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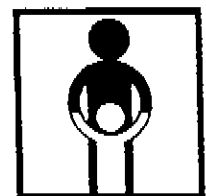
Original: English

Distr.: General

REDUCING THE RISK OF UNSAFE INJECTIONS IN IMMUNIZATION PROGRAMMES

The role of injection equipment

*Adapted version.





LOGISTICS FOR HEALTH INFORMATION SERIES

Ordering Code: WHO/EPI/LHIS/94.2

Printed December 1994

Note: This document is based on an article by Bruce Aylward *et al.* accepted for publication in the *Bulletin of the World Health Organization*. It has been adapted with the author's approval for reproduction as a document in the Logistics for Health Information Series. Reprints of the original article are available from WHO/EPI.

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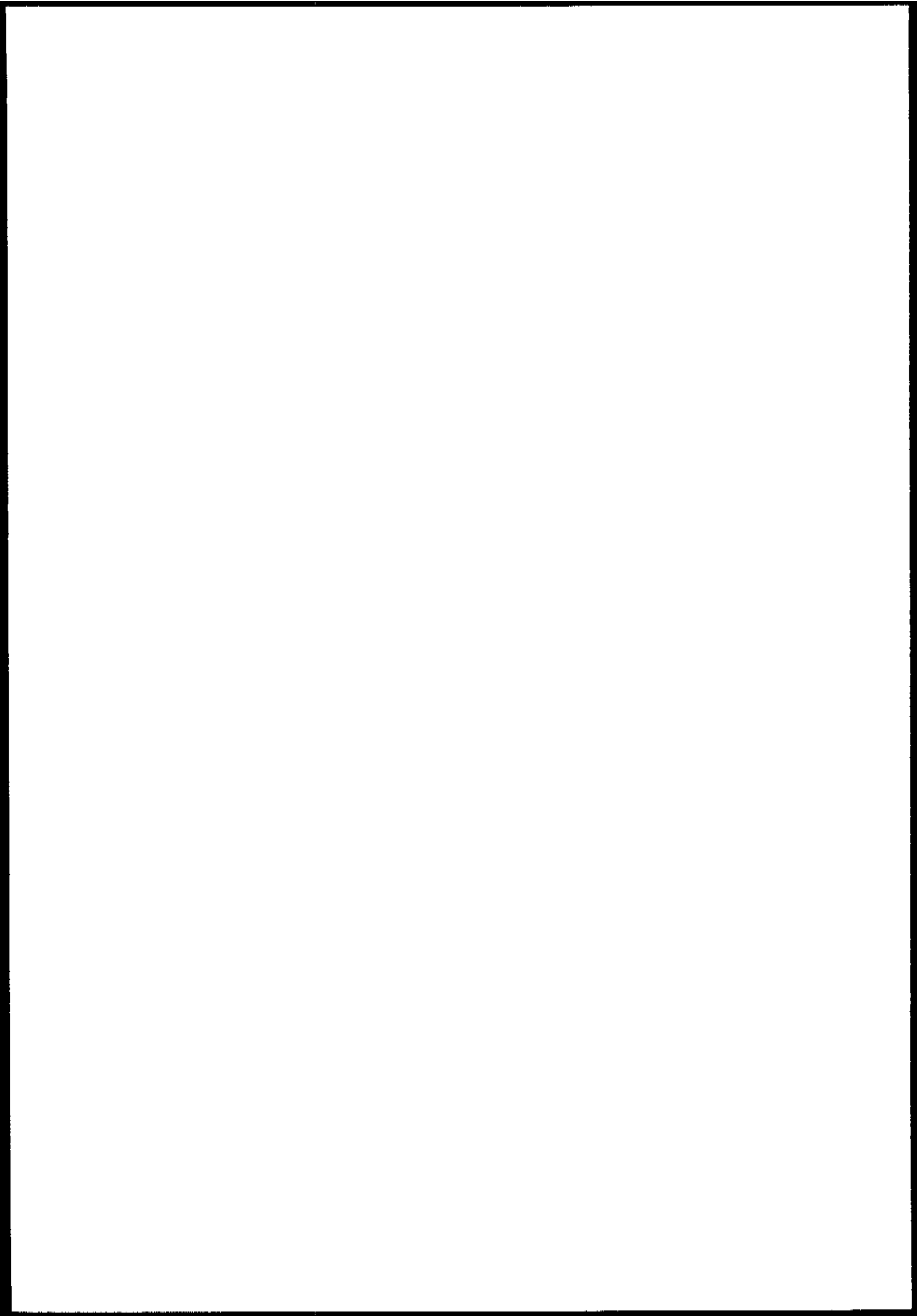
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1. INTRODUCTION

Unsterile medical practices continue to contribute to the transmission of diseases such as human immunodeficiency virus (HIV) and hepatitis B, despite advances in injection equipment and a better understanding of the risks of cross infection.

The problem is potentially greatest in developing countries as more injections are given and the prevalence of bloodborne diseases is higher. Every year the Expanded Programme on Immunization (EPI) administers over 550 million injections in developing countries. Even if this number comprises only a fraction of all injections given, safety must be a leading concern.

The spread of HIV has highlighted the need to ensure that individuals are only exposed to those injections which are necessary and safe. Injections for immunization *are* necessary -- they must be safe. Incorrect immunization practices continue to occur *despite* EPI's longstanding policy that "a single sterile needle and a single sterile syringe should be used with each injection".

To perform safe immunizations, the health care worker requires:

- a knowledge of correct sterilization, immunization and disposal procedures,
- the motivation and supervision to properly perform these procedures, and
- an adequate supply of appropriate injection equipment.

EPI has previously developed a wide range of materials on health care worker training and supervision. The purpose of this document is to:

- briefly review the complications of unsafe injections,
- present the different types of injection equipment,
- examine the potential risk of transmitting bloodborne organisms with each type of equipment,
- discuss the financial and operational implications of using each type of equipment.

2. COMPLICATIONS OF UNSAFE INJECTION PRACTICES

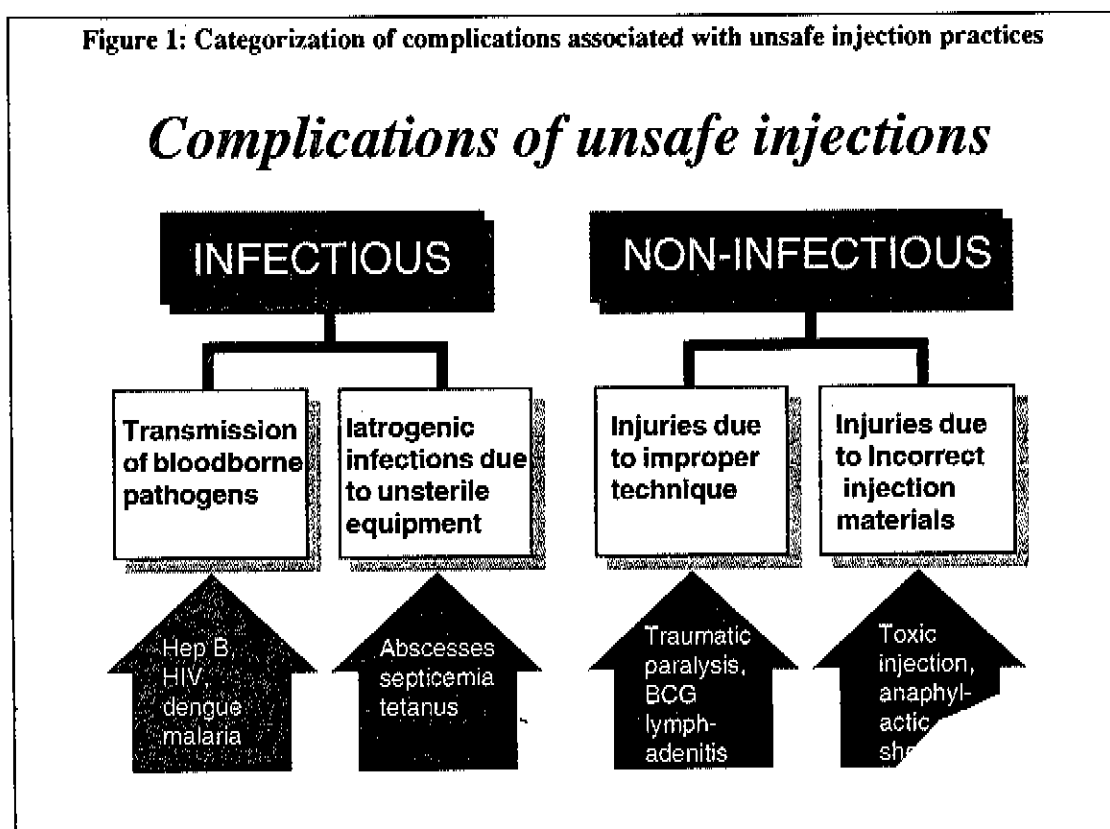
Immunization injections are only safe when the correct vaccine is properly administered with sterile equipment that is subsequently safely disposed of.

Unsafe injections can result in infectious and non-infectious complications (see Figure 1).

Infectious complications probably account for the majority of injection-associated. The risk of transmitting a bloodborne disease depends on:

- * the local injection practices,
- * the number of injections an individual receives, and
- * the prevalence and transmissibility of the bloodborne organisms.

Figure 1: Categorization of complications associated with unsafe injection practices



Who is affected?

Patients, health care workers and the general community are at risk of contracting an infectious disease through unsafe injection practices. Bloodborne diseases may be transmitted from patient to patient, patient to health care worker (HCW) and patient to the general community.

- **Patient to patient** transmission results primarily from injections with contaminated equipment.
- **Patient to health care worker** cross infection is usually due to needlestick injuries to health care workers. Such injuries can occur when the health care worker is:
 - * cleaning sterilizable needles,
 - * recapping used disposable needles or
 - * improperly disposing of either.

A study in Pakistan found that up to 1% of immunization workers experienced a needlestick injury during each clinic session.

- **Patient to community** transmission can occur when used injection equipment is not properly disposed of by burning. Members of the general community may suffer accidental needlestick

injuries or be exposed to the re-use of contaminated equipment within or outside the formal medical sector.

A high prevalence of unsafe injections and their complications has been documented throughout the world, particularly in developing countries. A study in West Africa estimated that 231 per 100,000 people in the local community suffered from abscesses caused by unsafe injections each year. In an East African country, 134 out of 360 households in an injection practices survey reported that at least one family member had developed an abscess following a recent medical injection.

3. REDUCING THE RISK DUE TO EQUIPMENT MISUSE

3.1. *Equipment selection and supply*

A comprehensive strategy is required to minimize the risk of injection-associated infections. An important component of this strategy is the selection and supply of appropriate equipment. This is as critical to the overall safety of an immunization programme as the existence of a clear policy, proper training and effective supervision (see Table 1)

EPI recommends a range of injection and sterilization equipment and outlines the critical steps for safe use in the World Health Organization policy document "Safety of Injections in Immunization Services"¹.

Incorrect use of any of the available equipment can result in the transmission of disease. The potential for misuse, however, varies significantly with the type of equipment.

Choosing the appropriate equipment should include consideration of:

- its **potential** for misuse resulting in unsafe injection practices,
- factors such as **cost, feasibility, acceptability and supply.**

3.2. *Importance of appropriate equipment*

Unsafe injections continue to occur, even in settings where health workers have been properly trained. The only way to ensure safe injections may be to design equipment that cannot be misused. It is, however, expensive and operationally difficult to completely eliminate the risk to patient, health care worker and the general community. It is critical, therefore, that management personnel understand the reasons for non-compliance with safe practices in order to **ensure selection of the most appropriate equipment for each immunization setting.**

¹ Document reference WHO/EPI/LHIS/94.1.

Table 1²: Components of an immunization safe injection strategy

Components	Principal Activities
1. Baseline assessment	<ul style="list-style-type: none"> • Evaluate injection policies and existing practices. • Establish an inventory the existing injection, sterilization & disposal equipment. • Identify the obstacles to safe injections.
2. Selection of injection, sterilization and disposal equipment	<ul style="list-style-type: none"> • Choose equipment that minimizes the risk of misuse in each immunization setting. • Calculate the equipment needed to reach coverage targets and maintain a reserve stock. • Ensure proper facilities for sterilization and/or disposal of used equipment.
3. Budget and supply of the required equipment	<ul style="list-style-type: none"> • Estimate the capital & recurrent costs of injection, sterilization & disposal. • Develop an adequate budget for both capital and recurrent costs. • Ensure a supply & financing mechanism for adequate quantities of injection equipment.
4. Health worker training	<ul style="list-style-type: none"> • Teach the risks of unsafe injections. • Train health workers in the proper use of injection, sterilization and disposal equipment.
5. Clinic supervision	<ul style="list-style-type: none"> • Review and correct injection, sterilization and disposal practices. • Ensure adequate reserve stocks of injection and sterilization equipment.
6. Public education	<ul style="list-style-type: none"> • Generate an awareness of injection risks. • Create a demand for safe injections. • Promote the refusal of unsafe injections.
7. Monitoring of adverse events after immunization	<ul style="list-style-type: none"> • Determine whether complications are due to unsafe injection practices and take appropriate action.

² EPI Update: Taking Short Cuts in Injection Safety Costs Lives (1995).

4. INJECTION EQUIPMENT

It is convenient to divide immunization injection equipment into four categories:

- sterilizable needles and syringes,
- disposable needles and syringes,
- auto-destruct syringes, and
- jet injectors.

The requirements and 1994 unit costs for each technology are summarized in Table 2.

Table 2: Equipment requirements and unit costs* of available equipment used for the administration of injectable vaccines		
Injection Equipment	Required Equipment	Unit Cost*
Sterilizable	Plastic BCG syringe	\$0.234
	Plastic 0.5 ml syringe (DPT, TT, measles)	\$0.182
	Hypodermic needle (22 gauge)	\$0.0375
	Steam sterilizer (double rack)	\$75.26
Disposable**	BCG disposable syringe with needle	\$0.056
	Plastic 2 ml syringe	\$0.020
	Hypodermic needle (22 gauge)	\$0.0174
	Incinerator disposal box (100 syringes)	\$0.85
Auto-destruct	Auto-destruct syringe (with needle, includes one incinerator box/100 syringes)	\$0.08
Jet Injector*	Jet Injector (high workload)	\$2,991.13
	Spare parts for jet injector	\$772.76
	Steam sterilizer	\$65.48
* UNICEF catalogue costs in US\$. Low workload jet injectors are not yet available through UNICEF.		
** UNICEF does not provide disposable equipment for immunization programmes. Costs are provided for purposes of comparison.		

4.1. Sterilizable syringes and needles

This equipment consists of a glass or, preferably, plastic syringe with a stainless steel needle. Immediately after use, the syringe and needle must be soaked, cleaned of visible debris, and then steam sterilized for 20 minutes at 121-126°C.

The needle has a lifespan of 50 injections. The lifespan of the syringe varies from 50 to 200 injections, depending on the hardness of local water used for the sterilization cycle. In some areas, the lifespan can be prolonged by placing a hard water pad³ in the sterilizer. A "TST spot"⁴ should be included with each sterilizer load to ensure that sterilization is satisfactorily completed.

4.2. Disposable syringes and needles

Disposable needles and syringes are sterilized at the time of manufacture. They are then packaged and their sterility is guaranteed until an expiry date which is stamped on each package.

Disposable equipment is designed to be used once. It must then be disposed of safely. Destruction by burning at high temperatures is the most effective way to ensure that discarded equipment is free of contamination and cannot be re-used.

4.3. Auto-destruct syringes

The auto-destruct syringe is designed with a mechanism which makes it impossible to use more than once. The auto-destruct models currently used in EPI have a device in the barrel which blocks the plunger after a single use. This automatically prevents the syringe from being used a second time. The syringe is calibrated for 0.5 ml, the standard dose for all EPI vaccines, except BCG. A model calibrated for BCG will be available in the near future.

At the time of manufacture, a needle is attached to each syringe; the unit is sterilized and individually packaged. The syringes are subsequently distributed in specially designed containers which function as incinerator boxes in which to destroy the used equipment can be destroyed relatively quickly.

4.4. Jet injectors

Jet injectors have no needles. They deliver immunizations with a high pressure jet of fluid generated by a hydraulic or a mechanical compression system.

Jet injectors were originally developed for high workload situations and have been used in immunization campaigns for many years. The recent development of low workload models may soon make jet injectors available for use in smaller clinic settings. The low workload injector can be loaded by hand (as opposed to the high workload model which requires a compression device) and has a lifespan of at least 20,000 injections.

³ US\$10.00-20.00 per pad.

⁴ Time, steam and temperature indicators; US\$0.07 per indicator.

5. THE POTENTIAL RISK OF BLOODBORNE INFECTIONS

A risk of injection-associated infections can result from:

- inadequate preparation of the equipment (including lack of sterilization),
- incorrect immunization practices,
- unsatisfactory disposal of contaminated equipment.

The potential risk of patient to patient, patient to health care worker or patient to community transmission with each injection technology is summarized in Table 3 and explained below.

Injection Equipment	Route of Transmission		
	Patient - Patient	Patient - Health Care Worker	Patient - Community
Sterilizable	High risk: equipment re-use without sterilization	High risk: needlestick injuries while cleaning equipment	Low risk: needlesticks due to unsafe disposal of needles
Disposable	High risk: equipment re-use instead of disposal	Medium risk: injury during re-use, recapping or disposal	High risk: re-use within and outside of the medical sector
Auto-destruct	No risk	Low risk: needlesticks during recapping or disposal	Medium risk: needlestick injury due to unsafe disposal
Jet Injector	Low risk: continued use with contaminated injector nozzle	No risk	No risk

Safe disposal of used equipment, whether sterilizable or single-use, requires incineration at a sufficient temperature to melt the needles. EPI is currently evaluating low volume incinerators that can generate temperatures of 1400°Celsius in urban and rural settings.

5.1. Sterilizable syringes and needles

Of the four technologies, the risk of unsafe practices that could expose patients or health care workers to bloodborne pathogens is probably greatest with sterilizable syringes and needles.

- **Cleaning and sterilization** of reusable needles and syringes requires eight separate steps. Failure to conduct any step correctly can result in *patient to patient* disease transmission.
- **Repeated handling** of the equipment continually puts the *health care worker* at risk.

Because the needles are used multiple times, the risk of transmitting disease to the *community* through unsafe disposal is very low.

5.2. Disposable syringes and needles

Disposable syringes and needles pose a risk of cross infection due to the potential for re-use either within or outside of immunization programmes. This risk is primarily due to the following factors:

- Shortages of injection materials provoked by:
 - * lack of resources
 - * poor storekeeping
 - * "diversion" of syringes to other uses.
- Reluctance to dispose of used equipment. In many cultures, particularly where resources are scarce, the disposal of syringes and needles after a single use appears needlessly wasteful. The equipment may therefore be re-used, exposing *both patients and health care workers* to contaminated syringes and needles.
- Inadequate disposal may result in substantial risk to the general *community*, due to:
 - * needlestick injuries and/or
 - * re-use of contaminated equipment outside of the formal medical sector.

UNICEF no longer supplies standard disposable needles and syringes for use in immunization programmes because of the risk of re-use.

5.3. Auto-destruct syringes

The auto-destruct syringe with its fixed needle is the only injection technology which virtually eliminates the risk of patient to patient transmission of bloodborne infections through re-use. The risk to *health care workers* is low, as the equipment requires minimal handling; each syringe can only be used once and safe disposal boxes are included at the time of distribution.

- The *community* may be placed at risk through **needlestick injuries** due to unsafe disposal. The special safe disposal boxes included in the purchase price should, however, facilitate incineration and minimise this risk.

5.4. Jet injectors

There is no risk of *patient to health care worker* transmission with jet injectors.

- *Patient to patient* cross infection can occur, however, if the injector head is **not routinely changed or sterilized** between patients.

It is not practical in the immunization clinic setting to sterilize injector heads between patients. However, the equipment can be used safely if the following recommendations are followed:

- * swab the injector head with acetone or alcohol after each injection,
- * sterilize the injector head at the end of each session,
- * sterilize the injector head if it is visibly contaminated with blood.

A number of laboratory studies have documented the potential for cross infection with contaminated injectors, and transmission of Hepatitis B has been reported with one type of jet injector. Although the risk of cross infection has generally been estimated to be very low, a study in an area with a high prevalence of Hepatitis B virus (HBV) estimated it to be as high as 1 per 388 to 3367 injections, under suboptimal conditions. As noted above, **this risk can be substantially reduced** by swabbing the nozzle with acetone or alcohol between injections.

Low workload jet injector

The low workload jet injector is still under development and remains to be appropriately field tested. Compared with the high workload injector, it has a lower risk of cross infection due to mechanical differences in the design. The fluid pathway is automatically cleared, minimizing the risk of

contamination through backsplash. A prototype model with a single-use auto-destruct sterilizable cap is under evaluation by EPI. The capital costs of making injectors with disposable caps available to national programmes on a global basis may prove to be prohibitive. However, if this technology is successful it could protect patients, health care workers and the community, at a cost per injection between that of sterilizable and auto-destruct technology.

6. COSTS ASSOCIATED WITH DIFFERENT IMMUNIZATION STRATEGIES

It could be argued, on the basis of safety alone, that only auto-destruct syringes should be used in immunization programmes. However, this is not always operationally possible or necessary. A number of factors affect a programme's capacity to use a particular type of equipment. One such factor is cost. Because cost frequently has the greatest impact on the choice of technologies it is considered in detail below.

The overall cost of using a particular type of injection equipment will depend on:

- the procurement costs of the equipment,
- the local cost of fuel for sterilization and disposal,
- the lifespan of the injection equipment, and
- the number of injections that are given during each immunization session.

Table 4: Estimated total costs and cost/injection of using four different types of injection equipment in a routine immunization programme over a one year period, by clinic workload				
Injection Equipment	Clinic Workload of 5 injections/day		Clinic Workload of 50 injections/day	
	Total Costs	Cost per injection	Total Costs	Cost per injection
Sterilizable	\$ 75.12	\$0.06	\$ 108.28	\$0.01
Disposable	\$ 69.55	\$0.05	\$ 695.50	\$0.05
Auto-destruct	\$104.00	\$0.08	\$1040.00	\$0.08
Jet Injector* (low workload)	\$121.55	\$0.09	\$ 380.00	\$0.03

* Low workload injectors will soon be available for use in immunization programmes. The manufacturer's price of US\$ 250 per injector is used in these calculations. The addition of a sterile auto-destruct cap would increase the cost by approximately US\$0.02-0.03 per injection.

Table 4 presents a comparison of the estimated total cost and cost per injection using each of the four types of injection equipment, in both a small and a large clinic setting. The equipment costs from Table 2 are used and the following assumptions are made:

- * immunization sessions are held 5 days per week,
- * the usual lifespan of a steam sterilizer is 10 years,
- * the cost of fuel for one sterilization session is US\$0.25 (fixed cost for 1 to 84 syringes),
- * disposal costs for burning used equipment in an incinerator box is US\$0.85 for 100 syringes.

Although these calculations are subject to wide variation, the examples illustrate several points:

- The size of the immunization session is an important factor in determining the overall cost of using a particular type of injection equipment. Although sterilizable equipment can be employed at a lower cost than auto-destruct, the financial advantage diminishes rapidly as the size of the immunization session decreases.
- If fuel is expensive, the relative cost of auto-destruct equipment falls markedly, particularly in the small clinic setting. If the price of fuel were double the estimate used here, the cost per injection using auto-destruct and sterilizable equipment would be similar.
- Immunization programmes could adopt a combination of different types of equipment to suit sessions sizes (e.g. auto-destruct for small sessions and sterilizable for larger sessions) without increasing overall costs.

7. THE CHOICE OF INJECTION EQUIPMENT

Although cost often determines the type of injection equipment that is chosen for an immunization programme, other factors have a significant impact on the successful implementation of a particular technology. Among these factors are:

- the **acceptability** of the equipment to the community and health care workers,
- the **training and supervision** required to ensure correct use,
- the **feasibility** of using the equipment in a particular setting, and
- the capacity to supply an **adequate stock**.

There is a common belief that communities will refuse injections with sterilizable equipment. It has been found, however, that the public reaction to the use of sterilizable equipment is variable. A recent study in a country where HIV is highly endemic found that the community accepted injections with reusable equipment because they were satisfied that the needles and syringes had been properly steam sterilized.

The safe use of any injection equipment requires:

- training
- ongoing supervision.

Supervision requirements are very different for each type of equipment. Sterilizable and disposable equipment require greater attention than auto-destruct. Therefore, in areas where close supervision cannot be maintained, auto-destruct equipment is an advantage.

7.1. *Immunization strategies*

The feasibility of using a particular type of injection equipment will depend on the immunization strategy.

- During **routine immunization sessions**, relatively small numbers of people are immunized through fixed sites, outreach clinics and mobile teams.
 - * **Sterilizable equipment** is well suited to fixed sites. In other settings it can be cumbersome, even if sterilizer drums are used⁵.
 - * **Auto-destruct syringes**, on the other hand, are readily portable and reduce the risk of unsafe injections in settings with minimal supervision.

⁵ Sterilized needles and syringes can be transported to the field in sterilizer drums, without compromising their sterility.

- During **special immunization activities**, such as National Immunization Days (NIDs), large numbers of people are immunized during each session. Often more than 200 are immunized, either at fixed sites or through house to house visits.
 - * **High workload jet injectors** are practical and cost effective at fixed sites. However, they require a large capital investment and cannot be taken from door to door.
 - * **Auto-destruct syringes** can be used in either fixed or mobile settings. Also, they do not incur the small potential risk of patient to patient disease transmission that exists with the high workload jet injector.

7.2. Equipment supply

A critical component of a safe injection strategy is ensuring a consistent supply of injection, sterilization and disposal materials, including spare parts. This aspect is frequently overlooked. A budget and careful plan must be established for the procurement and distribution of sufficient equipment, including reserve stocks.

In case of interruptions in supply, EPI recommends that sterilizable needles and syringes are always available in settings where disposable or auto-destruct technology is used. In settings where sterilizable equipment is only used as a 'backup', supervisors must ensure that the required skills are not lost.

8. ENSURING THE PROPER USE OF INJECTION EQUIPMENT

Sterilizable, disposable and auto-destruct needles and syringes eliminate the risk of exposing patients, health care workers and the general community to transmission of disease **only when they are properly used**.

Ensuring proper use of the equipment requires a combination of:

- thorough **training** for health care workers in safe injection practices,
- regular **supervision** of immunization sessions to achieve compliance with recommended practices,
- a consistent and adequate **supply** of materials.

8.1. Assessment of practices

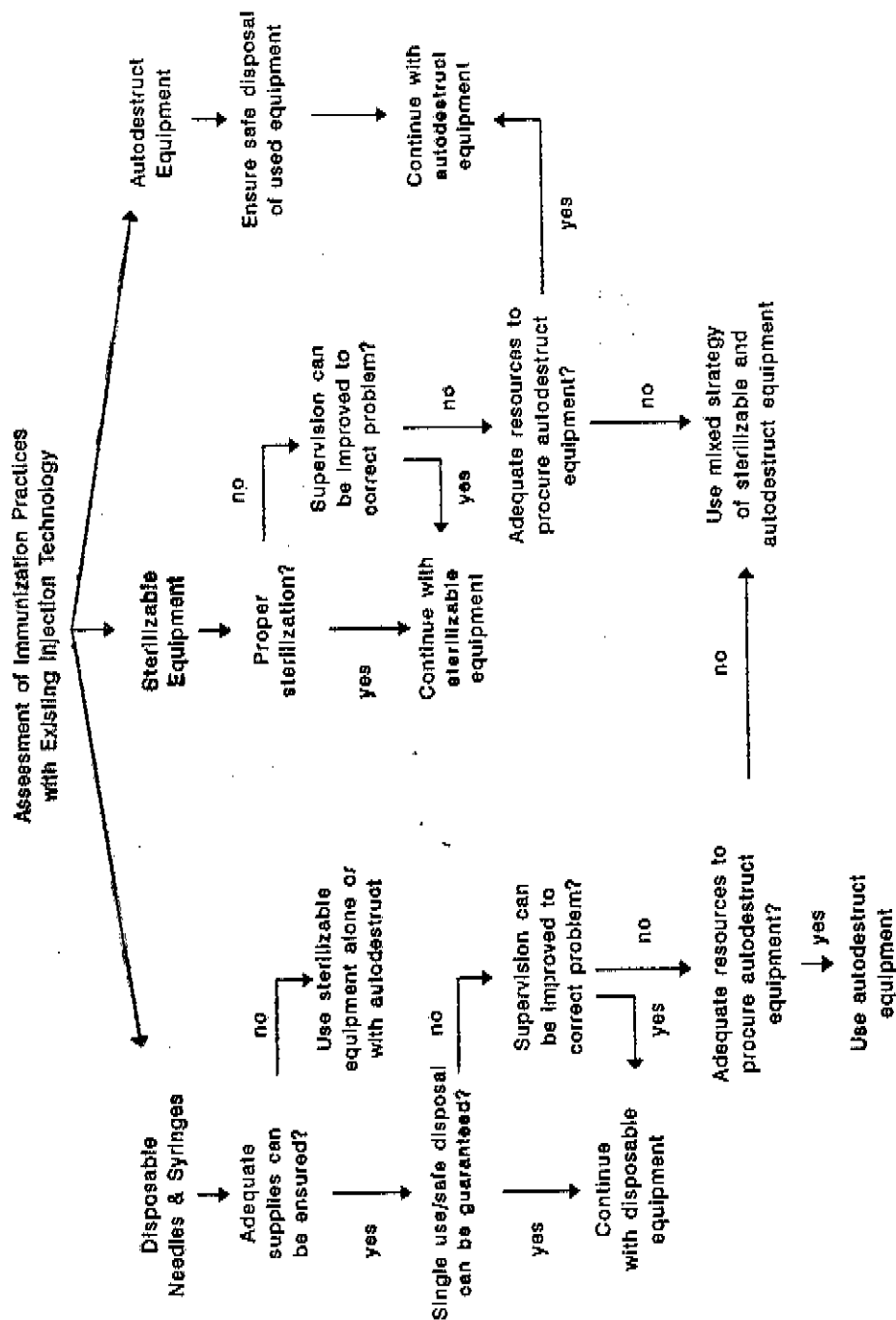
Changing the type of injection equipment that is used in an immunization programme can require extensive investments in terms of training and equipment. Therefore, an assessment of existing injection practices should be conducted to evaluate whether a change in equipment is necessary. It should focus on the correct use of sterilizable equipment and the proper disposal of single use needles and syringes.

The flow chart in Figure 2 shows how information from an assessment of injection practices can be used to improve the safety of an existing immunization programme. Health managers should monitor the safety of injection practices by:

- **periodic assessments**,
- **regular clinic supervision** and
- **investigation of vaccine associated adverse events⁶**.

⁶ Expanded Programme on Immunization. Surveillance of adverse events following immunization: Field guide for managers of immunization programmes. Geneva: World Health Organization, 1993: WHO Document: WHO/EPI/TRAM/93.2.

Figure 2: Flow chart for ensuring the safe use of injection equipment



8.2. *Selective introduction of equipment*

In some countries, auto-destruct equipment may be warranted but prove too costly to introduce at all levels. In such instances, areas with the highest risk of unsafe injections should be selectively targeted. Such areas usually include small clinics where supervision is limited and/or immunization skills are not used on a daily basis. The introduction of auto-destruct syringes in such settings could significantly reduce the prevalence of unsafe injections with minimum increase in overall programme costs.

9. CONCLUSIONS

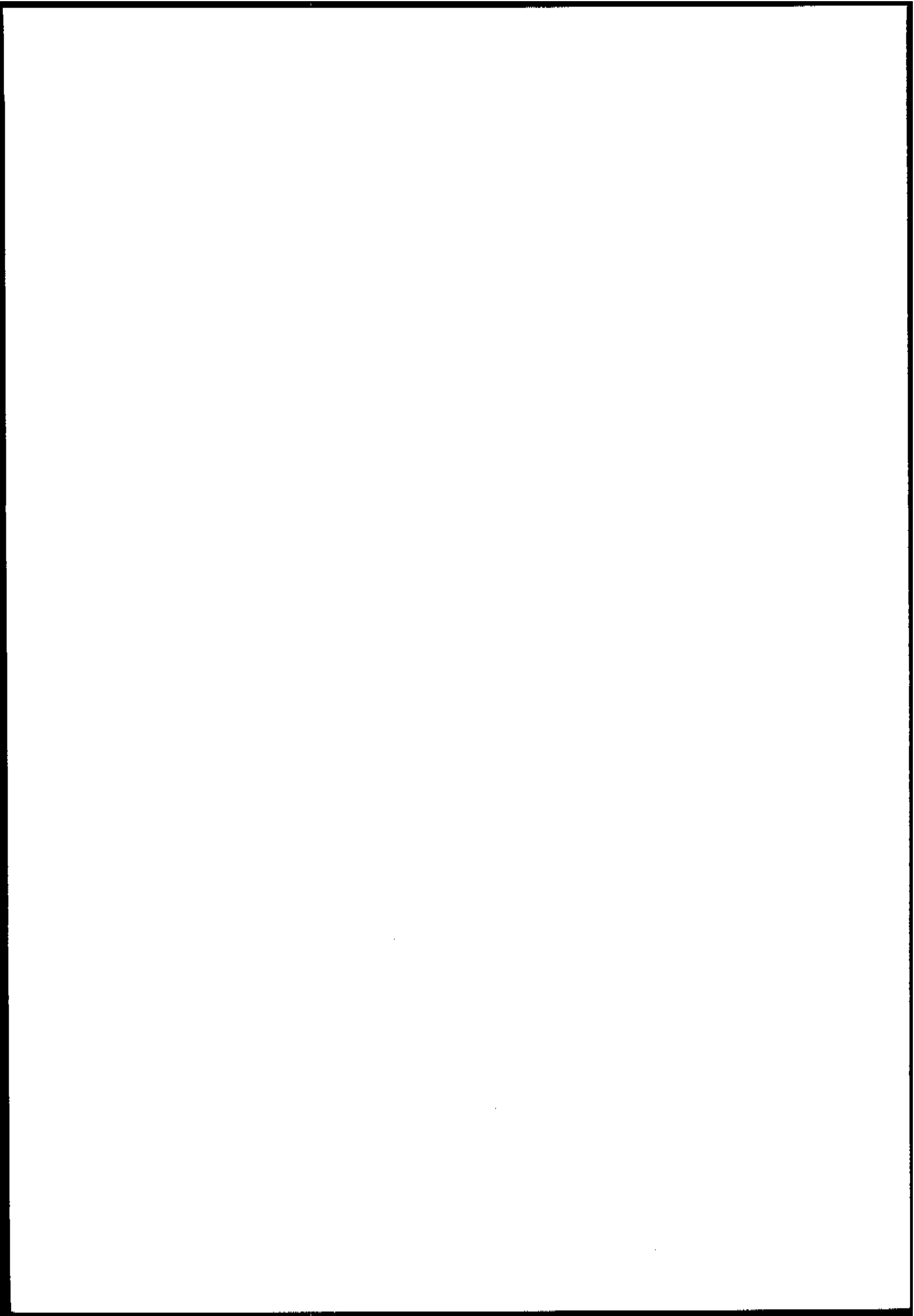
- **Current injection technologies alone cannot eliminate the potential for unsafe immunization practices.** Advances in injection technology combined with effective supervision have allowed EPI to substantially lower the risk of unsafe injections within national immunization programmes. Auto-destruct equipment removes the risk to patients, while jet injectors virtually guarantee the safety of the health care worker and the general community.

However, the safety of immunization injections can only be ensured by a comprehensive strategy which includes :

- * the selection of appropriate injection equipment
 - * the development of a national safe injection policy,
 - * effective training and supervision of health care workers,
 - * an uninterrupted supply of equipment,
 - * a sufficient budget for equipment and safe disposal.
- **A major challenge for EPI will be to educate the public as to the risks of all skin piercing procedures without compromising the acceptance of those interventions which are necessary and safe.**

Unsafe skin piercing procedures performed by traditional healers, itinerant injectionists and other paramedical personnel continue to pose a major threat to the health of developing country populations . While guaranteeing the safety of injections for immunization is the first priority, health staff should also attempt to ensure that individuals are not exposed to disease transmission through unsafe or unnecessary procedures performed in other settings.

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The EPI **Logistics for Health** documentation comprises two categories:

- Information Series
- Training Series

The **Information Series** focuses on the dissemination of updated information, guidelines, policies and procedures on the development and improvement of cold chain systems and technologies. Topics include the transport, storage, distribution and proper administration of vaccines, safe handling of injection equipment, field studies and reports.

The **Training Series** provides material for basic *and* specialised training in equipment maintenance and logistics support procedures. It aims to give health workers the skills necessary to maintain the level of support required to ensure sustained immunization coverage and service delivery.

TECHNET, a global network of logistics specialists for health, collaborates with WHO/EPI on the content and publication of the Logistics for Health documents.

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