



# **Proposed Agenda to Evaluate the Risks and Benefits Associated with Using Needle-Removing Devices**

Report of an ad hoc WHO meeting, 27 January 2004,  
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## ***Background***

Current WHO best infection control practices for injections do not address the use of needle-removing devices.<sup>1</sup> While needle removers/cutters are a potentially promising way to reduce the volume of sharps waste, evidence regarding the safety and effectiveness needs to be documented before recommending them or not as a best practice standard for routine use (See Potential issues, Table 2, page 12).

Of particular concern is the need to assess the trade-off between:

1. Adding a step in the collection of sharps waste that could result in more handling of dirty needles and thus more needle-stick injuries among health care workers;
2. Decreasing the volume of infectious sharps waste through (a) disposing of syringes as regular waste<sup>\*</sup> and (b) handling needles only as infectious sharps waste to be incinerated or encapsulated. This may result in fewer needle-stick injuries among waste handlers and the community.

In most industrialized countries, resources are available to collect syringes and needles together and to adequately manage the sharps waste generated that way.<sup>†</sup> This results in rates of needle-stick injuries ranging from 0.18 to 0.74 injuries per person and per year according to WHO regions.<sup>2</sup> Thus, an analysis of this trade-off is not in favour of the use of needle-removing devices. In contrast, in developing and transitional countries, resources are lacking to collect and manage sharps waste appropriately. As a consequence, reported rates of needle-stick injuries are higher (ranging from 0.93 to 4.68 injuries per person and per year according to WHO regions).<sup>2</sup> In addition, lack of measures to manage sharps waste is sometimes considered as an obstacle to the replacement of sterilizable injection devices by single use injection devices. Thus, needle removal may be considered as part of a comprehensive solution to prevent reuse of injection equipment and improve waste management. However, the impact that such an option could have on needle-stick injuries among health care workers, waste handlers and the community is not documented. A broad recommendation to use needle removers should be supported on the basis of evidence. An acceptable protocol to gather that evidence is needed. This "proposed agenda to evaluate the risks and benefits associated with using needle-removing devices" is also a logical follow up of the working group recommendations of the New Technologies Task Force of the Global Alliance for Vaccine and Immunization (GAVI).<sup>3</sup>

## ***Needle-removing devices available***

### Definitions

Needle removers available include:

- **Electric needle destroyers;**
- **Manual needle removers** that do not cut the syringe;  
(e.g., sharps boxes that "strip off" the needle from the syringe)
- **Hub cutters:** Devices that cut the syringe.

### Specifications

WHO has not yet formulated specifications for needle-removing devices. While final specification will not be formulated immediately, draft specifications would be useful to select devices for field assessment. Criteria to

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\* A consensus needs to be reached as to whether used plastic syringes without needles should be considered as "non-infectious waste" or not. However, the disposal of waste made of used syringes without needles should require less precautions than infectious waste.

† While some industrialized countries (e.g., Germany, Austria) may use needle-removing devices, experience is lacking to document the rates of needle-stick injuries that are associated with their use.

take into account include: (1) splatters (bench test), (2) resistance to shocks (drop test), (3) size and weight, (4) compatibility with various types of injection devices with fixed and / or removable needles, (5) absence of metal in the plastic syringe residue, \* (6) ergonomics, (7) distance between the hand and the sharp, (8) possibility to clean the cutting mechanism (if applicable) and the whole apparatus, (9) blade quality (if applicable), (10) needle container, (11) visibility of the needles in the container (to determine if full), (12) puncture- and liquid-resistance of the needle container and (13) possibility to seal the needle container. The Program for Appropriate Technology in Health (PATH) recommended three needle-removing devices for field assessment on the basis of bench testing, acceptability trials and availability (Table 1).

**Table 1: Needle-removing devices proposed for field assessment by PATH in developing countries.**

	<b>Balcan mini destructor ® (Figure 1)</b>	<b>Nomoresharps backpack model ® (Figure 2)</b>	<b>Hub Cutter ("yellow box") (Figure 3)</b>
<b>Description</b>	Hub cutter with separate needle container	Hub cutter with separate needle container	Single use hub cutter with single use needle container
<b>Cost of the device</b>	\$ 44 – 82 depending on order size	\$ 17.50 – 19 depending on order size	Under \$ 2 †
<b>Cost of needle container</b>	\$ 37.60 for a box of 24 containers	\$ 80 for a box of 40	N/A
<b>Blade life</b>	Approximately 200 000 cuts ‡	Approximately 200 000 cuts ‡	Sufficient for the life of the container
<b>Remarks</b>	Adapted to clinics Heavy for outreach	Adapted to clinics Heavy for outreach	Adapted to outreach Waste management more difficult

#### Risk of splatters

Needle removers can potentially lead to splatters. <sup>4</sup> These splatters could expose workers to blood and body fluids and could contaminate work surfaces, including injection preparation areas. However, when compared to tweezers, most needle removers do not produce large amounts of splatters. <sup>5</sup> Splatter is nevertheless a concern that is difficult to assess scientifically. Bench methods of assessing splatters associated with needle removers should be developed and used in parallel to the field assessment. In addition, in any field assessment, health care workers should be informed of the risk of splatters so that they keep needle removers away from injection preparation areas and so that they take into account needle removers in an overall approach to keep injection preparation areas clean and disinfected. <sup>1</sup>

#### ***Field experience with needle-removing devices in developing countries***

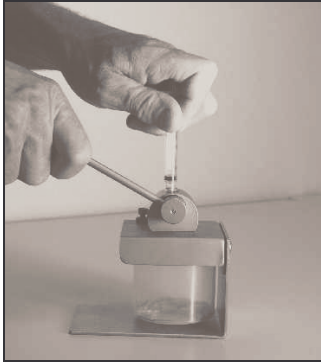
The experience with the use of needle-removing devices in developing countries so far as been mainly limited to user acceptability trials. Most of the data recovered so far does not allow a precise estimation of (1) the volume of waste produced and (2) the frequency of needle-stick injuries.

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\* Independently from needle remover designs, the presence of metal clips in single use syringes with reuse prevention features, including auto-disable syringes, needs to be considered.

† Sold with auto-disable injection devices.

‡ Manufacturer's estimate. Not validated.



**Figure 1: Balcan mini destructor ®**

### Completed studies

#### *Eritrea*

WHO coordinated limited introduction of needle removers in the immunization setting.

#### *West Africa*

PATH coordinated workshop / focus groups during which needle removers were presented and discussed. Balcan ® devices were introduced in about 150 health centres as well as protected needle pits at each centre. A several page training guide was developed and distributed. A 1/2 day orientation on how to use them correctly was added on to routine coordination meetings. No formal evaluation has been done. Reports exist that they are being used consistently. No acceptability problems have been reported.



**Figure 2: Nomoresharps backback model ®**

#### *India*

In India, the rules and regulations regarding medical waste management mandate that single use syringes be rendered unusable after use. Needle-removing devices were introduced in selected health care facilities, including one hospital. <sup>6</sup> Two facilities were evaluated as controls. The evaluation included an assessment of user acceptability, device performance, ease of use, needle-stick incidence and impact on waste streams created through clinic and outreach injection activities. Continuous review of results from prospectively collected acceptability and performance data allowed the investigators to eliminate a prototype that did not perform well in the field. Health care facilities were not randomized. Waste volumes were difficult to measure due to the variety of collection systems, but are being ascertained retrospectively. The frequency of needle-stick injuries was monitored through active surveillance by observers based in each clinic. No information was available regarding pre-intervention needle-stick rates and investigators identified that there was a stigma associated with experiencing a needle-stick injury which could have led to underreporting. However, despite these limitations, this trial generated the best available evidence to date on the rate of needle-stick injuries among injection providers and waste handlers in a setting where needle removers are used.

## *China*

There is experience with the new introduction of the Beckton Dickinson (BD) hub cutter in immunization services in China. A total of 10 000 units have been introduced since 2003 (they were sold together with auto-disable syringes). A controlled study in Tianjing is being conducted to assess user acceptability but not safety. Full results are not available because of disruptions secondary to the SARS outbreak. Preliminary assessments were held at over 20 immunization safe injection seminars, where user feedback was favourable overall.



**Figure 3: BD hub cutter**

### Planned studies

#### *European region*

A trial is about to be initiated in Ukraine. This trial may evaluate the Balcan ®, the Nomoresharps ® and the Becton Dickinson devices. A draft protocol was written for which comments are welcome. Another trial is considered in Belarus. More information is available from the WHO EURO office.

#### *South East Asia region*

A trial is being considered in Indonesia. In addition, WHO is considering a study in Nepal.

#### *African region*

WHO is considering an introduction of needle removers in the immunization setting in Kenya using the protocol that was used in Eritrea. Other introductions may be considered in Zimbabwe and in Zambia.

## ***Evidence to be generated***

### Number of studies

At least three assessments meeting the terms of reference below should have been completed and analyzed in three different WHO regions.

### Funding

#### *Estimated cost of each assessment*

Costing elements include (1) needle removers for the intervention area (including supplies of needle containers), (2) needle pits for the intervention area, (3) safety boxes for the intervention and control areas, (3) waste management for the intervention and control, (4) investigators and field workers and (5) data analysis and report writing. Each field study should be feasible for about US\$ 50 000.

## Potential funding sources

Donors and partners of the global measles mortality reduction initiative could be approached to fund assessments in the context of measles mass immunization campaigns.

**Table 2: Compared risks and benefits of needle removal versus immediate collection of syringe and needle sets in safety boxes for disposal. \***

	<b>Needle removal with separate management of the syringe and needle waste</b>	<b>Immediate collection of syringe and needle sets in safety boxes for disposal</b>
<b>Reuse of injection equipment</b>	<ul style="list-style-type: none"> <li>▪ Could decrease reuse of injection equipment if devices render the syringes unusable</li> </ul>	<ul style="list-style-type: none"> <li>▪ Depends upon the management of sharps boxes.</li> </ul>
<b>Contamination of injection preparation area</b>	<ul style="list-style-type: none"> <li>▪ Splatter potentially infectious agents on injection devices and preparation areas</li> </ul>	<ul style="list-style-type: none"> <li>▪ No splatter if used as recommended</li> </ul>
<b>Needle-sticks among health care workers</b>	<ul style="list-style-type: none"> <li>▪ Could increase needle-stick injuries among health care workers through adding an extra step in waste collection<sup>†</sup></li> </ul>	<ul style="list-style-type: none"> <li>▪ Can occur if boxes are overfilled or are not available in sufficient quantities</li> </ul>
<b>Needle-sticks among waste handlers</b>	<ul style="list-style-type: none"> <li>▪ Could increase needle-stick injuries among waste handlers through adding an extra step in waste collection</li> <li>▪ Could decrease needle-stick injuries among waste handlers if sharps in regular waste are decreased</li> <li>▪ Could increase needle-stick injuries among waste handlers if reusable needle containers are emptied in a small tube</li> </ul>	<ul style="list-style-type: none"> <li>▪ Can occur if sharps are collected in regular waste or if boxes are reused</li> <li>▪ Can occur if sharps are not immediately discarded in collector</li> <li>▪ Can occur if sharps container not appropriately closed or is overfilled</li> </ul>
<b>Waste management</b>	<ul style="list-style-type: none"> <li>▪ Allows separate management of syringes and needle waste</li> <li>▪ May require fewer safety boxes</li> <li>▪ May reduce volume of sharps waste requiring special handling</li> <li>▪ May contaminate waste handling sites</li> <li>▪ May facilitate plastic recycling and alternatives to incineration by removal of metal components</li> <li>▪ Needle box needs to be disposed of properly</li> </ul>	<ul style="list-style-type: none"> <li>▪ Sharps waste management difficult to implement: <ul style="list-style-type: none"> <li>▪ Restricted access to boxes</li> <li>▪ Requires waste treatment option that requires fuel and may generate pollution</li> <li>▪ Requires landfill space</li> </ul> </li> </ul>

## Terms of references for field assessment of needle-removing devices

### Study population

The study population will include all workers working in the health care setting, including injection providers and those potentially exposed to sharps waste downstream (e.g., waste handlers).

### End-points, indicators and data collection methods

Proposed end-points, indicators and data collection methods are listed on Table 3, page 12.

\* The recommended best practice for sharps waste collection and disposal.

<sup>†</sup> Anecdotal reports suggest that in South Asia, used syringes are sometimes stuck in a piece of foam for needles to be removed at the end of the day. Such practices may increase the risk of needle-stick injuries.

It should be possible to collect the data through (1) structured observations and (2) standardized interviews during monthly visits in each health care facility. In addition, an active system (daily observation and data collection) needs to be in place to report (1) device failures and (2) sharps injuries. To this effect, trained observers will ask all workers at risk if they had a sharps injury or experienced device failure during their shift. Investigators will then collect reporting forms on a monthly basis.

In addition to the main indicators, data to be collected regularly would include:

- Number of syringes used per time interval (e.g., monthly); \*
- Type of services provided (e.g., outpatient unit, immunization clinic, outreach, inpatient services);
- Identification of all persons at risk (e.g., health care workers, laboratory staff, cleaners, waste handlers etc., including number of active working hours of exposure);
- Hepatitis B vaccine status of the health care worker;
- Acceptability of needle removal devices by health care worker at the end of the study;
- Location of needle removers in the health care facility vis-a-vis where syringes are used;
- Health care worker practices, including:
  - Needle removal, disposal or emptying of the needle containers (needle removal intervention);
  - Sharps waste collection and sharps waste management practices (best practices intervention).

In addition to the data collected during the trial, pre-trial data on needle-stick injuries and reporting rates will be collected in order to assess reliability of trial information. The protocol and the data collection instrument should be submitted for external review. Reviewers should include manufacturers of injection devices and needle removers.

#### Types of devices to be assessed

- Non-electric devices should be assessed so that they can be used in all developing country settings, including outreach.
- Evaluations in the curative sector where fixed needles are uncommon should consider needle removers that do not cut needles (e.g., sharps boxes that strip off needles). Comparative evaluation of three types of intervention is possible (best practices, needle removers and hub cutters).
- Evaluations in the immunization sector where fixed needles are the rule should focus on needle removers that cut needles (i.e., hub cutters).

#### Study design

In the context of the high incidence of needle-stick injuries in developing countries, it is not relevant to define a safety threshold that would be based on the rates of needle-stick injuries in industrialized countries. Thus, studies should aim at comparing two or three interventions for safety (in terms of needle-stick injuries) and effectiveness (in terms of decreasing the volume of sharps waste). Thus, studies should be:

- Prospective studies (duration sufficient to (1) capture a sufficient number of injections and (2) assess beyond the immediate start-up phase).

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\* Syringes may be used for procedures other than injections (e.g., drawing blood).

- Controlled trials comparing two or three interventions for the safe collection and management of sharps waste under ideal conditions of use:
  - a) A reference intervention:  
Recommendations to collect and dispose of sharps waste according to best practices, <sup>1</sup> training, supervision, provision of sharps boxes and sharps waste management;
  - b) One or two interventions under evaluation:  
Recommendations to collect and dispose of sharps waste with needle-removing devices (that could include manual needle removers and hub cutters) for separation of syringes and needles with separate waste management pathways for syringes and needles, training, supervision, provision of sharps boxes \* and sharps waste management with provision of needle removers and needle pits.

The interventions being compared will be identical except for the recommended practice, the provision of needle removers and needle pits. Defining the intervention(s) in the needle remover arm(s) of the study and the control arm of the study may need to take into account local policies and regulations. In countries that may mandate the destruction (e.g., India) or the decontamination (e.g., former Soviet Union) of injection devices, it may be difficult to have a control arm using WHO best practices (i.e., immediate collection of dirty sharps in safety boxes, without disassembly).

#### Sample size and randomization

The unit of analysis will be a functional health care unit. This will be defined as a primary care facility or a department of a hospital. In one given health care facility, there should not be more than one intervention type. Sample size calculation, randomization and matching need to be conducted by a bio-statistician and reviewed by a scientific committee. Study design could consider a cross-over design where the needle remover intervention and the control intervention would be implemented successively in the same health care facilities after appropriate “run in” and “wash out” periods.

#### Setting

##### *Availability of single use injection devices*

To minimize the risk to human subjects, settings could be selected where there is no shortage of single use injection devices. Sharps waste containers shortages will be prevented as part of the intervention.

##### *Current use of needle removal devices*

Studies should be preferentially conducted in settings that already use needle-removing devices (e.g., Palestine, India, South Africa and China) or in settings where needles are removed through other means.

Other criteria to consider could include:

- Endemicity level for bloodborne pathogens
- Hepatitis B immunization coverage among health care workers

##### *Type of health care setting*

Potential facilities to assess include primary care, outreach settings and hospitals. The study sample should be homogeneous in terms of level of risk or stratify with homogeneous strata. Two specific settings deserve comments:

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\* Ultimately, syringes without needles could be managed in the regular waste. Thus, safety boxes would not be necessary. However, for the purpose of the study, provision of safety boxes will allow the measurement of the quantity of output using a common unit.

## Hospitals

Hospitals are tempting study sites as they allow a rapid access to a large number of injections. However, hospitals are a specific setting characterized by the presence of many other sharps (e.g., scalpel blades). In such an environment, the introduction of a needle remover may impact the whole sharps waste management system in an unexpected fashion. As a consequence, the risk of needle-stick injuries associated with needle-removing devices could be higher. In addition, in hospitals, needle removers may have a lower impact on waste reduction because of the presence of other bulky waste placed in sharps containers (e.g., intravenous lines). Overall, the trade-off between sharps waste volume reduction and risk of needle-stick injury may be less favourable. Initial studies should focus on primary care first. Hospitals could then be considered when the safety and effectiveness of needle removers have been established in primary care.

## Mass immunization campaigns

Mass immunization campaigns (e.g., for measles) are a setting where waste management issues are particularly challenging and where needle removers may be less likely to lead to needle-stick injuries. In addition, they provide an opportunity to examine many injections over a short period of time and to measure sharps waste volume production. Thus, they could constitute a good setting to study the field introduction of needle-removing devices. Advance planning will be necessary as measles campaigns are often scheduled on a short timeline and lead to intense efforts by many partners. Availability of a pre-cleared template protocol will help.

## Interventions

Interventions for each arm will be identical except for the provision of needle removers and set up of a mechanism to manage needle waste (e.g., needle pits). These should be described in full, including:

- The type and number of equipment (e.g., needle removers, hub cutters, needle pits) and supplies (e.g., boxes) provided;
- The type of back-up provided (e.g., focal points for device failure, maintenance and back-up)
- Waste management strategies;
- The type of training and supervision provided, including refresher courses in health care worker protection / needle-stick prevention according to WHO's key elements.<sup>7</sup>

## Conflicts of interest

Quality assurance steps need to be in place if studies are to be conducted by those involved in the development / sale of specific devices. These would include:

- Conflict of interest disclosure;
- Reporting any deviation from the study protocol;
- Presence of a scientific committee including WHO.

## Study quality

Quality control should be ensured for these studies through:

- Appointment of an external clinical trial monitor (if possible);
- Approval of the protocol by a bio-statistician;
- Listing of bias and effect modifiers with an evaluation of how those will be controlled in the sampling, intervention implementation, data collection and data analysis;

- Scientific committee including specialists in epidemiology, clinical trials, infection control, health care worker protection and waste management;
- A final report meeting standards acceptable to a peer-review journal.

#### Device failures

Device failure episodes need to be reported using a standardized report form. They will be classified as to whether or not they resulted in injury. Those resulting in patient or health care worker injury will be reported according to national regulations and to WHO.

#### Estimating costs

Data should be collected to allow for costing studies comparing the two approaches in waste management. The goal is to collect all data regarding costs and savings so that an analysis can be done from a system perspective. To allow for costing, two elements need to be estimated. First, quantification needs to occur (e.g., volume of sharps waste produced). Second, cost identification of specific items needs to be conducted (e.g., cost of a needle pit, savings on transport costs, etc.). While quantification will require quantitative input of data collected during the field assessment, cost identification may be conducted in parallel and should take into account the fact that some costs will vary by country and region so that estimates can be used globally.

#### Human subjects

Given that these evaluations would be conducted in settings where needle-stick injuries are high, all interventions (best practices and needle removal) should lead to a decrease in the overall rate of needle-stick injuries. On the basis of the information available to date, it is not possible to determine how the various interventions would affect the overall rates of needle-stick injuries among injection providers and waste handlers (see Table 2). Thus, a randomized assessment is appropriate. Guiding principles for the protection of human subjects should include:

##### *Ethical committee approval*

The protocol should be approved by a local ethical committee and WHO's SCRIHS ethical committee.

##### *Informed consent*

While institutional approval to participate will be necessary, it may be possible to request exemption from obtaining consent from individual workers since all workers will be affected whether or not they choose to participate in the study. To minimize coercion, it is suggested to implement the study where needle removers are currently in use.

##### *Confidentiality*

Needle-stick injuries should be reported in a way that protects the confidentiality of health care workers. Confidentiality should be ensured at all times, including data collection, data management, access to data and use of the information.

##### *Management of needle-stick injuries*

Written standardized procedures should be in place to manage needle-stick injuries. These should be compatible with national recommendations. Needle-stick injuries should lead to a case report form specifying the circumstance of the injury and attempting to identify missed opportunities for prevention.

#### Consideration for follow up after the study

Study protocols should consider the proposed follow-up in the health care facilities included in the study after the study so that lessons learned about the interventions conducted could lead to implementation of sustainable prevention measures in the two arms of the study.

### *Action points*

1. WHO and its partners planning field assessments of needle-removing devices will attempt to follow the terms of references proposed in this document.
2. The WHO occupational health group will finalize a guidance document on the surveillance and management of needle-stick injuries in collaboration with the International Council of Nurses (ICN). This guidance will be used in the field evaluation of needle-removing devices.
3. WHO will prepare a standardized protocol for the field evaluation of needle removers during measles campaigns. This template protocol will include data collection instruments, consent forms and a budget and will be submitted for ethical committee review.
4. WHO will propose field evaluation of needle removers to the partners in the global efforts to reduce measles-associated mortality. This could leverage funding sources and lead to trials soon (e.g., Nepal, West Africa).
5. WHO will develop draft specifications for needle removers to be evaluated in the field. The experience acquired by PATH in this field should be formalized to formulate specifications. PATH will provide input to the device case report form, so that ultimately the information collected from the field can be used to develop final specifications.
6. Bench methods of assessing splatter production of needle removers need to be developed so that needle removers can be assessed for splatters in parallel to the field assessment.
7. WHO will attempt to recover experience regarding the rates of needle-stick injuries in industrialized countries where needle-removing devices are used (e.g., Germany).

**Table 3: Indicators to measure with proposed data collection procedures, field assessment of single use syringes**

End points	Indicators	Proposed data collection method
<b>Primary end-point</b>		
<ul style="list-style-type: none"> <li>▪ Blood exposure among workers, including sharps injuries</li> </ul>	<ul style="list-style-type: none"> <li>▪ Rates of sharps injuries per productive working hours and per number of syringes used (stratified by job description) *</li> <li>▪ Surveillance characteristics of needle-stick injuries, including timing of occurrence (before or after injections)</li> <li>▪ Rates of exposure to blood (including sharps injuries) per productive working hours (stratified by job description)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Because of concerns of under-reporting, case ascertainment cannot be based upon passive reporting. Active reporting should be preferred †</li> <li>▪ Use of the needle-stick reporting form prepared for the WHO/ICN pilot needle-stick prevention project</li> </ul>
<ul style="list-style-type: none"> <li>▪ Volume of waste ‡</li> </ul>	<ul style="list-style-type: none"> <li>▪ Number of safety boxes filled §/ 100 syringes used</li> <li>▪ Number of needle containers filled **/ 100 syringes used (intervention arm only)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Facility records (inventory, disposal logs)</li> </ul>

\* This indicator should be calculated using the number of exposed workers as denominator (e.g., number of needle-stick injuries per person and per year) rather than the number of procedures as denominator (e.g., number of needle-stick injuries per injection given or per syringe used). The rate should be adjusted to reflect needle-stick rates per productive hour of work.

† e.g., system of employees logging in and logging out after work and self-recording injuries.

‡ For the collection of needles only or syringe and needle sets.

§ To be converted into volume taking into account the size of the box.

\*\* To be converted into volume taking into account the size of the needle container (that is device-specific).

End points	Indicators	Proposed data collection method
<b>Secondary end-points</b>		
▪ Episodes of device failures	▪ Rates of device failures / devices and / 100 syringes used, including: <ul style="list-style-type: none"> <li>▪ Needle remover device failure.</li> <li>▪ Sharps disposal box punctures and overfills.</li> </ul>	▪ Case report form <sup>*</sup>
▪ Sharps waste collection technique	▪ Proportion of injections for which the needle is immediately removed after use or for which the dirty sharps are immediately collected in a safety box	▪ Direct observation <sup>† 8</sup>
▪ Accumulation of contaminated syringes inside facilities	▪ Proportion of health care facilities where dirty sharps may be observed in areas where they expose health care workers to sharps, including in the regular waste	▪ Direct observation <sup>† 8</sup>
▪ Proportion of health care facilities managing syringe waste using various methods	▪ Proportion of health care facilities managing syringe waste using various methods	▪ Regular interviews with managers <sup>†</sup>
▪ Proportion of health care facilities managing needle waste using various methods	▪ Proportion of health care facilities managing needle waste using various methods	▪ Regular interviews with managers <sup>†</sup>
▪ Accumulation of dirty sharps in the surroundings of health care facilities	▪ Proportion of health care facilities with dirty sharps in the surrounding area	▪ Direct observation <sup>†</sup>
▪ Quantity of syringes recovered for plastic recycling (if applicable)	▪ Monthly quantity of syringes sent for plastic recycling <sup>‡</sup>	▪ Monthly health care facility records
▪ User acceptability	▪ Qualitative self-reported feedback (e.g., needle container reuse)	▪ Qualitative methods

<sup>\*</sup> Including whether the device was replaced and when.

<sup>†</sup> Use “tool C” methodology.

<sup>‡</sup> Optional. Information may not be available from the health care facility.

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