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Impact of the 2020 COVID-19 Pandemic on Ambulatory Hepatitis C Testing

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Abstract

Introduction: Coronavirus disease 2019 (COVID-19) has led to unprecedented modifications to healthcare delivery in the U.S. To preserve resources in preparation for a COVID-19 surge, Boston Medical Center (BMC) implemented workflows to decrease ambulatory in-person visits effective March 16th, 2020. Telemedicine was incorporated into clinical workflows and much preventive care, including Hepatitis C (HCV) testing, was not routinely performed. **Objective:** To explore the impact that the COVID-19 rapid restructuring response has had on HCV testing and identification hospital-wide and in ambulatory settings. **Methods:** BMC utilizes reflex confirmatory testing for HCV. When a sample is HCV Ab positive, it is automatically reflexed for confirmatory RNA and genotype testing. HCV test results for patients were collected daily. We compared unique patient tests for 3.5 month periods before and after March 16th, 2020. Descriptive statistics showed total tests and total new HCV RNA+ before versus after, both hospital-wide and in ambulatory clinics alone. Mean daily tests completed were compared. **Results:** Hospital-wide, total HCV testing decreased by 49.6%, and new HCV+ patient identification decreased by 42.1%. In ambulatory clinics, testing decreased by 71.9%, and new HCV+ identification decreased by 63.3%. Hospital-wide, mean daily tests decreased by 22.9 tests per day (95% CI: 17.9-28.0, $P < .001$), and mean daily new HCV+ identification decreased by 0.36 (95% CI: 0.20-0.53, $P < .001$). In ambulatory clinics, mean daily tests decreased by 22.1 tests per day (95% CI: 17.5-26.7, $P < .001$) and mean daily HCV+ decreased by 1.40 (95% CI: 1.03-1.76, $P < .001$). **Conclusion:** The COVID-19 systematic emergency response led to decreased HCV testing and identification, and in this regard telemedicine acts as a barrier to HCV care. Other public health initiatives must be monitored in the context of telemedicine workflows. Continued monitoring of HCV screening trends is vital, and adaptive approaches to work toward the goal of HCV elimination are needed.

Keywords

hepatitis C, telemedicine, preventive care

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Introduction

The coronavirus disease 2019 (COVID-19) pandemic has led to many major, unprecedented but necessary, modifications to the delivery of healthcare in the United States. It was appreciated early on that there was a need to preserve resources, including physical space and healthcare personnel, for critically ill patients suffering from COVID-19. This need, coupled with the recognition that increased disease transmission in a healthcare setting would be catastrophic, led healthcare organizations nationwide to limit or suspend non-emergent outpatient clinic activities. There were additional policy modifications including increased utilization of telemedicine options. While the rapid healthcare restructuring response to this public health crisis did mitigate the impact of COVID-19, some unintended consequences included delay or elimination of important public health initiatives, and the impact on these, including nationwide screening and medical care for hepatitis C virus (HCV), need to be evaluated in the context of this response.

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As the most commonly reported bloodborne infection in the U.S., HCV is a major cause of morbidity and mortality in the country. Chronic HCV infection, defined as having detectable viremia ≥6 months after initial infection, is the leading cause of liver disease-related deaths nationwide, with over 15 700 deaths in 2018.[1] It is estimated that there are 3.5 million people in the U.S. suffering from the disease, and the incidence is increasing due to the well-documented rise in injection drug use (IDU).[2] Adding to the public health concern, approximately 50% of patients in the United States with chronic HCV are unaware of their infection.[3] When the disease is diagnosed, it is curable. Direct-acting antiviral (DAA) treatments are highly effective and non-invasive, and are shorter and better-tolerated than previous HCV treatments. Approximately 90% of HCV+ patients can be cured with 8-12 weeks of DAA therapy. Treating and curing HCV infections will lead to decreased transmission, morbidity, and mortality.

In order to combat this public health need, in March 2020, the United States Preventive Services Task Force (USPSTF) released a recommendation to screen all adults aged 18-79 for HCV,[4] and in April 2020 the Centers for Disease Control and Prevention (CDC) also released new guidelines for HCV universal screening.[5] While historical guidance from the CDC recommended one-time testing for those in the "baby boomer" birth cohort (born between 1945 and 1965) and periodic testing for those at high risk for infection, the need to further expand screening became paramount as cases in young adults continue to rise in relation to the opioid epidemic.[6] This new screening guidance includes a recommendation for routine HCV screening at least once in a lifetime for all adults aged ≥18 years, except in settings where the prevalence of HCV infection is <0.1%. Additionally, HCV screening is recommended for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection is <0.1%.

Our institution has been consistently screening for HCV in the Emergency Department and many ambulatory clinics, in line with the prior USPSTF and CDC guidelines.[7,8] We use electronic medical record (EMR) modifications and educational outreach activities for providers to ensure patients are tested. This investigation sought to analyze the way in which these screening initiatives were impacted by the healthcare restructuring that was undertaken in response to the outbreak of COVID-19.

Methods

This is an updated descriptive analysis of the data from a protocol that integrated HCV screening and treatment into clinical services throughout multiple departments within BMC. The details of this protocol have been previously described.[7] HCV screening was chosen as a proxy for preventive health in this study because BMC has an already developed and maintained HCV screening database.

Study Setting

Boston Medical Center (BMC) is an urban, academic facility that receives approximately 1.1 million patient visits per year. The medical center is the largest safety net hospital in New England and is recognized as the primary safety net care provider for Boston's indigent and most vulnerable population.[7] In the medical center, more than 70% of patients identify as minority; more than 50% identify as African American; and more than 20% identify as Hispanic/Latino. Approximately 25% of BMC patients are homeless and >30% do not speak English.[9]

BMC developed an HCV screening program which was implemented in November 2016. This program has been previously described in great detail.[7] This screening program has been used in conjunction with the medical center's hospital-wide outreach, linkage, and treatment efforts. The objective has been to increase diagnosis of HCV and HCV linkage to care in the institution.[7] As an urban safety net hospital, BMC's prevalence of HCV RNA+ patients is approximately 3.94%, which is much greater than the national average of 0.93%.[10]

Boston diagnosed its first patient with COVID-19 on February 1, 2020, and on March 10 the governor declared a state of emergency in Massachusetts. Like many healthcare facilities across the country, BMC implemented many operational changes in response to the COVID-19 pandemic.

To preserve personal protective equipment and hospital personnel capacity in preparation for a COVID-19 surge, BMC implemented emergency preparedness workflow changes to decrease the volume of ambulatory in-person visits effective March 16. This included the adoption and utilization of telemedicine by outpatient clinics whenever possible. However, much preventive care, including phlebotomy for HCV screening, was not performed during this period.

Data Collection

The data for this analysis was collected prospectively beginning on December 1, 2019 and continued through June 30, 2020. Hospital-wide HCV antibody (Ab) tests and results, as well as confirmatory HCV RNA tests and results for those that were HCV Ab+, were collected and aggregated daily for all patients 18 years and older. Once collected, tests were organized by testing site and categorized as either "Emergency Department/Inpatient" or "Ambulatory." Occupational health tests were excluded and removed from the dataset. Tests were de-duplicated by patient medical record number, name, and date of birth. Previous HCV+ patients that have already been enrolled into our tracking were also excluded since we are capturing newly identified HCV+ patients.

Table 1. HCV Testing Numbers Before versus After March 16, 2020.

	Before	After	% Difference
Hospital-wide			
Mean daily HCV Ab tests (SD)	45.7 (24.7)	22.8 (8.9)	–50.1
Mean daily new HCV+ identified (SD)	1.9 (1.3)	1.5 (1.5)	–21.1
Total HCV Ab tests	4847	2442	–49.6
New HCV+ identified	159	92	–42.1
Ambulatory only			
Mean daily HCV Ab tests (SD)	30.7 (22.7)	8.5 (7.6)	–72.3
Mean daily new HCV+ identified (SD)	1.9 (1.8)	0.5 (0.7)	–73.7
Total HCV Ab tests	3249	912	–71.9
New HCV+ identified	60	22	–63.3

Data Analyses

HCV Ab tests were compared for the time periods before and after emergency response policies were implemented at BMC on March 16, 2020. The "before" period was from December 1, 2019 to March 15, 2020, and the "after" period went from March 16, 2020 to June 30, 2020. Descriptive statistics were used to show the total number of HCV tests that were ordered in each time period, as well as the total number of new HCV RNA+ patients that were identified before versus after the policy changes. This was done for all testing sites across the medical center, as well as for the ambulatory sites alone. For all ambulatory-only analyses conducted, all emergency department (ED) and inpatient testing sites were excluded. The ambulatory-only testing numbers are included within the hospital-wide testing numbers.

The mean daily tests for each time period were compared using a two-sample *t*-test, and confidence intervals and *P*-values are reported. This comparison was first performed on all testing and result data collected across the medical center and then repeated for testing and result data from ambulatory clinics only. Statistical analyses were completed using SAS 9.4 (SAS Institute, Cary NC).

This project was approved by the Institutional Review Board at Boston University Medical Center under IRB number H-35734. There was a waiver for informed consent since it was a research analysis of a clinical program. This study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cohort studies.

Results

HCV Ab testing and new HCV RNA+ identification decreased both hospital-wide and in the ambulatory clinics alone from the time period before to the time period after the operational changes were made on March 16, 2020. The Table 1 below shows the changes in HCV Ab testing numbers as well as new HCV RNA+ identification for the entire medical center as well as for the ambulatory clinics.

When the mean daily hospital-wide tests were compared for the periods before and after the policy changes, the mean decreased by 22.9 daily tests (95% CI: 17.9-28.0, $P < .001$). The mean new HCV+ patients identified daily hospital-wide decreased by 0.36 patients per day (95% CI: 0.20-0.53, $P < .001$). When comparing mean daily HCV tests ordered in ambulatory sites before and after the policy changes were implemented, the mean decreased by 22.1 daily tests (95% CI: 17.5-26.7, $P < .001$). The mean new HCV+ patients identified daily in ambulatory clinics decreased by 1.40 patients per day (95% CI: 1.03-1.76, $P < .001$).

Hospital-wide, there was a 49.6% decrease in HCV Ab testing in the 3 months after policy changes were implemented compared to the 3 months prior. New HCV+ identification decreased by 42.1% hospital-wide following the policy changes. In ambulatory clinics, HCV Ab testing decreased by 71.9% and new HCV+ identification decreased by 63.3% in the time period after policy change implementation.

Discussion

The systematic response to COVID-19 led to a large decrease in HCV testing and identification across the medical center. This decrease is greatly amplified in the ambulatory clinics, where operations were drastically impacted by the policy modifications put in place to mitigate the spread of COVID-19. As healthcare continues to evolve during the current COVID-19 pandemic and further incorporate telemedicine and technology, it is important to keep other key public health initiatives in focus.

The significant decrease in HCV screening reported here demonstrates the consequential tradeoffs that occur between workplace safety and preventive patient care services, as a result of health system responses during this pandemic. Like HCV, many chronic illnesses are being impacted by this pandemic. Dramatic decreases in preventive screening tests, missed prescription starts for chronic diseases due to delayed

diagnosis, delayed cancer treatment, and postponement of childhood vaccinations have been noted in multiple practice environments.[11-13] In light of the pandemic-related resource limitations and safety mitigation techniques, proactive healthcare models must be favored over reactive models, with interventions that reduce health risks, decrease avoidable emergency room visits, and minimize the burden of chronic disease-related complications.[14]

Healthcare providers utilizing telehealth visits should also use them as an opportunity for greater patient education and emphasize the importance of preventive care. Since telehealth visits do not negate the need for in-person healthcare visits for lab-work and vaccinations, telehealth visits can also be used to educate patients on the healthcare system safety measures that prevent the spread of COVID-19. This will serve to alleviate fears among those still hesitant to visit in-person.

Facilities should develop streamlined processes for rapid in-and-out lab and vaccination visits to supplement telehealth appointments. Non-traditional options, such as drive-through vaccination programs, street outreach coupled with telemedicine to engage people experiencing homelessness, and increased access to in-home care have been used at our institution and should be seen as best-practices to use when possible.[15]

The long-term impacts of these gaps in primary and preventive healthcare could be detrimental, and deliberate efforts to counteract this impact must be made. Preventive care gaps due to COVID-19 must be identified and targeted. Continued monitoring of HCV screening trends is vital, and adaptive approaches to working toward the goal of HCV elimination in the evolving virtual health world are needed.

Availability of Data and Materials

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Support for HCV testing was provided by a grant from Gilead Sciences, Inc.'s FOCUS Program. FOCUS funding does not support activities beyond screening and linkage to care.

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