

I. Introduction

Background

Substance users, particularly injection drug users (IDUs) are at high risk of acquiring HAV, HBV and HCV. More specifically, IDU is the single largest risk factor for HCV, the second largest risk factor for HBV and is also associated with significant risk for HAV.¹ HAV is usually transmitted through the ingestion of fecal matter, even in microscopic amounts from close person-to-person contact with an HAV-infected person, sexual contact with an HAV-infected person or ingestion of contaminated food or drinks.¹ Although transmission of HAV is predominantly through feces, it can also be transmitted through contact with contaminated drug injection equipment.^{2,3} Approximately 40%-70% of IDUs develop HAV at some time during their drug using careers,^{2,3} and, because of this, the HAV vaccine is recommended for IDUs. The HAV virus is responsible for about 25,000 new infections a year in the United States.¹ In NYC, there were 158 new HAV cases reported in 2007.⁴

The HBV virus is 100 times more infectious than the HIV virus.⁵ It is estimated that 43,000 persons are newly infected with HBV each year and 800,000-1.4 million persons have chronic HBV in the US.¹ In NYC, 12,652 new HBV cases were reported in 2007.⁴ HBV can be transmitted through exposure to infectious blood or body fluids. HBV risk factors include: having sex with an infected partner; sharing needles, syringes or drug-preparation equipment; contact with blood or open sores of an infected person; needle sticks or sharp instrument exposures and sharing items such as razors or toothbrushes with an infected person. HBV infected pregnant women are also at risk for transmitting HBV to their infants. IDU is the second greatest risk factor for HBV, after sexual transmission, therefore the HBV vaccine is also recommended for IDUs.

There are between 2.7 and 3.9 million Americans chronically infected with the HCV^{1,5} and each year an estimated 17,000 persons become newly infected.¹ Furthermore, 8,000-10,000 Americans die of HCV related cirrhosis or cancer of the liver each year.⁵ To date, there is no vaccine for HCV. HCV is transmitted primarily through contact with blood of an infected person, such as through sharing of contaminated needles, syringes, or other injection drug equipment. IDU is the single largest risk factor for HCV. In the US, approximately one third of young (aged 18 to 30 years) IDUs are HCV infected while older and former IDUs usually have a much higher prevalence (approximately 70%-90%) of HCV infection.¹ It is estimated that 75%-85% of substance users injecting for more than 2 years will become infected with HCV.⁵ IDU is also among the leading risk factors for HIV/AIDS in the US. HCV is acquired more rapidly than HIV in IDUs.⁵ Currently, about 1.1 million Americans are infected with HIV¹ and 350,000 Americans are co-infected with HIV and HCV.⁵

In New York State (NYS), it is estimated that 324,000 persons have been infected with HCV.⁵ In 2007, there were 16,691 newly reported cases of chronic HCV in NYC.⁴ IDUs are at increased risk for contracting both HIV and HCV. Historically IDUs have had less access to HCV evaluation and treatment than HIV related services. Therefore, it is

essential that HCV prevention and treatment efforts target substance users. Studies have shown that the majority of active IDUs do not know their hepatitis status but are more likely to reduce their high risk behaviors once their status is known.^{6,7}

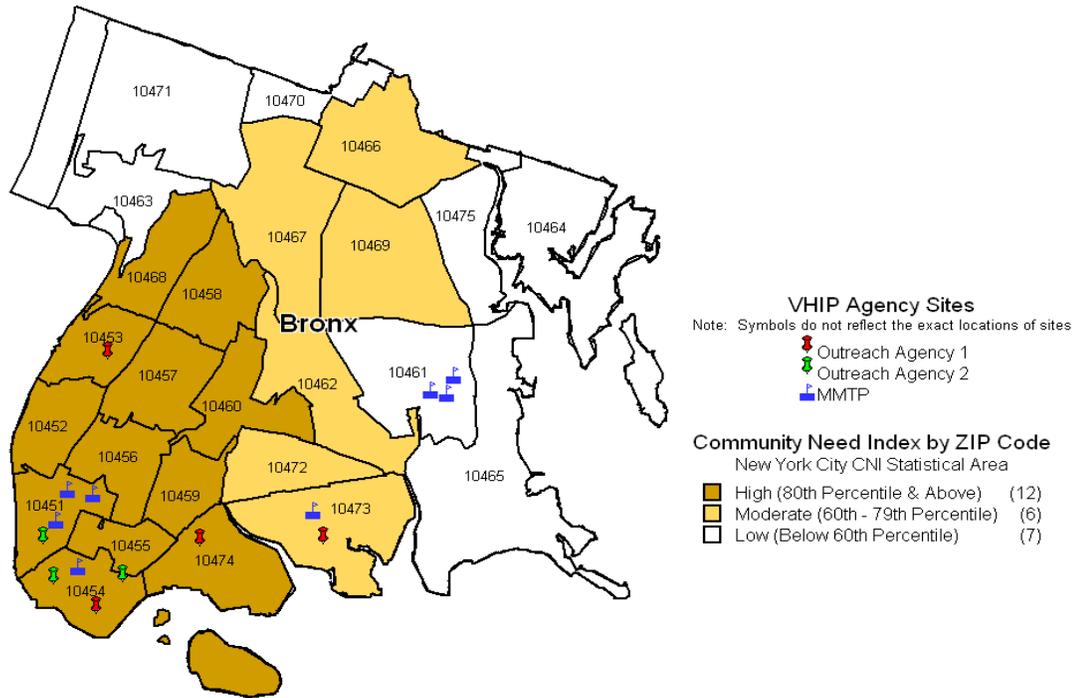
According to the National Institute on Drug Abuse, drug abuse treatment and community-based outreach programs have consistently demonstrated their effectiveness in working with drug users to reduce drug use and sexual behavior that put them at risk for blood borne infectious diseases.⁸ Hepatitis vaccination at SEPs has also been shown to be feasible and has the potential to reach persons vulnerable to hepatitis who might not otherwise receive this service.⁹ In addition, active IDU is no longer necessarily considered a contraindication for HCV treatment.¹⁰ In response to the HIV epidemic, MMTPs have also evolved by developing capacity for limited primary health care services which often include screening for HBV and HCV and vaccinating for HAV and HBV. Furthermore, methadone treatment has also been shown to reduce risky behaviors that can spread hepatitis and is not a contraindication to HCV treatment.¹⁰

In response to the fact that substance users are at an increased risk for contracting hepatitis and that they have limited access to hepatitis services, the NYSDOH received a five year grant in 2004 from the Centers for Disease Control and Prevention (grant #U50/CCU224192) to integrate viral hepatitis services into programs serving the highest risk population - IDU. The purpose of this grant was to establish and enhance hepatitis screening, testing, prevention, and treatment in both drug treatment and substance use settings currently providing HIV services. Two SEPs and one MMTP in NYC were chosen to participate in NY's Viral Hepatitis Integration Project (VHIP).

The participating programs operated multiple sites situated in and around the South Bronx, an area thought to be in high need for hepatitis and HIV prevention programs, as evidenced by the NYSDOH's Community Need Index (CNI)* (see Figure 1).¹¹

* The CNI, developed by the NYSDOH, is a zip code level multivariate measure comprised of rates of AIDS cases, newborn seroprevalence, HIV hospital discharges, and indicators of high risk behaviors including teenage pregnancy, sexually transmitted diseases, and drug-related hospital discharges. To avoid comparing urban zip codes to rural ones, the CNI is computed separately for NYC counties, NYC area counties, and for the rest of NYS. The top 20% of zip codes in each region with highest rates on the CNI are classified as "high need" zip codes, while the next 20% of zip codes are classified as "medium need" zip codes. The remaining 60% of zip codes are classified as "low need".

Figure 1: Location of VHIP Agencies in Relation to CNI Ranking



Services Offered

Prior to the VHIP grant, the two SEPs offered syringe exchange, outreach, support groups, meals (one location only), counseling for recovery readiness and relapse prevention, case management, referrals for health care, detoxification and drug treatment, and acupuncture and other crave reducing techniques to their clients. The VHIP grant added the following services to each SEP: an on-site Hepatitis Coordinator; HBV and HCV screenings; HAV and HBV vaccinations; referrals for evaluation and treatment of HCV; hepatitis related support groups; and a standardized set of hepatitis educational materials. The primary duties of the Hepatitis Coordinators included recruiting clients for hepatitis screenings and vaccinations, following up with clients when their test results were available and/or they needed additional doses of vaccine, delivering hepatitis screening results, scheduling and escorting HCV positive clients to referral appointments and liver biopsies, facilitating hepatitis related support groups at least once per week, providing educational materials to clients and reporting all hepatitis services provided to the NYSDOH on a bi-monthly basis. Because NYS requires a licensed clinician to administer vaccines, hepatitis vaccinations were administered by a Physician Assistant (PA) from the MMTP. The PA was on-site at the SEPs one day per week.

Existing services at the MMTP included: chemical dependency treatment and an integrated care model consisting of comprehensive on-site services such as psychiatric services, support groups, gynecological exams and primary care including HIV, HCV and tuberculosis specific care. After the implementation of VHIP, services were expanded to include a Hepatitis Coordinator, a Hepatitis Educator, on-site evaluation and treatment for HCV positive clients, client-centered HCV support groups and peer education as well as the availability of hepatitis educational materials. Primary duties of the Hepatitis Coordinator and the Hepatitis Educator were similar to those of the Hepatitis Coordinator at the SEPs.

Training Activities

All non-medical staff, including the Hepatitis Coordinators at both SEPs and the MMTP, received a two-day training on hepatitis (the CDC grant funded “It’s Time” training – grant #U50/CCU223249). Eight trainings were held initially and 165 staff members attended. The training provided an introduction to hepatitis A, B and C, and staff learned strategies for integrating hepatitis services into their existing services. Staff received an additional training on HIV/HCV co-infection. All medical staff at the MMTP were trained by the medical director, Dr. Alain Litwin on hepatitis vaccination, hepatitis screening, follow-up testing for hepatitis and HCV treatment. Additional trainings were held as new staff were hired at the MMTP. Training updates were also held with MMTP staff on a regular basis.

Standardization of Educational Materials

VHIP project staff gathered hepatitis educational materials from a variety of existing sources, including: the Hepatitis C Support Project, the CDC, the NYC Department of Health and Mental Hygiene, the Organization to Achieve Solutions in Substance Abuse (OASIS) and the NYSDOH. Focus groups were held with medical and non-medical staff from all three agencies so they could review the materials and provide feedback. A standardized set of educational materials were then selected for adoption based upon the information gathered at these groups. Project staff maintained a continual supply of these materials at the agencies. NYSDOH AIDS Institute staff also compiled a Hepatitis Education Packet (HEP) which included numerous fact sheets developed by the Hepatitis C Support Project and the CDC for use by all agencies. Overall, 42,688 fact sheets, brochures, and other hepatitis materials were distributed during the five year VHIP study period.

Evaluation Activities - Methods

Numerous evaluation activities were conducted during the VHIP study period, including: medical staff surveys (baseline and follow-up); non-medical staff surveys (baseline and follow-up); client surveys (baseline and follow-up); hepatitis awareness surveys; support group data; client and staff focus groups and qualitative interviews with medical and non-medical staff. The general methodology specific to each is described below.

Additional information is provided as necessary when the evaluation activities are discussed within the topic-specific areas of this report.

Medical and Non-Medical Staff Surveys

The purpose of the Medical and the Non-Medical Staff Surveys (Appendix A and Appendix B) was to establish a snapshot of staffs' understanding of hepatitis both at the start of the project (baseline) and again after the project had been running for a few years (follow-up). The Medical and Non-Medical Staff Surveys covered five topics: 1) demographics, 2) attitudes and beliefs regarding hepatitis, 3) knowledge of hepatitis, 4) practices related to hepatitis and HIV, and 5) self-reported proficiency in providing hepatitis and HIV services. The Non-Medical Staff Survey also assessed the non-medical staff's hepatitis and HIV related counseling and education practices in the past 12 months while the Medical Staff Survey assessed the medical staff's provision of HCV evaluation and treatment (either on-site or by referral) in the past 12 months.

Both the Medical Staff Survey and the Non-Medical Staff Survey were confidential self-administered surveys. The surveys took approximately 15 minutes to complete and participants received a \$10 gift card in exchange for their time. The baseline Medical Staff Survey was mailed to all 23 medical staff (i.e., physicians and physician assistants) at the MMTP clinics in May 2005 (the SEPs do not have medical providers on staff). A follow-up mailing was sent to non-responders. Baseline surveys were returned by 22 providers. One provider was on leave and ineligible to participate (response rate = 100.0%).

The baseline Non-Medical Staff Survey was completed by 165 of the 172 eligible staff who had attended one of eight viral hepatitis trainings held (response rate = 95.9%). This included all staff at the SEPs and all non-medical staff at the MMTP. Of note, nurses at the MMTP were grouped with the non-medical staff because their primary duty was dispensing methadone.

Both the Medical Staff Survey and the Non-Medical Staff Survey were re-administered approximately 3 years later. In addition to the original questions asked on the baseline survey, the follow-up Medical Staff Survey and the follow-up Non-Medical Staff Survey included additional questions regarding staff's awareness of VHIP. The follow-up Medical Staff Survey was completed by 14 of the 22 eligible medical staff at the MMTP clinics (response rate = 63.6%). Similarly, the follow-up Non-Medical Staff Survey was completed by 111 of the 165 non-medical staff (response rate = 67.3%). There was a smaller sample size at follow-up due to staff cuts and staff turnover. Only 50 of the 111 follow-up survey participants had originally completed a baseline survey (44 of the 67 MMTP follow-up survey respondents completed a baseline survey and just 6 of 44 SEP staff completing a follow-up survey also completed a baseline survey).

Client Surveys

The Client Survey (Appendix C) was an interviewer administered survey that was conducted between September 2005 and August 2006 (baseline) and between September 2007 and April 2008 (follow-up). The purpose of the Client Survey was to provide a representative picture of the impact of VHIP at the SEPs and the MMTP. The survey covered six topics: 1) demographics; 2) attitudes and beliefs regarding hepatitis; 3) knowledge and practices related to hepatitis and HIV; 4) experiences with hepatitis and HIV testing and hepatitis vaccination; 5) hepatitis and HIV risk; and 6) awareness of hepatitis and HIV marketing materials.

At both baseline and follow-up, the majority of the surveys were administered by the Hepatitis Educator at the MMTP clinics and by the Hepatitis Coordinators at the SEPs. The Hepatitis Coordinators and the Hepatitis Educator were trained by NYSDOH staff on how to administer the surveys and used an Interviewer Guide developed by NYSDOH staff for reference (Appendix D). Recruitment for the survey was both active (interviewers approached clients as they entered the site or were waiting for services) and passive (clients and other staff at the site referred clients to the interviewers). Interviews were conducted at multiple sites at each SEP and the MMTP. The surveys took approximately 20 minutes to complete and participants received a \$10 metrocard (subway fare). Clients who received any services (not limited to hepatitis services) at the SEPs or MMTP were eligible to complete the Client Survey. The Client Survey was administered in English at one SEP and in English and Spanish at the other SEP and the MMTP, which had a large proportion of clients who spoke Spanish only.

A total of 1,414 clients completed a baseline Client Survey. Staff from the MMTP interviewed 797 clients: approximately 200 in the intake clinic; 150 in each of two low HCV treatment clinics (where fewer HCV services were available at baseline) and 150 in each of two high HCV treatment clinics (where more HCV services were available at baseline). Staff at one of the SEPs (SEP-A) interviewed 338 clients and 279 clients were interviewed at the other SEP (SEP-B).

One thousand two hundred clients completed a follow-up Client Survey. Staff from the MMTP interviewed 600 clients: approximately 150 in the intake clinic; a total of 225 from the two low HCV treatment clinics (where fewer HCV services were available); and a total of 225 from the two high HCV treatment clinics (where more HCV services were available).¹ Staff at SEP-A interviewed 300 clients and 300 clients were interviewed at SEP-B.

¹It should be noted that the target sample size was reduced from 800 at baseline to 600 at follow-up at the MMTP because the originally conceived sampling stratum was unnecessary. Additional hepatitis services were now being offered at the low HCV MMTP clinic at follow-up.

Hepatitis Awareness Surveys

The purpose of the Hepatitis Awareness Survey (Appendix E) was to determine visual recognition of the Hepatitis Coordinator at the SEPs and the MMTP and knowledge and utilization of services provided by the Hepatitis Coordinator. To be eligible to take the survey, participants had to be a client of the SEP or the MMTP; they did not have to receive any related hepatitis services.

Surveys were read aloud to the participants and the interviewer wrote down the responses to the questions. The survey took between 3-5 minutes to complete. Spanish translation was available at SEP-B. At the conclusion of the survey, participants received the Hepatitis Coordinator's business card and a \$4.00 metrocard (subway fare) for their participation.

Two-hundred forty-seven surveys were completed. At the SEPs, surveys were administered to clients by NYSDOH staff between September 2006 and November 2006. A total of 147 SEP surveys were completed as follows: SEP-B's office site in September 2006 (n=42); SEP-A's office site in October 2006 (n=42); SEP-A's street-based site in October 2006 (n=17); and SEP-B's street-based site in November 2006 (n=46). Surveys were also administered to clients by the MMTP Hepatitis Educator at five of the MMTP clinic sites in January 2007. A total of 100 MMTP clients completed a survey (20 surveys were completed at each clinic).

Support Group Data

Hepatitis support groups (Appendix F) for clients were held at the SEPs and the MMTP. There were 153 support groups held at the SEPs between 2007 and April 2009. Overall, total client attendance at support groups was 2,361. This number includes clients who may have come to support groups multiple times. The mean group size was 15 and the median was 13. The support groups were facilitated by the Hepatitis Coordinator at each agency. In general, support groups were offered at least once a week for approximately one hour. Topics covered during the groups included: general HCV knowledge, HCV genotype and viral load, HCV treatment, viral hepatitis, co-infection, risk reduction, and liver biopsies.

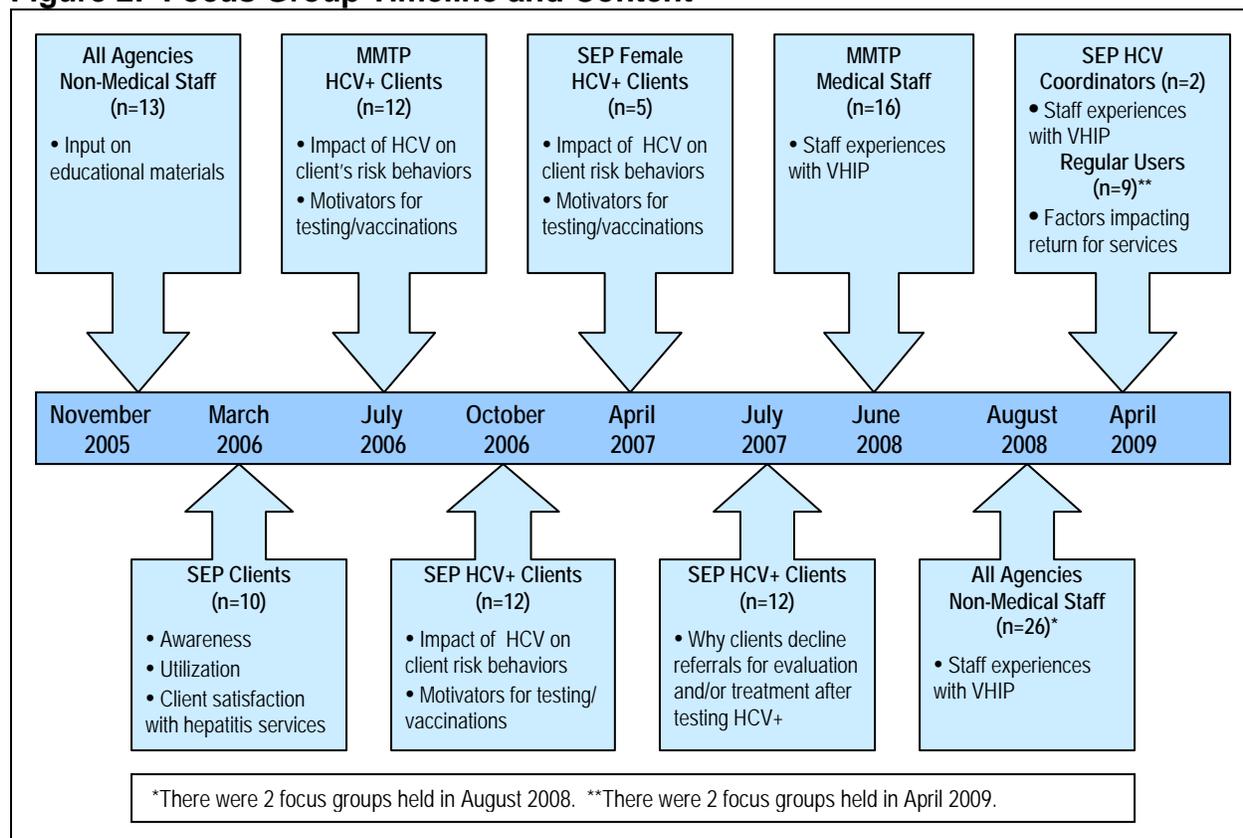
At the MMTP, there were a total of 319 hepatitis support groups held between January 2007 and April 2009. The support groups were active at four of the nine MMTP clinics. They were led by peer educators and facilitated by the Hepatitis Coordinator. The groups were offered at least once a week and were at least one hour in length. Overall, total client attendance at support groups was 2,592. Again, this number may include duplicate clients. The mean and median group size were 8. Topics included general HCV knowledge, HCV genotype and viral load, HCV treatment, viral hepatitis, co-infection, risk reduction, and liver biopsies.

Client Focus Groups/Qualitative Interviews with Medical and Non-Medical Staff

Focus groups with staff and clients were held throughout the project in order to gain a more in-depth understanding of participants' thoughts, opinions, knowledge and experiences related to hepatitis (Appendix G; Figure 2). There were seven focus groups held with clients (MMTP and/or SEP clients). Each client focus group was 1½ to 2 hours in length and audio-taped to facilitate data analysis. Two or three NYSDOH staff facilitated each of the groups and participants signed an IRB approved informed consent and completed a one-page demographic survey. Clients received \$30.00 gift cards (\$30.00 in metrocards/subway fare or \$30.00 in Dunkin Donuts gift cards).

There were three non-medical staff focus groups. Focus groups with staff were 1-2 hours long and audio-taped to facilitate data analysis. Two or three NYSDOH staff facilitated each group. Staff received a \$10.00 phone card or a \$20.00 Dunkin Donuts gift card, depending upon the length of the group.² In addition to the focus groups, qualitative interviews with medical staff and the Hepatitis Coordinators were held. Brief telephone interviews were conducted with medical staff from the MMTP and face-to-face interviews were conducted with the Hepatitis Coordinators. These staff received a \$10.00 Dunkin Donuts gift card for their time and participation. The dates and topics covered during the focus groups are detailed in Figure 2 below.

Figure 2: Focus Group Timeline and Content



²The appropriate incentive amount was determined based on the content and length of each group. Focus group participants attending the same group received identical incentives.