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Research Article

Hepatitis C Care Cascade among Incarcerated or Detained Persons and General Population in California, 2011-2021

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Abstract

Objective: To evaluate the Centers for Disease Control and Prevention hepatitis C care cascade, that assesses hepatitis C follow-up testing and laboratory evidence of likely clearance/cure and recurrent viremia, among incarcerated or detained persons (IDP) and general population.

Methodology: Laboratory test results were analyzed for hepatitis C virus (HCV) antibody, RNA, and genotyping from Quest Diagnostics among IDP persons and general population in California, 2011-2021.

Results: Overall, 27.4% (115,353/421,459) of the Californian IDP population who had HCV testing were initially HCV test positive. Of those with follow-up HCV RNA testing, 59.4% (24,694/41,539) had evidence of clearance/cure and of these 19.4% (4,793/24,694) had subsequent evidence of recurrent viremiaor reinfection. For the general population 6.2% (246,620/3,961,225) with HCV testing were initially positive. Of those with follow-up HCV RNA testing, 63.7% (45,819/71,965) had evidence of clearance/cure and 6.7% (3,068/45,819) had subsequent evidence of recurrent viremia.

Conclusions: Californian IDP population had a higher HCV positivity rate than the general population and evidence of subsequent recurrent viremia or reinfection. More resources and aggressive approaches are needed to successfully confront HCV in correctional facilities and after IDP community return.

Keywords: Hepatitis C virus, Hepatitis C care cascade, Incarcerated or detained persons, Correctional facilities

Introduction

Hepatitis C virus (HCV) is a blood-borne virus, commonly transmitted through shared injecting equipment. Due largely to the criminalization of injection drug use, the hepatitis C epidemic has disproportionately affected the incarcerated and detained person (IDP) ("correctional") population where many individuals originate from high-risk environments and engage in high-risk behaviors in their communities. Earlier estimates, from studies covering from 1994 to 2006, were 30% to 40% of the United States (U.S.) IDP population were infected with the HCV at some point in time in their lives, the majority of whom were infected before incarceration [1-5]. Recent estimates from the California Department of Correctional Health Care Services (CCHCS), based on testing from July 2018 through June 2019, found at entry, 18% of California-state IDP were HCV antibody positive confirmed by HCV RNA presence of whom 72% had evidence of chronic hepatitis C [6]. This rate is similar to a 2015 U.S. study of HCV infection among IDP [7].

The HCV care cascade provides uniformity to track frequency of presumed clearance/cure in the populations, including lack of follow-up, and recurrent viremia or reinfection – based solely on clinical laboratory test results. This care cascade provides a valuable public health perspective on the hepatitis C epidemic and may be applied to benchmark performance compared to World Health Organization elimination goals [8].

Although access to appropriate healthcare services is a right for U.S. IDP, HCV infection identification and treatment are challenging due to IDP turnover rates and inadequate follow-up care after return to the community. Many IDP are hepatitis C infected prior to becoming incarcerated or detained and some IDP may not be diagnosed with hepatitis C until after release or while on parole. Such individuals with undiagnosed and untreated hepatitis C may perpetuate community spread. Another challenge for correctional facilities to implement robust HCV treatment is the cost of these highly effective medications.

Given the prevalence of hepatitis C among IDP, and the advent of highly effective antiviral treatments, addressing hepatitis C clearance among IDP prior to and after release is critical if the U.S. is to achieve HCV elimination goals. Efforts must focus on establishing an accurate knowledge of who is infected and implementing education, policies, and procedures for the prevention and treatment of hepatitis C among IDP during their confinement and following their return to the community [9]. The CCHCS became a national model by expanding HCV testing statewide in 2016 and expanding treatment access to the general IDP population in 2018-2019 [6]. In 2022, the CCHCS developed detailed plans for addressing the burden of hepatitis C including expanding eligibility for treatment [10]. Based on analysis of Quest Diagnostics clinical laboratory test results, this study aims to determine prevalence of hepatitis C, and presumed clearance/cure rates among IDP, inclusive of state and other correctional facilities based in California, and for comparison, among the general population in that state.

Methods

Results of HCV-related laboratory testing performed by Quest Diagnostics were analyzed from client accounts identified as being from all jurisdictions within Californian jail, prison, and correctional (collectively referred to as "correctional") facilities from 2011 through 2021. For comparison, specimens from individuals tested by Quest Diagnostics in California who were not identified as being from correctional facilities were analyzed in a similar manner, defined as the "general population." Subsequent hepatitis Cvirus laboratory results analyses following that first encounter focused on HCV RNA testing. Mean age and sex distribution were based on first encounter, when available. Quest Diagnostics established an automatic HCV reflex test-only testing option for clinicians in November 2015, reflexing all positive HCV antibody specimens to HCV RNA testing to identify those who were actively HCV infected. Thus, data are separately evaluated for patients first tested in 2011-2015 and in 2016-2020. Follow-up testing of individuals was determined for up to one year subsequent to an initial HCV RNA positive result. Therefore, the study cohort had initial testing performed from January 2011 through December 2020 to allow up to a minimum of one-year follow-up through

December 2021.

The hepatitis C care cascade was applied to assign individuals into the defined categories [11]. For clarity, categories with no testing are listed and displayed first. Category 1 is defined as ever HCV infected, category 2 is based on HCV RNA testing (2a with no subsequent HCV RNA test and 2b as with subsequent HCV RNA testing), category 3 is based on the HCV RNA test result (3a with negative result and 3b as positive result), category 4 defines cured or cleared (4a1 no record of subsequent HCV RNA test, 4a2 subsequent HCV RNA test result remain positive, and 4b any subsequent HCV RNA negative test result after initial HCV RNA positive result), and category 5 includes people who had HCV RNA positive test result followed by negative and then subsequently a positive HCV RNA test result. In addition, because Quest Diagnostics also records HCV negative test results and the absence of subsequent testing performed within this laboratory network, absolute rates for testing and positivity were calculated. An individual with any initial HCV testing (antibody, RNA, and genotyping) results were accepted for study inclusion. A presumed HCV clearance/cure event was someone defined as having an HCV RNA negative result subsequent to an initial HCV RNA positive result, who was followed over a minimum of one year (category 4b). A presumed rebound infection or reinfection were those individuals having a subsequent HCV RNA positive result after HCV clearance/cure, who was followed over a minimum of one year (category 5).

Qualitative immunoglobulin G HCV antibody testing was performed using the U.S. Food and Drug Administration (FDA)-cleared automated VITROS ECi Immunodiagnostic System (Ortho Clinical Diagnostics). HCV RNA test methods included the quantitative COBAS AmpliPrep/COBAS TaqMan HCV v2.0 method and quantitative COBAS HCV nucleic acid test on the COBAS 6800/6880 systems (both from Roche Diagnostics). HCV genotyping was based on real-time- reverse transcription and amplification of the 5'untranslated region and core region of the viral genome (Quest Diagnostics laboratory developed test and Siemens Healthcare Diagnostics). WCG Institutional Review Board deemed this Quest Diagnostics Health Trends® study as exempt.

Results

For the initial HCV testing for the IDP population at Quest Diagnostics, the individual's mean age was 36.2 years (standard deviation 11.9) and 93.9% were male, 6.0% were female, and 0.06% were sex unspecified. For the general population tested, the mean age was 44.7 years (standard deviation 16.7) and 43.3% were male, 56.1% were female, and 0.17% were sex unspecified.

Incarcerated and detained persons

For the IDP population, 27.4% (115,353/421,459) of those with any HCV test (i.e., antibody, RNA or genotyping) were initially positive {Table 1, 2011-2015 and 2016-2020 displayed separately, Figure 1 (IDP) and Figure 2 (general population)}. Of these individuals, 86.1% (99,351) had any subsequent HCV RNA testing (category 2b); 13.9% (16,002/115,353) had no evidence of subsequent testing performed (category 2a). The rate of HCV RNA testing of specimens from antibody positive individuals increased from 54.4% (21,777/39,973) in 2011-2015 to 98.3% (58,387/59,378) in 2016-2020 after implementation of a single HCV antibody testing algorithm wherein all antibody positive results were automatically reflexed to HCV RNA testing in November 2015. Of those HCV RNA positive individuals with subsequent HCV RNA testing, 19.3% (19,197/99,351) had only negative HCV RNA test result(s) during the follow-up period (presumed self-limiting infection or an unconfirmed initial HCV antibody test result) (category 3a) whereas 80.7% (80,164/99,351) had positive HCV RNA test results (category 3b). No documented follow-up HCV RNA testing (category 4a1) was found in 69.6% (38,625/55,470) of the IDP population and 30.4% (16,856/55,470) had only positive HCV RNA results (presumed non-viral clearance/cured, category 4a2). Of those who had HCV RNA testing, 59.4% (24,694/41,539) with an initial positive HCV RNA test result had one or more subsequent negative HCV RNA test results (presumed viral clearance/cured) (category 4b): 44.8% (6,225/13,989) in 2011-2015 and 66.9% (18,429/27,550) in 2016-2020. Of the 24,694 individuals with presumed viral clearance/cured, 19.4% (4,793) had a subsequent positive HCV RNA result indicating either an HCV rebound from an originally suppressed undetectable level or became

Table 1: Hepatitis C Care Cascade Definitions, Californian incarcerated and detained persons and general populations, 2011-2021

		Incarcerated or Detained Persons				General Population			
Category	Description	2011-2015		2016-2020		2011-2015		2016-2020	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
0	Ever tested	421,458				3,961,225			
1	Ever HCV infected	55,975		59,378		139,400		107,220	
2	HCV RNA testing								
2a	No HCV RNA testing reported during follow-up period	15,011	26.82 (2a/1)	991	1.67 (2a/1)	46,542	33.39 (2a/1)	4,014	3.74 (2a/1)
2b	Any HCV RNA testing reported during follow-up period	40,964	73.18 (2b/1)	58,387	98.33 (2b/1)	92,858	66.61 (2b/1)	103,206	96.26 (2b/1)
3	Initial infection								
3a	Initial reported HCV RNA negative during follow-up period	6,388	15.59 (3a/2b)	12,799	21.92 (3a/2b)	19,139	20.61 (3a/2b)	46,053	44.62 (3a/2b)
3b	Initial reported HCV RNA positive during follow-up period	34,576	84.41 (3b/2b)	45,588	78.08 (3b/2b)	73,719	79.39 (3b/2b)	57,153	55.38 (3b/2b)
4	Cured or cleared								
4a	All reported HCV RNA positive during follow-up period	28,311	81.88 (4a/3b)	27,159	59.57 (4a/3b)	48,576	65.89 (4a/3b)	36,477	63.82 (4a/3b)
4a1 (subset of 4a)	Never tested after first HCV RNA positive	20,587	72.72 (4a1/4a)	18,038	66.42 (4a1/4a)	33,624	69.22 (4a1/4a)	25,283	69.31 (4a1/4a)
4a2 (subset of 4a)	Tested after initial HCV RNA positive but remained viral positive	7,724	27.28 (4a2/4a)	9,121	33.58 (4a2/4a)	14,952	30.78 (4a2/4a)	11,194	30.69 (4a2/4a)
4b	Any reported HCV RNA negative after initial testing positive during follow-up period	6,265	44.79 (4b/ (4a2+4b)	18,429	66.89 (4b/ (4a2+4b)	25,143	62.71 (4b/ (4a2+4b)	20,676	64.88 (4b/ (4a2+4b)
5	Persistent Infection or reinfection								
	Any HCV RNA positive after previous HCV RNA negative during follow-up period	1,280	20.43 (5/4b)	3,513	19.06 (5/4b)	2,327	9.26 (5/4b)	741	3.58 (5/4b)

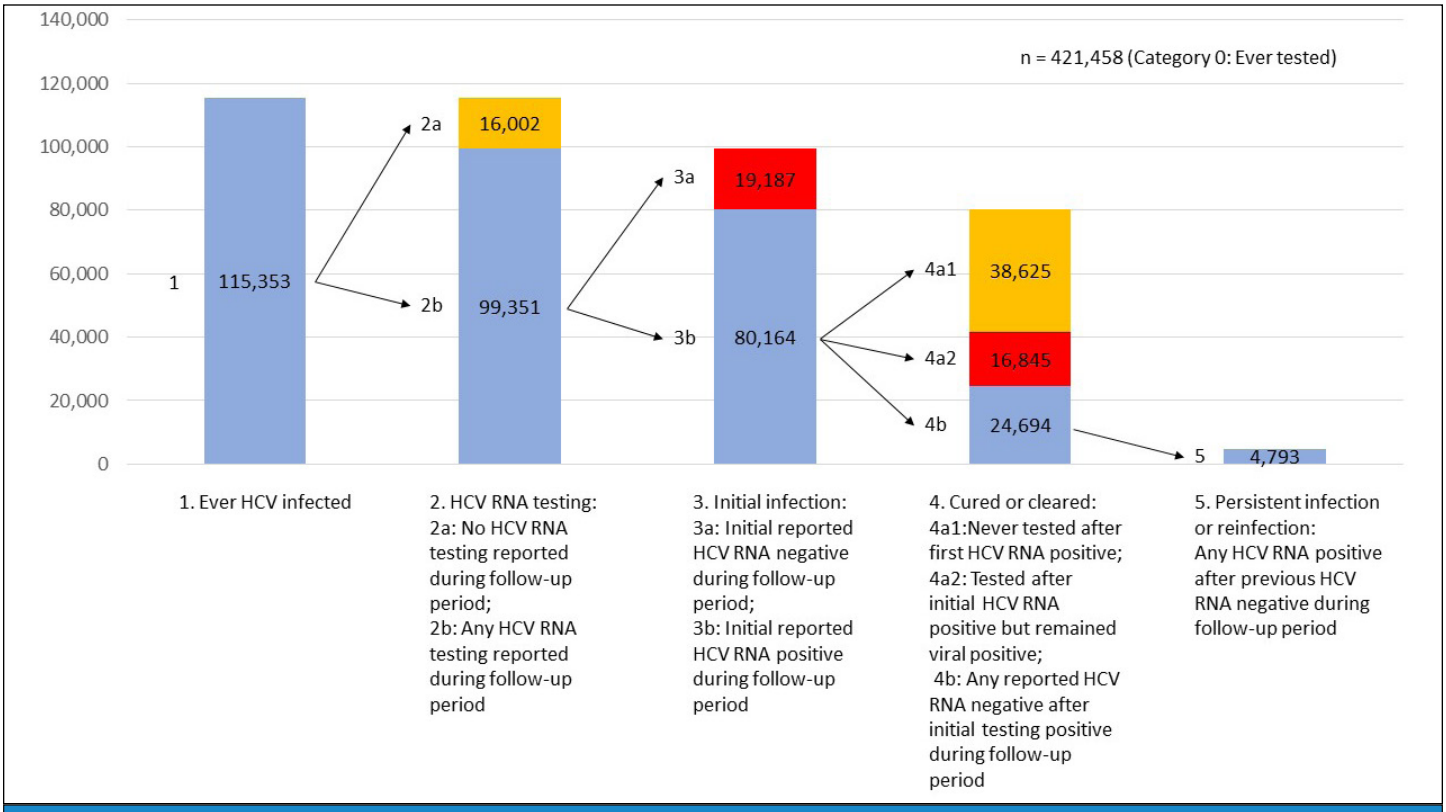

Figure 1: Number at each stage of hepatitis C virus (HCV) care cascade among Californian incarcerated and detained persons, 2011-2021

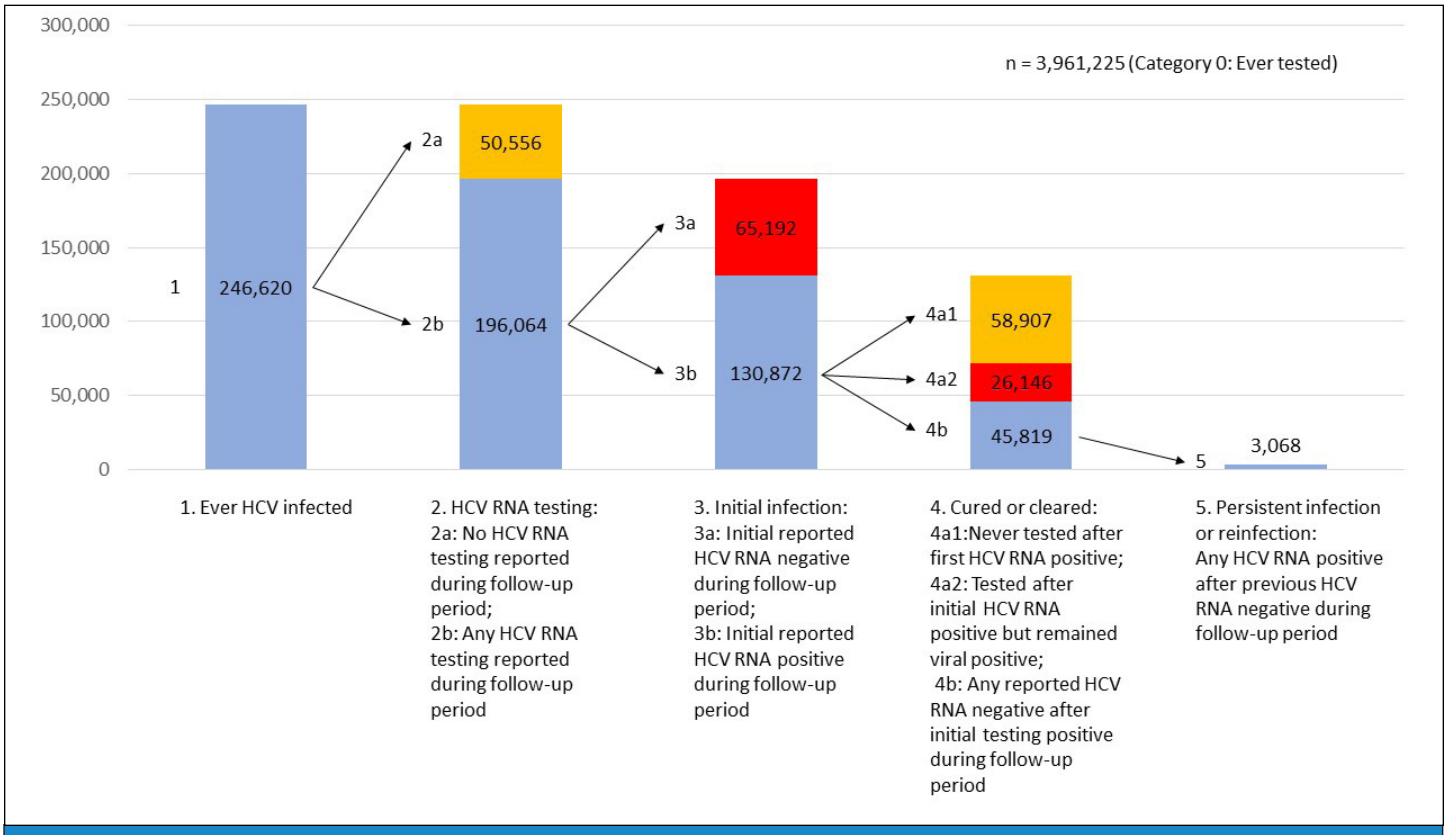

Figure 2: Number at each stage of hepatitis C virus (HCV) care cascade among Californian general population patients, 2011-2021

reinfected (category 5).

General population

In contrast, for the general population 6.2% (246,620/3,961,225) of HCV tests performed were positive for an initial HCV analyte (either antibody screen, RNA, or genotype) between 2011-2020. The rate of reflex HCV RNA testing of specimens from antibody positive individuals increased from 66.6% (92,858/139,400) in 2011-2015 to 96.3% (103,206/107,220) in 2016-2020 after implementation of a single HCV antibody testing algorithm option wherein all antibody positive results were automatically reflexed to HCV RNA testing in November 2015 (category 2b). Of those HCV RNA positive individuals with subsequent HCV RNA testing, 33.2% (65,192/196,064) had only negative HCV RNA test result(s) during the minimum of a one-year follow-up period (presumed self-limiting infection or an unconfirmed initial HCV antibody test result) (category 3a), whereas 66.8% (130,872/192,064) had a subsequent positive HCV RNA test result (category 3b). No documented follow-up HCV RNA testing (category 4a1) was found in 69.3% (58,907/85,053) of general population individuals and 30.7% (26,146/85,053) of general population individuals had only positive HCV RNA results (presumed non-viral clearance/cured, category 4a2). Of those tested, 63.7% (45/819/71,965) with an initial positive HCV RNA test result had one or more subsequent negative HCV RNA test results (presumed viral clearance/cured) (category 4b): 62.7% (25,143/40,095) in 2011-2015 and 64.9% (20,676/31,870) in 2016-2020. Of the 45,819 individuals with presumed viral clearance/cured, 6.7% (3,068) had a subsequent positive HCV RNA result, indicating either an HCV rebound from an originally suppressed undetectable level or who became reinfected (category 5).

Discussion

Study findings in context of other studies

A unique aspect of this study is the capture of both positive and negative HCV test results for each individual over time, allowing for a determination of who was or was not subsequently tested. For the IDP population, this observation interval is limited to their time within the correctional system. In contrast, most public health agencies typically only receive reports of positive HCV test results [12]. Capturing all HCV test results and all hepatitis C treatment information would provide for more robust analysis of effectiveness of screening, treatments, and follow-up care upon their return to community. Further, capturing data as individuals move between correctional and non-correctional care would enhance our ability to fully understand where gaps in care exist so that these gaps can be addressed. In this study, covering a significant portion of Californian IDP population, but only limited to their time spent within the correctional systems, we found that approximately 27% of tested Californian IDP population were HCV positive, consistent with national data from 2015 [1-7]. This compared to overall population HCV antibody prevalence estimates of approximately 1%, based on National Health and Nutrition Survey Examination, or 6% of the Californian general population observed in this study [13]. Of the Californian IDP population who were initially HCV RNA positive, 59.4% had at least one documented subsequent HCV RNA negative result from Quest Diagnostics, i.e., which is consistent with cure or clearance of infection, and of these 19.4% had subsequent HCV RNA positivity, thereby consistent with recurrent or rebound infections. The percent with presumed clearance or cure rose from 44.8% in 2011-2015 to 66.9% in 2016-2020, actually higher than observed for the general population (62.7% in 2011-2015 and 64.9% in 2016-2020. This suggests that treatment of the Californian IDP population became comparable or slightly better than for the general population. Though, the 19.4% of the IDP population with persistent or recurrent infection was much higher than the observed 6.7% observed for the general population.

A 1994 hepatitis C prevalence study of entrants to the California correctional system (n= ~5,000) found 41.8% of IDP were HCV positive (males, 39.4%; females, 54.5%) [14]. A 20-year study of Los Angeles County IDP found 34.6% (27,881/80,681) had positive HCV antibody test results [15]. A 2015 estimate of seroprevalence of HCV for U.S. IDP averaged 18% [7]. A recent study, including testing from July 2018 through June 2019, across California prisons, likewise found IDP at entry had approximately 18% HCV antibody positivity with opt-out screening [6].

In the current real world evidence-based study, 59.4%% (24,694/41,539) of the IDP population and 63.7% (45,819/71,965) of general population participants were cleared/cured of their HCV infection based on a negative HCV RNA test result following an initial HCV RNA positive test result – ignoring the sizable 48.2% (38,625/80,164) of the IDP population and 45.0% (58,907/130,872) of the general population who were not subsequently HCV RNA tested after their initial HCV RNA positive result. In contrast, another real-world evidence study in the general population demonstrated achieving 97% sustained virologic response at 12 weeks post-treatment[16]. In the current study, 19.4% (4793/24,694) of initially HCV RNA positive IDP participants initially positive had evidence of HCV viremia after a negative HCV RNA test result. This compares to the recent CCHCS report: 51.1% (1,909/3,376) of those with sustained viral response had subsequent HCV RNA testing and of these 19.8% (378/1,909) had a return to a viremic status during follow up while incarcerated in a California State prison[6]. Although the time periods evaluated differ between the two investigation and there may be substantial overlap in the populations studied, the relative similarity between the two datasets suggest that both approaches may be employed to describe the HCV care cascade for the IDP population.

Potential approaches to improve HCV care

One analysis estimated risk-based and opt-out screening could diagnose one-third of new hepatitis C infections, compared to no screening practices, and therefore would reduce many more liver-related deaths [17]. Risk-based screening of new IDP could be effective in identifying who is HCV infected and likely eligible for curative treatment [18]. Nevertheless, universal screening of all new and released IDP may be justified based on the high prevalence of HCV infection in that population and to reduce community spread of HCV [15,19]. Further, in a study of Massachusetts hospitalized IDP, 15% individuals with HCV died within 2 years after hospitalization [20]. Hepatitis C infection was associated with a 61% increased risk of 2-year mortality even after controlling for severity of disease [21]. Given the U.S. targets to reduce and eradicate hepatitis C infections and deaths, [21] and that most infections among IDP likely occur outside of correctional facilities, either prior to or after incarceration, routine HCV testing and treatment while incarcerated or detained and those on parole [22] may play an important role in achieving said goals [23]. In reality, for some correctional facilities there is a fluid migration of IDP in and out of jails and prisons with approximately one third annual turnover and median time incarcerated being less than three years and re-incarceration more common among some communities [24,25]. Further, nearly half of all patients with HCV infection are unaware of their infection (and can pass infection onto others) according to National Health and Nutrition Examination Surveys [26]. Thus, screening and treatment of IDP should have broad community benefits in achieving HCV elimination goals [8].

HCV opt-in testing in Massachusetts led to only 22% of IDP/detainees being tested [27]. Opt-out testing tends to me more effective [28,29]. In a modeling study, risk-based and universal opt-out hepatitis C screening in prisons, followed by treatment of those infected can avert many cases of hepatitis including avoiding 90% of infections would have occurred outside of prisons [30]. In another modeling study, a model based upon test all, treat all, and linkage to care at inmate release led to increased lifetime sustained hepatitis C virologic response, decreased cirrhosis, and an additional cost of $1,440 per inmate entrant and deemed cost-effective [31]. Further, co-infection of IDP with hepatitis B, hepatitis C, and/or human immunodeficiency virus are relative common and all three infections may warrant routine testing [32]. Likewise, tuberculosis is more common among IDP than the corresponding general population and such testing should also be considered [33,34]. Novel approaches may include, as suggested by the World Health Organization in 2007, prison needle and syringe programs if there is evidence that injecting drug use is taking place in prisons [35]. Such programs are rare due to many obstacles though considered effective [36,37].

Persistent or recurrent infection

The rate of persistent or recurrent infection was similar in both time periods for the correctional population (20.4% in 2011-2015 and 19.1% in 2016-2020). In contrast, it fell from 9.3% in 2011-2015 to 3.6%, a 61% relative decrease, in the general population during the period of 2016-2020. This may reflect improved ther-

apeutics available in the later time period. However, the minimal change and relatively higher rate of persistent or recurrent infection among the correctional population is of concern particularly since effective antiviral therapeutics were available in that latter period.

Challenges upon release

As we still grapple with the coronavirus disease-2019 (COVID-19) pandemic, we are reminded that IDP recently released back into their communities may be especially vulnerable to social and structural barriers that increase risk to COVID-19 and other infections [38]. In addition, released IDP have higher rates of several chronic medical conditions than does the general population which adds stress to those affected and our entire healthcare systems [39].

Study limitations

The evaluated HCV-related testing was limited to that performed at Quest Diagnostics and there are other clinical laboratory test providers in California. Secondly, California IDP and correctional facilities practices may not be representative of testing and treatment in place at such facilities in other states. Additionally, there may be differences among the various correctional facilities within California. The IDP population members may alternatively receive care prior to and after release from incarceration and such HCV test results would be unavailable for this study. Most significantly, some IDP may spend a limited time within the correctional facility system and therefore not been available for follow-up testing. Additionally, this study was unable to identify where or when HCV infection and rebounds or reinfections occurred. Any HCV treatment prescription data were unavailable to these authors so laboratory test results were relied upon to determine persistence of initial infection, cure, and potential re-infection or viral rebound after an initial infection. Differences in HCV infection detection and treatment practices likely exist during the interval before and after the introduction of highly-effective direct-acting antiviral therapies that were first approved by the U.S. Food and Drug Administration in 2013. Guidelines from American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) in 2018 introduced major changes in treatment eligibility [40]. Of note, the California Department of Corrections and Rehabilitation serves as a model for advancing IDP screening and treatment of hepatitis C, A direct comparison between the IDP and general populations in this study is limited by different criteria for HCV testing and different shares of testing of each group.

Summary

This study findings demonstrated that HCV infection was more common among Quest Diagnostics-tested Californian IDP population than in the general California population and provide evidence that HCV clearance was lower than generally recognized for available treatments [15]. Lastly evidence of recurring viremia or reinfection (HCV RNA positive results with intervening negative HCV RNA test results) was higher among IDP than for the general population. Due to availability of effective treatments and expanding testing and treatment services, current results should be more promising, although always challenging, due to the continual flux of the IDP population in and out of these facilities. This study found HCV treatment response rates and recurrent viremia rates similar to that reported by the CCHCS in 2020 [6]. Maximizing the effectiveness of community-wide HIV viral suppression programs requires correctional/community coordination. Likewise, reduction and elimination of hepatitis C will depend on a thoughtful, well-funded effort to manage this disease for IDP populations involving coordination among the criminal justice system, community health systems, and others [41].

Summary Box

What is the current understanding of this subject?

Hepatitis C virus (HCV) infection and treatment as evaluated by clinical laboratory data differ for the correctional and general populations.

What does this report add to the literature?

Unique comparison of the HCV care cascade of the correctional and general populations, covering 2011-2021.

What are the implications for public health practice?

HCV eradication goals can only be achieved by addressing HCV diagnosis and treatments among incarcerated and detained persons and after their reentry into the general population.

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