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## Risk of Window Period HIV Infection in High Infectious Risk Donors: Systematic Review and Meta-Analysis

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### Abstract

The OPTN defines high risk donors (HRDs), colloquially known as “CDC high risk donors,” as those thought to carry an increased risk of HIV window period (WP) infection prior to serologic detectability. However, the true risk of such infection remains unknown. To quantify the risk of WP infection in each HRD behavior category, we performed a systematic review and meta-analysis of studies of HIV prevalence and incidence. Of 3,476 abstracts reviewed, 27 eligible studies of HIV infection in HRD populations were identified. Pooled HIV incidence estimates were calculated for each category of HRD behavior and used to calculate the risk of WP HIV infection. Risks ranged from 0.09–12.1 per 10,000 donors based on WP for ELISA and 0.04–4.9 based on nucleic acid testing (NAT), with NAT reducing WP risk by over 50% in each category. Injection drug users had the greatest risk of WP infection (4.9 per 10,000 donors by NAT WP), followed by men who have sex with men (4.2:10,000), commercial sex workers (2.7:10,000), incarcerated donors (0.9:10,000), donors exposed to HIV through blood (0.6:10,000), donors engaging in high risk sex (0.3:10,000), and hemophiliacs (0.035:10,000). These estimates can help inform patient and provider decision-making regarding HRDs.

### Keywords

organ utilization; NAT; high risk donor; deceased donor transplantation; HIV

### INTRODUCTION

In the United States, all deceased donors are tested for HIV (1). Unfortunately, serologic testing does not completely eliminate the risk of HIV transmission (2). All serologic tests have a window period (WP), the time between acquisition of infection and serologic detectability (3). Infections acquired in the weeks to months before death, during the WP of

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#### DISCLOSURE

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the serologic test used, will result in false-negative serology and likely transmission to the recipient (4).

Enzyme-linked immunoassay (ELISA) is a testing method that relies on antibody formation for detection, with a WP of approximately 22 days for HIV. Nucleic acid testing (NAT) is an alternative method that detects nucleic acid particles rather than antibodies and as such has a shorter HIV WP of approximately 9 days (5). Arguments against universal adoption of HIV NAT have included cost, availability, time to run the test, and a higher rate of false positives (6). Currently the decision to perform NAT is made individually by OPOs; HIV NAT was routinely performed by only 50% of OPOs in the United States in 2008 (7). Regardless of testing modality chosen, a nonzero risk of WP transmission exists.

Although the limitations of serologic testing apply to all deceased donors, donors are classified as high risk donors (HRDs) by the OPTN if they fall into one of the following 7 behavioral categories thought to place them at increased risk for HIV infection: (1) men who have had sex with another man in the preceding 5 years (MSM), (2) persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years (IDU), (3) persons with hemophilia or related clotting disorders who have received human derived clotting factor concentrates (Hemophiliacs), (4) persons who have exchanged sex for money or drugs in the preceding 5 years (Commercial Sex Workers), (5) persons who have had sex in the preceding 12 months with any person described in items 1–4 above or with a person known or suspected to have HIV infection (High Risk Sexual Behavior), (6) persons who have been exposed in the preceding 12 months to known or suspected HIV infected blood through percutaneous inoculation or through contact with an open wound, non-intact skin, or mucous membrane (HIV Exposed), and (7) inmates of correctional systems (Incarcerated) (8). These donors have also been referred to as “CDC high risk donors.” Approximately 9% of donors where at least one organ is recovered are categorized as HRDs (9).

There is wide variation in HRD utilization nationally. The percent of donor volume in an OPO comprised of HRDs ranges from 2.3% to 26.1% (7). Furthermore, organs from HRDs are more likely to be discarded than their non-HRD counterparts (10,11). In November 2007, 4 transplant recipients contracted HIV from an infected HRD, an event that made national headlines (12). This was the first reported case of HIV transmission through transplantation in over 20 years; however, utilization of HRDs reportedly declined following this event (13). It is unclear if a regressive attitude towards HRD organs is in the interest of patients. Evidence suggests no difference in the hazard of death or graft loss for recipients of HRDs compared to those of SCDs (11). In contrast, expanded criteria donors (ECD) kidneys comprise approximately 18% of kidneys transplanted and are associated with a 34% increased hazard of death and a 76% increased hazard of graft loss (9).

Equipoise regarding utilization of HRD organs might result from the ambiguity of the classification and lack of quantification of the infectious risks. The criteria for classification of HRDs are based on guidelines developed in 1984 by the Public Health Service (PHS) to identify persons at risk of having prevalent HIV infection (14,15). The original PHS guidelines identified high risk groups as bisexuals, homosexuals, injection drug users, hemophiliacs, persons at increased risk of HIV through sexual contact, and persons of Haitian descent. These have since been modified to include specific sexual risk factors, incarcerated individuals, and persons exposed to HIV infected blood (16) (Table 1). In addition, laboratory exclusionary criteria were added so that persons without adequate blood samples, such as persons with significant hemodilution from transfusions, are also considered high risk. However, in transplantation the risk associated with HRDs is not from *prevalent* HIV, but from an *incident* infection that is acquired during the WP of the serologic

test being used. A recent consensus conference report evaluated the HRD criteria and recommended that the utility and appropriateness of these guidelines be re-examined (17).

The ability to estimate the risk of WP infection using transplant registry data has been limited by (1) only very recent recording of HRD flag, (2) lack of recording of the nature of the HRD behavior in national data, (3) the self-reported nature of WP infections, (4) the variety of HIV testing methods used in donors, and (5) an inability to statistically quantify the range of risk because the number of reported seroconversion events has been so low. A national survey of providers showed they were most likely to accept organ offers from HRDs classified as IDUs, followed by (in order of declining preference) MSMs, CSWs, incarcerated donors, hemophiliacs, donors engaging in high risk sexual behavior, and donors exposed to HIV-infected blood (18). Because the risk of a WP infection for each HRD category has never been systematically quantified, it is unclear whether provider preference and actual risk of WP infection are correlated.

We hypothesized that the variation in utilization and high discard rates of HRD organs might result from an inability to quantify the true risk of WP infection. The goals of our study were to (1) estimate the incidence and variance of HIV infection within each category of HRD behavior, and (2) estimate the risk of HIV WP infection within each category of HRD behavior.

## **METHODS**

### **Study Selection**

We hypothesized that there is significant heterogeneity in HIV prevalence and incidence even within HRD behavioral categories; as such we kept eligibility criteria very broad in order to present a range of estimates. Any study reporting an original estimate of prevalence or incidence of HIV in a population located in the United States or Canada on or after January 1, 1995 was eligible for inclusion. Studies before 1995 were excluded, as the dynamics of HIV transmission likely changed with the introduction of highly-active antiretroviral therapy (HAART). Prevalence or incidence had to be measured by detection of either antibodies, proteins, or RNA; studies based on self-report alone were excluded. Estimates without a defined denominator were excluded.

### **Search Strategy**

We performed a systematic search for articles meeting the above criteria. All abstracts were screened by two independent reviewers, and disagreements were adjudicated by another two (LK and DS). If eligibility could not be definitively determined from the abstract, the manuscript was included in the full-text screen. Two independent reviewers screened articles at the full-text level, with adjudication as above.

### **Reference Mining and NIH Grant Search**

To capture as many studies as possible, we mined the references of a 20% random sample of eligible studies. Because incidence studies require the recruitment and follow up of large cohorts and thus significant financial resources, we also searched the NIH grant database for any studies with keywords “HIV” and “Incidence” funded after 1995. References and publications resulting from NIH grants were checked against our database of eligible studies, and any studies not previously considered were reviewed as above.

### **Data Abstraction**

At least two independent reviewers abstracted data from all eligible articles. Additionally, one reviewer (LK) abstracted data from every eligible article and adjudicated disagreements.

Finally, all abstractions and calculations were double-checked by additional reviewers. The following data were abstracted from each article: dates of recruitment, country, state, city, and specific location where recruitment took place, sampling method (convenience, target, random sample, chain/referral sampling), inclusion criteria, testing method, number of patients approached, number eligible, number tested, and number positive. For incidence studies, the number of seronegative patients eligible for follow-up, the number tested at follow-up, the number of seroconversions, incidence rate, and the total number of person-years at risk were also abstracted. For each study, we abstracted overall HIV incidence and prevalence estimates as reported for the entire study population and risk-stratified sub-estimates if the risk factor was one of the seven behavioral risk factors used in HRD designations (Figure 1). Data not directly reported were back-calculated or obtained directly from the authors of the study when possible. Any studies where the number of person years at risk, number of seroconversions, dates of data collection, and study location could not be obtained or calculated were excluded.

### **Meta-Analysis**

The goal of the meta-analysis was to estimate the risk of HIV WP infection among individuals drawn from each category of HRD behavior. As such, studies of HIV incidence among persons demonstrating one of the HRD behaviors were eligible for inclusion. Each HIV incidence estimate was classified as falling into one of the seven categories (Table 1), other, or falling into multiple categories. Studies in the same category that took place in the same geographic location were re-evaluated to ensure that the estimates were not derived from the same cohort. Pooled incidence estimates were calculated by summing person-time at risk and number of HIV seroconversions for each study within categories of HRD behavior. Poisson exact 95% confidence intervals were calculated for each pooled incidence estimate using Stata 11/MP (College Station, TX) (19).

### **Estimating Incidence from Prevalence**

Incidence is difficult to study directly, as it requires the recruitment and follow-up of a large cohort and expensive serologic testing at multiple time points. Our analysis was restricted to individuals falling into very specific behavioral categories, which further narrows the pool of available studies. For the HRD category of CSWs, we did not find a sufficient number of incidence studies to derive pooled estimates for these populations. However, we did find a number of HIV prevalence studies in individuals falling into this category. We used methods previously described by Zou et al. (20) for estimating the incidence of a disease from the prevalence by comparing to a population where both incidence and prevalence are known, with studies of incidence and prevalence in IDUs as the comparison group to estimate incidence in CSWs (21–43).

### **Estimating the risk of window period infection**

Probability of seroconversion during one day in the life of a patient with the given behavioral risk was calculated from pooled incidence estimates. From this, probability of a window-period infection was calculated using iterative conditional probabilities (Figure 2A). Upper and lower bounds of the WP risk were calculated using the upper and lower bounds of the 95% CIs around the pooled incidence rates.

### **Estimates in hemophiliacs**

Very few sero-incidence studies of hemophiliacs were available since 1995. Given recent improvements in blood supply screening (44), we did not feel it was appropriate to estimate the risk of incident infection using older prevalence estimates. Instead, since the risk in this subgroup derives from risk of blood transfusions, we used studies of HIV incidence in blood

donors to calculate the risk of incident infection in hemophiliacs. The United States and Canada have national registries tracking all blood donors; we included only the most recent study from each country. In addition to incidence rates, we also abstracted the WP estimate and 95% confidence interval of the NAT used in blood screening from each study. We used the upper bounds of the 95% CI (11 days) to calculate the residual risk of undetected HIV infection in the blood supply (Figure 2B). We used the residual risk of blood contamination to calculate the risk of WP infection in hemophiliacs, making the conservative assumption (i.e. the assumption leading to a conservatively high estimate) that they received one unit of blood per day for the entire duration of the WP (Figure 2C).

### **Estimates in persons exposed to HIV infected blood percutaneously or mucocutaneously**

A recent systematic review pooled studies to estimate the per-exposure risk of HIV from percutaneous injuries involving exposure to HIV (+) blood. In this systematic review, the risk was estimated to be 0.24% per exposure (45). We used this estimate to calculate the risk of WP infection, assuming only one exposure event with equal probability of the event occurring on any day in the year prior to death (Figure 2D).

## **RESULTS**

### **Systematic Review**

We identified 3,298 eligible abstracts through a search of PubMed and 178 additional eligible abstracts through reference mining for a total of 3,476 eligible abstracts; after screening, 337 articles were eligible for inclusion at the full-text level (Figure 1) and 122 were eligible for data abstraction. Studies were further restricted to 27 unique estimates among populations meeting HRD behavioral criteria. Additionally, a recent review of 25 studies was used to estimate risk of WP infection from exposure to HIV infected blood (45).

### **Men Who Have Sex With Men**

Seven studies of HIV incidence among MSMs represented a total pooled sample of 19,567 participants and 53037.2 person-years of follow up (Table 2) (46–52). Incidence rates ranged from 0.9–7.1 per 100 person-years, with a pooled rate of 1.7 (95% CI: 1.6–1.8, Table 1). There was significant heterogeneity in estimates likely due to differences in inclusion criteria and recruitment strategy. The studies with convenience sampling of men seeking HIV or other STD testing reported higher incidences (1.1–7.1 per 100 person-years), whereas those with community-based recruitment reported lower incidences (0.6–2.1 per 100 person-years). Per 10,000 donors, the risk of HIV WP infection was 10.2 for ELISA (range 9.6–10.9) and 4.2 for NAT (range 3.9–4.5).

### **Injection Drug Users**

Six studies of HIV incidence among IDUs were identified (Table 3); however, one study was not included in the meta-analysis as the estimate was both inconsistent with the other estimates and highly influential (51). The remaining five studies represented a total pooled sample of 6698 participants and 10248.5 person-years of follow-up (24,47,50,53,54). Incidence rates ranged from 0.4–3.2 per 100 person-years, with a pooled rate of 2.0 (95% CI 1.8–2.3, Table 1). Studies that only enrolled participants who had injected drugs in the past month reported higher incidence estimates (3.2 per 100 person-years) compared to those who enrolled anyone who identified as IDU (0.2–1.8 per 100 person-years). Per 10,000 donors, the risk of HIVWP infection was 12.1 when ELISA was used (range 10.5–13.8), and 4.9 when NAT was used (range 4.3–5.6).

## Hemophiliacs

In total, 23,952,671 blood donations (not individual donors) from the United States and Canada were included in our pooled estimate (Table 4) (55,56). The HIV incidence among blood donors was estimated to be 0.00049 per 100 person-years in Canada and 0.00155 in the United States (Table 4); pooled incidence was 0.0013 per 100 person-years (Table 1). Per 10,000 donors, the risk of WP infection was 0.086 when ELISA was used (range 0.066–0.106), and 0.035 when NAT was used (range 0.027–0.043).

## Commercial sex workers

Seven eligible HIV prevalence studies represented a pooled total of 1703 participants (Table 5) (34–36,57–60). Using previously described methods to estimate incidence from prevalence (20), incidence among CSWs was 1.1 per 100 person-years (range 0.9–1.2, Table 1). Per 10,000 donors, the risk of WP infection was 6.6 when ELISA was used (range 5.4–7.2) and 2.7 when NAT was used (range 2.2–3.0).

## HIV Incidence and Risk of WP Infection among persons engaging in high risk sexual behavior

Two studies of HIV incidence among persons engaging in high risk sexual behavior represented a total of 1454 participants (Table 6) (47,51). Pooled HIV incidence was 0.12 per 100 person-years (95% CI: 0.09–0.16, Table 1). Per 10,000 donors, the risk of HIV WP infection was 0.7 when ELISA was used (range 0.5–0.9) and 0.3 when NAT was used (range 0.2–0.4).

## HIV Incidence and Risk of WP Infection among persons with percutaneous exposure to HIV infected blood

The risk of WP infection in this category was calculated using estimates from a recent review of sharps injuries with HIV infected blood which pooled 5810 participants from 25 studies (45). The per-exposure risk of transmission was estimated to be 0.24% (95% CI 0.14–0.40, Table 1). Assuming one exposure in the year prior to donation, per 10,000 donors, the risk of WP was 1.5 when ELISA was used (range 0.8–2.4) and 0.6 when NAT was used (range 0.4–1.0).

## HIV Incidence and Risk of WP Infection among incarcerated persons

Three HIV incidence studies among incarcerated individuals were identified (Table 7) (61–63) with a pooled total of 5168 participants and 2891.5 person-years of follow-up. Incidence estimates ranged from 0 to 0.5 per 100 person-years, and the pooled incidence was 0.4 per 100 person-years (95% CI 0.2–0.7, Table 1). Per 10,000 donors, the risk of WP HIV infection was 2.3 when HIV ELISA was used (range 1.3–4.1) and 0.9 when NAT was used (range 0.5–1.7).

## DISCUSSION

In this systematic review and meta-analysis of HIV risk among donors classified as high risk for infectious transmission of HIV (also referred to as CDC high-risk donors), the predicted risk of WP infection was low but varied significantly by category of HRD behavior. Risks ranged from 0.09–12.1 per 10,000 donors when based on WP for ELISA and 0.04–4.9 per 10,000 based on NAT. Donors falling into the IDU category had the greatest risk of WP infection (4.3–12.1 per 10,000 donors), followed by MSMs (4.2–10.2), CSWs (2.7–6.6), incarcerated donors (0.9–2.3), donors exposed to HIV through blood (0.6–1.5), donors engaging in high risk sexual behavior (0.3–0.7), and hemophiliacs (0.04–0.09). Our results are concordant with biological evidence that HIV is most efficiently transmitted parenterally



or from male to male by sexual contact, less effectively transmitted from male to female by sexual contact, and least efficiently from female to male by sexual contact (64).

Interestingly, estimated risk of WP infection did not correlate with provider perceptions of risk. A national survey found that transplant surgeons were most likely to accept HRD organs from IDUs (which in this study are shown to carry the highest risk of WP infection), followed by MSMs, CSWs, incarcerated donors, hemophiliacs, donors engaging in high risk sex, and donors exposed to HIV through blood (65). While overall HIV transmission was low, it is important to note that persons in these categories may be at high risk for other blood borne or sexually transmitted infections and the decision of whether to accept an HRD organ offer should not be made based on risk of HIV alone.

Our findings suggest that the binary HRD indicator may not be the most effective guide for clinical decision-making, as organs from hemophiliacs and IDUs carry very different infectious risks. Even within many categories of HRD behavior there was significant variation in the incidence rates, although the variation was generally limited to only one order of magnitude. For example, studies enrolling IDUs who injected in the past month reported higher incidence rates than those enrolling both current and former IDUs. According to current guidelines, anyone who injected in the past 5 years is classified as an HRD. Given that the real concern with HRDs is *recently acquired* infection, it might be more appropriate to classify persons who injected in the past year (or less) as HRDs, as recent injectors likely pose the greatest infectious risk. It is also important to note there is significant potential for misclassification in cases where donor history is incomplete or inaccurate; as such a non-HRD designation does not mean the risk is zero and should not be considered fail-safe.

Several limitations of this study merit discussion. Inclusion criteria were kept broad in order to present a range of estimates, as we felt there was likely to be significant behavioral heterogeneity even within each HRD category. There was likely sampling bias where higher risk individuals were more likely to be included in the studies that were analyzed. For example, among MSMs, four of the incidence studies recruited convenience samples of men who sought voluntary HIV or STD testing. Persons who seek HIV/STD testing are likely different from those who do not, and are likely to be at higher infectious risk. Bias of this type might have caused an overestimation of the risk of WP infection. Studies were clustered in urban areas and in some categories we did not have broad geographic coverage, as such the true range of incidence estimates might be larger than what we reported. A second limitation is that it is possible that participants fell into multiple categories of HRD behavior. Estimates where two behaviors were specifically reported (for example, an estimate among MSMs who also injected drugs) were excluded. However, most studies did not specifically measure all HRD behaviors or did not report estimates by combinations of behavior. As such it is possible that some of the risk reported is not due to the measured HRD behavior but to some other risky behavior. As such, this bias would also contribute to potential overestimation of WP infection risk. However, if persons falling into one category are very likely to exhibit a risky behavior from another category, this effectively increases the risk of that category and is still useful to quantify. Another issue is estimation of NAT and ELISA WPs. We used the most conservative estimates; however, data on this topic is limited and it is possible that some individuals may have significantly longer or shorter WPs. Finally, the estimates reported in Table 1 only reflect averages. Given the amount of variation in risk behavior within each category (and delineated in Tables 2 through 7), the actual risk of WP infection varies within each category.

This is the first systematic report of HIV WP infection risk in patients categorized by the OPTN as high-risk donors. The risk is low, but not insignificant. A recent consensus report

by experts in the United States and Canada found insufficient evidence to recommend universal NAT, in part due to the risk of false-positive results that might result in discard of viable organs. However, they did suggest NAT might be beneficial for HRDs (17), where the benefits of identifying WP infections might outweigh the risks of false-positives. We calculated that NAT significantly reduces the HIV WP risk when compared with ELISA (per 10,000, from 10.2 to 4.2 for MSMs, 12.1 to 4.9 for IDUs, and 6.6 to 2.7 for CSWs), supporting those consensus conference conclusions and identifying subgroups with higher pre-test probability. A comparison of our findings with a national survey of transplant surgeons suggests that decision-making regarding HRDs does not correlate with the actual hierarchy of HIV risk. Furthermore, given the significant heterogeneity within and between categories of HRD behavior, a binary indicator may not be the best metric for guiding this process. Regardless of HRD behavior category, the risk of a WP infection does not approach the risk of death while on the waitlist for most patients (66), and we believe our results support and better inform the use of HRD organs, especially for patients at highest risk of death on the waitlist.

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## ABBREVIATIONS

<b>WP</b>	Window Period
<b>ELISA</b>	Enzyme-Linked Immunoassay
<b>NAT</b>	Nucleic Acid Testing
<b>OPO</b>	Organ Procurement Organization
<b>OPTN</b>	Organ Procurement and Transplantation Network
<b>HRD</b>	High Risk Donor
<b>CSW</b>	Commercial Sex Worker
<b>MSM</b>	Men who have Sex with Men
<b>IDU</b>	Injection Drug User
<b>CDC</b>	Centers for Disease Control and Prevention

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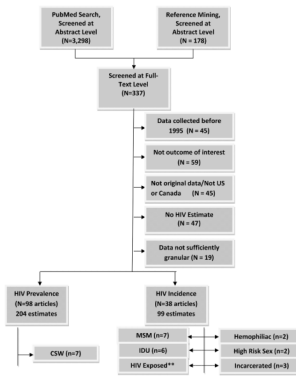
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## APPENDIX

PubMed Search, Performed November 27<sup>th</sup> 2008

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(
("hiv"[MeSH Terms] AND "prevalence"[MeSH Terms]) OR
("hiv seroprevalence"[MeSH Terms]) OR
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Caribbean Region[MeSH Terms] OR
Central America[MeSH Terms] OR
Latin America[MeSH Terms] OR
South America[MeSH Terms] OR
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Atlantic Islands[MeSH Terms] OR
Australia[MeSH Terms] OR
Europe[MeSH Terms] OR
Historical Geographic Locations[MeSH Terms] OR
Indian Ocean Islands[MeSH Terms] OR
Oceania[MeSH Terms] OR
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Pacific Islands[MeSH Terms] OR
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(English[lang]) NOT
(Clinical Trial[ptyp]
Editorial[ptyp] OR Letter[ptyp] OR
Randomized Controlled Trial[ptyp] OR Review[ptyp])
)
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**Figure 1.**

**Search/Selection**

\*Some studies reported both HIV prevalence and incidence; unique studies included totaled 122

\*\*A systematic review was recently performed on this topic and the estimates reported in this review were used to calculate the risk of WP infection in donors exposed to HIV



(a)  
Calculating the Probability of Window Period Infection Using Pooled Incidence Estimates\*  
 $Risk\ of\ WP\ Infection = 1 - e^{-P_{\text{pooled}} \times IIR \times WP\ duration}$

(b)  
Calculating Residual Risk of Infection in Blood Donors  
 $Residual\ Risk\ in\ Blood\ Donors = 1 - e^{-IR \times WP\ duration\ of\ blood\ screening\ test}$

(c)  
Probability that a Hemophilic was Infected During the WP  
 $P(at\ least\ 1\ unit\ Infected) = 1 - P(unit\ uninfected)^{Units\ Received\ in\ WP}$

(d)  
Risk of WP infection among persons with percutaneous exposure to known HIV infected blood  
 $Risk\ of\ WP\ Infection = P(infection\ per\ exposure) \times P(exposure\ occurred\ during\ WP)$

**Figure 2.**  
Equations Used in Meta-Analysis

\*Within each category, the total number of PYs at risk and the total number of sero-conversions were combined to derive pooled estimates for that category. Poisson exact 95% confidence intervals (CIs) were calculated for each pooled estimate; pooled incidence estimates and the bounds of their 95% CIs were used to derive the expected number of WP infections using the equation shown in (A)

**Table 1**  
Risk per 10,000 of an HIV infection occurring during the Window Period, by ELISA and NAT

HRD Category	# Patients	# HIV Seroconverted	Person-Years	Pooled Incidence (95% CI) (per 100 pys)	ELISA	NAT
MSM	19567	920	53037.2	1.7 (1.6-1.8)	10.2 (9.6-10.9)	4.2 (3.9-4.5)
IDU	6698	207	10248.5	2.0 (1.8-2.3)	12.1 (10.5-13.8)	4.9 (4.3-5.6)
Hemophilic	23,952,671	71	5651070	0.0013 (0.0010-0.0016)	0.086* (0.066-0.106)	0.035 (0.027-0.043)
Commercial sex worker	1722*	129*	NA	1.1** (0.9-1.2)	6.6 (5.4-7.2)	2.7 (2.2-3.0)
Sex with a partner in categories 1-4	1454	40	32295.1	0.12 (0.09-0.16)	0.7 (0.5-0.9)	0.3 (0.2-0.4)
HIV Exposed through blood	5810	**	**	0.0024** (0.0014-0.0040)	1.5 (0.8-2.4)	0.6 (0.4-1.0)
Incarcerated	5168	11	2891.5	0.4 (0.2-0.7)	2.3 (1.3-4.1)	0.9 (0.5-1.7)

\* Pooled incidence among blood donors was used to calculate residual risk of infection in blood supply using the upper estimate of the WP of the NAT used in blood screening (n=11 days). Residual risk in the blood supply was used to calculate the risk of WP infection in hemophiliacs, making the very conservative assumption that they received 1 unit of blood per day for the duration of the ELISA or NAT WPs.

\*\* Incidence calculated by pooling studies of prevalence then converting to incidence using previously described methods.

\*\*\* per exposure estimate taken from a systematic review of post-needlestick HIV seroconversion. Risk of WP infection was calculated using per needlestick risk x risk of exposure occurring during the WP.

Table 2

Studies of HIV Incidence in Men who Have Sex with Men

Study	Location	Population	Recruitment	# in Study	# Infected	Person Years	Incidence Rate (per 100 yrs)
A.E. Weber et al. 2001 (49)	Vancouver, Canada	Men aged 18–30 who identified as gay or bisexual or had sex with other men and were not sex trade workers	Target	629	4	444.4	0.9
K.H. Choi et al. 2004 (46)	San Francisco, CA	Asian/Pacific Islanders who identify as MSM	Target	483	4	225	1.8
E Lavoie et al. 2008 (48)	Montreal, Canada	Self identified as MSM	Target	1587	32	5121	0.62
H Weinstock et al. 2002 (50)	Los Angeles, Denver, Chicago, Houston, New Orleans, Miami, Atlanta, Baltimore, Newark	STD clinic patients who underwent routine syphilis testing and identified as MSM	Convenience	5284	132	1866.2	7.1
SE Fernyak, et al. 2002 (47)	San Francisco, CA	HIV testers at HIV testing sites who reported having unprotected receptive anal intercourse	Convenience	2312	114	3352.9	3.4
SE Fernyak, et al. 2002 (47)	San Francisco, CA	HIV testers at HIV testing sites who reported having protected receptive anal intercourse	Convenience	354	12	461.5	2.6
SE Fernyak, et al. 2002 (47)	San Francisco, CA	HIV testers at HIV testing sites who reported having protected receptive anal intercourse and unprotected receptive oral intercourse	Convenience	3288	92	4380.9	2.1
SE Fernyak, et al. 2002 (47)	San Francisco, CA	HIV testers at HIV testing sites who reported who identify as MSM but don't specify a risk behavior	Convenience	796	22	1100	2.0
SE Fernyak, et al. 2002 (47)	San Francisco, CA	HIV testers at HIV testing sites who reported unprotected insertive anal intercourse	Convenience	539	8	800	1.0
Calzavara et al. 2002 (51)	Ontario, Canada	Repeat voluntary HIV testers who identify as MSM	Convenience	Unk	241	22952	1.05
Koblin et al 2006 (52)	San Francisco, Seattle, Chicago, Denver, New York City	MSM who engaged in anal intercourse with at least 1 man in past year; those in a monogamous relationship with a known HIV (-) person for prior 2 years were excluded	Target, Referral	4295	259	12333.3	2.1

Table 3

Studies of HIV Incidence in Injection Drug Users

Study	Location	Population	Recruitment	# in Study	# Infected	Person Years	Incidence Rate (per 100 pys)
Nelson et al 2002 (53)	Baltimore, MD	Persons who reported injection drug use in past 10 years	Target	1311	58	3150.74	1.8
DC Des Jarlais et al, 2003 (24)	New York City, NY	Injection drug use in past 6 months	Target	241	1	250	0.4
H Weinstein et al, 2002 (50)	Los Angeles, Denver, Chicago, Houston, New Orleans, Miami, Atlanta, Baltimore, Newark	STD clinic patients undergoing routine syphilis testing who reported injection drug use	Convenience	2786	5	983.9	0.5
SE Fernyak et al, 2002 (47)	San Francisco, CA	Repeat HIV testers at HIV testing sites who report IDU	Convenience	1366	20	2020.1	1.0
Wood et al 2005 (54)	Vancouver, Canada	Injection at least once in past month	Target	994	123	3843.8	3.2
Calzavara et al, 2002	Ontario, Canada	Repeat voluntary HIV testers who identified as IDU	Convenience	Unk.	73	29233.7	0.2

**Table 4**

Studies of HIV Incidence in Blood Donors Used to Estimate HIV Incidence in Blood Donors (Used To Estimate Incidence in Hemophiliacs)

Study	Location	Population	Recruitment	# in Study	# Infected	Person Years	Incidence Rate (per 100 pys)	Residual Risk <sup>**</sup>
O'Brien et al, 2007 (56)	Canada	Donors who made at least 2 donations within 3 years of each other	100% of defined population	4,140,862*	6	1,469,070	0.00049	0.013
Dodd et al, 2002 (55)	United States	Blood donors	100% of defined population	19,811,809*	65	4,182,000	0.00155	0.047

\* Refers to # of donations, not # in the study

\*\* Residual risk is the risk per 100,000 donors of a recent HIV infection occurring during the window period and being undetected by conventional blood screening measures.

Table 5

Studies of HIV Prevalence in Commercial Sex Workers

Study	Location	Population	Recruitment	# Tested	# Infected	Percent Infected
Strathdee et al 2007 (60)	San Diego, CA and El Paso, TX	Female sex workers who traded sex for drugs, money or material benefit and had unprotected sex for drugs or money at least once; no previous positive HIV test result	Target	924	55	6.0
Rothenberg et al, 2001 (35)	Atlanta, GA	Received money for sex	Target	136	20	15.0
Rosenberg et al (34)	CT, MD, NH, NC	Inpatients or outpatients receiving treatment for severe mental illness who report ever engaging in prostitution	Target	225	15	6.7
Roy et al, 2000 (36)	Montreal, Canada	Homeless youth ages 12–25 who reported engaging in prostitution	Target	234	11	4.7
Marshall et al, 2008 (57)	Vancouver, Canada	Street youth ages 14–26 who reported using illicit drugs in past 30 days and had ever engaged in prostitution	Target/Snowball	115	8	6.9
Miller et al 2008 (58)	New York City, NY	Females who used drugs in past 30 days and reported exchanging sex for drugs or money	Target	51	13	25.5
Murrill et al 2008 (59)	New York City and continuous counties, NY	House ball community members who had ever attended a house ball event and exchanged sex for drugs or money	Target	37	7	18.9



**Table 6**  
Table of HIV Incidence Studies in Persons Having Sex with High Risk Individuals

Study	Location	Population	Recruitment	# in Study	# Infected	Person Years	Incidence Rate (per 100 pys)
Femyak et al, 2002 (47)	San Francisco, CA	Repeat HIV testers who have a heterosexual partner who injects drugs	Convenience	1454	7	2600	0.3
Calzavara et al, 2002 (51)	Ontario, Canada	Repeat voluntary HIV testers who reported having sex with someone known to have HIV or at high risk for HIV	Convenience	Unknown	33	29695.1	0.11

**Table 7**

Table of Studies of HIV Incidence Among Incarcerated Individuals

Study	Location	Population	Recruitment	# in Study	# Infected	Person Years	Incidence Rate (per 100 pys)
Macalino et al, 2004 (62)	Rhode Island, United States	Male prisoners in Rhode Island who had been in jail at least 12 months	100% defined population	446	0	693.70	0.0
Kim et al, 2008 (61)	San Francisco, CA	Women processed in central intake (so incidence on admission)	100% defined population	1552	3	722.4	0.4
Solomon et al, 2004 (63)	Baltimore, MD	Persons admitted to Maryland jails who provided samples for syphilis testing	Convenience	3170	8	1475.4	0.5