

WHO guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health-care settings



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Abbreviations and acronyms

AD	Auto-disable syringe
AEFI	Adverse Events Following Injections
AIDS	Acquired Immunodeficiency Syndrome
CDC	Centers for Disease Control and Prevention
EPSU	European Public Service Union
EU	European Union
EUCOMED	European Medical Technology Industry Association
FDA	Food and Drug Administration
FTE	Full-Time Equivalent employee
GAVI	Global Alliance for Vaccines and Immunization
GBD	Global Burden of Disease
GDG	Guideline Development Group
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HCW	Health-care worker
HOSPEEM	European Hospital and Healthcare Employers 'Association
ID	Intradermal
ILO	International Labour Office
IM	Intramuscular
ISO	International Organization for Standardization
IV	Intravenous
MS	Member State
NIOSH	CDC National Institute for Occupational Safety and Health
NSI	Needle-stick Injury
PEPFAR	The US President's Emergency Plan for AIDS Relief
PEP	Post Exposure Prophylaxis
PICO	Population, Intervention, Comparison, Outcomes
RUP	Syringe with reuse Prevention Feature
SIGN	Safe Injection Global Network
SIP	Syringe with sharps protection feature
SC	Sub cutaneous
UNICEF	United Nations Children's Fund
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization

WHO guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health-care settings

Executive summary

Injections are one of the most common health-care procedures. Every year at least 16 billion injections are administered worldwide. The vast majority – around 90% – are given in curative care. Immunization injections account for around 5% of all injections, with the remaining covering other indications, including transfusion of blood and blood products, intravenous administration of drugs and fluids and the administration of injectable contraceptives (1, 2).

Injection practices worldwide and especially in low- and middle-income countries (LMICs) include multiple, avoidable unsafe practices that ultimately lead to large scale transmission of blood-borne viruses among patients, health-care providers and the community at large. While data are not available on the associated burden of all possible diseases, unsafe injection practices would logically impact on other blood borne diseases transmitted through the reuse of injection equipment e.g. haemorrhagic fevers such as Ebola and Marburg viruses, malaria, and others. Reuse and unsafe practices also risk bacterial infections and abscesses at the injection site, which can cause long term damage.

Unsafe practices include, but are not limited to the following prevalent and high risk practices:

1. **Reuse of injection equipment** to administer injections on more than one patient including reintroduction of injection equipment into multi-dose vials, reuse of syringes barrels or of the whole syringe, informal cleaning with reuse and other practices. These practices are often ingrained and believed to be safe, but in reality lead to transmission of blood-borne viruses such as HIV, HBV, and HCV as well as bacterial infections and abscesses at the injection site. In 2000, at the start of the WHO Injection Safety programme and of the Safe Injection Global Network (SIGN), WHO estimated that 40% of the 16 billion injections were given with *reused* injection equipment leading to 21 million new HBV cases (32% of all new cases), 2 million new HCV cases (40% of all new cases) and around 260 000 HIV cases (5% of all new HIV cases)(2). Other diseases can also be transmitted through the reuse of injection equipment e.g. viral haemorrhagic fevers such as Ebola and Marburg.
2. **Accidental needle-stick injuries (NSIs) in health-care workers (HCWs)** which occur while giving an injection or after the injection, including handling infected sharps before and after disposal. Certain practices that are considered high risk for HCWs, such as recapping contaminated needles, are associated with NSIs and have frequently been observed during surveys on injection practices using WHO's injection safety assessment Tool C (http://www.who.int/injection_safety/toolbox/techttools/en/). In 2003, WHO published the burden of diseases from NSIs in HCWs which showed that there were 3 million accidental needle-stick injuries leading to 37% of all new HBV cases in HCWs, 39% of new HCV cases and around 5.5% of new HIV cases (3).
3. **Overuse of injections** for health conditions where oral formulations are available and recommended as the first line treatment. Demand for and prescriptions of injectable medicines that are inappropriate include overuse of antibiotics, use of unnecessary injectable products such as certain vitamins, moving directly to second line injectable treatments and others. Some of these issues are addressed through other WHO

interventions to promote rational and responsible use of medicines and specific initiatives to combat overuse of antibiotics. Such initiatives use information and communication campaigns to target both HCWs and communities to decrease inappropriate demands for medicines, including injectable medicines. Similarly and in support of the guidance in this document, WHO will embark on an injection safety global campaign targeting both health-care workers and communities as a means of decreasing demand for and over prescription on injections.

4. **Unsafe sharps waste management** putting health-care workers, waste management workers and the community at large at risk of needle-stick injuries and subsequent blood-borne infections. Unsafe management of sharps waste includes incomplete incineration, disposal in open pits or dumping sites, leaving used injection equipment in hospital laundry and other practices that fail to secure infected sharps waste. In some cases, used injection equipment is removed from open waste pits by people who scavenge through waste and then wash, repack and resell the equipment as new. These issues will be covered by the recommendations made in this document to procure sufficient safety boxes for the containment of all safety-engineered devices as well as through the global injection safety campaign to implement and adapt the recommendations to each country context.

Reuse prevention and needle-stick injury protection syringes, especially in curative services, are the focus of the recommendations contained in this document, along with provision of sharps waste management equipment. As above, reducing inappropriate demand will be addressed separately through other WHO initiatives. As part of a comprehensive package of interventions to ensure safe and rational use of injections--including communication and behaviour change strategies, supportive policies and provision of sufficient quantities of the appropriate injection equipment--WHO has analysed the potential contribution of safety-engineered syringes in reducing the problem of reuse and preventing needle-stick injuries.

Safety syringes are well-established and available in global markets. Official performance requirements and definitions have been added and developed over time, beginning with auto-disable syringes for immunization in 1990 and progressing to models with reuse prevention in 2006 and needle-stick protection features in 2012. The International Organization for Standardization (ISO) has well-defined requirements for producers of these products related to performance and fitness for purpose of safety syringes.

This document references safety syringes according to their ISO definition to provide an exact definition of the safety mechanism of each type of syringes and allow a common understanding between all guideline readers. The ISO definitions also provide guidance for procurers in determining the specifications and minimum standards for performance of safety engineered devices for selection of appropriate devices. The three main ISO definitions are below, along with additional clarifying descriptions.

- **ISO 7886 – Part 3:** “Sterile hypodermic syringes for single use- Part 3: Auto-disable syringes for fixed-dose immunization (AD).” This definition includes syringes that deliver fixed-doses, most have non-removable needles and all have a feature that blocks the syringe from being used a second time. This definition is limited to equipment for immunization services, and are typically 0.1 – 0.5 and 1.0 ml in size.
- **ISO 7886 – Part 4:** “Sterile Hypodermic syringes for single use with a reuse prevention feature (RUP).” This definition includes syringes that can measure flexible dosing amounts, have removable needles and a feature that blocks the syringe from being used a second time. The reuse prevention feature is activated following a single aspiration and injection in

reuse prevention syringes Type A while in syringes Type B the mechanism allows multiple plunger aspirations if reconstitution of the medication or the vaccine is required, or if multiple drugs need to be mixed in the same syringe before being injected to the patient. This definition is provided for syringes used in curative services where a broad range of injection procedures are performed and are typically 2.0 – 10.0 ml in size.

- **ISO 23908:** “Sterile hypodermic syringes with a sharps injury protection feature (SIPs)”. Some SIPs can also have a built-in reuse prevention feature. SIPs cover AD and RUP syringes that have an additional feature to prevent sharps injury, such as a means to contain the infected sharp after use.

The evidence-based policy guidance contained in this document will be the first WHO policy document that specifically addresses the use of safety-engineered injection devices for therapeutic injections. It complements and expands previously issued WHO guidance, including the following:

- WHO-UNICEF-UNFPA Joint Policy Statement issued in 1999 (http://www.who.int/injection_safety/toolbox/resources/en/). The 1999 policy recommends the exclusive use of AD syringes for all immunization injections.
- “Guiding principles to ensure injection device security” (4) issued by SIGN in 2003, which states: “Syringes with a reuse prevention feature offer the highest level of safety for injection recipients. They should be considered for use for therapeutic injections where local data indicate that unsafe practices are particularly common.”
- WHO best practices for injections and related procedures toolkit, published by WHO in 2010 (5), which notes the importance of sufficient supply of quality-assured syringes and matching quantities of safety boxes.

It is expected that the evidence-based policy guidance in this document will additionally contribute to preventing the reuse of syringes on patients and to a decrease in the rate of needle-stick injuries in health-care workers related to injection procedures, thus contributing to the prevention of injection transmitted infections. Based on the findings of the systematic review (Appendix 2), out of every 1000 health care workers in settings where SIP devices are introduced, 9 fewer (from 6 fewer to 11 fewer) are likely to suffer a needle stick injury in a one year period. There are no expected harms. Greater benefits can be expected in settings with higher HIV, HBV and HCV disease prevalence, higher sharps injury frequency and higher rate of reuse of injection equipment.

WHO has developed the policy recommendations in this document using the procedures from the WHO handbook for guideline development. The steps in this process included: (i) identification of priority questions and outcomes; (ii) retrieval of the evidence; (iii) assessment and synthesis of the evidence; (iv) formulation of recommendations, including research priorities; and (v) planning for dissemination, implementation, impact evaluation and updating of the guideline when new evidence is available.

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology was followed to prepare evidence profiles related to preselected topics, based on up-to-date systematic reviews.

The Guideline Development Group (GDG) and the Guideline External Expert Group comprise content experts, methodologists, representatives of professional associations, key NGOs and organizations working on injection safety and representatives of patients' associations.

The GDG met at a WHO technical consultation held in Geneva in March 2014. Members of the External Experts Group were identified through previous collaborative work in injection safety, from the Safe Injection Global Network (SIGN) members and through a public call for comment published in SIGN Post, an electronic weekly newsletter which has 1500 subscribers interested in injection safety. The SIGN Post members were involved in an external peer-review once the recommendations had been developed by the GDG.

The GDG agreed by consensus among its members on the strength of recommendations, taking into consideration (i) benefits and possible harms of this intervention; (ii) the quality of the available evidence; (iii) values and preferences related to the intervention in different settings; and (iv) the cost of different devices available in the international market.

To ensure there were no conflicts of interest, all members of the GDG completed a Declaration of Interests form prior to the meeting and the development of the policy recommendations.

The GDG made the following recommendations:

1. "We recommend the use of injection devices with sharps injury protection feature (SIPs), as opposed to devices without a sharps injury protection feature, by health-care workers delivering intramuscular, subcutaneous or intradermal injectable medications to patients (Conditional recommendation, moderate quality evidence)".
2. "We recommend the use of injection devices with a reuse prevention feature (RUPs), as opposed to devices without reuse prevention features, by health-care workers delivering intramuscular, subcutaneous or intradermal injectable medications to patients (Conditional recommendation, very low quality evidence)".

The conditional nature of the recommendations is consistent with the quality of the level of evidence on the impact of introducing safety engineered devices. The current prevalence of the problem, however, suggests that doing nothing is not an acceptable course of action (13)

WHO guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health-care settings

Scope and purpose

This guideline provides global, evidence-based recommendations on the use of safety-engineered injection devices to prevent the reuse of syringes and/or prevent needle-stick injuries in health-care workers. The ultimate aim is to make injection practices safer for patients and health-care workers and to prevent the injection-related transmission of deadly viruses, particularly HIV, Hepatitis C and Hepatitis B.

The procedures covered are intramuscular (IM), intradermal (ID) and subcutaneous (SC) injections including the syringes needed for the reconstitution of medication or vaccines when required. Other procedures e.g. intravenous injections and infusions, blood collection for laboratory testing, and capillary blood sampling will be covered by another guideline to be issued separately by WHO.

The policy recommendation aims to support Member States (MS) and development partners in making informed decisions on the appropriateness of introducing safety-engineered syringes for all injections in health-care settings.

Target audience

The target audience for this guideline includes the staff from ministries, agencies and other entities that have a critical role to play in the adoption and implementation of the policy i.e. in endorsing the policy, manufacturing the devices, ensuring their procurement and distribution at country level, promoting their correct use by health-care providers and their evaluation in terms of safety and effectiveness. Examples include:

- Ministers of health and finance
- National advisory bodies responsible for policy making on injection safety as part of a comprehensive infection control programme
- Public and private health institutions
- Professional societies
- Patients associations
- UN agencies
- International development partners
- Injection device manufacturers and their umbrella organizations.

Background

Injections are among the most common health-care procedures. Every year at least 16 billion injections are administered worldwide. The vast majority – around 90% – are given in therapeutic care. Immunization accounts for around 5% of all injections and the remaining percentage are associated with transfusion of blood and blood products, intravenous administration of drugs and fluids and administration of injectable contraceptives (1, 2).

Injections are invasive procedures and are administered in high frequency; therefore, meeting minimum safety standards is imperative as a means to protect against avoidable transmission of disease or injuries. However, assessments performed in many countries over the past decade show

that safety precautions are often not respected, exposing patients and health-care workers to severe risk of blood-borne infections and injuries, putting human lives at risk.

WHO defines a “safe injection” as one which does not harm the recipient, does not expose the provider to any avoidable risk and does not result in waste that is dangerous for the community (6) We can identify four main problems which make injections potentially dangerous for the patient, the health-care worker and the community at large, (when sharps waste is not safely collected and disposed):

1. Reuse of injection equipment for administering injections or to access shared medications leads to the transmission of blood-borne viruses such as HIV, HBV and HCV from one patient to another. A literature review, conducted in 2000, on the use of injections in health-care settings worldwide, estimated that the proportion of injections administered with unsterilized reused equipment, ranged from 1.2% to 75% (8). Also in 2000, at the start of the WHO Injection Safety programme and of the Safe Injection Global Network (SIGN), WHO estimated the global burden of disease attributable to contaminated injections given in health-care settings and concluded that 40% of the 16 billion injections were given with reused injection equipment leading to 21 million new HBV cases (32% of all new cases), 2 million new HCV cases (40% of all new cases) and around 260 000 HIV cases (5% of all new HIV cases), (2,8). Other diseases can also be transmitted through reused injection equipment, e.g. viral haemorrhagic fever such as Ebola and Marburg viruses, malaria and other diseases.

2. Accidental needle-stick injuries (NSIs) in health-care providers occur while giving an injection or after the injection, before, during or after disposal. For example, recapping contaminated needles is associated with NSIs and has been observed frequently during surveys on injection practices using the WHO injection safety assessment Tool C (http://www.who.int/injection_safety/toolbox/techttools/en/).

In 2003, WHO published the burden of diseases from NSIs in health-care workers (HCWs) which showed that there were 3 million accidental needle-stick injuries leading to 37% of all new HBV cases in HCWs, 39% of new HCV cases and around 5.5% of new HIV cases (3).

3. Overuse of injections for health conditions, where oral formulations are available and recommended as the first line treatment. In many countries, injections are perceived as the optimal form of care and assumed to be more effective and faster acting to treat health conditions. Surveys conducted in various settings have indicated that the proportion of prescriptions including at least one injectable preparation is high (up to 56%) and the annual ratio of injections per person per year ranged from 1.7 to 11.3, suggesting that injections are overused for administering medications when an oral formulation would be equally or more appropriate for the indication (7,8). Among injectable medicines, antibiotics are the most frequently overused drugs, including use for viral infections where they are not indicated. Therefore, reducing unnecessary injections may contribute to reductions in overuse of antibiotics and the associated concern around antimicrobial resistance, which is another WHO priority.

Injection overuse is a critical issue that will be addressed by a global campaign WHO is planning to implement in support of the new policy. This campaign will target reducing the overuse of injections through global communication, prescribers’ education, awareness-raising campaigns targeting health-care workers, communities and patients, to decrease demand for and over-prescription of injections

4. Unsafe sharps waste, when inappropriately collected and discarded putting the health-care provider, waste handler and the community at risk of sharps injuries and subsequent blood-borne infections. Unsafe management of sharps waste will be covered by the new policy through the recommendation to procure sufficient quantities of safety boxes for

containment of all safety-engineered devices and will also be addressed in the global campaign and implementation plan of the new policy and adapted to each country context.

Risks of unsafe injections include the transmission of blood-borne pathogens such as Hepatitis B and C and HIV to patients through the reuse of syringes, while risks for health-care workers are primarily related to accidental needle-stick injuries. Reusing syringes to access multi dose medication vials/containers that are used for multiple patients can also lead to the spread of viruses, bacteria and other pathogens. These diseases reduce the life expectancy and productivity of patients and health-care workers and burden communities and health-care systems with avoidable high treatment and opportunity costs.

Data are available on the prevalence and cost of treatment of HIV, Hepatitis B and C and on their potential to be transmitted by unsafe injection practices. In assessing the burden of disease caused by unsafe injections, these three infections are used to demonstrate significant areas of cost and burden (9,10). It should be noted, however, that the burden of unsafe injection carries much further than these three pathogens. Other complications include nosocomial bacterial infections, the transmission of malaria and viral haemorrhagic fever and other viruses. Muscle necrosis, various skin lesions due to cutaneous tuberculosis and skin granulomas were also documented. While it is logical that other bloodborne transmissions and infections are a risk, data for additional modelling are not sufficiently available and the large number of other potential risks could make additional modelling impractical.

Substantial efforts to address unsafe injection practices have been made by WHO, the Safe Injection Global Network (SIGN) and other key international health players since 2000. WHO, with the support of SIGN, has developed and assisted countries in implementing a strategy with three pillars consisting of (i) behaviour change among patients and health-care workers aiming to reduce unnecessary injections and ensure safe injection practices, (ii) increasing the availability of high quality injection devices and (iii) implementing a sound sharps waste management system. To support implementation of these strategies, WHO has issued a number of policies and guidance documents including:

- WHO-UNICEF-UNFPA Joint Policy Statement issued in 1999 (http://www.who.int/injection_safety/toolbox/resources/en/). The 1999 policy recommends the exclusive use of AD syringes for all immunization injections.
- “Guiding principles to ensure injection device security” (4) issued by SIGN in 2003, which states: “Syringes with a reuse prevention feature offer the highest level of safety for injection recipients. They should be considered for use for therapeutic injections where local data indicate that unsafe practices are particularly common.”
- WHO best practices for injections and related procedures toolkit, published by WHO in 2010 (5), which notes the importance of sufficient supply of quality-assured syringes and matching quantities of safety boxes.

Additionally, multiple recommendations to Member States to ensure the safety of all injections were also made by WHO via several World Health Assembly Resolutions, namely WHA55.18 on Quality of Care and Patient Safety in 2005, WHA63.18 on Viral Hepatitis in 2010 and WHA 67. 6 in 2014 on Hepatitis.

A list of key dates in injection safety is included in Table 1.

Table 1

Key dates in injection safety

1950	Glass syringes used as the norm
1960	Market authorization for sterile single-use syringes
1990	Market authorization for AD syringes
1999	WHO-UNICEF-UNFPA Joint Statement on the use of AD syringes for immunization injections
2003	WHO- SIGN “Guiding Principles for injection device security”
2004	Market authorization for RUP and SIP for therapeutic injections
2005	WHA 55.18 Quality of care and patient safety, referencing injection safety
2006	ISO standards developed for RUP
2010	WHA 63.18 Viral Hepatitis, referencing injection safety
2012	ISO standards developed for SIP
2014	WHA 67.6 Viral Hepatitis, referencing injection safety

A new study published in 2013 by Pepin et al (11) attempted to document the impact of all these global efforts by measuring the variation between 2000 and 2010 of the two key injection safety indicators, which are the number of injections per person per year and the reuse rate of injection equipment. The key findings of this study show that from 2000 to 2010, in LMICs, the average number of injections per person per year has decreased by 15% from 3.4 to 2.9 but two WHO sub-regions saw an increase (Americas Region B and Western Pacific Region B). The proportion of reuse of injection equipment decreased by 86% from 39.6% to 5.5%. This decrease was seen in all but two sub-regions (Americas Region B and European Region B). (Appendix 1: WHO Global Burden of Disease (GBD) sub-regions).

Such progress in injection practices are due to global multifaceted interventions developed and implemented worldwide, including the policy which supports the introduction of auto-disables syringes for immunization injections and introduction of injection safety into therapeutic programmes in PEPFAR-funded countries. Safety-engineered syringes with different mechanisms, including those which prevent reuse and/or needle-stick injuries, have been available on the international market since 1990 for AD syringes and 2004 for RUP and NSI models. Some models are similar in cost to standard single use syringes, while others, depending on the technical complexity of the safety mechanism, are up to 5X the cost, which can be prohibitive for some LMICs.

The definitions of safety features established by the ISO are important in understanding the various types of syringes available for different injection procedures. While research and development may yield additional product definitions in the future, it is important that syringes procured and distributed are certified against ISO standards or other internationally recognized standards to ensure their performance and quality. Tables 2 and 3 provide additional information to compare and describe the safety features.

Table 2 Different types of safety-engineered syringes available their advantages, disadvantages and cost profile (Approximate costs provided by WHO Prequalification Programme (PQS), PAHO Revolving Fund and UNICEF Supply Division, Copenhagen)

Category	Purpose of safety feature	Advantages	Disadvantages	Unit cost range (international prices) US\$
Traditional single use syringe without safety feature (ISO 7886 – Part 1 Sterile hypodermic syringes for single use – Part1: Syringes for manual use)	NA. These syringes do not have reuse or sharps injury protection mechanisms	- Provide sterile injections when used properly - Widely available - Low cost	- Can be repeatedly reused - Risk of Needle Stick Injuries remains - Sharps waste remains	0.03 -0.04
Auto-disable syringes for immunization (ISO 7886 – Part 3 Sterile hypodermic syringes for single use – Part3: Auto – disable syringes for fixed-dose immunization)	Prevents reuse of the syringe	- Widely available - No user intervention required if disabling mechanism activated before injection given	- Can be reused if safety feature is deliberately avoided on ADs with safety mechanism activated after completion of injection - Sharps waste remains - No sharps injury protection feature	0.04 -0.06
RUP syringes for therapeutic injections (ISO 7886 – Part 4 Sterile hypodermic syringes for single use: Part 4: Syringes with re-use prevention feature)	Prevents reuse of the syringe	- Full range of sizes including special sizes - Widely available	- Can be reused if the safety feature is deliberately avoided on syringes with a Reuse Prevention Feature Type 2 which requires elective activation upon completion of intended dose - Sharps waste remains - No sharps injury protection feature	0.05 - 0.08

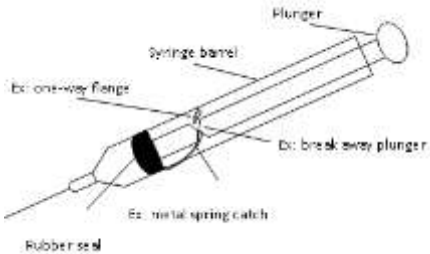


<p>SIP - Plastic needle shield to be added to a syringe (ISO 23908 Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling) Plastic needle shield</p>	<p>Prevents accidental needle-stick injuries among health-care workers, waste handlers and the community</p>	<p>- Full range of sizes - Sharp is contained</p>	<p>- Activation of the safety mechanism is dependent on user action and compliance - Not all models provide similar protection in all clinical applications</p>	<p>0.13 – 0.24</p>
<p>SIP + RUP: RUP with SIP feature (ISO 23908 and ISO 7886-4: SIPs + RUPs Needle shield plus a reuse prevention feature (i.e. plunger locks, breaks))</p>	<p>- Prevents reuse of the syringe - Prevents accidental stick injuries</p>	<p>- Full range of sizes - Sharp is contained</p>	<p>- Activation of the reuse prevention/safety feature is dependent on user action and compliance - Not all models provide similar protection in all clinical applications</p>	<p>0.09 -0.25</p>
<p>SIP + RUP: Manual Retractable syringes (ISO 23908 and ISO 7886-4: SIP + RUP: Manual Retractable syringes, active safety feature)</p>	<p>- Syringes with RUP and active sharps injury protection (SIP) features - Prevents reuse of the syringe - Prevents stick injuries</p>	<p>- Full range of sizes - Sharp is contained</p>	<p>- Highly dependent on user activation and compliance and sometimes the safety feature is not always obvious to the user</p>	<p>0.08 - 0.10</p>
<p>SIP + RUP: Automatic Retractable syringes (ISO 23908 and ISO 7886-4: SIP + RUP: Automatic Retractable syringes, passive safety feature)</p>	<p>- Syringes with RUP and passive sharps injury protection (SIP) features - Prevents reuse of the syringe - Prevents stick injuries</p>	<p>- Full range of sizes - Sharp contained</p>	<p>- Activation is tied to full delivery of dose, and additional user action and compliance is required (i.e. an extra push at the end of the injection)</p>	<p>0.15 -0.39</p>



AD: Auto-disable syringe for immunization

RUP: Syringe with a Re-Use Prevention feature

SIP: Syringe with a Sharps Injury Protection feature

Table 3: Description and sample images of safety features

Category	Description of safety feature	Images
<p>Auto-disable syringes for immunization (ISO 7886 – Part 3 Sterile hypodermic syringes for single use – Part3: Auto – disable syringes for fixed-dose immunization)</p>	<p>Auto-disable features are added to the syringe to prevent re-use. The features include clips, flanges, and other mechanisms inside the barrel of the syringe. Once the plunger is depressed past the point of the safety mechanism, it cannot be pulled backwards which prevents refilling and reuse of the syringe. Weak spots in the plunger will cause it to break if the user attempts to pull it back a second time.</p>	
<p>RUP syringes for therapeutic injections (ISO 7886 – Part 4 Sterile hypodermic syringes for single use: Part 4: Syringes with re-use prevention feature)</p>	<p>Re-use prevention features are essentially the same as auto-disable technologies. The main differences are that RUPs include variable dosing and some of them allow multiple plunger aspirations. Some models also include a weak spot in the plunger that causes it to break if the user attempts to pull back on the plunger after the injection.</p>	
<p>SIP –and SIP + RUP: (ISO 23908 and ISO 7886-4: SIPs + RUPs (ISO 23908 Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling) Plastic needle shield</p>	<p>SIP syringes have a mechanism that covers the needle after the injection is given. The purpose is to prevent exposure to needle stick injuries, especially to health care workers, but also to those who handle sharps waste.</p> <p>Needle assemblies with protective features can be added to syringe barrels, preferably syringe barrels with RUP features (e.g. blocks and breaking plungers).</p>	

<p>SIP + RUP: Manual Retractable syringes (ISO 23908 and ISO 7886-4: Manual Retractable syringes, active safety feature)</p>	<p>SIP syringes include syringes with a feature that draws the needle up into the syringe barrel. In the manual models, the injection provider must activate the safety feature, which is to pull the plunger backwards until the needle has retracted into the barrel.</p>	
<p>SIP + RUP: Automatic Retractable syringes (ISO 23908 and ISO 7886-4: Automatic Retractable syringes, passive safety feature)</p>	<p>SIP syringes also include automatic retractable models. These are essentially similar to the manual version, but they include a device, such as a spring, that automatically pulls the needle into the plunger once the plunger hits the bottom of the barrel.</p>	

Methodology

1. Guideline questions

Two research questions were developed by the WHO Guideline Steering Committee. These questions were structured in PICO format (Population, Intervention, Comparison, Outcomes) and important outcomes were identified for each research question. The guideline methodologist further refined the research questions.

Question 1: Should syringes with a sharps injury protection mechanism be introduced among health-care workers delivering intramuscular, subcutaneous, or intradermal injectable medications?

PICO elements of question 1:

- Population: Health-care workers delivering intramuscular, subcutaneous, or intradermal injectable medications
- Intervention: Introduction of syringes with a sharps injury protection mechanism
- Comparison: No Introduction of safety devices
- Setting: Health-care settings
- Perspective: Health systems.

Outcomes

Primary outcomes

- Incidence of HIV, HBV and HCV infections among HCWs
- Incidence of abscesses (septic, aseptic) among HCWs
- Incidence of other blood-borne infections (e.g. viral hemorrhagic fevers) among HCWs.

Secondary outcomes

- Incidence of needle-stick injuries among HCWs

- Quality of life among HCWs
- Social impact (e.g. stigma, job loss) among HCWs.

Question 2: Should syringes with a re-use prevention feature be introduced among health-care workers delivering intramuscular, subcutaneous, or intradermal injectable medications?

PICO elements of question 2:

- Population: Health-care workers (HCWs) delivering intramuscular, subcutaneous, or intradermal injectable medications
- Intervention: Introduction of syringes with a reuse prevention feature
- Comparison: No Introduction of safety devices
- Setting: Health-care settings
- Perspective: Health systems.

Outcomes

Primary outcomes

- Incidence of HIV, HBV and HCV infections among patients receiving injections
- Incidence of other blood-borne infections (e.g. viral hemorrhagic fevers) among patients.

Secondary outcomes

- Quality of life among patients
- Social impact (e.g. stigma, job loss) among patients
- Incidence of needle-stick injuries and incidence of HIV, HBV and HCV infections among HCWs.

2. Systematic review

In preparation for the guideline consensus meeting, the systematic review team conducted systematic reviews on:

- The effects of use by health-care workers of syringes with a sharps injury protection mechanism (Appendix 2)
- The effects of use by health-care workers of syringes with a reuse prevention feature (Appendix 2)
- The knowledge, attitudes, beliefs, values, preferences and feasibility related to sharp injury prevention syringes and reuse prevention syringes (Appendix 3)

Systematic reviews and meta-analysis of the literature were commissioned to address the research questions and outcomes. Criteria for inclusion and exclusion of literature for the reviews were based on relevance of available evidence in answering the research questions. Search strategies and summaries of the evidence are available in Appendix 2 and Appendix 3.

The systematic reviewers used the GRADE approach to rate the quality of evidence.

3. GRADE approach

WHO follows the Grading of Recommendations (12), Assessment, Development and Evaluation (GRADE) approach for grading the quality of evidence, and strength of recommendations (See Appendix 4 for a glossary of GRADE terms). GRADE emphasizes a structured, explicit and transparent approach.

GRADE separates rating of the quality of evidence from the grading of the recommendation itself.

(a) Quality of evidence

In the context of a recommendation, the quality of evidence reflects the confidence that the estimates of effect are adequate to support a particular recommendation. The GRADE system classifies the quality of evidence into one of four levels: high, moderate, low and very low.

Quality	Definition
High	This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different is low.
Moderate	This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different is moderate.
Low	This research provides some indication of the likely effect. However, the likelihood that it will be substantially different is high.
Very low	This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different is very high.

Based on a rating of the available evidence, the quality of evidence for each critical outcome was categorized as high, moderate, low or very low. Summaries of the quality of evidence to address each outcome were entered in a GRADE table (Appendix 5). Rating of the quality of evidence was first done by outcome before an overall assessment is made. Rating of the quality of evidence started as high when based on randomized controlled trials (RCTs), and as low when based on observational studies. Subsequently, the rating may be decreased for several reasons, including risk of bias, inconsistency of results, indirectness of evidence, imprecision and publication bias. In the case of both PICO questions, the body of observational studies had no reason for downgrading (Tables 5 and 6 in Appendix 2). It could be increased if the magnitude of the treatment effect is very large, if there is evidence of a dose–response relationship or if all plausible biases would underestimate the effect.

(b) Strength of recommendation

The strength of a recommendation reflects the extent to which confidence exists that the desirable effects of an intervention outweigh the undesirable effects. The GRADE system classifies recommendations into two strengths: “strong” and “conditional”. A recommendation can also be either in favour of or against the intervention in question. As a result, there are four types of recommendations based on the following combinations of strength and direction:

- Strongly in favour of the intervention
- Conditionally in favour of the intervention
- Conditionally against the intervention
- Strongly against the intervention.

The strength of recommendation has different implications for the patient, clinician and policy-maker, as follows:

	Strong recommendation	Conditional recommendation
Patients	Most people in your situation would want the recommended course of	The majority of people in your situation would want the recommended course of

	action and only a small proportion would not	action, but many would not
Clinicians	Most patients should receive the recommended course of action	Be prepared to help patients to make a decision that is consistent with their own values
Policy-makers	The recommendation can be adapted as a policy in most situations	There is a need for substantial debate and the involvement of stakeholders

Guideline development process

This guideline was developed in accordance with WHO evidence-based guideline development procedures as outlined in the WHO Handbook for Guideline Development (available at <http://intranet.who.int/homes/ker/grc/>) and followed the Evidence to Decision (ETD) framework. (Available at <http://www.implementationscience.com/content/8/1/6/abstract>)

In summary, the process included: (i) the identification of critical questions and critical outcomes, (ii) the retrieval of the evidence, (iii) the assessment and synthesis of the evidence, (iv) the formulation of recommendation and (v) planning for dissemination, implementation, impact evaluation and updating of the guideline.

Two technical groups worked on the development of this guideline:

1. The Guideline Steering Committee

An operative group composed of staff from the WHO Department of Service Delivery and Safety, the Department of Immunization, Vaccines and Biologicals, the Department of Health Work Force, the Department of Pandemic and Epidemic Diseases, the Global Hepatitis Programme and the Department of Public Health, Environmental and Social Determinants (where the Occupational Health and the Health Care Waste Management programmes are located) and the Department of Essential Medicines and Health Products. The steering committee formed at the onset of the process was asked to review previous WHO guidelines and recommendations related to injection safety. The steering committee identified the gaps that needed to be addressed through this policy guidance which intends to promote safety of all injections. The group identified the two key questions that need to be answered and put them in the PICO format.

Systematic reviews to answer the two guideline questions were outsourced to an expert who has worked extensively with WHO and is familiar with WHO guideline development procedures. The Guideline Steering Committee led by the Service Delivery and Safety Department guided the development of this guideline and provided overall supervision of the guideline development process.

2. Guideline Development Group

A Guideline Development Group was established to review the Grade tables related to the PICO questions and help WHO make an evidence-based policy recommendation. The group members were selected on the basis of their expertise in infection control, injection safety, occupational health and needle-stick injury prevention and reporting systems, procurement of injection equipment and supplies on behalf of Member States, and country work on injection safety.

The GDG met once in person after receiving full copies of the draft recommendations, the full systematic review report, the summary of evidence and the Grade tables. The in person meeting of the GDG was held at WHO/HQ on 18-19 March 2014 with the following objectives:

- Review the evidence and the grading of evidence on harm and benefits of safety-engineered syringes in response to the two PICO questions
- Develop recommendations on the use of RUPs and SIPs for injections and
- Discuss the outline of the policy flyer to be extracted from the full guideline document.

The draft recommendations, the full systematic reviews report, the summary of evidence and the Grade tables were provided to the meeting participants in advance.

Decision making, scope of the guideline and evidence appraisal by the GDG:

The systematic review team filled out the research evidence section where evidence was identified. During the meeting, any additional relevant information brought forward by the panel members was included under additional considerations. During the meeting, the panellists discussed and agreed on the rating for each criteria included in the EvidenceToDecision (EtD) table.

The panel used the “Evidence to Decision” framework to grade and develop the recommendations. The “Evidence to Decision table” is structured around the following criteria, listed in rows:

- Extent of the problem
- Values and preferences
- Quality of evidence
- Balance of benefits and harms
- Resource use
- Equity
- Feasibility
- Acceptability.

The panel completed one “Evidence to Decision” table for each recommendation (Appendix 5). The table included columns for:

- Research evidence: this was based on the evidence identified systematically by the systematic review process, was included in the table ahead of the guideline meeting, and presented to the panellists at the time of the meeting;
- Additional considerations: these were considerations brought up by the panellists and included in the table at the time of the meeting;
- Judgments: these reflected the panellists’ judgment for each of the criteria, were based on the research evidence and the additional considerations, and were completed at the time of the meeting.

After completing the “Evidence to Decision tables” for the above criteria, the GDG discussed the type of recommendation and developed the wording as a group. The process was by discussion consensus and not voting. GDG also agreed that the following aspects would be considered with each of the recommendations:

- Additional considerations
- Implementation considerations
- Monitoring and evaluation considerations
- Research priorities.

All judgments, the final recommendation statement and the accompanying statements were reached by consensus. All members of the GDG agreed on the recommendations and all other statements.

Based on the meeting discussions, grade tables and recommendations developed during the GDG meeting, a draft full guideline document was developed by the technical focal point on injection safety in the SDS Department. It was shared with the WHO Steering Committee, other WHO Departments at HQ, WHO Regional Injection Safety Focal points and the GDG for review. It was subsequently sent for external peer-review.

3. External Experts for final peer-review

This group was consulted on the scope of the guideline, the questions addressed and the choice of important outcomes for decision-making as well as to review the completed draft guideline. The external experts group included key WHO partners, country development partners, key funders of health programmes in countries, country injection safety /infection control focal points, professional associations, patients associations, infection control societies, NGOs and major injection devices manufacturers (contacted as observers through their umbrella organization the Global Medical Technology Alliance (GMTA)). The consultation with the external experts was carried out via email with selected members known for their experience in injection safety and also through the SIGN Post List Serve (an electronic weekly newsletter) which has more than 1500 subscribers. A high interest in this new policy guidance was expressed by the external experts who provided valuable comments. The comments were taken into account in the final version of the guideline. Comments were catalogued and addressed in the final drafts presented to support the GDG meeting above. External reviewers that responded are noted in the acknowledgements.

Management of conflicts of interest

According to WHO rules, all experts must declare their relevant interests prior to participating in WHO meetings. All GDG members were therefore required to complete a Declaration of Interest Form before the group composition and invitations were finalized.

The procedures for the management of conflicts of interest were followed in accordance with the “WHO guidelines for the declaration of interests (WHO experts)”.

In summary, all members of the GDG declared that they had no commercial, financial or personal interests which directly or indirectly related to the topic of the meeting/guideline.

Recommendations

Question 1: Should syringes with a sharps injury protection feature be introduced among health-care workers delivering intramuscular, subcutaneous, or intradermal injectable medications?

“We recommend the use of syringes with a sharps injury protection feature (SIP devices), as opposed to syringes without a sharps injury protection feature, by health-care workers delivering intramuscular, subcutaneous or intradermal injectable medications to patients (conditional recommendation, moderate quality evidence) “

Rationale for the recommendation

A systematic review concluded that moderate quality evidence supported a recommendation for the use of sharps injury protection syringes to reduce the incidence of needle-stick injuries per health-care worker and patients. Limitations of the review were lack of peer reviewed published studies that specifically link the use of particular injection devices with reduction of specific disease. While the evidence was considered to be of moderate quality, the benefit very likely would outweigh and risks. Preliminary results of a cost-effectiveness study undertaken by WHO support the recommendation. We anticipate the guideline will be published soon and the cost effectiveness analysis will be considered in the guideline update

- Moderate quality evidence for effectiveness, but the balance of benefit to harm is judged as probably favourable, with benefits outweighing harm: in settings where SIP devices are introduced, and when considering 1000 healthcare workers, 9 fewer (from 6 fewer to 11 fewer) are expected to suffer a needle stick injury over a one year period. There are no expected harms. Greater benefits can be expected in higher HIV, HBV and HCV disease prevalence/higher sharps injury frequency settings.
- Values and preferences that HCWs place on the outcomes highly depends on the culture and background of HCWs. It also highly depends on awareness raising campaigns on the risk of injury and the risk of transmission of diseases. A systematic review on “ Attitudes, values, preferences and feasibility” (Appendix3) identified evidence from 6 studies suggesting that safety syringes are generally perceived as easy to use, safe, and tolerated by patients. There were few reports of technical problems while using the devices. Nurses’ preferences and satisfaction were not consistent across studies. The included studies suffered from methodological limitations.
- Uncertainty was expressed by the panel concerning the cost-effectiveness of introducing SIP devices, because this aspect was not covered by the systematic reviews. A cost-effectiveness study coordinated by the SDS Department was completed subsequent to the GDG meeting. Preliminary results demonstrate cost-effectiveness of such introduction. This study will be published shortly and will be considered in the guideline update
- It is expected that market forces would have an impact on pricing, as economies of scale and competition will lower the price per unit. Accordingly the cost-effectiveness of SIP devices is expected to improve.
- There is a notable lack of published research from low- and middle-income countries (One unpublished PATH study on the use of retractable syringes in South Africa was

noted but not included in the review as it has not been published).

Considerations for end-users

- The use of SIP devices is an essential component of a comprehensive approach that must include an education and training strategy, surveillance, reporting and management of needle-stick injuries including post-exposure prophylaxis (PEP), involvement of frontline workers in the selection of the safety devices, immunization of health-care workers against hepatitis B, advocacy for standard precautions, monitoring and evaluation of recommendation implementation and impact as well as safety of the actual device.
- Estimated costs of implementing the recommendation should include the cost of implementation of all components of the comprehensive approach as well as the cost of SIP devices themselves.

Question 2: Should syringes with a reuse prevention feature be introduced among health-care workers delivering intramuscular, subcutaneous, or intradermal injectable medications?

“We recommend the use of syringes with a reuse prevention feature (RUP devices), as opposed to devices without, by health-care workers delivering intramuscular, subcutaneous or intradermal injectable medications to patients (conditional recommendation, very low quality evidence)”

Rationale for the recommendation:

Evidence from a systematic review supported a recommendation to incorporate re-use prevention syringes for health care workers administering injections. The evidence identified was considered to be of very low quality. A limitation of the study was the absence of peer reviewed studies linking re-use prevention syringes with specific re-use reduction. Practical experience with the use of a substantially similar product i.e. auto-disable syringes in immunization programs suggests strongly that the benefits outweigh any risks and is very likely to reduce re-use. A WHO cost effectiveness study pending publication supports the recommendation.

- Very low quality evidence for effectiveness, but the balance of benefit to harm is judged as probably favourable, with benefits outweighing harm: in settings where RUP devices have been introduced for immunization injections or for therapeutic injections post intervention assessments documented a decrease in the rate of reuse of syringes on more than one patient to give injections. This reduction has impacted on the number of diseases transmitted through unsafe injection practices (13). There are no expected harms. Greater benefits can be expected in higher disease prevalence/high reuse rate settings.
- Values and preferences that HCWs place on the outcomes highly depends on the culture and background of HCWs. It also highly depends on awareness raising campaigns on the risk of injury and the risk of transmission of diseases. A systematic review on “Attitudes, values, preferences and feasibility” (Appendix 3) identified evidence from 6 studies suggesting that safety syringes are generally perceived as easy to use, safe, and tolerated by patients. There were few reports of technical

problems while using the devices. Nurses' preferences and satisfaction were not consistent across studies. The included studies suffered from methodological limitations.

- Uncertainty was expressed by the panel concerning the cost-effectiveness of introducing SIP devices, because this aspect was not covered by the systematic review. A cost-effectiveness study coordinated by the SDS Department) was completed subsequent to the GDG meeting. The preliminary results showed clear cost-effectiveness of such introduction.
- It is expected that market forces would have an impact on pricing as economies of scale and competition will lower the price per unit. Accordingly, cost-effectiveness of RUP syringes is expected to improve
- There is a notable lack of published research, in particular in LMICs

Considerations for end-users

- The use of RUP devices is an essential component of a comprehensive approach that must include education and training; surveillance and the reporting of adverse events following injections in patients and needle-stick injuries in HCWs; surveillance, reporting and the management of needle-stick injuries including post-exposure prophylaxis (PEP); involvement of frontline workers in the selection of the safety devices, immunization of health-care workers against hepatitis B, advocacy for standard precautions and monitoring and evaluation of all components of the strategy including the safety of the devices and their use
- Estimated cost-effectiveness of implementing the recommendation should include the cost of implementation of all components of the comprehensive approach as well as the cost of the RUP devices themselves.

Implications for future research

Discussion during the Guideline Development Group meeting highlighted the limited evidence available in some areas and highlighted the need for further research on harms and benefits, effectiveness and cost-effectiveness of the adoption of RUP and SIP devices to administer intramuscular, subcutaneous and intradermal injections. The following suggestions for further research were made by the GDG:

1. Research needed for both types of devices RUPs and SIPs

- More effectiveness studies in LMICs following the introduction of safety-engineered syringes
- Research in LMIC on burden of diseases, in particular HIV, Viral Hepatitis B and Viral Hepatitis C following reuse of syringes on patients and needle-stick injuries (NSIs) in health-care workers
- Need for cost-effectiveness studies on the adoption of RUP and SIP syringes. Cost effectiveness must include the cost of implementation (for example the cost of training HCWs, cost of follow up of workers who experience NSI and the cost of losing a health-care worker to illness or death who would require replacement and retraining) as well as the price of the devices themselves

- Research on quality and safety aspects of individual devices since the safety features and their activation differ between devices
- More research is needed on needle-free devices which can address both issues of reuse and NSIs
- Studies on acceptability by health-care workers of the safety syringes, their clinical use and effectiveness
- Behavioural research on both unsafe practices i.e. reuse of syringes and occurrence and reporting of NSIs is needed to address the root causes of unsafe injection practices
- Regarding research and development by industry, better integration by manufacturers of reuse prevention and sharp injury protection as a single feature in the same device is needed.

2. Research specific to syringes with a sharps injury protection (SIP) mechanism:

- Update the 2003 WHO global burden of disease from needle-stick injuries in health-care workers
- Research on attitudes and practices at all levels of the health-care system towards needle-stick injury reporting and use of post-exposure prophylaxis (PEP) following NSIs
- Research on the probability of transmission of the three main blood-borne viruses following NSIs in HCWs to recheck the risk of transmission used which is from articles published from 1980-90 and also considering the new PEP regimen and availability.
- More information is needed on the potential impact of the SIP introduction on the waste disposal and in particular on recycling which is being promoted by WHO.

Considerations for the development of future guidelines

Discussion during the GDG meeting identified the following as important issues for WHO to consider developing guidelines for in future:

1. Guidance on the use of safety-engineered syringes for intravenous procedures including intravenous injections and infusions, blood collection, capillary blood sampling.
2. Introduction of needle-less injection devices as the research makes this possible.

Dissemination, adaptation and implementation

The ultimate goal of this guideline is to improve the quality and safety of care and health outcomes related to injection practices. Therefore, dissemination and implementation of this guideline are crucial steps that should be undertaken by the international community and local health-care services. The WHO Department of Service Delivery and Safety has developed a global campaign to promote injection safety which includes, in addition to this policy guidance, a list of priority actions including advocacy, information and communication which will be used by WHO and other partners to foster dissemination and implementation of this policy guidance.

1. Dissemination

The current guideline will be translated into all official UN languages and disseminated electronically through the WHO/HQ web site, as well as regional and WHO country office web sites. Other modes of dissemination will include CD-ROMs and slide presentations.

The guideline will also be disseminated through a broad network of ministries of health, international partners, other UN organizations managing injectable vaccines and medications (e.g. UNICEF, UNFPA, GAVI, Global Fund, UNITAID, UNAIDS), WHO collaborating centres, universities, professional associations, non-governmental organizations and trade union federations.

A brochure (Appendix 6) that summarizes the essential guideline information and recommendations will also be produced for ease of reference and to enhance dissemination of the guidance. It will also be used as an advocacy tool for high level decision-makers. It will include the rationale behind the policy development, guiding principles, the evidence based recommendation about the use of RUPs and SIPs syringes for all injections and the implementation requirements. Existing documents will either be incorporated or updated into the dissemination strategy as appropriate.

It is anticipated that the guideline will be launched by the Director-General of WHO during a high-level meeting where key WHO partners, UN organizations, WHO regional offices, NGOs and the umbrella organizations of injection device manufacturers, will be invited to promote broad uptake of the new policy guidance.

2. Adaptation and implementation

Despite the scarcity of studies, especially in LMICs, documenting the impact of introducing safety engineered syringes on reuse of syringes and needle stick injuries (leading to a conditional recommendation), based on the evidence that doing nothing will continue to cause significant harm (13), WHO recommends that all countries should transition by 2020 to the exclusive use, where appropriate (syringes which reuse prevention feature are not suitable for certain medical procedures including maintenance of intravenous lines, local anaesthesia and nasal feeding as examples), of WHO prequalified (or equivalent) safety-engineered injection devices, including reuse prevention (RUP) syringes and sharps injury protection (SIP) devices for therapeutic injections, and develop related national policies to bring about a smooth transition. Prior to country implementation of the policy, this new guideline should have well-defined objectives based on national epidemiological data on the reuse rate of injection devices and the frequency of needle-stick injury in health-care workers. Assessments have been performed by WHO in many countries over the past decade which show that safety precautions are often not respected, exposing patients and health-care workers to severe risk of blood-borne infections and injuries and putting human lives at risk. This information can be retrieved by looking at available injection safety assessments, grey literature, research reports and local studies looking at these two issues. Upon request, WHO can reach out to countries having a high burden of blood-borne diseases, high expected rates of transmission from reuse and high use of injections, to assist them in gathering local epidemiological data. Implementation of the guideline should also take available resources into account, existing injection safety/infection control policies, suitable delivery platforms and current injection device suppliers, communication channels and potential country stakeholders.

To ensure that WHO global evidence-informed policy recommendations on the use of RUP and SIP syringes for injections are better implemented in low- and middle- income countries, WHO will promote partnerships at country level between policy-makers, professional organizations, researchers and civil society to facilitate policy development and implementation through use of the best available local evidence.

While discussing implementation aspects of the new policy guidance, the GDG made the following comments which apply to both types of device:

a. Introduction

- Introduction of RUP and SIP devices is one component of comprehensive injection safety plans and strategies
- Consideration should be given to education/information/communication targeting both patients and health-care workers on the risks related to unsafe injections and their potential to transmit blood-borne infections

b. Training

- Appropriate training should be offered to health-care providers on the use of the selected safety devices prior to their formal introduction
- There is a need to provide rural and urban, public and private health-care facilities with RUP and SIP devices
- Existing quantification tools and specifications for procurement should be provided as part of the training programs

c. Waste management

- In the planning phase, there is a need to consider sharps waste management and the potential environmental impact of the new devices.
- It is essential that ADs, RUPs and SIPs and any other type of injection equipment be provided to health-care facilities with the necessary quantity of safety boxes for the safe collection of used devices (bundling principle)

d. Procurement

Regarding the procurement of RUP and SIP syringes, the following aspects should be considered:

- Consider the availability of affordable quality-assured supply of safety-engineered syringes.
- Suitability for use in the range of common clinical applications should be a primary factor in prioritizing and selecting injection devices
- Set health-system-wide policies and standards for procurement, use and safe disposal of disposable syringes in situations where they remain necessary as described above, including in syringe programmes for people who inject drugs.
- Procurement should be based on the development of tender specifications reflecting local needs and the safety profile of the device (Not all RUP and SIP models provide similar protection in all clinical applications)
- Priority should be given to the procurement of devices that have both reuse prevention and sharps injury protection features built into the same device
- Procurement should favour passive designs that offer safety passively and automatically, i.e. which do not require user compliance and additional action on the part of the user.
- As per ISO 7886-4, Clause 5.2, the reuse prevention feature is categorized as follows:
 - Type 1: Operates automatically during or upon completion of intended single use
 - Type 2: Requires elective activation upon completion of intended single use.

In high-risk countries, where reuse of syringes is highly prevalent, Type 1 RUP syringes would address the spread of infection/cross contamination from reuse and would therefore be the recommended type of device for these countries. Post-marketing surveillance would be needed to report on defects, effectiveness and any issues encountered during use of the new safety devices.

3. Monitoring and evaluation of guideline implementation

A plan for monitoring and evaluation with appropriate indicators is encouraged at all levels. Implementation of the recommendations can be evaluated within countries (i.e. monitoring and evaluation of the scale of implementation of the recommendation: nationwide versus partial, public versus private, urban versus rural) and across countries (i.e. adoption, adaptation and implementation globally). Its implementation should also be monitored at health-service level. Injection safety assessment, clinical audits, supervision, NSIs surveillance and reporting systems are some of the means to monitor the implementation and impact of the policy recommendation.

Clearly defined indicators are needed and these could be associated with locally agreed targets. The GDG strongly recommends that uptake of the recommendation to introduce safety-engineered syringes for all injections be used as a process indicator for the monitoring of injection practices and the prevention of blood-borne virus transmission through unsafe injection practices in health-care settings.

A set of key indicators were suggested by the GDG for each type of safety device:

a. Reuse Prevention Syringes (ADs and RUPs):

- Rate of reuse of syringes: this indicator can be measured through injection safety assessments, supervision and interview of patients (e.g. through demographic and health surveys - DHS)
- Proportion of devices with reuse prevention feature procured at national level and/or at health facility level if procurement is decentralized and proportion used
- Adverse events to patients from injections (i.e. abscesses, , blood-borne viruses infections etc...)
- Presence of an adverse event surveillance system and its level (e.g. at local, district/region or national level)
- Proportion of health workers who have received training on the use of ADs and RUPs
- Facility level data collection comparing syringe stock and injection records
- Incidence of infections from injections in patients (i.e. HIV, HBV and HCV)

b. Sharps Injury Protection devices (SIPs)

- Reported incidence of needle-stick injuries
- Incidence of infections following stick injuries in health-care workers
- Proportion of syringes with sharp injury protection procured at global and/or local level and proportion used
- Presence of NSI surveillance system and its level (at central and/or health facility level)
- Consider denominators for benchmarking to report on NSIs (e.g. per number of devices procured, number of devices used, type of device used, type of procedure, occupation of patient beds, per injection provider (full-time employees - FTE)
- Proportion of HCWs immunized against HBV
- Proportion of HCWs having received training on the use of SIPs
- Proportion of PEP received following a NSI
- Include NSI and adverse injection events in the Minimal Information Model for adverse patients events surveillance and reporting system that the Department of Service Delivery and Safety at WHO is currently developing.

Plans for updating this guideline

In view of the scarcity of studies identified during the systematic reviews on impact of the introduction of safety-engineered syringes on needle-stick injuries in health-care workers and on the reuse of syringes (for the latter, no studies were identified) and studies on the cost-effectiveness of such devices, it was agreed that the guideline will be reviewed as soon as new evidence is available. A guideline review group will be convened to evaluate the new evidence and revise the recommendation if needed. The Department of Service Delivery and Safety, along with its internal partners, will be responsible for coordinating the guideline update, following formal WHO handbook for guideline development procedures. WHO welcomes suggestions regarding additional questions for evaluation of the guideline when it is due for review.

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