

Quantitative risk assessment for needle reuse at a phlebotomy center: parameter estimation, scenario evaluation, and sensitivity analysis

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Travis C. Porco, Ph.D., M.P.H.^{*}, Tomás J. Aragón, M.D., Dr.P.H.^{*}, Susan E. Fernyak, M.D., M.P.H.^{*}, Sara H. Cody, M.D.[†], Duc J. Vugia, M.D., M.P.H.[‡], Mitchell H. Katz, M.D.[§], and David R. Bangsberg, M.D., M.P.H.^{||¶}

^{*} Community Health Epidemiology, Epidemiology and Effectiveness Research Unit, San Francisco Department of Public Health, 25 Van Ness Avenue, Suite 710, San Francisco, California 94102 USA

[†] Santa Clara County Public Health Department, 2220 Moorpark Ave #115, San Jose, California 95128 USA

[‡] Disease Investigations and Surveillance Branch, California Department of Health Services, 2151 Berkeley Way Rm. 708, Berkeley, California 94704-1011 USA

[§] San Francisco Department of Public Health, 101 Grove Street, San Francisco, California 94102 USA

^{||} Epidemiology and Prevention Interventions Center, Division of Infectious Diseases and Positive Health Program, San Francisco General Hospital, Rm. 301, Building 100, Box 1372, 1001 Potrero Ave., San Francisco, California 94110 USA

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Abstract

Objectives. To assess the risk of nosocomial infection at a patient service center when a phlebotomist reused needles, possibly exposing 3,810 patients to infection by the Human Immunodeficiency Virus (HIV), the hepatitis B virus (HBV), or the hepatitis C virus (HCV).

Methods. Risk assessment based on the prevalence of infection in the patient population, the number of reused needles, and the transmission probability from reusing a contaminated needle, supplemented by results from testing 1,699 patients from the center. The main outcome measures were the probability of infection per blood draw and the prevalence of infection among patients subsequently tested.

Results. Best-case risks per blood draw for HIV, HBV, and HCV were 1.4×10^{-8} , 1.1×10^{-6} , and 3.6×10^{-7} ; for the (unlikely) worst-case, these risks were 6.8×10^{-6} , 1.2×10^{-3} , and 4.8×10^{-4} respectively. In the patients tested, the infection prevalences were 0.12%, 0.41%, and 0.88%, lower than NHANES III rates for the general population.

Conclusions. The infection risk was very low; few, if any, nosocomial transmissions are likely to have occurred. However, significant levels of needle reuse in settings of high disease prevalence—unlike the current setting—could result in significant transmission.

Introduction

Reusing phlebotomy needles is contrary to accepted standards of health care because of the possibility of nosocomial transmission of blood-borne infection^{1,2,3}. Mathematical models have shown that in developing countries, transmission of the Human Immunodeficiency Virus (HIV) and the hepatitis B virus (HBV) through unsafe injections poses a threat to public health⁴ of sufficient magnitude to justify the costs of non-reusable syringes⁵.

In developed countries, such as the United States, it has been taken for granted that syringes should never be reused, and the public has been assured that there is no risk of contracting infection during a blood draw. It was therefore a tremendous surprise when in March 1999 a phlebotomist working at a patient service center (of a clinical laboratory) in Palo Alto, CA, admitted to occasionally reusing needles for drawing blood (EA Kaufman, personal communication; see also References (6-8)). In response, the company that operated the patient service center initiated a notification, counseling, and testing program for concerned patients who had accessed the patient service center (subsequently expanded to include approximately 15,300 patients at other service centers (EA Kaufman, personal communication)). Facing uncertainty regarding the likelihood of anyone having been infected by the needle reuse incident, company officials and state and local health officers conducted a quantitative risk assessment as one facet of an extensive investigation to assess the risks and the public health magnitude of this event. The model was useful for estimating the risk of infection under different scenarios, for communicating the estimated level of risk to the affected population, and for putting into proper perspective the results of the counseling and testing program for concerned patients.

We present here the risk assessment of acquiring HIV, hepatitis B virus (HBV) or hepatitis C virus (HCV) during phlebotomy at the facility where this phlebotomist worked. We address three questions: (1) what is the probability that a patient having blood drawn at the center would have become infected after a single blood draw? (2) what is the expected number of individuals who might have become infected due to needle reuse? (3) of the clients who utilized the counseling and testing program offered by the company,

what fraction of those found to be infected can be attributable to needle reuse at the center? Our model is based on the prevalence of infection at the patient service center, on the number of needles reused, and on the probability of transmission from a reused needle (based on estimates from needlestick injury studies^{4,9}). To incorporate uncertainty, we modeled a variety of scenarios, including “worst case scenarios,” and conducted a sensitivity analysis of the model.

We finally compare these results with preliminary results from the counseling and testing study of patients who received a blood draw at the center, still underway.

Methods

From June 1, 1997 to March 23, 1999, the implicated phlebotomist (Health Care Worker 1, HCW1) worked at a phlebotomy center in Palo Alto, California, a facility serving a largely suburban patient population. During this period, a total of 3,810 patients received a blood draw at this center; HCW1 was the sole phlebotomist during most of this time. After HCW1 was found to be reusing needles at this facility, she was terminated from employment. Statements from HCW1 suggest that at least five 23 gauge butterfly needles were reused once¹⁰; some consider such needles easier to use (especially on patients with difficult veins). Statements from another health care worker (HCW2) at the Palo Alto site alleged that HCW1 used butterfly needles more often than straight needles, and reused butterfly needles more often than she used sterile butterfly needles; HCW2 also alleged that HCW1 claimed needles could be reused more than once¹⁰. HCW1 reported rinsing and aspirating these butterfly needles with dilute hydrogen peroxide; this was not reported by HCW2.

To address the first research question, we constructed a model for the risk that an individual would become infected after a single blood draw. The risk is given by the probability that a contaminated needle is used on an individual, times the probability that a contaminated needle would transmit the infection (the transmission probability). When needles are only reused once, the probability that a contaminated needle is used on any given patient is given by the number of reused needles times the baseline prevalence

rate, divided by the total number of blood draws. In the more general case in which a needle may be reused more than once, the number of draws per needle and the probability that a contaminated needle would remain infectious after being reused on an uninfected person must be considered as well; we derive equations for the multiple reuse case in the Appendix. Because each of the parameters needed to calculate the risk of infection per draw is uncertain, we estimated a lower and an upper bound for each value; these are summarized in Table 1.

First, we estimated the number of needles that may have been reused. Since testimony from HCW1 revealed that between 5 and 10 butterfly needles may have been reused, we used 7 as the lower bound estimate. Nine hundred butterfly needles are known to have been ordered at the site between January 1998 and March 1999. Because of considerable uncertainty in the number of reused needles, we analyzed a wide range of possible values; for the upper bound, we multiplied the lower bound estimate of 7 by 100. Because of the possibility that needles may have been reused more than once, for the sensitivity analysis, we used 1 as the lower bound for the number k of times these particular needles were reused, and 3 as the upper bound. Finally, the total number of blood draws by HCW1 was 6,272.

The transmission probability, i.e. the probability that infection would be transmitted from a contaminated needle, is influenced by the volume of blood remaining in the device, whether that blood has been diluted, how much time has elapsed since the device was used on an infected person, and other factors. No estimates of the probability of transmission from reused needles have ever been reported. We used the probability of infection following needlestick injury as a guide^{4,9}. HCW1 reported rinsing butterfly needles with dilute hydrogen peroxide; this may have had some effect against HIV¹¹ in addition to diluting the blood. Investigators believe that some rinsing of the needles was likely to have occurred, since otherwise the formation of blood clots in the small bore would probably have prevented reuse. Thus, the needlestick injury estimates may overestimate the transmission probability. Estimates of the transmission probability following needlestick injury with contaminated blood are available for HIV¹²⁻¹⁹, HBV²¹⁻²⁴, and HCV²⁵⁻³⁰; these are shown in Table 1 and discussed more fully in the Appendix.

We next obtained estimates for the baseline prevalence for each infection in the clinic population, i.e. the prevalence in the clinic population prior to receiving a blood draw. This clinic population is suburban, and of the 3,810 patients who received blood draws at this site, a total of 1279 (34%) were male, with a median age of 49; the median age of the female patients was 44 (for 110 patients, the sex is undeclared). Of the female patients, 1.7% were under 18 years of age and 13.3% were over 65, while 4.5% of the male population was under 18 years and 19.9% was over 65 years of age.

We obtained estimates for the prevalence of each of HIV, HBV, and HCV infection in the center population, utilizing three sources of information: (1) the prevalence among those center patients who were tested for one of the three specific infections between June 1997 and March 1999, (2) the number of patients in the clinic population who apparently were being monitored while undergoing treatment for HIV, HBV, or HCV, and (3) NHANES-derived prevalence estimates. Individuals who were specifically tested for one of the three infections at the time of their blood draw are probably more likely to be infected than a randomly selected individual, since an individual is unlikely to have been tested in the absence of suspicion of infection or of risk factors for infection. For this reason, the prevalence among those specifically tested may overestimate the prevalence among all members of the clinic population; this prevalence does not however include individuals who are known prevalent cases (and who thus would be unlikely to be tested). For lower bound prevalence estimate of HIV, we use 0.5% instead of the NHANES III estimate³¹ of 0.32% to err on the side of caution; we used the estimates derived from NHANES III for HBV³² and HCV³³⁻³⁴ (see Table 1; further details are given in the Appendix). For upper bound prevalence estimates, we used the upper confidence limit from those individuals who were tested at the time of their phlebotomy (also shown in Table 1). For comparison, we also produced a minimum possible value for the prevalence, based on the assumption that all individuals who are infected are known.

A total of 245 HIV tests were performed by ELISA between June 1997 and March 1999. None were positive, yielding an estimate of 0% prevalence, with an exact one-sided 95% (binomial) upper confidence limit of 1.22%. Of the patient population, 17 out of 3810 had at least one of the following: an HIV viral

load test, a CD4 count, or a p24 antigen test. If we assume that all such individuals were HIV-infected, we would obtain a minimum possible estimate for the prevalence of 0.0045.

A total of 247 individuals had undergone testing for hepatitis B surface antigen (HBsAg) between June 1997 and March 1999, and 3 tested positive (for a prevalence of $3/247=1.2\%$; two-sided 95% exact (binomial) confidence interval is (0.25%,3.5%)). Individuals positive for HBsAg are chronically infected with hepatitis B and are more likely to be infectious to others²³. The minimum possible estimate of the prevalence is obtained by assuming that only the three known positives are in fact infected; this would yield a minimum possible estimate of $3/3810=7.9 \times 10^{-4}$.

For hepatitis C, a total of 148 individuals were tested between June 1997 and March 1999, and 3 tested positive. An additional three individuals in the patient population were known to have had hepatitis C viral load studies. Among those tested, the prevalence was $3/148=2.0\%$ (two-sided exact (binomial) 95% confidence interval is (0.42%,5.8%)); a minimum possible estimate would be $6/3810=0.16\%$.

Finally, we considered the probability that a contaminated needle remains contaminated after it is used on an uninfected patient (the contamination retention probability; see the Appendix). When needles are reused only once, this parameter does not affect the outcome; for the sensitivity analysis, we chose a range of 0 to 1. This parameter is discussed more fully in the Appendix.

For the second research question, determining the expected number of individuals infected due to needle reuse, we multiplied the number of people uninfected at baseline by (1) the number of draws per person, (2) the probability that a contaminated needle will be used on a given draw, and (3) the probability that a person will become infected given that a contaminated needle is used; the formula is given in the Appendix.

For the third research question, we computed the fraction of infections which are attributable to needle reuse. This fraction may be calculated by dividing the expected number of new infections by the total number of current infections (both baseline and new); see Appendix for the formula. Here we neglect incident cases arising from other sources as well as loss to follow-up of prevalent cases, so that the result we calculate may overestimate the true attributable fraction.

For each of HIV, HBV, and HCV, we analyzed 6 risk scenarios. In the first or baseline scenario A, we used the NHANES III estimates given above for the prevalence of the infection, we assumed that 7 needles were reused once each, and we used the lower bound estimates for the transmission probability. For scenarios B and C, we assumed that 70 and 700 needles were reused (respectively). For scenario D, we used the upper confidence limits from the available tests for the prevalence in the population utilizing the Palo Alto phlebotomy center (instead of the NHANES population estimates). For scenario E, we used the upper bounds of the infection probability following needlestick injury, and in the worst-case scenario F, for each disease, we used the highest values for the baseline prevalence, needle reuse rates, and transmission probabilities. In these scenarios, we assume that needles are only reused once. The possibility of multiple needle reuse and the effects of different needle lifetime distributions are considered in the Appendix.

Because of the uncertainty in the input parameters, and therefore in the estimates we computed for each research question, we supplemented the scenario analyses with a sensitivity analysis based on Latin Hypercube Sampling³⁵⁻³⁹. We represented the uncertainty in each parameter in Table 1 by a uniform distribution with the lower and upper bounds given in the table, and then selected a Latin Hypercube Sample of size 100 000 from the distribution of the input parameters. This results in 100 000 different model inputs; for each, each of the three outputs were computed. The partial rank correlation coefficient of each model output with respect to each input was then calculated to provide a measure of how much the uncertainty in each input contributes to the uncertainty in each output; values near zero indicate that the parameter has little effect on the output under discussion; values near 1 or -1 indicate strong dependence of the parameter on the output under discussion.

Results

For each of the three research questions, we present results of the scenario analyses in Table 2. For the case of HIV transmission, in the baseline scenario A, we found that the average risk per draw was 1.4×10^{-8} (approximately one in one hundred million), the expected number of individuals in the cohort

who would have become infected was 8.7×10^{-5} , and that the fraction of persons subsequently found to be infected in the counseling and testing program who acquired their HIV infection through needle reuse would be 4.6×10^{-6} (the attributable fraction). In the worst-case scenario F, we found that the risk of infection was 6.8×10^{-6} , and the expected number of new infections was 0.042, and the attributable fraction would be less than one in one thousand.

For Hepatitis B, in the baseline scenario, the probability that an uninfected individual would become infected after one blood draw was 1.1×10^{-6} ; in the worst-case scenario F, the risk per draw is 1.2×10^{-3} . We find that in scenario A, the attributable fraction would be 3.5×10^{-4} ; in the worst-case scenario F, this fraction would be 0.05.

Finally, for Hepatitis C, we find that in the baseline scenario A, the probability that an uninfected individual will become infected after a single draw is 3.6×10^{-7} . In the worst-case scenario F, the probability of infection per individual was 4.8×10^{-4} , and that 2.8 new cases of hepatitis C would have been expected. For the baseline scenario, the fraction of hepatitis C cases attributable to needle reuse would be 3.2×10^{-5} ; in the worst case scenario, this fraction rises to 0.0013.

We next analyzed the sensitivity of the risk of infection per draw (using Equation (1) in the Appendix) to determine which of the input parameters contributes the most to the uncertainty of this outcome variable. The partial rank correlation coefficients for the sensitivity of the risk of infection per draw are shown in Table 3. Not surprisingly, the uncertainty in the risk of infection per draw was most sensitive to uncertainty in N , the number of reused needles, in every case. Uncertainty in the number of reuses per needle played a moderately large role as well, even controlling for the number of draws with reused needles; see Appendix for further details. For hepatitis C, the transmission probability ranged over a factor of four, and this led to considerable sensitivity to this parameter; the sensitivities of the risk of infection with HIV and HBV per draw with respect to the transmission probability of HIV and HBV (respectively) were smaller. The uncertainty in the risk of infection per draw was sensitive to uncertainty in the baseline prevalence; the greatest sensitivity was seen for hepatitis B. Finally, for all three agents, uncertainty in the

contamination retention probability was the smallest contributor to the total uncertainty in the transmission risk; see Appendix for further details.

We also calculated the partial rank correlation coefficient for the sensitivity of the other output variables (the expected number of new infections and the attributable fraction). The results were almost identical to the sensitivity analysis results presented in Table 3 for the risk of infection per draw, except that the attributable fraction is approximately independent of the baseline prevalence. Uncertainty in the baseline prevalence contributes very little to our uncertainty in the attributable fraction.

Finally, we present preliminary prevalence estimates⁴⁰ from the counseling and testing program⁴¹ for individuals who accessed the center; these prevalence estimates are lower than NHANES population estimates. Of the 3,810 patients who had blood drawn, results are available for 1,699 individuals who were tested; comparing the 1,699 individuals for whom results are available with those for whom no results are available, we find no evidence of a difference by sex, but that the oldest and youngest individuals are underrepresented in the sample; see Appendix for further details. Finally, note that we cannot determine if newly identified infections are (1) prevalent, chronic infections, not previously identified in asymptomatic individuals, (2) incident infections acquired outside of the clinical lab, or (3) incident infections acquired because of needle reuse by HCW1.

Discussion

These results suggest that the patient population at the Palo Alto site was at very low risk for infection by any of HIV, hepatitis B, or hepatitis C due to the reuse of needles by HCW1. For the baseline scenarios, the risk for a random individual acquiring any infection per a single blood draw was one in one million or less. In the most pessimistic scenarios, we assumed that one hundred times as many needles were reused as HCW1 reported and that both the transmission probability and the baseline prevalence were very high; only in these worst-case scenarios did we find infection risks per draw on the order of one in 1000 (and then only for Hepatitis B). We also found that the expected number of new infections in the entire population

was very small; for HIV, even in the most pessimistic scenarios, the expected number of newly infected individuals was only 0.04; for hepatitis B and C, few new infections would be expected even in the most pessimistic scenario.

The preliminary results⁴⁰ from the counseling and testing program⁴¹, support the conclusion that the risk to each individual was very low. Of the 1,699 persons who were tested and for whom results are available, we found that the prevalence estimates were lower than NHANES III population estimates for the noninstitutionalized general population; thus, the available prevalence results from the counseling and testing program provide no evidence of substantial transmission. The results of our risk assessment suggest that very few, if any, infections can be attributed to needle reuse (in a statistical sense); for any particular individual, the results of a more detailed investigation would be needed to attribute infection to needle reuse. Finally, these prevalences suggest that our use of NHANES-derived results as the lower bound of the infection rate, would, if anything, overestimate the baseline prevalence (since the baseline prevalence cannot be larger than the prevalence in the patient population after blood draws have been undertaken at the center).

In interpreting the results, the following consequences of the assumptions should be kept in mind. First, as discussed above, while the available data provide no reason to believe otherwise, it is uncertain if the NHANES III estimates we used reflect the true prevalence of infection in the population served by the patient service center. Second, the most sensitive parameter in the model was the number of needles reused; it was necessary to estimate this based on the statements made by HCW1 and her coworker. We computed the model outputs using a wide range of possible values for this parameter, and we found that even in the worst-case scenario, few new infections could be expected. Third, no estimates of the transmission probabilities associated with reused needles are available, and it was necessary to estimate this probability by using estimates derived from needlestick injuries. Also, we modeled the risk of infection assuming that secondary transmission within the Palo Alto setting could be neglected; the small number of expected new infections, over a broad range of parameters, supports the use of this simplifying assumption.

Finally, we computed the risk for a random individual prior to having blood drawn; for any particular individual, further information regarding their risk factors would need to be used in order to produce the best possible estimate of their risk.

The results of this analysis were used by company representatives and public health authorities in several ways. In proceeding with the counseling and testing study, these results indicated that we would expect to detect, few, if any, new cases. These results were helpful to the company in reassuring concerned individuals that they were at very low risk for new infections. In addition, company representatives were able to arrange in advance for an adequate number of specialists to assist in evaluating and caring for any individuals identified as having disease in the course of the counseling and testing study. From the public health perspective, these results supported statements from public health officials that the affected individuals were at low risk for new infections from this incident. In addition, public health authorities were able to anticipate the epidemiological workload necessary to monitor the public health impact of this incident.

Finally, although there was no evidence to suggest that the very high reuse rates for needles which we assumed in the pessimistic scenarios ever occurred, these scenarios nevertheless demonstrate the very real threat that needle reuse would pose to public health should high levels of needle reuse ever occur in a setting of high prevalence of infection⁴. Thus, the low risk estimates we obtained for the Palo Alto cohort are not grounds for complacency, and vigilance to prevent similar incidents from occurring in the future is necessary.

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Appendix

“Needle demography” and the probability of infection per draw. In this section, we give the equations that we used to calculate the overall risks given in Table 1. We first determined the probability p that a particular draw would be made with a contaminated needle; multiplying this by b (the transmission probability) then gave the risk estimate in Table 1.

In order to calculate p , we assumed that the individuals arrived at random to the center (i.e., their order was independent of infection status). We also analyzed the possibility that needles could be reused more than once. Each time a needle is used, it has a chance of becoming contaminated, and the more times a needle is reused, the more chances it has had of becoming contaminated. If contaminated needles remain infectious use after use, then a higher contamination probability is expected for needles that have been reused many times. We assume that after a contaminated needle is reused on an uninfected person, it retains its contamination⁹ with probability r ; $r < 1$ due to flushing, dilution, or decontamination. If a contaminated needle were to always remain contaminated after being reused on an uninfected person, then $r = 1$; if a contaminated needle never remains contaminated after being reused on an uninfected person, then $r = 0$. If $r = 0$, a needle is only contaminated if the last person on whom the needle was used was infected; if $r > 0$, then needles may retain their contamination status.

If a total of D draws are undertaken, we will denote the number of needles that may be reused (possibly more than once), by N . If each of these N needles “survives” to be reused a fixed number k of times, then a total of $k + 1$ draws are made with the needle (counting the first), and the total number of draws made with reused needles is kN . However, little information is available about the distribution of the number of reuses for each needle; we accordingly consider a second alternative needle lifetime distribution in which we may assume that after each use, a needle is discarded with probability α (leading to a geometric distribution of the number of reuses, with the mean number of reuses $\frac{\alpha}{1-\alpha}$).

Using the baseline prevalence, we must calculate the probability that a needle becomes contaminated. Assuming that the individuals who were positive had the same number of draws on average as the negative

individuals, then we may assume that the probability that an uninfected needle becomes contaminated after a single draw is the same as the baseline prevalence.

We let the baseline prevalence of infection in the population be denoted s . Based on a discrete-time Markov model for the infective status of a given needle, it will be shown that the probability that a contaminated needle would be used on a randomly chosen individual is given by

$$p = \frac{sN}{D} \frac{1}{1 - (1 - s)r} \left[(k + 1) - \frac{1 - [(1 - s)r]^{k+1}}{1 - (1 - s)r} \right], \quad (1)$$

where each needle is assumed to be reused k times and then discarded, N is the number of needles to be reused, D is the total number of draws, and r is the contamination retention probability. With the geometric survival function for needles, we obtain

$$p = \frac{sN\alpha}{D(1 - \alpha)(1 - \alpha(1 - s)r)}. \quad (2)$$

The derivation of equation (1) is outlined in this paragraph. Let τ denote the number of times a needle has been used prior to the current use; the first time a needle is used, $\tau = 0$, the first time a needle is reused, $\tau = 1$, and so forth. Let $X(\tau) = 1$ if the needle is infected at use τ , and $X(\tau) = 0$ if the needle is uninfected at use τ ; since a needle is sterile when it is new, $X(0) = 0$. If a needle is uninfected, it becomes contaminated if it is used on an infected person (which occurs with probability s); if a needle is infected, it will be used on another infected person with probability s (in which case it remains infected), or on an uninfected person with probability $1 - s$ (in which case it remains infected with probability r). After canceling terms, the following difference equation for the probability of infection $P(X(\tau) = 1)$ is obtained:

$$P(X(\tau + 1) = 1) = s + r(1 - s)P(X(\tau) = 1);$$

the solution of this difference equation is

$$P(X(\tau) = 1) = s \frac{1 - (r(1 - s))^\tau}{1 - r(1 - s)}.$$

If a needle is discarded after the k -th reuse, then the expected number of infectious draws per needle is

$$\sum_{\tau=0}^k P(X(\tau) = 1) = \frac{s}{1 - r(1 - s)} \left((k + 1) - \frac{1 - (r(1 - s))^{k+1}}{1 - r(1 - s)} \right).$$

Finally, multiplying this by the total number of needles and dividing by the total number of draws gives the probability that a contaminated needle is used on a given, randomly chosen, individual, as given in Equation (1). The expression for the geometric lifetime distribution can be derived similarly.

When r is small, or when needles are reused at most once, we arrive at very similar numerical results whether we use a fixed needle lifetime or whether we assume the geometric distribution. If needles did not retain their contamination after being used on an uninfected patient (i.e. $r = 0$), then reusing one needle twice would be equivalent to reusing two needles once; the above equations reduce to the form $p = su$, where u is the number of times a reused needle is used divided by the total number of draws. For instance, for hepatitis C, if the baseline prevalence is assumed to be 1.8%, 70 needles are reused, the transmission probability is 7.4%, and needles are reused 3 times (for a total of 210 reuses), then with $r = 0.1$, the risk per draw would be 4.76×10^{-5} ; with all else kept constant, the geometric distribution (using $\alpha = 0.75$ for a mean reuse rate of 3 as well) leads to 4.81×10^{-5} . When r is small, only the total number of draws with reused needles matters.

If needles may be used very many times and have a very high contamination retention rate r , then the overall risk would be higher. For instance, in the hepatitis C scenario ($s = 0.018$, $b = 0.074$), with 1500 needles used once and $r = 0.1$, we find that the overall risk is 3.19×10^{-4} ; whereas in the extreme case where 10 needles were reused 150 times each (for the same total of 1500 draws with reused needles), the overall risk with $r = 0.1$ is 3.53×10^{-4} , with $r = 0.5$ is 6.22×10^{-4} , and with $r = 1$ is 1.17×10^{-2} . These and other numerical results (not shown) suggest that if the contamination retention rate r is small and the number of reuses per needle is not large, our assumptions about needle demography have not greatly affected our numerical results. When the contamination retention rate $r = 0.5$, even very high rates of needle reuse nevertheless do not lead to substantial increases in our risk estimates.

Expected number of individuals infected due to needle reuse. For the second research question, we calculated the expected number of individuals infected due to needle reuse as described in the text. We multiplied the number of uninfected individuals (the number of individuals n times the probability that a

given individual is not infected at baseline, $1 - s$) by (1) the number of draws per person d , (2) the probability that a contaminated needle will be used on a given draw, p (calculated in Equation 1), and (3) the transmission probability b . Thus, the expected number E of individuals infected by blood draws is found by $E = n(1 - s)dpb$.

Attributable fraction. For the third research question, we calculated the fraction of infections in individuals attributable to needle reuse. Here, s is the baseline prevalence of infection (the prevalence of infection in the population of center patients before they have received the first blood draw), and n is the number of patients. If transmission occurred due to needle reuse, the prevalence in these patients after March 23, 1999 would be larger than s , since E new infections would have been expected to have occurred. Thus, the attributable fraction can be found from the formula $\frac{E}{ns+E}$; this is an overestimate since we neglect incident cases arising from other sources.

Transmission probability due to needlestick injury. In this section, we provide estimates for the transmission probability (b) for each of the three pathogens HIV, HBV, and HCV.

HIV-1 has been found to survive in syringes for periods of up to four weeks at room temperature²⁰. Accidental inoculation with HIV-positive blood through a needlestick injury confers a risk of infection of approximately 0.3%¹²⁻¹⁸; factors which increase this risk are deep injury, visible blood on the device, a needle placed in the source patient's vein or artery, or terminal HIV disease in the source patient¹⁹. We did not adjust for these factors, since the risk (i.e., the probability of infection) when these factors are absent is unknown; nor did we adjust for the narrowness of the gauge of the needles. Ippolito et al.¹⁸ combined the results of several HIV needlestick injury studies, yielding 9 infections out of 3,628 injuries, for a best estimate of 0.25% and an upper 95% confidence limit of 0.5%.

Accidental inoculation with hepatitis B virus-contaminated blood through a needlestick injury confers a risk of infection between 6% and 30%²¹⁻²². The presence of hepatitis B e antigen is correlated with increased source-patient infectivity; one study reported that 44 out of 234 patients exposed to hepatitis B e antigen-positive blood seroconverted, for a risk of 19%²³. The hepatitis B virus itself is believed to be

relatively viable in contaminated equipment²⁴. We used 19% for our lower estimate (recognizing that this figure, derived from HBeAg-positive blood is, in all likelihood, too high).

Accidental inoculation with hepatitis C virus-contaminated blood through needlestick injury confers a risk of infection in between that of HIV and HBV; this risk has not been precisely determined. We first obtained an upper bound by examining two studies in which (1) the source cases were PCR positive for HCV RNA (the most infectious source cases), and (2) PCR and second-generation HCV antibody tests were used to detect infection in exposed individuals. Combining data from these two studies²⁵⁻²⁶ yielded an infection probability of 7.4% (9/121). A recent review estimated the risk of seroconversion following needlestick injury with HCV-antibody positive blood (rather than HCV RNA positive blood) at 1.8%²⁷; estimates based on second-generation antibody tests have ranged from 0% (0/81)²⁸, through 1.2% (4/331)²⁹, to 6% (3/50)³⁰.

Population prevalence estimates derived from NHANES III. The third National Health and Nutrition Examination Survey was conducted during 1988–1994 to provide population-based data to assess the health status of the noninstitutionalized nonmilitary population of the United States³³. NHANES III estimates the HIV prevalence in the general population of the US to be approximately 0.32%; this result is believed to be an underestimate³¹; to err on the side of caution, we used the larger value of 0.5% in our analysis. NHANES III estimated the prevalence of HBsAg positivity to be 0.5%³², providing an estimate of the prevalence of chronic infection with HBV. Finally, NHANES III data suggest a prevalence of HCV antibody positivity of 1.8% in the general (noninstitutionalized) population in the United States^{33,34}, with 74% of such individuals exhibiting detectable HCV RNA by PCR (for an estimate of 1.3% chronically infected). HCV-infected individuals may intermittently exhibit detectable viremia, so that 74% is an underestimate of the fraction of HCV-positive individuals who are chronically infected. As most individuals who are infected with HCV become chronically infected, we assume that all HCV-positive individuals are chronically infected (and thus infectious). It is possible that the prevalence in the population utilizing the center was lower than the estimates derived from NHANES (since the older,

suburban population may have fewer risk factors for infection by blood-borne pathogens); on the other hand, people who receive a blood draw at the center are sicker on average than an inclusive sample of community dwellers, so that the NHANES estimate may be too low.

Comparison of Individuals with and without available test results in the counseling and testing study. Of the 3,810 individuals who received a blood draw at the Palo Alto site, results are available for 1,699 individuals. Since these individuals chose testing through the company's testing program, it is difficult to assess the representativeness of these 1,699 as a sample of the 3,810. Data is available on sex, age, and zip code. Excluding individuals of unreported sex, we compared the fraction of men for whom test results are available with the fraction of women for whom test results are available, and found no evidence of a difference ($X^2 = 2.84$, $df=1$, $p=0.09$). Considering only individuals who are locally based at this time (ZIP code beginning with 94 or 95), we found no evidence of a geographic difference ($X^2 = 50.47$, $df=38$, $p=0.085$). Because information was provided by patients who came in for testing, less information is available for individuals who did not come in for testing. Thus, test results are much less likely to be available for individuals who are currently not locally based or for whom no ZIP code is available (as expected). Finally, comparing individuals in ten-year age intervals (excluding individuals of unknown age) reveals a statistically significant difference ($X^2 = 31.7$, $df=9$, $p=0.0002$); results are less likely to be available for individuals above 90 years of age or below 9 years of age.

Table 1: **Parameter Estimates.**

Agent	Parameter	Interpretation	Lower	Upper
HIV	b	transmission probability	0.25%	0.5%
HBV	b	transmission probability	19%	30%
HCV	b	transmission probability	1.8%	7.4%
HIV	s	baseline prevalence	0.5%	1.2%
HBV	s	baseline prevalence	0.5%	3.5%
HCV	s	baseline prevalence	1.8%	5.8%
-	N	number of reused needles	7	700
-	r	contamination retention probability	0	1
-	k	number of reuses per needle	1	3

Table 2: **Results from Scenario Analyses.**

Scenario	Note	Agent	Baseline	Number of	Transmission	Risk	Expected	Fraction of
			Prevalence	Reused	probability	per	new	infections which
			s	needles	b	draw	infections	are from reuse
A	baseline	HIV	0.005	7	0.0025	1.4×10^{-8}	8.7×10^{-5}	4.6×10^{-6}
B	high reuse	HIV	0.005	70	0.0025	1.4×10^{-7}	8.7×10^{-4}	4.6×10^{-5}
C	very high reuse	HIV	0.005	700	0.0025	1.4×10^{-6}	8.7×10^{-3}	4.6×10^{-4}
D	high s	HIV	0.012	7	0.0025	3.4×10^{-8}	2.1×10^{-4}	4.5×10^{-6}
E	high b	HIV	0.005	7	0.005	2.8×10^{-8}	1.7×10^{-4}	9.1×10^{-6}
F	worst-case	HIV	0.012	700	0.005	6.8×10^{-6}	0.042	9.1×10^{-4}
A	baseline	HBV	0.005	7	0.19	1.1×10^{-6}	6.6×10^{-3}	3.5×10^{-4}
B	high reuse	HBV	0.005	70	0.19	1.1×10^{-5}	6.6×10^{-2}	3.5×10^{-3}
C	very high reuse	HBV	0.005	700	0.19	1.1×10^{-4}	0.66	0.034
D	high s	HBV	0.035	7	0.19	7.4×10^{-6}	0.045	3.4×10^{-4}
E	high b	HBV	0.005	7	0.3	1.7×10^{-6}	0.010	5.5×10^{-4}
F	worst-case	HBV	0.035	700	0.3	1.2×10^{-3}	7.1	0.05
A	baseline	HCV	0.018	7	0.018	3.6×10^{-7}	2.2×10^{-3}	3.2×10^{-5}
B	high reuse	HCV	0.018	70	0.018	3.6×10^{-6}	2.2×10^{-2}	3.2×10^{-4}
C	very high reuse	HCV	0.018	700	0.018	3.6×10^{-5}	0.22	3.2×10^{-3}
D	high s	HCV	0.058	7	0.018	1.2×10^{-6}	6.9×10^{-3}	3.1×10^{-5}
E	high b	HCV	0.018	7	0.074	1.5×10^{-6}	9.2×10^{-3}	1.3×10^{-4}
F	worst-case	HCV	0.058	700	0.074	4.8×10^{-4}	2.8	0.013

Table 3: **Partial Rank Correlations** for the sensitivity of the Risk of Infection per Draw for each of five parameters.

Agent	Sensitivity to Prevalence	Sensitivity to Number of Reused Needles	Sensitivity to Transmission Probability	Sensitivity to number of reuses per needle	Sensitivity to Contamination Retention Probability
HIV	0.77	0.96	0.68	0.56	0.45
HBV	0.87	0.93	0.42	0.44	0.34
HCV	0.76	0.94	0.81	0.44	0.34

Values near 0 indicate low sensitivity; values whose magnitudes are near one indicate high sensitivity.

Table 4: **Population prevalence** of each agent.

Agent	NHANES III estimate	Investigation estimate
HIV	0.32%	0.12%
HBV	0.5%	0.41%
HCV	1.3%-1.8%	0.88%