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HepCCATT: a multilevel intervention for hepatitis C among vulnerable populations in Chicago

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Conflict of interest
The authors declare no conflicts of interest.

Ethical approval
HepCCATT was approved by the University of Chicago IRB, #18-0785.

Abstract

Background—Hepatitis C infection could be eliminated. Underdiagnosis and lack of treatment are the barriers to cure, especially for vulnerable populations (i.e. unable to pay for health care).

Methods—A multilevel intervention from September 2014 to September 2019 focused on the providers and organizations in 'the safety net' (providing health care to populations unable to pay), including: (i) public education, (ii) training for primary care providers (PCPs) and case managers, (iii) case management for high-risk populations, (iv) policy advice and (v) a registry (Registry) for 13 health centers contributing data. The project tracked the number of PCPs trained and, among Registry sites, the number of people screened, engaged in care (i.e. clinical follow-up after diagnosis), treated and/or cured.

Results—In Chicago, 215 prescribing PCPs and 56 other health professionals, 86% of whom work in the safety net, were trained to manage hepatitis C. Among Registry sites, there was a 137% increase in antibody screening and a 32% increase in current hepatitis C diagnoses. Engagement in care rose by 18%.

Conclusions—Hepatitis C Community Alliance to Test and Treat (HepCCATT) successfully targeted safety net providers and organizations with a comprehensive care approach. While there were challenges, HepCCATT observed increased hepatitis C screening, diagnosis and engagement in care in the Chicago community.

Keywords

disease registries; health services; liver disorders

Background

Chronic hepatitis C virus (HCV) infection is a leading cause of cirrhosis, hepatocellular carcinoma, liver transplantation and death.[1–3] In 2014–16, 2.4 million US adults were estimated to be chronically infected with HCV, with the highest prevalence among those born between 1945 and 1965,[4] likely via contaminated blood transfusions or past injection drug use.[5,6] However, rising incidence in younger populations parallels current trends in opioid injection drug use.[7] First-generation direct-acting antiviral agents (DAAs) were Food and Drug Association (FDA) approved in 2011.[8] The National Academies of Science, Engineering, and Medicine soon thereafter determined that control of HCV 'is feasible in the relatively short term'[9]; however, limited access to diagnostic services and to DAAs has been a barrier to cure, especially among vulnerable populations in the USA, including Medicaid-insured populations.[10] In the USA, with its market-based health care system, many cannot afford health care. One societal response to this is called 'the safety net'. While definitions vary, a common feature is that safety net organizations deliver health care services to persons unable to pay for them.[11] Medicaid is a combination state and federal health insurance program for the poorest Americans, commonly referred to as 'vulnerable populations', while Medicare is the federal health insurance plan providing health coverage mainly to Americans aged 65 and older.

Chicago has an estimated 2.7 million residents.[12] Chronic HCV has been a reportable condition in the state of Illinois since 2001, and the state began electronic reporting in 2004.[13] Based on the 2014 data, the year this project began, there were 2460 new HCV diagnoses and 22 478 known Chicagoans living with HCV In Chicago's most recent surveillance data (2017), new diagnoses had risen to 3067 and prevalence had risen to 25 363, with cases most common among men, African Americans and those born between 1945 and 1965. Persons born after 1986 have emerged as a second cohort with higher risk, with a 38% annual percentage increase in HCV cases from 2013 to 2017.[14] This increase in younger adults is thought to arise mainly from injection drug use amid the current opioid crisis.[7,15,16]

One major challenge to HCV treatment in Chicago is access to DAA medications. In August 2014, for DAA access, Illinois Medicaid required cirrhosis,[17] screening for active substance use which *de facto* excluded anyone using drugs from receiving treatment and a prescription written by or in consultation with a specialist.[18] In October 2016, the fibrosis requirement was lowered and the screening for active substance use was reduced but not removed.[19,20] In November 2018, the cirrhosis and substance use restrictions were removed entirely, and remote consultation with a specialist was permitted, expanding PCPs' ability to prescribe.[20]

With curative DAAs, there is the potential to reduce and even eliminate HCV morbidity, mortality and ongoing transmission.[21] However, elimination is estimated to require 90% diagnosis and treatment coverage by 2030.[22] HCV-infected individuals must be able to receive risk reduction counseling, screening and care from PCPs[23–25] as there are not enough hepatology and infectious disease specialists to treat the infected population. Preparing PCPs to counsel, screen, treat and cure people with HCV requires innovative strategies.

The Hepatitis C Community Alliance to Test and Treat (HepCCATT, http://hepccatt.org/) intervention was established in 2014 to increase the identification, treatment and cure of HCV among safety net populations living or receiving care in Chicago by developing a comprehensive primary care system for HCV This paper describes the intervention and select project impacts.

Methods

HepCCATT (Fig. 1) included cross-sector collaborations across five core elements: (i) public education campaigns; (ii) training for community-based PCPs and case management (CM) teams; (iii) CM for high-risk populations in need of help to manage the operational challenges of the health care system and the impacts of institutional racism and poverty on their ability to access care (i.e. people with substance use disorders, with HIV, recently incarcerated and/or with low income); (iv) policy advice at local and state levels to improve treatment access and (v) development of a HCV registry to enhance existing surveillance data. These broad project elements were requested by the US Centers for Disease Control (CDC) based on current best practices as well as CDC's experience with community-based HCV testing and linkage-to-care programs. We operationalized the model elements based on parallels in our experience in HIV care among vulnerable populations as well as our

experience in building community capacity using the Extension for Community Health Outcomes (ECHO) model.[26]

The intervention targeted PCPs in Chicago from safety net organizations (defined as federally qualified health centers (FQHCs), safety net hospitals and free and charitable clinics (FCCs)) or clinics that almost exclusively serve populations at increased risk for HCV (e.g. adults 65+, dual eligible patients on Medicaid/Medicare or persons with substance use disorders). Participants enrolled in the project between 30 September 2014 and 29 September 2018, with follow-up data provided through 30 September 2019. The project was approved by all relevant Institutional Review Boards and was approved or determined to be exempt from review by the participating health clinic sites.

Public education campaigns

Activities for raising public awareness of HCV included: advertisements on billboards, public transportation and local radio; and interviews on radio, print and television. Materials used included those from the CDC's 'Know More Hepatitis™' campaign[27] and additional materials developed by HepCCATT. Messaging was primarily targeted to persons born between 1945 and 1965 and other risk groups, focusing on the benefits of HCV testing and on the reduction of stigma associated with an HCV diagnosis. Radio interviews also mentioned other risk factors, such as injection drug use. Evaluation data were not collected for this activity.

Workforce development telementoring training

Workforce development training based on the ECHO[26] model used by ECHO-Chicago[28] was provided to the health centers' PCPs and CM teams. Safety net health providers were actively recruited, though all interested could participate. Curricula were developed by the ECHO-Chicago multidisciplinary subject matter expert (SME) team: a hepatologist, pharmacist, case manager and addiction specialist.

Curricula evolved over time, adapting to new treatments and policies. As treatment simplified, focus shifted to streamlining treatment and monitoring protocols, navigating authorization processes and screening emerging at-risk populations. Participants completed the 10-session training in cohorts of 10–25 persons by joining weekly, hour-long sessions via videoconferencing. Sessions were facilitated by the SME team and were comprised of a short lecture followed by at least two participant-led new case presentations. Discussion of prior patient cases occurred as needed. Protected health information was not shared.

The hepatologist and other members of the SME team facilitated DAA prescriptions by confirming specialist consultations and by providing support in navigating barriers.

Direct case management

Case managers were hired through the Community Outreach Intervention Program (COIP) at the University of Illinois School of Public Health. Described elsewhere,[29] direct CM was provided by a team of case managers to 181 HCV chronically infected clients receiving care at a HepCCATT-participating site.

Policy

Over 5 years, HepCCATT partners engaged the local and state policymakers to evaluate changes to Medicaid requirements, participated in statewide HCV coalitions, connected legal teams to patients' providers and raised awareness of the common barriers to HCV care through local media. Resources did not allow us to collect the necessary data to evaluate the impact of this work.

Surveillance registry

In partnership with the Illinois and Chicago Departments of Public Health (IDPH and CDPH), a HCV registry (Registry) was developed to track progression through the care cascade, which was defined as moving from diagnosis to engagement in HCV-specific care (defined below), treatment and cure. The Registry brought together existing state-collected HCV surveillance data (laboratory data and provider reports) with electronic health record (EHR) data from 108 participating clinical sites (90% FQHCs) from 13 health centers. Prescription information from two major pharmacy chains was included. Data were collected and linked as part of the state's Medical Study Act[30] for public health surveillance and were kept in a state-sponsored public health node.

Data were collected for the year prior to the start of HepCCATT (baseline) and then for project years (PYs) 1–5. The Registry code book was based on the requirements set forth by the CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention and was consistent with the IDPH requirements. In addition to analyzing data for surveillance purposes, starting in PY4, the Registry generated monthly alerts to HepCCATT sites about their HCV patients who had either fallen out of, or failed to initiate, the next level of care.

Data and statistical methods

Registry

Individuals were added to the Registry if they received a positive HCV antibody, RNA, or genotype test during the baseline or PYs of HepCCATT. Negative antibody screening was only provided in the aggregate by PY.

Analytic dataset

A de-identified restricted dataset from the Registry was provided for analysis that excluded patients with negative antibodies, health center identifiers (including FQHC status), patient identifiers, PCP identifiers (including ECHO–HCV training status) and masked sites of care and dates of service. Instead of dates, there was an indicator for the number of weeks between the initial diagnosis and each care event (e.g. treatment initiation). The PY of entry into the Registry was included, as were gender (male, female and any transgender as 'other'), birth year, race, ethnicity, zip code and insurance (Medicare, Medicaid, private or uninsured). Sustained viral response (SVR) was defined as undetectable viral load documented at least 3 months after the completion of therapy.

Baseline was defined as 29 September 2013 to 30 September 2014, with each subsequent year (PY1–5) beginning on 30 September. PY5 (30 September 2018–29 September 2019) was only used for follow-up data.

This analysis is restricted to patients with current HCV infection as defined by a positive RNA or genotype test ('RNA+') and includes descriptive comparisons based on the birth cohort. Birth cohorts were originally defined as born 'before 1945', from '1945 through 1965' and 'after 1965'. Because of low numbers for the oldest group, the two older cohorts were combined as born '1965 or earlier'.

'Engaged in care' was defined as receiving any of the following: a genotype test, any fibrosis staging test, or HCV-specific treatment. Likely cirrhosis was defined as an AST to Platelets Ratio Index (APRI) score of 1.0 or above.[31] Numbers of RNA+ people by zip code were categorized into five levels (created by ArcGIS and based on natural groupings within the data[32]) for each separate PY

Trained providers and their organizations

For this analysis, participants were limited to those from clinics within Chicago and were presented in five levels (again created by ArcGIS and based on natural groupings within the data[32]) cumulatively, as HCV knowledge following training was assumed to persist over time. Providers' health center types were categorized as (i) safety net organizations defined as FQHCs, safety net hospitals (either by state determination[33] or by being in the top 25% of Medicaid inpatient and charitable care in the state[34]), or FCCs; or (ii) health centers serving populations with increased HCV risk (adults 65+, dual eligible patients on Medicaid/Medicare, or patients with substance abuse disorder) and (iii) all others.

Software

Descriptive statistics were calculated in STATA 15.1 (College Station, TX), and maps were made in ArcGIS ArcMap 10.7 (Redlands, CA).

Results

Patient data

The number of individuals with HCV antibody testing was 13 278 in the baseline year, 17 778 in PY1, 22 095 in PY2, 31 474 in PY3 and 22 296 in PY4. Antibody testing increased 137% from baseline to PY3 before leveling off in PY4.

Table 1 shows RNA+ patients were mainly male (64%), born in 1965 or earlier (68%), and non-Hispanic African American (44%), though race/ethnicity was unknown for 25%. Medicaid was the most common insurance (33%), with 32% missing. Engagement in care was 74%, likely cirrhosis was 17% and treatment initiation was 11% (559 among 5307 engaged in care).

Total RNA+ diagnoses increased to 61% from baseline to PY3 before leveling off in PY4. The majority of newly diagnosed cases were born between 1945 and 1965 in all PYs. However, diagnoses among the younger cohort (born after 1965) increased 84% from

baseline to PY4. Diagnoses in those born on or after 1986 increased to 180% from 56 diagnoses in the baseline period to 157 in PY4.

Demography varied by birth cohort. In contrast to those born after 1965, persons born 1965 or earlier were notably more non-Hispanic African-American (51 versus 31%). Those born after 1965 had higher percentages Hispanic (23 versus 12%) and non-Hispanic white (24 versus 10%). Insurance also varied by birth cohort, with being uninsured higher among those born after 1965 (16 versus 10%); there were some expected differences, such as higher levels of Medicare in patients born 1965 or earlier (22 versus 3%). Among those born 1965 or earlier, both engagement in care (75 versus 70%) and likely cirrhosis (18 versus 14%) were slightly higher, but treatment and SVR levels were similar.

The HCV care cascade shows a high proportion engaged in care (74%), but lower percent for those treated (11%), Fig. 2. Among those treated, known SVR is 65%.

HCV RNA+ diagnoses and participants

Over the 5-year project, 215 PCPs with prescriptive capacity and 56 other health care professionals in Chicago were trained. Providers working in the safety net comprised 86% of participants (68% FQHC, 17% safety net hospital and 1% FCC). An additional 10% of participants served groups at increased HCV risk, and 4% were from pharmacies and smaller clinics.

HCV RNA+ diagnoses by zip code and participants are shown in Fig. 3. The zip code color darkens with more cases, and participants are shown in increasing size proportional with persons trained. The cumulative map (right) shows health centers by type. The RNA+ diagnoses are from HepCCATT participating sites only and account for 37% of the total cases in Chicago.

Discussion

Main findings of this study

The HepCCATT project was associated with an increase in testing, diagnosis and treatment of patients with HCV across the safety net sites in Chicago.

Workforce development telementoring training

Using the ECHO-Chicago program, HCV training was completed with many safety net providers. HepCCATT successfully reached the most vulnerable populations in Chicago, as seen in Fig. 3.

Providers showed significantly increased self-efficacy in providing hepatitis C care (data not shown). This is a relatively low-cost approach to rapidly expanding the number of providers over a geographic area capable of providing HCV care.

Case management

During the course of HepCCATT, efforts shifted from providing direct CM to increasing capacity as recognition grew that the need for CM services far exceeded the capacity of our

CM team. Interest in CM training resulted in 14 of 36 (39%) participating organizations participating in this additional voluntary training.

Policy

Illinois Medicaid restrictions proved a challenge in treating patients. In November of 2018, Illinois removed the advanced stage fibrosis and substance use requirements for Medicaid patients.[20] While these policy changes cannot be attributed solely to HepCCATT efforts, our input was often requested in meetings with the state to loosen DAA restrictions. Partnering with community organizations, HepCCATT shared policies from other states as well as the cost and outcome studies documenting the value of DAA treatment and provider and patient testimonials.

Surveillance registry

The Registry documented HCV at 109 sites of care and included 37% of all known Chicago cases, confirming higher prevalence in men and African Americans. Antibody testing rose each year at HepCCATT sites until likely reaching saturation in PY4. We believe this was an effect of the project, but without additional data, we cannot be sure. However, nearby large cities did not show the same trend. In the approximate time periods of HepCCATT, 2014–17, there are data available for St. Louis and Milwaukee Counties. HepCCATT sites showed a 61% increase in cases, while St. Louis and Milwaukee Counties both reported a decline.[35,36]

What is already known on this topic

The elimination of HCV is possible via DAAs. However, there are not enough specialists to treat all infected individuals, so they must be able to receive disease counseling, screening and care from PCPs.[23–25]

What this study adds

HepCCATT adds a rapid and scalable method to train PCPs in treating HCV patients, especially providers that serve high-risk populations. By merging HCV-relevant information from different EHRs with the pharmacy and public health data, HepCCATT made determinations of engagement in care, treatment initiation and cure possible in difficult-to-treat populations.

Limitations of this study

HepCCATT was designed as a Chicago-specific public health intervention and not as a research study. It coincided with new treatments, health trends and initiatives. HepCCATT may not be fully generalizable to other settings. However, the lessons learned in training PCPs and CM and in establishing a multi-organization disease Registry can serve future efforts for HCV elimination.

Our data do not allow us to definitively document whether treatment was missing or not prescribed for 92% of the RNA+ population. However, Illinois reports that the overwhelming majority of Medicaid patients obtain their medications through the pharmacy chains that submitted data to the Registry.

Only 65% of those treated were documented to achieve SVR, most likely due to the lack of follow-up RNA testing at the site of care. Treatment completion data were not available.

With dataset restrictions, we could not link ECHO participants with patient diagnoses. The analytic dataset contained only positive antibody tests; total screening numbers were only provided in the aggregate by PY, limiting the analysis. The reasons for the cohort differences between those born before and after 1965 could be related to the differences in risk factors (e.g. opiate use) or influenced by demographic characteristics.

We were unable to collect the data required to directly measure the impact of the public education campaigns or of increased awareness among PCPs.

Some of the missing staging information is attributable to providers' EHR practices. Clinical notes and free text fields were not included; only information in discrete fields was delivered.

Conclusions

Increased screening and diagnosis of HCV in Chicago co-occurred with HepCCATT's considerable efforts. A system that targets patient awareness, tracks patients and builds capacity by uptraining PCPs is essential for HCV elimination.

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Availability of data and materials

The data underlying this article cannot be shared publicly due to HIPAA issues and ownership by a third party. The data are available from the IDPH, but restrictions apply, as the data were used under license for the current study. Data are, however, available from the authors upon reasonable request and with the written permission of IDPH.

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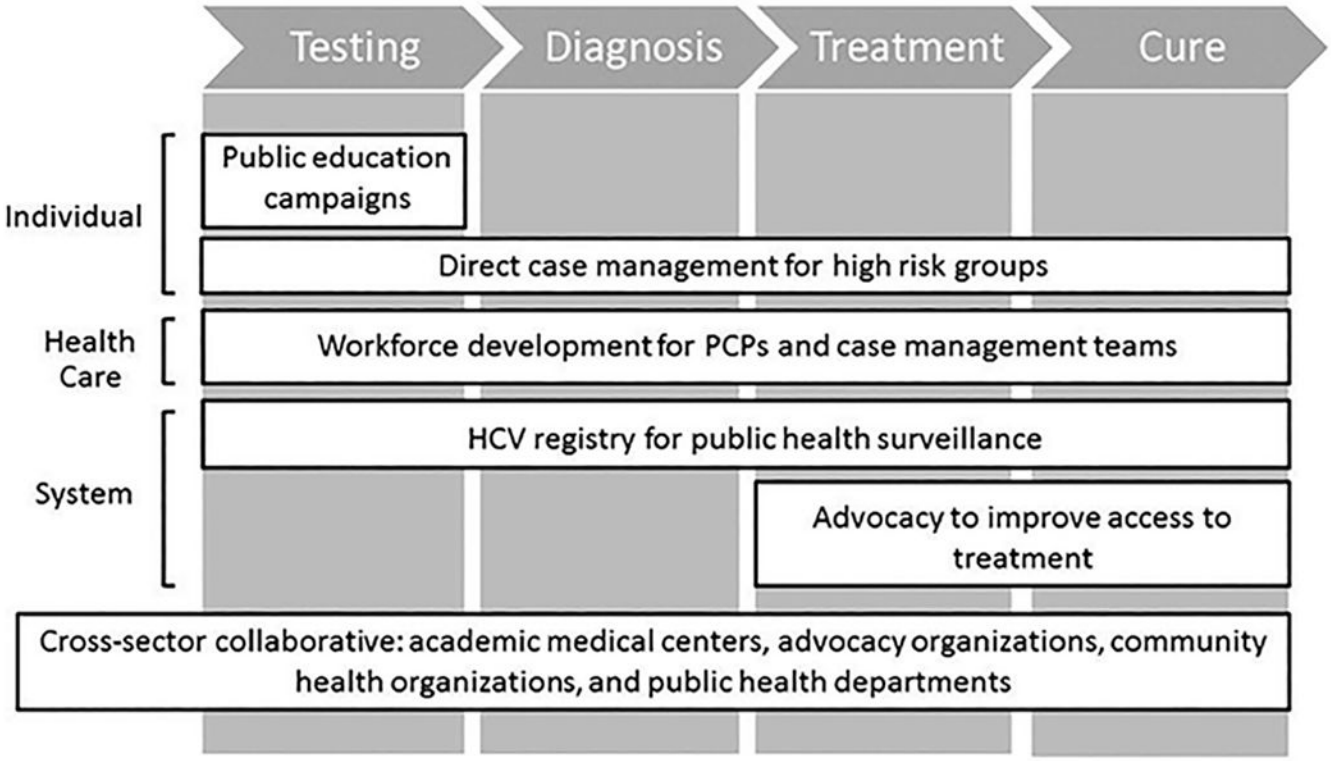

Fig. 1.
HepCCATT multilevel intervention and the hepatitis C care cascade.

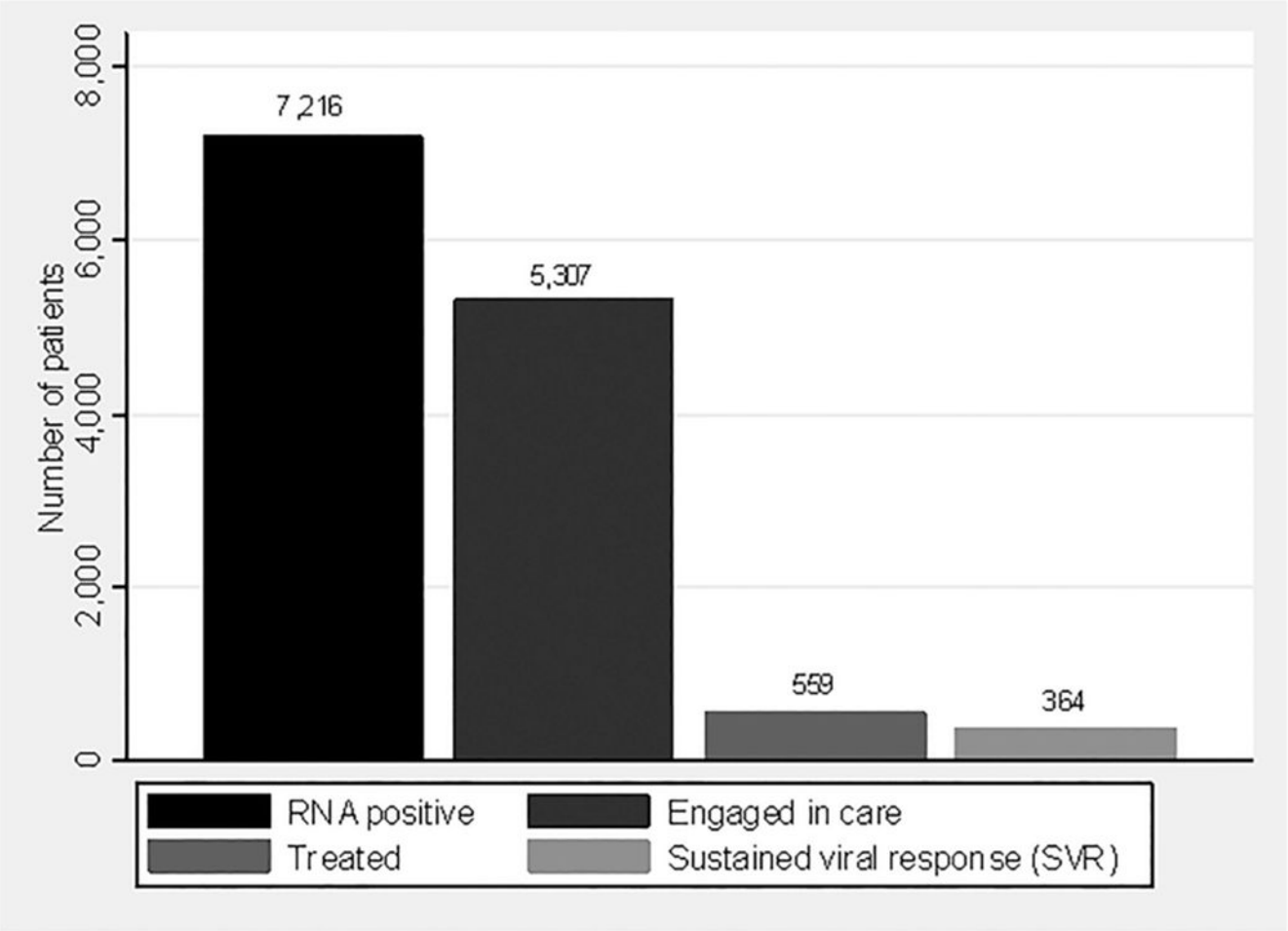

Fig. 2.
Hepatitis C cascade, PYs 1–5.

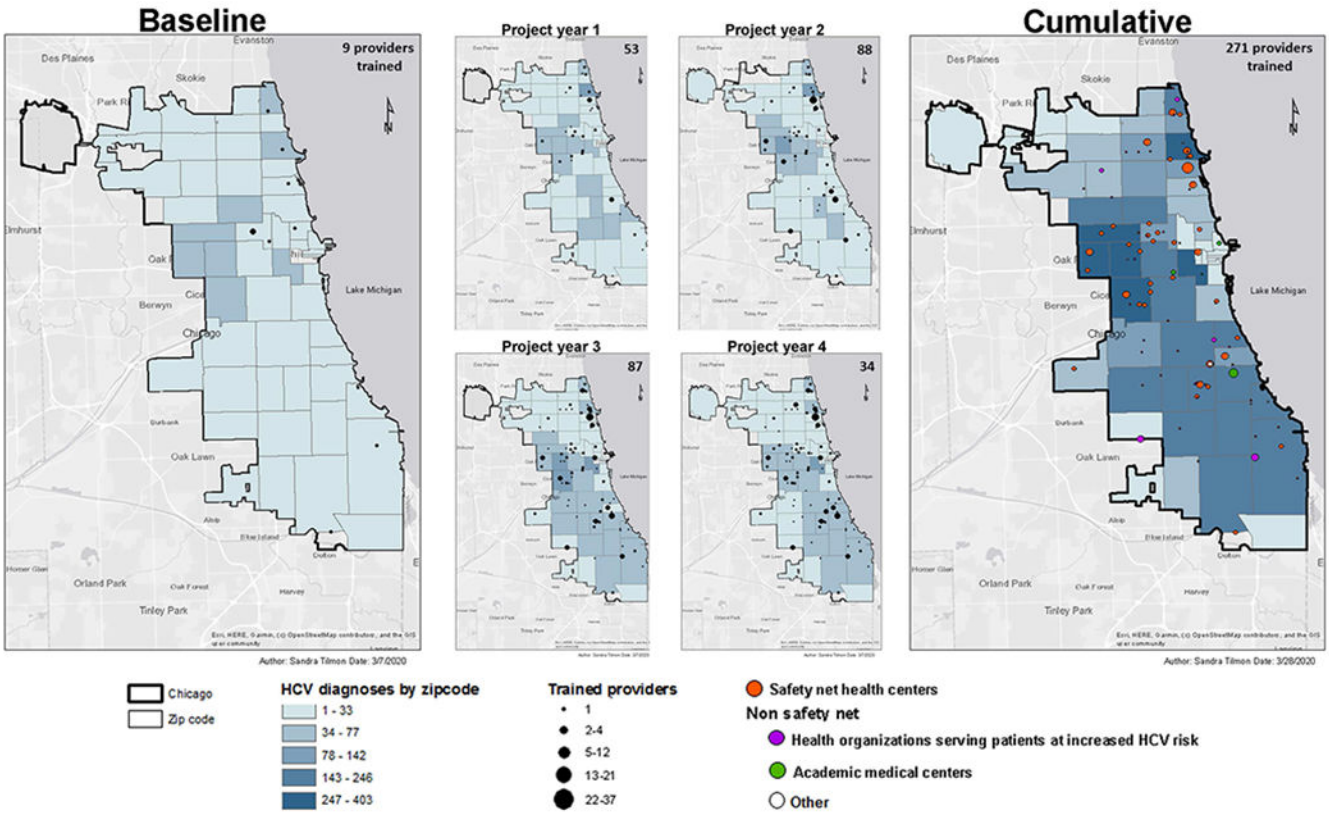

Fig. 3.

Number of RNA+ individuals by PY. Note: Darker polygon colors represent more cases, and circles represent cumulative participants, size proportionate to persons trained. Left: baseline. Center: by PY1–4. Right: cumulative for both participants (categorized by health center type by color) and HCV diagnoses (by zip code). Red circles indicate safety net health centers, while green circles represent health organizations serving patients at increased HCV risk. White circles are all other organizations.

Table 1

HepCCATT sites RNA+ patient characteristics

	Total, N = 7216	<=1965, N = 4938	After 1965, N = 2278
PY			
Baseline	15.5% (1121)	16.3% (806)	13.8% (315)
Year 1	19.0% (1373)	19.5% (965)	17.9% (408)
Year 2	18.6% (1342)	18.4% (908)	19.1% (434)
Year 3	25.0% (1806)	25.6% (1265)	23.7% (541)
Year 4	21.8% (1574)	20.1% (994)	25.5% (580)
Gender			
Male	63.8% (4601)	66.0% (3258)	59.0% (1343)
Female	36.1% (2605)	33.9% (1676)	40.8% (929)
Other	0.1% (10)	0.1% (4)	0.3% (6)
Race/ethnicity			
Hispanic, any race	15.1% (1088)	11.5% (566)	22.9% (522)
NH (non-Hispanic) Asian	1.1% (76)	0.9% (43)	1.4% (33)
NH Black	44.3% (3198)	50.6% (2500)	30.6% (698)
NH Native	0.3% (25)	0.2% (10)	0.7% (15)
NH Pacific Islander	0.0% (1)	0.0% (0)	0.0% (1)
NH White	14.4% (1036)	9.9% (488)	24.1% (548)
Unknown	24.8% (1792)	27.0% (1331)	20.2% (461)
Insurance			
Medicaid	32.8% (2366)	31.2% (1540)	36.3% (826)
Medicare	16.0% (1151)	21.9% (1082)	3.0% (69)
Private	7.5% (540)	6.2% (308)	10.2% (232)
Uninsured	11.9% (861)	9.9% (487)	16.4% (374)
Unknown	31.8% (2298)	30.8% (1521)	34.1% (777)
Engaged in care			
No	26.5% (1909)	24.8% (1226)	30.0% (683)
Yes	73.5% (5307)	75.2% (3712)	70.0% (1595)
Likely cirrhosis via APRI* score > = 1			

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	Total, N = 7216	**<=1965, N = 4938**	**After 1965, N = 2278**
No	83.4% (3499)	82.3% (2274)	85.7% (1225)
Yes	16.6% (694)	17.7% (489)	14.3% (205)
Treatment			
No treatment information	92.3% (6657)	92.0% (4543)	92.8% (2114)
Treated	7.7% (559)	8.0% (395)	7.2% (164)
SVR, if treated			
No	34.9% (195)	35.2% (139)	34.1% (56)
Yes	65.1% (364)	64.8% (256)	65.9% (108)