

# Assessment of Disposable Injection Equipment

## Investigation Guide : How to Use this Tool

You are going to perform an evaluation of disposable injection devices (syringes and needles). The purpose of this tool is to evaluate performance and safety of injection equipment under field conditions. This tool is a measure instrument. It can be used for evaluation at different levels, by supervisor on the fields, programme managers or manufacturers. This guide is not a study protocol. It explains how to use the tool. This tool can be used in various type of study and results must be interpreted according to the study design. Please, read this document before beginning a first investigation.

### 1 Objectives of the tool

The objective of the tool is to evaluate the safety and performance of selected injection equipments on the basis of standardized criteria under specific field conditions of use.

This questionnaire is designed to detect a problem and gather specific information about the device being used. This questionnaire must find out if a device is working out or not in a given setting and give information about the “ease of use” of a specific device. Devices are evaluated only for injection purposes (from the withdrawal of fluid from a vial to the end of the injection). Preparation phase as well as wasting phase is not evaluated here.

### 2 Principles of the evaluation

The object of the investigation is not to judge the users but to evaluate a specific type of device he used the day of observation. A device is assessed for a specific setting. Settings were defined as follow: therapeutic injections, routine immunization, mass vaccination campaign. The questionnaire of evaluation is self-administered with the help of a facilitator, as some questions may need clarification. A facilitator must describe precisely the purpose of the evaluation and the meaning of the questions, trying to be as objective as possible.

The day is the period chosen to observe quality of the device and gather quantitative information. That day, the user informed of the investigation will pay more attention to the device under observation and count the number of syringes opened, used, the number of injections given (according to the questionnaire). At the end of the day, the user with the investigator will sum up information on the questionnaire.

**One questionnaire is administered after one day of observation to**

- **One user**
- **For one specific device**
- **In one specific setting**

One questionnaire by user

- Different users can be interviewed on the same day about the same device.
- In that case, interview them separately to avoid the influence of one on the other.
- One questionnaire by user must be fully filled (including page one)

### One questionnaire by device

- If one user utilizes more than one type of device during the day of observation, one questionnaire must be filled for each type of device evaluated
- Do not evaluate more than 2 types of device on the same day in order to avoid confusion.
- The same type of device with different volume (e.g. 5 ml and 2.5 ml) must be considered as different devices and a questionnaire must be filled for each volume.

### One questionnaire by setting

- If the same device is used by one user for different settings (Therapeutic injection, Routine Immunization, Mass vaccination campaign), use one questionnaire by setting

## **3 Description of the tool**

The tool consists in 3 pages. The first page concerns the identification of the user, the type and conditions of use and an accurate description of the device under evaluation. The second page gathers quantitative information on the activity during the day of observation and about safety and resistance of the device. General qualitative information concerning the overall appreciation of the user interviewed is collected as well on the second page. Qualitative information about ease of use is collected through a set of questions on the third page. Answers of users are collected for each question on a scale of 7 degrees, from “impossible to do” to “very easy to do”. Questions are grouped into subset of items according to the theme they are investigating. These themes are named “dimensions” of the tool. For our purpose, dimensions are: Protective packaging, Needle, Friction of the plunger, Transparency and legibility, Air bubble and accuracy of dosage, Safety of the device for the recipient.

In order to ensure the link of the data to the same interview, an identification number must be written at the top of each page. The ID number must be filled according to the design of the study in order to clearly identify users interviewed and devices used.

A place for comments allows the user to explain more precisely what he feels concerning the device under evaluation.

## **4 One day investigation step by step**

1. Start to explain the objectives of the evaluation to the user, at the beginning of the day, or the day before the investigation. The user himself is not evaluated, but he must say what he thinks about the devices he is using.
2. Review quickly with him each domains and questions in order for him to pay attention to all of them during the day of observation.
  - a. Review first the quantitative information requested. The user must be aware that he must collect specific information about his own activity during the whole day of observation (number of syringes open, number of leaks...).
  - b. For qualitative information, explain the user that he must pay attention to specific quality of the devices, especially ease of use according to specific action during the injection.

- c. Explain the user how to answer to qualitative questions. He can choose his answer in a 7 degree scale, between “0 = impossible to do” and “6 = very easy to do”. 0 is the worse, 6 is the best. The user must circle the number closest to his feeling.
3. During the day of observation, it can be useful to spend time with users, so as to precise the different phases of injection. (For example for the questions 41 to 43, the user can touch the base of the needle unconsciously).
  4. At the end of the day, review each question with the user but let him fill the form alone.
    - a. If two or more users must be interviewed, they must fill the form separately in order to avoid influence of one to the other.
    - b. If the same user used 2 different devices during the day of observation, he must fill 2 separate forms.

## **5 Explanation about questions**

### **5.1 First part: Identification of the equipment and of the type of use**

**Questions 1 to 3:** Geographical information. Write directly the name of Country, District and Town or Village.

**Questions 4:** Write the date of the day of observation

**Question 5 and 6:** Write the name of the facilitator and his organization or function

**Questions 7:** There are 3 different settings defined for the evaluation : therapeutic injection, routine immunization and mass vaccination campaign. Only one setting must be under observation during the day of observation. Therefore circle only one item.

**Question 8:** Circle one answer according to the function of the user interviewed

**Question 9:** Type of administration: especially for therapeutic injections, various way of administration can be used for the same type of device. Circle the options that apply the day of observation.

**Question 10:** according to the sites where activities were carried out the day of observation, circle all the options that apply.

**Questions 11.1, 11.2 and 12:** Write directly names written on the packaging, for the manufacturer, the name of the product and the lot (batch) number.

**Questions 13 to 25:** Circle one answer by question according to the device used.

**Questions 26 and 27:** Write the information found on the packaging.

### **5.2 Second part**

**Quantitative information:**

**Question 1:** Number of injections performed during the day of observation for the observed setting (therapeutic injection or routine vaccination or mass vaccination campaign).

**Question 2:** The user has to count each syringe opened during the day of observation, even if syringes were not used whatever the reason is. Syringes taken out from the stock but not opened because of a problem with the blister or the protection must be added up in the same count.

**Question 3:** Number of syringes taken from the store to be used, but rejected because of mechanical or sterility problems (e.g. torn blister, auto-disable syringe already disabled...)

**Question 4 and 5:** Same questions as 3 and 4, for needles only, if needles are packed separately.

**Question 6, 7 and 8:** Number of accidental events during the injection phase.

**Question 9:** Total number of stick injuries occurring to the user during the days of observation (give an explanation and circumstances).

**Question 10 to 12:** Number of stick injuries by level of severity.

**Question 13:** Number of blood or medication exposures occurring during the injection (e.g. blood or drug sprayed in the users eyes but no wound).

#### **Qualitative information:**

**Question 14 to 16:** Qualitative evaluations: the user must rate his feeling concerning the overall ease of use (14), ease of safe use (15) and usefulness (16) of the device (0 = impossible to 6 = very easy). The user must circle the most appropriate answer that is the answer closest to his feeling.

#### **Other information:**

**Question 17:** If the device is new for the user, he must estimate how many times he had to use the device before feeling comfortable with it.

**Question 18:** Free space to explain any problem not listed in the previous questions.

### **5.3 Third part:**

The user must rate his feeling concerning the ease of use of the device for each phase of the injection.

**Question 19 and 20:** Packaging means the protective envelope around the syringe or the needle. This individual envelope does not exist if several syringes are packed altogether. In that case, syringes have individual protection. Protection means the caps or the various types of seals that ensure the sterility of the device.

**Question 22 to 25:** Evaluation of the needle, especially of the connection between needle and syringe: is the connection strong enough to facilitate the removing of the sheath; is the connection not too strong to allow an easy removing of the needle if needed.

**Question 26 to 30:** Evaluation of the friction of the plunger that is the strength needed to push or pull the plunger. This strength has an incidence on the injection practices (withdrawing fluids, expelling air and medication).

**Question 31 to 33:** According to the design and the material of the syringe, reading graduations and seeing fluids through the barrel may vary. These points are important to ensure a good dosage of the medication.

**Question 34 to 37:** Air bubble is often a problem for user. These questions measure the incidence of the air bubble on the accuracy and easiness of medication dosage.

**Question 38 to 42:** Various questions about sterility of the device and safety of practices linked to the design of the device.

## 6 Use of the collected data

This questionnaire will help you in detecting or point out problems in the routine use of syringes. One questionnaire (one day observation for one user, one device, in one particular setting) constitutes one unit of an investigation (one record). Different indicators can be calculated with quantitative and qualitative data and will be listed below. These indicators are designed to be applicable for one type of device as it is the object of the evaluation. But to be relevant and to reflect the situation in a given population, these indicators cannot be calculated over a small number of observations. The number of observations needed to calculate proportion with relevance (with a reasonable confidence interval) will depend on the design of the investigation. For that purpose, it is necessary to have the support of an epidemiologist or a person familiar with such study before beginning an investigation.

### Quantitative indicators:

Proportion of syringe used	Sum question 1 / Sum question 2
Proportion of syringes damaged	Sum question 3 / Sum question 2
Proportion of disconnection	Sum question 6 / Sum question 1
Proportion of breaking during injection	Sum question 8 / Sum question 1
Proportion of leaking	Sum question 7 / Sum question 1
Proportion of total needle stick injuries	Sum question 9/ Sum question 1
Proportion of superficial needle stick injuries	Sum question 10/ Sum question 1
Proportion of moderate needle stick injuries	Sum question 11/ Sum question 1
Proportion of severe needle stick injuries	Sum question 12/ Sum question 1
Proportion of blood exposures (without needle stick injuries)	Sum question 13/ Sum question 1
Proportion of total blood exposures	(Sum question 13 + Sum question 9) / Sum question 1

### Qualitative indicators:

Most of the questions have 7 distinct possible answers (7 modalities, from “very easy” to “impossible”). The simplest way to present results is for each question to give the proportion (percentage) of answer for each modality (with its confidence interval) among the total number of responses. Then, each answer and each modality is considered as purely qualitative. See example below:

Modality of response	0	1	2	3	4	5	6
	% [IC95%]	% [IC95%]	% [IC95%]	% [IC95%]	% [IC95%]	% [IC95%]	% [IC95%]
<b>Removing protecting sheath from the needle</b> n = 100	0%	3% [0.8 - 9.2]	15% [8.9 - 23.9]	37% [27.7 - 47.3]	29% [20.6 - 39.1]	14% [8.1 - 22.7]	2% [0.3 - 7.7]

It is possible as well to consider modality of response as a quantitative measure (and consider the questionnaire as a scale of subjective measures). Then it is possible to calculate scores for each question and each dimension and to calculate mean scores and a variance for each question or dimension. Comparisons between situations or devices are then easier. Such a scale needs to be validated before extrapolating and interpreting results. Validation still needs to be carried out before using the qualitative part of the questionnaire as quantitative measure.



# Assessment of Disposable Injection Equipment

Please answer each question by circling the best answer or writing numbers if required.

ID Number: / / / / / / / / / / / / / / / /

		Quantitative Information							If you feel not satisfied by an issue or an item, please fell free to write an explanation below :
Activity	1	Number of <b>injections performed</b> today							
	Syringes use	2	Number of <b>syringes opened</b> today						
3		Number of <b>syringes found damaged or unusable</b> when opened today (Give an explanation)							
Needles use	4	Number of <b>needles opened</b> today							
	5	Number of <b>needles found damaged or unusable</b> when opened today (Give an explanation)							
Needle and needle connection	6	Number of <b>accidental disconnections</b> between the syringe and the needle today							
	7	Number of <b>leaks</b> between syringe and needle today							
	8	Number of <b>needle breakage</b> or inadequate bending <b>during injection</b>							
Safety	9	Number of <b>needle stick injuries</b> sustained during use of the device today							
	10	Number of <b>superficial injuries</b> (little or no bleeding)							
	11	Number of <b>moderate injuries</b> (skin punctured or some bleeding)							
	12	Number of <b>severe injuries</b> (deep stick/cut or profuse bleeding)							
	13	Number of <b>blood or medication exposure</b> resulting from using the device (except needle stick injury)							

		Qualitatives general information	Impossible	→						Very easy		
User overall acceptability	14	To use the device is	0	1	2	3	4	5	6	Not Applicable		
	15	To use the device safely is	0	1	2	3	4	5	6	Not Applicable		
				Very useless	→						Very usefull	
	16	Is the device useful ?	0	1	2	3	4	5	6	Not Applicable		
	17	If new or recent, how many times did you use the syringe before you felt confortable with it ?									Not Applicable	
	18	Did you have any problem with the device ?	Yes	No	if yes, please write an explanation						Not Applicable	

COMMENTS :

