



GUIDING PRINCIPLES TO ENSURE INJECTION DEVICE SECURITY

WORLD HEALTH ORGANIZATION

BACKGROUND



Injections are the most common health care procedure worldwide. In developing and transitional countries alone, some 16 thousand million injections are administered each year.¹ Most injections, more than 90%, are given for therapeutic purposes while 5 to 10% are given for preventive services, including immunization and family planning. The majority of therapeutic injections in developing and transitional countries are unnecessary.

A safe injection does not harm the recipient, does not expose the health care worker to any avoidable risk and does not result in waste that is dangerous for the community.² When injections are medically indicated they should be administered safely. Unsafe injections place patients at risk of disability and death. Reuse of injection devices without sterilization is of particular concern as it may transmit hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV), accounting for 30%, 41% and 5% of new infections in 2000, respectively.³ In addition, inappropriate and unhygienic use of multi-dose vials may transmit bloodborne pathogens.²

Best infection control practices for intradermal, subcutaneous and intramuscular injections recommend the use of a new, single use injection device for each injection and for the reconstitution of each unit of medication.⁴ Sterile single use injection devices are widely available at low cost. The international retail price for a single use syringe and needle set ranges from 3 US cents (sterile hypodermic syringe 2 ml) to 6 US cents (auto-disable syringe 0.5 ml). Failure to systematically fund sufficient supplies of injection devices was identified as a key determinant of widespread reuse of syringes and needles in the absence of sterilization in immunization services.⁵ Interventions to increase the availability of injection devices in curative services have improved injection safety.⁶ Interventions to prevent infections with bloodborne pathogens through provision of single use devices are a very cost-effective investment in health.⁷

Sterile, single use injection devices include sterile hypodermic syringes, sterile hypodermic needles, auto-disable syringes for immunization purposes, syringes with a reuse-prevention feature for general purposes and syringes with needle-stick prevention features (e.g., safety syringes) for general purposes. WHO is strengthening its collaboration with national regulatory authorities to ensure the quality and safety of injection devices through: (1) the enforcement of national regulations based upon international standards for injection devices³ and (2) reliance on internationally accepted certifying bodies that provide the ISO certification and carry out the auditing function.⁸

The safe collection and disposal of used sharps (e.g., needles, syringes with fixed needles) is an integral part of the life cycle of injection devices. The collection of sharps waste in safety containers (e.g., safety boxes) at the point of use and their safe and environmentally-responsible disposal protect health care workers and the general public from needle-stick injuries. Interventions to reduce injection overuse reduce waste thereby facilitating its management. Management choices and technology options will depend on many considerations, including workers' safety, sustainability and acceptability. Low-cost, effective waste treatment options are available.

The safe collection and disposal of used sharps (e.g., needles, syringes with fixed needles) is an integral part of the life cycle of injection devices. The collection of sharps waste in safety containers (e.g., safety boxes) at the point of use and their safe and environmentally-responsible disposal protect health care workers and the general public from needle-stick injuries. Interventions to reduce injection overuse reduce waste thereby facilitating its management. Management choices and technology options will depend on many considerations, including workers' safety, sustainability and acceptability. Low-cost, effective waste treatment options are available.

INJECTION DEVICE SECURITY

In curative and preventive services, ensuring injection device security implies appropriate forecasting, financing, procurement and supply management so that the following items are available in adequate quantities:¹²

- Injectable products;
- Appropriate single dose diluents;
- Single use injection devices for injection and reconstitution;
- Safety boxes.

This procurement policy does not imply that items mentioned above must be physically packaged together, but ultimately these items should be available in a timely manner in health care facilities in adequate quantities. Suppliers and shipping routes may differ for injectable products, injection devices and other infection control supplies. The application and success of this policy is dependent on a reliable distribution system for health products.

UNFPA, UNICEF and WHO have reaffirmed the current policy stating that by the end of the year 2003, all countries should be using only auto-disable syringes in immunization services. Auto-disable syringes and safety boxes should be supplied in adequate quantities with all consignments of vaccines.⁹

RECOMMENDATION

WHO RECOMMENDS THAT INJECTION DEVICE SECURITY IS ENSURED IN ALL HEALTH CARE FACILITIES, INCLUDING THERAPEUTIC SERVICES (SEE BOX), SO THAT INJECTABLE MEDICINES, DILUENTS, SINGLE USE INJECTION DEVICES AND SAFETY BOXES ARE SUPPLIED IN A TIMELY MANNER IN ADEQUATE QUANTITIES.

IN PRACTICE

- WHO reaffirms the need to ensure access to single use injection devices and safety boxes of good quality. Sterile, single use injection devices for injection and reconstitution and safety boxes must be available in every health care facility in sufficient quantities for the number of injections administered;
- While the use of sterilizable injection devices is being phased out worldwide, WHO urges that all countries use only single use injection devices for therapeutic injections. 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 urges that by 2005 all injectable medications are supplied with matching quantities of single use injection devices, appropriate diluents and safety boxes through essential medicine programmes and other health programme supply mechanisms;
- To prevent injection overuse, national drug policies should promote the rational use of therapeutic injections. This may include removing unnecessary injectable medicines from the national essential medicines list;
- Health care services must manage sharps waste as part of the duty of care in a safe and environmentally responsible way, within a broader policy of health care waste management. Awareness and training for appropriate sharps waste management are required. Sharps waste disposal management should be costed, budgeted and funded.
- WHO requests all donors and lenders who finance injectable products (i.e., vaccines, contraceptives and medications) to also finance appropriate quantities of single use injection devices, single dose diluents, safety boxes and the cost of sharps waste management. All organizations involved in medicine donations should also ensure that they are following this recommendation.

STRATEGY

WHO developed a strategy to ensure that special attention is paid to the safe administration of all types of injections in health care services. A set of tools are available to support the assessment, planning, implementation and evaluation of national injection safety policies for preventive and curative services.^{10,11} Ministries of health, donors, lenders and partners who are active in the health sector, including in essential medicines programmes, are invited to endorse these recommendations. More information on injection safety is accessible on the WHO Injection Safety internet site (www.injectionsafety.org) which includes a toolbox of resources to assist in the management of national safe and appropriate use of injection policies.



REFERENCES

1. Hutin YJF, Hauri AM, Armstrong GL. Use of injections in healthcare setting worldwide, 2000. Literature review and regional estimates. *BMJ* 2003; 327:1075-8.
2. WHO Best infection control practices for skin-piercing intradermal, subcutaneous and intramuscular needle injections. WHO/BCT/DCT/01.02
3. Hauri AM, Armstrong GL, Hutin YJF: Contaminated injections in health care settings. In *Comparative Quantification of Health Risks: Global and Regional Burden of Disease Attributable to Selected Major Risk Factors*. Ezzati M, Lopez AD, Rodgers A, Murray CJL. Editors. Geneva: World Health Organization, 2003.
4. Hutin YJF, Hauri AM, Chiarello L, Catlin M, Stilwell B, Ghebrehwet T Garner J and the members of the injection safety best practices development group. Best infection control practices for intradermal, subcutaneous and intramuscular needle injections. *Bull World Health Organ* 2003; 81:491-500.01.
5. Dicko M, Oni A-Q Q, Ganivet S, Kone S, Pierre L, Jacquet B. Safety of immunization injections in Africa: not simply a problem of logistics. *Bull World Health Organ* 2000; 78: 163-9.
6. Logez S. Increased Access to Injection Equipment in Burkina Faso: When Essential Drug programmes Improve Injection Safety. In *Safe Injection Global Network (SIGN). Annual Meeting Report, 30-31 August 2001*. WHO/BCT/DCT/01.04.
7. Dziekan G, Chisholm D, Johns B, Rovira J, Hutin Y. The cost effectiveness of policies for the safe and appropriate use of injection in health care settings. *Bull World Health Organ* 2003; 81:277-85.
8. ISO standard: ISO 7886 -1: Sterile hypodermic syringes for single use - Part 1: Syringes for manual use, 1993. www.iso.ch
9. WHO-UNICEF-UNFPA Joint statement on the use of auto-disable syringes in immunization services. WHO/V&B/99.25
10. WHO. Tool for the assessment of injection safety, WHO/V&B/01.30
11. WHO. Managing an injection safety policy. March 2003. WHO/BCT/03.01
12. Hart C, M Usher. *Contraceptive Security, What Is It and What Best Practices Achieve It?* Arlington, VA.: DELIVER/John Snow, Inc. Presented in Cairo at the WHO Inter-country Meeting with Partners and Country Teams: Best Practices to Improve Reproductive Health. 2002



SAFE INJECTION GLOBAL NETWORK (SIGN) SECRETARIAT

Department of Essential Health Technologies
World Health Organization
E-mail: sign@who.int
Fax: + 41 (22) 791 4836