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

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Abstract

The OPTN classifies high infectious risk donors (HRDs) based on criteria originally intended to identify people at risk for HIV infection. These donors are sometimes referred to as "CDC high risk donors" in reference to the CDC-published guidelines adopted by the OPTN. However, these guidelines are also being used to identify deceased donors at increased risk of window period (WP) hepatitis C virus (HCV) infection, although not designed for this purpose. The actual risk of WP HCV infection in HRDs is unknown.We performed a systematic review of 3,476 abstracts and identified 37 eligible estimates of HCV incidence in HRD populations in the United States/ Canada. Pooled HCV incidence was derived and used to estimate the risk of WP infection for each HRD category. Risks ranged from 0.26–300.6 per 10,000 donors based on WP for ELISA and 0.027–32.4 based on nucleic acid testing (NAT). Injection drug users were at highest risk (32.4 per 10,000 donors by NAT WP), followed by commercial sex workersand donors exhibiting high risk sexual behavior (12.3:10,000),men who have sex with men (3.5:10,000), incarcerated donors (0.8:10,000), donors exposed to HIV infected blood (0.4:10,000), and hemophiliacs (0.027:10,000). NAT reduced WP risk by approximately 10-fold in each category.

Keywords

organ utilization; NAT; high risk donor; deceased donor transplantation; hepatitis C

INTRODUCTION

In 1985(1), and later updated in 1994 (2), the Public Health Service (PHS) developedguidelines to identify persons at increased risk for HIV infection. These guidelines were published by the Centers for Disease Control and Prevention (CDC) and adopted by the OPTN to identify deceased organ donors at increased risk of infectious transmission.

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DISCLOSURE

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Currently, any donor falling into one or more of the 7 specified behavioral categories (Table 1) is classified as a high risk donor (HRD) and subject to additional OPTN policies. Despite significant controversy surrounding their use, approximately 9% of donors where at least one organ is recovered are categorized as HRDs (3).

While the originally intended purpose of the HRD guidelines was to identify those at risk of prevalent infection, in practice this is not a relevant concern. UNOS mandates HIV and HCV antibody testing for all deceased donors and, as such, prevalent infections are detected (4,5). However, no serologic test can detect infections that occurred very recently, so theconcern isincident infection occurring during the window period (WP), the time between acquisition of infection and serologic detectability. This scenario will likely result in a false-negative test result and transmission to the recipient(6–8). As such, the HRD criteria are instead used as surrogate criteria to identify persons at risk of recently acquired infection

The PHS/CDC guidelines have not only been extrapolated in practice from prevalent HIV to WP incident HIV infection, but they have also been used as a default proxy for identifying deceased donors at risk for WP incident infections with hepatitis C virus (HCV)(9).While HIV and HCV share several modes of transmission, their epidemiology is not identical. Both are blood-borne illness that can bespread parenterally(10,11); however HCV transmission is thought to be more efficient by this route than HIV infection. Sexual transmission is considered one of the primary drivers of the HIV epidemic(12); in contrast, sexual transmission of HCV is thought to be extremely inefficient, if at all relevant(13).Several studies of HCV discordant couples found little to no evidence of sexual transmission(14,15). Having multiple sexual partners may increase the risk of HCV infection(16,17); however, it is unclear whether this is a real effect or the result of other confounding risk behaviors(18).Three of the HRD categories are based on sexual behaviors (MSM, CSW, and high risk sexual behavior). It is unclear whether these categories are truly indicative of an increased risk for HCV.

An additional problem with expanding guidelines intended for HIV to HCV is that the two diseases have distinct clinical courses with different implications for serologic testing. While antibodies to HIV are typically produced within 3 weeks of infection (19), HCV antibody formation does not occur for 8–12 weeks (20), making the WP between acquisition of infection and serologic detectability by Enzyme-Linked Immuno- Assay (ELISA), an antibody-based method, much longer for HCV (approximately 66 days for HCV compared with 22 for HIV). Nucleic acid testing (NAT) is an alternative method based on detection of viral particles that shortens the WP to approximately 1 week (21). While antibody testing is mandated for all donors (22), the decision to use NAT is left to the individual Organ Procurement Organization (OPO). A survey of OPOs performed in 2008 found that 48.3% performed HCV NAT for all donors and an additional 20.7% performed it under certain circumstances (i.e. for HRDs only, when requested by the transplant center) (23). NAT is not universally used because it is more expensive, time consuming, and thought to have a higher rate of false positives compared to ELISA (9,24). However, given that HCV NAT decreases the WP by several months, the benefits for HCV detection may outweigh the risks in a more pronounced way than with HIV.

We hypothesized that the risk of HCV WP infection would be higher than the risk of HIV for some categories and significantly lower for others, and that quantifying these risks would be essential for informed clinical decision-making with regards to HRDs. The goals of our study were to (1) estimate the incidence and variance of HCV infection within each category of HRD behavior, and (2) estimate the risk of HCV WP infection, by ELISA and NAT, within each category of HRD behavior.

METHODS

Systematic Review: Study Selection and Search Strategy

We performed a PubMed search on November 27th, 2008 for studies of HIV or HCV incidence or prevalence (see appendix for details of search). Studies were eligible for inclusion in our systematic review if they presented an original estimate of HIV or HCV prevalence or incidence in a population located in the United States or Canada on or after January 1, 1995. We chose this cut-off for two major reasons: (1) accurate screening tests for HCV were not developed until the early 1990s and screening of the blood supply dramatically changed the epidemiology of HCV, particularly among hemophiliacs (25); and (2) the dynamics of HIV transmission, and thus HIV/HCV coinfection, likely changed with the introduction of highly-active antiretroviral therapy. Two independent reviewers and two adjudicators performed a systematic review for manuscripts meeting inclusion criteria and mined references of a 20% sample of eligible studies to identify any studies that might have been missed (26). Since incidence studies require significant resources for the identification and follow-up of large numbers of individuals, we hypothesized that many studies would have NIH funding. As such, we searched the NIH grant database for keywords"HIV" or "HCV" and "Incidence" funded after 1995 in order to identify any studies that might have been missed by other methods..

Meta-Analysis: Inclusion Criteria

The goal of this meta-analysis was to estimate HCV incidence in HRD populations; as such only a subset of studies included in the systematic review were eligible for our meta-analysis. Eligible studies reported an estimate of HCV incidence in one of the 7 HRD populations outlined in Table 1. Studies reporting HCV prevalence estimates were included for HRD behavioral categories for which multiple incidence studies were unavailable Approximately 80–85% of persons exposed to HCV develop chronic infection with persistent HCV-RNA positivity while the remaining 15–20% eventually clear the virus(27). However, even those with eventual clearance were likely infectious during the acute phase, the point of interest when the concern is WP infection.As such,for consistency,it was decided*a priori* that only studies using HCV antibody testing only or a combination of HCV antibody and RNA (where everyone was tested with both and considered infected if positive by either method) would be included; fortunately, there were no studies in HRD populations that used only RNA without antibody testing, so no studies had to be excluded. Estimates lacking a denominator (for example, reported HCV cases over the total population) were also excluded.

Data Abstraction

Data from each eligible study were abstracted by at least 2 independent reviewers and disagreements were adjudicated as previously described (26). The following data were abstracted from each article: recruitment dates, county, state, city, and 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, number positive by HCV antibody and number positive by HCV RNA. We abstracted the overall HCV incidence and prevalence for each article, in addition to risk-stratified sub-estimates if the risk factor was one of the HRD criteria. 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 total number of person-years at risk were abstracted, back-calculated using other data from the manuscript, or obtained directly from the study authors.

Meta-Analysis

Any study of HCV incidence among persons demonstrating one of the HRD behavioral risk factors was eligible for inclusion in our meta-analysis. When we were unable to find multiple incidence studies in a behavioral category, we included all prevalence studies in this category and estimated incidence from prevalence as described below. Each HCV incidence estimate was classified as falling into one of the categories, falling into multiple categories, or other. All studies in the same behavioral category that took place in the same geographic location were flagged and re-examined to ensure that the estimate were not derived from the same cohort and could be combined without fear of counting the same individuals multiple times. Pooled incidence estimates were obtained by summing the person-years and number of HCV seroconversions for each study within categories of HRD behavior. Persons were considered to have seroconverted if they became HCV antibody or HCV-RNA positive over the course of the study. Poisson exact 95% confidence intervals were calculated for each pooled incidence estimate using Stata 11/MP (College Station, TX).

Estimating Incidence From Prevalence

Incidence studies are challenging and resource intensive, requiring recruitment, follow-up, and serologictesting of large cohorts over long periods of time. Furthermore, three of the HRD behavioral categories involve sexual risk factors, widely considered to be an inefficient mode of HCV transmission. As such, there have been few incidence studies of HCV specifically aimed at populations with sexual risk factors. To account for this, data were abstracted from HCV prevalence studies in each category, and methods for estimating the incidence of a disease in a given population based on its prevalence were used when insufficient incidence studies were found(28).Briefly, we compared the ratio of incidence to prevalence in an HRD population where both were known, in order to solve for the unknown incidence value using the pooled prevalence estimate in the HRD population of interest:

$$\frac{\text{Pooled HCV Incidence among IDUs}}{\text{Pooled HCV Prevalence among IDUs}} = \frac{\text{Unknown HCV Incidence}}{\text{Known Pooled HCV Prevalence in population of interest}}$$

Upper and lower bounds for the unknown incidence were computed by substituting the upper and lower bounds of the Poisson Exact 95% CI computed for HCV incidence in IDUs.

Estimating the Risk of Window Period Infection

Pooled incidence estimates from the meta-analysis were then used to calculate a per-day incidence rate (IR) and then combined with WP duration to calculate the probability of a WP infection using iterative conditional probabilities as shown in the following equation(26):

$$\text{Risk of WP Infection} = 1 - e^{-\text{Pooled IR} * \text{WP duration}}$$

Upper and lower bounds on the probability of a WP infection were calculated by using the upper and lower bounds of the Poisson exact 95% CIs around the pooled incidence rates for the pooled incidence value in the equation above.

Since very few studies of hemophiliacs were available since recent significant improvements in blood screening (29), estimates in hemophiliacs were determined based on studies of HCV incidence in blood donors described previously in more detail(26). Briefly, we used the WP of the serologic tests used to screen blood donors and HCV incidence in this population to calculate the residual risk of HCV in the blood supply:

$$\text{Residual Risk in Blood Donors} = 1 - e^{-\text{IR} * \text{WP duration of blood screening test}}$$

We then used this residual risk to calculate the probability that a hemophiliac might contract HCV, making the assumption that 1 unit of blood per day was transfused for the entire duration of the HCV NAT WP:

$$P(\text{at least 1 unit infected}) = 1 - P(\text{unit uninfected})^{\#\text{Units Received in WP}}$$

Estimates in persons exposed to HIV infected blood percutaneously or mucocutaneously

This category, taken literally from the HRD guidelines (based on the mechanism that percutaneous exposure to HIV infected blood might transmit HIV), makes little sense in the context of HCV (since percutaneous exposure to HIV infected blood will not, by mechanism, transmit HCV). However, to be most conservative, we felt the best approach to risk estimation in this category was to combine estimates of HCV infectious risk per percutaneous exposure and estimates of HCV prevalence among persons infected with HIV. A recent multicenter study in Italy followed persons percutaneously exposed to HCV infected blood over 55 hospitals and calculated the risk of HCV transmission per exposure involving blood infected with HCV only as well as blood coinfected with HIV and HCV. They found that the rate of HCV transmission was over twice as high when the blood was HIV and HCV coinfected as when the blood was infected with HCV only (0.35% versus 0.85%). As such we used an estimate of0.85% per exposure in our calculations. To estimate the percent of HIV infected blood coinfected with HCV, we compiled prevalence studies of HCV infection among persons with HIV. We used the per needlestick estimate for coinfected blood combined with the probability that HIV infected blood is coinfected with HCV to calculate the risk of WP infection, assuming only one exposure event occurred, and there was equal probability of the event occurring on any day in the year prior to death.

RESULTS

Systematic review

After screening, 337 articles were eligible for inclusion at the full-text level (Figure 1) and 103 were eligible for data abstraction. For the meta-analysis, these were further narrowed to 37 unique estimates among populations meeting HRD behavioral criteria.

Men Who Have Sex With Men

Six eligible prevalence studies were found in this category, for a total pooled sample size of 1341 participants (Table 3)(30–35). The incidence was estimatedusing established techniques(28)based on prevalence among IDUs as the reference category (32–65). Incidence was calculated to be 1.8 per 100 person-years (range 1.7–2.0, Table 2). Per 10,000 donors, the estimated risk of WP infection was 32.5 (range 30.7–36.1) with ELISA and 3.5 (range 3.3–3.8) with NAT.

Injection Drug Users

Nine studies of HCV incidence in IDUs were identified for a total pooled sample size of 1955 participants(Table 4)(43,45,47,49,52,54,66–68). Incidence rates ranged widely from 0.68 to 35.9 per 100 person-years; however, when limiting to studies that only recruited persons who reported injection in the preceding 6 months, the range was 10 to 35.9 per 100 person-years. Pooled HCV incidence among IDUs was 16.9 per 100 person-years (range

15.5–18.4, Table 2). Per 10,000 donors, the estimated risk of WP infection was 300.6 (range 276.1–326.8) with ELISA and 32.4 (range 29.7–35.3) with NAT.

Hemophiliacs

Results from 23,952, 635 individual blood donations from Canada and the United States were included in the pooled estimate (Table 5)(69,70). HCV incidence in Canada was 0.00163 per 100 person-years and in the United States was 0.00189 per 100 person-years. The pooled HCV incidence among blood donors was estimated to be 0.0018 per 100 person-years (range 0.22–0.32, Table 2). Per 10,000 donors, the estimated risk of WP infection was 0.26 (range 0.22–0.32) with ELISA and 0.027 (0.023–0.034) with NAT.

Commercial Sex Workers

Seven prevalence studiesof CSWs were identified, for a total pooled sample size of 678 participants (Table 6)(31,34,35,39,51,60,63). Using methods described above (see MSM category above), incidence was estimated to be 6.4 per 100 person-years (range 5.9–7.0, Table 2). Per 10,000 donors, the estimated risk of HCV WP infection was 114.9 (range 105.9–125.6) with ELISAand 12.3 (range 11.3–13.4) with NAT.

High Risk Sexual Behavior

Eighteligible prevalence studies were identified, with a total pooled sample size of 1361 participants (Table 7)(31,33,35,39–41,51,60). Incidence was estimated to be 6.4 per 100 person-years (range 5.8–6.9, Table 2). Per 10,000 donors, the estimated risk of HCV WP infection was 114.9 (range 104.2–123.8) with ELISA and 12.3 (range 11.1–13.2) with NAT.

Exposed Through Blood

A recent large 55-hospital prospective cohort study of workers percutaneously exposed to HCV infected blood found a per exposure risk of 0.85% when the blood was also coinfected with HIV (Table 8a)(71). To estimate the probability that HIV infected blood was coinfected with HCV, we compiled prevalence studies of HCV among HIV positive persons, identifying 4 studies for a total pooled sample size of 6736 participants (Table 8b) (39,49,72,73). Per 10,000 donors, the estimated risk of HCV WP infection was 4.0 (range 0.9–11.1) with ELISAand 0.4 (range 0.09–1.2) with NAT(Table 2).

Incarcerated

We were only able to identify one intra-prison incidence study of HCV incidence with a total sample size of 337 participants (Table 9)(74). Incidence was estimated to be 0.4 per 100 person-years (95% CI 0.04–1.3, Table 2). Per 10,000 donors, the estimated risk was 7.2 (range 0.7–23.5) with ELISA and 0.8 (range 0.08–2.5) with NAT.

DISCUSSION

We found that the risk of HCV WP infection varied significantly across HRD behavioral categories and testing methods.Estimated WP risk of HCV per 10,000 donors ranged from 0.26–300.6based on WP for ELISA and from 0.027–32.4 based on WP for NAT. This is significantly higher than the estimated WP risk of HIV infection which ranged from 0.04–12.9 per 10,000 donors in a similarly conducted systematic review and meta-analysis(26). IDUs carried the highest risk of HCV WP infection (300.6 per 10,000 donors with ELISA and 32.4 with NAT), followed by commercial sex workers and donors engaging in high risk sexual behavior (114.9 per 10,000 donors with ELISA and 12.3 with NAT), MSMs (32.5 per 10,000 with ELISA and 3.5 with NAT), incarcerated donors (7.2 per 10,000 donors with ELISA and 0.8 with NAT), donors exposed to infected blood (4.0 per 10,000 donors with

ELISA and 0.4 with NAT), and hemophiliacs (0.26 per 10,000 with ELISA and 0.027 with NAT).Relative order of risk differed somewhat from that for HIV WP infection, where IDUs also carried the highest risk of HIV WP infection but were followed by MSMs, CSWs, incarcerated donors, donors exposed to HIV through blood, donors engaging in high risk sexual behavior, and hemophiliacs. It is important to note that these estimates are only applicable to donors in the United States and Canada from which our data are drawn, and these estimates may be quite different in other parts of the world.

Previous studies have shown that the risk of sexual transmission of HCV is very low(14,15). It is thought that the risks might increase for persons with multiple sexual partners, STIs, and HIV infection but this has not been shown definitively(16–18). Commercial sex workers, persons engaging in high risk sexual behavior, and MSMs were among the highest risk categories for HCV WP infection in our analysis. While this might be partially explained by sexual risk factors, it is possible that the higher incidence in these populations is reflective of confounding resulting from high likelihood of exhibiting other high risk behaviors, such as injection drug use, shown to result in very efficient HCV transmission.

Our study has several limitations. Incidence and prevalence studies often target higher risk individuals to ensure a sufficient number of cases to examine outcomes of interest. As such our results are not necessarily generalizable to the underlying populations, and may be overestimates of the true WP risk.Another issue is the potential for overlap between categories. While we excluded estimates in persons with multiple risk factors, most studies did not measure all HRD behaviors and as such incidence in one category might be explained not by the risk of the behavior itself but by its correlation with another risky behavior. This is especially true for commercial sex workers who have been previously shown to have high rates of injection drug use.

Our study is the first to systematically report the risk of HCV WP infection in donors meeting the PHS/CDC high risk criteria, and we found a fairly significant risk of WP infection, particularly in the IDU category. HCV-specific antibodies are typically not detectable until 2 months or longer after acquisition of infection; as such the risk of WP infection in populations is quite high when ELISA is used. NAT, with a WP of approximately 7 days, reduces the risk of WP HCV infection by an order of magnitude compared to ELISA, from approximately 3 in 100 to 3 in 1000 among IDUs. Our findings suggest that the use of these categories to identify persons at risk of HCV infection is not unreasonable as risk of HCV WP infection is very high, particularly for injection drug users. However, for some categories (hemophiliacs and persons exposed to HIV (+) blood), the risk was minimal. Furthermore, because the guidelines were not specifically developed for HCV, there may be other behavioral risk factors not included in the criteria that place a person a high risk of acquiring HCV that are not currently captured.Previous studies have suggested that tattooing, body piercing, and intranasal cocaine use might be important routes of HCV transmission (75,76), as such these risk factors should be evaluated as potential additional categories in any future revisions of these guidelines.

In conclusion, we hope that these data, combined with those of HIV WP infection risk among patients in the same behavioral categories, will help clinical decision-making and counseling with regards to HRD organs.

ABBREVIATIONS

PHS	Public Health Service
UNOS	United Network for Organ Sharing

HIV	Human Immunodeficiency Virus
HCV	Hepatitis C Virus
WP	Window Period
OPO	Organ Procurement Organization
ELISA	Enzyme Linked Immunosorbent Assay
NAT	Nucleic Acid Testing
IDU	Injection Drug User
MSM	Men who have Sex with Men
CSW	Commercial Sex Worker

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APPENDIX

PubMed Search, Performed November 27th 2008

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((("hiv"[MeSH Terms] AND "prevalence"[MeSH Terms]) OR

("hivseroprevalence"[MeSH Terms]) OR

("hiv"[MeSH Terms] AND "incidence"[MeSH Terms]) OR

("hiv"[MeSH Terms] AND "seroepidemiologic studies"[MeSH Terms]) OR

("hepatitis c"[MeSH Terms] AND "prevalence"[MeSH Terms]) OR

("hepatitis c"[MeSH Terms] AND "incidence"[MeSH Terms]) OR

("hepatitis c"[MeSH Terms] AND "seroepidemiologic studies"[MeSH Terms])) AND

("1995/01/01"[PDAT]:"2008/11/27"[PDAT]) AND

("humans"[MeSH Terms]) AND

(English[lang]) NOT

(Clinical Trial[ptyp]

Editorial[ptyp] OR Letter[ptyp] OR

Randomized Controlled Trial[ptyp] OR Review[ptyp] OR

Africa[MeSH Terms] OR Asia[MeSH Terms] OR

Caribbean Region[MeSH Terms] OR

Central America[MeSH Terms] OR

Latin America[MeSH Terms] OR

South America[MeSH Terms] OR

Antarctic Regions[MeSH Terms] OR

Arctic Regions[MeSH Terms] OR

Atlantic Islands[MeSH Terms] OR

Australia[MeSH Terms] OR

Europe[MeSH Terms] OR

Historical Geographic Locations[MeSH Terms] OR

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Pacific Islands[MeSH Terms] OR

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("HCV"[tiab] AND "incidence"[tiab])) AND

("2008/01/01"[PDAT]:"2008/11/27"[PDAT]) AND

(English[lang]) NOT

(Clinical Trial[ptyp]

Editorial[ptyp] OR Letter[ptyp] OR

Randomized Controlled Trial[ptyp] OR Review[ptyp])

)

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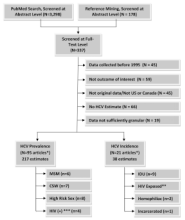

Figure 1. Search/Selection

* Some studies reported both HCV prevalence and incidence; unique studies included totaled 103

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

*** Used to calculate the probability that HIV infected blood was coinfected with HCV

Table 1

Categories of behavior leading to classification of High Risk Donor

Category	Description
MSM	men who have had sex with another man in the preceding 5 years
IDU	persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years
Hemophiliac	persons with hemophilia or related clotting disorders who have received human derived clotting factor concentrates
CSW	men and women who have engaged in sex in exchanged for money or drugs in the preceding 5 years
High Risk Sex	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
Exposed to HIV	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
Incarcerated	inmates of correctional systems

MSM = Men who have sex with other men, IDU = injection drug user, CSW = Commercial Sex Worker, HIV = Human Immunodeficiency Virus

Table 2

Risk per 10,000 of an HCV infection occurring during the Window Period, by ELISA and NAT

HRD Category	# Patients	# HCV Seroconverted or Prevalent	Person-Years	Pooled Incidence (95% CI) (per 100 pys)	ELISA WP=66 days	NAT WP = 7 days
MSM	1341	86*	**	1.8 (1.7–2.0)	32.5 (30.7–36.1)	3.5 (3.3–3.8)
IDU	1955	520	3081.4	16.9 (15.5–18.4)	300.6 (276.1–326.8)	32.4 (29.7–35.3)
Hemophiliac	23,952,635	103	5,651,063	0.0018 (0.0015–0.0022)	0.26 (0.22–.32)	0.027 (0.023–0.034)
Commercial Sex Worker	678	152*	**	6.4 (5.9–7.0)	114.9 (105.9–125.6)	12.3 (11.3–13.4)
Sex with a partner in categories 1–4	1361	301*	**	6.4 (5.8–6.9)	114.9 (104.2–123.8)	12.3 (11.1–13.2)
HIV Exposed through blood	6736	1674*	***	0.0085**** (0.0018–0.0247)	4 (0.9–11.1)	0.4 (0.09–1.2)
Incarcerated***	337	2	550.9	0.4 (0.04–1.3)	7.2 (0.7–23.5)	0.8 (0.08–2.5)

* Number of prevalent, not incident infections.

** Prevalence used to estimate incidence using methods previously described

*** Prevalence of HCV among HIV positive persons was estimated and combined with an estimate of per blood exposure risk of HCV to estimate WP infection in this category

**** Probability of infection per exposure

***** Only one study of intra-prison incidence available

Table 3

Studies of HCV Prevalence Among Men who Have Sex with Men

Study	Location	Population	Recruitment	# Tested	# Infected	Percent Infected
Hwang et al 2006 (33)	Houston, Texas	College students from 8 campuses who identify as MSM	Target	142	6	4.2
Hammer et al 2003 (32)	San Francisco, California	HIV counseling testing patients who received multiple tests and identify as MSM and do not report IDU	Convenience	746	15	2.0
Rosenberg et al 2001 (34)	Connecticut, Maryland, New Hampshire, North Carolina	Patients at mental health treatment centers who identify as MSM	Convenience	108	22	20.3
Dominitz et al 2005 (31)	United States	Patients at VA medical centers who identify as MSM	Cluster Sampling	47	1	2.1
Cohen et al 2006 (30)	Boston, MA	Patients receiving care at a free clinic who identified as MSM	Convenience	218	25	11.5
Roy et al 2001 (35)	Vancouver, Canada	Homeless street youth who report a homosexual partner	Target	80	17	21.3

Table 4

Studies of HCV Incidence in Injection Drug Users

Study	Location	Population	Recruitment	# in Study	# Infected	Person Years	Incidence Rate (per 100 pys)
Hahn et al, 2002 (67)	San Francisco, California	Injection drug users ages 18– 30 who injected at least once in past month	Target	195	48	191.2	25.1
Des Jarlais et al 2003 (43)	New York City, New York	Injection drug users ages 18– 30 who reported injection at least once in past 6 months	Target	141	25	120.8	20.7
Patrick, et al 2001 (52)	Vancouver, Canada	Injection drug users ages 18– 30 who injected at least once in past month	Target	155	62	213.1	29.1
Thorpe et al. 2002 (68)	Chicago, Illinois	Injection drug users ages 18– 30 who injected at least once in past month	Target	353	29	290	10
Roy et al 2007 (54)	Ontario and Quebec, Canada	Injection drug users who injected at least once in past 6 months and were visiting centers providing sterile injection equipment	Convenienc e	543	199	734.3	27.1
Augenbraun et al, 2003 (66)	New York City NY, DC, Los Angeles CA, San Francisco CA, Chicago IL	Women utilizing HIV primary care sites, drug treatment, or outreach facilities who reported ever injecting drugs	Convenienc e	Unk.	2	293.0	0.68
Hall et al, 2004 (49)	San Francisco CA	HIV positive homeless persons recruited from homeless shelters, free lunch programs, or residential hotels who reported injection drug use in past 30 days	Target	22	8	47.6	16.8
Hagan et al 2004 (47)	Seattle, WA	Injection drug users who reported injection at least once in previous year; recruited from drug treatment facilities	Convenience	484	134	1155.2	11.6
Fuller et al 2004 (45)	New York City NY	Injection at least once in past 2 months	Target	62	13	36.2	35.9

Table 5

Studies of HCV Incidence in Blood Donors

Study	Location	Population	Recruitment	# in Study	# Infected	Person Years	Incidence Rate (per 100 pys)	Residual Risk**
Obrien et al, 2007 (70)	Canada	Donors who made at least 2 donations within 3 years of each other	100% of defined population	4,140,862*	24	1,469,06 3	0.00163	0.0356
Dodd et al, 2002 (69)	United States	Blood donors	100% of defined population	19,811,809 *	79	4,182,00 0	0.00189	0.0414

* WP given as 8 days (range 6.8–9.2)

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

Table 6

Studies of HCV Prevalence Among Commercial Sex Workers

Study	Location	Population	Recruitment	# Tested	# Infected	Percent Infected
Bollepalli et al 2007 (39)	Phoenix, AZ	HIV positive patients recruited from 2 clinics catering to patients with HIV or liver disease who report having sex in exchange for money or drugs	Convenience	38	20	52.6
Weisbord et al 2003 (63)	Miami, FL	STI clinic patients who reported exchanging sex for drugs or money	Convenience	79	9	11.4
Rosenberg et al (34)	Connecticut, New Hampshire, Maryland, North Carolina	Patients receiving care at mental health treatment clinics diagnosed with severe mental illness who report ever having engaged in prostitution	Double check	190	50	26.3
Page-Shafer et al 2002 (51)	Alameda, San Francisco, San Joaquin, and San Mateo counties California	Women recruited from low income neighborhoods who reported exchanging sex for drugs or money	Cluster Sampling	207	28	13.5
Dominitz et al 2005 (31)	United States	Patients at VA medical center who reported exchanging sex for drugs	Cluster Sampling	12	3	25.0
Roy et al 2001 (35)	Montreal, Canada	Homeless street youths ages 14–25 who report engaging in prostitution	Target	107	24	22.4
Tabibian et al 2008 (60)	Los Angeles, CA	Psychiatric inpatients at VA medical center who report bartering sex	Convenience	45	18	40.0

Table 7

Studies of HCV Prevalence Among Persons Engaging in High Risk Sexual Behavior

Study	Location	Population	Recruitment	# Tested	# Infected	Percent Infected
Briggs et al 2001 (40)	San Francisco, CA	Veterans seeking care at a VA medical center who report having sex with a prostitute	Random Sample	540	116	21.5
Hwang et al 2006 (33)	Houston, TX	College students recruited from 8 campuses who report having sex with an injection drug users	Target	206	18	8.7
Bollepalli et al 2007 (39)	Phoenix, AZ	HIV positive patients at 2 urban clinics catering to those with HIV or liver disease who report having sex with an injection drug user	Convenience	79	43	54.4
Page-Shafer et al 2002 (51)	Alameda, San Francisco, San Joaquin, and San Mateo counties California	Women recruited from low income neighborhoods who reported having sex with an injection drug user	Cluster Sampling	176	22	12.5
Dominitz et al 2005 (31)	United States	Patients at VA medical centers who report unprotected sex with an injection drug user	Cluster Sampling	48	18	37.5
Roy et al 2001 (35)	Montreal, Canada	Homeless street youth who report having sex with an injection drug user	Target	222	42	18.9
Roy et al 2001 (35)	Montreal, Canada	Homeless street youth who report having sex with an HIV positive person	Target	24	7	29.2
Brillman et al 2002 (41)	Southwestern United States	Emergency room patients at a teaching hospital who are medically stable and report sex with an injection drug user	Convenience	20	10	50.0
Tabibian et al 2008 (60)	Los Angeles, CA	Psychiatric inpatients at VA hospitals who report having sex with an injection drug user	Convenience	17	11	64.7
Tabibian et al 2008 (60)	Los Angeles, CA	Psychiatric inpatients at VA hospitals who report having sex with a prostitute	Convenience	29	14	48.3

Table 8

Table 8a: Studies of HCV Incidence in Persons Exposed through Blood or Blood Products						
Study	**Location**	**Population**	**Recruitment**	**# in Study**	**# Infected**	**Per needlestick risk**
G.DeCarli et Al 2003 (71)	Italy	Anyone with a needlestick injury from a known HIV and HCV positive source in 55 Italian hospitals	Hospitals that voluntarily participated reported exposures and outcomes	352	3	0.0085

Table 8b: Studies of HCV Prevalence Among Persons Infected with HIV						
Study	**Location**	**Population**	**Recruitment**	**# Tested**	**# Infected**	**Percent Infected**
Hall et al 2004	San Francisco, CA	Homeless HIV positive persons	Target	249	182	73.1
Holland et al. 2000 (72)	New York City NY, Newark NJ, Baltimore MD, Washington DC, Philadelphia PA, Chicago IL, Birmingham AL, New Orleans LA, Atlanta GA, Memphis TN, Ft Lauderdale FL, Los Angeles CA	HIV infected adolescents ages 13–18	Target	254	4	1.6
Kim et al. 2008 (73)	New York City, NY	HIV infected patients seeking care at a hospital- based HIV treatment clinic	Convenience	5639	1411	25
Bollepalli et al. 2007 (39)	Phoenix, AZ	HIV infected patients recruited from 2 urban clinics catering to patients with HIV or liver disease	Convenience	242	74	30.1

Table 9

Studies of HCV Incidence in Incarcerated Individuals

Study	Location	Population	Recruitment	# in Study	# Infected	Person Years	Incidence Rate (per 100 pys)
Macalino et al 2004 (74)	Rhode Island	Men in jail at least 12 months	Target	337	2	550.9	0.4