**Hepatitis C cascade project analysis protocol**

Abbreviations:

CHS = Correctional Health Services

EHR = Electronic health records

ID = infectious diseases

HCV = hepatitis C virus

EIA = enzyme immunoassay

RNA = ribonucleic acid

DOHMH = New York City Department of Health and Mental Hygiene

SVR12 = sustained virologic response at 12 weeks

Cohort selection criteria:

* Include in our cohort
  + Everyone admitted to New York City jail system between Jan 1, 2014 - Dec 31, 2017 (because our new screening and therapy started around this time); we will follow these patients through to April 30, 2018 for the steps of the cascade
* Exclude from our cohort
  + Patients with no medical intake evaluation
  + Patients who completed interferon therapy and are cured
  + Patients who initiated HCV therapy in the community

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| **Step in the cascade** | **Definition / data source** |
| 1. Had HCV screening test = Screened | 1. HCV rapid point of care test done (data source: CHS electronic health record [EHR]) OR 2. HCV antibody test by EIA done (data source: BioReference Laboratories contracted commercial lab) OR 3. HCV RNA or genotype test done (data source: BioReference Laboratories) 4. Patient reports positive history of HCV on medical intake evaluation (data source: CHS EHR) |
| 1. Exposed to HCV (including active and cleared infections) = Screened positive | 1. Positive result from HCV antibody EIA or rapid point of care test OR 2. Patient reports history of positive HCV screening test OR 3. Positive result from HCV RNA or genotype test.   (data source: CHS EHR or BioReference Laboratories) |
| 1. Assessment for active HCV infection = HCV RNA sent | Of those who “screened positive,” HCV RNA PCR test was sent. (data source: BioReference Laboratories) |
| 1. HCV RNA detectable | Most recent HCV RNA PCR test result was positive.  (data source: BioReference Laboratories) |
| 1. Seen by HCV clinician | For patients who have detectable HCV RNA (from step 4), there was an Infectious Diseases (ID) visit in jail for evaluation.  (data source: CHS EHR) |
| 1. Treated | 1. Include all jail-based HCV treatment starts from Jan 1, 2014 to Dec 31, 2017. 2. Include all jail-based HCV treatment starts from Jan 1, 2018 to April 30, 2018 for patients who were admitted during our cohort time frame (Jan 1, 2014 - Dec 31, 2017)   (data source: CHS HCV treatment database where every treatment start is recorded) |
| 1. Had SVR12 lab done | Of the treated patients in our cohort, there was an HCV RNA level checked at least 64 days or later after the end of treatment date.  (data source: New York City Department of Health and Mental Hygiene city-wide HCV lab testing registry) |
| 1. SVR12 lab with undetectable HCV RNA | Of the treated patients in our cohort, whether there was an undetectable HCV RNA level at least 64 days or later after the end of treatment date.  (data source: New York City Department of Health and Mental Hygiene city-wide HCV lab testing registry) |

NOTE: Highlighted steps are displayed on the final cascade figures

**Detailed steps for data extraction:**

**Steps 1-3 in cascade:**

1. How many patients have been screened for HCV ever? (these patients are considered as “screened”)
   1. Defined as having a screening test at any time point in our testing dataset (April 2011 – April 2018).
   2. Count the most recent screening test and note the result.
2. How many of the patients who have been screened (i.e. meeting criteria from step 1) are positive for HCV exposure (i.e. positive result on the most recent HCV screening test from steps 1)? (these patients are considered “screened positive”)
3. Of the patients with positive HCV exposure (everyone who “screened positive” from step 2), how many have had HCV RNA testing done? (these patients are considered to have “HCV RNA sent”)

**Step 4 in cascade**

How to analyze the group who had HCV RNA testing done ever (step 3 patients):

1. We decided to take the most recent RNA testing done, up to the April 30, 2018.
2. If that test is positive (i.e. HCV RNA detected), that patient should be coded as positive for “HCV RNA detectable.”
3. Those with a negative HCV RNA test on the most recent test should be coded as negative for “HCV RNA detectable.”
4. Out of the negative group, we need to identify if any of those received HCV treatment in jail.
5. For those patients who received treatment, they should be reclassified as positive for “HCV RNA detectable” in our cascade, since they only tested negative because they were treated and cured.

The group that is positive for “HCV RNA detectable” are the group that we continue to analyze for the subsequent steps in the cascade.

**Step 5 in cascade**

Seen by HCV clinician (this strategy is to identify the ID specialist visits that were related to HCV evaluation, rather than visits for other indications besides HCV):

1. Take the cohort of patients who screened positive (step 2 in cascade).
2. Request a list of all ID specialist referrals and ID specialist clinic visits, from April 2011 until April 2018. Include the dates for the referral and visits.
3. Determine the **date that the “screened positive”** criterion was met (could be (a) HCV rapid screen, (b) HCV antibody by EIA (BioReference Laboratories), (c) HCV RNA (BioReference Laboratories), (d) patient reports positive history of HCV on medical intake evaluation).
4. Determine for each patient if there was an ID specialist **referral** made after the patient “screened positive”.
5. Determine whether there was an ID specialist clinic visit after the referral. (Latest date for clinic visit we include in our analysis is April 30, 2018).
6. We **exclude** the patients who did not have a detectable HCV RNA, since these patients were either referred to ID for a different reason, or were prematurely referred for HCV, but ultimately did not have detectable HCV RNA.

**Step 6 in cascade**

1. Use the CHS HCV treatment tracking database (Excel sheet) to identify all jail-based treatment starts from Jan 1, 2014 to Dec 31, 2017. These are automatically included.
2. Review the jail treatment starts from Jan 1, 2018 to April 30, 2018. Include the patients started on treatment during this period who are part of our cohort.

**Step 7-8 in cascade**

1. Match the list of treated patients (from step 6 of the cascade) with the DOHMH city-wide HCV surveillance registry to determine (a) whether they had an SVR12 viral load checked ≥64 days after the projected end date of the treatment course, and (b) whether the SVR12 lab result had an undetectable HCV RNA.