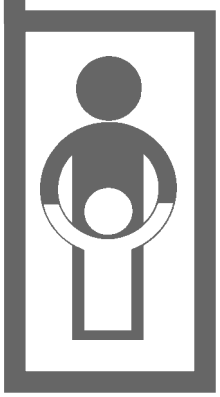
WHO/V&B/01.30
WHO/BCT/01.02
ORIGINAL: ENGLISH
DISTR.: GENERAL

Tool for the assessment of injection safety



DEPARTMENT OF VACCINES AND BIOLOGICALS

World Health Organization
Geneva
2001

BASICS II

SAFE INJECTION GLOBAL NETWORK
S.I.G.N.

The Departments of Vaccines and Biologicals and Blood Safety and Clinical Technology thank the US Agency for International Development (USAID), the Canadian International Development Agency (CIDA) and other donors, whose financial support has made the production of this document possible.

This document is also part of a toolbox that addresses broad concepts of assessment and evaluation of injection practices that were discussed during a workshop of expert consultants held at BASICS II (Basic Support for Institutionalizing Child Survival), Arlington, VA, USA in March 2000.

It was developed and drafted in cooperation with SIGN (Safe Injection Global Network), BASICS and WHO's Departments of Vaccines and Biologicals and Blood Safety and Clinical Technology.

It constitutes a dated draft. Later versions of this document will be adapted once consensus has been reached after extensive field-testing.

Comments and suggestions should be directed to the Immunization Safety Priority Project, WHO, CH-1211 Geneva 27, Switzerland, Fax +41 22 791 4210.

We are interested in your comments and results, please forward them to EPIDATA@who.ch or the above-mentioned address

This document was produced jointly by the Vaccine Assessment and Monitoring & Access to Technologies teams of the Department of Vaccines and Biologicals and the SIGN Secretariat of the Department of Blood Safety and Clinical Technology

Ordering code: WHO/V&B/01.30 and WHO/BCT/01.02
Printed: August 2001

This document is available on the Internet at:
www.who.int/vaccines-documents/
and www.injectionsafety.org

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Contents

Abbreviations

AD	auto-disable (syringes)
BASICS II	Basic Support for Institutionalizing Child Survival II
CSAMPLE	cluster sample analysis module of EpiInfo software package
DAP	Drug Action Programme (WHO)
EPI	Expanded Programme on Immunization (WHO)
HIV/AIDS	human immunodeficiency virus/acquired immunodeficiency syndrome
IMCI	integrated management of childhood illness
IRB	Institutional Review Board
ISPP	immunization safety priority project
MEASURE	monitoring and evaluation to assess and use results
NIDs	national immunization days
SIGN	Safe Injection Global Network
SNIDs	subnational immunization days
TST	time, steam and temperature
UNAIDS	Joint United Nations Programme on HIV/AIDS

Introduction

Injection safety should be assessed using standardized and representative methods to allow for a reliable assessment of the country situation and for comparisons with other countries. Additionally, if the assessment is done before the introduction of changes, a repeated assessment can then measure achievements consistently. These methods should be simple and flexible. This tool proposes a standardized methodology including concepts, study designs, sampling procedure, data collection, data analysis and reporting for the assessment of injection safety in health care facilities. It updates the structured observation tool that was proposed by the WHO Drug Action Programme (DAP) *(1)* and the various injection safety tools that have been developed in the context of the WHO Expanded Programme on Immunization (EPI).

The assessment estimates the frequency of unsafe injection practices. It determines whether a facility where injections are given meets the necessary requirements for equipment, supplies and waste disposal. It also identifies unsafe practices that may lead to infections, such as whether the critical steps of an injection administration are executed. Furthermore, it estimates the proportion of health care facilities where injection practices are safe. Three major considerations are especially relevant in the assessment of potential unsafe injections practices: 1) the safety of the injection recipient, 2) the safety of the health care worker, and 3) the safety of the community. Recommendations following an assessment should focus upon these considerations in regard to injection safety interventions.

The main object of the assessment is to assess the injection safety practice at a national level, but it may also be useful at other levels. If the country is large in terms of population it can be used to assess injection safety at a subnational level (province or state) without changes in the sampling strategy. The questionnaire can also be used for self assessment of safe injection practices at the district level, or even within a health facility.

Levels of definition for a safe injection

There are three levels for the definition of a safe injection. The first level is an ideal reference definition. The second level represents international best practices, which are a translation of the reference definition into an explicit list of critical steps on the basis of (a) best available evidence, or (b) expert consensus in the absence of evidence. The third level is the adaptation of international best practices into a national standard that takes into account operational constraints in the field.

1. Reference definition of a safe injection

A safe injection does not harm the recipient, does not expose the provider to any avoidable risk and does not result in any waste that is dangerous for other people. This reference definition is ideal but it cannot be used as a checklist of practices for assessment or evaluation.

2. Best injection safety practices

The reference definition of a safe injection can be translated into a list of critical steps for which best practices should be followed. For example:

1) In order not to harm the patient, the injection should be administered with a sterile syringe and needle, using the right medication, etc.
2) In order not to expose the provider to any avoidable risk, the needle should be placed in a puncture-proof container immediately after use.
3) In order not to result in any waste that is dangerous for other people, sharps waste should be discarded appropriately.

The draft of the international best injection practices document is available on the web site (www.injectionsafety.org).

3. National standards

At country level, the best injection practices document should be adapted into national standards. These should be developed through a participatory approach that involves all stakeholders (e.g. those who administer injections, those who prescribe them, those who are in charge of the logistics etc.). Guidelines to develop country-level standards have been proposed *(2)*.

Requirements of an injection safety assessment tool

This injection safety assessment tool was designed to determine how injections given in a health facility, a district, or a country, depart from the national standard. It attempts to meet the following three requirements:

1. Simplicity

An injection safety assessment tool needs to be simple, so that persons at country level can conduct an assessment rapidly and with limited resources. This tool is fully structured for ease of use and standardized administration. Although the tool asks a large number of questions it should require minimal training for someone familiar with injection safety.

2. Standardization

An injection safety assessment tool should include a core set of items that constitute a checklist based upon the critical steps that make an injection safe.

3. Flexibility

An injection safety assessment tool should be flexible so that assessment can be conducted under various circumstances. For example:

1) Need for an assessment at country, district, facility, or health post level.
2) Need for an assessment of the private, public, informal, or traditional sector.
3) Need for various levels of accuracy and precision, requiring various sampling and sample size schemes (e.g. structured, convenience, or key informant assessment).
4) Availability of various human, material and financial resources.

Objectives

The objectives of an injection safety assessment are:

1) To determine whether a facility where injections are given meets necessary requirements for staff competence, equipment, supplies and waste disposal.

2) To determine whether the critical steps of an injection administration are executed according to recommended best practices.

3) To identify the unsafe practices that may lead to infections and that should be targeted by interventions to improve injection safety.

4) To estimate the proportion of health care facilities where injection practices are safe.

Study design

1. Type of study

Cross-sectional, observational study.

2. Integration with facility surveys conducted for other purposes

2.1 Integrated management of childhood illness (IMCI) facility surveys

2.1.1 Background

In the context of the IMCI, health care facility surveys are conducted to assess the management of sick children.

2.1.2 The collection of information relevant to injection safety

During the IMCI health care facility surveys, information is collected regarding issues that are relevant to injection safety. Such issues include: sources of clean water, availability of syringes and needles for vaccination, presence of a functional sterilizer and the presence of a refrigerator.

2.1.3 Potential for integrated surveys

If IMCI health care facility surveys are planned, arrangements may be made to simultaneously conduct injection safety assessment.

2.2 WHO/UNAIDS/MEASURE (monitoring and evaluation to assess and use results) facility surveys

The WHO/UNAIDS/MEASURE project to define standardized packages to evaluate HIV/AIDS prevention activities will contain a facility assessment package with which the injection safety assessment tool may be integrated.

3. Settings

3.1 Type of injection providers

Various providers may give injections. Depending on the source of the injections received by the population, information on injection safety may be needed regarding several types of providers (e.g. primary care, lay health care workers, outreach facilities, etc.). An additional tool that is part of the SIGN Toolbox estimates the frequency of injections given by each provider and was primarily designed to assess the safety of injections administered by injection providers in primary health

care facilities. If injection practices of other providers need to be assessed this tool may still be used, but the proposed sampling may require adaptation, as a sampling frame may not be available for other injection providers.

3.2 Type of facilities

The data collection instrument proposed in this tool is designed for application in primary care settings, dispensaries and other facilities where injections constitute the majority of skin-piercing procedures.

For other settings where many other skin piercing procedures are conducted, including hospital and dental offices, the present injection safety assessment tool may be too limited in its scope to identify the infection control practices that may lead to the transmission of infections. Additional tools will be developed in the future to evaluate infection control procedures for all skin piercing procedures in these facilities.

Sampling procedure

Sampling should be done a few weeks before the planned date for the survey to allow sufficient time to schedule travel and relevant administrative authorizations.

1. Principle

The sampling unit will be the health care facility. To minimize travel within the country, a two-stage, cluster-sampling method is proposed as the easiest method to obtain a representative sample of health care facilities *(3)*. In such a cluster sampling, self-weighting is ensured through (1) choice of regions in which clusters are selected using probability proportional to population size, and (2) equal numbers of sampling units within each cluster.

1.1 First stage

1.1.1 Division of the country into regions

The country should be divided into regions (or other administrative areas, e.g. districts, provinces, etc.) that are (1) non-overlapping (i.e. no village should be located in two regions), and (2) exhaustive (i.e. all geographic areas of the country should be included). The level of regions (or other administrative areas, e.g. districts, provinces, etc.) should be chosen so that (1) the number exceeds eight, and (2) each contains at least 10 primary health care facilities. In case it is not possible to find regions with at least 10 primary health care facilities, adjacent regions may be merged to form larger regions containing a sufficient number of primary health care facilities.

> Note: If some regions of the country cannot be visited for any reason (e.g. civil unrest), they should be excluded from the list of regions to be sampled at this stage.

1.1.2 Choice of regions with a probability proportional to the population size

From the whole country, eight geographic regions will be selected with a probability proportional to the total population size. To proceed to this selection, the following six steps should be followed:

Step 1: Rank all regions in a table

All regions should be displayed in the first column of a table, in whatever order is most convenient (see example, Table 1).

Step 2: Determine the population size for each region

The population size should be obtained for each region and written in column 2, next to the region name (e.g. 30 000 for region 10, Table 1). Census data, even outdated, or the best available equivalent should be used.

Step 3: Calculate the cumulative population size

The cumulative population size should be calculated for each region and written in column 3 next to the population size. For region 1, the cumulative population size is the population of region 1. For region 2, the cumulative population size is the population of region 1 + population of region 2. For region n, the cumulative population size is the population of region 1 + population of region 2 + (…) + population of region n. For example: 565 000 for region 10 (Table 1). For the last region, the cumulative population size is the population of region 1 + population of region 2 + (…) + (…) + population of last region. The total should be equal to the country's population.

Step 4: Calculate the sampling interval

The sampling interval *s* should be calculated by dividing the country population by eight (the number of regions selected). For example: 1 177 000/8 = 147 125 (Table 1).

Step 5: Choose a random number between 1 and the sampling interval

A number *r* should be selected at random between 1 and the sampling interval (country population divided by eight, the number of regions selected). For example: 85 350 (Table 1).

Within each of the eight regions selected, a cluster of 10 facilities will be chosen where assessments will be conducted.

Step 6: Identify the clusters

First cluster: Column 4 of Table 1 should be used to identify the region in which the cluster is located. The first region selected will be the region for which the number of cumulative population size (column 3) is greater than the random number *r*, while the random number *r* is greater then the cumulative population size of the preceding region. The random number *r* should then be marked in column 4 opposite the region. For example: 85 350 is smaller than 100 000 (cumulative population size for region 3) but greater than 70 000 (cumulative population size for region 2), so region 3 is selected as containing the first cluster (Table 1).

Second cluster: The second region selected will be the region in which the cumulative population size (column 3) is greater than $r + s$, while $r + s$ is greater than the cumulative population size of the preceding region. The number $r + s$ should then be marked in the fourth column facing the region. For example: 85 350 + 147 125 = 232 475 is smaller than 425 000 (cumulative population size for region 7) but greater than 125 000 (cumulative population size for region 6), so region 7 is selected as containing the second cluster (Table 1).

Following clusters: Proceeding in the same way eight times, the regions will selected by adding the sampling interval *s* each time to the number in column 4, and by identifying the region for which the number of cumulative population size (column 3) is greater than the new number, while the new number is greater than the cumulative population size of the preceding region. In some cases, the new number may fall in the same region. In this case, the region is selected twice, and 2 x 10 facilities will be selected from this region. For example: region 7 is selected twice (Table 1).

Table 1. Example of selection of regions with a probability proportional to population size

Name of region	Population size	Cumulative population size	Numbers to identify clusters	
Region 1	50 000	50 000		
Region 2	20 000	70 000		
Region 3	30 000	100 000	85 350	
Region 4	10 000	110 000		
Region 5	5 000	115 000		
Region 6	10 000	125 000		
Region 7	300 000	425 000	232 475	379 600
Region 8	50 000	475 000		
Region 9	60 000	535 000	526 725	
Region 10	30 000	565 000		
Region 11	120 000	685 000	673 850	
Region 12	80 000	765 000		
Region 13	90 000	855 000	820 975	
Region 14	30 000	885 000		
Region 15	20 000	905 000		
Region 16	70 000	975 000	968 100	
Region 17	52 000	1 027 000		
Region 18	40 000	1 067 000		
Region 19	90 000	1 157 000	1 115 225	
Region 20	20 000	1 177 000		
Total	**1 177 000**			
Sampling interval:		**147 125**		
Random number:		**85 350**		
Regions selected:		**3, 7 (twice), 9, 11, 13, 16, 19**		

1.2 Second stage

In each of the eight selected regions, a cluster of 10 health care facilities will be selected. (Two additional facilities may be selected in each district to allow for replacements if needed.) A list of all facilities in the region should be obtained. Two sampling methods can be used to select the health care facilities to be assessed: random sampling or systematic sampling. Either method may be used.

1.2.1 Random sampling

From the list of facilities, 10 facilities are selected at random using a random number table if available, or serial numbers from bank notes.

1.2.2 Systematic sampling

Health care facilities in the region are displayed on a list and a ranking number is assigned to each facility. The total number of facilities is divided by 10 (the number of health care facilities to be selected in the region) in order to obtain the sampling interval *s'*. Then, a random number *r'* between 1 and the sampling interval *s'* is chosen. The health care facilities selected will be those with ranking number *r'*, *r'* + *s'*, *r'* + (2x *s'*), *r'* + (3x *s'*), etc., until *r'* + (9x *s'*). Note that the sampling intervals *s'* and ranking numbers *r'* are different from the one used for the selection of clusters (Stage 1).

> Note that if a list of facilities cannot be obtained, this sampling methodology is not possible.

2. Sample size

The total sample size will be 8 x 10 = 80 health care facilities.

3. Replacements

Care should be taken to visit all selected facilities without replacement wherever possible. Replacement should be limited to facilities that are not eligible (e.g. facilities where injections are never given, facilities that have closed, facilities under construction). Replacement of facilities that are difficult to access should be avoided as this could lead to a bias through over-representation of easily accessible facilities that may receive better staffing, equipment and supplies. Hard-to-reach facilities should be identified at an early stage to plan for extra access efforts, special transport arrangements, etc., so that they are not omitted from the survey.

Human subjects

This tool is designed for the assessment of injection safety during routine healthcare delivery. However, before conducting this assessment, evaluators should check whether the applicable Institutional Review Board (IRB), if any, would (1) consider this evaluation as research or not (as criteria may vary across countries and institutions), and (2) require an IRB ethical review. In addition, to prevent any ethical issue, evaluators will be asked to intervene to prevent potential harm if they are about to witness injection practices that are of particular danger to the injection recipients (e.g. re-use of syringes and/or needle without sterilization).

Data collection procedure

Methods that have been used in the past to assess or evaluate injection safety have been subject to potential bias. Collecting information on practices reported through interviews of injection providers alone is subject to reporting bias and observation of practices is subject to Hawthorne effect (observer-induced changes in practices). In order to obtain more accurate information this current tool proposes a method in which information is obtained using a combination of interview and structured observations. Information to be collected includes:

1) Structured observation of available supplies.

2) Structured observation of practices.

3) Reported availability of equipment and supplies.

Results obtained using (1), (2) and (3) may be combined to address specific questions (e.g. the number of injections given every day versus the number of syringes and needles available) and will allow for cross verification. A sample data collection instrument is provided in this tool (Instrument 1, Annex 2).

1. Pilot testing of the data collection instrument in the country

The three parts of the proposed data collection instrument should be pilot-tested in each country to ensure that it is suitable to the particular circumstances and that the right nomenclature is used. This pilot testing can be conducted in a limited number of health care facilities prior to the training of the fieldworkers. Following pilot-testing, certain minor adaptations to the data collection instrument might be relevant in specific areas, according to the type of injection equipment used or other local circumstances. These changes should be kept to the minimum in order to maintain the standardization.

2. Recruitment of the fieldworkers

A sufficient number of fieldworkers should be identified so that the fieldwork can be completed within two weeks. For an assessment of 80 facilities using structured sampling, it is estimated that four teams – each with one supervisor, one fieldworker and one driver – can complete the fieldwork in 10 days (Table 2).

Table 2. Estimated timeframe of fieldwork for an injection safety assessment of 80 facilities

Time spent in each facility	2-3 hours	
Number of facilities visited by one team in one day	2	
Number of facilities to visit in one district	10	
Number of working days needed for a team to complete one district	5	
Number of districts to visit	8	
Total number of team working days needed	40	
Number of days of work if 4 teams each with a vehicle and driver	**40/4 = 10 days**	

3. Training of the fieldworkers

3.1 Objective

The purpose of the training of fieldworkers is to ensure that all fieldworkers will collect information using the same methodology.

3.2 Initial briefing

Fieldworkers should be trained to collect data in an exhaustive and standardized way while remaining respectful of the health care workers and their work. Some background material on injection safety should be provided (available on the Internet at www.injectionsafety.org). The purpose of the assessment and the importance of its sampling methodology should be explained. The data collection instrument should be reviewed with the fieldworkers line by line to ensure that all of the questions are understood and that fieldworkers clearly understand what is required of them. Field workers should also be instructed on how to review the data collection questionnaires for accuracy and completion before leaving each health facility.

3.3 Standardization of the data collection procedure

Fieldworkers should be taken to several health care facilities so that they become accustomed to the assessment tool and data collection process. In the first facility, the principal investigator may collect the data while carefully explaining each step to the fieldworker. In the second facility, while the investigator still collects data, all fieldworkers should collect data on separate questionnaires in order to compare their results after the visit. Once fieldworkers feel confident with the tool, and the results across observers are uniform, the team may be split in smaller groups to assess different facilities while still comparing results obtained between various observers in the same facility. This procedure should be continued until the principal investigator is confident that all fieldworkers will collect data in the same way and obtain uniform results.

Ideally, standardization of the data collection procedure should be conducted in facilities that are not included in the assessment. Specific administrative authorizations may therefore be needed in addition to that obtained for fieldwork in the selected clusters. When it is not possible to do otherwise the standardization of the data collection procedure may be conducted in one of the clusters selected for the survey. Because of its large population size, the capital city will often be included in the sample. This provides an opportunity to standardize the data collection procedure across all teams before splitting in smaller groups.

Organization of the fieldwork

1. Timing of visits

To ensure observation of injections in a high proportion of health care facilities, care should be taken to visit health care facilities at a time when most injections are given (e.g. early in the morning in many tropical and subtropical countries). In order to ensure the best outcome of the survey, injections should be observed in every health facility visited. Ideally, these observations should include at least one vaccination and one therapeutic injection.

2. Supervision of the data collection

When fieldworkers are sent to the field, they should be supervised during and after data collection. Visits should be made while fieldworkers are collecting data to ensure proper data collection in the field. In addition, in the evening, the data collected should be reviewed to ensure consistency, completeness of data collection forms and clarity of the notes.

3. Completing the data collection instrument (Annex 2)

3.1 Introduction

A short word of introduction is proposed that may be adapted. It is important that health care workers in the facility feel comfortable with the assessment, that is being conducted voluntarily and that they have the right to refuse participation, and that they know the information gathered in the assessment is confidential.

3.2 Part 1: Structured observation of equipment and supplies

Part 1 of the instrument is a structured observation of equipment and supplies in the facility. While fieldworkers may speak to the health care worker, and ask to be shown the equipment and supplies, the form should be filled in only on the basis of what is observed and not on the basis of answers that may be given.

If the health care facility is equipped with a steam sterilizer, it should be tested by boiling water in it to check for steam leaks. In certain situations of limited resources, the health care workers may not have resources to purchase fuel for the sterilizer. Although this information should be collected in the third part of the data collection instrument, fieldworkers should carry small amounts of cash to be able to purchase the appropriate fuel so that steam sterilizers can be checked for leaks.

3.3 Part 2: Structured observation of injection practices

Part 2 should be used for structured observation of injections administered during the visit. If fieldworkers are about to observe practices that may expose the injection recipient to substantial risks (e.g. re-use of injection equipment in the absence of sterilization) the procedure should be tactfully interrupted to protect the injection recipient. However, the dangerous procedure that was about to occur should be recorded on the data collection form as if it had actually occurred.

3.4 Part 3 and part 4: Interviews with health care workers and supervisors

The questionnaires in part 3 (see Annex 2) should be used to interview the injection provider and the supervisor of the facility. If there is more than one injection provider in the facility, the one administrating the largest number of injections should be selected. Both questionnaires should be filled in on the basis of answers to the questions and not on the basis of the structured observations. Information collected through structured observation (part 1 and part 2) and through interviews (part 3 and part 4) will be compared in the analysis.

3.5 Leaving the facility

After thanking the staff and saying goodbye, all parts of the data collection forms should be checked for completeness, accuracy and clarity before the team leaves the facility.

Data analysis

1. Data entry and analysis programmes

Various analysis programmes may be used for data entry and analysis, including EpiInfo, the use of which is both free of charge and not restricted. Data entry and analysis programmes written for EpiInfo 6.04 can be provided upon request.

2. Confidence intervals

Calculation of confidence intervals and design effects can be done on EpiInfo using the CSAMPLE module.

3. Scores of injection safety

3.1 Defining scores

An overall safety score may be calculated for each injection event through attributing values to each of the critical steps. The values assigned to each critical step can then be added to obtain an overall score for each injection. Calculation of the mean score for all observed injections will allow changes in injection practices to be followed over time using smaller sample sizes. However, scoring procedures should be both standardized and validated.

3.2 Critical steps of injection safety

For the purpose of injection safety assessment in the context of EPI, scores are developed to assess three critical steps of injection safety:

1) The use of unsterile syringes or needles (a reflection of the risk of infection for the recipient).
2) Inappropriate waste collection (a reflection of the risk of infection for the health care worker).
3) Inappropriate waste disposal (a reflection of the risk of infection for the community).

Reporting

Injection safety assessment reporting should be reported by health care facilities using the standard tables below:

Table 3. Suggested reporting format for the injection assessment surveys

Table 3A. Information elements reflecting the risk to the recipient

Instrument	Item	#/N	%	95% CI
1- Supplies	Absence of leaks in all sterilizers currently used	—/—	— %	xx-xx
1- Supplies	Presence of one set of steam sterilizers spare parts	—/—	— %	xx-xx
1- Supplies	Presence of an updated TST spot register	—/—	— %	xx-xx
1- Supplies	Presence of a two-days supply of sterilizable equipment	—/—	— %	xx-xx
1- Supplies	Availability of a one-week supply of disposable/AD equipment	—/—	— %	xx-xx
1- Supplies	Absence of dirty or bloodstained swabs for skin preparation	—/—	— %	xx-xx
2- Practices	Preparation of injections in a clean dedicated area	—/—	— %	xx-xx
2- Practices	Breaking ampoules with a clean protective barrier	—/—	— %	xx-xx
2- Practices	Reconstitution with a sterile syringe and needle	—/—	— %	xx-xx
2- Practices	Reconstitution with recommended diluent (vaccine)	—/—	— %	xx-xx
2- Practices	Administration with an AD-syringe and needle (vaccine)	—/—	— %	xx-xx
2- Practices	Reconstitution with recommended diluent (curative)	—/—	— %	xx-xx
2- Practices	Administration with a sterile syringe and needle (vaccine)	—/—	— %	xx-xx
2- Practices	Administration with a sterile syringe and needle (curative)	—/—	— %	xx-xx
2- Practices	Removal of needles from multi-dose vials between injections	—/—	— %	xx-xx
2- Practices	Temperature sensitive products kept cool during preparation	—/—	— %	xx-xx
3- Interview	Provision of sufficient energy source for sterilization	—/—	— %	xx-xx
3- Interview	No shortages of disposable injection equipment	—/—	— %	xx-xx
3- Interview	Supply of vaccines with matching quantities of AD syringes	—/—	— %	xx-xx

Table 3B. Information elements reflecting the risk to the provider

Instrument	Item	#/N	%	95% CI
1- Supplies	Presence of at least 10 sharps containers	—/—	— %	xx-xx
1- Supplies	Absence of pierced, overflowing, or open sharps containers	—/—	— %	xx-xx
1- Supplies	Absence of sharps in open containers	—/—	— %	xx-xx
2- Practices	Absence of two-handed recapping	—/—	— %	xx-xx
2- Practices	Immediate collection of sharps in sharps boxes	—/—	— %	xx-xx
3- Interview	Absence of reported needle-stick injuries in the last 12 months	—/—	— %	xx-xx
3- Interview	No shortages of sharps containers	—/—	— %	xx-xx
3- Interview	Provision of sharps containers for vaccination injections	—/—	— %	xx-xx

Table 3C. Information elements reflecting the risk to the community

Instrument	Item	#/N	%	95% CI
1- Supplies	Absence of sharps around the health care facility	—/—	— %	xx-xx
1- Supplies	Absence of full sharps containers in unsupervised areas	—/—	— %	xx-xx
1- Supplies	Waste disposal in incinerators or transport of site	—/—	— %	xx-xx
3- Interview	Presence of an health care waste management policy	—/—	— %	xx-xx

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Annex 1:

Proposed schedule for an assessment of 80 facilities

In addition to the fieldwork, time must be scheduled for preparation and reporting. Overall, completion of the survey will normally require three weeks work for the principal investigator (Table 4).

Table 4. Proposed overall schedule for an injection safety survey of 80 facilities

Day	Proposed activities
D1 (Wednesday)	Briefing/pilot testing of the instrument in a few facilities
D2 (Thursday)	Photocopying of instrument/training of the fieldworkers
D3 (Friday)	Standardization of the data collection procedure in the first district
D4-D5 (weekend)	Break/travel
D6-D10 (Monday – Friday)	Fieldwork
D11-D12 (weekend)	Break/travel
D13-D17 (Monday – Friday)	Fieldwork
D18-D19 (weekend)	Fieldwork
D20 (Monday)	Data entry and analysis
D21 (Tuesday)	Debriefing and feedback

Annex 2:

Instrument 1: Sample data collection instrument to assess injection safety

Suggested word of introduction*

[Greetings] My name is _____, and I work with [Institution]. [Institution] is conducting an assessment about injections and health care. To do this survey, we are asking a series of questions and observing supplies as well as injection practices. Your health care facility has been chosen at random to take part in this survey. The questions will take approximately 10 minutes to complete, but I will be also observe your working conditions and will be around for about one hour. There is no risk to taking part in this survey, although you might feel you do not want to answer some of the questions. Taking part is your choice; you can choose not to answer any of the questions or tell us to stop at any time. If you decide you do not want to take part, you will not lose any employee benefits that you normally get. Your name will not be kept on the forms we use to write down your answers. If we write the results of the survey in a report, you will never be identified in the report. Please make sure any questions you have are answered before you agree to take part. If you have any questions about the survey you may ask them now or you can contact _____ and ask them before you agree to take part.

If possible, an introduction letter from the Ministry of Health or from the district should be presented.

Structured observations (part 1 and part 2)

Part 1 and part 2 should be used for structured observation (at the beginning of the visit, before questions in part 3 and part 4 are asked). Part 1 is a structured observation of equipment and supplies in the facility and part 2 covers the injections administered during the visit. For part 1 and part 2, you may ask the health care worker to show you the supplies you are looking for, but the form should be filled on the basis of what is observed only and not on the basis of answers that are given. Information from the health care worker will be collected in part 3. If the health care facility is equipped with a steam sterilizer, it should be tested by boiling water in it to check for steam leaks (part 1).

* This note should be adapted to each country and may be subject to ethical committee review or approval.

Questionnaire (part 3 and part 4)

The questionnaires in part 3 and part 4 should be used to interview the injection provider and the supervisor of the facility. If there is more than one injection provider in the facility, the one administrating the largest number of injections should be selected. Both questionnaires should be filled on the basis of answers to the questions and not on the basis of what you observed. Information collected through structured observation (part 1 and part 2) and through interviews (part 3 and part 4) will be compared in the analysis.

District (cluster) number: _____ Facility number: _____

Date and time of arrival: _____ Date and time of completion: _____

1. Structured observations of equipment and supplies available at the facility

I would like to start by observing some of the equipment and supplies available in this facility: *(this section is based upon observation only)*

Reuse of syringes or needles in this facility, either for immunization or for curative injections	1- Yes	2- No		3- Cannot be assessed
If yes, sterilization methods available (circle all that apply)	1-Steam sterilizer	2-Boiling	3-Both	4-Other (specify)
IF pressure sterilizer used in this facility (**If no**, skip next 8 items)				
Number of steam pressure sterilizers routinely in use	Single rack:	Double rack:		Triple rack:.....
Absence of leaks in routinely used sterilizers	1- Yes	2- No		3- Cannot be assessed
Number of spare sterilizer seals available	Number of seals	.....		3- Cannot be assessed
Number of spare sterilizer safety valves available	Number of valves	.....		3- Cannot be assessed
Number of spare sterilizer pressure valves available	Number of valves	.....		3- Cannot be assessed
Presence of a complete, updated register for logging TST spot indicators	1- Yes	2- No		3- Cannot be assessed
Presence of a functioning heater(s) for steam pressure sterilizer(s) in the facility	1- Yes	2- No		3- Cannot be assessed
Number of complete sterilizable injection equipment kits	Number of ..... Kit A	Number of ..... Kit B		

Total number of syringes available (including those in sterilizer racks and those kept in the store)					Total number of needles available (including those in sterilizer racks and those kept in the store)			
Size/type[1]	**Sterilizable**[2]	**Disposable**[3]	**Auto-disable**[3,4]	**Cannot be assessed**	**Size/type**	**Sterilizable**[1]	**Disposable**[2]	**Cannot be assessed**
0.05 ml					25-27G			
0.5 ml					21-23G			
5 ml					18G			
Other (specify)					Other (specify)			

Presence of swabs used for skin preparation that are dirty, bloodstained or kept wet	1- Yes		2- No			Cannot be assessed
Number of puncture-proof safety containers (safety boxes) in stock	0	1-4	5-9	10-20	= 20	Cannot be assessed
Presence of safety boxes in areas where injections are given	1- Yes		2- No			3- No safety boxes
Presence of overflowing, pierced, or open sharp box(es)	1- Yes		2- No			3- No safety boxes
Number of full sharps box(es) waiting for disposal/incineration stored safely	Number present		.....			Cannot be assessed
Number of full sharps box(es) waiting for disposal/incineration stored in unsupervised fashion	Number present		.....			Cannot be assessed
Sharps in plastic bottles, or open containers exposing staff to needle-stick injuries	1- Yes		2- No			3- Cannot be assessed
Evidence of used sharps around the health centre and/or the disposal site	1- Yes		2- No			3- Cannot be assessed
Type of waste disposal facility used for the disposal of the majority of sharps (circle only one)	1- Open burning on the ground 3- Incinerator 5- Dumping in pit latrine or other secure pit 7- Transport for off-site treatment			2- Open burning in a hole or an enclosure 4- Burial 6- Dumping in an unsupervised area		

[1] Might need adjustment if different types of syringes are distributed.
[2] Number of syringes or needles manufactured for re-sterilization.
[3] Number of disposable syringes and needles in sealed packets or fitted with 2 caps
[4] Number of AD syringes and needles in sealed packets or fitted with 2 caps

2. Structured observations of all injections given during the visit

I would now like to see you perform injections or intravenous infusions: *(this section is based upon observation only)*

Type of injection session (circle): 1. During routine consultation 2. During regular vaccination days 3. During campaigns (NIDs/SNIDs)	**Vaccination**	**Curative**
	"Y" when yes, "N" when no "/" if not applicable	
Preparation on a clean designated table or tray, where blood or body fluid contamination is unlikely[5]		
Type of syringe used (1= AD, 2= disposable, 3= sterilizable)		
Did the patient bring his/her own syringe & needle for the injection		
For each injection, use of **syringe** from sterile packet or fitted with 2 caps (disposable or AD syringes)[6] , or use of **syringe** taken from a sterilizer using a sterile technique (sterilizable syringes)		
For each injection, use of **needle** from sterile packet or fitted with a cap (disposable or AD syringes)[6] , or use of **needle** taken from a sterilizer using a sterile technique[6] (Sterilizable syringes)		
Removal of all needles from the vaccine/medication vial between injections		
(If glass ampoules are used) Use of clean barrier (e.g. small gauze pad) to protect fingers when breaking the top from the glass ampoule		
For each reconstitution, use of a sterile syringe and needle (from sealed packet, fitted with 2 caps, or taken out of a sterilizer)		
(**If vaccine**) Reconstitution of lyophilized vaccines with correct volume of diluent from the same manufacturer		
(**If other medication**) Reconstitution of powdered substances with diluent from a single-dose diluent vial		
(For heat sensitive vaccines and medications only) Vial kept between 2°C and 8°C during period of use		
Two-hands re-capping of the needle after the injection (compared to other items on the checklist, two-hands recapping is an undesirable practice)		
(**Disposable or AD syringes**) Collection in a puncture-proof safety container immediately after the injection		
(**Sterilizable syringes**) Flushing, disassembling and dropping of syringes and needles immediately after use into bowl containing enough water to cover them		

[5] Not an area also used for procedures that may lead to blood contamination (e.g. blood sampling, wound dressing etc.)

[6] If reuse of injection equipment is about to occur without sterilization, intervene to interrupt the procedure as tactfully as possible and a "N" should be marked on the checklist.

3. Interview of injection provider[7]

I would like to ask you a few questions about how you give injections:

How many injections are given per week on average in your facility?	..... Immunizations/week			..... Other injections/week		
	Circle answer (1 only)					
Do patients provide their own injection equipment for immunizations ?	1- Always		2- Sometimes		3- Never	4- Don't know
Do patients provide their own injection equipment for therapeutic injections?	1- Always		2- Sometimes		3- Never	4- Don't know
Are new, disposable syringes and needles available for purchase in this community?	1- Yes		2- No		3- Don't know	
Do you use needle removers or needle cutters before disposing of injection equipment?	1- Yes		2- No		3- Don't know	
How many accidental needle-sticks have you had in the last12 months?	..... Accidental needle-sticks in the last year					
Sterilizers and sterilizable equipment						
When was the steam sterilizer seal /gasket last changed?	< 1 month	< 6 month	< 1 year	> 1 year	5- Don't know	6- N/A[8]
When was the steam sterilizer safety valve last changed?	< 1 month	< 6 month	< 1 year	> 1 year	5- Don't know	6 - N/A[8]
When was the steam sterilizer pressure valve last changed?	< 1 month	< 6 month	< 1 year	> 1 year	5- Don't know	6 - N/A[8]
Are you provided with sufficient kerosene, other energy source, or sufficient funds to purchase it through your health services?	1- Yes		2- No		3- Don't know	
Do you re-sharpen needles after a certain number of injections or when blunt?	1- Yes		2- No		3- Don't know	

[7] If more than one injection provider in the facility, select the one administrating the largest number of injections

[8] For example, if the sterilizer is too new to require spare parts changes

4. Interview of injection supervisor

I would like to ask you a few questions about your policy and your supplies

Do you have a copy of the injection safety policy/recommendations issued by your health services?		1- Yes	2- No	3- Don't know	4 – N/A[9]
Do you have a copy of the safe sharps and health care waste disposal policy issued by your health services?		1- Yes	2- No	3- Don't know	4 – N/A[9]
For sterilizable equipment					
In the last year, how long in total have you been out of kerosene[10]	Never	< 1 month	< 3 month	=3 month	4- Don't know
For disposable or AD equipment					
In the last year, how long in total have you been out of new, disposable or AD syringes and needles?	Never	< 1 month	< 3 month	= 3 month	4- Don't know
In the last year, how long in total have you been out of puncture-proof, sharps containers?	Never	< 1 month	< 3 month	= 3 month	4- Don't know
Are stocks of vaccines always delivered with matching quantities of injection equipment?	1- Yes	2- No	3- Don't know	4- No vaccinations here	
Are stocks of vaccines always delivered with matching quantities of puncture-proof sharp containers?	1- Yes	2- No	3- Don't know	4- No vaccinations here	

Thank you very much for your time. Your participation in this survey will be useful in improving injection practices in your country.

[9] For example, if no policy/recommendations exist
[10] Or other energy source for sterilization