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Evaluation of a hepatitis C clinical care coordination programme's effect on treatment initiation and cure: A surveillance-based propensity score matching approach

R. Deming¹ | M. M. Ford¹ | M. S. Moore¹ | S. Lim¹ | P. Perumalswami² | J. Weiss³ | B. Wyatt² | S. Shukla⁴ | A. Litwin⁴ | S. Reynoso⁴ | F. Laraque¹

Correspondence

Regan Deming, New York City Department of Health and Mental Hygiene, Long Island City, NY, USA.

Email: rdeming@health.nyc.gov

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Abstract

Hepatitis C (HCV) is a viral infection that if left untreated can severely damage the liver. Project INSPIRE was a 3 year HCV care coordination programme in New York City (NYC) that aimed to address barriers to treatment initiation and cure by providing patients with supportive services and health promotion. We examined whether enrolment in Project INSPIRE was associated with differences in HCV treatment and cure compared with a demographically similar group not enrolled in the programme. INSPIRE participants in 2015 were matched with a cohort of HCV-infected persons identified in the NYC surveillance registry, using full optimal matching on propensity scores and stratified by INSPIRE enrolment status. Conditional logistic regression was used to assess group differences in the two treatment outcomes. Two follow-up sensitivity analyses using individual pair-matched sets and the full unadjusted cohort were also conducted. Treatment was initiated by 72% (790/1130) of INSPIRE participants and 36% (11 960/32 819) of study-eligible controls. Among initiators, 65% (514/790) of INSPIRE participants compared with 47% (5641/11 960) of controls achieved cure. In the matched analysis, enrolment in INSPIRE increased the odds of treatment initiation (OR: 5.25, 95% CI: 4.47-6.17) and cure (OR: 2.52, 95% CI: 2.00-3.16). Results from the sensitivity analyses showed agreement with the results from the full optimal match. Participation in the HCV care coordination programme significantly increased the probability of treatment initiation and cure, demonstrating that care coordination for HCV-infected individuals improves treatment outcomes.

KEYWORDS

care coordination, hepatitis C, New York City, propensity score matching, sustained virological response

1 | INTRODUCTION

Hepatitis C virus (HCV) is a viral infection that when left untreated can progress to liver damage, cirrhosis, and premature death. An estimated 2-4 million people in the United States (US) are chronically infected with HCV, with most unaware of their infection status. In

New York City (NYC), an estimated 146 500 people are infected with HCV.³ New HCV therapies, termed direct-acting antivirals (DAAs), have led to considerable improvements in achieving cure or sustained virological response (SVR).^{4,5} The availability of DAAs transformed the HCV treatment landscape; however, cost and access barriers to care and treatment remain.⁶

¹New York City Department of Health and Mental Hygiene, Long Island City, NY, USA

²Division of Liver Diseases, Icahn School of Medicine at Mount Sinai, New York, NY, USA

³Division of General Internal Medicine, Icahn School of Medicine at Mount Sinai, New York, NY, USA

⁴Montefiore Medical Center, Bronx, NY, USA

HCV disproportionally affects persons of colour and socioeconomically disadvantaged persons.⁷ Injection drug use (IDU) is the most commonly reported risk factor for HCV infection, while the highest prevalence of infection is among persons born between 1945 and 1965 ("baby boomers"). 8,9 Restrictive policies, such as requiring prior authorization or only treating those with advanced liver fibrosis, set by health insurance companies in response to the high cost of medications, limit access to HCV treatment. 10 Though guidelines exist, 11 there is no standard policy across health insurers, including Medicaid, to determine who qualifies for HCV treatment. 10,12 Additionally, Medicaid programmes often have restrictions on the type of provider who can prescribe HCV medication to patients, further limiting treatment access. 13 Navigating these complicated policies can be burdensome, especially for those struggling with substance misuse, HIV coinfection, diabetes, psychosocial conditions, financial insecurities, and/or unstable housing. 10,14

Care coordination has been found to reduce barriers to care and improve patient outcomes, particularly for hard-to-engage and hard-to-treat populations. Project INSPIRE was a comprehensive, evidence-informed care coordination intervention designed by the NYC Department of Health and Mental Hygiene (DOHMH) to increase access to HCV care, treatment, and cure for persons chronically infected with HCV in NYC. The intervention used an innovative care coordination model, which included health promotion, medication adherence support, coaching, and integrated HCV clinical care to improve HCV outcomes and overall health and wellbeing. The programme was funded by the Centers for Medicaid and Medicare Services (CMS) through a Health Care Innovation Award.

To determine if the programme increased treatment access and cure relative to those who were not enrolled in Project INSPIRE, we selected a propensity-score-matched control group of HCV-infected individuals identified through routine surveillance and assessed the odds of treatment initiation and SVR between first-year Project INSPIRE enrollees and controls.

2 | METHODS

2.1 | Project INSPIRE

INSPIRE was a 3-year HCV care coordination programme, enrolling Medicare and/or Medicaid beneficiaries at least 18 years of age. Participants were seen at 25 clinical sites belonging to two major health care systems, located in two neighbourhoods with the highest rates of HCV diagnoses in NYC. ¹⁸ Residents in these neighbourhoods experience significant health disparities, including high rates of poverty and limited access to health care. ^{19,20}

Upon enrolment into INSPIRE, participants were assigned a care coordinator who provided support navigating the health care system, accompaniment to medical appointments, medication adherence counselling, health promotion modules, and self-sufficiency coaching. Comprehensive intake assessments conducted by the care coordinators were used to tailor support and treatment plans to the needs of the patient.

2.2 | Data sources

Two data sources were used for this evaluation: the NYC DOHMH HCV surveillance registry and the INSPIRE programme database. As required by the NYC health Code, NYC DOHMH receives daily electronic laboratory reports for all positive HCV antibody tests and all HCV RNA tests (both positive and negative) for NYC residents.²¹

The INSPIRE clinical sites submitted data electronically to NYC DOHMH each month. These datasets included patient identifiers, demographical information, HCV care site, and current treatment initiation, completion and cure status. We identified INSPIRE participants in the surveillance database using patients' first and last names and dates of birth.

2.3 | Defining the cohorts

Eligibility as an **INSPIRE participant** included enrolment in Project INSPIRE in 2015 and having a positive RNA status in the surveillance database at the time of enrolment. Although infrequent, participants who enrolled into INSPIRE while HCV-negative were subsequently discharged from the programme.

Without a designated control group as part of Project INSPIRE and no other known comprehensive care coordination programmes for HCV infection operating in NYC during the study period, we created a control group using the city-wide surveillance registry. To be eligible for the control group, individuals must have been 18 years old or older on December 1, 2014, not known to have been recruited or enrolled in Project INSPIRE, and have a reported positive HCV RNA result between December 1, 2014 and January 31, 2016. Control group eligibility was not restricted to patients presenting for care at the same clinical sites as INSPIRE patients to increase power and extend generalizability to all HCV-positive patients in NYC. Finally, we excluded any individuals in INSPIRE or the control group whose most recently reported address was associated with a jail, correctional institution, or location outside of NYC. There were 1112 resulting exclusions, including 21 INSPIRE participants and 1091 potential controls.

2.3.1 | Ethics statement

The Project INSPIRE protocol was approved by the Institutional Review Board (IRB) at DOHMH and each clinical partner organization. Informed consent was obtained from each enrollee either verbally or in writing, based on requirements of each respective IRB. This analysis was reviewed by the DOHMH IRB and determined to be non-human subjects' research.

2.4 | Generating the matched cohort

We used propensity score matching to create a study population of INSPIRE enrollees and comparable individuals from the HCV surveillance registry to compare treatment and cure outcomes. Propensity

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score matching helps establish balance in covariates between the two groups in the absence of randomization. 22

2.4.1 | Covariates

Propensity scores were calculated to determine the odds of enrolment in INSPIRE using five variables available in the surveillance registry and associated with treatment and cure of HCV.²³ These included neighbourhood poverty level (percent of residents in the census tract associated with the most recent address living below the federal poverty level, per the American Community Survey 2011-2015²⁴), sex, number of years since HCV diagnosis (date of first HCV report in the registry), age, and number of days between study entry date and January 31, 2017. Study entry date was defined as the date of programme enrolment for INSPIRE participants and the date of the first reported positive RNA test between December 1, 2014 and January 31, 2016 for matched controls.

As an additional variable for stratification during propensity score matching, individuals were assigned to the neighbourhood tabulation area (NTA) associated with their most recent address. NTAs are geographical units roughly corresponding to historical neighbourhoods in NYC, and are more homogenous in terms of socioeconomic status and race/ethnicity compared with larger geographical boundaries.²⁵ NTA assignment requires a geocodable address; individuals with non-geocodable addresses were assigned a special 'missing' value for NTA.

2.4.2 | Propensity score matching

A propensity score was calculated for each study participant using logistic regression to model the odds of Project INSPIRE enrolment using the above covariates. Missing values were present for sex and neighbourhood poverty for some individuals; we assumed missingness to be unrelated to unmeasured characteristics not used to create the propensity score, and a special 'missing' value for the variable was created to include such persons in the analysis. ^{26,27} Using the assigned propensity score, we conducted optimal full matching to create matched sets of multiple INSPIRE and control individuals based on propensity score distance. Sets comprised of many-to-many were further split into smaller groups, each with the smaller within-group distance, known as the "optimal" match, until all matches computed were one-to-many sets.²⁷ As a sensitivity analysis, two alternative cohorts were created, using individual pair matching or unmatched controls. Individual pair matching used a 'greedy' matching approach, where one INSPIRE enrollee and one control with the closest propensity score were matched and then removed from the dataset, proceeding until all possible matches were made. This approach can cause competition among certain controls, which is not the case in full optimal matching, where one INSPIRE enrollee can have several matched controls.²⁸

Matching was conducted with the R package Optmach (RStudio: Integrated Development Environment for R, RStudio Inc. Boston MA, version 1.0.143), applying several constraints to optimize balance

and decrease computational burden. For maximum efficiency, a threshold limit of 1:5 (INSPIRE-to-controls) was applied. A caliper of 0.25 times the propensity score standard deviation was applied as the maximum allowable matching distance. Force matching on study entry date (with a Euclidean distance caliper of ±45 days) was included in an effort to account for changes that increased access to treatment during the study period, such as the release of new medications and the easing of some New York State Medicaid restrictions. Proce matching around the study entry date meant INSPIRE enrollees shared similar follow-up times to their matched controls. Finally, force matching by NTA controlled for possible differences in geospatial access to HCV care.

Balance after full optimal matching and individual pair matching was evaluated using the RITools package in R. The standardized difference for each covariate between INSPIRE enrollees versus controls was compared for the full optimal match, individual pairmatched sets, and -unmatched dataset. A standardized difference of <0.1 between INSPIRE and non-INSPIRE individuals was considered negligible, and balance was assumed to be met. 31-33

2.5 | Descriptive analyses and logistic regression models

We tested for socio-demographical differences by enrolment status in INSPIRE among the entire study-eligible population prior to matching. We used Pearson's χ^2 tests for the categorical variables. Because continuous variables were not normally distributed, we compared socio-demographical differences using Mann-Whitney-Wilcoxon tests. Using conditional logistic regression, we modelled the odds of initiating HCV treatment and achieving cure by INSPIRE enrolment status for full optimal matched sets.

Outcome Variables: We assessed treatment initiation and SVR using DOHMH-developed and validated algorithms that use reported positive and negative RNA tests to identify treatment and cure. Treatment initiation was defined as having any past high positive (viral load ≥1000 IU/mL) RNA test result followed by a negative RNA test result in the surveillance registry. Cure was defined relative to the date of an individual's first negative, indeterminate (positive, below the limit of detection), or low-positive (viral load <1000 IU/mL) RNA test result after their most recent high-positive RNA result. After this date, they must have at least one additional negative RNA test performed at least 4 months later and no subsequent high positive RNA results to be considered cured. S4

Exposure Variable: Enrolment in INSPIRE anytime in 2015 was the primary exposure variable. All individuals were given one year from study entry date to achieve treatment initiation and cure.

Models built using propensity score matched sets included exposure status as the only covariate. For the sensitivity analysis, similarly built conditional logistic regression models were used for the individually pair-matched sets, and an unconditional multivariable logistic regression model with an indicator for INSPIRE enrolment status was used for the unmatched cohort, which also included the covariates used to construct the propensity score. Odds ratios

(OR) and 95% confidence intervals (CI) for the two outcomes of interest were computed. Summary statistics and logistic regression were conducted using RStudio (RStudio: Integrated Development Environment for R, RStudio Inc. Boston MA version 1.0.143).

3 | RESULTS

During 2015, 1239 individuals were enrolled in Project INSPIRE, and 1103 (89%) met the study eligibility requirements (Figure 1). From the surveillance registry, 32 819 eligible matched controls were identified. There were several statistically significant differences between INSPIRE enrollees and eligible controls prior to matching. Those enrolled in INSPIRE had been diagnosed with HCV for longer (8 vs. 7 years), were less likely to be male (61% vs. 63%), were more likely to live in very high poverty neighbourhoods (≥30% of residents live below the poverty line; 57% vs. 36%) and live in the Bronx (67% vs. 28%) (Table 1).

Full optimal matching on propensity score resulted in 1098 matched sets of enrollees and controls; 21% were 1:1 matches, while other sets included between 2 and 5 controls. Full optimal matching reduced or removed differences in covariate distributions (Table 2). Imbalance by borough was addressed by stratification by NTA rather than by propensity score matching.

INSPIRE enrollees were more likely to initiate treatment (72% vs. 36%) and achieve SVR (65% vs. 47%) during 1 year of follow-up compared with all study-eligible controls (Table 3). The conditional logistic regression model indicated that those who initiated treatment had more than five times the odds of being an INSPIRE enrollee compared with matched controls (72% vs. 34%; OR = 5.25, 95% CI: 4.47-6.17). Of the 2168 patients identified as initiating HCV

treatment, those who achieved SVR had over two-times the odds of being an INSPIRE enrollee compared with controls (65% vs. 45%; OR = 2.52, 95% CI: 2.00-3.16). The sensitivity analyses confirmed the robustness of the optimal full match findings. Probability of treatment initiation was consistent with the full optimal match in the individual pair match (OR = 5.12, 95% CI: 4.12-6.36) and in the unmatched analysis (OR = 5.05, 95% CI: 4.43-5.79). Similar confirmation was found with the probability of SVR in the individual pair match (OR = 2.37, 95% CI: 1.66-3.39) and the unmatched analysis (OR = 2.49, 95% CI: 2.14-2.91).

4 | DISCUSSION

To our knowledge, INSPIRE was the largest and most comprehensive HCV care coordination programme operating in NYC and across the US at the time of the intervention. These results demonstrate that the INSPIRE care coordination intervention was associated with a significantly higher probability of HCV treatment initiation and SVR when compared with a demographically similar cohort of HCVpositive NYC residents. The full optimal matched model and the two models used in the sensitivity analysis confirmed this with similar relative rates of each outcome. These positive programme outcomes add to previously published literature that suggest HCV linkage to care and care coordination programmes lead to improved treatment outcome rates³⁵⁻³⁷ although to our knowledge INSPIRE is the first HCV care coordination model of its size to not only link patients to care but follow them through the care continuum to cure. While previous analyses of INSPIRE data demonstrated the programme's successes with achieving high treatment and cure rates (unpublished data), we were unable to determine effectiveness due to the lack of

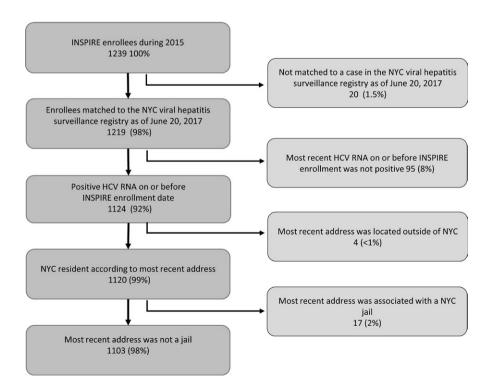


FIGURE 1 Flow chart of Project INSPIRE enrollee eligibility criteria for analysis

TABLE 1 Descriptive characteristics of Project INSPIRE enrollees and unenrolled HCV-positive NYC residents

	INSPIRE Enrollees N = 1103 N (%)	Unenrolled HCV-positive NYC residents N = 32 819 N (%)	P-value
Sex			
Female	419 (37.9)	11 933 (36.4)	0.014*
Male	675 (61.2)	20 776 (63.3)	
Missing	9 (0.8)	110 (0.3)	
Age (years)			
Mean	57.3	56.8	0.82
Median (IQR)	58.1 [51.7-63.8]	58.4 [50.5-64.2]	
New York City B	orough of Residence		
Manhattan	203 (18.4)	7478 (22.8)	<.0001
Bronx	736 (66.7)	9196 (28.0)	
Brooklyn	97 (8.8)	9239 (28.2)	
Queens	52 (4.7)	5363 (16.3)	
Staten Island	15 (1.4)	1543 (4.7)	
Neighborhood P	overty Level		
0 to <5% (low poverty area)	17 (1.5)	1213 (3.7)	<.0001
5 to <10%	71 (6.4)	3520 (10.7)	
10 to < 20%	123 (11.2)	7004 (21.3)	
20 to < 30%	207 (18.8)	6929 (21.1)	
30 to <40%	319 (28.9)	5679 (17.3)	
40 to < 100% (highest poverty areas)	306 (27.7)	6109 (18.6)	
Missing	60 (5.4)	2365 (7.2)	
Days from Study	Entry Date to January	1, 2017	
Mean	570	627	<.0001
Median (IQR)	568 [491-649]	649 [540-726]	
Years since HCV	diagnosis		
Mean	8.6	7.8	<.0001
Median (IQR)	8.5 [5.1-11.8]	7.9 [3.4-11.7]	

^{*}Statistically significant at the 0.05 alpha level; IQR, interquartile ratio.

a control group. This study was able to define a control group, allowing us to establish the effectiveness of INSPIRE at achieving these outcomes compared with usual or no care.

Access to HCV treatment is a key component of the NYC HCV elimination strategy.³⁸ This analysis provides evidence that the INSPIRE model, which targeted low-income neighbourhoods with high rates of HCV diagnoses, can be successfully applied to hard-to-treat individuals. Future programmes targeting demographically similar populations should use a care coordination model like INSPIRE to achieve long-term goals. However, securing funding for such a programme is a substantial barrier, and while federally funded care coordination programmes exist (e.g., the Ryan White HIV/AIDS Program), resources are not extensively available for HCV.

The SVR rates observed in this study are much lower than the 90-95% seen during clinical trials.^{4,7} This is not surprising given the

complex needs and challenges faced by HCV-positive individuals. However, the reliance on laboratory testing to confirm SVR might additionally explain some of the discrepancy. Clinical trial patients are often provided financial incentives to complete follow-up visits, while most patients in real-world settings do not receive compensation, and so might have less incentive to return for SVR confirmation. In this study, there might be cases of SVR that were not laboratory-confirmed and therefore not classified as SVR, both in INSPIRE and city-wide.

A strength of this analysis is that we used a novel strategy of combining HCV programme and surveillance data for evaluation purposes. Similar analyses have been conducted using HIV surveillance data to evaluate HIV programmes,³⁹ but to our knowledge, this is the first evaluation to examine the impact of HCV care coordination using a demographically similar comparison group reported to a city-wide surveillance registry. This novel method offers a relatively

TABLE 2 Standardized differences for covariates used to estimate propensity scores across three cohort definitions

	Unadjusted cohort (1103 INSPIRE enrollees, 32 819 controls)		Paired matched cohort (1096 INSPIRE enrollees, 1096 controls)		Full optimal matched cohort (1098 INSPIRE enrollees, 4094 controls)	
Covariate	Standardized differences	Z score	Standardized Differences	Z score	Standardized differences	Z score
Sex	0.34	0.11**	0.0024	0.19	-0.016	-1.5
Age	0.036	1.2	-0.0059	-0.16	-0.0035	-0.11
Neighborhood poverty level	0.15	5.0**	-0.069	-2.3*	-0.0094	-0.37
Days from study entry date to January 1, 2017	-0.49	-0.16**	-0.023	-3.3**	-0.022	-3.3**
Years since HCV diagnosis	-0.024	-0.77	0.013	0.31	-0.015	-0.41

^{*}Statistically significant at the 0.05 alpha level.

TABLE 3 HCV treatment initiation and SVR cure during 1 year post-baseline by INSPIRE enrollment status, 2015

	INSPIRE participants N = 1103 N (%)	Other HCV infected NYC residents N = 32 819 N (%)	<i>P-</i> value
Treatment initiation	790 (72)	11 960 (36)	<.0001*
SVR (cure)	514 (65)	5641 (47)	<.0001*

^{*}Statistically significant at the 0.05 alpha level.

inexpensive approach for local health departments to support HCV programme evaluation.

This analysis had several limitations. First, covariates included in the propensity score estimation were limited, likely leading to unmeasured confounding as we were not able to entirely account for meaningful differences between groups during matching of INSPIRE enrollees to the surveillance cohort (e.g., in terms of race/ethnicity, comorbidities, health insurance coverage and other factors associated with our outcomes of interest). This could explain the agreement between the primary and sensitivity analyses. However, previous studies comparing propensity score-derived models and unadjusted models have shown that results between the two methods often do not differ.⁴⁰

Secondly, we were unable to account for the degree of HCV care received by individuals included in the evaluation, including INSPIRE enrollees. Enrolment in INSPIRE did not guarantee that any or the intended extent of the INSPIRE services were received (i.e., number of health promotion modules, phone calls, treatment adherence sessions, etc.). Similarly, we were unable to account for the level of HCV care, if any, received by the matched control group at the start of the follow-up time. Furthermore, it was unknown whether any participant received care coordination services other

than INSPIRE. A further limitation is failure to account for individuals (INSPIRE enrollees or controls) who died during the study period. As individuals identified in the surveillance registry are not routinely matched to death data, we were unable to exclude them from the analysis.

5 | CONCLUSION

The Project INSPIRE care coordination model was effective at increasing the odds of HCV treatment initiation and cure. In addition to short-term outcomes such as these, providing care coordination to HCV-infected persons is also expected to improve long-term outcomes, such as slowing liver failure progression and decreasing hospital utilization rates. The success observed in the INSPIRE intervention provides evidence that the additional cost of care coordination leads to better outcomes. The analysis and methods presented here lay the groundwork for further analyses pairing programme and surveillance data that might inform policy, clinical operations and HCV treatment payment models.

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CONFLICT OF INTEREST

Jeffery Weiss has served as a speaker, a consultant and a PI of an Investigator Initiated Study by Gilead Sciences Inc. Alain Litwin has served as a speaker and has received research funding from both

^{**}Statistically significant at the 0.01 alpha level.

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Merck Pharmaceuticals and Gilead Sciences Inc. All other authors report no conflicts of interest.

DISCLAIMER

The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of the U.S. Department of Health and Human Services or any of its agencies. The findings presented are from analyses conducted by the New York City Department of Health and Mental Hygiene. Independent contractors have been hired by the Department of Health and Human Services to evaluate Project INSPIRE, and their findings might differ from those presented here.

ENDNOTE

¹For a more thorough description of the INSPIRE programme structure, aims, and monitoring and evaluation plan, please see.¹⁷

ORCID

R. Deming http://orcid.org/0000-0003-1576-0996

M. S. Moore http://orcid.org/0000-0003-3391-2818

J. Weiss http://orcid.org/0000-0003-0121-7167

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