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Preventing Needle Stick Injuries and the Use of Dental Safety Syringes

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EXECUTIVE SUMMARY:

Preventing Needle Stick Injuries and the Use of Dental Safety Syringes:

Part one of the study consists of an extensive literature review, undertaken to investigate the risks and nature of percutaneous, and in particular needle stick injuries in dentistry. It is shown and well documented that percutaneous injuries, and especially accidental needle sticks, pose a risk of transmission of blood borne pathogens to health care personnel. Recognizing that prevention of needle stick injuries in the workplace is a priority, many regulating bodies in Canada and the US have established guidelines, regulations and standards aimed at reducing the risk of such injuries. These guidelines are broadly directed to all health care personnel, however, there are unique aspects in the use of needles in a dental office setting (dental model) that create a unique situation, differentiating it from other health care settings (medical model).

In the dental model, local anesthetic is administered using a sterilizable aspirating anesthetic syringe with disposable, pre-proportioned anesthetic cartridges and delivered using single use sterile narrow-bore needles. Local anesthetic, delivered interstitially to multiple sites using more than one cartridge is fairly unique to and is common in the practice of dentistry. It is also important that on injection the needle resists deflection as it meets tissue resistance in its course to the target nerve, which could be as much as 10-15 mm deep into the oral tissues. In addition, sheathing and re-sheathing of needles and administering multiple injections over the time of a particular dental procedure routinely occurs. This is distinctly different from the medical model, wherein larger bore needles are often used for single use and single site intravascular injections or for withdrawal of blood that potentially subjects the health care worker to exposure to larger volumes of blood, and thus a higher risk of contracting a blood borne disease.

Although, as shown in the literature, the risk of a **dental** healthcare provider contracting a blood borne disease through needle stick injury is significantly less than with other healthcare providers, this study determines that a better surveillance system for tracking and documenting needle stick injuries to dental healthcare providers should be implemented to gather further information as to the incidence and the nature of dental needle stick injuries.

The introduction and use of the so-called **“safety engineered needles”** in the health care model setting has the potential to reduce the transmission of blood borne disease to health care workers. The practice of needle capping and recapping during local anesthetic delivery in dentistry can potentially increase the risk of an inadvertent needle stick injury, but requirements for a specifically

engineered syringe and needle apparatus have presented challenges in the design and therefore implementation of safety engineered syringes in dentistry.

In the second part of the study, a dental safety syringe recently made available in Canada was tested at The University of British Columbia, Faculty of Dentistry. Pre-clinical assessments were made by a variety of novice and experienced practitioners who typically use conventional dental anesthetic syringes. Concerns were expressed with this new syringe design in terms of patient and operator safety. Certain characteristics of the syringe were also tested in the Faculty's Biomaterials laboratory.

Significant findings included:

1) Instability of the needle apparatus and its' ease of separation from the syringe handle while engaging the safety feature. (Patient and operator safety)
2) Potential of deflection, due to increased lumen size, of the needle upon and during injection. (Patient safety)
3) False negative visualization on aspiration. (Patient safety)
4) Failure to clearly tell if safety feature is fully engaged thus increasing chance of injury. (Operator safety)

In addition, technical problems associated with the use of the test syringe were encountered:

1) Required more physical manipulation to load and retrieve cartridge than conventional syringe.
2) Increased learning curve for use vs. conventional syringe
3) Safety device requires conscious physical manipulation – no automatic re-sheathing capability of the device.

In light of these expressed concerns during pre-clinical testing, it was determined that while the safety engineered syringe can be considered as an option for use, additional design modifications are required prior to recommending universal use of the apparatus, and by strictly adhering to the following **existing engineering and workplace controls** that are designed to minimize risk of needle stick injuries would help minimize the risk of such injuries in the interim:

a. Placing used disposable syringes and needles, scalpel blades and other sharp items in appropriate puncture-resistant containers located as close as feasible to the area in which the items are used.
b. Not recapping used needles by using both hands or any other technique that involves directing the point of a needle toward any part of the body. Not bending, breaking or removing needles before disposal.

c. Using either a one-handed scoop technique or a mechanical device designed for holding the needle cap when recapping needles (e.g. between multiple injections and before removing from a non-disposable aspirating syringe).
d. Using a mouth mirror to retract cheeks and oral tissues during local anaesthetic administration.

Finally, recommendations and a template are provided to help in developing a process that could accurately track accidental needle stick injuries, their frequency and types to help further investigations into and hopefully solutions to improving accidental needle stick injuries in dentistry.

Preventing Needle Stick Injuries and the Use of Dental Safety Syringes

STUDY OBJECTIVES

A. To complete a literature based review of the risks of disease transmission as a result of a needle stick injury to health care workers (HCWs), and specifically as it pertains to dental health care providers (DHCPs).

B. To review current regulations in Canada and the US that are in place to help protect and reduce the risk of percutaneous injuries, and in particular, needle stick injuries to DHCPs.

C. To propose methods to reduce needle stick injury risk through education and implementation of administrative, workplace and engineering controls*.

D. To examine and evaluate the use of a recently developed safety engineered syringe.

E. To propose an injury reporting template that documents percutaneous injuries (including needle stick injuries) for implementation in dentistry.

*__Engineering controls__ isolate or remove the blood-borne pathogen hazard from the workplace. __Work practice controls__ reduce the likelihood of exposure by altering the manner in which a task is performed. __Administrative controls__ include education, training, and application of Standard Operating Procedures for preventing occupational exposure to blood and other potentially infectious fluids. (www.osap.org)

A) Review of the Literature

BLOOD BORNE PATHOGENS: DISEASES, TRANSMISSION AND RISKS:

The following are the most prevalent blood borne diseases and associated risk figures for health care workers (HCWs) percutaneous exposures, including transmissions by needle sticks[1].

Hepatitis B Virus: A 6-30% transmission rate to HCWs has been reported, and transmission is dependant upon the carrier state of the source patient. Transmission of HBV is a well recognized occupational risk for HCWs, and the best prevention mechanism is administering HBV vaccination early in the health care professionals' career.

Hepatitis C Virus: A 1.8% transmission rate to HCWs is reported. Hepatitis C infection is insidious, mild and slow to progress, and can be asymptomatic for the first 20 years of infection. From one study it appears that needle sticks is the only occupational potential risk factor for transmission of HCV in HCWs, but it appears that the HCV is not transmitted efficiently through occupational exposures to blood. Few seroconversions in dental health care providers (DHCPs) following a needle stick exposure have been identified, and thus the risk of such is limited. In a study published 2006, there were three reported seroconversions of dental professionals who were exposed to HCV. However, the nature of the exposures was not disclosed in the study[2].

HIV – Epidemiologic studies have shown that the risk of transmission of HIV to HCWs from HIV infected patients is approximately 0.3% following a needle stick exposure[3.] With percutaneous injuries to DHCPs, including hospital based dental healthcare workers where exposure is to relatively small volumes of blood, the risk of transmission to DHCP is extremely low. No DHCPs have seroconverted following an occupational exposure of HIV from a known source patient[4].

It is clearly evident that there is a risk, both real and theoretical, of dental healthcare providers acquiring a blood borne disease through needle stick exposures. It is important now to quantify and evaluate these risks, and to examine and propose ways to minimize these risks.

THE NATURE of PERCUTANOUS INJURIES

It is widely known and well documented that percutaneous injuries (punctures through the skin), included in which are accidental needle sticks, pose a risk of transmission of blood borne pathogens to health care workers, and pertinent to this study, dental health care providers (DHCPs). It has been estimated that about half of needle stick injuries to DHCPs could be preventable[5].

As a strategic method of risk reduction to all HCWs, "Standard Precautions"** have been introduced to help decrease the potential frequency of such an occupational hazard occurring. With the observance in the past decade of a likely decrease in percutaneous injuries[6] it is believed that this and other strategies indeed have had a positive effect on risk reduction. Notwithstanding the best of these efforts, injuries do occur.

In all health care settings, risk factors in disease transmission of a blood borne pathogen (specifically HIV, HBV and HCV) are assessed by "direction of transmission" – the possibility of transmission being either patient to HCW or vice-versa.

A WorkSafeBC publication[7] reports that "the greatest risk of blood borne pathogen for workers (is) caused by conventional hollow-bore intravascular needles", and that "a person contract(ed) a disease from an infected person involved hollow-bore used to draw blood, which are intravascular hollow bore needles".

According to an article published by the American Association of Occupational Health Nurses[8] the greatest risk of transmission of a blood borne pathogen is to the HCW. In order for there to be the risk of disease transmission of a blood borne pathogen from a needle stick injury, the following "Conditions for Transmission" are most critical:

Risk - - that the needle stick injury is associated with an infected patient.

Determinants -
- deep injury to the HCW.
- visible bloody contamination of needle.
- arterio-venous needle used which holds a substantive amount of inoculum.
- status of patient – the microbiological load in the patient's blood must be high. (In the case of HIV transmission, the source patient was typically terminally ill and died less than 2 months after the date of the HCWs exposure).
- risk of seroconversion – no vaccination (as with HBV) of exposed person.

In brief, the risk of infection, and in particular HIV, after exposure is influenced by the type and amount of inoculum, route of exposure and susceptibility of the

**Standard precautions refer to preventive practices used to reduce blood exposures, particularly percutaneous exposures, include 1) careful handling of sharp instruments, 2) use of rubber dams to minimize blood spattering; 3) hand washing; and 4) use of protective barriers (e.g., gloves, masks, protective eyewear, and gowns) - CDC MMWR2003

exposed DHCP[9]. Some valuable needle stick injuries studies exist regarding these injuries to hospital healthcare workers. The term “Health Care Worker” encompasses a huge catchment group (including dental healthcare workers) and covers many different procedures and types of needles being used[10].

Generally, transmissions have occurred in the hospital setting in instances where the procedure was in accessing a vein to withdraw blood from an infected donor via a large hollow bore needle.

INJURIES IN THE DENTAL ENVIRONMENT

In late 2003, the CDC in the US published *Guidelines for Infection Control in Dental Healthcare Settings,*[11] an extensive review and summary of more than 500 relevant papers and makes policy recommendations (Appendix I) that are based upon the results of this review that are aimed specifically at the healthcare ‘subset’ that encompasses dental healthcare providers (DHCPs). While there is the risk of transmission from an infected patient to health care providers of blood-borne pathogens such as the hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) through occupational exposure via needle-stick injuries, in the dental workplace where interstitial, rather than intravascular needles are used, the CDC report shows that the risk of disease transmission through needle-stick injuries to dental healthcare providers is extremely low. That notwithstanding, while the risk of transmission of HBV, HCV and HIV to DHCPs is low, the consequences can be serious.

Percutaneous injuries pose the single greatest risk of transmission of a blood borne infection to a dental healthcare worker in the oral health setting. Such exposures in the dental setting result from injuries caused by contaminated needles, burs, scalpels, broken glass, exposed ends of dental wires, or other sharps that penetrate or break skin[12].

One study, conducted by Siew et al,[13] investigated how, when and where percutaneous injuries in dentistry occur. It was found that 82 % occur extra orally, and most of these are caused by inadvertent contact with burs (37%) followed by sharp instruments (32%) and needles (7 - 17%). Intraoral injuries, which can be considered non-preventable, were most frequently caused by syringe needles (32%) The study is also predictive of a very low likelihood of disease transmission in dentistry (specifically HIV)[14].

When investigating needle stick injuries in dentistry, it is important to recognize that dental syringes are somewhat unique in their use - multiple injections are often employed, used in conjunction with one or more anesthetic cartridges that when spent are replaced for use in an immediately subsequent injection, or are uncapped and recapped during a patient visit. While there is no doubt that there

is the risk of needle stick injury and blood borne pathogen transmission to a DHCP using traditional dental aspirating syringes, it is nonetheless important to differentiate between the application and use of these syringes used to deliver dental local anesthetic through a very narrow bore needle and thus dissimilar to conventional medical hollow-bore needles used intravascularly that have been implicated in the transmission of blood borne diseases to other health care workers.

PERCUTANEOUS AND NEEDLE STICK INJURY REPORTING

Frequency and types of percutaneous injuries in Dentistry

Studies have been published pertaining to percutaneous injuries to DHCPs, but there is limited standardization as to the frequency and types of such occurrences. A needle stick exposure is considered to be a specific type of percutaneous accident. It is found that there are a variety of reporting methods of the frequency of percutaneous as well as needle stick exposures in the dental setting that are seen in the literature that refer to and include:

a) Percutaneous injuries in dentistry:

Studies show that percutaneous injuries can occur from 1.3 - 9 times per 10,000 patient visits[15,16]. Another report showed that percutaneous injuries occurred every 1.2/1000 dental procedures[17]. Yet another way of expressing rates of injury includes the rate of percutaneous injuries annualized to be 3.36 injuries per dentist per year[18].

In a study of one particular sub-group of DHCPs, percutaneous injuries in dental residents most frequently occurred during impression procedures, when using knives or scalpel blades as is typically done in denture making.[19]

b) Needle stick injuries in Dentistry

Of percutaneous injuries, from 27-33% can be due to needle sticks[20,21]. However, in one prospective study, following 362 procedures involving oral surgery there were 4 percutaneous exposures, none by needle stick[22]. Injury rates have also been expressed as 0.06 needlesticks/1000 procedures[23].

In one study, it was shown that 7% of all DHCP percutaneous exposures are due to needle recapping[24]. In another study,[25] Canadian dentists were surveyed and it was found that dental burs were the most frequent causes of percutaneous injuries. It also found that those who did not use puncture proof sharps disposal containers had a higher incidence of percutaneous injuries.

In general, published reports of percutaneous injuries which specifically refer to needle stick injuries in dentistry are relatively rare. In two studies, it was found that the most frequently associated percutaneous injury is due in fact to accidental contact with the dental bur rather than needle sticks. It was also noted that injuries occur regardless of age, experience or skill[26].

Bur punctures are seen as causing the most percutaneous injuries[27]. The risk of disease transmission due to percutaneous injury in dentistry (including needle sticks) will never be zero, but it will be immeasurably small.

Occupational percutaneous injuries (and thus by extrapolation needle stick injuries) have been decreasing in the current decade[28]. The decrease could be attributed to the adoption of universal, and later standard precautions, implementation of workplace and engineering controls, increased general awareness of the potential of blood borne pathogen disease transmission and information campaigns by OSHA and the CDC in the US and WorkSafeBC locally.

According to the Canadian Centre for Occupational Health and Safety, and the Canadian Needle Stick Surveillance Network, between April 1 2000 to March 31, 2001 there were no reported exposures to dentists or hygienists[29]. While this statistic seems to be encouraging, it does not seem to correspond to most other data concerning the frequency of needle stick injuries to DHCPs. It likely does demonstrate the need for a reliable needle stick reporting system.

Needle Sick Injuries: Under-reporting?

By extrapolation from the available data, notwithstanding the apparent duty in many jurisdictions to report needle stick injuries, it would appear that the reporting of such injuries is much lower than the true occurrence of such exposures.

In a retrospective survey, 53% of DHCPs in an Armed Forces Hospital did not report a percutaneous injury, even though it was their obligation to do so.[30] Under-reporting also is found in dental schools,[31,32] and was expressed as much as 66% of actual total number of exposures in dental school[33].

Under reporting of percutaneous, and in particular needle stick injuries is suspected of occurring nearly 80% of the time, and could be due to the perception that the exposed person believes it carries a low risk[34]. That figure was calculated to be 77% of those who did not report a needle stick injury - the major reason cited is because it also was believed it carried low risk. In another study, while 66.5% of dentists had experienced a needle stick injury in a preceding year, 78% did not report it. One reason given for this was that the dentist was unaware of the possible risk associated with the injury[35].

As well, an influencing factor in the reliability of injury reporting and the frequency of needle stick exposures is that in retrospective studies, recall bias is a limitation.[36]

Other possibilities of non-reporting could be due to

- embarrassment of situation.
- 'red tape' involved in reporting.
- confidentiality concerns.

The International Healthcare Worker Safety Center at the University of Virginia in the U.S. has established the EPINet Needle Stick and Sharps Injury Surveillance Network. There were over 75 participating hospitals that regularly submitted data on percutaneous injuries to health care workers at these hospitals. In the EPINet Sharps Injury Data Report from 2000 to 2006, of the hospitals contributing data, of 10,117 reported total injuries, there were only 23 reports of sharps injuries to dentists and dental hygienists[37]. However, for a more 'global' assessment of injury frequency, the Centers for Disease Control and Prevention estimates that U.S. healthcare workers sustain an estimated 384,000 needle stick injuries each year[38].

As noted in the discussion above, studies and statistics can be found regarding percutaneous injuries in general, which can include needle sticks, but also includes other types of injuries (scalpel blades, surgically placed wires etc,) to all types of health care workers (physicians, nurses, laboratory technologists, etc.). It is much more difficult to determine which reports of percutaneous injuries pertain to DHCPs in particular, and of those injuries (due to needle sticks, dental burs, orthodontic or surgical wire, scalpel blades, suture needles, scalers and curettes), how many are due to needle sticks.

NEEDLE STICK INJURIES: NEED FOR A CANADIAN REPORTING MECHANISM

There clearly exists the need for "real time," possibly web-based reporting system for Canadian DHCPs and that it be seen as non-threatening, anonymous and DHCW supported/administrated.

To go a step farther, it would be advantageous to have a report designed to enable a determination as to what number of needle stick injuries could have ostensibly been prevented, recognizing that some injuries, such as those due to sudden patient movement during injection cannot realistically be prevented. Finally it would be worthwhile to determine which of those needle stick injuries occurred to dentists, dental assistants, dental hygienists or other office staff.

In summary, it is important to first identify the subgroup of DHCPs from all HCW percutaneous injuries, and then break out accidental needle sticks from other percutaneous exposures. There appears to be a need for clarity and

standardization in reporting as to the frequency and type of needle stick injuries occurring to DHCPs.

A suggested reporting template can be found attached as “Appendix ll”.

ASPIRATING ANESTHETIC SYRINGES

As mentioned earlier, the use of sterilizable aspirating anesthetic syringes (Fig.1), along with the use of disposable, pre-proportioned anesthetic cartridges and pre-sterilized disposable needles is somewhat unique to and certainly common in the practice of dentistry. As well, sheathing and re-sheathing of needles and administering multiple injections using one or more cartridges, often over the time of a particular dental procedure has been routine in dentistry. This practice can potentially increase the risk of an inadvertent needle stick injury, but has presented challenges in the design and implementation of safety engineered syringes in dentistry (to be discussed in a following section), which are thought to have the potential to decrease preventable needle sticks.

There is then the need to further differentiate the ‘medical model’ (higher risk of blood borne disease transmission with intravascular applications) from the ‘dental model’ (lower risk of disease transmission due to interstitial injections with narrow bore needles) when investigating needle stick injuries and associated risks. Not only are the bore sizes of the needles (large vs. small) and the target area (intravascular vs. intrastitial) different, but the mechanism of use (single use/patient procedure vs. multiple use/patient procedure) and, in dentistry, the use of medication contained in cartridges (carpules) present different types of challenges.

Figure 1: A Conventional Dental Anesthetic Syringe Assembly

Needle stick – type percutaneous injuries in dentistry occur a) during the procedure of administering local anesthetic (i.e. procedural), b) during recapping of the needle or c) following inadvertent handling of an unprotected needle (passing of an unsheathed needle to an assistant or during disassembling of the needle from the syringe during clean-up and disposal).

Procedural injuries can be usually classified as either non-preventable or preventable. In the former case the needle is unsheathed, exposed and poised extra orally to deliver or immediately upon delivery of the local anesthetic. Sudden patient movement can cause an accidental needle stick to the operator[39]. In the latter case, some procedural injuries that occur can be operator self-inflicted injuries, as digital retraction and manipulation of the oral structures are usually needed to gain access to the site of injection, where accidental puncture can occur on either injection or withdrawal. The use of a mirror to retract the cheek after digital palpation of the injection site is recommended to avoid injury[40].

The administration of local anesthetic in dentistry often times requires that a second cartridge is immediately used. The procedure for reloading anesthetic cartridges involves removing the spent cartridge and replacing it with a new one. This often times occurs immediately following the initial injection, where the needle is typically unsheathed. One method suggests that at this time the entire needle is removed and replaced to avoid bending of the needle at the hub with the insertion of a new cartridge[41].

During the cartridge reloading procedure, re-sheathing of the exposed needle may or may not be done. The operator's hands typically remain distal to the exposed needle, which will reduce the risk of a needle stick injury during this procedure.

An analysis was undertaken of the needle stick injury report data at UBC clinic from 2001 to the present (Dec. 2009). Of 21 needle stick injuries reported, 12 were non-preventable procedural – upon injection or removal – while 9 were incurred on capping and recapping.

CURRENT NEEDLE STICK PREVENTION STRATEGIES

Engineering controls

Engineering controls are the primary method to reduce exposures to blood and other potentially infectious material (OPIM) such as saliva present on sharp instruments and needles. Engineering controls – controls that isolate or remove a worker from a hazard - can be practiced and include using puncture and leak proof sharps disposal containers at chairside,[42] and having the operator remove all sharps and place them directly in chair side disposal container[43]. Engineering controls are also frequently technology-based and often incorporate safer designs of instruments and devices (e.g., self-sheathing anesthetic needles)[44].

Safer versions of sharp devices used in hospital settings have become available (e.g., blunt suture needles, phlebotomy devices, and butterfly needles), and their

impact on reducing needle stick injuries has been documented. Aspirating anesthetic syringes that incorporate safety features have been developed for dental procedures, but the lack of accurate reporting of injury and transmission rates in dentistry limit assessment of their effect on reducing injuries among DHCPs[45].

In one hospital setting, it was noted that 22% of needle stick injuries were due to recapping. After needle disposal containers were added to all patient care areas, and educational efforts to decrease injuries were implemented, there was a 60% decrease in total needle stick injuries and an 81% decrease in recapping injuries[46].

In a Canadian study, dentists were surveyed and found that those who did not use puncture proof containers had a higher incidence of percutaneous injuries[47]. In records available at WorkSafeBC[48] there is no category specifically allocated for needle stick injuries to Dentists, Dental Assistants or Dental Hygienists. However in a recent Hazard Alert issued by WorkSafeBC, notice was given of a dental assistant having had a needle stick injury during dental instrument reprocessing at a site remote from chairside[49]. If there had been a sharps container at chair side and the operator had disposed of the needle after use, this could likely have been a preventable injury.

Work-practice controls

Work-practice controls have been recommended, employing strategies that would help to reduce injury in the workplace and establish practices to protect DHCPs whose responsibilities include handling, using, assembling, or processing sharp devices (in this case needles), or using approved sharps disposal containers. Work-practice controls can include: restricting use of fingers in tissue retraction or palpation and the use of a mirror to retract cheeks and oral tissues during administration of anesthesia; using a one-handed scoop and lift technique or use of a mechanical holding device for recapping needles after use; not passing syringes from operator to assistant; and immediately disposing of needles at site of use in a sharps container[50,51,52].

According to the Canadian Centre for Occupational Health and Safety, and the Canadian Needle Stick Surveillance Network, safe recapping procedures include utilizing a single handed scoop and lift technique. Between April 1 2000 to March 31, 2001 there were no reported exposures to dentists or hygienists[53].

This scoop and lift procedure has been reiterated most recently by OSAP as a safe method of preventing needle stick injuries[54]. Compliance with work practice controls is a key determinant in the reduction of needle stick injuries. While one handed scoop and lift is an effective way of reducing needle stick injuries, it requires conscious manipulation by the operator. Failure to follow protocol is a significant contributing factor in the occurrence of such injuries[55].

The act of disposing of a used needle is a time when many needle stick injuries do occur[56]. Non-compliance with established workplace controls during instrument clean up resulted in the majority of injuries occurring at that time[57.58].

It appears that in following the CDC guidelines of not manipulating needles (recapping, bending or breaking) using both hands, recapping using a one-handed scoop technique or mechanical sheath holding device, there seems to be a decrease in needle stick injuries.[59] The proper use of personal protective equipment will also reduce the risk of disease transmission. Gloves can reduce the volume of the blood inoculum in the case of a percutaneous injury[60].

Administrative controls

Administrative controls include education, training and the application of standard operating procedures in the practice and delivery of dental care. Most dental regulatory bodies have mandated that dental healthcare providers follow an approved protocol in dental infection prevention and control, and are up-to-date with the current local and federal regulations.

A recent published study[61] determined that "all dental practices should have a comprehensive written program for preventing needle-stick injuries that describes procedures for identifying, screening and, when appropriate, adopting safety devices, mechanisms for reporting and providing medical follow-up for percutaneous injuries". Wherever dental treatment is to be provided, it is important to have a needle-stick prevention framework in place that includes task specific standard operating procedures. This should include strategies implementing administrative controls (plans and systems), engineering controls (technology-based methods such as needle re-cappers) and behaviour-based work practice controls (such as the one-handed scoop technique for recapping needles)[62].

It was suggested that healthcare workers should "learn to engage in critical thinking skills that take compliance to a level beyond that of mere rule following without understanding the imperatives of sharps injury avoidance"[63], and that healthcare workers should be educated about the importance of preventing sharps injuries by determining the causes of these injuries and securing the best products to prevent them.

SELF RE-SHEATHING "SAFETY ENGINEERED" NEEDLES

Needles and syringes with safety engineered devices to help prevent accidental needle stick injuries in medicine are currently in their third generation of development. First generation devices were typically retrofitted mechanisms with add-on shields, sheaths or caps that covered an exposed needle. These were

deemed for the most part unacceptable as they were found to interfere with the procedure.

Second generation needles employ a needle designed to be manually retractable back into the barrel of the syringe. User activation is necessary and the safety feature should be enabled with a single-handed technique that allows the worker's hands to remain behind the exposed sharp. These devices with safety features decrease the frequency of needle stick injuries, but for many reasons they do not completely eliminate the risk. In some cases, the safety feature cannot be activated until after the needle is removed from the patient. Some health care workers fail to activate the safety feature, or the safety feature may fail. With some devices, users can bypass safety features altogether[64]. These second generation devices thus require operator compliance to ensure risk reduction.

Currently, third generation needles are available for certain medical applications. The device preferably works passively (i.e., it requires no activation by the user) and has automatically retractable needles. These automatic self-sheathing syringes are not available for use in delivering local anesthetic in dentistry[65].

Following the Needle Stick Safety and Prevention Act of 2000, the CDC recommended in 2003 that HCWs "identify, evaluate and select devices with engineered safety devices at least annually and as they become available on the market". OSHA requires that safety devices should be used or documentation be available that these devices have been considered but are not a practical alternative to traditional devices[66].

In a study by Cleveland et al,[67] nearly 50% of needle stick injuries observed were non-preventable (patient moving, injury on inserting or withdrawing the needle), that is to say that it would not have mattered if a safety device was available.

It is important for every dental setting to have an established comprehensive plan for preventing sharps injuries, describing mechanisms for the adoption of safety devices, reporting and follow-up of percutaneous injuries and proper injury prevention training. Having this will likely meet OSHA and other such jurisdictional requirements, keep DHCWPs aware of newly available safety devices and hopefully drive the development of improved safety devices.[68]

SAFETY ENGINEERED SYRINGES IN DENTISTRY

OSHA offers the following examples of criteria for employers to consider when using an objective product evaluation to determine which safety engineered mechanical sharps devices provide the highest level of protection:

- The device includes built-in protection of the needle or other sharp

- The user can easily tell whether the safety feature is activated
- The device performs reliably
- The device is easy to use and is self-evident
- The safety feature is in effect before disposal and remains in effect after disposal

Prior to and then in response to the introduction of safety syringe regulations, devices known as dental safety needles have become available to dental healthcare providers. A study of such safety needles available in 2000 determined that none of the safety needles tested passed clinical requirements for use[69].

The ***Ultra Safety Plus XL – injection protection system*** (***Septodont of Canada, Inc.*** Cambridge, ON www.septodont.ca) appears to be the only 'safety engineered syringe' that is currently available in Canada (Fig. 2). The Ultra Safety Plus XL injection system is comprised of a sterile, disposable single patient use, auto-aspirating, reloadable, injection system designed to reduce needle stick injuries. The system consists of a packaged, sterile triple bevel needle system that includes a removable needle cap and a sliding protective barrel inserted on a re-usable, sterilizable syringe. Each box of 100 Ultra Safety Plus XL needle systems comes with an autoclavable syringe. The protective barrel, when manipulated manually, slides back to expose the needle and then, when again manipulated manually moves forward into locked position to safely cover the needle after use. It could be considered as being a second-generation device, that is not capable of automatic retraction.

Figure 2: The Septodont (tm) "Safety Engineered" Syringe

In one study of the Septodont syringe[70] it was found that this safety syringe decreased the incidence of needle stick injuries. However, it was noted that those who did experience needle sticks were dental nurses that were exposed due to improper following of clinic protocol by the operator, who was supposed to immediately dispose of the sharp. There was also no mention of any difficulties that may have arisen during the administration of local anesthesia relating to the use of that particular safety syringe. A reduction in injuries was also noted in the control group using a conventional needle and syringe where education and

awareness of the risk of needle stick also plays an important role in injury reduction. As well, modifications to and adjustments of the device were made throughout the study period, suggesting the conclusions of the study could be construed as being overstated.

A follow-up paper states that there is the lack of an ideal syringe that incorporates all the features of a conventional syringe with new safety features, resulting in dissatisfaction amongst dental professionals. However, it recommends that consumers provide product evaluation and feedback to manufacturers which will help them in their quest to develop a more suitable safety syringe.[71]

The device was considered for use at the University of Texas Health Science Center at San Antonio but was not introduced due to various difficulties (unstable, safety device was unreliable). However, only eight evaluators were used.[72]

The Dental Evaluation and Consultation Service in the U.S. conducted a clinical user evaluation of Septodont's Ultra Safety Plus XL Safety Syringe. It found the needle was easily manually re-sheathed and disposed of, and functioned reliably. Five out of ten evaluators had difficulty visualizing aspirant. Five agreed that the device was safe, three disagreed and two were neutral. When asked if the device was safer than using a conventional one handed scoop recapping technique, four agreed, four disagreed and one was neutral (one did not reply)[73]. This would support individual provider preference and choice in determining risk/benefit in the use of such a device, as there was no equivocal support for nor dislike of the device.

In an informal unpublished evaluation of the SafetyPlus XL syringe system by 13 experienced dentists conducted in 2009 by the Member Services Division of the British Columbia Dental Association, feedback was that the assembly was bulky and unstable, that it was awkward to use and to exchange cartridges, that it was difficult to tell if the safety device was activated, and that there was the possibility of having a false negative aspiration. These findings were also iterated by two experienced practitioners at UBC's Faculty of Dentistry. (Appendix lll)

NEEDLE STICK INJURY PREVENTION AND THE 'SAFETY ENGINEERED' SYRINGE - CURRENT REGULATIONS:

Recognizing that prevention of sharps injuries, and in particular needle-stick injuries in the workplace is of particular concern, many regulating bodies in Canada and the US have established guidelines, regulations and standards aimed at reducing the risk of such injuries. These guidelines are directed at all health care personnel, thus the DHCP is included in these regulations.

Regulations in the USA:

In the US, legislation such as the Health Care Worker Needle Stick Prevention Act 2000 and the OSHA Blood Borne Pathogen Standard 2001 (Revised) contain regulations and guidelines to help reduce the risk of percutaneous injury and subsequent transmission of a blood borne disease to all health care workers.

In the US, OSHA (US Department of Labour, Occupational Safety and Health Administration) Blood **B**orne Pathogen Standard 1910.1030 requires that engineering and work practice controls be used to eliminate or minimize employee exposure, and that contaminated needles must not be recapped unless the employer can demonstrate that no alternative is feasible.

Also in the US, individual states have adopted regulations to help prevent the incidence of percutaneous injuries. As an example, the State of California Department of Industrial Relations[74] mandates that each employer must establish, implement and maintain an effective plan to reduce accidental needle-stick exposure, including engineering and workplace controls, and use a system wherein needles must not be recapped unless it "jeopardizes the patient's safety or the success of a dental procedure as determined by the dentist or their professional staff", and "is not more effective than the control currently in use".

As mentioned earlier, the CDC in the US published *Guidelines for Infection Control in Dental Healthcare Settings*[75], and offers procedures and protocol for the prevention of needle stick injuries in the dental setting. (Appendix l)

Regulations in British Columbia and Ontario

In British Columbia, changes to WorkSafeBC's Occupational Health and Safety Regulation (OHSR G6.36.1) came into effect on January 1st, 2008. The regulation, similar in intent to OSHA's regulation in the US, (OSHA 29CFR 1910), which applies to all health care facilities, and includes dental offices, specifically states that

"On and after January 1, 2008, a needleless device or safety-engineered hollow bore needle must be used for the following procedures performed to care for or treat a person:
(a) withdrawal of body fluids;
(b) accessing a vein or artery;
(c) administration of medications or fluids;
(d) any other procedure involving the potential for an exposure to accidental parenteral contact for which a needleless system or safety-engineered hollow bore needle system is available.

'However, there can be exceptions to the use of a safety-engineered needle system made if

"(a) use of the required device, needle or sharp is not clinically appropriate in the particular circumstances, or
(b) the required device, needle or sharp is not available in commercial markets."

A person who makes the determination of whether the use of a required device, needle, or sharp is clinically inappropriate should

- *Be qualified, which means being knowledgeable of the work, the hazards involved, and the means to control the hazards, by reason of education, training, experience, or a combination thereof.*
- *Have expertise in the procedure in question.*

Similar regulations mandating, with likewise similar provisions for exceptions, the use of safety engineered needles have been recently introduced in Ontario. The *Needle Safety Regulation 474/07* came into effect July 1, 2010. The Royal College of Dental Surgeons of Ontario (RCDSO) has issued a notice to its registrants[76] identifying concerns around the use of safety engineered needles currently available for use in dentistry, and has determined that there devices "are no safer and may pose a greater risk of harm than conventional hollow bore needles that dentists are currently using" and "dentists should consider safer versions as they become available…"

B) THE UBC EVALUATION OF A SAFETY ENGINEERED SYRINGE:

To further investigate the suitability of dental safety engineered syringes, it was determined that a simulation should be undertaken in a clinical setting to investigate if a clinician would perceive that the safety device being tested could be at least equal to or better in reducing the risk of needle stick injury as compared to the conventional method of delivering local anaesthesia using an aspirating anaesthetic syringe. If pre-clinical testing proved to be successful in determining that the safety syringe was effective then clinical testing would be undertaken to confirm the pre-clinical results.

PURPOSE: To determine through pre-clinical testing if available dental use safety engineered syringes would be suitable for use in a clinical setting, and if so, to then clinically evaluate the safety syringes as to if they were perceived to be at least equal to or better than conventional dental local anesthetic syringes.

MATERIALS and METHODS: The *Septodont Ultra Safety Plus* safety engineered syringe is the only commonly available syringe of its type in Canada, and was thus chosen to be evaluated in his study. The study was to have consisted of two parts: A pre-clinical and clinical evaluation as to the perceived effectiveness the safety syringe has in reducing the risk of a needle stick injury to a DHCP. The clinical component of the study was to be undertaken only if there was a positive pre-clinical evaluation of the syringe.

The study protocol and procedure was approved by the UBC Ethical Review Board. A pre-clinical evaluation and comparison of the currently available safety syringe to currently accepted local anesthetic delivery was conducted. Following the study protocol and procedure (Appendix lV), results were tabulated based upon a questionnaire (Appendix V) and simulated use that was performed by three groups:

- 10 Junior dental students, who have had minimal experience delivering local anesthesia;
- 10 Senior dental students, who have approximately one year of experience delivering local anaesthesia; and
- 10 Faculty members who are dentists with more than two years of experience routinely delivering local anaesthesia.

For each group, a supply of new, unassembled safety engineered syringes with the manufacturer's instructions for use, conventional syringes, with local

anesthetic cartridges were distributed, along with a ripe avocado into which local anesthetic was to be injected.

Following this pre-clinical exercise using both a conventional syringe and a safety syringe in a prescribed manner, participants would be asked to complete a questionnaire regarding the test device. An analysis was undertaken to identify the differences between the three groups of investigators as relating to their previous experience with delivering dental local anaesthesia and using the test device. The results of this questionnaire would determine if the safety device should be considered for clinical use and evaluation.

Physical properties of the needle and syringe were tested by the University's biomaterials laboratory. Calculations of the deflection coefficient of the safety engineered syringe needle under various loading conditions compared with a conventional needle were undertaken. (Needle Deflection Test)

The stability of the needle assembly on the safety syringe apparatus was also evaluated in the laboratory setting. This investigation focused on assessing the effect of multiple sterilization cycles on the plastic handle that is included with every 100 needles. (Pull Out Test)

Needle deflection test

The experimental design and the variables selected for this study were based on the review of several research articles, [77,78,79,80,81] and two ISO standards (ISO 7885 and ISO 9626).

The thirteen Septodont XL thin walled needles were modeled using the Structural Mechanics Module of the Comsol 3.5 FEM/FEA software. The nominal outer diameter (NOD), nominal internal diameter (NID), nominal wall thickness (NWT) used in modeling these thin walled needles were estimated from the literature supplied by the manufacturer. Thus, according to the manufacturer, the increase in NID ranges from 38 % for Gauge 30 needles, to 42 % for Gauge 27 needles, and to 43 % for Gauge 25 needles. Corresponding needles with "normal" wall thickness were calculated as well.

Stainless steel AISI 4340, having a modulus of elasticity of 205 GPa and a Poisson's ratio of 0.28 was used as the needle material for all the models. One end of the needle was fixed; loads, ranging between 50 mN and 400 Mn were applied at the other end, perpendicular to the long axis of the needle, subjecting the needles to a cantilever loading mode. The deflection of the needle tip was determined at mid shaft.

To check the validity of the models and analysis, the needle deflections evaluated by Goskel[82] were modeled and analyzed using the methodology described above.

The comparison of both the published and re-analyzed results supports the validity of the approach undertaken in this project. The linear correlation between load and deflection reduces the requirement for modeling and analysis to one load, i.e. to 50 mN.

Pull out test

Four syringe handles were evaluated in this part of the study: one was used as received while the other three were subjected to increasing number of sterilization cycles (35, 65, and 100). The syringe handle was centred, levelled, and then fixed in the lower grip of an Instron 4301 Universal testing machine. (Figs. 3 and 4) The other part of the assembly was centred, levelled, and fixed in the upper grip of the machine. The cross head was lowered until the two parts engaged, with no stress being detected. The cross head was then moved upwards at a cross head speed of 100 mm/s (max for the instrument) and the load (in N) required to separate the two components was recorded.

Two load peaks were recorded, one for disengaging the protective sleeve and the other for disengaging the entire needle-carrying component form the handle. Five insertion/removal cycles with two needle-carrying components were conducted for each of the four handles.

RESULTS:

Many of the responses to the questionnaire were favourable from all three test groups. These responses fell into the range of “meets expectations” to “exceeds expectations.” However, there were frequent common responses, consistent amongst the three testing groups that gave cause for the investigators to forego the clinical component of the study:

Questions that received a response of “less than meets expectations” in 50% or more of the responses included

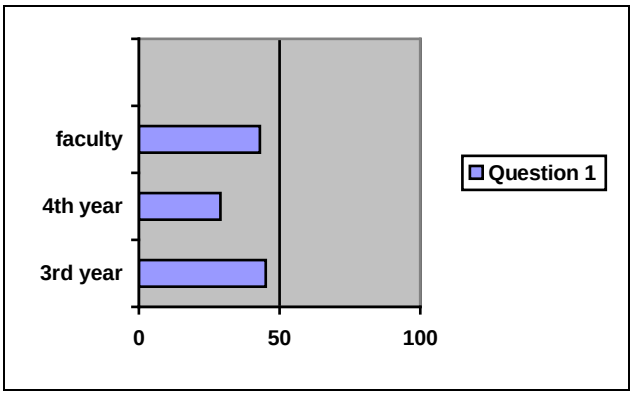
- Easy removal and exchange of carpule (cartridge)
- No more difficult to break down and disposed of
- Cannot be accidentally deactivated
- Easy to use

Additionally, other questions that evoked a response of “less than meets expectations in up to 30% of the evaluations were

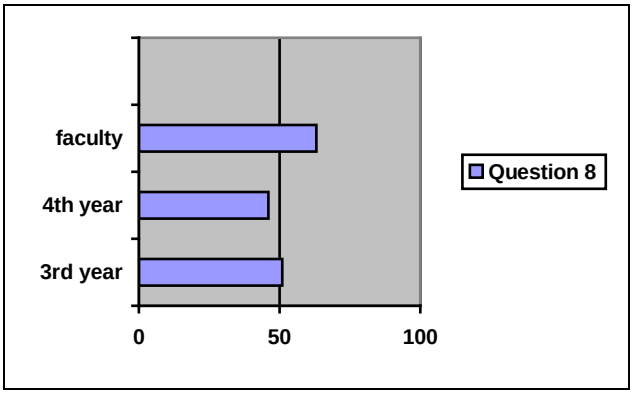
- Capable of aspiration before and during injections
- Safety feature activated by one hand
- Needle assembly compatible with re-useable syringe
- Will not increase sharps volume waste

AVERAGE VALUES OF RESPONSES

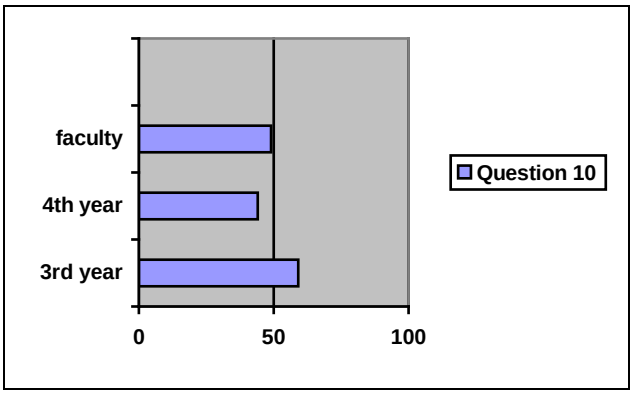
0 =:DOES NOT MEET EXPECTATIONS
50 = MEETS EXPECTATIONS
100 = EXCEEDS EXPECTATIONS



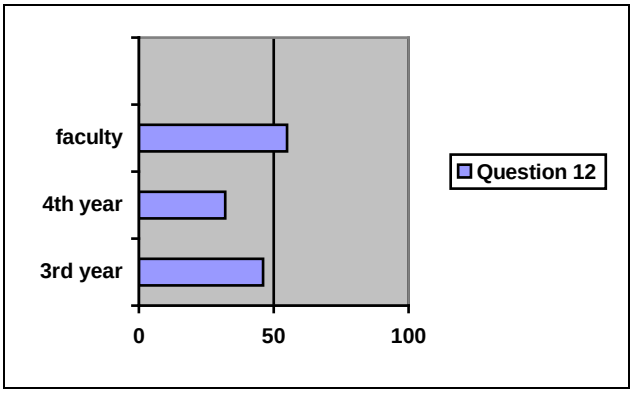
"The device permits the easy removal and exchange of carpules during a procedure"



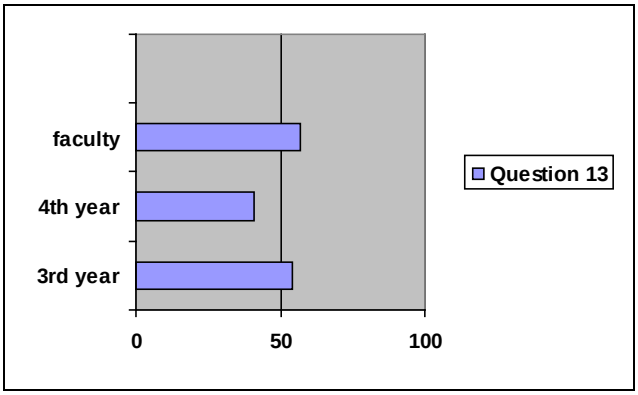
"The device is capable of aspiration before and during injections"



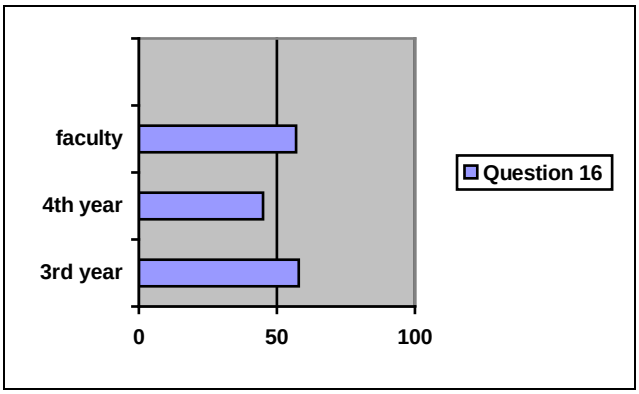
"The needle assembly is compatible with a re-useable syringe"



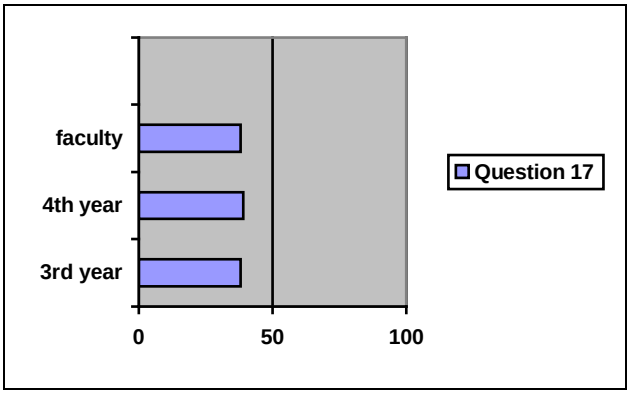
"The device is no more difficult to break down and dispose of in a sharps container than a traditional syringe"



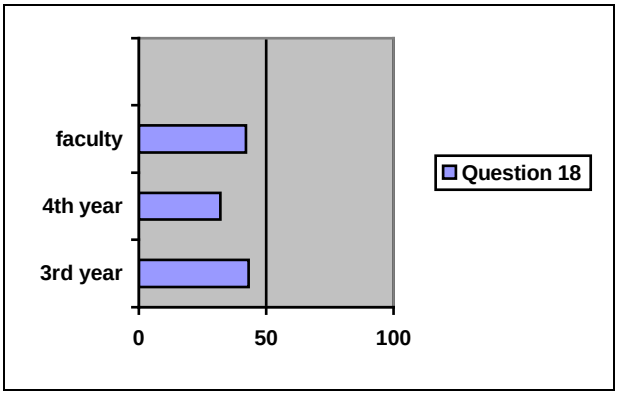
"The safety feature can be activated by one hand"



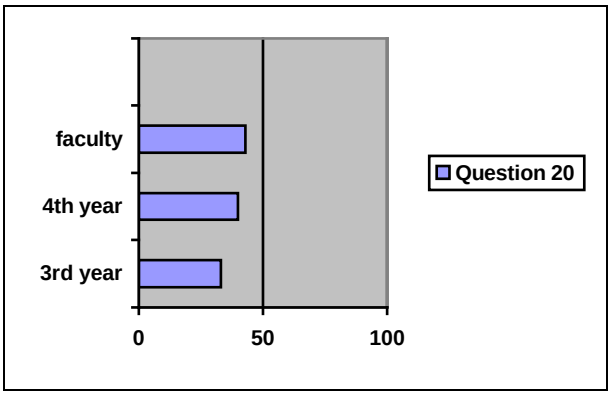
"The safety feature is easy to recognize and use"



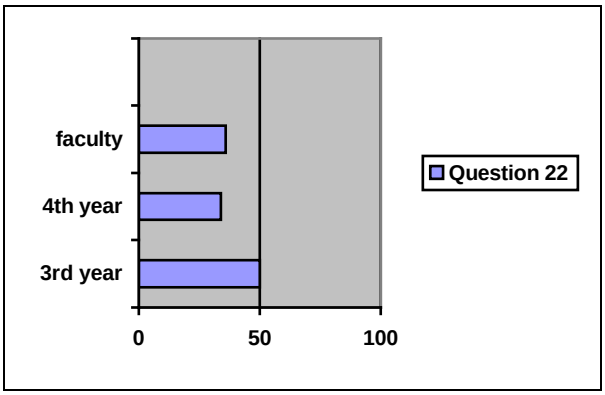
"The safety feature is self-activating"



"The safety feature cannot be accidentally de-activated"



"The instructions are included and the device is easy to use"



"The use of the safety device will not increase the volume of sharps waste"

Of particular note were the written comments added by virtually all of the participants, regardless of experience group. Common comments included

- Confusing instructions/difficult to use (15 comments)
- Difficulty with exchange of cartridge/additional local (14)
- Needle package not labeled as to gauge and length (1)
- Like the system (3)
- Easy to use (1)
- Unstable/flimsy, assembly accidentally disengaged (13)
- People may be less cautious due to 'safety' labeling (1)
- Need to actively reap the needle (1)
- Needle broke at hub (1)
- Needle deflects easily (1)
- Lightweight/bulky affecting control (3)
- Cannot see carpule (1)
- More waste (1)
- Not convinced this is needed (2)

Biomaterials laboratory testing determined that in general, a ~29 % increase in deflection was determined for the thin walled needles in comparison with their “normal” walled counterparts.

Based on the results of the ‘pull out’ assessment, sterilization did not diminish the pull out force for the autoclavable handles. However, only in a few of the syringe assembly components tested there were three clear load levels identified, corresponding, in the order of increased load levels, to passing the first dimple stop (5 N to 8 N), wherein the sleeve was not totally engaged in a locked position, but could be manipulated back to re-expose the needle, full engaging of the sleeve to its locked position (17 N to 25 N), and removal from the handle (35 N to 50 N). The other needle-carrying components tested disengaged from the handle before the complete engagement of the sleeve, at loads less than 15 N.

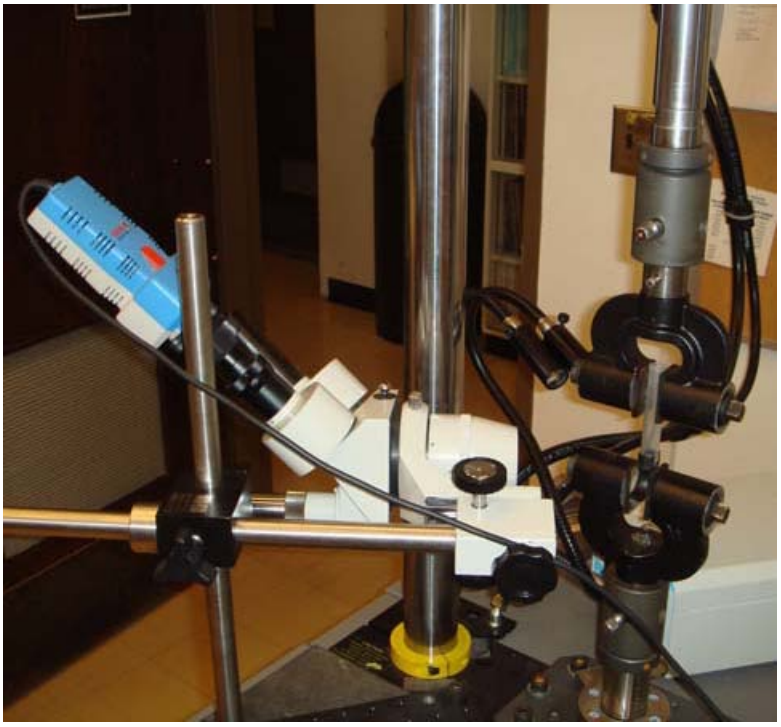


Fig.3 -“pull out” test assmbly

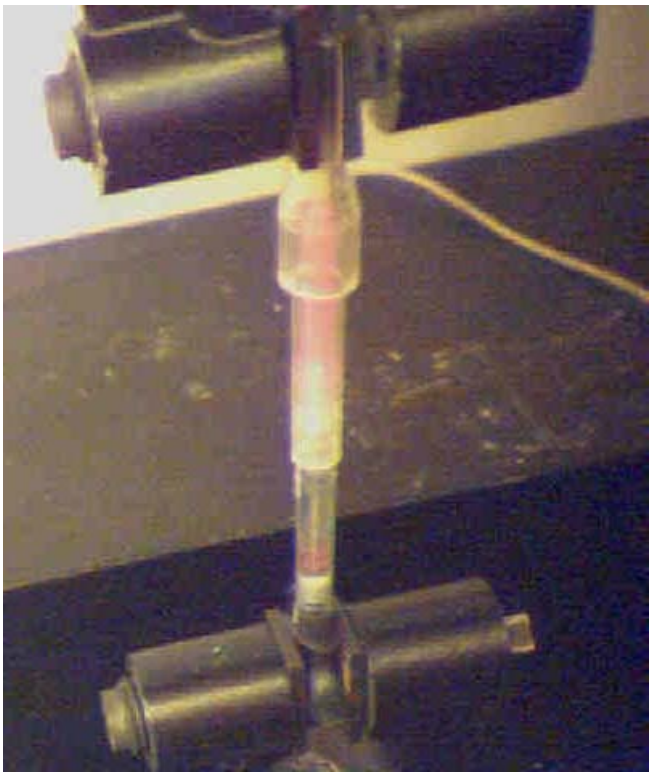


Fig.4 - "Pull out" test assembly

DISCUSSION

Due to these findings and comments, the investigators were unconvinced that the study should move forward for use in the clinic, as it was felt that the design of the safety syringe posed a possible risk to patients and operators. This possible risk was weighed against the possible benefit of using the syringe and in view of the current use of conventional syringes and the engineering and work practice controls that are in place in the University's clinics. It was deemed that the risks in this case outweighed the benefits. These were risks commonly cited in previous literature, namely an unstable connection between the needle apparatus and the syringe and the difficulty in determining if the safety feature was engaged or not.

Needle bore size:

In conversation with a representative of Septodont, and confirmed by the manufacturer (www.sofic.com) the investigators were made aware that although the gauge of the needle, a measurement of the outside circumference, was within standard size (i.e 25 ga, 27 ga.), the internal diameter had been enlarged by as much as 43% as compared with a standard needle, which would allow for easier delivery of the local anesthetic due to less pressure needed to be exerted on the

syringe and plunger. As an example, the Septodont 27ga. needle would have an internal diameter approaching that of a larger 25 ga. needle.

Using accepted modeling techniques in determining load deflection, it was found that In general, a ~29 % increase in deflection was determined for the thin walled needles in comparison with their "normal" walled counterparts.[83]

As a result of the modification, the needle could be more flexible and prone to deflection during the administration of anesthetic. The significance of this would be that for nerve block procedures requiring deeper tissue infiltration, the deflection of the needle through tissues could result in a missed nerve block and would necessitate the administration of additional local anesthetic solution. It may not have as significant effect on field infiltration of local anesthetic.

Stability of the syringe apparatus following multiple sterilization cycles:

It was hypothesized that the stability of the syringe/needle assembly interface could become compromised after 100 sterilization cycles.[84] This would pose difficulties from an administrative standpoint as it would be a challenge to monitor the number of cycles each of the many hundreds of syringes that are use in our clinics.

Following pull-out testing, it was found that repeated sterilization did not have a significant effect on the retention of the needle apparatus to the syringe. What was found is that there was a real possibility of premature disengagement of the needle apparatus from the re-useable syringe due to the force needed to lock the safety feature in place before it became fully engaged.

CONCLUSION:

The single available safety syringe in Canada for dentistry is a 'second generation' engineered sharp (non-self retracting) may be considered on an individual basis as an adjunct to accepted engineering and workplace controls in reduction of needle stick injuries. There however are some identifiable drawbacks to the system that would preclude the universal adoption of this device due to potentially compromised patient and operator safety. Compromised patient safety can be cited as a reason not to use a safety device.[85]

In a statement by NORA[86] "*it is acknowledged that not all sharps devices, with engineered safety features, are safer than their traditional counterpart*"

A reduction of the incidence of needle stick injuries in dentistry can be obtained by meticulously following existing preventive engineering and workplace control

protocol (Appendix VI), along with DHCP education into the safe handling and use of conventional dental aspirating anesthetic syringes.

The results of this study did not support the use of the test dental safety engineered syringe in the student and faculty dental clinics at the University of British Columbia. Additional design modifications are required prior to recommending universal use of the apparatus.

C) RECOMMENDATIONS – MOVING FORWARD

SUMMARY

Percutaneous injuries, and specifically needle stick injuries do occur in dentistry, Safety engineered needles are typically used in the medical 'model' or setting to help prevent such injuries. The dental 'model' use of local anesthetic syringes poses some challenges in the design of safety engineered syringes to be used in that milieu. As to the mechanism of injury, the extent that needle stick injuries occur is unclear and poorly documented at this time. This study can lend recommendation to some important steps that can be taken to reduce the risk of needle stick injuries in dentistry: - 1) immunization, 2) implementation of strategies to minimize needle stick injuries in the dental workplace 3) improvement in reporting of needle stick injuries in dentistry in order to better ascertain the frequency and type of injuries and 4) provide constructive feedback to manufacturers so they can design a more suitably compatible safety engineered device for the delivery of local anesthetic in the dental setting.

1) Immunization

Percutaneous injuries are an occupational hazard for health care workers, and avoiding occupational exposures to blood is the primary way to prevent transmission of blood borne pathogens such as HBV, HCV, and HIV to DHCPs. As there is a real risk of blood borne transmission of hepatitis B virus, it would be incumbent upon all DHCPs to have proven immunity to the virus through vaccination.[87]

2) Needle Stick Prevention and Safety Strategies

There are currently acceptable work practice, engineering and administrative controls and methods used to help decrease the risk of needle stick injuries, including:

- Routine wearing of personal protective equipment (gloves, masks, eyewear)
- Establishing safe recapping procedures:
  - one-handed scoop and lift
  - use of a recapping device
  - use of a safety engineered syringe
- Using a mirror or other type of check retraction on administering local anesthesia
- Not passing syringes or other sharps

- Disposing of needles and other sharps at chairside, immediately after use, by the operator and in an approved sharps container
- Not bending or breaking needles
- Having an infection prevention and safety plan, with an exposure protocol in place in every dental workplace. All DHCPs must be aware of this, and protocol must be updated regularly. Education is of utmost importance – the mental aspects and paying attention to process and procedures – means increased awareness of all DHCPs.

3) Surveillance and reporting
Needle sticks are one cause of percutaneous injuries to DHCPs, about half of which could be preventable. It is difficult to determine the exact number and types of needle stick injuries to DHCPs as reporting is poor. A DHCP voluntary, anonymous, real-time web-based surveillance system, at arms length from any government agency could be established and perhaps supported by the Canadian Dental, Canadian Dental Hygienists and the Canadian Dental Assistant's Associations could be established to facilitate this. An example of a reporting structure is included. (Appendix IV)

4) Communication with manufacturers
Providing feedback to manufacturers, via professional dental associations, universities, WorkSafeBC and other organizations, and through private correspondence, as to ideas and suggestions for improving the design and function of safety engineered needles in dentistry is encouraged.

POST EXPOSURE HIV PROPHYLAXIS: Clinical Management of Blood Borne Pathogen Exposures to DHCPs

When considering the use of post exposure prophylaxis (PEP) regimen following an exposure to a DHCW of a known HIV carrier, understanding the common characteristics of dental injuries as well as the factors associated with the risk of HIV transmission can help the evaluating health care professional balance the risk of HIV infection with the need for and side effects of PEP.

If one were to take the general risk factor for a HCW of 0.3% seroconversion, reduce the risk again by 79% if PEP is used,[88] the risk becomes 0.237%. Following that, we should consider that the risk is even less for a DHCP, as the parameters for transmission are usually not met. In one study, it was theorized that the annual risk of transmission of HIV through needle stick exposures to Canadian dental anaesthesiologists has been calculated to be 0.001%.[89] The administration of the PEP regimen to DHCPs experiencing a needle stick injury during the course of administering or clean up following a local anesthetic procedure would result in a negligible risk becoming even more negligible.

There is no doubt that there is an emotional impact on the HCW that suffers a needle stick exposure[90].

Whether or not a DHCP undergoes PEP is a personal decision, but should be an informed decision based upon the known facts and risks of transmission, regardless if the carrier status of the source patient is known or not. Certainly, obtaining a base-line blood sample for existing HIV status and HBV immunity immediately following a percutaneous exposure involving blood is advisable.

THE ROLE OF WorkSafeBC

Recommendations in Appendix VIl review the different steps that WorkSafe BC can embark on in moving forward with

a) surveillance and reporting of injuries
b) sharps evaluation and development
c) safety promotion
d) professional partnering

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APPENDIX I

CDC MMWR Vol. 52 / RR-17 Recommendations and Reports 13
Exposure Prevention Methods

Avoiding occupational exposures to blood is the primary way to prevent transmission of HBV, HCV, and HIV, to DHCPs in health-care settings (*19,96,97*). Exposures occur through percutaneous injury (e.g., a needle stick or cut with a sharp object), as well as through contact between potentially infectious blood, tissues, or other body fluids and mucous membranes of the eye, nose, mouth, or nonintact skin (e.g., exposed skin that is chapped, abraded, or shows signs of dermatitis). Observational studies and surveys indicate that percutaneous injuries among general dentists and oral surgeons occur less frequently than among general and orthopedic surgeons and have decreased in frequency since the mid-1980s (*98–102*). This decline has been attributed to safer work practices, safer instrumentation or design, and continued DHCP education (*103,104*).

Percutaneous injuries among DHCPs usually:
1) occur outside the patient's mouth, thereby posing less risk for recontact with patient tissues;
2) involve limited amounts of blood; and
3) are caused by burs, syringe needles, laboratory knives, and other sharp instruments (*99–102,105,106*).

Injuries among oral surgeons might occur more frequently during fracture reductions using wires (*104,107*). Experience, as measured by years in practice, does not appear to affect the risk of injury among general dentists or oral surgeons (*100,104,107*).

The majority of exposures in dentistry are preventable, and methods to reduce the risk of blood contacts have included use of standard precautions, use of devices with features engineered to prevent sharp injuries, and modifications of work practices. These approaches might have contributed to the decrease in percutaneous injuries among dentists during recent years (*98–100,103*). However, needlesticks and other blood contacts continue to occur, which is a concern because percutaneous injuries pose the greatest risk of transmission.

Standard precautions include use of PPE (e.g., gloves, masks, protective eyewear or face shield, and gowns) intended to prevent skin and mucous membrane exposures. Other protective equipment (e.g., finger guards while suturing) might also reduce injuries during dental procedures (*104*).

Engineering controls are the primary method to reduce exposures to blood and OPIM from sharp instruments and needles. These controls are frequently technology-based and often incorporate safer designs of instruments and devices

(e.g., self-sheathing anesthetic needles and dental units designed to shield burs in handpieces) to reduce percutaneous injuries (*101,103,108*).

Work-practice controls establish practices to protect DHCP whose responsibilities include handling, using, assembling, or processing sharp devices (e.g., needles, scalers, laboratory utility knives, burs, explorers, and endodontic files) or sharps disposal containers. Work-practice controls can include removing burs before disassembling the handpiece from the dental unit, restricting use of fingers in tissue retraction or palpation during suturing and administration of anesthesia, and minimizing potentially uncontrolled movements of such instruments as scalers or laboratory knives (*101,105*).

As indicated, needles are a substantial source of percutaneous injury in dental practice, and engineering and work practice controls for needle handling are of particular importance. In 2001, revisions to OSHA's bloodborne pathogens standard as mandated by the Needle stick Safety and Prevention Act of 2000 became effective. These revisions clarify the need for employers to consider safer needle devices as they become available and to involve employees directly responsible for patient care (e.g., dentists, hygienists, and dental assistants) in identifying and choosing such devices (*109*). Safer versions of sharp devices used in hospital settings have become available (e.g., blunt suture needles, phlebotomy devices, and butterfly needles), and their impact on reducing injuries has bee documented (*110–112*). Aspirating anesthetic syringes that incorporate safety features have been developed for dental procedures, but the low injury rates in dentistry limit assessment of their effect on reducing injuries among DHCP.

Work-practice controls for needles and other sharps include placing used disposable syringes and needles, scalpel blades, and other sharp items in appropriate puncture-resistant containers located as close as feasible to where the items were used (*2,7,13,113–115*). In addition, used needles should never be recapped or otherwise manipulated by using both hands, or any other technique that involves directing the point of a needle toward any part of the body (*2,7,13,97,113,114*). A one-handed scoop technique, a mechanical device designed for holding the needle cap to facilitate one-handed recapping, or an engineered sharps injury protection device (e.g., needles with re-sheathing mechanisms) should be employed for recapping needles between uses and before disposal (*2,7,13,113,114*). DHCP should never bend or break needles before disposal because this practice requires unnecessary manipulation. Before attempting to remove needles from non-disposable aspirating syringes, DHCP should recap them to prevent injuries. For procedures involving multiple injections with a single needle, the practitioner should recap the needle between injections by using a one-handed technique or use a device with a needle-re-sheathing mechanism. Passing a syringe with an unsheathed needle should be avoided because of the potential for injury.

APPENDIX II

Template for Voluntary/Anonymous On-Line Reporting of Percutaneous Injuries in Dentistry:

(Epinet modified; Callan, R et al. Injury Reports in a Dental School: A Two Year Overview. Journal of Dental Education Vol. 70 No. 10 October, 2006)

Date:

Source of injury:	**Needle stick**:	conventional – gauge _.
		safety engineered - engaged
	Blade:	scalpel conventional
		Scalpel - safety engineered -engaged
	Dental instrument	explorer
		Scaler
		Knife
		Ultrasonic scaler tip
		Other instrument
	Bur	Othodontic use
	Wire	Surgical use

Recipient:	**Dentist**
	Dental Hygienist
	Dental Assistant
	Office Staff
Time of day	
Location:	**Operatory**
	Sterilization area
	Laboratory
	Other

Action being performed:

During use:

Operator self inflicted on insertion/withdrawal
Patient movement
Passing of instrument

During clean up:

Needle stick – status of cap/sheath

Inadvertent accidental contact

body part,
depth of injury
presence of visible blood (amount)
known source patient

immediate first aid administered

ppe worn

DHCW's immune status	**Hepatitis B**
	Tetanus

Planned follow-up report

APPENDIX III

From an informal evaluation of the Septodont Syringe by 13 members of the BCDA (2009)

Following is a list of comments cut and pasted from e-mails from the participants in our exercise:

- The handle is plastic, it is light and flimsy and for me the thumb ring is too small. This makes it impossible to for me use the proximal part of my thumb to apply pressure to the plunger as I normally do.
- The attachment of the handle/plunger to the barrel is a little awkward to disengage, and I have noticed our assistants struggle with it. On one occasion the protective sleeve had not been locked in place properly and the assistant came closer to a needle stick injury than I have seen with a conventional system in a long time.
- It is not possible to change the LA carpule once it has been used; the result of this is that during a series in infiltration injections the whole barrel is discarded each time the carpule is changed.
- Conversely if bone is contacted the practitioner cannot change the needle by itself and will thus need to discard a partly used carpule.
- During injection the carpule is covered by a transparent plastic barrel and the retracted safety sleeve. Compare this with a conventional system were the carpule is not covered at all. This makes it much more difficult to see a positive aspirate. During mandibular block injection where accidental intravascular injection is the greatest problem this difficulty is compounded a tendency for condensation to form on the barrel or within the sleeve. As a result of these factors positive aspiration is less likely to be noticed and patient safety compromised.
- The disposable needle/barrel assembly is far more bulky than a conventional system, which will increase both the cost of sharps disposal and of adverse environmental impact.
- The cost is more than twice that of a conventional system. This is compounded by the need to=use more needle/barrel units or LA carpules during multiple injections on only one patient than with conventional systems.
- I received the safety engineered needles last week and tried expressing anaesthetic out of a carpule into the sink just to get a feel for the product. On my first attempt the needle assembly popped off the syringe half way through. I tried again with two other safely needles with the same result. Needless to say I will not be trying this product on any of my patients. It may have been engineered for my safety but what about the patient's safety!!! As far as I'm concerned this product is not suitable for intraoral use or any other use for that matter.
- The fact that we use a syringe more than once on a patient and place new carpules means I am still recapping in between uses. The recapping is the time when a needle stick might occur, so I don't see this system as having any advantage whatsoever. I find it more time consuming, costly, and increases the

plastic waste burden on our landfills. It may help in jobs where single use is the norm but for dentistry where multi use is common or even usual, it is less/not feasible. I did notice that the self aspiration was not consistent with all of the samples I used.

- I had a child bite on a regular syringe last week, and since it was metal one all was fine. How do these respond to a good crush by a child?
- I received and tried these safety needles and don't care for them. Negatives are as follows: They are 3x the cost of regular needles, the grip seems flimsy, if you don't ensure the protective sheath is securely locked in place the needle will fall off the holder, and they take up more space in the sharps container. We haven't had a "needle stick" incident for at least 25 years and have a system in place which seems to prevent them.
- If I am doing multiple injections I have to use a separate needle for each one as I cannot get the used carpule out. Seems like a total waste to me when the planet is going green and we are increasing our use of plastics. I find the needles quite flimsy also. I also believe that you can still get a needle stick injury from them and that they are no safer than the better quality needles that we use. If it's going to be mandated I will be ordering a ten year supply of the regular needles to get me through to retirement.

Additional comments from experienced UBC Faculty:

Participant "A" –

Liked:

- Bevel marker

Disliked:

- Required more physical manipulation to load and retrieve cartridge
- More bulky than conventional syringe due to double sleeve, which obscures the view of the cartridge thus impeding aspirant view.
- From an ergonomic standpoint, many more steps needed as compared with conventional aspirating anaesthetic syringes.
- Weak joint thus possible separation of needle assembly from autoclavable syringe.
- While it may appear that the sleeve is correctly in place covering the needle, it is not obvious that it is locked in place and may disengage and cause injury to the operator.
- Need two hands to activate and de-activate the device.
- Temporary means of covering the needle between injections by conscious physical manipulation is no different than conventional – no automatic re-sheathing.
- Safety device can be easily de-activated.
- Operator may chose to leave cover sleeve at first 'click' in anticipation of the need for another injection and fail to secure it.

As well, operator may try to force sleeve from closed position if required rather than discard and use a fresh needle assembly.

- Increased garbage.

:

Participant “B” –

Liked:

- sterile packaging
- bevel indicator.

Disliked:

- Slow to reload when giving multiple injections
- Must ensure that the sheath is fully retracted or else apparatus is unstable.
- Difficult to clearly see aspirant can give rise to false negative aspirations and intravascular injection of local anaesthetic.
- Have to engage cartridge with syringe or cannot remove it.
- Cannot clearly tell if safety feature is fully engaged thus increasing chance of injury.

APPENDIX IV

Pre-Clinical Protocol: Self-Recapping "Safety" Syringes vs conventional "scoop and lift" technique.

Familiarize yourself with the safety syringe apparatus.

Wear appropriate patient care gloves

First using conventional syringes:

Assemble 25 ga. needle on syringe

Load carpule

Inject into fruit – deep to pit, then withdraw.

Inject a few drops– "aspirate"

Deposit 1/4 carpule

Withdraw.

Recap (Scoop and lift)

Exchange carpule

Repeat.

Recap (scoop and lift) and **discard needle in sharps container**

Shift to 27 ga. Needle – repeat exercise, again exchanging carpules

Repeat entire procedure, using **safety syringe** (no scoop and lift indicated).

Fill out questionnaire

APPENDIX V

Pre-Clinical Evaluation of a Dental Safety Syringe*

QUESTIONNAIRE

Provider number_____

3rd year student ☐

4th year student ☐

Dentist ☐

Hand (glove) size: ☐ extra small ☐ small ☐ medium ☐ large

Clinical Considerations	Does not Meet Expectations	Meets Expectations	Exceeds Expectations
1. The device permits the easy removal and exchange of carpules during a procedure			
2. The weight and size of the device is acceptable.			
3. There is a clear view of the carpule contents during aspiration.			
4. The size and configuration of the device would permit a clear view of the injection site and needle tip			
5. No excessive force is required to activate or control the plunger			
6. The size and configuration of the device would permit access to all injection sites and use in all mouth sizes			
7. The device permits multiple injections on the same patient			
8. The device is capable of aspiration before and during injections.			
9. The degree of rigidity (deflection) of the needle is within acceptable tolerances			
10. The needle assembly is compatible with a reuseable syringe			
11. The workers hands are behind the sharp during activation			

12. The device is no more difficult to break down and dispose of in a sharps container than a traditional syringe

Safety Feature Considerations **Stongly Disagree** **Agree** **Strongly Agree**

13. The safety feature can be activated by one hand
14. The safety feature is integrated Into the syringe or needle
15. The safety feature provides a temporary means of protecting the needle between injections.
16. The safety feature is easy to recognize and use
17. The safety feature is self-activating
18. The safety feature cannot be accidentally deactivated
19. The device is conveniently packaged and easy to remove and use
20. Instructions are included and the device is easy to use
21. The device is easy to use for different hand sizes
22. The use of the safety device will not increase the volume of sharps waste
23. This is a single use disposable device
24. This device should be considered for further **clinical** evaluation
25. Using this device would help decrease the risk of an accidental needlestick as opposed to a conventional syringe (scoop and lift).

Additional comments for any responses:

APPENDIX VI

Kohn et al Guidelines for infection control in dental health care settings 2003. J Am Dent Assoc, Vol 135 No 1 33-47: (abridged)

B. **Preventing Exposures to Blood and Other Potentially Infectious Material (OPIM)**

1. General recommendations
    a. Use standard precautions (OSHA's blood-borne pathogen standard retains the term universal precautions) for all patient encounters (IA,IC) (11,13,19,53).
    b. Consider sharp items (e.g., needles, scalers, burs, lab knives and wires) that are contaminated with patient blood and saliva as potentially infective and establish engineering controls and work practices to prevent injuries (IB, IC) (6,13,113).
    c. Implement a written, comprehensive program designed to minimize and manage DHCP exposures to blood and body fluids (IB, IC). (13,14,19,97).
2. Engineering and work-practice controls
    a. Identify, evaluate and consider devices with engineered safety features at least annually and as they become available on the market (e.g., safer anaesthetic syringes, blunt suture needle, retractable scalpel or needleless IV systems) (IC) (13,97,110–112).
    b. Place used disposable syringes and needles, scalpel blades and other sharp items in appropriate puncture-resistant containers located as close as feasible to the area in which the items are used (IA, IC) (2,7,13,19,113,115).
    c. Do not recap used needles by using both hands or any other technique that involves directing the point of a needle toward any part of the body. Do not bend, break or remove needles before disposal (IA, IC) (2,7,8,13,97,113).
    d. Use either a one-handed scoop technique or a mechanical device designed for holding the needle cap when recapping needles (e.g., between multiple injections and before removing from a non-disposable aspirating syringe) (IA, IC) (2,7,8,13,14,113).

3. Post exposure management and prophylaxis.
    a. Follow current CDC recommendations after percutaneous, mucous membrane or non-intact skin exposure to blood or other potentially infectious material (IA, IC) (13,14,19) Exposure Prevention Methods

Sample evaluation forms for safety engineered needles and IV systems were developed through the training for Development of Innovative Control Technologies (TDICT) Project and are available at at http://www.osha.gov/. Type in the search term "TDICT" and click on the document noted as the 2001 -- 11/27/2001 CPL 02-02-069]CPL-2-2-69] - Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens

APPENDIX VII

Recommendations to WorkSafe BC

The following recommendations are based upon the National Occupational Research Agenda (NORA) , Draft Preliminary Public Comment Version, National Healthcare and Social Assistance Agenda for Occupational Safety and Health Research in the U.S Healthcare And Social Assistance (HCSA) Sector August 18, 2009:

OBJECTIVE: To reduce sharps injuries and their impacts among dental health care providers:

GOAL: By 2012, a surveillance and reporting system will be in place to identify the number and types of dental healthcare providers employed in all settings who sustain sharps injuries and the circumstances, mechanisms, procedures, and devices involved in those injuries.

1.0: Surveillance and Reporting System

1.1: WorkSafeBC**,** collaborating with partners including the BCDA, BCDHA and BCCDAA, will promote the development and use of an independent confidential surveillance and reporting system that monitors percutaneous injuries among all dental health care personnel in all settings. The system will identify the number and types of dental healthcare personnel who sustain percutaneous injuries, and the circumstances, mechanisms, procedures, and devices involved in those injuries.

.

1.2: Assess the barriers to accurate reporting, determine strategies to address the barriers and promote the adoption of innovative strategies to improve reporting by all dental healthcare personnel within all dental healthcare settings

2.0: Development of new sharps

It is acknowledged that not all sharps devices, with engineered safety features, are necessarily safer than their traditional counterpart. WorkSafeBC will promote the development of new and re-engineering of safe sharps with device manufacturers, with a priority on sharps-free alternatives wherever feasible.

2.1: Identify and characterize dental procedures and techniques for which viable safe sharps do not exist.

2.2: Partner with device manufacturers to ensure that product design involves user feedback.

2.3: Determine the quantity and circumstances of percutaneous injuries while using safety devices and partner with device manufacturers to address engineering failures.

2.4: Work with regulatory agencies and standard-setting groups to establish performance criteria for safety devices that address both worker and patient safety concerns. Disseminate performance criteria to manufacturers and users of these devices.

3.0: Safety Promotion

Promote the use of safety techniques, workplace practices and use of safety devices among all dental healthcare personnel.

3.1: Ensure that all relevant dental educational programs include sharps safety training in curriculums.

3.2: Collaborate with relevant dental professional associations in encouraging their constituents to be actively involved in selecting, evaluating, prescribing the use of, and using safety devices within their scope of practice.

3.3: In the event that safety devices are not used, identify the reasons they are not and collaborate with dental healthcare provider associations to establish a standard operating procedure (SOP) and best practices guidelines that sharps users can follow when they are provided with sharps lacking safety features.

4.0: Professional Partnerships

Partner with relevant professional organizations and associations to write, update, and ensure the implementation of exposure control plans. Develop tools to inform frontline healthcare workers of the employers' responsibility for ensuring a safe workplace that includes, but is not limited to, provisions for evaluating and selecting safety devices, training, injury reporting and appropriate pre- and post-exposure prophylaxis.

4.1: Partner with government agencies and standard setting organizations to incorporate sharps injury prevention into their policies, regulations and guidelines.