# Final Report

## Evaluation of Three Reuse-Prevention Feature Reconstitution Syringes in Three Districts of Indonesia

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unicef

PATH

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## Background

Although autodisable (AD) syringes are supplied by UNICEF for all immunization injections, standard disposable syringes continue to be used for reconstitution of lyophilized vaccines. This creates a risk that reconstitution syringes could be reused to reconstitute multiple vials, or reused for multiple injections into patients. Both practices could contaminate the vaccine and spread bloodborne disease.

To prevent the possibility of reconstitution syringe reuse, UNICEF intends to supply all immunization programs with syringes with reuse prevention features (RPF syringes) for vaccine reconstitution beginning in 2008. To prepare for global introduction, UNICEF contracted PATH to conduct a field evaluation of three World Health Organization (WHO) prequalified RPF syringes used during a measles campaign in Lombok, Indonesia, in August 2007. The objective of the field evaluation was to identify the training and introduction requirements of these syringes and establish an understanding of their acceptability, performance, and safety during field use.

In 2006, WHO and the International Organization for Standardization (ISO) completed specifications for curative RPF syringes (ISO 7886-4). These RPF syringes are similar to AD syringes but allow more flexibility for a wider variety of uses and variable dose sizes. They are appropriate for reconstitution because they are not intended to automatically disable and may require user compliance to do so. Three have been prequalified by WHO and were evaluated in this study: the Kojak Selinge from Hindustan Syringes & Medical Devices, Ltd. (HMD); the SoloMed™ from Becton, Dickinson, and Company (BD); and the VanishPoint® from Retractable Technologies, Inc.

## Study Methodology

The Ministry of Health (MOH) of Indonesia and PATH collaborated in designing and implementing the study, with support from UNICEF. PATH developed the study protocol with review by UNICEF and the MOH (Appendix A). The protocol was submitted to PATH's Research Determination Committee which concluded it did not constitute research on human subjects, and thus it did not have to undergo Human Subjects Protection Committee review.

### Design

The study took place in Lombok, Indonesia, during the August 2007 measles campaign for children ages 6–59 months. Each RPF reconstitution syringe was introduced into one of three districts: East, West, and Central Lombok. Although technically a separate district, Mataram, the provincial capital city, was included as part of West Lombok district for this evaluation. Convenience samples of 30 health workers in each of three districts were surveyed. Evaluation sites were selected to provide a broad representation of different facility settings, economic status, and levels of infrastructure.

Districts and a description of the syringe introduced in each location are listed below:

- East Lombok: **SoloMed** has a removable needle, is nonretractable, and requires an extra push after the dose is expelled.
- West Lombok: **Kojak Selinge** has a removable needle, is nonretractable, and disables when the complete dose is given.
- Central Lombok: **VanishPoint** has a fixed needle, is retractable, and requires an extra push after the dose is expelled.

The study was conducted among 94 vaccinators, 18 supervisors, 4 trainers, 4 logisticians, and 3 program managers. Table 1 displays the breakdown of participants by district.

**Table 1—Study Participants by District**

| | West Lombok District | Central Lombok District | East Lombok District | Province | Total |
|---|---|---|---|---|---|
| **Vaccinators** | 32 | 32 | 30 | 0 | 94 |
| **Posyandu (health facilities)** | 15 | 17 | 15 | 0 | 47 |
| **Trainers (performed training)** | 1 | 2 | 2 | 1 | 6 |
| **Trainers (interviewed)** | 1 | 1 | 1 | 1 | 4 |
| **Logisticians** | 1 | 1 | 1 | 1 | 4 |
| **Supervisors** | 6 | 5 | 6 | 1 | 18 |
| **Program Managers** | 1 | 1 | 1 | 0 | 3 |

Each vaccinator worked in their assigned district and used only the type of RPF syringe assigned to that district during the campaign. After having used the RPF reconstitution syringes for 3–4 days, approximately 30 vaccinators from each district/syringe group completed a standard verbal questionnaire and were observed giving at least two injections. During data collection, each RPF syringe was compared only to the standard reconstitution syringes used previously. There was no side-by-side field comparison of one RPF syringe to another.

## Timeline

The evaluation schedule was as follows:

- Early July: Syringes shipped directly from UNICEF to each district.
- July 23: Orientation of the district health teams to the evaluation and training of the provincial and district staff on the use of RPF reconstitution syringes.

- July 26–28: Training of vaccinators in the three major districts of Lombok on RPF reconstitution syringe use and the study design.
- August 1: Start of measles campaign.
- August 6–16: Field evaluation of the RPF reconstitution syringe. Observation and interviews were scheduled to begin after vaccinators had used the syringes for 3–4 days.

## Training

The orientation and training session for six district trainers (two from each district) was conducted during a one-day meeting. Participants included EPI Unit representatives, Provincial Health Office representatives, three district health staff trainers, three PATH-Indonesia representatives, and a UNICEF-Jakarta representative. The primary aim of the orientation was to familiarize the trainers with the purpose of the evaluation and to train them on use of the RPF reconstitution syringes. Following a demonstration of syringe use and a question and answer session, each trainer practiced using each type of RPF reconstitution syringe. Each district health trainer went on to train the vaccinators in their district on use of the designated syringe.

Training of vaccinators was done by MOH trainers in July as part of the routine campaign preparation training for all health workers in Lombok. PATH and UNICEF served as observers in the training. Approximately 2,000 vaccinators were trained to use one of the RPF reconstitution syringes in training sessions that were conducted simultaneously in all three districts over a three-day period. Training sessions lasted approximately two hours and consisted of explanation, demonstration, individual practice, and questions/answers.

The study was intended to evaluate introduction issues of the RPF reconstitution syringes in a typical environment of training and use for a new device. Accordingly, the primary training materials were the leaflets provided by each syringe manufacturer which were translated from English into Bahasa Indonesia. The training leaflets are attached as Appendix B. To ensure the training was equivalent across all syringe types, manufacturers were not invited to attend the training session.

Vaccinators from six to ten health centers were trained in each two-hour session with approximately 72–120 total participants per day. Each participant used two to three RPF syringes for practice. The trainer's demonstration was done using real diluent and vaccine vials with the practice sessions using drinking water in cups. Practice sessions in two of the districts were conducted as two concurrent groups of 10–12 people with 2–3 trainers. In West Lombok, the demonstration and practice sessions were conducted as a single group, due to space limitations.

## Data Collection

Qualitative data on syringe acceptability and performance were collected from a total of 94 vaccinators as well as a subset of trainers, supervisors, program managers, and logisticians. The

campaign was conducted primarily at the *posyandu* (health post) and the former National Immunization Day posts, for a total of 47 facilities where data were collected. The daily coverage target during the campaign was 20–100 children per post.

Data were collected through observations of training; observations of campaign use of the syringes; and structured interviews with supervisors, program managers, trainers, and logisticians. These methods were used to gather input on syringe performance, acceptability, introduction requirements, and logistical fit with existing operations. Evaluation team members were from the MOH, PATH, and UNICEF. Each team member signed a confidentiality agreement and a conflict of interest statement prior to their participation in the study.

## Study Findings

### Training

- All participants felt that hands-on training and practice were necessary to understand and use the syringes properly. Although they felt the manufacturers' materials were adequate, the most effective aspect of training was demonstration of use followed by actual practice with at least two syringes.
- To save vaccine, many training sessions used a cup of water to simulate drawing up the diluent. Vaccinators felt this was inadequate and recommended using an actual ampoule of diluent and vaccine vial to best understand the proper use of the syringe. Thirty percent of vaccinators felt the training was inadequate, primarily due to the need for more practice, smaller group sizes, and absence of real ampoules for practice.
- Trainers felt the most important training messages for all the RPF syringes were: (1) do not push the plunger forward before filling; and (2) push the plunger all the way in after the injection to make sure the syringe disables.

### Acceptability

- Ease of use: 88% of vaccinators felt the RPF syringes were easy to use, while 75% of vaccinators felt the RPF syringes were similar or easier to use than standard syringes. Those who felt the RPF syringes were more difficult to use cited higher friction during filling and expelling as the main difficulty.
- User compliance with disabling feature: 97% of vaccinators said the RPF syringes always disabled properly. All users were observed disabling the syringes properly and immediately after use.

## Safety

- Prevention of reuse: 90% of users felt the RPF syringes were safer than a standard syringe because they could not be reused, thus reducing possibilities of vaccine contamination. A total of 69% percent of vaccinators admitted reusing standard reconstitution syringes in the past. A total of 7% percent of users felt the syringes with a detachable needle were less safe than a standard syringe, because the needle could be removed and reused.
- Needle stick prevention: Of the retractable syringe users, 100% felt the syringe was safer than a standard syringe since it prevented needlestick as well as vial contamination.
- Medical waste: Users of the retractable syringe felt that medical waste was safer for handing and disposal since the needle was no longer exposed. They also noted that more syringes would fit in the safety box with the needle retracted.

## Performance

- Reliability of disabling feature: During observations, the disable feature worked 100% of the time. Many vaccinators had to "push hard" to activate the disable mechanism, but all did it successfully and consistently.
- Wastage of syringes due to premature locking: 2% of vaccinators experienced a syringe that locked prematurely. One observer noted one case where the plunger was pushed forward prior to filling and the device deactivated before use. Once users were familiar with the syringes, premature locking rarely occurred.
- Speed of reconstitution: Most vaccinators reported the RPF syringes were faster and more efficient to use than standard disposable syringes.
- Vaccine wastage due to residual vaccine in vial or syringe: Users felt the amount of vaccine remaining in the syringe and diluent vial were similar compared to standard syringes. There were no reports of vaccine wastage related to the RPF syringes.

## Logistical fit with existing operations

- Logistics and supply issues: Managers did not think RPF syringes would pose any new logistics or supply issues. They emphasized the need for adequate training, supply management, and planning but did not feel the new syringes presented any new challenges. They saw the training requirement as an opportunity to reinforce all safe injection messages.
- Best fit for RPF syringes: Users and managers felt the RPF reconstitution syringes should be introduced and used in all immunization settings and facilities. They felt that 5-ml

syringes with 10-dose vials would be more appropriate for routine immunization while 10-ml syringes with 20-dose vials were best for campaigns.

## Conclusions and Recommendations

RPF reconstitution syringes are well received by managers and health workers; improve injection safety; fit easily into country logistical systems; and, although they are easy to learn to use, will require sufficient training support. The study found all three types of WHO prequalified RPF reconstitution syringes to be highly acceptable for use in immunization campaign settings. Results suggest these syringes will increase injection safety by preventing reuse of reconstitution syringes. The RPF reconstitution syringes improved health worker satisfaction because of the added measure of safety compared to a standard syringe, since RPF syringes could not be reused, thus reducing possibilities of vaccine contamination or injection use.

As the availability of safety syringes increases and the mechanisms and features become more diverse, it will be important to develop clear descriptions that help distinguish among the devices. These descriptions will help governments and programs make informed decisions when procuring safety syringes that allow the procedures and their level of risk determine the appropriate choice of syringe. In addition, adequate training will be the key factor to ensuring successful introduction. This study indicates that hands-on training demonstrations and user practice with two or three actual syringes and vaccine vials is essential to ensure successful introduction of RPF syringes in immunization settings.

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# Appendix A—Protocol for evaluating the introduction of reuse-prevention feature (RPF) reconstitution syringes in three districts of Indonesia

## Background

Due to the high risk of spreading bloodborne diseases through reuse of needles and syringes, WHO and UNICEF recommend that autodisable (AD) syringes be used for all immunizations. Since their introduction in the mid-1990s, AD syringes have been widely accepted and are now used for approximately half the immunizations given globally.

One gap in this strategy, however, is in the reconstitution of lyophilized vaccines. Measles, BCG, and several other vaccines are commonly distributed in lyophilized form. To make the vaccine suitable for injection, a reconstitution syringe is used to withdraw diluent from a vial or ampoule and then inject it into the lyophilized vaccine vial. The reconstitution syringe is then discarded into a safety box. If the syringe is used and disposed of properly, this procedure is not problematic; however improper practices are frequent and can cause significant risks of unsafe injection. For example:

- Although not a recommended practice, the reconstitution syringe is sometimes used to mix the vaccine; after injecting the diluent into the vaccine vial, the health worker repeatedly draws up and ejects the mixture several times to ensure it is well mixed. If not discarded immediately, remnants of the vaccine in the syringe can support microbial growth and become contaminated. If the syringe is subsequently reused to mix a new vial of vaccine, contamination can be introduced into the new vaccine and injected into another patient, potentially causing adverse events.
- The used reconstitution syringe could be used subsequently for injection into patients as well as reconstitution, possibly transmitting bloodborne pathogens from a patient to a multi-dose vial, then to additional patients.

Use of a nonreusable syringe for reconstitution in conjunction with AD syringes for injections would eliminate all possibility of syringe reuse during immunization sessions. Requiring this procedure would provide a more comprehensive and consistent injection safety policy and close a safety gap in current immunization programs.

Syringes with reuse-prevention features (RPFs) have recently been developed. These syringes are similar to AD syringes but allow more flexibility and variable dose size. RPF syringes are appropriate for vaccine reconstitution. In 2006, WHO and the International Organization for Standardization (ISO) completed specifications for curative syringes with reuse-prevention features (ISO 7886-4). Three RPF syringes have been prequalified by WHO and introduced for curative injections. Over the last three years, PATH has introduced over 100 million RPF syringes in Africa and the Caribbean as part of a US-funded injection safety project supported under the President's Emergency Plan for AIDS Relief (PEPFAR). Monitoring of the introduction of the syringes has shown excellent acceptability, ease of use, performance, and safety.

The three RPF reconstitution syringes that will be evaluated in Indonesia have all received WHO prequalification. They are the Kojak Selinge from Hindustan Syringes & Medical Devices, Ltd. (HMD), the SoloMed™ from Becton Dickinson and Company (BD), and the VanishPoint® from Retractable Technologies, Inc. Based on the use of 20-ml dose ampoules of measles vaccine in Indonesia, 10-ml reconstitution syringes will be used in this study.

## Study overview

The Ministry of Health (MOH) of Indonesia and PATH will collaborate on this study, with support from UNICEF. PATH will design the study, with input from the MOH and UNICEF. PATH will conduct, monitor, and manage the pilot introduction of the three RPF reconstitution syringes in a measles campaign in Lombok, in collaboration with the Ministry of Health of Indonesia. All RPF reconstitution syringes needed for training and for the campaign will be supplied by UNICEF who is providing financial support for the study.

Indonesia was selected as a suitable evaluation site because of the MOH's willingness to participate, the upcoming measles campaign in Lombok (scheduled to occur in late August), and the country's lack of prior exposure to RPF syringes. In addition, PATH has had extensive experience collaborating with the MOH on immunization programs in Indonesia. The PATH office in Jakarta is able to facilitate study planning and approvals in Indonesia.

The study will take place in Lombok, West Nusa Tenggara Province, Indonesia during the August 2007 measles campaign for children ages 6–59 months. The campaign will begin on August 10 and will last for two to three weeks. Training will take place in July as part of the routine training for all health workers in Lombok. Although RPF reconstitution syringes will be introduced throughout Lombok during this August measles campaign and all vaccinators will be trained to use the new reconstitution syringes, the evaluation will only be conducted among a group of 30 vaccinators per district and a subset of trainers, supervisors, program managers, and logisticians. The campaign will take place primarily at the posyandu (health post) and the former National Immunization Day (NID) posts. The daily coverage target during the campaign is 100–200 infants and children per post.

## Study objectives

The aim of the study is to conduct and monitor a pilot introduction of three WHO prequalified RPF reconstitution syringes (RPF syringes) in a measles campaign in Indonesia. This study is expected to provide data to UNICEF on acceptability, performance, and training requirements for each of the syringes, as well as document any introduction issues that would be useful to anticipate prior to large-scale, global introduction in 2008 in all UNICEF-supported immunization programs. Acceptability, performance, introduction requirements, and logistical fit within existing operations will be evaluated as indicated below:

**Acceptability**

- Ease of use.
- User compliance with disabling feature.
- Safety (during use and disposal).
- Effect on immunization program.

**Performance**

- Reliability of disable feature.
- Wastage of syringes due to premature locking.
- Speed of reconstitution.
- Vaccine wastage due to residual vaccine in vial or syringe.

**Introduction requirements**

- Training requirements.
- Suitability of training materials.

**Logistical fit with existing operations**

- Logistics and supply issues.

## Methods

### Evaluation design

This is an operational study that will be conducted during the introduction of three RPF syringes during a routine measles campaign in Lombok, Indonesia. The three different RPF reconstitution syringes will be introduced in three different districts: West, Central, and East Lombok. Although technically a separate district, Mataram, the provincial capital city, will be treated as part of West Lombok district. The study will be conducted among vaccinators, supervisors, trainers, logisticians, and program managers. Each RPF syringe will be compared only to the conventional reconstitution syringes used previously. There will be no side-by-side field comparison of one syringe to another.

Qualitative data on syringe acceptability and performance will be collected from a total of 90 vaccinators, 30 vaccinators per study district. Survey sites will be selected to provide a range of urban/rural, poor/less poor, busy/less busy immunization posts. Although all vaccinators in Lombok will be trained to use the new RPF reconstitution syringes during the measles campaign, only 30 vaccinators per district will participate in the study. Structured interviews with supervisors, program managers, trainers, and logisticians will gather input on RPF syringe performance, acceptability, introduction requirements, and logistical fit with existing operations.

### Data collection

There will be three evaluation teams, one for each district. Each team will each be made up of three members including MOH/EPI staff from the province and/or district and a PATH staff member. Prior to commencement of the evaluation each evaluation team member will sign a confidentiality agreement and a statement assuring that no conflict of interest exists..

The study will be conducted in approximately 15–20 campaign sites per syringe type (district). Campaign sites will be made up of health posts and the former National Immunization Day (NID) posts in each district. The study sites will be identified by the Provincial MOH/EPI team to ensure representation from a mix of settings including those with high and low injection volumes, urban and rural infrastructures, and fixed post and outreach situations.

After a minimum of four days' use of the RFP syringes, the evaluation teams will visit campaign health posts to collect data. An evaluation team member will observe a vaccinator using at least two reconstitution syringes and complete the observation check list. The evaluator will then

interview the vaccinator using the vaccinator questionnaire. Typically, this will be done for two vaccinators per immunization post. All questionnaires and interviews will be conducted in the local language.

Interviews with supervisors, program managers, logisticians, and trainers from each district could take place at the immunization posts, or at the health centers and health offices within the week following completion of the campaign.

Prior to the campaign, during the district training of vaccinators, two members of each evaluation team will observe the training session in their district and complete a training observation form.

Data collection forms include:

1. Observations of field use of syringes.
2. Questionnaire/interviews for vaccinators.
3. Interviews of supervisors, program managers, logisticians, and trainers.
4. Observations of training.

**Data to be collected by interview and observation**

| District | Health Worker Observation | Health Worker Interview | Program Manager Interview | Supervisor Interview | Training Observation | Trainer Interview | Logistics Manager Interview |
|---|---|---|---|---|---|---|---|
| **West Lombok/ Mataram** | 30 | 30 | 1 | 3–5 | 1 | 1 | 1 |
| **Central Lombok** | 30 | 30 | 1 | 3–5 | 1 | 1 | 1 |
| **East Lombok** | 30 | 30 | 1 | 3–5 | 1 | 1 | 1 |
| **TOTAL** | **90** | **90** | **3** | **9–15** | **3** | **3** | **3** |

### Data management, analysis, and reporting

Data collection instruments have been developed by PATH, with input from the MOH and UNICEF. PATH will manage the data collected and conduct the analysis. The analysis will characterize key acceptability, performance, introduction, and logistics issues for each type of RPF reconstitution syringe. Recommendations will be made to UNICEF regarding improvements to syringe introduction materials and strategy for introduction. Any negative findings affecting safety or performance of a device will be highlighted.

## Ethical considerations

### Confidentiality

Confidentiality of all information collected in this evaluation will be maintained in several ways. No personal identifiers will be included on data collection forms or study records. In addition, results on each syringe type will be reported in the aggregate and not by named facility or campaign location. Participants may be photographed or videotaped during training and use of

the syringes; they will be informed of this before the training and will be given the opportunity to decline..

**Informed consent**

Because this is an evaluation of WHO prequalified medical devices and is not research being conducted on people, it is not expected that informed consent will be required. When participants are introduced to the evaluation, they will be told that their participation is voluntary and that they are free to not answer any or all questions, without concern of repercussion.

**Ethical approval**

Before beginning any study activities, the evaluation protocol will be reviewed and approved by PATH's Research Determination Committee. If deemed to be human subjects research, the protocol will be reviewed and approved by PATH's Human Subjects Protection Committee and the local ethical review board in Indonesia prior to commencement of the study.

**Risks**

The syringes are being introduced by UNICEF as a means of minimizing risk to patients from potential contamination of vaccine from the reuse of reconstitution syringes. No risks to study participants are anticipated from introduction of this reuse-prevention feature reconstitution syringe. Three already licensed, commercially-available, WHO-approved RPF reconstitution syringes are being used in a standard approach.

**Benefits**

The data from this evaluation will provide UNICEF with evidence on the acceptability and performance of RPF reconstitution syringes. It will help UNICEF prepare for the wide-scale introduction of these syringes in all UNICEF-supported immunization programs. The RPF reconstitution syringe is expected to prevent the reuse of the syringe for mixing multiple vials of lyophilized vaccines thus preventing a common practice that can cause vial contamination. Vial contamination can lead to the growth of toxic substances in the vial which can cause harm to injection recipients.

## Attachment A—Study Timeline and Responsibilities

| Task | Responsible Party | Completion Date |
|---|---|---|
| **Agreements and Approvals** | | |
| Develop proposal, including protocol outline and budget. | PATH | End March |
| Approve proposal; contract with PATH. | UNICEF | May |
| Obtain approval to conduct study from Indonesian national MOH/EPI. | UNICEF | May |
| Brief province and district authorities and obtain approval. | PATH, national EPI | Ongoing March–April |
| Establish contract with Indonesian EPI for coordination, evaluation, travel. | PATH | May |
| Develop study protocol and data forms; get UNICEF and Indonesian input and approval. | PATH | May–June |
| Submit protocol to PATH HSPC and Indonesian IRB. | PATH | May–June |
| **Preparations** | | |
| Confirm syringe types and place orders with manufacturers. Arrange shipment of study quantities of the three syringe types to Indonesia. Ensure adequate supplies of standard reconstitution syringes are available, in reserve. | UNICEF | May |
| Obtain syringe samples and training materials from manufacturers. | PATH | May |
| Brief local EPI managers and trainers about introduction/study. | PATH, national EPI | May–June |
| Select study sites, prepare evaluation schedules, define evaluation teams. | PATH, national EPI, provincial EPI | May–June |
| Provide training materials to EPI. | PATH | June |
| Translate data collection forms. | PATH | June |
| Translate training materials. | PATH | June |
| Ship syringes to evaluation districts. | National EPI | July |
| Train province/district trainers. | PATH, national EPI | July |

| Task | Responsible Party | Completion Date |
|---|---|---|
| **Evaluation** | | |
| Observe training for campaign and use of new RPF reconstitution syringes. | PATH, national EPI, provincial EPI | July |
| During campaign, visit sites, complete questionnaires and observations. | PATH, national EPI, provincial EPI | End August |
| Conduct interviews. | PATH, national EPI, provincial EPI | End August |
| Summarize & analyze data. | PATH | September |
| Develop final report. | PATH | October |

## Attachment B—Data Collection Tools

### Vaccinators Interview Questionnaire

Thank you for taking the time to answer the questions on this questionnaire. The Ministry of Health, UNICEF, and PATH are interested in learning more about your experience using reuse prevention feature (RPF) reconstitution syringes in an immunization campaign setting. The information we learn from use of these RPF reconstitution syringes in Lombok will assist UNICEF as they introduce these syringes worldwide in 2008. It will take you no longer than 15 minutes to respond to the questions I will ask you. This questionnaire is anonymous— we will not write down your name on this questionnaire. The information that you provide will not be linked to you.

It is your choice to respond to this questionnaire. You may decide not to answer some of the questions. If you decide not to answer any of the questions, or to respond to only some of the questions, it will not affect your job in any way. We appreciate your participation in this study.

**Completed by:** _____

**Date**:_____

- West Lombok or Mataram District
- Central Lombok District
- East Lombok District

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- Have you ever given injections before this campaign? If yes, how many years of experience do you have giving injections?
  - No
  - Yes; number of years of experience _____

- During this campaign, approximately how many times did you use the RPF reconstitution syringes?

  _____ Number of times vaccine reconstituted during this campaign

- How would you compare the ease of use of the RPF syringe to standard reconstitution syringes?
  - More difficult
  - Same
  - Easier

  Why? Describe advantages and disadvantages of RPF syringe. (Probe for premature locking, time differences, vaccine wastage…)_____

  _____

- Were you aware when the RPF syringe was disabled after reconstitution? How did you know it was disabled?
  - Yes; Explain_____

  - Sometimes; Explain_____
  - No, Explain _____

- How often did the RPF syringe lock prematurely, requiring you to use a new RPF syringe?
  - Frequently
  - Sometimes
  - Never

- Did the RPF syringe improve safety, compared to the standard reconstitution syringe you have been using?
  - Yes
  - No difference
  - No

  Who is safer as a result of using RPF reconstitution syringes?

  _____

- In the past, did you ever reuse standard reconstitution syringes on more than one vial?
  - No
  - Yes

- Was the training on how to use the RPF syringe sufficient or insufficient?
  - Sufficient
  - Insufficient

  Do you have suggestions on how RPF syringe training can be improved?_____

  _____

- In which settings would the RPF reconstitution syringe be most useful? (Check all that apply)
  - Campaigns
  - Puskesmas—routine use
  - Posyandu—routine use
  - Pustu —routine use
  - Hospital
  - No opinion

- Would you prefer to use an RPF reconstitution syringe or a standard reconstitution syringe?
  - Standard reconstitution syringe (does not lock)
  - RPF reconstitution syringe (locks after use)
  - No opinion

  Why?_____

  _____

Thank you!

## Training Checklist

**Completed by**:_____

**Date**:_____

- West Lombok or Mataram District
- Central Lombok District
- East Lombok District

| | |
|---|---|
| **Number of trainers** | |
| **Number of trainees** | |
| **Describe the training methods used. (Check all that apply)** | ▪ Participatory<br>▪ Demonstration of syringes<br>▪ Role plays<br>▪ Didactic, lecture style<br>▪ Small group discussion and observation<br>▪ Hands-on practice with real RPF reconstitution syringes<br>▪ Question and answer<br>▪ Other |
| **Which training methods seemed most effective? (Check all that apply)** | ▪ Participatory<br>▪ Demonstration of syringes<br>▪ Role plays<br>▪ Didactic, lecture style<br>▪ Small group discussion and observation<br>▪ Hands-on practice with real RPF reconstitution syringes<br>▪ Question and answer<br>▪ Other |
| **Describe the training materials. (Check all that apply.)** | ▪ Written handouts<br>▪ Pictorial and written handouts<br>▪ Blackboard<br>▪ PowerPoint presentation<br>▪ Video<br>▪ Flipcharts<br>▪ Hands-on demonstration with syringes<br>▪ Other: |

| | |
|---|---|
| **Which of the training materials seemed the most effective?** | ▪ Written handouts<br>▪ Pictorial and written handouts<br>▪ Blackboard<br>▪ PowerPoint presentation<br>▪ Video<br>▪ Flipcharts<br>▪ Hands-on demonstration with syringes<br>▪ Other |
| **How many times did each participant practice reconstituting with a real syringe?** | |
| **Were actual vials of diluent/sterile water used for reconstitution during the training?** | ▪ Yes<br>▪ No |
| **Were there any steps in use of the syringe that were difficult for some trainees to learn? Please describe.** | |
| **How long did the training last?** | |
| **Should more time have been given to any part of the training? Please describe.** | |

**Recommendations for future training:**

## Observation Checklist – Health Workers

To be completed by evaluation team members. Each evaluation team member will observe 15 different health workers per district as each uses at least 2 RFP syringes.. The 15 health workers should be working in mix of campaign settings – health center, health post, or other. Complete one form per health worker observed.

**Completed by**:_____

**Date**:_____

- West Lombok or Mataram District
- Central Lombok District
- East Lombok District

**Type of campaign setting**: (check all that apply)

- Puskesmas (health center)
- Pustu (health sub-center)
- Posyandu (integrated service post)
- Relaxed slow setting
- Rural setting
- Urban setting
- Crowded busy setting
- Other (describe)

| | |
|---|---|
| **Did the health worker (HW) use an RPF reconstitution syringe?** | ▪ Yes<br>▪ No |
| **How many RPF reconstitution syringes did you observe this HW use?** | |
| **Was the RPF reconstitution syringe used according to instructions?** | ▪ Yes<br>▪ No |
| **Was there residual vaccine left in either the vial or syringe following reconstitution?** | ▪ Vial<br>▪ Syringe<br>▪ Both |
| **Did the HW have any difficulties using the reconstitution syringe?** | ▪ Yes<br>▪ No |
| **Please describe.** (Probe for premature locking, plunger breaks off, faulty packaging, needle doesn't retract) | |
| **Was the reuse-prevention feature activated immediately at the end of reconstitution?** | ▪ Yes<br>▪ No |
| **Did the HW reuse the RPF syringe?** | ▪ Yes<br>▪ No |

## Interview guide—Program managers and supervisors

**Completed by**: _____

**Date**:_____

- West Lombok or Mataram District
- Central Lombok District
- East Lombok District

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1. Is there evidence that reconstitution syringes are reused in your district/province?

2. Is reuse of reconstitution syringes a concern to you? Why or why not?

3. How has the introduction of RPF reconstitution syringes affected this immunization campaign? Please describe.

4. How would you describe the performance of the RPF reconstitution syringes?

5. How easy was it for health workers to learn to use the RPF reconstitution syringes?

6. In your opinion, how much training would be required to introduce RPF reconstitution syringes in Lombok? What problems would you expect if no training occurred?

7. In future years, when would training in use of these syringes occur?

8. Where do you think RFP syringes should be used? (Routine? Campaign? Hospital? PKM? Posyandu? All?)

9. What other comments or suggestions do you have regarding the introduction of RPF syringes in your work place?

Thank you

## Interview Guide –Trainers and Logisticians

**Completed by**: _____

**Date**:_____

- West Lombok or Mataram District
- Central Lombok District
- East Lombok District

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**Trainers**

1. How easy was it for the HW to learn to use the RPF reconstitution syringes?

2. What training methods were most effective in training the HW to use this RPF reconstitution syringe?

3. How many syringes did the HW practice using before they could correctly use the syringe?

4. Did health workers experience any problems learning to use the RPF reconstitution syringe? Please describe steps that were difficult.

5. Were there any training messages or images that were unclear or confusing? Please describe.

6. In your opinion, how much training is needed to introduce RPF reconstitution syringes in Lombok? What problems would you expect if no training occurred?

7. How suitable were the training materials? Do you have any suggestions for changes or improvements?

**Logisticians**

8. How easy or difficult has it been to introduce the RPF reconstitution syringe into your district/province?

9. Did any issues or challenges arise that required your logistics systems to change? Please describe.

10. Have you noticed any benefits or advantages to logistics systems from the use of RPF reconstitution syringes? Please describe.

11. Have RPF reconstitution syringes had any affect on logistics for medical waste management?

12. Do you have any concerns or suggestions for the future introduction of RPF reconstitution syringes?

# Appendix B—Training Leaflets

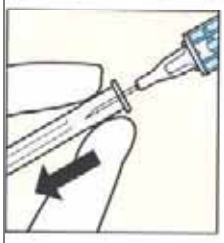
## BD SoloMed

**Side 1**

*Instructions:*

- *Check that the syringe package is undamaged and unopened. Discard if damaged or opened.*
- *The plunger on this syringe is designed to break, to help prevent reuse of the syringe.*

❶ Attach needle to syringe or, if pre-attached, ensure needle is securely attached.



❷ Remove the needle shield by pulling straight off.

*A simple push of the plunger rod permanently disables the syringe.*


*Syringe cannot be reused*

**Side 2**

❸ Perform procedure following institutional guidelines.

❹ After the procedure, ensure the syringe is empty and continue to push on the plunger **with force** until the plunger breaks (click is heard).

❺ After single use, discard needle/ syringe barrel and plunger into appropriate container.

***Cautions:***

- Breakage of the device may cause splatter. Ensure that syringe is **empty before** breaking the plunger. For greatest safety, when breaking the plunger, hold the syringe **downward** at arm's length away from self and others. Keep syringe within sight at all times to avoid accidental needlestick injury.
- If the plunger breaks prematurely while injecting, continue to depress the plunger until the dose is delivered completely. When injecting very viscous medications at high speed, use 21 gauge or larger needles.

## HMD Kojack Selinge

## RTI VanishPoint