REPORT NUMBER 1

Should the McGill University Health Center replace the Jelco/Cathlon catheter by the ProtectIVPlus catheter for intravenous infusions?

A Technology Assessment

by

The Technology Assessment Unit (TAU)
of the McGill University Health Center
(MUHC)

Needlestick8
Feb 26.2002.

This analysis was prepared for the Technology Assessment Unit (TAU)
of the McGill University Health Center (MUHC)
by
Dr. Maurice McGregor, Cardiology Division, Department of Medicine of the MUHC

and approved and adopted by the Committee of the TAU:
Dr. J. Barkun, Mr. W. Brodie, Mr. J. Johnston, Ms. M Kaplow, Ms. J. MacPhail, Dr. G. Pekeles, Dr. R. Rajan, Ms. J. Ritchie, Dr. F. Salevsky, Dr. S. Suissa, and Dr. J. Brophy (Director).

Acknowledgments. The assistance of Elizabeth Turner (graduate student) and Dr. James Hanley, Dept. of Epidemiology and Biostatistics, McGill, who carried out the Monte Carlo statistical analysis is gratefully acknowledged. A previous evaluation of this device, the "Business Case " [1], carried out by a committee of the MUHC chaired by Mr Larry Sidel has been a source of valuable information. The assistance of Dr. P. Robillard of the Institut de la santé publique de Québec, Mr Yves Grenier, Ms Lianne Steinagel and Ms Heather Pace of the Johnson & Johnson Company (J&J) are gratefully acknowledged. This study could not have been carried out without the invaluable help of numerous members of the MUHC, in particular Mr Stephane Beaudry of the Department of Financial Services, Dr M Deschenes of the Hepatitis Clinic , Dr. Richard Lalonde of the HIV Clinic, Ms. Filomina Pietrangelo of the Occupational Health and Safety Division and Ms Marie de Lorimier of the Occupational Health and Safety Division of the MUHC and the Montreal Children's Hospital (MCH).

Invitation. This document was designed to assist decision-making in the McGill University Health Center. Others are welcome to make use of it, preferably with acknowledgment. More important, to assist us in making our own evaluation, it would be *deeply appreciated* if potential users could inform us whether it has influenced policy decisions in any way, and even if it has not, whether it has been helpful in informing decision makers.

e-mail maurice.mcgregor@mcgill.ca

Executive Summary.

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.

Should the McGill University Health Center (MUHC) replace the Jelco/Cathlon catheter by the ProtectIVPlus catheter for intravenous infusions?

This study was carried out in response to a request from the Director of Nursing of the MUHC, Ms. Valerie Shannon, to evaluate the cost-effectiveness of replacing the Jelco/Cathlon catheter presently used for intravenous infusions at the MUHC, by a safety device, the ProtecIVPlus, produced by the Johnson and Johnson company,

The protective safety catheter in question is used only for intravenous infusion lines. It has been available since 1989, and the manufacturer estimates that this or a comparable safety device now occupies 20% of the Canadian market [2]. Use of such safety devices has been mandatory throughout the USA since November 6, 2000 (Needlestick Safety and Prevention Act. S 3067) [1]. They are also used to a limited extent in France, and their use is reported to be under consideration in several Canadian provinces [2]. They are used in all the member hospitals of the Centres Hospitaliers Universitaires de Montreal [2].

Whether this device should be adopted in the MUHC depends first on objective assessment of the benefits and costs involved. The benefits consist of those risks that might be avoided by introduction of the safety device. They include the risk of infection, the risk of requiring treatment, and the associated anxiety. The costs consist of the greater cost of the safety device compared to the needle currently used, less the costs that will be incurred if the decision is to not introduce the device. These consist of the costs of potentially avoidable consequences of needlestick injuries, including lost work time. The final decision will of course be made by the hospital decision makers, informed by these estimates.

Since the issue in question is the safety of personnel, whenever there is any doubt concerning the input variables, estimates are chosen so as to favour acquisition of the safety device. Throughout, the analysis is set out in such a way that any alternative estimate preferred by the reader can be substituted for the estimate used, and the effect of the change on the final outcomes easily calculated.

This study only compares use of the ProtectIVPlus device with use of the Jelco/Cathlon needle. No attempt is made to compare the relative merits and costs of the different safety devices, of which the J&J product is but one example, nor does the study consider the relative benefits of safety education programs, some of which already take place at the hospital. The risks and frequencies of events used in this evaluation are based on local data supplied by the institutions concerned, and on extensive literature search. Sources are cited throughout.

Risk of Infection.

The infections of concern following needlestick injury at the MUHC are the Human Immunodeficiency Virus (HIV), Hepatitis C and B. (HC and HB). The risk of becoming infected by these agents depends on the answers to the following questions.

a). How many IV lines are installed at the MUHC each year?
In the year 2000, 293,469 Jelco devices were used [1].

For present estimation:
Assume the number of IV lines installed each year to be …….300,000

b*). How many needlestick injuries can be expected to result from IV line installation?*

In the MUHC in the year 2000 there were approximately 250 needlestick injuries reported, only 20 of which involved intravenous catheter insertion [3,4]. However, not all needlestick injuries are reported. In a study in five Québec acute care hospitals in 1991-92, it was found that only 40% of percutaneous exposures were reported. (However, the response rate to the questionnaire was only 38%) [5]. Whatever the number, unreported injuries will not influence the estimated number of prophylactic interventions and their costs. They will however, render the estimated infection rates too low.

For present estimation:
Assume an annual incidence of reported injuries associated with IV infusions, with an estimated upper bound for sensitivity analysis of +50% shown in brackets ( ), to be……...20(30)
Assume also that there may be an additional 20 cases that are not reported.

c) In what proportion of these injuries might the source be infective?

- In the year 2000, at the MUHC, the sources of approximately 283 reported needlestick injuries, were tested for infectivity.(Most were unrelated to IV catheter insertion). The percent infective [3,4] were:
  HIV 2%, HC 4.3%, HB 1.3%.
- In an across Canada study involving approximately 420 needlestick injuries, the percent of sources found to be infective were [6] :
  HIV 2.3%, HC 2.8%, HB 1.8%.
- In a 3 year study (1997-8, 1998-9, 1999-00) involving 16 Québec hospitals, of which 8 were in Montreal Center Region, the positivity rate of sources involved in blood exposure of health workers was approximately [7]: HIV 3.3%, HC 5.6%, HB 3.3%. (Approximately 20% of exposed individuals had more than one infection).

For present estimation:
Assume the infectivity of sources (with an upper bound of probability
of +33%) to be as follows:
HIV ……..…….……..3.3, (+33%, = 4.4%)
HC ……..……4.5, (+33%, = 6.0%)
HB ……..……..….2.6, (+33%, =3.47%)

d).Thus, the number(and upper bound) of individuals receiving needlestick injuries involving infective sources will be (c% of b):
HIV ……..…….... 0.66 (0.88)
HC……..……...0.90.(1.20)
HB……..…0.52 (0.69)

e). *What proportion of health-care workers at the MUHC who receive a needlestick injury might be susceptible to infection?*
The baseline tests at the time of exposure of 304 MUHC personnel were –ve for HIV and HC. Six percent had not been successfully vaccinated for HB [3,4].

f). *How many <u>susceptible</u> workers report a needlestick injury involving an <u>infective</u> source each year?* The number*(e% of d*), and upper bound ( ), are as follows:
HIV (see d)…….0.66(0.88)
HC (see d)……....0.9 (1.20)
HB (see d,e)……..0.03 (0.04)

g) What proportion of susceptible workers might become infected following a needlestick injury involving an infective source?

The following conversion rates following percutaneous injury of susceptible individuals involving an infective source are reported :

HIV. 4 of 1103 exposures [8]……. ……. . .0.36%
1 of 1003 exposures [9]……...0.10 %
1 of 327 exposures [10] …… …… 0.34%
Weighted average of [8,9,10]……..….0.25%
6 of 2042 exposures (meta-analysis of 14 studies)[11]…….. 0.29%
20 of 6202 exposures, aggregated from [8,9,10]+other sources[12]. 0.32%

HC 4 of 110 exposures [13]……..….4.0 %
0 of 81 exposures [14]…… …...0 %
7 of 68 exposures [15]…… …10.3 %
1 of 556 exposures [10]…… ….0.18%
Weighted average of [10,13,14,15]……..…..1.47%
One recent reviewer estimates this risk at 3% [16]

HB 14 of 182 exposures [10]*…… …… …..7.69%
13 of 102 exposures [17]*…… ……. ..12.7 %
(* in spite of vaccination at time of exposure)
47 of 351exposures [18] ……...….13.4 %
(For recipients of HbeAg+ve blood rate=19% [18]
Weighted average of [10,17,18]……..……11.6 %

One recent reviewer estimates this risk at 30% [16].

In Québec, less than 10% of HB+ve individuals will be e antigen +ve, with an associated risk of 40-50%. Over 90% will be e antigen –ve, with an associated risk of 2-6%[19]. This could result in an average risk of up to : (10x50)+(90x6)/100 ……..10.4 %.

For present estimation:

Assume the following conversion rates, with upper bounds at +33%( ), in *susceptible* recipients of reported needlestick injuries involving an *infected* source :

HIV……...0.3%, (0.3+1/3 of 0.3=0.4%)

HC……....1.5%, (1.5+1/3 of 1.5=2%)

HB…….……...12.0%, (12.0+1/3 of12.0=16%)

h). *How many susceptible individuals each year might become infected from reported IV needlestick injuries? (g % of f).*

HIV= 0.3% of 0.66= 0.00198 per year. (upper bound, 0.4% of 0.88=0.0035)

HC = 1.5% of 0.9 = 0.0135 per year. (upper bound, 2.0% of 1.2 =0.024)

HB = 12.0% of 0.03= 0.0036 per year. (upper bound, 16% of 0.004=0.0064)

i). What is the expected efficacy of the safety device?

Studies carried out before and after the introduction of safety devices indicate that injury rates may be reduced by 84 % [20] to 89% [21].

For present estimation

Assume that introduction of the safety device will result in a reduction in needlestick injury of……..……..……100%.

In summary,

1) based on best estimates of all variables, the number of infections resulting from reported needlestick injuries that might be prevented by use of the safety device would be:

HIV…..……0.002 per year, or 1 every 500 years.

HC……0.0135 per year, or 1 every 71 years.

HB……0.0036 per year, or 1 every 250 years.

2) Based on a combination of the upper bounds of each input variable (see Appendix 1), the highest infection rates that might result from reported needlestick injuries would be:

HIV……..0.0036 per year, or 1 every 278 years.

HC……0.024 per year, or 1 every 42 years.

HB…… ..0.0068 per year, or 1 every 147 years.

3) If it is assumed that in addition to the 20 reported needlestick injuries, another 20 are unreported, the total number of infections that might be prevented would be:

HIV……0.004 per year, or 1 every 250 years.

HC…….0.027 per year, or 1 every 37 years.

HB…….0.007 per year, or 1 every 142 years.

These estimates are based on observations that were made before it became routine practice to administer triple therapy and HB vaccine with immunoglobulin at the time of injury. There is reason to believe that the former measure might be 80 % effective [22] and the latter over 90 % effective [23]. Thus, if promptly reported, and promptly treated, as is the present practice at the MUHC, the risk of contracting HIV or HB would be lower than these estimates.

The risk of Non-infectious Consequences of Needlestick Injury

The non-infectious consequences of a needlestick will only apply to those injuries that are reported . They will vary according to the circumstances. Except where noted, estimates are based on the recommendations of the Medical Surveillance Programme for Accidental Exposure to Blood and Body Fluids of the Montreal General Hospital [24]. The detailed estimations are shown in Appendix 2.

In summary, it is estimated that introduction of the safety device will reduce the non-infectious consequences of needlestick injuries as follows :

Seven Individuals each year will *not* require triple therapy for 28 days and follow-up for 6 months, and will be spared the associated anxiety.

Twenty individuals each year will avoid the initial clinic visit and the associated anxiety.

One individual each year will avoid measurement of anti-HBV serology, and HB vaccination and administration of HB immunoglobulin at 0, 3, and 6 months.

Although anxiety following a needlestick injury is much reduced at 24 hours when the source is shown to be non-infective, anxiety, sometimes considerable, may persist for up to 6 months [3].

Costs

In the following section, except where specified, the costs referred to are the direct costs incurred by the Québec health care system, through either the MUHC or the Commission de la santé et sécurité du travail (CSST). Needlestick injury of a Physician or Student might result in damage suits. However, neither are hospital employees, and the hospitals carry insurance against such eventualities.

To estimate the *net cost* to the health-care system of introducing the ProtectIVPlus safety device, the costs resulting from the reported and potentially preventable needlestick injuries must first be estimated, and then subtracted from the costs of purchasing the device.

The annual cost to the health-care system of not introducing the safety device is the sum of the products of each of the items listed under the “recommendations for care”, and the cost of each of these items in Québec. The latter are taken from Bouchard [25]. These estimations are shown in Appendix 3, in which it can be seen that the total annual cost that might be incurred if the safety device is not introduced would be:……..……...$25,723

The increased cost to the health-care system of introducing the safety device would be the unit cost of the device ($ 1.85) [26], less the unit cost of the presently used Jelco/cathlon needle ($0.95) [1], x 300,000 uses each year (see a)=… $270,000

The *net* annual cost to the *health care system* of introducing the ProtectIVPlus device would be: $270,000- $25,723 =……..… $244,277

The potentially preventable costs that would be borne by a hospital in the Québec health care system will vary according to circumstances. They can be approximated by assuming that the hospital will have to reimburse CSST by a sum equivalent to the treatment costs plus 90 % of the net salary costs, $25,723 in the example considered in Appendix 3, times three, or approximately $77,169 per year.

The net annual cost *to the MUHC* of introducing the device would thus be approximately: $270,000-$77,169 =…….…….. $192,832.

Possiblity of "disaster" costs due to HC Infection. It has been estimated above that the most likely infection to result from a needlestick injury, HC, might occur once every 71 years. Any estimates of the costs related to such an event are extremely hypothetical, but let us consider the following possible scenario:

A health care worker, aged 30, receives a needlestick injury and becomes HC positive. She receives Interferon/Ribovirin treatment for 6 months at a cost of approximately $10,000 [27]. Because of treatment side effects and subsequent depression she is unable to work for one year during which she reimbursed at a rate of 90% of the net salary,= $32,000 per year . The "initial" costs incurred up to the end of the first year would then be$10,000+$32,000 =…….…… $42,000.

Thereafter, she remains asymptomatic for 20 years and then develops progressive cirrhosis. (Such progression, to severe complications and death can be expected in 15 to 20% of chronically infected individuals [16]). Costs could include salary support for up to 10 years (at $32,000 per year, and increasing health costs up to the time of death, assume $50,000). The "delayed" costs incurred after the end of the first year would then total $370,000.

Thus, the total cost of this event would be $42,000+$370,000=$412,000. Since infection is estimated to occur once every 71 years, and progression to severe cirrhosis or cancer to occur in 20% of those infected, the annualized cost would be:**(**$42,000 / 71) + ($370,000 / 71 / 5) = ……$1,633 per year.

Inclusion of this cost in the cost-effectiveness estimation carried out above would increase the annual costs incurred by the Québec health-care system as a consequence of *not* using the safety needle from $25,723 to…….. $27,356.

Thus, inclusion of the potentially high costs associated with an HC infection might reduce the annual net cost to *the health-care system* of introducing the protective device to: $270,000-$27,356 =……..…$242,644.

The above estimates reflect the direct costs to the Québec health-care system, whether paid by the hospital or by the CSST. Estimation of the costs that might be incurred by a hospital within that system will vary according to the particulars of each case. In this example the initial costs (incurred in the first year) would have to be refunded to the CSST, multiplied by a factor of approximately three.
Thus, initial costs incurred in the first year= $42,000x3 =…….$126,000.

Thereafter, the delayed costs might be handled in three different ways.

1) If the delayed illness was recognized by the CSST as being a relapse of the initial illness, no further refund would be required.

2) If the delayed illness was not considered a relapse, but was considered to be the consequence of a new work-related injury, the sum to be refunded to the CSST would consist of the treatment costs ($5,000 per year), plus salary costs ($32,000

per year), for four years ($148,000), times a factor of approximately seven: [($5,000x4)+($32,000x4)]x7 =……....$1,036,000.

However, not all of this sum would have to be refunded. There is a limit on the total amount refundable by the hospital to the CSST in any one year. The amount to be refunded as a result of this event would depend on the number of other work related claims and their size. This can of course not be predicted, but in recent years it would have been necessary to refund on average approximately $260,000 of the $1,036,000 incurred.

3) A third possibility is that the CSST would not accept the late illness as being work related. Under these circumstances the hospital would pay 80% of gross salary for two years ($51,500 x 0.8x2= $82,400) after which time costs would be assumed by insurance.

If the second and most costly scenario pertained, the total costs to the MUHC. as a result of this illness would be the sum of the initial costs ($126,000) plus delayed costs ($260,000) = $386,000. Annualized over 71 years =……$5,437 per year.

The annual cost to the MUHC that would be incurred if the safety device were not introduced would then be $77,169+ $5,437=……..…….$82,606.

The annual net cost to the MUHC of introducing the safety device, including this "disaster" scenario, would then be $270,000 - $82,606 = ……$187,394.

Thus, it can be seen that estimates of the overall costs are insensitive to even very high costs of possible disasters that are experienced infrequently.

Other issues to consider.

The economic impact of a decision to introduce this device would not be very great. However, it would result in no easily measurable reduction in the risk of infection. The principal benefit that would result from purchase of the device would be that approximately 7 individuals each year would avoid a 28 day course of triple therapy (throughout which most continue working) and the associated anxiety. In trying to decide whether the MUHC should adopt this or any comparable device, the following pertinent issues must also be considered.

- *Opportunity costs*. It is beyond the scope of this report to consider where the necessary funds would be found, and what hospital services would be curtailed in order to find the funds. However, such opportunity costs are an important reality in our health care system.
- *Morale*. Health services cannot be provided to patients if staff cannot be recruited and retained. It is essential, therefore, that the staff should not only *be* safe, but feel that they are in an institution that makes their safety a high priority. Failure to achieve this could result in loss of staff with consequent inability to serve patients. Morale might well suffer if it came to be perceived that the MUHC was failing to provide a safety device that is mandated in the USA, particularly if it becomes more widely used in Canada. Accordingly, staff perceptions are important and any decision not to purchase the device would need to be accompanied by education concerning the risks and benefits of this intervention.
- *Safety.* Staff health and safety must have a high priority in the allocation of hospital resources. Presumably, however, there is some point at which any further increase in staff safety will be too small to justify the reduction in

patient services that would be necessary to achieve it. Exactly where this point is reached is critical to the final decision.

- *Education.* The principal adverse effect of needlestick injuries lies in the fear of infection that they entail. This largely unnecessary anxiety could be greatly reduced if all health care workers at risk were to be made aware of the extremely low chance of their becoming infected. Whether the safety device is introduced or not, an education campaign directed both at avoidance of needlestick injuries and at spreading knowledge concerning their low infectivity could be beneficial.

  .

Appendix 1

Estimation of upper bounds of infection rates.

The best estimate of the expected number of infections is the product of four quantities, three of which were considered uncertain. The uncertainty on the product was calculated from the uncertainty on each of the three uncertain components. For each of these three, the uncertainty was represented as a bell-shaped (Gaussian) probability distribution (or histogram) centered on the best estimate, and the upper bound was considered to be at the 97.5th percentile of the distribution. A random value was 'drawn' separately (and independently) from each of the three distributions and the product of these three possibilities (and the constant representing the proportion susceptible) was calculated to give a possible value for the expected number infected (in mathematical statistics this is called a 'realization'). This process was repeated a total of 20,000 times and the upper 97.5th percentile of the distribution (the 500th largest value) determined. This was taken as the upper bound.

The calculations were carried out in the WINBUGS (Windows version of Bayesian Inference under Gibbs Sampling) PACKAGE, Version 1.3software developed and provided by D J Spiegelhalter and A Thomas and N G Best and W R Gilks (2000).MRC Biostatistics Unit, Cambridge, UK(http://www.mrc-bsu.cam.ac.uk/bugs/).

The above uses a symmetric (and Gaussian) curve for the uncertainty in each of the three inputs. We also represented the three uncertainties as Gamma (for the number injured) and beta (for the proportions) distributions, with parameter values derived from the amount of information (numbers of cases, reported numbers where source was infected and not infected, reported numbers where exposed person became or did not become infected). These three distributions are slightly asymmetric, but gave upper bounds that were very close to those actually used. The resulting upper bounds on the product of these are quite similar to those derived from the Gaussian model.

Apppendix 2

Non-infectious Consequences of needlestick injuries

Except where noted, the following measures are those recommended by the Medical surveillance programme for accidental exposure to blood and body fluids of the Montreal General Hospital [24].

Recommendation **Individuals involved**

Immediate care (First visit)

Clinical examination and evaluation of the incident ……20

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

Injections

Tetanus antitoxin if vaccinations have lapsed .(Assume all)…….. 20
HB vaccine if not already vaccinated. (6%)……1
HB immunoglobulin (HBIG) if not already vaccinated. (6%)……..……....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 [3]. For present estimate assume 33% ……..7

Subsequent care (Follow up)

Of every 20 needlestick injuries that are expected each year, in a varying number the source will be found to be infective. (see d).The consequences of this will vary with the infection concerned, as follows:

HIV. In addition to the 0.66 individuals per year (or one every 18 months) who may be exposed to an HIV positive source, all individuals for whom the source is considered to be "high-risk" even though testing negative for HIV, are recommended to undergo 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

HC. At MUHC, 0.9 individuals per year may receive an injury involving an HC+ve source (see f). There is no accepted treatment but follow-up would include anti-HCV serology and liver enzymes at 3, 6 and 9 mths[24] …….1

HB. After initial treatment there is no subsequent care other than follow-up. At the MUHC 0.52 individuals may receive a needlestick involving an HB+ve source each year (see d). Of these, 94% will have already been immunized.Thus, the number requiring follow up, 6% of 0.52 =……..0.03

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

- Seven Individuals each year will *not* require triple therapy for 28 days and follow-up for 6 months, and will be spared the associated anxiety.
- Twenty individuals each year will *not* require the initial visit and will be spared anxiety. Although anxiety following a needlestick injury is much reduced at 24 hours when the source is shown to be non-infective, anxiety may persist for up to 6 months [3].
- One individual each year will not need to undergo HB testing at 0, 3, and 6 months and will avoid HB vaccination and administration of HB immunoglobulin.

Appendix 3

Estimation of the annual costs that might be incurred as a consequence of not adopting the ProtectIVPlus device.

Each cost related item that might result from a needlestick injury (Appendix 2), its unit cost, the number of individuals involved, and the resulting costs are listed below.

Item	*Unit Cost $*	*Number*	*Cost $*
Immediate care (first visit)			
Clinical examination			
Nurse,($30/hr)1.5 hours	45.00	20	900.00
Lab.Tests:anti-HIV	16.50	20	330.00
anti-HCV	13.20	20	264.00
ALT	3.30	20	66.00
anti-HBs	7.70	1	7.70
HbsAg	7.70	1	7.70
Triple therapy toxicity tests (blood count,liver&renal function)	23.65	7	165.55
Treatment			
Tetanus anti-toxin	1.84	20	36.80
HB vaccine ,3 doses.	62.25	1	62.25
HB gammaglobulin (provided by Héma Quebec)		1	
Lab. Tests. For source			
HIV,HbsAg,HC	37.40	20	748.00
Associated nurse time 1.5 hrs	45.00	20	900.00
TOTAL……..			$3,488.00

Subsequent care (follow up)

HIV treatment			
Triple therapy for 28 days	1,192.00	7	8,344.00
Tri.Ther. toxicity tests at 2, 4 weeks	53.90	7	377.30
Tests for:			
anti-HIV at 6weeks,3and6 months	49.50	7	346.50
anti-HBs at 7 months	7.70	1	7.70
HbsAg at 3 and 6 months	15.40	1	30.80
anti-HC at 3 and 6 months	26.40	1	26.40
ALT (hep surveillance) at 3, 6 mths	6.60	1	6.60
Nursing time,			
5x 1hr visits x $30	150.00	7	1,050.00
Treatment for HC			
One individual every 71 years may contract HC (see h).They would receive Interferon + Rivavirine for approximately 6 mths, costing approximately $2,000 per mth [26]	12,000	1/70	114.00
Absence from work.			
MUHC experience indicates that approximately 3 of every 7 individuals undergoing tripple therapy for one month will be off work due to side effects[3].They will receive 90 % net salary, assume $32,445 per year,			
Thus, salary costs per month =	2,,704	3	8,112

In the last 5 years, one needlestick injury has resulted
in 6 months absence from work. Assume this might occur
once every 4 years[3].
Annual cost , $2,500x6=……..… …1500 1 /4 3,750

One in every 3 individuals may not be able to work for
6 months while receiving HC antiviral therapy [25].
Annual cost, $2,500x6 =……..15,000 1/71/3 70
Total…… ……....$22,235

TOTAL (Immediate plus subsequent care = $3,488+$22235)=…… ……...$25,723

Comparison with other estimates.

This estimate can be compared with two previous reports which estimate the average direct cost per needlestick injury. Neither consider the cost of a possible prolonged absence from work. If this cost is also subtracted from the above estimate we arrive at an average cost per injury of ($25,723-$3,750) /20 = $1,099.

A US study reported by Jagger et al [28] does not include the costs of antiretroviral therapy. Adjusting their results by adding the cost of 28 days triple therapy for 7 individuals, gives an average cost in the more expensive of two hospitals studied, of US $918, or Ca$1413.(assuming Ca$ 1=US $ 0.65).

In Québec, Dupont and Thibodeau [29] made an estimate based on the costs of a Montreal hospital. After adjustment to allow for 28 days triple therapy for 7 individuals, their estimate of the average cost of a transdermal exposure becomes $1,155.

Thus, our estimate of the costs of needlestick injury which could potentially be saved by the introduction of a safety device is very comparable to both the US and the previous Québec estimates,

REFERENCES

1 Business Case. Safety IV Catheters for the MUHC. Report of an MUHC Task Force on IV Safety Catheters. Chair, Sidel L. McGill University Health Center. 2001.

2 Pace H. Product Manager, Johnson and Johnson Medical Products. Markham, Ontario. Personal communication.

3 Pietrangelo F. Occupational Health and Safety Department of the MUHC .

4 DeLorimier M. Occupational Health and Safety Department of the MCH.

5 Robillard P,Roy E. Underreporting of BEF exposures in health-care settings: an alarming issue. Frontline Healthcare Workers: National Conference on Prevention of Sharps Injuries and Bloodborn Exposures. 1995.

6 Villeneuve P. Canadian Needle Stick Surveillance Network (CNSSN). Analysis of exposures between April 1, 2000 and September 30, 2000. *A report prepared for:* The Division of Nosocomial and Occupational Infections, Bureau of Infectious Diseases, Population and Public Health Branch, Health Canada. March 13, 2001.

7 Robillard P, Roy É, Ferron M. Rapport Préliminaire. Système Intégré de Surveillance des Expositions et des Séroconversions {SISES). Expositions déclarées au 31 Mars 2000.

8 Tokars JI, Marcus R, Culver DH, Schable CA, McKibben PS, Bandea CI, Bell DM. Surveillance of HIV infection and Zidovudine use among health care workers after occupational exposure to HIV-infected blood. Ann Intern Med 1993;118: 913-19.

9 Ippolito G, Puro V, De Carli G. The risk of occupational human immunodeficiency virus infection in health care workers. Italian Multicenter Study. Arch Intern Med 1993;153:1451-58.

10 Gerberding 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 Inf Dis 1994:170:1410-7.

11 Henderson DK, Fahey BJ, Willy M, Schmitt JM, Carey K, Koziol DE, Lane HC, Fedio J, Saah AJ. Risk for occupational transmission of human immunodeficiency virus type 1 (HIV-1) associated with clinical exposures. Ann Intern Med 1990;113:740-46.

12 Bell DM. Occupational risk of human immunodeficiency virus infection in healthcare workers: An overview. Am J Med 1997;102:9-15.

13 Kiyosawa K, Sodeyama T, Tanaka E, Nakano Y, Furuta S, Nishioka K, Purcell R, Alter HJ. Hepatitis C in hospital employees with needlestick injuries. Ann Intern Med 1991;115:367-69.

14 Hernandez E, Bruguera M, Puyuelo T, Barrera JM, Tapias JMS, Rodés J. Risk of needle-stick infuries in the transmission of hepatitis C virus in hospital personnel. J Hepatol 1992;16:56-58.

15 Mitsui T, Iwano K, Masuko K, Yamazaki C, Okamoto H, Tsuda F, Tanaka T, Mishiro S. Hepatitis C virus infection in medical personnel after needlestick accident. Hepatology 1992;16:1109-14.

16 Lauer GM, Walker BD. Hepatitis C virus infection.NewEngl J Med 2001; 345:41-52.

17 Masuko K, Mitsui T, Iwano K, Yamazaki C, Aihara S, Baba K, Takai E, Tsuda F, Nakamura T, Miyakawa Y, Mayumi M. Factors influencing postexposure immunoprophylaxis of hepatitis B virus infection with hepatitis B immune globulin. Gastroenterology 1985;88:151-5.

18 Werner BG, Grady GF. Accidental hepatitis-B-surface-antigen-positive inoculations. Use of e antigen to estimate infectivity. Ann Intern Med 1982;97:367-69.

19 Robillard P.Institute nationale de la santé publique de Québec. Personal communication.

20 Jagger J, Bentley M. Injuries from vascular access devices: high risk and preventable. Advances in Exposure Prevention 1998;3:37-7.

21 Mendelson MH, Chen L, Solomon R, Bailey E, Kogan G, McCarthy D. Evaluation of a safety IV catheter. Society for Healthcare Epidemiology of America. Convention. 1999.

22 Interagency Working Group of CDC, FDA, the Health Resources and Services Administration, and the National Institutes of Health . Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis.http://www.cdc.gov/mmwr/preview/mmwrhtm/rr5011al.htm

23 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.

24 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.

25 Bouchard F. Prévention des piqûres d'aiguilles. Association pour la santé et la sécurité du travail, secteur affaires sociales. Colloque ASSTASAS, mai 2001.

26 Grenier Y. Products Specialist, Vascular Access. Johnson and Johnson Medical Products. Montreal. Personal communication.

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

28 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. The International Health Care Worker Safety Center. University of Virginia. 1998.

29 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.

.