



**AUTO-DESTRUCT MINI
SYRINGE**

**HEALTH TECHNOLOGY ASSESSMENT SECTION
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA**

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DISCLAIMER

Technology review is a brief report, prepared on an urgent basis, which draws on restricted reviews from analysis of pertinent literature, on expert opinion and / or regulatory status where appropriate. It has not been subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of this review.

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DISCLOSURE

The author of this report has no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia.

EXECUTIVE SUMMARY

Introduction

National immunisation programmes have effectively reduced infant and child mortality rates in developing countries. However, estimation indicates that at least 30% of the approximately one billion vaccine injections administered each year are unsafe. Due to these injections was delivered with contaminated disposable syringes or reusable syringes that were not properly sterilised, which dramatically propagate the transmission of hepatitis B, hepatitis C, and human immuno-deficiency virus (HIV). WHO estimated that unsafe injections have been linked to around 23 million new hepatitis B, hepatitis C, and HIV infections each year. Hence, concern has frequently been raised about the safety of vaccine delivery with injections, especially in low-income countries. The expansion of auto-disabled syringes for vaccination has reduced the problem of reuse of needles and syringes, needlestick injuries and unsafe disposal of sharps waste still leave healthcare workers, patients, and the community at risk.

In Malaysia, personal communication with the officer of vaccine unit, the wastage of BCG immunisation was high (14 out of 20 doses per vial), while for tetanus toxoid was 2 to 3 doses/per vial using disposable syringes (personal communication, 31 October 2013)

This review was requested by the Head of The TB/Kusta Section, Disease Control Division, Ministry of Health Malaysia following a proposal from a company to use mini syringe for BCG immunisation.

Objective/aim

The objective of this systematic review was to assess the safety, efficacy/effectiveness and cost-effectiveness of auto-destruct mini syringe for immunisation.

Results and conclusions

Limited good level of evidence showed that auto-destruct mini syringe improved vaccination coverage and reduced vaccine wastage. Theoretically, it may reduce needle stick injury and blood-borne infection which may occur through contaminated re-used needle. However, there was insufficient evidence on the safety. The cost of auto destruct syringes is more expensive than sterilized syringes, which may increase the national immunisation budget but may save the cost of vaccine wastage. However, proper training on the usage and safety measures of the syringe is required especially among the experience vaccinators.

Methods

Electronic databases were searched from inception: MEDLINE including MEDLINE In-Process & Other Non-Indexed Citations (Ovid); Pubmed; EBM

Reviews, Cochrane database of systematic; EBM Reviews - Health Technology Assessment; NHS economic evaluation database.

Searches were also run in Horizon Scanning database (National Horizon Scanning Centre, Australia and New Zealand Horizon Scanning Network, National Horizon Scanning Birmingham, EuroScan) and FDA.

In addition to the database searches, articles were identified from reviewing the bibliographies of retrieved articles and hand searching of journals.

A combination of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords free text.

AUTO-DESTRUCT MINI SYRINGE

1. INTRODUCTION

National immunisation programmes have effectively reduced infant and child mortality rates in developing countries. However, it was estimated that at least 30% of the approximately one billion vaccine injections administered each year were unsafe.¹ This was due to the fact that these injections were delivered with contaminated disposable syringes or reusable syringes that were not properly sterilized, which dramatically propagated the transmission of hepatitis B, hepatitis C, and human immuno-deficiency virus (HIV).^{2,3} WHO estimated that unsafe injections have been linked to around 23 million new hepatitis B, hepatitis C, and HIV infections each year.⁴ Hence, concern was raised about the safety of vaccine delivery with injections, especially in low-income countries.^{2,5,6} The introduction of auto-disabled syringes for vaccination has reduced the problem of reuse of needles and syringes.⁷

In Malaysia, personal communication with the officer of vaccine unit, the wastage of BCG immunisation was high (14 out of 20 doses per vial), while for tetanus toxoid was 2 to 3 doses/per vial using disposable syringes (personal communication, 31 October 2013)

This review was requested by the Head of The TB/Kusta Section, Disease Control Division, Ministry of Health Malaysia following a proposal from a company to use mini syringe for BCG immunisation.

2. OBJECTIVE/AIM

The objective of this systematic review was to assess the safety, efficacy/effectiveness and cost-effectiveness of auto-destruct mini syringe for immunization.

3. TECHNICAL FEATURES

3.1 SoloShot Syringe

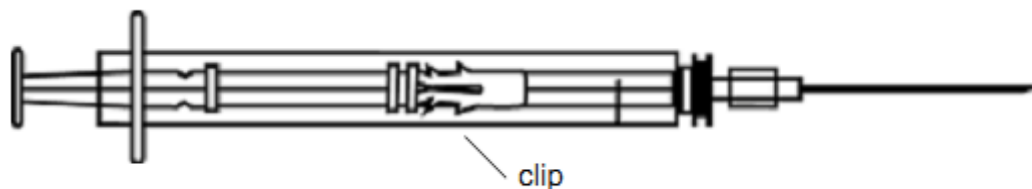
SoloShot (SS) is a plastic disposable syringe that has been equipped with a syringe LOCK metal clip inserted into the syringe barrel at the time of manufacturer. After permitting a single filling and emptying, the metal clip is designed to lock the plunger and prevent the plunger from being drawn back 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 and a barrier rib

on the plunger to guard the clip against intentional defeat. A 23 gauge 25 mm needle is permanently attached.

BD SoloShot mini auto disable syringe for immunisation programme are available in three sizes: 0.5mL capacity for administrating vaccines such as measles and diphtheria-tetanus toxoids-pertusis and 0.05mL for bacilleCalmette-Guerin vaccination

This syringe is a class II device and had received 510k premarket approval from FDA in 2004.

Figure 1: BD SoloShot Mini Syringe



3.2 Competing Technologies

K1™ Auto-Disable syringes - K1 syringe is a single-use, disposable, auto-disable syringe with a safety plunger that breaks off after a single use. This syringe must be triggered before use. The K1 syringes usually have a small, plastic tab or one or two small twist tabs that must be removed. This will assure that the syringe is un-used. A BCG syringe with a 0.05 ml dose line is available.

Figure 2: K1 Syringe with twist tab

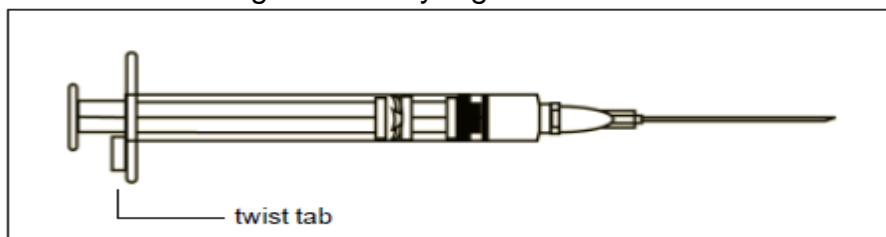
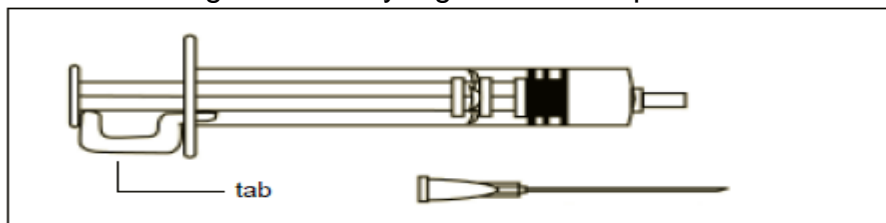
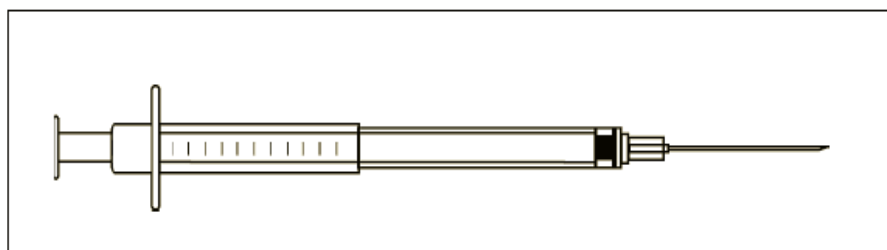


Figure 3: K1 Syringe with tab to pull off



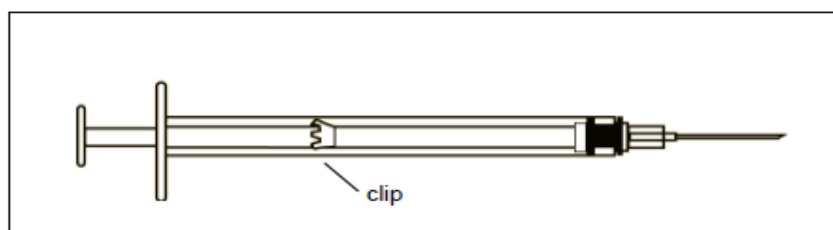
Destroject Auto-Disable Syringe - The Destroject syringe is a single-use, disposable syringe comes with a fixed needle, and the sterile packaging includes a plunger cap and needle shield. The plunger of this syringe can be pushed one time only. Thus, users should not draw the plunger back to inject air into the vial prior to drawing up a dose. It is not possible to aspirate blood when using this syringe. This syringe is available in a 0.5 ml size.

Figure 4: Destroject Auto-Disable Syringe



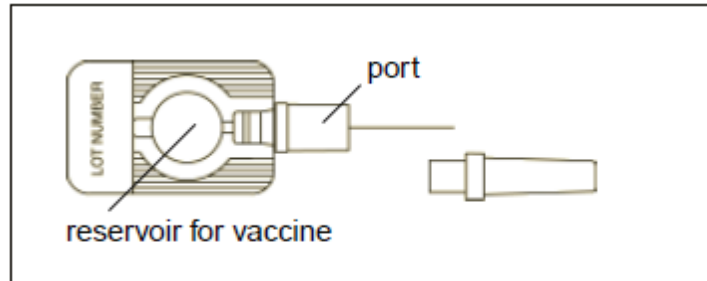
Univec™ Auto-Disable Syringe - The Univec syringe is a 0.5 ml syringe which comes with a fixed needle or detachable needle. The plunger locks once it is depressed, but it can be withdrawn slightly to aspirate blood when checking the needle position. A BCG syringe with a 0.05 ml dose line is also available.

Figure 5: Univec™ Auto-Disable Syringe



Uniject™ Prefill Injection Device- The Uniject is a single-use, disposable, auto-disable injection device that contains one dose of vaccine or medicine. The use of Unijects can increase the volume of cold storage required, particularly at central levels of the cold chain. The device needs to be activated by pressing the needle shield into the port. This opens the canal that allows medication or vaccine to flow into the needle. The health worker then removes the needle shield. While holding the Uniject by the hard plastic port, the health worker inserts the needle into the patient and squeezes the bubble-like reservoir until the entire dose has been injected.

Figure 6: Univec™ Auto-Disable Syringe



4. METHODS

4.1 Searching

Electronic databases were searched from inception: MEDLINE including MEDLINE In-Process & Other Non-Indexed Citations (Ovid); Pubmed; EBM Reviews, Cochrane database of systematic; EBM Reviews - Health Technology Assessment; NHS economic evaluation database.

Searches were also run in Horizon Scanning database (National Horizon Scanning Centre, Australia and New Zealand Horizon Scanning Network, National Horizon Scanning Birmingham, EuroScan) and FDA.

In addition to the database searches, articles were identified from reviewing the bibliographies of retrieved articles and hand searching of journals.

A combination of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords free text. Copies of the search strategies used in MEDLINE are included in Appendix 1 (these were adapted for use in other databases). The search was limited by including search filters for 'human studies'

4.2 Selection

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full-text articles for final article selection.

Inclusion and exclusion criteria

Inclusion criteria

Patient/problem	Immunization
Intervention	Soloshotsyringe, auto disable syringe, auto destruct syringe
Comparator	Uniject™ Prefill Injection Device, Univec™ Auto-Disable Syringe, Destroject Auto-Disable Syringe, K1TMAuto-Disable syringes
Outcome	safe injection, vaccine wastage, accuracy dose deliver
Study design	All studies of acceptable quality, English full text article

Exclusion criteria

Studies conducted in animals and non- English full text article or abstract only.

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) checklist and evidence was graded according to the US/Canadian Preventive Service Task Force Level of Evidence (2001) as in Appendix 2. Data were extracted and summarized in evidence table as in Appendix 3.

5. RESULT AND DISSCUSSION

There were two studies on SoloShot syringe and two studies on auto-destruct (AD) syringe included in this review.

5.1 Safety

A narrative review conducted by Aylward et al. found that the auto-destruct syringe with a fixed needle virtually eliminates the risk of patient-to-patient transmission of blood-borne infections that usually occurs with contaminated re-use needle. Once it was used, the syringe cannot be reloaded to provide another injection. Apart from this, safe disposal box which was included at the time of purchase, allows minimal handling of used syringes, this lowers the risk to healthcare workers.^{8, level III}

5.2 Efficacy/Effectiveness

Drain et al. conducted a non-randomised study among 15 public clinics in five districts in the central region of Madagascar found that the use of AD (DestroJect syringe and SoloShot syringe) syringes improved coverage rates of vaccination, and significantly increased the percentage of vaccines administered on non-routine immunization days [AD-only was 4.3%, mixed (use sterilized syringe on routine children's immunization days and AD syringe on non-routine immunization days) was 5.7% while control was 1.1% ($p < 0.05$)]. However, the clinics differed in the size of the target population of children, the number of routine immunisation days, and the average number of children vaccinated on routine immunisation days. The mixed programme had fewer immunisation days and also vaccinated more children on routine immunisation days than both the AD-only and control groups. However, it was not reported whether the difference was statistically significant. Differences in vaccination of women at antenatal consultations (ANC) showed that the control programme had slightly more sessions per week than the AD-only and the mixed programmes. It was not reported whether this difference was significant. The result also showed that before the study, the 15 clinics sterilized syringes 4.7 times per week on average. After introducing AD syringes, both AD-only and mixed programmes reduced crude sterilization practices by 63%. After adjusting by the total number of routine immunization days per week, the AD-only and mixed programmes significantly reduced the number of sterilization sessions by 68% ($p = 0.02$) and 64% ($p = 0.04$), respectively.^{9, level II-1}

An observational study by Nelson et al. investigated the appropriateness of SoloShot usage during a national immunization campaign in Indonesia compared to a standard disposable syringe, in terms of vaccine wastage, dose accuracy and user acceptance. The study found that eleven (2.8%) SoloShot syringes were rendered unusable when the vaccinator tried to expel air from it before complete filling, which activated the non-reuse device and prevented complete filling. The SoloShot delivered an average of 1.02 (15%) more doses per vial than the disposable syringes. There was an average of 2.6 doses of vaccine per vial wasted by users who used the disposable syringe, while users of SoloShot wasted 1.2 doses of vaccine per vial used. Vaccinators indicated strong preference for SoloShot than the disposable syringe. The reasons given were, it is easier to use, faster and more accurate.^{10, level II-3}

Steinglass et al. conducted a study on 48 vaccinators who were randomised according to whether they receive training or no training in the use of SoloShot syringe and the conventional syringe. Each vaccinator was first attempted 30 injections with conventional syringe and then 50 injections with the SoloShot syringe. A total of 3840 attempted injections

were observed, (2400 injections with SoloShot and 1440 with the conventional syringe). The result showed that the average volume required per delivered dose was comparable for both syringe. However, SoloShot delivered more quickly than conventional syringe. In term of training and experience requirement, it was found that training and experience had a statistically significant effect on some characteristics of the SoloShot syringe used such as syringe wastage, presence of air, expulsion of air with ease, attempted blood aspiration and time per injection(sec) [$p < 0.005$]. The two areas in which training had a large effect were average elapsed time per injection and syringe wastage. Overall, untrained vaccinators took 7% (2.2 seconds) longer per injection than trained vaccinator. The vaccinators preferred SoloShot syringe than the conventional syringe ^{11, level 1}

5.3 Cost-effectiveness/Cost Analysis

Drain et al. conducted an non-randomised study among 15 public clinics in five districts in the central region of Madagascar using AD syringe only, or mixed syringe (ADsyringe used only on non-routine immunization days or sterilisable syringe only and control), The cost analysis included the direct costs (for AD systems, the two types of syringe (DestroJect and Soloshot and the two types of sharps boxes [the "most economic" and DanaPak]). For sterilisable systems, these costs were for UNICEF's sterilisable syringe Kit B, steam sterilisers and fuel costs. The relevant costs specifically excluded were training, worker efficiency, safe administration, vaccine wastage, transportation and destruction costs and also indirect cost. The study result found that the average total cost of one ADsyringe injection was US\$0.081 (ranging from \$0.078 to \$ 0.084), while the average total cost of one sterilisable syringe injection was \$0.017, (ranging from \$0.014 to \$0.021). The estimated annual injection costs for an average clinic were calculated for each of the three groups. An average clinic in the AD-only programme would have administered 4504 injectable vaccines and spent US\$ 366 on AD syringes and safety boxes. Clinics in the mixed and control programmes administering the same number of injectable vaccines would have spent US\$ 96 and US\$ 79, respectively. Compared to control, AD-only and mixed programmes would increase costs by 363% and 22%, respectively. However, introducing AD syringes for all vaccination would only increase the national immunisation budget by 2%, assuming that it costs US\$ 20 to fully immunize a child for a schedule with five injectable vaccines. ^{9, level II-I}

An observational study by Nelson et al. investigated the appropriateness of SoloShot compared to a standard disposable syringe in a national immunisation campaign in Indonesia. In this study, 11 SoloShot syringes

were wasted, while about 40 doses of vaccine were saved using SoloShot. At a UNICEF price of US\$0.10 per SoloShot and the cost of a tetanus toxoid was US\$0.05 per dose, the vaccine cost saving halved the syringe wastage.^{10, level II-3}

A cost analysis was conducted based on the study done by Nelson et al. where BD Soloshot syringe usage was able to reduce half of the vaccine wastage.

Currently, BCG immunisation programme in Malaysia used disposable syringe and on average about 14 doses of vaccine were wasted from a 20 doses vial. Table 1 showed the calculation of the cost of BCG vaccination per person for the current BCG programme and Table 2 showed the calculation using BD Soloshot syringe (the cost of BD Soloshot syringe is based on the price given by the company).

Table 1: Current BCG programme using disposable syringe

No	Items	Cost (RM)
1	Cost of one vial of BCG vaccine <ul style="list-style-type: none"> • Expected usage = 20 doses/vial • actual usage = 6 doses/vial • Current wastage =14 doses/vial 	13.07
2	Cost per dose of BCG vaccine without wastage (RM 13.07/20)	0.65
5	Cost per dose of BCG vaccine with wastage (RM13.07/6)	2.20
6	Cost of current disposable syringe and needle	0.55
7	Cost of BCG vaccine per person (RM 2.20+ RM 0.55)	2.75

Table 2:BCG programme using BD Soloshot syringe

No	Items	Cost (RM)
1	Cost of one vial of BCG vaccine <ul style="list-style-type: none"> • Expected usage = 20 doses/vial • Assumption of usage = 13 doses/vial • Assumption of wastage = 7 doses/vial 	13.07
4	Cost per dose of BCG vaccine without (RM13.07/20)	0.65
5	Cost per dose of BCG vaccine with wastage (RM 13.07/13)	1.00
6	Cost of BD soloshot syringe	2.00
7	Cost of BCG vaccine per person (RM 1.00 + RM 2.00)	3.00

Thus, the above calculation showed that using current disposable syringe seemed to be cheaper than using BD Soloshot syringe by RM 0.25. However, the calculation above do not take into account other cost such as training of personnel and improvement in vaccine coverage, as well as reduction of needle stick injury which may cause blood bore infection.

5.5 Limitations

This report has several limitations. The selection of the studies was done by one reviewer. Although there was no language limit was apply during the search, however, only English full text articles were included in this report, the studies included involving small sample size.

6. CONCLUSION

Limited good level of evidence showed that auto-destruct mini syringe improved vaccination coverage and reduced vaccine wastage. Theoretically, it may reduce needle stick injury and blood-borne infection which may occur through contaminated re-used needle. However, there was insufficient evidence on the safety. The cost of auto destruct syringes is more expensive than sterilized syringes, which may increase the national immunisation budget but may save the cost of vaccine wastage. However, proper training on the usage and safety measures of the syringe is required especially among the experience vaccinators.

7. REFERENCES

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9. APPENDIX

9.1. Appendix 1: LITERATURE SEARCH STRATEGY

Ovid MEDLINE® In-process & other Non-Indexed citations and OvidMEDLINE® 1948 to present

1. Immunization Programs/ or Vaccination/
2. (immunization adj1 program*).tw.
3. (active adj1 immunization*).tw.
4. vaccination*.tw.
5. 1 or 2 or 3 or 4
6. Disposable Equipment/ or Syringes/
7. (disposable adj1 equipment).tw.
8. (hypodermic adj1 syringe*).tw.
9. syringe*.tw.
10. 6 or 7 or 8 or 9
11. "auto disable syringe".tw.
12. "auto destruct syringe".tw.
13. "soloshot syringe".tw.
14. 10 or 11 or 12 or 13
15. 11 or 12 or 13
16. 5 and 14
17. 5 and 15

OTHER DATABASES	
EBM Reviews - Cochrane database of systematic reviews	} Same MeSH, keywords, limits used as per MEDLINE search
EBM Reviews - Health Technology Assessment	
PubMed	
NHS economic evaluation database	
FDA	} Auto destruct syringe, SoloShot Syringe
Euroscan	
Australia and New Zealand Horizon Scanning Network (ANZHSN)	
NHSC	

9.3 Appendix 2

HIERARCHY OF EVIDENCE FOR TEST ACCURACY STUDIES

DESIGNATION OF LEVELS OF EVIDENCE

- I Evidence obtained from at least one properly designed randomised controlled trial
- II-1 Evidence obtained from well- designed controlled trial without randomization
- II-2 Evidence obtained from well- designed cohort or case-control analytic studies, preferably from more than one centre or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- III Opinions or respected authorities, based on clinical experience, descriptive studies and case reports, or reports of expert committees

SOURCE: US/CANADIAN PREVENTIVE SERVICE TASK FORCE (Harris 2001)

