

"First, do no harm"

Introducing auto-disable syringes and ensuring injection safety in immunization systems of developing countries

Department of Protection of the Human Environment
Department of Vaccines and Biologicals



World Health Organization

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Copies may be requested from:
World Health Organization
Department of Vaccines and Biologicals
CH-1211 Geneva 27, Switzerland
• Fax: + 41 22 791 4227 • Email: vaccines@who.int •

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Abbreviations

| | |
|----------------|--|
| AD | auto-disable (syringes) |
| AEFI | adverse events following immunization |
| DTP | diphtheria–tetanus–pertussis vaccine |
| EPI | Expanded Programme on Immunization (WHO) |
| HepB | hepatitis B |
| Hib | <i>Haemophilus influenzae</i> type b |
| HIV | human immunodeficiency virus |
| ICC | interagency coordinating committee |
| IFRC | International Federation of Red Cross and Red Crescent Societies |
| SIGN | Safe Injection Global Network |
| UNFPA | United Nations Population Fund |
| UNICEF | United Nations Children’s Fund |
| V&B | Department of Vaccines and Biologicals |
| WHO | World Health Organization |

1. Introduction

While the main goal of immunization is to prevent illness and death, the overriding concern of any public health intervention must be *primum non nocere* ("First, do no harm").

It is well known that giving injections using non-sterile procedures can cause abscesses and transmit life-threatening infectious diseases, including hepatitis B, hepatitis C and HIV. Not only do unsafe injection practices pose a direct danger to the recipient and health worker, but improper disposal of used injection equipment presents a continued risk of infection and an environmental hazard to individuals and local communities. The safety of injections, including the proper disposal of used injection equipment, is therefore a concern for the entire healthcare sector.

National immunization services, although responsible for only 5–10% of all injections given, are particularly concerned because (a) they deal with infants and children who are generally in good health, and (b) when used syringes and needles are carelessly thrown away, it is children who are often the most likely to be exposed.

Auto-disable (AD) syringes virtually eliminate the risk of patient-to-patient infection with bloodborne pathogens (such as hepatitis B or HIV) because they can not be reused. AD syringes are now widely available at low cost (less than a 20% increase over the cost of standard disposable syringes). Indeed,

Auto-disable syringe



Safety box



AD syringes are currently the preferred equipment for administering vaccines, both in routine immunization and for mass campaigns (Fig 1).

In a joint statement, WHO–UNICEF–UNFPA–IFRC have urged that, by the end of 2003, all countries should use only AD syringes for administering all immunizations.¹ (Annex 1)

The introduction of AD syringes provides an excellent opportunity to review and improve injection safety as a whole. This document aims to assist policy-makers and programme managers to plan the introduction of AD syringes as part of a comprehensive national policy and plan of action to improve injection safety, both for routine immunization and for mass campaigns.

¹ Safety of injections. WHO–UNICEF–UNFPA joint statement on the use of auto-disable syringes in immunization services (WHO/V&B/99.25).

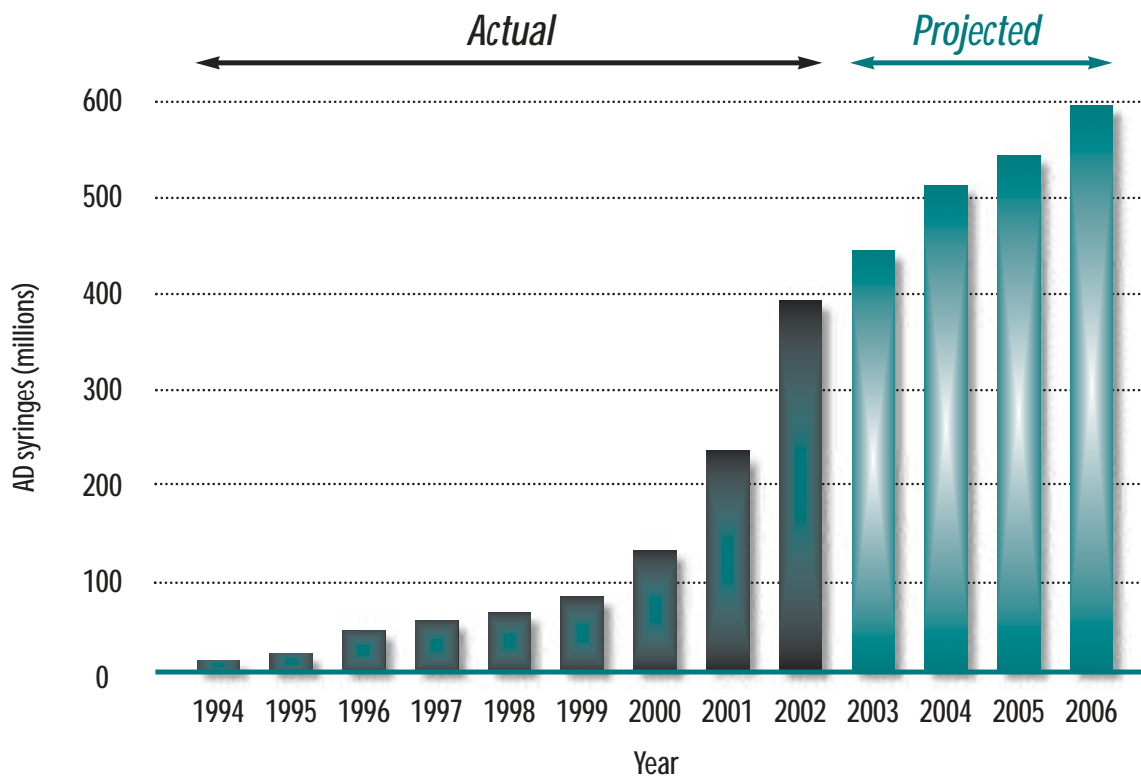
The actions required to achieve the successful introduction of AD syringes and ensure injection safety include:

- Conducting an injection safety assessment.
- Developing an injection safety policy, strategy and annual work plan.
- Establishing a reliable estimate of equipment requirements, minimum stock levels and effective supply and distribution systems for injection equipment.
- Securing the required financial resources for all the components of the injection safety plan, including safe disposal of used equipment.

- Planning the safe disposal of used injection equipment through the progressive introduction of appropriate waste management options.
- Providing training for health workers and managers on safe injection and disposal procedures.
- Instituting monitoring and supervision procedures to ensure correct practices by health workers and provide adequate supplies and disposal facilities at all levels.

These steps will be discussed in more detail in Sections 2 to 8.

Figure 1. Actual and projected number of AD syringes purchased through UNICEF



Source: UNICEF

2. Conducting an injection safety assessment

Conducting a comprehensive assessment of injection safety will provide baseline data on the situation that can be used to influence decision-makers and monitor progress over time. Assessments can help to clearly define problems and help to design effective, efficient interventions.

A standard methodology for conducting injection safety assessments has been developed and field tested.² Generally an injection safety assessment takes 2-3 weeks, and costs between US\$ 5 000 – US\$ 10 000. The injection safety assessment estimates the frequency of unsafe injection practices within health facilities. It determines whether a facility meets the minimum requirements for

equipment, supplies and waste disposal. The assessment also identifies unsafe injection practices that may result in blood-borne infections. Furthermore, by sampling health facilities throughout the country, the assessment can provide an overall estimate of the proportion of health care facilities where injection practices are safe.

Recommendations from the assessment focus upon these considerations in regard to injection safety interventions. Finally, it should be noted that the introduction of AD syringes and improvements to injection safety practices do not necessarily need to wait for an assessment to be conducted. Action can and should be taken immediately!

² *Tool for the assessment of injection safety*. Geneva 2001. (Unpublished document WHO/V&B/01.30 & WHO/BCT/01.02)

3. Planning for injection safety

An effective planning and management system is needed to support the introduction of AD syringes. Specifically, immunization systems must develop a comprehensive approach to immunization safety that includes policy statements, strategy, financing, supplies and annual workplans.

A policy statement can be considered as a vision or overall goal for injection safety e.g. “the Ministry of Health pursues the policy that 100% of injections given in immunization systems must be safe”. Generally the vision cannot be achieved in a short time and a multi-year immunization safety action plan is therefore required, which states yearly objectives and the strategies to achieve them.

A strategy is not a detailed plan or programme of instructions but rather a general overview of how objectives will be achieved, i.e. the types of services or interventions that must be initiated. The annual work plan outlines the annual activities that must be undertaken to implement the strategies and should include a timeline and a budget.

Strategies for the introduction of AD syringes, injection safety and safe disposal of used injection equipment should target all levels of the immunization service, from decision-makers to health workers and the general public. Decision-makers must know the extent (i.e. magnitude and severity) of the threats to public health caused by unsafe injections, as well as the feasibility of

interventions required to solve them. All health workers must have the knowledge, skills and proper equipment to administer injections safely. Finally, the general public must be educated on the need for all immunizations to be administered safely and to demand the appropriate service.

To ensure coordination and action, a national level injection safety officer should be appointed. At provincial or district levels, specific immunization safety officers should be identified to be responsible for injection safety and the safe disposal of used injection equipment. These officers should be sufficiently senior (e.g. deputy Expanded Programme on Immunization (EPI) manager) to carry the

responsibility for all aspects of safety, since technical issues, operations and monitoring (including cold chain and logistics) are closely linked.

The designated immunization safety officers will be responsible for managing the system, ensuring adequate supplies and equipment are available at all levels, calculating requirements, maintaining inventories, controlling the safety of immunization injections and establishing efficient ways for disposing of used syringes and needles. At the levels where the disposal actually takes place, operators responsible for safe disposal should also be designated and appropriately trained.

Planning checklist for injection safety

Develop an injection safety plan

- identify stakeholders;
- assess the situation;
- include the costs for safety in the financial plan;
- ensure injection safety through education and provision of supplies;
- manage sharps waste;
- monitor and document results;
- evaluate results and identify lessons learned.

Ensure vaccine safety: from delivery up to and including vaccine administration

- use pre-qualified or national regulatory authority-approved vaccine and injection materials;
- bundle lyophilised vaccines with the corresponding diluent, reconstitution syringes, AD syringes and sharps boxes;
- communicate risks associated with unsafe practices to all levels;
- train health care workers in proper techniques.

Manage disposal of used injection equipment

- assess local environmental regulations and options for sharps treatment and disposal;
- plan storage, transportation, and disposal;
- identify practical, simple solutions;
- monitor disposal on a regular, frequent basis.

4. Ensuring an adequate supply of AD syringes and safety boxes and estimating the costs

A reliable and adequate supply of AD syringes, disposable reconstitution syringes, and safety boxes is necessary to ensure injection safety. Indeed, it is the policy of WHO and UNICEF that all vaccine orders be “bundled” with the corresponding numbers of AD syringes and safety boxes.

A 5 litre³ safety box can hold approximately 100 used needles and syringes. All fixed centres and mobile teams need to be regularly provided with an adequate supply of safety boxes.

Estimates for equipment requirements can be calculated using the example shown in table 1 (this calculation should be repeated for each vaccine used in the national immunization schedule and for special mass campaigns).

The term “bundling” has been chosen to define the concept of a theoretical “bundle” which must comprise each of the following items:

- ☞ good quality vaccines
- ☞ auto-disable syringes
- ☞ safety boxes

The implication is that none of the component items can be considered alone; each component must be considered as part of a “bundle” which contains the other two. However, “bundling” has no physical connotation and does not imply that the items must be physically “packaged” together.

Table 1. Example calculation of supplies needed for DTP–HepB–Hib vaccine
(Note: this table should be repeated and completed for each vaccine in the national immunization schedule)

| Calculations | 2002 | 2003 | 2004 |
|---|-----------|-----------|-----------|
| a) Total number of children under one year | 871 983 | 894 654 | 917 915 |
| b) Anticipated coverage | 80% | 80% | 80% |
| c) No. of children targeted for vaccination (a x b) | 697 586 | 715 723 | 734 332 |
| d) Doses per child | 3 | 3 | 3 |
| e) Wastage factor | 1.32 | 1.30 | 1.18 |
| f) No. of doses required (c x d x e) | 2 762 441 | 2 791 320 | 2 599 535 |
| g) Doses buffer stock (f x 25%*) | 690 610 | 7220* | * |
| h) Total no. of doses (f + g) | 3 453 051 | 2 798 539 | 2 599 535 |
| i) Doses per vial | 2 | 2 | 2 |
| j) Total no. vials (h + i) | 1 726 525 | 1 399 270 | 1 299 768 |
| k) AD syringes [(c x d) + 10% wastage**] | 2 302 034 | 2 361 886 | 2 423 296 |
| l) AD syringes buffer stock (k x 25%*) | 575 508 | 14 963* | 15 352* |
| m) Total AD syringes (k + l) | 2 877 542 | 2 376 849 | 2 438 648 |
| n) Reconstitution syringe (disposable) ⁴ (j + 10%) | 1 899 178 | 1 539 197 | 1 429 744 |
| o) Safety boxes [(m + n) + 100] + 10% | 52 544 | 43 077 | 42 552 |

* Buffer stock should always be maintained at 25%. The first year order establishes the buffer stock; for subsequent years the buffer stock required is calculated as the difference between anticipated use (including population growth of the target group) and the remaining buffer stock.

** 10% wastage is an indicative figure; countries should determine their wastage factor based on actual programme experience and adjust calculations accordingly.

³ Ten, 15 and 20 litre safety boxes are also available. However, those considering using these larger sized safety boxes are advised to check that they fit with the method or technology for waste disposal. It is also necessary to consider issues of logistics (e.g. expected number of children to be vaccinated per team, physical constraints of carrying larger boxes, etc.).

⁴ For the time being, standard disposable syringes are recommended for reconstitution of vaccine.

After calculating the safety equipment requirements for each vaccine in the national schedule, the totals

should be tallied in a summary table as shown below in table 2.

Table 2. Example calculation of TOTAL injection safety supplies needed for all vaccines

(Note: For each item, add together the number needed for each vaccine, e.g. as calculated per Table 1 and its repeats, to determine the total required)

| Item (quantity) | 2002 | 2003 | 2004 |
|---|-----------|-----------|-----------|
| Total AD syringes (0.05 ml for BCG) | 959 181 | 792 283 | 812 883 |
| Total AD syringes (0.5 ml for all other) | 5 541 932 | 4 577 635 | 4 696 654 |
| Total reconstitution syringes (5 ml disposable) | 2 200 840 | 1 788 370 | 1 684 298 |
| Total safety boxes | 104 567 | 86 048 | 86 629 |

Finally, once the total safety equipment requirements are known then the next step is to estimate the costs

as shown below in table 3 and storage space requirements as illustrated in table 4.

Table 3. Example estimation of costs* of total injection safety supplies (all vaccines)

(Note: For each item, multiply the total number needed, as calculated in Table 2 by the cost per item)

| Item (cost in US\$) | 2002 | 2003 | 2004 |
|--|---------|---------|---------|
| Total AD syringe (0.05ml for BCG) \$0.06 each | 57 551 | 47 537 | 48 773 |
| Total AD syringes (0.5ml all other) \$0.06 each | 332 516 | 274 658 | 281 799 |
| Reconstitution syringes (5ml disposable) \$0.05 each | 110 042 | 89 418 | 84 215 |
| Safety boxes \$1.00 each | 104 567 | 86 048 | 86 629 |
| Total | 604 676 | 497 661 | 501 416 |

* Note: Costs may vary, particularly if locally-produced supplies are available (generally locally-produced equipment is much cheaper).

Table 4. Example calculation of storage space requirement for syringes and safety boxes

(Note: The volumes will vary depending on the type and manufacture of equipment that is ordered – this is an example only)

| Item (volume m ³) | 2002 | 2003 | 2004 |
|--|--------------------|--------------------|--------------------|
| Total space AD syringes (0.05ml for BCG)* | 58 m ³ | 47 m ³ | 49 m ³ |
| Total space AD syringes (0.5ml all other)* | 333 m ³ | 275 m ³ | 282 m ³ |
| Total space reconstitution syringes (5ml disposable)** | 146 m ³ | 119 m ³ | 112 m ³ |
| Total space safety boxes*** | 84 m ³ | 69 m ³ | 69 m ³ |
| Total | 621 m ³ | 510 m ³ | 512 m ³ |

* 100 AD syringes (0.05ml or 0.5ml) = 0.006 m³

** 1600 reconstitution syringes (5ml) = 0.106 m³

*** 25 safety boxes = 0.02 m³

An efficient stock management and distribution system needs to be developed to ensure continuous, sufficient availability of injection safety equipment in all healthcare facilities. Spreadsheets should be

issued at national, provincial and district levels, to clarify the distribution procedures and ensure the correct delivery up to the point of use.

5. Ensuring adequate financial resources

The annual work plan for injection safety should include a budget estimating the yearly costs of the following items:

- purchase of AD syringes and safety boxes;
- purchase of waste disposal equipment and construction costs;
- maintenance and operation of waste disposal systems (e.g. running costs);

- training of personnel;
- advocacy activities;
- evaluation and monitoring.

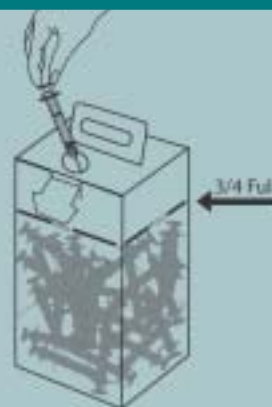
Donors and agencies should include the cost of safe disposal of used injection equipment when funding the purchase of vaccines and AD syringes.

6. Safe disposal of used injection equipment

To prevent risk of infection, the safe disposal of used needles and syringes is a critical component of any vaccination programme. Vaccinators should place used needles and syringes in safety boxes immediately after administering vaccine, tape the nearly (approximately 3/4) full box securely shut and store the box in a safe place until it can be properly disposed of, so as to prevent infecting themselves, other health care workers and the community. To avoid an occupational hazard, safety boxes should not be over-filled.

There is no perfect "generic" method for safely disposing of used injection equipment. Each immunization programme must assess local conditions and find appropriate waste disposal solutions. Any selected method of waste disposal must be in compliance with national and subnational environmental regulations. Table 5 summarizes in matrix format the environmental desirability and technological complexity/cost of different immunization waste disposal options.

Safety boxes (also known as "sharps containers") are puncture resistant, impermeable containers for the safe and convenient disposal of used syringes and needles and other contaminated sharps. Safety boxes should be filled only once, then destroyed immediately. When they are used consistently and correctly, safety boxes can help prevent disease-spreading needle-stick injuries.⁵



⁵ The publication WHO/UNICEF Product Information Sheets (2000 Edition) provides general information on choice of equipment for immunization programmes, together with specific technical and purchasing data for individual selected items.

Table 5. Matrix of environmentally desirable and technologic complexity/cost of various immunization waste disposal options

| | | Technologic complexity/cost | |
|--------------------------|-------------|--|---|
| | | Simple/low cost | Complex/higher cost |
| Environmentally friendly | Burning | Burning (<400°C) 1) Pit burning 2) Drum or brick burning Medium Temperature Incineration (800-1000°C) | High temperature incineration (>1000°C) |
| | Non-burning | Waste burial pit/encapsulation Manually operated needle and syringe cutters** | Steam sterilization (autoclave or hydroclave), and microwaving** Melting Power-operated needle removers/needle destroyers |

** May need further processing for safe final disposal.

Currently, there are three commonly used and readily available options for the safe disposal of used injection equipment: burial/encapsulation; burning; and incineration. In some countries, other disposal

options such as autoclaving/shredding, needle removal/destruction may also be available. Table 6 compares the strengths and weaknesses of the various treatment/disposal options.

Table 6. Comparison of various methods for processing and disposing of immunization waste

| Method | Strengths | Weaknesses |
|--|--|--|
| Waste burial pit/cement encapsulation or other immobilizing agent (sand, plaster) | <ul style="list-style-type: none"> □ Simple □ Inexpensive □ Low tech □ Prevents unsafe needle and syringe reuse □ Prevents sharp related infections/injuries to waste handlers/scavengers | <ul style="list-style-type: none"> □ Potential of being unburied (if pit is only soil covered and waste not encapsulated) □ No volume reduction □ No disinfection of wastes □ Pit will fill quickly during campaigns □ Not recommended for non-sharp infectious wastes □ Presents a danger to community if not properly buried □ Inappropriate in areas of heavy rain or if water table is near the surface |
| Burning (<400°C) • Pit burning • Drum/Brick burning | <ul style="list-style-type: none"> □ Relatively inexpensive □ Reduction in waste volume □ Reduction in infectious material | <ul style="list-style-type: none"> □ Incomplete combustion □ May not completely sterilize □ Results in heavy smoke & potential fire hazard □ May require fuel, dry waste to start burning □ Toxic air emissions (i.e. heavy metals, dioxins, furans, flyash) which may violate environmental or health regulations □ Production of hazardous ash containing leachable metals, dioxins, and furans □ Potential for needlestick injuries since needles are not destroyed |
| Medium Temperature Incineration (800-1000°C) | <ul style="list-style-type: none"> □ Less expensive than high-temperature incinerators □ Reduction in waste volume □ Reduction in infectious material | <ul style="list-style-type: none"> □ Incomplete combustion □ Potential for heavy smoke □ May require fuel and dry waste for start up and maintenance of high temperatures □ Requires trained personnel to operate □ Potential emission of toxic air pollutants to some low level (i.e. heavy metals, dioxins, furans, flyash) which may violate environmental or health regulations in particular settings □ Production of hazardous ash containing variable amounts of leachable metals, dioxins, and furans □ Potential for needlestick injuries since some needles may not be destroyed □ Needs constant attention during operation and regular maintenance throughout year |
| High Temperature Incineration (>1000°C) | <ul style="list-style-type: none"> □ Almost complete combustion and sterilization of used injection equipment □ Further reduces toxic emissions if pollution control devices are installed. □ Greatly reduces volume of immunization waste | <ul style="list-style-type: none"> □ Expensive to build, operate and maintain □ Requires electricity, fuel and trained personnel to operate □ Toxic air emissions (i.e. metals, dioxins, furans, flyash) may still be released unless pollution control devices are installed □ May still produce hazardous ash containing variable amounts of leachable metals, dioxins, and furans |
| 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"> □ Prevents needle reuse □ Reduces occupational risks to waste handlers and scavengers □ In some instances, plastic may be recycled for other uses after treatment □ Manual or battery operated models available | <ul style="list-style-type: none"> □ Fluid splashes may contaminate work area and/or operator □ Fluid splash back and used needle manipulation may result in disease transmission in some cases □ Used needles/syringes need further treatment for disposal in some cases □ Safety profile is not established |
| Melting syringes | <ul style="list-style-type: none"> □ Greatly reduces volume of immunization waste □ Prevents reuse | <ul style="list-style-type: none"> □ Emission of potentially toxic gases □ Electricity required □ Safety profile not established. |
| Steam sterilization (autoclaving or hydroclaving), microwaving (with shredding) | <ul style="list-style-type: none"> □ Successfully used for decades to treat sharps and non-immunization health-care wastes (hospital staff may be familiar with autoclave technology) □ Range of models (simple to complex) and capacities available □ Sterilizes used injection equipment □ Less hazardous air emissions (no dioxins or heavy metals) than burning or incineration □ Reduced waste volume when used with shredder □ Plastic may be recycled for other uses after separation | <ul style="list-style-type: none"> □ High capital cost (but may be less than high temperature incinerators with pollution control devices) □ Requires electricity and water □ High operational costs □ High maintenance □ May emit volatile organics in steam during depressurization and opening of chamber. □ Requires further treatment to avoid reuse (e.g. shredding) □ Resulting sterile waste still needs to be disposed. |

6.1 Immunization waste disposal options that are currently available in most developing countries

6.1.1 Burial/encapsulation

In rural areas where groundwater is not shallow and when volume is not a primary concern, burial/encapsulation can be a good interim method of disposal. These methods are simple, low-cost, safe and friendly to the environment.

Small health facilities that generate small volumes of waste may use waste burial pits. The bottom of the pit should be 1.5 metres above groundwater level. The pit should be 3–5 metres in depth and approximately 2 metres wide. The bottom of the pit should be lined with a material of low permeability such as clay. An earth mound around the hole is used to keep surface water out of the pit. The pit should be carefully fenced off to prevent unauthorized access. Caution should be exercised and proper measures taken when digging waste burial pits to ensure that they are dug by competent people in such a way that the sides do not collapse and cause accidents.

Full safety boxes and ashes resulting from burning or incineration (see below) can be placed in waste burial pits. Each layer of waste is covered with a layer of soil. When full, the pit should be permanently sealed with cement and marked with an inscription in the concrete seal warning against the use of the site for later construction below ground level.

In general, waste burial pits are suitable for small health facilities that do not generate large volumes of used injection equipment. Waste burial pits, however, may not be the ideal solution for use in mass immunization campaigns due to the large volume of waste involved.

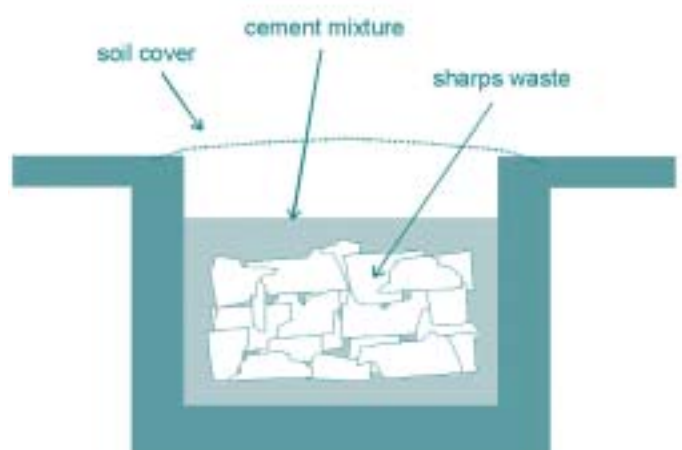
Encapsulation is a process in which full safety boxes are placed inside cement or high-density plastic containers or metal drums. When the containers are full, an immobilizing material such as plastic foam, sand, cement or clay is added. When the immobilizing material has dried, the containers are sealed and disposed of in landfill sites or left in place if they are constructed in the ground.

The main advantages of encapsulation are that it is inexpensive, low tech and very effective in reducing the risk of scavengers gaining access to the potentially hazardous immunization waste. Similar to pit burial, the main disadvantage is that the immunization waste remains potentially infectious. In some instances, chemical treatments or disinfectants can be used prior to or with encapsulation to reduce the threat of infection.

Encapsulation is safe as long as waste is properly handled and transported, and standard safety procedures are followed when working with cement or other immobilizing agent. Planning is required to determine the size of the trench based on the amount of waste generated for a specific period. A storage area where the waste can be safely accumulated is also required.

The cement encapsulation method involves: (1) digging a trench large enough to hold the accumulated waste; (2) adding a cement mixture to line the bottom of the trench and allowing it to set; (3) carefully placing the waste inside the trench; (4) encasing the waste completely with the cement mixture; (5) after the cement has hardened, it should be covered with approximately 15 cm of soil. A typical recipe for the cement mixture is: 1 part cement: 1 part lime: 4 parts sand: one-third to one-half part water. Ideally, the bottom of the trench should be about 1.5 meters above the water table. The depth of the water table in the area may be available from the water authority.

Cement encapsulation



6.1.2 Low temperature burning

Used injection equipment may be readily burned at relatively low temperatures (< 400°C) either in open pits, in brick burners or in “drum” burners. These devices are inexpensive, simple to build and easy to maintain. However, burning at low temperatures does **not** achieve the complete combustion nor destruction of used needles and syringes, and does **not** guarantee sterilization. Other weaknesses include fire hazards, smoke generation and toxic pollution, hazardous ash and continued risk of needle-stick injuries.

Clearly, given these shortcomings, burning at low temperatures is not an ideal long-term solution for safely disposing of waste generated from immunization programmes. When possible, the use of burial/encapsulation is often a better option for rural health facilities. On the other hand, low temperature burning may be a reasonable and practical short-term solution for safely disposing of used needles and syringes generated during mass immunization campaigns or for small rural health facilities. An obvious danger, however, is that that short-term solutions (such as low temperature burning), often become long-term practices.

Burning in a metal drum or in a protected brick hearth is the preferred option for low temperature burning of used injection waste. The burning site should be located in an unused area as far from houses and buildings as possible and the area should be fenced-off and cleared. Once the filled safety boxes have been placed in the metal drum, paper, leaves, and other flammable material can be mixed among them to help them burn and a fine metal screen can be placed over the top of the drum to reduce the release of ashes.

The fire should be allowed to burn until all the boxes have been destroyed. Once the fire is out and the residue at the bottom of the drum has cooled, the residue should be carefully collected and buried (covered with at least 13 cm of soil) and, where possible, the residue pit sealed with cement once full.

For pit burning, an adequate sized pit should be approximately 1–2 metres in diameter and about 1 metre deep and should be placed at least 50 metres from any houses or buildings. Full safety boxes and the bags of empty, crushed vaccine vials should be burned in the pit (the purpose of crushing the empty

Burning drum



vaccine vials before burning is to avoid explosion of the vials). Paper, dry leaves, wood and/or fuel can be used to start the fire. After burning has been completed, the pits should be filled in with soil or concrete and fenced-off if possible, to prevent access by scavengers, local children and others.

6.1.3 Medium and high temperature incineration

Medium temperature (800-1000°C) and high-temperature (>1000°C) incineration is defined as burning that reduces combustible waste to incombustible matter and results in a very significant reduction of waste volume and weight. In contrast to low-temperature burning, incineration ensures greater combustion and sterilization of used needles and syringes. However, incineration can still produce toxic pollutants such as heavy metals, dioxins, furan, and flyash. Expensive pollution control devices to prevent the release of these pollutants are generally only available on high-temperature incinerators. Residual ash and waste material that results from incineration needs to be safely handled (medium temperature incineration may not completely destroy needles), properly buried or ideally encapsulated to prevent leaching of toxic substances.

A well-trained and motivated staff is needed to keep incinerators functioning correctly. It is important to understand that incinerators will not work without proper operation and maintenance. When planning annual immunization budgets, it is necessary to budget for incinerator operation and maintenance costs, including the purchase of fuel where required.

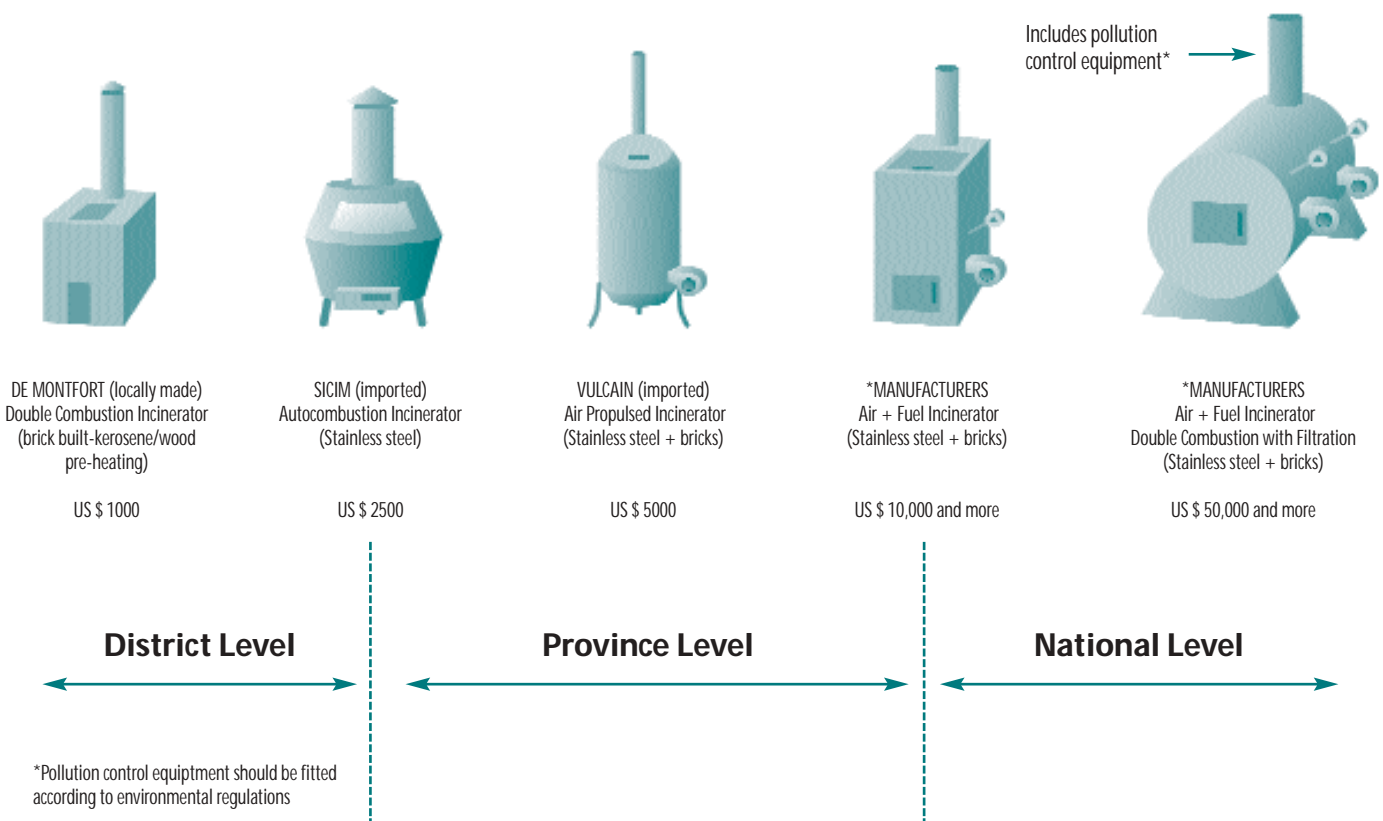
Several types of medical incinerators are available, ranging from the extremely sophisticated centralized operating plants with comprehensive pollution control devices to basic, relatively inexpensive, stand-alone incinerators that may be installed and operated at the district and peripheral levels (e.g. SICIM, de Montfort, Medicin 400). (For specifications see Annexes.) The price of appropriate, low-technology, medium-temperature incinerators ranges from US\$1 000 to over US\$ 5 000. High-temperature incinerators with temperature controls and multiple chambers cost \$150 000 or more, and costs are even higher when pollution control devices are added to comply with international environmental standards.

The cost of incineration per syringe varies greatly according to the amount of waste generated. The more the incinerator is being used, the less the disposal cost per syringe. Country studies that have included all the cost components of waste management with medium-temperature incineration have indicated that the disposal cost per syringe ranges from US \$0.08 for routine health services alone to \$0.02 when used for both routine services and immunization campaign waste disposal.

Incineration at the peripheral health centre level will usually not be feasible, due to the price and the capacity of current incinerators. The location of incinerators needs to be carefully chosen, both to optimize their use (i.e. depending on volume of waste generated, it may make sense for several areas or health facilities to share the same incinerator) and to reduce the public health risks resulting from toxic emissions for the surrounding population.

A solution that has proven to be both practical and effective in many countries, for both routine immunization and mass campaigns, is disposal of used needles and syringes at the district level. Used injection equipment is collected from health centres and mobile teams and transported to a district health facility that has a well-functioning incinerator or centralized autoclave/shredder for disposal. To facilitate collection some countries are using an "exchange strategy", whereby new needles, syringes and safety boxes are given in exchange for full safety boxes (Fig. 2).

Type of incinerators for syringes/needles and medical wastes disposal



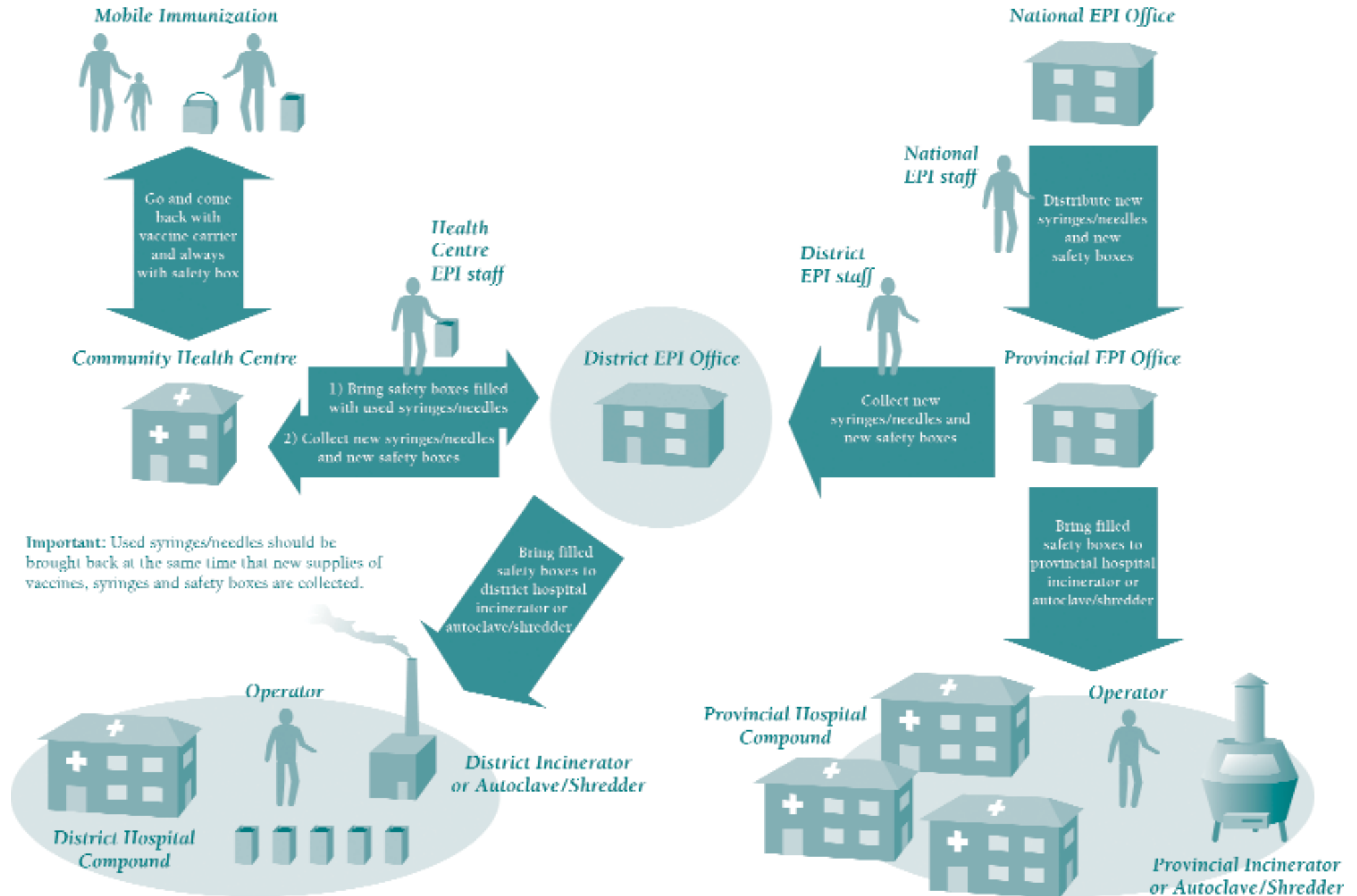
Locally-built de Montfort incinerator and operator



SICIM incinerator



Figure 2. Flow chart and exchange strategy for collection and disposal of used syringes & needles at the provincial facility level



6.2 Immunization waste disposal options for the future

6.2.1 Needle removal and shredding

Needle removal (or "defanging") the syringe at the point of use ensures immediate isolation of potentially contaminated needles, which can then be stored in a secure container. This decreases required safety box volumes, eliminates the risk of needle-stick injuries, and prevents reuse of syringe and needle. Various types of needle removers/destroyers are available ranging from manual to battery and electrically-operated models.

Manual models cut or pull needles from the syringes to render them unusable. The waste produced consists of contaminated needles which are collected in a disposable or re-usable container and the needle-less syringe which can be disposed of in a safety box. Some models require dismantling and disinfection of the needle container and guillotine mechanism at the end of the session. If not conducted safely, this handling process may expose the health worker to possible needle-stick injury.

The electrical models, are more expensive to purchase, require more expertise to operate, and obviously depend on a regular electrical supply to be usable. They produce a non-contaminated, non-sharp residue in a disposable cartridge, but are prone to emission of sparks and fumes and require regular maintenance with a supply of manufacture-specific spare parts. Work is in progress to evaluate needle and syringe removal/shredding technologies that do not require electricity and do not pose potential infection/contamination risks caused by fluid splashing. Programmatic issues also need to be evaluated.

6.2.2 Melting

Using industrial ovens, used needles and syringes may be processed at high temperature which results in melting and disinfection of the syringes. Although the needles do not melt, they become disinfected, encapsulated in the melted plastic, and thus no longer pose an infection or injury risk. The resulting mass of melted plastic and sterile needles can then be buried or placed in landfills.

The major challenge in implementing such a disposal system is its relatively high cost. Moreover, the thermal process may result in the generation of

noxious fumes. Currently, WHO has not tested or recommended the use of syringe melting ovens and evaluation of this technology is still in progress.

6.2.3 Steam sterilization (autoclaving and hydroclaving) and microwaving

Autoclaves are regularly used in medical facilities for the sterilization of medical equipment, and are a proven method for the sterilization and processing of used injection equipment in an environmentally friendly manner.

An autoclave uses steam to disinfect waste, which is achieved through the combination of sufficient temperature and time of exposure. A typical operating system uses steam at 121°C for 30 minutes. Biological monitors or colour changing indicators may be added to waste loads to ensure that sufficient steam penetration has occurred.

At autoclave temperatures of around 140°C or higher, many plastic materials soften and form an amorphous mass in the waste. In order to physically destroy sharps, the autoclaved waste is then fed into a shredder or grinder, which also reduces the waste volume by 60–80%. The sterile waste can safely be recovered and recycled for other uses, buried, or safely placed into municipal landfills. Disposing of immunization waste in this manner does not result in the release of smoke, particles or toxic emissions.

Autoclave with shredder



Autoclaves are available in various sizes, from small units used on site to very large units operating in centralized treatment facilities. If a regional autoclave facility is used, careful planning is necessary to develop a transportation system to collect waste from the districts. In such situations, an “exchange strategy” could be implemented, whereby new needles, syringes and safety boxes are exchanged for full safety boxes.

An autoclave with a capacity of about 250 litres costs around US\$ 25 000, while a large autoclave capable of treating 500 kg of waste per cycle may cost about US\$ 50 000. Other advanced autoclaves incorporate continuous feeding, internal shredding, mixing, drying, and/or post-treatment compaction. An advanced autoclave with a capacity of around 40 to 70 kg per hour costs between US\$ 47 000 and US\$ 70 000.

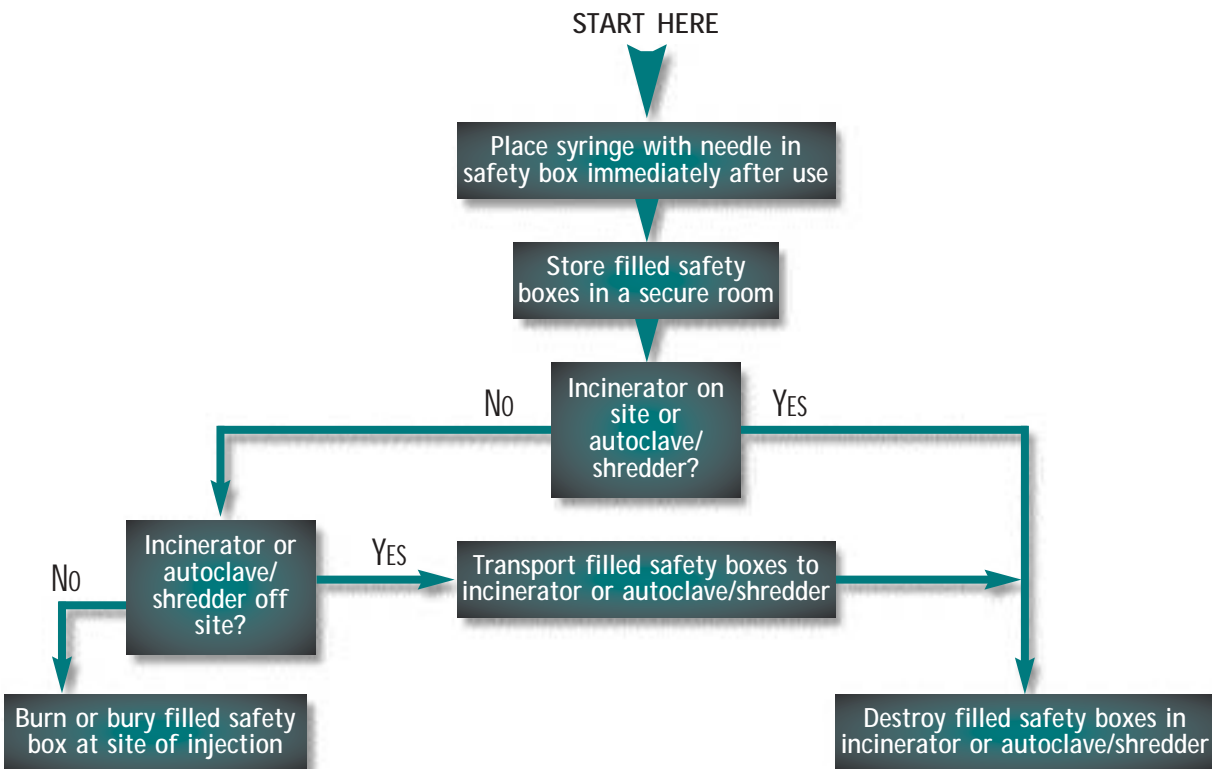
A hydroclave operates in a similar manner to an autoclave, but includes an internal shredding device and is often completely automated.

Steam sterilization can also be achieved through microwaving. Waste is loaded into a chamber and sealed, wetted with water or steam, then heated by microwave until it is non-infectious. The processed waste may then be shredded and compacted as in autoclaving, and disposed as solid waste.

The obvious disadvantages of using waste disposal autoclaves or microwaves in developing countries are that they are expensive, require a regular supply of water and electricity and are relatively high tech. A trained operator is needed and ongoing maintenance and repairs are required and the resulting sterile waste needs to be disposed of as solid waste.

However, the important advantages outlined above, combined with the fact that these devices may also be used to safely process non-immunization health care waste, suggests that this or similar non-burning disposal methods may be of interest to policy-makers in developing long-term health care waste management plans.

Criteria for decision-making and decision flow chart



7. Training health care workers in injection safety

Training on injection safety and safe disposal is an essential requirement before the introduction of AD syringes. In addition to vaccine delivery training, mid-level management courses and in-service refresher training, provision should be made for training on safety and adverse events following immunization (AEFI) monitoring. In order to ensure across-the-board collaboration, relevant partners such as nongovernmental organizations and private practitioners need to be included in these training activities. Moreover, educational establishments should revise their curricula to include injection safety so that the pre-service training of health professionals follows the national standards for safe injection practices.

For both routine services and campaigns, training issues for health workers and managers include (but are not restricted to):

- Arranging the workspace and disposal practices to prevent needle-stick injuries.
- Correct use of AD syringes and safety boxes as per national policy (i.e. no recapping or carrying used syringes).
- Appropriate disposal and destruction of used equipment.
- Correct calculation of the requirements and monitoring of stocks.

Simple guidelines should be developed to describe the step-by-step process for these technical and operational issues. Existing training materials can be found in the reference section at the end of this document.

KEY TRAINING MESSAGES FOR INJECTION SAFETY

- Use a sterile AD syringe and needle to vaccinate each child.
- Use a disposable syringe and needle to reconstitute each vaccine.
- Prevent contamination of injection equipment and vaccine.
- Prepare each injection in a designated, clean area where blood or body fluid contamination is unlikely.
- Always pierce the septum of multi-dose vials with a sterile needle.
- Do not leave a needle in the stopper.
- Protect fingers with small gauze pad when opening ampoules.
- Discard a needle that has touched any non-sterile surface (hands, environmental surfaces).
- Anticipate and take measures to prevent sudden patient movement during and after injection.
- Prevent needlestick injuries by not recapping, and placing used needles directly in safety boxes.
- Collect used syringes and needles at the point of use in a safety box, that is sealed when full (do not transfer contents or overfill safety boxes).
- Seal safety boxes for transport to a secure area. Do not open, empty or reuse them.
- Manage injection waste in an efficient and environment-friendly way.
- Prevent accidents to personnel in charge of waste disposal.
- Do not place empty vials in the safety box, they may explode while burning.
- Put only potentially contaminated injection equipment in the safety boxes. Do not put empty vials, cotton pads, compresses, etc. in the safety boxes.

8. Supervision and monitoring

Regular monitoring and supervisory visits are essential to ensure the implementation of safe injection practices, including the disposal of used injection equipment/material or sharps waste disposal.

The following should be monitored in both routine and mass immunization campaign settings:

- Adequate supplies of AD syringes, needles, and safety boxes are available at each immunization site.
- Immunizations are administered in a safe and correct manner.
- Safety boxes are properly assembled (i.e. with the top securely closed).
- Needles and syringes are placed immediately in safety boxes after use, and are not recapped.
- Empty vaccine vials are not thrown into the safety boxes.
- Safety boxes are filled only to appropriate levels (i.e. approximately 3/4 full; no needles are sticking out of the box) and are properly closed.
- Safety boxes are not opened and the contents are not transferred to other containers or other safety boxes.
- Full safety boxes are safely and completely disposed of (e.g. buried, incinerated, etc.).

☛ Evaluation activities that take place after an immunization campaign are important learning opportunities to identify areas for improvement of injection safety. Results from the evaluation should be shared with health workers to ensure ongoing safe injection practices.

- Burial areas and waste disposal equipment (e.g. incinerators, autoclaves and microwaves) are properly maintained and used.

Given the importance of injection safety, it is recommended that national immunization services select a few key indicators for monitoring performance.

The following are examples of indicators that could be regularly monitored and periodically assessed:

- Safe injection practices
 - proportion of health facilities in which, during the supervisory visit, immunizations were observed to be administered in a safe and correct manner
- Adequacy of syringe and needle supplies at health facility level
 - proportion of facilities (districts) supplied with adequate (i.e. equal or more) number of AD syringes for all routine immunization during the year (or quarter or other specified period);
 - frequency of deliveries of supplies to each facility.
- Disposal of used injection equipment
 - proportion of health facilities with adequate stock of safety boxes;
 - availability of appropriate waste disposal options;
 - absence of used syringes and needles at the facility, in rubbish areas close to the health centre or present in municipal waste dumps where public access is not controlled.
- Existence of a system to monitor adverse events following immunization (AEFI).

National immunization programmes are encouraged to integrate information about injection safety in the regular weekly or monthly routine reporting forms (i.e. those reports that are submitted regularly by the health facility to the district level).

“First, do no harm” Introducing AD syringes and ensuring injection safety in immunization systems of developing countries

9. Advocacy for injection safety

Advocacy strategies for injection safety must be developed to target not only managers of immunization services but also government decision-makers and managers, health workers, and the general population. Promoting the safe use of injections requires a behaviour change strategy, which must involve consumers as well as public, private and traditional health workers.

Injection safety



Statistical data on existing risks and practices can be a useful tool for convincing policy and decision-makers of the importance of injection safety. This may already be available if an injection safety assessment has already been undertaken, and, if not, such an assessment should be considered.

Simple communication messages should also be disseminated among health staff about the impending switch to AD syringes. For example:

- *"Use a new syringe and needle for every immunization, or do not immunize!"*
- *"If it's not new, it won't do"*

Finally, the neighbouring community should be aware that high quality immunization services are available that provide safe and effective vaccines which are safely administered using proper equipment. This information should help result in increased community awareness and demand for immunization.

Further advocacy suggestions are available in the References section.

10. Injection safety in mass immunization campaigns

Mass vaccination campaigns pose special injection safety challenges because they aim to immunize many thousands of people over a short period of time. The large amount of used injection equipment generated by the campaign can cause severe waste management problems, increasing the chance that safety breaches may occur.

Although injection safety procedures should not differ markedly from those used for routine immunization, vaccination campaigns merit special attention. Ensuring injection safety should be the highest priority during any mass campaign using injectable vaccines. The provision of safe equipment and supplies does not avoid all of the risks. Careful planning and the sensitization of those who will administer the vaccine is essential to conduct a safe campaign. The efforts to ensure injection safety during campaigns, can also help to improve the safety of routine immunization services long after the campaign is finished (e.g. staff training, pit digging, building of incinerators).

Measles campaign in Burkina Faso



Planning checklist for injection safety during campaigns

Detailed campaign plans must

- ✓ Identify all key players and partners
- ✓ Plan, budget for and order adequate supplies of all necessary items
- ✓ Assess the current injection safety situation
- ✓ Include a detailed budget with costs of all safety components
- ✓ Plan for staff training and media messages
- ✓ Include safety in the campaign from the start
- ✓ Monitor, document and disseminate results
- ✓ Evaluate and identify lessons learned

Safe vaccine administration

- ✓ Use WHO/UNICEF pre-qualified or nationally approved vaccine and injection material
- ✓ Bundled distribution of vaccine and diluent with reconstitution syringes, auto-disable (AD) syringes and sharps boxes to the immunization sites
- ✓ Emphasize need for sterile technique, correct reconstitution and safe administration
- ✓ Train healthcare workers in proper techniques
- ✓ Ensure traceability of vaccine by manufacturer and lot number

Sharps waste management

- ✓ Assess local regulations and possibilities for sharps treatment and disposal
- ✓ Identify practical, simple solutions for waste collection and disposal
- ✓ Ensure availability of sharps waste disposal facilities, adequate safety boxes
- ✓ Plan transportation, storage and disposal procedures before the campaign begins
- ✓ Provide clear instructions and guidelines for health staff on disposal
- ✓ Monitor disposal on a daily basis

AEFI management and monitoring

- ✓ Assess or set up AEFI monitoring system
- ✓ Develop rapid reporting channels
- ✓ Decide which AEFI are to be reported and which contraindications to observe
- ✓ Train health care workers to investigate and manage AEFI and respond to rumours
- ✓ Explain to key people involved in the campaign why the campaign may result in the perception of increased rates of AEFI
- ✓ Plan and transmit media messages on the campaign which address locally perceived safety concerns
- ✓ Form an AEFI review committee
- ✓ Keep alert for "issues" and rumours

11. Implications for other parts of the health services

A committee for injection safety (possibly part of an existing committee such as the Interagency Coordinating Committee) should be activated. This committee should include key partners such as EPI, WHO, UNICEF and others, brought together as members of the Safe Injection Global Network (SIGN). Efforts should also be made to include representatives from curative services, the environmental health department and donors. The committee should examine and make recommendations to the ministry of health on the implications of introducing AD syringes into one health programme while other health services continue to use non-AD equipment to administer injections.

Ensuring injection safety within immunization services can serve as a model for preventing blood-borne infections in other components of the health system. The committee for injection safety should promote injection safety activities in all areas of the health care system. Potential activities of various programme areas are outlined in the table below.

Table 7. Roles of other health programmes in promoting injection safety

| Programme area | Role in promoting injection safety |
|---|---|
| HIV/AIDS prevention programme | <ul style="list-style-type: none"> ❑ Communicate the risk of unsafe injections to patients and health care workers |
| Essential Drugs and Medicines Programme | <ul style="list-style-type: none"> ❑ “Bundle” appropriate injection equipment and safety boxes with all injectable medications ❑ Promote rational use of injections within the national drug policy |
| Family planning services | <ul style="list-style-type: none"> ❑ Supply auto-disable (AD) injection equipment and safety boxes with injectable contraceptives |
| Curative services | <ul style="list-style-type: none"> ❑ Train health care workers to safely administer injections ❑ Manage sharps waste within the health care waste management plan |

12. Conclusion

Injection safety concerns all health workers, supervisors, managers and the general public. While the use of AD syringes and safety boxes by immunization programmes will greatly reduce the risk of transmitting bloodborne infections, their introduction alone will not ensure immunization safety. Proper equipment must be accompanied by careful planning, management, training and

supervision in the safe use and disposal of AD syringes. Finally, the experience gained in ensuring injection safety in immunization services should be used as a model to ensure that **all** medical injections, including those for preventive and therapeutic services, are safely administered and that the used injection equipment is safely disposed of after use.

➡ *National immunization systems that follow good injection safety and waste management practices deliver injections that result in no harm to the recipient, no harm to the health worker, and no harm to the community.*

References and further reading

Documents and sources of information relevant to injection safety, including the safe disposal of immunization waste:

General issues:

Safety of injections: WHO–UNICEF–UNFPA joint statement on the use of auto-disable syringes in immunization services. Geneva, 1999 (unpublished document WHO/V&B/99.25; available from Vaccines and Biologicals, World Health Organization, 1211 Geneva 27, Switzerland and on the Internet at www.who.int/vaccines-documents/DocsPDF99/www9948.pdf).

The SIGN toolbox, available on the Internet at www.injectionsafety.org.

Assessment and monitoring:

Tool for the assessment of injection safety. Geneva, 2001 (unpublished document WHO/V&B/01.30 and WHO/BCT/01.02; available from Vaccines and Biologicals, World Health Organization, 1211 Geneva 27, Switzerland and on the Internet at www.who.int/vaccines-documents/DocsPDF01/www576.pdf).

Supplies:

Product information sheets, 2000 edition. Geneva, 2000 (unpublished document WHO/V&B/00.13; available from Vaccines and Biologicals, World Health Organization, 1211 Geneva 27, Switzerland and on the Internet at www.who.int/vaccines-documents/DocsPDF00/www518.pdf).

Policy and planning:

Aide-mémoire for a national strategy for the safe and appropriate use of injections. Available on the Internet at www.injectionsafety.org. SIGN Toolbox (1.1).

Safety of injections in immunization programmes: WHO recommended policy. Geneva, 1996 (unpublished document WHO/EPI/LHIS/96.05 Rev.1; available from Vaccines and Biologicals, World Health Organization, 1211 Geneva 27, Switzerland and on the Internet at www.who.int/vaccines-documents/DocsPDF/www9665.pdf). SIGN Toolbox (1.4).

Waste management:

Options for waste disposal systems. Available on the Internet at www.healthcarewaste.org.

Resource documentation on waste management. Available on the Internet at www.healthcarewaste.org.

Aide-mémoire for a national strategy for health care waste management. SIGN Toolbox (1.2).

Training:

Giving safe injections: Using auto-disable syringes for immunization. Available on the Internet at www.path.org/resources/safe-inj-pdf.htm.

Safe management of wastes from health care activities. Available on the Internet at www.who.int/water_sanitation_health/Environmental_sanit/MHCWHanbook.htm.

Advocacy:

Creative brief: your guide to safe disposal; SIGN Toolbox (4.3).

Creative brief: always use a safety box; SIGN Toolbox (4.8).

Creative brief: safe waste management; SIGN Toolbox (4.10).

Campaigns:

Safety of mass immunization campaigns. WHO/V&B/02.10

WHO web sites:

V&B (Vaccines and Biologicals): www.vaccines.who.int

ISPP (Immunization Safety Priority Project): www.who.int/vaccines-surveillance/ispp

SIGN (Safe Injection Global Network): www.injectionsafety.org

Environmental Health: www.healthcarewaste.org and

www.who.int/water_sanitation_health/environmental_sanit/health_care_waste.htm

Safety of injections

WHO-UNICEF-UNFPA joint statement* on the use of auto-disable syringes in immunization services

1. The reuse of standard single-use disposable syringes¹ and needles places the general public at high risk of disease and death.
2. The auto-disable syringe, which is now widely available at low cost, presents the lowest risk of person-to-person transmission of blood-borne pathogens (such as Hepatitis B or HIV) because it cannot be reused. The auto-disable syringe is the equipment of choice for administering vaccines, both in routine immunization and mass campaigns.
3. "Safety boxes", puncture-proof containers - for the collection and disposal of used disposable and auto-disable syringes, needles and other injection materials - reduce the risk posed to health staff and the general public by contaminated needles and syringes.
4.
 - WHO, UNICEF and UNFPA reaffirm the current policy that auto-disable syringes, vaccines and safety boxes should continue to be supplied as a "bundle" (see box, page 4) for all elective and emergency campaigns.
 - UNICEF reaffirms its current policy that UNICEF programme funds cannot be used to procure standard disposable syringes for any immunization purpose.
 - UNICEF announces that, as of 1 January 2001, no procurement service contracts² for standard disposable syringes will be entered into.
 - WHO, UNICEF and UNFPA urge that, by the end of 2001, all countries should use only auto-disable syringes or syringes which are designed to be sterilized. Standard disposable syringes should no longer be used for immunization.
 - WHO, UNICEF and UNFPA urge that, by the end of 2003, all countries should use only auto-disable syringes for immunization.
5. All partners of immunization services are requested to finance not only the vaccines, but also the safe administration of vaccines, auto-disable syringes and safe management of waste. Partners should do this by planning and implementing the above strategy, as well as by supporting related training, supervision and sensitization activities.



*This joint policy statement revises and replaces the document WHO-UNICEF policy statement for mass immunization campaigns, WHO/UNICEF/UNFPA, 2000. It is issued by the World Health Organization, Geneva, Switzerland (Department of Vaccines and Biologicals), the United Nations Children's Fund (UNICEF Programme Division, New York, USA) and UNICEF Supply Division, Copenhagen, Denmark) and the United Nations Population Fund, New York. This policy is also the adopted practice of the International Federation of Red Cross and Red Crescent Societies in their operations.



Background

Information reaching WHO, UNICEF and UNFPA consistently highlights the widespread occurrence of unsterile injection practices and identifies a major cause as insufficient supplies of syringes and needles¹. Unsafe injections can result in the transmission of blood-borne pathogens from patient-to-patient, patient-to-health worker and, more rarely, health worker-to-patient. The community at large is also at risk when injection equipment is used and then not safely disposed of. In many instances, used equipment is reused, sold or recycled because of its commercial value. The imperative to improve safety of injections in immunization services is underlined by the publication of articles in the *WHO Bulletin* (October 1999) which show that, although immunization injections are thought to be safer than curative injections, around 30% of immunization injections are still unsafe. Much evidence of reuse of disposable syringes exists and even recent country reviews suggest that sterilization of syringes and maintenance of sterilization equipment is not systematic.

Last year, in the developing world, routine immunization of children under one year and immunization of women of childbearing age with tetanus toxoid (TT) accounted for over one billion injections. In addition to routine immunizations, measles control/elimination activities and disease-outbreak control operations together delivered more than 200 million injections in the same year.

Hepatitis vaccine is now in use in half of the developing countries and Hib, measles-mumps-rubella (MMR) and pentavalent vaccines are already widely used in the Americas. Acceleration of special activities which aim at the elimination of maternal and neonatal tetanus and at better control of measles has begun. And a Global Alliance for Vaccines and Immunization (GAVI) is being formed to assure access to new vaccines for many of the poorest countries where the vaccines are needed most.

These increases of immunization services, including the elimination and control campaigns, offer an opportunity for improvement and make it imperative that injections are made safe for people.

The disease burden associated with unsafe injection practices has been estimated² and the cost implications of treatment of these diseases has been quantified³. Each unsafe injection costs governments between three to five times the extra cost of auto-disable syringes (which guarantee a sterile injection), not to mention the toll in terms of human suffering.

Strategy

Over the past years, WHO, UNICEF and UNFPA have launched a number of initiatives which aim to improve the safety of injections. The most recent was the precursor to this joint statement in 1997⁴ which related to the use of auto-disable syringes and safety boxes in immunization campaigns. That policy has assured the simultaneous budgeting and parallel purchasing and shipping of sufficient syringes and safety boxes for each consignment of vaccines for mass campaigns. Now, with a broad experience of the use of this equipment in the field, is the time to consolidate a policy to cover all administration of vaccine.

1

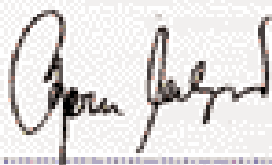
The use of auto-disable syringes in immunization services

Annex 1

WHO and UNICEF have agreed to implement a strategy to ensure that special attention is paid to the safe administration of vaccines, both in routine immunization services and during mass campaigns. The policy statement (on page 1) defines the position of WHO and UNICEF and is intended as a guide to other partners of immunization services, including national ministries of health.

In addition to this policy statement, WHO and UNICEF recommend that:

- Countries exert maximum effort to ensure that procedures for injection safety are rigorous -this includes routine use and monitoring of indicators of sterilization while sterilizable equipment is still used. Partner agencies involved in immunization programmes in countries should provide maximum support for the strengthening of safe injection practices.
- Urgent attention be given to develop appropriate tools (current monitoring tools are still insufficient to objectively demonstrate compliance to safe injection practices).
- Agencies supporting immunization services be encouraged to provide time-limited financial support to countries procuring standard disposable syringes for immunization until government-won budgets can be increased to cover the additional cost of auto-disable syringes.
- Agencies supporting immunization services which fund the purchase of locally-manufactured standard disposable syringes for immunization should assist countries with technology transfer to enable them to switch to auto-disable syringes in the shortest possible time.
- Used auto-disable syringes should be deposited in safety boxes without re-capping, burned locally and the remains buried underground - until improved disposal methods are developed. Urgent attention should be given to develop improved means for effective, safe and environmentally-acceptable waste processing and final disposal of auto-disable syringes.



E. Melgaard
Director, Vaccines & Biologicals
World Health Organization



V. Li-Franco
Director, UNICEF Supply Division
United Nations Children's Fund,
Copenhagen



S. Rashood
Director, UNICEF Programme Division
United Nations Children's Fund,
New York



M. Wazemuddin
Director, Technical and Policy Division
United Nations Population Fund



Ibrahim Danon
Under Secretary General, National Society,
Cooperation and Development (NSCD),
International Federation of Red Cross
& Red Crescent Societies

Annex 1

FOOTNOTES

- ¹ Auto-disable (A-D) syringes conform to the WHO/VacB Performance Specifications E0/D01 and D02 and include pre-filled pouch-and-needle injection devices. This statement applies only to available supplies of A-D syringes.
- ² UNICEF procurement service contracts cover the procurement of supplies and equipment by UNICEF as a service to governments and other organizations.
- ³ Review: Unsafe injections in the developing world and transmission of blood-borne pathogens, Solomon L (Ph.D.), Kane A, Lloyd J, Zalloum M, Kane M (M.D.), *WHO Bulletin* October 1999.
- ⁴ Unsafe injections in the developing world: Region based estimates of the transmission of blood-borne pathogens, Kane A et al. *WHO Bulletin* October 1999.
- ⁵ Direct and indirect costs of alternative injection technologies used in immunization services, Ekweonu et al. (Personal communication, October 1999).
- ⁶ Safety of Injections: WHO-UNICEF policy statement for mass immunization campaigns, WHO/EPL/UIS/97.04 Rev.1 – replaced by this statement, WHO/VacB/99.25.

The term "bundling" has been chosen to define the concept of a theoretical "bundle" which must comprise each of the following items:

- Good quality vaccines
- Auto-disable syringes
- Safety boxes

The implication is that none of the component items can be considered alone; each component must be considered as part of a "bundle" which contains the other two. "Bundling" has no physical connotation and does not imply that items must be "packaged" together.

Copies and information may be requested from:

World Health Organization (WHO)

Department of Vaccines and Biologicals, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland
Phone: +41 22 797 4374; Fax: +41 22 791 4182; E-mail: vaccines@who.int

United Nations Children's Fund (UNICEF)

3 United Nations Plaza, New York, NY 10017, United States of America
Phone: +1 212 624 6313; Fax: +1 212 624 6462; e-mail: scs@unicef.org

United Nations Children's Fund (UNICEF)

Supply Division, Frejborg, 2100 Copenhagen ØS, Denmark
Phone: +45 35 27 25 27; Fax: +45 35 25 94 72; E-mail: s4publications@unicef.dk

United Nations Population Fund (UNFPA)

Technical and Policy Division, 220 East 42nd Street - 17th floor, New York, NY 10017, United States of America
Phone: +1 212 297 5213; Fax: +1 212 297 4915; E-mail: HQ@unfpa.org

International Federation of Red Cross and Red Crescent Societies (IFRC)

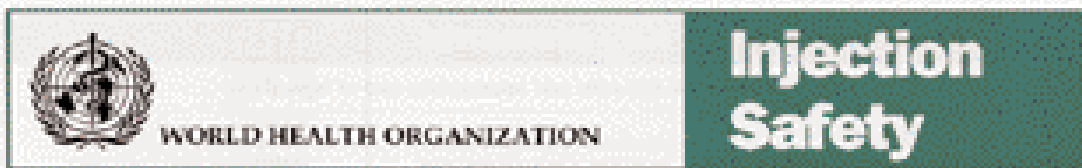
Case postale 312, CH-1211 Geneva 19, Switzerland
Phone: +41 22 730 42 22; Fax: +41 22 732 0265; e-mail: secretariat@ifrc.org

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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, 1.3 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

* Kasr A et al. Bull World Health Organ 1996; 77: 661-667.

Annex 2

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

Finalization 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:

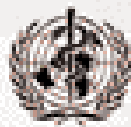
- Formulation of a policy stating that disposal is part of the syringe lifecycle and that healthcare services have a duty to manage sharps waste
- Assessment of the waste management system, including expressed and real needs
- Selection of appropriate waste disposal systems for all levels of healthcare 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 and on the Safe Injection Global Network internet forum at siginet.org

Secretariat of the Safe Injection Global Network
 Department of Blood Safety and Clinical Technology
 World Health Organization
 20 Avenue Appia, CH-1211 Geneva 27, Switzerland
 Fax: +41 22 794 8004. Email: siginet@who.int

"First, do no harm" Introducing AD syringes and ensuring injection safety in immunization systems of developing countries

30



WORLD HEALTH ORGANIZATION

Safe health-care waste management

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

September 2000

| Key elements | | |
|---|---|---|
| National policy for safe health-care waste management | | |
| <p>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.</p> <p>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.</p> <p>Important activities for a national strategy to achieve safe health-care waste management include:</p> <ul style="list-style-type: none"> ■ Identification of key partners, including but not necessarily limited to: Ministry of Health, Environment Agency, non-governmental organisations, waste producers and waste disposal companies or services | <ul style="list-style-type: none"> ■ 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 | <ul style="list-style-type: none"> ■ 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) |
| <p style="text-align: center;">Comprehensive system</p> <p>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.</p> <p>Important activities include:</p> <ul style="list-style-type: none"> ■ 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. | <p style="text-align: center;">Awareness and training</p> <p>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.</p> <p>Important activities include:</p> <ul style="list-style-type: none"> ■ 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. | <p style="text-align: center;">Selection of options</p> <p>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.</p> <p>Important activities include:</p> <ul style="list-style-type: none"> ■ Identification of available centralized waste management and disposal resources ■ Choice of sustainable management and disposal options, according to: <ul style="list-style-type: none"> — 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. |
| <p>Related documents and additional information on health-care waste management can be obtained on the World Wide Web at www.healthcarewaste.org</p> | | |
| <p>Department of Protection of the Human Environment World Health Organization 20 Avenue Appia, CH-1211 Geneva 27, Switzerland Fax: +41 22 791 4139. E-mail: hwaste@who.int</p> | | |

Department of Vaccines and Biologicals

Safety of mass immunization campaigns

To ensure safety during mass immunization campaigns with injectable vaccines

Mass immunization campaigns pose specific safety challenges, due to their objective of immunizing large populations over a short period of time and often being conducted outside the normal healthcare setting. Two of the most notable challenges are injection safety and adverse events following immunization (AEFI). Firstly, with respect to injection safety, the large number of injections to be administered and the large volume of waste generated pose added strains on the system. This increases the probability that breaches in safety may occur. Secondly, with respect to AEFI, there might be the perception of increased rates of AEFI. Reasons for this include the large number of doses being given over a short period of time and the administration of vaccine to a wider, usually older, age group.

If not prevented or managed properly, these safety issues can result in transmission of infections, impaired public and donor confidence in the campaign, and ultimately, reduced coverage and public health impact. However, one can avoid such problems by considering safety issues from the start of the campaign. Components to ensure safety include:

1. Assessing the existing injection safety situation
2. Preparing a detailed campaign plan which addresses key issues identified by the assessment.
3. Implementing the plan.
4. Monitoring the results.

Managers also need to ensure that they have a simple and timely monitoring system for adverse events for campaigns. Such a system not only supports the ongoing campaign, but also provides opportunities to identify key immunization and injection safety issues. These issues should then be addressed in routine immunization activities and included in a longer term immunization safety plan.

The main elements in ensuring immunization safety during a mass campaign are:

- An assured source of safe vaccines, safe injection supplies and other materials.
- Measures to ensure safety of vaccine administration.
- Measures to ensure safe sharps waste management.
- A system for AEFI monitoring and management.
- An advocacy and safety awareness strategy for the public and health staff.
- A budget to ensure funding of all planned components.

Checklist

Detailed campaign plans must

- Identify all key players and partners
- Plan, budget for and order adequate supplies of all necessary items
- Assess the current injection safety situation
- Include a detailed budget with costs of all safety components
- Plan for staff training and media messages
- Include safety in the campaign from the start
- Monitor, document and disseminate results
- Evaluate and identify lessons learned

Safe vaccine administration

- Use WHO/UNICEF pre-qualified or nationally approved vaccine and injection material
- Bundled distribution of vaccine and diluent with reconstitution syringes, auto-disable (AD) syringes and sharps boxes to the immunization sites
- Emphasize need for sterile technique, correct reconstitution and safe administration
- Train healthcare workers in proper techniques
- Ensure traceability of vaccine by manufacturer and lot number

Sharps waste management

- Assess local regulations and possibilities for sharps treatment and disposal
- Identify practical, simple solutions for waste collection and disposal
- Ensure availability of sharps waste disposal facilities, adequate safety boxes.
- Plan transportation, storage and disposal procedures before the campaign begins
- Provide clear instructions and guidelines for health staff on disposal
- Monitor disposal on a daily basis

AEFI management and monitoring

- Assess or set up AEFI monitoring system
- Develop rapid reporting channels
- Decide which AEFI are to be reported and which contraindications to observe
- Train health care workers to investigate and manage AEFI and respond to rumours
- Explain to key people involved in the campaign why the campaign may result in the perception of increased rates of AEFI.
- Plan and transmit media messages on the campaign which address locally perceived safety concerns.
- Form an AEFI review committee
- Keep alert for "issues" and rumours

Annex 4

| Words of advice | | |
|--|--|---|
| <ul style="list-style-type: none"> • Campaign policies and strategies should be identified well in advance of the campaign. • Practical, country specific solutions for sharps waste management should be identified and planned well in advance. • All supplies and materials should be ordered at least six months before the campaign. • Roles and responsibilities for the campaign should be clearly stated from the start and should include deadlines for completing all tasks. • All players and partners (including nongovernmental organizations, medical and nursing associations, religious groups, etc.) should be contacted to help disseminate safety awareness messages. • Regular monitoring throughout the campaign, followed by a final evaluation should be conducted so as to identify successes, problems and lessons learned. The findings should then be disseminated to all partners. | | |
| Key elements | | |
| <p>Planning for mass campaigns, including safety components:</p> <ul style="list-style-type: none"> • Identify the different key players and clearly assign activities, roles and responsibilities to each player. • Ensure that campaign advocacy messages include safety issues. • Conduct an assessment of current injection safety practices to assess the situation and identify the needs and challenges for the forthcoming campaign. The standard WHO tool for the assessment of injection safety practices might be considered for this. • Include the following safety components in immunization mass campaigns: | <ol style="list-style-type: none"> 1. A detailed budget with identified funding sources; 2. A micro-plan for distributing vaccines, diluents, injection and reconstitution materials, and safety boxes; 3. A plan for training on safe injections and AEFI monitoring; 4. A comprehensive waste disposal plan; 5. The information flow on AEFI; 6. A crisis management plan with communication strategies to prevent rumours from endangering the campaign. <ul style="list-style-type: none"> • Prepare "Questions and Answers" for the media on the background for the campaign and the potential for AEFI. | <ul style="list-style-type: none"> • Decide on a protocol for treatment of anaphylaxis, and provide the necessary training, drugs and equipment. • Review contraindications to vaccination (e.g. AIDS) and implications for the campaign; train staff accordingly. • Plan to monitor activities, successes and problems through routine reporting by all vaccination sites. • Plan from the start to undertake a final evaluation and use this to develop a long term plan of action to address the problems and issues that have been identified. Disseminate lessons learned so that others can learn from the experience. |
| Vaccine administration | Sharps waste management | AEFI monitoring |
| <ul style="list-style-type: none"> • Procure vaccines, AD syringes and safety boxes (and reconstitution syringes if necessary), from pre-qualified WHO/UNICEF or national regulatory authority-approved sources. • Ensure that quantities of all supplies match and that all distribution is bundled. Plan logistics carefully to ensure availability of all supplies at all vaccination posts. • Place orders well in advance (at least six months) before the start of the campaign. • Raise health care worker awareness on the need for safety throughout the campaign • Needles should never be recapped but must be placed into an approved safety box or puncture-resistant container immediately, and disposed of safely as soon as possible after use. • The training of staff at each level must include reconstitution of freeze-dried vaccine (use only the diluent supplied with the vaccine, use whole amount of diluent), the use of AD syringes and of the need for proper disposal in a safety box. | <ul style="list-style-type: none"> • The safe disposal of used injection equipment is one of the most important issues in assuring injection safety. There is no single, universally accepted method, but a locally acceptable solution needs to be identified and agreed upon with all partners before the campaign. • Assess local possibilities of sharps treatment and disposal (e.g. identify functioning incinerators, sites for burning, re-cycling, safe burial, etc.). • Construct incinerators where needed, or find temporary treatment sites. • Plan for transportation, storage and treatment of sharps waste. Safety boxes should be numbered so as to verify their return to the destruction point. • Identify practical, simple solutions that can be implemented during the campaign. Use the waste disposal plan and system developed for routine sharps waste management in the future. (Possibilities include incineration, burning, recycling, safe burial.) • Prepare clear instructions and guidelines for health staff on sharps disposal and waste management. • Instruct personnel on practices recommended for the campaign and monitor the compliance on a daily basis. | <ul style="list-style-type: none"> • Institute a simple surveillance system for adverse events, if one does not exist already, with case definitions, a reporting form and instructions on how and where to report. • Monitor the distribution and use of all vaccine lots. • Ensure routine reporting and managing of AEFI at vaccination sites/clinics through training staff at all points where AEFI might occur, points for acute AEFI and points for delayed AEFI. • Maintain monitoring for at least four weeks after the campaign and introduce as a permanent system wherever possible. • Estimate the expected rates of AEFI for the vaccine(s) to be used, and the differences in background rates of diseases in target age groups involved in the campaign. Use these baseline figures to compare with actual rates occurring in the campaign. • Identify a focal point and form a committee to receive and review reports of AEFI during the campaign. • Ensure rapid response to AEFI with the necessary investigation and correction of potential programmatic errors. • Be sensitive to rumours that might arise about AEFI and follow them up actively. |

Ordering code: *WHO/VG-B/02.10*

This document is available on the Internet at: <http://www.who.int/vaccines-documents>

Additional information on immunization safety can be obtained on the Internet at <http://www.who.int/vaccines>

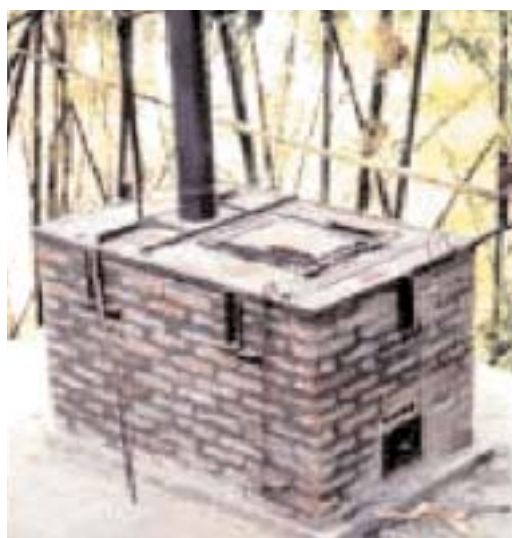
Immunization Safety Priority Project
Department of Vaccines and Biologicals

World Health Organization

20 Avenue Appia, CH-1211 Geneva 27, Switzerland

Fax: +41 22 791 4210; Email: epidata@who.int

Annex 5: Specifications of the De Montfort Incinerator



De Montfort Mark 8a

| | |
|---------------------------------|---|
| Model | Mark 8a |
| Description | Low cost medical waste incinerator |
| Capacity (weight/volume) | 12 kgs/0.7m ³ |
| Cycle time/loading | 240 mins/continuous |
| Temperatures low/high | 600°C/800°C |
| Energy source(s) | Kerosene, diesel, gas, wood |
| Energy consumption(s) | 2 litres kerosene per cycle plus start-up paper |
| Flue emission data | Flue height 4-6m |
| Shipping weight/volume | NA |
| Manufacturer | Local manufacture with local materials. DeMontfort University, UK http://www.appsci.dmu.ac.uk./mwi/ |
| Approximate unit cost | US\$ 700 |

Advantages

- ✓ The incinerator is built on site with materials available nationally including refractory bricks, refractory mortar, mild steel door, frame, grates and stack and standard building bricks.
- ✓ The incinerator has a secondary combustion chamber to reduce harmful emissions. When residual combustible gases reach the secondary combustion chamber they meet a further supply of air and they undergo secondary combustion, raising the temperature even higher, and reducing the gases to stable compounds such as carbon dioxide.
- ✓ The incinerator is loaded at start-up and may then be re-loaded from time to time while in operation.
- ✓ The walls of the incinerator never become dangerously hot to touch, even during operation, because of the double walls and sand infill between the walls.

Issues

- ▶▶ The incinerator operates with natural draught, requires fuel to start and takes time to reach operating temperature from cold. It is therefore best operated for long periods, not less than four hours at a time.
- ▶▶ It is not suitable for operation in a closed room. Smoke will be emitted whenever the loading door is opened. A roof may be fitted to protect the operator from rain, but only minimum walls.
- ▶▶ Overloading with syringes causes leakages of molten plastic into ash box and out of the ash door. When cooled, this plastic can block the door and cause it to break away from the incinerator wall.
- ▶▶ Lack of pollution control equipment means that emissions may not meet environmental regulations or international standards.

Annex 6: Specifications of the SICIM Incinerator



SICIM Pioneer AC/01

| | |
|---------------------------------|--|
| Model | Pioneer AC/01 |
| Description | Auto-combustion incinerator |
| Capacity (weight/volume) | 20-30 kgs/1m ³ |
| Cycle time/loading | 180 mins/single load |
| Temperatures low/high | 700°C/900°C |
| Energy source(s) | Start-up paper |
| Energy consumption(s) | None, auto-combustion |
| Flue emission data | Emissions not measured, but smoke and particulates observed during field trials in Viet Nam and Cambodia |
| Shipping weight/volume | 250kgs/3m ³ |
| Manufacturer | SICIM Spa Via Aquileia, 94 34076 Romans d'Isonzo (GO), Italy Tel: (34) 0481 90188 Fax: (34) 0481 90332 |
| Approximate unit cost | US\$ 2 500 |

Advantages

- ✓ The SICIM auto-combustion incinerator is designed to burn mixed medical waste.
- ✓ Requires no fuel except paper/packaging or leaves to start up.
- ✓ Is widely used in Cambodia without serious difficulties.
- ✓ Stainless steel 3mm DIN 304 is now used in the walls of the incinerator which will extend its life significantly.

Issues

- ▶▶ The body of the incinerator becomes very hot during use and so a protective fence is needed to restrict access.
- ▶▶ Dense smoke and particulates have been observed during start-up and during re-loading during field trials.
- ▶▶ The incinerator should be located well away from occupied buildings.

Experience

- ▶▶ Cambodia, Laos and Viet Nam (widespread use), Solomon Islands, Kiribati, Federated States of Micronesia, Fiji, Vanuatu, Philippines.

Annex 7: Specifications of the Medicin 400 Incinerator



Medicin 400

| | |
|---------------------------------|--|
| Model | Medicin 400 |
| Description | LP gas incinerator with two burners |
| Capacity (weight/volume) | 5kgs/0.012m ³ |
| Cycle time/loading | 15 mins/single load |
| Temperatures low/high | 900 ^o C/1100 ^o C |
| Energy source(s) | 2 x 45 kgs LPG cylinders |
| Energy consumption(s) | 90 kgs per 36 months |
| Flue emission data | NA |
| Shipping weight/volume | NA |
| Manufacturer | Health Care Waste Solutions P.O. Box 1647 Silverton 0127 Pretoria South Africa |
| Approximate unit cost | US\$ 2 500 (including fence and 90kgs of gas) |

Advantages

- ✓ Because this incinerator is gas powered, it can be started up easily and very quickly – and equally easily shut down at the end of a cycle. This would permit it to be used only once or twice a week in a health centre with a light load and many times per day in a bedded health centre with a large load.
- ✓ The tray under the furnace is filled with water to douse the ashes as they fall, thus reducing the risk of fire. The tray is emptied after each cycle into the ash bucket below that has a capacity of one year (at 100 cycles per year workload).
- ✓ The incinerator burns so cleanly that there is no flue: no smoke is visible during burning. Any load of any type of medical waste is acceptable.
- ✓ The body of the furnace, the protection grid and the loading door are in stainless steel. After three years' use, no physical damage is visible. Most other metal parts are galvanised against rust.
- ✓ The incinerator has more than three years of experience without a model change. It is supplied with a sturdy outer fence to prevent intrusions.
- ✓ The two gas cylinders have lasted three years without needing to be changed at a usage of two cycles per week. There is a manual changeover valve to permit one cylinder to be changed while the other continues to supply the incinerator.

Issues

- ▶▶ Because the incinerator is gas powered, the large 45kg cylinders have to be replaced periodically. This requires transport, funds to buy the gas and assurance that the cylinder, which is valuable, will not be stolen en route.
- ▶▶ Some needles are burned, others are not – requiring care to dispose of the ash.
- ▶▶ The spark gas lighter may not always function and matches may be needed.
- ▶▶ The supporting frame under the furnace and supports to the burners are made of mild steel and rust slowly. Although it did not need to be changed after three years, when it does require changing, the incinerator will have to be dismantled by a technician. The tray under the furnace is also in mild steel and will eventually rust through, but this is more easily replaced without technical help.
- ▶▶ The dimensions and capacity of the loading tray are somewhat limited. One 10-litre sharps box fits easily, but not two.

Annex 8: Specifications of an Autoclave with shredder



Hydroclave H-15

| | |
|---------------------------------|---|
| Model | Hydroclave: Model H-15 |
| Description | Autoclave with shredder |
| Capacity (weight/volume) | 50 kgs/hour |
| Dimensions: | 195x105x89cm |
| Manufacturer | Hydroclave Systems Corp. 1371 Middle Road K7L 5H6 Kingston, Canada Tel: +1 (613) 545 1933 Fax: +1 (613) 547 4521 |
| Approximate unit cost | US\$ 35 000 (Running cost, approx. US\$ 3 000) |

Advantages

- ✓ High weight and volume reduction.
- ✓ Dry waste.
- ✓ Skilled operator not required.
- ✓ High disinfection capacities.
- ✓ Entire process is done internally without any pre-shredding or pre-venting, which provides safer working conditions.
- ✓ Can recycle plastics, glass and metal.

Issues

- ▶▶ Odorous process.
- ▶▶ requires electricity and water.
- ▶▶ Cannot treat anatomical radioactive and cytotoxic wastes.

Experience



















- ▶▶ Can be built in low-income country (done in India).
- ▶▶ Construction - to be installed by the private contractor.
- ▶▶ Operation - the unit is self operating. Only one person is required for the loading and the unloading. Once the unit is loaded and secure, the machine runs itself until waste is sterilized.
- ▶▶ Materials needed for construction: hydroclave vessel, shredder, conveyor, control panel, strip chart recorder/controller, condensing system, steam valves and actuators.

Annex 9





Use & Disposal of AD syringes & safety boxes

Sample Job Aid for Health Workers (to be adapted as required)

USE:

-  First of all, assemble the safety box following instructions on box
-  As for reusable syringes, the policy "one sterile syringe with one sterile needle for one injection only" should strictly be applied for AD syringes
-  Before use of any AD syringe, check that the seal is not damaged or opened:
 - For AD syringes packed in individual packaging, the package should be well sealed
 - For AD syringes packed in bulk, there is a seal on the cap of the needle (plastic slightly welded). Verify that the welding is not broken
 - Do not use the AD syringe if any of these conditions are not respected
-  When using the AD syringe:
 - For AD syringes packed in individual packaging, open the package and remove the needle cap
 - For AD syringes packed in bulk, remove first the piston cap and then the needle cap
-  Throw the needle cap and the piston cap into the safety box. Do not keep it for re-capping
-  Do not pull the piston before filling with the vaccine (it will disable the syringe before use)
-  Stick the needle into the vaccine vial rubber cap (vaccine vial in inverted position)
-  Pull gently the piston to fill the AD syringes a bit over the 0.5ml graduation mark (to be able to remove the air)
-  Push gently the piston to remove the air up to the 0.5ml graduation mark
-  Stop immediately at 0.5ml graduation (otherwise the piston will block if you try to pull again)
-  Remove the vaccine vial from the syringe
-  Inject the dose of vaccine
-  Immediately put the AD syringe in the safety box (Do not recap)
-  Do not put the empty vial or any other waste products in the safety box
-  Put the empty vial into a separate container (e.g. plastic bag). At the end of the day, dig a small pit, throw the empty vials into it, crush them with a stone and cover with earth.
-  For all immunization sites (fixed post, outreach, mobile), always take the safety box with you (even if the safety box contains already some used syringes).
-  Fill the safety box to approximately 3/4's full. Do not over fill. (a five litre box contains approximately 100 used syringes, a ten litre box contains 200 used syringes)
-  Once the safety box is 3/4's full, close the lid to avoid syringes spilling out.

DISPOSAL:

-  Store full safety boxes in a safe and dry place in the health centre. Avoid keeping filled safety boxes more than one month at the health centre.
-  Take the full safety boxes back to the EPI District Manager when you collect your new supplies (vaccines, AD syringes, safety boxes)
-  New AD syringes and safety boxes will be given to you in exchange for your filled safety boxes.
-  This exchange strategy will allow the district to properly dispose of (e.g. incinerate) the used syringes and safety boxes. It also allows a comparison of the number of used syringes and safety boxes distributed and returned.

Annex 10

Distribution of AD syringes and safety boxes

Sample Job Aid for Managers of Immunization Programmes (to be adapted as required)



Safety boxes should always be distributed at the same time with AD syringes.



AD syringes and safety boxes should be distributed according to the requirements at provincial and district level.



AD syringes should be distributed according to the vaccines distribution scheme, (national to provinces, province to districts, district to health centres) or to the drugs scheme (national to districts, district to health centre).



AD syringes should be distributed according to vaccine distribution frequency (every 3 months from national to province, every month from province to district, every week from district to health centre).



Mode of transportation should be adapted to local conditions



During transportation, precautions should be taken to avoid contact with water and dust.



AD syringes and safety boxes should be stored:
a) in the place under control of the person in charge of immunizations;
b) in a clean, waterproof and restricted area;
c) in the same unit vaccines are stored.



At each level, the person in charge of immunization should monitor the stock (income, outcome and balance) with separate stock cards for AD syringes and for safety boxes.



At each level, the person in charge of immunization is responsible for AD syringes and safety boxes reception, stock monitoring, distribution and stock reporting.












At each level, the person in charge of immunization is responsible for budgeting operational costs for distribution of injection safety equipment (AD syringes and safety boxes).

Annex 11

Destruction of AD syringes and safety boxes

Sample Job Aid for Managers of Immunization Programmes and Incinerator Operators (to be adapted as required)

-  When receiving safety boxes filled with used syringes from the various health centres and hospitals, keep them in a safe and dry place. Avoid keeping filled safety boxes longer than one month.
-  It is recommended to perform one incineration at least each week, if enough filled safety boxes are available.
-  The person in charge of the pharmacy must keep a record of the number of safety boxes burned each time.
-  Prior to operating the incinerator, always wear safety gloves and safety glasses (goggles).
-  **IMPORTANT** - Do not incinerate filled safety boxes only. The safety boxes must be mixed with dry waste (leaves, paper, cardboard).
-  Respect the following ratio between the different wastes:
 - 1/3 of safety boxes + 2/3 of dry waste.
-  The filling procedures are as follows (for the SICIM incinerator):
 - a) Check that the incinerator is clean before filling (combustion chamber and ashtray free of residue)
 - b) Before filling the incinerator with dry waste you may have to put some paper on the grate of the incinerator to avoid the dry waste falling into the ashtray before it is burned.
 - c) Always put the dry waste first, filling half to two-thirds of the incinerator.
 - d) Then put the safety boxes on top of the dry waste.
 - e) The maximum quantity of safety boxes to burn at each time is:
 - 10 safety boxes of 5 litre size
 - 5 safety boxes of 10 litre size.
-  The lighting and burning procedures are as follows:
 - f) Ignite the dry waste, preferably at the top.
 - g) When the fire is well started, close the loading door.
 - h) For the Vulcain incinerator, switch on the fan after 1 minute and leave it on during the entire combustion process.
 - i) Depending on the incinerator model, the time for the combustion process will vary. The combustion process will last for 1 hour for the Vulcain and 2 hours for the Sicim incinerator.
 - j) During the incineration, NEVER open the loading door until the incinerator is cold.
-  The cleaning procedures are as follows:
 - k) Only when the incinerator is cold, open the loading door and clean the grate with the rake.
 - l) Then close the loading door, open the ashtray door and pull the ashes (residues) into the ash collector with the rake.
 - m) Bury the residues in an appropriate pit and don't forget to cover it with earth.

The Department of Vaccines and Biologicals was established by the World Health Organization in 1998 to operate within the Cluster of Health Technologies and Pharmaceuticals. The Department's major goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases.

Five groups implement its strategy, which starts with the establishment and maintenance of norms and standards, focusing on major vaccine and technology issues, and ends with implementation and guidance for immunization services. The work of the groups is outlined below.

The *Quality Assurance and Safety of Biologicals team* ensures the quality and safety of vaccines and other biological medicines through the development and establishment of global norms and standards.

The *Initiative for Vaccine Research* and its three teams involved in viral, bacterial and parasitic

diseases coordinate and facilitate research and development of new vaccines and immunization-related technologies.

The *Vaccine Assessment and Monitoring team* assesses strategies and activities for reducing morbidity and mortality caused by vaccine-preventable diseases.

The *Access to Technologies team* endeavours to reduce financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies.

The *Expanded Programme on Immunization* develops policies and strategies for maximizing the use of vaccines of public health importance and their delivery. It supports the WHO regions and countries in acquiring the skills, competence and infrastructure needed for implementing these policies and strategies and for achieving disease control and/or elimination and eradication objectives.

Department of Vaccines and Biologicals

Health Technology and Pharmaceuticals

World Health Organization

CH-1211 Geneva 27

Switzerland

Fax: +41 22 791 4227

Email: vaccines@who.int

or visit our web site at: <http://www.who.int/vaccines-documents>

