An Independent Assessment of the Sharps Terminator

by

Enhealth Sdn Bhd



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For

Lifeapps Sdn Bhd



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Enhealth Sdn Bhd hereby declares that the company and its directors and shareholders have no financial interests in relation to the sharps terminator. This report has been prepared based on information provided by the Executive VP (Sales and Marketing) of Sharps Terminator LLC, the Malaysian distributor (Lifeapps Sdn Bhd), discussion with staff involved in the trial run, and actual sighting and use of the device.



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| A & E | Accident and Emergency |
|--------|--|
| AHA | American Hospital Association |
| AIDS | Acquired Immune Deficiency Syndrom |
| CC | Concessionaire |
| сс | Cubic Centimeter |
| CDC | US Centers for Disease Control and Prevention, Atlanta |
| CMIS | Central Management Information System (of the hospital support services privatization programme) |
| CW | Clinical waste |
| CWMS | Clinical Waste Management Services |
| DAGRID | Division of Anesth., General Hospital, Resp., Infection Control and Dental Devices |
| EHSB | Enhealth Sdn Bhd |
| EPINet | Exposure Prevention Information Network |
| Faber | Faber Medi-Serve Sdn Bhd |
| FDA | US Food and Drug Administration |
| GBP | Great Britain Pound |
| GMP | Good manufacturing practice |
| HBV | Hepatitis B |
| HBC | Hepatitis C |
| HCW | Healthcare worker |
| HIV | Human Immunodeficiency Virus |
| HKL | Hospital Kuala Lumpur |
| МОН | Ministry of Health, Malaysia |
| NaSH | National Surveillance System for Healthcare Workers |
| NHSS | National Health Service of Scotland |
| OC | Office of the Commissioner, FDA |
| ODE | Office of Device Evaluation, FDA |
| OSHA | US Occupational Safety and Health Administration |
| PMA | Premarket Approval Applications |
| PPE | Personal protective equipment |
| RM | Ringgit Malaysia |
| SAE | Serious adverse event |
| SC | Sharps container |
| SI | Sharps injury |
| UADE | Unanticipated adverse device effect |
| USD | United States Dollar |
| UV | Ultra violet |
| WHO | World Health Organization |
| | |

ABBREVIATIONS



EXECUTIVE SUMMARY

Sharps injuries have been associated with occupational transmission of hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) as well as over 20 other pathogens. It is recognized as a major public health concern. The World Health Organization (WHO) estimates that 37.6% of Hepatitis B, 39% of Hepatitis C and 4.4% of HIV/AIDS in healthcare workers around the world are due to needlestick injuries. The CDC estimates that about 385,000 sharps-related injuries occur annually among health care workers in hospital in the US.

The estimated costs of sharps injuries (SIs) vary from USD 5,000 to as much as USD 1 million if all costs are taken into account, e.g. treatment, drug toxicities, lost time from work, legal and compensation costs etc. Costs that are more difficult to quantify include the emotional cost associated with trauma, fear and anxiety from worrying about the possible consequences of an exposure. There is also the possibility of social stigma and impairment on family and social interactions, which may extend to family members of the injured as well.

Various preventive measures have been recommended and put in place including legislation in some countries. Notwithstanding the high cost of some of these interventions, sharps injuries continue to occur. While these interventions such as use of sharps containers should continue, it is clear that additional interventions are necessary.

The *sharps terminator* is such an intervention that should be considered as it is a point-of-use device, designed to destroy disposable syringes. Thus it has the potential of eliminating or significantly reducing disposal related sharps injuries (occurring after use and before disposal as well as during and after disposal), which has been estimated to be between 40 - 55% of all sharps injuries. It also has the potential to eliminate or significantly reduce a significant number of injuries caused by hollow-bore needles, which is the cause of most of the occupationally-acquired HIV among healthcare personnel.

In a trial run conducted in Hospital Kuala Lumpur, the majority of respondents found the *sharps terminator* easy to use, felt more comfortable knowing that the needle had been removed, and were satisfied that the device performed as expected. The majority also felt that removing and destroying the needle is a safer solution than using safety-designed sharp devices. During the trial run that ran for four and a half months from December 2014 to April 2015, no needlestick injuries were sustained in the two wards where the *sharps terminators* were being used. As there had been incidents prior to the trial run, this is indicative of two things, i.e. 1) the *sharps terminator* is an effective sharps injury prevention strategy, and 2) the change in work process required with the use of the *sharps terminator* did not result in any adverse events.

Savings in clinical waste management is also possible as the capacity of the sharps container is effectively increased. This is because after a hypodermic needle is processed by the sharps terminator the remaining barrel or needle hub would tend to lie flat in the sharps container and empty spaces are filled up by the swarf (the processed end of the needle). Based on feedback of the HKL trial, clinical waste generation and other data obtained, and extrapolation of available



data, it is estimated that the following savings can be achieved in 2016 in Faber's northern zone of operations:

| 2016 | Revenue (RM) | Cost of SCs (RM) | Cost of Terminator (RM) | Balance (RM) |
|------------------|--------------|---------------------|----------------------------|--------------|
| | а | b | С | a-b-c |
| Using Terminator | 26,996,542 | 2,745,090 | 787,184 | 23,464,268 |
| Current Practice | 27,387,517 | 4,162,381 | - | 23,225,136 |
| | 239,132 | | | |

Savings in 2016 (See Appendix 7, 8 & 9)

It may be argued that the savings in relation to total revenue is small. However it should be borne in mind that the calculation in potential savings described in this report is only in terms of savings for purchase of sharps containers.

Additional savings are possible if needle hubs are recycled. Historical data shows that the amount of waste increases each year, which would necessitate the upgrading of existing treatment facilities or installation of new facilities. Recycling can substantially reduce the amount of waste that needs to be incinerated or treated, which would in turn delay the need for expensive upgrades and new installations. The residue from incineration or other treatment options can be reduced as well, thus reducing final disposal costs. Thus, processing sharps with the *Sharps Terminator* has the potential for great financial savings when all aspects of waste management are considered.

This financial savings has the added bonus that the Concessionaire would be taking the path of "environmentally sound management of waste" which is an objective of both the Basel Convention and Agenda 21.

As described earlier the financial costs of sharps injuries can be extensive if all consequences are



considered. This added cost to the healthcare sector is an added cost to the taxpayer. In addition, there is the more difficult to quantify emotional and societal costs of such injuries. Hence any slight inconvenience resulting from work process change (that is required with the use of the *sharps terminator*), as expressed by some of the respondents of the HKL trial, is worth the effort if it will bring a positive impact on this pervasive problem.

Thus the *sharps terminator* should be considered as an added intervention strategy for sharps injury prevention and for the transformation of clinical waste management in Malaysia.



1. Introduction

Sharps injuries have been associated with occupational transmission of hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) as well as over 20 other pathogens. It is recognized as a major public health concern and continued efforts are therefore required to find a solution to minimize the risks of sharps injuries. This report provides an independent assessment of the *sharps terminator* as a possible solution to this problem and examines other possible benefits in utilizing this technology.

2. Background

2.1. Data on Sharps Injuries

A sharps injury is described by the US Centers for Disease Control and Prevention (CDC) as a penetrating stab wound from a needle, scalpel, or other sharp object that may result in exposure to blood or other body fluids. A needlestick injury more specifically addresses injuries caused by a needle. Estimates of sharps related injuries that have been reported by various organizations are as follows:

- a) The CDC estimates that about 385,000 sharps-related injuries occur annually among health care workers in hospitals in the US. This equates to an average of around 1,000 sharps injuries occurring per day in U.S. hospitals.
- b) The US Occupational Safety and Health Administration (OSHA) estimates 5.6 million workers in the U.S. healthcare industry are at risk of occupational exposure to bloodborne pathogens via needlestick injuries and other sharps-related injuries.
- c) The World Health Organization (WHO) reported in the World Health Report 2002 that of 35 million health-care workers, 2 million experience percutaneous exposure to infectious diseases each year. It further notes that 37.6% of Hepatitis B, 39% of Hepatitis C and 4.4% of HIV/AIDS in healthcare workers around the world are due to needlestick injuries.
- d) The American Nurses Association reports that studies have estimated that between 600,000 and 800,000 needlestick and other percutaneous injuries occur annually to health care workers when accounting for both hospitals and other health care settings, such as private clinics, home care operations and long-term care facilities.
- e) The Office of the Australian Safety and Compensation Council reports that one in nine nurses in Australia has had at least one needlestick injury over a 12 month period.

In summary, sharps injuries are a major concern in the healthcare setting. It is also acknowledged that the true magnitude of the problem is difficult to assess because of under- reporting. Surveys of healthcare personnel indicate that underreporting of sharps injuries range from 22 – 99%.



2.2. Economic Burden of Sharps Injuries

CDC estimates that direct costs for testing and follow-up treatment of healthcare personnel receiving a sharps injury can be up to USD 5,000 depending on the treatment provided.

Costs that are more difficult to quantify include the emotional cost associated with trauma, fear and anxiety from worrying about the possible consequences of an exposure. There is also the possibility of social stigma and impairment on family and social interactions, which may extend to family members of the injured as well.

Other costs include costs associated with drug toxicities and lost time from work, as well as the societal cost associated with an HIV or HCV seroconversion. The societal cost and impact include possible loss of a worker's services in patient care, the economic burden of medical care, and the cost of any associated litigation. The American Hospital Association (AHA) estimates that for a serious infection by a bloodborne pathogen, the costs can be up to USD 1 million if all of these are added up – testing, treatment, follow-up, lost time, and disability payments. The National Health Service of Scotland (NHSS) estimates that legal and compensation costs, loss of staff time and treatment could be about GBP 260,000.

2.3. Existing Preventive Measures

Sharps injuries were first described in the early 1980s and since then there have been many recommendations on prevention strategies, which include the following:

- a) Recommendations on avoidance of recapping through educational programs and use of puncture proof sharps disposal containers
- b) Incorporation of sharps prevention guidance into CDC's universal precautions (1987)
- c) Implementation of a hierarchy of controls, i.e. 1) elimination and reduction of sharps use,
 2) use of engineering controls, 3) work practice controls, and 4) use of personal protective equipment
- d) Development of standards and legislation.

In line with the CDC, the Ministry of Health in Malaysia also incorporated recommendations on handling of sharps, the use of sharps containers, and the use of retractable needles for high-risk patients in its 1995 Universal Infection Control Precautions. Incineration or interment was also recommended as disposal measures. However the use of sharps containers and incineration were not universally practiced until 1997 due to lack of facilities and funding.

With the privatization of the Clinical Waste Management Service (CWMS) in 1997, sharps containers became available at all healthcare facilities for the first time. The Concessionaires were also contractually required to install state-of-the-art incinerators for treatment of clinical waste and to provide dedicated porters equipped with PPE, dedicated collection and transportation trolleys, and dedicated vehicles, all of which facilitated safer handling of clinical waste.



The recommendations on handling of sharps and use of sharps containers were reiterated in the Ministry of Health's Standard Precautions, published in 2002. A manual on sharps injury surveillance was also published in 2007 by the Ministry of Health.

3. Challenges Faced in Prevention of Sharps Injuries

3.1. Literature Review on Effectiveness of Prevention Strategies

Although a systematic management of clinical waste and use of sharps containers are clearly a necessity to prevent sharps ending up in open dumpsites or landfills and exposing the general public and HCWs to sharps injuries, the impact of these measures on reduction of sharps injuries among HCWs is still being discussed. Most studies on efficacy of using sharps containers and education of healthcare personnel on the dangers of recapping, bending, and breaking used needles document limited success in preventing sharps injuries.

To complement the above measures, safety-designed sharp devices were developed. However, a systematic review conducted of 19 studies showed that there was very low quality, inconsistent evidence that safety-designed sharp devices prevent sharps injuries. In fact, there was some moderate quality evidence in 4 other studies that using safe IV devices increased the number of blood splashes when the user had to activate the safety mechanism. There have also been reports that safety mechanisms failed to trigger or were accidentally triggered. In one retrospective study ineffective safety mechanisms was found to contribute to 50% of injuries involving disposable syringes. Not only is there insufficient evidence to demonstrate that the use of safety-designed sharp devices is effective in reducing the number of sharps injuries, the use of such devices is also significantly more costly than conventional needles.

3.2. Prevalence of Sharps Injuries in Malaysia

Similarly, in Malaysia, various studies conducted show that the prevalence of sharps injuries remains high. This is despite the various prevention measures that have been put in place as described in section 2.3. See **Table 1**.

| Hospital | Period of Study | No of HCWs | Prevalence of sharps injuries |
|--|--------------------------------|------------|-------------------------------|
| Melaka General Hospital, Orthopaedic Department | February 2013 to March 2013 | 153 | 20.9% |
| Serdang Hospital | 2010 | 345 | 23.5% |
| Teaching hospital in Negeri Sembilan | May 2003 | 285 | 24.6% |
| A&E of 2 Teaching Hospitals | August to November 2003 | 136 | 31.6% and 52.9% |

| Table 1: Com | nilation of Stu | idies on Preva | elence of Shar | ns Iniurie | s in Malay | vsia |
|--------------|-----------------|-----------------|----------------|------------|--------------|------|
| Table I. Com | pliation of St | iules off Fleve | alence of Shar | ps injune: | 5 III IVIAIA | ysia |



In addition to the studies above, 2005 data obtained from the Ministry of Health, Malaysia (MOH) shows that the percentage of sharps injuries to total incidents was high. This is illustrated in **Chart 1**.



Chart 1: Percentage of Needlestick Injuries to Total Injuries Among MOH Personnel

Note: MOH data did not provide staff numbers nor incidence rate but only numbers of total injuries and injuries due to hollow-bore needles

In the Serdang Hospital study it was found that of the healthcare workers that had sustained sharps injuries, only 30.9% had officially reported the incident. Thus there is a gap between knowledge and practice among the HCWs. The other studies also acknowledged that under- reporting is an issue and therefore the exact magnitude of the problem is unknown. Suffice to say, sharps injuries continue to be a problem in Malaysia as with other countries despite the introduction of various preventive measures.

3.3. Cost of Sharps Containers

Puncture proof sharps container for the safe disposal of sharps is one of the engineering controls recommended and made mandatory through legislation in some countries. While not legislated in Malaysia, it is an integral component of the clinical waste management system and a healthcare facility's sharps injury prevention program. Notwithstanding the necessity for the use of such containers, it is nevertheless a cost to the healthcare sector.

Information obtained in 2011 shows that an estimated 1 million sharps containers were purchased by the Concessionaires, amounting to approximately RM 10 million. This was estimated to represent about 15% of the Concessionaires' revenue.



3.4. Health and Environmental Impact of Incineration

It is reported that 15 to 25 % of hospital waste in the US is made up of plastic. Although the percentage of plastic in hospital waste in Malaysia is unknown, it has been estimated that sharps waste (contents and sharps containers) represent more than 50% of clinical waste. Thus plastic is still a major component of waste in Malaysia.

Currently, incineration is the primary treatment and disposal method in Malaysia for contaminated plastic wastes such as hypodermic needles and syringes. While incineration is effective in destroying infectious agents, it nevertheless presents its own set of problems. Burning of plastics create emissions that contain toxic pollutants including dioxins and furans, which are carcinogenic. According to WHO, long-term low-level exposure of humans to dioxins and furans may lead to impairment of the immune system, and impaired development of the nervous system, the endocrine system and reproductive functions. Short-term high level exposure may result in skin lesions and altered liver function.

Incineration also produces carbon dioxide and nitrous oxide emission that contribute to climate change. U.S. regulatory agencies have found that incinerators are prone to various types of malfunctions, system failures and breakdowns, which routinely lead to serious air pollution control problems and increased emissions that are dangerous to public health. This is also true in Malaysia as there have been several incidents of incinerator failures and non-compliance with emission standards.

An impact study on modern European incinerators found that despite modern technologies incinerators are a major source of ultra-fine particulate emissions, which are more toxic that larger particles. Adverse health effects of particulate inhalation are not limited to lung injuries alone but include cardiovascular diseases and cancers. It is estimated that about 2 million deaths per year are attributed to inhalation of particles.

3.5. Sustainability

Based on data obtained in 2011, generation of clinical waste would soon exceed the combined incineration capacity of the Concessionaires' facilities. See **Chart 2**.

Several incidents of stockpiling of waste have in fact occurred due to incinerator breakdown, reduced efficiencies due to aging of the incinerators, and insufficient capacity. Installation of more incinerators or bigger incinerators would therefore be needed in order to cope with the amount of waste generated. This is a huge capital expense. There is also the high maintenance costs involved to ensure optimum efficiency.

While waste-to energy (WTE) plants may be considered, there is still a lot of debate on the benefits. According to the U.S. Energy Information Administration Annual Energy Outlook 2010, waste incinerator operations and maintenance costs are ten times greater than coal-fired power and four times greater than nuclear energy.





Chart 2: Waste Generation VS Concessionaires' Incineration Capacity

Note: 1) CW generation from 2003 – 2011 is actual data obtained in 2011; CW generation from 2012 onwards is extrapolated based on average percentage growth rate.

- 2) The incineration capacity is based on data obtained from the Concessionaires in 2011. A downtime of 15% was factored in for preventive and breakdown maintenance
- 3) The incineration capacity in this chart does not include additional capacities that have since been made available by other licensed treatment facilities such as Kualiti Alam Sdn Bhd etc.

Apart from the cost factor of installing new incinerators, there is also the problem of finding suitable locations for new incinerator plants. This is a problem that the Concessionaires faced, which in part contributed to the delay in providing the much needed additional incineration capacity for treatment of clinical waste. Even if other treatment technologies such as microwave or steam sterilization are being considered, the fact remains that more treatment facilities are required. And, the residue from such treatment systems would still need to be disposed.

4. The *Sharps Terminator*® – a Possible Solution

While legislation, implementation of standards, use of puncture-proof sharps containers, safety designed sharp devices and other measures remain important as components of a sharps injury prevention program, it is undeniable that despite these measures sharps injuries continue to be a pervasive problem for healthcare workers throughout the world including Malaysia. Thus, it is clear that additional interventions are needed.

The CDC estimates that between 62 percent and 88 percent of sharps injuries can be prevented by using engineering controls. Since existing engineering controls have had only a modest impact on reducing sharps injuries, the *sharps terminator* could be an additional intervention that would help a healthcare establishment in reducing sharps injuries.



4.1. Description of Sharps Terminator



The *sharps terminator* is a device used to disable and completely remove the metal needle from hypodermic syringes. It operates via a single-step, single-handed process that is extremely simple to use.

Once the needle is withdrawn from the patient, the healthcare worker simply inserts the needle into the *sharps terminator* and holds it for 3 seconds. As the needle body completes a circuit between two angled copper electrodes, resistance from the needle creates sufficient heat to destroy the metal portion of the needle from the tip to the hub. The *sharps terminator* then cuts the plastic "hub" above the needle so that no

metal is left on the syringe. See **Picture 1**. Finally, the debris from the needle falls into a collection tube at the base of the device where it is exposed to UV light to eliminate contaminants. See **Picture 2**.

Picture 1: A Hypodermic Needle Before and After Processed by the Sharps Terminator



Before processing:
 A – hypodermic needle

 After processing two main categories of remain are left:
 B – Needle hub
 C – Example of swarf

Picture 2: Sharps Terminator





A pictorial illustration of how the *sharps terminator* works is shown in **Appendix 1-1** and a step- bystep guide on how to use and maintain the *sharps terminator* is shown in **Appendix 1-2**. The full manual with information about warranty is shown in **Appendix 1-3**. Please click on this link to view a video on how the sharps terminator works:

https://www.facebook.com/TheSharpsTerminator/videos/103663466449665/

4.2. Safety features of Sharps Terminator

The sharps terminator will neither work nor charge if the collection tube is not securely in place. Various indicators lights have also been incorporated into the design of the *sharps terminator* to ensure correct and safe operation of the device. This is illustrated in **Picture 3**.



Picture 3: Control and Indicators

| Controls and Indicators | Function |
|-------------------------|---|
| On/off switch | To activate or switch off device |
| Blue power light | To indicate when device is ready to use and when the next needle can be inserted after each destruction activity. This light will flash 3 times after 25 needles have been burned, indicating that the collection tube is almost full and needs to be emptied. |
| Red battery light | Charging in progress, device not operational |
| Yellow battery light | Charging in progress, device operational |
| Green battery light | Charging complete |
| White UV light | UV lamp is active |

4.3. Effectiveness of Sharps Terminator

A clinical study was conducted in the United States based on the FDA Guidance Document titled "Premarket Approval Applications (PMA) for Sharps Needles Destruction Devices: Final Guidance for Industry and FDA March 2, 2001". The study involved 6 medical facilities and 720 assorted combination of needles with the following criteria:

a) Destruction of the needle body to a blunt "stub" of 1/16 inch or less in length (Rating 1 or 3 on Destruction Scale) for 95% of all tested needles.



b) No complications or adverse event rates are observed that appear to be associated with inferior performance of the investigational device as demonstrated by device related SAE's (serious adverse event) or UADE's (Unanticipated Adverse Device Effect).

The study found that the *sharps terminator* performed well above the established criteria above. For more information on the study, please refer to **Appendix 2**.

A trial run was also conducted in Wards 18A and 24 at Hospital Kuala Lumpur (HKL) from December 16, 2014 to April 30, 2015. Hypodermic needles tested ranged from 5 cc to 30 cc. The findings from the 4 $\frac{1}{2}$ month study, involving 40 respondents were as follows:

- a) 89.2 % (N=33) felt that the *sharps terminator* was easy to use. Three (3) did not provide feedback.
- b) Of those that said that the sharps terminator was easy to use, 24.3% (N=9) expressed an opinion that its use could be inconvenient. Most of these respondents commented about the 3 second time needed to destroy the needle. (*This is quite normal as new technologies and changes to work process will always result in some initial resistance as was the case when sharps containers were first introduced.*)
- c) 87.5% (N=35) felt more comfortable knowing that the needle had been removed with the *sharps terminator.*
- d) 92.3% (N=36) expressed satisfaction that the device performed as expected. One respondent did not provide feedback.
- e) 92.5% (N=37) of respondents felt that removing and destroying the needle using the *sharps terminator* was a safer solution than using safety-designed sharp devices
- f) There were zero needlestick injuries during the trial run.
- g) Respondents informed that the capacity of the sharps container was effectively increased as the remaining needle hub tended to lay flat within the container. The estimated increase in capacity ranged from 25 to 50% with an average of 34.05%.

During the preparation of this report a discussion was held with one of the Matron and Sisters of one of the wards and it was confirmed that the trial run was indeed conducted and that the *sharps terminator* is an easy device to use and is useful in preventing sharps injuries.

Although the Matron and Sister were not in a position to provide data on needlestick injuries, they nevertheless acknowledged that there had been incidents prior to the trial run but that there were none during the trial run. Hence, this is indicative of two things, i.e. 1) the *sharps terminator* is an effective sharps injury prevention strategy, and 2) the change in work process required with the use of the *sharps terminator* did not result in any adverse events.

Both of them also expressed their eagerness for the device to be introduced for use on a permanent basis.



4.4. Certification and Awards

- a) In the 2012 Emergency Medical Services (EMS) Convention, the *sharps terminator* was featured as one of the hot products of the year.
- b) A declaration of conformity with EU Directives has been made for the *sharps terminator*.
- c) The premarket approval application (PMA) to FDA has been approved.

See Appendix 3.

4.5. Comparison of *Sharps Terminator* with Other Needle Destruction Devices

Although other needle destruction devices have been developed, the advantages of the *sharps terminator* over other devices are as follows:

- a) The sharps terminator is designed for clinical use and not just for the home setting.
- b) It is easy to operate single-handed and single-step process. Two alternative brands require a two handed operation i.e., one hand to hold needle and device down while the other hand to pull a lever to cut the hub. One brand also requires the user to maneuver the syringe and needle within the machine.
- c) There is no sparking with the sharps terminator and it is therefore safe to use. Two alternative brands produce sparks.
- **d)** The sharps terminator uses UV light to decontaminate the swarf in the collection tube. Alternative brands do not have this feature.

Most other brands are also no longer available in the market due to their design deficiencies.

5. Benefits of Using the Sharps Terminator

5.1. Sharps Injury Prevention

It is estimated that 40 - 55% of injuries occur after use and before disposal of sharp devices as well as during and after disposal, and that hollow-bore needles alone account for more than 50% of all sharps injuries. This is illustrated in **Charts 3 – 6**, which depict data obtained from two surveillance studies in the US.





Chart 3: Occurrence of Sharps Injuries (NaSH)





Chart 4: Occurrence of Sharps Injuries (EPINet)

Note: EPINet is a product of the International Health Care Worker Safety Center and the University of Virginia Health System. This system was developed in 1991 and collects blood exposure information from approximately 70 hospitals.











Note: 2010 findings from the Massachusetts Sharps Injury Surveillance System demonstrate a similar pattern of injuries by type of devices as those reported by NaSH and EPINet.

Since the Sharps Terminator is a point-of-use device, its use has the potential of eliminating or significantly reducing disposal related sharps injuries.

Among all sharps, injuries by hollow-bore needles are of particular concern. Of the 57 documented cases of occupational HIV transmission to healthcare personnel reported to CDC from June 1995 to December 2002, most of these were caused by hollow bore needles. The use



of the *sharps terminator* to destroy hypodermic needles can also significantly reduce the risk of injury by hollow bore needles and the risk of HIV transmission.

Another cause of concern is the reuse of needles. It is a significant cause of infection throughout the world. WHO estimates that annually 21 million hepatitis B infections, 2 million hepatitis C infections and 260 000 HIV/AIDS cases may be caused by re-use of syringes and needles without sterilization. In 2002 WHO estimates that 5% of new HIV infections in developing and transitional countries may be attributable to unsafe health care injections (This estimate varies according to regions, with higher figures for Asia). Thus in addition to reducing sharps injuries, opportunities for reuse of needles are eliminated as the needle is rendered non-functional after processing with the *sharps terminator*.

5.2. Environmental Protection and Sustainability

Minimizing wastes, maximizing environmentally sound waste reuse and recycling, and promoting environmentally sound waste disposal and treatment are three of the focus areas for environmentally sound management of solid wastes. Processing of needles by the *sharps terminator* would assist the Concessionaire towards achieving these objectives through the following ways:

a) The capacity of the sharps container is effectively increased. A schematic illustration is shown in **Picture 4**.



Picture 4: Schematic Illustration of Sharps Container and Contents

b) With the effective capacity of the sharps container increased, the number of sharps containers entering the waste management stream can be reduced. This would in turn reduce burning of plastic, which would reduce the amount of toxic and greenhouse gas emissions.



c) There is also the potential for the needle hub to be recycled. Recycling plastics reduces the amount of energy and natural resources (such as water and petroleum) needed to create virgin plastic. Thus, judicial and sustainable use of resources can be promoted.

5.3. Financial Savings

There is the potential for savings in terms of sharps container costs for the Concessionaires. An illustration of this is made in this section by using data for Faber's northern zone of operations, which comprise the states of Pulau Pinang, Kedah, Perak and Perlis.

As current data and other data that are required for this analysis are not available, extrapolations and estimates had to be made based on data obtained in 2011. This, including additional data and assumptions that had to be made for this analysis is show in **Table 2**.

| Description of data | Data obtained and used in analysis | Source |
|--|---------------------------------------|---|
| Waste generated in 2011 in Faber northern zone | 3,058,183 kg | Obtained from the CMIS (see Appendix 4 for more details on waste generation) |
| Average growth rate in Faber Northern zone | 11.49% | Calculated from waste generation figures of preceding years (Appendix 4) |
| Estimated numbers and cost of sharps containers in 2011 in Faber Northern zone | ~ 234,966 units = RM 2,416,885 | Calculated based on figures provided by manufacturer and then apportioned to waste generation in the Concessionaire's zone of operations (see Appendix 5 for more details on sharps container numbers and cost) |
| Average weight of sharps containers | 0.54568 kg | Calculated based on figures provided by manufacturer (see Appendix 6) |
| Average cost of sharps container | RM 10.29 | Calculated based on figures provided by manufacturer (see Appendix 5) |
| Proportion of sharps waste (waste container plus contents) to total clinical waste | 50% | Literature and information from a former clinical waste incinerator manager gives an estimate of >50% |
| Increase in effective capacity of sharps container | 34% | Based on feedback from HKL trial |
| Weight of sharps waste content after processing with the <i>sharps terminator</i> | No change | Although volume is reduced, the weight would remain relatively the same as the needle hub and swarf remains after processing |
| Cost of sharps terminator | USD 900 | Sharps Terminator (M) Sdn Bhd |
| Lifespan of sharps terminator | 2 years | Sharps Terminator (M) Sdn Bhd |
| Number of <i>sharps terminator</i> required | 1 device for every 2 SCs/day | An estimate after discussion with Sharps Terminator (M) Sdn Bhd |
| Maintenance cost of <i>sharps</i> terminator | 10% per device per annum | An estimate after discussion with Sharps Terminator (M) Sdn Bhd |

Table 2: Data used as Basis for Analysis



Based on the figures above, the reduction in number of sharps containers required, clinical waste generation, and savings in 2016 for Faber's Northern zone of operations are as follows:

Reductions (See Appendix 7 & 8)

| Reduction in number of sharps containers (See App 7) | 137,787 | units |
|--|-----------|-------|
| Reduction in cost of sharps containers (See App 7) | 1,417,291 | RM |
| Reduction in waste generation (See App 8) | 75,187 | kg |

Cost of *Sharps Terminators* (See Appendix 9)

| Estimated numbers of sharps terminators required | 366 | units |
|---|---------|-------|
| Estimated annual costs of <i>sharps terminators</i> (amortised capital cost + maintenance cost) | 787,184 | RM |

Revenues (See Appendix 8)

| Estimated revenue based on current practice (See App 8) | 27,387,517 | RM |
|---|------------|----|
| Estimated revenue with use of <i>sharps terminators</i> (See App 8) | 26,996,542 | RM |
| Loss in revenue | 390,975 | RM |

Savings in 2016 (See Appendix 7, 8 & 9)

| 2016 | Revenue (RM) | Cost of SCs (RM) | Cost of Terminator (RM) | Balance (RM) |
|------------------|--------------|---------------------|----------------------------|--------------|
| | а | b | с | a-b-c |
| Using Terminator | 26,996,542 | 2,745,090 | 787,184 | 23,464,268 |
| Current Practice | 27,387,517 | 4,162,381 | - | 23,225,136 |
| | 239,132 | | | |

Potential Savings until 2020 are shown below:

| Year | 2016 | 2017 | 2018 | 2019 | 2020 |
|-------------------|---------|---------|---------|---------|---------|
| Potential Savings | 239,132 | 266,597 | 297,216 | 331,352 | 369,408 |

6. Conclusion

It may be argued that the savings in relation to total revenue is small. However, it should be borne in mind that the calculation in potential savings described in this report is only in terms of savings for purchase of sharps containers.

Additional savings are possible if needle hubs are recycled. Historical data shows that the amount of waste increases each year, which would necessitate the upgrading of existing treatment



facilities or installation of new facilities. Recycling can substantially reduce the amount of waste that needs to be incinerated or treated, which would delay the need for expensive upgrades and new installations. The residue from incineration or other treatment options can be reduced as well, thus reducing final disposal costs. Thus, processing sharps with the *Sharps Terminator* has the potential for great financial savings when all aspects of waste management are considered.

These financial savings have the added bonus that the Concessionaires would be taking the path of "environmentally sound management of waste" which is an objective of both the Basel Convention and Agenda 21.

The greatest benefit would be the potential to reduce sharps injuries: by as much as 55% in terms of disposal related injuries and 50% in terms of hollow-bore needle injuries. As described earlier the financial costs of these injuries can be extensive if all consequences are considered. This added cost to the healthcare sector is an added cost to the taxpayer. In addition, there is the more difficult to quantify emotional and societal costs of such injuries. Hence any slight inconvenience resulting from work process change (that is required with the use of the *sharps terminator*), as expressed by some of the respondents of the HKL trial, is worth the effort if it will bring a positive impact on this pervasive problem.

Thus, the Sharps Terminator should be considered as an added intervention strategy for sharps injury prevention and for the transformation of clinical waste management in Malaysia.





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