GUIDELINES FOR IMPLEMENTING A NATIONAL PROCUREMENT POLICY TO INTEGRATE SAFE-INJECTION EQUIPMENT

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Guidelines for implementing a national procurement policy to integrate safe-injection equipment

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Disclaimer

The author's views expressed in this publication do not necessarily reflect the views of OGAC, the USAID, or the CDC.

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Purpose

The purpose of this document is to identify steps and information relevant to the development and implementation of a national procurement policy on safe-injection equipment. The intention is to increase patient and health worker safety, and especially to avoid medical transmission of bloodborne diseases such as HIV, hepatitis B, and hepatitis C. For this document, safe-injection equipment is defined as safety devices for medical injections covering immunization, preventative, therapeutic, phlebotomy, infusion therapies and intravenous (IV) catheters, and safety boxes.

Need for safe-injection procurement policy

The greatest safety risks posed by syringes are their potential reuse. The World Health Organization (WHO) estimates that approximately 50 percent of people in less economically developed countries are exposed to the risk of unsafe injections through needle reuse in both immunization and curative services.[1] The secondary safety risk which directly impacts health workers is the potential of infection through accidental needlestick injuries during injection and waste disposal procedures. Because the risk level for disease transmission is based on quantity of blood as well as infectivity, the unsafe management of lancets and phlebotomy equipment used for diagnosis and treatment of diseases is particularly hazardous. Phlebotomy is considered by the US Centers for Disease Control and Prevention (CDC) to be one of the highest risk procedures involving sharps, primarily because of the large-size needle bore (18 to 22 gauge) and the quantity of blood that may still be in the needle after use.[2] Sharps create a transmission route for HIV and other bloodborne infections especially in countries with populations where these infections are highly endemic.[3] Improper management of injection waste also puts the community at risk of injury and infection.[4] Each of these factors contributes to the estimated 23.5 million new HIV, hepatitis B, and hepatitis C infections transmitted every year through unsafe injections.[3] The risk of infection also depends on the prevalence of bloodborne pathogens in the population.[1] According to the CDC, the average risk of HIV infection after a needlestick exposure to HIV-infected blood is 0.3 percent or 1 in 300. The average risk of hepatitis B infection after needlestick exposure to hepatitis B-infected blood ranges from 6 to 30 percent. Even though the risk of seroconversion after needlestick is relatively low, injured health care workers may suffer disabling physical side effects from postexposure antiviral medication as well as severe emotional trauma as they await their test results.[5] Ensuring adequate injection safety equipment and supplies and the safe management of the resulting health care waste (HCW) are recognized as two crosscutting issues that affect all programs using sharps and producing infectious waste.

Policy content

A national policy for safe-injection equipment should be specific to the procurement of the equipment, not just an overarching safe-injection policy. It should address specific safe-injection equipment, defining and detailing each item for clear and concise interpretation. The policy should consider safety issues and quality standards by referencing applicable international and national standards. Any required procurement

regulations should also be addressed in the policy. In addition to the policy, a transition plan should be developed to address the introduction of new technologies. The details of developing a policy can be found in Annex 1. Guidelines for developing a procurement policy to integrate safe-injection equipment.

For detailed information on standards, specifications, quality, and manufacturers of safe-injection equipment reference the industry landscape entitled *Landscape for Safe Injection, Phlebotomy, and Waste Management Equipment*. The information within the document is based upon experience gained during the Making Medical Injections Safer (MMIS) project and the Guyana Safe Injection project. The landscape is located at the website: http://www.path.org/projects/health_care_waste_resources.php.

Policy considerations

During the development of a policy, consideration should be given to anticipated problems with implementation. In turn, once potential problems have been identified, proposed solutions should be incorporated into the policy. Often it is difficult to determine all the issues that may arise, but being proactive is beneficial.

The policy should be flexible so it does not preclude certain commodities. The policy should not impede on the open and fair market for existing or future commodities. The importance of affordability should also be kept in mind. If a policy is too specific about a commodity, there will be limited competition, which could ultimately raise the cost to the purchaser.

Avoiding limitations on syringe type keeps user choice varied and compatible with all medical procedures. The impact of specifying a specific syringe type should be considered throughout all facets (medical, dental, veterinary).

Finally, ensure the technology listed in the policy meets international standards.

Policy challenges

Potential challenges could occur during the development, implementation, and enforcement of a policy. Some of those challenges may be the influence of industry, local manufacturer's ability to compete, and the implications of safe-injection nomenclature.

Industry may lobby for safe-injection equipment that may be too specific and not adaptable to all needs of the country. This can present challenges to the implementation and enforcement of a policy if it is not flexible. It is important that those involved with policymaking consult with health care workers and end users before making a final decision.

Another challenge is that local manufacturers are often subject to duties and taxes that international manufacturers are not, thus reducing the local manufacturer's competitiveness. This was seen in Tanzania where local manufacturers pay duty and tax on the plastics and other raw materials to make syringes. However, the imported syringes

are duty and tax exempt because they are medical devices. The duty and tax laws place local manufacturers at a price disadvantage.

The nomenclature of safe-injection equipment can cause confusion and ultimately limit product availability. It is challenging because there are different terms that are used, such as autodisable (AD) syringes, reuse-prevention (RUP) syringes, retractable syringes, and needlestick-prevention (NSP) syringes. Often these terms are used interchangeably or are not clearly defined as products with different features. If a country uses just one word to describe multiple types of devices, it can cause confusion in the policy, procurement, and use. In Nigeria this became an issue because the safe-injection equipment policy had conflicting language on RUP syringes and retractable syringes. There were two local manufacturers that brought this to the attention of the Nigerian Ministry of Health, and the three parties worked together to resolve the conflicting language in the policy. This allowed for products of both companies to be in compliance with the policy.

These are just a few of the potential policy challenges a country could face. The development of a flexible policy can help alleviate roadblocks during implementation.

References

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Annex 1. Guidelines for developing a procurement policy to integrate safe-injection equipment

This guideline outlines the following key information and activities that should be considered when developing a procurement policy on safe-injection equipment.

- Definitions of various safety-enhanced injection equipment.
- Regulatory references.
- Transition planning from policy to implementation.
- Procurement considerations for the public sector.
- Sensitization of private importers and manufacturers.
- Sharps waste management.
- Managing cost implications.
- Monitoring and evaluation.

Definitions of various safety-enhanced injection equipment

Safe-injection equipment prevents needle reuse and/or needlestick injury, thus protecting health care workers, end users, and communities. In order to integrate appropriate safe-injection equipment, it is important to note that there are several types of equipment available in the marketplace, including international and local markets. It is essential to understand safety features of the device so the appropriate device is selected for a required clinical procedure.

The following definitions cover currently available devices; however, since 2004, new technologies have been emerging and are likely to continue emerging as awareness of safe-injection issues increase. At present, many medical devices with safety features including those for immunization, preventative, therapeutic, phlebotomy, infusion therapies, and IV catheters are available. The World Health Organization (WHO) has developed definitions as has the International Standards Organization (ISO). The following is an abbreviated summary of existing definitions.

Autodisable: A mechanism integrated into the syringe that disables the syringe after use. This prevents reuse from patient to patient or other inadvertent forms of reuse. The origins of this definition were developed in immunization programs, and therefore; it primarily addresses immunization syringes and specifies fixed dosing, non-removable needles, and “automatic” disabling.

Note that the official definition of “automatic” is complex and can create controversy at policy levels but is not clearly linked to the end user’s ability to effectively and safely use the devices in curative settings (see User’s Guide: Resource Materials on Procurement of Safe-Injection Equipment, Annex 10 and Annex 11 located at the website http://www.path.org/projects/health_care_waste_resources.php).

- *Reuse-prevention feature:* A mechanism integrated into the syringe that disables the syringe after use. This prevents reuse from patient to patient or other inadvertent forms of reuse. This definition is mainly for syringes designed for therapeutic injections. It includes variable dosing, removable needles, and options whereby the device disables automatically or in a manner where the injection practitioner must take a final step to disable the syringe (see User's Guide: Resource Materials on Procurement of Safe-Injection Equipment, Annex 12 located at the website http://www.path.org/projects/health_care_waste_resources.php).
- *Needle-stick prevention device:* A syringe and needle or other needle assembly with an engineered feature to shield the needle after use. Many NSP devices are either AD or RUP devices with an additional feature to protect against needlestick injury. They prevent reuse, protect health care workers from sharps injury, and reduce the risks of sharps waste. For syringes, NSPs include therapeutic and immunization equipment (see User's Guide: Resource Materials on Procurement of Safe-Injection Equipment, Annex 10 located at the website http://www.path.org/projects/health_care_waste_resources.php).
- *Other technologies:* Since 2004, industry has responded to injection safety needs with a variety of specialty devices. Most of the specialty devices focus on NSP as the primary technology to avoid reuse and to protect health care workers. Examples include vacuum collection systems, butterfly needles, infusion sets, and IV catheter inserters (see User's Guide: Resource Materials on Procurement of Safe-Injection Equipment, Annex 10 located at the website http://www.path.org/projects/health_care_waste_resources.php).

Regulatory references

Safe-injection equipment is available on the international market. In some countries local manufacturers are also starting to shift production toward safety syringes. International regulatory standards are available that address quality, sterility, and performance of safe-injection equipment. To ensure that the policy is successfully implemented, the equipment made available on the local market should conform to these standards whether imported or locally manufactured.

National regulations on safe-injection equipment may already conform in some cases to the requirements of the ISO and WHO. In such a case, countries may wish to retain the higher of the two (its own or the international agency's). In cases where a national standard could be updated to accommodate the new safe-injection equipment, the references below are provided along with abstracts from ISO (see User's Guide: Resource Materials on Procurement of Safe-Injection Equipment, Annex 10 located at the website http://www.path.org/projects/health_care_waste_resources.php).

The following information provides international references on quality and performance. Additionally, WHO has prequalified a large number of safe-injection equipment under their Performance, Quality, and Safety (PQS) program. Depending on the availability of local regulatory resources, devices approved under the PQS program may be considered preapproved by national regulatory authorities. Information from WHO is available on

their website http://www.who.int/en/. Detailed standards are available for purchase from ISO at www.iso.org (they are copyright protected and copies are not permitted). Costs to purchase standards are published online and range in cost from approximately US$50 to US$100 each.

- *AD syringes:*
  - ISO 7886-3 for immunization.
  - WHO PQS E08.

- *RUP syringes:*
  - ISO 7886-4.
  - WHO PQS E13.

- *NSP devices:*
  - Models may include any of the above ISO and WHO standards with the addition of an NSP feature.
  - ISO/CD 23908-1: The sharps injury-protection standard is under development. It is anticipated that it will cover single-use hypodermic needles and syringe combinations, catheters, introducers for catheters, and lancing devices.

- *Specialty devices for insulin, infusion, and IV catheters:*
  - Performance requirements for blood collection, infusion sets, and IV catheter inserters are referenced in multiple standards (see User's Guide: Resource Materials on Procurement of Safe-Injection Equipment, Annex 10 located at the website http://www.path.org/projects/health_care_waste_resources.php).

- *Safety boxes for disposal:*
  - WHO PQS E10.
  - ISO/CD 23907: The sharps containers standard is under development, as of March 10, 2010.

Transition planning from policy to implementation

Countries that are thinking of integrating safe-injection equipment within their national procurement policies will need to dedicate efforts to plan carefully for the practical implementation of the policy. As a general rule, introducing new technologies into a country requires substantial efforts in planning and budgeting for costs of introduction, training of health workers, procurement, and advocacy related to behavior change.

When transitioning from policy to implementation, the following considerations and planning tools should be taken into account:

Stakeholders consensus

Public procurement agencies, representatives from state government, and private importers will benefit from an opportunity to fully understand the policy and what will be

expected of them. A stakeholders meeting, or if necessary a regional stakeholders meeting, can be held to share important information. In addition, stakeholders may propose modifications to the implementation or overall plan for consideration.

Transition time period

Injection equipment has an established market with an existing pipeline of inventory. Manufacturers who have existing inventories and who cannot meet the policy deadline may need to apply for an extension which should articulate a phase-in plan. Extensions may be considered to allow manufacturers and importers to develop experience with safe-injection equipment and also to allow them to phase in new products while they deplete existing inventories.

Importers and manufacturers may be required to apply for a specific time period, time by which their current stocks will be depleted and a specific time by which they will begin distributing safe-injection equipment. Because injection equipment moves in large volumes, a minimum time frame for inventory to revolve is approximately 12 to 18 months. In addition to importers, manufacturers should also apply for a time period by which production will shift to safety devices or request other accommodations.

As updates to the policy are introduced, such as new standards or newly emerged technologies, a similar transition time period may be beneficial.

Introduction of safe-injection equipment to the supply chain

The Making Medical Injections Safer (MMIS) project experience shows that limiting distribution to a single type of device is generally too restrictive to reasonably accommodate all medical procedures. Additionally, safe-injection equipment designs are not available for all sizes and procedures; therefore, a small percentage of standard disposable syringes and other devices may continue to be required.

A mix of safe-injection equipment is recommended to accommodate the broad range of medical procedures that rely on syringes, including continued use of limited quantities of standard disposable syringes. As the transition moves forward, monitoring the mix to review actual demand and need is recommended prior to fixing limitations on any specific type.

Based on experience from countries in the MMIS project, an initial mix of products is proposed in Table 1 below. This mix should be revised depending on available information in each country. Specialty equipment has not been documented, which is due to the fact that it has not been previously available in many countries.

Table 1. Initial product mix recommendation

Type of safe-injection equipment	Estimated consumption
Standard procedure equipment: intramuscular, subcutaneous, IV ports, and blood drawing	
AD syringes, with or without NSP for all immunizations (lower-level facilities).	10 to 20 percent
RUP syringes, with removable needles for therapeutic injections, including injections via IV ports (hospital level).	30 to 60 percent
RUP with NSP (fixed or removable needles) for therapeutic and diagnostic injections (hospital level and facilities with lab services), including vacuum collection devices where applicable and available.	30 to 60 percent
Standard disposable syringes for general procedures such as naso-gastric feeding, wound irrigation, joint aspirations, or other procedures where the safe-injection equipment may not be available, especially 20 to 50 cc sizes.	10 to 20 percent
Safety boxes for curative sharps disposal.	1 to 5 L box / ~70 syringes
Safety boxes for immunization sharps disposal.	1 to 5 L box / ~100 syringes
Specialty equipment	
Infusion and blood-giving sets.	Unknown
IV catheters.	Unknown
Butterfly needles (pediatric).	Unknown
Standard disposable syringes for procedures where safe-injection equipment is not available including 20 to 50 cc syringes, veterinary syringes, and syringes used for mechanical purposes such as in pumps.	Unknown

- *Use of standard disposable syringes in the mix:* Little data is available on the percentage of standard disposables that is truly required; importations and sales should be registered, monitored, and periodically reassessed.
- *Hospitals:* While exact data has not been established in many areas of injection use, the experience of MMIS shows that hospitals require the largest variety in their mix due to the level of services provided. Hospitals are also assumed to provide at least 50 percent of all injections on a national basis. Consumption should be carefully monitored at hospitals in order to meet demand.

- *Lower-level facilities:* Lower-level facilities can focus their planning mainly on requirements for delivering intramuscular and subcutaneous injections (immunization and preventative services) and in some cases phlebotomy.

Training

For the transition to be successful, training of users will remain an ongoing need. While public-sector facilities may have access to continued training from the government and nongovernmental organization programs, importers and manufacturers should establish minimum training materials to ensure that private facilities and providers have access to training information and users are able to fully understand the operations of the equipment.

Procurement

When procuring safe-injection equipment, it is important to articulate clear categories, as features and cost ranges are significantly different and do not allow for straight comparisons.

Procurement considerations for the public sector

The procurement of safe-injection equipment should be specific and detailed to ensure good quality. The following sections describe the level of detail that should be contained within a tender.

Rationale for creating categories

While safe-injection equipment specifications should be largely based on international standards for quality, performance and physical characteristics, the environment for procuring injection equipment often needs to have categories that are more specific to how products are used, rather than the definitions in the available standards.

Establishing categories for procurement that allow for logical and transparent comparison across procurement offers is critical, especially in the transition phases. It also facilitates feedback from end users who may not be familiar with the standards. Without a logical means for comparing, evaluations are often questioned, protests occur, and the procurement process is delayed. This creates supply shortages and problems in enforcing the policy.

MMIS project experience with categories

Through its global procurement, the MMIS project identified six categories for procurement, as shown below. For the MMIS pooled procurements, product specifications were developed for categories 1, 2, 3, and 6. The product specifications can be found in Landscape for Safe Injection, Phlebotomy, and Waste Management Equipment located at the website: http://www.path.org/projects/health_care_waste_resources.php.

The following are the six categories for procurement:

1. AD syringes

- Sizes and types for immunization (fixed needles)

2. RUP technology, therapeutic injections

- Sizes and types for prevention (fixed needles)
- Sizes and types for general therapeutic injections (fixed or detachable needles)

3. NSP technology, therapeutic injections

- Therapeutic injection equipment (fixed or detachable needles)

4. NSP technology, blood drawing

- Syringes used for blood drawing with needle-prevention device
- Vacuum collection for blood drawing
- Butterfly needles for blood drawing

5. NSP technology, other specialty devices:

- Infusion sets
- Catheter inserters

6. Safety boxes for disposal

- Sizes and types

Use of international standards documents

International standards for safe-injection equipment may include details that conflict with country requirements. For example, marking and labeling requirements in the standards may conflict with country requirements. Therefore, while conformance to ISO standards should be required, disclaimers should be included in procurement documents noting that country requirements may supersede ISO standards at the discretion of the national regulatory authority.

Criteria for acceptable offers

The MMIS project developed criteria for evaluation (not including physical testing) in safe-injection equipment tender. To ensure a level environment for offerers, it is recommended that imported and locally manufactured safe-injection equipment conform to international standards. Products that fail to comply at this level may be less expensive but are likely to be inferior and possibly unsafe or not sterile. When low-quality safe-injection equipment is allowed to flood the market, the economic pressure can compromise enforcement of a safe-injection policy.

Sensitization of private importers and manufacturers

Public-sector procurement entities, including federal, state, and municipal, can be sensitized through existing channels regarding the adoption of and planning for the transition to procurement of safe-injection equipment. The MMIS project experience in several countries, however, shows that approximately 50 percent of national availability comes through private-sector supply chains and local manufacturing.

The transition period recommends stakeholder meetings for initial sensitization; however, associations of pharmaceutical importers or other forums for ongoing education should be identified to encourage regular updates and sharing of information to enable and facilitate compliance of private-industry participants.

Sharps waste management

Addressing safe-injection equipment includes the full life cycle of the equipment from manufacturing standards, performance in use, to final treatment and disposal. National policies on health care waste management are essential to include as a reference in national injection safety policies.

As a step in implementing the broad aspects of the policy, matching quantities of safe disposal boxes and final treatment and disposal systems should be available with all injection equipment.

Managing cost implications

Safe-injection technologies may have higher costs depending on the model and design. Studies from the United Nations Children's Fund, PATH, and WHO have been undertaken that illustrate that the reduction in health worker injuries and disease transmission support the increased costs. Planning for costs can be managed at a national level or district level using various costing tools. A tool to compare costs of various mixes of syringes can be found in the User's Guide: Resource Materials on Procurement of Safe-Injection Equipment, Annex 5 located at the website http://www.path.org/projects/health_care_waste_resources.php.

The costing tool does not include costs for training, advocacy efforts, sharps waste management, or monitoring of the policy after implementation. These costs should also be part of the planning for implementation.

Monitoring and evaluation

Monitoring and evaluation is an essential component of project implementation. The ability to verify success and adherence to the policy will require including monitoring and evaluation within the planning stages of the policy. Aspects to consider when developing the evaluation criteria are:

- Assign responsibility for monitoring adherence to the policy (at the national level, district level, and local level).

- Monitor facilities.
- Monitor proper use of new equipment.
- Identify corrective action for nonconforming facilities.
- Identify incentives for compliant facilities.
- Communicate with local manufacturers to ensure policy acceptance.
- Track the inventory and pipeline for stock levels of new and old equipment.

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