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**A reference outline for developing a  
National Policy and Plan of Action  
for injection safety in national immunization  
programmes**

This document was jointly developed by various teams of the World Health Organization Headquarters and Regional Offices working on immunization safety.

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## **Purpose and Acknowledgments**

The purpose of this document is to provide a structured outline to assist countries with development of an injection safety policy and plan of action.

Significant portions of this document have been based on the injection safety policy and plan of action developed by the WHO Regional Office for the Western Pacific for countries in that region. In addition, other countries have developed national policy documents and plans of action, particularly in the context of applications to the Global Alliance for Vaccines and Immunization (GAVI) and the Vaccine Fund. Several of these existing documents are of high quality and have been used as resources in developing this outline. Sample documents may be used for further reference. If used, however, it is recommended that they be carefully adapted to the particular situation in a country and the country-specific needs.

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## Elements of a National Policy and Plan of Action for Injection Safety

- A **policy** is defined as a set of statements and decisions defining priorities and main directions for attaining a goal. Thus, a national policy statement on injection safety should set the goals and standards to be achieved in injection practices with regard to safety (including safe injection waste disposal).
- A **plan of action** is needed to bridge the gap between the policy statement and the stated goals. The plan of action can be seen as a time-driven scheme defining 'who' does 'what', 'when', 'how' and for 'how much' in order to generate a product under a specific programme or programme component. A plan of action generally comprises the specific **strategies, activities and workplan** by which the policy goals/standards will be met. The plan of action should also include the planned methods and indicators for monitoring implementation.
  - A **strategy** should define the overall broad lines of action adopted to implement a national policy, with its endpoints being clear and measurable goals. A strategy is further operationalized into a series of annual activities and objectives.

Example of strategy: Reinforce the application of safe injection practices

- **Activities** should describe the more specific means by which available resources will actually be used, managed and evaluated.

Examples of activities related to the strategy stated above: (1) Ensure distribution of the national policy on safe injection to all health facilities (2) Conduct an injection safety assessment and plan for follow up activities to address problems identified.

- A **workplan** should be developed to provide well defined timelines with corresponding milestones/targets as well as to name a responsible officer/group for each activity. The workplan will assist with implementation of the plan of action, and particularly with monitoring progress.

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National Policy for Injection Safety and Safe Disposal of Injection Equipment in  
(Country)

Month, Year

### 1. Preamble

Provide a brief paragraph on the importance of injection safety globally, and more specifically in the country's immunization programme. Include a statement on the previous policy, if one exists, and why it is important to develop or revise a national policy. Suggested reference: Sample national policy document.

### 2. Policy statement

This should be the actual statement of the national policy on injection safety. The statement should be brief, concise and clear as to the elements of injection safety covered by the policy (i.e., administration of injections and disposal of used injection equipment). This outline is primarily provided to assist with development of a policy for safe immunization injection practices, however, a country may choose to develop a national policy that concurrently addresses the immunization programme and other health services. The national policy statement on injection safety should set the goals and standards to be achieved in injection practices with regard to safety (including safe injection waste disposal).

**Example:** The policy of the Ministry of Health is that 100% of immunization injections given in both the public and private sectors must be safe. This means that every injection must be given with a sterile single-use syringe and needle, which is then safely disposed of after use.

A subparagraph should describe the policy specific to mass immunization campaigns.

### 3. Definition of a safe injection

In general, a safe injection is one that is given using the appropriate equipment and that 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. The definition of a safe injection in the context of the national programme and the specific equipment used should be stated in the policy. For example, if a country no longer uses sterilizable needles and syringes, safe injections should not be defined in that context. In addition, the recommendation by the *WHO/UNICEF/UNFPA joint statement on the use of auto-disable syringes in immunization services* (December 1999- WHO/V&B/99.25) that AD syringes should be used exclusively by the end of 2003 should be considered in making the decision on what the national policy statement of a safe injection should be.

Existing definitions for safe injection (according to type of equipment) that may be adapted are as follows:

An injection is safe if it respects aseptic techniques and if it is given with:

- (a) A disposable syringe and needle (including those of the autodisable<sup>1</sup> type)
  - that is packaged and sealed by the syringe manufacturer and is sterile prior to being used,

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<sup>1</sup> Autodisable syringe: Disposable syringe which is automatically blocked after use and cannot be reused (also called autodestruct or AD syringe)

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- which is taken from a sterile package (or fitted with two caps) immediately prior to injection, and
  - which is disposed of without being recapped, in a puncture-proof safety box or similar designated sharps container after the injection is completed.
- (b) A reusable needle and syringe (where still appropriate during a transition period)
- which after use in conformance with accepted infection control procedures, has been safely disassembled and washed properly for re-sterilization, and
  - which has been properly sterilized in a steam sterilizer or autoclave designed for sterilizing medical equipment, (proper sterilization means that the full sterilization cycle has been completed as shown by an appropriate indicator such as a TST spot).

**Note:** The national policy should also include a statement on the need to ensure that vaccine reconstitution is done with appropriate aseptic technique (one sterile dilution syringe and needle per vaccine vial and ensuring no contact between the needle and any unsterile surface).

#### **4. Acceptable equipment for injections**

The type(s) of injection equipment considered acceptable should be clearly stated and conditions specific to each should be briefly described (e.g., timelines by which equipment will no longer be acceptable etc.). Reference should be made to the *WHO/UNICEF/UNFPA joint statement on the use of auto-disable syringes in immunization services* and the national policy decision should reflect appropriate timelines for complete switch to AD syringes, and discontinuation of use of standard disposables and syringes which are designed to be sterilized, if those are still in use.

#### **5. Disposal and destruction of used injection equipment**

Describe the national policy regarding disposal and destruction of used injection equipment, noting specific policies and procedures for routine immunization and mass immunization campaigns. Specific mention should be made of the recommended best practices (use of puncture-proof safety boxes, no recapping etc.).

There is currently no ideal solution for the safe destruction of used injection equipment. Available alternatives are listed below. A more comprehensive comparison of various methods for disposing of immunization waste is provided in the WHO document *First, do no harm. Introducing auto-disable syringes and ensuring injection safety in immunization systems of developing countries* (WHO/V&B/02.26). All method(s) of waste management or destruction recommended by the national policy should be stated, noting which method will be available at each level of the health care service (regional, district, health unit etc.) and explaining, where appropriate, specific circumstances in which they are to be used. Where applicable, collaboration with other sectors of government and private sectors should be stated.

##### **Incineration and other burning techniques:**

- Incineration, preferably in an appropriate high-temperature incinerator (> 800°C).
- If such an incinerator is unavailable, a low-temperature incinerator (300-400°C) may be used (limited to area with no surrounding population).
- Full safety boxes may be incinerated in small numbers by open burning (limited to area with no surrounding population).
- Residue from incineration (oxidized needles, vials, etc.) should be safely removed and properly buried in an appropriate pit.

**Non-incineration techniques:**

- Needle removal/needle destruction.

**6. Training of health care workers**

Describe the country-specific policy on training of health care workers, including in-service training as well as development of curricula for future professionals. The text below is an example only and if adopted should be adapted to the specific country situation.

*Example:* All health workers, including those in the private sector, will be given training on the principles of injection safety. Provision will be made for in-service training of existing health workers. Formal training curricula for physicians, pharmacists, nurses and other categories of health professionals will be revised to include appropriate instruction and materials on injection safety.

**7. Management**

Management issues include training of health staff and supervision of practices, but also equipment requirement calculation, budgeting and monitoring. Trained and competent people at all levels of the health system should be identified to monitor and manage injection safety issues, including the safe disposal and destruction of used injection equipment, in order to ensure that injection safety activities are carried out properly. The policy should set the goals to be achieved in this area.

**8. Advocacy and Communication**

Describe the plans for (a) diffusion of the national policy to health facilities and institutions;(b) development and diffusion of standard operating procedures or guidelines for all health facilities; and (c) community awareness. The policy should reflect the government and Ministry of Health's thinking on the public's right to know about and ensure injection safety for themselves. Where appropriate, collaboration with other sectors of government should be stated.

**9. Conclusion**

A concluding paragraph may be added summarizing the importance of injection safety and the government investment in this area.

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## **Plan of Action (200Y-200Z) to Improve Injection Safety and Safe Disposal of Injection Equipment, Country**

The plan of action should lay out the strategies, activities and workplan by which the policy goals/standards will be met. The plan of action should also demonstrate the intention to comply with the 1999 WHO/UNICEF/UNFPA statement both at the current time and when external funding is no longer available.

It should address each of the main aspects of injection safety in the policy document, including the plans for:

- Ensuring the application of the national policy in immunization practice
- Providing adequate supplies of the recommended injection equipment for routine immunization and mass immunization campaigns.
- Improving the safety of the disposal of medical waste resulting from immunization activities.
- Providing training (including development of guidelines for use etc.) on the use of new injection equipment as well as disposal and destruction of used equipment.
- Training and supporting the necessary behavior change among health care providers.
- Ensuring adequate management of injection safety issues at all levels.
- Monitoring progress, including specific indicators that will be used and annual targets for these indicators.
- Providing information, education and communication to the public on the risks resulting from unsafe injections and poor sharps waste management.

### **1. Situation analysis**

Briefly, (in one page or less), describe the present situation in the country (in the public sector as well as the private sector if information is available) with regard to safety of injections e.g., the kind of injection equipment used presently, health workers and community behavior.

Document problems with injection safety from previous studies, supervisory visits etc. Information may be provided on the current situation relating to each strategy specified below as this will help in defining specific activities to address the issues identified and in presenting a logical flow to the plan of action.

### **2. Objective and strategies of the injection safety plan of action 200Y-200Z**

#### **Objective**

**Example:** To ensure the safe administration of all immunization injections and safe and appropriate disposal of injection waste throughout the country by *the year* \_\_\_\_\_

**Note:** Countries may find it appropriate to define specific sub-objectives for injection supply, sharps disposal and injection waste management. The objectives and sub-objectives should be defined in accordance with the national policies for injection safety and disposal of injection waste, if such policies exist. If policies do not exist, development of national policies should be considered as a primary objective.

#### **Strategies**

The broad strategies and specific activities (for each strategy) should be stated so that the distinction is clear – refer to page 1. Examples of strategies and possible related activities are provided in Annex 1. The next sections of the plan of action can be structured according to the main strategies

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defined and should describe in more detail the activities to be implemented, making sure to address the standards or goals to be achieved (as per national policy), logistics required (including calculation of annual requirements), budget, training (needs, methods, schedule and target groups), operational management, monitoring and advocacy. Ensure consistency of activities with National Policy document. The outline below provides examples which, if used, need to be adapted for country-specific needs.

### **3. Choice of injection equipment**

Refer to the injection equipment recommended by the national policy, and describe plans for ensuring adequate supplies and appropriate use for both routine immunization and campaigns.

### **4. Calculation of annual requirements**

Reference should be made to existing documents such as the WHO document *First, do no harm. Introducing auto-disable syringes and ensuring injection safety in immunization systems of developing countries* (WHO/V&B/02.26) and the GAVI application guidelines (*Proposal for support submitted to the Global Alliance for Vaccines and Immunization (GAVI) and the Vaccine Fund*).

### **5. Distribution of injection equipment**

Describe the methods, frequency and schedule for distribution of supplies of injection and disposal equipment. The schedule should be updated yearly, by administrative area (province, district, health center). Auto-disable syringes, vaccines and safety boxes should continue to be supplied as a bundle for all elective and emergency campaigns

A distribution spreadsheet should be developed as part of the plan of action.

### **6. Disposal of used equipment**

Refer to the methods of disposal and destruction recommended by the national policy, and describe plans for ensuring adequate supplies and appropriate use for both routine immunizations and campaigns.

### **7. Indicators to monitor safe injection practices**

The plan should include how monitoring will be carried out in general (e.g., injection safety survey using the standard WHO/BASICS tool, inclusion in supervisory checklists, standard reporting forms...) and how each indicator will be calculated (numerator and denominator), with targets defined for specific time periods (annual, mid-year etc.). The indicators should be measurable and should relate to the national strategy, objectives and activities (i.e., what is the expected impact of the activities defined on achieving the objectives?). Ideally, they should provide an indication on all three aspects of a safe injection, covering recipient, provider and population-related risks.

#### *Examples of indicators:*

#### Adequacy of syringe and needle supplies at health facility level:

- Proportion of facilities provided with the injection equipment recommended by national policy.

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- Proportion of districts provided with an adequate number of AD syringes for routine immunizations (adequate if number of syringes  $\geq$  total number of immunization injections given in the same period).
- Proportion of procurements and distribution at national level for routine and mass campaigns for which the “bundling” strategy is used.

Disposal of used injection equipment:

- Proportion of districts provided with adequate safety boxes (adequate if [number of safety boxes X 100]  $\geq$  total number of immunization injections given in the same period).
- Proportion of districts with an accessible and functioning incinerator or non-incineration safe facility for waste disposal.
- Proportion of facilities in a district with presence of used syringes and needles in garbage, dumping area or close to the health facility

Sterile injections:

- Number of abscesses following injection reported (AEFI). *Note:* This may only be a crude indicator as its interpretation may be difficult unless abscesses are shown to be bacterial.
- Proportion of observed injections at district level during monthly supervisory visits with single use of sterile syringe and needle. (*An acceptable threshold can be set according to current baseline in order to monitor progress.*)

*Examples of quantified targets:*

- By December 2003, 90% of immunization injections given with a sterile single-use syringe and needle must be disposed of in safety boxes, as measured during a standard WHO assessment.

Numerator = Total number of single-use syringes and needles disposed of in safety boxes  
Denominator = Total number of injections given using a sterile single-use syringe and needle

- In 2004, 100% of immunization injections given with a sterile single-use syringe and needle must be disposed of without recapping, as observed during supervisory visits.

Numerator = Total number of single-use syringes and needles disposed of without recapping  
Denominator = Total number of injections given using a sterile single-use syringe and needle

## 8. Management and operation

For example, describe plans for designating (or recruiting) responsible officers for injection safety at the different levels and operation officers for safe disposal and incineration and what their main responsibilities will be.

## 9. Training requirements

Describe the approach to assessing training needs, how, when and who will be trained on the different aspects of injection safety. Training materials to be developed should be noted. Plans should be made to provide training when health workers are not able to:

- Correctly use the recommended injection equipment or when new equipment is being introduced. Appropriately dispose of and destroy used equipment.

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- Correctly calculate the equipment requirements and monitor stocks.
- Routinely report on equipment and supply levels to EPI managers, or
- Where any of the above practices are being introduced for the first time,

Injection safety training should be done as part of other EPI or primary health care training. Plans for training/retraining physicians, pharmacists, nurses and other categories of health professionals on injection safety should also be described.

## **10. Advocacy requirements**

A strategy for advocating safety of injection and safe disposal of used injectables should be developed, targeting all levels from decision makers to health workers and the general public.

## **11. Surveillance and management of AEFI**

Describe plans for developing a system (or strengthening an existing system) for AEFI surveillance and management, ensuring good collaboration between the relevant health sectors (e.g., EPI and National Regulatory Authority). The plan should consider how to improve the capacity for routine surveillance as well as surveillance during campaigns, management of severe cases, investigation of clusters and other events (when an investigation is indicated), and a communication strategy to manage rumors about vaccine safety. Consider the setting-up of an ad hoc committee.

## **12. Budget estimates**

An annual budget should be developed as part of the national plan of action, to include the annual cost of equipment, the cost of disposal, and the cost of training and supervision. Reference may be made to existing documents such as the GAVI application guidelines (*Proposal for support submitted to the Global Alliance for Vaccines and Immunization (GAVI) and the Vaccine Fund*) for help with estimation of a budget for injection equipment.

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**Annex 1**  
**Examples of strategies and activities**

**1. Strategy: Reinforce the application of safe injection practices**

**Activities:** *The following are examples.*

- 
- Ensure distribution of the “safe injection policy” document to all health facilities.
- Conduct an injection safety assessment and plan for follow up activities to address problems identified.
- Develop a behaviour change strategy to promote safe and appropriate use of injections.
- Develop or revise (*Note: choice depends on existing situation*) training material to incorporate appropriate guidelines on injection safety.
- Develop or revise (*Note as above*) a supervisory checklist to incorporate injection safety.
- Develop or revise (*Note as above*) IEC materials on injection safety (targeted at health workers and the public).
- Work with medical and nursing schools to incorporate appropriate safe injection material in training curricula.
- Provide training (and retraining) on safe injection practices for health workers and managers.

**2. Strategy: Ensure provision of adequate supplies of AD syringes and safety boxes**

**Activities:**

- Training of EPI supervisors and logisticians (*specify administrative levels if needed*) on supply management.
- Establish reliable annual estimates of injection requirements, minimum stock levels and effective supply and distribution systems for injection and disposal equipment.
- Develop budget and secure required funds for injection safety materials.
- Ensure that all partners continue providing vaccines with required materials for injection safety.
- Support national self-sufficiency through building the capacity for local manufacture of *safe injection materials* (e.g., safety boxes, AD syringes).

**3. Strategy: Improve monitoring and supervision of injection practices**

**Activities:**

- Organise workshop for EPI supervisors, including review and revision of supervisory checklist to incorporate injection safety.
- Incorporate regular reporting on injection safety into the existing EPI reporting system (e.g., numbers of AD syringes, non-AD disposables, dilution syringes, and safety boxes received and in stock per month or per other specified reporting period; or proportion of observed injections during supervisory visits that are safe).
- Train staff to calculate indicators and measure performance and progress for injection safety.

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**4. Strategy: Ensure adequate disposal of used injection materials and immunization waste management.**

**Activities:**

- Develop and distribute a quick reference guide for appropriate disposal of used injection material and waste management.
- Ensure all necessary supplies for safe disposal of used injection materials and waste management are available at every location.
- Conduct a national workshop involving *all relevant sectors* (e.g., medical and nursing associations, environmental protection council) to develop a joint strategic plan for health care waste management.
- Develop a budget for safe disposal of used injection material and immunization waste management and secure funds (*partner support etc.*) for effective implementation.

**5. Strategy: Improve community awareness about injection safety**

**Activities:**

- Design a strategy for advocating injection safety to senior staff in the Ministry of Health and other decision-makers.
- Develop appropriate strategies for behaviour change among the public.
- Develop and disseminate IEC materials targeted at the public.
- Provide support to local initiatives to promote injection safety issues

**6. Strategy: Develop a system (or improve the existing system ) for detection, investigation and management of adverse events following immunization (AEFI).**

**Activities:**

- Develop a strategy for AEFI surveillance and management ensuring good collaboration between the *relevant health sectors* (e.g., EPI and National Regulatory Authority).
- Develop and disseminate guidelines on the AEFI surveillance system.
- Form a national expert committee on immunization adverse events to review causality of serious adverse events.
- Hold a training workshop for national and regional level staff on AEFI surveillance and management
- Support regional staff to provide training of EPI supervisors and health workers at the district and health unit levels on AEFI surveillance and management.
- Revise supervisory checklist to include adverse events.

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Annex 2  
Sample Workplan

Strategy	Activity	Responsible officer/institution	Indicator	Target			
				2002	2003	2004	2005
<b>1. Reinforce the application of safe injection practices</b>	<ul style="list-style-type: none"> <li>▪ Ensure distribution of the “safe injection policy” document to all health facilities.</li> </ul>		Proportion of health facilities that have received the policy		<b>50%</b>	<b>100%</b>	
	<ul style="list-style-type: none"> <li>▪ Conduct an injection safety assessment and plan for follow up activities to address problems identified.</li> </ul>		<ul style="list-style-type: none"> <li>▪ Completion of an injection safety assessment by standard method.</li> <li>▪ Development of a follow up plan.</li> </ul>		<b>Assessment done</b>	<b>Plan developed and implemented</b>	
	<ul style="list-style-type: none"> <li>▪ Develop a behaviour change strategy to promote safe and appropriate use of injections.</li> </ul>						
	<ul style="list-style-type: none"> <li>▪ Develop/revise training material to incorporate appropriate guidelines on injection safety</li> </ul>						

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Strategy	Activity	Responsible officer/institution	Indicator	Target			
				2002	2003	2004	2005
<b>2. Ensure provision of adequate supplies of AD syringes and safety boxes</b>	Training of EPI supervisors and logisticians on supply management.						
	<ul style="list-style-type: none"> <li>▪ Establish reliable annual estimates of injection requirements, minimum stock levels and effective supply and distribution systems for injection and disposal equipment.</li> </ul>		Proportion of districts in the country that have been supplied with adequate (equal or more) number of AD syringes for all routine immunizations during the year		<b>50%</b>	<b>75%</b>	<b>90%</b>
	<ul style="list-style-type: none"> <li>▪ Secure the required budget for injection safety including safe disposal of used equipment.</li> </ul>						
<i>Include other strategies and activities</i>							