Centre universitaire de santé McGill
McGill University Health Centre

Should the McGill University Health Centre use safety devices to reduce needlestick injuries associated with intravascular infusions?

REPORT No 25

An update

of

TAU report Number 1, Feb 28,2002.

"Should the McGill University Health Center replace the Jelco/Cathlon catheter by the ProtectIVPlus catheter for intravenous inclusions."

Report available at **www.mcgill.ca/tau/**

May 23th , 2006

This report was prepared for the Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC)

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Acknowledgments

The assistance of the following individuals is gratefully acknowledged:

Consultants:
Marc Deschênes, Director, Hepatology Unit. MUHC
Richard Lalonde, Director, Infectious Diseases Unit. MUHC
Filomena Pietrangelo. Division of Occupational Health and Safety. MUHC
Katherine Defalco, Standardization Officer, Materials Management, MUHC

Literature Search :
Lorraine Mines, Coordinator, Technology Assessment Unit. MUHC

Thanks for Provision of Information and Help:
Drew Johnston. Project Manager, Emergency Services, Saskatchewan Health.
Dave Ames. Johnson and Johnson Medical Products.
Gavin Morcom. BD Medical

Invitation.

This document was developed to assist decision-making in the McGill University Health Centre. All are welcome to make use of it. However, to help us estimate its impact, it would be deeply appreciated if potential users could inform us whether it has influenced policy decisions in any way.

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Executive Summary

BACKGROUND

Needlestick injury is a frequent occurrence amongst hospital personnel and is a source of risk of infection by the Human Immunodeficiency Virus (HIV), Hepatitis C (HC), and Hepatitis B (HB). A small proportion of such injuries are associated with the introduction of intravascular (IV) lines, and safety devices are now available that significantly reduce this risk. The use of such devices is now mandated in the USA, and in Canada in Alberta, Saskatchewan, and Manitoba, and is likely soon to become so in Ontario and Nova Scotia. They are increasingly used in Québec. An evaluation of one such device was carried out by the TAU for the Department of Nursing of the MUHC in 2001. The object of the present report is to access all new relevant information and to consider whether it significantly changes the conclusions arrived at that time. Where appropriate, the previously reported estimates are shown *[in brackets]* next to the contemporary estimates to facilitate comparison.

RESULTS

Risk of Infection

In 2004/5, 293,409 *[300,000]* intravascular IV (venous, arterial, central) lines were installed at the MUHC. On average over the last two years 245 *[250]* needlestick injuries were reported, and of these 26 were associated with the insertion of an IV catheter. In the same year 93% *[96%]* of healthcare workers at risk in the MUHC had been vaccinated against HB.

The proportion of the source patients (of all percutaneous injuries reported) found to be infective (+/-2SD) were:

HIV 3.0%(2.20,3.98) *[3.3%],* HC 6.7%(5.25, 8.15) *[4.5],* HB 2.9 (1.9,3.9)*[2.6%].*

In the absence of postexposure prophylaxis (PEP) the rates of seroconversion (95%CI) following needlestick involving an infected source are estimated to be approximately: HIV 0.56%(0.34,0.78), HC 1.8%(0.30, 3.0), HB 8.4%(6.7,10.1).

Those workers who report needlestick injuries receive immediate postexposure prophylaxis (PEP) for HIV and HB (there is no PEP for HC). The efficacy of PEP is not known precisely but there is evidence to support the assumption that prompt PEP would prevent at least 80% HIV and 85% HB needlestick injuries from seroconversion.

The number of unreported injuries is an unknown. We will assume that for every 26 reported injuries another 26 are unreported. There is evidence to support the assumption that the efficacy of the safety device is 83%.

Sensitivity analysis The likely upper and lower bounds of the following input variables were tested in sensitivity analysis: infectivity of sources, conversion rates of individuals receiving an infected needlestick, number of unreported needlestick injuries, efficacy of the safety device.

With these assumptions, the number of reported and unreported infections that might be prevented by use of the safety device would be as follows. The range based on sensitivity analysis is shown in parenthesis:

HIV…0.0044 (0.0017 , 0.0094) **per year, or 1 every 227** (106 , 588) *[250]* **years.**
HC….0.0521 (0.014 , 0.097) **per year, or 1 every 19** (10 , 71) *[37]* **years.**
HB….0.0042 (0.0019 , 0.0078) **per year, or 1 every 238** (128 , 526) *[142]* **years.**

Other outcomes

Introduction of the device would result in avoidance of anxiety and inconvenience for 22 *[20]* individuals making one clinic visit following injury, and the need for an

estimated 7 *[7]* individuals to receive HIV triple therapy for 28 days, with 6 months follow-up.

Costs

The net, direct, annual cost to the MUHC consists of the additional costs of acquiring the safety devices less the costs associated with management of needlestick injuries and any resulting infections:

Equipment acquisition The unit cost of the ProtectIVPlus ($1.75), less the average cost per item of currently used equipment ($1.18), times the number of uses per year (293,409) = ……..……..…..$167,243 *[$270,000]*

Treatment (excluding infections) Assuming that only reported cases will incur costs to the hospital, the cost of surveillance and treatment when necessary of the 26 recipients of reported needlestick injuries is estimated to be… $27,677 *[$25,723]*

The annual net cost (excluding infections) of introducing the safety device is therefore $167,243 – $27,677 =…….$139,566 *[$244,277]*

Costs of infections The frequency of HB and HIV infections that might occur in the 26 reported cases is so low (< 1 every 650 years) that the costs of such events will not be considered.

The immediate costs associated with one HC infection are estimated to be $43,469. Assuming a frequency of 0.0314 HC infections per year, the annual cost =….$1,365.

Such treatment, administered early, is reported to eliminate infection in most (98%) cases. However, the evidence for this is not strong enough to serve as a basis for policy decisions. *Untreated*, after a relatively symptom free interval lasting 20-30 years, up to 20% of such cases will progress to hepatic failure, cancer, and death. The cost of such an outcome is estimated at …$386,000.

The frequency of such an event, in the absence of treatment, would be 0.00521 per year. Even if treatment of the acute infection were only 75% effective, the frequency of such disastrous events in treated patients would be 0.00130, or one case every 769 years. The cost per year would then be…… $502

The annual cost associated with HC infections (acute + chronic)=…… $1,867

The annual net cost of introducing the protective device, (including costs associated with HC infections) is $139,566 - $1,867 =…….. $137,699

Note

1) Treatment of early HC infection is reported to be highly successful. If the above cost was attributed entirely to prevention of one HC infection every 19 years, the cost of each infection avoided would be:…….. **$2,642,957**

2) As noted above, the Protect IVPlus at $1.75 is the second least expensive of the available devices,(range $1.49 to $1.98). If the least expensive were found to be satisfactory, the estimated annual net cost of its introduction would be $ 61,413 instead of $137,699.

DISCUSSION

Incorporation of new information has not resulted in any substantial change in the estimates arrived at in the previous report.

Because safety devices of this type are now widely used, and mandatory in many jurisdictions the MUHC must again seriously consider this issue. Although the principal reason for their use is purported to be prevention of infection, this is clearly not the case under the conditions presently pertaining at the MUHC. The only infection that might be significantly reduced is HC, and that at the rate of one case every 19(10-71) years.

Thus, the real health benefits of this program are the avoidance of fear experienced by injured personnel, the inconvenience of making one health visit for each of the 22 reported cases, and use of PEP with follow-up for the approximately 7 cases contaminated by a “high-risk” contact.

An additional benefit of the use of the safety device is its effect on the morale and confidence of workers in their institution. Personnel should feel that they are in a hospital that makes their safety a high priority. Accordingly, a decision to continue to not purchase the device requires that the reasons behind the decision should be widely made known.

Furthermore, the anxiety experienced by injured personnel, which is the principal ill-effect following such injuries, could be significantly diminished by a widespread understanding of the low probability of acquiring such infections at the MUHC.

The only argument against the introduction of this device is the opportunity cost involved. What specific items would have to be given up is of course, unknown. However, the annual sum involved, $137,699 is approximately the equivalent of the direct costs involved in maintaining two acute medical beds.

Finally, it must be clearly understood that these estimates of risk are only applicable as long as the input variables of the estimates remain the same. Any institution that uses this report in making policy decisions must be sure that comparable conditions prevail.

CONCLUSION

The principal health benefit of the introduction of a safety device to prevent needlestick injuries associated with insertion of intravascular lines would be the elimination of fear, the inconvenience of a clinic visit for 22 injured personnel, and the need for 28 day prophylactic treatment and follow-up for approximately 7 of them. In

addition it would eliminate one reported HC infection approximately every 38 years. If the number of unreported injuries were equal to those reported, use of safety needles would prevent one case (reported and unreported) of HC every 19 years. With prompt treatment a high cure rate of such cases could be expected

The net cost of achieving this would be approximately $137,699 *[$187,394]* per year, (a sum approximately equivalent to the direct cost of maintaining two acute medical beds). If all these costs were attributed to the prevention of one HC infection every 19 years, the cost of each infection prevented would be $2,642,957. The reduction in the risk of acquiring HB and HIV is so low as to make estimation of costs inappropriate.

RECOMMENDATIONS

- The fact that injuries still occur through inadequate disposal of sharps and that only 93% of health workers are at present immunized against HB suggests that there is a need for increased expenditure on health information for all healthcare workers. Some fraction of the $137,699 expenditure envisaged might be better used on education directed to the reduction of *all* needlestick injuries.
- The greatest negative effect of needlestick injuries under conditions currently pertaining at the MUHC is the fear of infection. Understanding of how small this risk really is might diminish the fear experienced by healthcare workers who are injured.
- Use of such safety devices should be considered in all areas where there is a high incidence of patients with these infections, such as the HIV clinic (where they are already in use).
- This issue should be decided at a provincial level rather than each hospital making its own decisions in isolation. It is recommended that the MUHC refer this problem to the appropriate authorities.

- Until such time as the Ministry undertakes to fund their use, the opportunity costs of introducing these safety devices are too great to justify the benefits achieved by their introduction.

Accordingly, a general conversion to these safety devices throughout the institution is not recommended at this time.

Should the McGill University Health Centre use safety devices to reduce needlestick injuries associated with intravascular infusions?

Glossary

HIV Human Immunodeficiency Virus
HC Hepatitis C
HB Hepatitis B
PEP Post-Exposure Prophylaxis
MUHC McGill University Health Centre

Contents

INTRODUCTION

Occupational exposure of healthcare workers to blood-borne pathogens is a frequent occurrence amongst hospital personnel. A survey carried out by the Canadian Needle Stick Surveillance Network in 2000/01 [1], involving 1436 such exposures in 12 participating hospitals found an exposure rate in teaching hospitals of 4.41 per 100 (full time equivalent) workers. Of all occupational exposures in hospitals 66% were due to needlestick injuries (others being mucocutaneous 15%, sticks other than needlesticks 7%, cuts 9%, scratches 2%, and bites 1%). Of all needlestick injuries, 12% occurred during installation of intravascular lines. Safety needles are now available that significantly reduce this latter risk, and these are the subject of this review.

The principal health benefit of use of such devices is the avoidance of infection by the Human Immunodeficiency Virus (HIV), Hepatitis C (HC), and Hepatitis B (HB). The level of this risk is not obviously high. In Québec in the five-year period 2000-2005, the Commission de la santé et de la securité du travail (CSST), is aware of one HC and one HB seroconversion. There has been no case of HIV seroconversion. [Julie Provencher, CSST Personal communication]. In Canada according to the Canadian Center for Occupational Health and Safety in a report dated January 25, 2005, there has so far been one clearly identified case of occupational transmission of HIV, and two possible cases, both in laboratory workers[2]. Occupational infection by HB virus is rare in those countries in which vaccination is widespread. A major review published in 2003 records that in Italy a national registry reported only one occupational HB infection between 1986 and 1999 [3]. The risk of occupational HC infection is difficult to document in population studies. The same reviewer records that a level of HC infection higher than in the general population has been found in only one of six such studies [3].

Additional health benefits resulting from the use of safety devices are avoidance of the need for prophylactic treatment and elimination of the anxiety experienced by

health workers who receive such injuries. The *costs* to consider are the marginal cost of the safety devices, less the costs of caring for individuals who have suffered potentially avoidable needlestick injuries.

In February 2002, the TAU carried out an analysis of the benefits and costs that would result if the MUHC replaced the needles used for initiating IV lines with a safety device, the ProtectIVPlus [4]. The Executive Summary is reproduced in Appendix 1, and the original report can be obtained at WWW.mcgill.ca/tau/. In the present document we revisit this issue with the objective of identifying any new information that has become available since the original report, and estimating its influence on the effectiveness and costs of a contemporary policy to introduce such safety devices.

Only devices used for the initiation of intravascular (IV) lines (venous, arterial, central) are considered here. Of four that are presently available, one that is widely used and moderately priced, the ProtectIVPlus (Johnson &Johnson) is used for comparison with the non-safety needles in current use at the MUHC. Analyses are easily adjusted to reflect the cost or health benefit of any other device that might be selected. No attempt is made to compare their relative merits.

BACKGROUND

Use of needlestick safety devices. The ProtectIVPlus (Johnson&Johnson) safety device for the prevention of needlestick injuries associated with initiation of intravascular (IV) lines became available in 1989. Its use or that of comparable devices, has since increased progressively, becoming mandatory in the USA since passage of the Needlestick safety and prevention act in 2000 with revision of the OSHA norms relating to blood-borne pathogens in 2001[5].

In Canada the situation varies from province to province:

In Manitoba, Bill 23, the Workplace Safety and Health Amendment Act (Needles in Medical Workplaces) 2005 requires “so far as is reasonably practicable, that workers use only safety-engineered needles” [6]

In Saskatchewan, the Occupational Health and Safety Amendment Regulations of 2005 stipulate that the employer must: identify, evaluate and select needles with engineered sharps injury protection in consultation with representatives of the workers concerned, and ensure that they are used [7].

In Ontario, the government has tabled a bill that obliges employers to furnish safety equipment, in consultation with the Mixed Committee on Workers’ Health and Safety, and to assure its utilization[8]. Furthermore, it has announced an investment of approximately $11.6 million to enable hospitals to purchase safety equipment [8].

In Nova Scotia, Bill 175 “An act to provide for the use of safe needles in workplaces” has received first reading [9].

In Québec, there is no specific legislation on this subject. However, the Réglement sur la santé et la sécurité du travailleur, which has been in force since 2001, stipulates that the employer “utiliser les methods et techniques visant à identifier, controller et éliminer les risques pouvant affecter la santé et la securité du travailleur” [10] . While the Commission de la santé et de la sécurité du travail (CSST) has no overall policy on this matter, its inspectors have ruled that such devices should be used in certain workplaces.(A Gillespie, CSST. Personal communication) In 2004 L’Association Québecoise de santé et des services sociaux (AQESSS) carried out a survey of 352 health establishments, (35% response rate). Of 28 short-stay hospitals, 4 reported consistent use of safety devices for introduction of intravenous catheters while 7 reported their partial use. The remaining 17 did not use such equipment. However, in contrast to this, one supplier alone (BD), lists 60 Québec hospitals as purchasers of safety needles in the current year[11]

In the MUHC a safety device is presently used in the HIV clinic.

METHODS

Literature A search of peer reviewed literature and of HTAs was carried out using the PUBMED online database and the University of York NHS Centre for Review and Dissemination to identify English language publications for the years 2001-5, inclusive (the previous report covered earlier publications). Also consulted was the Bibliography of Occupational Exposures to Bloodborne Pathogens of the International Health Care Worker Safety Center of the University of Virginia, updated to January 2006< dbirch@jwasearch.com; ckong@jwasearch.com>. Key words used were: needlestick injuries, safety devices, PEP, sero-conversion, prophylaxis. References listed in articles were also used.

MUHC data relating to needlestick injuries were supplied by Filomena Pietrangelo of the Department of Occupational Health and Safety of the MUHC.

Equipment costs The costs of the various needles and safety devices were kindly supplied by Lorraine Rozon, Approvisionments Montréal, Santé et Services Sociaux. They reflect the prices paid by hospitals in the Montréal region under contract number “2004-602602-00-02, Produits de perfusion, hypodermiques et à prélèvement. Du 2005/10/01 au 2006/09/30. Entente globale filtrée”.

Sensitivity Analysis Multivariate probabilistic sensitivity analyses on specific input variables were performed using 1000 Monte Carlo simulations [11,12] (TreeAge Pro 2004 Suite TreeAge Software Inc.). Each simulation randomly samples values from pre-specified distributions for each variable, resulting in simulated population distributions for the outcomes being evaluated [12,13].

In our analysis, the variables of interest (see Appendix 2) were simultaneously varied around the most likely value using triangular distributions where the extremes were obtained by increasing and decreasing these values by an estimated range of

probability as indicated in the text and Appendix 2. The Monte-Carlo simulations were used to estimate the 95% confidence interval [13].

Presentation Estimates are presented in such a way that readers can insert different input variables to reflect differences in such items as equipment used, injury and infectivity rates, conversion rates, and effectiveness. ***The estimates arrived at in this analysis can only be applied elsewhere to the extent that this is done.***

RESULTS

Estimation of the costs of using the safety device for all intravascular insertions, and the net health benefits that can be expected, will depend on the input variables listed below. To facilitate comparison with our 2000/1 report, after each estimate the estimates arrived at in the previous report are shown in *[brackets].*

Risk of infection

The infections of concern following needlestick injury are the Human Immunodeficiency Virus (HIV), and Hepatitis C (HC) and Hepatitis B (HB). The number of infections that might be prevented by introduction of the safety device and the cost depends on the following estimates:

A) Number of devices used

In the five hospitals of the MUHC in the year 2004/5 a total of 293,409 IV lines were installed (table 1).

Assume for present estimates that the number of IV lines installed each year is:…….*293,409 [300,000]*

B) The number of reported needlestick injuries

The number of needlestick injuries reported over the last five years range from 171 to 252 per year, averaging 245 over the last 2 years. The number of injuries related to the insertion of intravascular (IV) lines ranges from 20 to 27 per year (Table 2). Other sources of injury not considered here are: blood drawing 27%, percutaneous injections 15%, suturing 15%, injections into IV lines 4%, incisions 4%, other and unknown 12%. For purposes of risk estimation we will use the average of the two most recent years, 2003/4 and 2004/5.

Assume the annual incidence of reported injuries to be:…….…..…. 26 *[20]*

C) The infectivity of sources

A Health Canada survey of health care workers carried out between April 2000 and March 2002, involved 12 hospitals, 509,312 hospital admissions, and 2621 exposures to blood-borne pathogens of which 1722 were needlestick injuries. Source patients were identified in 85.3% of these exposures. Infection rates of source patients were: HIV 2.6%, HC 7.6%, and HB 1.8%. More than one infection was involved in 1.6% of exposures[15].

At the MUHC approximately 90% of the source patients involved in all types of injury are tested for infectivity. Infectivity rates over the last five years are shown in Table 2. The average percent found to be infective over the last two years (the only years for which data are complete) were: HIV 3.0% *[3.3%],* HC 6.7% *[4.5%],* HB 2.9% *[2.6%].* For purposes of risk estimation we will use these values,+/- 2 SD for sensitivity analysis

Assume % of sources who are infected to be: HIV 3.0% (2.20 , 3.98) *[3.3%],* HC 6.7% (5.25 , 8.15) *[4.5%],* HB 2.9% (1.9 , 3.9) *[2.6%]*

D) The HB vaccination rate

In the Health Canada surveillance study referred to above, 97% of exposed healthcare workers had been vaccinated for HB [14]. At the MUHC over the past five years, the average number of employees at risk who had been vaccinated for HB

varied between 92% and 94% (Table 2). For present purposes we will assume 93% (the average of the last two years) of personnel to be protected.
Assume: 7% *[6%]* of exposed workers are susceptible to HB infection.

E) The number of susceptible personnel who report needlestick injuries involving an infective source each year

For HIV and HC this will be the percentage of sources who are infected times the number of injuries (C % of B). For HB it will be the percentage of sources who are infected times 7 % of the number of injuries. (C% of 7% B).
Assume: HIV 0.78 (0.59 , 0.96) *[0.66],* HC 1.74 (1.48 , 2.0) *[0.9],* HB 0.053(0.039 , 0.067) *[0.03].*

F) The conversion rate without prophylactic treatment

HIV. In 1994 Geberding [16] in a 10-year dynamic cohort study found that one of 327 (0.31%) needlestick exposures involving blood or body fluids of HIV positive patients resulted in seroconversion (CI 0.008 – 1.69). In a CDC surveillance project in the USA, 1440 healthcare workers who had received a percutaneous exposure to HIV infected blood were followed and retested at least six months later. Four (0.28%) had seroconverted. With aggregation of these data and 22 other studies involving a total of 6200 healthcare workers, a total of 20 had seroconverted (0.32%, 95% CI= 0.2 - 0 .5%)[17]. The Centers for Disease Control and Prevention of the USA considers the average risk of infection after a needlestick or cut exposed to HIV-infected blood to be 0.3%[18.]

However, this is an average risk, and there is reason to believe that the greater volume of blood carried in a hollow, blood-containing needle would carry a higher risk. This is supported by the findings of a large case-control study, in which the placement of a needle in a blood vessel was found to be associated with an increased risk of conversion, with an OR 4.3 (95% CI 1.7-12) [19].

There is no direct evidence on the probability of seroconversion following injuries with blood-containing hollow needles. However, an estimate can be arrived at on the basis of the following assumptions. On the basis of the evidence cited above, assume the *average* risk of conversion following needlesticks by hollow, blood-containing needles, and all other needles, is 0.3%(95% CI=0.2-0.5%). Few seroconversion studies state the proportion that these two types of needlestick contribute to the average conversion rates reported. However, there is evidence as to the relative frequency of these two types of needlestick injury in general. Thus, from Graph 28.2 of Jagger and colleagues [3] it can be estimated that blood-filled needles in the US and in Italy constitute approximately 41% and 39% of transcutaneous needlesticks, respectively. In Canada, a Health Canada survey involving 12 Hospital sites in 2000 and 2001, found that 40% of 724 reported needlestick injuries involved the use of intravascular needles. Thus we will assume that the average conversion rate of 0.3% is the result of 40% injuries involving blood-containing hollow-bore needles with a high-risk of conversion (x), and 60% of injuries from all other types of percutaneous needlestick with a low risk of conversion (y), and that the difference in risk is reflected by the Odds Ratio of 4.3 [19]. With these assumptions, x (the risk of conversion associated with hollow blood-filled needles) = 0.56%, and that associated with other percutaneous needlestick injuries (y) = 0.13%. We will assume for present purposes, a conversion rate of 0.56%. For sensitivity analysis we will test values +/- 40%, a range that allows for the upper limit of the 95% CI of Cardo et al.[19].

HB. The risk of seroconversion following a needlestick injury involving HB infected blood varies with the hepatitis B status of the source individual , ranging from 1 to 30%. It is reported that in Québec < 10% of HB infected individuals will be HBeAg positive (Robillard P. 2002,Institute Nationale de la santé du Québec. Personal communication). We will assume that on average 10% of sources will be HBeAg positive (carrying a risk of transmission of >30%*), and 90% of sources will be negative (carrying a risk of transmission of > 6%*).

*Lanphear BP.Transmission and control of blood-born viral hepatitis in health care workers. Occupational Medicine. 12. (4): 717-30.1997.

With these assumptions the average HB conversion rate would be (0.1x30%)+(0.9x6%) = 8.4%. In sensitivity analysis we will test values of +/- and 20% which would allow for the possibility that as many as 25% of source individuals might be HB eAg positive.

HC. Variable seroconversion rates have been reported following needlestick injury involving HC positive blood. The most substantial study is that of Puro et al. who followed up to 646 such events and observed 4 seroconversions (0.6 %). However, all of these resulted from 331 injuries by presumably high-risk hollow-bore needles. Thus the conversion rate of injuries with hollow-bore needles was 1.2% (95%CI, 0.3-3%) [20.] Hernandez et al. found no seroconversions in a follow up of 81 needlesticks involving HC positive sources [21]. Kiyosawa et al. found seroconversion in 3 of 110 needlestick injuries involving HC positive sources (2.3%)[22]. Lanphear et al. found that 3 of 50 (6%) such needlestick injuries resulted in seroconversion [23]. In neither of the latter studies was the nature of the needles reported. In a 2003 report the CDC considered the conversion rate to be approximately 1.8% [18]. Apart from the study of Puro et al. cited above there is no evidence that the level of risk associated with the use of blood filled hollow-bore needles is increased. We will accept the 1.8% CDC rate and test the 95%CI (0.3-3.0) established for hollow-bore needles in the study of Puro et al. [20], in sensitivity analysis.

Assume: Conversion rates for individuals not receiving prophylactic treatment would be: HIV 0.56% (0.34- 0.78%), HC 1.8% (0.3 – 3.0%), HB 8.4% (6.7 –10.1 %).

G) The conversion rate with prophylactic treatment

HIV. For HIV the best evidence of efficacy of post-exposure prophylactic treatment (PEP) consists of an extensive case control study in which, after controlling for other risk factors, the odds of HIV infection among healthcare workers who took zidovudine prophylactically after exposure was reduced by approximately 81% (95% CI, 43%-94%)[19]. Contemporary triple therapy is presumably more effective, but no data are

available on which to base a precise estimate. An efficacy of 100% cannot be assumed. A 2003 review reports 16 cases of HIV PEP failure, in three of which three or more drugs were used[24]. Thus, even contemporary triple therapy cannot be assumed to be 100% effective. For present purposes we will assume a risk reduction with prompt HIV PEP of 80%, and in sensitivity analysis test values of 43% and 94%, the 95% CI in the study of Cardo et al.[19].

HB Post-exposure management for susceptible workers consists of combined active (vaccination) and passive (immune globulin) prophylaxis. Based on studies of the prevention of perinatal transmission to newborns from their HB infected mothers, this is believed to provide 85% to 97% protection [3]. For present purposes we will assume the effectiveness of such therapy to be 85%, and test values +/- 20% in sensitivity analysis, which allows for a range of effectiveness from complete protection to as low as 68%.

HC. There are at present no effective prophylactic measures against HC.

Assume: Conversion rates for individuals receiving prompt post-exposure prophylactic treatment : HIV(20%*0.56) = 0.112%(0.034-0.319),
HC = 1.8% (0.3-3.0), HB (15%* 8.4%) = 1.26%.(1.01-1.51).

H) The number of unreported needlestick injuries

We have assumed that 26 needlestick injuries will be reported each year, and that these will receive prophylactic treatment. The number of unreported needlestick injuries is unknown. A CDC survey in 12 hospitals in 1998 concluded that an average of 52% of injuries of health workers (excluding surgeons) were not reported [25]. A NIOSH Alert also cites evidence that about half of all such injuries may be unreported [26]. Such injuries would, of course, not receive prophylactic treatment for HIV and HB. We will assume the same number of unreported as reported injuries, and in sensitivity analysis test values of +/- 40%.

Assume: 26 (16 – 36.4) unreported needlestick injuries at the MUHC each year.

I) Infection rates (without prophylaxis)

The number of susceptible individuals who might each year become infected would be the number of unreported injuries (H) x the infectivity rate of sources (C) x conversion rates (F) . For HB with a 93% vaccination rate the injury rate should be multiplied by 0.07.

HIV= 26 * 0.03 * 0.0056 = ……..0.0044 (0.0017, 0.0088)

HC = 26 * 0.067 * 0.018 =…….... 0.0314 (0.0077 , 0.067)

HB = 26 * 0.029 * 0.084 * 0.07 = …0.00443(0.0019, 0.0082)

J) Infection rates (with prophylaxis)

Of 26 individuals who report needlestick injuries and receive postexposure prophylaxis, the number who might become infected would be 26 x the infection rate of sources (C), x the conversion rates (G). Assuming 93% HB vaccination rate, the infection rate for HB is again multiplied by 0.07:

HIV= 26 * 0.03 * 0.00112 = 0.00087 (0.00044, 0.0024)

HC =26 * 0.067 * 0.018 = 0.0314 (0.0125, 0.048)

HB = 26 * 0.029 * 0.0126 * 0.07 = 0.00067 (0.00047, 0.00088)

K) Total number of needlestick infections without use of safety device

Assuming 26 reported and 26 unreported injuries at the MUHC, the number of infections that may result is the infection rate without prophylaxis (I) plus the rate with prophylaxis (J). Figures in parenthesis represent the 95% confidence interval resulting from use of the upper and lower bounds of each input variable:

HIV = 0.00527 (0.00215 , 0.0112) per year, or 1 case every 189 (89 , 465) years

HC = 0.0628 (0.017 , 0.114) per year, or 1 case every 16 (8.8 , 59) years

HB = 0.0051 (0.0023 , 0.0091) per year, or 1 case every 196 (110 , 435) years

L) The efficacy of the safety device

It appears that no safety device can be considered 100% effective. One review reports data suggesting that 77% of injuries from hollow needles are “potentially preventable” [3]. Furthermore, 100% compliance with use of devices by nursing

personnel cannot be assumed. In one 800 bed US hospital, after education and a period of trial, only 82.8% of workers eventually felt comfortable using the device [27.] (We will presume that at the MUHC, if the device were accepted, its use would not be optional.)

Two studies (reported only in abstracts), carried out before and after the introduction of safety devices of this type found reductions of injury rates of 29% [28], and 89% [29]. In a 1996 study in which a safety device was simultaneously introduced into certain areas of three hospitals, its use was associated with an 84% reduction in injuries compared to conventional devices [30]. A review carried out for the American Nurses Association [31] concluded that such devices can be expected to reduce needlestick injuries related to catheter insertion by 83%.
Assume : the safety device will reduce needlestick injuries by 83%,+/- 20% (66-100) *[100%].*

M) Number of needlestick infections (reported and unreported) that might be prevented by the safety device 83% of reported and unreported injuries (values in parenthesis represent the 95% confidence interval):
HIV…0.0044 (0.0017 , 0.0094) **per year, or 1 every 227** (106 , 588) *[250]* **years.**
HC….0.0521 (0.014 , 0.097) **per year, or 1 every 19** (10 , 71) *[37]* **years.**
HB….0.0042 (0.0019 , 0.0078) **per year, or 1 every 238** (128 , 526) *[142]* **years.**

Other consequences of needlestick injuries

The non-infectious consequences of a needlestick injury can only be estimated for those injuries that are reported. Except where noted, the following estimates are based on the recommendations of the Medical Surveillance Programme for Accidental Exposure to Blood and Body Fluids of the Montreal General Hospital [32].
It is estimated that introduction of the safety device will reduce the non-infectious consequences of reported needlestick injuries as follows. (see Appendix 2).

Assuming device effectiveness to be 83%, 22 *[20]* individuals (26 x 0.83) each year will avoid an initial clinic visit that normally follows each injury, and the associated anxiety.

Seven *[7]* of the 22 individuals will avoid post-exposure prophylaxis consisting of immediate administration of HB immune globulin and HB vaccination, undergoing HIV treatment with triple therapy for 28 days, and subsequent follow-up for 6 months. As many as three quarters of individuals receiving PEP for HIV will experience side effects (nausea 57%, fatigue/malaise 38%, headache 18%, vomiting 16%, diarrhea 14%, myalgia 6%), and "serious" side effects in 1.3% [33].

Costs

In Québec work related injuries are covered by the Commission de la santé et de la securité au travail (CSST). However, many institutions assume all costs themselves because of the upward adjustment of premiums that may result from a CSST claim. Except where specified, the costs referred to below are the direct costs incurred by the MUHC. Although physicians, residents and students may receive needlestick injuries which involve costs and possibly even litigation, they are not hospital employees, and the hospital carries insurance against such eventualities. Thus, for purposes of cost estimation it will be assumed that all injuries involve nursing personnel.

Equipment Costs

The cost of currently used non-safety equipment and the frequency of its use are shown in table 1. The weighted average cost per item is $1.18. There are now four different safety devices on the market. The cost of each to the MUHC would be $1.49, $1.75, $1.93, $1.98 respectively. The cost of the second least expensive, the ProtectIVPlus is $1.75 . The difference ($1.75 -$1.18)=$0.57x the number of uses (293,409) =$167,243 . If the least expensive ($1.49) were found to be satisfactory,

the difference would be $90,957. For present purposes we will base cost comparisons on the widely used ProtectIVPlus.
Thus, the increase in equipment costs that would result from use of this safety device for 293,409 procedures per year would be…….. **$ 167,243** *[$270,000].*

Management Costs of 26 reported injuries (excluding infections)

The interventions routinely undertaken following needlestick injury are listed in Appendix 3. The unit cost, the frequency, and the total cost of each intervention are shown in Appendix 4. The potentially avoidable annual cost (excluding infections) of not using the safety device would be……..**$27,677** *[$25,723]*
Average cost per avoidable injury; $27,677 /22 =……. **$1258**

Comparison with other estimates.

While precise comparison of this estimate with other studies is not possible, a rough comparison can be made with the results of four previous reports.

Jagger et al. [34] estimated the average cost of managing percutaneous injuries in two hospitals in 1995-1997 to be US$ 672 and US$ 539. With upward adjustment to recognize the added cost of HIV treatment of 7 of every 26 subjects (US$ 330), the average cost per needlestick injury would be US$ 1,002 and US 869, or (assuming Ca$ 1=US $ 0.8) respectively…… ……. **$1,121** and **$1,086.**

Dupont and Thibodeau [35] estimated the costs in 1999, in a Montréal hospital, resulting from exposure to potentially infected blood. Adjustment of their estimates to include treatment of 7 of every 22 exposures with triple therapy results in a total per exposure cost of……. **$1648**

In Québec, Bouchard [36] estimated the costs in 1999 associated with exposure to high and average risk sources. Assuming 9 of every 26 exposures to be high-risk, of which 4 would result in the recipient being off work for one month because of side effects, results in an average cost of……. **$1520**.

In Winnipeg, Manitoba, Yassi et al. found the cost of managing a needlestick injury to be $559 [37]. At that time no post-exposure prophylaxis for HIV was administered. Addition of the costs of such treatment (Appendix 3) with the assumption that one third of sources are "high-risk", results in an average cost per injury of……. **$1024**

Thus, if we accept the estimated management costs ($27,677), the *net* annual cost of introducing the ProtectIVPlus device (excluding the cost of treating infections) would be: $167,243- $27,677 =…… **$139,566** *[$244,277]*

Costs due to infection

The costs that might be incurred if a seroconversion were to occur have been a major argument in favor of the use of safety devices. These are considered below.

It is unlikely that infections that followed *unreported* needlestick injuries would incur costs to the hospitals concerned. Among the 26 recipients of reported injuries, HIV and HB infections together would be so infrequent (< 1 every 650 years) that their influence on annual costs would be negligible. However, it is estimated (paragraph J above) that the frequency of reported HC infections would be 0.0314 (CI, 0.0107, 0.0476) per year, or once every 32 (CI 21,93) years.

Estimation of the costs related to such an event must be extremely hypothetical. A possible scenario is set out below:

Immediate costs

Treatment with pegalyted Interferon/Ribavirin for 6 months [38]…… $1,700
Side effects and depression might cause inability to work for up to one year,
with reimbursement at 90% of net salary = …….. $41,769.
Total ……..$43,469.

Bouchard et al. [39] estimated the direct costs resulting from an HC seroconversion in Québec in 2002 to be $32,564.

We will assume the costs of managing an HC seroconversion :
($43,469*0.0314) =…… $1,365 per year

Long-term costs

The probability of further costs are low. It is now reported that prompt treatment of acute HC infection results in a very high cure rate, and in one recent study 43 of 44 patients (98%) had undetectable levels of HCV RNA after an average of 3.2 weeks of treatment [40]. However, a 98% efficacy rate cannot be assumed on the basis of so few data with such short follow-up. Thus it must be assumed that some cases may not tolerate or not respond to treatment. Let us assume initially that treatment is not undertaken or is completely ineffective.

Under these conditions between 15% and 50% of infected patients would clear the infection, and between 50% and 85% would become chronically infected with HC virus[41]. After a relatively asymptomatic period lasting 20-30 years, 2%-20% of such patients would develop cirrhosis, and progress to liver failure, carcinoma and death [41]. We have previously estimated that the total cost of such an event might be of the order of $386,000 [4]. Under the worst scenario, namely that 20% of patients experience this disastrous outcome, its frequency would be (0.2 x 0.026) = 0.00521 (CI, 0.0018 , 0.0079) per year, or once every 192 (CI, 127, 556) years. Even if treatment were only 75% effective, the frequency of such events in treated patients would be 0.00130 (CI, 0.00045, 0.0020), or one case every 769 (CI, 500 , 2222) years and incur a cost of ($386,000/769) =…….$502 per year.

Short and long-term costs of HC infections

Thus, the cost of treating HC infections resulting from reported needlesticks would be: $1,365 +$502 =…….. $1,867 per year.

Annual net cost

Thus, the *annual net* cost of introducing the protective device, including the costs of HC infection: $139,566 - $1867 =…… $137,699 *[$187,394].*

Note:

1) If all the above costs were attributed to prevention of one HC infection every 19 years, (resulting from reported and unreported injuries) the cost of each infection prevented would be $137,699/ 0.0521 =…….... $2,642,975 .

2) As noted above, the Protect IVPlus at $1.75 is the second least expensive of the available devices, which range from $1.49 to $1.98 each. If the least expensive were found to be satisfactory, the estimated annual cost of its introduction would be $61,413 instead of $137,699.

DISCUSSION

Neither changing circumstances nor new information deriving from literature review has caused major changes in the estimates made five years ago. The largest change is the higher rate of HC infection (1 every 19 years vs 1 every 71 years). At the same time the prognosis for promptly treated HC infection has greatly improved, a change that modestly influences estimates of cost.

Another difference is the incorporation of the estimated efficacy of prompt post-exposure prophylaxis for HB and HIV into estimates. Though noted in the previous report, the effectiveness of such treatments was not included in the principal estimates.

The biggest change since the last report however, is the fact that use of these devices is now mandatory throughout the USA, Alberta, Manitoba, and Saskatchewan, and

probably will shortly become so in Ontario and Nova Scotia. Although not yet mandatory in Québec, they are already in use in 60 hospitals[11]. Thus, in considering whether they should be used at the MUHC it is important to try to understand why so many jurisdictions elsewhere have already decided to adopt them.

The principal reason for their use is to prevent infection. However, this is clearly not the case, at least under the conditions presently pertaining at the MUHC. The only infection that might be clinically significantly reduced is HC, and that at a rate of one reported case every 38 years, or if estimated unreported injuries are included, one every 19 (10-71) years.

The real health benefits of this program are the avoidance of fear, and the inconvenience of making one health visit, which would be experienced by each of the 22 avoidable reported cases. There is also the sometimes very considerable discomfort of 28 days of triple therapy for HIV with follow-up, for the approximately 7 cases in which the sources are considered to be “high-risk”.

An additional important benefit is the effect on the morale of workers and their confidence in their institution. It is important that personnel should feel that they are in a hospital that makes their safety a high priority. Accordingly, a decision to not purchase the safety device would require that all concerned should clearly understand the reasons behind the decision.

However, in addition to the above reasons, a convincing argument for decision makers would be the possibility that the introduction of these safety devices might also result in net cost savings. And savings could indeed be anticipated if the cost of the device compared to conventional needles was sufficiently low and the cost associated with needlestick injuries sufficiently high. This was demonstrated in an influential analysis prepared by the United States General Accounting Office [42], and endorsed by the Centers for Disease Control and Prevention at the time of the introduction of the US Needlestick Safety and Prevention Act in 2000. In this analysis three cost

scenarios for post-exposure treatment were considered, together with three hypothetical increases in equipment costs. If the cost per post-exposure treatment was US $ 1,500 or higher the introduction of safety devices could result in net savings. However, for an increase in the costs of safety devices comparable to those used in the present study, their findings demonstrate that if the cost per injury was lower ($500), introduction of the device would result in a net increase in costs. The estimated average cost per injury in the MUHC in 2006 was $1,065, or US $691 (Can$ 1= US $0.65 in 2000).

A more definite prediction of cost savings comes from the Ontario Hospital Association in which it is predicted that safety devices could be introduced into Ontario's acute care hospitals with a saving of between $10.5 million and $27 million each year[43]. (The report is not referenced and the way in which these conclusions were arrived at is not explained).

In summary, while the prevention of fear and inconvenience to healthcare workers are very real arguments favoring the introduction of these devices, the effects on infection would be marginal and a small but real budget impact can be expected.

The only argument against the introduction of this device is the opportunity cost involved. Although the estimated net annual expenditure is relatively small, approximately $137,699 per year, or $61,413 if the least expensive device is selected for use, there is no reason to anticipate that new money will be forthcoming to meet this expense. What specific items would have to be given up because of such a purchase is of course unknown, but the annual sum involved is approximately equivalent to the direct costs of maintaining two acute medical beds.

Finally, it must be clearly understood that these low estimates of risk are only applicable while the input variables of the estimates remain the same. These (injury rates, infectivity of sources, HB vaccination rates, conversion rates, and use of prophylactic treatment) must continue to be monitored. Likewise, any institution that

uses this report in making policy decisions must be sure that comparable conditions pertain in their institutions.

CONCLUSIONS

Most needlestick injuries do not involve placement of IV lines and would not be affected by the introduction of the safety devices in question.
The principal health benefit of the introduction of safety devices to prevent needlestick injuries associated with intravascular infusions would be the elimination of the fear associated with 22 reported and possibly 22 unreported injuries, and the inconvenience of a clinic visit for 22 personnel who report those injuries. Also the need for prophylactic treatment and follow-up for approximately 7 of them each year. In addition it would eliminate one infection by the HC virus approximately every 19 (or possibly 10) years. The cost of these benefits would be approximately $137,699 per year.

RECOMMENDATIONS

- The fact that injuries still occur through inadequate disposal of sharps and that only 93% of health workers are at present immunized against HB suggests that there is a need for increased health information for all healthcare workers. Some fraction of the $137,699 expenditure envisaged might be better used on education directed to the reduction of *all* needlestick injuries.
- The greatest negative effect of needlestick injuries under conditions currently pertaining at the MUHC is the fear of infection. Widespread understanding of how small this risk really is might diminish the fear experienced by healthcare workers who are injured.
- Use of such safety devices should be considered in all areas where there is a high incidence of patients with these infections, such as the HIV clinic (where they are already in use).

- This issue should be decided at a provincial level rather than each hospital making its own decisions in isolation. It is recommended that the MUHC refer this problem to the appropriate authorities.
- However, until such time as the Ministry undertakes to fund their use, the opportunity costs of introducing these safety devices are too great to justify the benefits achieved by their introduction.

Accordingly, a general conversion to these safety devices throughout the institution is not recommended at this time.

Table 1 MUHC PERIPHERAL IV CATHETERS 2005						
brands	**mms**	**gauge/length**	**users**	**usage (ea)**	**unit cost**	**cost**
Cathlon non-radiopaque metal hub	8003000262	14/2.25	MGH	1,038	1.20 $	1,246 $
	8003058554	16/1.25	RVH	2,400		2,880 $
	8003000265	16/2.25	MGH, MNH	3,720		4,464 $
	8003021934	18/1.25	MNH	1,508		1,810 $
	8003000263	18/1.75	MNH, MGH	17,080		20,496 $
	8003000264	20/1.25	MGH, MNH	50,092		60,110 $
	8003000269	22/1.00	MGH, MNH	54,650		65,580 $
				130,488		**156,586 $**
Cathlon radiopaque metal hub	8003020510	14/2.25	MCH, RVH	2,372	1.20 $	2,846 $
	8003020511	16/2.25	RVH	3,334		4,001 $
	8003020519	18/1.75	RVH	20,572		24,686 $
	8003020518	20/1.25	RVH	44,110		52,932 $
	8003020520	22/1.00	RVH	35,294		42,353 $
				105,682		**126,818 $**
Angiocath radiopaque plastic hub	8003020553	16/1.25	MCI	284	0.96 $	273 $
	8003020558	16/1.75	MCI	74		71 $
	8003020555	18/1.75	MCI	0		0 $
	8003020554	20/1.25	MCI	3,505		3,365 $
	8003020556	20/1.75	MCI	0		0 $
				3,863		**3,708 $**
Insyte radiopaque plastic hub	1014044328	16/1.77	nil	0	1.03 $	0 $
	1014044329	18/1.16	RVH	220		227 $
	8003021878	20/1.25	RVH	2,400		2,472 $
	8003021881	22/1.00	RVH	2,150		2,215 $
	8003020929	24/0.56	MGH, MCH, RVH	7,724	2.03 $	15,680 $
				12,494		**20,593 $**
Autoguard radiopaque plastic hub	8003040906	20/1.16	nil	0	1.84 $	0 $
	8003042397	22/1.00	MCI	50		92 $
				50		**92 $**
Jelco radiopaque plastic hub	8003058553	14/1.25	RVH	800	0.95 $	760 $
	8003009851	16/2.25	MCH	296		281 $
	8003009850	18/1.75	MCH	468		445 $
	8003009849	20/1.25	MCH	2,060		1,957 $
	8003009848	22/1.00	MCH	15,864		15,071 $
	8003021939	24/0.75	MNH	3,784		3,595 $
	8003009847	24/0.75	MCH	17,560		16,682 $
				40,832		**38,790 $**
			TOTALS	**293,409**	1.18$	**346,587$**

Table 2

The number of needlestick injuries, the number associated with an intravascular (IV) line, the percentage of source patients found to be infected, and the percentage of health-workers vaccinated for HB. Only the years 2003/4 and 2004/5 include data for all MUHC hospitals. Data from the Montréal Children's Hospital not available for the first three years.

	2000/1	**2001/2**	**2002/3**	**2003/4***	**2004/5***	**Average 2003/4 and 2004/5**
Needlestick injuries	-	207	171	238	252	**245**
Injuries with IV line	20	-	20	24	27	**26**
Source HIV+ (%)	1.9	2.0	4.4	3.6	2.3	**3.0**
Source HC+ (%)	5.6	4.4	3.0	6.6	6.7	**6.7**
Source HB+ (%)	2.1	4.4	2.6	3.0	2.7	**2.9**
% Vaccinated	93.8	92.0	92.0	92.4	93.5	**93**

*Only data for 2003/4 and 2004/5 include the Montreal Children's Hospital

Appendix 1

Executive Summary of TAU report dated February 26, 2002

Conclusion.

The principal benefit that would result from the introduction of the ProtectIVPlus (J&J) safety device for all intravenous infusions carried out at the McGill University Health Center (MUHC) would be relief from fear of infection for approximately 20 individuals per year, and protection of 7 individuals from the need to undergo 28 days prophylactic triple therapy. It would have no easily measurable effect on the risk of infection of health workers. The estimated direct net cost of obtaining these benefits would be approximately $244,000 per year to the Québec health-care system or $193,000 to the MUHC.

Background

This study assesses the benefits and costs involved if the four hospitals that make up the MUHC should replace the presently used Jelco/Cathlon Needle with a safety device, the ProtectIVPlus. The objective of this device, used only for intravenous infusion lines, is to reduce the risk of needlestick injuries with their associated risk of infection by the Human Immunodeficiency Virus (HIV), Hepatitis C (HC), and Hepatitis B (HB). Such devices now occupy approximately 20 percent of the Canadian market, and their use is mandated throughout the USA.

Results.

Risk of Infection. Approximately 300,000 intravenous lines are installed at these MUHC hospitals each year, approximately 250 needlestick injuries are reported, and of these, 20 are associated with the insertion of an intravenous (IV) catheter. Not all needlestick injuries are reported, and we will assume here that each year there are also 20 unreported IV needlestick injuries.

- The proportion of patients undergoing intravenous procedures (the sources) who are infective, are approximately: HIV 3.3%, HC 4.5%, HB 2.6%.
- 94 percent of MUHC health-care workers have been vaccinated against HB. The number of MUHC personnel *susceptible* to these three infections, who report a needlestick injury from an *infective* source in any one year are approximately: HIV 0.66, HC 0.9, HB 0.03.
- Of *susceptible* workers whose injury involves an *infective* source, the following percentages will become infected: HIV 0.3%, HC 1.5%, HB 12.0%.
- The ProtectIVPlus device is probably over 80% effective.

Based on these estimates, a decision *not* to introduce the device might result in the following number of reported, potentially preventable, infections each year. A second estimate, based on the upper bound of probability is shown in brackets( ) :
HIV 0.002 (0.0036), HC 0.0135 (0.024), HB 0.0036 (0.0068).

Expressed differently, with the limits of probability again shown in brackets ( ), if the device were 100 % effective, it could prevent one case of HIV infection every 500(276) years, one case of HC infection every 71(37) years, and one case of HB infection every 250(147) years.

The above estimates apply to *reported* injuries. If there were also 20 *unreported* injuries (40 in all), the number of preventable infections per year would become:
HIV 0.004 per year, or one infection every 250 years.
HC 0.027 per year, or one infection every 37 years.
HB 0.007 per year, or one infection every 142 years. .

Risk of other (non-infectious) outcomes. Introduction of the device would result in 7 individuals not having to receive triple therapy for 28 days, with 6 months follow up and the associated anxiety. Twenty individuals would avoid having to make one clinic visit with the associated anxiety. One individual would not need to measure anti-HCV serology at 3 and 6 months. One individual would avoid administration of HB immunoglobulin and vaccination.

Costs. The marginal direct cost of purchasing the device would be $270,000 per year. The potentially avoidable costs of managing those needlestick injuries that would occur if the device were not introduced, would be approximately $25,723 per year.

The *net* annual direct cost to the *Québec health-care system* (the MUHC and the Commission de la santé et sécurité du travail CSST) of introducing the safety device would thus be $270,000-$25,723=$244,277. The equivalent cost *to the MUHC* would be approximately = $192,832 per year.

If high estimates of the possible costs resulting from an HC infection are included, the costs *to the health-care system* of not using the device could be increased by $1,633 per year. The costs that would be incurred *by the MUHC* because of such an event would vary according to circumstances, but would be most unlikely to exceed $5,437 per year. Accordingly, the annual net cost to the MUHC of introducing the safety device, even including the possible costs of an HC infection, would not be less than $187,394.

Other Issues. Apart from considerations of efficacy and cost, there are other relevant issues that are not considered here. These include the following:
Opportunity costs. It is beyond the scope of this report to consider the source of the funds necessary to cover the cost of purchasing this device and whether hospital services might have to be curtailed in order to find such funds. However, such opportunity costs are an important reality in our health-care system.
Morale. To recruit and retain staff, it is important that they should feel that they are in an institution that makes their safety a high priority. Accordingly, any decision not to purchase the device in question would need to be accompanied by widespread education concerning the reasons behind the decision.
Education. A principal adverse effect of needlestick injuries lies in the fear of infection. Unnecessary anxiety might be significantly reduced by an education campaign directed both at the avoidance of needlestick injuries and at increasing the level of public knowledge as to the low probability of becoming infected.

Appendix 2

Variables and ranges used in the probabilistic sensitivity analyses

Variable	Most likely value (range used in the sensitivity analysis)
Infectivity rate	HIV: 3.0% (2.29 , 3.71) HC: 6.7% (5.70 , 7.70) HB: 2.9% (2.15 , 3.66)
Seroconversion rate without prophylaxis	HIV: 0.56% (0.34 , 0.78%) HC: 1.8% (0.3 , 3.0%) HB: 8.4% (5.04 , 11.76%)
Seroconversion rate with prophylaxis	HIV: 0.112% (0.034 , 0.319%) HC: 1.8% (0.3 , 3.0%) HB: 1.26% (1.01 , 1.51)
Efficacy of device	83% (66% , 100%)
Number of unreported injuries	26 (16 , 36)

Appendix 3

Consequences of *reported* needlestick injuries excluding infections

Except where noted, the following measures are those recommended by the Medical surveillance programme for accidental exposure to blood and body fluids of the Montréal General Hospital [32] .

Recommendation **Individuals involved**

Immediate care (First visit)

Clinical examination and evaluation of the incident (83%of 26)……22 *[20]*

Lab. tests for, anti-HIV, anti-HCV, Liver function (ALT) (all) ……22 *[20]*
anti-Hbs if not known to have a protective level.
HbsAg and Hbc for those not vaccinated. (6% of 22)…….1.5 *[1]*

Injections
Tetanus antitoxin if vaccinations have lapsed .(Assume all)……22 *[20]*
HB vaccine if not already vaccinated. (5% of 22)……..1.5 *[1]*
HB immunoglobulin (HBIG) if not already vaccinated. (5% of 22)……..1.5 *[1]*

Other Treatment.
HIV triple therapy for 28 days when the source is considered "high-risk", and tests for toxicity (blood count, renal and hepatic function). At the MUHC over the past 3 years approximately 20% of sources have been considered high-risk [44].
For present estimate assume 33% of 22…… …..7 *[7]*

Subsequent care (Follow up)

Of every 22 [20] needlestick injuries that are expected each year, in some the source will be found to be infective. The consequences of this will vary with the infection concerned, as follows:

HIV.
All recipients of injuries involving the estimated 7 sources considered to be "high-risk"(regardless of their HIV status) will be recommended to undergo short-term treatment and follow-up. This will involve the following interventions :

Anti-HIV testing at 6 weeks, 3 months, 6 months.
Triple therapy for 28 days, blood count, renal function, and liver function at 2 and 4 weeks……..…7 *[7]*

HC.
There is no accepted preventive treatment for suspected HC infection, but cases involving HC positive sources would be followed up with testing for anti-HCV serology and liver enzymes at 3, 6 and 9 months [32].
The number of individuals per year at the MUHC who may receive an injury involving an HC+ve source (see paragraph E).= ……1.7 *[1]*

In summary, introduction of the safety device might reduce the non-infectious consequences of needlestick injuries as follows :

- 7 *[7]* individuals each year will not require triple therapy for 28 days and follow-up for 6 months, and will be spared the associated anxiety.
- 22 *[20]* individuals each year will not require the initial visit and will be spared the associated anxiety.
- 1.5 *[1]* individuals each year will not need to be given HB immunoglobulin.
- 1.7individuals each year will not need to be followed three monthly for nine months for possible H. C. infection

Appendix 4

The annual costs that might be incurred as a consequence of not adopting the safety device (excluded: costs of infection, costs of unreported cases).

Each cost related item that might result from a needlestick injury (Appendix 3), its unit cost, the number of individuals involved, and the resulting costs are listed below.

Item	**Unit Cost $**	**Number**	**Cost $**
Immediate care of recipient (first visit)			
Clinical examination			
Nurse ($30/hr *)1.5 hours	45.00	22	990
Lab.Tests:			
anti-HIV	16.50	22	363
anti-HCV	13.20	22	290
ALT	3.30	22	73
Triple therapy toxicity tests (blood count,liver&renal function)	23.65	7	166
Treatment			
Tetanus anti-toxin	1.84	22	40
Testing of sources			
Lab. Tests. For HIV, HbsAg, HC	37.40	22	823
Associated nursing 1.5 hrs	45.00	22	990
Total……		……	$3,735
Subsequent care of recipient (follow up)			
Tests			
anti-HIV at 6weeks,3 and 6 months	49.50	7	346
anti-HC at 3 and 6 months	26.40	1	26
ALT (hep surveillance) at 3, 6 months	6.60	1	7
HIV treatment			
Triple therapy for 28 days	1,192.00	7	8,344
Tri.Ther. toxicity tests at 2, 4 weeks	53.90	7	377

Nursing: 5 x 1hr visits x $30	150.00	7	1,050
Absence from work. MUHC experience indicates that approximately 4 [3]of every 9 [7]individuals undergoing HIV triple therapy for one month will be off work due to side effects [41]. They will receive 90 % net salary, assume (46,410 x 0.09)/12 =	2,434	4	9,736
In the last 5 years, one needlestick injury has Resulted in 6 months absence from work [44]. Assume this might occur once every 4 years. Annual cost , ($2,704x6)	16,224	1 /4	4,056

Total…….. ……$23,942 *[$22,235]*

TOTAL (Immediate + subsequent care) = $3,735 + $23,942= **$27,677***.[$25,723]*

Average cost per exposure ($27,677/22) **=**…….**$1,258**

*Assume a nurse receiving $54,600 pa (including benefits), working 35 hours per week = $30 per hour.

REFERENCES

1. Canadian Centre for Occupational Health and Safety. Needlestick Injuries. January, 2005.www.ccohs.ca/oshanswers/diseases/needlestick_injuries.html

2. Health Canada. Prevention and Control of Occupational Infections in Health Care. Canada Communicable Disease Report Volume 2851. March 2002.

3. Jagger J, De Carli G, Perry JL, Puro V, Ippolito G. Occupational exposure to blood-borne pathogens : Epidemiology and prevention p448. In : Prevention and control of nosocomial infections, ED. Wenzel RP.2003.Lippincott Williams & Wilkins. Philadelphia.

4. Technology Assessment Unit, MUHC. Should the McGill University Health Centre replace the Jelco/Cathlon catheter by the protectIVPlus catheter for intravenous infusions? Feb 2002. www.mcgill.ca/tau/

5. Occupational Safety and Health Administration. Department of Labor.29 CFR Part 1910. Occupational Exposure to Blood-borne Pathogens; Needlesticks and Other Shops Injuries; Final Rule. Federal Register, Part 1X. Thursday, January 18, 2001.

6. Province of Manitoba.The workplace safety and health amendments act (needles in medical workplaces). Bill 23. The Legislative Assembly of Manitoba. 2005.

7. Province of Saskatchewan. The Occupational Health and Safety Amendment Regulations. 2005.

8. Province of Ontario. Loi visant à reduire les incidences de blessures causées par des piqûres d'aiguille. Projet de loi 179-2005. Assemblée legislative de l'Ontario. 2005.

9. Province of Nova Scotia. Status of bills . 2006. http://www.gov.ns.ca/legislature/HOUSE_BUSINESS/status.html#175

10. Association Québecoise d'établissement de santé et de servives sociaux, 2006 La Direction des ressources humaines, Secteur de la santé et sécurité au travail. http:/www.aqess.qc.ca

11. Lyne Besner. BD Medical. Personal communication.

12. Critchfield, G. C.; Willard, K. E., and Connelly, D. P. Probabilistic sensitivity analysis methods for general decision models. Comput Biomed Res. 1986 Jun; 19(3):254-65.

13. Doubilet, P.; Begg, C. B.; Weinstein, M. C.; Braun, P., and McNeil, B. J. Probabilistic sensitivity analysis using Monte Carlo simulation. A practical approach. Med Decis Making. 1985 Summer; 5(2):157-77.

14. Manning WG; Fryback DG, and Weinstein MC. Reflecting Uncertainty in Cost-Effectiveness Analysis. Gold MR; Siegel JE; Russel LB, and Weinstein MC. Cost-Effectiveness in Health and Medicine . New York: Oxford University Press; 1996; p. 262.

15. Nguyen M, Paton S, Koch J. Update-surveillance of health care workers exposed to blood, body fluids and bloodborne pathogens in Canadian hospital settings : 1 April, 2000, to 31 March, 2002. www.phac-aspc.gc.ca/publicat/ccdr-rmtc/03vol29/dr2924ea.hmtl

16. Geberding JL. Incidence and prevalence of human immunodeficiency virus, hepatitis B virus, hepatitis C virus, and cytomegalovirus among health care personnel at risk for blood exposure : Final report from a longitudinal study. J Infect Dis 1994 ;170 :1410-7

17. Bell DM,.Occupational risk of human immunodeficiency virus infection in health-care workers: An overview.Am J Med. 1997;102(5B): 9-15.

18. Center for Disease Control and Prevention. Exposure to Blood. What Healthcare Personnel Need to Know. National Center for Infectious Diseases. Department of Health and Human Services. USA. 2003 .http//bookstore.phf.org.

19. Cardo M, Culver DH, Ciesielski CA, Srivastava PU, Marcus R, Abitiboul D, Heptonstal J, Ippolito G, Lot F, McKibben PS, Bell DM. A case-control study of HIV seroconversion in health-care workers after percutaneous exposure. N Engl J Med 1997; 337 : 1485-90.

20. Puro V, Petrosillo N, Ippolito G, Risk of hepatitis C conversion after occupational exposures in health-care workers. Am J Infection Control 1995;23(5): 273-7.

21. Hernandez ME, Bruguera M, Puyuelo T, Barrera JM, Sanchez Tapias JM, Rodés J.Risk of needle-stick injuries in the transmission of hepatitis C virus in hospital personnel. J Hepatol.1992;16 :56-8.

22. Kiyosawa K, Tanaka E, Furuta S, Purcell RH. Hepatitis C in hospital employees with needlestick injuries. Ann Int Med 1991; 115(5):367-9.

23. Lanphear BP, Linnemann CC Jr, Cannon CG, DeRonde MM, Pendy L, Kerley LM. Hepatitis C virus infection in health-care workers: Risk of exposure and infection. Infect Control Hosp Epidemiol 1994; 15: 745-50.

24. Alvarado F, Panlilio A, Cardo D, NaSH. Surveillance Group. But Occupational Blood Exposures Among Pregnant Healthcare Workers 1998 [abstract]. Infect Control Hosp Epidemiol 2000;21(2) : 106.

25. Alvarado F, Panlilio A, Cardo D, NaSH Surveillance Group. Percutaneous injury reporting in you S. hospitals, 1998 [abstract].Infection Control Hosp Epidemiol.2000;21: 106.

26. NIOSH Alert. Preventing needlestick injuries in health care settings. U.S. Department of Health and Human Services. Public health service. Centers for Disease Control and Prevention. National Institute for Occupational Safety and Health. Nov. 1999.

27. Rivers DL, Aday LA, Frankowski RF, Felknor S, White D, Nichols B. Predictors of Nurses' Acceptance of an Intravenous Catheter Safety Device. Nursing Research 2003;52(4):249-55.

28. Mendelson MH, Chen L, Solomon R, Bailey E, Kogan G, McCarthy D. Evaluation of the safety i.e. the catheter (protect IV plus) *Abstract*. SHEA (Society for Healthcare Epidemiology of America) convention. April 1999

29. Mendelson MH, Chen LBY, Finkelstein LE, Bailey E, Kogan G. Evaluation of a safety IV catheter (Insyte Autogard, Becton Dickenson) using the Centers for Disease Control and Prevention (CDC) national surveillance system for hospital healthcare workers database. Infect Control Epidemiol 2000; 21(2):111.

30. Jagger J. Reducing occupational exposure to blood-borne pathogens: Where do we stand a decade later? Infect Control Hosp Epidemiol.1996;17 (9):573-5.

31. Foley M, Leyden AT. American Nurses Association-Independent Study Module Needlestick Safety and Prevention. 2003. www.nursingworld.org

32. Occupational Health and Safety Department of the Montreal General Hospital. Medical Surveillance Program for Accidental Exposure to Blood and Body Fluids. Montreal General Hospital Dec. 15, 1995.

33. Wang SA, Panlilio AL, Doi PA, White AD, Stek MJ, Saah A. Experience of healthcare workers taking postexposure prophylaxis after occupational HIV exposures: findings of the HIV Postexposure Prophylaxis Registry. Infect Control Epidemiol 2000; 21(12): 780-85.

34. Jagger J, Bentley M, Juillet E. Direct cost of follow-up for percutaneous and mucocutaneous exposures to at-risk body fluids: data from two hospitals. Advances in Exposure Prevention 1998: 3(3): 33-5.

35. Dupont M, Thibodeau P. Exposition au sang et aux autres liquides biologiques. Régie Régionale de la santé et des services sociaux de Montreal-Centre.2000.

36. Bouchard F. Une exposition au sang pour un travailleur : L'impacts économiques.Objectif Prévention 2002; 25(2) :7-9.

37. Yassi A, McGill ML, Khokar JB. Efficacy and cost-effectiveness of a needleless intravenous access system. Am J Infection Controlled. 1995; 23: 57-64.

38. Deschènes M. Director, Hepatitis C Clinic, MUHC. Personal communication.

39. Bouchard F, Gourdeau M, Gagnon J. La séroconversion d'un travailleur: impacts cliniques et ëconomiques. Objectif Prévention 2002;25(2):3-6.

40. Jaeckel E, Cornberg M, Wedemeyer H, Santantonio T, Mayer J, Zankel M, Pastore G, Dietrich M, Trautwein C Manns MP. Treatment of acute hepatitis C with Interferon Alfa-2b.N Engl J Med 2001; 343: 1452-7.

41. Wong T,Lee SS. Hepatitis C : a review for primary care physicians.CMAJ 2006;174(5):649-57.

42. Occupational Safety: Selected Cost and Benefit Implications of Needlestick Prevention Devices for Hospitals. GAO-01-60R. Needlestick Prevention .Nov 7,2000. United States General Accounting Office. Washington, DC 20548. http://www.gao.gov/new.items/d0160r.pdf

43. Capital Planning and Investments In Ontario's Hospitals: A Sustainable and Comprehensive Approach to Meeting Patient Needs. The Ontario Hospital Association Capital Investments Working Group. November, 2003 pp 23-4.

44. Pietrangelo F. Department of Occupational Health and Safety, MUHC. Personal communication.