Strategies for Hepatitis C Testing and Linkage to Care for Vulnerable Populations: Point-of-Care and Standard HCV Testing in a Mobile Medical Clinic

Jamie P. Morano, M.D., M.P.H.[*,1], **Alexei Zelenev, Ph.D.**[*,1], **Andrea Lombard, R.N., M.P.H**[2], **Ruthanne Marcus, Ph.D., M.P.H.**[1], **Britton A. Gibson, M.P.H.**[1], **Frederick L. Altice, M.D., M.A.**[1,3]

[1]Yale University School of Medicine, Department of Medicine, Section of Infectious Diseases, AIDS Program, New Haven, CT, USA

[2]Connecticut Department of Public Health, Public Health Initiatives Section, Hepatitis Program

[3]Yale School of Public Health, Division of Epidemiology of Microbial Diseases, New Haven, CT, USA

INTRODUCTION

Hepatitis C virus (HCV) infection affects approximately 170 million people worldwide, including 5 million in the U.S., and contributes significantly to morbidity and mortality, including end-stage liver disease, and hepatocellular carcinoma.[1–3] Several U.S. concerns about HCV are emerging. A recent CDC review of death certificates found that HCV mortality increased substantially from 1999-2007, with the median age of death being 57 years, or approximately 20 years below the national average life expectancy.[4] For the first time, HCV mortality surpassed HIV mortality in 2007,[5] and the number of deaths annually is expected to reach 34,900 by 2030, unless effective HCV treatment is provided.[6] HCV infection is the leading cause of liver transplantation,[7] and new HCV infections are on the rise with more than 16,500 new reported cases in 2011.[8] The total estimated cost of HCV is currently $6.5 billion, but it will exceed $9.1 billion annually by 2024.[9]

With the increasing availability of more tolerable and efficacious direct-acting antiviral (DAA) medications, eradicating HCV will require a strategic combination of prevention (e.g., harm reduction) and treatment strategies, including treatment as prevention, which requires improvements in diagnosis and linkage to care. Though improvements are needed, evidence of effective HCV treatment has been documented in primary care, specialty clinics, drug treatment programs,[10] and correctional facilities.[11]

Recent evidence suggests that receiving positive testing results for HCV significantly reduces risk behaviors among people who inject drugs (PWIDs).[12] PWIDs, however, are

Corresponding Author: Jamie P. Morano, M.D., M.P.H., **Address:** Yale University AIDS Program, 135 College Street, Suite 323, New Haven, CT 06510, USA., Telephone: +1-203-687-7162 Facsimile: +1-877-552-0363, jpmorano@alumni.princeton.edu.
[*]represents co-first authorship between Drs. Morano and Zelenev

one of the least likely populations to be tested for HCV and even less likely to be treated due to fear of stigma or discrimination, co-existing mental illness, ongoing drug use or structural impediments,[13] including limited access or financial barriers to traditional health care services. Yet, active PWIDs with HCV are the most likely to transmit HCV infection to others.[14] A recent systematic review and meta-analysis suggests that sustained virological response (SVR), or "cure", among PWIDs are similar to those who don't inject drugs, providing empiric support that PWIDs should be screened and treated for HCV.[15] Furthermore, young PWIDs are a particularly high-risk group for new HCV infections and HCV progression, especially in the Northeast U.S., based on recent data from Massachusetts and Connecticut.[16,17] Young injectors are less likely to be screened for HCV where drug injection remains secretive, and these individuals are often unaware of HCV testing and treatment options. As a highly sensitive and specific (98%) rapid, point-of-care (POC) HCV antibody test (HCV test) that is comparable to traditional serological blood tests[18] became FDA-approved in 2012, new opportunities emerged to reach high risk marginalized populations outside traditional healthcare settings.

MMCs are non-traditional healthcare units that increase healthcare access removing geographic and social barriers associated with traditional, "brick and mortar" healthcare settings. According to the Mobile Health Map Project, there are approximately 1,500-2,000 MMCs across the U.S. providing a variety of prevention and treatment services to 6.5 million people (see http://www.mobilehealthmap.org). MMCs play a vital role in healthcare delivery, by accessing care for minorities, the poor, migrant workers, the homeless, adolescents, and uninsured/underinsured adults and children. For these people, MMCs create a convenient and unintimidating healthcare access point, while reducing disparities and healthcare costs. As such, they are frequently regarded as venues of convenience, delivering healthcare at the doorstep of communities that are otherwise limited by location,[19,20] cost,[21] insurance status,[21,22] literacy,[23] stigma,[24,25] or other structural barriers such as proximity and access to transportation.[26–28]

METHODS

New Haven is one of the poorest U.S. cities, with high rates of poverty, unemployment, crime, substance abuse and HIV/AIDS.[29,30] Recent data from New Haven also documented a particularly high prevalence of HCV and HCV/HIV coinfection.[31] When the new HCV POC test became commercially available, a "HepHome" program was initiated in the greater New Haven area, utilizing the Community Health Care Van (CHCV), a free MMC that has operated in marginalized communities since 1993.[32] The MMC is a 40-foot mobile clinic that travels weekdays to four of New Haven's most vulnerable neighborhoods most profoundly impacted by HIV/HCV, substance abuse and poverty. It provides a variety of services including acute and primary care, prevention services, health fair screenings, tuberculosis screening and treatment,[33,34] directly administered antiretroviral therapy (DAART),[35–40] buprenorphine and extended-release naltrexone treatment of substance use disorders,[33,41,42] screening and treatment for HIV, mental illness, sexually transmitted infections (STIs),[43] HCV, and a variety of case management[40,44] and post-prison release services.[39,45–51] POC HCV testing has been largely understudied among PWIDs within MMCs and for difficult-to-reach populations.

With the availability of free, POC HCV testing kits, we initiated a pilot study to improve HCV testing among all patients presenting for any care on a MMC in New Haven, CT over the 12-month period from March 2012 to March 2013. All POC HCV testing was provided free of charge (patient insurance was leveraged as applicable), and confirmatory HCV testing was performed through the Connecticut Department of Public Health (CTDPH).

Using New Haven's innovative MMC, our aims were to: 1) examine correlates of accepting HCV screening; 2) measure prevalence and correlates of reactive HCV status; 3) identify significant correlates of selecting POC HCV testing (OraQuick® HCV Rapid Antibody Test, OraSure Technologies, Inc., Bethlehem, Pennsylvania)[18] versus standard phlebotomy; and 4) compare the proportion linked to specialized HCV care between patients preferring POC HCV versus standard testing among those identified as being HCV-infected.

All MMC clients undergo a standardized medical intake assessment that includes demographic and social characteristics, drug and sexual behaviors, and past medical history. Variables for the comprehensive and follow-up questionnaires have been described previously.[52] Clients were classified as being a "baby boomer" if born from 1945 to 1965. Stably housed was defined as living in one's own apartment, one's own house, or with one's family, while unstably housed was defined as living with a friend, in a hotel or shelter, or on a street or public place. Being in a relationship was defined as being married or cohabitating with a significant other. Health insurance status was self-reported. Standardized measures of type, route, and frequency of drug use were assessed using the drug component of the Addiction Severity Index.[53] Foreign-born were those self-reporting being born outside the United States or Puerto Rico. History of interpersonal violence was self-reported experience as a victim of domestic violence or sexual assault. Men-who-have-sex with men (MSM) were defined as males reporting having had sexual relations with another man. Additional variables required for mandatory state HCV surveillance reporting included tattoo history, occupational exposure to blood, and cohabitation with an individual known to be HCV-infected.

During the study period, all MMC clients were offered HCV testing, either using 1) standardized phlebotomy, in which other tests were "bundled", including hepatitis A, hepatitis B, HIV, or syphilis where results returned within a week, or 2) fingerstick POC testing with immediate results provided in approximately 20 minutes. Clients self-selected either HCV testing strategy based on priorities and personal preferences. The trade-offs between the two screening strategies included waiting time for results, ability to bundle testing with other screenings, and fingerstick versus phlebotomy (Figure 1). All individuals with a reactive test result using either method underwent confirmatory HCV RNA testing and were referred to an HCV specialty clinic for additional treatment options (Figure 2). This study was approved by Yale University's Institutional Review Board (#1306012179).

DATA ANALYSIS

Because <10% of data had missing observations, with the frequency of missing data ranging from 0% to 17.7% across all variables, we did not find evidence that the difference between the clinical intake surveys was related to systematic heterogeneity among patients.

Therefore, multiple imputations were implemented to address any missing data concerns. [54] Analytical results for the variables that were missing less than 10% of observations were not sensitive to the departures from missing at random (MAR) assumptions. For the small set of variables which were missing >10% of observations, we performed additional sensitivity analyses and found that the pattern in the imputed data were consistent with patterns of observed, non-imputed data. Rubin Rules were applied to combine the results from different imputations for each of our analyses.[54]

First, we used a Pearson Chi-squared test to (1) examine the differences between clients who accepted HCV testing and those who did not; (2) assess differences between clients testing positive versus negative for HCV antibody; (3) examine differences between clients who preferred POC versus phlebotomy HCV testing, using all available covariates. Second, we estimated two separate multivariate logistic models for the two outcomes: acceptance of HCV testing and preferring POC HCV testing over phlebotomy. The Akaike Information Criterion (AIC) was used as a measure of relative-goodness-of-fit to discriminate among various models that we estimated. Our final set of models is based on a combination of AIC goodness-of-fit as well as inclusion of clinically relevant variables. We report both the adjusted odds ratios (AOR), as well as marginal effects, which represent a change in probability of the outcome based on a unit of change in the covariate, while other variables are fixed at their means.[55]

In our final analysis, we examined the differences in the percentage of HCV-infected clients linked to specialty HCV care among those testing positive using the two HCV testing strategies. In addition to using Chi-squared testing, we constructed a 95% Bayesian credible intervals analysis using the Metropolis-Hastings algorithm that sampled from a posterior distribution specified by a uniform prior and a binomial likelihood.[56] All empirical analyses were conducted using STATA 12.[57]

RESULTS

Over the 12-month testing period, 438 (32.6%) of the 1345 unique clients seen on the MMC accepted HCV screening. Those agreeing to HCV testing (Table 1) were on average in their mid-thirties (35.6 years), and were more likely than those not being tested to be born after 1965 (83.2%), US-born (66.4%), black (44.5%), had more than 15 lifetime sexual partners (35.3%), and self-identified as PWID (22.0%). Of the 438 screened, 209 (47.7%) selected POC testing (Table 2) and were more likely to be white, US-born, and have a higher number of lifetime sexual partners, compared to those selecting standard phlebotomy testing.

Among those tested, HCV prevalence was 6.2% (27/438), with no differences in HCV prevalence among the POC and standard testing groups (7.7% versus 4.8%; p=0.219) (Table 2). All those with positive HCV antibody tests had confirmatory HCV RNA levels drawn, consistent with HCV infection. Those with HCV infection (Table 3) were significantly older (43.2 vs 35.2 years old; p<0.01), baby boomers (33.3% vs 15.8%; p=0.027), white (55.5%; p<0.01), foreign-born (59.3%;p<0.047), and PWID (81.5% vs 18.2%; p<0.01); 81.5% (n=22) patients suspected that they were HCV-infected, but had not ever been confirmed or linked to care and were included in the testing assessment.

Accepting HCV testing was positively and significantly correlated with having been diagnosed with a STI, being US-born, and being a PWID (Table 4). Covariates associated with choosing POC testing included having >15 lifetime sexual partners, being white, and being US-born (Figure 3 and Table 4). While there was no difference in HCV prevalence among the type of HCV testing strategy selected, those selecting POC testing were significantly more likely (93.8% vs 18.2%; p<0.0001) to be linked to HCV specialty care (Figure 4).

DISCUSSION

MMCs are highly acceptable to medically disenfranchised patients, including patients with HCV and underlying substance use disorders. They provide immediate, point-of-care treatment for patients across a range of medical conditions and are convenient for patients due to their user-friendly, street outreach, and non-judgmental nature. As such, they are emerging as important sources of non-specialty treatment and may provide an alternative patient-centered treatment strategy to traditional "brick and mortar" facilities.[58,59] MMCs, due to their mobility and user friendly services, innovatively increase healthcare accessibility and reduce health disparities for communities marginalized by geographic, social, and structural barriers through delivering essential services for preventative,[28,33,48,60,61] primary care,[19,25,26,62,63] and targeted disease-specific care.[20,43,64–67]

Overall, one third of all MMC clients opted for HCV testing. With expanded education and social marketing due to the more tolerable and efficacious HCV treatment strategies, HCV testing acceptability is likely to improve, especially among at-risk populations. Of concern here is the reduced likelihood of baby boomers to accept HCV testing in this population despite a high overall HCV prevalence among those tested. Strategies to improve HCV testing among this group is increased targeting of this high-risk group and our findings may reflect that current CDC messages about testing is not yet reaching marginalized populations.

POC HCV testing is an acceptable testing strategy in MMC settings with nearly half preferring POC testing. Importantly, a secondary and unanticipated benefit of our expanded HCV testing program was that it actively engaged HCV-infected patients and brought them into care, including acceptance of referrals to treatment. Thus, this modality of healthcare delivery is effective in both identifying new infections and also re-engaging those who have been previously diagnosed.

It is not surprising that patients have different preferences about HCV testing, specifically with different client profiles among those choosing one strategy over another. Importantly, those with the highest levels of perceived sexual risk (i.e., multiple sexual partners), preferred POC testing, yet those with injection-related risk selected standard phlebotomy testing. Though we did not specifically ask why clients chose one HCV testing strategy over another, one unsubstantiated speculation is that clients with many sexual partners may have been previously screened for other conditions (e.g., HIV, syphilis) but had not been tested for HCV since it is not traditionally associated with sexual risk, while PWIDs who are greatest risk for HCV plus numerous other conditions may have opted to "bundle" their

screening for several conditions in favor of a more comprehensive assessment that could be obtained only through phlebotomy. The influence of patient preferences and expectations on patient reported outcomes remains an important issue in providing acceptable healthcare. Patients who actively engage in the decision-making process experience an empowerment effect, ultimately receive their preferred treatment, and may become more motivated to adhere to their selected treatment.[68]

There is increasing emphasis on patient preferences and choice in healthcare decision-making,[69] as recent research has shown evidence that expansion of choices can lead to improvements in patient health outcomes and quality of life. A 2008 systematic review and meta-analysis by the Preference Collaborative Review Group suggests that preferences positively affect patient outcomes in clinical trials, with those receiving their preferred treatment demonstrating better treatment outcomes.[70] For this reason, the patients in our setting were offered an option to be screened for HCV, as well as a choice between two HCV screening strategies.

In the context of this study, HCV-infected patients identified using POC testing were dramatically more likely to be linked to HCV specialty care. While it is unlikely that patient preference contributed to linkage to care, it is likely that immediate intervention once a diagnosis was made contributed to improved intervention outcomes. A recent systematic review of HIV rapid POC testing confirmed higher likelihood of linkage to care.[71] Taken together, these findings support that POC HCV testing using community outreach from a MMC is a complementary public health strategy to overcome health disparities for high risk, vulnerable populations. In particular with the increasing incidence of new HCV infections among young PWID, it is important for MMCs to promote early identification and linkage to care. Specific from this study was the ability to engage younger at-risk populations through the MMC, who might not otherwise be engaged in care, and effectively screen them for HCV. POC HCV testing at an MMC provides an important and complementary health delivery approach to access vulnerable populations who are otherwise estranged from healthcare

LIMITATIONS

The pilot nature of study lends itself to several important limitations. First, routine risk information was gleaned from routine clinical intake instrument on the MMC and not designed specifically to identify HCV-related risks. The addition of the HCV surveillance reporting information, however, supplemented the clinical information. Second, though there were few missing data, multiple imputations were deployed to enrich the data for completeness. Third, though we were able to determine how patient preferences influenced several outcomes, we collected insufficient data to determine "why" patients selected POC or standard HCV testing. Last, this study assessed POC HCV testing strategies only as the technology became available, and such findings may not persist as clinical care sites and patients have more experience with POC testing, including for HCV. Last, because HCV testing was provided for free, pragmatic studies may show lower acceptability of HCV testing, and if patients or providers had to consider costs, such constraints may influence HCV testing from a pragmatic perspective. Despite these limitations, however, important

findings gleaned here provide insights into HCV testing acceptability by vulnerable populations, POC testing preferences and the ability of POC to improve linkage to care, which ultimately may improve individual and public health.

CONCLUSIONS

Acceptability of HCV testing, irrespective of strategy, was high and resulted in several newly identified HCV-infected patients. Differing demographic and motivations provided insights into preferences for POC and standard testing. POC testing, however, resulted in markedly higher linkage to HCV specialty care, but should be confirmed through an informed decision-making process, perhaps using an informed decision-making aid, to help guide future testing and linkage strategies.

Funding:

Competing Interests:

References

1. Wendt A, Adhoute X, Castellani P, Oules V, Ansaldi C, Benali S, et al. (2014). Chronic hepatitis C: future treatment. Clin Pharm, 6 (eCollection), 1–17.

2. Shepard C, Finelli L, Alter M (2005). Global epidemiology of hepatitis C virus infection. Lancet ID, 5 (9), 558–567.

3. National Institute for Clinical Excellence (2004). Interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment of chronic hepatitis C. http://www.nice.org.uk/nicemedia/live/11524/32809/32809.pdf, accessed May 10, 2014.

4. Ly K, Xing J, Klevens M, Jiles R, Ward J, Holmberg S (2012). The growing burden of mortality from viral hepatitis in the US, 1999-2007. Ann Int Med, 156, 271–278. [PubMed: 22351712]

5. Keeling M, Eames K (2005). Networks and epidemic models. J Royal Soc Int, 2, 295–307.

6. Rein D, Wittenborn J, Weinbaum C, Sabin M, Smith B, Lesesne S (2011). Forecasting the morbidity and mortality associated with prevalent cases of pre-cirrhotic chronic hepatitis C in the United States. Dig Liver Dis, 43 (1), 66–72. [PubMed: 20739252]

7. Chou R, Cottrell E, Wasson N, Rahman B, Guise J (2013). Screening for hepatitis C virus infection in adults: A systematic review for the U.S. Preventive Services Task Force. Ann Int Med, 158, 101–108. [PubMed: 23183613]

8. Centers for Disease Control and Prevention (2011). Viral hepatitis surveillance – United States, 2011. http://www.cdc.gov/HEPATITIS/Statistics/index.htm, accessed Apri 4, 2014.

9. Razavi H, ElKhoury A, Elbasha E, Estes C, Pasini K, Poynard T, et al. (2013). Chronic hepatitis C Virus (HCV) disease burden and cost in the United States. Hepatology, 57 (6), 2164–2170. [PubMed: 23280550]

10. Bruce RD, Eiserman J, Acosta A, Gote C, Lim JK, Altice FL (2012). Developing a modified directly observed therapy intervention for hepatitis C treatment in a methadone maintenance program: implications for program replication. Am J Drug Alcohol Abuse, 38 (3), 206–212. [PubMed: 22242700]

11. Maru DS, Bruce RD, Basu S, Altice FL (2008). Clinical outcomes of hepatitis C treatment in a prison setting: feasibility and effectiveness for challenging treatment populations. Clin Infect Dis, 47 (7), 952–961. [PubMed: 18715156]

12. Bruneau J, Zeng G, Abrahamowicz M, Jutras-Aswad D, Daniel M, Roy E (2014). Sustained drug use changes after Hepatitis C screening and counseling among recently infected persons who inject drugs: a longitudinal study. Clin Inf Dis, 58, 755–761.

13. Sala A, Cao L, Wilson C, Zablit R, Zheng H, Zhao B Measurement-calibrated graph models for social network experiments 19th International Conference on World Wide Web. (2010). Raleigh, North Carolina. pp. 861–870.

14. Page K, Morris M, Hahn J, Maher L, Prins M (2013). Injection drug use and hepatitis C virus infection in young adult injectors: using evidence to inform comprehensive prevention. Clin Inf Dis, 57 (Suppl 2), S32–S38.

15. Carrington P, Scott J, Wasserman S (2005). Models and methods in social network analysis. New York, NY: Cambridge University Press.

16. Hutchinson S, Bird S, Taylor A, Goldberg D (2006). Modelling the spread of hepatitis C virus infection among injecting drug users in Glasgow: Implications for prevention. Int J Drug Policy, 17, 211–221.

17. Centers for Disease Control and Prevention (2011). Hepatitis C virus infection among adolescents and young adults: Massachusetts, 2002-2009. MMWR, 60 (17), 537–541. [PubMed: 21544042]

18. OraSure Technologies Inc. (2014). OraQuick® HCV Rapid Antibody Test. Bethlehem, Pennsylvania. http://www.orasure.com/company/company-overview-profile.asp, accessed April 4, 2014.

19. Leese GP, Ahmed S, Newton RW, Jung RT, Ellingford A, Baines P, et al. (1993). Use of mobile screening unit for diabetic-retinopathy in rural and urban areas. Brit Med J, 306 (6871), 187–189. [PubMed: 8443485]

20. Sarnquist CC, Soni S, Hwang H, Topol BB, Mutima S, Maldonado YA (2011). Rural HIV-infected women's access to medical care: ongoing needs in California. AIDS Care, 23 (7), 792–796. [PubMed: 21287418]

21. Edgerley LP, El-Sayed YY, Druzin ML, Kiernan M, Daniels KI (2007). Use of a community mobile health van to increase early access to prenatal care. Maternal and Child Health J, 11 (3), 235–239.

22. Heller BR, Goldwater MR (2004). The Governor's wellmobile: Maryland's mobile primary care clinic. The Journal of Nursing Education, 43 (2), 92–94. [PubMed: 14974519]

23. Guruge S, Hunter J, Barker K, McNally MJ, Magalhaes L (2010). Immigrant women's experiences of receiving care in a mobile health clinic. J Adv Nurs, 66 (2), 350–359. [PubMed: 20423418]

24. Whelan C, Chambers C, Chan M, Thomas S, Ramos G, Hwang S (2010). Why do homeless people use a mobile health unit in a country with universal health care? J Primary Care Comm Health, 1 (2), 78–82.

25. Daiski I (2005). The health bus: healthcare for marginalized populations. Policy Polit Nurs Pract, 6 (1), 30–38. [PubMed: 16443957]

26. Hastings J, Zulman D, Wali S (2007). UCLA mobile clinic project. J of Health Care Poor Underserved, 18 (4), 744–748. [PubMed: 17982203]

27. Shannon K, Rusch M, Shoveller J, Alexson D, Gibson K, Tyndall MW (2008). Mapping violence and policing as an environmental-structural barrier to health service and syringe availability among substance-using women in street-level sex work. Int J Drug Policy, 19 (2), 140–147. [PubMed: 18207725]

28. Collinson S, Ward R (2010). A nurse-led response to unmet needs of homeless migrants in inner London. Br J Nurs, 19 (1), 36–41. [PubMed: 20081711]

29. (12 17, 2006). New Haven's Problems and Promise. The New York Times. New York, NY.

30. Rosenfeld E New Haven fourth most dangerous city in U.S., according to preliminary FBI data. Yale Daily News. New Haven, CT.

31. Morano JP, Gibson BA, Altice FL (2013). The burgeoning HIV/HCV syndemic in the urban Northeast: HCV, HIV, and HIV/HCV coinfection in an urban setting. PloS One, 8 (5), e64321. [PubMed: 23691197]

32. Heimer R, Kaplan EH, O'Keefe E, Khoshnood K, Altice F (1994). Three years of needle exchange in New Haven: what have we learned? AIDS Public Policy J, 9 (2), 59–74.

33. Schwarz RK, Bruce RD, Ball SA, Herme M, Altice FL (2009). Comparison of tuberculin skin testing reactivity in opioid-dependent patients seeking treatment with methadone versus buprenorphine: policy implications for tuberculosis screening. Am J Drug Alcohol Abuse, 35 (6), 439–444. [PubMed: 20014914]

34. Morano JP, Zelenev A, Walton MR, Bruce RD, Altice FL (2014). Latent tuberculosis infection screening in foreign-born populations: A successful mobile clinic outreach model. Am J Pub Health, 104 (8), 1508–1515. [PubMed: 24922157]

35. Altice FL, Maru DS, Bruce RD, Springer SA, Friedland GH (2007). Superiority of directly administered antiretroviral therapy over self-administered therapy among HIV-infected drug users: a prospective, randomized, controlled trial. Clin Infect Dis, 45 (6), 770–778. [PubMed: 17712763]

36. Altice FL, Mezger JA, Hodges J, Bruce RD, Marinovich A, Walton M, et al. (2004). Developing a directly administered antiretroviral therapy intervention for HIV-infected drug users: implications for program replication. Clin Infect Dis, 38 (Suppl 5), S376–387. [PubMed: 15156426]

37. Maru DS, Bruce RD, Walton M, Springer SA, Altice FL (2009). Persistence of virological benefits following directly administered antiretroviral therapy among drug users: results from a randomized controlled trial. J Acquir Immune Defic Syndr, 50 (2), 176–181. [PubMed: 19131891]

38. Maru DS, Kozal MJ, Bruce RD, Springer SA, Altice FL (2007). Directly administered antiretroviral therapy for HIV-infected drug users does not have an impact on antiretroviral resistance: results from a randomized controlled trial. J Acquir Immune Defic Syndr, 46 (5), 555–563. [PubMed: 18193497]

39. Saber-Tehrani AS, Springer SA, Qiu J, Herme M, Wickersham J, Altice FL (2012). Rationale, study design and sample characteristics of a randomized controlled trial of directly administered antiretroviral therapy for HIV-infected prisoners transitioning to the community - a potential conduit to improved HIV treatment outcomes. Contemp Clin Trials, 33 (2), 436–444. [PubMed: 22101218]

40. Smith-Rohrberg D, Mezger J, Walton M, Bruce RD, Altice FL (2006). Impact of enhanced services on virologic outcomes in a directly administered antiretroviral therapy trial for HIV-infected drug users. J Acquir Immune Defic Syndr, 43 Suppl 1, S48–53. [PubMed: 17133204]

41. Altice FL, Bruce RD, Lucas GM, Lum PJ, Korthuis PT, Flanigan TP, et al. (2011). HIV treatment outcomes among HIV-infected, opioid-dependent patients receiving buprenorphine/naloxone treatment within HIV clinical care settings: results from a multisite study. J Acquir Immune Defic Syndr, 56 (Suppl 1), S22–32. [PubMed: 21317590]

42. McCoy C, Metsch L, Chitwood D, Pereyra M (2000). Use of preventive health services by chronic drug users. Drug and Alcohol Dep, 60 (Suppl 1), S143.

43. Liebman J, Pat Lamberti M, Altice F (2002). Effectiveness of a mobile medical van in providing screening services for STDs and HIV. Public Health Nurs, 19 (5), 345–353. [PubMed: 12182694]

44. Thompson AS, Blankenship KM, Selwyn PA, Khoshnood K, Lopez M, Balacos K, et al. (1998). Evaluation of an innovative program to address the health and social service needs of drug-using women with or at risk for HIV infection. J Community Health, 23 (6), 419–440. [PubMed: 9824792]

45. Springer SA, Altice FL, Herme M, Di Paola A (2013). Design and methods of a double blind randomized placebo-controlled trial of extended-release naltrexone for alcohol dependent and hazardous drinking prisoners with HIV who are transitioning to the community. Contemp Clin Trials, 37 (2), 209–218. [PubMed: 24384538]

46. Springer SA, Qiu J, Saber-Tehrani AS, Altice FL (2012). Retention on buprenorphine is associated with high levels of maximal viral suppression among HIV-infected opioid dependent released prisoners. PloS One, 7 (5), e38335. [PubMed: 22719814]

47. Springer SA, Chen S, Altice FL (2010). Improved HIV and substance abuse treatment outcomes for released HIV-infected risoners: the impact of buprenorphine treatment. J Urban Health, 87 (4), 592–602. [PubMed: 20177974]

48. O'Grady J, Hoelscher M, Atun R, Bates M, Mwaba P, Kapata N, et al. Tuberculosis in prisons in sub-Saharan Africa - the need for improved health services, surveillance and control. Tuberculosis, 91 (2), 173–178.

49. Zelenev A, Marcus R, Kopelev A, Cruzado-Quinones J, Spaulding A, Desabrais M, et al. (2013). Patterns of homelessness and implications for HIV health after release from jail. AIDS Behav, 17 (Suppl 2), S181–194. . [PubMed: 23657757]

50. Althoff AL, Zelenev A, Meyer JP, Fu J, Brown SE, Vagenas P, et al. (2013). Correlates of retention in HIV care after release from jail: results from a multi-site study. AIDS Behav, 17 (Suppl 2), S156–170. [PubMed: 23161210]

51. Draine J, Ahuja D, Altice FL, Arriola KJ, Avery AK, Beckwith CG, et al. (2011). Strategies to enhance linkages between care for HIV/AIDS in jail and community settings. AIDS Care, 23 (3), 366–377. [PubMed: 21347900]

52. Morano J, Gibson B, Altice F (2013). The burgeoning HIV/HCV syndemic in the urban northeast: HCV, HIV, and HIV/HCV coinfection in an urban setting. PloS One, 8 (3), e64321. [PubMed: 23691197]

53. McLellan AT, Kushner H, Metzger D, Peters R, Smith I, Grissom G, et al. (1992). The fifth edition of the addiction severity index. J Subst Abuse Treat, 9 (3), 199–213. [PubMed: 1334156]

54. Rubin D (1987). Multiple imputation for non-response in surveys. New York, NY: Wiley.

55. Greene WH (2007). Econometric analysis, 4th edition. Upper Saddle River, NJ: Prentice-Hall.

56. Gelman A, Carlin JB, Stern HS, Rubin DB (1997). Bayesian data analysis. London, U.K.: Chapman and Hall.

57. Stata Corporation (2011). STATA: Release 12. Statistical Software College Station, TX: StataCorp LP.

58. Angora B, Assemien JD, Laurent A, Febro V, Coulibaly-Offia M, Masumbuko JM, et al. HIV in prison in low income countries. AIDS, 25 (9), 1244–1246.

59. Gibson B, Ghosh D, Morano J, Altice F (2014). Accessibility and utilization patterns of a mobile medical clinic among vulnerable populations. Health & Place, 28, 153–166. [PubMed: 24853039]

60. Jit M, Stagg HR, Aldridge RW, White PJ, Abubakar I (2011). Dedicated outreach service for hard to reach patients with tuberculosis in London: observational study and economic evaluation. Brit Med J, 343, d5376. [PubMed: 22067473]

61. Vyas A, Madhavan S, Lemasters T, Atkins E, Gainor S, Kennedy S, et al. (2011). Factors influencing adherence to mammography screening guidelines in Appalachian women participating in a mobile mammography program. J Community Health, 37 (3), 632–646.

62. Simsek Z, Koruk I, Doni NY (2012). An operational study on implementation of mobile primary healthcare services for seasonal migratory farmworkers, Turkey. Maternal Child Health J, 16 (9), 1906–1912.

63. Pollack HA, Khoshnood K, Blankenship KM, Altice FL (2002). The impact of needle exchange-based health services on emergency department use. J Gen Intern Med, 17 (5), 341–348. [PubMed: 12047730]

64. Maheswaran H, Thulare H, Stanistreet D, Tanser F, Newell ML (2012). Starting a home and mobile HIV testing service in a rural area of South Africa. J Acquir Immune Defic Syndr, 59 (3), e43–46. [PubMed: 22107821]

65. Ruiz M, Briones-Chavez CS (2010). How to improve the health of undocumented Latino immigrants with HIV in New Orleans: an agenda for action. Rev Panam Salud Publ, 28 (1), 66–70.

66. Ruiz P, Vazquez W, Vazquez K (1973). The mobile unit: a new approach in mental health. Com Mental Health J, 9 (1), 18–24.

67. Massie HN (1972). Neighborhood psychiatry in a mobile health unit: a report on psychiatric contact with adolescents and young adults in the Judson Mobile Health Unit in New York's Lower East Side in 1969 and 1970. Comprehensive Psychiatry, 13 (5), 429–433. [PubMed: 5080388]

68. Torgerson D, Klaber-Moffett J, Russell IT (1996). Patient preferences in randomised trials: threat or opportunity? J of Health Serv Res Pol, 1, 194–197.

69. Gallos L, Liljeros F, Argyrakis P, Bunde A, Havlin S (2007). Improving immunization strategies. Physical Review E, 7 (045104-R), 1–4.

70. Preference Collaborative Review Group (2008). Patients' preferences within randomised trials: systematic review and patient level meta-analysis. Brit Med J, 337, a1864. [PubMed: 18977792]

71. Wynberg E, Cooke G, Shroufi A, Reid SD, Ford N (2014). Impact of point-of-care CD4 testing on linkage to HIV care: a systematic review. J Int AIDS Soc, 17, 18809. [PubMed: 24447595]
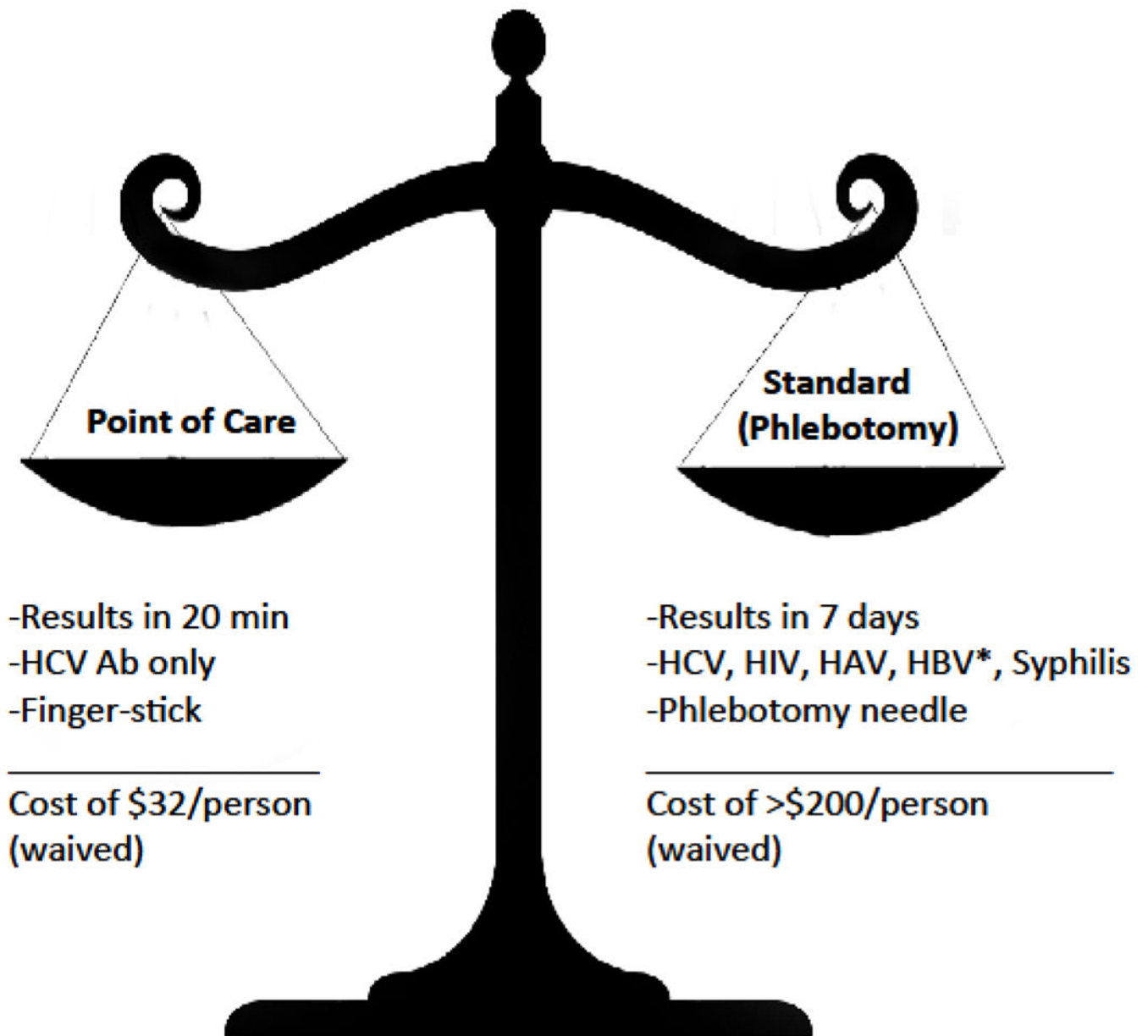
Figure 1:
Decision-based trade-offs between HCV screening strategies, New Haven, Connecticut, 2012-2013.
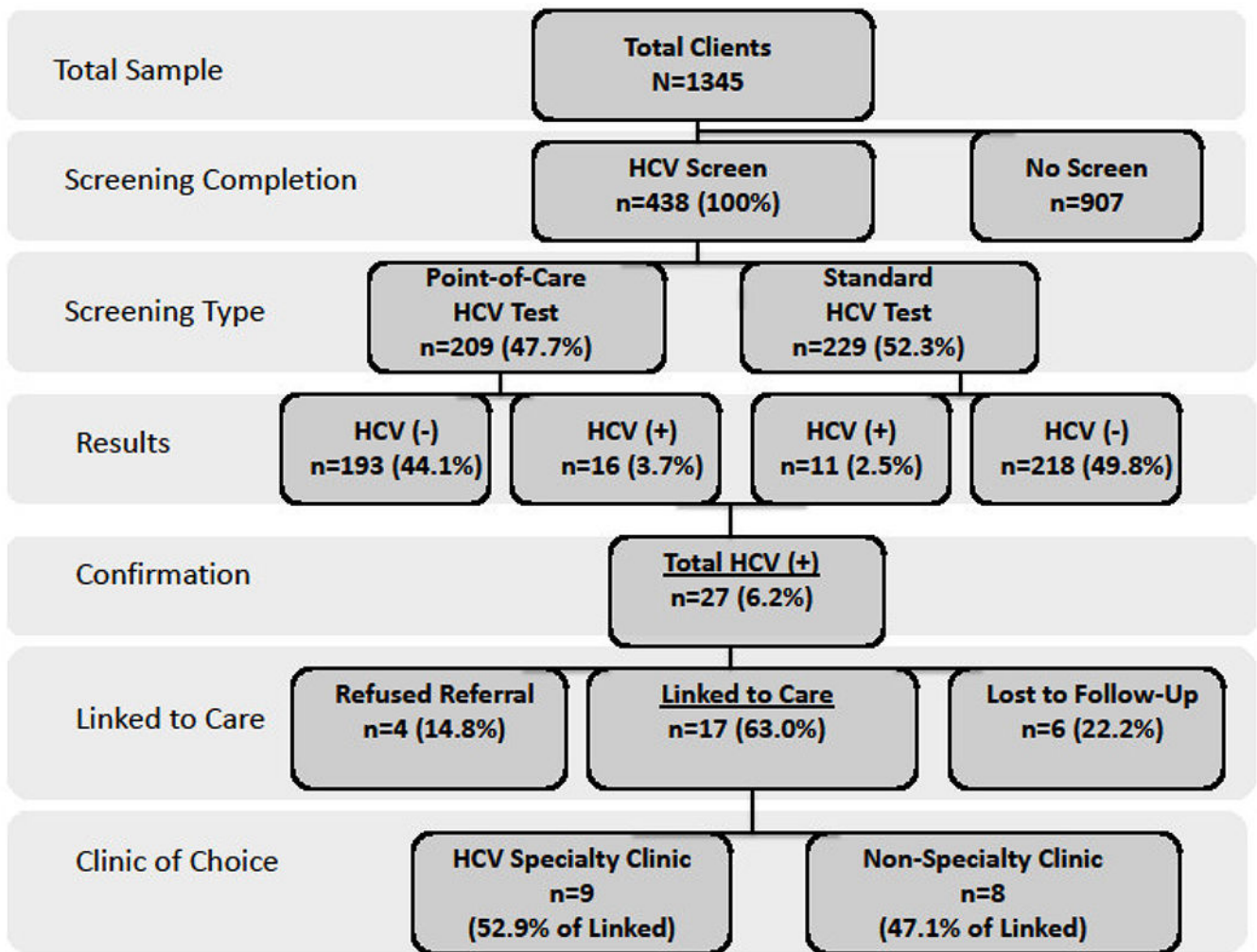HCV: Hepatitis C virus antibody; HAV: Hepatitis A virus IgM; HBV: Hepatitis B virus surface antigen

Figure 2:
Screening and referral to care algorithm for point-of-care (POC) Hepatitis C virus (HCV) antibody testing versus standard phlebotomy testing in a mobile medical clinic, New Haven, Connecticut, 2012-2013.
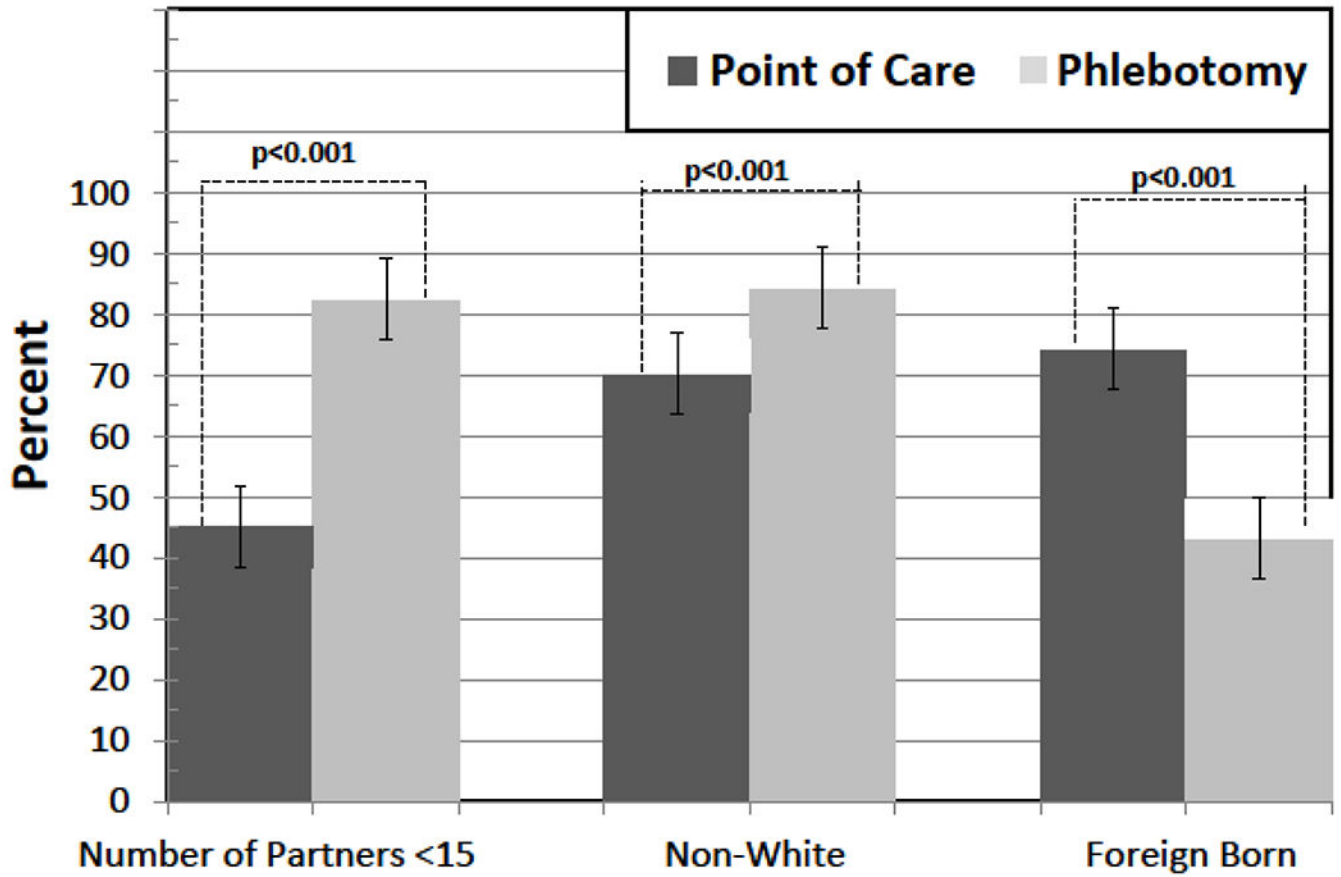
Figure 3:
Key determinants of HCV testing strategy for clients on the mobile medical clinic model;
point-of-care (POC) vs standard (phlebotomy) testing, New Haven, Connecticut, 2012-2013.
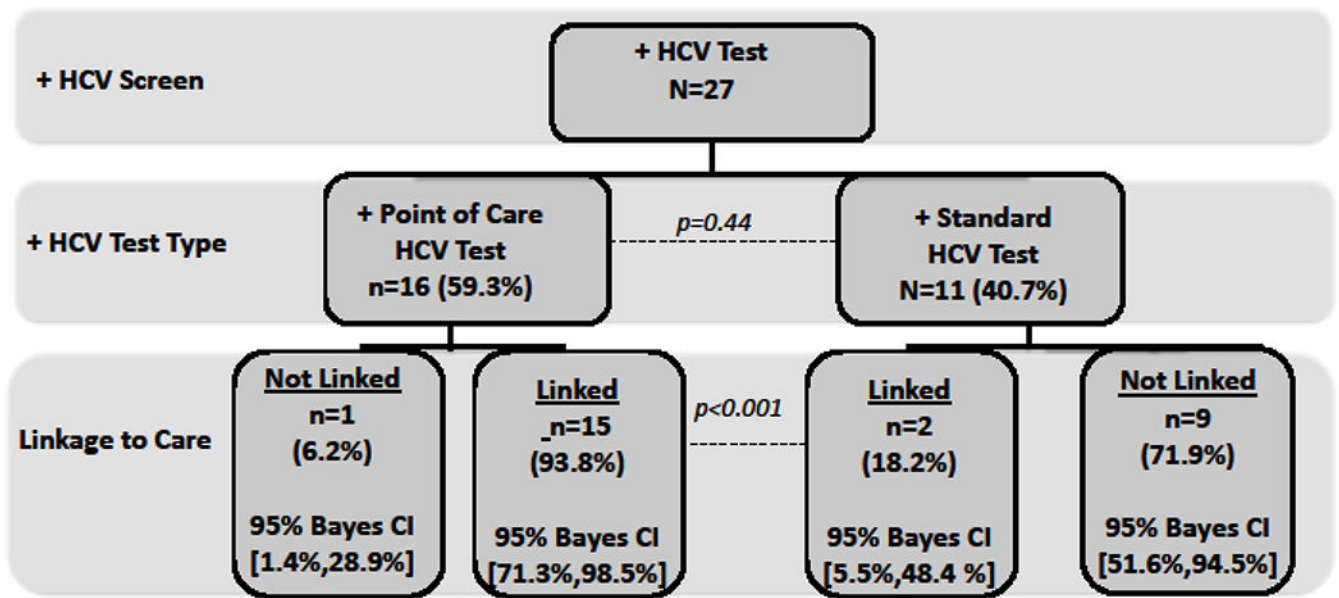
Figure 4:
Linkage to care algorithm for point-of-care (POC) Hepatitis C virus (HCV) antibody testing versus traditional phlebotomy testing in a mobile medical clinic, New Haven, Connecticut, 2012-2013.

Table 1:

Baseline demographics and propensity to undergo Hepatitis C virus (HCV) antibody screening among clients within a mobile medical clinic (MMC) in New Haven, Connecticut, 2012-2013 (N=1345).

Correlate	Total Patients Seen N=1345		HCV Screening Performed				Screened vs Not Screened
			Yes N=438		No N=907		
	N observed (95% CI)	N imputed (%)	N observed (95% CI)	N imputed (%)	N observed (95% CI)	N imputed (%)	p-value
Mean Age, years [S.D.]	37.5	37.5	35.6	35.6	38.5	38.5	<0.01
	(36.9,38.2)	[12.0]	(34.5,36.7)	[11.7]	(37.7,39.3)	[12.1]	
Baby boomer generation	278	294	57	74	221	221	<0.01
	(263,324)	21.8%	(58,90)	16.8%	(196,246)	24.4%	
Gender							
Male	738	751	242	256	496	497	0.220
	(715,788)	55.8%	(235,277)	58.4%	(467,526)	54.7%	
Female	607	594	196	182	411	410	0.220
	(557,630)	44.2%	(161,203)	41.6%	(381,440)	45.3%	
Race							
White	347	359	89	99	258	258	0.028
	(326,391)	26.7%	(81,117)	22.6%	(231,285)	28.4%	
Black	528	546	175	195	353	353	0.050
	(510,582)	40.6%	(173,216)	44.5%	(324,382)	38.9%	
Hispanic	411	425	126	142	285	285	0.644
	(391,459)	31.6%	(121,163)	32.4%	(258,312)	31.4%	
Foreign-born	671	711	147	183	524	524	<0.01
	(673,748)	52.8%	(160,207)	41.8%	(495,553)	57.7%	
Unstable housing	409	496	63	144	346	350	0.177
	(453,539)	36.8%	(111,178)	32.9%	(321,379)	38.6%	
No health insurance	584	708	112	235	472	472	0.232
	(661,755)	52.6%	(195,275)	53.6%	(442,502)	52.0%	
Not in a stable relationship	933	1146	173	383	760	764	0.315
	(1114,1177)	85.2%	(358,407)	87.3%	(742,785)	84.2%	
Prior diagnosis of hepatitis C	46	46	23	26	23	23	<0.01
	(33,60)	3.4%	(15,37)	5.9%	(14,32)	2.5%	
Prior STI diagnosis	253	363	105	228	148	148	0.004
	(257,468)	27.0%	(110,345)	52.0%	(126,170)	16.3%	
Injection drug history (PWID)	188	204	76	96	112	113	<0.01
	(177,231)	15.2%	(78,115)	22.0%	(93,133)	12.5%	
Heroin	203	268	39	108	164	164	0.015
	(237,300)	20.0%	(86,130)	24.7%	(141,187)	18.0%	

Correlate	Total Patients Seen N=1345		HCV Screening Performed				Screened vs Not Screened
			Yes N=438		No N=907		
	$N_{observed}$ (95% CI)	$N_{imputed}$ (%)	$N_{observed}$ (95% CI)	$N_{imputed}$ (%)	$N_{observed}$ (95% CI)	$N_{imputed}$ (%)	p-value
Cocaine	345	435	70	164	275	275	0.070
	(393,476)	32.3%	(131,196)	37.4%	(248,302)	30.3%	
Use of	38	57	7	28	31	31	0.380
NSEP	(26,88)	4.2%	(0,59)	6.3%	(20,42)	3.4%	
Crack cocaine use	268	334	50	118	218	218	0.166
	(296,371)	24.8%	(87,148)	26.8%	(193,243)	24.0%	
Non-injection drug use	514	625	106	218	408	408	0.096
	(585,665)	46.4%	(193,242)	49.6%	(379,437)	45.0%	
History of incarceration	531	676	106	246	425	433	0.091
	(628,725)	50.3%	(205,287)	56.1%	(404,463)	47.8%	
History of interpersonal violence	251	315	44	108	207	207	0.313
	(280,351)	23.4%	(82,134)	24.7%	(182,232)	22.8%	
MSM	47	51	20	24	27	27	0.037
	(36,65)	3.7%	(13,35)	5.6%	(17,37)	3.0%	
Lifetime sexual partners > 15	133	145	133	155	0	0	na
	(121,168)	10.7%	(134,175)	35.3%	na	0%	

Note: $N_{imputed}$ is sample size based on the frequency estimate from multiple imputation procedure. Cocaine and heroin numbers reflect total users of either intravenous, oral, or inhaled routes.

LEGEND: HCV: Hepatitis C Virus; NSEP: Needle Syringe Exchange Program; STI: Sexually Transmitted Infection; PWID: People Who Inject Drugs; MSM: Men Who Have Sex with Men

Table 2:

Decision to select point-of-care (POC) versus standard phlebotomy HCV antibody testing among clients in a mobile medical clinic (MMC) in New Haven, Connecticut, 2012-2013 (N=438).

Correlates	Total observed	HCV Testing Strategy Selected N=438				Pearson Chi-squared p-value
		Point-of-Care N=209		Standard N=229		
		N observed (95% CI)	N imputed (%)	N observed (95% CI)	N imputed (%)	
HCV test						
Positive	27	16	-	11	-	0.219
		(8,24)	7.7%	(5,17)	4.8%	
Negative	411	193	193	218	218	0.219
		(185,201)	92.3%	(212,224)	95.2%	
Mean age [S.D.]	35.6	36.0	36.0	35.3	35.3	0.497
		(34.2,37.7)	[12.2]	(33.9,36.8)	[11.0]	
Baby boomer generation	57	32	36	25	38	0.857
		(25,47)	17.2%	(26,49)	16.6%	
Gender						
Male	242	113	119	129	137	0.604
		(105,134)	56.9%	(121,152)	59.8%	
Female	173	86	90	87	92	0.604
		(75,104)	43.0%	(77,108)	40.2%	
Race						
Non-Hispanic White	89	58	62	31	36	<0.01
		(48,75)	29.7%	(24,48)	15.7%	
Non-Hispanic Black	175	87	92	88	103	0.853
		(78,106)	44.0%	(87,119)	45.0%	
Hispanic	126	50	53	76	89	<0.01
		(40,65)	25.4%	(73,106)	38.9%	
Foreign-born	147	49	54	98	130	<0.01
		(40,67)	25.8%	(112,147)	56.8%	
Unstable housing	63	18	68	45	76	0.244
		(39,98)	32.5%	(59,93)	33.2%	
No health Insurance	112	31	112	81	123	0.198
		(78,147)	53.6%	(103,142)	53.7%	
Not in a stable relationship	173	50	183	123	200	0.887
		(163,203)	87.7%	(188,211)	87.3%	
Prior diagnosis of HCV	23	12	12	11	14	0.351
		(5,19)	5.7%	(5,22)	6.1%	
Prior diagnosis of STI	105	23	95	82	133	0.660

| Correlates | Total observed | HCV Testing Strategy Selected N=438 | | | | Pearson Chi-squared p-value |
| | | Point-of-Care N=209 | | Standard N=229 | | |
		N observed (95% CI)	N imputed (%)	N observed (95% CI)	N imputed (%)	
		(0,205)	45.5%	(103,162)	58.1%	
Injection drug history (PWID)	76	47	53	29	44	0.187
		(40,66)	25.4%	(30,57)	19.2%	
Heroin	39	16	56	23	52	0.43
		(39,73)	26.8%	(37,67)	22.7%	
Cocaine	70	22	78	48	86	0.954
		(51,104)	37.2%	(68,104)	37.6%	
Use of NSEP	7	4	16	3	12	0.623
		(0,39)	7.7%	(0,24)	5.2%	
Crack cocaine use	50	21	63	29	55	0.453
		(34,91)	30.1%	(38,72)	24.0%	
Non-injection drug use	106	23	95	83	122	0.305
		(72,118)	45.5%	(103,141)	53.3%	
History of incarceration	106	30	119	76	127	0.779
		(90,149)	57.0%	(107,146)	55.5%	
History of interpersonal violence	44	20	66	24	42	0.085
		(39,94)	31.6%	(28,56)	18.3%	
Occupational exposure to blood	9	8	11	1	8	0.674
		(3,19)	5.1%	(0,25)	3.5%	
Household known HCV+ individual	20	17	39	3	50	0.972
		(0,82)	18.6%	(0,146)	21.8%	
MSM	20	12	13	8	11	0.460
		(6,20)	6.3%	(3,19)	4.8%	
Tattoo history	112	90	121	22	102	0.197
		(104,139)	57.9%	(0,160)	44.5%	
Lifetime sexual partners > 15	133	106	115	27	40	<0.01
		(100,129)	55.0%	(26,54)	17.5%	

Note: N$_{imputed}$ is sample size based on the frequency estimate from multiple imputation procedure. Cocaine and heroin numbers reflect total users of either intravenous, oral, or inhaled routes.

LEGEND: HCV: Hepatitis C Virus; HCV Ab: Hepatitis C Antibody; STI: Sexually Transmitted Infection PWID: People Who Inject Drugs; NSEP: Needle Syringe Exchange Program; MSM: Men Who Have Sex with Men.

Table 3:

HCV antibody testing results (positive vs negative) stratified by test type and client characteristics in a mobile medical clinic (MMC) in New Haven, Connecticut, 2012-2013 (N=438).

| Correlates | HCV Antibody Testing Result | | | | HCV+ vs HCV – |
| | HCV Positive N=27 | | HCV Negative N= 411 | | |
	N observed (95% CI)	N imputed* (%)	N observed (95% CI)	N imputed* (%)	p-value
HCV Ab Test					
Point-Of-Care	16	16	193	193	0.215
	(11,21)	59.3%	(173,213)	46.9%	
Standard Phlebotomy	11	11	218	218	0.215
	(6,16)	40.7%	(198,238)	53.0%	
Mean age, years [S.D.]	43.2	43.2	35.2	35.1	<0.01
	(38.8,47.6)	[10.6]	(34.0,36.2)	[11.6]	
Baby boomer generation	8	9	49	65	0.027
	(3,14)	33.3%	(50,80)	15.8%	
Gender					
Male	13	14	229	242	0.373
	(8,19)	51.8%	(222,263)	58.8%	
Female	13	13	160	169	0.373
	(8,19)	48.1%	(148,189)	41.1%	
Race					
Non-Hispanic White	14	15	75	84	<0.01
	(9,21)	55.5%	(67,100)	20.4%	
Non-Hispanic Black	6	6	169	188	0.027
	(2,11)	22.2%	(168,209)	45.7%	
Hispanic	5	6	121	136	0.186
	(1,11)	22.2%	(116,157)	33.0%	
Foreign-born	15	16	132	167	0.047
	(10,22)	59.3%	(145,189)	40.6%	
Unstable housing	9	11	54	133	0.206
	(4,18)	40.7%	(99,167)	32.4%	
No health insurance	8	11	104	223	0.200
	(5,18)	40.7%	(184,263)	54.3%	
Not in a stable relationship	19	24	154	359	0.571
	(20,28)	88.9%	(334,383)	87.3%	
Prior diagnosis HCV	22	22	1	4	<0.01
	(18,26)	81.5%	(0,10)	1.0%	
Prior diagnosis STI	10	13	95	215	0.414
	(7,20)	48.1%	(99,330)	52.3%	

Correlates	HCV Antibody Testing Result				HCV+ vs HCV −
	HCV Positive N=27		HCV Negative N= 411		
	N observed (95% CI)	N imputed* (%)	N observed (95% CI)	N imputed* (%)	p-value
Injection drug history (PWID)	19	22	57	75	<0.01
	(17,26)	81.5%	(58,91)	18.2%	
Heroin	17	21	22	87	<0.01
	(16,26)	77.8%	(67,107)	21.1%	
Cocaine	16	20	54	144	<0.01
	(14,26)	74.1%	(113,175)	35.0%	
Use of NESP	5	6	2	21	<0.01
	(1,12)	22.2%	(0,53)	5.1%	
Crack cocaine use	16	19	34	99	<0.01
	(14,25)	70.3%	(69,128)	24.0%	
Non-injection drug use	2	-	104	215	<0.01
	(0,6)	7.4%	(190,240)	52.3%	
History of incarceration	14	19	92	227	0.119
	(13,25)	70.3%	(185,269)	55.2%	
History of interpersonal violence	9	10	35	98	0.051
	(4,15)	37.0%	(72,124)	23.8%	
Occupational exposure to blood	2	3	7	19	0. 232
	(0,7)	11.1%	(5,32)	4.6%	
Household known HCV+ individual	7	11	13	78	0.274
	(5,16)	40.1%	(0,227)	19.0%	
MSM	1	-	19	23	0.658
	(0,3)	3.7%	(12,34)	5.6%	
Tattoo history	14	24	98	260	0.052
	(19,29)	88.9%	(228,291)	63.2%	
Lifetime sexual partners > 15	4	5	129	150	0.035
	(0,9)	18.5%	(130,170)	36.5%	

Note: The number of individuals in each group (N-imputed) as well as 95% confidence interval have been estimated using Rubin Rules for combining multiple imputations (in this case 10 imputations).

LEGEND: HCV: Hepatitis C Virus; HCV Ab: Hepatitis C Antibody; STI: Sexually Transmitted Infection PWID: People Who Inject Drugs; NSEP: Needle Syringe Exchange Program; MSM: Men Who Have Sex with Men. Cocaine and heroin numbers reflect total users of either intravenous, oral, or inhaled routes

Table 4:

Multivariate Logistic Regression Analysis of HCV Screening and Selection of Point-of-Care HCV Testing among Clients on a Mobile Medical Clinic in New Haven, Connecticut, 2012-2013 (N=1345).

Outcome: Decision to Accept HCV Ab Screening N=1345					Outcome: Choosing Point-of-Care HCV Ab Screen versus Standard Phlebotomy N=438				
Covariate	AOR	(95% CI)	Marginal Effects (dy/dx)	p-value	Covariate	AOR	(95% CI)	Marginal Effects (dy/dx)	p-value
Prior STI	**5.03**	**(1.76,14.26)**	**0.36**	**<0.01**	> 15 sex partners	**5.84**	**(3.14, 10.8)**	**0.41**	**<0.01**
Non-Hispanic White	**0.55**	**(0.36,0.78)**	**−0.11**	**<0.01**	Non-Hispanic White	**3.21**	**(1.58, 5.96)**	**0.27**	**<0.01**
Non-Hispanic Black	0.76	(0.53, 1.09)	−0.05	0.13	Non-Hispanic Black	1.15	(0.62, 1.85)	0.04	0.65
Hispanic		Referent			Hispanic		Referent		
US-born	**1.76**	**(1.25,2.46)**	**0.12**	**<0.01**	US-born	**2.31**	**(1.26, 3.68)**	**0.21**	**<0.01**
Injection Drug Use (PWID)	**2.21**	**(1.12,4.46)**	**0.14**	**0.03**	Injection Drug Use (PWID)	**0.31**	**(0.19, 1.01)**	**−0.20**	**0.01**
Baby Boomer	**0.67**	**(0.46,0.97)**	**−0.07**	**0.04**					
Prior HCV Diagnosis	1.94	(0.94,4.31)	0.16	0.09	Prior HCV Diagnosis	2.10	(0.67, 6.58)	0.18	0.2
Non-injection Drug Use	0.71	(0.82,1.97)	0.05	0.23					
Unstable	0.76	(0.50,1.19)	−0.04	0.21					
Housing									
Median AIC: 1392					Median AIC: 67				

LEGEND: HCV: Hepatitis C Virus; HCV Ab: Hepatitis C Antibody; STI: Sexually Transmitted Infection; AOR: Adjusted Odds Ratio; CI: Confidence Interval; PWID: People Who Inject Drugs; AIC: Akaike Information Criterion; Covariates significant at the p<0.05 level are boldfaced.