Impact of an interdisciplinary patient care model and routine screening on clinical outcomes in patients with hepatitis C

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Abstract
Testing for hepatitis C in hospital emergency departments (ED) and linkage to care to clinics have been reported to provide the most opportunity for screening patients and facilitating continuum of care. Treatment model initiatives have expanded to include telehealth services and open treatment capacity to non-physician providers, such as pharmacists. This study's objective was to assess the impact of implementing automated routine screening for hepatitis C virus (HCV) and a clinical pharmacist into the interdisciplinary care model on HCV diagnosis and treatment outcomes.

This retrospective cohort study compared outcomes in a pre-intervention and post-intervention group. Patients were screened and diagnosed with HCV at Jersey City Medical Center (JCMC) and completed linkage to care at JCMC Center for Comprehensive Care. Interventions were the implementation of automated routine HCV screening in the ED and addition of a clinical pharmacist to the interdisciplinary patient care model. Primary endpoints analyzed the number of patients who have achieved sustained virologic response after 12 weeks of treatment (SVR12) and patients who have completed treatment with no reported record of SVR12. Secondary endpoints analyzed the number of patients lost to follow-up, appointment type, time spent in appointments, and clinical pharmacist specialist interventions. Data was collected as categorical variables and chi-squared tests assessed if there were differences between the two samples.

Data was collected from 46 patients in the pre-intervention group and 37 patients in the post-intervention group. Patients consisted of mostly males. Ages ranged from 27 to 83 years old. Race included Black, White, Asian, and Other. This study's results showed the positive impact on implementation of routine screening, telehealth services, and an interdisciplinary team approach to HCV diagnosis and management. Given the timeframe, it also showed the potential positive impact on these interventions during a global pandemic.

Keywords: hepatitis C, interdisciplinary, routine screening, telehealth

Background

In 2019, the Centers for Disease Control and Prevention (CDC) estimated 57,500 acute infections for hepatitis C (HCV). The groups most affected by acute hepatitis C in 2019 were male patients who were 30-39 years of age.[1] If left untreated, the liver can progress into fibrosis (scarring) and cirrhosis (permanent, irreversible scarring) and lead to several long-term complications, such as liver cancer, liver transplant, and premature death. With the introduction of direct acting antivirals (DAA) for HCV treatment in 2011, patients can be treated within eight to twelve weeks of completing DAA therapy.[2] In lieu of these strides in HCV treatment, the World Health Organization (WHO) Global Health Sector Strategy (GHSS) on viral hepatitis envisioned a goal of 90% reduction in incidence and 65% reduction in mortality by 2030.[3] On March 2, 2020, USPSTF Guidelines were updated to recommend screening for HCV in adults aged 18 to 79 years with the intent to increase testing and treatment outcomes.[4] Testing for hepatitis C in the hospital emergency department (ED) and linkage to care to clinics have also been reported to provide the most opportunity for screening patients and facilitating continuum of care.[5] The WHO established the importance of team-based, interprofessional collaboration in improving patient outcomes.[6]

Treatment model initiatives such as Project ECHO (Extension for Community Healthcare Outcomes) have been created to implement telehealth services to train community healthcare providers in treatments for human immunodeficiency virus (HIV) and hepatitis C virus (HCV). In doing so, HCV treatment capacity has expanded by incorporating HCV treatment into other existing systems of care to include non-physician providers. Non-physician providers include advanced practice nurses, physician assistants, pharmacists, registered nurses, social workers, or other members of the healthcare team.[7] These interventions have been reported to have efficient outcomes in HCV treatment.[8] Increasing didactic training for HCV treatment for non-specialist providers can further aid in bridging gaps in continuum of care for patients with HCV infection.[9] The shift in this collaborative healthcare model has also become a platform for healthcare professional students, such as pharmacy students, to continue to implement their interprofessional educational experiences.[10]

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Some institutions have also implemented a treatment model where a clinical pharmacist optimizes HCV treatment under a collaborative practice agreement with an authorizing physician. Additional responsibilities for pharmacists expand to facilitating treatment access, providing patient education, assessing safety and efficacy, and offering mitigation strategies for adverse drug reactions (ADRs). As a result of these interventions, HCV sustained virologic response (SVR) rates have been found to be comparable to studies with other specialists and non-specialists (e.g., nurse practitioners and primary care providers).[11] These comparable rates show the extensive capabilities and skillset that pharmacists possess to provide patient care in comparison with other healthcare providers. Pharmacists can further contribute in their unique role and medication expertise through medication reconciliation, education on adherence and potential side effects, and interventions on potential drug-drug interactions.

Jersey City Medical Center's Center for Comprehensive Care (CCC) was created in 1987 with the goal to provide comprehensive medical services and care management to children, adolescents, and adults infected with HIV in Jersey City and other areas of Hudson County. These services utilize a multidisciplinary team approach to ensure that medical, case management, and supportive services are received in the most comprehensive and cost-effective manner. Current services offered by the center include free confidential HIV and sexually transmitted diseases (STD) testing, pre-exposure prophylaxis (PrEP) counseling, treatment adherence support programs, medical case management, mental health services, support groups, and HCV treatment.[12]

CCC introduced the JCMC FOCUS (Jersey City Medical Center - Frontlines of Communities in the United States) team in 2016 with the purpose to screen, identify, diagnose, and link patients being routinely screened at the hospital to ambulatory care facilities. CCC is a grant-funded facility and contains no conflict of interest. Gilead® FOCUS funding supports HIV, HCV and HBV screening and linkage to a first appointment after diagnosis. Funding for support staff, through the Gilead® Sciences FOCUS awardee, does not support activities after linkage to a first appointment after diagnosis. In 2019, the JCMC FOCUS team implemented a model that provided diagnosis and linkage to care for patients being treated in the ED at JCMC. Linkage to care is defined as the first appointment that patients attend at a clinic following referral and discharge from the hospital. With the updated USPSTF Guideline recommendation for HCV screening in adults 18 to 79 years in 2020, there became an increased need for patient access to testing. Subsequently, in June 2020, the JCMC FOCUS team expanded on their model to provide automated routine universal HCV screening in patients over the age of 18 receiving routine bloodwork in the ED. The goal of this optimization was to increase the identification of patients with HCV and link them to care to any clinic that provides HCV treatment. This model also excluded those who have been tested for HCV in the last twelve months.

In addition to the improved screening process, the interdisciplinary patient care model was also modified to include an ambulatory care clinical pharmacist in August 2019. Aside from real-time consults with providers and increased collaboration with the team, the clinical pharmacist performs counseling sessions and coordinates follow-up with patients who are being initiated on new medication treatment for HIV, PrEP and/or HCV. Other interventions include identifying potential drug-drug interactions, initiating smoking cessation regimens, and communicating amongst nurses, physicians, and insurance companies. Prior to August 2019, there was no automated routine screening process for HCV implemented at JCMC and no clinical pharmacist who was a part of the interdisciplinary team model. There was also delay to care and follow-up as patients had to wait for the provider to be in office to initiate HCV treatment.

The modified interdisciplinary patient care model for HCV treatment encompasses close collaboration between the provider and clinical pharmacist. During a patient's initial visit for HCV treatment, the provider and clinical pharmacist discuss potential guideline directed therapy in accordance with American Association for the Study of Liver Diseases (AASLD) Recommendations for the Testing, Managing, and Treating Hepatitis C Virus Infection.[13] Through chart review, the clinical pharmacist identifies and intervenes on potential drug-drug interactions that may impact the efficacy of selected treatment. Following chart review, the prescription is sent to a specialty pharmacy that is able to fill the patient's medications. The patient is then seen in clinic by the clinical pharmacist and pharmacy students (under the supervision of a clinical pharmacist) who conduct a final medication reconciliation and medication education to address gaps in health literacy. Clinical pearls are provided to the patient including: medication adherence, potential side effects, and efforts to mitigate liver toxicity (e.g., refrain from alcohol and acetaminophen use).[13] The patient's estimated completion date, estimated 12-week post completion date, and time spent with the pharmacist are quantified in the patient's electronic health record (EHR). Following this appointment, patients are officially initiated on HCV treatment and closely followed by the pharmacy team in conjunction with the provider. Through this integrated workflow, the clinical pharmacist can bridge gaps in care and adherence and coordinate extensive follow-up without the provider needing to be in office.

With the COVID-19 pandemic, this model shifted to a remote workflow in which telehealth calls conducted by providers, clinical pharmacists, and pharmacy students allowed patients to be seen remotely and increased access to care. Following completion of HCV treatment, patients are seen by the provider to assess sustained virologic response after 12 weeks of

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treatment (SVR12). With this increase in efficiency with remote visits and interdisciplinary collaboration, the clinical pharmacist and providers can expend resources and complete additional clinical responsibilities. The objective of this study was to assess the implementation of automated routine screening as well as the interdisciplinary patient care model on diagnosis and treatment outcomes in patients diagnosed with HCV at JCMC.

Materials and Methods

Study Design

This was an Institutional Review Board approved retrospective cohort study that compared outcomes in patients who were screened and diagnosed with HCV at JCMC and received linkage to care at CCC. Linkage to care is the first appointment that patients attend at a clinic following referral and discharge from the hospital. Data was collected from two groups of patients: the pre-intervention group and the post-intervention group.

The interventions were the implementation of routine screening for HCV in the ED in June 2020 and the addition of a clinical pharmacist to the interdisciplinary patient care model in August 2019. In the pre-intervention group, there was no clinical pharmacist in the interdisciplinary model. Documentation was primarily completed through paper charts. There was no formal process for documented medication reconciliation and education and no standardized form of follow-up via telehealth services. In the post-intervention group, patients were linked to care following the implementation of routine screening for HCV in the ED. Additionally, the clinical pharmacy team, consisting of the clinical pharmacist and pharmacy students, conducted medication reconciliation, provided education for HCV treatment, and coordinated patient follow-up. Medication reconciliation and education utilized a formal encounter template and were documented in the patient's EHR.

Time periods for the pre- and post-intervention group were chosen to reflect the impact of these interventions over the course of one year. The pre-intervention group consisted of patients who were seen prior to the implementation of routine screening and the interdisciplinary patient care model from June 2018 to June 2019. The post-intervention group consisted of patients who were seen after implementation of routine screening and the interdisciplinary patient care model from June 2020 to June 2021. All patients included in the study were screened and diagnosed with HCV at Jersey City Medical Center (JCMC) via positive antibody (Ab) and positive ribonucleic acid (RNA) test and received linkage to care at CCC. Patients were excluded if they were diagnosed with HCV outside of pre- and post-intervention periods, declined referral to linkage to care established by the FOCUS team, or were diagnosed with HCV with hepatocellular carcinoma (HCC). Patients diagnosed with HCC were referred to outside facilities for more comprehensive care with specialists.

Outcomes Measures

Primary endpoints analyzed the number of patients who have achieved SVR12 and patients who have completed treatment with no reported record of SVR12. This was assessed through telehealth notes and records of patients being lost to follow-up. Secondary endpoints analyzed the number of patients lost to follow-up, number of in-person and telehealth appointments, and time spent in appointments (minutes). Patients lost to follow-up were defined as not returning to CCC for at least three months following their previous appointment or after not answering at least three contact attempts from CCC. Clinical pharmacist interventions were also reported as secondary endpoints and included the number of follow-up calls, identified potential drug-drug interactions, and documented medication reconciliations. Baseline characteristics included sex, age, race, ethnicity, comorbidities (hepatitis B, HIV, chronic kidney disease), HCV genotype, fibrosis score (F1-F4), insurance type, prescribed regimen, previous intravenous (IV) drug use, homelessness within the last six to twelve months of diagnosis, alcohol use within the last six to twelve months of diagnosis, and history of solid organ transplantation.

Data Collection and Analysis

Data was collected from electronic health records, self-tracking database from the FOCUS team, and physical medical charts that are accessible only at the clinic. Patients were identified according to inclusion and exclusion criteria. Data was collected as categorical variables and exported to statistical analysis software. Primary endpoints were calculated as percentages over the total number of patients who received linkage to care. Chi-squared tests with confidence intervals were conducted to assess if there were differences between the two samples. P-values of significance were < 0.05. All data was maintained electronically in the institution's protected data center during and after the study. Electronic files containing patient identifiers linked to the assigned study identifier were deleted at the conclusion of the study.

Results

Data was collected from 83 patients with 46 patients in the pre-intervention group and 37 patients in the post-intervention group, respectively. Ages ranged from 27 to 83 years across the total study population. Race in both study groups included Black, White, Asian, and Other. Ethnicities included Black, White, Indian, Vietnamese, Haitian, Egyptian, Hispanic, and Other. No patients reported history of solid organ transplantation. Seven patients (6 patients in pre-intervention and 1 patient in post-intervention group, respectively) did not attend their first appointment due to unforeseen circumstances and were included in the data analysis. This analysis was completed with an intent-to-treat model to reflect

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the real-world setting. Table 1 displays the baseline characteristics from both pre- and post-intervention groups.

Eleven patients (23.9%) in the pre-intervention group and twelve patients (32.4%) in the post-intervention group were reported to have achieved SVR12, respectively. Table 2 displays the primary endpoints reflected in this study. Chi-square tests were conducted and reported no statistically significant results in patients who reported to have completed treatment (p=0.11) and patients reported to have achieved SVR12 (p=0.39). There were no patients who were reported to have experienced treatment failure in the pre- and post-intervention groups.

Table 3 displays the secondary endpoints of this study. Chi-square tests were conducted and reported statistically significant results (p-values < 0.05) between the pre- and post-intervention group regarding patients lost to follow-up (80.4%, 35.1%), documented appointments for initiation of HCV treatment (32.6%, 78.4%), patients who answered follow-up calls (6.5%, 73%), and medication reconciliation being completed and documented (6.5%, 75.7%), respectively. Potential drug-drug interactions and medication interventions were identified in the pre- and post-intervention groups and included: HMG-CoA reductase inhibitors (e.g., atorvastatin, pravastatin), proton pump inhibitors (e.g., omeprazole, pantoprazole), carbamazepine, warfarin, and acetaminophen. Potential drug-drug interactions were left to the discretion of the provider and clinical pharmacist.

Discussion

The interventions of routine screening, telehealth, and a clinical pharmacist consultation were implemented as best practice measures. A strength of this retrospective study was the use of SVR12 as the primary endpoint, which is an objective measure and shows clinical significance. Pre- and post-intervention groups were appropriate time periods to collect data as these patients were seen before and after implementation. The methodology was reflective of endpoints, baseline characteristics, and statistical analysis that were utilized in other studies.

Secondary endpoints for patients lost to follow-up, HCV treatment-initiated appointments, patients who answered follow-up calls, and completed medication reconciliations showed statistical significance. Fewer patients were diagnosed in the post-intervention group (37 patients) than in the pre-intervention group (46 patients) despite the implementation of routine screening in the ED. This lower prevalence of patients in the post-intervention group may have occurred due to the period taking place during the COVID-19 pandemic. A study, by Kaufman HW, et al., reports HCV antibody testing volume decreased 59% during April 2020 and HCV treatment prescriptions decreased 43% in May, 37% in June, and 38% in July 2020 respectively in comparison with corresponding months in 2018 and 2019.[14]

Despite fewer patients being diagnosed in the post-intervention group, the percentage of patients in the pre-intervention (23.9%) and post-intervention group (32.4%) yielded comparable results in reported SVR12. This result was also supported by a study, by Koren D, et al., that reported HCV SVR12 rates by clinical pharmacists to be comparable to real world studies with specialists and nonspecialists.[11] Additionally, the use of telehealth services may have served a role in medication adherence and consistent provider-patient interactions during the pandemic. A study in Romania, by Doica IP, et al., evaluated the use of telemedicine and an interdisciplinary approach for HCV treatment during the COVID-19 pandemic. SVR12, medication adherence, and telemedicine satisfaction in patients receiving direct-acting antiviral (DAA) regimens for HCV were assessed and reported that 100% of patients were adherent and achieved SVR12. The interdisciplinary team included general practitioners, pharmacists, and gastroenterologists and reported an average telemedicine satisfaction questionnaire item score (TSQ) of 4.92 of 5. This study in Romania suggested that interdisciplinary collaboration and telemedicine serve as important tools to help disadvantaged communities with HCV disease management and monitoring.[15]

A study conducted at the University of Colorado Hospital Hepatology Clinic, by Langness JA, et al., found that clinical pharmacists within an interdisciplinary team can be beneficial for assessing drug-drug interactions, medication adjustments, and increased monitoring.[16] An area of opportunity for pharmacists to make interventions in treatment for HCV is through appointments where HCV medications are initiated and was reflected in this study. In the post-intervention group, these appointments provided continued access to care where the clinical pharmacist and pharmacy students conducted medication education and assessed health literacy. Medication reconciliation and potential drug-drug interactions were identified and extensively documented in the EHR in the post-intervention group. Potential drug-drug interactions were identified for 26.1% of patients in the pre-intervention group and 35.1% of patients in the post-intervention group, respectively. Pharmacists can also utilize these appointments to develop trust and rapport with their patients, therefore promoting follow-up.

Limitations

Limitations included lack of primary endpoint data for patients lost to follow-up and retrospectively collecting demographic data based on medical record documentation. The inclusion criteria in this study originally included patients who were linked to care and attended their first appointment at CCC. The inclusion criteria was revised to patients who received linkage to care to CCC to reflect our data more appropriately and was approved by the Institutional Review Board. Patients who

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received linkage to care, but did not attend their first appointment due to unforeseen circumstances, were included in our data analysis as part of an intent-to-treat model. The exclusion criteria in this study did not exclude patients who were breastfeeding. One patient in the post-intervention group did not receive HCV treatment following a recommendation from the physician to return to the clinic upon completion of breastfeeding.

Additional exploration of this study could have investigated the number of antibody tests conducted in the ED to further trend the continuum of care through the hospital system. Due to the retrospective nature of this study, patient satisfaction was not assessed and could be explored using a telemedicine or medication education assessment tool in future studies.[15] Assessment of interventions following drug-drug interactions identified by the pharmacist can be further expanded on as well. Other studies reported on additional comorbidities (e.g., diabetes, psychiatric illness, dialysis) which may have provided more representation and context to this study's patient demographic.[11] Incorporating social determinants of health into our baseline characteristics can also assess the impact of these interventions on access to care. Completing a study across multiple clinical sites can also provide further context in a larger patient population. Future studies emphasizing pharmacist-driven interventions may also be pertinent to expanding the role and presence of pharmacists within the healthcare team and patient care treatment models for other disease states with elimination efforts (e.g., HIV).

Conclusion

Results of this study showed the positive impact on the implementation of routine screening, telehealth services, and an interdisciplinary team approach to HCV diagnosis and management. Given the timeframe, it also showed the potential positive impact on these interventions, even during a global pandemic. These interventions were implemented out of best practice measures and hepatitis C programs and initiatives should continue to be prioritized to promote HCV elimination efforts.

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Table 1: Patient Baseline Characteristics*

Baseline Characteristics		Pre-Intervention Group (n=46)	Post-Intervention Group (n=37)
Median Age (years)		53.5 (27-83)	56 (29-80)
Sex	Male	36 (78.3%)	25 (67.6%)
	Female	10 (21.7%)	12 (32.4%)
Race**	Black	17 (37%)	19 (51.4%)
	White	17 (37%)	3 (8.1%)
	Asian	4 (8.7%)	0 (0%)
	Other	8 (17.4%)	15 (40.5%)
HIV		2 (4.3%)	1 (2.7%)
Hepatitis B		0 (0%)	1 (2.7%)
Chronic Kidney Disease		1 (2.2%)	3 (8.1%)
IV Drug Use		15 (32.6%)	11 (29.7%)
Alcohol Use		9 (19.6%)	11 (29.7%)
Homelessness		1 (2.2%)	1 (2.7%)
Treatment	Naïve	34 (73.9%)	33 (89.2%)
	Experienced	2 (4.3%)	3 (8.1%)
	Unknown	10 (21.7%)	1 (2.7%)
HCV Medication Prescribed	Sofosbuvir/velpatasvir ***	14 (30.4%)	25 (67.6%)
	Glecaprevir/pibrentasvir	23 (50%)	3 (8.1%)
	Unknown	9 (19.6%)	9 (24.3%)
HCV Fibrosis Score	F0	8 (17.4%)	11 (29.8%)
	F0-F1	3 (6.5%)	7 (18.9%)
	F1	2 (4.3%)	3 (8.1%)
	F1-F2	13 (28.3%)	4 (10.8%)
	F2	1 (2.2%)	1 (2.7%)
	F3	7 (15.2%)	5 (13.5%)
	F4	9 (19.6%)	3 (8.1%)
	Unknown	3 (6.5%)	3 (8.1%)
Insurance	Charity Care and Self-Pay	5 (10.9%)	3 (8.1%)
	Medicare and Medicaid	37 (80.4%)	29 (78.3%)
	Commercial	4 (8.7%)	5 (13.5%)
HCV Genotype	1, 1a, 1b	25 (54.3%)	22 (59.5%)
	1b/4	0 (0%)	1 (2.7%)
	2, 2a/2c, 2b	7 (15.2%)	5 (13.5%)
	3, 3a	9 (19.6%)	5 (13.5%)
	4	2 (4.3%)	2 (5.4%)
	6	1 (2.2%)	0 (0%)
	Unknown	2 (4.3%)	2 (5.4%)

*No patients reported history of solid organ transplantation.

**Ethnicities included: Black, White, Indian, Vietnamese, Haitian, Egyptian, Hispanic, and Other.

***One patient in the pre-intervention group received a combination of sofosbuvir/velpatasvir and ribavirin.

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Table 2: Primary Endpoints

	Pre-Intervention (n=46)	Post-Intervention (n=37)	χ^2 test and p-value
Patients Reported to Have Completed Treatment	18 (39.1%)	21 (56.8%)	$\chi^2(1, N = 83) = 2.56$ $p = 0.11$
Patients Reported to Have Achieved SVR12	11 (23.9%)	12 (32.4%)	$\chi^2(1, N = 83) = 0.74$ $p = 0.39$

Table 3: Secondary Endpoints

	Pre-Intervention (n=46)	Post-Intervention (n=37)	χ^2 test and p-value
Patients Lost to Follow-Up	37 (80.4%)	13 (35.1%)	$\chi^2(1, N = 83) = 17.57$ $p < 0.05$
Documented Appointments for Initiation of HCV Treatment	15 (32.6%)	29 (78.4%)	$\chi^2(1, N = 83) = 17.25$ $p < 0.05$
Patients who answered follow-up calls	3 (6.5%)	26 (73%)	$\chi^2(1, N = 83) = 39.23$ $p < 0.05$
Medication Reconciliation Completed	3 (6.5%)	27 (75.7%)	$\chi^2(1, N = 83) = 41.91$ $p < 0.05$
Drug-Drug Interactions Identified*	12 (26.1%)	13 (35.1%)	$\chi^2(1, N = 83) = 0.80$ $p = 0.37$
Total Number of In-Person Appointments	77 appointments	74 appointments	N/A
Total Number of Telehealth Appointments	5 appointments	155 appointments	N/A
Total Reported Time HCV Initiation	35 minutes	522 minutes	N/A
Total Reported Time in Follow-Up Calls	0 minutes	210 minutes	N/A

* Potential drug-drug interactions and medication interventions were identified and included: HMG-CoA Reductase Inhibitors (e.g., atorvastatin, pravastatin), Proton Pump Inhibitors (e.g., omeprazole, pantoprazole), carbamazepine, warfarin, and acetaminophen.

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