Safety, effectiveness and ease of use of a non-reusable syringe in a developing country immunization programme

R. Steinglass (Resources for Child Health (REACH) (John Snow, Inc.).)
D. Boyd,M. Grabowsky (1616 N, Fort Myer Drive, Suite 1100, Arlington, VA 22209, U.S.A.)
A. G. Laghari (EPI/CDD, Sindh, Pakistan.)
M. A. Khan (EPI/CDD National Project, Pakistan.)
A. Qavi (Field Supervisory Medical Officer, Karachi, Pakistan.)
P. Evans (Global Programme for Vaccines, World Health Organization, Geneva, Switzerland.)

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Abstract

Unsterile needles and syringes may transmit blood-borne infectious agents such as HIV and hepatitis B virus. The emergence of these diseases as major public health concerns and the risk of nosocomial transmissio has heightened interest in the development of single-use injection devices. WHO and UNICEF embarked on a programme to develop and introduce these devices in 1987. We report on a field trial in Karachi, Pakistan, of the SoIoShotTM (SS) plastic disposable syringe, which has a metal clip in the syringe barrel to prevent second-time withdrawal of the plunger. A conventional disposable syringe (CS) was used as a comparison. We observed 48 vaccinators giving 2400 injections with the SS and 1440 with the CS; 98.7% of SS performed as designed. The average volume required per delivered dose was comparable for the two syringes and was delivered more quickly with SS. Training and experience had a small but statistically significant effect on several aspects of SS use. Vaccinators who indicated a syringe preference preferred SS on 7 out of 9 indicators. SS is safe and effective in preventing reuse and is easier and quicker to use than the CS. Vaccinators require little, if any, special training. It could directly replace disposable syringes in expanded programmes on immunization (EPI) in countries where use of unsterile disposable devices occurs or when sterilization is not practical.

Introduction

The use of unsterile needles and syringes is a risk factor for the transmission of blood-borne infectious agents, such as HIV and hepatitis B virus. The emergence of these diseases as major public health concerns in the early 1980s and their relationship to the reuse of contaminated syringes has led to heightened interest in the development of single- use injection devices. Use of incorrectly sterilized syringes and needles and reuse of disposables are frequently observed[1-9,a,b] so that alternatives to existing injection devices are clearly needed. This paper describes a field trial of the performance and user acceptability of one such non- reusable injection device.

Material and Methods

Syringes and Vaccines: SoloShotTMc (SS) is a plastic disposable syringe, which has been equipped with a syringe Lock TMd metal clip inserted into the syringe barrel at the time of Manufacture (Figure).

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Fig. 1. SoloShot™ non-reusable disposable syringe.

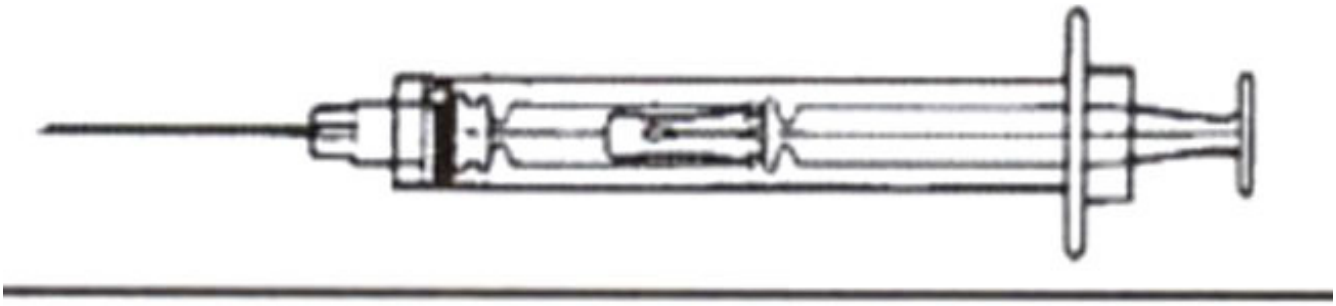

Figure.

After permitting a single filling and emptying, the metal clip is designed to lock the plunger and prevent the plunger from being drawn back a second time. The metal clip is set to permit filling up to 0.575 ml of vaccine with a head space to allow removal of air bubbles and adjustment for the exact dose. The clip is never in contact with the vaccine liquid. SS has a breakaway notch in the plunger to inhibit twist out (not shown in the diagram) and a barrier rib on the plunger to guard the clip against intentional defeat. A 23-gauge, 25-mm needle suitable for intramuscular and subcutaneous injection is permanently attached. The conventional syringe (CS) used in this trial was a plastic disposable which is routinely used by the Expanded Programme on Immunization (EPI) in Pakistan. Manufactured by Becton Dickenson and Company, it is a long narrow lmL tuberculin syringe with a pre-fixed detachable 24-gauge, 20-mm needle. TT (tetanus toxoid) and DT (diphtheria-tetanus) vaccines were used. The required dose was 0.5 ml.

Vaccinators and vaccination sessions: Twenty-four experienced vaccinators with at least one year of immunization experience and 24 inexperienced vaccinators (defined as having less than one year of experience) were randomly selected from rolls of vaccinators. The 48 study vaccinators were randomly assigned to either receive training or receive no training in the use of SS. Training consisted of a short group presentation on SS, distribution of a leaflet, and individual practice in handling the syringes. Vaccination sessions were observed by trained medical officers in fixed facilities or at sites served by outreach teams. Standard EPI policies on injection practices were followed. Each vial of vaccine was used until finished, or until completion of the required number of injections with either SS or CS. At the day's end, completely or partially used vials were withdrawn from further use. Vaccines remaining in used vials was withdrawn and measured. The average filling volume for each of the vaccines used in the trial was supplied by the manufacturer.

Definitions: Syringe wastage was determined by the number of functioning syringes which were unsuccessfully used to give an injection. Injection technique was judged to be sterile if the needle touched nothing other than the inside of the cap, the rubber stopper of the vial, or the injection site. Vaccine withdrawal from the vial was considered to be "with ease" when at least 0.5 ml of vaccine was withdrawn on a single pullback. Air was considered to be present in the syringe if the observer could see any air in the barrel of the syringe following withdrawal of vaccine from the vial. Expulsion of air

from the syringe following vaccine withdrawal was deter- mined to be “with ease” if all the visible air was expelled with less than four finger flicks on the syringe barrel. (This was recorded only for those injections in which air expulsion was attempted.) Aspiration for blood was considered to have been attempted if, after needle insertion in the patient, the vaccinator pulled back on the plunger before giving the injection. Aspiration was rated “easy” if performed with a single pulling action. The presence of vaccine remaining in the syringe following injection was determined by depressing the plunger fully and observing if more than one drop could be expelled from the needle. The duration of each vaccination for either syringe was defined as the time from the opening of the syringe packaging until the withdrawal of the needle from the patient. Rates were compared using chi-squared analysis.

Results

Of the 24 inexperienced vaccinators selected, 22 were females hired three months before the field trial. All 24 experienced vaccinators and observers were male. Sixteen vaccinators received “full training” in SS, lasting one hour by which time the vaccinators ceased asking for more instruction or practice. The vaccinators practiced with an average 8 SS each (range 6-14).

Each vaccinator first attempted 30 injections with the CS and then 50 injections with SS. A total of 3840 attempted injections were observed, 1440 with the CS and 2400 with SS. Observers reported needing to interrupt the injection 21 times with SS and 4 times with the CS. Most of the interruptions were due to insufficient volume of the dose. Virtually all syringes of both types functioned as designed. Of the two CS which malfunctioned, one leaked and one had an occluded needle. Of the 30 SS which malfunctioned, 9 were missing the metal clip and 21 had a stuck piston due to a faulty clip. A clustering of malfunctions occurred in a box of 100 syringes in which 9 were missing a clip and 3 malfunctioned due to a stuck plunger. The 9/2400 (0.4%) SS which were missing a clip were potentially reusable. The plunger could not be withdrawn a second time in any of the syringes which had a clip. All of the CS which could be used once were potentially reusable. Regardless of training and experience, vaccinators maintained sterile techniques with both types of syringe. The rate of accidental needlestick injury was similar for SS (0.17%) and CS (0.2 1%).

The average volume delivered per dose with the SS was comparable to that with CS and was administered in less time. Use of the SS resulted in insufficient volumes of the does in 2.4% of attempted injections.

Other results are presented in Table 1.

Table 1. Summary of results with conventional and SoloShot™ syringes.

Characteristic	Attempted injections with the characteristic (%) Conventional	SoloShot™	P
Syringe wastage	0.8	3.5	<0.001
Sterile technique	98.3	98.9	NS*
Vaccine withdrawal with ease	47.9	92.2	<0.001
Presence of air	93.0	59.1	<0.001
Expulsion of air with ease	54.1	87.6	<0.001
Attempted blood aspiration	38.0	29.3	NS*
Aspiration attempted with ease	97.2	99.3	NS*
Residual vaccine	10.5	0.7	<0.001
Time per injection	43.3 sec	30.7 sec	<0.001

*NS = not significant by X^2 test.

Of the 82 functioning SS which were not used successfully, 56 were wasted due to failure to withdraw 0.5m1 on the first attempt (the syringe locked on the second attempt), 10 were due to premature activation of the clip, and 10 were due to nonsterile technique. SS was quicker to use than the CS for each antigen ($P<0.05$ in every case). Aspiration for blood was attempted in significantly greater proportions of injections with CS, although there was no significant difference in the rate at which attempted aspiration was performed "with ease".

Training and experience had a statistically significant effect on some characteristics of SS use (Table

2).

Table 2. Summary of effect of training and experience for SoloShot™.

Characteristic	Attempted injections with the characteristic (%)			
	Trained	Not trained	Experienced	Not experienced
Syringe wastage	2.9	5,3*	2.0	6.2*
Sterile technique	99.1	98.9	98.8	99.2
Vaccine withdrawal with ease	90.3	91.1	86.9	94.5*
Presence of air	62.0	53.4*	49.3	66.6*
Expulsion of air with ease	93.7	78.7*	83.5	89.4*
Attempted blood aspiration	24.3	14.4*	23.5	15.1*
Aspiration attempted with ease	99.5	100.0	99.5	100.0
Residual vaccine	1.3	0.4	1.2	0.5
Time per injection (sec)	30.2	32.4*	27.1	35.6*

P <0.05

Two areas in which training had a large effect were average elapsed time per injection and syringe wastage. Overall, untrained vaccinators took 7% longer (2.2 seconds) per injection with SS than did trained vaccinators.

On a written questionnaire, the vaccinators preferring a syringe favoured SS on seven of nine indicators, including overall preference (Table 3).

Table 3. Summary of results on user acceptability survey.

Question	Percent of those responding who favoured SoloShot™
Which syringe allowed you to withdraw vaccine more easily from a full vial? (45)*	71.1
Which syringe allowed you to withdraw vaccine more easily from a vial with a few doses remaining? (43)	39.5
Which syringe allowed you to expel air bubbles more easily? (46)	89.1
Which syringe allowed you to aspirate for blood more easily? (30)	13.3
Which syring allowed you to give the correct dose more easily? (48)	97.9
Which syringe allowed you to complete the injection more easily? (40)	77.5
Which syringe was easier to use? (46)	78.3
Which syringe was faster to use? (47)	93.6
Which syringe would you prefer to use? (47)	80.9

* Numbers indicating a preference are given in parentheses.

In the case of vials with only a few doses remaining, vaccinators reported withdrawal to be easier with CS than SS, but this was not statistically significant. The longer needle on SS was reported by some vaccinators to contribute to the frequency of withdrawing a dose of insufficient volume. After needle thickness and length, the increased friction associated with using SS (due to the clip) was most often cited as a negative feature. Forty out of the 48 vaccinators reported that practice with five or fewer SS would be adequate to ensure proper use.

Discussion

SoloShotTM, a prototype non-reusable syringe, was used safely and effectively by vaccinators in Karachi, regardless of their past experience or specific training in SS use. SS was non-reusable, was easily learned, required little if any training in its use, was considerably faster to use than CS, and was clearly preferred by the vaccinators themselves. Some 98.7% of SS performed according to their design, exceeding the 98% requirement set by WHO.E SS meets the WHO performance requirements for those criteria tested.[c]

SS can be introduced into the EPI as a direct replacement for disposable injection devices for intramuscular and subcutaneous injections in countries where reuse of disposables commonly occurs or where sterilization is not practical. As a result of this field trial, WHO recommends the supply of SS to immunization programmes in developing countries; UNICEF entered into a procurement agreement with the manufacturer and delivery started in 1992.

The field trial indicated that introduction of SS into the Pakistan EPI would be accepted by vaccinators.

Although the needle affixed to SS conforms to the WHO- recommended size and gauge for intramuscular and subcutaneous injections,Y vaccinators in Pakistan are accustomed to unusually short and narrow needles on the CS. Modifying the needle to meet local specifications should present little manufacturing difficulty.

The few instances in which SS was potentially reusable owing to absent clips was an issue of manufacturing quality control rather than design failure. The SS used in the field trial had been hand assembled by the manufacturer. While SS could not be reused under normal clinical practice, a few vaccinators who were challenged to defeat SS intentionally did succeed in removing the clip and rendering the syringe reusable. Design modifications intended to remedy this problem have since been made.

Vaccinators injected more quickly with SS than with CS because of the relative ease of filling the syringe with vaccine and the reduced frequency of attempted aspiration. The differential in speed of use would have been even greater if the needle on the CS was not already pie-fixed, as is often the case. The time to give a SS injection clustered around a very narrow range-95% of injections took less than 42 seconds; with CS, 95% took less than 50 seconds. SS was considerably faster to use than a non-reusable pre-filled injection device recently tested in Guatemala.[10]

The pre-set volume on SS, dictated by placement of the syringe LOCKTM clip, allowed for rapid pullback on the plunger without concern for overfilling. However, because this single-use feature does not permit repeated manipulation of the plunger to correct the dose, more vaccinators withdrew an inadequate dose of vaccine with SS than with CS.

Prior experience in using CS had inconsistent effects on SS performance. This may have been because experienced vaccinators had to unlearn certain practices when using SS, which was not the case with the inexperienced vaccinators. Experienced vaccinators naturally found the CS easier to use than did inexperienced vaccinators, but the latter took readily to SS. The longer elapsed time per injection among untrained vaccinators using SS versus the CS was confined to the inexperienced group and was only significant for the first injection, indicating that hands-on experience quickly achieved similar results as training. Regardless of training or experience, vaccinators quickly learned about the pre-set clip and single-use feature of SS during practical use and could similarly withdraw a dose of vaccine using SS.

Given the results of the trial, introduction of SS may pose little additional training burden on the existing EPI. Training should emphasize the need to adjust carefully the depth of needle insertion according to the level of vaccine remaining in the upturned vial, before pulling slowly on the plunger. This point is also rapidly learned with a little practice. Vaccinators most often cited the need to prevent syringe wastage and to explain the benefits of SS as reasons for providing training. Concern about safety was not mentioned (or observed) and vaccinators and observers felt SS could be used safely without any prior training.

Vaccinators had difficulty in withdrawing a dose of measles vaccine because SS does not allow injection of air to neutralize the vacuum inside these vials. Under controlled conditions after the field trial, however, vaccinators demonstrated their ability to use SS as effectively as CS in withdrawing adequate doses of measles vaccine. Consequently, with focused training and practice, SS should be equally effective in delivering all the vaccines.

Blood aspiration was attempted significantly less often with SS. The EPI did not advocate such aspiration prior to injection of vaccine as a routine practice.[11] Of 17 vaccinators who aspirated more than 50% of the time using CS, a significant change in behaviour using SS was observed for 11, with 10 vaccinators decreasing the frequency of attempted aspiration. Vaccinators reported that aspiration was easier with CS.

The field trial identified some operational issues to be considered before SS is introduced. With its volume of deliverable fluid dictated by the clip setting, SS is not currently suitable for administering

BCG or reconstituting lyophilized multiple-dose vials of BCG and measles. Therefore, if SS is introduced into EPI, strict attention to the sterile use of other injection devices will continue to be needed. Research and development to bring a variety of nonreusable syringes to market should be encouraged.[3]

The lack of a system for disposal of syringes and needles is a safety concern in Pakistan and elsewhere. WHO and UNICEF recommend that disposable syringes and needles should only be used if their destruction after a single use can be assured. During the field trial and according to a recent logistics survey report in Pakistanj little evidence of strict accounting and disposal of used syringes and needles was observed. Used syringes were recapped and generally returned from outreach sessions, usually in thin plastic bags, to the base health facility, where they were dumped into an open cardboard box without security precautions. While SS addresses the issue of reuse, the problem of destroying unsterile SS (or CS) would still need resolution. UNICEF plans to provide immunization programmes with non-reusable syringes, either SS or other types, in combined transport, safety and combustion boxes.

At all levels of the distribution system. Storekeepers may need training in determining supply requirements with sufficient lead time. Shortages in an EPI relying largely on SS could result in a cessation of vaccination, or in repeated unsterile use of a small number of over- or undersized syringes and needles.

Some additional training costs mould be expected with the introduction of SS, particularly training of storekeepers in management. To the extent that disposable syringes are being reused, future use of a single non- reusable syringe and needle for each injection could increase costs due to the ordering, storage, transport and disposal of greater numbers of syringes, and due to the higher unit price per syringe (approximately $0.12 versus $0.05). However, assuming that conventional disposable syringes are now being used only once, then future use of SS mayresult in savings in shipping and storage, given its smaller volume per packaged syringe.

SoloShotTM has minimal dead space and allows less vaccine wastage by virtue of its integral cannula. Its pre-set clip limits overfilling of the syringe. However, greater wastage of SS syringes and vaccine due to withdrawal of doses of insufficient volume can be expected. The slightly higher vaccine economy with SS during the field trial is unlikely to translate into much savings, except in a narrow range of circumstances, where staff at busy vaccination sessions must open another multi-dose vial for only 1 or 2 additional persons. SS is faster to use but, unless the vaccination site is very busy, the overall savings in terms of staff time is unlikely to be large. The introduction of SS could lead to greater costs for EPI, but has the potential to reduce transmission of bloodborne agents and avert the associated economic and human costs.

Use of SS should not be expected to reduce the incidence of needlestick injuries in clinical settings, as these are commonly due to re-sheathing" and faulty technique."J2 Reported needlesticks with both the SS and CS were similar to rates with disposable syringes reported in other settings.[13,14K] However, increased numbers of non- reusable syringes requiring safe disposal in a country previously reusing disposables would probably increase the frequency of needlestick injuries to the public, unless antineedlestick protective features were included in the syringe design.[4]

Introduction of SoloShotTM is unlikely to stop the problem of unsterile injections completely since so many of these occur outside the EPI, but it should make public health practice meet the expected standards of quality of care which, in EPI, includes the dictum, "One sterile syringe, one sterile needle for each injection."

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