ASSESSMENT OF UNIJECT TRAINING CURRICULUM AND DEVICE PERFORMANCE DURING STUDENT IMMUNIZATION SESSIONS IN YOGYAKARTA, INDONESIA

Muljati Prijanto*, Jane Soepardi, Asmaniar**, Umar Fidaus*, Sumarjati Arjoso***

ABSTRAK

Penggunaan ulang alat suntik sekali pakai rusak merupakan pilihan dalam mencapai suntikan aman. Salah satunya adalah Uniject™ berisi vaksin Hep B atau TT yang dapat disimpan pada suhu kamar selama 1-2 bulan. Penggunaannya merupakan alternatif untuk meningkatkan cakupan dan mencegah penyakit yang dapat ditularkan melalui jarum suntik, terutama di daerah terpencil.

Dalam pencapaian Eliminasi Tetanus Neonatorum di Indonesia, imunisasi TT pada siswa SD dilakukan pada bulan imunisasi anak sekolah (BIAS), setiap bulan November mulai tahun 1998. Penelitian yang bertujuan untuk menilai pemahaman materi latihan dan praktek penggunaan Uniject™ pada 1788 orang siswa SD kelas 2-6 pada program BIAS, serta mengetahui penerimaan vaksinator dan siswa telah dilakukan di 3 kabupaten di Yogyakarta.

Hasil penelitian menunjukkan bahwa materi pelatihan telah dapat dimengerti oleh supervisor dan vaksinator. Kemudahan mengaktivasi Uniject™ adalah 97,76% dan vaksinator yang merasa tidak mengalami kesulitan sebanyak 97,87%. Hanya 1,94% yang belum dapat menekan reservoir secara benar sehingga dosis vaksin menjadi kurang. Pembuangan alat suntik bekas 99,89% telah dilakukan dengan benar. Jumlah Uniject yang rusak saat akan digunakan sebanyak 24 buah (1,35%), sebagian besar karena jarum belum teraktivasi dengan baik sehingga timbul kebocoran atau jarum terlepas.

Pada pelatihan yang perlu diperhatikan adalah: Cara menekan reservoir dengan benar agar diperoleh dosis yang tepat dan cara menyuntik dengan memperhatikan posisi Uniject™ dan kedalaman jarum. Hasil pemantauan menunjukkan tidak ditemui adanya reaksi samping akibat imunisasi TT.

A survey in developing countries revealed that 30 to 50% of injections are administered in an unsterile condition[1]. Disposable syringes are used more than once with improper sterilization procedures. Changing needles without changing the syringe does not solve the problem and still poses significant risks for transmission of infectious blood-borne diseases such as Hepatitis B, Hepatitis C, and HIV[2]. This practice primarily resulted from budget limitation and insufficient

* Pusat Penelitian dan Pengembangan Pemberantasan Penyakit, Badan Litbang Kesehatan, Jakarta
** Subdit Imunisasi, Ditjen P2M & PL, Jakarta.

comprehension of, or adherence to safe injection procedures and requirements. Autodestruct single use injection device therefore is one the choice to achieve safe injection in mass immunization campaigns.

During the last decade there have been a number of developments for autodestruct single use injection devices, one of which is UniJect™. This device was developed by Program for Appropriate Technology in Health (PATH) with funding from the United States Agency for International Development (USAID). In 1996 the UniJect™ technology was licensed to Becton Dickinson and Company (BD) who is currently manufacturing and distributing the device globally. As with standard autodestruct syringes, the UniJect™ device addresses the issue of assured sterility, and since the UniJect™ device is prefilled with a single dose of vaccine, it has additional advantages of minimizing the steps required for dose delivery, maximizing dose accuracy and reducing vaccine wastage[3].

The availability of heat stable vaccines such as tetanus toxoid (TT) and Hepatitis B (HB)[4] make the use of UniJect™ devices an option for improving the immunization coverage. Prefilled UniJect™ devices with TT and HB vaccines can be kept at ambient temperature for direct access and on-time immunization by root level service providers in villages without requiring the cold chain for up to 1-2 months before a resupply is needed. Between 1995 and 1996, 10,000 UniJects™ were used in this manner by midwives to deliver TT and HB vaccines to mothers and infants respectively in their homes on the islands of Lombok and Bali[5,6].

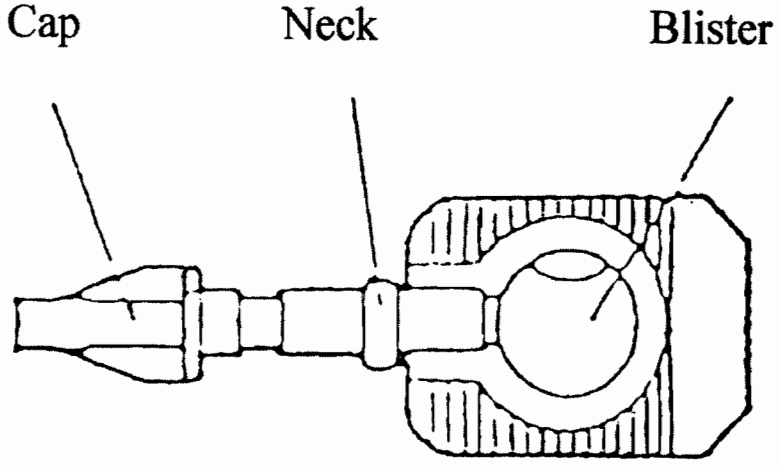
In 1998 the government introduced an annual student immunization month (BIAS) for delivering TT to all grade II-VI primary school students, with the goal that each student will have received TT vaccination 5 times by the time they finish primary school. There is interest in using UniJect™ in this program as one of the alternative to increase the TT immunization coverage into remote areas. Additionally in 1999, there will be a program to start using UniJect™ with HB in mass immunization campaign. Because of its unique properties supplementary training for the UniJect™ procedure usage is deemed necessary for the vaccinators. To assess whether the current training materials will result in proper comprehension and practice, an assessment of training is performed.

The aims of the study were: To evaluate the training result on the comprehension and practice of using UniJect™; to evaluate the performance of UniJect™ with TT on students of grade II to VI in BIAS program and to assess the acceptability of UniJect™ among the vaccinators and students.

MATERIALS AND METHODS

UniJect™ is a single-use plastic injection device prefilled with a single dose of vaccine or medicament enclosed in a sealed blister with a permanent needle attached. The device cannot be reused or refilled. Injection is administered by squeezing the reservoir to get the dose out leaving air and a small amount of vaccine inside the blister.

UniJect™ syringe



Filling of 2600 UniJect™ with tetanus toxoid was conducted in the Communicable Disease Laboratory in Jakarta. Sterility test was conducted alongside during the filling according to the WHO recommendation and the result formed the basis for releasing the vaccine for use. The vaccine-filled UniJects™ were kept at 2-8° C through out the storage period except on the day of immunization when they were transported to the schools. After the study leftover UniJects™ were discarded into a special sharps disposal box made of thick cardboard.

The study was conducted in 3 districts in Yogyakarta: Gunung Kidul, Bantul and Sleman based on the availability of good health infrastructures and good cooperation from the community. The activity consisted of training on the use of UniJect™ followed by TT immunization. All 24 vaccinators attended the training in which they were introduced to UniJect™, and trained on its use. In the practice session each vaccinator used UniJect™ to inject an orange each 10 times. Supervisors of vaccinators were also trained on conducting observation, interview, and filling of a checklist form.

Following the training, immunization was conducted for 6 consecutive days at the 3 above mentioned districts. Out of each district 2 health centers were selected and out of each health center 2 schools were requested to participate in the study. The target sample was 1788 students from grade II to VI. Details are described below:

Tabel 1. The location of study and the number of students.

NO.	DISTRICT	HEALTH CENTER	SCHOOL	NUMBER OF STUDENTS
1.	Gunung Kidul	Wonosari 2	Piyaman I	113
			Piyaman IV	136
		Playen 2	Madrasah Negeri	125
			Gubug Rubuh	127
2.	Bantul	Bantul 2	Manding	169
			Sabdodadi II	154
		Kasihan I	Donotirto	161
			Sembungan	161
3.	Sleman	Tempel	Klegung I	226
			Klegung II	103
		Turi	Turi I	152
			Turi III	161

Following each immunization day the vaccinator's comments and impression on UniJect™ was discussed and recorded in a checklist form together with the supervisors, observation throughout the day's activity.

RESULTS AND DISCUSSION

The immunization result is summarized in Table 2. The average time required to administer an injection using UniJect™ starting from preparation to finish was relatively short that is 44.77 seconds.

The supervisors' observation during the activity is summarized in Table 3. The activity is divided into 3 stages:

1. Preparation or activation of UniJect™: opening the foil pouch, activation, checking the connection between the UniJect™ neck and cap and inspecting for any leakage. The study shows that 97.76% of the vaccinators found activation to be easy, and only 2.24% had trouble with this step.
2. Injection: squeezing the vaccine-containing reservoir. Most of the vaccinators (97.87%) could also perform the injection correctly and only 1.94% did not squeeze the reservoir properly such that less vaccine was delivered.
3. Disposal: not recapping the UniJect™ after use, and proper disposal procedure. The study shows that most of the vaccinators (99.89%), disposed of UniJect™ correctly.

Table 2. Average Time Required by 24 Vaccinators to Perform TT Immunization using UniJect™ on Primary School Students at 3 Districts in Yogyakarta.

Location	Average of Vaccinators	Average of Students	Ave. Time per Injection (seconds)
Gunung Kidul	8	501	41.68
Bantul	8	642	48.32
Sleman	8	645	43.63
Total	24	1788	44.77

Table 3. Details on the Use of UniJect™ during TT Immunization on 1788 Primary School Students at 3 Districts in Yogyakarta

NO.	ACTIVITIES	Number of Students	% True
Preparation			
1.	The foil pouch opened on the first pull	1788	100
2.	The device was easy to activate	1747	97.76
3.	The blister was not pressed during activation	1783	99.72
4.	The vaccinator inspected the connection between the neck and the cap	1782	99.83
5.	Cap was easy to remove	1782	99.66
6.	Vaccinator did not stick him/herself with the needle	1782	99.66
7.	Vaccine leaked upon cap removal (lose a few drops)	1782	99.66
Injection			
8.	The injection site was cleaned prior to injection	1788	100
9.	Injection was administered at the center of the injection site	1784	99.78
10.	The vaccinators had no difficulty performing the injection	1735	92.96
11.	Blister was squeezed/pressed correctly (able to get out the whole dose)	1753	98.04
12.	No difficulty experienced with UniJect™	1750	97.87
Disposal			
13.	The needle was not recapped	1788	100
14.	Used UniJects™ were disposed of properly	1786	99.89

These results show that all of the activities required in performing an injection with UniJect™ could be performed properly with only very few mistakes (92.96%). It can therefore be concluded that there was sufficient comprehension of the training material.

Table 4. Number of Defective UniJect™ and Possible Causes

No.	Explanation	Number	%
1.	Vaccine dripped/leaked through the UniJect™ port during injection	7	0.39
2.	Vaccine leaked through the sealed top part of UniJect™	2	0.11
3.	Vaccine leaked around the needle hub	7	0.39
4.	Needle was detached before activation	3	0.17
5.	Label came off	1	0.06
6.	Foil pouch was no longer sealed	1	0.06
7.	Dull needle (unable to penetrate skin)	1	0.06
8.	UniJect™ leaked before use (no specific explanation)	2	0.11
	Total	24	1.35

Number of UniJect™ used for the study: 1788

Out of the 1788 UniJect™ used for immunization, 24 of them (1.35%) were found defective as detailed in Table 5. Further examination overseas concluded that most of the problem resulted from incomplete activation that gave rise to leakage or detachment of the needle. This could be a point of consideration in future use of UniJect™.

Table 5. Acceptability of UniJect™ Among 24 Vaccinators during the Study in Yogyakarta

No.	Explanation	Number of Responses	%
1.	Problem in using UniJect™:		
	- no problem	19	79.16
	- some problem: - difficult to activate	4	16.67
	- vaccine leaked from the needle hub	1	4.17
2.	Defects found in UniJect™:		
	- no defects found	5	20.83
	- yes, found some defects or label came off	19	79.17
3.	Use of UniJect™ compared with reusable injection devices:		
	- easier to use	24	100
	- practical and already sterile	19	79.16
	- no comments	5	2.10
4.	Use of UniJect™ compared with disposable injection devices:		
	- easier to use	24	100
5.	Use of UniJect™ compared with T-PAD:		
	- easier to use	21	87.50
	- the same	2	8.33
	- more difficult	1	4.16
6.	Opinion about UniJect™ compared with other injection devices:		
	UniJect™ is more practical and easier to use	24	100

No.	Explanation	Number of Responses	%
7.	Opinion about dislike the most of UniJect™		
	- is activated too soon	1	4.16
	- difficult to activate	6	25.0
	- neck too short	1	4.16
	- needle too long	1	4.16
	- need to have a lot in stock	1	4.16
	- a little problem	2	8.60
	- no problem	12	50.0
8.	Injection device of choice: UniJect™ with reason:		
	- practical	20	83.33
	- no reason	4	16.67
9.	Frequency of accidentally sticking oneself with the needle compared with other devices:		
	- no accidental needle stick	24	100
10.	Evaluation of UniJect™		
	- easy to use	22	91.66
	- average	2	8.33
11.	Vaccinator's opinion about UniJect™:		
	- like it	24	100
12.	Students' opinion about UniJect™:		
	- like it	24	100
13.	Disposal of UniJect™ using a cardboard container		
	- yes	24	100
14.	Common disposal procedure of used needles and sharps		
	- burned	18	75.0
	- buried	2	8.33
	- collected	4	16.67
15.	Opinion about the written instructions on how to use UniJect™:		
	- easy to understand	23	96.0
	- difficult to understand	1	4.0
16.	Opinion about the illustration in the instructions on how to use UniJect™:		
	- clear	22	91.67
	- not clear	2	8.33
17.	Suggestions to improve the instructions:		
	- quite clear	11	45.8
	- adjust needle size	2	8.33
	- add color	5	20.8
	- no comments	6	25.0

All of the vaccinators and students (100%) had a favorable impression toward UniJect™ and accepted the device. The vaccinators consider UniJect™ as practical, sterile, and more easily transported because of the less rigid cold chain requirement, while the UniJect™'s small size created less fear and therefore less perceived pain among the students.

Disposal of the used device was properly done as evident from the responses where 75% commonly burn the sharps disposal boxes, while the rest (25%) bury them.

Close monitoring of the students did not report any adverse effects resulting from the immunization.

CONCLUSION AND RECOMMENDATION

Based on the results of the observation and interviews it is concluded that:

1. There was sufficient comprehension of the training materials among the supervisors as well as the vaccinators. Both the written instructions and the illustrations were clear.

2. UniJect™ is well accepted by the vaccinators for its practicality, ease of use, and less rigid cold chain requirement. Students had less fear toward the device, and therefore perceived the injection as less painful.

Recommendations

1. It may be worthwhile to include the activation procedure of UniJect™ on the foil pouch.

2. Several points that need closer attention and emphasis during the training:
   - Correct activation procedure of UniJect™
   - How to properly squeeze the reservoir to obtain a correct dose
   - How to administer injection with attention on the UniJect™'s position and depth of needle.

ACKNOWLEDGEMENTS

We thank the Yogyakarta Regional Health Office for their assistance throughout this study. We also thank Dr. Riyanto and all the health service staff from the provincial, and the district, to the health center, as well as the school principals for the participation and assistance in this study. Lastly we thank PATH/Indonesia and PATH/USA for the technical assistance and funding support that made this study possible.

REFERENCES

1. World Health Organization, Safety of Injections in Immunization Programmes. WHO Recommended Policy, WHO, 96.05.
2. Hu Dj, Kane MA, Heymann DL. (1991). Transmission of HIV, Hepatitis B and Other Blood-borne Pathogens in Health Care Settings. Bulletin of the World Health Organization, 324 (14): 995-997.
3. Lloyd J.S, Aquado M.T. (1998). Prefilled Monodose Injection Devices, GPV World Health Organization, May 1998.
4. Galazka A. Stability of Vaccines. Expanded Programme on Immunization. WHO, 89.8.
5. Otto B, Suarnawa IM, et al. (1996). Immunogenicity in Newborns of HBC in a Prefilled Injection Device Stored Outside the Cold Chain. 1996 (to be published).
6. Sutanto A, Suarnawa IM, et al. (1998). Home Delivery of Heat-stable Vaccines in Indonesia: Outreach Immunization with a Prefilled, Single-use Injection Device. Accepted as a research article in the Bulletin of the World Health Organization. (to be published in late 1998).