



## Cost of providing co-located hepatitis C treatment at a syringe service program exceeds potential reimbursement: Results from a clinical trial

Shashi N Kapadia<sup>a,b,\*</sup>, Benjamin J Eckhardt<sup>c</sup>, Jared A Leff<sup>b</sup>, Chunki Fong<sup>d</sup>,  
Pedro Mateu-Gelabert<sup>d</sup>, Kristen M Marks<sup>a</sup>, Yesenia Aponte-Melendez<sup>d,e</sup>, Bruce R Schackman<sup>b</sup>

<sup>a</sup> Weill Cornell Medicine, Division of Infectious Diseases, 1300 York Ave Rm A-421, New York, NY 10065, United States

<sup>b</sup> Weill Cornell Medicine, Department of Population Health Sciences, 425 E 61st Street, Ste 301, New York, NY 10065, United States

<sup>c</sup> Division of Infectious Diseases, New York University Grossman School of Medicine, 550 First Avenue, New York, NY 10016, United States

<sup>d</sup> CUNY Graduate School of Public Health and Health Policy, 55W 125th Street, New York, NY 10027, United States

<sup>e</sup> New York University Rory Meyers College of Nursing, 433 1st Avenue, New York, NY 10010, United States

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### ABSTRACT

**Background:** Co-located hepatitis C treatment at syringe service programs (SSP) is an emerging model of care for people who inject drugs (PWID). Implementation of these models can be informed by understanding the program costs.

**Methods:** We conducted an economic evaluation of a hepatitis C treatment intervention at an SSP in New York City implemented as one arm of a randomized trial from 2017 to 2021. Start-up and operating costs were determined from the treatment program's perspective using micro-costing and were compared to potential Medicaid reimbursement. We applied nationally representative unit costs and wage rates. Results are reported in 2020 USD.

**Results:** The treatment program was staffed by one physician and one care coordinator. Participants were offered hepatitis C clinical evaluation and treatment, a 45-min reinfection prevention education session, and additional care coordination as needed. The trial enrolled 84 PWID with hepatitis C in the intervention arm; 64 initiated treatment and 55 achieved sustained virological response. Start-up costs including training and equipment totaled \$4677. Overhead costs including rent, utilities and software totaled \$2229 per month. Clinical and care coordination totaled \$4867 per participant, of which \$3722 was care coordination. The total cost excluding startup was \$6035 per enrolled participant and \$7921 per treated participant; estimated potential reimbursement was \$628 per enrolled participant.

**Conclusion:** Our results provide insight to US-based SSPs seeking to provide co-located hepatitis C care and highlight the intensive care coordination services provided. Successful implementation likely requires funding sources beyond health insurers or substantial changes to insurance reimbursement for care coordination.

### 1. Background

Chronic hepatitis C virus (HCV) infection is increasing in people who inject drugs (PWID) in the United States (Holtzman et al., 2021). The innovation of direct acting antiviral (DAA) treatment, which is highly effective and well-tolerated, has brought the promise of universal treatment and eventually HCV elimination (National Academies of Sciences, Engineering, and Medicine et al., 2017). Treatment initiation rates in the United States have been low. A recent analysis from the US Centers for Disease Control and Prevention reported that only about a third of people with HCV in the US received treatment within one year of diagnosis, and this number was lower for those enrolled in Medicaid (Thompson et al., 2022). As a result

of the slow uptake of treatment, a recent modeling study shows that only 3 states are on track to meet HCV elimination goals by 2030 (Sulkowski et al., 2021). Major barriers to timely diagnosis and treatment include the stigma that PWID routinely experience in the healthcare system and logistical barriers to their accessing treatment providers. Additionally, policy-based barriers continue to be prevalent in the United States, including lack of insurance coverage, and prior authorization restrictions employed by insurance programs that restrict treatment access to people with advanced liver disease and/or require documentation of sobriety (Liao and Fischer, 2017). Treatment of HCV improves individual health and prevents future transmissions. Treatment of HCV in PWID is cost-effective and a critical pillar of HCV elimination plans (Barbosa et al., 2019).

\* Corresponding author at: Weill Cornell Medicine, Division of Infectious Diseases, 1300 York Ave Rm A-421, New York, NY 10065, United States.  
E-mail address: [shk9078@med.cornell.edu](mailto:shk9078@med.cornell.edu) (S.N. Kapadia).

Syringe service programs (SSPs), in the United States, are often community-based organizations that provide low-stigma and non-judgmental services to PWID. In New York City, there are 15 operational programs, which served over 18,000 PWID in 2018 alone (New York City Department of Health 2019; New York State Department of Health, 2022). While many SSPs operate outside of traditional healthcare settings, there is emerging interest in SSPs as sites for healthcare delivery (Behrends et al., 2022). These co-located models avoid the stigma that PWID face in traditional healthcare settings. Several studies have reported successful demonstrations of HCV treatment at SSPs, and this model has been shown to be cost-effective in one setting in the United Kingdom (Eckhardt et al., 2018; Schulkind et al., 2019; Ward et al., 2018).

We conducted an economic evaluation alongside a randomized controlled trial that evaluated co-located HCV treatment at an SSP in New York City compared to the standard of care of referral to community providers. The main trial outcome was sustained virological response at 12-weeks after treatment (SVR-12), synonymous with cure of HCV. This manuscript reports the estimated cost of the co-located HCV treatment intervention arm of the trial, which was more effective in achieving HCV cure than usual care (67% versus 22%) (Eckhardt et al., 2022). This study represents the first cost estimate of implementing an HCV treatment program at an SSP in the United States.

## 2. Methods

### 2.1. Description of intervention

The study site was an SSP in New York City that had already implemented an HCV antibody testing program. The trial was conducted from 2017 through 2021. Individuals were eligible if they had a positive HCV antibody test, were 18 years of age or older, reported injecting drugs in the past 90 days, and had not been engaged in hepatitis C care (defined as having 2 or more medical visits with a hepatitis C treatment provider in the past 6 months, by self-report). Participants were randomized if they had a positive RNA test. Participants who did not have a documented RNA test were provided RNA testing by intervention staff. Participants who were newly diagnosed by the intervention staff were still considered eligible for randomization. Participants determined to have decompensated cirrhosis were excluded from further trial participation and referred to liver disease specialists.

Participants were randomized to either the intervention arm (called “Accessible Care”) or to usual care. Accessible Care participants received an appointment with an on-site physician and a care coordinator employed by the study who were both located at the SSP. Appointments were scheduled by the study staff, but participants were also able to “walk-in” if needed. The on-site physician and care coordinator were not employed by the SSP, but instead were outside providers in a co-located care model. The care coordinator had a multifaceted role that included care coordination, administrative tasks such as scheduling patient appointments and verifying insurance status, and conducting phlebotomy for required blood testing. Accessible Care participants were provided HCV-related laboratory testing and treatment according to the current clinical standard of care, which included baseline assessment of liver disease using non-invasive serum biomarkers, HCV genotype, and testing for co-infections including HIV and hepatitis B (AASLD-IDS 2022). The intervention followed a flexible low-threshold care model, meaning participants were not penalized for deviations from the clinical protocol, such as missed appointments or lab work. Additional lab work or clinical visits were performed based on clinical need as determined by the study physician.

Accessible Care participants who were medically eligible and interested in treatment were offered treatment with a direct acting antiviral regimen, on-treatment laboratory monitoring, adherence support, and a re-infection prevention training session during treatment. Those partic-

ipants who completed treatment received an HCV RNA test at 12 weeks or more after treatment (SVR12) to ascertain HCV cure.

Participants randomized to usual care were directly referred to the HCV patient navigator employed by the SSP; data on costs associated with these participants are not analyzed here because they did not participate in the co-located treatment intervention.

### 2.2. Data collection and analysis

We used a micro-costing approach, the method preferred by the Second Panel on Cost-Effectiveness in Health and Medicine, to estimate program costs (Neumann et al., 2016). Micro-costing generates cost estimates from a “bottom-up” philosophy, attempting to enumerate and place a dollar value on each input used in the treatment of each participant. The analysis was conducted from the SSP perspective to reflect costs that would be applicable to similar SSPs that are considering implementing this treatment model. HCV medication costs were, therefore, not included, as these costs are borne by insurers and not the treatment program.

Table 1 summarizes labor time and unit cost data inputs. Physician and care coordinator times spent on specific clinical and administrative tasks were determined using a staff data collection form which the physician and care coordinator completed from October 2017 to September 2018 and were confirmed in interviews with these individuals. Task durations recorded included face to face visits, telephone calls, administrative work, phlebotomy, street outreach to participants, and obtaining prior authorization.

Individual participants’ utilization of these clinical and administrative resources, as well as laboratory testing, were determined from the electronic medical record that was used in the study. We analyzed these data on the number of services utilized for all participants enrolled in the trial who were randomized to the intervention arm from the first enrollment in July 2017 until October 2019 ( $n = 77$ ), 6-months before the onset of the COVID-19 pandemic, to reflect the average resource utilization during normal study operations; seven additional participants were offered the intervention prior to study close. We applied the resulting cost estimates to all intervention arm participants ( $n = 84$ ), in order to appropriately allocate costs to the entire population that was enrolled. HCV viremia was a study enrollment criterion, but many participants were referred before knowledge of their viral load and offered RNA testing by study staff. Therefore, we also included the costs of conducting HCV RNA testing for individuals who tested negative and therefore were not eligible for the trial. This reflects the clinical reality that some patients will be referred for HCV testing but deemed ineligible for HCV treatment. We included costs for only half of these negative HCV RNA tests representing the proportion of individuals that would have been eligible to receive the intervention if they had tested positive, with the other half being eligible to receive usual care.

A substantial portion of care coordination time was spent performing outreach and non-face-to-face communication such as text messages, and these activities could not be feasibly assigned to individual participants. Instead, we estimated weekly time spent on these activities from the data collection forms and interviews and divided the total by the average weekly caseload to estimate the cost of these services per participant. The caseload was calculated as the sum of the total number of weeks each of the 77 participants enrolled before October 2019 who were either in pre-treatment or on-treatment (‘active’ participants), when most care coordination activities took place. This was divided by the study duration in weeks through October 2019, to determine an average caseload of active participants per week. Visits that were conducted for research purposes only are not included in the cost estimates.

Labor time was converted into a dollar values using the 2020 US national wage and fringe rates from the Bureau of Labor Statistics (US Bureau of Labor Statistics 2020a, 2020b). Laboratory testing unit costs were from the US Medicare Fee Schedule (Centers for Medicare and Medicaid Services, 2020). Phlebotomy costs

**Table 1**  
Labor and cost inputs.

Resource	Value	Source
<b>Labor Time, Hours</b>		
Physician initial visit (per visit)	0.5	Staff data collection forms
Physician follow-up visit (per visit)	0.25	Staff data collection forms
Physician administrative (per week)	2	Staff data collection forms
Phlebotomy (per lab test)	0.33	Staff data collection forms
Reinfection prevention (per visit)	0.75	Staff data collection forms
Appointment scheduling (per week <sup>d</sup> )	7	Staff data collection forms
Care team coordination (per week <sup>d</sup> )	4	Staff data collection forms
Follow-up outreach (per week <sup>d</sup> )	8	Staff data collection forms
Other care coordination (per week <sup>d</sup> )	22.75	Staff data collection forms
<b>Unit Costs, 2020 USD</b>		
<b>Clinical and Care Coordination Costs</b>		
Physician time (per hour <sup>b</sup> )	145	(US Bureau of Labor Statistics, 2020a, 2020b)
Care coordinator time (per hour <sup>b</sup> )	43	(US Bureau of Labor Statistics, 2020a, 2020b)
HCV RNA test	38	(Centers for Medicare & Medicaid Services, 2020)
<b>Monthly Overhead Costs</b>		
Rent	2000	Study records
Cell phone usage	100	Study records
Electronic medical record	99	Study records
Electronic Fax	30	Study records
<b>Start-Up Costs</b>		
<b>Equipment</b>		
Centrifuge <sup>c</sup>	693	(Medical Device Depot, 2021a)
Desktop Computer	636	Study records
Printer <sup>c</sup>	198	(Amazon.com 2021a)
Safe <sup>c</sup>	149	(Amazon.com 2021b)
Exam Table <sup>c</sup>	812	(Medical Device Depot, 2021b)
Filing Cabinet(s)	364	Study records
Cell Phone purchase	530	Study records
<b>Training and Certification</b>		
Phlebotomy Training	999	Study records
CLIA Certificate	297	Study records

HCV = hepatitis C virus; USD = US dollars; CLIA = Clinical Laboratory Improvement Amendments.

<sup>a</sup> assumes average weekly caseload of 14 participants observed in trial<sup>b</sup> includes fringe benefits at 30% of total compensation<sup>c</sup> donated items, costs estimated from market price.

were additionally valued as the time spent on phlebotomy, with the assumption that the study care coordinator or an equivalent person would normally conduct all phlebotomy, although some phlebotomy during the trial was conducted by the study physician based on availability. Costs for material items, space, communications, and software were determined from actual payments. When the study utilized donated items, we assigned market prices of the purchased item, as noted in Table 1.

We separated costs into 3 broad categories: 1) start-up costs, which are one-time fixed costs needed to start the program, 2) clinical and care coordination (variable) costs, which depend on the number of participants, and 3) monthly overhead (time-dependent) costs, which are incurred at a fixed rate over time regardless of participant volume.

We also calculated the cost of the physician's down-time, excluding clinical and administrative activities, because the treatment model depended on the physician being available on-site for "walk-in" appointments. Down-time was calculated as the difference between the total number of hours worked on site and the time spent on clinical visits and administrative activities. We report this cost separately from clinical and administrative costs, because the amount of down-time when the model is implemented at an SSP will depend on what other unrelated activities the clinical provider can accomplish while on site and the number of "walk in" appointments that occur.

Data collected from participants, the physician, and the care coordinator were recorded in REDCap, and quantitative analyses were conducted in Microsoft Excel (Harris et al., 2019). Costs are reported in 2020 USD and results are rounded to nearest \$1.

To estimate the costs that would be eligible for Medicaid reimbursement, we assumed that both initial and follow-up medical visits were reimbursed as moderate complexity medical visits (CPT codes 99,204 and 99,214), and that laboratory test costs were reimbursed based on

the laboratory test reimbursement code. Reimbursement rates were obtained from the New York State Medicaid Fee Schedule for 2021, using the non-facility fee.

### 3. Results

The program enrolled 84 participants who were HCV RNA positive and randomized to the Accessible Care intervention; two of these participants were subsequently excluded after medical evaluation. Sixty-four of the participants randomized to Accessible Care (76%) initiated treatment and 55 (65%) achieved SVR12. A total of 84 participants were screened negative for HCV RNA and not randomized to either arm (costs are reported for 42 of these participants).

#### Start-up costs

Total start-up costs were \$4677 including \$3678 for equipment to create a clinical infrastructure in the syringe service program. The remaining \$999 was for the care coordinator to receive phlebotomy training to function as a phlebotomist, of which \$60 was the cost of enrolling in the training program and the remainder the cost of the care-coordinator's time.

#### Clinical and care coordination costs

Participants who initiated treatment had on average 2.7 medical visits and 4 HCV RNA tests after their original HCV RNA screening. Participants who did not initiate treatment had an average of 0.5 medical visits and 1 HCV RNA test after their initial HCV RNA screening. The

**Table 2**  
Summary of costs per-participant (2020 USD).

Cost-type	Cost per enrolled participant (n = 84)	Cost per treated participant (n = 64)
Physician Visits	109	143
Physician Administrative Activities	471	618
Laboratory Costs	565	741
Care Coordination Costs	3722	4886
Overhead Costs	1168	1532
<b>Total</b>	<b>6035</b>	<b>7921</b>

Note, excludes the down-time physician cost amounted to \$3030 per enrolled participant and \$3977 per treated participant.

study physician cost an average of \$109 per participant on medical visits (an average of 45 min) and \$471 per participant on administrative activities (an average of 3.5 h). The additional cost of HCV RNA screening for 42 participants who were identified as RNA negative is included in laboratory cost. Care coordination amounted to an average of 3 h per active participant per week. Of participants randomized to the intervention arm, 72% attended a reinfection training session. Total clinical and care coordination costs were \$4867 per participant enrolled in the intervention; \$3722 (76%) of these costs were for care coordination and the remainder were for physician visits, additional physician time spent on administrative activities, and the costs of laboratory testing (Table 2).

#### Overhead costs

Monthly overhead costs totaled \$2229 including \$2000 for rent and \$229 for utilities and electronic health record software. The overhead cost per enrolled participant was \$1168.

#### Cost of physician's down-time

The study physician was at the clinical site for 12 h per week. Given an average weekly caseload of 14 active (pre-treatment or on-treatment) participants per week, and an average duration of 29 weeks in the active phase, this results in a total of 25 h on-site per participant, or \$3610. After subtracting the cost of the time spent on clinical visits (\$109) and administrative activities (\$471), the down-time cost amounted to \$3030 per enrolled participant and \$3977 per treated participant.

#### Comparison of total costs and potential reimbursement

Excluding start-up costs and the cost of the physician's down-time, the total program cost was \$6035 per enrolled participant randomized to Accessible Care (n = 84). This amounted to \$7921 per participant initiating treatment (n = 64), and \$9217 per SVR12 achieved (n = 55). Care coordination amounted to approximately 60% of the total costs (Table 2). The anticipated Medicaid reimbursement was \$628 per enrolled participant (\$147 for medical visits, and \$481 for laboratory costs), resulting in \$5407 in unreimbursed costs per enrolled participant, which increased to \$8437 if clinician down-time was included.

#### Discussion

We report the program costs of a novel intervention providing co-located HCV treatment and care coordination at an SSP in New York City. Multiple studies describe successful real-world outcomes of providing co-located care for HCV at SSPs, including several in New York City (Eckhardt, 2016; Miller et al., 2019; Muncan et al., 2021; Schulkind et al., 2019; Winetsky et al., 2020). While data collected from PWID show a high level of acceptability for this intervention, investments in staff and equipment are necessary to build and maintain such a program. SSPs have varying levels of medical infrastructure and frequently do not have the administrative capacity to bill for medical services. Indeed, each of the studies cited and the current study have used funding

for HCV treatment and care coordination from health departments or research grants to deliver the intervention.

In this study, half of intervention costs were related to care coordination. The amount of care coordination costs may be overstated, however, because we assumed that the care coordinator was always working at a full capacity caseload. These results can be compared to other, similar integrated care interventions for HCV. In a clinical trial evaluating a 6-month care facilitation intervention for HIV/HCV co-infected individuals with substance use disorder, the average cost of care facilitation was nearly \$4000 per participant which was higher than our care coordination cost estimate of approximately \$3200 per enrolled participant (Gutkind et al., 2022). In contrast, an HCV care coordination intervention based at primary care sites in New York City reported lower average care coordination costs of between \$400–500 per participant (Behrends et al., 2019). The differences among these costs likely stem from differences in the intensity of care coordination service needs of the underlying populations. Care coordination costs are not traditionally covered by insurance payments and this is an area in which supplemental funding or new insurance reimbursement approaches are needed to support this clinical intervention. Even where care coordination insurance payments currently exist, such as in Medicare, the amount of reimbursement is well below the costs we identified for the population served in this study, and the professional training of the care coordinators delivering these services may not be what is required for reimbursement (Fluegge et al., 2019; O'Malley et al., 2017).

Medicaid reimbursement was better matched to the per participant cost of physician visits (\$145 versus \$100 cost) and laboratory visits (\$480 versus \$510 cost), although these reimbursements did not cover substantial physician administrative time costs and overhead costs. The intervention also relied upon a “drop-in” model, where the study physician was available on site at the SSP regardless of scheduled medical visits. Participants who visited the SSP or met with the care coordinator may also have had informal interactions with the physician outside of the scheduled medical visits and not included as clinical costs. This increased physician availability may have contributed substantially to the study's successful HCV treatment outcomes. If SSPs opt for this model and cannot fill clinician down-time with other reimbursable services, such as telemedicine visits, they would require supplemental funding almost equal to that required to cover unreimbursed care coordination services.

There are opportunities to increase efficiencies in care delivery compared to what was seen in this clinical trial. While our program was physically co-located in the SSP, it was not administratively integrated, and personnel were employees of a health care organization rather than the SSP. It is possible that the care coordination component of the intervention could be more efficiently provided by SSP staff, who may already be familiar with clients' individual needs. Likewise, our program was a standalone HCV treatment program that did not provide other medical or behavioral health services. Integrating HCV treatment into an existing clinical program, such as a co-located buprenorphine clinic, could result in a lower incremental cost by spreading overhead costs across a larger patient panel and reducing clinician down-time (Fox et al., 2015; Hood et al., 2020). Finally, all medical visits in this

study were in-person, but telemedicine provides an opportunity for HCV treatment using less clinical infrastructure and avoiding down-time, although perhaps at the risk of less participant engagement (Yeo et al., 2021).

There are several limitations to this analysis. First, we report data from a program operating at a single, urban SSP site. The resources used to conduct the intervention and their unit costs may differ for SSPs in different settings, such as those in rural areas. That site was already conducting HCV antibody testing and patient navigation, which is not the case at many SSPs (Behrends et al., 2018). This SSP also had available the physical space required to implement a clinical program, which is not expected to be the case at all programs. Additionally, data on the utilization of care coordinator outreach and text-messages were not available at the participant level, so we could not examine differences between “high” and “low” utilizers of care coordination services. Finally, we did not conduct an incremental cost-effectiveness analysis of this intervention because we did not have the ability to estimate the cost of usual care from study records. However, the intervention was highly effective in achieving HCV cure compared to usual care. Taking into account future benefits and costs, long-term cost-effectiveness has been demonstrated for HCV treatment programs in a variety of settings (Brain et al., 2020; Gutkind et al., 2020; Palmer et al., 2021). Relatedly, we did not incorporate the cost of HCV medication, as this cost was incurred by health insurance programs and not by the SSP implementing the clinical program. Medications to treat HCV have been demonstrated to be cost-effective in multiple studies (Moreno et al., 2017; Najafzadeh et al., 2015; Stevens et al., 2020; Zhang et al., 2015). Implementing HCV treatment programs for PWID may require addressing remaining barriers to health insurance coverage of these medications in some states.

In conclusion, co-located HCV treatment at an SSP coupled with care coordination was able to effectively engage PWID in HCV care. The resources needed to achieve this engagement were largely one-time investments related to creating a clinical infrastructure in the SSP, resources to provide care coordination for participants receiving treatment, clinician costs for administrative time and down-time, and overhead costs. SSPs adopting this HCV treatment model that have the capability to bill for medical services or partner with a medical provider that has this capability may be able to receive some reimbursement for these costs. Current health insurance reimbursement models, however, seem unlikely to cover the substantial cost of care coordination for this population so SSPs will need to obtain additional funding sources to successfully implement the model, or couple HCV care coordination with other services to help offset these costs.

## Contributors

Dr. Kapadia was responsible for conceptualization, methodology, data collection and analysis, and writing of the original draft. Drs. Eckhardt, Mateu-Gelabert, and Marks contributed to conceptualization of the study. Dr. Aponte-Melendez and Mr Fong contributed to data collection. Dr. Schackman and Mr. Leff contributed to conceptualization and methodology. All authors reviewed and edited the manuscript and approved of the final version.

## Conflicts of Interest

Drs Kapadia, Eckhardt and Marks report research grants paid to their institutions from Gilead Sciences Inc, unrelated to the current study. Dr Aponte-Melendez reports research grants paid to their institution from Abbvie Inc, unrelated to the current study. All other authors report no potential conflicts of interest.

## CRedit authorship contribution statement

**Shashi N Kapadia:** Conceptualization, Methodology, Data curation, Writing – original draft, Writing – review & editing. **Benjamin J Eckhardt:** Conceptualization, Writing – review & editing. **Jared A Leff:** Writing – review & editing. **Chunki Fong:** Writing – review & editing. **Pedro Mateu-Gelabert:** Writing – review & editing. **Kristen M Marks:** Writing – review & editing. **Yesenia Aponte-Melendez:** Writing – review & editing. **Bruce R Schackman:** Conceptualization, Methodology, Writing – review & editing.

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