

Dialysis facility screening and testing practices in the era of improved hepatitis C treatment

M. S. Moore  | A. Bocour | A. Winters

Viral Hepatitis Program Surveillance Unit, New York City Department of Health and Mental Hygiene, Division of Disease Control, Bureau of Communicable Diseases, Queens, NY, USA

Correspondence

Miranda S. Moore, Viral Hepatitis Program Surveillance Unit, New York City Department of Health and Mental Hygiene, Division of Disease Control, Bureau of Communicable Diseases, Queens, NY, USA.

Email: mmoore3@health.nyc.gov

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1 | INTRODUCTION

Chronic hepatitis C virus (HCV) infection is a problem for patients receiving haemodialysis; the last estimate of HCV prevalence in this population was 8.9%, more than 5 times the rate in the general population.¹⁻³ Because of the need for prolonged vascular access, exposure to body fluids, and reusable equipment shared between patients, there is elevated risk of HCV transmission and outbreaks in dialysis facilities, and the risk of infection increases with successive years on dialysis.³ HCV infection also decreases survival among haemodialysis patients.² Previous HCV treatment options for patients with end-stage renal disease (ESRD) were limited and often unsuccessful; fortunately, in 2016 and 2017, two new medications were approved to treat HCV of all genotypes in dialysis patients with high cure rates.⁴

Given the high prevalence of HCV and risk of transmission, it is recommended that dialysis facilities screen all patients for HCV antibody (anti-HCV) on intake and bi-annually for those who are anti-HCV negative.¹ Once an individual tests anti-HCV positive, additional anti-HCV testing is unnecessary. Additionally, with highly effective treatments now available, it is more important than ever that anti-HCV positive dialysis patients be tested for HCV RNA to determine current infection status and assessed for treatment.

The NYC Department of Health and Mental Hygiene (DOHMH) examined anti-HCV and RNA testing performed by dialysis centres in NYC between 1 January 2014 and 31 December 2017 to assess HCV testing practices.

2 | METHODS

The Department of Health and Mental Hygiene has near real-time electronic laboratory reporting for all positive anti-HCV and genotype tests, and all positive and negative HCV RNA tests performed

on NYC residents. Laboratory reports include the name and address of the ordering facility and physician. To identify HCV reports ordered by dialysis facilities, ordering facility and provider addresses were matched to a list of NYC dialysis centres available from the New York State Health Facility Information System (NYS HFIS).⁵ Additionally, ordering facility and provider names were searched for keywords including “dialysis,” “renal,” and “kidney.” Matched facilities were manually reviewed for overmatches, such as matches to renal medicine or kidney transplant specialists. Inpatient dialysis facilities were excluded because of difficulty in differentiating tests ordered by the dialysis centre versus elsewhere in the hospital.

To examine repeat anti-HCV testing, all individuals with a positive anti-HCV test collected in 2014 from a dialysis facility were selected. Among these individuals, all subsequent anti-HCV tests ordered by any dialysis facility in 2014-2017 were tallied. Excess antibody tests (all tests after the first test in 2014) were graphed by month and year. To assess anti-HCV testing after confirmed (RNA/genotype positive), each patient's first positive RNA or genotype test was identified and antibody testing after this date was tallied.

To examine RNA confirmation practices in dialysis facilities, individuals with a positive anti-HCV test ordered by a dialysis facility in 2016 were identified; 2016 was chosen to measure recent RNA confirmation only. Confirmatory testing included a positive or negative RNA or genotype test reported in 2016-2017 by any facility to DOHMH among these individuals. Confirmatory testing was broken down by testing performed by a dialysis facility or by any healthcare facility in NYC.

Finally, treatment initiation among dialysis patients was estimated using a DOHMH-developed and validated treatment algorithm.⁶ Treatment initiation is defined as at least one negative RNA result preceded by a high positive (viral load ≥ 1000 IU/mL) RNA result. As the first ESRD-approved treatment became

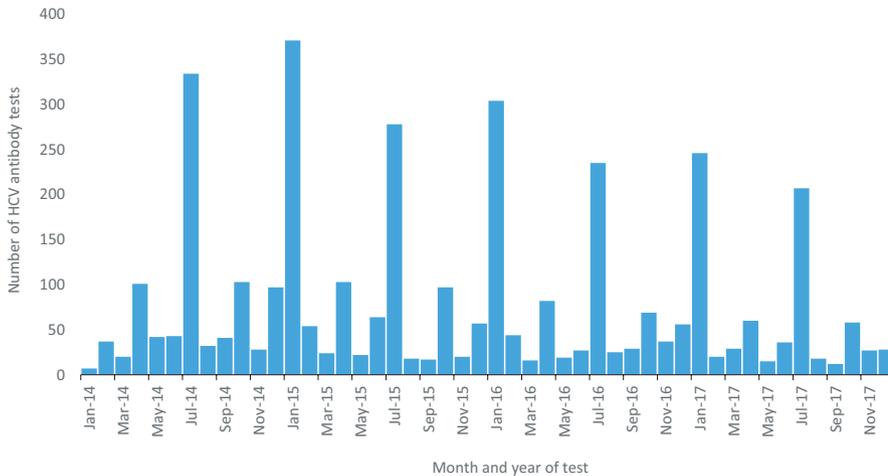


FIGURE 1 Timing of additional dialysis-ordered anti-HCV tests performed between 2014 and 2017 among 709 patients testing anti-HCV positive at a New York City dialysis facility in 2014

available in January 2016, the treatment algorithm was applied to all individuals with a positive anti-HCV test from a dialysis facility in 2016 (same cohort used to assess RNA confirmation) and examined all positive RNA tests and negative RNA tests performed in 2016-2017. Repeat antibody testing after treatment was examined by tallying anti-HCV tests ordered by a dialysis facility after a reported negative RNA test through December 2017.

All analyses were completed using SAS 9.4 (Cary, NC). This analysis was classified as public health surveillance that is non-research by the DOHMH IRB.

3 | RESULTS

There were 112 dialysis facilities reporting at least one positive anti-HCV test during January 2014-December 2017. In all, there were 7918 positive anti-HCV tests for 2277 patients ordered by dialysis facilities in the study period.

3.1 | Repeat antibody testing

In 2014, 931 individuals had at least one reported positive anti-HCV test from one of 77 dialysis facilities. Of these, 709/931 (76.2%) patients had at least one additional dialysis-ordered anti-HCV test in 2014-2017, averaging 6.2 (standard deviation (SD): 4.4) additional tests. When graphed by month, testing appeared most frequent in January and July, with smaller peaks in April and October of each year (Figure 1). Additionally, 840/931 (90.2%) patients ever had a positive RNA/genotype test; 809/840 (96.2%) of them had anti-HCV testing after their positive result, with an average of 5.0 tests (SD: 4.4) after testing RNA positive.

3.2 | RNA confirmatory testing

There were 1077 individuals with a positive anti-HCV test performed at one of 92 dialysis facilities in 2016. Among these patients,

943 (87.6%) had RNA or genotype testing in 2016-2017 anywhere in NYC. However, only 317 individuals (29.4%) had a confirmatory test ordered by a dialysis facility during this period.

3.3 | HCV treatment and subsequent testing

Among the same 1077 individuals with a positive anti-HCV test in 2016, 263 (24.4%) initiated treatment at some point in 2016-2017. Of these patients, 81 (30.8%) had at least one anti-HCV test after their first negative RNA test, with an average of 2.0 anti-HCV tests (SD: 1.9).

4 | DISCUSSION

Dialysis facilities routinely order unnecessary anti-HCV tests for antibody- and/or RNA-positive patients, and even for patients receiving HCV treatment. Based on the timing of repeat tests, it appears that this testing follows the screening schedule for HCV-uninfected individuals. In a survey of NYC dialysis facility administrators in 2014-2015, we found that nearly 40% reported performing bi-annual anti-HCV screenings at their facilities, with testing occurring in January and July, and another quarter reported testing quarterly [NYC DOHMH; unpublished data]. These findings corroborate the monthly pattern of excess antibody tests presented here and suggests that when dialysis staff perform scheduled screenings, they test all patients of the facility, regardless of their antibody or RNA status. Unnecessary testing wastes resources that could be spent on confirmatory RNA testing when indicated. The extent of excess testing is especially relevant to facilities in NYC given a October 2017 Health Code change that mandates reflex RNA testing, which will substantially increase the cost associated with unnecessary, repeat positive antibody tests.

Currently, few dialysis facilities appear to be ordering RNA confirmatory testing. All individuals who test anti-HCV positive should have RNA testing to determine current infection status

and should receive no further antibody testing. Individuals identified as RNA positive should be connected to a specialist who could prescribe HCV treatment or, alternatively, nephrologists could prescribe the medications with the new simplified treatment regimens.

With safe and effective HCV medications now available, the elimination of HCV in the dialysis population is a viable goal, and treatment should be considered for patients with HCV infection.^{7,8} Although other clinical factors can complicate or delay treatment, dialysis patients represent a readily identifiable population, already engaged in medical care, to target for HCV treatment. We found that treatment uptake was generally low in the dialysis population, although it may increase given the release of a pan-genotypic treatment option for people with ERS in August 2017. Although their primary role is to provide dialysis, dialysis facilities have a vested interest in treating HCV, as it can improve patient kidney function and overall survival,^{2,8} reduce HCV prevalence in the dialysis population, and reduce the risk of transmission and potential outbreaks within facilities.

There are limitations to this analysis. In measuring excess antibody testing, individuals included have different follow-up times, as individuals could be initially tested any time between January and December of 2014. However, we decided this was acceptable, as we were most interested in the overall extent of excess testing through 2017 and not specifically in how many tests an individual has received in a certain number of years. Additionally, the analysis counted tests from any dialysis facility for each patient to more fully capture patients' test histories. However, if patients switch facilities, some may experience multiple anti-HCV intake screenings, which is recommended upon entering a new facility. This is likely a small problem, as a manual review of a sample of patients revealed that repeated antibody tests were usually from the same facility, and experience from DOHMH case investigations suggests that dialysis patients do not frequently switch facilities. Another limitation is the exclusion of inpatient dialysis centres. However, only 16 hospital locations were listed in NYS HFIS, and the majority of chronic dialysis is performed in the outpatient setting, meaning most dialysis patients in NYC were captured in our analysis.

To achieve improved HCV care and increased treatment for dialysis patients in NYC, workflows in dialysis facilities should change to only screen antibody-negative individuals; this change will reduce waste and unnecessary spending. Simultaneously, more attention should be given to identifying currently infected individuals through RNA testing and either providing or referring for HCV care and treatment.

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CONFLICT OF INTEREST

The authors declare no conflict of interests.

ORCID

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

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