Report of

A Randomized Controlled Trial of Use of Needle Removal Devices during Routine Immunization in Bangladesh

Study Period:

01 November, 2009 to 31 January,2010

Study Supported by:

WHO-SEARO and WHO Country Office, Bangladesh with GAVI funds

Study Implemented jointly by:

Expanded Programme on Immunization (EPI)
Directorate General of Health Services
Ministry of Health and Family Welfare, Government of Bangladesh
and

Child Health Unit
Public Health Sciences Division
ICDDR,B - Bangladesh

Acknowledgements

We would like to acknowledge the large number of individuals and organizations that helped in the successful completion of this study in the different upazilas of Bangladesh. We express our profound appreciation to the government health workers and their supervisors who were directly engaged in the implementation of the trial. We thank them for their willingness to participate in the study and maintaining high technical standards. We would also like to thank the Upazilla Health and Family Planning Officers (UHFPO), the Medical Technologists-EPI (MT-EPI) and Upazila Family Planning Officers of the selected upazilas for providing essential support to the study and the study teams. We also thank the Smiling Sun Franchise Program* for providing paramedics as vaccinators in 3 wards of Shibchar upazila.

We particularly thank the district Civil Surgeons and EPI Supervisors for guidance and oversight of field implementation, and the Divisional Coordinators and Surveillance Medical Officers of WHO, District Immunization Medical Officers of GAVI for their valuable efforts in training the health workers and technical support to the Field Research Assistants of ICDDR,B.

WHO-SEARO and the WHO Country Office, Bangladesh, provided technical, financial and logistics support, and the Expanded Programme on Immunization (EPI), Directorate General of Health Services, Ministry of Health and Family Welfare, Government of Bangladesh provided valuable and substantive technical support on the design, staff training and field implementation. We thank the Programme Manager, Child Health and LCC and WHO-SEARO and WHO Bangladesh IVD team for their contribution in making this effort a success. We would like also to dedicate a special thanks to GAVI who provided the funding to conduct this study.

**Smiling Sun Franchise Program is an USAID funded Essential Health and Family Planning Service Delivery in the urban and rural Bangladesh through more than 30 NGOs.*

Table of Content:

List of Tables:

List of figure:

Abbreviation and acronyms:

EPI	Expanded Programme on Immunization
GoB	Government of Bangladesh
ICDDR,B	International Centre for Diarrheal Disease Research, Bangladesh
WHO	World Health Organization
HA	Health Assistant
FWA	Family Welfare Assistant
AHI	Assistant Health Inspector
HI	Health Inspector
MT-EPI	Medical Technologist-EPI
UHC	Upazila Health Complex (Upazila=Sub-district)
UH&FPO	Upazila Health and Family Planning Officer
FRA	Field Research Assistant
FRO	Field Research Officer
ITT	Intension to treat analysis
SOP	Standard Operating Procedures

Executive Summary

A trial was carried out in 2009-2010 to assess the effect of introduction of needle removal devices in routine outreach immunization sites of Bangladesh on the frequency of needle-prick injuries and other blood exposures among workers potentially exposed to sharps waste. It also evaluated the effect of needle removal devices on the volume of sharps waste and the rate of needle removal device failures over the study period.

This study was conducted in rural Bangladesh as a collaborative effort of the Expanded Programme on Immunization (EPI), Directorate General of Health Services of the Ministry of Health and Family Welfare, Government of Bangladesh (GoB), the World Health Organization and ICDDR,B. ICDDR,B adapted the generic WHO protocol, prepared the study methodology and plan of implementation, managed the data collection, processing and analysis. Upazila and district level GoB staffs were engaged in the implementation of the study, particularly and the community- level workers (HAs and FWAs) performed the vaccination of children and women, used the needle removal devices and provided daily reports. WHO-SEARO and the Country Office Bangladesh provided technical assistance, and logistics support. The Global Alliance for Vaccines and Immunization (GAVI) secretariat funded this study through WHO.

A total of 408 wards/clusters were selected for the study from 9 systematically selected upazilas around the country. Wards were randomly allocated to intervention and control arms within each of the selected upazilas to result in 204 wards in each arm. Each ward/cluster had one vaccinator (subject) who was engaged to vaccinate children and women. The study was implemented from November 2009 – January 2010.

Total 92,207 injections were given from 4,667 vaccination sessions in the intervention wards (19.8 injections per session) and 88,493 injections were given from 4,571 sessions in the control wards (19.4 injections per session). A total of 14 needle-stick injuries were reported from the intervention wards from 101,945 syringes used (1.38 per 10,000 syringes used) and 16 injuries were reported from control wards from 97,777 syringes used (1.64 per 10,000 syringes used). The number of syringes was more than the number of injections because of wastage and use for reconstituting vaccines. There were 5 exposures to blood or body fluid reported from each of the study arms (0.54 and 0.57 exposures per 10,000 injections provided in the intervention and control wards respectively). No needle-stick injury was reported by the waste handler for the disposal of sharps waste in the intervention wards but one injury was reported by a waste handler engaged for the control wards (0.12 person work days)

Estimated sharps waste volume in the needle removal devices from the available data of daily log sheet (MIS-1). 269 needle cutter devices were used by 204 vaccinators and total 101,945 syringes were used. Total sharps waste volume for 269 devices was 0.08m^3 (Each device

produces volume of 0.0003m^3) and the rate of production of sharps waste volume was 0.08m^3 per 100,000 syringes used. Estimated sharps waste volume in the safety boxes, data were analysed restricted to only safety boxes deposited during study period. Each safety box produces volume of 5L of sharps waste which is equal to 0.005m^3. In the intervention arm, 450 safety boxes were used to accommodate 94,415 syringes and produced a volume of 2.25m^3. The rate was 2.38m^3 per 100,000 syringes used. In the control wards total 492 safety boxes were used to accommodate 90,350 syringes and produced a volume of 2.46m^3 of sharps waste and the rate was 2.72m^3 per 100,000 syringes. So, total waste volume per 100,000 syringes were 2.46m^3 (needle cutter devices plus safety boxes) in the intervention wards and 2.72m^3 (only safety boxes) in the control wards. Difference of production of sharps waste volume between the two arms was statistically significant.

Sixty-five needle removal devices out of the total 269 supplied had permanent failure to cut needles. The device failure rate was 24.2%.

The mean time duration of vaccine administration in each vaccination session was 3.46 hours in the intervention wards and 3.31 hours in the control wards. It was 0.15 hours (9 minutes) longer on average in the intervention wards than in the control wards. Mean number of injections provided per hour was 5.73 and 5.86 in the intervention and control arm respectively. On average, the needle removal devices stored 465 (range 124-987) needles. The safety boxes in the intervention wards stored more syringes on average (221) than the boxes in the control area (197). Around a third (74) of the total devices used developed problems with failure to cut needles from the syringes, including about a quarter (65) with permanent failure.

Among the 31 needle stick injuries reported during the study, the most common timing of needle-stick injuries in the intervention arm were during the removal of the cap of the needle and introduction of the needle into the opening on the needle removal device; in the control arm, needle-stick injuries commonly occurred while putting syringes into the safety box, movement of the client and taking the vaccine from the vial. Only 7% of the injuries were reported as severe (deep stick / cut, or profuse bleeding)

When assessing user acceptability of the needle removal device, all the 47 (100%) interviewed vaccinators reported that they needed to use two hands to cut the needles (one to hold the device and press and the other to hold the syringe). Acceptability of the needle cutter device was found very high, and 46 of the 47 (98%) vaccinators reported that it was easy to use the needle removal device. 34 (72%) of the vaccinators reported that the use of the device slightly increased the time to vaccinate. 44 (94%) vaccinators thought that the use of the device would reduce needle stick injuries and all 47 (100%) felt that the use of the device was safer. 28 (60%) vaccinators rated the performance of the device as “excellent”, while 15 (32%) rated as “very good” and 4 (8%) rated as “good”.

Summary of the findings: The rate of needle-stick injury was slightly higher in the control arm than in the intervention arm, although the difference was not statistically significant. Only 5 exposures to blood or body fluid were reported from each arm and the rate was very low (0.54 and 0.57 per 10,000 injections provided in the intervention and control wards respectively), there was no significant difference in rate between the arms. Only one needle-stick injury was reported by the waste handlers. The needle removal devices performed reasonably well with regard to cutting the needle from the used syringes and many of the devices were able to cut and store needles from more than 500 syringes. Around a fourth of the devices used had permanent failure. Compared to the control arm, there was a slight increase of session time in the intervention arm, but the difference was not statistically significant. Safety boxes used in the intervention arm accommodated a higher number of syringes than those in the control arm. Intervention arm produced 2.46m^3 sharps waste volume while control wards produced 2.72m^3 and the difference of production of sharps waste volume between the two arms was statistically significant.

▣ Chapter-1: Introduction

1.1 Background

Current WHO best infection control practices[1] for injections have initiated the use of needle removal devices. While needle removals are a potentially promising way to reduce the volume of sharps waste, evidence regarding the safety and efficiency needs to be documented before recommending them as a best practice standard for routine use. Of particular concern is the need to assess the trade-off between (1) adding a step in the collection of sharps waste that could result in more handling of used needles and thus more needle stick injuries among health care workers; and (2) decreasing the volume of infectious sharps through (a) disposing of syringes alone with less precautions than regular infectious waste and (b) handling needles only as infectious sharps waste to be incinerated or encapsulated. This may result in fewer needle stick injuries among waste handlers and the community. Thus, the introduction of needle removal devices in routine immunization could either decrease the frequency of needle-stick injuries (through facilitated waste management) or increase the frequency of needle-stick injuries (through adding a step in the collection of used needles).

In industrialized countries, resources have been mobilized to support the adequate management of sharps waste to prevent infections from blood borne pathogens. The proper collection and management of syringes and needles in developed countries result in the rates of needle-stick injuries ranging from 0.18 to 0.74 events per person per year.[2] In contrast, in most developing and transitional countries, there is inadequate resources for appropriate sharps waste collection and management. As a consequence, reported rates of needle-stick injuries are higher, ranging from 0.93 to 4.7 injuries per person per year.[2] In addition, lack of measures to manage sharps waste is sometimes considered as an obstacle to the replacement of sterilizable devices by single-use injection devices. Thus, needle removal may be considered as part of a comprehensive solution to prevent reuse of injection equipment and improve waste management. A master protocol to conduct randomized controlled trials to assess the use of needle removal devices during routine immunization and in mass immunization campaigns was developed by WHO and approved by WHO's Research Ethical Review Committee. The impact that such needle removal devices could have on needle-stick injuries among health workers, waste handlers and the community was documented in Madagascar[3] and Myanmar[4] using the WHO protocol during mass immunization campaigns. In both countries, the “BD hub cutter” was assessed. A longitudinal observational study was conducted in Uganda to assess the acceptability of the BD devices.[5] However evidence on the effect of needle removal in routine immunization settings on needle-stick injuries is not

available. Such evidence is essential before needle removal devices can be considered for regular use.

1.2 Objectives of the study:

The primary objective of the study was to assess the impact of the introduction of needle removal devices in routine outreach immunization sites of Bangladesh on the frequency of needle-stick injuries and other blood exposures among workers potentially exposed to sharps waste. The secondary objectives were to evaluate the impact of needle removal devices on the volume of sharps waste in routine immunization setting and to measure the rates of needle removal device failures over the study period.

1.3 Current Immunization Services in Bangladesh and Waste Disposal Practices:

In Bangladesh, community-based government health workers (HAs and FWAs) are primary providers of immunizations (as vaccinators) through outreach sessions. A study in 2005 estimated that more than 93% of immunization sessions in Bangladesh are conducted in outreach sites.[6] Rural Bangladesh is administratively divided into six divisions, 64 districts and 476 sub-districts (upazilas). Upazilas are further divided into unions and unions into wards. In every Upazila, immunization services are provided through a fixed site at the Upazila Health Complex (hospital) and outreach sites. The HAs and FWAs organize eight outreach sessions every month in each of the 3 wards of a union. The average population of a ward is around 8,000.

Auto Disable Syringes (AD Syringes) were introduced in the national immunization programme in Bangladesh (EPI) in 2004. EPI follows WHO best practices for the collection and disposal of sharps waste. This involves the immediate collection of sharps in a safety box without recapping and without separating the syringe from the needle. The filled safety boxes are transported to the Upazila Health Complexes where they are periodically disposed of by incineration or pit burning at the upazila health complex.

Chapter-2: Methodology

2.1 Study Design

A randomized controlled design was used to compare the following two interventions under field conditions:

Reference (control) group - current practices

Collection and disposal of sharps waste according to current WHO best practices: immediate collection of sharps in a safety box without recapping and without separating the syringe from the needle. The intervention included training of the vaccinators, waste handlers, and the persons in charge of final disposal (Medical Technologist- EPI), supervision and provision of safety boxes and management of safety boxes of sharps waste appropriately according to current EPI practices.

The intervention under evaluation (intervention group)

Collection and disposal of sharps waste using needle removal devices (BD hub-cutter) to separate needles from syringes and the storage of the separated needles in the hub-cutter and the syringes in safety boxes. The intervention included the training of the vaccinators, waste handlers, and the persons in charge of final disposal (Medical Technologist - EPI), supervision, provision of needle removal devices, safety boxes and management of needle waste.

All the health workers in both arms were trained on best practices on collection and disposal of syringes and needles after use. Health workers in the intervention arm were also trained on the correct use of the needle removal device. The two interventions were identical except in terms of the supply, use and disposal of the BD hub-cutter in the new intervention arm.

Setting and study period

The study was conducted in rural outreach sites during routine immunization sessions in Bangladesh and was carried out over three months (November 2009 to January 2010)

Study population

The study population included two types of workers:

1. Vaccinators: Health workers involved in reconstituting and administering vaccines at outreach sites; (Health Assistant (HA) / Assistant Health Inspector (AHI) / NGO paramedic assigned for each ward to conduct EPI session).*
2. Waste handlers: Waste handlers, who were responsible for waste handling, transport and disposal.

**Study did not include FWA (Family Welfare Assistant) as a vaccinator or subject. In few wards FWAs were present in the EPI session as a record keeper*

Study sample

The event of interest (i.e. the sampling units) was the syringes used for vaccination during routine immunization. Our sample studied these syringes clustered by wards (i.e., the unit, where one health worker provided EPI services in 8 outreach sites). Hence, the clusters for randomization were the wards. This study was limited to 9 (nine) randomly selected upazilas (*sub-districts*). These were larger upazilas (having 15-20 unions each), provided 45-60 clusters (wards) each for the total requirement of about 400 clusters. All 64 districts of Bangladesh were grouped into three strata (cut-offs of startum: >65%, 55-65% and <55%) based on the crude coverage of fully-immunized child (FIC) from card only [Data source: EPI coverage evaluation survey, 2009]. This was done to ensure representation of both good, average and poorly performing upazilas. Within each stratum, upazilas were listed by district (Only medium size upazilas having 15-20 unions each were included in the list) and 3 upazilas were systematically selected from each of the three strata. Smaller and larger upazilas were excluded to ensure that the study management workload on the upazila study teams were within an accepatble range. Following table 2.1.1 shows the distribution of the selected upazilas by districts and divisions (there were 6 divisions in the country at the time of this study).

Table-2.1.1 Distribution of selected upazilas by district and by division:

Strata	*District*	*% coverage of FIC*	*Upazila (sub-district)*	*# of unions*	*Division*
1	Jhenaidha	81.0	Jhenaidha Sadar	17	Khulna
1	Chapai Nawabganj	71.4	Shibganj	16	Rajshahi
1	Madaripur	65.2	Shibchar	18	Dhaka
2	B.Baria	61.4	Nabinagar	20	Chittagong
2	Jessore	56.7	Jessore Sadar	15	Khulna
2	Jessore	56.7	Monirampur	17	Khulna
3	Gopalganj	54.8	Moksudpur	17	Dhaka
3	Chittagong	54.3	Banshkhali	15	Chittagong
3	Noakhali	51.9	Begumganj	16	Chittagong

Randomization

The wards were randomly allocated to the intervention being evaluated (needle cutter) or the control (reference intervention) arm within the selected upazilas. Randomization was performed using computer generated random number list by a computer programmer who was blind to the identity of the wards (clusters).

2.2 Sample size:

The rate of needle-stick injuries among health workers, the main outcome of the study, varies considerably depending on the country, the job, the procedure and the device used.[2] Little is known about the risk among workers handling sharps waste. To calculate the sample size needed

for the trial, we used the rate of 2.12 needle-stick injuries/person/year, an average of the rates reported in developing regions (World Health Report 2002)[2] and 4,235 injections given/provider/year, an average reported by the injection givers interviews during the rapid assessment of injection practices conducted in India, Mongolia and Albania.[7,8,9] Therefore, five needle-stick injuries/10,000 syringes is the background rate used in the calculations. The number of clusters (i.e., wards, one worker per ward) needed per arm, given different assumptions regarding power and the percent difference expected to be seen in the rate of needle-stick injuries in the intervention, are presented in Table-2.2.1. We estimated that a sample of 200 clusters per arm, assuming each ward will use 500 syringes during a three month period (reference; the 2005 study on vaccine wastage in Bangladesh estimated an average of 25 syringes used per vaccinator per session in routine immunization settings), will have 80% power to detect a 50% difference in the rate of needle-stick injuries per syringes used.

Table 2.2.1: Number of clusters per arm assuming outcome is needle sticks per needles used, baseline rate is 5/10,000 needles, 500 needles used per cluster, alpha=0.05, two-sided test, coefficient of variation between clusters (k) = 0.5 (conservative estimate).

Percent Reduction	*Power*	***Number of injections delivered by ward vaccinator in three months period***						
		200	**300**	**400**	**500**	**600**	**700**	**800**
30%	70%	1,191	803	609	492	414	359	317
	80%	1,515	1,021	774	626	527	456	403
	90%	2,028	1,367	1,036	838	705	611	540
40%	70%	631	425	322	260	219	190	168
	80%	802	540	409	331	279	241	213
	90%	1,073	723	548	443	373	323	285
50%	70%	378	255	193	156	132	114	101
	80%	481	324	246	**199**	167	145	128
	90%	644	434	329	266	224	194	171
60%	70%	245	165	125	101	85	74	65
	80%	312	210	159	129	109	94	83
	90%	417	281	213	172	145	126	111
70%	70%	168	113	86	69	58	51	45
	80%	213	144	109	88	74	64	57
	90%	285	192	146	118	99	86	76
80%	70%	119	80	61	49	42	36	32
	80%	151	102	77	63	53	46	40
	90%	202	136	103	84	70	61	54

Based on these calculations a sample of 204 clusters per arm was selected to have 80% power to detect a 50% reduction in the rate of needle-stick injuries per 10,000 syringes used (Table 2.2.2).

Table 2.2.2: Number distribution of wards/clusters after randomization by study arm and upazila

Upazila (sub-district)	*Code*	*Total # of wards*	*Total wards selected for the study**	*Total Intervention wards*	*Total Control wards*
Shibganj	1	48	47	23	24
Moksudpur	2	51	40	21	19
Shibchar	3	54	44	22	22
Banshkhali	4	45	37	18	19
Begumganj	5	48	48	24	24
Nabinagar	6	60	60	30	30
Jhenaidha Sadar	7	51	45	23	22
Jessore Sadar	8	45	42	21	21
Monirampur	9	51	45	22	23
Total:		453	408	204	204

**Excluded the wards where GAVI volunteers run EPI sessions or the position of Health Assistant was vacant or the HA was about to retire*

2.3 Equipment provided

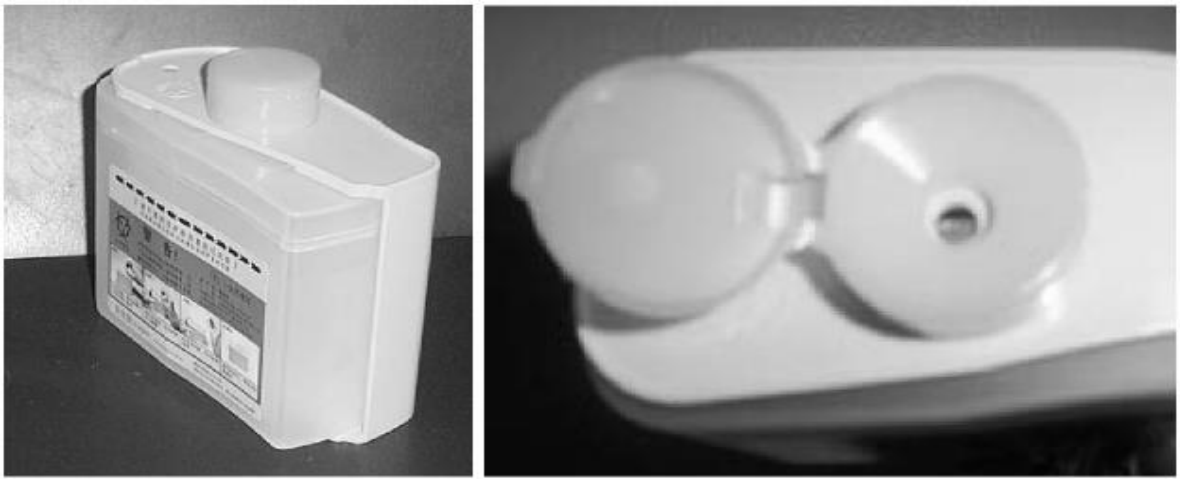
Intervention group:

In the intervention group, each health worker was equipped with:

a) One needle cutter device at the beginning of the study. A stock of 30-50 devices was kept in each upazila for replacement of dysfunctioned devices in the field or in case a device is full of needles. Finally in total 269 needle removal devices were actually used for the study in the intervention wards.
b) Syringes and safety boxes (according to the best practices on injection safety).

The needle removal device selected in the trial was the BD ® Hub cutter (Figure 2.1). Each device has a hole at the top through which the used needle is inserted. By means of a mechanical action involving a blade, the device separates the needle from the syringe's hub. The needle is collected in a secure container which is part of the device. When the needle removal device is full with the used needles, the whole unit is disposed of. The vaccinators using the needle removers kept the needle containers until they are full, when they were disposed of. Disposal of the used/full needle removal devices was centralized (at the Upazila Health Complex) and were carried out as per national guideline for sharps waste disposal. (Incineration or open pit burning as per EPI guidelines). Used syringes without needles were collected in safety boxes. In case of device failure during the session, the health worker collected the syringe and needle together in the safety boxes according to the WHO best practices on injection safety.

Figure 2.1: BD hub cutter



Reference group (control):

The control EPI sites were equipped with syringes and safety boxes (according to the best practices on infection control). Three safety boxes were provided to each vaccinator (ward/cluster) for the study period with the assumption that one safety box can accommodate around 200 AD syringes, filling about 3/4th of the box. There was stock of safety boxes in the Upazila Health Complex (UHC).

The provision of safety box allowed the measurement of the quantity of non-sharps waste syringes alone [intervention] and syringes and needle sets together [control].

Safety box:

Three different types (1.Yellow color "PAHU", Finland; 2. White color "BIOHAZARD, Smurfit" and 3. White color JMI, Bangladesh) of safety boxes are supplied by the national EPI programme. For this study, it was decided to use the same type of safety boxes in the intervention and control wards of an upazila for the study period, but it was not possible to maintain the comparibility of type of safety boxes across the upazilas.

Table 2.3.1: Type of safety boxes used by upazila

Upazila Code	*Name of Upazila*	*Type of safety box used during the study*
1	Shibganj	Yellow "PAHU" Finland
2	Moksudpur	Yellow "PAHU" Finland
3	Shibchar	White "JMI" Bangladesh
4	Banshkhali	White "JMI" Bangladesh
5	Begumganj	Yellow "PAHU" Finland
6	Nabinagar	Yellow "PAHU" Finland
7	Jhenaidha Sadar	White "BIOHAZARD" Smurfit, Lagamil
8	Jessore Sadar	White "JMI" Bangladesh
9	Monirampur	Yellow "PAHU" Finland

2.4 Training

With technical support from the EPI and WHO country office, the study team provided 3 days training of trainers to a group of 9 independent data collectors (Field Research Assistants), 2 Field Research Officers, 1 Field Research Manager and 9 District Immunization Medical Officers. Upon received the TOT, the team of trainers provided one day training to 566 health workers and supervisors including the respective UH&FPO and Civil Surgeons using a (a) standardized curriculum and (b) practical exercises (Appendix-1) and completed the trainings in 36 batches from 1st November to 9th November, 2009 (Annex-1). 420 vaccinators (Health Assistants / Paramedics), 109 supervisory personnel (Medical Technologist-EPI, Health Inspector, Assistant Health Inspector, EPI Supervisor) and 18 waste handlers received the day-long training (average number of participants in each batch was 16). Trainings for the workers from the intervention and control wards were organized separately and were held in the respective upazilas. The training covered best practices on injection safety, correct operation of the needle removal devices, final disposal of syringes and needles after use, and the completion of daily log including roles and responsibilities (Table 2.4.1). Each vaccinator (injection provider) received a unique identifier number.

Table 2.4.1: Scheme of personnel training for the trial of needle removal device

Training topic	Intervention	Control
Best practices on injection safety	✓	✓
Use of Needle removal device	✓	✖
Report of needle-stick injury	✓	✓
Daily log sheet	✓	✓
Standard operating procedures	✓	✓

2.5 Implementation

All trained intervention and control subjects (vaccinators) received logistics from the upazila store (two safety boxes and daily log sheets in both areas, and one needle cutter device in the intervention wards). Study implementation was started just after completion of training and thus the start date were different for different batches of workers.

Vaccinators of the intervention wards were trained to cut the needles of the used syringes by the supplied needle cutter devices and then dropping the needle-less syringes in the safety boxes. They were instructed to report immediately to MT-EPI or the FRA for any kind of failure of the device through the daily log sheet and a cell phone call, if available. Vaccinators in both arms were also instructed to report any needle-stick injury in daily log sheet. Daily log sheets were sent to the UHC along with the EPI tally sheet at the end of each session. Log sheets were reviewed by the FRA (Field Research Assistant) on the same day.

The FRA immediately (the following day) investigated all reported needle-stick injury or device failure and supplied a new device in case of device failure. Two needle cutter devices were never provided to a vaccinator at a time, so in case of device failure, some syringes were dropped in the safety boxes (intervention area only) without cutting the needles.

Four different types of syringes were used in the session:

- 0.5 ml AD syringes for Pentavalent, TT and Measles vaccination.
- 0.05 ml AD syringe for BCG vaccination
- 2/3 ml disposable syringe to dilute BCG vaccine
- 5 ml disposable syringe to dilute Measles vaccine

Supervision and Monitoring

Nine Field Research Assistants (FRA), two Field Research Officers (FRO), one Medical officer and the Study Coordinator were engaged in the supervision of study activities. FRAs were based in the upazilas (one in each study upazila) and were also responsible for data collection on needle stick injury and device failure, logistic supplies, field supervision, review of daily log sheets, maintenance of records and local coordination. FROs provided technical support to the FRAs, MT-EPI and vaccinators during field visits, collected daily log sheets and data records of needle-stick injuries and device failures, investigated the causes of device failure and interviewed vaccinators on the use of needle removal devices. They maintained an excel database to monitor the progress and reviewed all data records before data entry.

2.6 Data collection

The following data collection forms were used in the study and were translated into the local language, Bangla (except MIS-4 and MIS-5)

MIS-1: Daily log sheet for the vaccinator (appendix-2); Vaccinators filled out one log sheet for each outreach immunization session and submitted the form to the Medical Technologist-EPI of the upazila on the same day along with the EPI tally sheet. The daily log contained information of working hours, total number of injections given including the number of syringes used, number of needle-stick injury and blood exposure and device failures.

MIS-2: Report form for needle-stick injury (appendix-3); Field Research Assistant (FRA) filled-out this form when informed about a needle-stick injury of the vaccinator through daily log sheet or verbal report from a waste handler. One report form was filled-out for one or multiple needle-stick injuries from the same needle. The form captured the date and time of injury, category of worker, location or site of injury occurred, timing f injury and the contamination status of the syringe at the time of injury.

MIS-3: Report form for needle removal device failure (appendix-4); Field Research Assistants filled-out this form when they received any report of device failure through daily log sheet or a cell phone call. The FRAs ascertained the failure as temporary or permanent and recorded the conditions and reasons of device failure.

MIS-4: Data collection instrument to assess the user acceptability of needle removal devices (appendix-5); Investigators filled-out this form while visiting the outreach EPI sessions.

MIS-5: (appendix-6) To record information on safety boxes and needle removal devices after submission at the storage site (Upazila Health Complex). Vaccinators were instructed to record the number of syringes used and syringes dropped in the safety box by date and deposit the box to the Upazila Health Complex when it was filled-up with used syringes. In the same manner, information of used needle removal devices was recorded in this form at the storage site. This form was introduced to keep records of safety boxes and needle removal devices used in the study.

2.7 Quality Assurance Procedures

Adequate quality measures were taken to maintain technical standards:

a) Standardization of data collection procedures
b) Providing guidelines in Bangla on study procedures to all study subjects
c) Independent research team composed of Field Research Assistant (one in each study upazila) closely monitored study activities and data collection for needle-stick injury or device failure, Field Research Officers (2) supervised the FRAs and also undertook random visits to EPI sessions and provided feedback, A Medical Officer (1) ensured the quality of training and collected data on the acceptability of the needle removal device. Study investigators visited study sites regularly to check on technical standards of the trial and completed device acceptability form.

2.8 Waste disposal

The Upazila Health Complex functioned as the waste storage site in every upazila. Health workers deposited filled safety boxes and needle removal devices at the Upazila Health Complex and MT-EPI stored these boxes separately for the intervention and control wards till final disposal. The FRAs kept the records of syringes dropped in the safety boxes and observed the final disposal. From each health complexes, two waste handlers, (one for intervention and one for control wards) were identified to transport waste from the Upazila Health Complex to the disposal site and dispose the waste (safety boxes and needle removal devices). Disposal of the used needle removal devices and safety boxes were carried out as per national guidelines for sharps waste disposal (Incineration or open pit burning). In case of needle-stick injury, the waste

handler reported to the focal person responsible for EPI (Medical Technologist, EPI) at the UHC and the independent data collector (FRA) investigated the needle stick injury by interviewing the waste handler using MIS-2. (Appendix-3)

2.9 Data entry and Analysis

The data entry system was developed in Visual Basic 6.0 and data was stored in SQL Server database. Data analysis was performed by using SPSS 12.0. Rates of occurrence of needle-stick injuries, exposure to blood and device failure were calculated in each cluster and then compared between the intervention and the control arm. In addition, the volume of syringe and needle waste was calculated from the volume in safety boxes and needle containers. In case of safety box, we calculated the volume of syringes without needles and syringes with needles from the data recorded on the safety boxes (number of syringes dropped in the box by date by subject).

Table 2.8.1: Outline of the analysis plan for the trial of needle removal devices

	Numerator	Denominator(s)	Comments
Primary outcomes			
Needle-stick injuries	-Number of needle- stick injuries	-Number of syringes used	- For the vaccinators
	Number of needle- stick injuries	-Number of waste handlers -Number of work days	- For the waste handlers
Exposure to blood	- Number of exposures to blood	- Number of injections provided	- For the vaccinators
	- Number of exposures to blood	- Number of waste handlers	- For the waste handlers
Secondary outcomes			
Device failures	-Number of needle removal device failure	-Number of devices used -Number of syringes used with needle removal devices	-
Sharps waste volume[1]	- Number of needle removal devices used -Number of used safety boxes (control and intervention)	- Number of syringes used	-

[1] *These will be converted in m^3 using the volume of safety boxes and needle containers*

2.10 Ethical committee approval

The adapted study protocol was approved by the ICDDR,B Ethical Review Committee.

2.11 Informed consent

The vaccinators and the waste handlers were informed about participation through an information statement including information about the purpose of the study and the possible risks. Vaccinators and waste handlers were asked to sign a certificate of consent printed in Bangla (country language) to participate in the study. All participants/subjects signed the consent form before they were enrolled in the study.

2.12 Confidentiality

Confidentiality of data was ensured in all steps of the study including data collection and management, access to data and use of the information. Health workers were assigned unique identification numbers (ID number) which were used in the reporting and data collection forms (MIS 1-4). Names or other identifier of the workers were never recorded in the forms except in the daily log sheet. Computer data files only contain the identification number and no names or other identifiers. The entry and analysis of data was done by the Data Management Section of the Child Health Unit at ICDDR,B, who was not aware of the immunization sites or the vaccinators.

2.13 Management of needle-stick injuries

As there is no national guideline in place, a decision was made to immunize vaccinators and waste handlers with three doses of Hep-B vaccine prior and during the study period. In addition, usual management of injuries were provided. It was found that all vaccinators (Health Assistants) engaged in the study had already received 3 doses of Hep-B vaccines. Waste handlers received two doses of Hep-B vaccines during the study period.

▣ Chapter-3: Results

4.1 Primary and secondary outcomes of the trial (MIS-1):

A total of 4,667 and 4,571 daily log sheets for vaccination were received from the intervention and control wards/vaccinators respectively. The total number of injections provided in the intervention wards was 92,207 (19.8 injections per session) and 88,493 injections were provided in the control wards (19.4 injections per session). The total number of syringes used during the routine outreach EPI sessions was 101,945 and 97,777 in the intervention and control wards respectively. The number of syringes was more than the number of injections because of wastage and use for reconstituting vaccines. A total 14 needle-stick injuries were reported from the intervention wards and the rate was 1.38 per 10,000 syringes used [95%CI 1.28-1.65]; 16 needle-stick-injuries were reported from the control wards and the rate was 1.64 per 10,000 syringes used [95%CI 1.34-1.72]. Though the rate of needle stick injury was lower among vaccinators in the intervention wards than the vaccinators engaged in the control wards, the difference was not statistically significant. There were 5 exposures to blood or body fluids reported by the vaccinators from each of intervention and control wards and the rate was 0.54 (95%CI 0.17-1.26) and 0.57 (95%CI 0.18-1.31) per 10,000 injections provided respectively.

During the study period, disposal of sharps waste was only done once in each of 9 study upazilas. There were two waste handlers in each upazila, one assigned for disposal of sharps waste from intervention wards and the other for control wards. There was no needle-stick injury reported from waste handlers engaged in the disposal of sharps waste from intervention wards but one needle-stick injury was reported by a waste handler engaged for the disposal of sharps waste from the control wards (0.12 injuries per person-workdays)

To estimate sharps waste volume in the needle removal devices, data gathered from daily log sheet. 269 needle removal devices were used by 204 vaccinators and total 101,945 syringes were used. Total sharps waste volume for 269 devices was $0.08m^3$ (Each device produces volume of $0.0003m^3$) and the rate of production of sharps waste volume was $0.08m^3$ per 100,000 syringes used. To estimate sharps waste volume in the safety boxes, analysed data restricted to only safety boxes deposited during study period. It has mentioned that each safety box produces volume of 5L of sharps waste which is equal to $0.005m^3$. In the intervention arm, 450 safety boxes were used to accommodate 94,415 syringes and produced a volume of $2.25m^3$. The rate was $2.38m^3$ per 100,000 syringes used. In the control wards total 492 safety boxes were used to accommodate 90,350 syringes and produced a volume of $2.46m^3$ of sharps waste and the rate was $2.72m^3$ per 100,000 syringes. So, total waste volume per 100,000 syringes were $2.46m^3$ (needle cutter devices + safety boxes) in the intervention wards and $2.72m^3$ (only safety boxes) in the control wards. Difference of production of sharps waste volume between the two arms was statistically significant.

Sixty-five needle removal devices out of the total 269 supplied had permanent failure to cut needles. The device failure rate was 24.2% (95%CI 19.2-29.7). A few vaccinators reported device failures twice or more times and received 2-3 needle removal devices during the study period, suggesting the possibility of misuse of the devices.

Table 4.1.1 below shows the results of the primary and secondary outcomes.

Table 4.1.1: Result of primary and secondary outcomes

Outcome	**Intervention**			**Control**			**Comparison**
	Numerator	Denominator	Rate (95% CI)	Numerator	Denominator	Rate (95% CI)	Fisher's chi^2 test
Primary							
Needle-stick injury among vaccinator	14	101,945 syringes	1.38 (1.28-1.66) per 10,000 syringes	16	97,777 syringes	1.64 (1.34-1.72) per 10,000 syringes	Not significant
Exposure to blood among vaccinator	5	92,207 injections	0.54 (0.17-1.26) per 10,000 injections	5	88,493 injections	0.57 (0.18-1.31) per 10,000 injections	Not significant
Needle-stick injury among waste handler	0	9 waste handler work days	0	1	9 waste handler work days	0.12 person workdays	1.000 Not significant
Exposure to blood among waste handler	0	9 waste handler work days	0	0	9 waste handler work days	0	
Secondary							
*Device failure	65	269 devices	24.2 % (19.2-29.7)				
Sharps waste volume in needle removal devices	269 (0.08m^3)	101,945 syringes	0.08m^3 per 100,000 syringes				
Sharps waste volume in safety boxes	450 (2.25m^3)	94,415[1] syringes	2.38m^3 per 100,000 syringes	492 (2.46m^3)	90,350[1] syringes	2.72m^3 per 100,000 syringes	
Total waste volume (per 100,000 syringes)			2.46m^3			2.72m^3	Difference is statiscally significant

[1]Restricted to only safety boxes deposited during study period
*Devices with permanent failure
Total volume of safety box is 5L and Needle Cutter Device is 0.3L

Table 4.1.2: Mean time of injections in a routine immunization session by upazila and by arm

Upazila	Intervention			Control			Mean Difference (in hours)
	# session	Average # of injection given per session	Mean time (in hours) per session	# session	Average # of injection given per session	Mean time (in hours) per session	
Shibganj	538	22.96	3.39	544	22.77	3.09	0.30
Moksudpur	463	14.85	3.30	417	13.71	2.92	0.38
Shibchar	503	12.81	3.07	486	12.77	2.88	0.19
Banshkhali	416	26.28	4.30	403	23.66	4.04	0.26
Begumganj	547	33.16	4.14	540	31.83	4.32	-0.18
Nabinagar	689	21.12	3.88	688	20.41	3.42	0.46
Jhenaidha Sadar	510	14.36	2.96	468	14.54	2.95	0.01
Jessore Sadar	469	18.91	3.23	476	19.37	3.28	-0.05
Monirampur	520	12.96	2.82	543	13.66	2.85	-0.03
Total:	4,655	19.81	3.46	4,565	19.39	3.31	0.15

Table 4.1.2 shows the mean time spent for injections per session by upazila and by arm. The total time of a session (time between the first and the last injection) was recorded by the vaccinator in the daily log sheet. Mean time spent for injections in each vaccination session of intervention area was 3.46 hours and in the control area was 3.31 hours. It was 0.15 hours (9 minutes) longer on average in the intervention wards than in the control wards. The mean number of injections provided per hour was 5.73 and 5.86 in the intervention and control arm respectively.

4.2 Details of needle-stick injuries

A total of 31 needle-stick injuries were reported during the study period, 30 were from vaccinators and 1 was from waste handlers. Among vaccinators, 14 (46.7%) were from the intervention arm and 16 (53.3%) were from the control arm. All the needle-stick injuries among the vaccinators occurred while working at the outreach vaccination sites in both study arms and one injury of a waste handler occurred at the waste disposal site. The syringes caused needle-stick injuries were contaminated (used) in 16 (51.6%; 95%CI 33-70) cases, uncontaminated in 13 (41.9%; 95%CI 25-61) cases and contamination status was not known in 2 (6.5%; 95%CI 1-21) cases. The ratio of injury by contaminated syringe was higher in the control arm (56.3%; 95%CI 30-80) than in the intervention arm (50%; 95%CI 23-77). [Table 4.2.1]

Table 4.2.1: Status of contamination of needles caused injury (n=31)

		Contaminated syringe	*Uncontaminated syringe*	*Unknown*	*Total*
Vaccinator	Intervention	7 (50%)	6 (43%)	1 (7%)	14
	Control	9 (56%)	7 (44%)	0 (0%)	16
Waste handler	Intervention	0	0	0	0
	Control	0	0	1 (100%)	1
TOTAL:		16 (51.6%; 95%CI 33-70)	13 (41.9%; 95%CI 25-61)	2 (6.5%; 95%CI 1-21)	31

Table 4.2.2 shows the distribution of needle-stick injuries by timing during the routine outreach immunization sessions. In the intervention arm, the most common timing of injuries was while removing the cap of the needle (4, 28.6%; 95%CI 8-58), while introducing the needle into the opening on the needle removal device (4, 28.6%; 95%CI 8-58) and when there was body movement of the client (3, 21.4%; 95%CI 5-51). In the control arm, the timing of injuries were while putting used syringes in the safety boxes (6, 37.5%; 95%CI 15-64), when there was body movement of the client (4, 25.0%; 95%CI 7-52), while drawing the vaccine from the vial (2, 12.5%; 95%CI 2-38) and before use of syringe (2, 12.5%; 95%CI 2-38). There was no injury reported during the transportation of the waste.

Table 4.2.2: Timing of injury occurred during routine immunization session (n=30)

	Intervention (n=14)		**Control (n=16)**	
	#	%	#	%
a. Before use of syringe	0	0.0	2	12.5
b. During use of syringe				
While opening the packet	1	7.2	0	0.0
While removing cap	4	28.6	1	6.3
While taking vaccine from vial	0	0.0	2	12.5
While giving injection	1	7.2	0	0.0
Movement of the client	3	21.4	4	25.0
c. After the use of the syringe				
While putting syringes into safety box	0	0.0	6	37.5
While the syringes pierced the side of the safety box	1	7.2	0	0.0
While introducing the needle into the device	4	28.6		
Other cause	0	0.0	1	6.3

Table 4.2.3 provides information on the severity of the needle-stick injuries. Superficial injury means skin scratched, no bleeding when pressure is applied in proximity of the injury; moderate injury means skin punctured, visible bleeding and the severe injury means deep stick/cut, or profuse bleeding. Out of total 30, 17(56.7%; 95%CI 37-75) had superficial injuries, 11(36.7%; 95%CI 20-56) had moderate and 2(6.6%; 95%CI 1-22) had severe injuries. Superficial injury was more common in the intervention arm (9, 64.3%; 95%CI 35-

87) than in the control arm (8, 50%; 95%CI 25-75), while moderate injury was more in the control arm (7, 43.8%; 95%CI 20-70) than the intervention arm (4, 28.6%; 95%CI 8-58).

Table 4.2.3: Severity of needle-stick injury

Arm		Superficial		Moderate		Severe	
		#	%	#	%	#	%
Intervention	N=14	9	64.3	4	28.6	1	7.1
Control	N=16	8	50.0	7	43.8	1	6.2
Total:	*N=30*	*17*	*56.7*	*11*	*36.7*	*2*	*6.6*

4.3 Reason of failure of needle removal device:

Seventy-four needle removal devices from total 269 supplied to the vaccinators of intervention arm (204 wards/clusters) were reported failed to function and of them 9 (3.4%) had temporary non-function and 65 (24.2%; 95%CI 19.2-29.7) had permanent failures. Around one-fourth of the total devices supplied had problems and the most common cause of device failure was bad functioning of the blade due either to displacement or detouched/breakage (>75%). Tables 4.3.1, 4.3.2 and 4.3.3 present the reasons of temporary non-function of devices, how the devices with temporary non-function were made functioning, and the reasons of permanent device failure.

Table 4.3.1: Reasons of temporary non-function of the device

Reason of temporary non-function	***N=9***	***Percentage***
Device was locked due to movement (pressing did not work)	3	33.3
Did not know the use properly	2	22.2
Did not know the technique of cutting 0.5ml syringe	1	11.1
Blade slightly lost its sharpness	2	22.2
Failed to cut due to inadequate pressure	1	11.1

Table 4.3.2: Ways to restart function of the device (among temporary failures)

Ways to restart function of the device	***N=9***	***Percentage***
FRA provided orientation to use the device	6	66.7
Cutting the hub by pressing the device twice	1	11.1
Using the sharp side of the blade	1	11.1
Missing data	1	11.1

Table 4.3.3: Reasons of permanent failure of the device

Reason of permanent failure	***N=65***	***Percentage***
Blade was displaced to one side	29	44.6
Blade was detached or broken	31	47.7
Cover was locked	2	3.1
Cover of the device was broken	1	1.5
Blade lost its total sharpness	2	3.1

No escape of needles from the needle cutter devices and no needle punctures were reported. One vaccinator reported needle-stick injury due to needle removal failure, another vaccinator reported that there was leakage of liquid from the device and 5 workers said that the lid of the needle removal device was broken during use.

4.4 Acceptability of the needle removal device:

A total of 47 device acceptability forms were filled out by the investigators based on interviews with vaccinators and observations of the sessions. The needle removal device was found within arm's reach and was located on the table during immunization session. No problems with use and transport were reported by the vaccinators at the time of interview. One provider mentioned that the use of the needle removal device was a complex procedure.

Most (40/47) of the providers interviewed reported that they used the device to cut the needles immediately after the administration of the vaccine. Seven vaccinators did not use the device immediately after using syringes and the maximum delay in using the device was 1 day - meaning that they could not use the device for the remaining part of the day. The reasons for not being able to use the device immediately are shown in table 4.4.1

Table 4.4.1: Reason for not able to use the device immediately after vaccination

	Frequency	Percentage
Able to use the device immediately after vaccination	40	85.1
Not able to use immediately after vaccination	7	14.9
Reason for not able to use the device:	n=7	
Blade was displaced	3	42.9
Blade was dropped from the cutter	1	14.3
Device was locked	1	14.3
Syringe was dropped to the safety box with the needle	1	14.3
Cover was detached	1	14.3
Total	**7**	**100.0**

Among 47, 7(15%; 95%CI 6-28) vaccinators reported that their device had previously stopped working (3 displaced blades, 2 device cover locked, 1 device cover detached, and 1 worker did not know the use of the device).

Among 47, 6(13%; 95%CI 5-26) vaccinators reported that they failed to remove the needle completely from the syringe once while one vaccinator reported such a failure twice since they had started to use the device. All of them dropped the syringes with the needles in the safety boxes.

Among 47, all of the interviewed vaccinators reported using two hands (one to hold the device and press and the other to hold the syringe) to cut the needles and cutting needles at

the level of the needle shaft. Three vaccinators reported suffering needle stick injury at least once since they started to use the needle removal devices.

Among 47, 11(23.4%; 95%CI 12-38) vaccinators reported that the use of the device did not increase the time to vaccinate a client, 34 (72%; 95%CI 57-84) reported a slight increase of total vaccination time, and 2 (4.3%; 95%CI 1-15) mentioned that there was a moderate increase of the time for each client to be vaccinated (including removing the needles and disposing the syringes).

Among 47, 44(94%; 95%CI 82-99) vaccinators thought that the use of the device could reduce needle stick injuries and all of them felt that the use of the device was safer. Twenty-eight (60%; 95%CI 44-73) vaccinators rated the performance of the device as “excellent”, while 15 (32%; 95%CI 19-47) rated as “very good” and 4 (8%; 95%CI 2-20) rated the performance of the device as “good”.

▣ Chapter-4 Discussion

The trial of use of needle removal devices was successfully conducted in rural outreach routine immunization centres in Bangladesh. The results showed that the device was generally well received by the vaccinators. They perceived this as a safe device and easy to use although there was a small increase in the time needed to immunize a client. There was almost no difference in the rate of exposures to blood and body fluids between the intervention and the reference arms, while vaccinators in the intervention wards had an absolutely lower likelihood of being exposed to needle-stick injuries than those in the control wards, the difference was small and not statistically significant.

Previous studies were conducted in Madagascar and Myanmar in 2004 and 2005 respectively in mass vaccination campaign settings. In Madagascar, there was no report of any needle-stick injury while in Myanmar there were a total of 16 needle-stick injuries and of which 11 were in intervention vaccination posts (using the needle removal device) and 5 were in reference vaccination posts. Though the risk of needle-stick injuries was double in the intervention arm than in the control arm (who did not use the device), the numbers were too small for definitive conclusions.

In this study, we found that the needle removal devices performed reasonably well with regard to cutting the needle from the used syringes and many of the devices were able to cut and store needles from more than 500 syringes. Around a fourth of the devices used had permanent failure.

We also collected data to answer the question whether the time needed to immunize a person increased with the use of the device. Though there was a small increase in the time needed to immunize clients in the intervention area, this was not significant. The mean number of injections provided per hour was not significantly different between the two arms. These findings indicate that the use of the device does not increase the time needed for vaccination although an additional step was added in routine immunization practice.

The sharps waste volume was 2.38m^3 per 100,000 syringes used in the intervention arm while it was 2.72m^3 per 100,000 syringes used in the control arm. The difference in volume was significant and sharps waste volume generated in the control wards was much more than intervention wards.

This was the first trial in a routine immunization setting. Further trials, in different health system contexts, would be needed to repeat and confirm the findings from this study.

References

[1]*Hutin YJF, Hauri AM, Chiarello L, Catlin M, Stilwell B, Ghebrehiwet T Garner J and the members of the injection safety best practices development group. Best infection control practices for intradermal, subcutaneous and intramuscular needle injections. Bull World Health Organ 2003; 81:491-500.*

[2] *World Health Organization. The World Health Report 2002: reducing risks, promoting healthy life. Geneva: World Health Organization; 2002:74.*

[3] *World Health Organization. Pedalino B. A randomized controlled trial of use of needle removal devices during Measles mass immunization campaigns: Madagascar. September-October 2004.*

[4] *World Health Organization. Pedalino B. A randomized controlled trial of use of needle removal devices during MNT immunization campaign: Myanmar. March 2005.*

[5] *PATH 2005. Muller N. Evaluation of a disposable needle-removal device in Uganda. September 2005.*

[6]*Guichard S et al . Vaccine wastage in Bangladesh, Vaccine (2009). Doi:10.1016/j-vaccine.2009.08.035.*

[7] *Hutin Y. Injection Practices in Albania: Rapid Assessment and Proposed Action Plan. June 2000. Final report.*

[8] *Sneller V-P, Lee C. Injection Practices in Tamilnadu, India: Rapid Assessment and Proposed Plan of Action, January 2001. Final report*

[9] *Logez S, Rapid Assessment of Injection Practices in Mongolia. September 2001.Final Report - February 2002.*

[10] *CDC: Recommendations for prevention of HIV transmission in health-care settings. MMWR 1987;36 (suppl no2S)*

[11] *CDC. Update: universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in healthcare settings. MMWR 1988;37:377-82, 387-8.*

Annexure-1

Status of training of Vaccinators by upazila and date

I= Intervention batch

C= Control batch

Upazila Code	Name of Upazila		Date of training by batch and by category (November'09)								
			1/11	2/11	3/11	4/11	5/11	6/11	7/11	8/11	9/11
1	Shibganj	Study arm		I	I	C	C				
		# subject trained		14	15	13	16				
2	Moksudpur	Study arm		I	C	I	C				
		# subject trained		9	9	12	13				
3	Shibchar	Study arm	I	I	C	C					
		# subject trained	11	12	10	13					
4	Banshkhali	Study arm		I	I					C	C
		# subject trained		15	4					11	9
5	Begumganj	Study arm		C	I	I	C				
		# subject trained		12	14	10	14				
6	Nabinagar	Study arm		I	I	C	C				
		# subject trained		13	18	16	15				
7	Jhenaidha Sadar	Study arm		I	I	C	C				
		# subject trained		13	10	13	11				
8	Jessore Sadar	Study arm			I	C	C		I		
		# subject trained			15	11	11		7		
9	Monirampur	Study arm		I	I	C	C				
		# subject trained		11	11	14	11				

Annexure-2

Report of important variables of the trial (Needle Cutter study) by upazila and by arm

Upazila	Total # wards/clusters		Total # waste handler		Total # of EPI sessions held			Total # injections provided			Total # syringes used		
	Int[v]	Con[t]	Int[v]	Con[t]	Int[v]	Con[t]	Total	Int[v]	Con[t]	Total	Int[v]	Con[t]	Total
Shibganj	*23*	*24*	*1*	*1*	*538*	*544*	*1,082*	*12,351*	*12,382*	*24,733*	*13,875*	*13,827*	*27,702*
Moksudpur	*21*	*19*	*1*	*1*	*464*	*417*	*881*	*6,872*	*5,714*	*12,586*	*7,740*	*6,441*	*14,181*
Shibchar	*22*	*22*	*1*	*1*	*505*	*489*	*994*	*6,441*	*6,203*	*12,644*	*7,276*	*6,957*	*14,233*
Banshkhali	*18*	*19*	*1*	*1*	*416*	*403*	*819*	*10,930*	*9,532*	*20,462*	*11,842*	*10,397*	*22,239*
Begumganj	*24*	*24*	*1*	*1*	*547*	*540*	*1,087*	*18,136*	*17,187*	*35,323*	*19,622*	*18,598*	*38,220*
Nabinagar	*30*	*30*	*1*	*1*	*689*	*688*	*1,377*	*14,546*	*14,039*	*28,585*	*16,108*	*15,590*	*31,698*
Jhenaidha Sadar	*23*	*22*	*1*	*1*	*511*	*471*	*982*	*7,323*	*6,803*	*14,126*	*8,214*	*7,591*	*15,805*
Jessore Sadar	*21*	*21*	*1*	*1*	*469*	*476*	*945*	*8,869*	*9,218*	*18,087*	*9,728*	*10,180*	*19,908*
Monirampur	*22*	*23*	*1*	*1*	*528*	*543*	*1,071*	*6,739*	*7,415*	*14,154*	*7,540*	*8,196*	*15,736*
Total:	*204*	*204*	*9*	*9*	*4,667*	*4,571*	*9,238*	*92,207*	*88,493*	*180,700*	*101,945*	*97,777*	*199,722*

Upazila	Needle-stick injury				Exposure to blood				Permanent failure of Needle Removal Device			Temporary failure of Needle Removal Device		
	Int[v]	Rate per 10,000 syringes used	Con[t]	Rate per 10,000 syringes used	Int[v]	Rate per 10,000 injections provided	Con[t]	Rate per 10,000 injections provided	Total # device used	Total # of device failure	Rate of device failure (%)	Total # device used	Total # of device failure	Rate of device failure (%)
Shibganj	*2*	*1.44*	*1*	*0.72*	*0*	*-*	*2*	*1.62*	*34*	*11*	*32.4*	*34*	*0*	*0.0*
Moksudpur	*1*	*1.29*	*2*	*3.11*	*0*	*-*	*0*	*-*	*27*	*6*	*22.2*	*27*	*4*	*14.8*
Shibchar	*0*	*0*	*3*	*4.31*	*0*	*-*	*0*	*-*	*25*	*3*	*12.0*	*25*	*0*	*0.0*
Banshkhali	*1*	*0.84*	*1*	*0.96*	*0*	*-*	*0*	*-*	*24*	*6*	*25.0*	*24*	*1*	*4.2*
Begumganj	*2*	*1.02*	*0*	*0*	*1*	*0.56*	*0*	*-*	*39*	*15*	*38.5*	*39*	*1*	*2.6*
Nabinagar	*5*	*3.10*	*5*	*3.21*	*4*	*2.75*	*3*	*2.14*	*35*	*5*	*14.3*	*35*	*0*	*0.0*
Jhenaidha Sadar	*2*	*2.43*	*2*	*2.63*	*0*	*-*	*0*	*-*	*27*	*4*	*14.8*	*27*	*1*	*3.7*
Jessore Sadar	*0*	*0*	*1*	*0.98*	*0*	*-*	*0*	*-*	*27*	*6*	*22.2*	*27*	*1*	*3.7*
Monirampur	*1*	*1.33*	*1*	*1.22*	*0*	*-*	*0*	*-*	*31*	*9*	*29.0*	*31*	*1*	*3.2*
Total:	*14*	*1.38*	*16*	*1.64*	*5*	*0.54*	*5*	*0.57*	*269*	*65*	*24.2*	*269*	*9*	*3.3*

Annexure-3

Table: Summary findings of needle cutter study

	Variables	Intervention	Control	Total	Remarks
1	Total # of wards in the study	204	204	408	
2	Total # of vaccinators enrolled in the study	212	208	420	There were replacement of 12 vaccinators
3	Total # of daily log-sheet entered (total sessions under study)	4,667	4,571	9,238	7.6 sessions / vaccinator / month
4	Total # of injection given	92,207	88,493	180,700	# of injections given per session = 20
5	Total # of syringes used	101,945	97,777	199,722	# of syringes used per session = 22
6	Total # of Needle-stick injury reported by the vaccinator	14	16	30	Rate of injury per 10,000 syringes used: 1.38 in the intervention wards and 1.64 in the control wards.
7	# of waste handlers per arm	9	9	18	Rate of injury: 0.12 person work days in the control arm
8	# of work days of waste handlers	1	1	1	
9	Total # of needle-stick injury reported by waste handler.	0	1	1	
10	Total # of exposure to blood or body fluid (Vaccinator)	5	5	10	Rate of exposure to blood or body fluid per 10,000 injections provided: 0.54 in the intervention arm and 0.57 in the control arm.
11	Total # of exposure to blood or body fluid (Waste handler)	0	0	0	
12	# of needle prick injury during EPI session (site of occurrence of injury)	14	16	30	100% injury occurred during the EPI session
13	# of needle cutter devices reported as temporary failure	9	NA	9	3.4% (Total # of devices used = 269)
14	# of needle cutter devices reported as permanent failure	65	NA	65	24.2% (Total # of devices used = 269)
15	Rate of sharps waste volume in the safety boxes	2.38m^3 per 100,000 syringes	2.72m^3 per 100,000 syringes	-	
16	Rate of sharps waste volume in the needle cutter device	0.08m^3 per 100,000 syringes			
17	Total sharps waste volume produced (per 100,000 syringes)	2.46m^3	2.72m^3		Difference of sharps waste volume between the arms was statically significant

Appendix-1

Training curriculum:

Schedule of the one-day training session for intervention and control vaccinators, waste handlers and supervisors

Field supervisors and Vaccinators

- Overview
- Pre-test

Injection safety and best practices

- Best infection control practices for injections
- Best practices for the collection and disposal of syringes and needles after use (WHO injection safety toolbox tools).
- Needle-stick injuries - an occupational risk, importance of reporting
- Practical section.

Use of needle removal devices

- Proper operation of the needle removal devices.
- Separate disposal of the syringes and the needles after use.
- Practical section.

Standard operating procedures (SOP) for the trial

- Introduction to the standard operating procedure for the trial.
- Completion of the daily log sheet.
- Completion of the needle-stick reporting form and standard operating procedures in case of needle-stick injury.
- Standard operating procedures in case of device failure, including completion of the form.
- Post-test.
- Take home messages.

Waste handlers

- Overview
- National SOP for the sharps waste disposal
- Repotting of needle-stick injury to the focal person responsible for the waste storage at Upazila Health Complex

Informed consents for the vaccinators and waste handlers

Appendix-2

Daily log sheet for the vaccinator (MIS-1)
(to be filled by vaccinator)

Upazilla/Sub district code |___| Union code |___|___| Ward No |___|

Vaccinator's name and code number (Vaccinator's code three digits)

1. Name: _____Code no: |__|__|__|
2. Name: _____Code no: |__|__|__|

(Date and number- Always write in English)

1	Date:	|___|___|-|___|___|-|___|___|___|___| Day month Year
2	Starting time of the first injection given in session (Write the correct time)	|___|___| : |___|___| AM/PM
3	End time of the last injection given in session (Write the correct time)	|___|___| : |___|___| AM/PM
4	Number of injections given	|___|___|
5	Number of syringes used	|___|___|
6	Number of needle-stick injuries[1]:	1) |___|___| code no: |___|___|___| 2) |___|___| code no: |___|___|___|
7	Number of exposures to blood among vaccinators[2]:	1) |___|___| code no: |___|___|___| 2) |___|___| code no: |___|___|___|
8	Safety box filled today :	Yes |___| No |___|
9	Needle removal devices filled today[3]	Yes |___| No |___| NA |___|
10	Needle-removal device failures [4]:	Yes |___| No |___| NA |___|

[1]In case of needle stick injury, the FRA should fill form no- 2;
[2] Number of other blood exposures of the vaccinator without needle stick injury;
[3] Only for the intervention site where needle removal device used;
[4] In case of failure of the needle removal device, the FRA should fill form no 3

Appendix-3

Report form for needle-stick injuries (MIS-2)

(to be filled by FRA)

Instruction: One report form to be filled for one needle stick injury, if multiple injures occurs from same needle, in that circumstances also only one report form to be filled.

Upazilla/ Sub district Code: |___| Union Code: |___|___| Ward no: |___|

1) ID number of injured provider by needle |___|___|___|

2) Date of injury: |___|___|-|___|___|-|___|___|___|___|

3) Time of injury: |___|___|-|___|___| AM/PM

4) What is the job category of the injured worker: (Tick one only)
   a. Vaccinator |___|
   b. Waste Handler (Porter) |___|
   c. Other (describe) |___|

5) Where were the vaccinator or waste handlers when the injury occurred? (Tick one only)
   a. Working at outreach site |___|
   b. Traveling to outreach site |___|
   c. Waste storage facility at Upazila Health Complex |___|
   d. Waste disposal sites |___|
   e. Other, describe _____ |___|

6) Was the injured worker the original user of the syringe? (Tick one box only)
   |___| Yes |___| No

7) The syringe which caused the needle stick injury, was: (Tick one box only)
   a. Contaminated |___|
   b. Uncontaminated |___|
   c Unknown |___|

8) Where did the injury occur? (tick one only)

8.1 **At Outreach Site**,

   a. Before use of the syringe |___|
   b. During use of the syringe;
      b1. While opening the packet |___|
      b2. While removing the cap |___|
      b3. While mixing with diluents |___|
      b4. While withdrawing vaccine from the ampoule or vial |___|
      b5. While administering injection |___|
      b6. Movement of the client |___|
      b7. Other (describe)_____ |___|

c. After the use of the syringe

c1. While withdrawing the syringe just after injection |___|

c2. While recapping used needle |___|

d. Syringes left on floor, table, or other inappropriate place |___|

e. While putting syringes into safety box |___|

f. Stuck by the needle protruding from the opening of the safety box |___|

g; Because the syringes pierced the side of the safety box |___|

h. Other (please describe)_____ |___|

i. During use of needle removal device *(provide the LOT number written on the needle removal device)*

i1. While introducing the needle into the opening on the needle removal device|___|

i2. From a partially cut needle of the syringe |___|

i3. Stuck by the needle protruding from the opening of the needle removal device |___|

i4. Because the needles pierced the side of the needle container |___|

i5. Other (describe) _____ |___|

8.2 During transporting the waste

a) Transporting the safety box, from one outreach site to another outreach site |___|
b) Transporting the filled safety box, from one site to Upazila storage health facility |___|
c) Transporting the filled safety boxes to the disposal site (burning/incineration site |___|
d) Transporting the needle removal device from one outreach site to another outreach site |___|
e) Transporting the needle removal device to the storage facility of Upazila health facility |___|
f) Transporting the filled needle removal device to the disposal site (burning/incineration site) |___|
g) Others, please describe: _____ |___|

9. Was the injury?

1 Superficial *(skin scratched, no bleeding when pressure is applied in proximity of the injury)* |___|

2 Moderate *(skin punctured, visible bleeding)* |___|

3 Severe *(deep stick/cut, or profuse bleeding)* |___|

Appendix-4

Report form for needle removal devices failure (MIS-3)

(to be filled by FRA)

Upazilla code/Sub district code: |___| Union code: |___|___| Ward No: |___|

1.Date : |___|___|-|___|___|-|___|___|___|___|

2.ID number of vaccinator: |___|___|___|

3.Needle removal device LOT number: |__|__|__|__|__|__|__|__|__|__|

4.Did the needle removal device stop temporarily? Yes |___| No |___|

If yes, describe problems:_____
Please describe how you restart use of the needle removal device :
_____

5.Did the needle removal device stop permanently? Yes |___| No |___|
If yes describe problems:

6.Did any needle escape from the needle removal device? Yes |___| No |___|

7.Did the needle puncture the needle container? Yes |___| No |___|

If yes did this occur; (Tick in applicable box)

a. During removing the needle |___|
b. During transporting the device |___|

Other (please describe)|___| _____

8.Did the needle removal device remove the needle completely from the syringe?
Yes |___| No |___|

9.Did you experience a needle stick injury because of the needle removal device failure?
Yes |___| No |___|

10.Did any liquid leak from the needle removal device? Yes |___| No |___|

11.Did the lid of the needle removal device break? Yes |___| No |___|

Appendix-5

Form to assess the user acceptability of needle removal devices (MIS-4)

(To be filled by the principal investigator interacting with vaccinators)

1. ID number of the Health worker: |___|___|___|

2. Date: |___|___|-|___|___|-|___|___|___|___| DD/ MM /YYYY

3. LOT number of the needle removal device you are using? |__|__|__|__|__|__|__|__|__|__|

4. Did the device jam or stop working since you started to use? 1 Yes 2 No

   4 a) If yes, describe what happened ----------

5. For how many days were you not able to use the device? |___|___| Days

   5 a) Device was not used because----------

6. Did you use the needle removal device to remove the needles from the syringes immediately after you gave the injection?

   1 Yes (if yes, go to question 7) 2 No

   6 a) If no, when did you use the needle removal device:

   1) At the outreach site, when there was time between patients
   2) At the outreach site, after finishing all injection
   3) Other----------

   6 b) Where did you leave the syringes with the needles before removing them?

_____

7. Did any needles escape from the device?

   1 Yes 2 No

   7 a) If yes, did this occur while:

   1) Cutting the needle
   2) Transporting the device
   3) Other----------

8. Where was the device located in the facility?
   1) Device was within arm's reach
   2) Worker had to walk over to device
   3) Device was not in use

9. If you used the device were there any problems with use?

   1 Yes 2 No

   9 a) If yes, describe problems----------

10. If you used the device, were there any problems with transport? 1 Yes 2 No

    10 a) If yes, describe problems: ----------

11. If you used the device, where was the device located? ----------

12. Did the needle removal device ever fail to remove the needle completely from the syringe?
1 Yes 2 No
12 a) If yes, how many times did this happen? ----------
12 b) How did you proceed when this occurred----------

13. Did you use two hands while cutting the needle with the removal device?
1 Yes 2 No

14. At what level is the needle cut from the syringe?
1 Below the shaft (nib)
2 At the level of the shaft
3 At the level of the barrel
4 Other----------

15. Did you cut the needle below the shaft (nib)?
1 Never
2 Sometimes
3 Often
15 a) How did you proceed when this occurred? ----------
---

16. Did you have any needle-stick injuries since you started to use the needle removal device?
1 Yes 2 No
16 a. If yes, how many times till now ----------

17. Do you find the needle removal device easy to use? 1 Yes 2 No
17 a) If no, why not: ----------
18. Does use of the needle removal device increase the time needed to immunize one patient?
1 No increase
2 A slight increase
3 A moderate increase
4 A significant increase
5 A large increase
19. Do you think that using the needle removal device contributes to reducing needle-stick injuries?
1 Yes 2 No

20. How do you feel using a needle removal device? 1 Safer 2 Less safe

21. How would you rate the performance of the needle removal device you used?
1 Excellent 2 Very good 3 Good 4 Fair 5 Poor

Appendix-6

Needle Cutter Study

Records on Disposal Safety Box and Needle Cutter Device (MIS-5)

Name of Upazila: _____Upazila Code: |___|

Study arm: Intervention |__| / Control |__|

Information of used safety box (after submission at UHC)			
Code # of Injection provider	Date of receipt used safety box at the UHC	# of syringes in each safety box (source: written on the box by injection provider)	Date of disposal of safety box

Information of used Needle Cutter Device (only for intervention arm)			
Date of receipt used needle cutter device	Functioning status: A=well functioning B=Device failed to function	Date of disposal of the device	Code # of the waste handler