PROTOCOL FOR A FIELD EVALUATION
OF THE SOLOSHOT AUTO-DESTRUCT,
SINGLE-USE DISPOSABLE SYRINGE

SEPTEMBER 1989

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DISPOSABLE SYRINGE

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<thead>
<tr>
<th>ACRONYM</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>AID</td>
<td>Agency for International Development</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
</tr>
<tr>
<td>ANE</td>
<td>Asia and Near East</td>
</tr>
<tr>
<td>ASV</td>
<td>Assistant Supervisor of Vaccination</td>
</tr>
<tr>
<td>CC</td>
<td>Cubic Centimeter</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control</td>
</tr>
<tr>
<td>CDCO</td>
<td>Communicable Disease Control Officer</td>
</tr>
<tr>
<td>DHO</td>
<td>District Health Officer</td>
</tr>
<tr>
<td>DPT</td>
<td>Diphtheria-Pertussis-Tetanus Vaccine</td>
</tr>
<tr>
<td>DSV</td>
<td>District Supervisor of Vaccination</td>
</tr>
<tr>
<td>DT</td>
<td>Diphtheria-Tetanus Vaccine</td>
</tr>
<tr>
<td>EMRO</td>
<td>Eastern Mediterranean Regional Office</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded Program on Immunization</td>
</tr>
<tr>
<td>EPITECH</td>
<td>Evaluation Panel for Injection Technologies</td>
</tr>
<tr>
<td>FDA</td>
<td>(US) Food and Drug Administration</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<tr>
<td>GOP</td>
<td>Government of Pakistan</td>
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<tr>
<td>GVA</td>
<td>Geneva</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>I.M.</td>
<td>Intra-muscular</td>
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<tr>
<td>IU</td>
<td>International Units</td>
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<tr>
<td>MOH</td>
<td>Ministry of Health</td>
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<td>MPH</td>
<td>Master of Public Health</td>
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<tr>
<td>MSD</td>
<td>Merck, Sharp and Dohme Company</td>
</tr>
<tr>
<td>PATH</td>
<td>Program for Appropriate Technology in Health</td>
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<tr>
<td>REACH</td>
<td>Resources for Child Health Project</td>
</tr>
<tr>
<td>SOW</td>
<td>Scope of Work</td>
</tr>
<tr>
<td>SPSS PC+</td>
<td>Statistical Package for the Social Sciences Data Analysis Package, Personal Computer version</td>
</tr>
<tr>
<td>S&amp;H</td>
<td>(AID) Office of Science and Technology/Health</td>
</tr>
<tr>
<td>TDY</td>
<td>Temporary Duty Assignment</td>
</tr>
<tr>
<td>TM</td>
<td>Trade Mark</td>
</tr>
<tr>
<td>TT</td>
<td>Tetanus Toxoid Vaccine</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children's Fund</td>
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<tr>
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<td>United States Agency for International Development</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<td>WHO/Pakistan</td>
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I. Executive Summary

The REACH Project, which is funded by the U.S. Agency for International Development (AID), has been requested by AID to conduct a field evaluation of the performance, user acceptability and programmatic impact of a new single-use, disposable syringe (SOLOSHOT™) developed by the Program for Appropriate Technology in Health (PATH). PATH, whose HealthTech Project is also funded by AID, has entered into a licensing agreement with Becton, Dickinson and Company to manufacture the syringe. The development of a non-reusable disposable syringe has been encouraged by AID, World Health Organization (WHO), UNICEF and other agencies concerned about the health risks (most notably AIDS and hepatitis B) posed by the improper re-use of currently available injection devices.

The SOLOSHOT device consists of a disposable syringe equipped with the "syringeLOCK™" auto-destruct system and a permanently fixed needle. The auto-destruct feature consists of a small metal flute inserted into the syringe barrel which prevents the plunger from being drawn back after delivering a single injection. Except for the flute preventing re-use, the syringe is expected to function and perform like any other disposable syringe with a permanently fixed needle.

With the concurrence of the Pakistan National Institute of Health (NIH), REACH will direct a SOLOSHOT field evaluation in Pakistan in which approximately 4,000 prototype syringes will be used. The two person REACH team will include a senior technical officer and a technical associate. The REACH team, counterpart Pakistan NIH/MOH Field Evaluation Medical Supervisors, MOH Coordinators and two national WHO Operations Officers will in turn direct a contingent of 64 Pakistan Government staff (16 observers and 48 vaccinators) who will use the prototype device to immunize approximately 2,400 women and children during routine immunization sessions. The REACH and WHO staff will not directly perform any of these immunizations but will observe and evaluate, along with national MOH staff, the prototype syringe's performance as specified in this protocol. REACH will also be responsible for describing the circumstances under which any of the prototype syringes failed to perform as intended by the manufacturer. In such cases, REACH will collect the syringe(s) involved and arrange for their return to the manufacturer for a thorough analysis of the cause of failure.

The field evaluation is tentatively scheduled to take place in late 1989 and will be of two weeks duration. A preparatory visit by one member of the REACH team is proposed four to six weeks before the beginning of the field evaluation. Annexes 11 and 12, respectively, outline scopes of work for the full field evaluation and the preparatory visit.

REACH will be responsible for data analysis and the drafting of the final report in consultation with WHO and the NIH.

*SOLOSHOT is a trademark of Becton, Dickinson and Company.*
II. Objectives

The objectives of the field evaluation are as follows:

1. assess implications of introducing auto-destruct single use disposable syringes into an immunization program in terms of:
   - mechanical performance under field conditions
   - acceptability to users

2. assess functioning of the auto-destruct syringes, document any circumstances under which the syringes fail to perform as expected, and return these syringes to the manufacturer for analysis

3. identify design advantages/disadvantages and recommend improvements in the injection device itself

4. identify operational issues relating to its introduction as direct replacement for conventional syringes in terms of:
   - logistics
   - training
   - costing

5. inform the design of future field evaluations of other single-use injection devices in the areas of:
   - overall field evaluation design
   - protocol format
   - data collection forms
   - data analysis
   - training design

III. Background

To administer the full course of vaccines used in the Expanded Program on Immunization (EPI), the primary products currently in use are reusable glass or plastic syringes which must be sterilized prior to each injection. This can be done by steam sterilization. Depending on the altitude, open boiling can also achieve a high level of disinfection. Re-use of up to 200 times is theoretically possible for some re-usable plastic syringes, although under field conditions the actual number of reuses is significantly less.

In addition, sterile packaged disposable syringes and needles are in use in some immunization programs. These devices are intended to be used a single time and disposed after use. Nevertheless, field experience shows that these syringes are sometimes reused, often without being properly handled or sterilized, in spite of the well-known risks this practice implies.
The improper re-use of needles and syringes is a risk factor in the transmission of Acquired Immune Deficiency Syndrome (AIDS) and hepatitis B. The emergence of these diseases as major public health concerns in the early 1980's has led to heightened interest in the development of single-use injection devices for immunization programs in developing countries. As many EPIs currently use both reusable and disposable injection devices and, under field conditions, the improper use of these devices is commonly observed, alternatives to existing injection devices are clearly needed. In its role as a coordinating agency for immunization efforts worldwide, WHO has taken a leading role in the development and review of fail-safe, non-reusable injection technologies for use in the EPI.

In 1976, the Merck, Sharp and Dohme Company (MSD) developed a prototype, pre-filled, single-use injection device (EZEJECT) for the administration of measles vaccine. While this device was successfully demonstrated in clinical trials and was judged acceptable from a clinical standpoint, the perception of an insufficient commercial market for the device led to the decision to abandon further development efforts.

In 1985, an evaluation team led by Drs. Neal Halsey and Susan Berry of the Johns Hopkins University conducted a field test of the MSD EZEJECT device in Guatemala (REFERENCE: Field Evaluation of Ezeject: A Simplified Unit Dose Syringe for Administration of Measles Vaccine, Reviews of Infectious Diseases, [in press]). During this trial, 446 doses of lyophilized measles vaccine were administered with the EZEJECT device. A major focus of this trial, in addition to assessing the clinical efficacy of the EZEJECT in terms of seroconversion levels in the children immunized, was to assess EZEJECT's suitability for field use in a developing nation's immunization program. In such settings, the experience level of the vaccinators and their level of training can vary considerably. EZEJECT's acceptability in the hands of both experienced and inexperienced vaccinators was evaluated in terms of correctness of injection technique, proper aspiration and time needed to administer a dose of vaccine. Conventional 3cc plastic disposable syringes were used as a comparison/control during the trial. The EZEJECT device performed acceptably both in terms of producing proper seroconversion levels as well as ease of use by both experienced and inexperienced vaccinators. The EZEJECT device was preferred to conventional syringes by a majority of inexperienced vaccinators. However, experienced vaccinators preferred traditional needles and syringes. Although the EZEJECT device did not meet the current criteria for a single-use injection device, Dr. Halsey concluded that with some design modifications, the device would be suitable for the administration of measles vaccine.

In 1986, the Program for Appropriate Technology in Health (PATH) began further development of the original MSD EZEJECT device. Additionally, PATH began evaluating other forms of single-use injection technologies in conjunction with WHO. The two major lines of development have been non-reusable, auto-destruct syringes which are pre-filled and those which are not. A series of meetings between WHO, PATH, AID, UNICEF and REACH representatives in the first half of 1987 led to the creation of an Evaluation Panel for Injection Technologies (EPITECH). The mandate of the EPITECH was to review approximately 40 prototype proposals/devices for technical merit and to assess their potential for procurement and use in EPIs throughout the world (REFERENCE: Evaluation of Injection
Another meeting of the EPITECH was held in November, 1987 (REFERENCE: WHO/EPI/CCIS/87.2). As an outcome of that meeting and subsequent discussions, the PATH-developed SOLOSHOT device was judged to be one of the most promising auto-destruct devices. Subsequent activities for the advancement of SOLOSHOT, leading to its licensing with Becton-Dickinson, were supported by AID under the HealthTech Cooperative Agreement with PATH, signed September 1, 1987.

Before the planned field evaluation of the SOLOSHOT begins, several stages of external review and independent lab testing will be conducted including:

a) external review of the field evaluation protocol by individuals at AID, Government of Pakistan, MOH, WHO/Geneva, PAHO, CDC, UNICEF and The Johns Hopkins University School of Hygiene and Public Health;

b) evaluation of the mechanical performance and design of the device by an independent laboratory;

c) assessment of the mechanical design and function of the device by WHO and members of EPITECH;

d) testing the mechanical function of the device by clinicians of The Johns Hopkins University at the request of REACH; and

e) ethical review of the field evaluation protocol by EPITECH and by the Government of Pakistan. Any informed consent procedures specified by these or any other organization with a regulatory interest will be fully adhered to during the course of the field evaluation.

Before the field evaluation begins, AID will obtain certification from the syringe manufacturer that the device conforms to applicable Good Manufacturing Practice (GMP) codes, that sterilization meets applicable national requirements and that the U.S. FDA has approved the device for clinical use.

IV. Field Evaluation Design

Pakistan has been selected as the site for the initial field evaluation of the device for the following reasons:
Disposable syringes have been used there for many years. This prior familiarity with disposables will serve as a baseline for comparison between the currently-used disposable syringes and the SOLOSHOT device in terms of the acceptability, field efficacy, and programmatic impact of a switch to single-use, disposable syringes.

The Government of Pakistan has expressed interest in participating in the evaluation and has granted tentative approval for the evaluation to take place.

The USAID mission to Pakistan has similarly expressed an interest in undertaking a field evaluation and has offered its assistance as needed.

National WHO Operations Officers in Pakistan, one of whom has been involved as a member of the WHO Evaluation Panel for New Injection Technologies (EPITECH), are available to assist in field supervision. This joint collaboration at field level between WHO and USAID will facilitate acceptance of field evaluation findings.

The field evaluation will be conducted in conjunction with the urban acceleration effort about to begin in Sind Province. The acceleration effort is scheduled to last until the end of 1990. At least two districts within the urban area of Karachi will be chosen. The proximity of the districts will allow close coordination and supervision and simplified logistics. The GOP/UNICEF plan in Karachi is to identify particularly underserved areas of the city, and in each electoral ward establish a fixed immunization post staffed by three vaccinators. Each post will field an outreach team consisting of a male and female vaccinator who will establish temporary vaccination posts in the ward. A large attendance can be expected, speeding up the field work and creating the sort of crowded conditions under which disposables are often preferred to re-usable syringes.

A major advantage of conducting the trial in Karachi will be the fact that a diversity of expertise exists in terms of vaccinators' experience with many vaccinators having been newly trained for the acceleration. A guiding principle of the field evaluation is to minimize any disruption to the ongoing EPI. In fact, it is hoped that the field evaluation will encourage acceleration of immunization delivery in the study sites by promotion of immunization demand in the community during the trial.

V. Organization of Field Work

A description and diagram of the evaluation's staffing pattern appears in Annex 1. A timeline for the completion of all scheduled activities appears as Annex 2. Overall supervision of the field evaluation will be jointly provided by MOH/NIH Field Evaluation Medical Supervisors, MOH.
Coordinators, two REACH staff members (principal investigators) and two national WHO Operations Officers (investigators). In each district, an investigation team will be deployed, consisting of a REACH staff member and a national WHO Operations Officer. The Field Evaluation Medical Supervisors and/or Coordinators will be available throughout the field evaluation to assist the investigation teams. Each district investigation team may also be periodically joined by the District Health Officer, who is the MOH supervisory physician in the district. They will work with sixteen Observers, eight in each district. The Observers will be selected from among local, English-speaking MOH/EPI medical officers.

A total of 48 Vaccinators, 24 in each district, will be observed giving a total of 2,400 intramuscular DPT, TT, and DT, and subcutaneous measles injections with the new device, and 1,440 with conventional (control) disposable syringes and needles. The 1,440 conventional/control syringes will be the same syringes normally supplied through the Pakistan MOH/EPI. The conventional/control syringes will be similar to the SOLOSHOT device in terms of volume, needle length and needle gauge. These conventional/control syringes, however, will not have the flute assembly which prevents re-use or a permanently fixed needle. Each Vaccinator will be observed giving 50 injections with the new device and 30 with conventional disposables. The above totals are estimates and may vary slightly depending upon field conditions. Lyophilized measles vaccine will be reconstituted with a conventional mixing syringe as the present SOLOSHOT device is not designed to deliver the 5 or 10 cc volume of diluent needed for reconstitution. Also, the SOLOSHOT is not currently produced in a configuration suitable for administration of BCG. Accordingly, BCG will also be reconstituted and administered with conventional syringes and not with the SOLOSHOT devices.

Existing community promoters will visit the target community door-to-door one day in advance of each session and on the immunization day itself. This will encourage a larger attendance, speed up the evaluation and create the sort of crowded conditions under which disposables are often preferred to re-usable syringes, such as during national immunization days. Distribution of Vitamin A capsules for children, ferrous sulfate tablets for women, the use of loudspeakers, noisemakers and balloons, etc., as observed in vaccination campaigns, will also take place if deemed culturally appropriate. If the full complement of test syringes is expended before the session is concluded, syringes normally supplied through the MOH will be used to complete the session so that no eligible person is denied vaccination.

Use of the SOLOSHOT and control syringes for TT immunization of married women and DT immunization of school children will further assure that the expected number of immunizations can be performed within the timeframe of the field evaluation. It is anticipated that two to three days of observation of each Vaccinator will be needed to reach the required number of vaccinations. This means that, with a total of 48 Vaccinators and sixteen Observers, each Observer will have to be engaged full-time in the field evaluation for as much as a two week period, which includes training and closing sessions.
At any one time within each district, four Investigators and sixteen Observers will be observing sixteen Vaccinators in different vaccination sessions. On any given day, Observers and Vaccinators will be paired one to one, while Investigators will work with four Observers. The Vaccinators already have some means of transport to the session sites. The four Investigators and sixteen Observers will need at least four to six vehicles, full time, depending on vehicle capacity. Needed vehicles will be obtained through USAID, WHO, UNICEF, the Pakistan MOH or rented/chartered from private operators as appropriate.


VI. Training Design

A consideration informing the design and organization of the field test is that new technologies are often sent into field conditions with little or no instruction in their proper use. The expertise of potential users also varies widely. In an attempt to simulate this diversity, the SOLOSHOT field evaluation protocol stipulates 6 different evaluation cells, outlined as follows:

<table>
<thead>
<tr>
<th>Vaccinators</th>
<th>Experienced</th>
<th>Less experienced</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving full training in use of SOLOSHOT device</td>
<td>8</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>Receiving only an explanatory flyer plus 5-8 minute briefing on purpose of field evaluation</td>
<td>8</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>Receiving no SOLOSHOT training/flyer other than 5-8 minute briefing on purpose of field evaluation</td>
<td>8</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>24</td>
<td>48</td>
</tr>
</tbody>
</table>

Assuming each Vaccinator gives the expected 50 injections with the SOLOSHOT device, 400 injections will be evaluated in each of the six cells outlined. This will allow for both adequate descriptive field observation and will provide sufficient data for later statistical analysis of the evaluation results.

Experienced and less-experienced MOH vaccinators will be chosen at random from prepared lists of MOH employees, stratified by level of experience. Specific characteristics differentiating experienced from less-experienced vaccinators will be determined in-country on the basis of
whether the person does or does not customarily give injections as part of their day to day job responsibilities. Compilation of these lists will take place during the preparatory visit, 4-6 weeks prior to the actual field evaluation. Only one person will be selected from any single operating unit or outreach team.

The twenty-four experienced and twenty-four less-experienced vaccinators will then be randomly assigned to one of three training cells, with eight in each group. Annex 5 lists the content, duration, and teaching methods in the "Full," "Flyer Only," and "None" training cells. Selection of vaccinators for Groups 2 and 3 ("Flyer Only" and "None," respectively) will be made one or two days prior to their actual participation in the field evaluation.

Annex 6 presents the current PATH training protocol which will be used in the "Full" training regime. Annex 7 shows the illustrated flyer, developed by PATH, which will be used in the "Full" and "Flyer Only" training regime. This flyer will be in English on the assumption that the flyer will eventually be printed in the major international languages (English, French, Spanish), but that accurate translation into every possible language/dialect will be impossible when the device is mass produced and distributed on a world-wide basis. Training/explanatory materials may require further modification.

Training materials and lesson plans used in the evaluation, including the descriptive flyer, will be prepared by PATH, the developer of the SOLOSHOT device. These materials will be prepared well in advance of the beginning of the evaluation and will be reviewed by the Principal Investigators for technical appropriateness with the assistance of a medical officer designated by the MOH at the time of the preparatory visit.

Training of Vaccinators assigned to training cell #1 ("Full") will be conducted by the MOH Field Evaluation Medical Supervisor, the National WHO Operations Officers and the MOH Coordinators at the start of the field evaluation in the respective districts using the standardized curricula and training design developed by PATH. All Observers will attend the "Full" training session as well. Trainers and Observers will become proficient in using the SOLOSHOT device prior to the training sessions.

Vaccinators in training cells #2 ("Flyer only") and #3 ("None") will be segregated and given a standardized 5-8 minute briefing on the purpose of the field evaluation on the day before the evaluation begins.

Community promoters will receive a standardized briefing by Observers prior to the beginning of the vaccination session. This briefing will include the importance of immunization, eligible age groups, time and place of session, need for multiple doses, etc.

While all of the less-experienced Vaccinators will have received training and had experience in giving injections through their duties with the MOH, it is acknowledged that some may not be the most senior staff potentially available. However, as the purpose of the field evaluation is to assess the performance of the device under conditions as close as possible to those encountered in day-to-day operations, it is felt that testing of the device under these conditions is not only desirable but
essential. Distribution of the syringe without ever having assessed its performance under real-life conditions would potentially constitute a greater risk.

VII. Field Procedures

All sixteen Observers will be trained a few days before the evaluation by the MOH Coordinators and the national WHO Operations Officers together in Karachi. They will be available full-time for the entire duration of the Field Evaluation. They will first practice using the device themselves and will then learn how to observe unobtrusively, and record information on a standardized Observer Data Collection Instrument (Annex 8), covering the following points:

a) syringe type and identification number;
b) vaccine type and vial number (individually designated in advance);
c) time for administration: a stopwatch will be started as soon as the Vaccinator picks up the syringe or needle and stopped when the needle is removed from the skin after completing the injection;
d) ease or difficulty of vaccine withdrawal;
e) ease or difficulty of air expulsion;
f) ease or difficulty of aspiration;
g) acceptable or non-acceptable sterile technique;
h) whether excessive vaccine remains in syringe;
i) whether the syringe malfunctioned or leaked;
j) whether the plunger can be withdrawn a second time (to be checked at the conclusion of each evaluation session); and
k) detailed remarks concerning any syringe malfunction or anomaly observed in the above categories.

Standardization of Observers will be achieved by having all Observers, prior to the beginning of the evaluation, simultaneously observe and score approximately 50 consecutive injections with conventional and SOLOSHOT devices.

Teams will consist of an Observer, Vaccinator, and community promoters. The session will be set up as normal with all antigens in use. Unexpired 20 dose vials of DPT and 10 dose vials of measles for children 2 - 23 months old, 20 dose vials of DT for school children, and 20 dose vials of TT for married women will be used. All antigens will be supplied through the MOH EPI. Because injection of toxoids which have frozen can
cause abscesses, recently supplied unopened vials will be used. A visual 
inspection and shake test will be performed prior to use on all vials using 
as a reference a purposely frozen vial from the same manufacturer. DPT 
injections will be administered I.M., preferably in the anteriolateral 
thigh, or else in the upper outer buttocks depending on clinic practice. 
Measles vaccine will be administered subcutaneously in the deltoid. DT and 
TT will be administered I.M. in the deltoid.

Each vaccinator will first use 30 conventional syringes followed by 50 
SOLOSHOT devices. All injections performed with a SOLOSHOT or control 
syringe will be observed by a field evaluation Observer. As all injections 
will be numbered, subsequent analysis will be able to detect a "learning 
curve" (if one exists) regarding the continued use of the syringes. 
Interrelations between experience and/or training levels and successful use 
of the syringes will also be determined.

Detection of gross trends towards under or over-filling either the 
SOLOSHOT or the control syringes will be accomplished through comparing the 
average number of doses per vial administered with the SOLOSHOT device 
against the number delivered with the conventional syringes. To determine 
this, individual TT, DPT, and DT vials will be randomly selected at the 
start, numbered and then reserved by Vaccinator for exclusive use with 
either SOLOSHOT or conventional syringes. Each vial will be used until all 
possible 0.5cc doses have been withdrawn, or until the end of the day. At 
the day's end, the completely or partially used vials will be withdrawn 
from further use in keeping with MOH recommended policies. Vaccine 
remaining in the opened vials will be withdrawn at the end of the field 
evaluation by a member of the investigation team using a conventional 5 cc 
syringe. The mean volume of vaccine utilized per vaccination administered 
will be computed.

Any individual session using the SOLOSHOT device will be terminated 
on safety grounds by the Observer if any of the following conditions are 
noted:

- 5 consecutive syringes leak;
- 5 consecutive syringes cannot be filled with the 
correct vaccine dose;
- 5 consecutive syringes show any other form of 
failure which materially affects the performance 
of the syringe.

In the case of suspension, that District's investigation team (REACH 
Principal Investigator/WHO national Operations Officer) will be located and 
consulted immediately. A daily schedule and route for the supervisory team 
will be circulated to ensure this can be done on a timely basis. If the 
team's immediate investigation indicates the suspension was justified, or 
if the cumulative failure rate of the SOLOSHOT devices at the end of any 
day exceeds 2% of the total SOLOSHOT injections, all further sessions in 
all locations will be suspended until the reason for the failure is 
determined and clearance to proceed is given by the Field Evaluation 
Medical Supervisor in concurrence with WHO, MOH and the manufacturer.
Malfunctioning auto-destruct syringes will be identified and the nature and circumstances of the problem described. Each auto-destruct syringe will be returned to the principal investigators. Used SOLOSHOT devices which functioned normally will be collected each day by the Observers and destroyed by the Principal Investigators at the end of the field evaluation. Any malfunctioning SOLOSHOT devices will be returned to the manufacturer in an appropriately sized glass or metal specimen tube. Unused SOLOSHOT devices will be returned to the manufacturer in their original packaging.

If for any reason the Observer is unable to observe each injection performed with a SOLOSHOT or control syringe, or the session is suspended due to suspected failure of the test syringes, the Vaccinator may continue to perform immunizations during the remainder of the session with non-test syringes supplied through regular MOH/EPI stocks. This is consistent with the policy of not denying vaccination to any eligible person who is present during a session.

An individual session will also be suspended on safety grounds if, in the judgement of the Observer, the Vaccinator is failing to comply with customary MOH medical practice in any of the following areas:

- selecting the proper injection site;
- drawing and expelling a correct vaccine dose;
- aspiration for blood;
- excessive air in syringe;
- proper needle control; and
- sterile technique.

As the purpose of the evaluation is to evaluate the performance of the test syringes rather than the Vaccinator, the Observer is not to intervene or assist the Vaccinator in any manner other than calling attention to an improper medical practice and/or suspending the Vaccinator’s participation in the evaluation if the Vaccinator grossly or consistently fails to adhere to proper medical practice. The Observer is not to assist or guide the Vaccinator in the use of test syringes in any manner other than that specified in the training design. Any interventions made should be noted in the "remarks" section of the "Observer Data Collection Instrument" and identified by syringe number. Any unintentional needle-stick will also be noted in the remarks column of the Observer Data Collection Instrument, with the circumstances of the incident fully described.

Field evaluation Investigators will meet daily to review progress and solve implementation problems.

Proper disposal of used syringes is in many ways as crucial an issue as their proper use. As the SOLOSHOT device was developed to function in an identical fashion to current disposable syringes, with the exception of the feature which prevents re-use, its disposal characteristics and
requirements should not differ markedly from disposable syringes currently in use. An analysis of actual disposal practices of conventional devices based upon observations at the end of each vaccination session will be made using a form adapted from one developed by WHO/EPI (Annex 9) (REFERENCE: DRAFT PROTOCOL FOR THE FIELD TRIALS OF AUTODESTRUCT SYRINGES, WHO/EPI/GENEVA, UNPUBLISHED, JANUARY 1988). Recommended MOB/EPI disposal policies and procedures will be incorporated into the data collection instrument.

VIII. Data Collection, Entry and Analysis

Syringe Performance and Acceptability:

The central or "null" hypothesis of the field evaluation is that there are no differences between the SOLOSHOT devices and conventional syringes, under field conditions, in the effective delivery of the required dose of vaccine. It is further hypothesized that there will be no differences in performance between the SOLOSHOT devices and conventional syringes in the hands of experienced versus less-experienced vaccinators. Further, it is hypothesized that the type and amount of training received in the use of the SOLOSHOT will have no effect on its successful use by either experienced or less-experienced vaccinators. To accept or reject these hypotheses, frequency distributions, cross-tabulations and chi-square analyses of selected variables will be performed during the field evaluation. Chi-square analysis of categorical variables (level of training, experience, ease or difficulty of use, etc.) will be used to determine whether statistically significant differences exist at the .05 level between SOLOSHOT and the control syringes. Secondary analysis will control for each variable by type of training and/or level of experience. These initial tests will serve to identify variables and issues which need more thorough statistical analysis after completion of the field work.

Study Investigators will review collected data for completeness and accuracy each evening to identify any errors in the completion of the forms. A local firm will be contracted for data entry on computers. The actual data entry program and procedures will have been tested with dummy forms and hypothetical data beforehand. Data will be entered onto microcomputer diskettes using DBASE III Plus and analyzed using SPSS PC+. Range and logic checks will be performed on the entered data to identify and correct any inconsistent or implausible responses.

User acceptability will be determined at the conclusion of each individual field session by means of an individual questionnaire (Annex 10) and by structured group interviews with participating Vaccinators and Observers as part of a wrap-up session at the end of the full field evaluation. These group interviews will be stratified by training cell and will rely on the same questionnaire (Annex 10). SOLOSHOT users will be asked to comment on:

- preference for syringe type:
- relative ease of use of the new device in terms of:
  - vaccine filling
  - air expulsion
  - aspiration for blood
  - giving correct dose (volume control);
- time required for correct use;
- potential areas for misuse/abuse/tampering;
- disposal methods;
- operational concerns about replacing conventional with auto-destruct disposable syringes; and
- adequacy of training received at the start of the field evaluation.

During the wrap-up session, discussions will also be held concerning practical implementation issues in the introduction of SOLOSHOT, use of disposable syringes on outreach, and correct injection/sterilization techniques. Based upon their experience in the field evaluation, Vaccinators will also be asked to suggest and/or demonstrate ways in which the SOLOSHOT device could be reused or misused.

The degree of acceptability by a small sample of senior physicians and nurses will also be assessed. They will use the SOLOSHOT and control syringes with the "Flyer only" training regime for approximately 200 injections. The questionnaire on user acceptability (Annex 10) will be used but modified slightly to determine performance in injecting a range of viscous solutions (e.g. aqueous penicillin, etc.). Results will be discussed with these senior physicians and policy makers and comments/suggestions for improvements in the test syringes will be solicited and transmitted to the manufacturer.

A selected group of experienced laboratory technicians will be invited to examine the SOLOSHOT device and will be challenged to tamper with it to enable re-use or extraneous use. The descriptive results of this sub-study will also be reported to the manufacturer. Any syringes defeated in this sub-study will also be returned to the manufacturer.

Operational Issues:

A descriptive assessment of the projected logistical burden imposed by the new device, relative to existing disposable syringes, will also be undertaken. This assessment will focus on:

- extent of re-use of existing disposable syringes;
- estimate of increased quantities required of the new device;
- storage requirements at the national, regional and local levels;
additional transport requirements at all levels;
- time/financial costs of proper disposal;
- additional program costs associated with single-use devices;
- lead/lag times in ordering supplies and commodities at all levels of the distribution system;
- frequency and implications of stock-out and over-stock at various levels of the distribution system; and
- potential for diversion of EPI supplied syringes to other uses.

The general model and format used in the REACH study "New Injection Technologies: An Economic Analysis of Cost Effects for EPI," prepared in October 1987 for the WHO, will serve as the basis for the logistics and cost analyses of SOLOSHOT's programmatic impact.

Training Implications:

Based upon the observed injections, a determination will be made regarding the adequacy and length of training required by vaccinators and storekeepers for the introduction of the new device. Topics for learning and "unlearning" will be identified.
ANNEX 1
STAFFING PATTERN

A. Multi-District Team
   - NIH/MOH Field Evaluation Medical Supervisors (2)
   - MOH Chief Coordinator, Coordinator and Assistant Coordinator (3)

B. Karachi District "A" Investigation Team
   - WHO national Operations Officer (1)
   - REACH Senior Technical Officer* (1)
   - District Medical Officer (1) (part-time)

C. Karachi District "B" Investigation Team
   - WHO national Operations Officer (1)
   - REACH Technical Associate* (1)
   - District Medical Officer (1) (part-time)

D. Observers (8 in each district for a total of 16)
   NOTE: Each Observer will observe 3 Vaccinators (48 Vaccinators/16 Observers) for approximately 2.5 days on average. This will equal 12 days of observer time, which includes 8 days of evaluation and 4 days for training and closing sessions.

E. Vaccinators (24 in each district for a total of 48)
   NOTE: Each Vaccinator will be observed giving approximately 50 injections with the SOLOSHOT devices and approximately 30 with conventional syringes. It is estimated that each Vaccinator will need to be observed for a period of 2.5 days to ensure 80 injections are observed.

F. Community Promoters (as available)

G. Support Staff
   - Drivers (4-6)
   - Data Entry Personnel (2)

* Principal Investigators
ANNEX 1

FIGURE 1

ORGANIZATION OF WORK IN EACH DISTRICT

Investigator 1
( WHO )

-Observer 1
------
Vaccinator 1
Vaccinator 2
Vaccinator 3

-Observer 2
------
Vaccinator 1
Vaccinator 2
Vaccinator 3

-Observer 3
------
Vaccinator 1
Vaccinator 2
Vaccinator 3

-Observer 4
------
Vaccinator 1
Vaccinator 2
Vaccinator 3

Investigator 2
( REACH )

-Observer 5
------
Vaccinator 1
Vaccinator 2
Vaccinator 3

-Observer 6
------
Vaccinator 1
Vaccinator 2
Vaccinator 3

-Observer 7
------
Vaccinator 1
Vaccinator 2
Vaccinator 3

-Observer 8
------
Vaccinator 1
Vaccinator 2
Vaccinator 3
<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBLE</th>
<th>MAY</th>
<th>JUNE</th>
<th>JULY</th>
<th>AUG</th>
<th>SEPT</th>
<th>OCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Prepare SOW/Budget</td>
<td>REACH</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Share draft protocol with AID and send to WHO, CDC, UNICEF, Hopkins for external review</td>
<td>REACH</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>3 Send reviewed protocol to USAID/Pak.</td>
<td>REACH</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>4 Revise training materials/checklists and print</td>
<td>REACH, WHO/PAK</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>5 Receive GOP and WHO/GVA and WHO/PAK comments on training materials, protocol and checklists and put into final protocol</td>
<td>REACH, GOP, PATH</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>6 Give REACH final OK on protocol and syringes (GMP, FDA clearance)</td>
<td>AID</td>
<td></td>
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</tr>
<tr>
<td>7 Send final protocol, checklist, training materials to WHO/GVA, WHO/PAK, GOP, UNICEF, USAID, PATH</td>
<td>REACH</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>8 Human subjects ethical review panel approval and clearance</td>
<td>WHO/GOP</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 UNICEF/NY to telex UNICEF Pakistan</td>
<td>UNICEF NY</td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>10 Receive USAID concurrence for field evaluation timing based on SOLOSHOT production date</td>
<td>AID/USAID</td>
<td>X</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>11 Prepare job descriptions for supervisors, observers, vaccinators, promoters</td>
<td>REACH</td>
<td>X</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>12 WHO GVA to telex EMRO and Pakistan WHO</td>
<td>WHO GVA</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 Obtain lab results and EPITECH comments on SOLOSHOT and share with AID &amp; REACH</td>
<td>WHO GVA</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14 Preparatory visit to Pakistan</td>
<td>REACH</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15 Select study districts</td>
<td>GOP &amp; REACH</td>
<td>X</td>
<td>X</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>ACTIVITY</td>
<td>RESPONSIBLE</td>
<td>JULY</td>
<td>AUG</td>
<td>SEPT</td>
<td>OCT</td>
<td>NOV</td>
<td>DEC</td>
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<td>-------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>16 Stratify vaccinators by degree of experience</td>
<td>GOP, REACH</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17 Arrange for GOP customs clearance and re-export permit for unused and failed SOLOSHOTS</td>
<td>USAID, GOP</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 Select observers</td>
<td>GOP</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 Select vaccinators</td>
<td>GOP</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 Field-test training materials, forms and checklists</td>
<td>GOP, WHO/PAK</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 Collect all supplies</td>
<td>REACH</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22 Field Team travels to Pakistan</td>
<td>REACH</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23 Train observers and measure inter-observer variation</td>
<td>REACH, WHO/PAK</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 Conduct full training (Cell 1)</td>
<td>REACH, WHO/PAK</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25 Begin field evaluation</td>
<td>REACH, GOP, WHO/PAK</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26 WHO GVA visit to trial site</td>
<td>WHO GVA</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27 Conduct evaluation visits in non-study areas</td>
<td>REACH, WHO/PAK</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28 User acceptability questionnaires and interviews</td>
<td>REACH, GOP, WHO/PAK</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29 Supervise destruction used syringes/needles</td>
<td>REACH, WHO/PAK</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 Brief GOP, USAID, WHO/PAK</td>
<td>REACH</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31 Brief WHO/GVA</td>
<td>REACH</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32 Return unused/failed/damaged syringes to manufacturer for analysis</td>
<td>REACH</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33 Brief AID, UNICEF, PATH</td>
<td>REACH</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>34 Send draft report to AID, USAID, GOP, UNICEF, WHO/GVA, PATH</td>
<td>REACH</td>
<td></td>
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</tr>
<tr>
<td>35 Finalize report</td>
<td>REACH</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>36 Distribute final report</td>
<td>REACH</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
FIELD EVALUATION MEDICAL SUPERVISOR
JOB DESCRIPTION

- Obtain written concurrence to conduct study from Pakistan MOH with study area and dates specified
- Obtain written statement regarding no objection for using SOLOSHOT on human subjects
- Provide medical input to the design and implementation of the field study
- Ensure participation and cooperation of study participants
- Authorize use of MOH vehicles required for the study
- Consult with principal investigators when a medical judgement is required during the course of the trial
- Participate, as required, in training sessions for observers and fully trained vaccinator group and in the wrap-up discussions of user acceptability and the potential reuse or misuse of the SOLOSHOT device
- Review draft study report before finalization.
ANNEX 3B

INVESTIGATOR
JOB DESCRIPTION

- Identify study location, randomly assign selected participants to training groups and develop a schedule for observers and investigators during the field trial

- Review training materials for technical content and compatibility with Pakistan national EPI policies

- Become proficient in use of SOLOSHOT device

- Train sixteen observers to use the SOLOSHOT device, observe vaccination sessions, complete all data collection instruments and label the syringes and vaccine vials used during the trial

- Standardize the methods observers use to record vaccinator activities during the field trial

- Train or brief 48 vaccinators, as appropriate.

- Randomly assign vials of vaccine to vaccinators prior to start of field trial

- Work with Assistant Coordinator to implement daily schedules for observers and vehicles

- Consult with observers and Field Evaluation Medical Supervisor regarding the suspension of a vaccination session due to failure of the SOLOSHOT device or unsafe health worker practices

- Review data collected for completeness and accuracy, discuss progress and solve implementation problems each day prior to leaving the study site

- Forward completed data forms to data entry personnel

- Develop data entry program, train personnel to enter study data, supervise data entry process and review entered data to identify any inconsistent or implausible responses.

- Measure the volume remaining in each vial of vaccine used during the field trial

- Dispose of all properly functioning SOLOSHOT devices

- Return all malfunctioning SOLOSHOT devices to the manufacturer

- Facilitate wrap-up session and discussion of user acceptability, practical issues surrounding the introduction of SOLOSHOT, possible ways to reuse or misuse SOLOSHOT, and design modifications
- Determine the number of doses of each vaccine which can be withdrawn by vaccinators using conventional and SOLOSHOT devices under controlled conditions at the conclusion of the study.

- Complete descriptive assessment of the projected logistical impact of introducing the SOLOSHOT relative to the disposable devices currently in use.

- Obtain signed receipts for all per diem paid to field trial participants.

- Analyze and interpret study results, prepare final report.

- Brief MOH, USAID and WHO personnel on study results.
ANNEX 3C

OBSERVER
JOB DESCRIPTION

- Attend training to become familiar with the study protocol and SOLOSHOT and to learn standardized methods of observation and data recording on collection instruments

- Become proficient in use of SOLOSHOT syringe

- Attend training sessions for vaccinators

- Learn criteria for terminating vaccination session due to unsafe health worker practices or malfunctioning SOLOSHOT syringes

- Brief community promoters, when appropriate, prior to start of immunization session on the importance of immunization, target age groups, time and location of session

- Pay per diem to promoters at the end of the promoter’s involvement in the study

- Label all vials of vaccine at the beginning of each vaccination session with the date, vaccinator ID number, antigen type and number of vial and the type of syringe with which it is to be exclusively used

- Label disposal containers for functioning and malfunctioning SOLOSHOT syringes with vaccinator name and ID number

- Observe all assigned vaccinators during vaccination sessions to:
  - Complete the data collection form for each vaccination given
  - Terminate the use of SOLOSHOT during the session if the syringe fails on five consecutive attempts
  - Call attention to unsafe health worker practices or terminate vaccination session based on unsafe health worker practices
  - Label all malfunctioning syringes with vaccinator ID number and the number of the syringe
  - Collect, clip and dispose of all malfunctioning SOLOSHOT syringes in designated container and return to study supervisors at the end of each vaccination session
  - Collect, clip and dispose of all functioning SOLOSHOT syringes in designated container and return to study supervisors at completion of field trial
  - Collect all vials of vaccine in designated envelope and return to study supervisors at the end of each session
- Complete disposal practices data collection instrument at the end of each vaccination session

- Complete user acceptability data collection instrument at the end of the observation of each vaccinator

- Attend wrap-up session at end of full field evaluation to test defeatability of SOLOSHOT and to provide feedback regarding user acceptability, design modifications, and impact of introducing SOLOSHOT into EPI
ANNEX 3D

VACCINATOR
JOB DESCRIPTION

- Participate in training session on the use of the SOLOSHOT device if included in the "fully trained" study group

- Give vaccinations with conventional and SOLOSHOT device in accordance with MOH and EPI routine policies.

- Dispose of conventional syringes in accordance with normal practice at the conclusion of each vaccination session

- Complete the User Acceptibility questionnaire as requested by study Observers

- Participate in wrap-up session to discuss the user acceptibility of SOLOSHOT, potential for reusing or misusing SOLOSHOT and the practical issues regarding its introduction
ANNEX 4

FIELD EVALUATION SUPPLIES AND MATERIALS

SUPPLIES AND EQUIPMENT *

FROM THE USA

FIELD EVALUATION MATERIALS:

4,000 auto-destruct syringes and needles )provided
1 complete set of PATH training materials & flyers ) by mfr.
3 Zenith Z-184 computers (w/ 20 mb hard disk)
1 SPSS PC+ (or equivalent) statistical analysis package
2 computer printers and paper
1 camera
10 rolls film
18 stopwatches
1 set of office supplies (stapler and staples, tape, envelopes, flip charts, pens, markers, etc.)
waterproof, self-adhesive labels for marking vials and syringes

WITHIN PAKISTAN

conventional/control syringes and all antigens and diluents )provided by
loudspeakers )MOH/EPI

batteries
locks and keys
promotional materials, as appropriate

cups
oranges

* provided by REACH unless otherwise specified
<table>
<thead>
<tr>
<th>Training Cell</th>
<th>Duration</th>
<th>Curricula</th>
<th>Teaching Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. &quot;Full&quot;</td>
<td>1-2 hours</td>
<td>Study Objectives</td>
<td>- flyer provided</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rationale</td>
<td>- lecture</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Demonstration</td>
<td>- visual presentation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- filling</td>
<td>- demonstration</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- expulsion</td>
<td>- group practice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- reading scale</td>
<td>- individual supervised practice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Giving injection</td>
<td>- questions and answers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- sterile technique</td>
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<tr>
<td></td>
<td></td>
<td>- aspirating</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- angle and site of injection</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Disposal</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>- needle protection</td>
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<tr>
<td></td>
<td></td>
<td>- storage/transport</td>
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<tr>
<td></td>
<td></td>
<td>of used supplies</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- destruction</td>
<td></td>
</tr>
<tr>
<td>2. &quot;Flyer only&quot;</td>
<td>10 minutes</td>
<td>Study Objectives</td>
<td>- demonstration syringes provided</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- 5-8 minute standard verbal briefing on purpose of the field evaluation prior to first use of syringe</td>
</tr>
<tr>
<td>3. &quot;None&quot;</td>
<td>10 minutes</td>
<td>Study Objectives</td>
<td>- 5-8 minute standard verbal briefing on purpose of the field evaluation prior to first use of syringe</td>
</tr>
</tbody>
</table>
NOTE TO THE TRAINER

The goal of this training course is for vaccinators to learn the skills necessary to immunize using the one-time use, self-destruct SOLOSHOT syringe. The course is not intended as a comprehensive training course in how to immunize; rather it is specific to the particular task of learning how to use the self-destruct SOLOSHOT syringe.

The following lesson plan and enclosed materials constitute your guide to training vaccinators to use this new syringe.

The training session should emphasize what vaccinators must do differently when they use the SOLOSHOT syringe. It is estimated that the training session should take you between one and two hours to complete. The training session will consist of three sections:

1. The presentation and description of the SOLOSHOT syringe.
2. The demonstration of how the SOLOSHOT self-destruct syringe works.
3. A practice session and the evaluation of the vaccinators' use and understanding of the SOLOSHOT syringe.

Follow the steps below to proceed with the training in the most effective way:

1. Read the goals and objectives of the lesson plan very carefully. They will help you to explain to the participants what they will learn and what they will be able to do at the end of the session.
2. Read and study the information found in the enclosed materials and in the flyer. This will help you become familiar with the way the SOLOSHOT syringe works, so you feel comfortable in the training and in answering the questions that may come up.
3. Rehearse the questions you will ask trainees at the end of the session, and be familiar with the correct answers. The questions will help you evaluate whether the information you covered was well understood and what areas you may need to review with the trainees.
4. Make sure you feel comfortable using the SOLOSHOT syringe. Practice using the SOLOSHOT syringe before the training. Also practice the steps you will follow in your demonstration exercise.

*SOLOSHOT is a trademark of Becton, Dickinson and Company.
5. Make sure you have all the equipment you need ready ahead of time.

6. As a prerequisite for this training, health workers must have a basic knowledge and understanding of certain immunization terms and procedures. Define what these are and assess the participants' levels of knowledge of the terms and procedures. (For example, you want to make sure all trainees know correct dosage, what the six target diseases are, what a plunger is, what you mean by needle cap, what is meant by aspiration, what sterile is, etc.) You can assess the participants' knowledge at the beginning of the training through an informal group discussion, and a question and answer session. It is important that the trainees not feel that this is a test. You may approach the assessment by asking participants to briefly introduce themselves, where they are from, how often they give immunizations at their centers, what types of immunizations they give, what doses of vaccine they give, and whether aspiration is a practice in their area. Add any other questions you think would provide you with useful information about the participants. Try to have everyone participate to some degree in the discussion, so you get a good feel for the knowledge level in the group.

At the end of the session give each participant a flyer to keep. Make sure you are very familiar with the contents of the flyer. The flyer summarizes the information you covered during the training. Allow the vaccinators a few minutes to look over the flyer and to ask questions.
THE LESSON PLAN: TRAINING HEALTH WORKERS TO USE THE NEW SELF-DESTRUCT SOLOSHOT SYRINGE.

OBJECTIVES:

GENERAL:
By the end of the training session vaccinators should have a clear understanding of how SOLOSHOT works and should be able to demonstrate proper use of this new, self-destruct SOLOSHOT syringe.

SPECIFIC:
By the end of the training session the vaccinators should be able to:

1. Describe the self-destruct syringe, list its main characteristics, and tell you why it is important to use SOLOSHOT syringes.
2. Describe the differences between the SOLOSHOT syringe and other syringes they use.
3. Demonstrate the proper use of the SOLOSHOT syringe.

METHODS:

The trainer will use three methods:

1. The oral presentation
   During the presentation the trainer will give a detailed description of the SOLOSHOT syringe, its main characteristics, why it should be used, what differentiates SOLOSHOT syringes from other syringes, and how it works. Illustrations and models of SOLOSHOT syringes will be passed around to participants to illustrate the points made.

2. The demonstration of the use of the SOLOSHOT syringe
   After the SOLOSHOT syringe has been described in detail, the trainer will carry out a step by step demonstration of its use. The demonstration should be as similar to the real situation as possible. All the tools needed for the demonstration must be prepared ahead of time. It is estimated that the presentation and the demonstration should take no more than one hour.
3. **The practice session on the use of the SOLOSHOT syringe**

The practice session will give each trainee the chance to practice using SOLOSHOT syringes in a controlled situation. The trainer can observe whether any difficulties or problems are being faced by the participants, and can answer questions that may arise as a result of the practice session. The practice session will take approximately one hour, depending on the number of participants.

**CONTENTS OF THE TRAINING:**

I. **DESCRIPTION OF THE SELF-DESTRUCT SOLOSHOT SYRINGE**

**INTRODUCTION:**

As you all know, the EPI is one of our most important programs. The goal of the EPI is to promote the well being of the people of this land by protecting the children from childhood diseases and by reducing the amount of sickness and death that is caused by the six diseases targeted by the program.

Many components are crucial to the success of such an effort: for example, proper storing and handling of vaccines, the proper timing for the administration of the vaccines, the exact dosage, the method of administration of the vaccine, and the proper handling of the tools for the administration of the vaccines are all important. (There may be other factors that are as important that you may wish to mention).

All the above factors are important, but the session today will focus on the use and handling of a new kind of syringe called the SOLOSHOT that self-destructs after one use.

**WHAT IS THE NEW SELF-DESTRUCT SOLOSHOT SYRINGE?**

The self-destruct SOLOSHOT syringe is a disposable syringe that can only be used once. It is nearly the same as other syringes you have used. The difference is that it is equipped with a simple metal device that locks the plunger and renders the SOLOSHOT syringe nonreusable.

Note to the trainer: Pass around a self-destruct SOLOSHOT syringe so that trainees may have a chance to look at it more closely. Ask participants not to pull on the plunger but just to observe the different parts of the SOLOSHOT syringe. Encourage participants to stop you and ask questions if anything is unclear.
The lock on the SOLOSHOT's plunger permits only two movements: a single movement pulling the plunger back to load the vaccine into the syringe, and a single movement pushing the plunger forward to administer the vaccine. The plunger will then lock in place, preventing re-use of the syringe.

Note to the trainer: Demonstrate the two motions and the locking of the plunger. Have the trainees note the position of the lock when the syringe is first unpacked, the position after the syringe is loaded, and finally the position of the lock once the vaccine has been administered.

MAIN CHARACTERISTICS OF SOLOSHOT SYRINGES:

1. The plunger can be pulled back only once to fill the syringe with vaccine and can be pushed forward in the barrel only once before it locks into position. The plunger must be pulled back slowly.

2. The SOLOSHOT syringe automatically locks after one full dose of 0.5 ml of vaccine has been delivered. No liquid can be drawn into the syringe after one dose has been administered.

3. The SOLOSHOT syringe has a set volume of 0.5 ml, allowing a head space to insure removal of air bubbles and to adjust for the exact dose.

Note to the trainer: Aspiration is no longer considered necessary with vaccines. If it is not the common practice in your area, skip the next point and go on to number 5.
4. Aspiration for blood after the needle has been inserted into the skin can be carried out when using the self-destruct SOLOSHOT syringe. Aspiration is done by pulling back gently on the plunger. Wait a moment to see if any blood is drawn into the syringe.

5. The SOLOSHOT syringe cannot be used to inject air into the vial before any vaccine is withdrawn.

6. Under no circumstances should the locking device be removed from the barrel of the syringe.

7. The SOLOSHOT syringe is designed so that vaccine wastage may potentially be reduced. The lock is placed so that only the required amount of vaccine can be drawn from the vial into the syringe.

8. The use of the SOLOSHOT syringe does not change the need for following all the EPI guidelines for proper use and handling of vaccines. Vaccinators must check vaccine expiration dates, handle the vaccines with care, and store vaccines under proper conditions.

**WHY USE SOLOSHOT SYRINGES?:**

Infections can easily be transmitted by improperly sterilized syringes and needles. This concern is especially serious due to the risk of transmitting hepatitis B and AIDS viruses by reusing contaminated syringes. Improved safety and efficiency in the delivery of maternal and child immunizations is a top priority for EPI programs worldwide. The SOLOSHOT syringe provides health workers with a tool that will result in a decrease in the risk of contamination and infection.

SOLOSHOT syringes will also prevent a certain amount of vaccine wastage, since they are designed in such a way that only the required amount of vaccine can be withdrawn from the vaccine vial.
II. INSTRUCTIONS AND DEMONSTRATION OF THE USE OF SOLOSHOT SYRINGES:

Note to the trainer: Make sure all the equipment you need for the demonstration is prepared ahead of time.

Materials needed for the demonstration:
- syringes & needles;
- vaccine vial (filled with water);
- potato, orange, or empty container in which to inject the contents of the syringe; and
- appropriate container in which to place the used syringes and needles.

Explain the following instructions to the vaccinators, go over each step, and demonstrate as you go. Make sure everyone can hear and see the demonstration. Allow time for questions, and repeat the demonstration if necessary. Ask questions and talk to the trainees to see if everyone understood. Be sure to emphasize the points that appear in darker print.

1. Remove the caps from the end of the plunger and the tip of the needle. Notice that the plunger of the syringe is inserted all the way into the barrel of the syringe.

Do not move the plunger of the syringe until you are ready to withdraw the liquid from the vaccine vial. Remember SOLOSHOT syringes allow you only one backward and one forward motion of the plunger of the syringe. If you move the plunger back and forth it will lock so the syringe cannot be filled.

When using SOLOSHOT syringes, you cannot inject air into the vaccine vial before drawing in the vaccine.
2. To fill the syringe, insert the needle into the vaccine vial. **Slowly** pull the plunger back to fill the syringe with the usual dose. If you pull the plunger back fast you may feel some resistance and it may be a little harder to withdraw vaccine.

![Image of a syringe being filled]

3. Withdraw the needle from the vaccine vial. Point the needle upwards and tap the side of the barrel to bring any air bubbles to the top. **Slowly** push the plunger forward to adjust the dose of vaccine at the 0.5 ml mark.

![Image of a syringe with air bubbles]

4. Clean the skin around the injection site and insert the needle. If you are aspirating to check for blood, gently pull the plunger back against the lock, and check for blood in the syringe.

5. **Slowly** push the plunger forward and inject the vaccine. Note that the syringe is now locked and cannot be refilled.

![Image of a syringe being injected]

6. Withdraw the needle and place the syringe and the needle in the designated container for proper disposal.
PRACTICE AND EVALUATION OF THE USE OF THE SELF-DESTRUCT SOLOSHOT SYRINGE:

Note to the trainer: Once the demonstration is completed, allow the trainees to practice using the self-destruct SOLOSHOT syringe. Provide each trainee or group with a vial full of water, and an object (fruit, vegetable, etc.) in which to inject the liquid. You may wish to organize the trainees in working groups of two or three persons. However, each person should get at least one chance to do the task. You may also wish to have the trainees role-play an immunization session using the SOLOSHOT syringe. It is estimated that this part of the training should take approximately 30 minutes to 1 hour. During the practice session, make sure that you observe the trainees practicing and note the following:

1. Do any vaccinators have a tendency to pull the plunger back and forth to "loosen it"? It is important that vaccinators not do this; it would lock the syringe before use and result in a lot of wasted syringes.

2. Do any vaccinators have problems filling the syringe with vaccine? Many vaccinators are still instructed to inject air into the vial first, a practice that is not possible with the SOLOSHOT syringe.

3. Do vaccinators have any problems with the use of the SOLOSHOT syringe? Record what these are for later discussion.

CONCLUSION:

Note to the trainer: After each participant has had a chance to practice with a SOLOSHOT syringe, have a short group discussion to assess problems, reactions, and lessons learned during the practice session. Allow time for questions, for the group to share their observations and reactions, and for you to give feedback on what you observed during the practice session. Without identifying the persons point out some of the more common mistakes you observed. Describe the problem and suggest a better way of resolving the problem.

To conclude the training session, summarize the main points covered, or ask participants to help you do so (i.e., the self-destruct SOLOSHOT syringe has a metal locking device in the barrel, can be used only once, etc.). Tell them when they can expect to start using the self-destruct syringes.

Distribute the flyers. Go over the flyer briefly with the trainees. Allow a few minutes for the trainees to look at the flyer and ask questions. Finally, thank the participants for their time and effort and encourage trainees to seek your help anytime they have problems with the use of a SOLOSHOT syringe.

EA00114V
What Is SOLOSHOT?

The SOLOSHOT syringe is a single use disposable syringe. A metal device that is in the barrel of the SOLOSHOT syringe locks the plunger and renders the syringe nonreusable after one dose of vaccine has been delivered.

- The lock allows only two movements of the plunger of the SOLOSHOT syringe.
- The plunger can be pulled back once to fill the vaccine.
- The plunger can be pushed into the barrel once to administer the vaccine.
- The plunger is then locked into position and the SOLOSHOT syringe becomes nonreusable.

How To Use The SOLOSHOT Syringe.

1. Remove the caps from the end of the syringe and the tip of the needle. CAUTION: Do not pull the plunger back and forth to loosen it. This will lock the plunger so the syringe cannot be filled.

2. Insert the needle into the vaccine vial and slowly pull the plunger back to fill the syringe with the usual dose. The plunger will stop slightly beyond the 0.5 ml mark.

3. Remove the needle from the vial. Point upward and tap the side of the syringe to expel any air bubbles. If needed, slowly push the plunger to adjust the dose of vaccine at exactly the 0.5 ml mark.

4. Clean the skin and insert the needle. If aspirating for blood, pull the plunger back slightly.

5. To administer the vaccine, slowly push the plunger forward and inject the vaccine. The plunger is now locked into position and the SOLOSHOT syringe cannot be refilled.

6. Place the SOLOSHOT syringe in the proper disposal container.

REMEMBER:
- Do not move the plunger back and forth.
- Do not use SOLOSHOT to inject air into the vial before drawing the vaccine.
- Only move the plunger to fill the SOLOSHOT syringe and to give the vaccine.
- Reuse of contaminated syringes can cause disease.

*SOLOSHOT is a trademark of Becton, Dickinson and Company.
### ANNEX 8

**OBSERVER DATA COLLECTION INSTRUMENT**

<table>
<thead>
<tr>
<th>STRING</th>
<th>VACCINE TYPE</th>
<th>Elapsed Time</th>
<th>VACCINE INGESTION</th>
<th>AIR ASPIRATION</th>
<th>VACCINE ADMINISTRATION</th>
<th>ACCEPTABLE STERILE TECHNIQUE</th>
<th>VACCINE LEFT IN STRING?</th>
<th>INSTRUMENT PERFORMANCE</th>
<th>PLUMBER CAN BE WITHDRAWN SECOND TIME?</th>
<th>REMARKS</th>
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(reduced from 8½" x 14" paper)
## ANNEX 9

**DISPOSAL PRACTICES DATA COLLECTION INSTRUMENT**

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<th>DISTRICT:</th>
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<td>DATE OF OBSERVATION:</td>
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<tr>
<td>OBSERVER'S NAME:</td>
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**EVALUATE DISPOSAL AT END OF DAY'S SESSION:** ANSWER EACH QUESTION BY TICKING THE APPROPRIATE RESPONSE(S)

1) Were the syringes disposed of at the end of the day's session?
   - [ ] YES
   - [ ] NO

2) Where were the syringes kept until disposal?
   - [ ] IN A LOCKED CUPBOARD
   - [ ] IN A LOCKED ROOM
   - [ ] IN A LOCKED CUPBOARD IN A LOCKED ROOM
   - [ ] OTHER (SPECIFY):

3) In what type of container were the syringes kept before disposal?
   a) if open container (large enough for hand):
      - [ ] CARDBOARD
      - [ ] PLASTIC
      - [ ] METAL
      - [ ] WOODEN
      - [ ] OTHER (specify):
   b) if closed container (not large enough for hand):
      - [ ] CARDBOARD
      - [ ] PLASTIC
      - [ ] METAL
      - [ ] WOODEN
      - [ ] OTHER (specify):

   **ANSWER ONLY IF DISPOSAL WAS OBSERVED** (IF NOT, GO TO QUESTION 8)

4) At the time of disposal, was the container full?
   - [ ] YES
   - [ ] NO

5) Were there any syringes or needles sticking out?
   - [ ] YES
   - [ ] NO

6) How were the syringes disposed of? (CHECK ALL THAT APPLY)
   - [ ] COMPLETELY BURNED
   - [ ] INCOMPLETELY BURNED
   - [ ] NOT BURNED
   - [ ] OTHER (specify):
   - [ ] COMPLETELY BURIED IN THE SOIL
   - [ ] INCOMPLETELY BURIED
   - [ ] NOT BURIED
   - [ ] OTHER (specify):

---

(reduced from 8 1/2" x 14" paper)

38
7) Who disposed of syringes?

- VACCINATOR
- CLEANER
- OTHER (specify):

8) Did staff travel less than 1/4 kilometer from vaccination session to dispose of syringes?

- YES
- NO

9) Were syringes disposed of in less than 15 minutes?

- YES
- NO

REMARKS:

10) Was any needle-stick observed?

- YES (If yes, describe fully)
- NO

REMARKS:

ANSWER ONLY IF DISPOSAL WILL NOT BE OBSERVED

11) According to vaccinator, disposal will take place:

- WHEN THE CONTAINER IS FULL
- AT THE END OF THE DAY
- APPROXIMATELY ___ DAYS LATER
- OTHER (specify):

12) Who will dispose of syringes?

- CLEANER
- VACCINATOR
- OTHER (SPECIFY):

13) Will staff travel less than 1/4 km. from vaccination session to dispose of syringes?

- YES (HOW FAR ___)
- NO

14) How will syringes be disposed of?

- BURNED
- BURIED
- DISCARDED ABOVE THE SOIL
- OTHER (SPECIFY):

15) Will it take more or less than 15 minutes to dispose of syringes?

- MORE
- LESS

REMARKS: (approx. how many minutes?)
**Annex 12**

**User Acceptability Data Collection Instrument**

<table>
<thead>
<tr>
<th>Full Name of Vaccinator (Print)</th>
<th>District</th>
<th>Basic Health Unit</th>
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<tbody>
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**Part I** - Circle the choice for each question

1) a. Was it easy or difficult to withdraw vaccine from a full vial?

- Using conventional syringe
  - Very easy
  - Easy
  - Difficult
  - Very difficult

- Using SOLOSHOT
  - Very easy
  - Easy
  - Difficult
  - Very difficult

b. Which syringe allowed you to more easily withdraw vaccine from a full vial? (Circle one)

<table>
<thead>
<tr>
<th>Conventional</th>
<th>SOLOSHOT</th>
<th>No Difference</th>
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<tbody>
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</table>

2) a. Was it easy or difficult to withdraw vaccine from a vial with a few doses remaining?

- Using conventional syringe
  - Very easy
  - Easy
  - Difficult
  - Very difficult

- Using SOLOSHOT
  - Very easy
  - Easy
  - Difficult
  - Very difficult

b. Which syringe allowed you to more easily withdraw vaccine from a vial with a few doses remaining?

<table>
<thead>
<tr>
<th>Conventional</th>
<th>SOLOSHOT</th>
<th>No Difference</th>
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<tr>
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3) a. Was it easy or difficult to expel air bubbles?

- Using conventional syringe
  - Very easy
  - Easy
  - Difficult
  - Very difficult

- Using SOLOSHOT
  - Very easy
  - Easy
  - Difficult
  - Very difficult

b. Which syringe allowed you to more easily expel air bubbles?

<table>
<thead>
<tr>
<th>Conventional</th>
<th>SOLOSHOT</th>
<th>No Difference</th>
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4) a. Was it easy or difficult to aspirate for blood?

- Using conventional syringe
  - Very easy
  - Easy
  - Difficult
  - Very difficult

- Using SOLOSHOT
  - Very easy
  - Easy
  - Difficult
  - Very difficult

b. Which syringe allowed you to more easily aspirate for blood?

<table>
<thead>
<tr>
<th>Conventional</th>
<th>SOLOSHOT</th>
<th>No Difference</th>
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5) a. Was it easy or difficult to give a correct dose?

- Using conventional syringe
  - Very easy
  - Easy
  - Difficult
  - Very difficult

- Using SOLOSHOT
  - Very easy
  - Easy
  - Difficult
  - Very difficult

b. Which syringe allowed you to more easily give the correct dose?

<table>
<thead>
<tr>
<th>Conventional</th>
<th>SOLOSHOT</th>
<th>No Difference</th>
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6) a. Was it easy or difficult to fully complete the injection?

- Using conventional syringe
  - Very easy
  - Easy
  - Difficult
  - Very difficult

- Using SOLOSHOT
  - Very easy
  - Easy
  - Difficult
  - Very difficult

b. Which syringe allowed you to more easily complete the injection?

<table>
<thead>
<tr>
<th>Conventional</th>
<th>SOLOSHOT</th>
<th>No Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
**PART II**

7) Which syringe was easier to use? (TICK ONE)

<table>
<thead>
<tr>
<th></th>
<th>CONVENTIONAL</th>
<th></th>
<th>SOLOSHOT</th>
<th></th>
</tr>
</thead>
</table>

*Both were about the same*  
Write reason why if not about the same:

8) Which syringe would you prefer to use? (TICK ONE)

<table>
<thead>
<tr>
<th></th>
<th>CONVENTIONAL</th>
<th></th>
<th>SOLOSHOT</th>
<th></th>
</tr>
</thead>
</table>

*Both were about the same*  
Write reason why if not about the same:

9) List 3 positive and 3 negative things about using the SOLOSHOT device in your daily work:

<table>
<thead>
<tr>
<th>POSITIVE</th>
<th>NEGATIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
<td>3.</td>
</tr>
</tbody>
</table>

10) How much training do you think vaccinators will need to use the SOLOSHOT device correctly? (TICK ONE)

|   | More than I received |   | Less than I received |   | The same |

11) If this field evaluation were to be repeated in another country, what changes can you suggest?

12) If approved by the MOH in Pakistan, do you think the SOLOSHOT could be introduced without specific training?

|   | Yes |   | No |

Explain:       

[Blank spaces for additional comments or responses]
ANNEX 11

SCOPE OF WORK FOR FULL FIELD EVALUATION

1) Develop a protocol for a field evaluation of the PATH SOLOSHOT single use syringe.

2) Preliminary visit to WHO/Geneva and Pakistan, approximately 4-6 weeks prior to field evaluation, to finalize protocol and to make preparatory arrangements/contacts for full-scale field evaluation. (See supplemental scope of work attached.)

3) Conduct 3 week field evaluation of up to 3,000 SOLOSHOT devices in Pakistan using REACH/WHO evaluation protocol. The 2 REACH staff members will serve as co-leaders of the 2 District level Supervisory teams. REACH staff members will arrive one week prior to the field evaluation to prepare for the field work and will remain for one week after the completion of the field work to analyze data collected and prepare a draft final report.

ANNEX 12

SCOPE OF WORK
PREPARATORY VISIT FOR SOLOSHOT FIELD EVALUATION

1) Meet with USAID/Islamabad, Pakistan MOH and WHO/Pakistan representatives to present field evaluation design and protocol, scopes of work/expected levels of participation for local personnel, data collection instruments and procedures, training design/materials, budget and proposed timing for full field evaluation.

2) Verify that all necessary clearances needed from USAID/Islamabad and Pakistan MOH (including ethical clearance from latter) have been secured or will be granted by start of field evaluation.

3) Initial briefing of Pakistan MOH/EPI and WHO personnel who will assume major field duties during the field evaluation. Specifically, this will include the MOH Field Evaluation Medical Supervisor, 2 national WHO Operations Officers, 2 District Health Officers and at least 8 Observers/Evaluators. The field evaluation design/protocol, data collection instruments and training materials will be critically reviewed during a 1 - 2 day field test.

4) Assist MOH in stratifying participating Vaccinators into "more experienced" and "less experienced" groupings as specified in protocol.

5) Verify that suitable office/desk space, transport, secretarial, data entry and allied resources are available or can be procured by the beginning of the field evaluation and will available throughout the period.

6) Visit proposed field evaluation sites to verify that travel distance/times, clinic sites, expected immunization workloads, clinic hours/days of service, scheduled immunization campaigns, vaccination techniques and disposal practices are consistent with the design/schedule of the field evaluation. Courtesy calls should also be paid to local government, community and religious leaders as appropriate, to inform them of the proposed use of the newly developed non-reusable syringe for eliminating the risk of transmitting infectious diseases, and receive their comments and enlist local support.

7) Conduct debriefings for USAID/Islamabad, Pakistan MOH, and WHO/Pakistan on the outcome of the TDY and any resulting changes in the field evaluation design/protocol.

8) Conduct debriefing for S&T/H, ANE Bureau and other participating organizations (UNICEF, PAHO, PATH, etc.).