WHO/HIS/SDS/2015.30

GUIDING PRINCIPLES TO ENSURE INJECTION DEVICE SECURITY

BACKGROUND

Injections are the most common health- care procedure worldwide. In developing and transitional countries alone, some 16 billion 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. The new WHO guidelines recommend using auto disable/reuse prevention/sharps injury prevention devices for most therapeutic injections. The approximate cost of these syringes are AD for immunization 0.04-0.06; RUP for therapeutic injections 0.05-0.08; SIP for therapeutic injections 0.013-0.24 and SIP+RUP 0.09-0.25. 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]

- AD-autodisable syringes
- RUP-reuse prevention
- SIP-sharp injury prevention

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 devices[3] 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.

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]

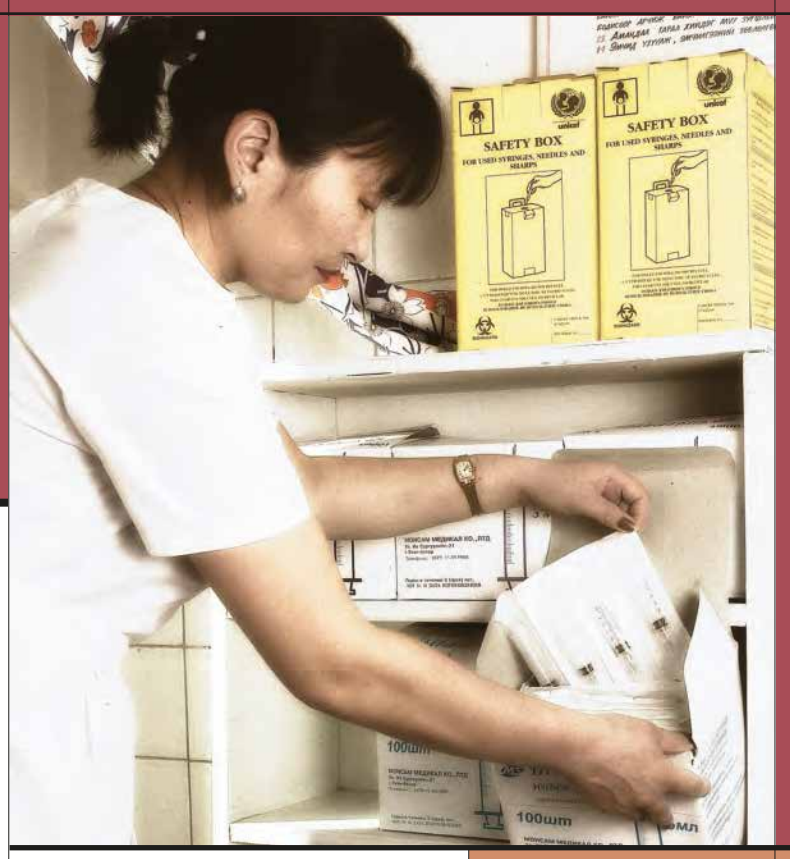
- Injectable products (AD/RUP/SIP);
- Appropriate single dose diluents;
- Single use injection devices for injection and reconstitution;
- Safety boxes.

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 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, AD/RUP/SIP INJECTION DEVICES AND SAFETY BOXES ARE SUPPLIED IN A TIMELY MANNER IN ADEQUATE QUANTITIES.



IN PRACTICE

- WHO reaffirms the need to ensure access to AD/RUP/SIP 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;
- Syringes with a reuse-prevention feature offer the highest level of safety for injection recipients. They are recommended for use for therapeutic injections where local data indicate that unsafe practices are particularly common;
- WHO urges that 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.,v accines,c ontraceptives and medications) to also finance appropriate quantities of AD/RUP/SIP 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 (http://www.who.int/injection_safety/en/) which includes a toolbox of resources to assist in the management of national safe and appropriate use of injection policies.

Syringes engineered to prevent reuse are not suitable for certain medical procedures e.g. when administering multiple medicines, maintenance of IV lines, local anaesthesia and nasal feeding. Conventional disposable syringes should be used safely in these and similar instances.

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