### Title

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### Journal

Journal of General Internal Medicine, 37(5)



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### Publication Date

2022-04-01

### DOI

10.1007/s11606-021-06933-z

Peer reviewed

# Is the Availability of Direct-Acting Antivirals Associated with Increased Access to Hepatitis C Treatment for Homeless and Unstably Housed Veterans?

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***OBJECTIVE:*** Hepatitis C virus (HCV) treatment has experienced a rapid transformation in the USA. New direct-acting antiviral (DAA) medications make treatment easier, less toxic, and more successful (90% or greater viral cure) than prior, interferon-based HCV medications. We sought to determine whether DAAs may have improved access to HCV treatment for hard-to-reach populations such as the homeless.

***METHODS:*** In a retrospective study of VA electronic medical record data, a cohort was created of 63,586 veterans with a positive HCV RNA or genotype test taken at any point from January 1, 2012, through December 31, 2016. Patient data were examined for up to 5 years using a discrete time survival model to assess the relationship between their housing status and receipt of HCV medications in 6-month time periods in both the interferon and DAA eras.

***RESULTS:*** In the interferon era, the probability of HCV treatment in a given 6-month window among housed veterans, at 6.2% (95% CI: 5.3–7.1%) was significantly higher than among veterans who were homeless or unstably housed; for example, among currently homeless veterans, the probability of treatment initiation, in a given 6-month window, was 2.6% (95% CI: 1.9–3.3%). With the arrival of DAAs, each housing category had an increased probability of treatment initiation. For housed veterans, the probability was 8.6% (95% CI: 8.3–8.9%) while for currently homeless veterans, it was 6.3% (95% CI: 5.7–6.9%).

***CONCLUSIONS:*** We found a clear indication that the likelihood of treatment initiation was greater for all veterans in the DAA era as compared to the interferon era. However, disparities in treatment initiation rates between housed and homeless veterans that were observed in the interferon era persisted in the DAA era.

***Prior presentations:*** *Preliminary findings from this study were presented at the American Public Health Association Annual Meeting, Philadelphia, PA, November 5, 2019.*

*Received January 6, 2021*
*Accepted May 12, 2021*
*Published online June 25, 2021*

*KEY WORDS:* homeless; veterans; hepatitis C; direct-acting antivirals; treatment initiation.

J Gen Intern Med 37(5):1038–44
DOI: 10.1007/s11606-021-06933-z


## INTRODUCTION

The treatment of hepatitis C virus (HCV) transformed rapidly with the development in 2014 of interferon-free, oral, and brief regimens using medications called direct-acting antivirals (DAAs). DAAs, according to a *New England Journal of Medicine* article, have "revolutionized HCV treatment".[1] While interferon era treatments had cure rates of 50% or less,[2,3] DAAs resulted in viral HCV cure 90% of the time.[4] The high cure rates, mild side effects, and shorter regimens have helped dramatically increase patient treatment initiation rates.

Not all populations have had easy access to HCV medications. Veterans have an estimated HCV prevalence of 6.2%[5] compared to around 1.5% in the non-veteran US population.[6,7] Homelessness has been identified as a barrier to HCV care and treatment generally[8] and has been observed as such specifically among veterans.[9] In the interferon era, homeless veterans were less likely than housed veterans to receive antiviral treatments (22.9% and 31.0% respectively)[10]—this despite the prevalence of HCV being substantially higher in homeless veterans (13.4%) than in housed veterans (3.5%) and despite cure rates being similar in both populations.[10]

Between 2015 and 2016, the VA invested over 1.5 billion dollars in DAAs in an effort to treat virtually all veterans with HCV.[11–13] By October 2016, approximately 125,000 veterans had been treated with DAAs, and about 27,000 veterans in VA care remained untreated.[14]

DAA treatments, with shorter duration (12–24 weeks of one pill a day) and fewer side effects than interferon-containing regimens, could potentially reduce treatment-specific barriers

to HCV therapy that limited the success of the interferon-based regimen among persons experiencing housing instability or homelessness. Additionally, with DAAs, treatment guidelines were revised to reinforce a message that substance use disorder (SUD) and lack of a caregiver were not contraindications to treatment, unlike with prior interferon therapies.[15] These have traditionally represented barriers to treatment initiation for homeless and unstably housed populations.[16] The risk of SUD in those who are homeless is higher[17,18] and social support is generally lower than in housed populations.[19]

,1,2) Are categories of unstable housing and homelessness meaningful in terms of differing rates of HCV treatment initiation?

## METHODS

Using VA's electronic medical record data, we selected a cohort of 63,586 veterans who tested positive for chronic HCV infection between 2012 and 2016. We defined chronic HCV infection as a positive HCV RNA test or an HCV genotype test taken between January 1, 2012, and December 31, 2016. We structured our data in discrete time-to-event format, examining up to 5 years of a patient's data from their initial positive HCV test until the date they initiated HCV medications, or until censoring at the end of the study period (December 31, 2016).

Specifically, we examined receipt of HCV treatment and housing status in a series of 6-month windows, defined by the date a veteran first received a positive HCV test. These 6-month periods constitute our unit of analysis and the number of person 6-month periods each patient contributes to the analysis varies as a function of their HCV diagnosis date and whether and when they received HCV treatment. For example, for a patient diagnosed January 1, 2013, their initial 6-month window starts that date and would end on June 30, 2013. If they initiated HCV treatment on July 3, 2013 (i.e., in their 2nd 6-month period), they would contribute two person-6-month periods to the study; if alternatively they had initiated treatment on January 3, 2014, they would contribute three person-6-month periods.

,1,[20] (1) currently housed; (2) at risk of homelessness; (3) currently homeless; (4) formerly homeless; and (5) multiple homelessness indicators (see Table 1,

To assess whether both current housing instability and a recent history of housing instability were associated with HCV treatment initiation, we included measures of housing status both in each six-month period and in the previous 6-month period. We used a discrete time-to-event data structure, meaning we examined whether patients initiated HCV treatment at some point within a series of 6-month periods relative to their initial date of HCV diagnosis. We used survival analysis, which is designed for time-to-event data and can handle the timing of event occurrence (initiation of HCV treatment) and the possibility that individuals are censored (i.e., not observed to initiate HCV treatment prior to the end of the study period). Conventional logistic regression, which requires a fixed time interval during which an event occurred or not, would not have been suitable. Instead, we used a discrete time survival model—intended to handle discrete time-to-event data—to assess the relationship between housing status, treatment era, and treatment initiation.

We defined the start of DAA era as 1/1/2015, the date ledipasvir/sofosbuvir was added to the VA formulary, marking a rapid increase in HCV treatment initiation.[13] In our primary analyses, covariates of interest were housing status in the current 6-month window, housing status in the prior 6-month window, a binary indicator of interferon era (prior to 1/1/2015) or DAA era (on or after 1/1/2015), and interaction terms representing every possible combination of our housing status measures and the treatment era indicator (e.g., current homelessness in the DAA era, at risk of homelessness in the interferon era). The inclusion of these interaction terms enabled an assessment of whether the relationship between housing status and treatment initiation differed between the

**Table 1 Housing Categories, with Definitions, used in Analyses**

| Category | Definition (from Byrne et al. 2019*) |
|---|---|
| Housed | Lack of any indicator, in VA administrative data, that they meet criteria for any of the four categories below |
| At risk of homelessness | Screened positive for risk (by reporting concern they would lose housing in <60 days) when responding to the Homelessness Screening Clinical Reminder or if they accessed Supportive Services for Veteran Families homelessness prevention services |
| Currently homeless | Using federal statutory definitions, we included veterans who accessed a VA residential homeless program (based on the Homeless Operations Management and Evaluation System), used Supportive Services for Veteran Families rapid rehousing services (which requires literal homelessness as an eligibility criterion), or reported current homelessness when responding to the Homelessness Screening Clinical Reminder. |
| Formerly homeless | Received services from the US Department of Housing and Urban Development/VA Supportive Housing (HUD-VASH) program, which provides HUD housing vouchers and VA supportive services to permanently house highly vulnerable, chronically homeless veterans. This designation reflects the fact that, once housed, veterans residing in HUD-VASH housing are no longer considered homeless per the federal definition. |
| Multiple homelessness indicators | Based on a hierarchy in which former homelessness superseded current homelessness and current homelessness superseded risk of homelessness. Former homelessness superseded current homelessness in this hierarchy because a veteran had to be homeless to be eligible for the HUD-VASH services we used to identify formerly homeless veterans. |

,*Public Health Reports. 2019;134(2):126–131*

interferon and DAA eras. This model also controlled for sociodemographic characteristics, physical and mental health diagnoses, and VA Medical Center (VAMC) (see Table 2) and parameterized time as a cubic function. Physical health was represented by a count of Elixhauser comorbidities,[21] while the mental health variable ranged from zero to four based on the presence of diagnoses for depression, bipolar disorder, psychoses, and post-traumatic stress disorder (see Supplement 2 for all ICD-9 and ICD-10 codes included). Because there was a period when both DAAs and interferon-based regimens were in use, we conducted sensitivity analyses comparing treatment rates in 3 time periods—interferon (<1/1/2014), combined (1/1/2014–12/31/2014), and DAA (≥1/1/2015). Because results indicated little difference between the interferon era and combined era in terms of treatment initiation rates, we present only the primary analyses described above. The sensitivity analyses can be found in Supplement 3.

To facilitate interpretation of this model, we provide an indication of how likely one group (e.g., currently homeless) is to receive treatment compared to the other groups, using Stata's margins command to estimate predicted probabilities of treatment initiation in an average 6-month window, stratified by housing status and treatment era, holding all other covariates at their mean values. We plotted these predicted values and their associated 95% confidence intervals in Figure 1. Because these confidence intervals can overlap even in instances where there are statistically significant differences between these values, we used Stata's pwcompare function to conduct pairwise comparisons of the mean values of these adjusted predicted probabilities, using a Bonferroni correction to account for multiple comparisons. All assessments of statistically significant differences in the probability of treatment initiation presented in the results section are based on these pairwise comparisons. The VA Bedford Healthcare System's IRB approved the study.

## RESULTS

Demographic information and treatment probabilities in the interferon and DAA eras are shown for the cohort of 63,586 veterans who tested positive for HCV between 2012 and 2016 (Table 2). This sample was largely male (96%), and mostly between 50 and 69 years of age. Most were white (60%); 29% were African American. Other characteristics included in the survival models are also shown. Most of the sample were housed in at least one of their observed 6-month periods (73%). Of the 27% remaining, in any of the 6-month windows, 8% were at risk of homelessness, 22% currently homeless, 13% formerly homeless/in long-term housing, and 14% with multiple indicators of homelessness (percentages do not equal 100% because the categories are not mutually exclusive).

Treatment initiation rates were substantially higher in the DAA era compared to the interferon era, in raw terms, regardless of whether one was currently housed or had experienced one or more of the forms of homelessness/housing instability. For example, for those housed, the treatment initiation rate was 47.6 per 1000 person-years in interferon and 229.1 per 1000 person-years in DAA era. For those at risk of homelessness, the respective treatment initiation rates per 1000 person-years were 31.2 and 216.6; similarly, the other 3 categories of homelessness showed higher treatment initiation rates in DAA era compared to interferon era.

The results of the discrete time survival model are shown in Figure 1. The figure displays the adjusted predicted probabilities of treatment initiation in both the interferon and DAA eras, stratified by housing status. In the interferon era (red bars), the probability of HCV treatment initiation in a given 6-month period among housed veterans (6.2%, 95% CI: 5.3–7.1%) was significantly higher than veterans who were currently homeless (2.6%, 95% CI: 1.9–3.3%), formerly homeless (3.9%, 95% CI: 2.5–5.2%), or who had multiple indicators of homelessness (2.0%, 95% CI: 1.3–2.7%), but not significantly different from veterans who were at risk of homelessness (3.8%, 95% CI: 1.9–5.8%). The pairwise comparisons also found that those with multiple indicators of homelessness had a significantly lower probability of treatment initiation as compared to those who were formerly homeless, but there were no other significant differences among the groups with some indicator of homelessness. Each housing category had an increased probability of treatment initiation with the arrival of the DAAs (blue bars), with four of the five differences being statistically significant. The sole group without a statistically significant difference was at risk for homelessness. The largest increase was in currently homeless veterans, whose probability of treatment initiation in a six-month window increased from 2.6% in the interferon era to 6.3% in the DAA era, nearly a two-and-a-half-fold increase. As in the interferon era, the probability of HCV treatment initiation in the DAA era in a 6-month window was significantly higher for housed veterans (8.6%, 95% CI: 8.3–8.9%) than for those at risk, (6.5%, CI 5.5–7.6%), formerly homeless (6.6%, 95% CI: 5.9–7.3%), currently homeless, (6.3%, 95% CI: 5.7–6.9%), and who had multiple indicators of homelessness (4.7%, 95% CI: 4.1–5.2%). In pairwise comparisons, those with multiple indicators of homelessness had a significantly lower probability of treatment initiation than those who were at risk, currently homeless, and formerly homeless. In separate analyses, we found that there was relatively little evidence that recent past history of housing status (i.e., in the prior 6-month window) was associated with the probability of treatment initiation in a given 6-month window (Supplement 4).

## DISCUSSION

This is the first study, to our knowledge, of how DAAs have influenced HCV treatment access among the homeless and marginally housed. DAAs appear to have dramatically increased access to HCV treatment among veterans, compared

**Table 2 Treatment Initiation Rates by Sample Demographics, Comparing the Interferon to the DAA Era**

| Characteristic | Overall | Interferon ERA (1/1/2012-12/31/2014) | | DAA era (1/1/2015-12/31/2016) | |
|---|---|---|---|---|---|
| | Total veterans, *N* (%) | Total veterans *N* | Treatment initiated veterans, *N* (rate per 1000 person-years) | Total veterans, *N* | Treatment initiated veterans, *N* (rate per 1000 person-yrs) |
| Total | 63586 (100.00%) | 37133 | 2826 (44.19) | 60760 | 20396 (229.13) |
| Male | 60833 (95.67%)) | 35601 | 2716 (44.17) | 58117 | 19635 (230.66) |
| Female | 2749 (4.32%) | 1529 | 110 (44.89) | 2639 | 760 (195.78) |
| Unknown sex | 4 (0.01%) | 3 | 0 (0.00) | 4 | 1 (200.00) |
| 18–29 | 3766 (5.92%) | 1896 | 83 (28.72) | 3683 | 826 (149.29) |
| 30–39 | 2602 (4.09%) | 1377 | 84 (37.71) | 2518 | 567 (149.33) |
| 40–49 | 6643 (10.45%) | 3849 | 304 (47.31) | 6339 | 1975 (210.17) |
| 50–59 | 32825 (51.62%) | 19482 | 1656 (48.98) | 31169 | 11788 (261.38) |
| 60–69 | 15760 (24.79%) | 9340 | 677 (41.22) | 15083 | 4947 (224.49) |
| 70+ | 1990 (3.13%) | 1189 | 22 (10.14) | 1968 | 293 (92.97) |
| American Indian/Alaska Native | 546 (0.86%) | 313 | 34 (65.45) | 512 | 162 (209.30) |
| Asian | 197 (0.31%) | 102 | 1 (6.31) | 196 | 38 (131.03) |
| Black/African American | 18166 (28.57%) | 10558 | 525 (28.19) | 17641 | 6323 (245.00) |
| Hispanic or Latinx | 3376 (5.31%) | 2006 | 155 (46.19) | 3221 | 948 (196.03) |
| Multi-race | 509 (0.80%) | 295 | 19 (36.71) | 490 | 159 (217.51) |
| Native Hawaiian/Other Pacific Islander | 345 (0.54%) | 203 | 25 (74.74) | 320 | 98 (204.59) |
| White | 38202 (60.08%) | 22342 | 1977 (51.89) | 36225 | 12117 (229.29) |
| Unknown Race/Ethnicity | 2245 (3.53%) | 1314 | 90 (38.54) | 2155 | 551 (169.56) |
| Divorced or Separated | 27536 (43.31%) | 16413 | 1190 (41.48) | 26346 | 8864 (227.70) |
| Married | 20622 (32.43%) | 11730 | 1076 (54.16) | 19546 | 6859 (246.26) |
| Single | 12154 (19.11%) | 7106 | 443 (36.43) | 11711 | 3728 (212.93) |
| Widowed | 2868 (4.51%) | 1687 | 107 (36.73) | 2761 | 828 (199.25) |
| Unknown marital status | 406 (0.64%) | 197 | 10 (31.60) | 396 | 117 (206.17) |
| Not service connected (NSC) | 31808 (50.02%) | 18556 | 1505 (47.29) | 30303 | 10690 (242.63) |
| NSC, VA pension | 3852 (6.06%) | 2423 | 123 (28.03) | 3729 | 1145 (199.46) |
| Other | 955 (1.50%) | 604 | 20 (18.17) | 935 | 249 (171.43) |
| Service connected (SC) 50–100% | 15219 (23.93%) | 8778 | 619 (41.03) | 14600 | 4376 (202.42) |
| SC less than 50% | 11731 (18.45%) | 6759 | 559 (48.54) | 11172 | 3930 (243.92) |
| Unknown VA eligibility | 21 (0.03%) | 13 | 0 (0.00) | 21 | 6 (196.72) |
| AUD* | 4934 (7.76%) | 2976 | 166 (30.18) | 4768 | 1292 (174.80) |
| SUD* | 5918 (9.31%) | 3464 | 183 (29.83) | 5735 | 1590 (178.62) |
| HIV* | 437 (0.69%) | 284 | 21 (41.54) | 416 | 125 (195.47) |
| Liver Disease* | 1279 (2.01%) | 764 | 99 (77.22) | 1180 | 292 (165.25) |
| Housed* | 46619 (73.32%) | 27406 | 2494 (47.58) | 48174 | 17490 (229.08) |
| At risk of homelessness* | 5287 (8.31%) | 2809 | 22 (31.18) | 2831 | 150 (216.61) |
| Currently homeless* | 13752 (21.63%) | 7889 | 128 (25.63) | 9731 | 986 (218.17) |
| Formerly homeless—in long term supportive housing* | 8522 (13.40%) | 4407 | 66 (35.53) | 6621 | 760 (228.37) |
| Multiple indicators of homelessness* | 8799 (13.84%) | 4613 | 116 (29.22) | 5837 | 1010 (244.79) |
| Mental illness diagnoses, mean (SD) | 0.22 (0.54) | 0.21 (0.54) | 0.17 (0.47) | 0.22 (0.55) | 0.18 (0.50) |
| Elixhauser index, mean (SD) | 0.48 (1.13) | 0.48 (1.10) | 0.34 (0.83) | 0.48 (1.15) | 0.35 (0.89) |
| Outpatient visits*, mean (SD) | 11.91 (16.40) | 12.56 (16.59) | 19.56 (15.09) | 11.44 (16.25) | 18.13 (16.10) |
| Inpatient stays*, mean (SD) | 0.22 (0.73) | 0.25 (0.77) | 0.15 (0.53) | 0.20 (0.70) | 0.15 (0.54) |

*Notes: Treatment initiation differed significantly (Bonferroni-adjusted $p < 0.01$) by all characteristics except for sex and HIV status based on chi-square tests (or Fisher's exact tests when appropriate). *Indicates characteristics that were allowed to vary by person-period. Frequencies reported in "Total veterans" columns for these characteristics represent the number of veterans who ever held this characteristic (e.g., total veterans who had AUD in ≥1 person-period)*

to the era in which interferon-based treatments were used. Among veterans linked to HCV care, the treatment rates went from 11.8% in the interferon era to 59% in the DAA era.[13] Not unexpectedly, housing status was associated with access to treatment. We found that regardless of treatment era (interferon or DAA), being homeless or unstably housed was associated with lower HCV treatment initiation rates compared to being housed. In the interferon era, currently homeless veterans were only 42% as likely as stably housed veterans to initiate treatment. This difference persisted in the DAA era but was attenuated: in a given 6-month window, currently homeless veterans were only 73% as likely as stably housed to initiate treatment.

Not all types of housing instability (at risk of homelessness, currently homeless, formerly homeless, multiple types of homelessness) were associated with lower odds of treatment initiation, compared to being housed. For instance, there was no significant difference in treatment initiation rates between the at-risk group versus the housed group. A potential explanation for this is that because the at-risk group resides in

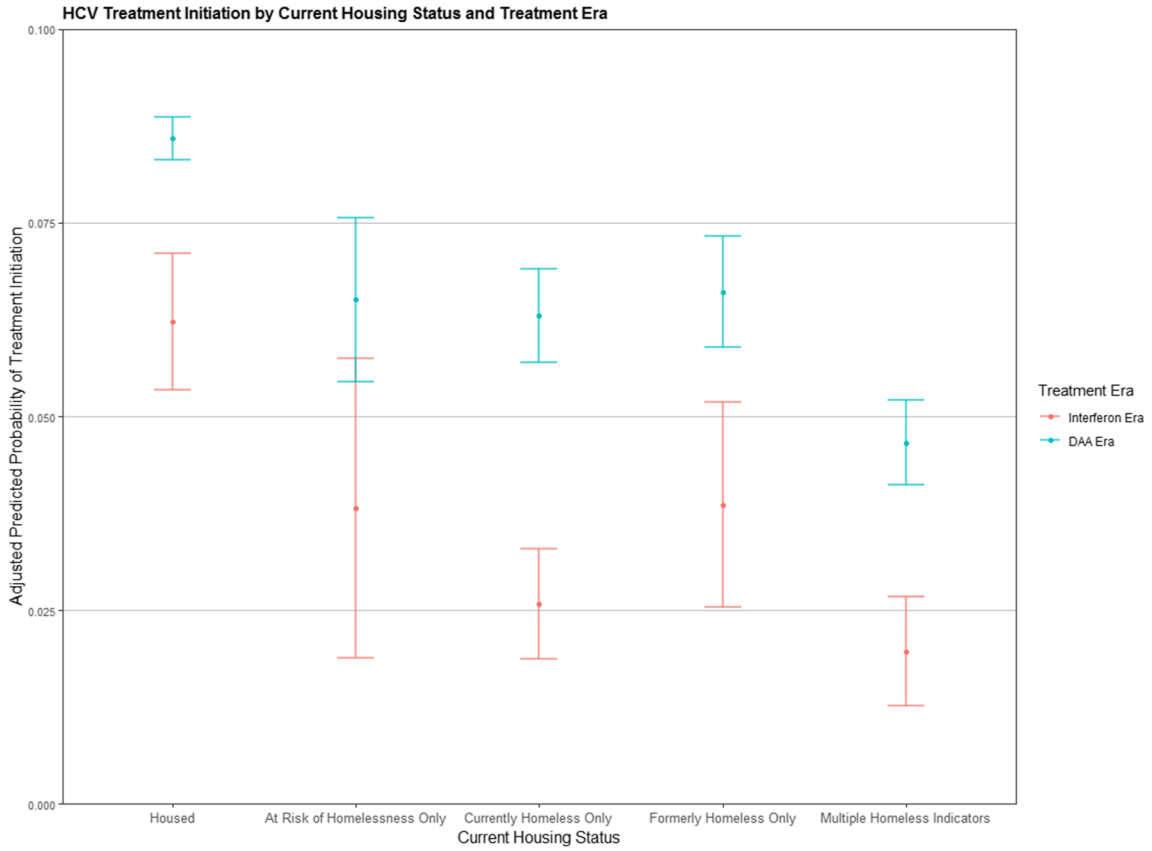


**Figure 1 Homelessness interaction with treatment era. Adjusted predicted probabilities of treatment initiation in a given 6-month window. *"Housed" indicates a lack of an indicator of homelessness in a subject's record. DAA, direct-acting antiviral.**

housing, albeit tenuously, they may share features of the housed group (access to internet, calendar for keeping track of appointments, etc.) which enable regular contact with the healthcare system.

Our findings are consistent with research indicating that unstable housing and homelessness may present barriers to medication adherence in tuberculosis[22] and HIV.[23,24] Research into social determinants of health, more broadly, suggests that making treatments accessible to the widest population possible will require fundamental socio-economic changes, such as affordable housing and job opportunities.[25,26] Availability of mental health and substance use services is important because mental illness and SUD are implicated among the causes of homelessness and contribute to its prolongation.[27]

Our study had several limitations. By focusing on treatment initiation, we highlight only one facet of DAAs' impact. We emphasized access to treatment, often a barrier to improved health among vulnerable populations; nevertheless, additional work is needed to follow patients all the way to sustained HCV viral response, to determine the extent of inadequate medication adherence and lost to follow-up. The veterans in our dataset were enrolled in VA healthcare and thus not representative of all veterans; similarly, our findings may not generalize to the non-veteran populations. Treatment initiation was only captured if a veteran received treatment in the VA, thus excluding outside treatments that some patients in our dataset may have received. Hence, our treatment initiation rates may be a lower-bound. Nevertheless, the VA's full payment for the expensive HCV treatment would have been a strong incentive for veterans eligible for VA care to seek treatment in VA.

The classification of veterans into housing categories was based on administrative databases which may, in some cases, have lags resulting in a homelessness episode being attributed to the wrong 6-month period. Our currently homeless category encompassed both sheltered and unsheltered veterans (with the latter presumably encountering more HCV treatment barriers than the former) because it was not possible to easily separate them in this study. For our housed category, misclassification was possible if veterans experiencing homelessness had not used any VA homelessness-related services nor reported their homelessness to any VA personnel. Finally, while our analytic approach examines housing status and treatment initiation in 6-month windows, we could not identify with any more precision whether a change in housing status within a given 6-month window preceded or followed treatment initiation.

There are other possible drivers of the increased treatment rates we observed in the DAA era. The arrival of DAAs was

anticipated among hepatologists potentially leading them to advise some patients to delay treatment until better regimens became available. This may have led to pent-up demand making treatment rates artificially elevated after DAAs became available. Data showing declining rates of treatment initiation among veterans in the years preceding DAAs support this assertion.[28] Additionally, pressures to rapidly treat veterans led to congress infusing the VA healthcare system with funds to purchase substantial quantities of DAAs, creating pressures on providers to quickly treat veterans, as described by Moon et al.[28]

Despite the shortcomings, this study's strengths outweigh the limitations, including the size of the dataset and the ability to classify patients based on different types of homelessness. It provides a novel view into how innovations (in this case dramatically improved HCV medications) spread to populations and the extent to which they reduce disparities or not.

In conclusion, the arrival of DAA's helped all groups of veterans, housed and non-housed, achieve substantially better access to HCV treatment. Nevertheless, disparities in access to treatment, which had existed in the era of interferon-containing treatments, persisted even with the introduction of highly effective, tolerable, and shorter duration DAA treatments. In a system where the patient cost of HCV treatments would not have been a barrier, there must be other explanations for lower initiation rates among patients experiencing homelessness. Some providers, for example, may consciously or unconsciously offer HCV treatments less often to patients experiencing homelessness due to concerns that this population's higher rates of substance use may lead to higher rates of HCV re-infection after treatment.[29,30] Another provider concern—about the frequent theft or loss of medications among persons unstably housed[31]—represents both a perceived and a true barrier to patients' treatment adherence. Additional understanding of these barriers and how to overcome them are needed to make these life-saving treatments available to all patients, regardless of their housing status or other social or economic vulnerabilities.

***Supplementary Information*** *The online version contains supplementary material available at https://doi.org/10.1007/s11606-021-06933-z.*

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***Funders*** *This material is based upon work supported by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Health Services Research and Development grant number IIR 14-322.*

***Data Availability*** *The datasets generated during and analyzed during the current study are not publicly available due to data security and privacy policies at the VA Bedford Healthcare System, but individuals willing to undergo necessary background checks and credentialing may be able to gain access. They may contact the corresponding author to make a request.*

***Declarations:***

***Disclaimer:*** *The findings and conclusions in this article are those of the authors and do not represent the views of the VA or the US Government.*

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