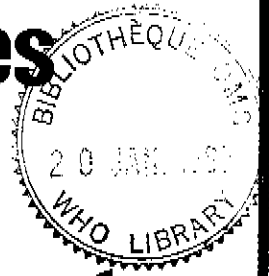




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Selection of Injection Equipment



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EXPANDED PROGRAMME ON IMMUNIZATION



SELECTION OF INJECTION EQUIPMENT FOR THE EPI
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WHO/UNICEF JOINT GUIDELINES**SELECTION OF INJECTION EQUIPMENT FOR THE
EXPANDED PROGRAMME ON IMMUNIZATION**

EPI/UCI 1990

1. Introduction

Since the possibility exists that unsterile needles and unsterile syringes can transmit not only the AIDS-related human immunodeficiency virus (HIV), but also other infectious agents including hepatitis viruses, immunization programmes have the obligation to ensure that a sterile syringe is used with each injection.

The above recommendation was made by the EPI Global Advisory Group in November 1985 (1). Countries which for many years have tolerated the use of unsterile techniques for immunization and other injections are now faced with rising concerns about the risks which such practices entail. This paper provides guidelines for the choice of equipment for countries wishing to assure that immunizations and other injections do not serve as vehicles for the transmission of disease. It stresses the importance of the effective sterilization of syringes and needles. Providing the equipment, training and supervision needed for safe immunization injections is expected to have important benefits in assuring the safety of other injections given within the health services.

2. Recommendations

2.1 A single sterile needle and a single sterile syringe should be used with each injection.

2.2 Reusable needles and syringes are recommended for use in developing countries. They should be steam sterilized between uses. Boiling is an acceptable alternative procedure until steam sterilization is available. The number of reusable needles and syringes, and sterilizers, should be adequate to ensure that operations are not impeded by sterilization requirements. The low cost of the new reusable plastic syringes now makes this possible.

2.3 Disposable needles and syringes should only be used if it can be assured that they will actually be destroyed after a single use. If this cannot be assured, reusables should be used with scrupulous attention to sterilization.

2.4 Disease transmission by use of jet injectors is theoretically possible and has been documented in humans in a single situation. Until further studies clarify the risks of disease transmission

with different types of jet injectors, their use should be restricted to special circumstances where the use of needles and syringes is not feasible because of the large numbers of persons to be immunized within a short period of time.

3. Injection equipment currently available

Three types of equipment are in common use for the injection of vaccines: reusable syringes and needles, disposable syringes and needles and jet injectors.

3.1 Reusable needles and syringes

The cannulas, or needle shafts of reusable needles are made of stainless steel and they have either nickel-plated brass or plastic hubs. Reusable syringes are made of glass, nylon or plastic. A combination glass and metal syringe has been used for BCG immunization.

The brass-hubbed needle and glass and nylon syringes (and the glass/metal BCG syringe) have in the past been the only types of reusable equipment available for general use. They are being superseded, however, by reusable metal or plastic-hubbed steel needles and plastic syringes. These are unbreakable, and withstand between 50 and 200 steam sterilizations, and cost much less than earlier types of reusable needles and syringes. The reusable plastic BCG syringe has a capacity of 0.1 ml, encouraging its use for the administration of only a single dose of BCG. For other immunizations, reusable plastic syringes are available in 1 ml and 2 ml sizes. Although a capacity of 0.5 ml is sufficient for EPI use, a capacity of 1 ml is needed for general clinic use. The use of 2 ml syringes is discouraged. (2)

3.2 Disposable needles and syringes

The hubs of disposable needles and disposable syringes are also made of plastic but of a less robust type than the reusables. They are not able to withstand proper boiling or steam sterilization without becoming distorted. They are available in several different capacities and types. For example, there is a 1 ml tuberculin syringe which can be used to give BCG vaccine and 2 ml to 3 ml capacity syringes which may be used for other immunizations.

3.3 Jet injectors

These are precision instruments designed to provide large numbers of injections at high speed. The nozzle of the injector is held against the skin and the vaccine, ejected in a thin stream at high speed, penetrates the skin with no additional instrument being necessary.

4. Advantages and disadvantages of equipment options

4.1 Plastic reusable needles and syringes

The new reusable steel needle with metal or plastic hub is less expensive than the all-steel needle. Some of the new reusable plastic syringes are also less expensive than glass, nylon or glass/metal syringes, and are unbreakable. In addition, plastic reusables can be bought in a sterile pack for immediate initial use. They must then be sterilized for further uses.

The preferred method of sterilization for the EPI is steam sterilization at a temperature of 121 degrees Celsius (15 psi) for 20 minutes. Newly developed steam sterilizers, modified from home pressure cookers and specially designed for use in immunization clinics, are available through UNIPAC for this purpose. (2) The alternative method is boiling in a container with the lid in place. Submersion of needles and syringes in boiling water for 20 minutes will not necessarily kill all micro-organisms, but will destroy most bacteria, HIV, and hepatitis viruses. This is an acceptable sterilization method until steam sterilization is available. Manual cleaning of the syringe and flushing of the needle remain essential procedures whichever method is used. Attempting to disinfect syringes by short exposure to boiling water or by immersion in disinfectant or sterile water does not achieve sterility and poses a high risk of transmission of infectious agents.

The newly-available low cost reusable needles and syringes are also appropriate for special immunization days. Since they are supplied already sterile, they can be used immediately upon receipt. The additional costs of supplying them in numbers large enough to provide one sterile needle/syringe for each injection during an immunization day are offset by the double benefit of lower costs in the long run, and the availability of injection equipment for continued use in routine health services. It is hoped that as larger quantities are purchased, and more manufacturers are found, prices will become still lower.

Sterilization requires extra equipment, time and energy, all of which add costs. Even so, estimates made by WHO (3), taking these costs into account, indicate that plastic reusables are less expensive, per fully immunized child, than disposables (US\$ 0.04 to 0.07 per fully immunized child with reusables, versus US\$ 0.08 or more per fully immunized child with disposables or jet injectors).

In rare cases, and in spite of correct flushing procedures, deposits can occur on the syringes and/or block the needles after only a few sterilizations. This happens in those areas with hard water. These deposits can cause leakages of vaccine and difficulty in giving injections. Adding a hard water filter (available as an inexpensive metal sponge) to the water prior to boiling can minimize such difficulties.

4.2 Disposable needles and syringes

Industrialized countries have generally turned to the use of disposable injection equipment, used once and then discarded, to assure sterility. This avoids the high cost of staff-time required for sterilization and is compatible with practices common in other sectors of these societies, where disposable materials are becoming increasingly common and where the means of proper disposal exist. Disposables have been used in developing countries, particularly where a national immunization day or mass campaign strategy has been adopted. In these circumstances there have been advantages in not having to slow down immunizations by taking time to sterilize the syringes and needles. This of course implies that a sufficient number of disposable needles and syringes have been provided for all the injections required. As mentioned above, the same advantage can be obtained by using sufficient numbers of sterilized, reusable needles/syringes.

In many developing countries, however, disposable needles and syringes cannot be recommended. In practice, they are not destroyed after a single use, but reused. Therefore, there is the same or even greater risk of disease transmission as with reusable equipment, for two reasons:

(1) disposables which are discarded but not destroyed by the formal health services easily find their way into less formal systems of health care where cleaning/sterilization practices are significantly less satisfactory than in the formal services; and

(2) proper sterilization shortens the life of much disposable equipment to the extent that health workers frequently do not sterilize properly.

Disposable equipment also imposes a sizable logistics burden. The number of disposable needles and syringes exceeds the number of reusables required by 50 to 200 times, multiplying the transport and storage needs by this amount. A backup system based on the sterilization of reusables should also be maintained in reserve, for use if the supply system for disposables fails.

Some countries have adopted a mixed strategy of using disposable needles with reusable syringes. The needles are changed between injections, but the same syringe is used for several successive individuals. This practice can only be condemned, as it provides no security against the transmission of infectious agents. The same syringe and needle are often used to administer BCG, but the only acceptable practice here is to flame the needle between injections. The heating process kills the vaccine in the needle and the needle hub, and the remaining vaccine is ejected prior to the next immunization. A high degree of training and supervision is required for this to be done correctly.

4.3 Jet Injectors

The principal advantage of the jet injector is its speed of operation and, therefore, the ability to immunize large numbers of people in a short time.

Jet injectors have been used for a wide range of live and killed vaccines. These have included DPT and yellow fever, meningococcal meningitis, measles and quadruple DPT/IPV vaccine.

There are also disadvantages of the jet injector. A single injector can inject only one vaccine at a time. Therefore, an injector must be supplied for every vaccine to be administered. Occasional breakdowns of the jet injector during a vaccinating session requires the availability of a backup injector, or syringes and needles.

The injector must be sterilized every working day by steam or boiling water, as for syringes and needles, or by iodine. Iodine sterilization should be followed by scrupulous flushing with distilled water in order to avoid inactivation of the vaccine and the risks of increased local reactions.

The price per injection by jet injector is high and when all costs are expressed per immunized child, the jet injector is more costly than needles and syringes.

Finally, there is one further concern with jet injectors. While they have been used for many years with no suggestion of their being implicated in disease transmission, recently published studies have documented virus transmission by means of one type of jet injector (4) (5).

Unless the numbers of persons to be immunized in a single session is more than one hundred, jet injectors are not generally for routine use in the EPI.

5. Equipment preferences

The use of reusable equipment along with the use of improved methods and materials for its sterilization is strongly recommended for most developing countries. Training materials on proper methods of sterilization are available and should be used, with local adaptation as necessary (6). Supervision should be reinforced to assure that national sterilization policies are adhered to.

If it is considered essential to use disposables during national immunization days or similar activities where very large numbers of individuals may need to be immunized in a short period of time, measures must be taken to assure that they are destroyed after a single use. However, programme managers could also provide reusables in these circumstances, in sufficient quantities so that sterilization need take place only after the given day or session is over. These reusables can then be placed in the routine immunization services.

Until further studies clarify the risks of disease transmission associated with jet injectors, general caution in their use is recommended.

WHO and UNICEF, together with others, are actively supporting the search for new methods and materials which would assure the sterility of each immunization provided. A single-dose, self destructing injection device is in an advanced stage of development, and other approaches are also being investigated. While these activities provide some hopes for improving current approaches to the sterilization issue, none are likely to result in products which will be widely used in developing countries within the next two years or so. Immunization programmes cannot wait for such improvements. Every effort should be exercised now to introduce adequate sterilization practices in all immunization programmes as soon as possible.

6. Equipment costs

Table 1

Reusable Needles and Syringes for the EPI

<u>Item</u>	<u>Size</u>	<u>Use</u>	<u>UNIPAC</u>	<u>No.</u>	<u>Price</u> (\$) (1986)
Needle (Luerlock)	10mm, 26 gauge	For BCG		07-515-02	0.45/12
Needle (Luerlock)	32mm, 22 gauge	For other vaccines		07-505-00	0.45/12
Needle (Luerlock)	76mm, 18 gauge	For reconstitution of vaccine		07-488-00	0.35/12
Syringe	0.1 ml	BOG, single dose		07-822-15	5.10/10
Syringe	1.0 ml	Other vaccines, single dose		07-822-20	2.00/10
Syringe	5.0 ml	For reconstitution		07-819-05	0.18 ea.

The life of needles is dependent on many factors including needle gauge, whether or not the needles are resharpened and the hardness of water used for sterilization. Good field data are scarce but on the basis of evidence from the WHO sterilizer study it is estimated that the 10 mm, 26 gauge needle can withstand between 30 and 60 uses while the 20 mm, 22 gauge needle can be used between 100 and 200 times.

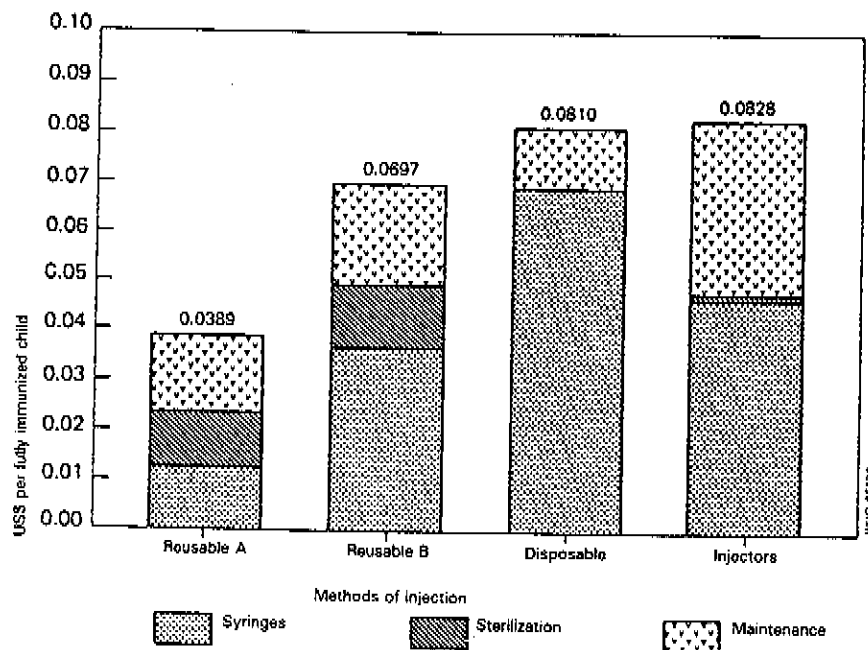
Local reviews of immunization practice, including study of the life of needles will refine these figures.

The prices in Table 1 are taken from the 1986 edition of the UNIPAC Catalogue (obtainable from: UNICEF, UNICEF Plads, Freeport, DK-2100 Copenhagen). Sterile, disposable syringe/needle sets are also available as stock number 07-822-25, for US\$ 0.03/set. The jet injection apparatus costs approximately US\$ 2,500.00, and a spare parts set is US\$ 670.00. The jet injector will not in future be available from

UNIPAC stock. Glass and glass/metal syringes will also not be available from UNIPAC stock. They are being superseded by the plastic reusable syringes.

Figure 1

Costs of injection methods (US\$ per fully immunized child)



Reusable A = lowest cost all-purpose syringe
Reusable B = EPI single-dose syringe

BIBLIOGRAPHY

1. Expanded Programme on Immunization: Global Advisory Group. Weekly Epidemiological Record; 61 (3): 13-16 (1986). N.B: At the time that the recommendation was formulated, in November 1985, the virus was referred to as LAV/HTLV-III.
2. The Cold Chain Product Information Sheets. SUPDIR 55, AMT 5 (1985), Section "E9". Expanded Programme on Immunization, World Health Organization, Geneva.
3. Expanded Programme on Immunization: Choice of syringes for the EPI. Weekly Epidemiological Record; 61 (6): 41-43 (1986).
4. Brink, P. R. G. et al. Virus transmission by subcutaneous jet injection. J. Med. Microbiol. 20: 393-397 (1985).
5. Morbidity and Mortality Weekly Report (US PHS), June 1986, Vol. 35, No. 23, pp. 373-376.
6. Immunization in Practice: A guide for health workers who give vaccines. Expanded Programme on Immunization, World Health Organization, Geneva.