

Development and Validation of an Electronic Medical Record–Based Algorithm to Identify Patient Milestones in the Hepatitis C Virus Care Cascade

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Disease-specific care cascades are important public health and organizational tools to characterize gaps in care and target resources, but they are labor-intensive to maintain. Using data available from the electronic medical record, we developed an algorithm with high accuracy for correctly representing an individual's status in the hepatitis C virus care cascade.

Keywords. HCV epidemiology; HCV treatment; HCV care cascade; hepatitis C.

Hepatitis C virus (HCV) is the most common blood-borne infection in the United States and remains the leading cause of cirrhosis, hepatocellular carcinoma, and liver transplantation [1, 2]. HCV treatment with highly effective, well tolerated direct-acting antiviral agents (DAA) improves health outcomes, may be cost-effective at any time [3], and has the potential to eliminate HCV as part of a treatment-as-prevention strategy [4, 5].

The care cascade is a framework for the continuum of care that was first developed for persons living with HIV. The care cascade model helps programs target gaps in care and develop interventions. The hepatitis C care cascade (HCV-CC) starts with diagnosis and ends with a sustained virologic response. The Chronic Hepatitis Cohort Study (CHeCS) demonstrated that gaps in care exist at every step along this cascade [6]. In the

United States, it was estimated that only 50% of individuals were aware of their diagnosis, 16% had been prescribed treatment, and only 9% reached SVR [6–9].

We describe the development of an algorithm that, using data routinely collected by the electronic medical record (EMR), automates generation of a care cascade for persons diagnosed with HCV.

METHODS

We sought to create an EMR-based algorithm to automatically establish an individual's stage in the HCV-CC from routinely collected data. We limited our analysis to patients with a first anti-HCV antibody (HCV Ab) positive at our institution from 2013 to 2015, coinciding with the release of the DAAs. This was designed to mimic the process of an HCV testing and linkage to care team.

This study was performed at an urban academic medical center consisting of inpatient services at 2 sites in Upper Manhattan in addition to a number of ambulatory care sites. The EMR is shared with another academic medical center, with data viewable in the EMR but unavailable for analysis. The medical center serves a community in which 72% of residents are Hispanic and 25% of households are below the federal poverty line [10, 11].

Defining Milestones

To develop the stages in the cascade, we started with the steps identified by Yehia et al. and identified 5 milestones to represent the stages of care in our clinical environment (Figure 1) [6]: stage 1: all patients with a first positive HCV Ab at our institution; stage 2: confirmed infection with HCV RNA testing; stage 3: linkage to care, defined as a completed outpatient visit with either an infectious disease or gastroenterology provider; stage 4: treatment initiation; and stage 5: reaching sustained virologic response at 12 weeks after end of treatment (SVR12). We included linkage to care, as opposed to referral for care, which has been used in other studies, as this represents a more meaningful outcome [6].

Selection of Electronic Medical Record Data

From the cohort of all individuals with a first positive HCV Ab from 2013 to 2015, we collected basic demographic and HCV-related laboratory information (HCV Ab, HCV RNA qualitative and quantitative) between January 1, 2013, and December 31, 2015. Information regarding all hospitalizations, affiliated outpatient visits, and clinical notes was obtained. Data were extracted from the 2 different EMR systems used at our institution (Allscripts Sunrise and Clinical Records Online Web Network [CROWN], Allscripts Corp., Chicago, IL).

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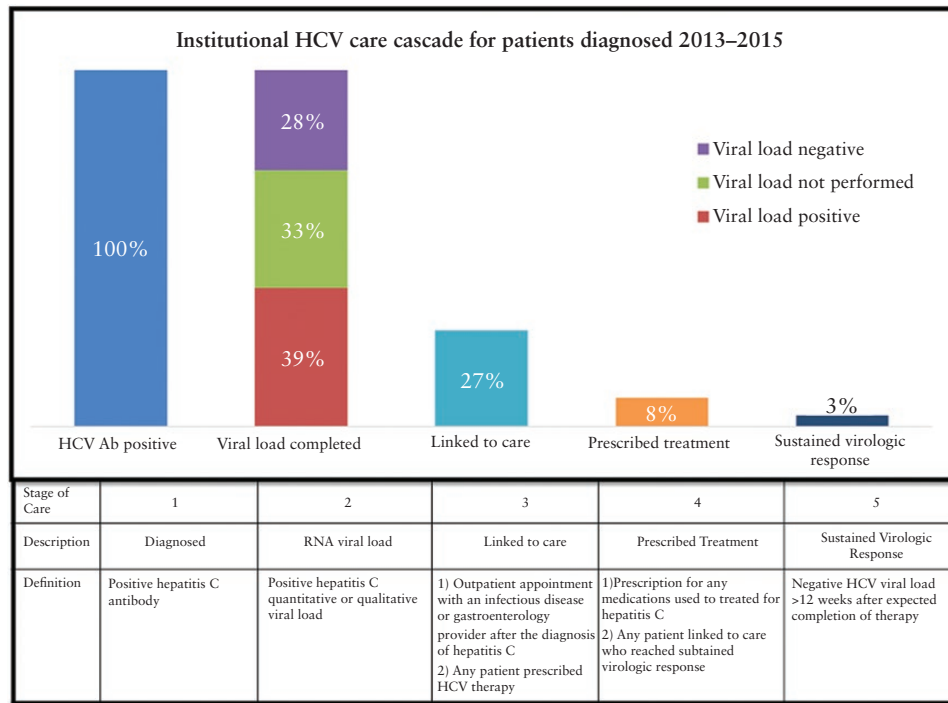


Figure 1. Hepatitis C care cascade for patients diagnosed 2013–2015. Abbreviation: HCV, hepatitis C virus.

Algorithm

Using EMR data, we developed criteria to represent each milestone within the HCV-CC. Through a review of the hospital data dictionary, we identified HCV laboratory tests that had been used including 1 anti-HCV Ab test and 9 HCV RNA tests. Additionally, we identified 14 clinical note headers used by HCV providers that served as a marker of linkage to care and 7 different medication orders for HCV treatment.

Steps in the HCV-CC did not have to be documented sequentially as it was noted that some patients who were linked to care and reached SVR had medications documented but did not have a visit with an HCV provider within our system. A manual review of these charts revealed that these patients were being treated by an unaffiliated physician. Therefore, after stage 2, all dependencies were removed, and patients were considered to have reached any stage of care preceding their final classification.

Reference Standard

To evaluate the algorithm's accuracy, we created a reference standard to replicate a clinician's review of the chart using all available medical records [12]. This consisted of a manual review of the chart by a single researcher without access to the algorithm. Data unlikely to be used by clinicians (ie, billing codes, pharmacy records) were not included. In all instances where the reference standard and algorithm were discordant, the result was reviewed by the study team; if the manual review was thought to be incorrect, this was confirmed with the manual reviewer.

Determination of Algorithm Performance

We applied the algorithm to all patients with a first positive anti-HCV Ab from 2013 to 2015. Using random sampling, we reviewed 125 patients for manual classification of their HCV stage of care. Results from the algorithm were compared with those of the reference standard.

RESULTS

The algorithm identified 1825 patients with a first positive HCV Ab (stage 1); 58% of identified patients were male, 42% female, 26% white, 20% Hispanic, and 18% African American.

A total of 1311 (72%) had a viral load performed (stage 2). Six hundred (33%) patients had an HCV RNA viral load that was undetectable and were removed from the cascade at this stage as they did not require linkage to care. The resulting 1225 patients, 711 (39%) of whom were HCV RNA positive and 514 (28%) of whom were without a viral load, were included in further analysis. The algorithm classified 330 (27%) patients as reaching stage 3, 100 (8%) as reaching stage 4, and 39 (3%) as reaching stage 5 (Figure 1). Among patients linked to care, 30% received HCV treatment and 39% receiving treatment reached SVR.

There were no differences in progression through the care cascade by gender. Hispanic patients were less likely to receive treatment; 33% of new HCV diagnoses were outside the birth cohort, with 9% born before 1945 and 25% born after 1965. Those born before 1945 were less likely to have a viral load

performed, to be linked to care, or to have been prescribed treatment (Figure 2).

A random sample of 125 (10%) patients were selected to undergo the reference standard review. The algorithm correctly categorized 117 of 129 (90%) patients, compared with 126 of 129 (98%) for the reference standard. Ten of 12 errors were related to care that was documented but provided outside of the institution.

DISCUSSION

We developed an automated EMR algorithm to classify a patient's stage in the HCV-CC using routinely collected electronic data. Several organizations have attempted to create an HCV-CC for their institutions utilizing case registries, manual data collection, meta-analysis, and HCV care coordinators [6–9]. To our knowledge, this is the first description of an algorithm using EMR data to automate identification of a patient's stage in the HCV-CC.

It is estimated that only 16% of HCV-infected individuals in the United States have received antiviral therapy and only 9% reached SVR [6]. The HCV-CC in the Veterans Health Administration (VHA), the largest provider of HCV care in the United States, found higher rates of linkage, similar rates of treatment, and lower rates of SVR when compared with our institution and the CHecs [7, 13].

Three community-based primary care clinics affiliated with Montefiore Medical Center found no difference in stage of care in patients identified by birth cohort vs risk-based screenings [9]. The primary care clinics' care cascade had higher rates of viral load testing when compared with our center but a similar rate of linkage to care and lower rates of treatment and SVR.

The VHA and CHecs data ended in 2013, and the Montefiore data ended in 2011, representing the pre-DAA era. In the post-DAA era, 2014–2016, the VHA, an integrated system, found higher rates of linkage (93%), treatment (59%) and SVR (84%).

The use of an EMR-based algorithm has several advantages. The HCV-CC allows providers and health care systems to assess and monitor the quality of HCV care. For example, our electronic care cascade recognized that 33% of new HCV diagnoses were outside the birth cohort, prompting a change in internal screening recommendations. Some health care systems utilize HCV care coordinators to track patient progress, and this system could enhance the coordinator role [8].

Our algorithm used commonly available data elements to be widely applicable. A major challenge for future research will be to identify clear and consistent milestones for the HCV-CC to allow for better comparisons across institutions and to share best practices.

This algorithm is not without limitations. Our reviewer could view records from the outside but affiliated hospital; however,

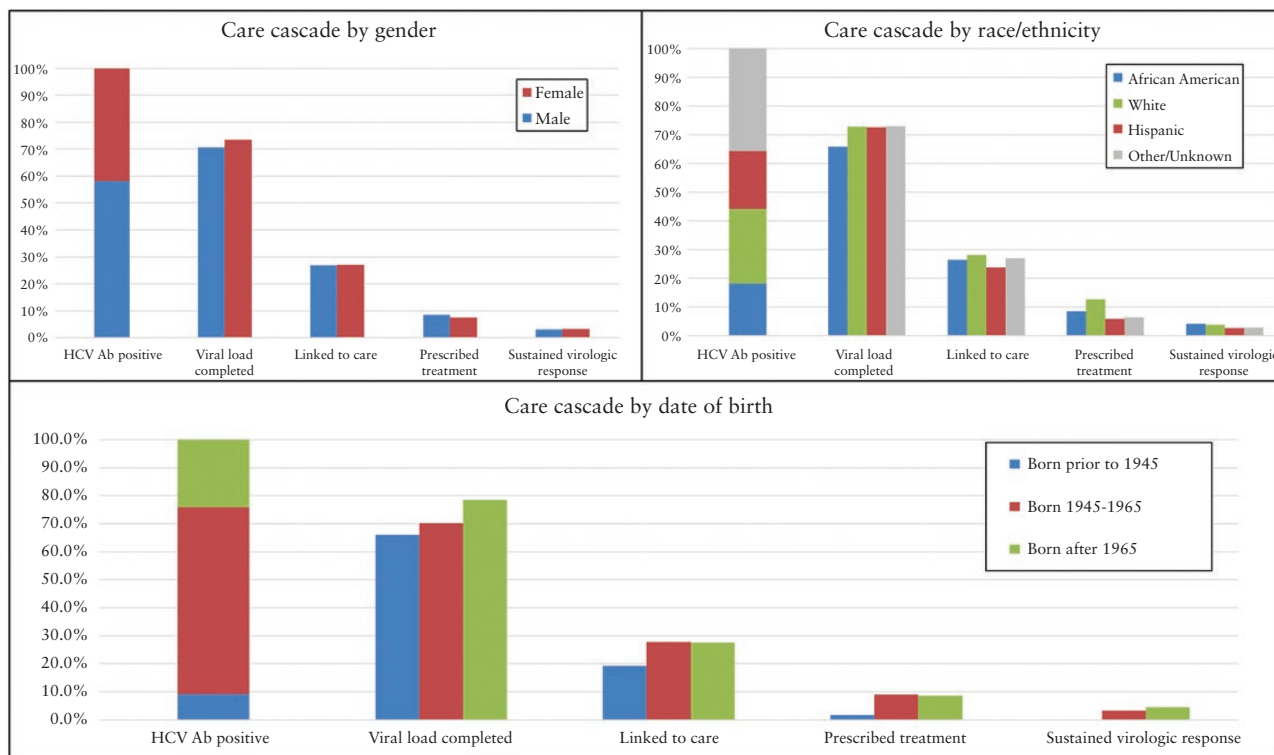


Figure 2. Hepatitis C care cascade by demographics, 2013–2015. Abbreviation: HCV, hepatitis C virus.

the algorithm could not use this information. Utilizing a regional health information organization could lead to a more complete HCV-CC. Future iterations may consider including any patient with a history of chronic HCV infection and not just new diagnosis; however, this would require the identification of any additional test names and note types that may have been previously used. Our definition of linkage to care relies on an outpatient visit with an infectious disease or gastroenterology provider, and although the visit occurred, we have no way of ensuring that HCV care was provided. Our model ends at SVR and does not account for re-infection or relapse after 12 weeks, which could be validated in future versions of this algorithm [14]. Finally, in our model, patients were assumed to have completed all stages before their final stage. Our random sample validated this assumption; however, it is possible that an individual could have been misclassified.

CONCLUSION

The dramatic improvements in HCV treatment have created both an individual and public health imperative to assist patients in completing the care cascade. The currently available HCV-CC demonstrates that gaps remain. Our HCV-CC offers health care systems the ability to measure and monitor performance to allow prioritization of resources to improve the overall quality of HCV care and help expand HCV linkage to care and optimize treatment strategies.

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