BRIEF REPORT

Aggregate Trends of Hepatitis C Virus Identification and Treatment in Maryland Corrections Fiscal Years 2012–2016

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Published online: 6 December 2017
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In a given year, it is estimated that 1 in 3 individuals with HCV in the USA will pass through a jail or prison [1]. Despite the high disease burden in January 2015, less than 1% of individuals with known chronic HCV in state prisons received HCV treatment [2]. As highlighted in a recent paper by Beckman et al., longitudinal data pertaining to HCV treatment access in incarceration systems overtime has remained out of the public domain up until this point.

With the approval of sofosbuvir in December 2013, treatment paradigms have significantly altered from pegylated interferon-based therapy to oral direct-acting antiviral (DAA) therapies because they reliably cure HCV in 12 to 24 weeks and because of their minimal side effect profile [3, 4]. The manufacturers of DAAs have priced these therapies at unprecedented levels with a course of curative therapy ranging from \$54,600–\$147,000 (Wholesale Acquisition Cost) [5]. This has placed major financial pressures on state incarceration systems [2, 6]. However, the

proportion of inmates who received any HCV treatment in Maryland Department of Public Safety and Correctional Services (DPSCS) began to trend down shortly before and after the approval of the first DAAs in fiscal year (FY) 2014 (Fig. 1). While the proportion of individuals has decreased from 6% in FY 2012 to 2% in FY 2016, this decline in HCV treatment utilization in Maryland DPSCS is still higher than the reported 1% national average among state incarcerated facilities [2].

Overview of Maryland DPSCS

With an annual budget of approximately \$1.2 billion dollars, the Maryland DPSCS operates the state prison system and Baltimore City jails [7]. Approximately, one third of inmates are from 25 communities in Baltimore City [8]. This system includes 22 prison and prerelease centers incarcerating approximately 21,000 individuals [7]. The Maryland DPSCS utilizes a multi-vendor model to provide the health care needs of Maryland DPSCS.

A combination of legislative interest and litigation concerns led Maryland DPSCS to begin the testing and treatment of HCV in 2005 [7]. Although the clinical criteria and considerations for treatment have changed with clinical practice during the examined time frame of FY 2012 to FY 2016, screening of HCV has not. Maryland DPSCS does not utilize a universal testing policy; instead relying on the presence of designated risk factors, self-request, or when clinically necessary. Once an inmate has been identified as having HCV, they are

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Fig. 1 Proportion of inmates with chronic hepatitis C virus receiving treatment in Maryland DPSCS. Sources: author's analysis of aggregated monthly data of Maryland Department of Public

Safety and Correctional Services (DPSCS) inmates. Notes: inmates considered eligible for treatment defined as having an active hepatitis C virus (HCV) infection

subsequently enrolled in a chronic care clinic, referred to and assessed by an infectious disease specialist, and brought to an HCV panel for a comprehensive clinical review and possible treatment determination.

Each request for treatment is comprehensively reviewed by a multidisciplinary team that considers both clinical and incarceration-specific characteristics related to HCV and liver function, comorbid conditions, medication compliance, abstinence from illicit drugs and/or alcohol, and remaining length of sentence. Consideration of remaining length of sentence is prudent to allow for assessment of sustained virologic response, or cure, after completion of therapy. If a detainee is present in Maryland DPSCS while on HCV therapy, it is a departmental policy to continue treatment.

HCV Screening and Diagnosis

As is typical in clinical practice, the screening and diagnosis of HCV is a two-step process [4, 7]. The first step typically consists of a preliminary HCV antibody screening. However, this does not determine an active HCV infection; rather, it indicates that an individual either has an active infection or has spontaneously cleared the virus. A subsequent HCV RNA test is warranted several months after a positive HCV antibody to confirm chronic HCV infection. This confirmatory period is particularly important in the correctional environment where inmates often leave the correctional system prior to second step confirmative testing due to short or variable sentences.

Study Data and Methods

Data are from FY 2012–2016 (July 1, 2011 through June 30, 2016) and were extracted from reports regularly tracked and maintained by the medical vendor and reported to Maryland DPSCS. Maryland's fiscal year runs from July 1 to June 30 with the year designation being determined with the calendar year of the last date. For example, July 1, 2011 through June 30, 2012 would be FY 2012. Fiscal years 2012 through 2016 of Maryland DPSCS were chosen, because they allow for a before and after snapshot surrounding the approval of sofosbuvir in December 2013. To generate these reports, the infectious disease specialist regularly reviewed electronic health records and communicated with on-site clinicians to aggregate numbers on data points of interest including number of HCV antibody tests, number of newly confirmed HCV positive inmates, estimated prevalence of inmates with active chronic HCV, individuals brought to panel for treatment consideration, and the treatment selected (DAA agent or interferon).

The number of HCV antibody tests and confirmed HCV positive inmates are sum totals for the given fiscal year. With the exception of estimated HCV positive inmates, all values are 12-month averages of the aggregate reports collected by the infectious disease specialist. In this report, estimated number of inmates with chronic HCV infection is based on the number of individuals with antibody positive test results less than the average number of individuals who had previously and spontaneously cleared the disease or who had completed treatment with a confirmed cure.

Results

Identification of HCV

Although Maryland DPSCS policies to only screen individuals that present with high-risk factors, self-requesting, or with clinical need have their drawbacks, the consistent enforcement of this policy led to a similar proportion of positive HCV antibody screenings across all examined fiscal years (Fig. 2). Although there have been modest decreases in the number of screenings performed between 2012 and 2016, this corresponds to a gradual decline of the daily Maryland DPSCS census [9]. In addition, the proportion of the inmate population that has been identified as having been exposed and have an active infection remained fairly similar over the same period (Fig. 3). This proportion ranged from 4.3:1 to 4.7:1 across all years.

Access to HCV Treatment

Throughout FY 2012 and 2016, between 28 and 33% of inmates that had chronic HCV were evaluated by the interdisciplinary HCV panel for further evaluation or treatment (Fig. 1). Among inmates with chronic HCV, the highest proportion of HCV positive inmates receiving any therapy peaked in FY 2013 with 6.4% on treatment and decreased to a low of 2.12% in FY 2016.

Discussion

Similar to many incarceration systems, Maryland DPSCS has never implemented universal opt-out screening protocols for HCV. This creates an underreporting of HCV positive inmates in Maryland DPSCS. This is substantiated by a study published in 2004 that found an HCV antibody positive rate among Maryland DPSCS entrants of approximately 29.7% [10] compared to our studies' results ranging between 21 and 23% confirm from FY 2012–2016.

It is important to note that not all inmates with chronic HCV are actively considered for therapy. Many have already been evaluated, or were not eligible for consideration due to the small remainder of their sentence to be served, or experienced treatment failures on interferon-based therapy, or opted to forgo further evaluation and liver biopsy for staging. Prior to DAA therapy, interferon-experienced inmates remained eligible for HCV therapy and were considered high priority for future treatment. However, for much of the time period after the approval of sofosbuvir, Maryland DPSCS reviewed, and continues to review, treatment on a case-by-case basis due to the absence of Maryland DPSCS protocols for treatment-experienced individuals and/or due to the anticipation of additional DAA regimens.

The observed decrease in the proportion of HCV positive inmates that received treatment over the study period, 6% in FY 2012 to 2% in FY 2016, can be explained through external and internal factors. External factors may include the approval of sofosbuvir during FY 2014; partially consistent with clinical guidelines at that time, clinicians and their patients may have selected to defer treatment among those who were less clinically

Fig. 2 Frequency of antibody testing and subsequent confirmation as having been exposed to chronic hepatitis C virus in Maryland DPSCS. Sources: author's analysis of aggregated monthly data of Maryland Department of Public Safety and Correctional Services

(DPSCS) inmates. Notes: positive hepatitis C virus (HCV) antibody only confirms exposure and not active infection. Due to varying sentence length, not all inmates are able to be definitively identified as having an active infection while in Maryland DPSCS

Fig. 3 Average number of inmates having been exposed and subsequently confirmed as having chronic hepatitis C virus in Maryland DPSCS. Sources: author's analysis of aggregated monthly data of Maryland Department of Public Safety and Correctional Services

severe in hopes of future utilization of DAA therapies. However, internal factors such as the implementation of protocols that resulted in the increased use of DAA therapies likely resulted in delayed utilization.

It would be incorrect to utilize this report to determine the rates of spontaneous clearance and chronic HCV infections among inmates of Maryland DPSCS. Due to varying lengths of an incarcerated individuals' stay in prison, not all individuals who meet the high-risk opt-in screening policies of Maryland DPSCS receive a follow-up RNA test. This results in an underestimation of both spontaneous clearance and chronic infections.

Results do not capture recent changes in Maryland DPSCS treatment protocols beginning in first half of FY 2017. This is particularly noteworthy as Maryland DPSCS has recently expanded protocols to increase access and utilization of DAA regimens. Maryland DPSCS formulary does not explicitly prefer one HCV agent over another and leaves it largely to the discretion of the infectious disease specialist with the input from the clinical pharmacist.

Conclusion

In Maryland DPSCS, the proportion of identified individuals with chronic HCV on treatment decreased over FY 2012 to 2016. However, the percentage of individuals with known chronic HCV on treatment decreased from 6 to 2%. The utilization of pegylated interferon for the treatment of chronic HCV dominated throughout the study period. At the close of FY 2016, approximately 2% of inmates with HCV were receiving any therapy with approximately half receiving DAA therapy. A noticeable decline of individuals on treatment occurred in the end of the study is likely

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due to clinician and patient preference of DAA therapies over interferon-based therapies, and Maryland DPSCS implementation of protocols that reflected changing clinical guidelines. Inclusion of additional state correctional systems is needed in order to determine national longitudinal trends regarding the accessibility of curative HCV therapy among the incarcerated.

Acknowledgements The authors would like to thank Kelly Calabrese, BS for her editorial input.

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Note: This aggregate analysis received a not human subject research designation from the University of Maryland, Baltimore institutional review board.