

**Batch:** The quantity of a product produced in one production run.

**Disposal:** The collection, storage, and subsequent destruction of all syringes and needles to avoid any accidents.

**EO:** sterilization by ethylene oxide gas

**EPI:** Expanded Programme on Immunization.

**Expiry date:** The date appearing on the packaging of the injection equipment and established by the manufacturer, beyond which the manufacturer will not guarantee the efficiency and the sterility of the injection equipment.

**EXW: Ex-works-** (common trade term - need to state a named place.): Ex works represents the minimum obligation of the seller. The seller pays for expenses at factory or warehouse. The buyer assumes all onward expenses (loading and transport of the goods). The seller's only responsibility is to make the goods available at the seller's premises for collection by the buyer.

**FCA:** Free carrier- (common trade term - need to state a named place) The seller's obligation is to pack and deliver the goods on hand of the first or only carrier at the named port of carriage (seaport or airport) into the custody of the first or only carrier and clear them for export. The risk of loss or damage to the goods is transferred from the seller. The buyer's responsibility is to pay for the onward shipment of goods to the destination.

**FOB:** Free on board- (common trade term - need to state the loading port) The seller is responsible for placing the goods on board the first ship or carrier at a named port of shipment in the sales agreement. The seller pays the cost of loading the goods. Once the goods are on ship's platform, the risks and responsibility pass onto the buyer, and so does the cost of onward shipping.

**ILAC: International Laboratory Accreditation Cooperation.** Laboratory Accreditation provides formal recognition to competent laboratories. An international guide, called ISO/IEC Guide 25, describes the basis for the accreditation of a country's testing and calibration laboratories. Adoption of this international guide has helped countries adopt a uniform approach to determining laboratory competence. To find accredited laboratories around the world, open the web page <http://www.ilac.org/>. Click "the "Directory" button will result in a world map and instructions to find members in different regions and their addresses or websites for communications.

**Infection control:** The activities aiming at the prevention of the spread of pathogens between patients, from health care workers to patients, and from patients to health care workers in the health care setting.

**Integrated needle:** The needle is fixed on the syringe and it cannot be removed.

**International Organization for Standardization (ISO):** The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies from some 140 countries. ISO is a nongovernmental organization established in 1947. The mission of ISO is to promote the development of standardization and related activities in the world to facilitate the international exchange of goods and services and to develop cooperation in the area of intellectual, scientific, technological and economic activity.

**International procurement services:** Organizations such as WHO, UNICEF, IDA, etc., and other groups that supply medicines and medical equipment on a non-profit basis.

**ISO standards:** Standards of general quality assurance are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics to ensure that materials, products, processes and services are fit for their purpose. The standards are not official standards and may be seen as voluntary, unless a government adopts them as part of regulatory legislation.

**Gauge:** Measuring system for coding thickness. For needles, the Gauge defines the external diameter of needles tube, it varies from 8 to 30 which correspond respectively to 4 and 0,3 mm. The higher the Gauge number is, the thinner the needle tube is. The gauge does not take into account the wall thickness of the needle tube, therefore the gauge do not give idea about internal diameter.

**Good Manufacturing Practice (GMP):** Good Manufacturing Practice is the part of quality assurance that ensures that the pharmaceutical products (medicines and medical devices) are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. The certificate is issued following inspection of the premises, manufacturing equipment, personnel, product and marketing documentation, in-house quality control, in-house process validation, etc. and is valid for a certain period of time. Hence, lack of GMP certificate or quality system certificate from a manufacturer may be a cause for concern.

**Limited International Bidding (LIB):** LIB is essentially international competitive bidding conducted by direct invitation to all qualified suppliers and without open advertisement. This method may be more appropriate when there is only a limited number of potential suppliers (e.g., in the case of AD syringes).

**Luer conical fitting system:** "Luer" fitting refers to the international standard ISO 594: Conical fittings with a 6% (Luer) taper for hypodermic syringes, needles and certain other medical equipment. This includes (1) a syringe, or certain other medical equipment such as transfusion and infusion sets, with a nozzle of specific dimensions and (2) a needle with a hub of specific dimensions compatible with each other, regardless of manufacturers.

**Luer Lock conical fitting system:** Luer Lock fittings refer to a screw-on conical fitting with a 6% (Luer) taper for hypodermic syringes, needles and certain other medical equipment for medical use e.g. transfusion equipment (international standards ISO 594-2)

**Lead-time:** The time interval needed to complete the procurement cycle. It begins at the time the need for new stock is recognized and ends when that stock is received and available for issue.

**MIS:** Management information system.

**NGOs:** Nongovernmental Organizations.

**NRA:** National regulatory authority.

**QAS:** Quality Assurance System.

**Request For Quotation (RFQ):** This method of procurement is used in those cases where the health sector goods are available from only one source, or for emergency supply. It is the least favoured method because in the absence of the competitive element it is more difficult to determine whether the prices quoted are economic and reasonable.

**Restricted tender:** Procurement procedure in which participation in bidding is limited to suppliers that meet certain prerequisites or have previously registered as suppliers.

**Safety stock:** The buffer or minimum stock that is kept on hand to protect against stock-outs. In theory, the safety stock is separate from the working stock, but in practice there is no separation of the two and sometimes safety stock must be issued.

**Safety boxes:** Safety boxes, also known as sharps containers, are puncture-proof, impermeable containers for the safe and convenient disposal of used syringes and needles and other contaminated sharps. Safety boxes must be filled only once, collected safely then destroyed immediately. When they are used consistently and correctly, safety boxes can prevent needle-stick injuries.

**Safety syringes:** Single-use syringes that are designed with a needlestick-prevention feature

**Shelf life:** The shelf life is the length of time that a product may be stored without affecting its usability, safety or potency.

**SIGN:** Safe Injection Global Network.

[http://www.who.int/entity/injection\\_safety/sign/en](http://www.who.int/entity/injection_safety/sign/en) or [www.injectionsafety.org](http://www.injectionsafety.org)

**Single-use syringes:** include syringes designed for a single use, with a separate, stainless steel needle, auto-disable syringes designed for immunization, syringes with a reuse-prevention feature for general purpose and syringes with needlestick-prevention feature.

**Supplier:** Suppliers are primary manufacturers of health sector goods or individuals/organizations with authority to act as an agent for the primary manufacturer.

**Tendering:** The procedure by which competing bids are entered for a particular contract

**UNFPA:** United Nations Population Fund.

**UNICEF:** The United Nations Children's Fund.

**WHO:** The World Health Organization.

**Working stock:** Stock that is on hand in the warehouse or storeroom and is shipped to requesting operating units.

## **Appendices**

### **Appendix 1: Sharps waste management**

#### **Managing sharps waste as a duty of care**

Poorly managed sharps waste expose health workers and the community to injuries and infection. The efficient, safe and environmentally-friendly management of sharps waste is the only means of ensuring that single-use syringes and needles are not reused and do not lead to needle-stick injuries.<sup>17</sup> Thus, it is important to include in the policy a statement specifying that disposal is part of the syringe life cycle and that health care services have a duty to manage sharps waste.

#### **Integrating sharps waste management within health care waste management**

The management of sharps waste must be considered within the broader context of health care waste management. Implemented as such, sharps waste management will be cheaper and more sustainable. Key elements of health care waste management are summarized in the WHO health care waste management "Aide Memoire"<sup>18</sup> and in the WHO injection safety planner. For practical purposes, general health care services are in the best position to implement sharps waste management from a sector-wide perspective. However, to coordinate sharps waste management activities stakeholders in charge of injection equipment procurement will liaise with general health care services and purchase safety boxes as a first step of appropriate sharps collection and disposal, while new technologies are being evaluated such as used needle remover devices and needle cutters which aim to reduce the volume of sharps waste.

#### **Information sources on health care and sharps waste management:**

##### ***The WHO working group on health care waste management***

<http://.www.healthcarewaste.org>

##### ***The Safe Injection Global Network (SIGN)***

[http://www.who.int/entity/injection\\_safety/sign/en](http://www.who.int/entity/injection_safety/sign/en) or

<http://www.injectionsafety.org>

##### ***WHO's Immunization Safety Priority Project***

<http://www.stage/vaccines-surveillance/ISPP>

## Appendix 2: Characteristics of injection equipment

### *Product description:*

#### **Syringe, single-use**

General characteristics	Sterile Nozzle with a Luer fitting Single-use Polypropylene (material)
Use	<ul style="list-style-type: none"> <li>• Injection for general purpose and other uses including, reconstitution and feeding (e.g., into a naso-gastric tube)</li> <li>• For intradermal injection (tuberculin testing)</li> </ul>
Type	<ul style="list-style-type: none"> <li>• 2 pieces: one barrel and one plunger</li> <li>• 3 pieces: one barrel, one plunger and one elastomeric piston seal</li> <li>• Luer fitting</li> <li>• Luer Lock fitting</li> </ul>
Need for a fixed needle	<ul style="list-style-type: none"> <li>• Yes: with by-packed needle (see needle nomenclature)</li> <li>• No: without a needle</li> </ul>
Volume	<ul style="list-style-type: none"> <li>• 0.3, 0.5, 1, 2 ml for insulin</li> <li>• 0.5 ml or 1ml for tuberculin</li> <li>• 1, 2, 3 ml for general purpose</li> <li>• 5, 10, 20 ml for general purpose               <ul style="list-style-type: none"> <li>- nozzle located centrally</li> <li>- nozzle located eccentrically</li> </ul> </li> <li>• 50 ml with Luer nozzle for mixing,</li> <li>• 50 ml for feeding and other uses</li> </ul>
Specific packaging	<ul style="list-style-type: none"> <li>• Individual sterilized blister or ribbon packs made of paper and plastic</li> <li>• Protective end capped syringes</li> </ul>
Sterilization	<ul style="list-style-type: none"> <li>• Ethylene oxide (EO)</li> <li>• Irradiation (R)</li> </ul>
Shelf life remaining	Minimum of 2/3 of the life time when leaving the supplier warehouse
Requirements	Conform to ISO standards: <ul style="list-style-type: none"> <li>• ISO 7886 –1: Sterile hypodermic syringes for single use - Part 1: Syringes for manual use<sup>19</sup></li> <li>• ISO 8537: Sterile single-use syringes, with or without needle, for insulin</li> </ul>

## Auto-Disable syringes

General characteristics	Single-use Sterile Including a mechanism to prevent reuse
Material	<ul style="list-style-type: none"> <li>• Polypropylene</li> <li>• Stainless steel for some mechanisms preventing reuse</li> </ul>
Use	<ul style="list-style-type: none"> <li>• For immunization</li> <li>• For curative and preventive care</li> </ul>
Syringe size with pre-set volume and single marking	<ul style="list-style-type: none"> <li>• 0.05 ml for BCG vaccine</li> <li>• 0.1 ml for BCG vaccine</li> <li>• 0.5, 1 ml for immunization</li> </ul>
Syringe size with graduated scale	<ul style="list-style-type: none"> <li>• 1, 2, 3, 5, 10 ml for preventive or curative care</li> </ul>
Needle for immunization	<ul style="list-style-type: none"> <li>• Diameter: e.g.: 23G , 24G, 25G for 0.5 ml and 1ml syringes e.g.: 27 G for 0.05 ml syringe</li> <li>• Length: e.g.: 30mm (1 1/4"), 25mm (1"), 16mm (5/8") for 0.5 ml and 1 ml syringes e.g.: 10mm (3/8"), 12mm ( 1/2") for 0.05 ml syringe</li> </ul>
Needle for general purpose	<ul style="list-style-type: none"> <li>• Diameter: for IM, IV and subcutaneous injection</li> <li>• Length: for IM, IV and subcutaneous injection</li> </ul>
Types	<ul style="list-style-type: none"> <li>• Syringes with permanently attached needle</li> <li>• Syringes packed with non standard Luer needle in the blister or ribbon pack</li> <li>• Syringes packed with a Luer needle in the blister or ribbon pack.(once the needle is fixed, the needle becomes permanently attached)</li> </ul>
Packaging	<ul style="list-style-type: none"> <li>• Individual sterilized blister or ribbon pack made of paper and plastic</li> <li>• Needle cap and cap over thumb plate (if applicable) make syringe into a sterile unit</li> </ul>
Shelf life remaining	<ul style="list-style-type: none"> <li>• Minimum of 2/3 of the life time when leaving the supplier warehouse</li> </ul>
Requirements	<p>Conform to:</p> <ul style="list-style-type: none"> <li>• WHO performance specification E8/DS.1<sup>20</sup> if AD syringes for immunization purpose</li> <li>• WHO specifications WHO/BCT/02.12<sup>21</sup> if AD syringes for general purpose</li> </ul> <p>In progress: ISO standard ISO 7886-3: Sterile hypodermic syringes for single use - Part 3: Auto-Disable syringes for fixed doses immunization<sup>22</sup></p>

**Needle single-use, hypodermic**

General characteristics	Single-use Sterile Luer conical fitting Stainless steel (material)	
Purpose	<ul style="list-style-type: none"> <li>• intramuscular</li> <li>• intravenous</li> <li>• subcutaneous</li> <li>• intradermal</li> </ul>	
Length	<ul style="list-style-type: none"> <li>• 10 mm (3/8")</li> <li>• 12 mm (1/2")</li> <li>• 16 mm (5/8")</li> <li>• 25 mm (1")</li> <li>• 30 mm (1 1/4")</li> <li>• 40 mm (1 1/2")</li> <li>• 50 mm (2")</li> </ul>	
Diameter of the needle tube and Luer colour code of the needle hub	External Diameter (Gauge and mm)	Colour code of the hub (in accordance with ISO 6009 <sup>23</sup> )
	27G : 0.4 mm	Grey
	26G : 0.45 mm	Brown
	25G : 0.5 mm	Orange
	24G : 0.55 mm	Purple
	23G : 0.6 mm	Blue
	22G : 0.7 mm	Black
	21G : 0.8mm	Deep green
	20G : 0.9 mm	Yellow
	19G : 1.1mm	Cream
	18G : 1.2 mm	Pink
	17G : 1.5 mm	Deep red
	16G : 1.6 mm	White
	15G : 1.8 mm	Blue Grey
	14G : 2.0mm	Pale green
Packaging	Individually sterilized blister or ribbon packs made of paper and plastic	
Shelf life remaining	Minimum of 2/3 of the life time when leaving the supplier warehouse	
Requirements	Conform to ISO standards: <ul style="list-style-type: none"> <li>• ISO 7864: Sterile hypodermic needles for single use<sup>24</sup></li> </ul>	

***Proposed Nomenclature of needle size for each route***

Length in mm	30 mm	16 mm	16 mm	25 mm	30 mm	40 mm	50 mm	40 mm	25 mm	40 mm	30 mm	30 mm			
Outside diameter in mm	0.45 mm	0.5 mm	0.55 mm	0.6 mm	0.7 mm	0.8 mm	0.8 mm	0.9 mm	0.9 mm	1.1 mm	1.1 mm	1.2 mm			
Outside diameter in Gauge	26G	25G	24G	23G	22G	21G	21G	20G	20G	19G	19G	18G			
Length in inch	1 1/4"	5/8"	5/8"	1"	1 1/4"	1 1/2"	1 1/2"	1 1/2"	1"	1 1/2"	1 1/4"	1 1/4"			
Colour code of Luer needle hub	brown	orange	purple	blue	black	deep green	deep green	yellow	yellow	cream	cream	pink			
Intradermal	Adults Children	Adults Children	Adults Children	Adults	Adults Children										
Subcutaneous	Children	Children	Adults Children	Adults Children	Adults Children										
Intravenous	Injection			Adults Children	Adults Children				Adults Children	Adults Children		Adults			
	Tap														
Intramuscular	Intra-arterial	Injection	Middle	Deep	Tap										
						Surface									
Intra-articular												Adults Children			

### Appendix 3: Characteristics of safety boxes

General characteristics	Containers for the collection of used syringes and/or needles Potentially for initial distribution of syringes and needles Disposal and destruction by incineration of used syringes and needles
Material	Waterproof, puncture-proof cardboard <sup>*</sup>
Volume	<ul style="list-style-type: none"><li>• 5 litres</li><li>• 10 litres</li><li>• 15 litres</li><li>• 20 litres</li></ul>
Labelling	Pictorial instructions printed on the box to describe the use and the disposal of the box once filled Separate sheet with pictorial instructions on how to assemble the flat-packed boxes
Shelf life	Not applicable
Requirements	Conform to WHO procurement specifications E10/IC.1 for safety boxes and incineration containers <sup>25</sup>

\* Other types of sharps containers exist such as plastic sharps containers for which some national standards exist. this guide only mentions the cardboard safety boxes.

## Appendix 4: List of potential suppliers

### *International low-cost suppliers*\*

#### **IDA**

Procurement unit  
PO Box 37098  
1030 AB Amsterdam  
THE NETHERLANDS  
Telephone: + 31 20 40 33 051  
Fax: + 31 20 40 31 854  
E-mail: [info@ida.nl](mailto:info@ida.nl)  
<http://www.ida.nl>

#### **Médecins Sans Frontières logistique**

14 rue de l'Argone  
F- 33700 Mérignac  
FRANCE  
Telephone: + 33 556 13 73 73  
Fax: + 33 556 13 73 74  
E-mail: [standard@bordeaux.msf.org](mailto:standard@bordeaux.msf.org)

#### **Transfer**

Preenakker 20  
B-1785 Merchtem, BELGIUM  
Tel. + 32 52 26 10 21  
Fax + 32 52 26 10 04  
[office-transfer@msf.be](mailto:office-transfer@msf.be)  
[www.tranfer.be](http://www.tranfer.be)

#### **Action Medeor**

Deutsches Medikamenten Hilfswerk  
St. Töniser Strasse 21  
D 47918 Tönisvorst  
GERMANY  
Telephone: + 49 21 56 97 88 0  
Fax: + 49 21 56 97 88 88  
E-mail: [info@medeor.org](mailto:info@medeor.org)  
<http://www.medeor.org>

#### **Missionpharma**

Vassingerødvej 9  
DK-3540 Lyngø  
DENMARK  
Telephone: + 45 48 16 32 00  
Fax: + 45 48 16 32 48  
E-mail: [info@missionpharma.com](mailto:info@missionpharma.com)  
<http://www.missionpharma.com>

#### **CHMP**

4 voie militaire des gravanches  
63100 Clermont Ferrand  
FRANCE  
Telephone: + 33 473 98 24 71  
Fax : + 33 473 98 24 80  
E-mail: [contact@chmp.org](mailto:contact@chmp.org)  
[www.chmp.org](http://www.chmp.org)

#### **The Medical Export Group**

Papland 16 / P.O. Box 598  
NL-1200 An Gorinchem  
THE NETHERLANDS  
Telephone: + 31 183 356 100  
Fax: + 31 183 356 115  
E-mail: [sales@meg.nl](mailto:sales@meg.nl)  
[www.meg.nl](http://www.meg.nl)

\* This proposed list of low-cost suppliers is indicative and not exhaustive.

## *UN Agencies*

### **UNICEF Supply Division**

Freeport  
DK-2100 Copenhagen 0  
DENMARK  
Telephone: + 45 35 27 35 27  
Fax: + 45 35 26 94 21  
E-mail: [supply@unicef.dk](mailto:supply@unicef.dk)  
[www.supply.unicef.dk](http://www.supply.unicef.dk)

### **UNFPA**

Procurement Unit  
220 East 42<sup>nd</sup> Street  
New York, NY 10017  
USA  
Telephone: + 212 297 53 84/5392  
Fax: + 212 297 49 16/5220  
E-mail: [saunders@unfpa.org](mailto:saunders@unfpa.org)

### **WHO**

Procurement Services  
20 avenue Appia  
CH-1211 Geneva 27  
SWITZERLAND  
Telephone: + 41 22 791 28 01  
Fax: + 41 22 791 41 96  
E-mail: [procurement@who.int](mailto:procurement@who.int)

## *Manufacturers*

A list of potential manufacturers of injection equipment can be obtained through the International Association of Safe Injection Technology (IASIT):

### **IASIT**

24, chemin de Mont-Rose  
CH-1294 Genthod  
SWITZERLAND  
Tel: +41 22 731 73 80  
Fax: +41 22 731 73 82  
<http://www.iasit.org>

## Appendix 5: International standards and supplier information

### *International standards for injection equipment<sup>11</sup>*

The ISO standards are available on the Internet site: [www.iso.ch](http://www.iso.ch)

#### **Product standards**

Product standards listed in the Table 5 describe the current international standards governing single-use injection equipment recognized by the five founding members of the Global Harmonization Task Force (GHTF). The founding members are Australia, Canada, the European Union, Japan and the United States.

**Table 5: International Standards for single-use syringes and needles**

1	ISO 7886-1	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
2	ISO 7886-2	Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps
3	<i>ISO 7886-3 in progress</i>	<i>Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed dose immunization</i>
4	<i>ISO 7886-4 in progress</i>	<i>Sterile hypodermic syringes for single use - Part 4: Syringes for manual use - with reuse prevention feature</i>
5	ISO 8537	Sterile single-use syringes, with or without needle, for insulin
6	ISO 7864	Sterile hypodermic needles for single use

#### **Quality standards**

Quality systems are defined as the organizational structure, responsibilities, procedures, processes and resources needed to implement quality management. The quality standards used by the five founding members of GHTF are listed in Table 6.

**Table 6: Quality standards of the five founding members of the GHTF<sup>11</sup>**

Founding members	Quality standards
Australia	ISO13485 or EN 46001, ISO13488 or EN46002
Canada	ISO13485, ISO13488
European Union	EN46001, EN46002, ISO13485, ISO13488
Japan	GMP (QS Standard for medical devices #1128)
United States	QS (21 CFR part 820)

Note: EN46001 and EN46002 will be phased out by the end of March 2004

### *Standards for safety boxes*

In the absence of international standards for safety boxes, the WHO specifications E10/IC.1 for safety boxes and incineration containers and E10/IC.2 for safety boxes are used to determine procurement requirements.

## Appendix 6: Checklist to collect information on quality from vendors or manufacturers

Information item		Details			
Item short description*	Status† and Name	Address	Phone and Fax	Remarks	
1 <input type="checkbox"/>	Brand name			Contact quality assurance	Web-site, e-mail
2 <input type="checkbox"/>	Vendor				
3 <input type="checkbox"/>	Manufacturer				
4 <input type="checkbox"/>	Parent company (if any)				
		<b>Regulatory authority (check all applicable)</b>	<b>Number (provide number)</b>	<b>Device name as submitted to authorities</b>	
5 <input type="checkbox"/>	Compliance with regulations	<input type="checkbox"/> Australia <input type="checkbox"/> Canada <input type="checkbox"/> European union <input type="checkbox"/> Japan <input type="checkbox"/> United states <input type="checkbox"/> Other, specify:	License number: License number: CE mark number: License number: 510(k) number:		
6 <input type="checkbox"/>	Conformity with quality system standards	<b>Standards used (check applicable)</b>	<b>Assessment body* (name, country), (attached a copy of the certificate)</b>	<b>Last audit date</b>	<b>Expiration date</b>
		<input type="checkbox"/> ISO13485 /ISO13488 <input type="checkbox"/> EN46001 / EN46002 <input type="checkbox"/> Japan QS Standard #1128 <input type="checkbox"/> United States QS (21 CFR part 820) <input type="checkbox"/> ISO9001 /ISO9002 <input type="checkbox"/> Other, specify: (e.g. ISO9001:2000)			
7 <input type="checkbox"/>	Conformity with product standards	<b>Standards used (check applicable)</b>	<b>Test laboratory (name, country) (attached a copy of the certificate)</b>	<b>Laboratory accreditation body</b>	
		<input type="checkbox"/> ISO 7864 for needles <input type="checkbox"/> ISO 7886-1 syringes for single-use <input type="checkbox"/> ISO 7886-2 syringes for power-driven pumps <input type="checkbox"/> ISO 8537 for insulin <input type="checkbox"/> WHO performance specifications for AD syringes for immunization: E8/DS1 <input type="checkbox"/> WHO procurement specifications for syringes with a reuse-prevention feature for general purpose			
8 <input type="checkbox"/>	Post-market surveillance reports	<input type="checkbox"/> Yes ( <b>check applicable</b> ). If yes, please provide all reports including sources. Use additional pages if necessary)			
9 <input type="checkbox"/>	Other evaluation reports	<input type="checkbox"/> No <input type="checkbox"/> ? Yes ( <b>check applicable</b> ). If yes, please provide all reports including sources. Use additional pages if necessary)			

\* In addition to this checklist, the manufacturer can provide a technical description of the product.

† Status: please provide the status as a vendor such as wholesaler, manufacturer, distributor, etc.

‡ e.g., Notified bodies in the European Union; Quality Systems Registrars in North America.

### *Instructions for completing the checklist*

All potential suppliers (or original manufacturers) please fill in items 1,2,3,4,8,9. In addition,

- If a regulatory authority has cleared the device, fill in item 5.
- If a regulatory authority of the GHTF founding members has not cleared the device, fill in items 6 and 7.

**Item 1:** Please provide the brand name that is used on the market. If there is more than one name, please provide all names.

**Item 2 and item 3:** The vendor may also be the manufacturer. But if the addresses are different, please provide all information.

**Item 4:** If the manufacturer is a subsidiary of a parent company or is contracted from another company, please supply the necessary information. A parent company may be located locally or in another country.

**Item 5:** If there is more than one regulatory authority that has cleared the device, please check all applicable authorities and provide all clearance numbers with the corresponding device names as they were submitted to the regulatory authorities. The device name submitted to the regulatory authorities, which may be different from the brand name, is necessary for verification of marketing clearance by the relevant regulatory authorities.

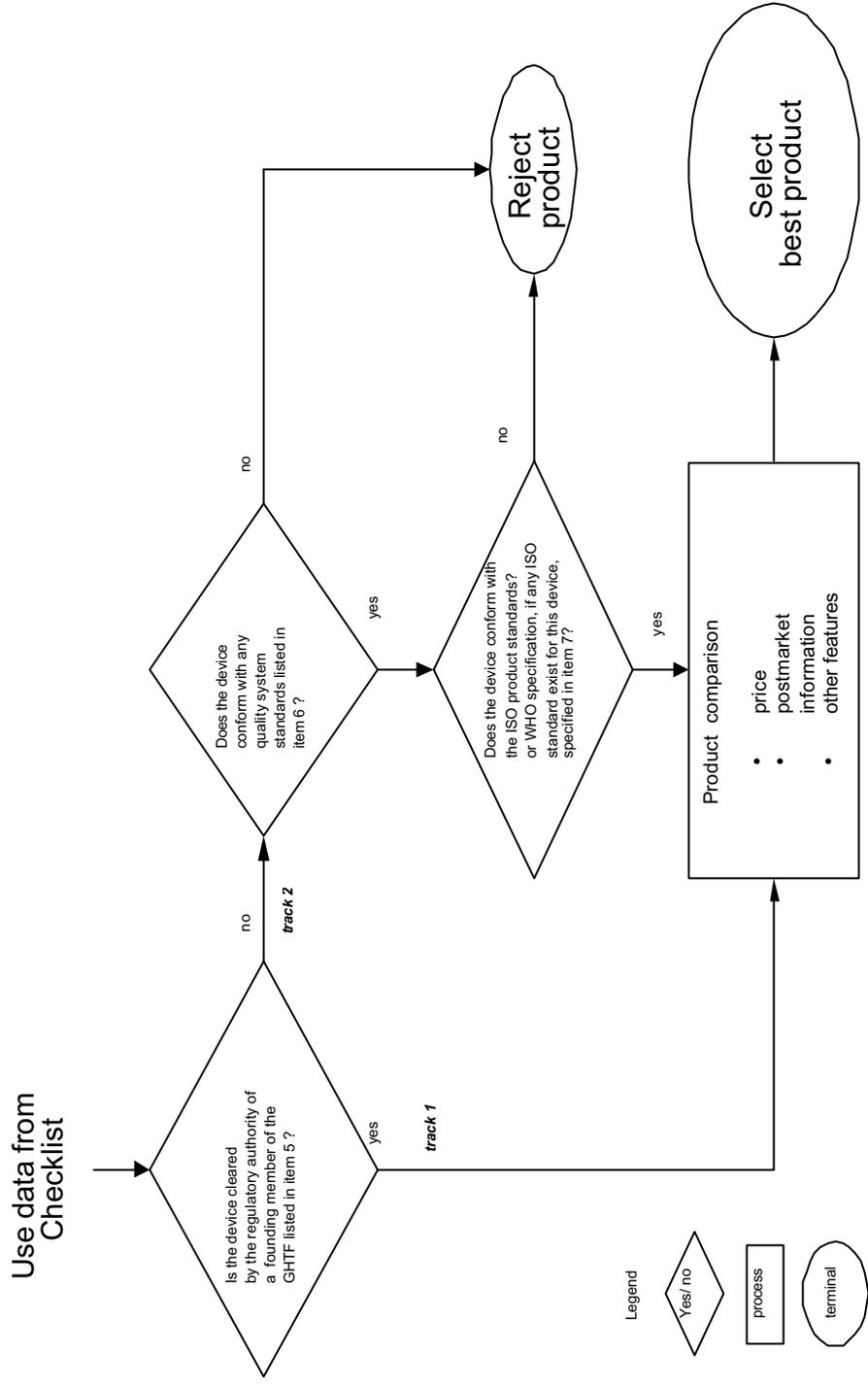
**Item 6:** Please confirm the applicable standard. Quality system assessment must include: (1) the proposed product is manufactured under the quality system audited; (2) appropriate international (ISO) standards for sterilization and packaging are used for Section 4.9 “process control”, (3) last audit date and expiration date of certificate. Maximum audit period must not exceed 12 months. Note that devices that are manufactured in conformity with ISO13485/88 will be given preference to those manufactured with ISO9001/02 or ISO 9001:2000.

**Item 7:** Please check all applicable standards with the corresponding test laboratories. Product testing must include sterility, packaging and labelling requirements. Indicate the accreditation status of the laboratories.

**Item 8:** Please provide all post-market surveillance reports by regulatory authorities, users or other parties and specify the sources.

**Item 9:** If available, provide any other third party evaluation reports.

**Appendix 7: Algorithm for injection equipment selection<sup>11</sup>**



Please make sure the checklist (Appendix 6) is correctly completed. Follow the algorithm for product selection.

**Track 1.** If there are no applicable local national regulations, and if the proposed product has marketing clearance from one or more of the five GHTF listed authorities (item 5), this product can be accepted as a candidate for product selection. You may be able to verify the regulatory clearance by the Internet, if available.

**Track 2.** If the proposed product has not been submitted to any of the five listed authorities, then it is necessary to assure that:

1. the manufacturer has a quality system in place (any one of the systems listed on item 6 is acceptable),
2. the proposed product conforms with specified product standards (item 7) and all additional specifications. You may verify the accreditation status of the test laboratory by following the information given by the International Laboratory Accreditation Cooperation (ILAC).

If both quality system standards and product standards are satisfactory, the proposed product can be accepted as a candidate for product selection.

If the proposed product is manufactured with an acceptable quality system, but either the conformity of the proposed goods with specified product standards or any additional specifications have not been certified by an accredited laboratory of any founding member of the GHTF, an option is to submit the proposed product to WHO accredited testing laboratories. The expense for this testing will be charged to the potential supplier. If the proposed product passes the laboratory test, then it can be accepted as a candidate for product selection.

Note: The ISO9001 and ISO9002 standards are for general application for products or services. The ISO13485 and ISO13488 standards are for the medical device industry. ISO13485 includes all the elements of ISO9001 plus a minimum set of supplementary requirements for the quality assurance of medical device manufacturing. The same relationship exists for ISO13488 and ISO9002. ISO13488 is equivalent to ISO13485 but without the design control requirements.

The ISO13485 and ISO13488 standards are recently specified by regulatory authorities while the ISO9001 and ISO9002 standards have been in common use worldwide. To allow a phase-in period, manufacturers registered with ISO9001, ISO9002, ISO9001:2000 should be accepted as having quality systems in place. However, preference should be given to products from manufacturers registered with ISO13485 / ISO13488 if other value indicators are equal.

## Appendix 8: Criteria for evaluating suppliers

### *Criteria for evaluating new suppliers*

Status	<ul style="list-style-type: none"><li>• Is the supplier a primary manufacturer or a distributor?</li><li>• If a distributor, who is the primary manufacturer for each product offered?</li></ul>
Quality control	<ul style="list-style-type: none"><li>• Does the supplier have quality control procedures in place such as an on-site quality control laboratory, independent audit ?</li><li>• Is the manufacturer in compliance with quality system standards? Has the suppliers sent the appropriate certification to quality system standards ?</li><li>• Does the supplier have appropriate regulatory certificates?</li></ul>
Inspection	<ul style="list-style-type: none"><li>• What official government agencies or international organizations have inspected the manufacturing facilities?</li><li>• What certification documents are available from the NRA concerning the supplier's status and compliance with quality system standards?</li></ul>
Personnel and facilities	<ul style="list-style-type: none"><li>• What are the qualifications of key production and quality control personnel?</li><li>• What is the capacity of the supplier's plant(s)?</li></ul>
Trade references	<ul style="list-style-type: none"><li>• What other local or foreign public procurement offices and hospitals buy from the supplier?</li><li>• How long has the supplier served the above groups?</li></ul>
Corporate associations	<ul style="list-style-type: none"><li>• Is the supplier a parent company with any known supplier?</li><li>• If so, what is the reliability of the known company?</li><li>• Is the supplier producing a certain product under a supervised licensing agreement with known supplier ?</li></ul>
Local reputation	<ul style="list-style-type: none"><li>• How is the supplier regarded by hospital pharmacists and national regulatory authorities?</li></ul>

### Criteria for evaluating past suppliers

Service	
Participation record	<ul style="list-style-type: none"> <li>• Has the supplier accepted an award of a bid and subsequently failed to deliver the product?</li> </ul>
Response to enquiries	<ul style="list-style-type: none"> <li>• Has the supplier adequately responded to all enquiries from the purchaser within a reasonable period of time?</li> <li>• Did the supplier provide regular information regarding the status of outstanding orders?</li> </ul>
Delivery time	<ul style="list-style-type: none"> <li>• What was the supplier's average promised lead time?</li> <li>• What was the actual lead time for the last procurement cycle?</li> <li>• What percentage of shipments were late? How many days late?</li> <li>• What additional costs were incurred due to late shipments?</li> </ul>
Adherence to delivery Instructions	<ul style="list-style-type: none"> <li>• Did the shipments arrive under the proper shipping conditions?</li> <li>• Did the shipments arrive at the correct port?</li> <li>• Did the supplier send full shipments as requested or were there partial shipments?</li> </ul>
Provision of documents	<ul style="list-style-type: none"> <li>• Did the supplier provide advance copies of documents according to contract terms?</li> <li>• Did shipments arrive with all required documents correctly filled out and signed?</li> <li>• If required documents were omitted, how did the supplier correct the problem?</li> </ul>
Packing and labelling	<ul style="list-style-type: none"> <li>• Did the supplier always ship the correct package size? Correct quantity in each package?</li> <li>• Was labelling complete and adequate for proper use? Was it in the correct language?</li> </ul>
Product shelf life	<ul style="list-style-type: none"> <li>• Did all products shipped comply with contractual terms for remaining shelf life?</li> <li>• If not, how many products were shipped with a shelf life less than that called for in the contract?</li> </ul>
Compliance to contract financial terms	<ul style="list-style-type: none"> <li>• Did all invoices comply with contract pricing terms?</li> <li>• Were all shipments correctly insured and shipped according to financial terms in the contract?</li> <li>• Were there any problems obtaining compensation or reimbursement for lost or damaged goods?</li> </ul>

Quality	
Injection equipment product and safety boxes	<ul style="list-style-type: none"> <li>• Have validated complaints been received concerning product quality for this supplier?</li> <li>• Did the supplier cooperate in making sample and quality control tests performed by independent agencies available?</li> </ul>
Packing materials	<ul style="list-style-type: none"> <li>• Were there specific examples of loss due to damage to packaging during shipments?</li> <li>• Did the external packaging protect the product from damage during transport within the country?</li> </ul>

## **Appendix 9: Resources for standard bidding documents**

Standard Bidding Document for the procurement of health sector goods and its companion Technical Note are available on the Internet at :

<http://www.worldbank.org/html/opr/procure/healthdocs.html>

Procurement under IBRD loans and IDA Credits is available on the Internet:

<http://www.worldbank.org/html/opr/procure/guidelin.html>

Management sciences for health (MSH) , Managing the tender process. Managing drug supply, second edition, chapter 16.

<http://www.msh.org>

WHO/GPV. Procurement of vaccines for public-sector programmes: A reference manual, Vol. 1&2, Geneva, Switzerland: WHO, 1998.

[http://www.who.int/vaccines-access/Vaccines/Vaccine\\_Supply/PDF\\_Proc\\_Manual/03-9848.pdf](http://www.who.int/vaccines-access/Vaccines/Vaccine_Supply/PDF_Proc_Manual/03-9848.pdf)

Operational issues in the procurement of essential drugs and medical supplies, WHO Drug Information 2000, Vol.14, No. 3: 168-80.

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- <sup>2</sup> Hauri A, Armstrong G, Hutin Y. The Global Burden of Disease Attributable to Contaminated Injections Given in Health care Settings. Comparative Risk Assessment. WHO, Book in press.
- <sup>3</sup> WHO. Managing an injection safety policy. Department of Blood Safety and Clinical Technology, final draft. February 2003
- <sup>4</sup> Dicko M, Oni A-Q Q, Ganivet S, Kone S, Pierre L, Jacquet B. Safety of immunization injections in Africa: not simply a problem of logistics. Bulletin of the World Health Organization 2000; 78: 163-9.
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- <sup>6</sup> WHO. Report on the 12<sup>th</sup> Expert Committee on the Selection and Use of Essential Medicines, WHO Technical Report Series, WHO Geneva, 2002.
- <sup>7</sup> WHO. Leading the health sector response to HIV/AIDS. HIV/AIDS department, September 2002. WHO/HIV/2002.16.
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# WHO template procurement specifications for sterile hypodermic syringes for single use including a reuse-prevention feature

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# WHO template procurement specifications for sterile hypodermic syringes for single use including a reuse-prevention feature \*

8 November 2002

*The syringes will meet ISO standard 7886-1 on sterile hypodermic syringes for single use unless specified otherwise in this document.*

## **Type and application**

- Non-prefilled, single-use syringes for general purpose.
- Including a reuse prevention feature, i.e., a feature that activates after intended use to prevent subsequent reuse of the syringe.<sup>†</sup>

## **Nominal capacity**

1.0 ml, 2.0 ml, 3.0 ml, 5.0 ml or 10 ml.

## **Reuse-prevention feature**

The syringe will include a feature that prevents subsequent reuse.

**a. For syringes that will not allow reconstitution and subsequent injection with the same syringe,** the syringe shall be passively and automatically rendered unusable following completion of its intended use. No secondary or additional action on the part of the user shall be required. The syringe may not be re-filled beyond the limits set for aspiration either by withdrawal of the plunger (<100N) nor by liquid back pressure through the needle (<300kPa) when a full dose of liquid has been delivered.

**b. For syringes that will allow reconstitution and subsequent injection with the same syringe,** it shall be possible to voluntarily inactivate the syringe after completion of its intended use or the syringe shall be passively and automatically rendered unusable following completion of its intended use. After inactivation, the syringe may not be re-filled beyond the limits set for aspiration either by withdrawal of the plunger (<100N) nor by liquid back pressure through the needle (<300kPa).

## **Resistance to shock and shipping**

There shall be no effect on the performance of the syringe after it has been dropped in its single unit packaging from a height of one metre onto a concrete surface. In addition, there will be no effect on the performance of the syringe when tested in accordance with ASTM D

\* Auto-disable syringes for immunization are excluded from these specifications.

<sup>†</sup> Syringes designed to reduce the risk of needlestick injuries may also comply with the present specifications with regard to their reuse prevention feature. However, anti-needlestick properties of syringes are not in themselves addressed in these specifications.

99/01 and ASTM D/5276/98. This means no premature activation of the reuse-prevention feature or any other damage that could affect the safe use of the product.

### ***Needle***

The syringe will have an integrated needle or non-integrated needle.

- **For syringes with integrated needle:** fixed needle should have a minimum needle union force applied as pull in the direction of the needle axis in accordance with ISO 7864:1993.
- **For syringes with non-integrated needle:** once fixed, the needle cannot be removed again and should become an integral part of the syringe.

### ***Bubble exclusion***

Excessive air bubbles introduced during filling will be easily moved to the top of the barrel by flicking the finger-nail against the barrel and then expelled by depressing the plunger.

### ***Aspiration for blood***

When the syringe is filled with liquid to the maximum graduated capacity, sufficient flexibility will be provided to enable the plunger to be withdrawn sufficiently to check for the presence of blood. Aspiration will be possible at any position of the plunger within the graduated range.

# A Guide for the Quality Assurance of Single use Injection Equipment

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## A GUIDE FOR THE QUALITY ASSURANCE OF SINGLE USE INJECTION EQUIPMENT



Final - 17 February 2003

This document was prepared for the WHO Department of  
Blood Safety and Clinical Technology by:

Michael Cheng

145 Carleton Ave  
Ottawa, Canada K1Y 0J2  
Phone/fax: 1 613 722 3344  
Email: [cheng@sympatico.ca](mailto:cheng@sympatico.ca)

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## **ACKNOWLEDGEMENTS**

The author would like to thank the regulatory authorities of the founding members of the Global Harmonization Task Force (GHTF) and the International Association of Safe Injection Technology (IASIT) for their contributions in developing this guide.

# 1 OBJECTIVE

This guide is intended to aid procurement officers who wish to purchase single use injection equipment on a national market or an international market. It is constructed around three components. First, it provides an overview of the relevant standards available and the current regulatory requirements. Second, it recommends a checklist of essential information that must be obtained from potential suppliers about the proposed products. Third, it provides a flow-chart to check information and guide decision-making in terms of product quality.

This guide focuses on sterile hypodermic syringes and needles for single use. Devices included are:

- Conventional single use syringes and needles;
- Single use syringes and needles with features to guard against needle-stick;
- Auto-disable single use syringes and needles.

# 2 BACKGROUND INFORMATION

The means to ensure the safety and performance of injection equipment include standards and national regulations. In general, standards are voluntary while regulations are mandatory. Regulations, however, can make certain standards mandatory. In addition, purchasers may also have their own specifications that a product must fulfill (e.g., a purchaser may only want syringes of a certain volume or a certain feature such as auto-disable).

There are different types of standards and they cover a wide range (e.g., private, public, organizational, regional, national and international standards). As global health care products, single use injection equipment normally follows international standards. In this guide only the product standards and the quality system standards will be referred to. Product standards describe characteristics for general safety and performance of the product (Table 1). Quality system standards (see Table 2) provide the essential elements and requirements that a manufacturer should have in place to ensure that the quality of products manufactured is consistent.

The government authorities of the country in which a product is manufactured or imported usually enforce regulations. However, many countries do not yet have regulations for medical devices, although some are in the process of establishing such regulations. While this is encouraging, a proliferation of different national regulations can hinder access to technology and thus should be avoided. The Global Harmonization Task Force (GHTF) ([www.ghtf.org](http://www.ghtf.org)) aims at harmonizing regulatory requirements and practices based upon essential principles and common criteria. GHTF recommendations provide a useful reference to assist countries in the development of medical device regulations.

This guide is based upon the regulatory requirements for single use syringes/needles of the five founding members of the GHTF. These are Australia, Canada, the European Union, Japan and the United States. Although many countries that are capable of manufacturing single use syringes have no established regulatory systems, it is anticipated that the global market will lead them to follow the recommendations of the GHTF.

## 2.1 Standards

### 2.1.1 Product standards

Table 1 lists the current international standards governing injection equipment that are recognized by Australia, Canada, the European Union, Japan and the United States of America, the five founding members of the GHTF.

Table 1: International standards for single use syringes and needles \*

1	ISO 7864	Sterile hypodermic needles for single use
2	ISO 7886-1*	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
3	ISO 7886-2	Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps
4	ISO 8537	Sterile single use syringes, with or without needle, for insulin

\* Standards for auto-disable syringes (ISO 7886-3 for fixed dose immunization and ISO 7886-4 for general purpose) are being developed and should be available soon.

### 2.1.2 Additional specifications

In addition to product standards, purchasers may specify the characteristics of the product they want to purchase through other procurement specifications (e.g., volume, type of syringe, safety devices). WHO procurement specifications for auto-disable (AD) syringes for immunization (WHO/EPI/LHIS/97.11) and for general purpose (WHO/BCT/02.12) constitute an example. While the standard for auto-disable syringes for fixed dose immunization (ISO 7886-3) is being developed, WHO specifies the technical characteristics of the auto-disable syringes that should be purchased by UNICEF for use in immunization programs worldwide.

### 2.1.3 Quality system standards

Quality systems are defined as the organizational structure, responsibilities, procedures, processes and resources needed to implement quality management (see Section 2.2.2). The quality system standards used by the five founding members of GHTF are listed in Table 2.

Table 2: Quality system standards of the five founding members of the GHTF

Country	Quality system standards
Australia	ISO13485 or EN46001, ISO13488 or EN46002
Canada	ISO13485, ISO13488
European Union	EN46001, EN46002, ISO13485, ISO13488
Japan	GMP (QS Standard for medical devices #1128)
United States	QS (21 CFR part 820)

\* Standards for auto-disable syringes (ISO 7886-3 for fixed dose immunization and ISO 7886-4 for general purpose) are being developed and should be available soon.

Note: EN46001 and EN46002 will be phased out by the end of March 2004

## **2.2 Regulatory requirements.**

### *2.2.1 Product safety and performance*

All medical devices (including injection equipment) must comply with the essential principles of safety and performance in design and construction recommended by the GHTF (ref. GHTF document SG1-N02R5)\*. The GHTF recommends a risk management approach in medical device regulations. Medical devices are classified from the lowest risk, class I, to the highest risk, class III or IV (ref. GHTF document SG1-N015R14). The higher the risk –class, the more regulatory scrutiny there is before a product is placed on the market. The GHTF founding members classify injection syringes and needles as class II products (Appendix B ).

#### 2.2.1.1 Conformity with product standards

Conformity with international standards (Table 1) is voluntary for partial fulfillment of the essential principles of safety and performance. Manufacturers, however, can choose other means to demonstrate fulfillment of regulatory requirements. Nevertheless, the majority of manufacturers follow available international standards as a convenient and effective way to comply with regulatory requirements.

### *2.2.2 Consistency in product quality*

Consistency in the quality of the product is ensured by mandating that the manufacturing processes meet quality system standards or "Good Manufacturing Practices". Quality systems are audited by the government or third-party agencies depending on the country. Since most medium to low risk medical devices are relatively simple in design, once the design has been validated to demonstrate fulfillment of regulatory requirements for safety and performance, quality systems in manufacturing become the principal safeguard for consistency in product quality.

### *2.2.3 Packaging and labeling of products*

Adequate packaging and labeling are also regulatory requirements (ref: GHTF document SG1-N009R6). In general, for syringes and needles, the packaging must retain the sterility of the content. Labeling serves to communicate safety and performance related information to users and patients as well as to identify individual devices. Specific packaging and labelling recommendations are given in the product standards listed in Table 1.

\* GHTF documents can be obtained free of charge from [www.ghf.org](http://www.ghf.org)

## 2.3 Marketing clearances

The marketing clearances for the five founding members of the GHTF are listed in Table 3. They signify product compliance with regulatory requirements.

Table 3: Marketing clearances by regulatory authorities

Regulatory authority	Australia (new legislation)	Canada	European Union	Japan	United States
Marketing clearance	GMPALS License or CE Mark	Device license	CE mark *	Device license	510k device letter
Web site checking of marketing clearance †	Awaiting	Yes	Awaiting	Yes ‡	Yes

In summary, for single use syringes and needles, the regulations in these countries ensure that the general requirements for safety and performance are met, that the quality systems for manufacturing are followed, that the packaging is secure and that the labeling is clear. They do not, however, address any special needs for individual device applications. For example, at present, the standard ISO7886-1 commonly adopted by manufacturers covers a wide range of single use syringes of different capacities and needle gauges as well as a guard against needle-stick or auto-disable after use. As certain special needs become more common, the development of international standards follows. ISO 7886-3 (auto-disable syringes for fixed dose immunization) and ISO 7886-4 (auto-disable syringes for general purpose) are being developed.

## 3 RECOMMENDATIONS FOR PURCHASING SPECIFICATIONS

Calls for tender or purchase orders should specify (1) the product standards that are required,(2) other procurement specifications that the purchaser wishes to apply, (3) the quality system standards that are required and (4) essential information required for product selection.

### 3.1 Product standards

It is recommended to ask for products that conform with the applicable ISO standards for products listed on Table 1.

\* The CE mark is not a permit issued by an external authority but a declaration by the manufacturer of product conformity with regulatory requirements. It is important to verify that an accredited Notified Body has done conformity assessment and that the identification number is on the CE marking.

† See appendix A.

‡ Available in Japanese language only.

### **3.2 Additional specifications**

Special features of the required products must be clearly stated in the purchasing specifications. Make sure that any such additional specifications do not conflict with international standards.

### **3.3 Quality system standards**

It is recommended to ask for products that are manufactured in conformity with one of the quality system standards listed on Table 2 that are required by the GHTF founding members.

It should be noted that the ISO13485 and ISO13488 standards have recently been specified by regulatory authorities while the ISO9001 and ISO9002 standards have been in common use worldwide. To allow a phase-in period (till July 2004), manufacturers registered with ISO9001, ISO9002, ISO9001:2000 should be accepted as having quality systems in place. However, preference should be given to products from manufacturers registered with ISO13485 / ISO13488 if other value indicators are equal.

The ISO9001 and ISO9002 standards are for general application for products or services. The ISO13485 and ISO13488 standards are for the medical device industry. ISO13485 includes all the elements of ISO9001 plus a minimum set of supplementary requirements for the quality assurance of medical device manufacturing (see Appendix C ). The same relationship exists for ISO13488 and ISO9002. ISO13488 is equivalent to ISO13485 but without the design control requirements.

### **3.4 Essential information required for product selection**

It is recommended to ask the potential suppliers to complete the checklist for product information provided in Table 4 by following the accompanying instructions.

## **4 RECOMMENDATIONS FOR PRODUCT SELECTION**

It is recommended to use the flow-chart provided in Figure 1 to qualify proposed products for selection. Two categories of qualified products are:

1. Track 1: Clearance by a founding member of the GHTF

Products that comply with regulatory requirements of at least one of the founding members of the GHTF and that also satisfy other procurement specifications.

2. Track 2: Clearance by alternative means

Products that are manufactured in conformity with acceptable quality system standards and specified product standards and that also satisfy additional specifications.

### **Comparison of products**

All factors including price, post-market evaluation or any special features must be taken into consideration. Technical expertise is required in evaluating incident reports; it is not the number of reports that is the indicator of quality but the seriousness of the incidents that counts.



Table 4: Checklist of product information

Information item		Details				Remarks	
Item short description	Status* and Name	Address	Phone and Fax	Contact person for quality assurance	Web-site, e-mail		
1	<input type="checkbox"/> Brand name						
2	<input type="checkbox"/> Vendor						
3	<input type="checkbox"/> Manufacturer						
	<input type="checkbox"/> Manufacturing site (Origin of goods)						
4	<input type="checkbox"/> Parent company (if any)						
		<b>Regulatory authority (check all applicable)</b>	<b>Number (provide number)</b>	<b>Device name as submitted to authorities</b>			
		<input type="checkbox"/> Australia	License number:				
		<input type="checkbox"/> Canada	License number:				
		<input type="checkbox"/> European Union	CE mark number:				
		<input type="checkbox"/> Japan	License number:				
		<input type="checkbox"/> United States	510(k) number:				
		<input type="checkbox"/> Other, specify:					
5	<input type="checkbox"/> Compliance with regulations						
		<b>Standards used (check applicable)</b>	<b>Assessment body† (name, country), (attached a copy of the certificate)</b>	<b>Last audit date</b>	<b>Expiration date</b>		
		<input type="checkbox"/> ISO13485 /ISO13488					
		<input type="checkbox"/> EN46001 / EN46002					
		<input type="checkbox"/> Japan QS Standard #1128					
		<input type="checkbox"/> United States QS (21 CFR part 820)					
		<input type="checkbox"/> ISO9001 /ISO9002					
		<input type="checkbox"/> Other, specify: (e.g. ISO9001:2000)					
6	<input type="checkbox"/> Conformity with quality system standards						
		<b>Standards used (check applicable)</b>	<b>Test laboratory‡ (name, country) (attached a copy of the certificate)</b>	<b>Laboratory accreditation body</b>			
		<input type="checkbox"/> ISO 7864 for needles					
		<input type="checkbox"/> ISO 7886-1 syringes for single use					
		<input type="checkbox"/> ISO 7886-2 syringes for power-driven pumps					
		<input type="checkbox"/> ISO 8537 for insulin					
		<input type="checkbox"/> Other standards, specify:					
		<input type="checkbox"/> Yes ( <b>check applicable</b> . If yes, please provide all reports including sources. Use additional pages if necessary)					
		<input type="checkbox"/> No					
7	<input type="checkbox"/> Conformity with product standards						
		<b>Standards used (check applicable)</b>	<b>Test laboratory‡ (name, country) (attached a copy of the certificate)</b>	<b>Laboratory accreditation body</b>			
		<input type="checkbox"/> ISO 7864 for needles					
		<input type="checkbox"/> ISO 7886-1 syringes for single use					
		<input type="checkbox"/> ISO 7886-2 syringes for power-driven pumps					
		<input type="checkbox"/> ISO 8537 for insulin					
		<input type="checkbox"/> Other standards, specify:					
		<input type="checkbox"/> Yes ( <b>check applicable</b> . If yes, please provide all reports including sources. Use additional pages if necessary)					
		<input type="checkbox"/> No					
8	<input type="checkbox"/> Post-market surveillance reports						
		<b>Standards used (check applicable)</b>	<b>Test laboratory‡ (name, country) (attached a copy of the certificate)</b>	<b>Laboratory accreditation body</b>			
		<input type="checkbox"/> ISO 7864 for needles					
		<input type="checkbox"/> ISO 7886-1 syringes for single use					
		<input type="checkbox"/> ISO 7886-2 syringes for power-driven pumps					
		<input type="checkbox"/> ISO 8537 for insulin					
		<input type="checkbox"/> Other standards, specify:					
		<input type="checkbox"/> Yes ( <b>check applicable</b> . If yes, please provide all reports including sources. Use additional pages if necessary)					
		<input type="checkbox"/> No					
9	<input type="checkbox"/> Other evaluation reports						
		<b>Standards used (check applicable)</b>	<b>Test laboratory‡ (name, country) (attached a copy of the certificate)</b>	<b>Laboratory accreditation body</b>			
		<input type="checkbox"/> ISO 7864 for needles					
		<input type="checkbox"/> ISO 7886-1 syringes for single use					
		<input type="checkbox"/> ISO 7886-2 syringes for power-driven pumps					
		<input type="checkbox"/> ISO 8537 for insulin					
		<input type="checkbox"/> Other standards, specify:					
		<input type="checkbox"/> Yes ( <b>check applicable</b> . If yes, please provide all reports including sources. Use additional pages if necessary)					
		<input type="checkbox"/> No					

\* Status: please provide the status as a vendor such as wholesaler, manufacturer, distributor, etc.

† E.g., Notified bodies in the European Union; Quality Systems Registrars in North America.

‡ Product testing must include sterility, packaging and labeling requirements.

*Instructions for completing Table 4 : Checklist of product information*

All potential suppliers (or original manufacturers) please fill in items 1,2,3,4,8,9. In addition,

- If a regulatory authority has cleared the device, fill in item 5.
- If a regulatory authority of the GHTF founding members has not cleared the device, fill in items 6 and 7.

**Item 1:** Please provide the brand name that is used on the market. If there is more than one name, please provide all names.

**Item 2 and item 3:** The vendor may also be the manufacturer. But if the addresses are different, please provide all information.

**Item 4:** If the manufacturer is a subsidiary of a parent company or is contracted from another company, please supply the necessary information. A parent company may be located locally or in another country.

**Item 5:** If there is more than one regulatory authority that has cleared the product, please check all applicable authorities and provide all clearance numbers with the corresponding device names as they were submitted to the regulatory authorities. The device name submitted to the regulatory authorities, which may be different from the brand name, is necessary for verification of marketing clearance by the relevant regulatory authorities.

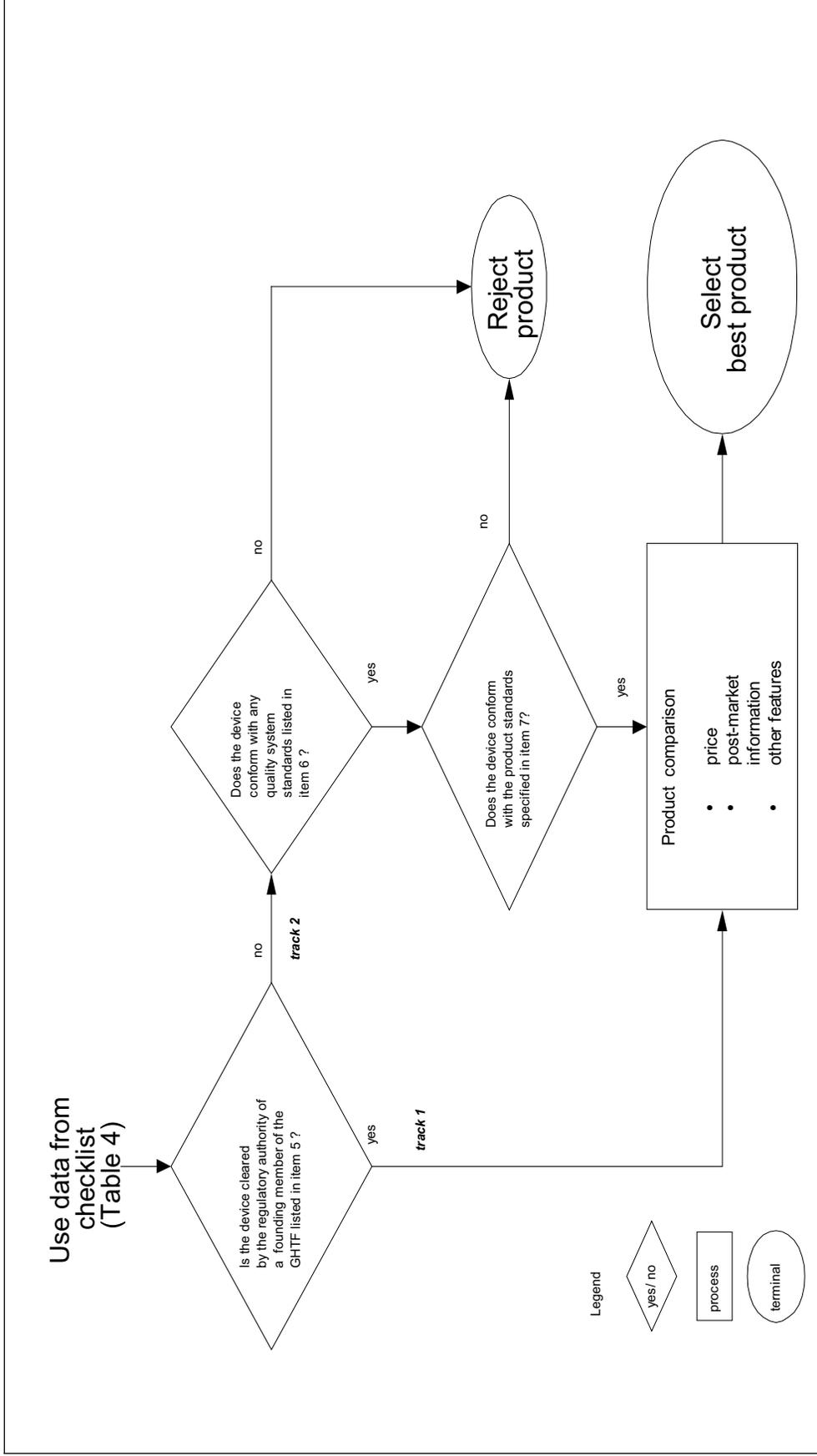
**Item 6:** Please confirm the applicable standard. Quality system assessment must include: (1) whether the proposed product is manufactured under the quality system audited; (2) whether the appropriate international (ISO) standards for sterilization and packaging are used for Section 4.9 “process control”, (3) last audit date and expiration date of certificate. Maximum audit period must not exceed 12 months. Note that devices that are manufactured in conformity with ISO13485/88 will be given preference to those manufactured with ISO9001/02 or ISO 9001:2000.

**Item 7:** Please check all applicable standards with the corresponding test laboratories. Product testing must include sterility, packaging and labeling requirements. Indicate the accreditation status of the laboratories.

**Item 8:** Please provide all post-market surveillance reports by regulatory authorities, users or other parties and specify the sources.

**Item 9:** If available, provide any other third party evaluation reports.

Figure 1 – Flow chart (decision tree) for product selection



*Instructions for using the flow chart for product selection (Figure 1)*

Please make sure the checklist (Table 4) is correctly completed. Follow the flow chart (Figure 1) for product selection.

**Track 1.** If there are no applicable local national regulations, and if the proposed product has marketing clearance from one or more of the five GHTF listed authorities (item 5), this product can be accepted as a candidate for product selection. You may be able to verify the regulatory clearance on the Internet, if available. (See Table 3 and Appendix A)

**Track 2.** If the proposed product has not been submitted to any of the five listed authorities, then it is necessary to assure that:

1. the manufacturer has a quality system in place (any one of the systems listed under item 6 is acceptable),
2. the proposed product conforms with specified product standards (item 7) and all additional specifications. You may verify the accreditation status of the test laboratory by following the information given by the International Laboratory Accreditation Cooperation (ILAC) (see Appendix A).

If both quality system standards and product standards are satisfactory, the proposed product can be accepted as a candidate for product selection.

If the proposed product is manufactured with an acceptable quality system, but either the conformity of the proposed goods with specified product standards or any additional specifications have not been certified by an accredited laboratory of any founding member of the GHTF, an option is to submit the proposed product to the Force Institute for testing. The expense for this testing will be charged to the potential supplier. If the proposed product passes the laboratory test, then it can be accepted as a candidate for product selection.

**Note:** The ISO9001 and ISO9002 standards are for general application for products or services. The ISO13485 and ISO13488 standards are for the medical device industry. ISO13485 includes all the elements of ISO9001 plus a minimum set of supplementary requirements for the quality assurance of medical device manufacturing (see Appendix C ). The same relationship exists for ISO13488 and ISO9002. ISO13488 is equivalent to ISO13485 but without the design control requirements.

The ISO13485 and ISO13488 standards have recently been specified by regulatory authorities while the ISO9001 and ISO9002 standards have been in common use worldwide. To allow a phase-in period (till July 2004), manufacturers registered with ISO9001, ISO9002, ISO9001:2000 should be accepted as having quality systems in place. However, preference should be given to products from manufacturers registered with ISO13485 / ISO13488 if other value indicators are equal.

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## APPENDIX A VERIFYING REGULATORY COMPLIANCE

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**Australia license listing.** Currently not available on the Internet.

Mailing address: Conformity Assessment Branch  
Therapeutic Goods Administration  
PO Box 100, Woden, ACT, 2609, Australia

**Canada license listing.** Open the Web page at address:

[http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guides/meddev/lic020103\\_e.pdf](http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guides/meddev/lic020103_e.pdf)

Download **Acrobat Reader** if you do not already have it in the computer.

On the tool bar, click on the “Find” icon (binocular) to verify the device listing. In order of speed, the following keywords can be use for the search:

- Device License Number
- Registered device name
- Company name
- Use words such as “syringe”, “single use”...The word must be part of the registered device name

N.B. (1) the search starts from current page and stops at first item that matches the entire word or number being searched. For example, if you start to search the Device License Number 4243 at the beginning of the database, it will stop at 14243 if 14243 is listed before 4243. At this point, you have to click “Find again” to continue the search for 4243 until the end of the database. (2) If you start the search at a current page that comes after the target is listed, it will arrive at the end of database and tell you that the device is not found. Then you have to start search from the beginning page of the database.

Only license number, risk class, device name, registering manufacturer’s name are provided; other information about the device is currently not available from the Web.

**CE Marks.** Currently not available on the Internet. Please check again with the European Community if any progress has been made.

**Japan license.** The Japan Association for the Advancement of Medical Equipment operates a website (<http://www.jamme.or.jp>) providing services for searching approved medical device licenses. This service, however, can only be assessed through members paying annual fees.

**FDA device listing.** Open the Web page at address:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

A search table will appear. Enter official device name or 510k number, and then clicking on the search button will reveal whether the device is listed.

Alternatively, enter the parent company name, and then clicking on search will result in a listing of all 510k-cleared products of the company. FDA listing will provide details about the company, and in some cases statements about the products.

## Post-market vigilance information

**Australia** Internet site: [www.health.gov.au/tga](http://www.health.gov.au/tga). Click on the “recall” button.

**United Kingdom** Internet site: [www.medical-devices.gov.uk](http://www.medical-devices.gov.uk) Click on the “incident reports” button.

**United States FDA** Internet sites:

[Manufacturer and User Facility Device Experience Database \(MAUDE\)](#) represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.

Open the web page at address

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm>

A search table will appear. Enter official device name or 510k number, and then click on the search button will confirm whether the device has any post-market information.

[Medical Device Reporting Database \(MDR\)](#) allows you to search the database of the Center for Devices and Radiological Health (CDRH) for information on medical devices which may have malfunctioned or caused a death or serious injury during the years 1992 through 1996.

Open the web page at address

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.CFM>

A search table will appear. Enter official device name or parent company name, and then click on search button will confirm whether the device has any mandatory post-market Medical Device Reports.

**ECRI** (the Emergency Care Research Institute) also has a database on medical device alerts (HDA). This service, however, can only be assessed through members paying an annual fee. The website is [www.ecri.org](http://www.ecri.org)

## ILAC International Laboratory Accreditation Cooperation

Laboratory Accreditation provides formal recognition to competent laboratories. An international guide, called ISO/IEC Guide 25, describes the basis for the accreditation of a country's testing and calibration laboratories. Adoption of this international guide has helped countries adopt a uniform approach to determining laboratory competence.

To find accredited laboratories around the world, open the web page <http://www.ilac.org/> Click “the “Directory” button will result in a world map and instructions to find members in different regions and their addresses or websites for communications. Enquiries can then be made to regional authorities for further information about accredited laboratories.

## APPENDIX B SUMMARY OF REGULATORY REQUIREMENTS

Table 5: Requirements in the five founding members of the GHTF

	Australia Under the proposed new legislation	Canada	European Union	Japan	United States
Regulation	Yes	Yes	Yes	Yes	Yes
Device Class	Ila	II	Ila	II	II special control
Safety and effectiveness	Yes	Yes	Yes	Yes	Yes
Recognized device & test standards *	5 standards	Manufacture declaration	5 standards	1 standard	9 standards
Labeling	yes	Yes	Yes	Yes	Yes
Quality systems for manufacturing	ISO 13488 or ISO 13485	ISO13488	EN46002	GMP based on ISO13485	QS (21CFR part 820)
Quality systems audit	Government and 3rd Party	3rd party	3rd party	Government	Government
Pre-market review or conformity assessment	Review by TGA	Vendor attestation of compliance to Health Canada	Conformity assessment by a Notified Body. Special requirements depend on individual state	Review by MHLW (Ministry of Health & Labor Welfare)	510k review by FDA or accredited person †
Marketing permit	GMPALS License or CE Mark	Device license	CE mark	Device license	510k device letter
Website verification of marketing permission	Not presently	Yes	Not presently	Yes, but Japanese language only	yes

\* Conformity with recognized standards are voluntary. Manufacturers can choose other means to satisfy safety and effectiveness requirements.

† A person or an organization in any country may apply for accreditation by FDA. This accredited person can do the 510K reviews but not the quality system inspection. At present, quality systems audits must be done by FDA.

Table 6: Australia, Canada and the European Union recognized standards

	<b>Standards</b>	<b>Title</b>
1	ISO 6009	Hypodermic needles for single use - Color coding for identification
2	ISO 7864	Sterile hypodermic needles for single use
3	ISO 7886-1	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
4	ISO 7886-2	Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps
5	ISO 8537	Sterile single use syringes, with or without needle, for insulin

Table 7: FDA recognized standards

	<b>Standards</b>	<b>Title</b>
1	ISO 6009	Hypodermic needles for single use - Color coding for identification
2	ISO 7864	Sterile hypodermic needles for single use
3	ISO 7886-1	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
4	ISO 8537	Sterile single use syringes, with or without needle, for insulin
5	ISO 594	Conical fittings with Luer taper
6	ISO 9626	Stainless steel needles
7	ANSI/HIMA	Luer taper
8	Military Std	MIL-S-36157 or later edition
9	ASTM	for stainless steel tubing testing

Table 8: Japan recognized standards

	<b>Standards</b>	<b>Title</b>
1	Notification No. 1079 of Japanese MHLW	Standard for Sterile Hypodermic Syringe

Note: The above standard partly refers to following ISO and Japanese standards.

- ISO 7886-1 Sterile hypodermic syringes for single use - Part 1: Syringes or manual use
- ISO 594 Conical fittings with Luer taper
- The Standard for Silicone Oil as A Lubricant for Use in Medical Devices (I) (Notification No.327 of Japanese MHLW)
- Japanese Pharmacopoeia
- Guidelines for basic biological tests of medical materials and devices based on ISO 10993-1 (Notification No.99 of Japanese MHLW)
- Standard for Sterilization Validation based on ISO and EN (Notification No.1 of Japanese MHLW)

## APPENDIX C ISO9001:1994 AND ISO13485:1996 RELATIONSHIP

**Quality System requirements** are specified in the standard ISO9001 for the twenty main elements (4.1 to 4.20) listed under the ISO9001 column. Additional requirements for medical devices are listed under the ISO13485 column. An updated stand-alone ISO13485 is being developed to be the sole international quality system standard for regulatory purposes with medical devices.

For sterile products, the conformity with applicable international (ISO) standards on sterilization and packaging is the audit responsibility under 4.9 “process control”.

Table 9: ISO 9001 and ISO 13485 relationship (main sections only)

	ISO 9001:1994	ISO 13485:1996
3	Definitions of ISO 8402 + 2 additional ones	Same as ISO 9001 + 8 additional definitions
4.1	Management Responsibility	Same as ISO 9001
4.2	Quality System	4.2.1 Establish and document specified requirements 4.2.3 Specification and quality system requirements for each model
4.3	Contract Review	Same as ISO 9001
4.4	Design Control	4.4.1 Evaluate needs for risk analysis and maintain records 4.4.8 Clinical evaluation in design validation
4.5	Document and data control	4.5.2 Obsolete documents retained for lifetime of device
4.6	Purchasing	4.6.3 Traceability in 4.8 applies
4.7	Control of Customer Supply Product	Same as ISO 9001
4.8	Production identification and traceability	4.8 Procedures for returned devices and for traceability to facilitate corrective and preventive action
4.9	Process control	4.9 Personnel, environment, cleanliness, maintenance, installation and software-related requirements
4.10	Inspection and testing	4.10.5 Identify personnel
4.11	Control of Inspection, Measuring and Test Equipment	Same as ISO 9001
4.12	Inspection and Test Status	Same as ISO 9001
4.13	Control of non-conforming product	4.13.2 Regulatory requirements have precedence
4.14	Corrective and preventive action	4.14.1 Complaints and feedback system regarding problem investigation, advisory notice, etc.
4.15	Handling, storage, packaging, preservation and delivery	4.15.1 Control for product with limited shelf life 4.15.4 Identify personnel performing labeling 4.15.6 Identify shipping package consignee
4.16	Quality record	4.16 Retention of records, for lifetime of product, but not less than 2 years
4.17	Internal Quality Audit	Same as ISO 9001
4.18	Training	Same as ISO 9001
4.19	Servicing	Same as ISO 9001
4.20	Statistical Techniques	Same as ISO 9001

## APPENDIX D RESOURCES

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1. WHO Product Information Sheets 2000 Edition.  
Section 8 Equipment for administration of vaccine and micronutrients.  
WHO/V&B/00.13 ORIGINAL: ENGLISH DISTR.: GENERAL (PIS)
2. WHO injection safety toolbox at [www.who.int/injection\\_safety](http://www.who.int/injection_safety)
3. Safe Injection Manual. PATH Technologies for Immunization.  
[http://www.path.org/technos/ht\\_safe\\_injection\\_manual.htm](http://www.path.org/technos/ht_safe_injection_manual.htm)
4. Single use medical products price guide: ECRI <http://www.ecri.org>
5. Weekly e-mail newsletter of the Safe Injection Global Network (SIGN) [[sign@who.int](mailto:sign@who.int)]
6. International Association of Safe Injection Technology: <http://www.iasit.org>
7. The Global Alliance for Vaccines and Immunization. <http://www.vaccinealliance.org>

## APPENDIX E FEEDBACK QUESTIONNAIRE

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Your comments and suggestions will be greatly appreciated. They may be sent to the World Health Organization, Department of Blood Safety and Clinical Technology, Avenue Appia 20, 1211 Geneva 27, Switzerland. Fax +41 22 791 4836. E-mail: sign@who.ch.

1. Is this guide easy to understand?

Very dissatisfied	Dissatisfied	Neutral	Satisfied	Very satisfied
1	2	3	4	5

Specific comments

2. Did you identify any imprecision and / or inaccuracies?

3. Has this guide achieved its objectives? (Does this guide provide sufficient guidance to a non-specialized purchasing agent to make decision about the quality of proposed products)?

4. What other information do you think should be included in this guide?

5. Do you use single use injection syringes?

6. In what way are you involved with purchasing single use injection syringes?

7. What is the percentage (%) of injection equipment currently accepted that would now be rejected following the guide recommendations?

8. Please give an overall rating on this guide.

Very dissatisfied	Dissatisfied	Neutral	Satisfied	Very satisfied
1	2	3	4	5